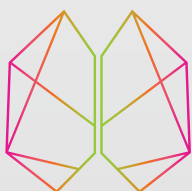




**DESIGNED TO REMOVE TOUGH
CLOTS FOR SUCCESSFUL
REVASCULARIZATION**

Digitally signed by Kojevnikov Dmitrii
Date: 2022.10.06 14:30:57 EEST
Reason: MoldSign Signature
Location: Moldova



CERENOVUS

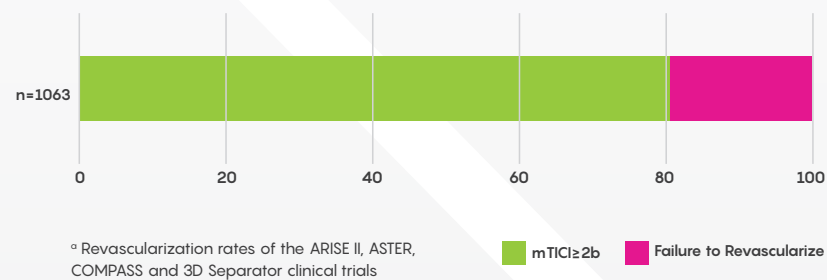
PART OF THE **Johnson & Johnson** FAMILY OF COMPANIES

**CERENOVUS
NIMBUS™**
geometric clot extractor

CERENOVUS NIMBUS™

geometric clot extractor

Almost 20% Of Thrombectomies Fail To Revascularize The Vessel Within 3 Retrieval Attempts^{a,1-4}

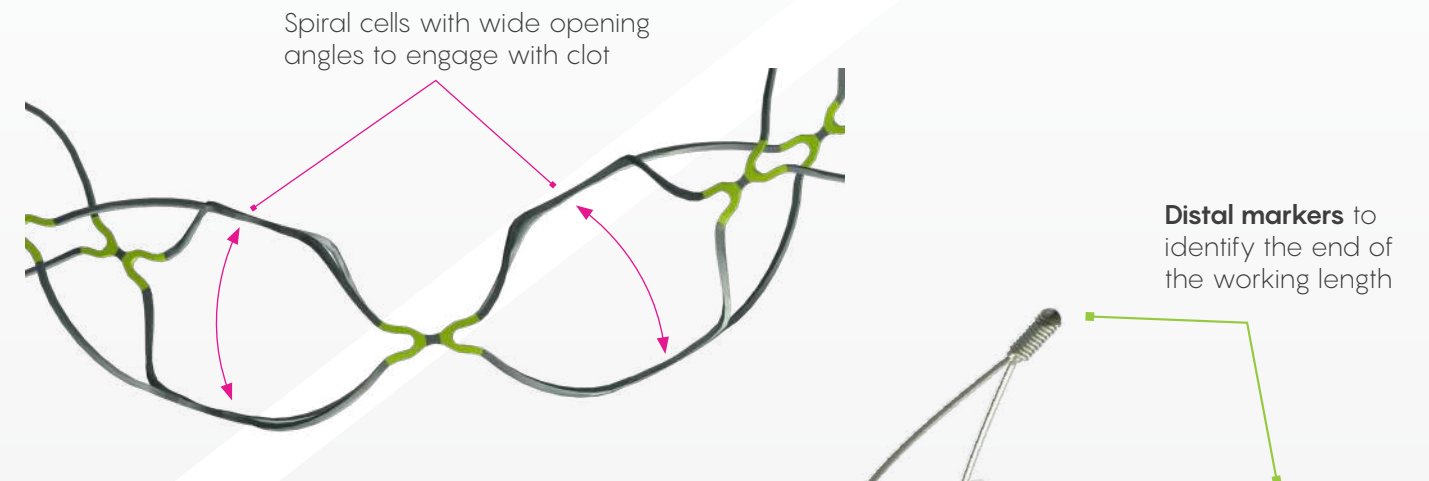


Tough clot properties:

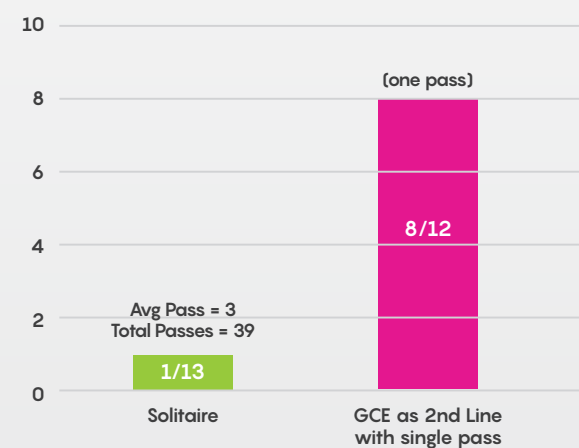
- Difficult to grip with traditional stent retrievers
- Difficult to aspirate
- Stick to blood vessel wall increasing retrieval difficulty

Pinch-pull technology:

- CERENOVUS NIMBUS has spiral cells with multiple pinch points to pull out tough clot



CERENOVUS NIMBUS™ exceeds Solitaire™ performance for tough clot removal



What to do about fibrin rich “tough clots”? Comparing the Solitaire™ stent retriever with a novel geometric clot extractor in an in vitro stroke model
Journal of Neurointerventional Surgery 2018
Fennell VS, Siddiqui AH et al.

Clot type: fibrin rich.

Flow conditions: no flow arrest, no aspiration.

Success: mTICI ≥ 2b

*In vitro Study

Spiral cells: pinch the clot from the proximal end to pull the clot from the blood vessel

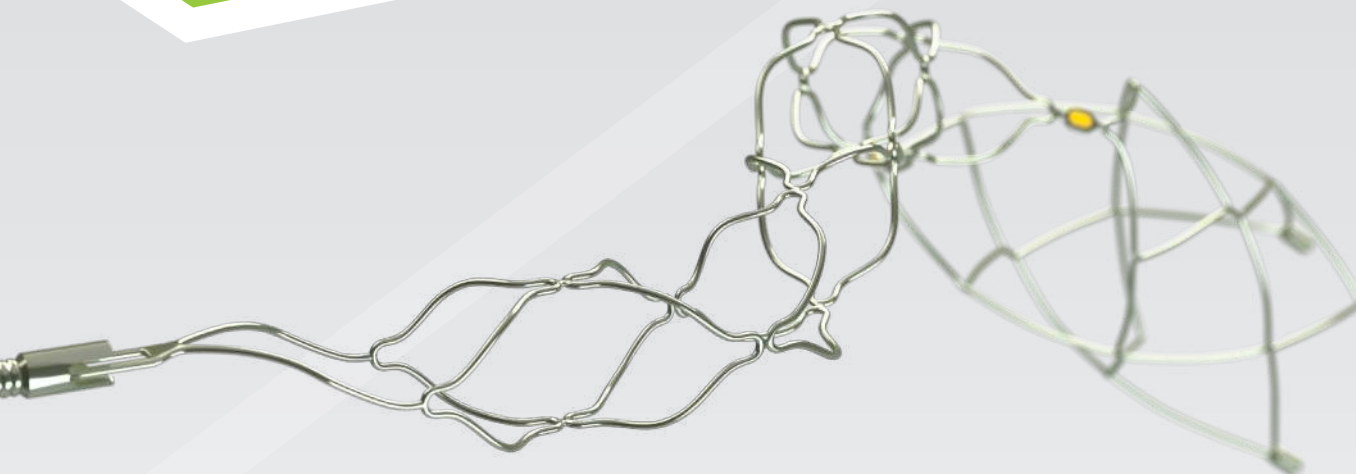
Barrel section to maintain control of the clot during retrieval and to funnel the clot/device into the receiving catheter

Mid markers for positioning and to delineate the end of the spiral section

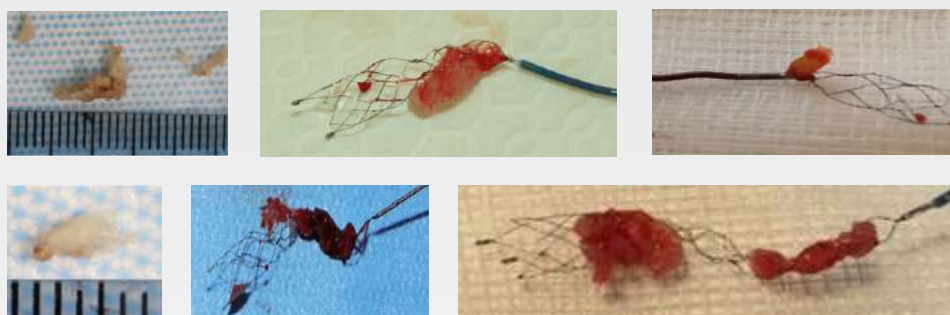
Proximal coil: radiopaque for positioning guidance

CERENOVUS NIMBUS™

geometric clot extractor



Tough clot retrieved using CERENOVUS NIMBUS™



CERENOVUS NIMBUS™ geometric clot extractor

Product Code	Indicated Vessel Diameter	Distal Barrel Section Outer Cage Diameter	Working Length	Proximal Spiral Section Outer Cage Diameter	Microcatheter Compatibility	Proximal Coil Length	Overall Length
GCE4528	1.5-5.0mm	4.5mm	28mm	2.25mm	0.021"	20cm	193cm

¹ Zaidat et al 2018, Primary results of the multicenter ARISE II study

² Lapergue et al 2019, Effect of endovascular contact aspiration vs stent retriever on revascularization in patients with acute ischemic stroke and large vessel occlusion. The ASTER randomized clinical trial.

³ Turk et al 2019, Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicenter, randomized, open label, blinded outcome, non-inferiority trial

⁴ Nogueira et al 2018, Safety and Efficacy of a 3-Dimensional Stent Retriever With Aspiration-Based Thrombectomy vs Aspiration-Based Thrombectomy Alone in Acute Ischemic Stroke Intervention: A Randomized Clinical Trial

⁵ Fennel et al 2018, What to do about fibrin rich "tough clots"? Comparing the Solitaire stent retriever with a novel geometric clot extractor in an in vitro stroke model

A tough clot is an adherent, durable thrombus that has high stiffness making it resistant to endovascular thrombectomy. General characteristics of these clots are that they are fibrous and consist of few RBCs. In vitro thrombectomy simulation with tough clots result in inferior revascularization rates compared to more compliant clots.

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Wokingham, RG40 3EW
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Registered Office:

Baird House,
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Edinburgh EH3 9QP

Registered in Scotland, No.SC 132162

Legal Manufacturer:

Neuravi Ltd.
Block 3,
Ballybrit Business Park
Galway, H91 K5YD
Ireland

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

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CERENOVUS

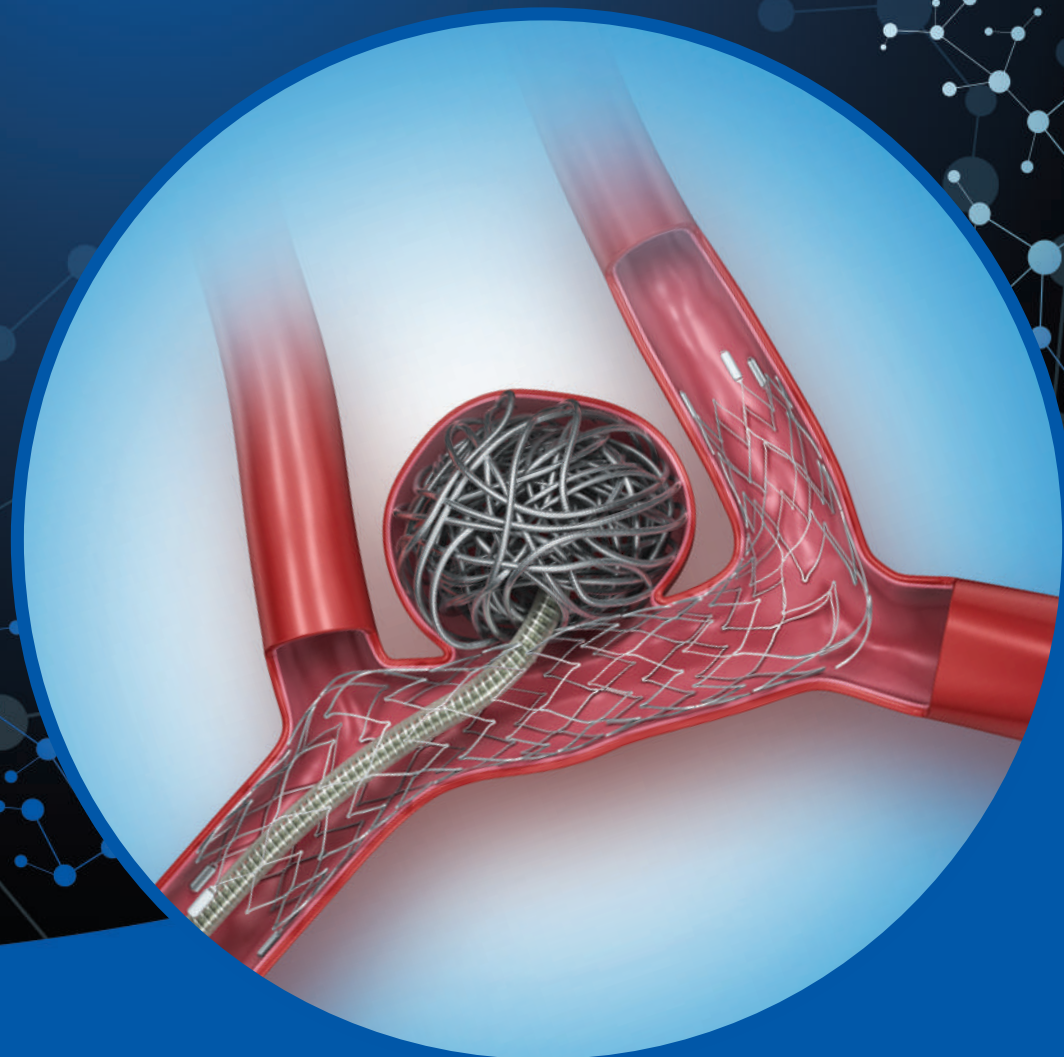
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Neuroform Atlas™

STENT SYSTEM

Bending expectations of conformability and stability.

The Neuroform Atlas Stent System is purposefully designed to provide enhanced conformability, stability and ease of use with the goal of improving patient outcomes. The adaptive cell design provides the coil support and wall apposition needed to perform effective stent-assisted coiling procedures.



Product Number	Stent Diameter	Stent Length	Unconstrained Stent Diameter	Recommended Parent Vessel Diameter
M003EZAS30150	3.0mm	15mm	3.5mm	≥2.0 and <3.0mm
M003EZAS30210*	3.0mm	21mm	3.5mm	≥2.0 and <3.0mm
M003EZAS30240	3.0mm	24mm	3.5mm	≥2.0 and <3.0mm
M003EZAS40150	4.0mm	15mm	4.5mm	≥3.0 and <4.0mm
M003EZAS40240	4.0mm	24mm	4.5mm	≥3.0 and <4.0mm
M003EZAS40300*	4.0mm	30mm	4.5mm	≥3.0 and <4.0mm
M003EZAS45210	4.5mm	21mm	5.0mm	≥4.0 and ≤4.5mm
M003EZAS45300	4.5mm	30mm	5.0mm	≥4.0 and ≤4.5mm

All stent sizes are compatible with Stryker Neurovascular 0.0165-0.017in (0.42-0.43mm) ID microcatheters, excluding Tracker™ 17 Microcatheter.
The stents above are available without a distal delivery wire tip.
*These stent sizes will be available starting January, 2016.

Neuroform Atlas™

STENT SYSTEM

See package insert for complete indications, contraindications, warnings and instructions for use.

INTENDED USE/INDICATIONS FOR USE
The Neuroform Atlas™ Stent System is intended to be used with occlusive devices in the treatment of intracranial aneurysms.

THIS DOCUMENT IS INTENDED SOLELY FOR THE USE OF HEALTHCARE PROFESSIONALS.
A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area. The Stryker products listed above are CE marked according to the Medical Device Directive 93/42/EEC.

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strykerneurovascular.com
Date of Release : SEP/2015
EX_EN_JL

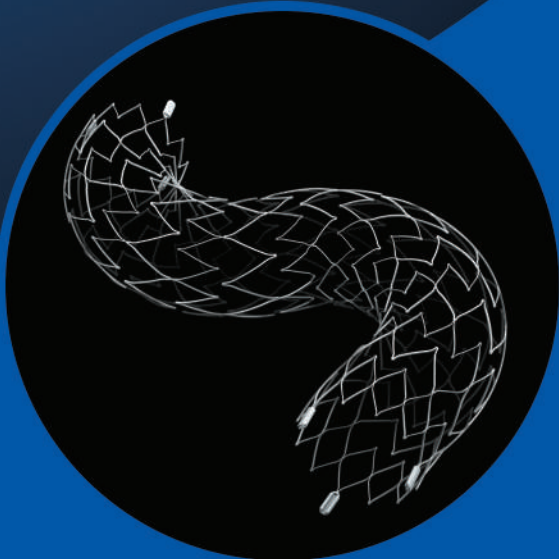
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stryker®
Neurovascular

Purposeful innovation in mind.



Bending expectations of
conformability and stability.

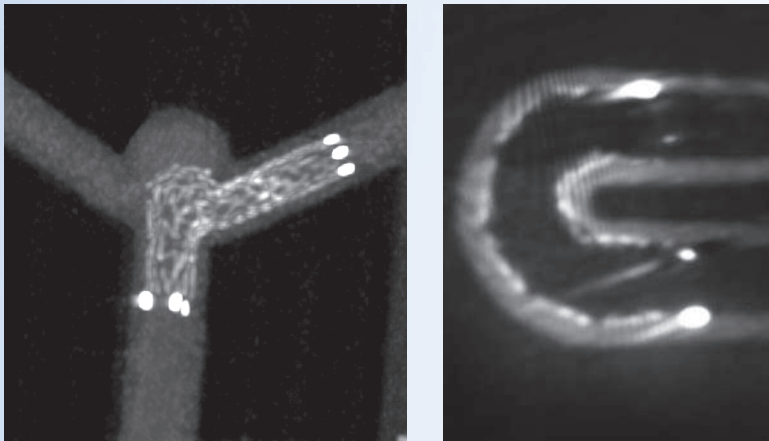


Neuroform Atlas™
STENT SYSTEM

CONFORMABILITY

Wall apposition

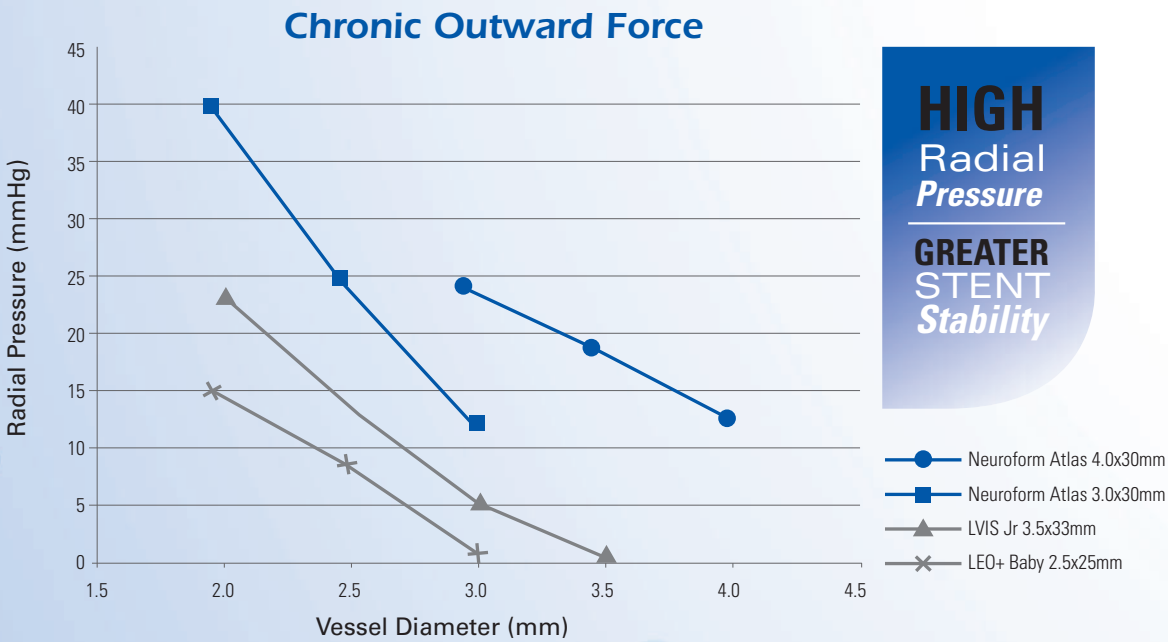
The adaptive cell structure is designed to enhance stent opening and conformability in bifurcations and tight curves.



STABILITY

Superior radial force

The high radial pressure of the Neuroform Atlas™ Stent leads to greater stent stability.



Adaptive cell design with varying strut width

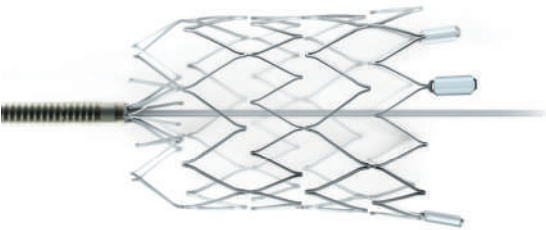
The Neuroform Atlas™ Stent's adaptive cell design featuring 8- and 12-crown rows is designed to optimize both device conformability and stability.

12-crown
row designed to provide flexibility, improve scaffolding and prevent 'gapping' on bends

8-crown
row designed to provide support and anchoring

Segmental™ Expansion

Each segment of the Neuroform Atlas Stent acts independently to provide high radial force, anchoring the stent and ensuring that the stent opens fully.



Closed cell proximal end

The ring of closed cells on the proximal end improves stent stability when recrossing with a microcatheter.

EASE OF USE

Microcatheter compatibility

All sizes of the Neuroform Atlas™ Stent are deliverable down coiling microcatheters, such as Excelsior™ SL-10™ Microcatheter*.

With Neuroform Atlas Stents and the Excelsior family of microcatheters, the same 2-tip microcatheter can be used to deliver both stents and coils.

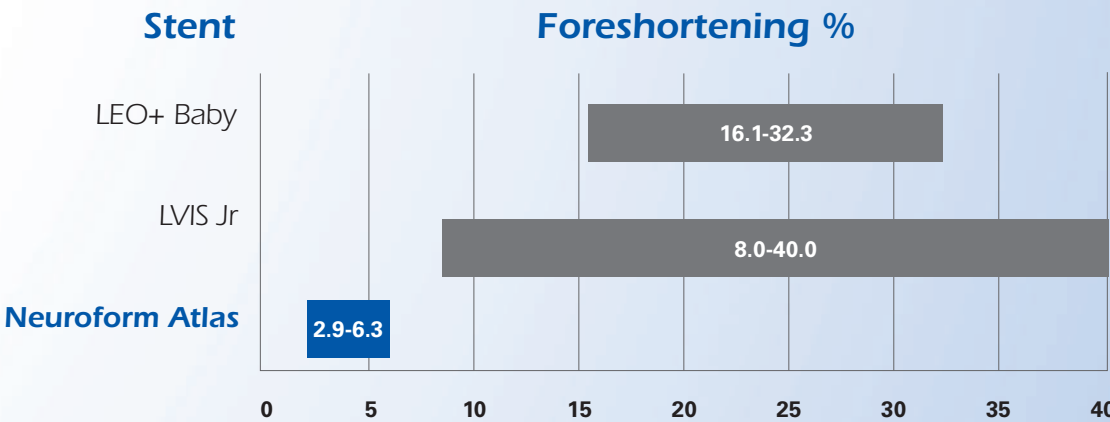


Predictable recrossability

The Neuroform Atlas Stent balances both consistent neck coverage and recrossability. The adaptive cell design facilitates recrossability by 1.7F tip microcatheters while providing a scaffold for the entire line of Target™ Detachable Coils.

Low foreshortening

The very low foreshortening of the Neuroform Atlas Stent leads to higher deployment accuracy.



*Stryker Neurovascular 0.0165-0.017in ID microcatheters, excluding Tracker™ 17.

📍 Europe

(<https://europe.medtronic.com/xd-en/healthcare-professionals/products/neurological/access-delivery-nv/avigo/indications-safety-warnings.html>)
[Hydrophilic Guidewire](https://europe.medtronic.com/xd-en/healthcare-professionals/products/neurological/access-delivery-nv/avigo/indications-safety-warnings.html)



The Avigo™ hydrophilic guidewire provides support for tracking, crossing and maintaining catheter stability. Learn more about its Twister™ technology and MicroRidge™ technology here.

SEE ALL ACCESS & DELIVERY DEVICES ([HTTPS://EUROPE.MEDTRONIC.COM/XD-EN/HEALTHCARE-PROFESSIONALS/PRODUCTS/NEUROLOGICAL/ACCESS-DELIVERY-NV.HTML](https://europe.medtronic.com/xd-en/healthcare-professionals/products/neurological/access-delivery-nv.html))

▲ [Indications, Safety & Warnings \(https://europe.medtronic.com/xd-en/healthcare-professionals/products/neurological/access-delivery-nv/avigo/indications-safety-warnings.html\)](https://europe.medtronic.com/xd-en/healthcare-professionals/products/neurological/access-delivery-nv/avigo/indications-safety-warnings.html)

THE SUPPORT YOU NEED

TRACKING

The Avigo™ guidewire provides support for tracking 021 and 027 systems smoothly.¹

CROSSING

Increased tip buckling strength to cross challenge clots.²

MAINTAINING

The Avigo™ guidewire's core wire design provides support for maintaining catheter stability during precise navigation.

TECHNOLOGIES TO IMPROVE THE WIRE¹

TWISTER™ TECHNOLOGY

The core wire is twisted and annealed to improve torque.

MICRORIDGE™ TECHNOLOGY

The distal tip is designed to minimise prolapse, enhance proximal push forces, and provide distal tip support.

INDICATIONS

The Avigo™ hydrophilic guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral and cerebral vasculature during diagnostic and/or therapeutic procedures. The device is not intended for use in the coronary arteries. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

IFU

View full instructions for use.

[AVIGO IFU \(PDF\) \(opens new window\)](/content/dam/medtronic-com/xd-en/c/od08014-nv-access-delivery/pdfs/Avigo_IFU.pdf) (/content/dam/medtronic-com/xd-en/c/od08014-nv-access-delivery/pdfs/Avigo_IFU.pdf)

CHARACTERISTICS

- Platinum coil radiopaque marker
- Tungsten-doped radiopaque jacket with hydrophilic coating: 38cm
- Reshapeable tip: 2cm
- PTFE cover
- Stainless steel core wire

AVAILABLE CFN

CFN	Diameter (in)	Total Length (cm)	Coil Length (cm)	Tip Shape
103-0606-200	0.014	205	5	Straight

RELATED PAGES

- [MirageTM Hydrophilic Guidewire \(/xd-en/healthcare-professionals/products/neurological/access-delivery-nv/mirage.html\)](/xd-en/healthcare-professionals/products/neurological/access-delivery-nv/mirage.html)

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- [Access & Delivery Products for Neurovascular \(/xd-en/healthcare-professionals/products/neurological/access-delivery-nv.html\)](/xd-en/healthcare-professionals/products/neurological/access-delivery-nv.html)

ANY QUESTIONS?

Do you need support for procedures? Or information on our products and solutions?

Our team is happy to help answer any questions you may have.

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1

IFU 70719-001 Rev. 06/13

2

TRNV-10563 Rev. A



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Informații pentru comenzi - Firul de ghidaj hidrofil Avígo™.014”			
Număr de referință	Diametru (inci)	Lungime totală (cm)	Lungime bobină (cm)
103-0606-200	.014	205	5

Detaliile dispozitivului Firul de ghidaj hidrofil Avígo™.014”



CARACTERISTICI FUNDAMENTALE FIRULUI DE GHIDAJ:

Nu se răsucește	Hidratare eficientă	Forma vârfului
Evită răsucirea firelor, pentru a susține performanța maximă.	Se hidratează timp de cel puțin 30 de secunde, pentru a avea o bună lubrifiere.	Formatare “odată cu banda” pentru a menține integritatea vârfului .

Ghidajul hidrofil este indicat pentru aplicații intravasculare generale, pentru a ajuta la plasarea selectivă a cateterelor în vasculatura periferică și cerebrală, în timpul procedurilor de diagnostic și / sau terapeutice. Dispozitivul nu este destinat utilizării în arterele coronare.

Indicațiile, contraindicațiile, avertismentele și instrucțiunile de utilizare se găsesc pe eticheta aflată pe fiecare dispozitiv.

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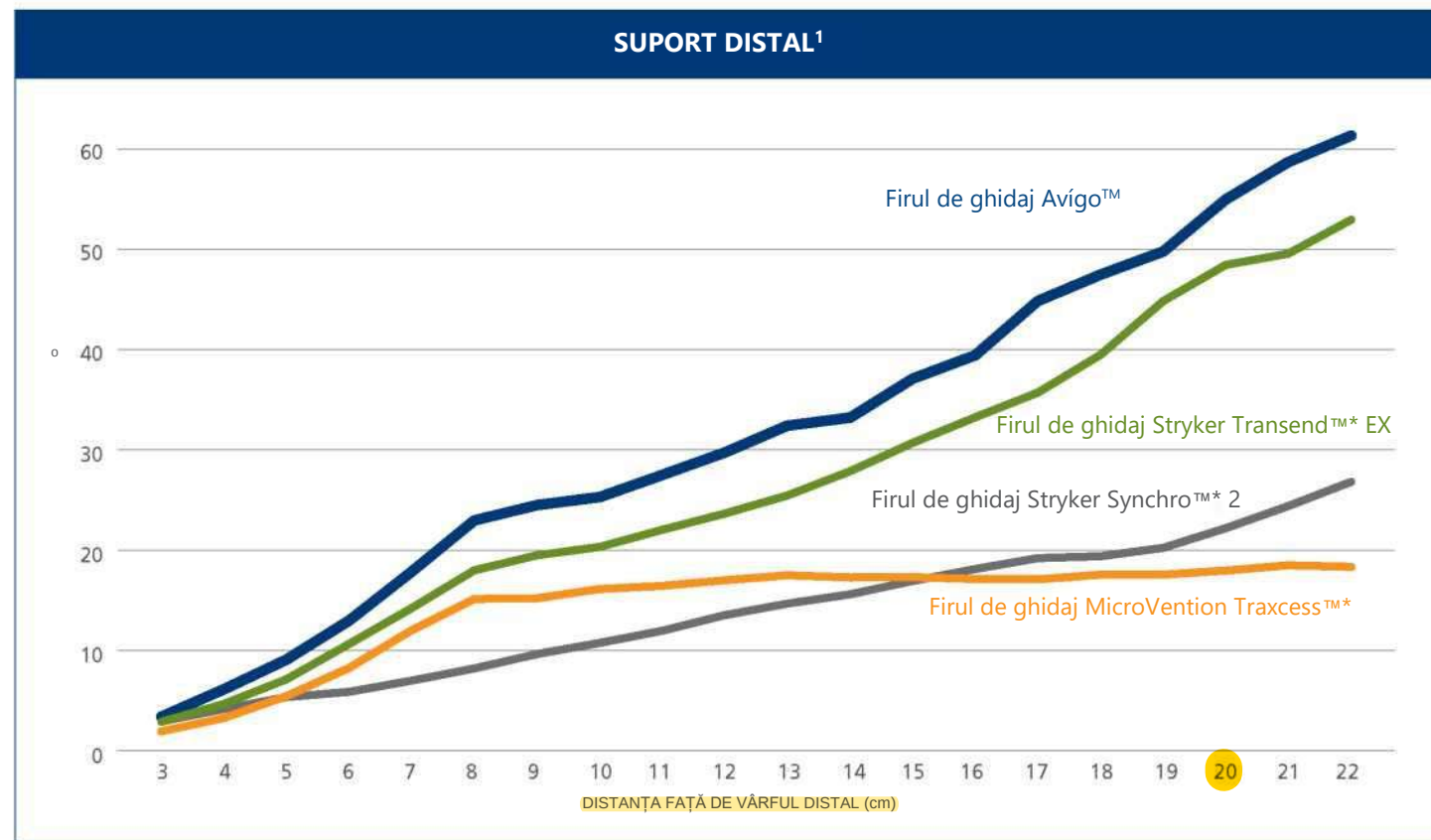
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+33 6 08 23 10 59 [m]

www.covidien.com

De fiecare dată când aveți nevoie de suport.



Oferă o platformă FOARTE SOLIDĂ pentru plantarea dispozitivelor¹



Tehnologie Twister™*

Tratare patentată a miezului firului de ghidaj²

- Suport pe șină, pentru urmărire și stabilitate
- Rezistență la deformare
- Menține controlul cuplului

Tehnologie Microridge™*

Tratare patentată a miezului firului de ghidaj²

- Navigare distală îmbunătățită
- Urmărirea cateterului în zona distală
- Prolaps redus al vârfului

Sisteme robuste de URMĂRIRE

Firul de ghidaj Avigo™ oferă asistența necesară pentru **urmărirea fără probleme** a sistemelor 021 și 027, de exemplu cu cateterul Marksman™ pentru plantarea dispozitivului de embolizare Pipeline™, sau cu micro-cateterul Orion™-21 pentru plantarea stentului.

TRAVERSARE Cheaguri dificile

Firul de ghidaj Avigo™ oferă suportul necesar pentru **traversarea** cheagului, cu prolaps redus la vârf în traversul cateterului, în cazurile de accident vascular cerebral ischemic.

MENTȚINEREA poziției cateterului

Miezul firului de ghidaj Avigo™ oferă suportul necesar pentru **menținerea stabilității** cateterului pe durata navigării de precizie, de exemplu atunci când selectați anevrismele mici sau rupte, sau atunci când navigați în proximitatea anevrismelor "cu gât larg".

Cămașă radioopacă de 38 cm, saturată cu tungsten²

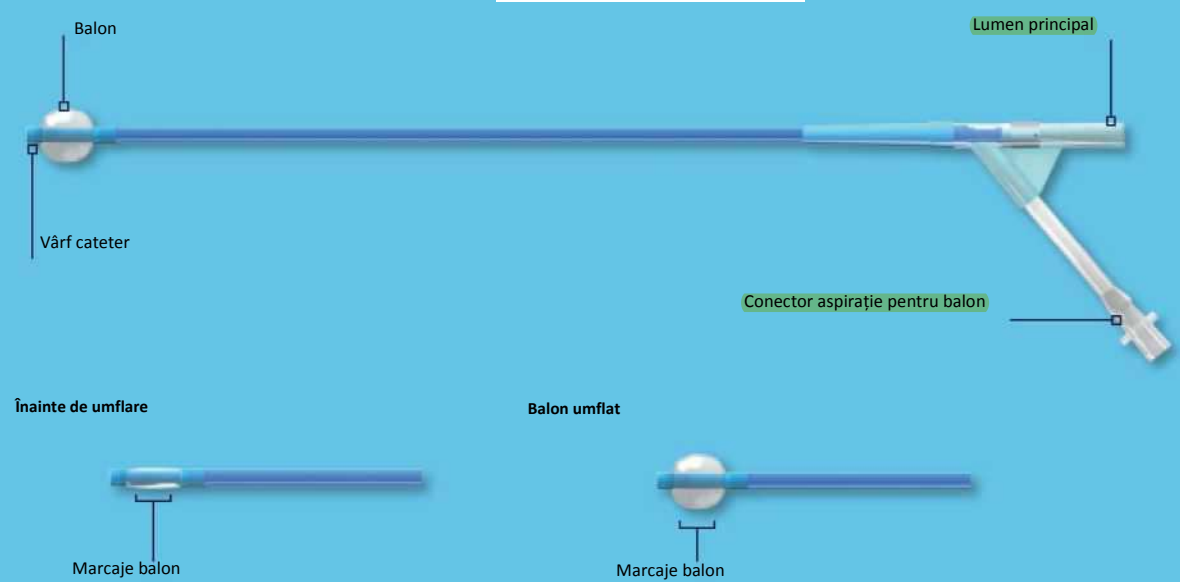
- Radioopacitatea soft permite vizualizarea anatomiei cerebrale

Marker radioopac de 5 cm²

- Vizualizare excelentă a vârfului



Detalii dispozitiv



Gama de dispozitive

Nr, catalog	Denumire produs	Manșon conform (F)	Lungime vârf (mm)	Lungime balon (mm)	Diametru exterior (inch)	Diametru interior (inch)	Lungime utilă (cm)	Lungime totală (cm)
1610060	Cello 6F+	7	3	7	2,0 mm (0,079)	0,051	95	103
1610070	Cello 7F+	8	3	7	2,4 mm (0,094)	0,067	95	103
1610080	Cello 8F	8	3	10	2,7 mm (0,106)	0,075	95	103
1610090	Cello 9F	9	3	10	2,9 mm (0,114)	0,085	92	100

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Bibliografie

1. TR-NV13032 Rev A. Cateterul de ghidaj cu balon Cello™ Raport de evaluare clinică.
2. Mueller-Kronast, NH; Zaidat OO - Systematic Evaluation of Patients Treated With Neurothrombectomy Devices for Acute Ischemic Stroke - Primary Results of the STRATIS Registry - Stroke. 2017;48:00-00. DOI: 10.1161/STROKEAHA.117.016456.
3. Nguyen TN, et al. Balloon guide catheter improves revascularization and clinical outcomes with the Solitaire device: analysis of the North American Solitaire Acute Stroke Registry. Stroke. Jan 2014;45(1):141-145.
4. Comparison of a Balloon Guide Catheter and a Non-Balloon Guide Catheter for Mechanical Thrombectomy, Aglae Velasco <https://doi.org/10.1149/radiol.201515057>.
5. Etichetare Cateter de ghidaj cu balon Cello™*.
6. TR-NV13900 Rev A. Cateterul de ghidaj cu balon, Test de fezabilitate.

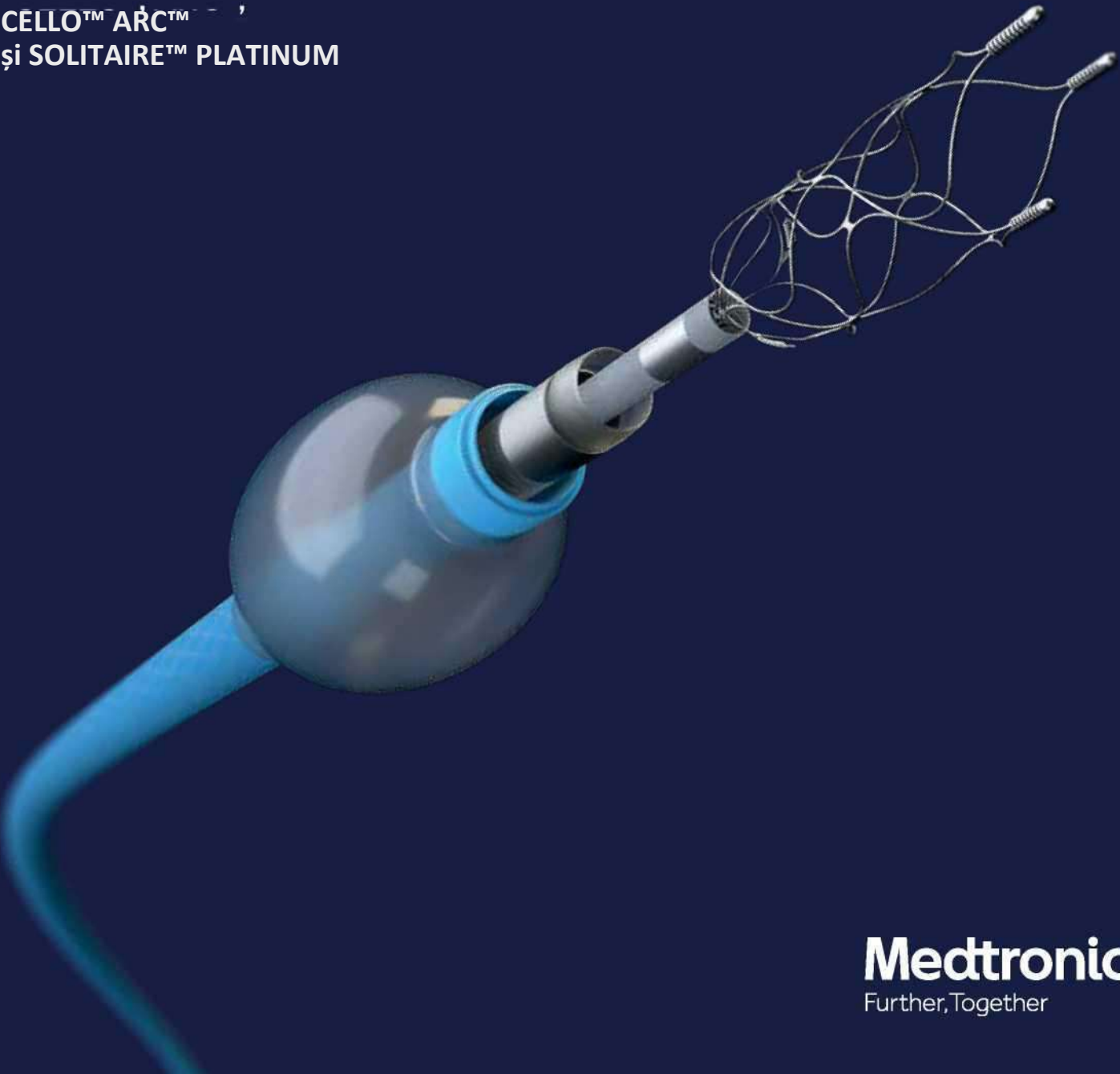
Cateterul de ghidaj cu balon Cello™ este indicat pentru a facilita inserția și ghidarea cateterelor intravasculare într-un vas de sânge selectat, în sistemele periferice și neurovasculare. Balonul asigură ocluzie vasculară temporară în timpul acestor proceduri și al altor proceduri angiografice. Indicațiile, contraindicațiile, avertismentele și instrucțiunile de utilizare se găsesc pe eticheta produsului, furnizată cu fiecare dispozitiv. Toate declarațiile și descrierile sunt destinate țărilor cu reglementări CE. Disponibilitatea acestor produse poate varia în țările din afara UE. Cateterul de ghidaj cu balon Cello™ este destinat blocării temporare a fluxului sanguin prin extinderea unui balon în interiorul vaselor de sânge în timpul operațiilor, cum ar fi: hemostază de urgență, hemostază pentru chirurgie, perfuzie de sânge în vasul periferic și injecție arterială pentru chimioterapie.

Consultați prospectul IFU pentru instrucțiunile complete.

Cello este produs de Fujii Systems Corporation
200-2 Aza Ohira, Odakura, Nishigo, Nish Shirakawa Gun Fukushima, 961-8061 Japonia
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CELLO™*
Cateter de ghidaj cu
balon
Controlul
Curgerii proximale.¹

Familia de microcatetere
CELLO™ ARC™
și SOLITAIRE™ PLATINUM



Medtronic
Further, Together

De să folosim un Cateter de ghidaj cu balon

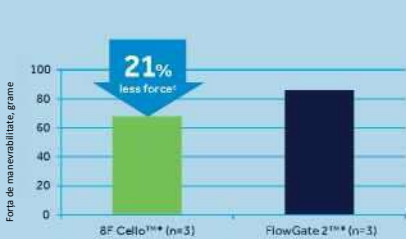
- Piața SUA potențială, o singură ramură, multi-centru, non-aleator
- Evaluarea recuperatoarelor de stent Medtronic în situații reale
- 936 de pacienți ai STRATIS au fost incluși în analiză
- Recuperatoarele de stent Medtronic sunt destinate a fi utilizate doar cu catetere de ghidaj cu balon nr. 8F & 9F
- Concluzii: utilizarea BGC ca abordare primară în STRATIS a demonstrat o rată mai mare de independență funcțională după 90 în comparație cu CGC (catetere de ghidaj convenționale) și DLBC (catetere distale de diametru mare).

Analiza rezultatelor BGC conform registrului STRATIS ²				
Rezultat BGC	Definire rezultat	Recuperare stent + BGC	Recuperare stent + DLBC	Valoare P
rată mai mare de independență funcțională	mRS 0-2 la 90 zile	61,8% (291/471)	50,2% (138/275)	P = 0,002
Efect mai mare al primei treceri	Prima trecere, TICI 2b-3 – pe laborator, tehnică de bază	67,5% (339/502)	55,0% (164/298)	p = 0,0004
Număr total mai mic de treceri ale dispozitivului total	Numărul mediu de treceri ale dispozitivului în același vas	1,7±1,10 (504)	2,0±1,30 (301)	P = 0,0014

De ce să utilizăm CELLO™*

- Opțiuni în creștere, cu 4 mărimi diferite¹
- Spirale împletite din Oțel inoxidabil oferă report echilibrat între rezistență mecanică și rezistență la sugrumare¹
- Balon conform din silicon cu două marcaje (proximal și distal) pentru poziționare și control al umflării¹

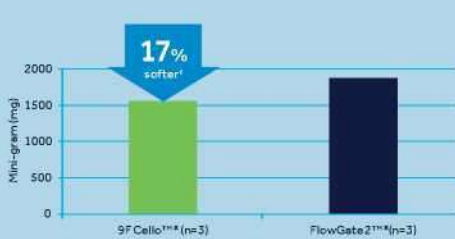
Navigația BGC cu un model ICA din Silicon^o



Durată dezumflare balon^o



Rigiditate vârf la BGC, la 2 mm de la capăt^o



Beneficiile utilizării unui BGC cu un recuperator de stent

		Sub-studiu BGC NASA ³		Valoare P	Articol VELASCO ⁴		Valoare P
		BGC	NBGC		BGC	NBGC	
Caracteristicile studiului și de referință	Perioada de participare la studiu	3/2012-2/2013			2013-2014		
	Nr. de pacienți participanți	149	189	P = N/A	102	81	P = N/A
	Scorul de referință NIHSS (Median)	17,6	18,3	P = 0,3	NR	NR	NR
Caracteristicile procedurale	Durată până la re-vascularizare	NR	NR	P = N/A	20,5 min, (durată procedură)	41 min, (durată procedură)	P<0,0001
	Utilizare BGC, %	100%	0%	P = N/A	100%	0%	P = N/A
	Numărul de treceri pentru a complete 1 revascularizare mediane	1 median	2 mediane	NR	1 mediană	2 mediane	NR
Rezultate clinice	Dispozitiv TICI 2b-3	76% SA (113/149)	71% SA (133/189)	P = 0,3	94,1% (96/102)	75,3% (61/81)	P = 0,0016
	Dispozitiv TIMI 2b-3	86% SA (86/149)	84% SA (158/189)	P = 0,6	NR	NR	NR
	mRS 0-2 la 90 zile	51,6%	35,8%	P = 0,02	NR	NR	NR
	sICH	12,2% (18/149)	9% (17/189)	P = 0,4	NR	NR	NR
	Embolizare la un nou teritoriu vascular (ENT)	5% (8/149)	5,2% (10/189)	P = 0,9	NR	NR	NR
	Mortalitate la 90 zile	26,2% (33/149)	31,8% (55/189)	P = 0,3	NR	NR	NR

ENT: Embolizare la un nou teritoriu
N/A: Nu este cazul
NIHSS: National Institutes of Health Stroke Scale
NR: Neraportat
DAC: Cateter de acces distal
SA: Zonă evaluată
sICH: Hemoragie intra-craniană simptomatică
BGC: Cateter de ghidaj cu balon
NBGC: Cateter de ghidaj fără balon

TICI: Scara Trombolizei în Infarct cerebral:
2b: Umplerea completă a teritoriului vascular prevăzut, conform vizualizării, dar umplerea este mai lentă decât normal.
3: Perfuzie completă; curgerea antegradă în spațiul distal în raport cu obstrucția apare la fel de rapid ca în interiorul obstrucției, iar eliminarea substanței de contrast din spațiul implicat este la fel de rapidă ca din cel neimplicat.

TRADUCĂTOR INTERPRET AUTORIZAT
HRIȘAN CĂTĂLIN IULIAN
Aut. nr.: 18790
ENGLER

Abordare coaxială



- Cateter de ghidaj cu balon Cello™ (9F OD)
- Micro-cateter Marksman™ 153cm, Rebar 18, 27 (3F OD)
- Recuperator de stent Solitaire™ Platinum

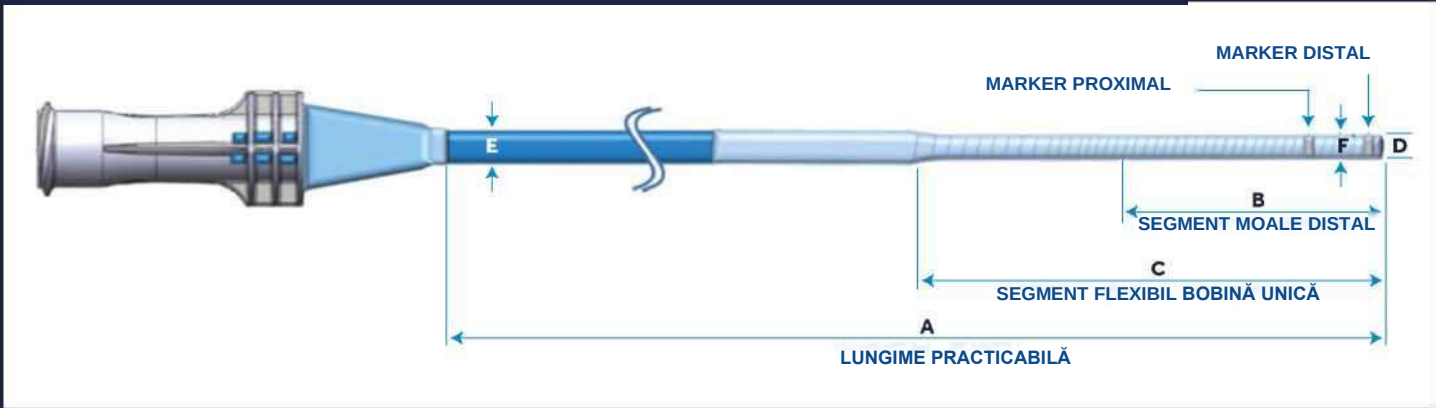
Abordare triaxială



- Cateter de ghidaj cu balon Cello™ (9F OD)
- Cateter intra-cranial sau intermediar ARC™ (6F OD)
- Micro-cateter Marksman™ 160cm (3F OD)
- Recuperator de stent Solitaire™ Platinum

MICROCATETER PHENOM™ 17

SPECIFICAȚII PENTRU COMENZI



	EXPLICAȚIE Nr. CODURI PIESE									
	Microcateter Phenom™*	FG	MĂRIME	A	-	B	C	-	MARKERI VÂRF	FORMĂ VÂRF
Exemplu	Microcateter Phenom™* 17	FG	11	150	-	06	15	-	2	S

Diversele scenarii clinice au cerințe specifice de suport și de navigație. Pentru microcater Phenom™*, vă oferim specificații diversificate, pentru a vă satisface nevoile. Pentru a vă asigura dispozitivul adecvat, selectați cateterul:

MICROCATETERUL PHENOM™* 17: SELECTAȚI FORMA VÂRFULUI					
	D: DI CATETER	E: DE PROXIMAL	F: DE DISTAL	FORMA VÂRF	NUMĂR PIESĂ
Microcater Phenom™* 17	0.017" (0.43mm)	0.029" (2.2F)	0.024" (1.8F)	DREPT	FG11150-0615-2S
				CURBAT, în "J"	FG11150-0615-2J
				CURBAT,, la 45°	FG11150-0615-2X
				CURBAT la 90°	FG11150-0615-2R

REFERINȚE:
1. Document Cathera ML-0001.B
2. Document Cathera ML-0001.A
3. ENR-0029.A

Microcater Phenom™ sunt destinate introducerii dispozitivelor de intervenție și perfuziei de agenți de diagnostic sau terapeutici în vasculaturile neurologice, periferice și coronare.

Bobinele detașabile The Axiom™ și Axiom™ Prime nu sunt indicate pentru toți pacienții, și este posibil să nu reprezinte tratamentul adecvat pentru toate scenariile clinice.

Bobinele detașabile Axiom™ și Axiom™ Prime sunt destinate embolizării endovasculare a anevrismelor intracraniene. Bobinele detașabile Axiom™ și Axiom™ Prime sunt, de asemenea, destinate embolizării altor anomalii neurovasculare, cum ar fi malformațiile arteriovenoase și fistulele arteriovenoase.

Indicațiile, contraindicațiile, avertismentele și instrucțiunile de utilizare se găsesc pe eticheta existentă pe fiecare dispozitiv.

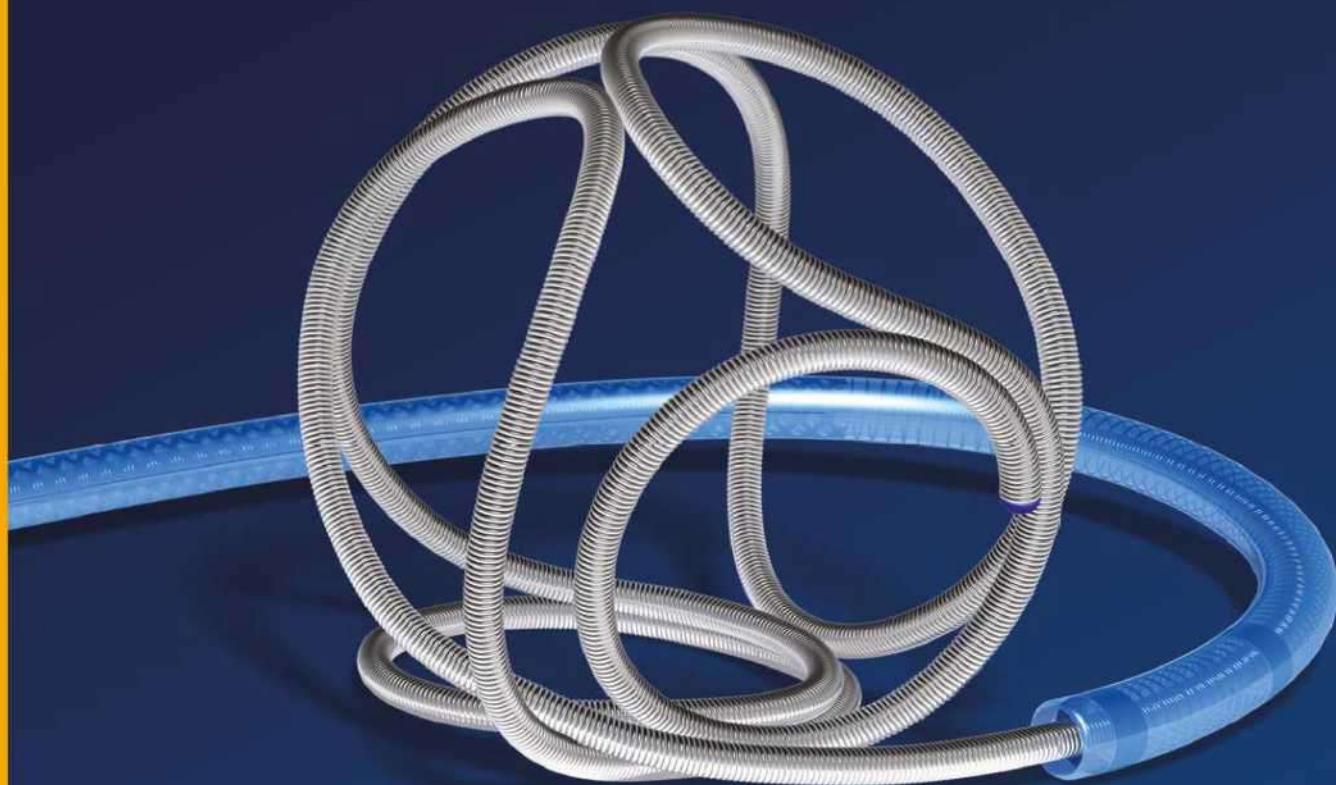
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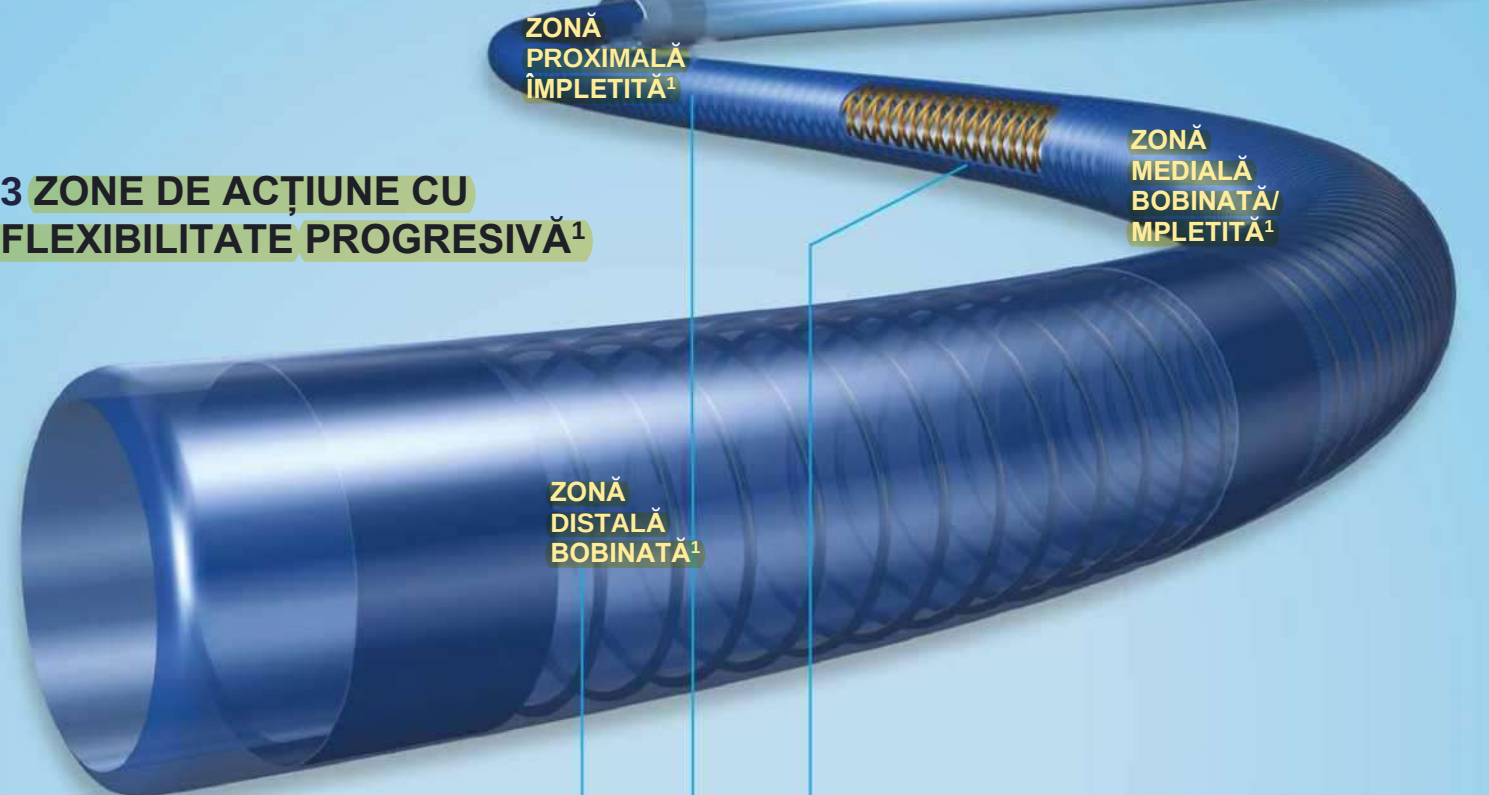
SOLUȚII PENTRU
TRATAREA
ANEVRISMULUI
MICROCATETERUL
PHENOM™ 17
ACȚIONEAZĂ CU
ÎNCREDERE



Platformă de plantare
pentru bobine și stenturi¹

Microcateterul
Phenom™ 17

3 ZONE DE ACȚIUNE CU FLEXIBILITATE PROGRESIVĂ¹



MICROCATETERUL PHENOM™ 17

Zonă distală bobinată:

- Asigură flexibilitatea și stabilitatea vârfului, ceea ce permite schimbarea tecii dispozitivului¹

Zonă medială bobinată/împletită:

- Permite transferul constant al forței de împingere proximal → distal¹

Zonă proximală împletită:

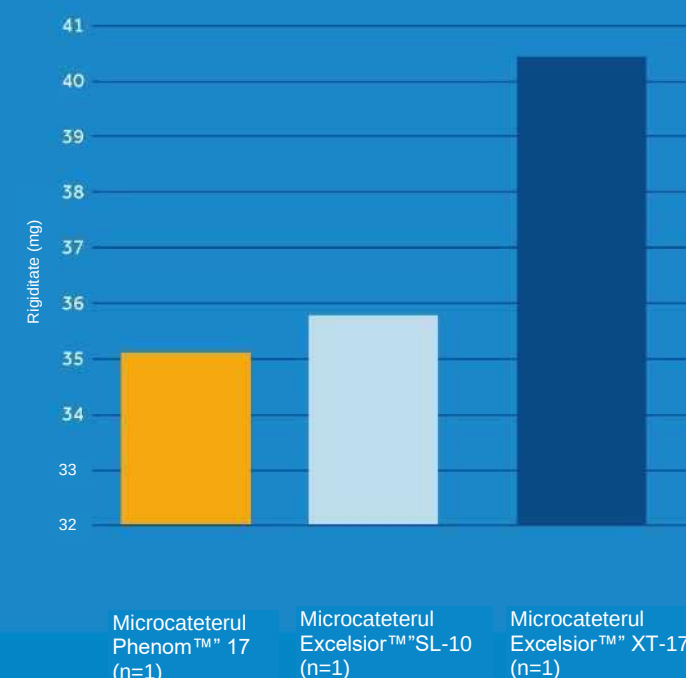
- Oferă profil proximal redus și împingere optimă

Avantaje suplimentare:

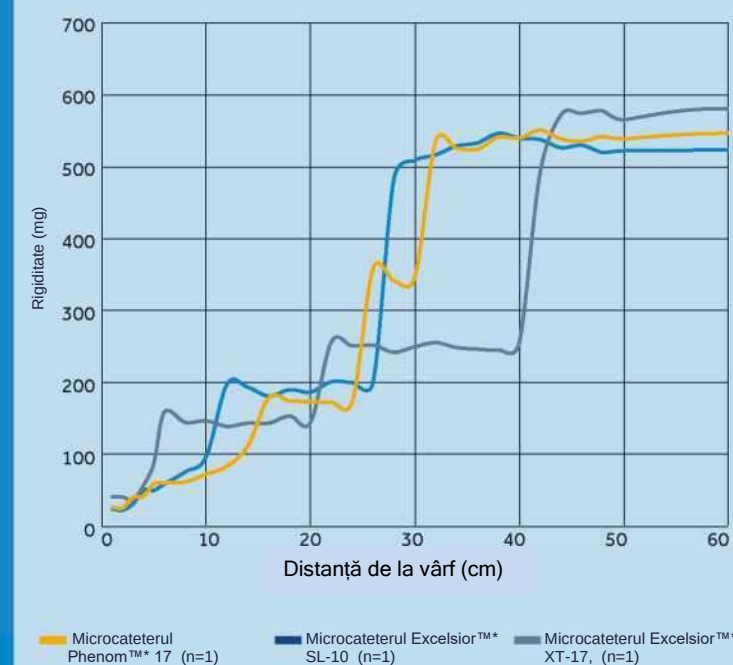
- Vârful cu profil redus permite accesarea vasculaturii distale și traversarea cu ușurință prin interstițiile stentului²
- Vârf distal atraumatic moale și totunjit²
- Lumenul interior, proiectat pentru a preveni ovalizarea și a planta dispozitivele cu frecare minimă²

Platformă de plantare pentru bobine și stenturi¹

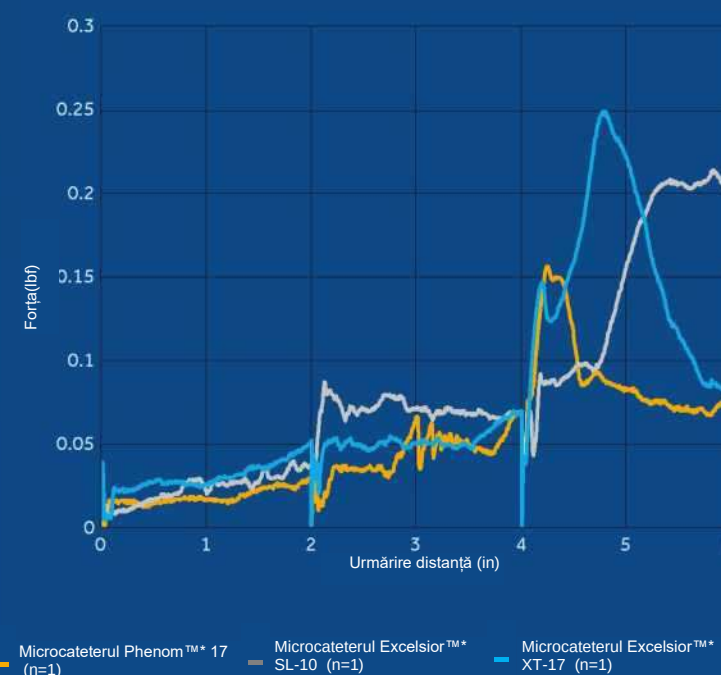
RIGIDITATE VÂRF³



RIGIDITATE AX CATETER³



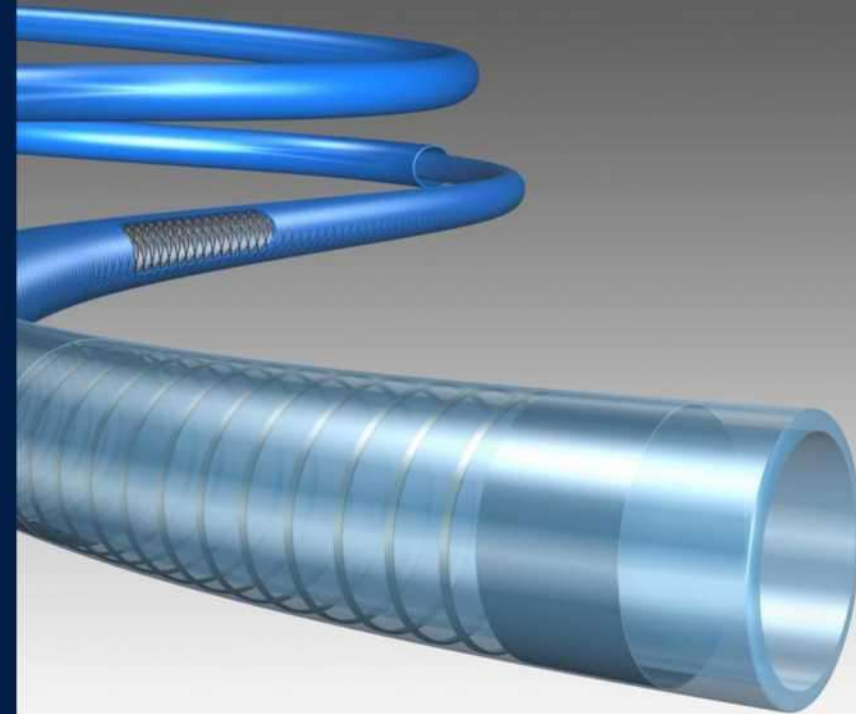
FORȚĂ URMĂRIRE CATETER³



FORȚA DE ÎMPINGERE LA PLANTAREA BOBINEI³ (BOBINA AXIUM™ 3D, 20X50)



CATETERELE PHENOMTM * GHID DE LUCRU

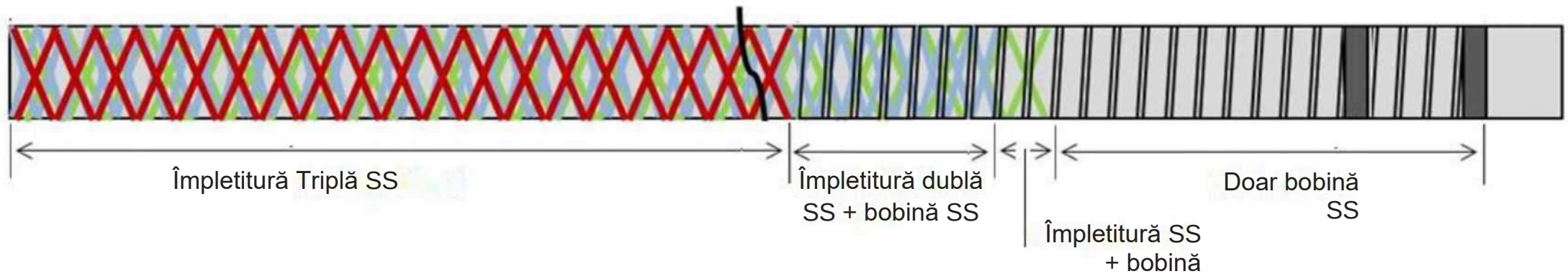


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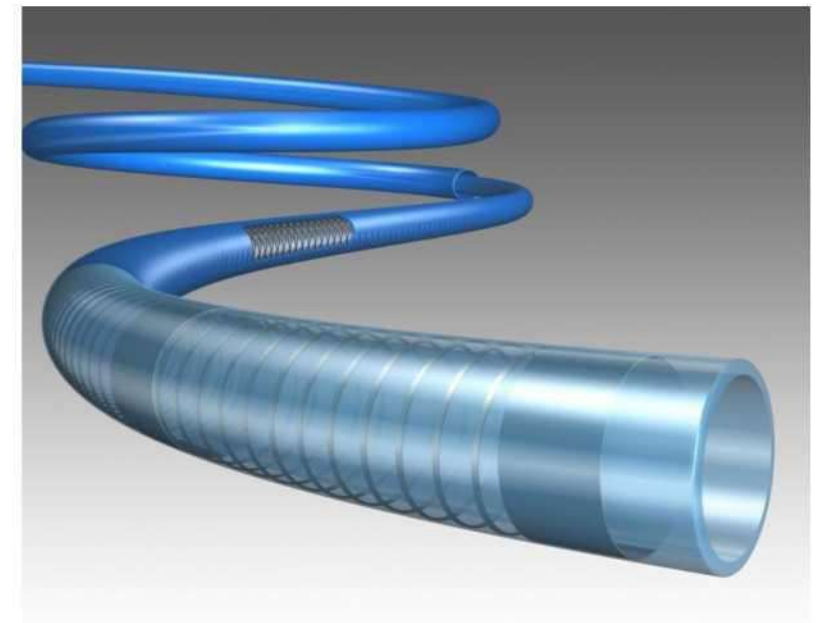
CATETERELE PHENOMTM *

PREZENTARE GENERALĂ A MATERIALELOR

CUM SUNT PROIECTATE¹



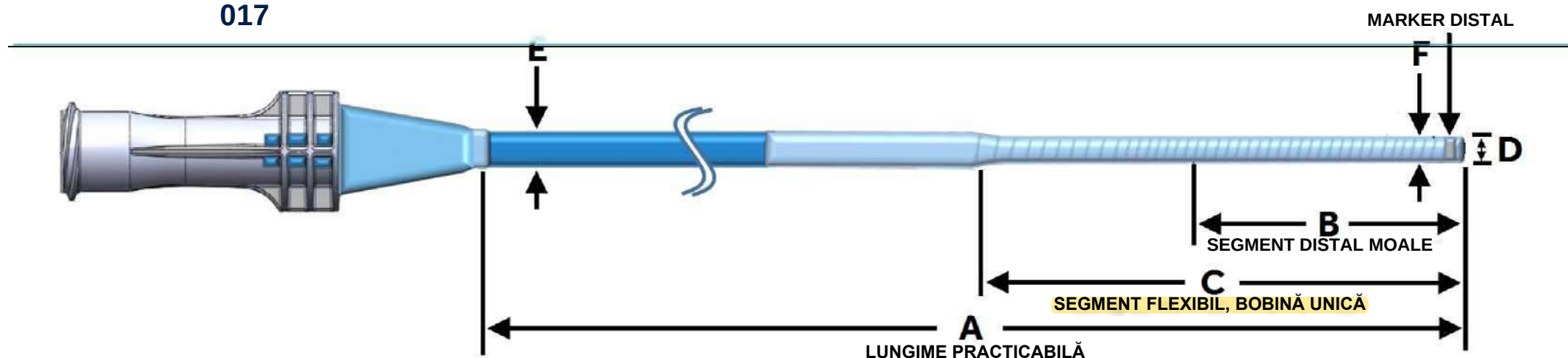
- 4 zone de tranziție
 - Proximal - împletitură triplă SS
 - Ax medial - împletitură dublă SS și bobină
 - Ax medial - împletitură SS și bobină unică
 - Segment distal – bobină SS
- Materiale corp cateter
 - Straturi exterioare din Pebax^{TM*} (strat interior din oțel inoxidabil împletit/bobinat, PTFE și elastomer poliolefinic)
- Vârf distal rotunjit
- Căptușeală interioară lubrifiantă
- Marker radioopac
 - Platină/Iridiu
- Tub suport
 - Nailon



CONFIGURAREA VÂRFULUI DISTAL² CE REPREZINTĂ?

EXPLICAȚII NUMĂR PIESĂ

	Cateter Phenom™*	FG	Mărime	A	-	B	C	-	Marker vârf	Formă vârf
Exemplu	Cateter Phenom™* 017	FG	11	150	-	16	15	-	2	S



B: Lungimea segmentului moale distal, în centimetri, măsurată de la vârful distal.

C: Lungimea segmentului ranforsat cu bobină unică, în centimetri, măsurată de la vârful distal.

SPECIFICAȚII PENTRU COMENZI³

CATETERUL PHENOM™* 027: SELECTAȚI LUNGIMEA PORȚIUNII FLEXIBILE CU BOBINĂ UNICĂ

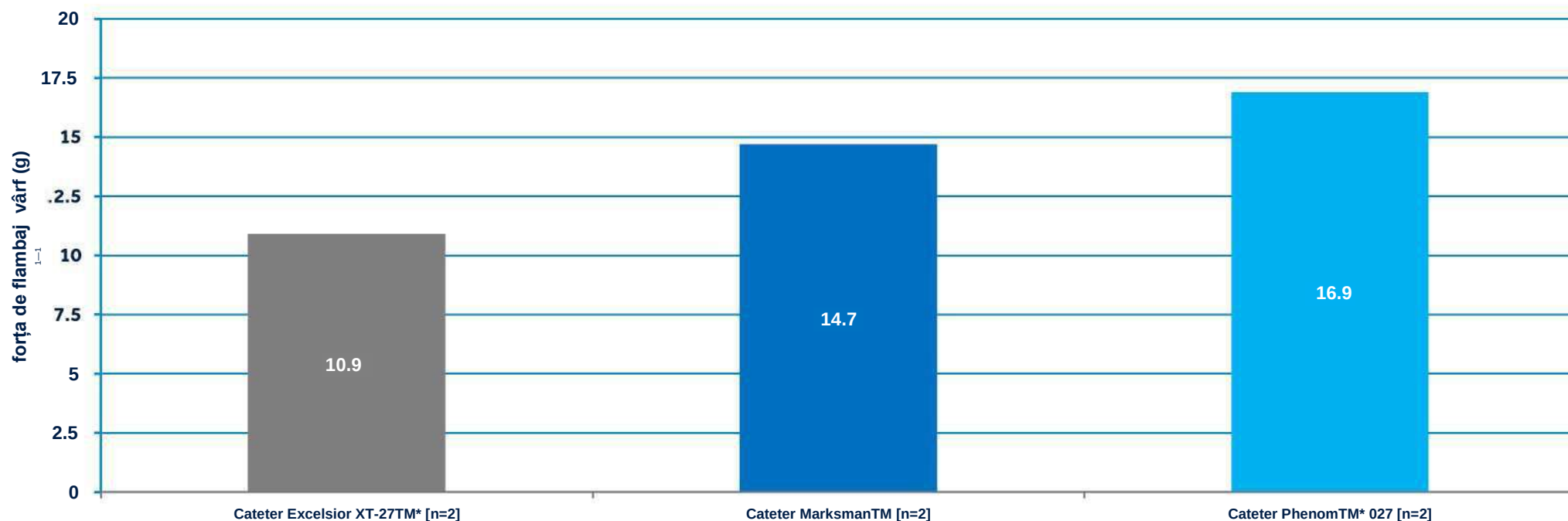
	D: DI Cateter	E: DE Proximal	F: DE Distal	C: Lungimea flexibilă cu bobină unică	Număr piesă
Cateterul Phenom™* 027	0.027" (0.69 mm)	0.040" (3.1F)	0.036" (2.8F)	15 cm 30 cm	FG15150-0615-1S FG15150-0630-1S

CATETERELE PHENOM^{TM*} BENEFICIILE PRODUSULUI

CATETER PHENOM™* 027

AVANTAJE

Phenom™* 027 – comparație pentru forța de flambaj măsurată a vârfului distal (g)¹



Avantajele esențiale²

- Lumenul cateterului este proiectat strategic, pentru a preveni ovalizarea și pentru durabilitate, cu scopul plantării de dispozitive terapeutice avansate, cu fricțiune minimă.
- Vârful distal rotunjit este conceput pentru a spori trasabilitatea acestuia peste fir, și pentru a ajuta la recaptarea dispozitivului.
- Modelele optimizate ale axului distal al cateterului Phenom™* sunt flexibile, dar stabile

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2016

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Toate drepturile rezervate.

REFERINȚE

TR-NV12653A1 2. Document Cathera ML-0001.A 3. DC00039504B

COMPLICAȚII POTENȚIALE: pentru lista completă de avertismente, precauții și contraindicații consultați instrucțiunile de utilizare.

Indicațiile, contraindicațiile, avertismentele și instrucțiunile de utilizare se găsesc pe eticheta produsului existentă pe fiecare dispozitiv.

Cateterele Phenom™ sunt destinate plasării dispozitivelor de intervenție și a celor pentru perfuzia de agenți de diagnostic sau terapeutici în vasculatura neurologică, periferică și coronară.

™* Phenom este marcă comercială a Cathera, Inc. Mărcile terțe sunt mărci comerciale ale proprietarilor respectivi.

SOLUTIONS FOR **ANEURYSM TREATMENT** **PIPELINE™ FLEX** **WITH SHIELD** TRUSTED IN ACTION

PIPELINE™ Flex Embolization Device
with SHIELD TECHNOLOGY™

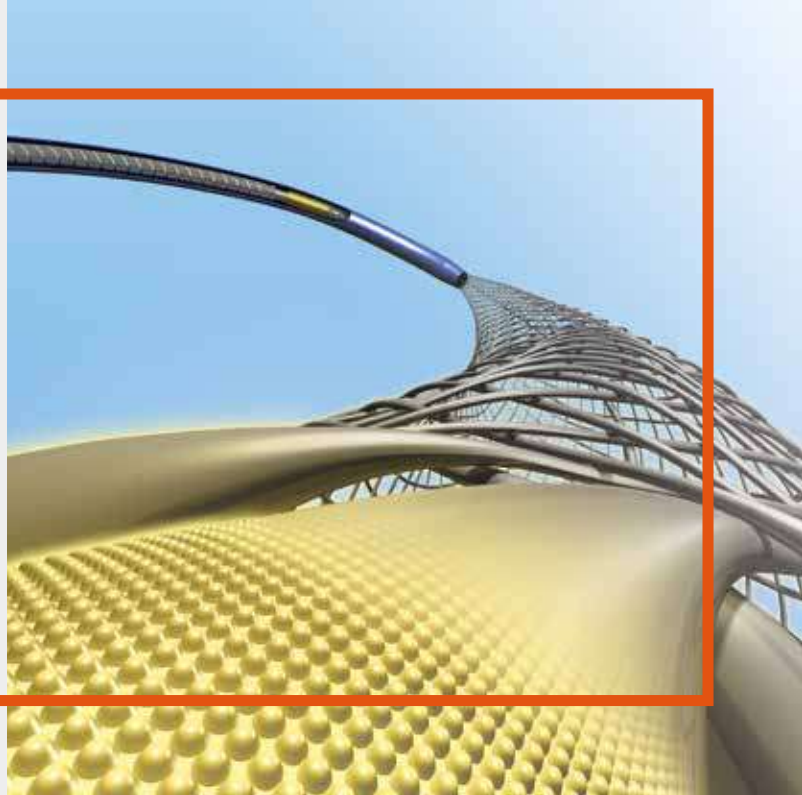
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SAFETY
EFFICACY
SIMPLICITY



WHAT IS **SHIELD TECHNOLOGY™**?

FULL FLOW DIVERSION
LOW THROMBOGENIC
PROFILE



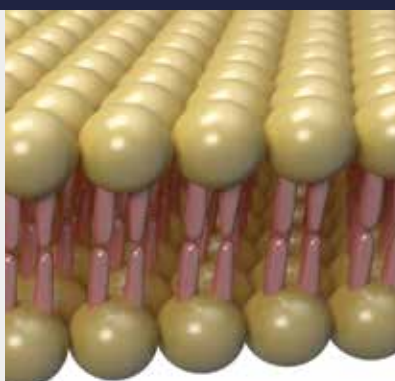
- **SHIELD TECHNOLOGY™** is designed to improve the **hemocompatibility and deliverability** of the Pipeline™ implant by addressing material thrombogenicity.
- **SHIELD TECHNOLOGY™** is a surface modification where synthetic phosphorylcholine (PC) polymer is covalently-chemically-bonded to the strands that make up the Pipeline™ device braid.

SHIELD TECHNOLOGY™ provides biomimicry properties the blood cells won't react to the Pipeline™ implant.

Phosphorylcholine is present in the **outer membrane** of red blood cells

Synthetic phosphorylcholine is produced and **covalently bonded to the braid**

**OUTER
MEMBRANE
OF RED
BLOOD CELLS**

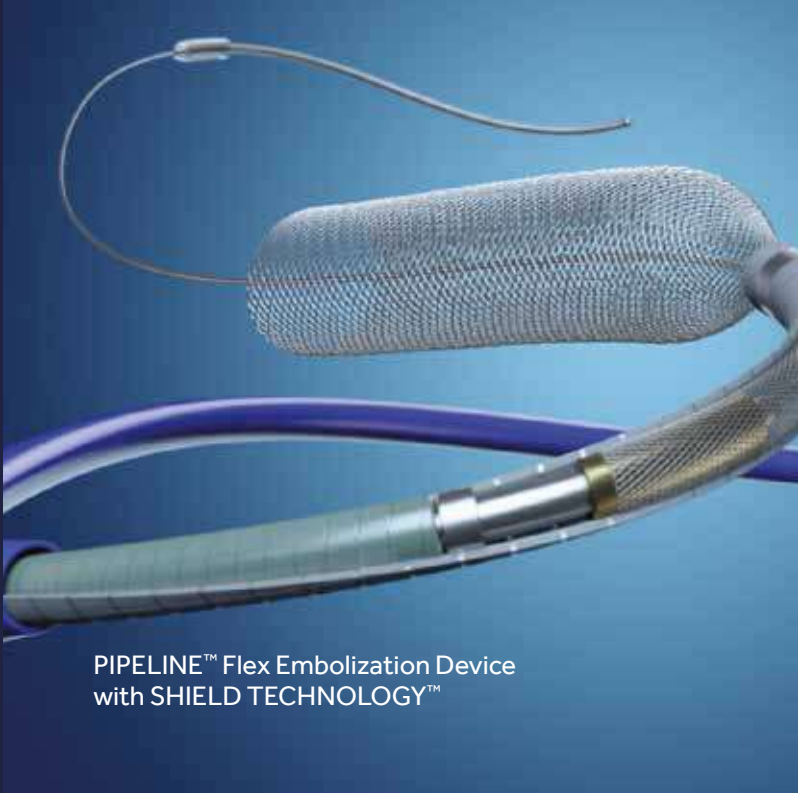


**SHIELD
TECHNOLOGY™**



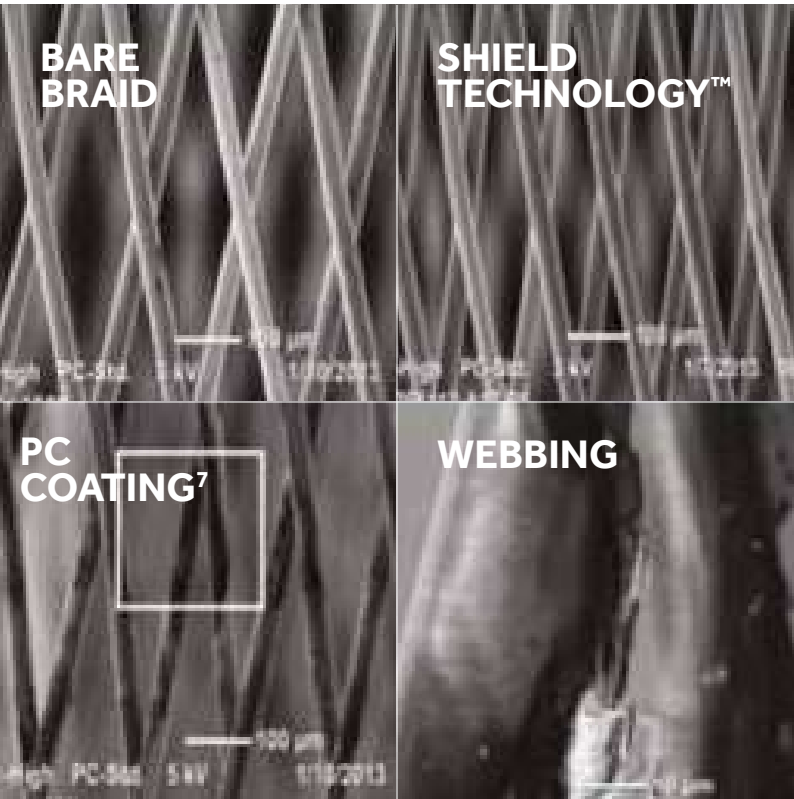
TRADITIONAL COATINGS VERSUS THE **SHIELD TECHNOLOGY™** SURFACE MODIFICATION

FULL FLOW DIVERSION
LOW THROMBOGENIC
PROFILE



PIPELINE™ Flex Embolization Device
with SHIELD TECHNOLOGY™

Method	Shield Technology™	PC Coating (Use on initial prototypes)
Mode of Action	Inert Polymer	Polymer ± Drug
Thickness	<3 Nanometers ⁷ (0.01% of one braid strand)	>500 Nanometers ⁷
Adhesion to the Substrate	Chemical Bonding	Physical Encapsulation
Process	Chemical Reaction	Dipping, Spray or Brush

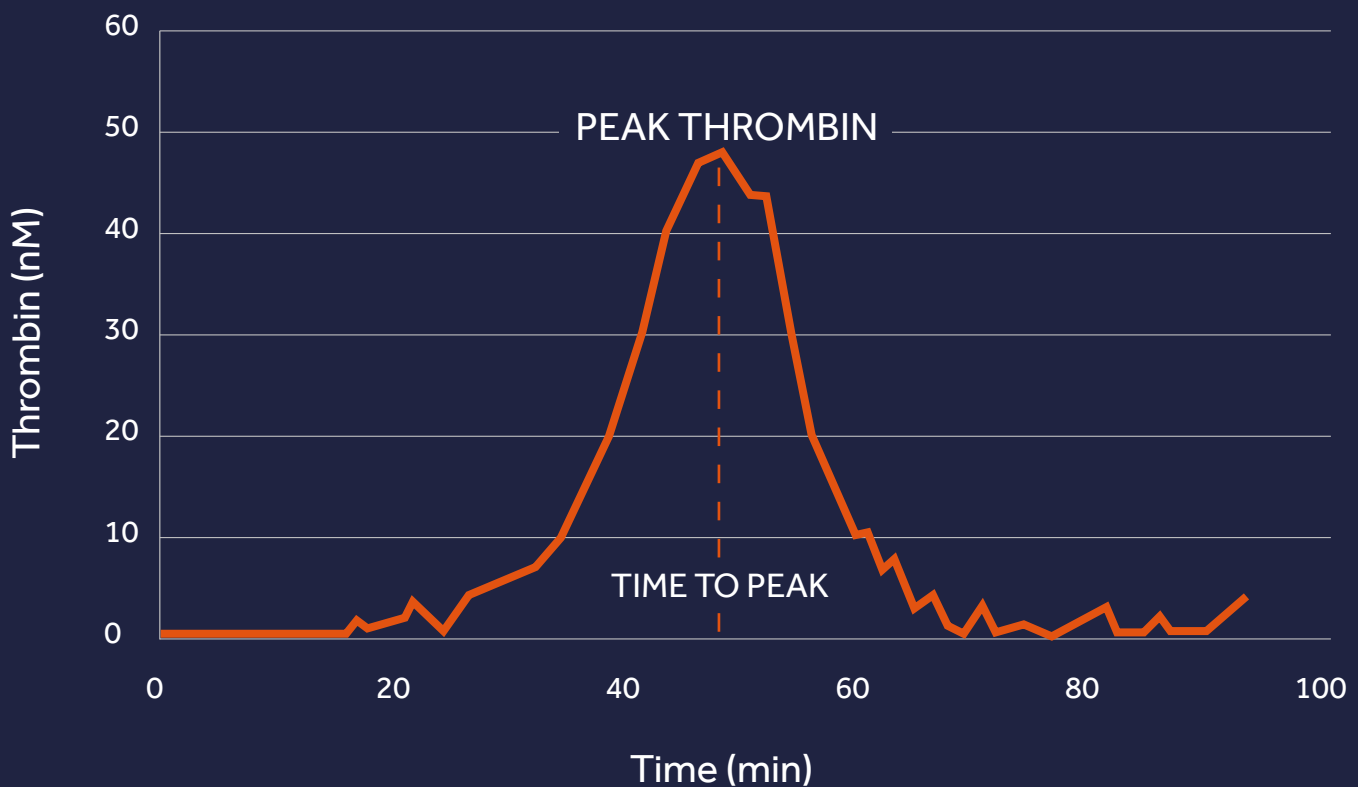


PIPELINE™ Flex with
SHIELD TECHNOLOGY™⁸
Surface =

- Smoother with less asperities for better deliverability
- Less thrombogenic risk
- Thinner to keep the optimal lumen diameter.

THROMBOGRAM ANALYSIS¹

This test, peak thrombin³ was measured as well as the time to peak thrombin.



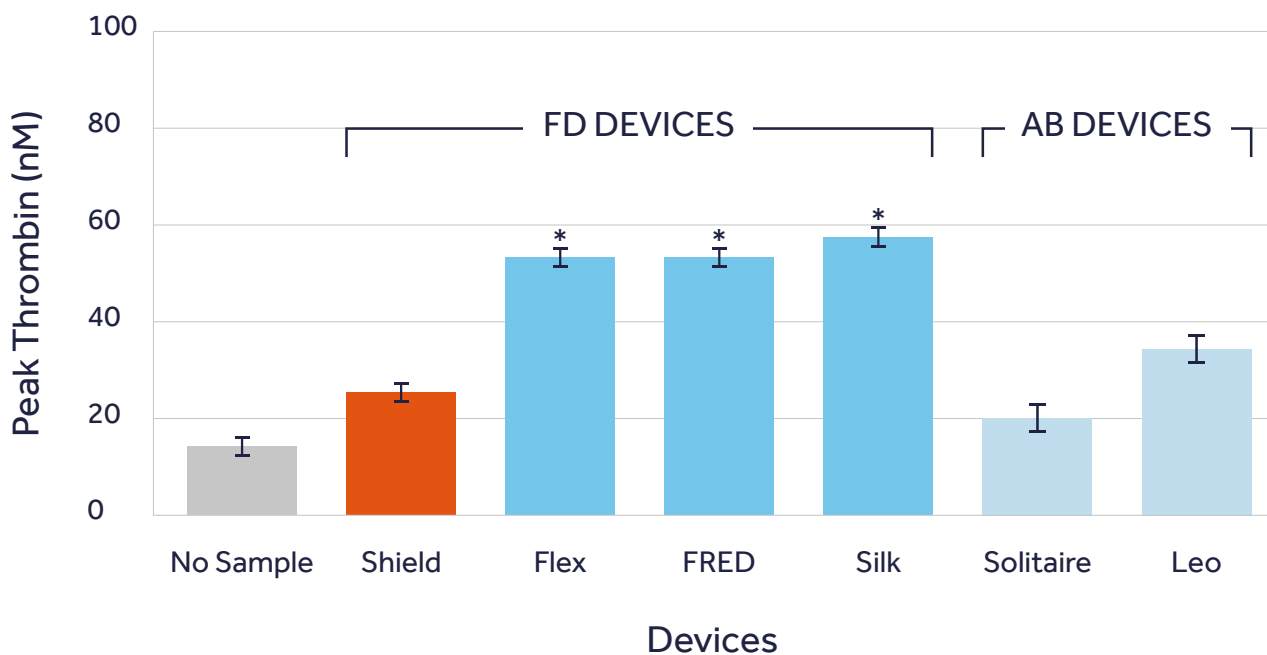
Measurement of thrombin generation³ is central to understanding and developing therapeutics for thrombosis treatment.

Increased thrombin generation predicts an increased risk of thrombosis.

THROMBOGRAM ANALYSIS¹

Pipeline™ Flex with Shield Technology™ = significant reduction³ in thrombin peak and time to peak, leading to less thrombogenic risk

Thrombin peak is equal to stent with better clinical outcomes⁵ in aneurysm treatment²

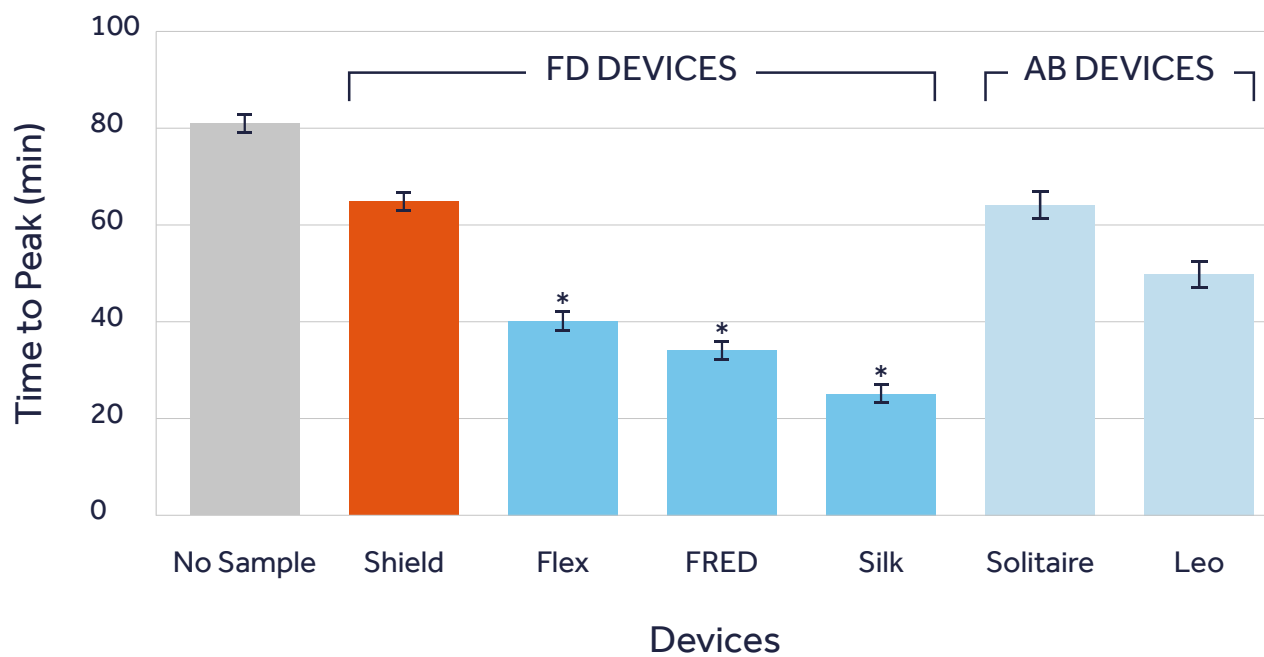


60%³

**LOWER PEAK
THROMBIN WITH
SHIELD COMPARED
TO SILK**

55%³

**LOWER PEAK
THROMBIN WITH
SHIELD COMPARED
TO FRED AND
PIPELINE FLEX**



60%³

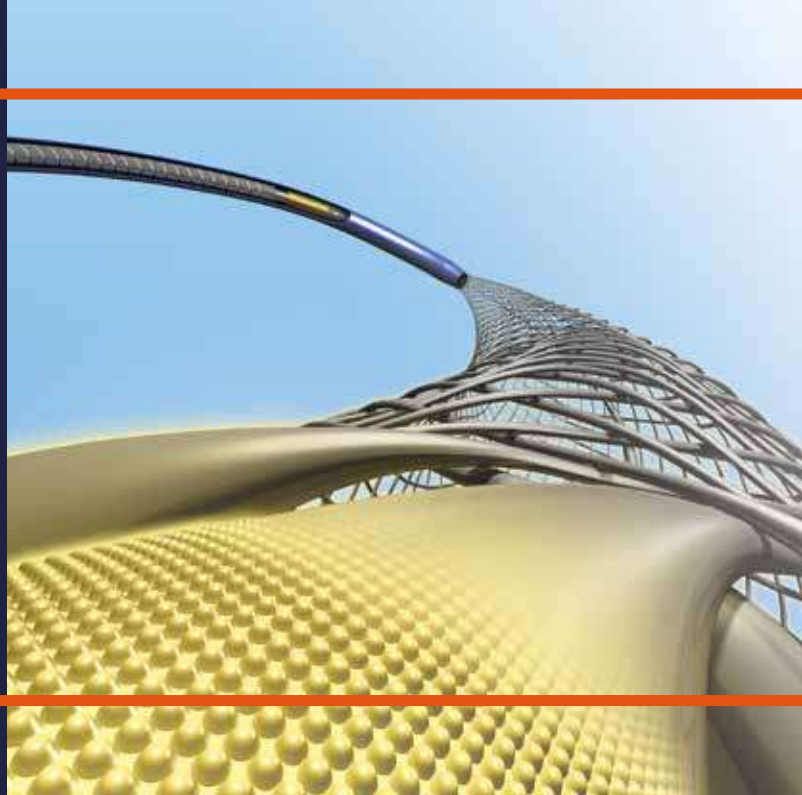
**HIGHER TIME TO
PEAK THROMBIN
WITH SHIELD
COMPARED TO SILK**

45%³

**HIGHER TIME TO
PEAK THROMBIN
WITH SHIELD
COMPARED TO FRED**

PFLEX⁶ STUDY

SOLUTIONS FOR ANEURYSM TREATMENT PIPELINE[™] FLEX WITH SHIELD TECHNOLOGY TRUSTED IN ACTION



STUDY OBJECTIVE⁶

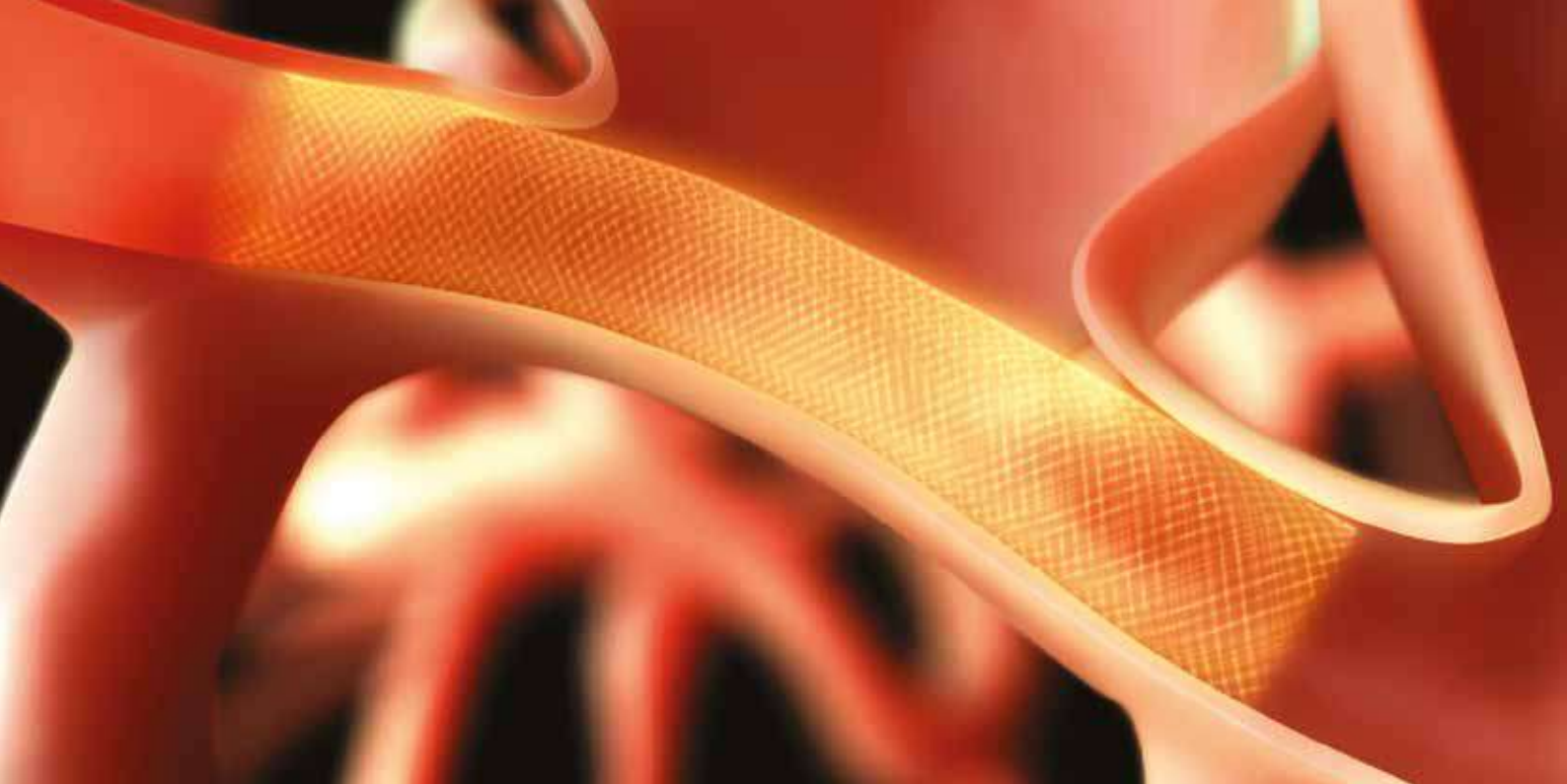
- To assess the incidence of safety outcomes in patients treated with the Pipeline[™] Flex Embolization Device with Shield Technology[™]

PRIMARY STUDY SAFETY ENDPOINT⁶

- Occurrence of major stroke in the territory supplied by the treated artery or neurological death at 1 year post-procedure

SECONDARY STUDY SAFETY ENDPOINT⁶

- Pipeline[™] Flex Embolization Device with Shield Technology[™] – related neurologic adverse event rate at one year post-procedure



ANEURYSM CHARACTERISTIC		n (%) (N=50)
Morphology	Saccular	49 (98%)
	Fusiform	1 (2%)
Parent Artery Location	Internal Carotid Artery	47 (94%)
	Vertebral Artery	3 (6%)

MEASUREMENT	MEDIAN (MEAN ± SD)
Aneurysm Max Diameter (mm)	7.15 (8.82 ± 6.15)
Neck Length (mm)	4.55 (5.06 ± 2.12)
Dome-to-neck Ratio	1.30 (1.52 ± 8.85)

PFLEX
STUDY

0%⁶

**TARGET
ANEURYSM
RECURRENCE**

0%⁶

**TARGET
ANEURYSM
RETREATMENT**

ANEURYSM OCCLUSION ⁴	n (%) (N=33)
Complete Occlusion	27 (81.8%)
Residual Neck	2 (6.1%)
Residual Aneurysm	4 (12.1%)

INITIAL CLINICAL DATA
SHOWS THAT PIPELINE™ FLEX
WITH SHIELD TECHNOLOGY™
**IS SAFE AND EFFECTIVE
FOR THE TREATMENT OF
INTRACRANIAL ANEURYSMS**

0%⁶

**MAJOR STROKE
IN THE TERRITORY
SUPPLIED BY THE
TREATED ARTERY**

0%⁶

**NEUROLOGICAL
DEATH**

PRIMARY SAFETY ENDPOINTS

SECONDARY SAFETY ENDPOINTS⁶

- 14% (n=7) Pipeline™ Shield related neurologic adverse event
- 6 in-stent stenosis; all asymptomatic and non-serious
- ICA thrombosis; asymptomatic, serious, resulted in no clinical sequelae

References

1. MedicineNet.com: <https://www.medicinenet.com/script/main/art.asp?articlekey=25023>
2. <http://www.worldthrombosisday.org/issue/thrombosis/>
3. Girdhar G, Li J, Kostousov L, et al. J Thromb Thrombolysis. 2015;40: 437. <https://doi.org/10.1007/s11239-015-1228-0>
4. Raymond-Roy Occlusion Scale³
5. Becske T. et al, Long-Term Clinical and Angiographic Outcomes Following Pipeline Embolization Device Treatment of Complex Internal Carotid Artery Aneurysms: Five-Year Results of the Pipeline for Uncoilable or Failed Aneurysms Trial, Neurosurgery. 2017 Jan 1;80(1):40-48
6. Galdámez M. PFLEX Study 1-year Results, SNIS Presentation, July 24, 2017.
7. Matsuda Y, et al. Analysis of neointima development in flow diverters using optical coherence tomography, JNIS, 2017.
8. Medtronic Study Performance Evaluation of Pipeline™ Flex Embolization Device with Shield Technology™, 12 September 2014, TR-NV11991 Rev. B

Indications

The Pipeline™ Flex embolization device is intended for endovascular embolization of cerebral aneurysms. The Pipeline™ Flex embolization device redefines the scope of treatment for large, giant, wide-necked, failed-treatment, and fusiform aneurysms by reconstructing the parent artery and restoring its natural course with or without the use of adjunctive embolic devices.

The Pipeline™ Flex embolization device with Shield Technology™ is intended for endovascular embolization of cerebral aneurysms.

Indications, contraindications, instructions for use and caution statements can be found in the product labelling supplied with each device.

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Captura website 1

The screenshot shows the Medtronic website for Axiom Detachable Coils. The page features the Medtronic logo at the top left, a search bar, and navigation links for Healthcare Professionals, Patients & Caregivers, Our Company, and Our Impact. The breadcrumb trail reads: Home > Healthcare Professionals > Products > Neurological > Aneurysm Treatment > Axiom. The main heading is "AXIUM™ Detachable Coils". Below this, a paragraph states: "The Axiom™ coils family offers an optimised packing volume and provides a stable frame and soft finish." Another paragraph mentions: "Its delivery is smooth thanks to the instant detacher, enabling less microcatheter kick-back¹, and a fast, reliable mechanical detachment²." To the right of the text is a 3D rendering of a coiled catheter. On the far right, there is a vertical sidebar with three icons: a printer, an envelope, and a link. At the bottom left, there is a blue shield icon with a checkmark. At the bottom right, there is a yellow warning icon followed by the text "Important Safety Information".

Medtronic

Healthcare Professionals Patients & Caregivers Our Company Our Impact

Home > Healthcare Professionals > Products > Neurological > Aneurysm Treatment > Axiom

AXIUM™ Detachable Coils

The Axiom™ coils family offers an optimised packing volume and provides a stable frame and soft finish.

Its delivery is smooth thanks to the instant detacher, enabling less microcatheter kick-back¹, and a fast, reliable mechanical detachment².

Important Safety Information

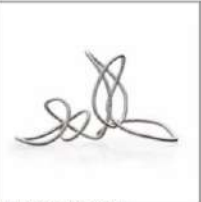
Captura website 2

The screenshot shows the Medtronic website for Axiom Detachable Coils, specifically the "EXPLORE THE AXIUM™ DETACHABLE COILS FAMILY:" section. This section contains a grid of six images, each showing a different type of coil. The first row shows three coils: "Axiom™ Prime FC: stable & conformable framing coils", "Axiom™ Prime SS: soft filling coils (3D & helical)", and "Axiom™ Prime ES: soft finishing coils (3D & helical)". The second row shows three coils: "Axiom™ Micro FX: fibred coils (3D & helical)", "Axiom™ Bare: conformable & utility coils (3D & helical)", and "Assisted delivery of Axiom™ coils". The page also features the Medtronic logo, navigation links, and a search bar. A blue shield icon with a checkmark is visible at the bottom left.

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EXPLORE THE AXIUM™ DETACHABLE COILS FAMILY:

		
Axiom™ Prime FC: stable & conformable framing coils	Axiom™ Prime SS: soft filling coils (3D & helical)	Axiom™ Prime ES: soft finishing coils (3D & helical)
		
Axiom™ Micro FX: fibred coils (3D & helical)	Axiom™ Bare: conformable & utility coils (3D & helical)	Assisted delivery of Axiom™ coils

Captura website 3

Medtronic Aneurysm Treatment Products - x +

europ.medtronic.com/xd-en/healthcare-professionals/products/neurological/aneurysm-treatment/axium.html

Apps Medtronic Sites My-source DRG - Centul de C... Rapoarte și situați... Institutul Național d... Database - Eurostat Main tables - Euro... Seturi de date - dat... SEAP Reading list

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AXIUM™ FAMILY

99.7% PROVEN RELIABILITY OF THE DETACHMENT SYSTEM

(in a study including 205 Axiom™ coils*)

BETTER TRACKABILITY THROUGH TORTUOUS ANATOMY

Tapered pusher with Contour® technology at the distal segment of pusher enhances trackability through tortuous anatomy³

MINIMAL MICROCATHETER KICK-BACK

Ball & socket design allows for 360° axial rotation⁴ which facilitates coil delivery with less microcatheter kick-back⁵

Captura website 4

Medtronic Aneurysm Treatment Products - x +

europ.medtronic.com/xd-en/healthcare-professionals/products/neurological/aneurysm-treatment/axium.html

Apps Medtronic Sites My-source DRG - Centul de C... Rapoarte și situați... Institutul Național d... Database - Eurostat Main tables - Euro... Seturi de date - dat... SEAP Reading list

Healthcare Professionals Patients & Caregivers Our Company Our Impact

PROGRESSIVE & OPTIMISED PACKING VOLUME

The entire Axiom™ family features a progressive outer diameter matched to the implant size optimises stability and volume throughout the entire coil line.

PROGRESSIVE COIL DESIGN: LESS COILS, MORE VOLUME

Classic & Frame OD: 0.0115"	Classic & Frame OD: 0.0125"	Classic & Frame OD: 0.0135"	Classic & Frame OD: 0.0145"
ExtraSoft OD: 0.0108"	SuperSoft OD: 0.0115"		
			

0mm 5mm 10mm

Captura website 5

Medtronic

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AXIUM™ PRIME FRAME

AXIUM™ PRIME FRAME (FC)

Axium™ Prime Frame are memory-shaped nitinol coils with a unique loop configuration, hybrid of open & closed loops.

Versatility to conform to different aneurysm morphologies with the flexible OMEGA open loops⁶.

Stability enhanced with OMEGA closed-loop patterns for the first and last loops⁷.

Consistent and dense neck coverage as the successive loops change directions⁸.



Captura website 6

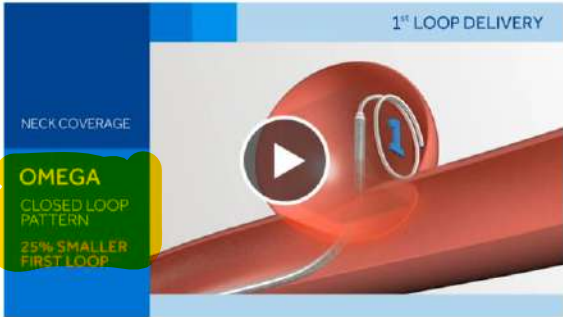
Medtronic

Healthcare Professionals Patients & Caregivers Our Company Our Impact

1st LOOP DELIVERY

NECK COVERAGE

OMEGA
CLOSED LOOP PATTERN
25% SMALLER FIRST LOOP



Captura website 7

Medtronic

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CHARACTERISTICS

Coil O.D. (in)	0.0115	0.0125	0.0135	0.0145
Diameter (mm)	3.0 - 3.5	4.0 - 6.0	7.0 - 10.0	12.0 - 25.0
Length (cm)	6 - 10	6.0 - 25.0	12.0 - 40.0	30.0 - 50.0
Vol. (mm ³)	4.02 - 6.70	4.75 - 19.79	11.08 - 36.94	31.96 - 53.27

Captura website 8

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AXIUM™ PRIME SUPER SOFT AND EXTRA SOFT



Axiom™ Prime Extra Soft and Super Soft are one of the softest coils on the market. This softness is achieved with a thinner filar and thinner stretch resistant stranders.

WHAT ARE THE KEY BENEFITS OF AXIUM™ PRIME ES AND SS COILS?

- Conformability and random loops
- Optimal softness for filling and finishing

Captura website 9

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CHARACTERISTICS

	ES 3D	ES HELIX	SS 3D	SS HELIX
Coil O.D. (in)	0.0108	0.0108	0.0115	0.0115
Diameter (mm)	1.0 - 3.5	1.0 - 3.0	4.0 - 6.0	4.0 - 6.0
Length (cm)	2 - 10	1 - 10	6 - 20	6 - 20
Vol. (mm ³)	1.34 - 6.70	0.67 - 6.70	4.02 - 13.40	4.02 - 13.40

Captura website 10

Medtronic

Healthcare Professionals Patients & Caregivers Our Company Our Impact

AXIUM™ MICRO FX™

Axiom™ MicroFX™ coils with LatticeFX™ technology have overlapped individual nylon or PGLA microfilaments between coil loops, forming an intra-aneurysmal surface area for stable scar tissue formation and high thrombogenicity.

These coils provide the acute performance of an Axiom™ Bare coil with the added benefit of LatticeFX™ technology.

- Flow reduction across the neck⁹
- Increased thrombogenicity⁹
- 33% less flow through MicroFX™ coils vs. standard Axiom™ coils¹⁰



Captura website 11

Aneurysm Treatment Products

europa.medtronic.com/xd-en/healthcare-professionals/products/neurological/aneurysm-treatment/axium.html

Apps Medtronic Sites My-source DRG - Centrul de C... Rapoarte si situati... Institutul National d... Database - Eurostat Main tables - Euros... Seturi de date - dat... SEAP

Medtronic Healthcare Professionals Patients & Caregivers Our Company Our Impact

FOR VARIOUS SITUATIONS

Axium™ MicroFX™ coils are particularly indicated for aneurysms that have a high likelihood of rupture or are already ruptured given their high thrombogenicity and filling capacity. They should also be considered for vessel take down and fistulae as the increased filling capacity will likely reduce the procedure time and cost.

Finally, they can assist a flow diversion procedure where a quick thrombus formation inside the aneurysm is needed.

CHARACTERISTICS

	PGLA 3D	PGLA Helix	Nylon Helix
Coil O.D. (in)	0.0115 - 0.0145	0.0115 - 0.0135	0.0115 - 0.0125
Diameter (mm)	2 - 18	2 - 10	2 - 4
Length (cm)	2 - 40	1 - 30	1 - 10
Vol. (mm³)	1.34 - 42.61	0.67 - 27.7	0.67 - 7.92

Captura website 12

Aneurysm Treatment Products

europa.medtronic.com/xd-en/healthcare-professionals/products/neurological/aneurysm-treatment/axium.html

Apps Medtronic Sites My-source DRG - Centrul de C... Rapoarte si situati... Institutul National d... Database - Eurostat Main tables - Euros... Seturi de date - dat... SEAP

Medtronic Healthcare Professionals Patients & Caregivers Our Company Our Impact

AXIUM™ BARE (QC)



Axiom™ Bare coils pioneered the Axiom™ family's benefits of high volumetric filling, progressive coil diameter as well as a highly reliable smooth and instant detachment system. The system offers the optimal balance with the softness of a "10" coil and the stability/volume of an "18" coil.

Since 2007, several product enhancements have been made to optimise the design of Axiom™ Bare (QC) coils. Their unique combination of softness and stability is obtained by balancing the size of the primary wire and the outer diameter.

The 3D design has a large loop diameter to sphere diameter ratio and infinite, random break points.

Captura website 13

Medtronic

Healthcare ProfessionalsPatients & CaregiversOur CompanyOur Impact

FOR VARIOUS SITUATIONS

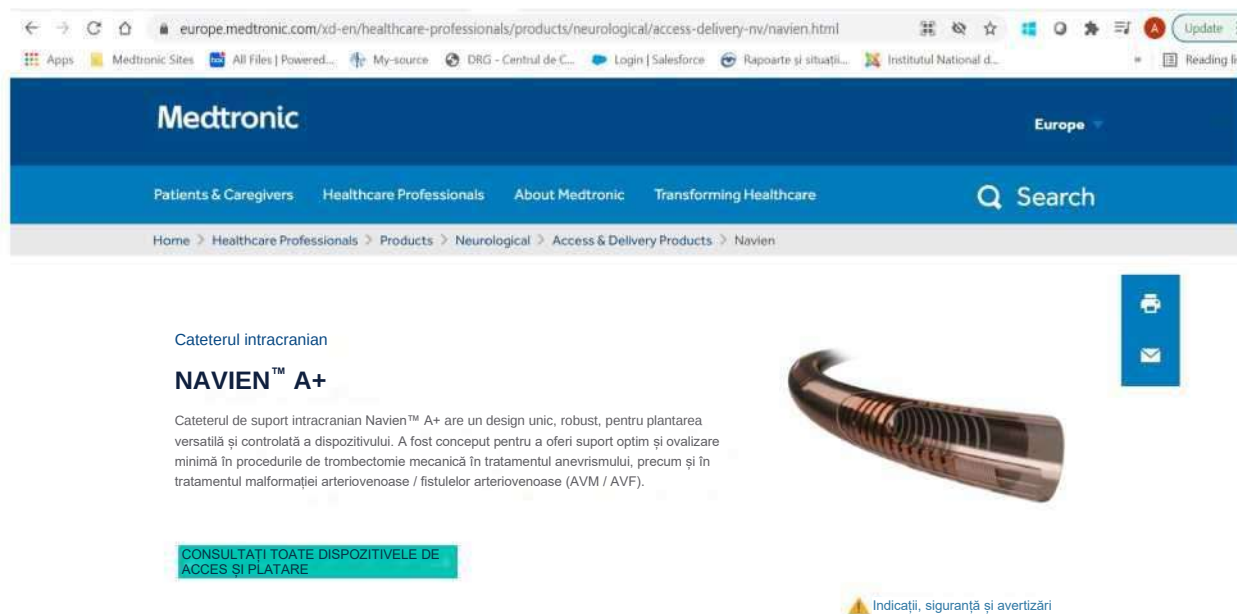
In sizes 1-6mm, QC coils have a larger OD than our Axiom™ Prime line making it an ideal choice to frame and fill smaller a-morphic aneurysm where a robust coil is required and less softness is desired.

- Enhanced conformability and reduced compartmentalisation
- Deflected into aneurysm spaces more effectively for better packing
- Reduced "tumbling"
- Facilitated repositioning
- Small first loop (~70% of nominal loop diameter) anchors coil in aneurysm

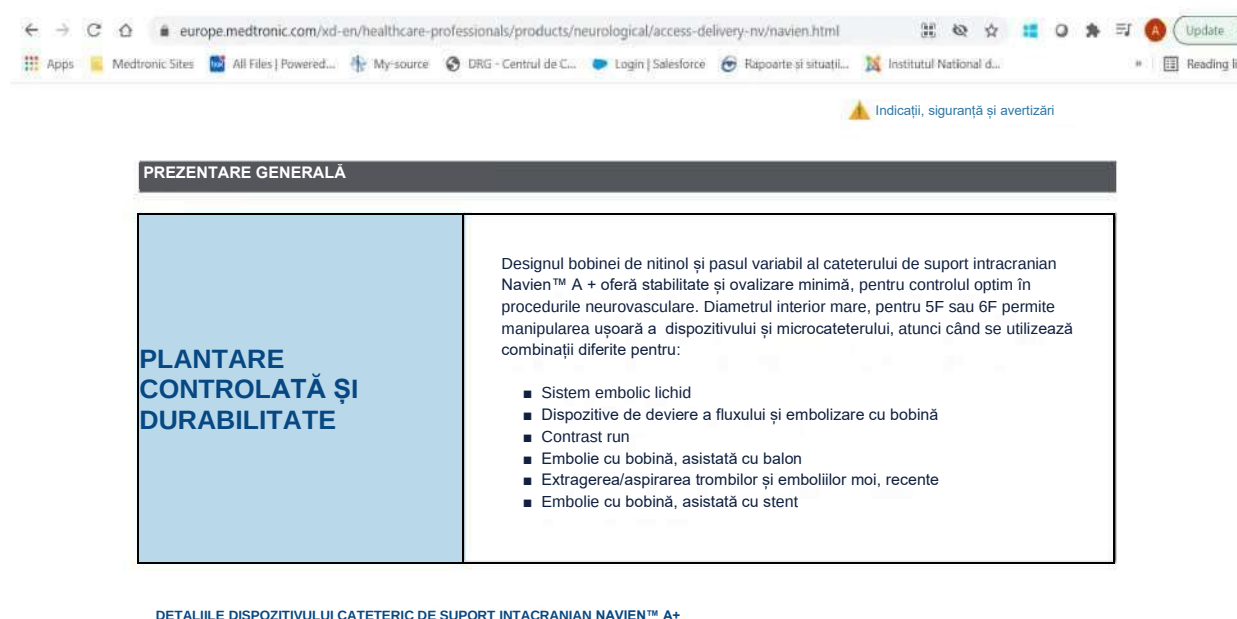
CHARACTERISTICS

	3D	Helix
Coil O.D. (in)	0.0115 - 0.0145	0.0115 - 0.0145
Diameter (mm)	2 - 25	1.5 - 20
Length (cm)	2 - 50	1 - 50
Vol. (mm³)	1.34 - 53.27	0.67 - 53.27

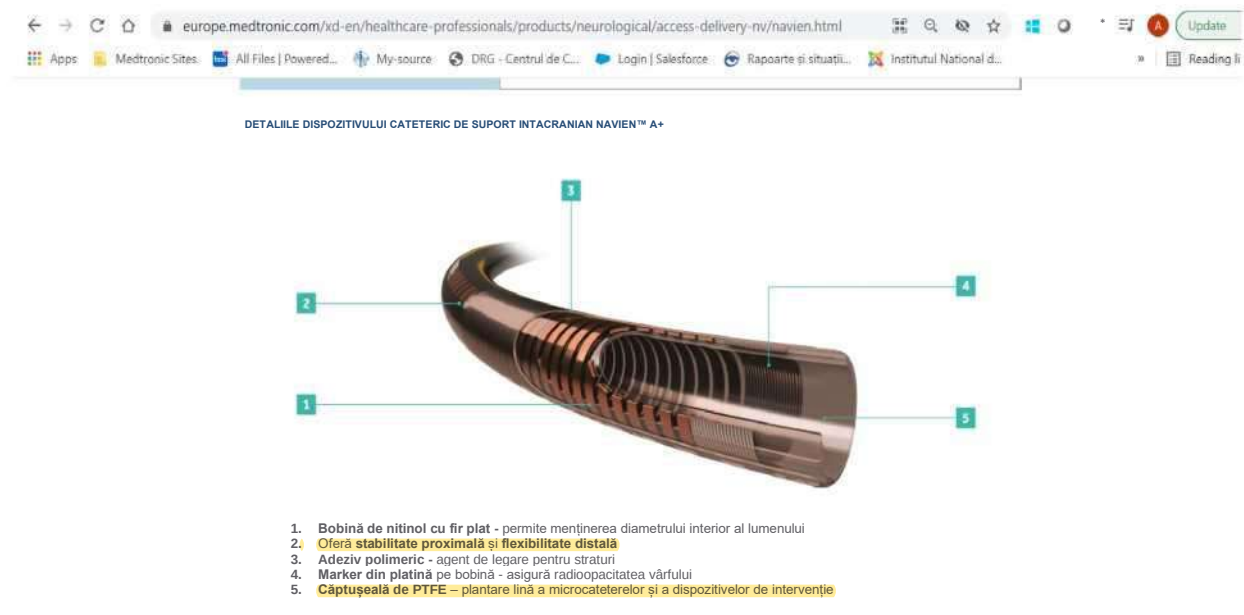
Captura website 1



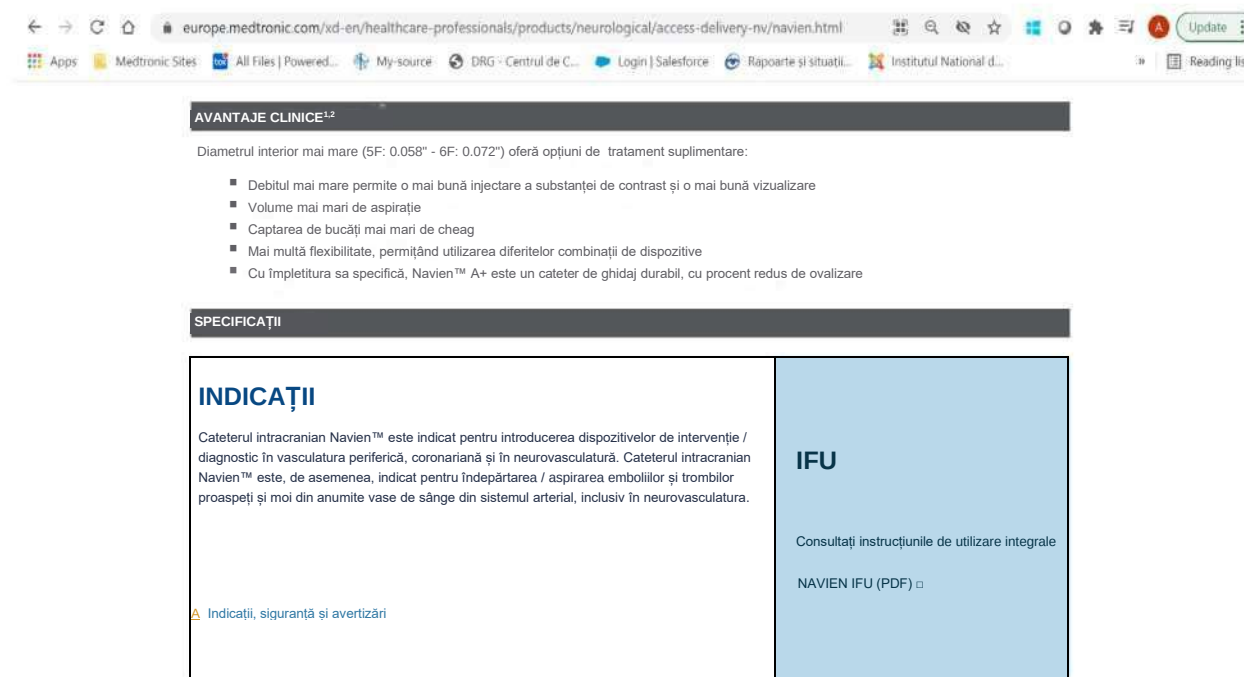
Captura website 2



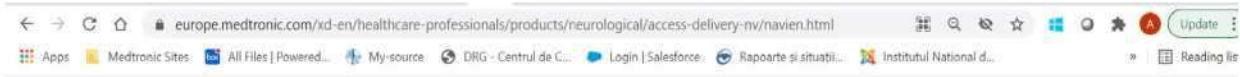
Captura website 3



Captura website 4



Captura website 7



CFNS DISPONIBILE PENTRU NAVIEN™ 6F

COLUMNS: STACK ▼

CFN	Diametrul maxim exterior (inci)	Diametrul interior (inci)	Lungimea totală (cm)	Forma vârfului
RFXA072-95-08	0.084	0.072	95	Drept
RFXA072-95-08MP	0.084	0.072	95	Multi-scop, la 25°
RFXA072-105-08	0.084	0.072	105	Drept
RFXA072-105-08MP	0.084	0.072	105	Multi-scop, la 25°
RFXA072-115-08	0.084	0.072	115	Drept
RFXA072-115-08MP	0.084	0.072	115	Multi-scop, la 25°
RFXA072-125-08	0.084	0.072	125	Drept
RFXA072-125-08MP	0.084	0.072	125	Multi-scop, la 25°
RFXA072-130-08	0.084	0.072	130	Drept
RFXA072-130-08MP	0.084	0.072	130	Multi-scop, la 25°

Captura website 1

The screenshot shows the Medtronic website for the Pipeline Flex embolization device. The page features the Medtronic logo at the top left, a search bar, and a location selector set to "United States". A navigation bar includes links for "Healthcare Professionals", "Patients & Caregivers", "Our Company", and "Our Impact". The breadcrumb trail reads: "Home > Healthcare Professionals > Products > Neurological > Aneurysm Treatment > Pipeline".

PIPELINE™ FLEX

Embolization Device

The clinically proven¹ Pipeline™ Flex embolization device redefines treatment for certain wide-necked intracranial aneurysms by diverting flow away from the aneurysm neck, reconstructing the parent artery and restoring its natural course.^{2,3}

[DOWNLOAD BROCHURE](#)

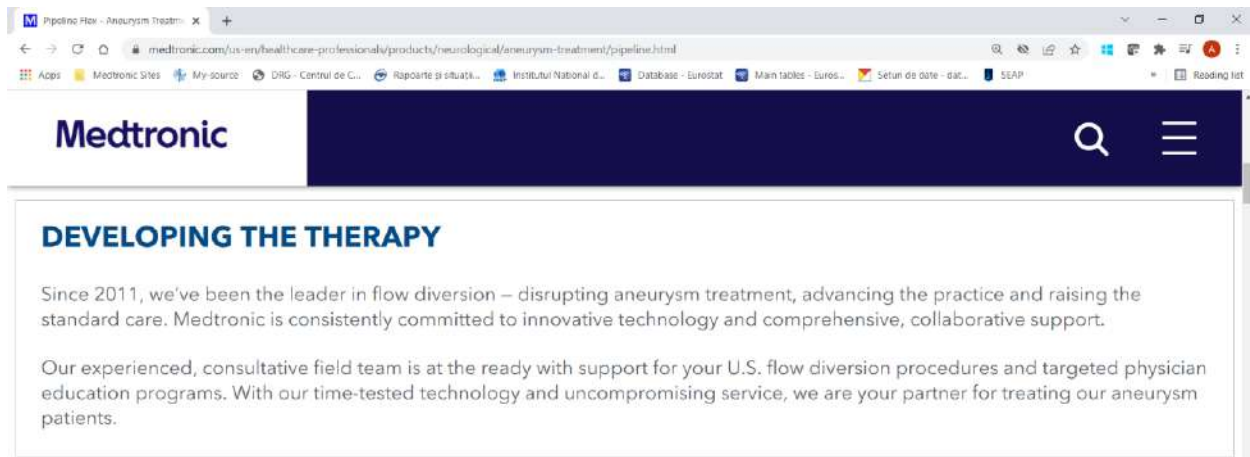
[Indications, Safety and Warnings](#)

On the right side of the page, there is a vertical menu with icons for printing, email, and linking.

Captura website 2

This screenshot shows the "OVERVIEW" section of the Pipeline Flex product page. It features a video player with a play button in the center. To the left of the video, the text reads: "ACCEPT NO SUBSTITUTE. Pipeline™ Flex". The video itself shows a 3D anatomical model of a brain aneurysm with the Pipeline Flex device being deployed into it. The video player has a progress bar at the bottom showing "0:00 / 0:30".

Captura website 3



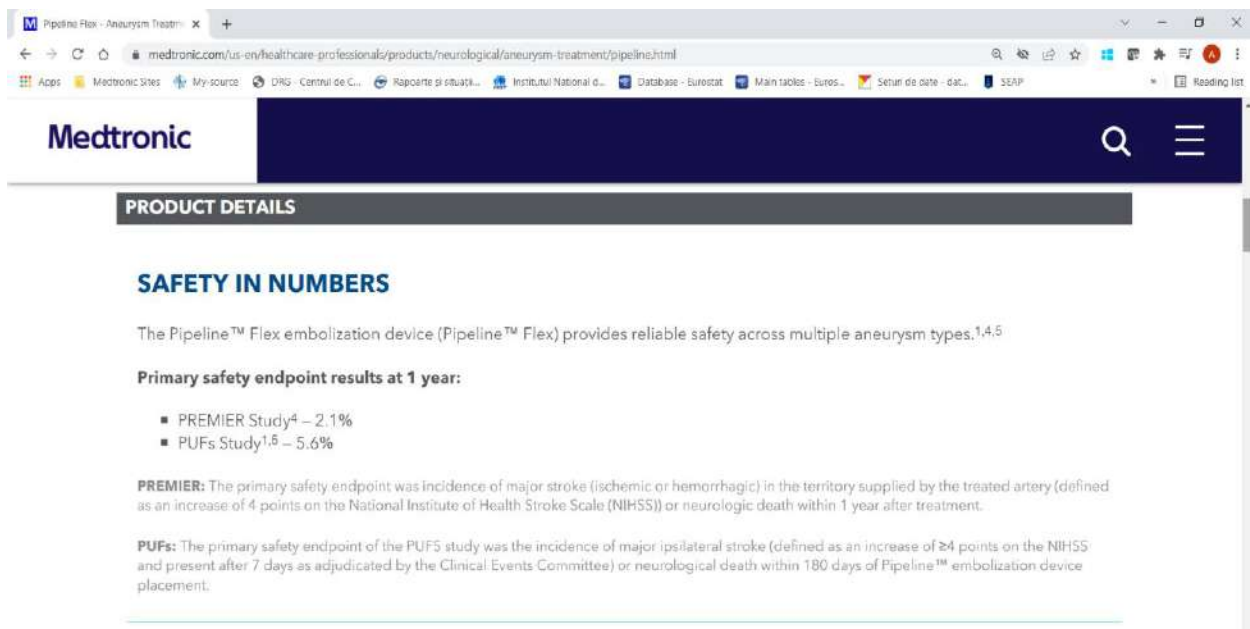
The screenshot shows a web browser window with the URL medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/pipeline.html. The Medtronic logo is in the top left. The main heading is "DEVELOPING THE THERAPY". Below it, the text reads: "Since 2011, we've been the leader in flow diversion – disrupting aneurysm treatment, advancing the practice and raising the standard care. Medtronic is consistently committed to innovative technology and comprehensive, collaborative support." Another paragraph follows: "Our experienced, consultative field team is at the ready with support for your U.S. flow diversion procedures and targeted physician education programs. With our time-tested technology and uncompromising service, we are your partner for treating our aneurysm patients."

DEVELOPING THE THERAPY

Since 2011, we've been the leader in flow diversion – disrupting aneurysm treatment, advancing the practice and raising the standard care. Medtronic is consistently committed to innovative technology and comprehensive, collaborative support.

Our experienced, consultative field team is at the ready with support for your U.S. flow diversion procedures and targeted physician education programs. With our time-tested technology and uncompromising service, we are your partner for treating our aneurysm patients.

Captura website 4



The screenshot shows the same web browser window as before, but scrolled down to the "SAFETY IN NUMBERS" section. A dark grey bar with the text "PRODUCT DETAILS" is visible above the heading. The text reads: "The Pipeline™ Flex embolization device (Pipeline™ Flex) provides reliable safety across multiple aneurysm types.^{1,4,5}" Below this, it states "Primary safety endpoint results at 1 year:" followed by a bulleted list: "PREMIER Study⁴ – 2.1%" and "PUFs Study^{1,5} – 5.6%". Two paragraphs of detailed definitions for PREMIER and PUFs follow.

PRODUCT DETAILS

SAFETY IN NUMBERS

The Pipeline™ Flex embolization device (Pipeline™ Flex) provides reliable safety across multiple aneurysm types.^{1,4,5}

Primary safety endpoint results at 1 year:

- PREMIER Study⁴ – 2.1%
- PUFs Study^{1,5} – 5.6%

PREMIER: The primary safety endpoint was incidence of major stroke (ischemic or hemorrhagic) in the territory supplied by the treated artery (defined as an increase of 4 points on the National Institute of Health Stroke Scale (NIHSS)) or neurologic death within 1 year after treatment.

PUFs: The primary safety endpoint of the PUF5 study was the incidence of major ipsilateral stroke (defined as an increase of ≥ 4 points on the NIHSS and present after 7 days as adjudicated by the Clinical Events Committee) or neurological death within 180 days of Pipeline™ embolization device placement.

Captura website 5

medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/pipeline.html

Apps Medtronic Sites My source DRG - Control de C... Rapoarte si situati... Institutul National d... Database - Eurostat Main tables - Euros... Seturi de date - dat... SEAP Reading list

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TIME-TESTED EFFICACY

Pipeline™ Flex achieves reliable efficacy across multiple aneurysm types at 1 year⁶ and out to 5 years.^{1,8*}

Primary effectiveness endpoint results at 1 year:

- PREMIER Study⁴ – 76.8%

Long term complete occlusion rates:

- PUFs Study^{1,5} – 95% at 5 years with 0% recurrence

PREMIER: The primary effectiveness endpoint of the study was complete aneurysm occlusion of the target aneurysm without major stenosis ($\leq 50\%$) of the parent artery or retreatment of the target aneurysm at one year post-procedure, as adjudicated by an independent core laboratory ("Core Lab"), or retreatment of the target intracranial aneurysms (IA) one year post-procedure.

PUFs: The primary effectiveness endpoint of the study was complete occlusion of the aneurysm without major ($>50\%$) stenosis of the parent artery or adjunctive use of complimentary embolic agent as seen on 180-day angiography and judged by the independent core research lab (CRL).

*Data based on follow up images available.



Captura website 6

medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/pipeline.html

Apps Medtronic Sites My source DRG - Control de C... Rapoarte si situati... Institutul National d... Database - Eurostat Main tables - Euros... Seturi de date - dat... SEAP Reading list

Medtronic 🔍 ☰

TRUSTED POSITIONING

The design and material properties of Pipeline™ Flex lead to uniform wall apposition.⁷ When delivered through the Phenom™ 27 catheter, specifically designed for flow diversion,⁸ system stability is optimized.⁹



Pipeline™ Flex Wall Apposition

Internal Bench Top Study⁷ PED-300-30 in 3mm vessel.



Captura website 7

medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/pipeline.html

Medtronic

PIPELINE™ FLEX TECHNICAL FEATURES

The technical features of Pipeline™ Flex support a safe and highly effective procedure.²

- 48-strand braided mesh design and a soft low profile distal tip¹⁰ for flexible conformability
- 75% cobalt chromium / 25% platinum tungsten for radial force and uniform radiopacity¹¹
- 30-35% surface coverage at nominal diameter¹²
- Trackable through tortuosity, enabling better vessel deflection and allowing for a controlled distal landing zone¹⁰
- Fully resheathable and can be repositioned and redeployed up to two times¹⁰

Captura website 8

medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/pipeline.html

Medtronic

Healthcare Professionals Patients & Caregivers Our Company Our Impact

INVESTING IN EVIDENCE-BASED MEDICINE

Pipeline™ Flex is the most studied flow diverter worldwide with a proven safety and efficacy profile.^{12,13}



OVER 1700 PATIENTS
clinically evaluated with the Pipeline™ embolization device.

PREMIER¹ n=141
INTREPED² n=793
ASPIRE¹³ n=191
BEUNOS AIRES EXPERIENCE¹⁴ n=53
PUFS¹ n=107
PITA¹² n=31
ANKARA EXPERIENCE¹⁵ n=191
HONG KONG EXPERIENCE¹⁶ n=143
AUSTRALIAN REGISTRY²⁰ n=54

Medtronic

2022 catalog

Neurovascular

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Aspiration

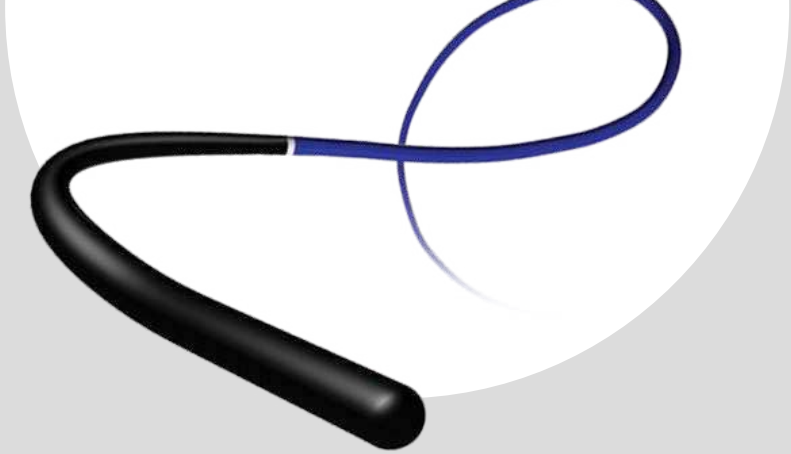
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Guidewires

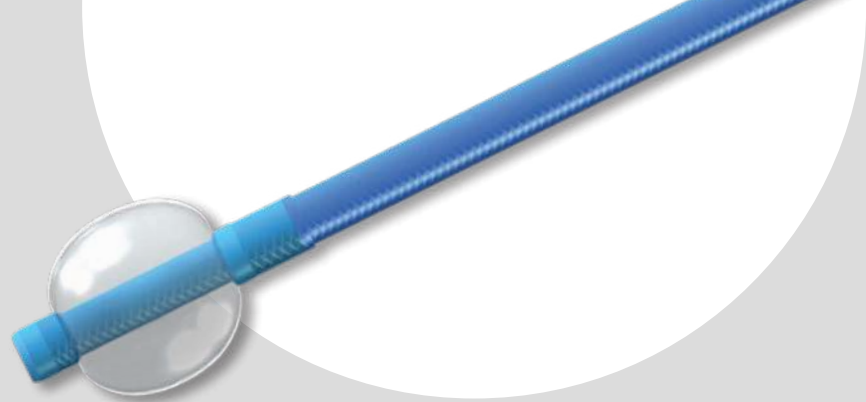


Avigo™ .014" Hydrophilic Guidewire			
Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0606-200	.014	205	5

Mirage™ .008" Hydrophilic Guidewire			
Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0608	.012>.008	200	10

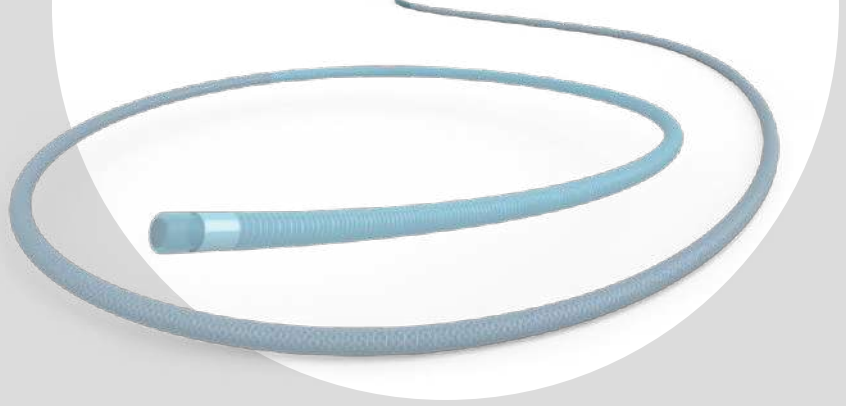
X-Pedion™ Hydrophilic Guidewire			
Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0605-200	.012>.010	200	10

Balloon Guide Catheters



Cello™ Balloon Guide Catheter								
Product Catalog Number	Product Name	Conformable Sheath (F)	Tip Length (mm)	Balloon Length (mm)	OD (in)	ID (cm)	Effective Length (cm)	Total Length (cm)
1610560	Cello 6F+	7	3	7	0.075	0.051	95	103
1610570	Cello 7F+	8	3	7	0.095	0.067	95	103
1610580	Cello 8F	8	3	10	0.102	0.075	95	103
1610590	Cello 9F	9	3	10	0.118	0.085	92	100

Distal Access Catheters



Phenom™ Plus Catheter

Product Catalog Number	Working Length (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Catheter Inner Diameter (in)
FG19120-1030-1S	120	0.061	0.055	0.0445

React™ 68 Catheter

Product Catalog Number	ID (in)	Max OD (in)	Working Length (cm)
REACT-68	0.068	0.083	132

React™ 71 Catheter

Product Catalog Number	ID (in)	Max OD (in)	Working Length (cm)
REACT-71	0.071	0.0855	132

Radial Access System



The Rist™ Radial Access System features the first guide catheter designed for the unique demands of accessing the neurovasculature through the radial pathway.¹⁻⁹

Rist™ 079 Radial Access Guide Catheter^{6,7}

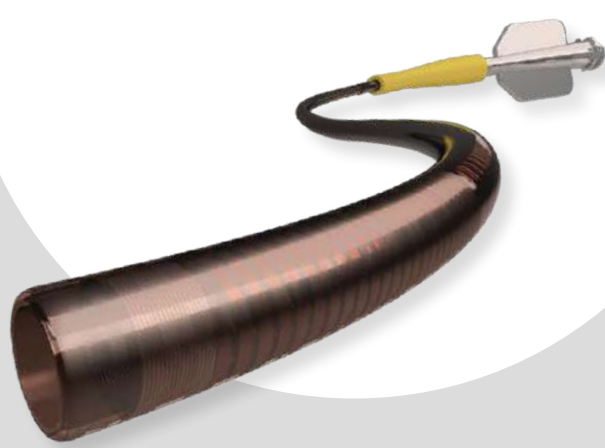
Product Catalog Number	Working Length (cm)	OD (in / F)	ID (in)	Hydrophilic Coating Length (cm)
107F-079-95	95	0.093 / 7F	0.079	25
107F-079-100	100	0.093 / 7F	0.079	25
107F-079-105	105	0.093 / 7F	0.079	25

Rist™ Radial Access Selective Catheter⁸

Product Catalog Number	Working Length (cm)	OD (in / F)	ID (in)	Tip Shapes
105F-BER-120	120	0.070 / 5.5F	0.040	Berenstein
105F-BER-130	130	0.070 / 5.5F	0.040	Berenstein
105F-SIM-120	120	0.070 / 5.5F	0.040	Sim2
105F-SIM-130	130	0.070 / 5.5F	0.040	Sim2

1. INC TR-12549
2. INC TR-12736
3. INC TR-13494
4. INC TR-13523
5. K191551
6. K201682
7. INC-11816
8. INC-11694
9. D00312142

Intracranial Support Catheters



Navien™ Intracranial Support Catheter

Product Catalog Number	Maximum Outer Diameter (F / in)	Inner Diameter (in)	Length (cm)	Tip Shape	Max Wire Compatibility (in)	Flexible Distal Length (cm)
RFX058-105-08	5 / 0.070	0.058	105	Straight	0.038	8
RFX058-115-08	5 / 0.070	0.058	115	Straight	0.038	8
RFX058-125-08	5 / 0.070	0.058	125	Straight	0.038	8
RFX058-130-08	5 / 0.070	0.058	130	Straight	0.038	8
RFX072-95-08	6 / 0.084	0.072	95	Straight	0.038	8
RFX072-95-08MP	6 / 0.084	0.072	95	Multi-Purpose 25°	0.038	8
RFX072-105-08	6 / 0.084	0.072	105	Straight	0.038	8
RFX072-105-08MP	6 / 0.084	0.072	105	Multi-Purpose 25°	0.038	8
RFX072-115-08	6 / 0.084	0.072	115	Straight	0.038	8
RFX072-115-08MP	6 / 0.084	0.072	115	Multi-Purpose 25°	0.038	8
RFX072-125-08	6 / 0.084	0.072	125	Straight	0.038	8
RFX072-125-08MP	6 / 0.084	0.072	125	Multi-Purpose 25°	0.038	8
RFX072-130-08	6 / 0.084	0.072	130	Straight	0.038	8
RFX072-130-08MP	6 / 0.084	0.072	130	Multi-Purpose 25°	0.038	8

Micro Catheters



Phenom™ 17 Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Working Length (cm)	Soft Distal Segment (cm)	Flexible Single Coil Segment (cm)	Tip Shape	Max. Guidewire (in)
FG11150-0615-2S	2.2>1.8	0.017	150	6	15	Straight	0.014
FG11150-0615-2J	2.2>1.8	0.017	150	6	15	J Curve	0.014
FG11150-0615-2X	2.2>1.8	0.017	150	6	15	45 Curve	0.014
FG11150-0615-2R	2.2>1.8	0.017	150	6	15	90 Curve	0.014

Phenom™ 21 Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Working Length (cm)	Soft Distal Segment (cm)	Flexible Single Coil Segment (cm)	Tip Shape	Max. Guidewire (in)
FG13150-0615-2S	2.6>2.3	0.021	150	6	15	Straight	0.018
FG13160-0615-1S	2.6>2.3	0.021	160	6	15	Straight	0.018

Phenom™ 27 Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Working Length (cm)	Soft Distal Segment (cm)	Flexible Single Coil Segment (cm)	Tip Shape	Max. Guidewire (in)
FG15150-0615-1S	3.1>2.8	0.027	150	6	15	Straight	0.025
FG15150-0630-1S	3.1>2.8	0.027	150	6	30	Straight	0.025
FG15160-0615-1S	3.1>2.8	0.027	160	6	15	Straight	0.025

Rebar™ 18 Reinforced Micro Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)
105-5081-153*	2.7>2.4	.021	153	0.018

Rebar™ 27 Reinforced Micro Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)
105-5082-130	2.8>2.8	.027	130	0.021

Micro Catheters



Apollo™ Onyx™ Delivery Micro Catheter

Product Catalog Number	Proximal Outer Diameter (F/in)	Distal Outer Diameter (F/in)	Inner Diameter (in)	Total Length (cm)	Tip Length (cm)	Tip Shape	Wire Compatibility (in)	Minimum Dead Space (ml)
105-5095-000	2.7 / 0.036	1.5 / 0.020	0.013	165	1.5	Straight	0.008 & 0.010 hydrophilic	> 0.23
105-5096-000	2.7 / 0.036	1.5 / 0.020	0.013	165	3.0	Straight	0.008 & 0.010 hydrophilic	> 0.20

Marathon™ Flow Directed Micro Catheter

Product Catalog Number	Stylet	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Distal Length (cm)	Max. Guidewire (in)
105-5056	Without	2.7>1.5	.015>.013	165	25	0.010

Marksman™ Micro Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Distal Length (cm)	Max. Guidewire (in)
FA-55105-1015	3.2>2.8	0.027	105	10	0.021
FA-55135-1030	3.2>2.8	0.027	135	10	0.021
FA-55150-1030	3.2>2.8	0.027	150	10	0.021
FA-55160-1030	3.2>2.8	0.027	160	10	0.021

Echelon™ 10 Micro Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)	Tip Configuration
105-5091-150	2.1>1.7	.017	150	0.014	Straight
145-5091-150	2.1>1.7	.017	150	0.014	45°
190-5091-150	2.1>1.7	.017	150	0.014	90°

Echelon™ 14 Micro Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)	Tip Configuration
105-5092-150	2.4>1.9	.017	150	0.014	Straight
145-5092-150	2.4>1.9	.017	150	0.014	45°
190-5092-150	2.4>1.9	.017	150	0.014	90°

Balloons



HyperForm™ Occlusion Balloon Systems

Product Catalog Number	Usable Length (cm)	Balloon Diameter (mm)	Balloon Length (mm)	Tip Length (mm)	Proximal OD (FR)	Distal OD (FR)	Guidewire (in)
104-4370	150	3	7	2	2.8	2.2	.010
104-4153	150	3	15	2	2.8	2.2	.010
104-4470	150	4	7	2	2.8	2.2	.010
104-4415	150	4	15	2	2.8	2.5	.010
104-4420	150	4	20	2	2.8	2.5	.010
104-4770	150	7	7	2	2.8	3.0	.010
104-4715	150	7	15	2	2.8	3.0	.010

All systems packaged with an X-Pedion™ hydrophilic guidewire (103-0605-200). Balloon component not sold individually.

HyperGlide™ Occlusion Balloon Systems

Product Catalog Number	Usable Length (cm)	Balloon Diameter (mm)	Balloon Length (mm)	Tip Length (mm)	Proximal OD (FR)	Distal OD (FR)	Guidewire (in)
104-4310	150	3	10	4	2.8	2.2	.010
104-4315	150	3	15	4	2.8	2.2	.010
104-4113	150	4	10	4	2.8	2.2	.010
104-4112	150	4	15	4	2.8	2.2	.010
104-4127	150	4	20	4	2.8	2.2	.010
104-4132	150	4	30	4	2.8	2.2	.010
104-4515	150	5	15	4	2.8	2.2	.010
104-4520	150	5	20	4	2.8	2.2	.010
104-4530	150	5	30	4	2.8	2.2	.010

All systems packaged with an X-Pedion™ hydrophilic guidewire (103-0605-200). Balloon component not sold individually.

Liquid Embolics



Onyx™ Liquid Embolic System

Product Catalog Number	Description
105-7100-060	Onyx™ 18 LES
105-7100-080	Onyx™ 34 LES

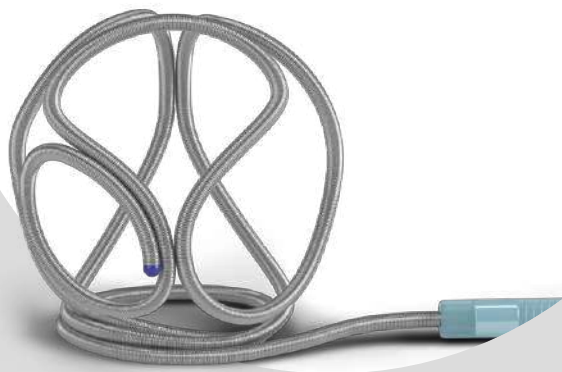
The Onyx™ 18 and 34 LES Kits contain¹:

- 1.5 ml vial of Onyx™ LES (1)
- 1.5 ml vial of DMSO (1)
- 1 ml DMSO syringe (1)
- 1 ml Onyx™ LES syringe (2)

Onyx™ LES Accessories

Product Catalog Number	Description
103-1205-001	Vial Mixer

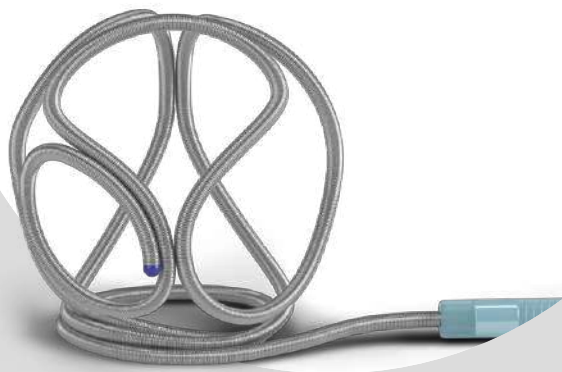
3D Framing Detachable Coils



Axiom™ Prime Detachable Coils (Frame)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
FC-3-6-3D	3	6	0.0115
FC-3-8-3D	3	8	0.0115
FC-3-10-3D	3	10	0.0115
FC-3.5-6-3D	3.5	6	0.0115
FC-3.5-8-3D	3.5	8	0.0115
FC-3.5-10-3D	3.5	10	0.0115
FC-4-6-3D	4	6	0.0125
FC-4-8-3D	4	8	0.0125
FC-4-10-3D	4	10	0.0125
FC-4-12-3D	4	12	0.0125
FC-4-15-3D	4	15	0.0125
FC-5-8-3D	5	8	0.0125
FC-5-10-3D	5	10	0.0125
FC-5-15-3D	5	15	0.0125
FC-5-20-3D	5	20	0.0125
FC-6-10-3D	6	10	0.0125
FC-6-15-3D	6	15	0.0125
FC-6-20-3D	6	20	0.0125
FC-6-25-3D	6	25	0.0125
FC-7-12-3D	7	12	0.0135
FC-7-15-3D	7	15	0.0135
FC-7-20-3D	7	20	0.0135
FC-7-30-3D	7	30	0.0135
FC-8-15-3D	8	15	0.0135
FC-8-20-3D	8	20	0.0135
FC-8-30-3D	8	30	0.0135

3D Framing Detachable Coils



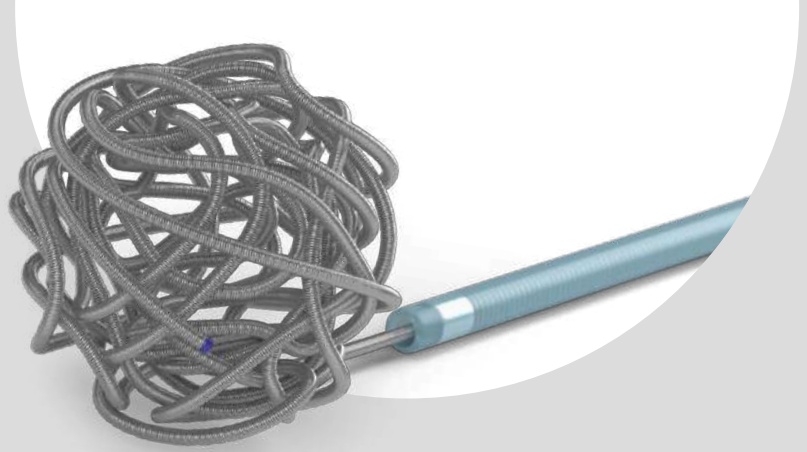
Axium™ Prime Detachable Coils (Frame)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
FC-9-20-3D	9	20	0.0135
FC-9-30-3D	9	30	0.0135
FC-10-20-3D	10	20	0.0135
FC-10-30-3D	10	30	0.0135
FC-10-40-3D	10	40	0.0135
FC-12-30-3D	12	30	0.0145
FC-12-40-3D	12	40	0.0145
FC-12-50-3D	12	50	0.0145
FC-14-30-3D	14	30	0.0145
FC-14-40-3D	14	40	0.0145
FC-14-50-3D	14	50	0.0145
FC-16-40-3D	16	40	0.0145
FC-16-50-3D	16	50	0.0145
FC-18-40-3D	18	40	0.0145
FC-18-50-3D	18	50	0.0145
FC-20-50-3D	20	50	0.0145
FC-22-50-3D	22	50	0.0145
FC-25-50-3D	25	50	0.0145

ID Instant Detacher (5 Pack)

Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

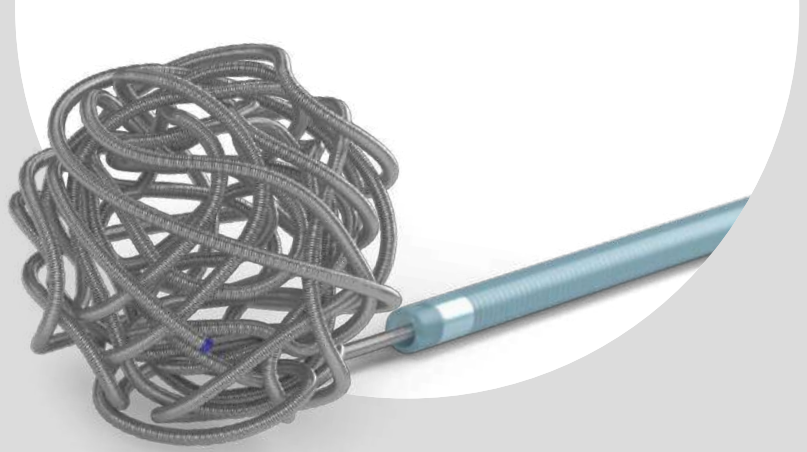
3D Soft Detachable Coils



Axiom™ Prime 3D Detachable Coils (Soft)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-4-6-3D-SS	4	6	0.0115
APB-4-8-3D-SS	4	8	0.0115
APB-4-10-3D-SS	4	10	0.0115
APB-4-12-3D-SS	4	12	0.0115
APB-5-8-3D-SS	5	8	0.0115
APB-5-10-3D-SS	5	10	0.0115
APB-5-15-3D-SS	5	15	0.0115
APB-6-10-3D-SS	6	10	0.0115
APB-6-15-3D-SS	6	15	0.0115
APB-6-20-3D-SS	6	20	0.0115

Helical Soft Detachable Coils



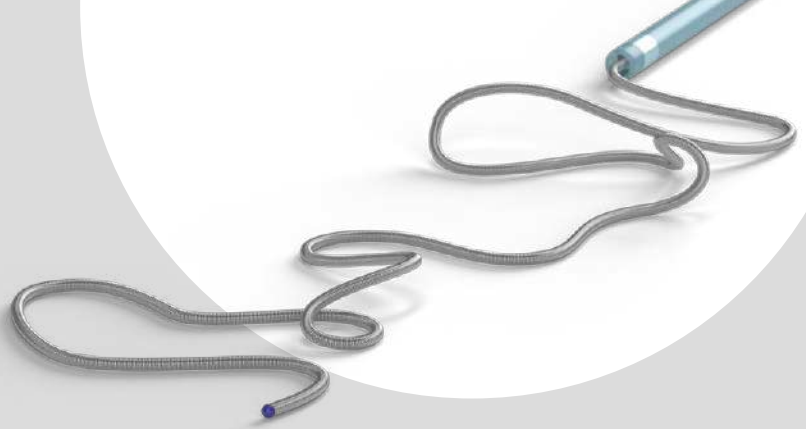
Axium™ Prime Helical Detachable Coils (Soft)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-4-6-HX-SS	4	6	0.0115
APB-4-8-HX-SS	4	8	0.0115
APB-4-10-HX-SS	4	10	0.0115
APB-4-12-HX-SS	4	12	0.0115
APB-5-10-HX-SS	5	10	0.0115
APB-5-15-HX-SS	5	15	0.0115
APB-5-20-HX-SS	5	20	0.0115
APB-6-12-HX-SS	6	12	0.0115
APB-6-20-HX-SS	6	20	0.0115

ID Instant Detacher (5 Pack)

Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

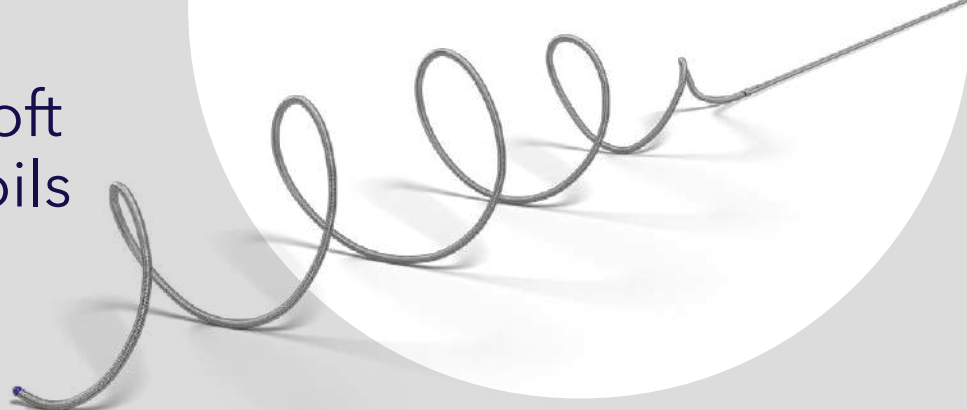
3D Extra Soft Detachable Coils



Axium™ Prime 3D Detachable Coils (Extra Soft)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-1-2-3D-ES	1	2	0.0108
APB-1-3-3D-ES	1	3	0.0108
APB-1-4-3D-ES	1	4	0.0108
APB-1.5-2-3D-ES	1.5	2	0.0108
APB-1.5-3-3D-ES	1.5	3	0.0108
APB-1.5-4-3D-ES	1.5	4	0.0108
APB-2-2-3D-ES	2	2	0.0108
APB-2-3-3D-ES	2	3	0.0108
APB-2-4-3D-ES	2	4	0.0108
APB-2.5-4-3D-ES	2.5	4	0.0108
APB-2.5-6-3D-ES	2.5	6	0.0108
APB-3-4-3D-ES	3	4	0.0108
APB-3-6-3D-ES	3	6	0.0108
APB-3-8-3D-ES	3	8	0.0108
APB-3.5-6-3D-ES	3.5	6	0.0108
APB-3.5-8-3D-ES	3.5	8	0.0108
APB-3.5-10-3D-ES	3.5	10	0.0108

Helical Extra Soft Detachable Coils



Axium™ Prime Helical Detachable Coils (Extra Soft)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-1-1-HX-ES	1	1	0.0108
APB-1-2-HX-ES	1	2	0.0108
APB-1-3-HX-ES	1	3	0.0108
APB-1.5-1-HX-ES	1.5	1	0.0108
APB-1.5-2-HX-ES	1.5	2	0.0108
APB-1.5-3-HX-ES	1.5	3	0.0108
APB-1.5-4-HX-ES	1.5	4	0.0108
APB-2-1-HX-ES	2	1	0.0108
APB-2-2-HX-ES	2	2	0.0108
APB-2-3-HX-ES	2	3	0.0108
APB-2-4-HX-ES	2	4	0.0108
APB-2-6-HX-ES	2	6	0.0108
APB-2-8-HX-ES	2	8	0.0108
APB-2.5-3-HX-ES	2.5	3	0.0108
APB-2.5-4-HX-ES	2.5	4	0.0108
APB-2.5-6-HX-ES	2.5	6	0.0108
APB-2.5-8-HX-ES	2.5	8	0.0108
APB-3-4-HX-ES	3	4	0.0108
APB-3-6-HX-ES	3	6	0.0108
APB-3-8-HX-ES	3	8	0.0108
APB-3-10-HX-ES	3	10	0.0108

ID Instant Detacher (5 Pack)

Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

3D Detachable Coils



Axium™ 3D Detachable Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
QC-2-2-3D	2	2	0.0115
QC-2-4-3D	2	4	0.0115
QC-2-6-3D	2	6	0.0115
QC-2.5-2-3D	2.5	2	0.0115
QC-2.5-4-3D	2.5	4	0.0115
QC-2.5-6-3D	2.5	6	0.0115
QC-2.5-8-3D	2.5	8	0.0115
QC-3-4-3D	3	4	0.0115
QC-3-6-3D	3	6	0.0115
QC-3-8-3D	3	8	0.0115
QC-3-10-3D	3	10	0.0115
QC-3.5-6-3D	3.5	6	0.0115
QC-3.5-12-3D	3.5	12	0.0115
QC-3.5-15-3D	3.5	15	0.0115
QC-4-6-3D	4	6	0.0125
QC-4-8-3D	4	8	0.0125
QC-4-10-3D	4	10	0.0125
QC-4-12-3D	4	12	0.0125
QC-5-8-3D	5	8	0.0125
QC-5-10-3D	5	10	0.0125
QC-5-15-3D	5	15	0.0125
QC-6-10-3D	6	10	0.0125
QC-6-15-3D	6	15	0.0125
QC-6-20-3D	6	20	0.0125

3D Detachable Coils



Axium™ 3D Detachable Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
QC-7-15-3D	7	15	0.0135
QC-7-20-3D	7	20	0.0135
QC-7-30-3D	7	30	0.0135
QC-8-15-3D	8	15	0.0135
QC-8-20-3D	8	20	0.0135
QC-8-30-3D	8	30	0.0135
QC-9-20-3D	9	20	0.0135
QC-9-30-3D	9	30	0.0135
QC-10-20-3D	10	20	0.0135
QC-10-30-3D	10	30	0.0135
QC-12-30-3D	12	30	0.0145
QC-12-40-3D	12	40	0.0145
QC-14-30-3D	14	30	0.0145
QC-14-40-3D	14	40	0.0145
QC-16-40-3D	16	40	0.0145
QC-18-40-3D	18	40	0.0145
QC-20-50-3D	20	50	0.0145
QC-22-50-3D	22	50	0.0145
QC-25-50-3D	25	50	0.0145

Helical Detachable Coils



Axium™ Helical Detachable Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
QC-1.5-1-HELIX	1.5	1	0.0115
QC-1.5-2-HELIX	1.5	2	0.0115
QC-1.5-3-HELIX	1.5	3	0.0115
QC-1.5-4-HELIX	1.5	4	0.0115
QC-2-1-HELIX	2	1	0.0115
QC-2-2-HELIX	2	2	0.0115
QC-2-3-HELIX	2	3	0.0115
QC-2-4-HELIX	2	4	0.0115
QC-2-6-HELIX	2	6	0.0115
QC-2-8-HELIX	2	8	0.0115
QC-2.5-2-HELIX	2.5	2	0.0115
QC-2.5-4-HELIX	2.5	4	0.0115
QC-2.5-6-HELIX	2.5	6	0.0115
QC-2.5-8-HELIX	2.5	8	0.0115
QC-3-4-HELIX	3	4	0.0115
QC-3-6-HELIX	3	6	0.0115
QC-3-8-HELIX	3	8	0.0115
QC-4-8-HELIX	4	8	0.0125
QC-4-10-HELIX	4	10	0.0125
QC-4-12-HELIX	4	12	0.0125
QC-5-15-HELIX	5	15	0.0125
QC-5-20-HELIX	5	20	0.0125
QC-6-20-HELIX	6	20	0.0125

Helical Detachable Coils



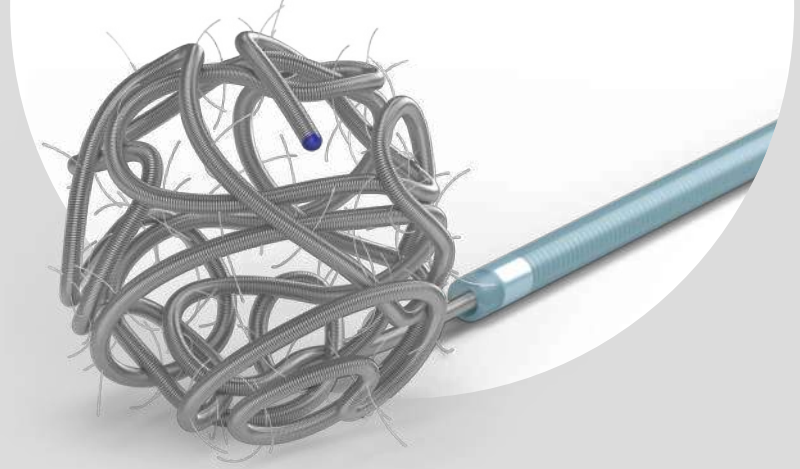
Axium™ Helical Detachable Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
QC-7-20-HELIX	7	20	0.0135
QC-7-30-HELIX	7	30	0.0135
QC-8-20-HELIX	8	20	0.0135
QC-8-30-HELIX	8	30	0.0135
QC-9-20-HELIX	9	20	0.0135
QC-9-30-HELIX	9	30	0.0135
QC-10-20-HELIX	10	20	0.0135
QC-10-30-HELIX	10	30	0.0135
QC-12-30-HELIX	12	30	0.0145
QC-12-40-HELIX	12	40	0.0145
QC-14-30-HELIX	14	30	0.0145
QC-14-40-HELIX	14	40	0.0145
QC-16-30-HELIX	16	30	0.0145
QC-16-40-HELIX	16	40	0.0145
QC-18-40-HELIX	18	40	0.0145
QC-20-40-HELIX	20	40	0.0145
QC-20-50-HELIX	20	50	0.0145

ID Instant Detacher (5 Pack)

Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

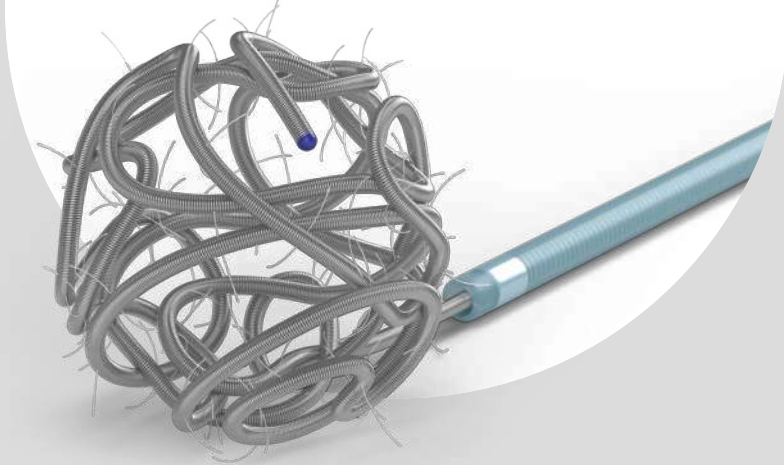
PGLA 3D Coils



Axiom™ MicroFX™ PGLA 3D Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
PC-2-2-3D	2	2	0.0115
PC-2-4-3D	2	4	0.0115
PC-2-6-3D	2	6	0.0115
PC-3-4-3D	3	4	0.0115
PC-3-6-3D	3	6	0.0115
PC-3-8-3D	3	8	0.0115
PC-4-6-3D	4	6	0.0125
PC-4-8-3D	4	8	0.0125
PC-4-10-3D	4	10	0.0125
PC-4-12-3D	4	12	0.0125
PC-5-8-3D	5	8	0.0125
PC-5-10-3D	5	10	0.0125
PC-5-15-3D	5	15	0.0125
PC-6-10-3D	6	10	0.0125
PC-6-15-3D	6	15	0.0125
PC-6-20-3D	6	20	0.0125
PC-7-15-3D	7	15	0.0135
PC-7-20-3D	7	20	0.0135
PC-7-30-3D	7	30	0.0135
PC-8-15-3D	8	15	0.0135
PC-8-20-3D	8	20	0.0135

PGLA 3D Coils



Axium™ MicroFX™ PGLA 3D Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
PC-8-30-3D	8	30	0.0135
PC-9-20-3D	9	20	0.0135
PC-9-30-3D	9	30	0.0135
PC-10-20-3D	10	20	0.0135
PC-10-30-3D	10	30	0.0135
PC-12-30-3D	12	30	0.0145
PC-12-40-3D	12	40	0.0145
PC-14-30-3D	14	30	0.0145
PC-14-40-3D	14	40	0.0145
PC-16-40-3D	16	40	0.0145
PC-18-40-3D	18	40	0.0145

PGLA Helical Coils



Axiom™ MicroFX™ PGLA Helix Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
PC-2-1-HELIX	2	1	0.0115
PC-2-2-HELIX	2	2	0.0115
PC-2-3-HELIX	2	3	0.0115
PC-2-4-HELIX	2	4	0.0115
PC-2-6-HELIX	2	6	0.0115
PC-2-8-HELIX	2	8	0.0115
PC-3-4-HELIX	3	4	0.0115
PC-3-6-HELIX	3	6	0.0115
PC-3-8-HELIX	3	8	0.0115
PC-4-8-HELIX	4	8	0.0125
PC-4-10-HELIX	4	10	0.0125
PC-4-12-HELIX	4	12	0.0125
PC-5-15-HELIX	5	15	0.0125
PC-5-20-HELIX	5	20	0.0125
PC-6-20-HELIX	6	20	0.0125
PC-7-20-HELIX	7	20	0.0135
PC-7-30-HELIX	7	30	0.0135
PC-8-20-HELIX	8	20	0.0135
PC-8-30-HELIX	8	30	0.0135
PC-9-20-HELIX	9	20	0.0135
PC-9-30-HELIX	9	30	0.0135
PC-10-20-HELIX	10	20	0.0135
PC-10-30-HELIX	10	30	0.0135

Nylon Helical Coils



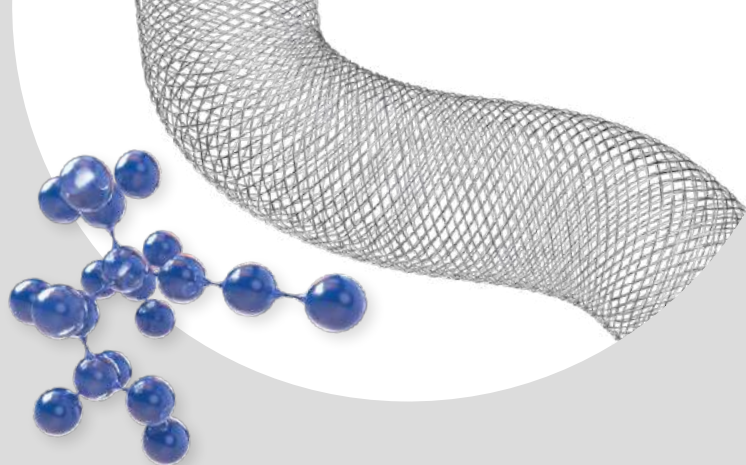
Axium™ MicroFX™ Nylon Coils

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
NC-2-1-HELIX	2	1	0.0115
NC-2-2-HELIX	2	2	0.0115
NC-2-3-HELIX	2	3	0.0115
NC-2-4-HELIX	2	4	0.0115
NC-2-6-HELIX	2	6	0.0115
NC-2-8-HELIX	2	8	0.0115
NC-3-4-HELIX	3	4	0.0115
NC-3-6-HELIX	3	6	0.0115
NC-3-8-HELIX	3	8	0.0115
NC-4-8-HELIX	4	8	0.0125
NC-4-10-HELIX	4	10	0.0125

ID Instant Detacher (5 Pack)

Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

Flow Diverters



Pipeline™ Flex Embolization Device with Shield Technology™ is designed to divert blood flow away from certain brain aneurysms. The device features a braided cylindrical mesh that is implanted across the base or neck of the aneurysm.¹ Shield Technology™ builds on the clinically proven Pipeline™ Flex Embolization Device² by introducing an innovative implant surface modification, designed to reduce material thrombogenicity.^{3,4*}

Pipeline™ Flex Embolization Device with Shield Technology™

Product Catalog Number	Diameter (mm)	Length (mm)
PED2-250-10	2.50	10
PED2-250-12	2.50	12
PED2-250-14	2.50	14
PED2-250-18	2.50	18
PED2-275-12	2.75	12
PED2-275-16	2.75	16
PED2-300-10	3.00	10
PED2-300-12	3.00	12
PED2-300-14	3.00	14
PED2-300-20	3.00	20
PED2-325-12	3.25	12
PED2-325-14	3.25	14
PED2-325-16	3.25	16
PED2-325-20	3.25	20
PED2-350-12	3.50	12
PED2-350-14	3.50	14
PED2-350-16	3.50	16
PED2-350-18	3.50	18
PED2-350-20	3.50	20
PED2-375-10	3.75	10
PED2-375-12	3.75	12
PED2-375-14	3.75	14
PED2-375-16	3.75	16
PED2-375-18	3.75	18
PED2-375-20	3.75	20
PED2-375-25	3.75	25
PED2-400-12	4.00	12

*Data is derived from the referenced pre-clinical studies and may not be representative of clinical performance.

1. M002318CDOC2_B. Pipeline Flex with Shield Technology IFU.

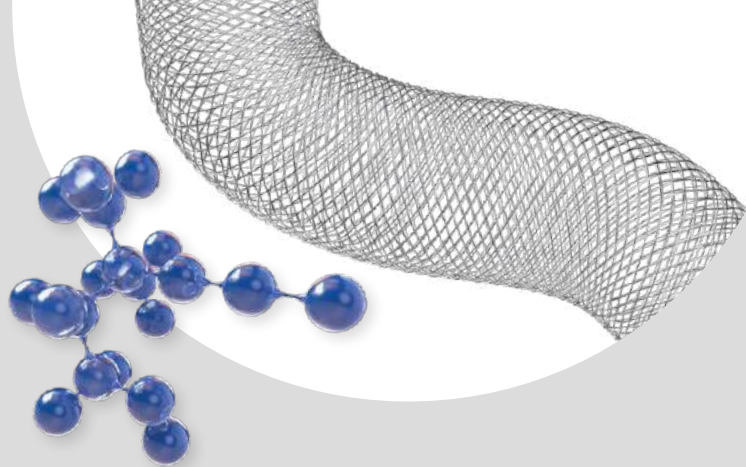
2. Kallmes, DF et al. International Retrospective Study of the Pipeline Embolization Device: A Multicenter Aneurysm Treatment Study. AJNR Published online, Oct 29, 2014.

3. Medtronic Internal Study, D00422708 Rev. A, Competitive Test Report - Material Thrombogenicity Evaluation of Flow Diversion Devices.

4. Girdhar G, Li J, Kostousov L, Wainwright J, Chandler WL. In-vitro thrombogenicity assessment of flow diversion and aneurysm bridging devices. J Thromb Thrombolysis. 2015 Nov;40(4):437-43. doi: 10.1007/s11239-015-1228-0. PMID: 25975924

For information on additional sizes not listed above, contact your Medtronic Neurovascular representative.

Flow Diverters



Pipeline™ Flex Embolization Device with Shield Technology™

Product Catalog Number	Diameter (mm)	Length (mm)
PED2-400-14	4.00	14
PED2-400-16	4.00	16
PED2-400-18	4.00	18
PED2-400-20	4.00	20
PED2-400-30	4.00	30
PED2-425-12	4.25	12
PED2-425-14	4.25	14
PED2-425-16	4.25	16
PED2-425-18	4.25	18
PED2-425-20	4.25	20
PED2-425-25	4.25	25
PED2-450-12	4.50	12
PED2-450-14	4.50	14
PED2-450-16	4.50	16
PED2-450-18	4.50	18
PED2-450-20	4.50	20
PED2-450-25	4.50	25
PED2-450-35	4.50	35
PED2-475-12	4.75	12
PED2-475-14	4.75	14
PED2-475-16	4.75	16
PED2-475-20	4.75	20
PED2-475-30	4.75	30
PED2-500-12	5.00	12
PED2-500-14	5.00	14
PED2-500-16	5.00	16
PED2-500-18	5.00	18
PED2-500-20	5.00	20
PED2-500-25	5.00	25
PED2-500-30	5.00	30
PED2-500-35	5.00	35

*Data is derived from the referenced pre-clinical studies and may not be representative of clinical performance.

1. M002318CDOC2_B. Pipeline Flex with Shield Technology IFU.

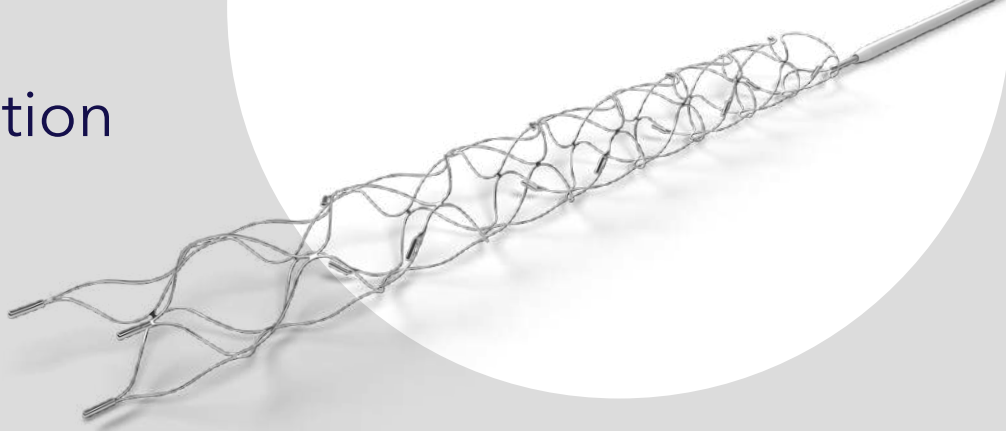
2. Kallmes, DF et al. International Retrospective Study of the Pipeline Embolization Device: A Multicenter Aneurysm Treatment Study, AJNR Published online, Oct 29, 2014.

3. Medtronic Internal Study, D00422708 Rev. A, Competitive Test Report - Material Thrombogenicity Evaluation of Flow Diversion Devices.

4. Girdhar G, Li J, Kostousov L, Wainwright J, Chandler WL. In-vitro thrombogenicity assessment of flow diversion and aneurysm bridging devices. J Thromb Thrombolysis. 2015 Nov;40(4):437-43. doi: 10.1007/s11239-015-1228-0. PMID: 25975924

For information on additional sizes not listed above, contact your Medtronic Neurovascular representative.

Revascularization Devices



The Solitaire™ X Revascularization Device is a mechanical thrombectomy device designed to restore blood flow by removing thrombus to reduce disability in patients experiencing ischemic stroke due to large intracranial vessel occlusion.¹ The Solitaire™ X device is designed with an optimized delivery system - produces lower delivery force for improved procedural efficiency and smooth navigation through even the most complicated anatomy.^{2,3}

Solitaire™ X Revascularization Device³⁻⁵

Product Catalog Number	Size (mm)	Recommended Vessel Diameter (mm)	Minimum Micro Catheter ID (in / mm)	Push Wire Length (cm)	# of Radiopaque Markers		Radiopaque Marker Spacing (mm)
					Distal End	Proximal End	
SFR4-3-20-10	3 x 20	1.5 - 3.0	0.017 / 0.43	200	3	1	10
SFR4-3-40-10	3 x 40	1.5 - 3.0	0.017 / 0.43	200	3	1	10
SFR4-4-20-05	4 x 20	1.5 - 4.0	0.021 / 0.53	200	3	1	5
SFR4-4-20-10	4 x 20	1.5 - 4.0	0.021 / 0.53	200	3	1	10
SFR4-4-40-10	4 x 40	1.5 - 4.0	0.021 / 0.53	200	3	1	10
SFR4-6-20-10	6 x 20	2.0 - 5.5	0.021 / 0.53	200	4	1	10
SFR4-6-24-06	6 x 24	2.0 - 5.5	0.021 / 0.53	200	4	1	6
SFR4-6-40-10	6 x 40	2.0 - 5.5	0.021 / 0.53	200	4	1	10

1. M003592CDOC2

2. TR-NV16168 Rev A

3. Compared to Solitaire™ Platinum

4. K203358

5. K193576

Aspiration



The React™ 68 Catheter and the React™ 71 Catheter feature a coil and braid design - easing navigation to the M1 and M2 segments. Combined with the Riptide™ Aspiration System, these catheters are designed to revascularize patients experiencing acute ischemic stroke.¹

Riptide™ Aspiration System

Product Catalog Number	Description
MAP-1000	Riptide™ Aspiration System

Riptide™ Collection Canister & Intermediate Tubing

Product Catalog Number	Description	Volume (ml)
MAC-1200	Riptide™ Collection Canister & Intermediate Tubing	1200

Riptide™ Aspiration Tubing

Product Catalog Number	Description	Inner Diameter (in)	Tubing Length (in)	Distal Length (in)
MAT-110-110	Riptide™ Aspiration Tubing	0.110	112	7

Riptide™ Aspiration Catheters

Product Catalog Number	Description	Working Length (cm)	Max OD (in)	Max ID (in)
REACT-68	React™ 68 Catheter	132	0.083	0.068
REACT-71	React™ 71 Catheter	132	0.0855	0.071

1. M994065ADOC2

Accessories



The Cadence™ Precision Injector provides precision inflation of balloon catheters; 0.02 ml inflation per rotation offers tactile feedback.

Cadence™ Precision Injector Accessory		
Product Catalog Number	Capacity (ml)	Quantity
103-0304	1	5

1 ml Injection Syringe		
Product Catalog Number	Capacity (ml)	Syringes/Box
103-1203	1	10

Indications for use

CAUTION: Federal (USA) law restricts this device to sale distribution and use by or on order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Avigo™ Hydrophilic Guidewire

The Avigo™ Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral and cerebral vasculature during diagnostic and/or therapeutic procedures. The device is not intended for use in the coronary arteries.

Mirage™ Hydrophilic Guidewire

The Mirage™ Hydrophilic Guidewires are indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

X-Pedion™ Hydrophilic Guidewire

The X-Pedion™ Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

Phenom™ Plus and Phenom™ Catheter

Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.

React™ 68 and 71 Catheter

The React™ Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Rist™ 079 Radial Access Guide Catheter

The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Rist™ Radial Access Selective Catheter

The Rist™ Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.

Cello™ Balloon Guide Catheter

The Cello™ Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Cello™ is a trademark of and is manufactured by Fuji Systems Corporation.

Navien™ Intracranial Support Catheter

The Navien™ Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Rebar™ Micro Catheter

The Rebar™ Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

Apollo™ Onyx™ Delivery Micro Catheter

This product is for the exclusive use by medical specialists experienced in angiographic and percutaneous neurointerventional procedures.

Indications For Use: The Apollo™ Onyx™ Delivery Micro Catheter is intended to access the neuro vasculature for the controlled selective infusion of the Onyx™ Liquid Embolic System (LES).

Contraindications:

- The Apollo™ Onyx™ Delivery Micro Catheter is contraindicated when, in the medical judgment of the physician, use of such product may compromise the patient's condition.
- Not intended for use in the coronary vasculature.

Precautions: 1) Select tip size based on angioarchitecture. The detachment zone should never be distal to the last tortuous curve of the vessel. Refluxing over the detachment zone distal to the last tortuous curve may result in catheter entrapment. Do not place catheter such that the detached tip could interfere with patent vessels. 2) Prior to use, carefully examine the Apollo™ Onyx™ Delivery Micro Catheter and its packaging to verify that it has not been damaged during shipment. Do not touch or manipulate the catheter tip prior to use. 3) Prior to use, all accessory devices and agents should be fully prepared according to the manufacturer's instructions. 4) During navigation, check that the distal tip of the catheter is not kinked before passing the guidewire through it. Kinking or prolapsing of the catheter may result in unintended rupture of the catheter. 5) Always monitor infusion rates when using the catheter. 6) The Apollo™ Onyx™ Delivery Micro Catheter has a hydrophilic coating on the outside of the catheter which must be kept hydrated. 7) This catheter is not intended for use with chemotherapy agents. 8) When the infusion catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response. 9) Navigating or repositioning the catheter while it is in a wedged position or with vessels that are in vasospasm may cause premature tip detachment. 10) When performing angiography, it is recommended to use a 3cc syringe rather than a 1cc syringe to reduce the risk of catheter over-pressurization. 11) The Apollo™ Onyx™ Delivery Micro Catheter is a flow directed micro catheter that can optionally be used with hydrophilic, 0.010" or less sized guidewires. The Apollo™ Onyx™ Delivery Micro Catheter is not compatible with non-hydrophilically coated guidewires or guidewires greater than 0.010" in diameter. 12) It is recommended that the Apollo™ Onyx™ Delivery Micro Catheter be used with an appropriately sized guiding catheter which allows adequate clearance (minimum internal diameter of 0.053" or 1.35mm). 13) When withdrawing the catheter, monitor the distal tip under angiography. Pulling the catheter against significant resistance can cause patient injury. If significant catheter resistance is felt, refer to the precaution in the procedure section of the Instructions for Use provided with the device for guidance. 14) If catheter entrapment is suspected, fast catheter retrieval technique may result in catheter shaft separation and potential vascular damage. Follow catheter retrieval instructions at the end of instructions for use.

Potential Complications: Potential complications include, but are not limited to: Puncture site hematoma, Vessel perforation, Vessel spasm, Hemorrhage, Pain and tenderness, Thrombolytic episodes, Neurological deficits including stroke and death, Vascular thrombosis.

Marathon™ Flow Directed Micro Catheter

The Marathon™ Flow Directed Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media. Not intended for use in the coronary vasculature.

Marksman™ Micro Catheter

The Marksman™ Micro Catheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculature.

Echelon™ Micro Catheter

The Echelon™ Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.

Hyperform™ and HyperGlide™ Occlusion Balloon System

The Hyperform™ and HyperGlide™ Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow; the occlusion balloon catheters may also be used in balloon-assisted embolization of intracranial aneurysms.

Indications for use

Onyx™ Liquid Embolic System (AVM)

This product is for the exclusive use by medical specialists experienced in angiographic and percutaneous neurointerventional procedures.

Indications For Use: Presurgical embolization of brain arteriovenous malformations (bAVMs).

Contraindications: The use of the Onyx™ LES is contraindicated when any of the following conditions exist:

- When optimal catheter placement is not possible.
- When provocative testing indicates intolerance to the occlusion procedure.
- When vasospasm stops blood flow.

Precautions: 1) The safety and effectiveness has not been studied in the following patient populations: pregnant and nursing women, individuals less than 18 years old, individuals with aneurysms not associated with a bAVM nidus, or distal feeders to a bAVM nidus or dural AV fistulas. 2) Some data indicate that dimethyl sulfoxide potentiates other concomitantly administered medications. 3) A garlic-like taste may be noted by the patient with use of the Onyx™ LES due to the DMSO component. This taste may last several hours. An odor on the breath and skin may be present. 4) Inspect product packaging prior to use. Do not use if sterile barrier is open or damaged. 5) Use prior to expiration date. 6) Verify that the catheters and accessories (see directions for use) used in direct contact with the Onyx™ LES polymer are clean and compatible with the material and do not trigger polymerization or degrade with contact. Use only ev3 approved, Onyx™ LES/DMSO compatible micro catheters indicated for use in the neurovasculature and ev3 syringes. Other micro catheters or syringes may not be compatible with DMSO and their use can result in thromboembolic events due to catheter degradation. Refer to the Warnings and Directions for Use sections. 7) Wait a few seconds following completion of the Onyx™ LES injection before attempting catheter retrieval. Failure to wait a few seconds to retrieve the micro catheter after the Onyx™ LES injection may result in fragmentation of the Onyx™ LES into non-target vessels.

Difficult catheter removal or catheter entrapment may be caused by any of the following: Angioarchitecture: very distal bAVM fed by afferent, lengthened, small, or tortuous pedicles, Vasospasm, Reflux, Injection time. To reduce the risk of catheter entrapment, carefully select catheter placement and manage reflux to minimize the factors listed above.

Should catheter removal become difficult, the following will assist in catheter retrieval: Carefully pull the catheter to assess any resistance to removal. If resistance is felt, remove any "slack" in the catheter. Gently apply traction to the catheter (approximately 3-4 cm of stretch to the catheter). Hold this traction for a few seconds and release.

Assess traction on vasculature to minimize risk of hemorrhage. This process can be repeated intermittently until catheter is retrieved.

Alternate Technique for Difficult to Remove Catheters: Remove all slack from the catheter by putting a few centimeters of traction on the catheter to create a slight tension in the catheter system. Firmly hold the catheter and then pull it using a quick wrist snap motion (from left to right) 10 - 15 centimeters to remove the catheter from the Onyx™ LES cast (Note: Do not apply more than 20 cm of traction to catheter, to minimize risk of catheter separation).

For entrapped catheters: Under some difficult clinical situations, rather than risk rupturing the malformation and consequent hemorrhagic complications by applying too much traction on an entrapped catheter, it may be safer to leave the micro catheter in the vascular system. This is accomplished by stretching the catheter and cutting the shaft near the entry point of vascular access allowing the catheter to remain in the artery. If the catheter breaks during removal, distal migration or coiling of the catheter may occur. Same day surgical resection should be considered to minimize the risk of thrombosis.

Potential Complications: The following adverse events occurred using Onyx™ during a prospective, randomized, multi-center clinical trial for the presurgical treatment of bAVMs: Death, Headache +/- nausea and vomiting, Patient discomfort, Laboratory/Imaging abnormalities (Endocrine/Metabolic, Hematologic, Asymptomatic MRI/CT Findings, Respiratory/ Pulmonary, General, Gastrointestinal (GI)), Worsening Neurologic Status (Persistent, Resolved), Hyperglycemia, Infection, Bleeding and/or Low Hct requiring transfusion (Surgical Bleeding, Decreased Hct Requiring Transfusion), Intracranial Hemorrhage, Medication reaction, Failed access, Access site bleeding, Fever, Delivery Catheter removal difficulty, Poor penetration/visualization, Hypotension, Stroke, Cardiac arrhythmia, Hydrocephalus, SIADH (Syndrome of inappropriate antidiuretic hormone secretion, dilutional

hyponatremia), Vessel Dissection, Hypertension, Limb ischemia, Respiratory failure, Seizures, UTI (Urinary tract infection), Vasospasm, Vaso-vagal episode, catheter shaft rupture, delivery catheter rupture, fragmentation of the Onyx™ LES, hypoxia, laryngospasm, peptic ulcer disease, psychotic episode, pulmonary edema, skin abrasion, subintimal injection, tachypnea, and tongue swelling.

Additional adverse events, which may be associated with embolization procedures include: Allergic reaction, Thrombocytopenia, Pulmonary embolism, Catheter entrapment, Catheter rupture, Device migration and cast movement, Hemorrhagic complications related to attempts to remove entrapped catheter.

WARNINGS: Serious, including fatal, consequences could result with the use of the Onyx™ LES without adequate training. Contact your Medtronic sales representative for information on training courses.

Complete indications, Contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Axium™ and Axium™ Prime Detachable Coils

The Axium™ and Axium™ Prime Detachable Coils are not intended for all patients and may not be the appropriate treatment for all clinical scenarios. Axium™ and Axium™ Prime Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. Axium™ and Axium™ Prime detachable coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. Axium™ Prime Detachable Coil (Frame): The Axium™ Prime Detachable Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Axium™ Prime Detachable Coils are also indicated for arterial and venous embolizations in the peripheral vasculature.

Pipeline™ Flex Embolization Device with Shield Technology™

CAUTION: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. Indications, contraindications, warnings and instructions for use for the Pipeline™ Flex Embolization Device with Shield Technology™ can be viewed at <https://www.medtronic.com/manuals>. Indications for Use: The Pipeline™ Flex Embolization Device with Shield Technology™ is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments. The Pipeline™ Flex Embolization Device with Shield Technology™ is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm. Contraindications: 1) Patients with active bacterial infection. 2) Patients in whom dual antiplatelet and/or anticoagulation therapy (aspirin and clopidogrel) is contraindicated. 3) Patients who have not received dual antiplatelet agents prior to the procedure. 4) Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location. 5) Patients in whom the parent vessel size does not fall within the indicated range. Warnings: 1) Pushing delivery wire without retracting the micro catheter at the same time will cause the open end braid to move distally in the vessel. This may cause damage to the braid or vessel. 2) Use in tortuous anatomy may result in difficulty or inability to deploy the Pipeline™ Flex embolization device with Shield Technology™ and can lead to damage to the Pipeline™ Flex Embolization Device with Shield Technology™ and microcatheter. To mitigate potential problems as a result of increased delivery forces, reduce the load in the system by: Unloading the microcatheter to the inner curves of vessel by pulling back on the system (i.e., the microcatheter and delivery wire together). Continue unloading the system until advancement of the device (inside the microcatheter) is observed, while minimizing the distal tip movement to prevent loss of position. Begin to re-advance the delivery wire while maintaining reduced load in the microcatheter. This process should be repeated until the device passes through tortuous area and the delivery force is decreased. 3) Resheathing of the Pipeline™ Flex Embolization Device with Shield Technology™ more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 4) Persons with known allergy to platinum or cobalt/chromium alloy (including the major elements platinum, cobalt, chromium, nickel, molybdenum or tungsten) may suffer an allergic reaction to the Pipeline™ Flex Embolization Device with Shield Technology™ implant. 5) Person with known allergy to tin, silver, stainless steel, or silicone elastomer may suffer an allergic reaction to the Pipeline™ Flex Embolization Device with Shield Technology™ Delivery System. 6) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection

Indications for use

and compromised device performance. 7) Post-procedural movement (migration and/or foreshortening) of the Pipeline™ Flex Embolization Device with Shield Technology™ implant may occur following implantation and can result in serious adverse events and/or death. 8) Factors which may contribute to post procedural device movement include (but are not limited to) the following: Failure to adequately size the implant (i.e., under sizing), Failure to obtain adequate wall apposition during the implant deployment, Implant stretching, Vasospasm, Severe vessel tapering, Tortuous anatomy 9) Delayed rupture may occur with large and giant aneurysms. 10) Placement of multiple Pipeline™ Flex Embolization Device with Shield Technology™ may increase the risk of ischemic complications. 11) Use in anatomy with severe tortuosity, stenosis or parent vessel narrowing may result in difficulty or inability to deploy the Pipeline™ Flex Embolization Device with Shield Technology™ and can lead to damage to the Pipeline™ Flex Embolization Device with Shield Technology™ and microcatheter. Advancement or retraction of the Pipeline™ Flex Embolization Device with Shield Technology™ against resistance may result in damage, including unintended device or component separation, fracture, or breakage of the delivery system due to inherent flexibility limits of device design. Device damage may result in patient injury or death. Refer to page 4 in the instructions for use for additional information. 12) Do not attempt to reposition the device after full deployment. 13) The benefits may not outweigh the risks of treatment of small and medium asymptomatic extradural intracranial aneurysms, including those located in the cavernous internal carotid artery. The risk of rupture for small and medium asymptomatic extradural intracranial aneurysms is very low if not negligible. 14) A decrease in the proportion of patients who achieve complete aneurysm occlusion without significant parent artery stenosis has been observed with the use of the device in the communicating segment (C7) of the internal carotid artery (47.4% (9/19 subjects in the PREMIER study at 1 year)), including those IAs fed by the posterior circulation or have retrograde filling. Ensure appropriate patient selection and weigh the benefits and risks of alternative treatments prior to use of this device for the treatment of intracranial aneurysms located in this region of the ICA. The following anatomical characteristics, associated with retrograde filling, should be carefully considered during procedural planning of C7 intracranial aneurysms: PComm of fetal origin (A PCA of fetal origin is defined as a small, hypoplastic, or absent P1 segment of the PCA with the PComm artery supplying a majority of blood flow to the ICA); PComm overlapping with the aneurysm neck; and/or PComm branch arising from the dome of the aneurysm. 15) The safety and effectiveness of this device for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient. Precautions: 1) The Pipeline™ Flex Embolization Device with Shield Technology™ should be used only by physicians trained in percutaneous, intravascular techniques, and procedures at medical facilities with the appropriate fluoroscopy equipment. 2) Physicians should undergo appropriate training prior to using the Pipeline™ Flex Embolization Device with Shield Technology™ in patients. 3) The Pipeline™ Flex Embolization Device with Shield Technology™ is intended for single use only. Store in a cool, dry place. Carefully inspect the sterile package and device components prior to use to verify that they have not been damaged during shipping. Do not use kinked or damaged components. Do not use product if the sterile package is damaged. 4) Use the Pipeline™ Flex Embolization Device with Shield Technology™ system prior to the "Use By" date printed on the package. 5) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 6) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 7) Use of implants with labeled diameter larger than the parent vessel diameter may result in decreased effectiveness and additional safety risk due to incomplete foreshortening resulting in an implant longer than anticipated. 8) The Pipeline™ Flex Embolization Device with Shield Technology™ may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment. 9) Take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible. 10) Carefully weigh the benefits of treatment vs. the risks associated with treatment using the device for each individual patient based on their medical health status and risks factors for intracranial aneurysm rupture during their expected life time such as age, medical comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent

pathology. The benefits of device use may not outweigh the risks associated with the device in certain patients; therefore, judicious patient selection is recommended. 11) The safety and effectiveness of the device has not been established for treatment of fusiform IAs. 12) There may be a decrease in effectiveness and increase in safety events when the device is used in patients ≥ 60 years old. 13) The safety and effectiveness of the device has not been evaluated or demonstrated for ruptured aneurysms. 14) If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient. Potential Complications: Potential complications of the device and the endovascular procedure include, but are not limited to, the following: Access site complications like hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; Adverse reaction to anti-platelet/anticoagulation agents, anesthesia, reactions due to radiation exposure (such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts and delayed neoplasia) or contrast media, including organ failure; Vascular Complications like vasospasm, stenosis, dissection, perforation, rupture, fistula formation, pseudo aneurysm, occlusion, thromboembolic complications including ischemia (to unintended territory); Device complications like fracture, breakage (including unintended device or component separation), misplacement, migration/delayed foreshortening or reaction to device materials may occur; Systemic Complications like: Infection, Pain, fever, allergic reactions, organ failure, nerve damage; Bleeding/hemorrhagic complication including retroperitoneal hemorrhage; Neurological Deficits or dysfunctions including Stroke, Infarction, Loss of vision, Seizures, TIA, Headache, Cranial Nerve Palsies, Confusion, Coma, Hand Dysfunction; Decreased therapeutic response including need for target aneurysm retreatment; Risks associated with visual symptoms include Amaurosis Fugax/transient blindness, Blindness, Diplopia, Reduced visual acuity/field, Retinal artery occlusion, Retinal ischemia, Retinal infarction, Vision impairment including scintillations, blurred vision, eye floaters; Intracranial Hemorrhage (including from Aneurysm Rupture) Brain Edema, Hydrocephalus, Mass Effect; Death.

Solitaire™ X Revascularization Device

The Solitaire™ X Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset. The Solitaire™ X Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment. The Solitaire™ X Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (<70 cc by CTA or MRA, <25 cc by MR-DWI). Endovascular therapy with the device should start within 6-16 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Indications, contraindications, warnings and instructions for use for Solitaire™ X Revascularization Device can be viewed at www.medtronic.com/manuals.

Indications, contraindications, warnings and instructions for all other products can be found in the product labeling supplied with each device.

Riptide™ Aspiration System

The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Indication, contraindication, warnings and instructions for use for the Riptide™ Aspiration System can be viewed at www.medtronic.com/manuals.

Cadence™ Precision Injector

The Cadence Precision Injector is intended for the controlled delivery of fluids in the inflation and deflation of temporary occlusion balloons.

Medtronic

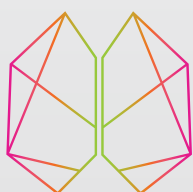
9775 Toledo Way
Irvine, CA 92618
USA
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Fax 763.526.7888

medtronicNV.com

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**GO DISTAL...
MORE TRACKABILITY
FOR MORE SUPPORT¹**



CERENOVUS

PART OF THE **Johnson & Johnson** FAMILY OF COMPANIES

CEREBASE™ DA
guide sheath

ENGINEERED TO SECURE DISTAL ACCESS FOR GEOMETRIC ANCHORING²

8F Short Sheath
Compatible

Available in 80, 90,
and 95cm lengths

MORE SUPPORT¹

ENGINEERED TO SECURE DISTAL ACCESS FOR GEOMETRIC ANCHORING, RESULTING IN MORE PROCEDURAL SUPPORT².

FEATURES:

- More proximal shaft stiffness designed for arch support³
- More procedural support²

Dexterous (DEX) Tip
facilitates tight turns



Large Inner
Diameter
ID (.090")
for more
clearance

MORE TRACKABILITY¹

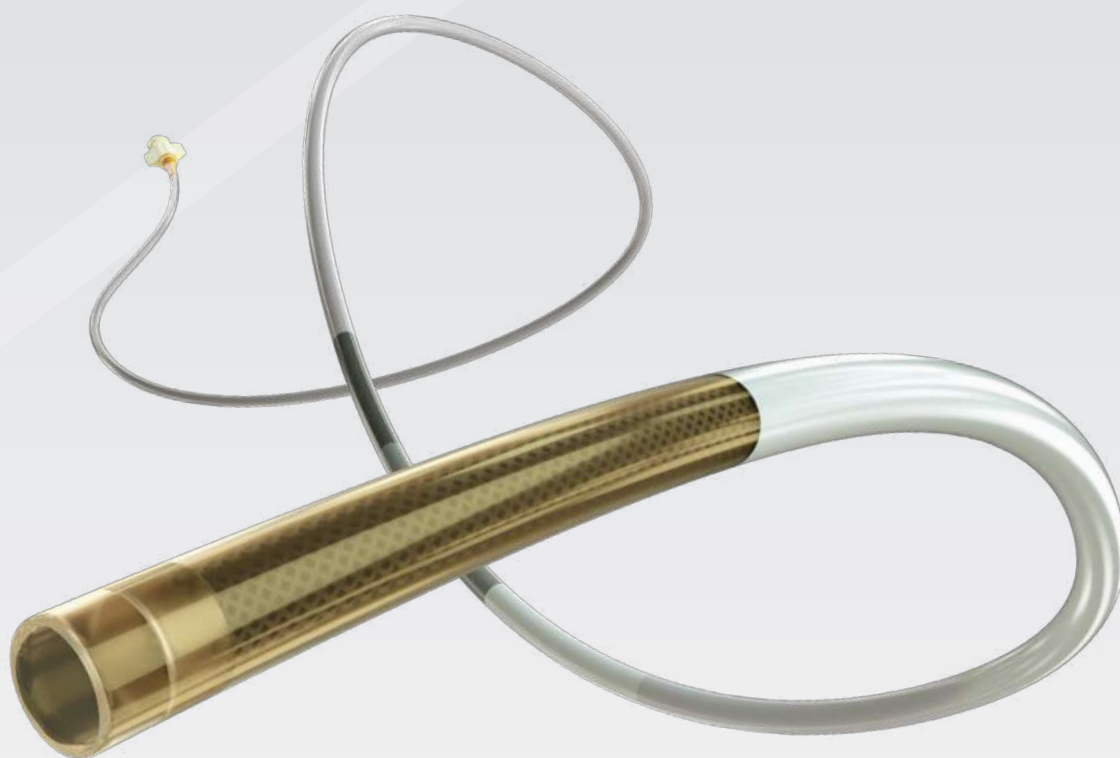
DEX TIP FACILITATES TIGHT TURNS FOR ENHANCED TRACKING THROUGH CHALLENGING ANATOMY

FEATURES:

- DEX Tip - short, flexible and soft⁴
- Soft and compliant, rounded distal edges
- Flexibility of the CEREBASE™ DEX Tip is similar to the flexibility of an aspiration catheter
- Smooth transition zones for pushability
- Excellent⁵ kink resistance

CEREBASE™ DA

guide sheath



CEREBASE™ DA Guide Sheath

Product Code	ID	OD (compatible short sheath)	Usable Length
GS9080SD	0.090"	8F	80cm
GS9090SD	0.090"	8F	90cm
GS9095SD	0.090"	8F	95cm

¹ More trackability and more support than NeuronMax™, Infinity™, Shuttle™ and Fubuki™. More support than Ballast™.

² More support than Neuron™ MAX, Infinity™, Shuttle™, Fubuki™ and Ballast™ when placed in a distal cervical position.

³ More shaft stiffness than Neuron™ MAX, Infinity™, Shuttle™, Fubuki™ and Ballast™

⁴ Short flexible and softer than Neuron™ MAX, Infinity™, Shuttle™, Fubuki™ and Ballast™.

⁵ More kink resistance than Neuron™ MAX, Infinity™, Shuttle™, Fubuki™, Ballast™.

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Competitive Test Report #103618595 Rev2, April 2020

Competitive Test Report #10364599 Rev1, April 2020

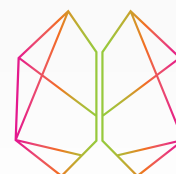
Competitive Test Report #103628641 October 2019 (Aspiration Catheter

Türk A, Manzoor MU, Nyberg EM, et al. Initial experience with distal guide catheter placement in the treatment of cerebrovascular disease: clinical safety and efficacy. J Neurointerv Surg. 2013 May;5(3):247-52. doi: 10.1136/neurintsurg-2011-010256. Epub 2012 Mar 13

Johnson & Johnson Medical Limited
Baird House, 4 Lower Gilmore Bank,
Edinburgh,
EH3 9QP
United Kingdom

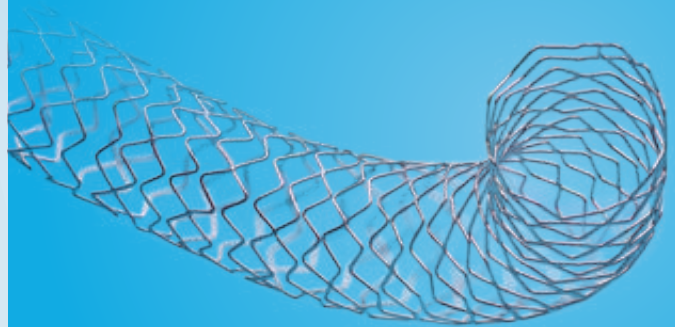
Legal Manufacturer:
Medos International SARL
Chemin-Blanc 38
CH-2400 Le Locle
Switzerland

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.
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CERENOVUS
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

CORONARY VASCULAR AND RENAL DENERVATION PRODUCT CATALOGUE



Medtronic
Further, Together



INTRODUCTION

GOING "FURTHER, TOGETHER"

As a global leader in medical technology, services and solutions, Medtronic improves the health and lives of millions of people each year. We believe our deep clinical, therapeutic, and economic expertise can help address the complex challenges — such as rising costs, aging populations, and the burden of chronic disease — faced by families and healthcare systems today. But no one can do it alone. That's why we're committed to partnering in new ways and developing powerful solutions that deliver better patient outcomes.

We call this new approach **"Further,Together."** "Further," because we will continue to drive progress in innovation, and devise powerful solutions with proven clinical and economic value as the basis of our offerings and value proposition. And "Together," because we will forge new, different, and stronger partnerships to help our customers achieve their goal of delivering more seamless, integrated care across the healthcare continuum.

The main tenets of "Further, Together." focus on developing **meaningful innovations** at the therapy, procedural, and system levels; leveraging our capabilities and expertise to align value among the various stakeholders in the healthcare system; and expanding global access to healthcare — all while developing new partnerships with those who are committed to transforming healthcare.

Founded in 1949 as a medical repair company, we're now among the world's largest medical technology, services and solutions companies, employing more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 155 countries. Join us in our commitment to take healthcare Further, Together. Learn more at **Medtronic.com**.

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- c. Resolute Onyx™

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11. PEDIATRIC AND TRANSSEPTAL PRODUCTS

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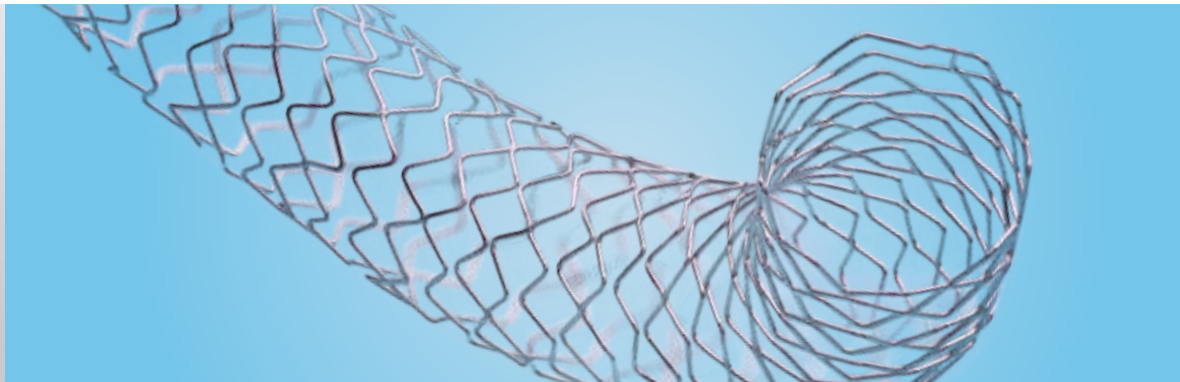
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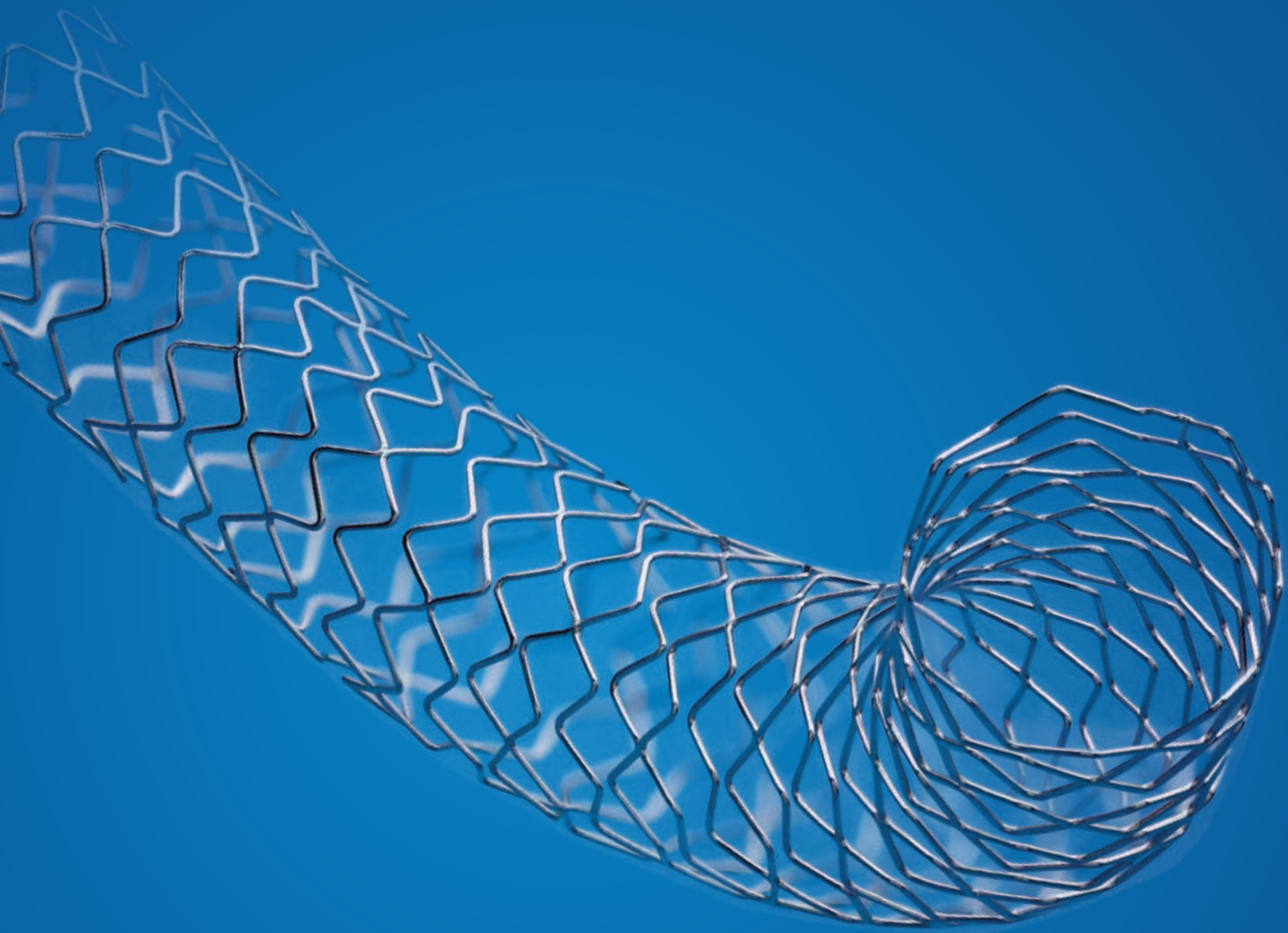
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9. INTRODUCERS	10. INTERVENTIONAL ACCESSORIES
11. PEDIATRIC AND TRANSSEPTAL PRODUCTS	12. RENAL DENERVATION



DRUG ELUTING STENTS

CORONARY STENTS

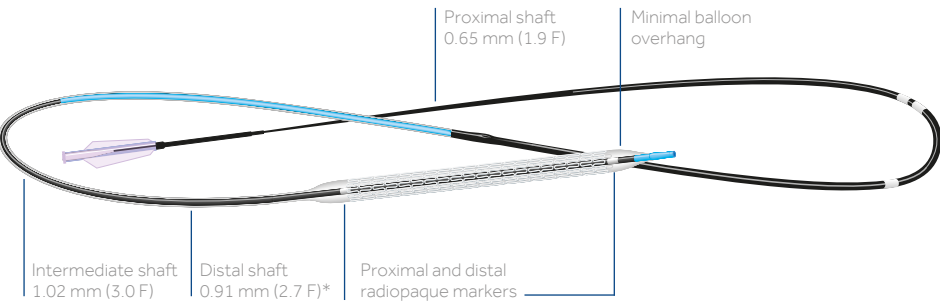
Resolute™
Drug-Eluting Stent System. Proven Value

GENERAL CHARACTERISTICS

▪ Supplied sterile. ▪ Items per box: 1 ▪ Label color: White

PRODUCT DESCRIPTION

The Resolute zotarolimus-eluting rapid exchange coronary stent system offers safe long-term drug elution with the BioLinx polymer specifically designed for DES.



*1.02 mm (3.0F) for all 4.00 mm stent sizes
00643169265455
Crossing Profile: 2.25–4.00 mm stents = 1.01–1.22 mm (0.040–0.048 in.)

RESOLUTE DRUG-ELUTING STENT SYSTEM

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
ERES22508X	2.25	8
ERES25008X	2.50	8
ERES27508X	2.75	8
ERES30009X	3.00	9
ERES35009X	3.50	9
ERES40009X	4.00	9
ERES22512X	2.25	12
ERES25012X	2.50	12
ERES27512X	2.75	12
ERES30012X	3.00	12
ERES35012X	3.50	12
ERES40012X	4.00	12
ERES22514X	2.25	14
ERES25014X	2.50	14
ERES27514X	2.75	14
ERES30015X	3.00	15
ERES35015X	3.50	15
ERES40015X	4.00	15
ERES22518X	2.25	18
ERES25018X	2.50	18

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
ERES27518X	2.75	18
ERES30018X	3.00	18
ERES35018X	3.50	18
ERES40018X	4.00	18
ERES22524X	2.25	24
ERES25024X	2.50	24
ERES27524X	2.75	24
ERES30024X	3.00	24
ERES35024X	3.50	24
ERES40024X	4.00	24
ERES22530X	2.25	30
ERES25030X	2.50	30
ERES27530X	2.75	30
ERES30030X	3.00	30
ERES35030X	3.50	30
ERES40030X	4.00	30
ERES30038X	3.00	38
ERES35038X	3.50	38
ERES40038X	4.00	38

CORONARY STENTS

Resolute™
Drug-Eluting Stent System. Proven Value

COMPLIANCE DATA

PRESSURE (ATM)	DIAMETER (MM)					
	2.25	2.50	2.75	3.00	3.50	4.00
7 (709 kPa)	2.20	2.48	2.67	2.90	3.32	3.82
8 (811 kPa)	2.24	2.53	2.73	2.96	3.40	3.90
9 (912 kPa)	2.28	2.58	2.80	3.02	3.49	3.96
10 (1013 kPa)	2.32	2.62	2.85	3.06	3.53	4.01
11 (1115 kPa)	2.36	2.66	2.89	3.10	3.57	4.07
12 (1216 kPa)	2.40	2.70	2.93	3.15	3.63	4.11
13 (1317 kPa)	2.44	2.73	2.97	3.19	3.68	4.16
14 (1418 kPa)	2.48	2.77	3.02	3.24	3.73	4.20
15 (1520 kPa)	2.52	2.81	3.07	3.29	3.78	4.25
16 (1621 kPa)	2.56	2.85	3.11	3.34	3.84	4.29
17 (1722 kPa)	2.60	2.89	3.16	3.38	3.89	4.34
18 (1824 kPa)	2.65	–	3.20	3.44	3.94	4.38
MSID	3.50	3.50	3.50	4.75	4.75	4.75

Nominal pressure	Rated burst pressure ¹	Maximum Stent I.D. ²
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1. Do not exceed rated burst pressure.
2. Do not expand to a diameter beyond 0.5 mm of its nominal diameter

CORONARY STENTS

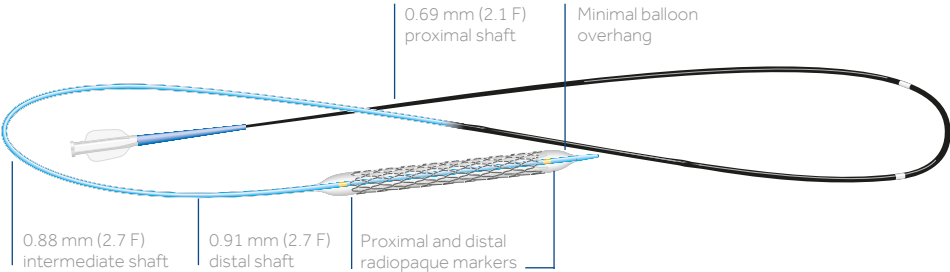
Resolute Integrity™
Drug-Eluting Stent System. Everyday Performance

GENERAL CHARACTERISTICS

▪ Supplied sterile. ▪ Items per box: 1 ▪ Label color: White

PRODUCT DESCRIPTION

The Resolute Integrity zotarolimus-eluting rapid exchange coronary stent system effectively combines the superior deliverability¹ of the Integrity stent platform utilizing continuous sinusoid technology and offers key performance attributes with the proven long-term safety and efficacy of Resolute DES.²



RESOLUTE INTEGRITY
DRUG-ELUTING
STENT SYSTEM

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
RSINT22508X	2.25	8
RSINT22512X	2.25	12
RSINT22514X	2.25	14
RSINT22518X	2.25	18
RSINT22522X	2.25	22
RSINT22526X	2.25	26
RSINT22530X	2.25	30
RSINT25008X	2.50	8
RSINT25012X	2.50	12
RSINT25014X	2.50	14
RSINT25018X	2.50	18
RSINT25022X	2.50	22
RSINT25026X	2.50	26
RSINT25030X	2.50	30
RSINT27508X	2.75	8
RSINT27512X	2.75	12
RSINT27514X	2.75	14
RSINT27518X	2.75	18
RSINT27522X	2.75	22
RSINT27526X	2.75	26
RSINT27530X	2.75	30
RSINT30009X	3.00	9
RSINT30012X	3.00	12
RSINT30015X	3.00	15

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
RSINT30018X	3.00	18
RSINT30022X	3.00	22
RSINT30026X	3.00	26
RSINT30030X	3.00	30
RSINT30034X	3.00	34
RSINT30038X	3.00	38
RSINT35009X	3.50	9
RSINT35012X	3.50	12
RSINT35015X	3.50	15
RSINT35018X	3.50	18
RSINT35022X	3.50	22
RSINT35026X	3.50	26
RSINT35030X	3.50	30
RSINT35034X	3.50	34
RSINT35038X	3.50	38
RSINT40009X	4.00	9
RSINT40012X	4.00	12
RSINT40015X	4.00	15
RSINT40018X	4.00	18
RSINT40022X	4.00	22
RSINT40026X	4.00	26
RSINT40030X	4.00	30
RSINT40034X	4.00	34
RSINT40038X	4.00	38

1. Bench test data vs. Abbott Xience Prime and Boston Scientific Promus Element on file at Medtronic, Inc.
2. RESOLUTE All Comers 12-month data. RESOLUTE All Comers evaluated the Resolute stent.
3. Internal bench test data on file at Medtronic, Inc.

Technical Information:
5F Minimum guide catheter I.D. 1.4 mm (0.056 in.)
Crossing Profiles:³
2.25–2.75 mm: 1.01–1.10 mm (0.040–0.043 in.)
3.0–4.0 mm: 1.10–1.31 mm (0.043–0.052 in.)

CORONARY STENTS

Resolute Integrity™
Drug-Eluting Stent System. Everyday Performance

COMPLIANCE DATA

PRESSURE (ATM)	DIAMETER (MM)					
	2.25	2.50	2.75	3.00	3.50	4.00
6 (608 kPa)	2.20	2.45	2.70	2.90	3.30	3.75
7 (709 kPa)	2.20	2.45	2.70	2.95	3.35	3.80
8 (811 kPa)	2.25	2.50	2.75	3.00	3.40	3.90
9 (912 kPa)	2.30	2.55	2.80	3.05	3.50	3.95
10 (1013 kPa)	2.30	2.60	2.85	3.10	3.55	4.05
11 (1115 kPa)	2.35	2.60	2.90	3.15	3.60	4.10
12 (1216 kPa)	2.40	2.65	2.95	3.20	3.65	4.15
13 (1317 kPa)	2.40	2.70	3.00	3.20	3.70	4.20
14 (1419 kPa)	2.45	2.70	3.05	3.25	3.75	4.25
15 (1520 kPa)	2.50	2.75	3.10	3.30	3.80	4.30
16 (1621 kPa)	2.55	2.80	3.15	3.35	3.85	4.35
17 (1723 kPa)	2.60	2.80	3.20	3.40	3.90	4.40
18 (1824 kPa)	2.60	2.85	3.25	3.45	3.95	4.45
19 (1925 kPa)	—	2.90	3.30	3.50	4.00	4.50
20 (2027 kPa)	—	2.95	3.40	3.55	4.05	—
MSID	3.50	3.50	3.50	4.75	4.75	4.75

Nominal pressure	Rated burst pressure ¹	Maximum Stent I.D. ²
------------------	-----------------------------------	---------------------------------

1. Do not exceed rated burst pressure.
2. Do not postdilate the 2.25–2.75-mm stents to greater than 3.50 mm.
Do not postdilate the 3.00–4.00-mm stents to greater than 4.75 mm.

CORONARY STENTS

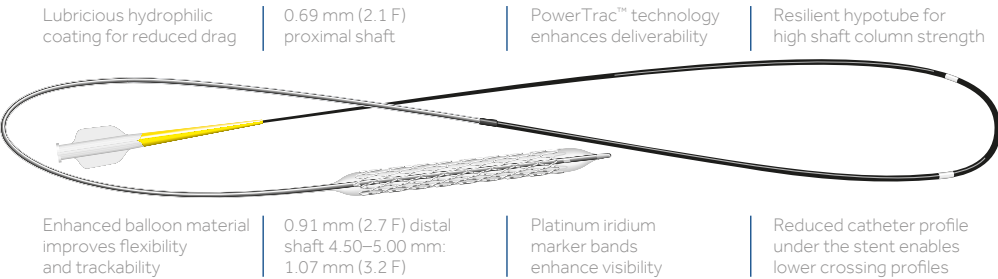
Resolute Onyx™ Drug-Eluting Stent System. Advanced Workhorse

GENERAL CHARACTERISTICS

▪ Supplied sterile. ▪ Items per box: 1 ▪ Label color: White

PRODUCT DESCRIPTION

Resolute Onyx zotarolimus-eluting coronary stent builds on the Integrity™ platform's acute procedural success¹ utilizing Continuous Sinusoid Technology and introduces Core Wire Technology for increased radiopacity, deliverability² and performance, the broadest size matrix to optimize treatment of complex clinical scenarios and the proven long-term safety and efficacy shown in the Global RESOLUTE Program



RESOLUTE INTEGRITY DRUG-ELUTING STENT SYSTEM

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
RONYX20008X	2.00	8
RONYX20012X	2.00	12
RONYX20015X	2.00	15
RONYX20018X	2.00	18
RONYX20022X	2.00	22
RONYX20026X	2.00	26
RONYX20030X	2.00	30
RONYX22508X	2.25	8
RONYX22512X	2.25	12
RONYX22515X	2.25	15
RONYX22518X	2.25	18
RONYX22522X	2.25	22
RONYX22526X	2.25	26
RONYX22530X	2.25	30
RONYX22534X	2.25	34
RONYX22538X	2.25	38
RONYX25008X	2.50	8
RONYX25012X	2.50	12
RONYX25015X	2.50	15
RONYX25018X	2.50	18
RONYX25022X	2.50	22
RONYX25026X	2.50	26
RONYX25030X	2.50	30
RONYX25034X	2.50	34
RONYX25038X	2.50	38
RONYX27508X	2.75	8
RONYX27512X	2.75	12
RONYX27515X	2.75	15
RONYX27518X	2.75	18
RONYX27522X	2.75	22
RONYX27526X	2.75	26
RONYX27530X	2.75	30
RONYX27534X	2.75	34
RONYX27538X	2.75	38
RONYX30008X	3.00	8
RONYX30012X	3.00	12
RONYX30015X	3.00	15

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
RONYX30018X	3.00	18
RONYX30022X	3.00	22
RONYX30026X	3.00	26
RONYX30030X	3.00	30
RONYX30034X	3.00	34
RONYX30038X	3.00	38
RONYX35008X	3.50	8
RONYX35012X	3.50	12
RONYX35015X	3.50	15
RONYX35018X	3.50	18
RONYX35022X	3.50	22
RONYX35026X	3.50	26
RONYX35030X	3.50	30
RONYX35034X	3.50	34
RONYX35038X	3.50	38
RONYX40008X	4.00	8
RONYX40012X	4.00	12
RONYX40015X	4.00	15
RONYX40018X	4.00	18
RONYX40022X	4.00	22
RONYX40026X	4.00	26
RONYX40030X	4.00	30
RONYX40034X	4.00	34
RONYX40038X	4.00	38
RONYX45012X	4.50	12
RONYX45015X	4.50	15
RONYX45018X	4.50	18
RONYX45022X	4.50	22
RONYX45026X	4.50	26
RONYX45030X	4.50	30
RONYX50012X	5.00	12
RONYX50015X	5.00	15
RONYX50018X	5.00	18
RONYX50022X	5.00	22
RONYX50026X	5.00	26
RONYX50030X	5.00	30

CORONARY STENTS

Resolute Onyx™ Drug-Eluting Stent System. Advanced Workhorse

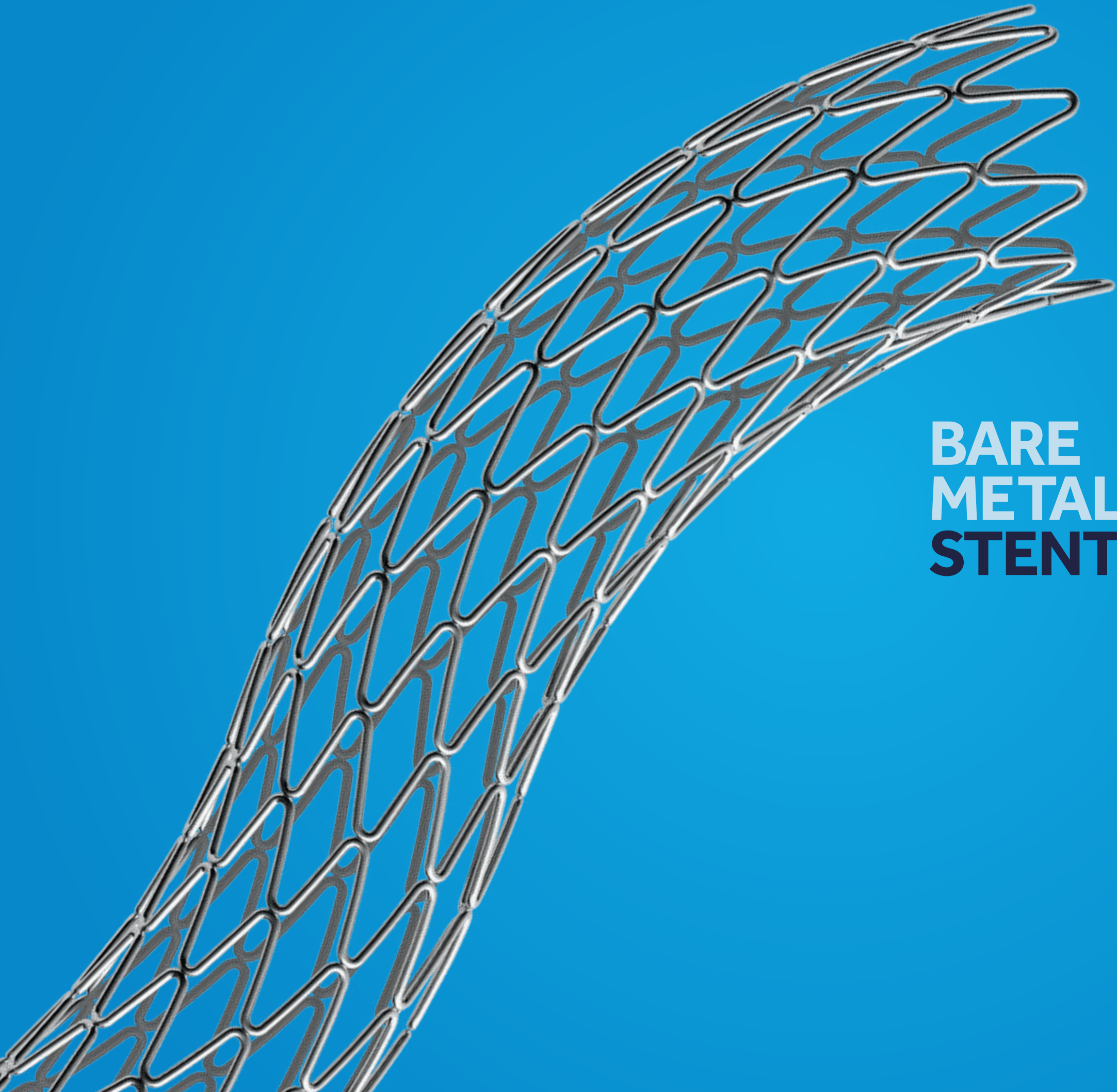
COMPLIANCE DATA

PRESSURE (ATM)	STENT DIAMETER, DEPLOYED STENT I.D. (MM)								
	2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50	5.00
7 (709 kPa)	1.85	2.05	2.25	2.45	2.75	3.05	3.60	4.10	4.55
8 (811 kPa)	1.90	2.10	2.30	2.55	2.80	3.15	3.70	4.20	4.65
9 (912 kPa)	1.90	2.15	2.35	2.60	2.90	3.25	3.80	4.30	4.80
10 (1013 kPa)	1.95	2.20	2.45	2.65	2.95	3.35	3.85	4.40	4.90
11 (1115 kPa)	2.00	2.25	2.50	2.70	3.00	3.40	3.95	4.45	4.95
12 (1216 kPa)	2.05	2.30	2.55	2.75	3.05	3.45	4.00	4.50	5.05
13 (1317 kPa)	2.05	2.35	2.55	2.80	3.10	3.50	4.05	4.55	5.10
14 (1419 kPa)	2.10	2.35	2.60	2.80	3.10	3.55	4.05	4.60	5.15
15 (1520 kPa)	2.10	2.35	2.60	2.85	3.15	3.55	4.10	4.65	5.20
16 (1621 kPa)	2.15	2.40	2.65	2.90	3.20	3.60	4.15	4.70	5.25
17 (1723 kPa)	2.15	2.40	2.70	2.90	3.20	3.65	4.20	4.80	5.30
18 (1824 kPa)	2.20	2.45	2.70	2.95	3.25	3.70	4.25	4.85	5.35
19 (1925 kPa)	2.20	2.45	2.75	3.00	3.30	3.75	4.30	–	–
20 (2027 kPa)	2.25	2.50	2.75	3.00	3.35	3.80	4.35	–	–
21 (2128 kPa)	2.25	2.50	2.80	3.05	3.40	3.80	4.40	–	–
MSID	3.25	3.25	3.25	3.75	3.75	4.75	4.75	5.75	5.75

Nominal pressure	Rated burst pressure ¹	Maximum Stent I.D. ²
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1. Do not exceed rated burst pressure.
2. Do not postdilate greater than listed value.

1. DELIVER study
2. Based on bench test data vs. Promus Premier™ DES, Synergy™ II DES, Xience Xpedition™ DES, Xience Alpine™ DES, BioMatrix NeoFlex™ DES, Orsiro™ DES Ultimaster™ DES and Resolute Integrity™ DES.



BARE METAL STENTS

CORONARY STENTS

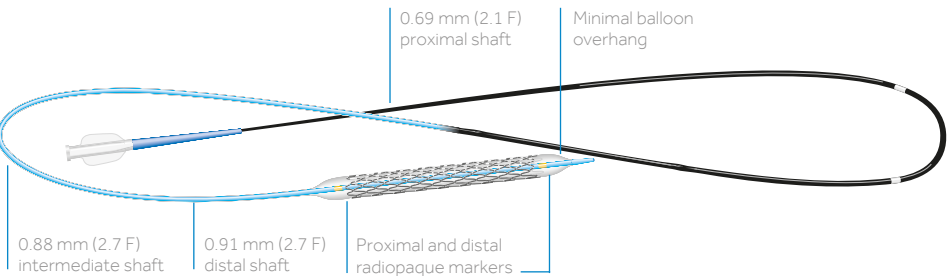
Integrity™ Bare-Metal Rapid Exchange Coronary Stent System

GENERAL CHARACTERISTICS

• Supplied sterile • Items per box: 1

PRODUCT DESCRIPTION

The Integrity™ Bare-Metal Rapid Exchange Coronary Stent System is a low-profile advanced cobalt alloy stent manufactured using Continuous Sinusoid Technology and mounted on the extended-pressure, semi-compliant, rapid exchange MicroTrac delivery system with a low-profile exchange joint for 6 F KBT and 7 F KST* compatibility and an enhanced tip design.



INTEGRITY RAPID EXCHANGE CORONARY STENT SYSTEM

PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)	PRODUCT CODE	STENT DIAMETER (MM)	STENT LENGTH (MM)
INT22508X	2.25	8	INT30009X	3.00	9
INT22512X	2.25	12	INT30012X	3.00	12
INT22514X	2.25	14	INT30015X	3.00	15
INT22518X	2.25	18	INT30018X	3.00	18
INT22522X	2.25	22	INT30022X	3.00	22
INT22526X	2.25	26	INT30026X	3.00	26
INT22530X	2.25	30	INT30030X	3.00	30
INT25008X	2.50	8	INT35009X	3.50	9
INT25012X	2.50	12	INT35012X	3.50	12
INT25014X	2.50	14	INT35015X	3.50	15
INT25018X	2.50	18	INT35018X	3.50	18
INT25022X	2.50	22	INT35022X	3.50	22
INT25026X	2.50	26	INT35026X	3.50	26
INT25030X	2.50	30	INT35030X	3.50	30
INT27508X	2.75	8	INT40009X	4.00	9
INT27512X	2.75	12	INT40012X	4.00	12
INT27514X	2.75	14	INT40015X	4.00	15
INT27518X	2.75	18	INT40018X	4.00	18
INT27522X	2.75	22	INT40022X	4.00	22
INT27526X	2.75	26	INT40026X	4.00	26
INT27530X	2.75	30	INT40030X	4.00	30

CORONARY STENTS

Integrity™ Bare-Metal Rapid Exchange Coronary Stent System

COMPLIANCE DATA

PRESSURE KPA (ATM)	DEPLOYED STENT I.D. (MM)					
	2.25	2.50	2.75	3.00	3.50	4.00
608 (6)	2.25	2.50	2.75	2.95	3.35	3.80
709 (7)	2.25	2.50	2.80	3.00	3.40	3.85
811 (8)	2.30	2.55	2.85	3.05	3.45	3.95
912 (9)	2.35	2.60	2.85	3.10	3.50	4.00
1013 (10)	2.35	2.65	2.90	3.15	3.60	4.05
1115 (11)	2.40	2.70	2.95	3.20	3.65	4.15
1216 (12)	2.45	2.70	3.00	3.25	3.65	4.20
1317 (13)	2.50	2.75	3.05	3.30	3.70	4.20
1419 (14)	2.50	2.80	3.10	3.30	3.75	4.25
1520 (15)	2.55	2.80	3.10	3.35	3.80	4.30
1621 (16)	2.60	2.85	3.15	3.40	3.85	4.35
1723 (17)	2.65	2.90	3.20	3.45	3.90	4.40
1824 (18)	2.70	2.95	3.25	3.50	3.90	4.45
1925 (19)	2.75	3.00	3.30	3.55	3.95	4.50
2027 (20)	2.80	3.05	3.40	3.60	4.00	—
MSID	3.50*	3.50*	3.50*	4.75*	4.75*	4.75*

Nominal pressure	Rated burst pressure ¹	Maximum Stent I.D. ²
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1. Do not exceed rated burst pressure.
2. Do not dilate the 2.25–2.75-mm stents to greater than 3.50 mm.
Do not dilate the 3.00–4.00-mm stents to greater than 4.75 mm.

BALLOON DILATATION CATHETERS



CONTENTS	1. DRUG-ELUTING STENTS	3. BALLOON DILATATION CATHETERS	4. DRUG-ELUTING BALLOONS	5. GUIDE CATHETER FAMILY	6. INTERVENTIONAL GUIDEWIRES	7. ASPIRATION CATHETERS	8. ANGIOGRAPHIC CATHETERS AND WIRES	9. INTRODUCERS	10. INTERVENTIONAL ACCESSORIES	11. PEDIATRIC AND TRANSSEPTAL PRODUCTS	12. RENAL DENERVATION
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BALLOON DILATATION CATHETERS

Euphora™ Semicompliant Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

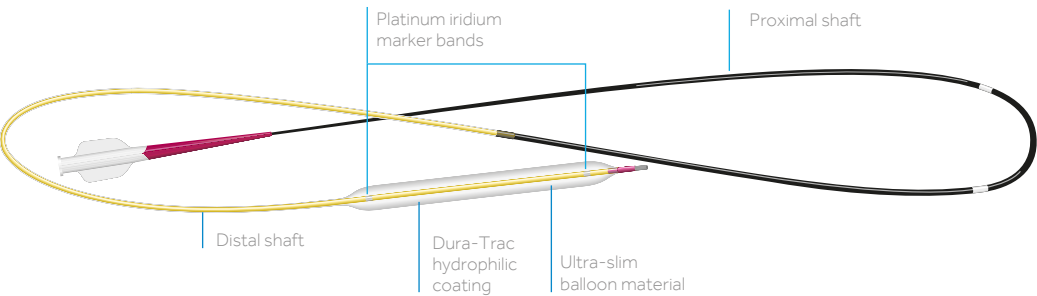
▪ Supplied sterile ▪ Items per box: 1

PRODUCT DESCRIPTION

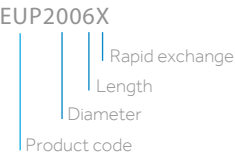
From materials to design, every Euphora™ balloon component was developed to provide superior deliverability¹ with unmatched crossability¹ and pushability

FEATURES

- Ultra-slim balloon material
- Optimised miniwrap
- Low profile marker bands
- Tapered shaft
- PowerTrac™ shaft technology
- Low-profile inner/outer shaft



PRODUCT CODE



SIZE MATRIX

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)						
	06	10	12	15	20	25	30
1.50	EUP1506X	EUP1510X	EUP1512X	EUP1515X	EUP1520X	—	—
2.00	EUP2006X	EUP2010X	EUP2012X	EUP2015X	EUP2020X	EUP2025X	EUP2030X
2.25	EUP22506X	EUP22510X	EUP22512X	EUP22515X	EUP22520X	EUP22525X	—
2.50	EUP2506X	EUP2510X	EUP2512X	EUP2515X	EUP2520X	EUP2525X	EUP2530X
2.75	EUP27506X	EUP27510X	EUP27512X	EUP27515X	EUP27520X	EUP27525X	—
3.00	EUP3006X	EUP3010X	EUP3012X	EUP3015X	EUP3020X	EUP3025X	EUP3030X
3.25	EUP32506X	EUP32510X	EUP32512X	EUP32515X	EUP32520X	EUP32525X	—
3.50	EUP3506X	EUP3510X	EUP3512X	EUP3515X	EUP3520X	EUP3525X	EUP3530X
3.75	EUP37506X	EUP37510X	EUP37512X	EUP37515X	EUP37520X	EUP37525X	—
4.00	EUP4006X	EUP4010X	EUP4012X	EUP4015X	EUP4020X	EUP4025X	EUP4030X

BALLOON DILATATION CATHETERS

Euphora™ Semicompliant Balloon Dilatation Catheter

COMPLIANCE DATA

PRESSURE KPA (ATM)	AVERAGE BALLOON DIAMETER (MM)									
	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
608 (6)	1.49	2.03	2.27	2.50	2.70	2.92	3.17	3.39	3.66	3.88
709 (7)	1.51	2.05	2.30	2.52	2.73	2.95	3.21	3.43	3.70	3.93
811 (8)	1.52	2.07	2.32	2.55	2.77	2.99	3.25	3.48	3.75	3.99
912 (9)	1.54	2.09	2.35	2.58	2.80	3.03	3.30	3.53	3.80	4.04
1013 (10)	1.55	2.12	2.38	2.61	2.84	3.06	3.34	3.58	3.85	4.10
1115 (11)	1.57	2.14	2.41	2.64	2.87	3.10	3.38	3.62	3.90	4.14
1216 (12)	1.58	2.17	2.43	2.67	2.91	3.14	3.42	3.67	3.95	4.19
1317 (13)	1.60	2.19	2.46	2.70	2.94	3.17	3.46	3.71	4.00	4.23
1419 (14)	1.61	2.22	2.49	2.73	2.98	3.21	3.51	3.76	4.05	4.28
1520 (15)	1.62	2.25	2.52	2.76	3.02	3.25	3.56	3.81	4.10	4.33
1621 (16)	1.64	2.28	2.56	2.79	3.06	3.29	3.61	3.86	4.16	4.38
1723 (17)	1.65	—	2.60	2.83	3.11	3.34	3.66	3.91	4.22	4.43

Nominal pressure ¹	Rated burst pressure ²
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1. Nominal pressure: the pressure at which the balloon approximates its labeled diameter
2. Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated – do not exceed.

TECHNICAL INFORMATION

Catheter length	142 cm	
Platinum iridium marker bands	1.50 mm 2.00 – 4.00 mm	Single Double
Coating	Selective Dura-Trac	
Balloon material	Ultra-Slim	
MiniWrap	1.50 mm 2.00-3.50 mm 3.75 – 4.00 mm	2 folds 3 folds 5 folds
Shaft dimensions: 1.50 – 3.50 mm	Proximal Distal	0.69 mm (2.1 F) 0.84 mm (2.5 F)
Shaft dimensions: 3.75 – 4.00 mm	Proximal Distal	0.69 mm (2.1 F) 0.91 mm (2.7 F)
MGCID	For 1.50-4.00 mm balloon	1.42 mm/0.056 in.
Nominal pressure, atm	8	
Rated burst pressure (RBP), atm	14	
Cycles to RBP	10	
Lesion entry profile	0.016 in.	

1. Competitive testing vs. NC Trek and NC Quantum Apex™ balloons on file at Medtronic.
2. Rated burst pressure—do not exceed.

BALLOON DILATATION CATHETERS

NC Euphora™ Noncompliant Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

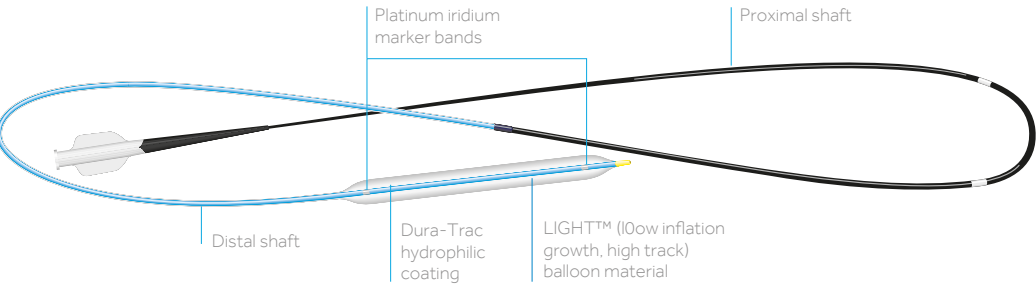
▪ Supplied sterile • Items per box: 1

PRODUCT DESCRIPTION

From material to design every NC Euphora™ balloon component was developed to provide superior growth profile and deliverability, excellent recross and high-pressure capability

FEATURES

- Strong, durable and flexible LIGHT™ (Low Inflation Growth, High Track) balloon material
- Low profile platinum iridium marker bands
- Optimized tapered tip
- PowerTrac™ shaft technology
- Low-profile inner/outer shaft



PRODUCT CODE

NCEUP2006X
|
|
| Rapid exchange
| Length
| Diameter
| Product code

SIZE MATRIX

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)					
	06	08	12	15	20	27
2.00	NCEUP2006X	NCEUP2008X	NCEUP2012X	NCEUP2015X	NCEUP2020X	—
2.25	NCEUP22506X	NCEUP22508X	NCEUP22512X	NCEUP22515X	NCEUP22520X	—
2.50	NCEUP2506X	NCEUP2508X	NCEUP2512X	NCEUP2515X	NCEUP2520X	NCEUP2527X
2.75	NCEUP27506X	NCEUP27508X	NCEUP27512X	NCEUP27515X	NCEUP27520X	NCEUP27527X
3.00	NCEUP3006X	NCEUP3008X	NCEUP3012X	NCEUP3015X	NCEUP3020X	NCEUP3027X
3.25	NCEUP32506X	NCEUP32508X	NCEUP32512X	NCEUP32515X	NCEUP32520X	NCEUP32527X
3.50	NCEUP3506X	NCEUP3508X	NCEUP3512X	NCEUP3515X	NCEUP3520X	NCEUP3527X
3.75	NCEUP37506X	NCEUP37508X	NCEUP37512X	NCEUP37515X	NCEUP37520X	NCEUP37527X
4.00	NCEUP4006X	NCEUP4008X	NCEUP4012X	NCEUP4015X	NCEUP4020X	NCEUP4027X
4.50	—	NCEUP4508X	NCEUP4512X	NCEUP4515X	NCEUP4520X	—
5.00	—	NCEUP5008X	NCEUP5012X	NCEUP5015X	—	—

BALLOON DILATATION CATHETERS

NC Euphora™ Noncompliant Balloon Dilatation Catheter

COMPLIANCE DATA

PRESSURE KPA (ATM)	AVERAGE BALLOON DIAMETER (MM)										
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
608 (6)	1.89	2.12	2.35	2.54	2.77	2.94	3.13	3.43	3.67	4.09	4.64
709 (7)	1.91	2.15	2.37	2.57	2.80	2.97	3.17	3.47	3.72	4.14	4.71
811 (8)	1.93	2.17	2.40	2.60	2.84	3.01	3.22	3.51	3.78	4.19	4.79
912 (9)	1.95	2.19	2.43	2.63	2.87	3.06	3.27	3.56	3.84	4.25	4.86
1013 (10)	1.97	2.21	2.46	2.66	2.91	3.10	3.32	3.61	3.90	4.31	4.92
1115 (11)	1.98	2.23	2.48	2.69	2.94	3.14	3.37	3.66	3.95	4.37	4.95
1216 (12)	1.99	2.25	2.50	2.71	2.97	3.18	3.41	3.70	3.99	4.42	5.00
1317 (13)	2.00	2.26	2.51	2.73	2.99	3.21	3.44	3.73	4.03	4.47	5.04
1419 (14)	2.02	2.28	2.53	2.75	3.01	3.23	3.47	3.76	4.07	4.51	5.08
1520 (15)	2.03	2.29	2.54	2.77	3.03	3.26	3.50	3.78	4.10	4.54	5.12
1621 (16)	2.04	2.30	2.56	2.78	3.05	3.28	3.52	3.81	4.13	4.58	5.15
1723 (17)	2.05	2.31	2.58	2.80	3.07	3.30	3.55	3.83	4.15	4.60	5.19
1824 (18)	2.06	2.33	2.59	2.81	3.09	3.33	3.57	3.86	4.18	4.63	5.23
1925 (19)	2.07	2.34	2.61	2.83	3.11	3.35	3.59	3.88	4.21	4.66	5.27
2027 (20)	2.09	2.36	2.63	2.84	3.13	3.37	3.62	3.91	4.24	4.69	5.30
2128 (21)	2.10	2.37	2.65	2.86	3.15	3.39	3.64	3.93	4.28	4.72	5.35
2229 (22)	2.12	2.39	2.66	2.88	3.17	3.41	3.66	3.96	4.31	4.75	5.39
2330 (23)	2.14	2.40	2.68	2.90	3.20	3.43	3.69	3.99	4.34	4.78	—
2432 (24)	2.15	2.42	2.71	2.92	3.22	—	3.71	—	—	4.81	—
2533 (25)	—	2.44	—	2.94	3.25	—	3.74	—	—	4.84	—

Nominal pressure ¹	Rated burst pressure ²
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1. Nominal pressure: the pressure at which the balloon approximates its labeled diameter
2. Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated – do not exceed.

TECHNICAL INFORMATION

Catheter length	142 cm	
Platinum iridium marker bands	2.00 – 5.00 mm	Double
Coating	Selective Dura-Trac	
Balloon material	LIGHT (Low Inflation Growth, High Track)	
MiniWrap	2.00 – 3.75 mm 4.00 – 5.00 mm	3 folds 5 folds
Shaft dimensions For 2.00 – 3.75 mm	Proximal Distal	0.69 mm (2.1 F) 0.84 mm (2.5 F)
Shaft dimensions For 4.00 – 5.00 mm	Proximal Distal	0.69 mm (2.1 F) 0.91 mm (2.7 F)
MGCID	For 2.00 - 4.00 mm balloon For 4.50 - 5.00 mm balloon	1.42 mm/0.056 in. 1.68 mm/0.066 in.
Nominal pressure, atm	12	
Rated burst pressure (RBP), atm	20	
Cycles to RBP	20	
Lesion entry profile	0.015 in.	

BALLOON DILATATION CATHETERS

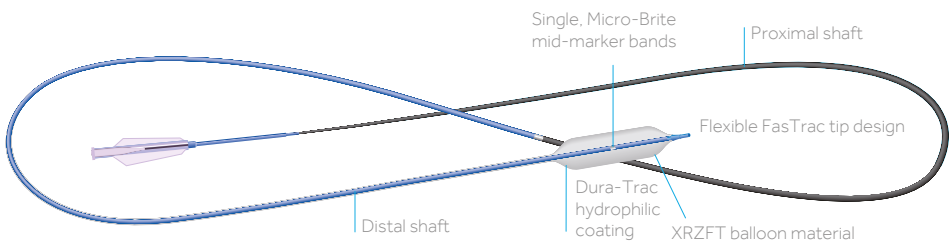
Sprinter Legend™ RX 1.25 mm Semicompliant Rapid Exchange Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

- Supplied sterile
- Items per box: 1

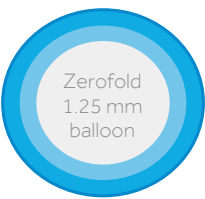
PRODUCT DESCRIPTION

The Sprinter Legend™ RX 1.25 mm semicompliant rapid exchange balloon dilatation catheter, with its SuperCROSSER ZeroFold Technology, (no balloon wrap or shoulders) helps provide your best chance at crossing even the most difficult lesions



FEATURES

- Lesion entry profile: 0.41 mm (0.016")
- Crossing profile: 0.5 mm (0.020")
- Profile over mid-marker: 0.6 mm (0.024")
- No wrapped material allows for ultra-low catheter profile. Expands from a straight tube into a balloon
- No balloon shoulders,¹ Facilitates balloon passage through the lesion



ORDERING INFORMATION

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)				
	6	10	12	15	20
1.25	SPL12506X	SPL12510X	SPL12512X	SPL12515X	SPL12520X

1. Test data on file at Medtronic, Inc. Best-in-class profiles based on distal balloon shoulder outer diameter vs. key competitors. Bench test data may not be indicative of clinical results.

Test data on file at Medtronic, Inc. Bench testing not necessarily indicative of clinical performance.

Nominal pressure: the pressure at which the balloon reaches its labeled diameter. Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated (95% confidence that 99.9% will not fail below rated burst pressure).

COMPLIANCE DATA

PRESSURE KPA (ATM)	BALLOON DIAMETER 1.25
405 (4)	0.60
507 (5)	0.60
608 (6)	0.63
709 (7)	0.67
811 (8)	0.75
912 (9)	0.86
1013 (10)	0.99
1115 (11)	1.11
1216 (12)	1.20
1317 (13)	1.28
1419 (14)	1.35
1520 (15)	1.40
Nominal pressure & Rated burst pressure	

BALLOON DILATATION CATHETERS

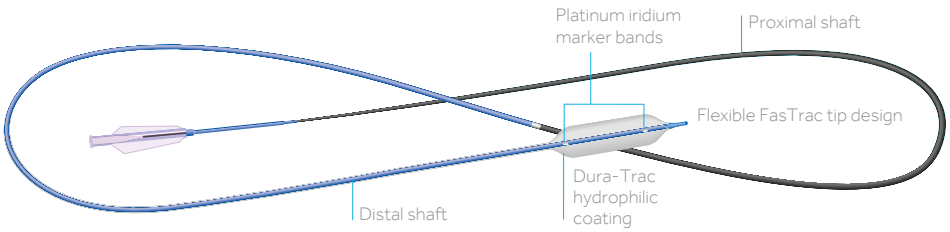
Sprinter Legend™ RX Semicompliant Rapid Exchange Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

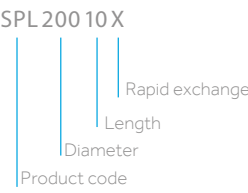
- Supplied sterile
- Items per box: 1

PRODUCT DESCRIPTION

A high-performing semicompliant balloon available in a wide range of diameters and lengths, designed to meet a comprehensive spectrum of interventional needs and maximise your success in treating patients



PRODUCT CODE



ORDERING INFORMATION

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)						
	6	10	12	15	20	25	30
1.25	SPL12506X	SPL12510X	SPL12512X	SPL12515X	SPL12520X	—	—
1.50	SPL15006X	SPL15010X	SPL15012X	SPL15015X	SPL15020X	—	—
2.00	SPL20006X	SPL20010X	SPL20012X	SPL20015X	SPL20020X	SPL20025X	SPL20030X
2.25	SPL22506X	SPL22510X	SPL22512X	SPL22515X	SPL22520X	SPL22525X	—
2.50	SPL25006X	SPL25010X	SPL25012X	SPL25015X	SPL25020X	SPL25025X	SPL25030X
2.75	SPL27506X	—	SPL27512X	SPL27515X	SPL27520X	SPL27525X	—
3.00	SPL30006X	SPL30010X	SPL30012X	SPL30015X	SPL30020X	SPL30025X	SPL30030X
3.25	—	—	SPL32512X	SPL32515X	SPL32520X	—	—
3.50	SPL35006X	SPL35010X	SPL35012X	SPL35015X	SPL35020X	SPL35025X	SPL35030X
3.75	—	—	SPL37512X	SPL37515X	SPL37520X	—	—
4.00	SPL40006X	SPL40010X	SPL40012X	SPL40015X	SPL40020X	SPL40025X	SPL40030X

BALLOON DILATATION CATHETERS

Sprinter Legend™ RX Semicompliant Rapid Exchange Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

• Supplied sterile • Items per box: 1

COMPLIANCE DATA

PRESSURE KPA (ATM)	BALLOON DIAMETER (MM)										
	1.25	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
405 (4)	0.60	1.36	—	—	—	—	—	—	—	—	—
507 (5)	0.60	1.41	—	—	—	—	—	—	—	—	—
608 (6)	0.63	1.47	1.91	2.23	2.34	2.60	2.81	3.14	3.32	3.61	3.85
709 (7)	0.67	1.53	1.95	2.29	2.41	2.67	2.89	3.22	3.42	3.70	3.96
811 (8)	0.75	1.58	2.00	2.33	2.47	2.74	2.97	3.29	3.50	3.79	4.05
912 (9)	0.86	1.61	2.03	2.38	2.53	2.79	3.04	3.35	3.57	3.86	4.12
1013 (10)	0.99	1.64	2.06	2.41	2.57	2.84	3.09	3.40	3.63	3.93	4.18
1115 (11)	1.11	1.67	2.09	2.44	2.61	2.89	3.14	3.44	3.68	3.98	4.23
1216 (12)	1.20	1.70	2.12	2.47	2.64	2.93	3.18	3.48	3.73	4.02	4.29
1317 (13)	1.28	1.73	2.14	2.51	2.67	2.96	3.22	3.52	3.77	4.07	4.35
1419 (14)	1.35	1.75	2.16	2.54	2.70	3.00	3.25	3.56	3.82	4.12	4.40
1520 (15)	1.40	1.78	2.19	2.58	2.73	3.03	3.29	3.59	3.87	4.16	4.45
1621 (16)	—	—	2.21	2.61	2.76	3.07	3.33	3.64	3.92	4.21	4.50

Nominal pressure ¹	Rated burst pressure ²	Nominal pressure & rated burst pressure
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1. Nominal pressure: the pressure at which the balloon approximates its labeled diameter.
2. Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated – do not exceed.

TECHNICAL INFORMATION

Catheter length (cm)	142
Distal shaft length (cm)	21
Platinum iridium marker bands 1.25-1.50 mm 2.00-4.00 mm	Single Double
Coating	Selective Dura-Trac
MiniWrap 1.25 mm 1.50 mm 2.00 mm-3.75mm 4.00 mm	Zero Fold 2 folds 3 folds 5 folds
Shaft dimensions for 1.25-3.5mm Proximal Distal	1.9F 2.4F/2.6F
Shaft dimensions for 3.75-4.00 mm Proximal Distal	1.9F 2.5F/2.7F
MGCID	1.4 mm/0.056" (1.25-3.50)



• Compatible with 6 F kissing balloon technique.

• Any combination of two Sprinter Legend rapid exchange balloon models (1.25 - 3.50 mm) can be used for the Kissing Balloon Technique within a 6 F (MGCID 0.070") guide catheter. Test data on file at Medtronic, Inc.

BALLOON DILATATION CATHETERS

Sprinter Legend™ 1.25 OTW Semi-compliant Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

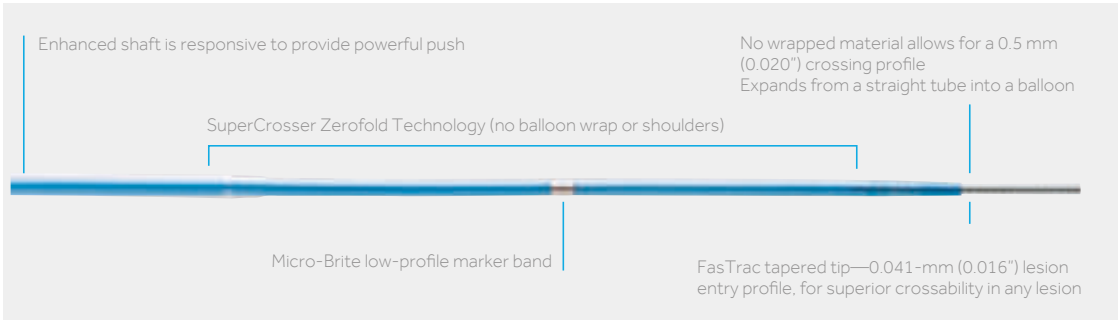
• Supplied sterile • Items per box: 1

PRODUCT DESCRIPTION

Sprinter Legend™ 1.25 OTW semicompliant balloon is designed to maximise your chances for a successful outcome on highly complex, challenging and tightly occluded lesions.

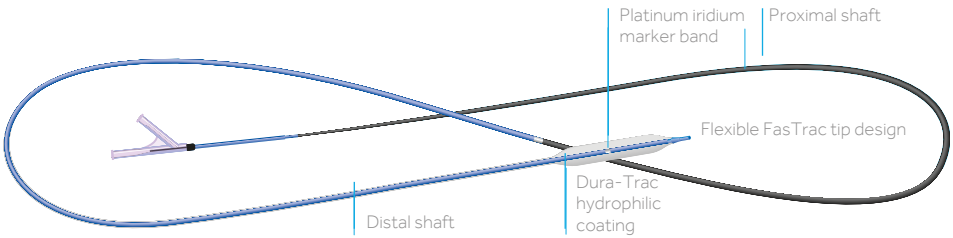
FEATURES

- Superb push and track—for easier lesion access
- Excellent postinflation profile—for smooth recross
- Ultralow crossing profiles—for advanced lesion crossing
- 152-cm catheter length—to facilitate extended vasculature



PRODUCT CODE

SPL 125 10 WL
Over the wire
Length
Diameter
Product code



TECHNICAL INFORMATION

Catheter length (cm)	152
Distal shaft length (cm)	22.5
Platinum iridium marker band 1.25mm	single
Coating	Selective Dura-Trac
SuperCROSSER Zerofold technology	
Shaft dimensions Proximal Distal	3.2F 2.4F/2.6F
MGCID	1.42 mm/0.056"
Crossing profile	1.25 MM 0.5 mm (0.020 in)

ORDERING INFORMATION

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)	6	10	15	20
1.25	SPL12506WL		SPL12510WL	SPL12515WL	SPL12520WL

COMPLIANCE DATA

PRESSURE KPA (ATM)	BALLOON DIAMETER 1.25
405 (4)	0.60
507 (5)	0.60
608 (6)	0.63
709 (7)	0.67
811 (8)	0.75
912 (9)	0.86
1013 (10)	0.99
1115 (11)	1.11
1216 (12)	1.20
1317 (13)	1.28
1419 (14)	1.35
1520 (15)	1.40
1621 (16)	
Nominal pressure & rated burst pressure	

BALLOON DILATATION CATHETERS

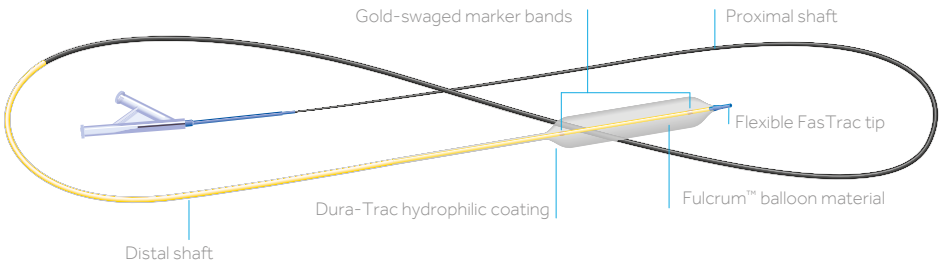
Sprinter™ OTW
Semi-compliant Over-the-Wire Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 1

PRODUCT DESCRIPTION

A high-performing semicompliant balloon available in a wide range of diameters and lengths, designed to meet a comprehensive spectrum of interventional needs and maximise your success in treating patients.



PRODUCT CODE

SPL 200 10 W
W = Over-the-Wire
Length
Diameter
Product code

ORDERING INFORMATION

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)						
	6	10	12	15	20	25	30
1.50	SPR15006W	SPR15010W	SPR15012W	SPR15015W	SPR15020W	—	—
2.00	SPR20006W	SPR20010W	SPR20012W	SPR20015W	SPR20020W	SPR2025W	SPR2030W
2.25	SPR22506W	SPR22510W	SPR22512W	SPR22515W	SPR22520W	—	—
2.50	SPR25006W	SPR25010W	SPR25012W	SPR25015W	SPR25020W	SPR2525W	SPR2530W
2.75	SPR27506W	—	SPR27512W	SPR27515W	SPR27520W	—	—
3.00	SPR30006W	SPR30010W	SPR30012W	SPR30015W	SPR30020W	SPR3025W	SPR3030W
3.25	—	—	SPR32512W	SPR32515W	SPR32520W	—	—
3.50	SPR35006W	SPR35010W	SPR35012W	SPR35015W	SPR35020W	SPR3525W	SPR3530W
3.75	—	—	SPR37512W	SPR37515W	SPR37520W	—	—
4.00	SPR40006W	SPR40010W	SPR40012W	SPR40015W	SPR40020W	SPR4025W	SPR4030W

BALLOON DILATATION CATHETERS

Sprinter™ OTW
Semi-compliant Over-the-Wire Balloon Dilatation Catheter

COMPLIANCE DATA

PRESSURE KPA (ATM)	BALLOON DIAMETER (MM)									
	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
405 (4)	1.37	1.77	2.00	2.22	2.40	2.62	2.87	3.01	3.35	3.48
507 (5)	1.42	1.83	2.07	2.29	2.49	2.71	2.98	3.14	3.48	3.64
608 (6)	1.47	1.88	2.14	2.37	2.57	2.81	3.08	3.25	3.60	3.78
709 (7)	1.52	1.93	2.20	2.44	2.66	2.90	3.18	3.37	3.70	3.91
811 (8)	1.55	1.97	2.25	2.50	2.73	2.98	3.25	3.47	3.80	4.02
912 (9)	1.58	2.01	2.30	2.55	2.80	3.05	3.32	3.55	3.87	4.11
1013 (10)	1.60	2.04	2.33	2.59	2.85	3.10	3.38	3.62	3.93	4.19
1115 (11)	1.63	2.07	2.37	2.63	2.89	3.14	3.42	3.68	3.98	4.25
1216 (12)	1.65	2.10	2.40	2.66	2.93	3.18	3.46	3.72	4.03	4.31
1317 (13)	1.67	2.12	2.43	2.69	2.97	3.22	3.51	3.77	4.08	4.37
1419 (14)	1.69	2.15	2.46	2.72	3.00	3.26	3.55	3.82	4.13	4.42
1520 (15)	1.72	2.17	2.49	2.76	3.04	3.29	3.59	3.87	4.19	4.48
1621 (16)	-	2.19	2.53	2.79	3.08	3.33	3.64	3.92	4.24	4.54
1723 (17)	-	2.21	2.56	2.82	3.11	3.37	3.69	3.97	4.30	4.60
1824 (18)	-	2.24	2.59	2.86	3.15	3.42	3.73	4.02	4.38	4.67

Nominal pressure ¹	Rated burst pressure ²
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1. Nominal pressure: the pressure at which the balloon approximates its labeled diameter
2. Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated – do not exceed.

TECHNICAL INFORMATION

Catheter length	138 cm
Gold-swaged marker bands	
1.5mm	Single
2.00 – 4.00mm	Double
Coating	Dura-Trac selective
Balloon material	Falcrum™
MiniWrap	
1.5mm	2 folds
2.00 – 3.75mm	3 folds
4.00 – 5.00mm	5 folds
Shaft dimensions for 1.5 – 3.5mm	
Proximal	3.2 F
Distal	2.4 F / 2.6 F
Shaft dimensions for 3.75 – 4.0mm	
Proximal	3.2 F
Distal	2.5 F
MGCID	1.42 mm/0.056"

BALLOON DILATATION CATHETERS

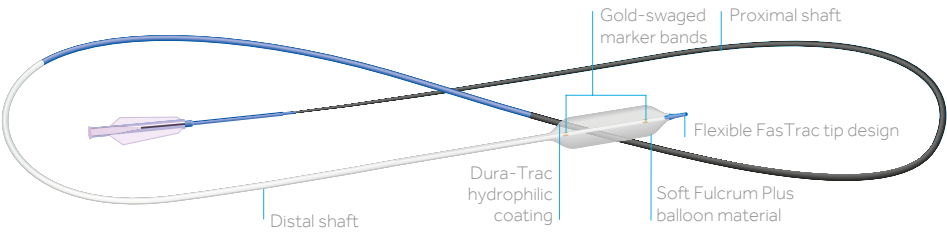
NC Sprinter™ Noncompliant Rapid Exchange Balloon Dilatation Catheter

GENERAL CHARACTERISTICS

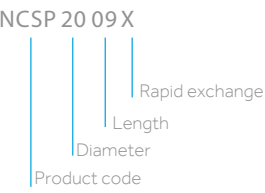
▪ Supplied sterile ▪ Items per box: 1

PRODUCT DESCRIPTION

The NC Sprinter™ noncompliant rapid exchange balloon dilatation catheter combines proven Sprinter technology with the high-pressure capability and controlled expansion of a noncompliant balloon-performance for optimal stenting results.



PRODUCT CODE



ORDERING INFORMATION

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)					
	6	9	12	15	21	27
2.00	NCSP2006X	NCSP2009X	NCSP2012X	NCSP2015X	NCSP2021X	—
2.25	NCSP22506X	—	NCSP22512X	—	NCSP22521X	—
2.50	NCSP2506X	NCSP2509X	NCSP2512X	NCSP2515X	NCSP2521X	NCSP2527X
2.75	NCSP27506X	NCSP27509X	NCSP27512X	NCSP27515X	NCSP27521X	—
3.00	NCSP3006X	NCSP3009X	NCSP3012X	NCSP3015X	NCSP3021X	NCSP3027X
3.25	NCSP32506X	NCSP32509X	NCSP32512X	NCSP32515X	NCSP32521X	—
3.50	NCSP3506X	NCSP3509X	NCSP3512X	NCSP3515X	NCSP3521X	NCSP3527X
3.75	NCSP37506X	NCSP37509X	NCSP37512X	NCSP37515X	NCSP37521X	—
4.00	NCSP4006X	NCSP4009X	NCSP4012X	NCSP4015X	NCSP4021X	NCSP4027X
4.50	—	—	—	NCSP4515X	NCSP4521X	—
5.00	—	—	—	NCSP5015X	—	—

BALLOON DILATATION CATHETERS

NC Sprinter™ Noncompliant Rapid Exchange Balloon Dilatation Catheter

COMPLIANCE DATA

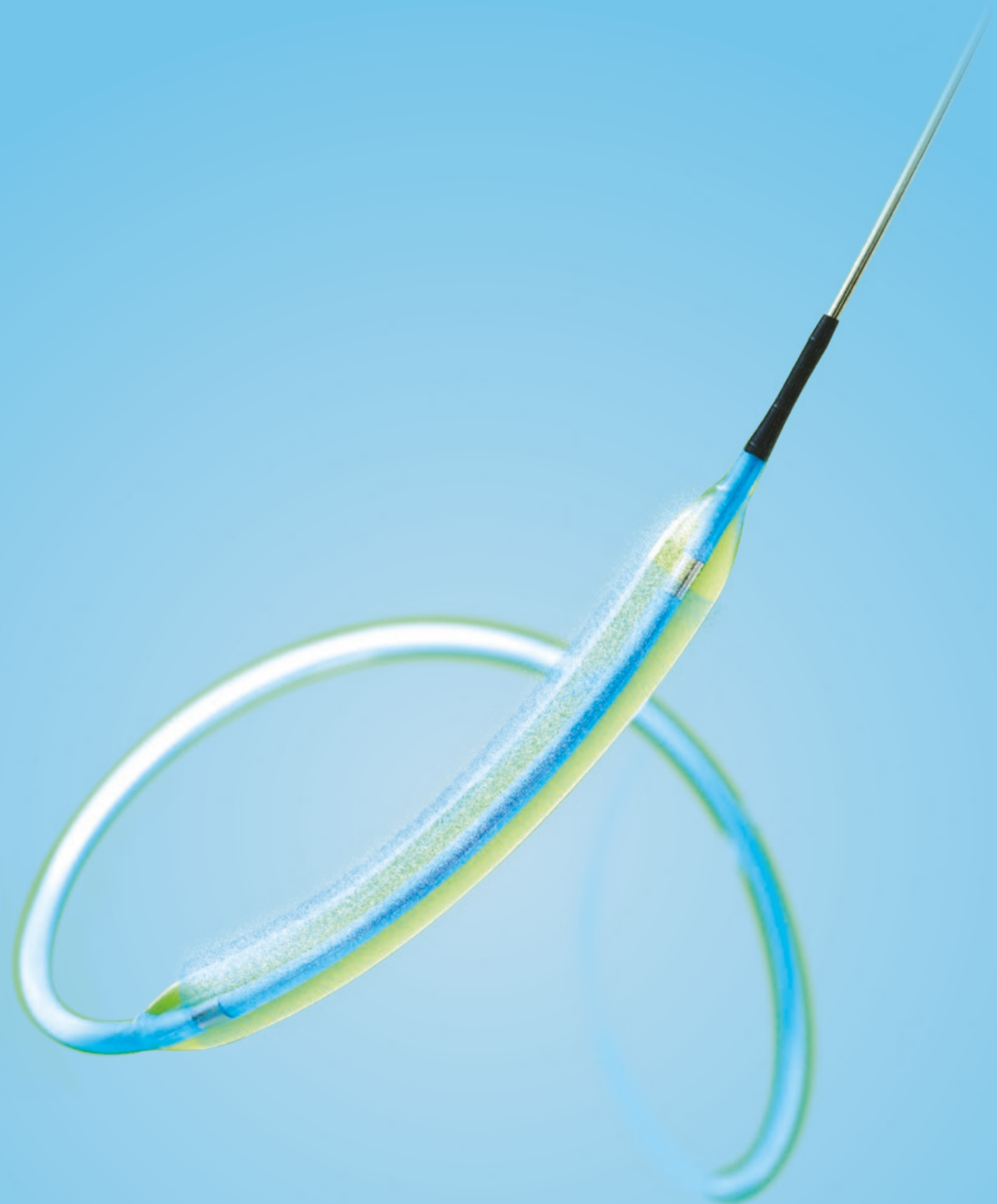
PRESSURE KPA(ATM)	BALLOON DIAMETER (MM)										
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
811 (8)	1.98	2.17	2.45	2.70	2.97	3.09	3.36	3.62	3.87	4.27	4.75
912 (9)	2.00	2.20	2.49	2.74	3.01	3.15	3.42	3.68	3.93	4.34	4.84
1013 (10)	2.02	2.23	2.51	2.77	3.04	3.18	3.45	3.72	3.97	4.39	4.91
1115 (11)	2.03	2.24	2.53	2.80	3.07	3.22	3.49	3.76	4.01	4.44	4.97
1216 (12)	2.05	2.26	2.55	2.82	3.10	3.25	3.52	3.79	4.05	4.48	5.01
1317 (13)	2.07	2.28	2.57	2.84	3.13	3.28	3.55	3.82	4.08	4.51	5.06
1419 (14)	2.08	2.30	2.58	2.87	3.15	3.31	3.58	3.85	4.11	4.55	5.10
1520 (15)	2.10	2.32	2.60	2.89	3.18	3.33	3.61	3.88	4.15	4.58	5.14
1621 (16)	2.12	2.33	2.62	2.91	3.20	3.36	3.63	3.90	4.18	4.61	5.18
1723 (17)	2.13	2.36	2.63	2.93	3.23	3.39	3.65	3.93	4.22	4.65	5.22
1824 (18)	2.15	2.38	2.65	2.95	3.26	3.41	3.68	3.96	4.25	4.68	5.26
1925 (19)	2.17	2.40	2.66	2.98	3.29	3.44	3.71	3.99	4.29	4.72	5.30
2026 (20)	2.19	2.42	2.68	3.00	—	3.47	3.73	4.02	—	4.76	—
2128 (21)	2.21	2.44	2.70	3.03	—	3.50	3.77	4.05	—	4.80	—
2229 (22)	2.23	2.46	2.72	3.05	—	3.53	—	4.08	—	4.84	—

Nominal pressure¹	Rated burst pressure²
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1. Nominal pressure: the pressure at which the balloon approximates its labeled diameter
2. Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated – do not exceed.

TECHNICAL INFORMATION

Catheter length	142 cm
Gold-swaged marker bands 2.00 - 5.00mm	Double
Coating	Selective Dura-Trac
Balloon material	Soft Fulcrum Plus
MiniWrap 2.00mm - 3.75mm 4.00mm - 5.00mm	3 folds 5 folds
Shaft dimensions for 2.00 - 3.75mm Proximal Distal	0.65 mm (1.9F) 0.81 mm/0.86 mm (2.4F/2.6F)
Shaft dimensions for 4.00 - 5.00mm Proximal Distal	0.65 mm (1.9F) 1.02 mm (3.0F)
MGCID 2.00mm - 4.00mm 4.50mm - 5.00mm	1.42 mm/.056" 1.68 mm/.066"



DRUG ELUTING BALLOONS

CONTENTS	1. DRUG-ELUTING STENTS	2. DRUG-METAL STENTS	3. BALLOON DILATION CATHETERS	4. DRUG-ELUTING BALLOONS	5. GUIDE CATHETER FAMILY	6. INTERVENTIONAL GUIDEWIRES	7. ASPIRATION CATHETERS	8. ANGIOGRAPHIC CATHETERS AND WIRES	9. INTRODUCERS	10. INTERVENTIONAL ACCESSORIES	11. PEDIATRIC AND TRANSCATHETER PRODUCTS	12. RENAL DENERVATION
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DRUG ELUTING BALLOONS

In.Pact Falcon™ Paclitaxel-Eluting Coronary Balloon Catheter

GENERAL CHARACTERISTICS

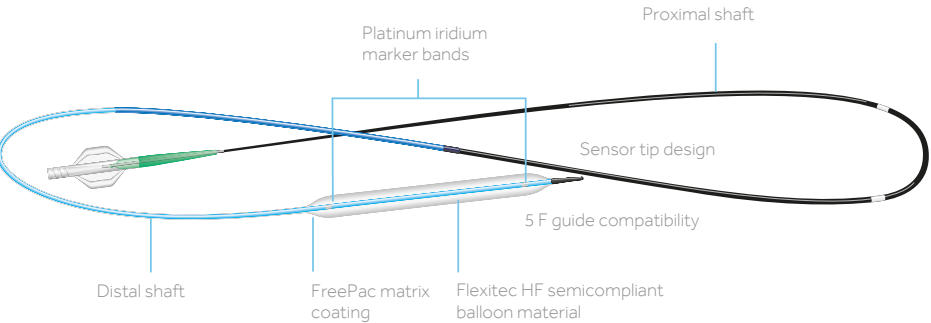
▪ Supplied sterile; items per box: 1

PRODUCT DESCRIPTION

The balloon's unique FreePac coating combines urea and paclitaxel molecules into a compound that provides increased drug solubility and optimal diffusion into the vessel wall, short-term drug delivery and continued antirestenotic protection.

FEATURES

- Paclitaxel drug
- Urea drug carrier
- Falcon™ Bravo semi-compliant balloon



PRODUCT CODE

FLC P20 014 B12

Product code | Diameter | Length | Semi-compliant construction

ORDERING INFORMATION

BALLOON DIAMETER (MM)	BALLOON LENGTH (MM)			
	14	20	30	40
2.00	FLC P20 014 B12	FLC P20 020 B12	FLC P20 030 B12	—
2.25	FLC P22 014 B12	FLC P22 020 B12	FLC P22 030 B12	—
2.50	FLC P25 014 B12	FLC P25 020 B12	FLC P25 030 B12	FLC P25 040 B12
2.75	FLC P27 014 B12	FLC P27 020 B12	FLC P27 030 B12	—
3.00	FLC P30 014 B12	FLC P30 020 B12	FLC P30 030 B12	FLC P30 040 B12
3.25	FLC P32 014 B12	FLC P32 020 B12	FLC P32 030 B12	—
3.50	FLC P35 014 B12	FLC P35 020 B12	FLC P35 030 B12	FLC P35 040 B12
3.75	FLC P37 014 B12	FLC P37 020 B12	FLC P37 030 B12	—
4.00	FLC P40 014 B12	FLC P40 020 B12	—	—

DRUG ELUTING BALLOONS

In.Pact Falcon™ Paclitaxel-Eluting Coronary Balloon Catheter

COMPLIANCE DATA

PRESSURE KPA (ATM)	BALLOON LENGTH (MM)								
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
507 (5)	1.90	2.15	2.40	2.65	2.90	3.15	3.40	3.65	3.90
608 (6)	1.95	2.20	2.45	2.70	2.95	3.20	3.45	3.70	3.95
709 (7)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.35
811 (8)	2.02	2.27	2.52	2.78	3.03	3.28	3.54	3.80	4.05
912 (9)	2.04	2.29	2.54	2.82	3.07	3.32	3.58	3.85	4.10
1013 (10)	2.06	2.31	2.57	2.86	3.11	3.36	3.62	3.90	4.15
1115 (11)	2.08	2.34	2.60	2.90	3.15	3.40	3.66	3.95	4.20
1216 (12)	2.11	2.37	2.63	2.94	3.19	3.45	3.70	4.00	4.25
1317 (13)	2.14	2.40	2.67	2.98	3.23	3.50	3.75	4.05	4.30
1419 (14)	2.17	2.43	2.71	3.02	3.27	3.55	3.80	4.10	4.35
1520 (15)	2.20	2.46	2.75	3.06	3.31	3.60	3.85	4.15	4.40
1621 (16)	2.23	2.50	2.80	—	—	—	—	—	—
1723 (17)	2.26	—	—	—	—	—	—	—	—

Nominal pressure	Rated burst pressure ¹	
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1. Do not exceed rated burst pressure.
Test data on file at Medtronic, Inc.

TECHNICAL INFORMATION

Catheter length, cm	142	
Platinum iridium marker bands 2.00 – 4.00 mm	Double	
Coating	FreePac matrix	
Balloon material	Flexitec HF	
Guide compatibility	5F	
Nominal pressure, atm	7	
Rated burst pressure (RBP), atm	2.00 mm	17
	2.25 - 2.50 mm	16
	2.75 - 4.00 mm	15



GUIDE CATHETERS

CONTENTS	1. DRUG-ELUTING STENTS	2. DRUG-METAL STENTS	3. BALLOON DILATION CATHETERS	4. DRUG-ELUTING BALLOONS	5. GUIDE CATHETER FAMILY	6. INTERVENTIONAL GUIDEWIRES	7. ASPIRATION CATHETERS	8. ANGIOGRAPHIC CATHETERS AND WIRES	9. INTRODUCERS	10. INTERVENTIONAL ACCESSORIES	11. PEDIATRIC AND TRANSCATHETER PRODUCTS	12. RENAL DENERVATION
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CORONARY GUIDE CATHETER FAMILY

LAUNCHER™

- Balanced guide for stable and consistent performance
- Workhorse construction suitable for a variety of anatomies and takeoffs
- Flexible distal segment for manipulation if case requires
- Large 6F I.D. (0.071"). allows for increased contrast flow for enhanced visualization
- Multiple guide catheter platforms provide options for guide engagement



SHERPA NX™ ACTIVE

- Soft distal segment for active engagement with soft tip and advanced material liner for consistent low-friction device passage
- Distal segment allows for manipulation of the catheter to obtain stable position
- Distal segment can reshape in anatomy
- Large I.D. allows for enhanced contrast flow and better visualization



SHERPA NX™ BALANCED

- Balanced guide for stable consistent performance with soft tip and advanced HDPE liner for smooth, low-friction device passage
- Workhorse construction suitable for a variety of anatomies and takeoffs
- Flexible distal segment for manipulation if case requires
- Supportive secondary curve for increased backup support and curve retention
- Large ID for maximum contrast flow and absolute visualization



CORONARY GUIDE CATHETER FAMILY

ZUMA 2™

- Soft, flexible distal segment for atraumatic engagement
- Soft tip polymer construction to minimize vessel trauma



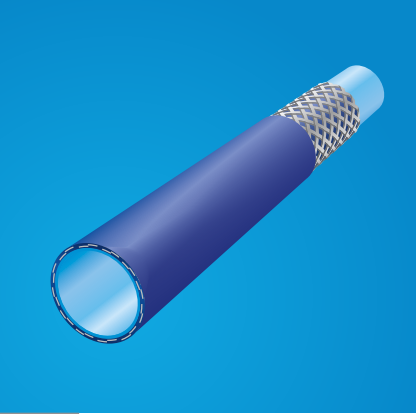
ZUMA™

- Supportive stiff guide for passive use
- Available sizes: 6F - 9F



UNIQUE FULL WALL TECHNOLOGY

- Encapsulated flat wire braid enables thinner, robust walls without compromising support or retention
- Designed for large lumens and enhanced flexibility without loss of support



1. SH available on all curves. 2. Custom built curves also available.
The curve recommendations on this sheet are not intended to replace patient specific clinical judgement.
Caution: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner.

CORONARY GUIDE CATHETER FAMILY

Curve Selection Femoral approach

COMMON ANATOMIES

Three Types of Ostial Takeoffs (Can occur in right or left arteries)



Three Types of Aortic Roots

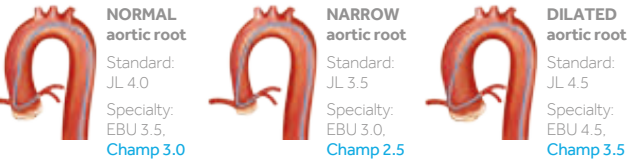


LEFT CURVES

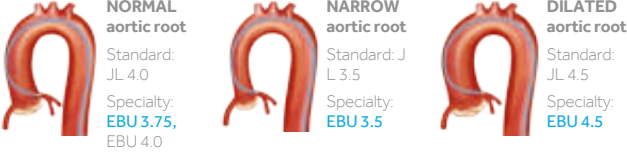
Normal Left Takeoffs



Superior Left Takeoffs



Inferior Left Takeoffs



Normal Takeoffs and Short Left Mains

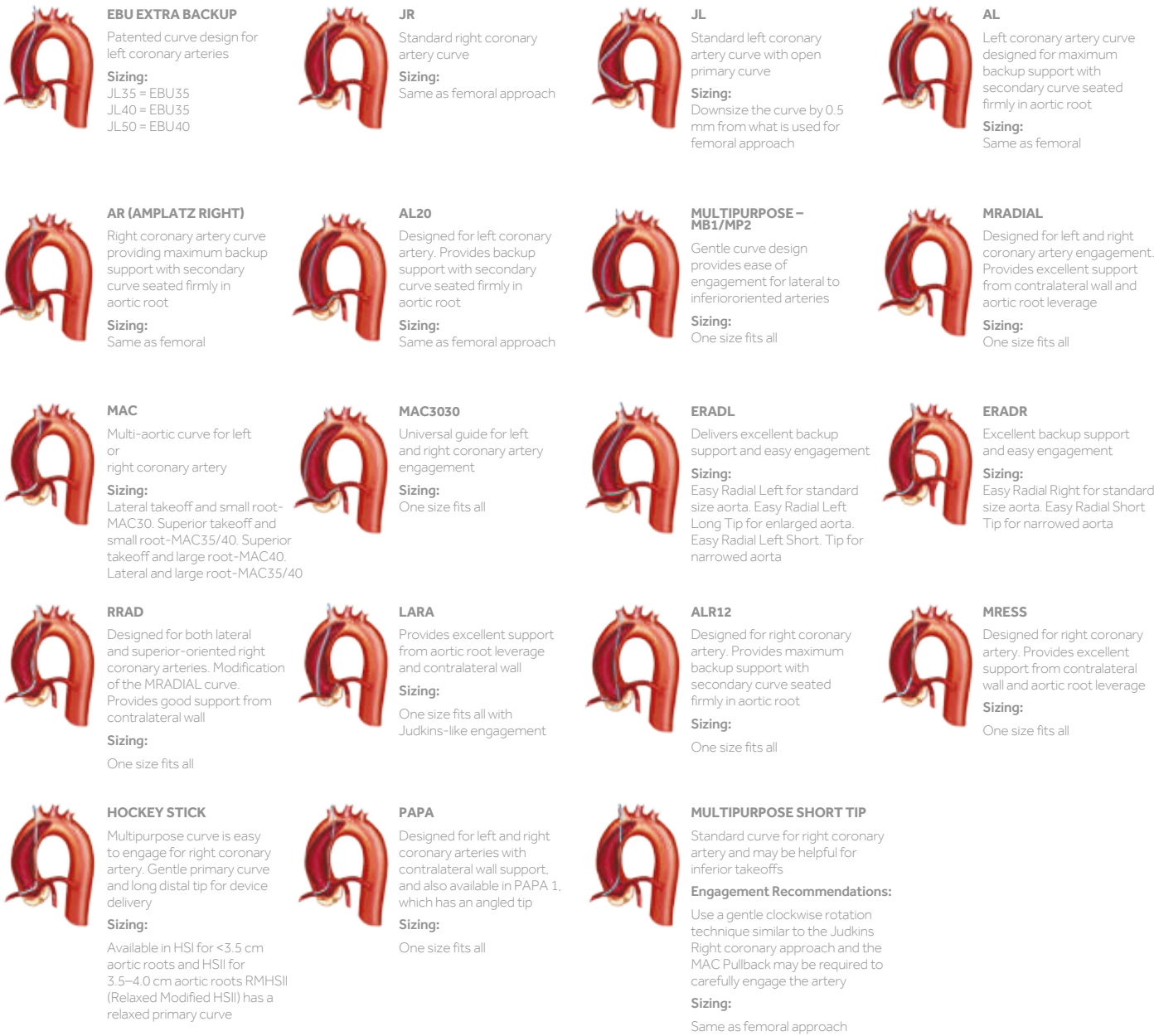


BYPASS GRAFTS



CORONARY GUIDE CATHETER FAMILY

Curve Selection Transradial approach



CURVE ABBREVIATION KEY

ERAD = Easy Radial
EBU = Extra Backup
HS = Hockey Stick
LCB = Left Coronary Bypass
MAC = Multi-aortic Curve
NOTO = No Torque Right
RBU = Right Backup
RCB = Right Coronary Bypass
RMHS = Relaxed Modified Hockey Stick
SAL = Short Amplatz Left
SL = Short Left
NOTE: Curves in **BLUE** text indicate type of curve used in illustration.

Note: SH available on all curves

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Left Coronary Curve

GENERAL CHARACTERISTICS

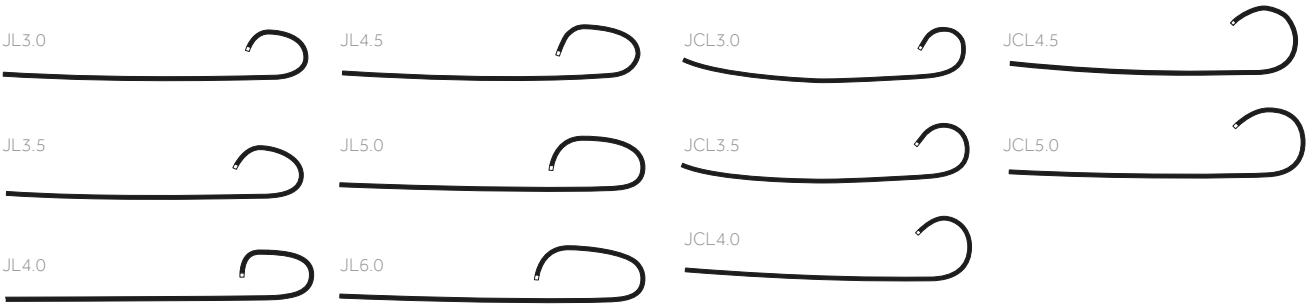
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID allows for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



LEFT STANDARD

PRODUCT CODE	5F	6F	7F	8F
	I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
JL3.0	LA5JL30	LA6JL30	LA7JL30	LA8JL30
JL3.5	LA5JL35	LA6JL35	LA7JL35	LA8JL35
JL4.0	LA5JL40	LA6JL40	LA7JL40	LA8JL40
JL4.5	LA5JL45	LA6JL45	LA7JL45	LA8JL45
JL5.0	LA5JL50	LA6JL50	LA7JL50	LA8JL50
JL6.0	LA5JL60	LA6JL60	LA7JL60	LA8JL60
JCL3.0	LA5JCL30	LA6JCL30	LA7JCL30	LA8JCL30
JCL3.5	LA5JCL35	LA6JCL35	LA7JCL35	LA8JCL35
JCL4.0	LA5JCL40	LA6JCL40	LA7JCL40	LA8JCL40
JCL4.5	LA5JCL45	LA6JCL45	LA7JCL45	LA8JCL45
JCL5.0	LA5JCL50	LA6JCL50	LA7JCL50	LA8JCL50

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Short Left Coronary Curve

GENERAL CHARACTERISTICS

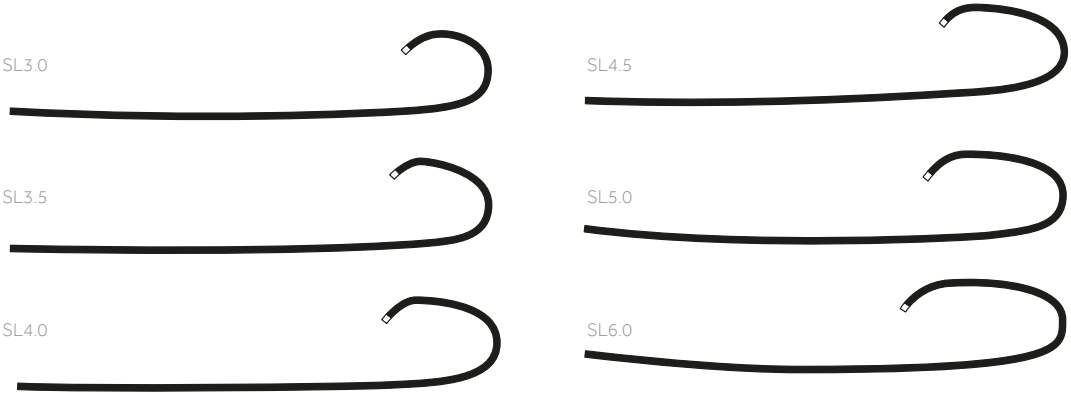
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



SHORT LEFT

PRODUCT CODE	5F	6F	7F	8F
	(I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
SL3.0	LA5SL30	LA6SL30	LA7SL30	LA8SL30
SL3.5	LA5SL35	LA6SL35	LA7SL35	LA8SL35
SL4.0	LA5SL40	LA6SL40	LA7SL40	LA8SL40
SL4.5	LA5SL45	LA6SL45	LA7SL45	LA8SL45
SL5.0	LA5SL50	LA6SL50	LA7SL50	LA8SL50
SL6.0	LA5SL60	LA6SL60	LA7SL60	LA8SL60

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Amplatz Left Coronary Curve

GENERAL CHARACTERISTICS

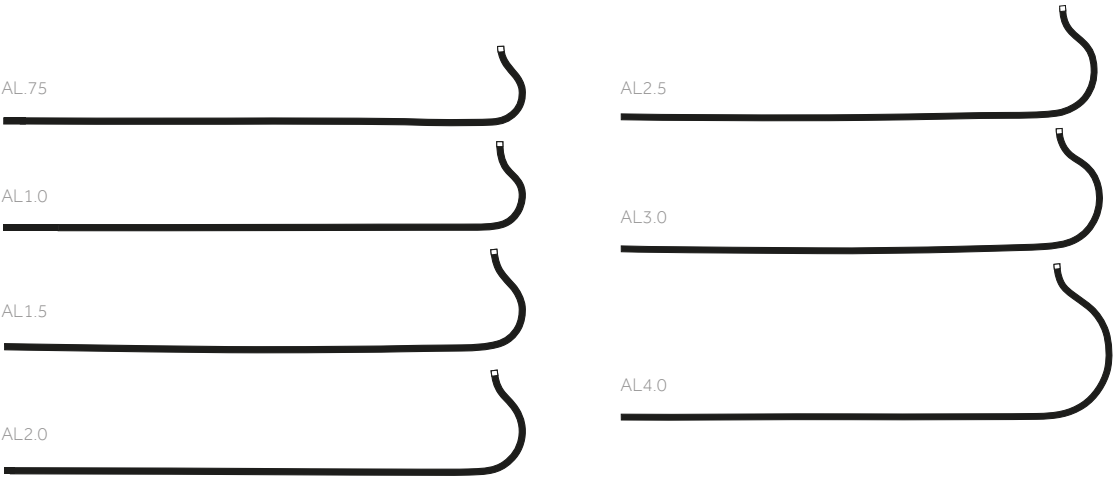
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID allows for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



AMPLATZ LEFT

PRODUCT CODE	5F I.D. 0.058 IN.)	6F (I.D. 0.071 IN.)	7F (I.D. 0.081 IN.)	8F (I.D. 0.090 IN.)
AL75	LA5AL75	LA6AL75	LA7AL75	LA8AL75
AL1.0	LA5AL10	LA6AL10	LA7AL10	LA8AL10
AL1.5	LA5AL15	LA6AL15	LA7AL15	LA8AL15
AL2.0	LA5AL20	LA6AL20	LA7AL20	LA8AL20
AL2.5	LA5AL25	LA6AL25	LA7AL25	LA8AL25
AL3.0	LA5AL30	LA6AL30	LA7AL30	LA8AL30
AL4.0	LA5AL40	LA6AL40	LA7AL40	LA8AL40

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Short Amplatz Left Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



SHORT AMPLATZ LEFT

PRODUCT CODE	5F (I.D. 0.058 IN.)	6F (I.D. 0.071 IN.)	7F (I.D. 0.081 IN.)	8F (I.D. 0.090 IN.)
SAL75	LA5SAL75	LA6SAL75	LA7SAL75	LA8SAL75
SAL1.0	LA5SAL10	LA6SAL10	LA7SAL10	LA8SAL10
SAL1.5	LA5SAL15	LA6SAL15	LA7SAL15	LA8SAL15
SAL2.0	LA5SAL20	LA6SAL20	LA7SAL20	LA8SAL20
SAL2.5	LA5SAL25	LA6SAL25	LA7SAL25	LA8SAL25
SAL3.0	LA5SAL30	LA6SAL30	LA7SAL30	LA8SAL30
SAL4.0	LA5SAL40	LA6SAL40	LA7SAL40	LA8SAL40

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Left Coronary Backup Support

GENERAL CHARACTERISTICS

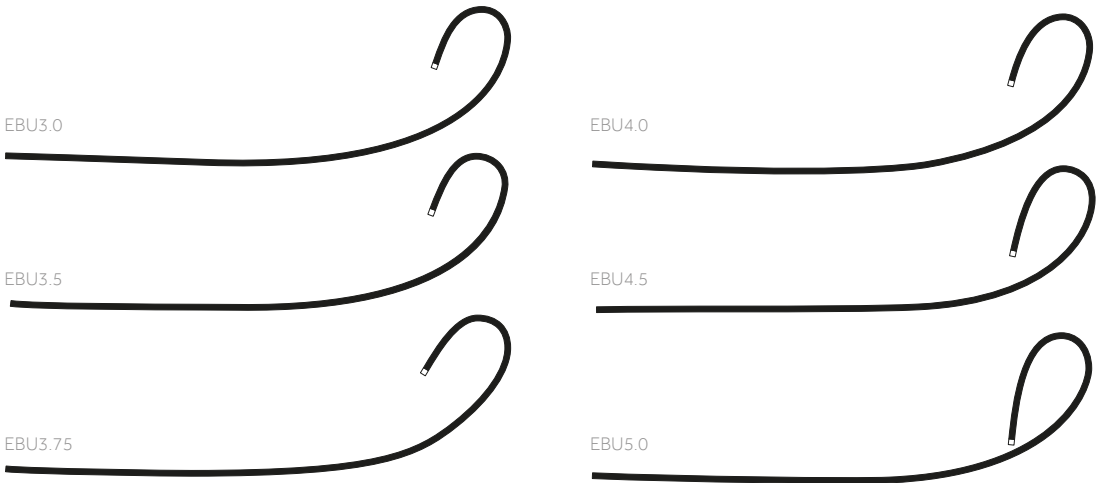
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



EBU (EXTRA BACKUP)	PRODUCT CODE	5F	6F	7F	8F
		I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
	EBU3.0	LA5EBU30	LA6EBU30	LA7EBU30	LA8EBU30
	EBU3.5	LA5EBU35	LA6EBU35	LA7EBU35	LA8EBU35
	EBU3.75	LA5EBU375	LA6EBU375	LA7EBU375	LA8EBU375
	EBU4.0	LA5EBU40	LA6EBU40	LA7EBU40	LA8EBU40
	EBU4.5	LA5EBU45	LA6EBU45	LA7EBU45	LA8EBU45
	EBU5.0	LA5EBU50	LA6EBU50	LA7EBU50	LA8EBU50

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Right Coronary Curve

GENERAL CHARACTERISTICS

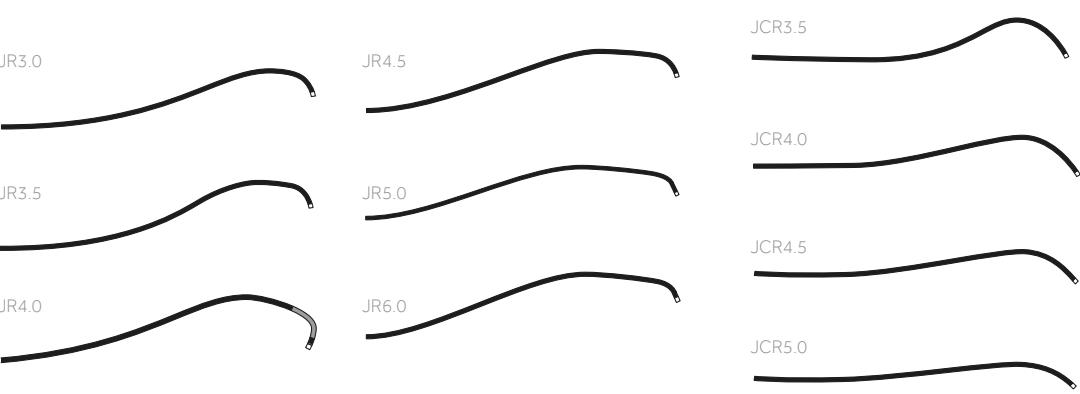
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



RIGHT STANDARD	PRODUCT CODE	5F	6F	7F	8F
		(I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
	JR3.0	LA5JR30	LA6JR30	LA7JR30	LA8JR30
	JR3.5	LA5JR35	LA6JR35	LA7JR35	LA8JR35
	JR4.0	LA5JR40	LA6JR40	LA7JR40	LA8JR40
	JR4.5	LA5JR45	LA6JR45	LA7JR45	LA8JR45
	JR5.0	LA5JR50	LA6JR50	LA7JR50	LA8JR50
	JR6.0	LA5JR60	LA6JR60	LA7JR60	LA8JR60
	JCR3.5	LA5JCR35	LA6JCR35	LA7JCR35	LA8JCR35
	JCR4.0	LA5JCR40	LA6JCR40	LA7JCR40	LA8JCR40
	JCR4.5	LA5JCR45	LA6JCR45	LA7JCR45	LA8JCR45
	JCR5.0	LA5JCR50	LA6JCR50	LA7JCR50	LA8JCR50

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Short Right Coronary Curve

GENERAL CHARACTERISTICS

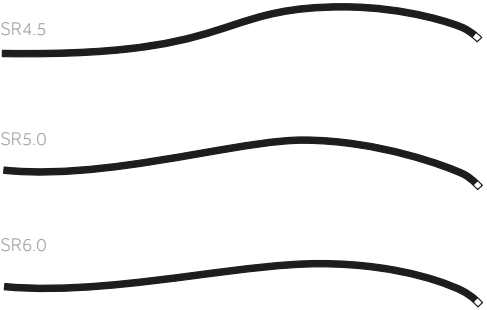
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID allows for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



SHORT RIGHT

PRODUCT CODE	5F I.D. 0.058 IN.)	6F I.D. 0.071 IN.)	7F I.D. 0.081 IN.)	8F I.D. 0.090 IN.)
SR3.0	LA5SR30	LA6SR30	LA7SR30	LA8SR30
SR3.5	LA5SR35	LA6SR35	LA7SR35	LA8SR35
SR4.0	LA5SR40	LA6SR40	LA7SR40	LA8SR40
SR4.5	LA5SR45	LA6SR45	LA7SR45	LA8SR45
SR5.0	LA5SR50	LA6SR50	LA7SR50	LA8SR50
SR6.0	LA5SR60	LA6SR60	LA7SR60	LA8SR60

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Amplatz Right Coronary Curve

GENERAL CHARACTERISTICS

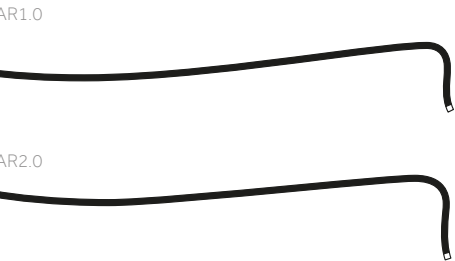
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID allows for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



AMPLATZ RIGHT

PRODUCT CODE	5F I.D. 0.058 IN.)	6F I.D. 0.071 IN.)	7F I.D. 0.081 IN.)	8F I.D. 0.090 IN.)
AR1.0	LA5AR10	LA6AR10	LA7AR10	LA8AR10
AR2.0	LA5AR20	LA6AR20	LA7AR20	LA8AR20
ALR1-2	LA5ALR12	LA6ALR12	LA7ALR12	LA8ALR12

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Short Amplatz Right Coronary Curve

GENERAL CHARACTERISTICS	▪ Supplied sterile Items per box: 1 ▪ Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue ▪ Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"
PRODUCT DESCRIPTION	Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.
FEATURES	▪ Custom lengths and custom curve program available ▪ Over 230 specialty curves available ▪ SH available on all curves

SAR1.0



SAR2.0



SHORT AMPLATZ RIGHT

PRODUCT CODE	5F	6F	7F	8F
	I.D. 0.058 IN.)	I.D. 0.071 IN.)	I.D. 0.081 IN.)	I.D. 0.090 IN.)
SAR1.0	LA5SAR10	LA6SAR10	LA7SAR10	LA8SAR10
SAR2.0	LA5SAR20	LA6SAR20	LA7SAR20	LA8SAR20

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Shepherd's Crook Coronary Curve

GENERAL CHARACTERISTICS	▪ Supplied sterile Items per box: 1 ▪ Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue ▪ Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"
PRODUCT DESCRIPTION	Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.
FEATURES	▪ Custom lengths and custom curve program available ▪ Over 230 specialty curves available ▪ SH available on all curves

SCR3.5



SCR4.0



SCR5.0



SHEPHERD'S CROOK RIGHT

PRODUCT CODE	5F	6F	7F	8F
	I.D. 0.058 IN.)	I.D. 0.071 IN.)	I.D. 0.081 IN.)	I.D. 0.090 IN.)
SCR3.5	LA5SCR35	LA6SCR35	LA7SCR35	LA8SCR35
SCR4.0	LA5SCR40	LA6SCR40	LA7SCR40	LA8SCR40
SCR5.0	LA5SCR50	LA6SCR50	LA7SCR50	LA8SCR50

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Right Coronary Backup Support

GENERAL CHARACTERISTICS

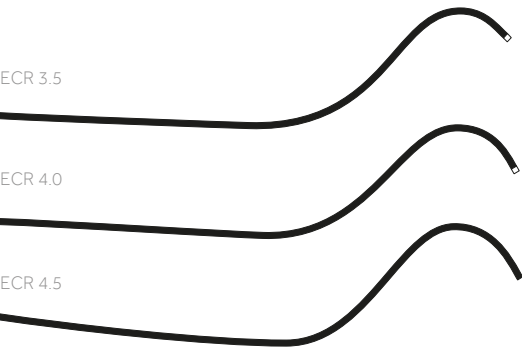
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



ECR CURVES

PRODUCT CODE	5F	6F	7F	8F
	I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
ECR 3.5	LA5ECR35	LA6ECR35	LA7ECR35	LA8ECR35
ECR 4.0	LA5ECR40	LA6ECR40	LA7ECR40	LA8ECR40
ECR 4.5	LA5ECR45	LA6ECR45	LA7ECR45	LA8ECR45

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Right Coronary Backup Support

GENERAL CHARACTERISTICS

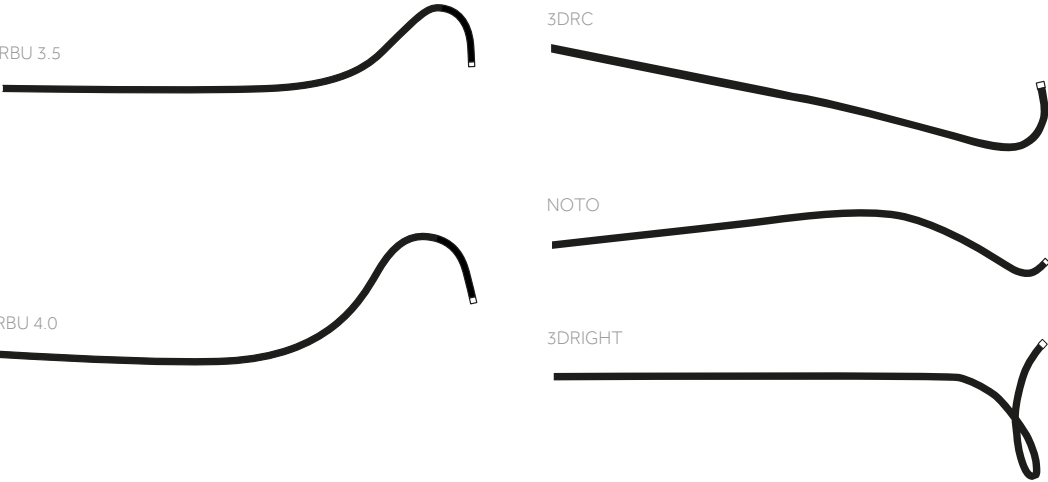
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



RBU CURVES

PRODUCT CODE	5F	6F	7F	8F
	(I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
RBU 3.5	LA5RBU35	LA6RBU35	LA7RBU35	LA8RBU35
RBU 4.0	LA5RBU40	LA6RBU40	LA7RBU40	LA8RBU40
3DRC		LA63DRC	LA73DRC	LA83DRC
3DRIGHT	LA53DRIGHT	LA63DRIGHT	LA73DRIGHT	
NOTO	LA5NOTO	LA6NOTO	LA7NOTO	LA8NOTO

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Multipurpose Curves

GENERAL CHARACTERISTICS

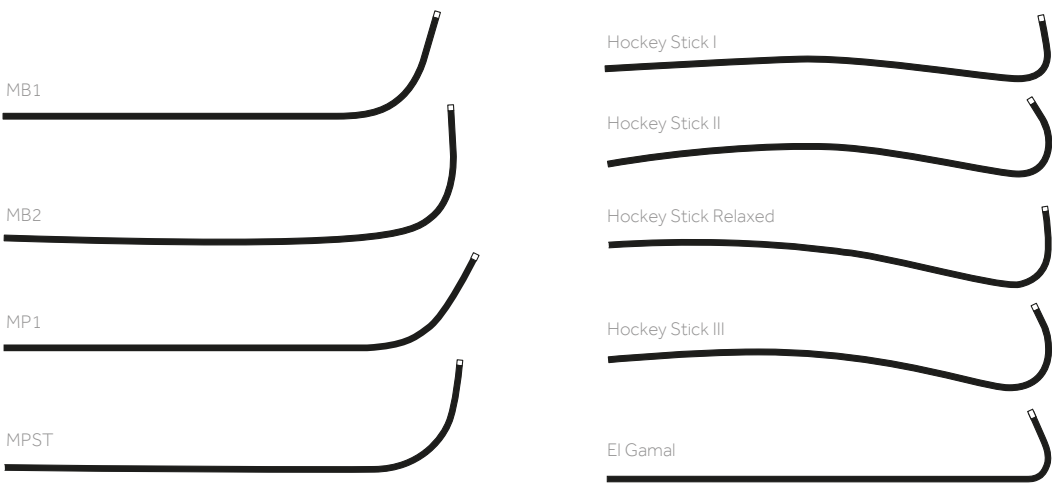
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



MULTIPURPOSE	PRODUCT CODE	5F	6F	7F	8F
		I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
	MB1	LA5MB1	LA6MB1	LA7MB1	LA8MB1
	MB2	LA5MB2	LA6MB2	LA7MB2	LA8MB2
	MP1	LA5MP1	LA6MP1	LA7MP1	LA8MP1
	MP2		LA6MP2		
	MB Short Tip	LA5MPST	LA6MPST	LA7MPST	LA8MPST
	Hockey Stick I	LA5HSI	LA6HSI	LA7HSI	LA8HSI
	Hockey Stick II	LA5HSII	LA6HSII	LA7HSII	LA8HSII
	HS II Relaxed	LA5HSREL	LA6RMHSII	LA7RMHSII	LA8RMHSII
	Hockey Stick III	LA5HSIII	LA6HSIII	LA7HSIII	LA8HSIII
	El Gamal	LA5ELGAMAL	LA6ELGAMAL	LA7ELGAMAL	LA8ELGAMAL

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Other Curves

GENERAL CHARACTERISTICS

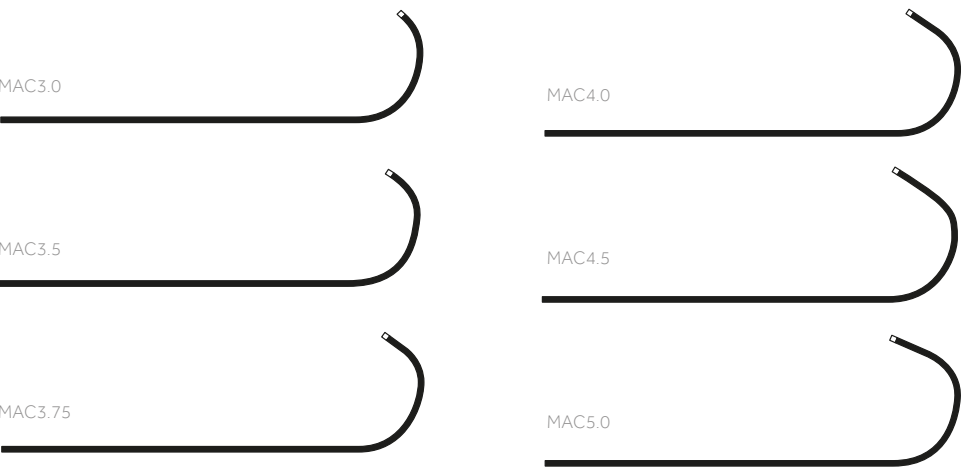
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



MAC (MULTI-AORTIC CURVES)	PRODUCT CODE	5F	6F	7F	8F
		(I.D. 0.058 IN.)	(I.D. 0.071 IN.)	(I.D. 0.081 IN.)	(I.D. 0.090 IN.)
	MAC3.0	LA5MAC30	LA6MAC30	LA7MAC30	LA8MAC30
	MAC3.5	LA5MAC35	LA6MAC35	LA7MAC35	LA8MAC35
	MAC3.75	LA5MAC375	LA6MAC375	LA7MAC375	LA8MAC375
	MAC4.0	LA5MAC40	LA6MAC40	LA7MAC40	LA8MAC40
	MAC4.5	LA5MAC45	LA6MAC45	LA7MAC45	LA8MAC45
	MAC5.0	LA5MAC50	LA6MAC50	LA7MAC50	LA8MAC50

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Bypass Curves

GENERAL CHARACTERISTICS

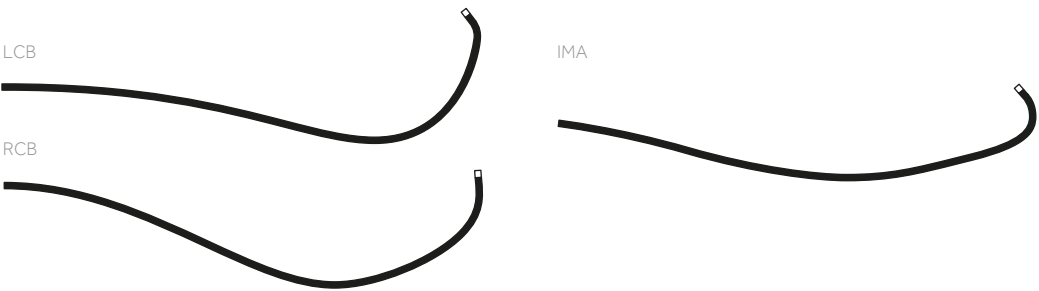
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



BYPASS GRAFTS

PRODUCT CODE	5F I.D. 0.058 IN.)	6F (I.D. 0.071 IN.)	7F (I.D. 0.081 IN.)	8F (I.D. 0.090 IN.)
LCB	LA5LCB	LA6LCB	LA7LCB	LA8LCB
LCB Relaxed	-	LA6RELAXLCB	-	-
RCB	LA5RCB	LA6RCB	LA7RCB	LA8RCB
RCB (90 cm)	LA5RCBD	LA6RCBD	LA7RCBD	LA8RCBD
IMA	LA5IMA	LA6IMA	LA7IMA	LA8IMA
IMA (90 cm)	LA5IMAD	LA6IMAD	LA7IMAD	LA8IMAD

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Other Curves

GENERAL CHARACTERISTICS

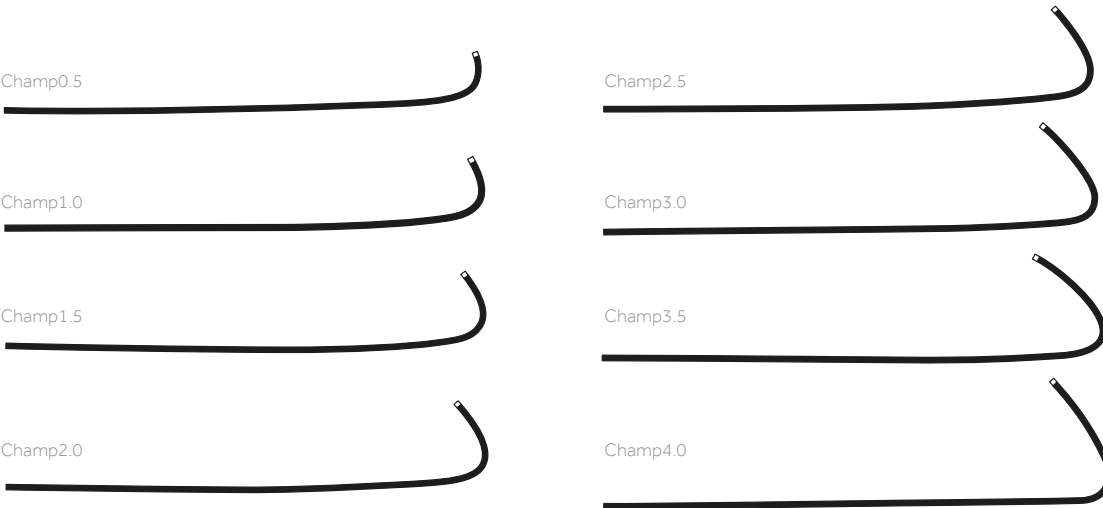
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



CHAMP

PRODUCT CODE	5F (I.D. 0.058 IN.)	6F (I.D. 0.071 IN.)	7F (I.D. 0.081 IN.)	8F (I.D. 0.090 IN.)
CHAMP 0.5	LA5CHAMP05	LA6CHAMP05	LA7CHAMP05	LA8CHAMP05
CHAMP 10	LA5CHAMP10	LA6CHAMP10	LA7CHAMP10	LA8CHAMP10
CHAMP 15	LA5CHAMP15	LA6CHAMP15	LA7CHAMP15	LA8CHAMP15
CHAMP 20	LA5CHAMP20	LA6CHAMP20	LA7CHAMP20	LA8CHAMP20
CHAMP 25	LA5CHAMP25	LA6CHAMP25	LA7CHAMP25	LA8CHAMP25
CHAMP 30	LA5CHAMP30	LA6CHAMP30	LA7CHAMP30	LA8CHAMP30
CHAMP 35	LA5CHAMP35	LA6CHAMP35	LA7CHAMP35	LA8CHAMP35
CHAMP 40	LA5CHAMP40	LA6CHAMP40	LA7CHAMP40	LA8CHAMP40

CORONARY GUIDE CATHETERS

Launcher™ Guide Catheter Radial Curves

GENERAL CHARACTERISTICS

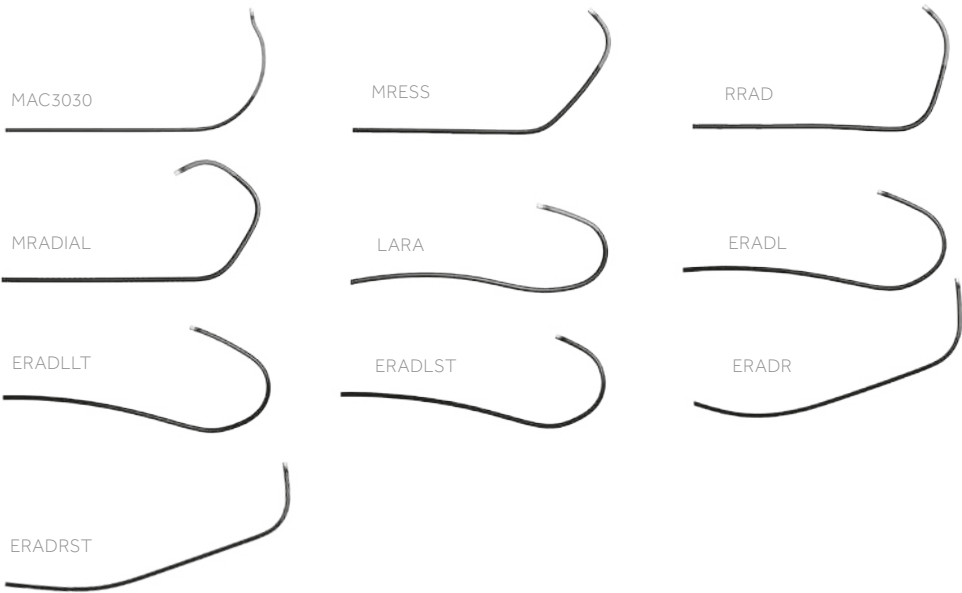
- Supplied sterile Items per box: 1
- Label colour: 5F: Grey, 6F: Green, 7F: Orange, 8F: Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.071", 7F = 0.081", 8F = 0.090"

PRODUCT DESCRIPTION

Full-Wall Technology construction provides kink resistance and stable torque control; large ID alloes for increased contrast flow for enhanced visualization. Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity.

FEATURES

- Custom lengths and custom curve program available
- Over 230 specialty curves available
- SH available on all curves



ADDITIONAL RADIAL CURVES

PRODUCT CODE	5F I.D. 0.058 IN.)	6F (I.D. 0.071 IN.)	7F (I.D. 0.081 IN.)	8F (I.D. 0.090 IN.)
MRADIAL	LA5MRADIAL	LA6MRADIAL	-	-
MRESS	LA5MRESS	LA6MRESS	-	-
RIGHT RADIAL	LA5RRAD	LA6RRAD	-	-
ERADL	LA5ERADL	LA6ERADL	-	-
ERADLLT	LA5ERADLLT	LA6ERADLLT	-	-
ERADLST	LA5ERADLST	LA6ERADLST	-	-
ERADR	LA5ERADR	LA6ERADR	-	-
ERADRST	LA5ERADRST	LA6ERADRST	-	-
LARA	LA5LARA	LA6LARA	-	-
MAC3030	LA5MAC3030	LA6MAC3030	-	-

CORONARY GUIDE CATHETERS

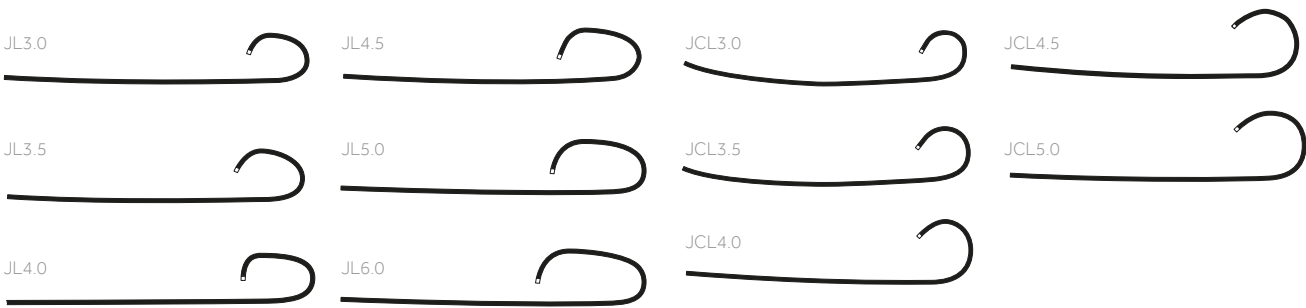
Sherpa NX™ Active Left Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



LEFT STANDARD

	5F ACTIVE CODE	6F ACTIVE CODE
JL3.0	SA5JL30	SA6JL30
JL3.5	SA5JL35	SA6JL35
JL4.0	SA5JL40	SA6JL40
JL4.5	SA5JL45	SA6JL45
JL5.0	SA5JL50	SA6JL50
JL6.0	SA5JL60	SA6JL60
JCL3.0	SA5JCL30	SA6JCL30
JCL3.5	SA5JCL35	SA6JCL35
JCL4.0	SA5JCL40	SA6JCL40
JCL4.5	SA5JCL45	SA6JCL45
JCL5.0	SA5JCL50	SA6JCL50

CORONARY GUIDE CATHETERS

Sherpa NX™ Active Short Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT LEFT

	5F ACTIVE CODE	6F ACTIVE CODE
SL3.0	SA5SL30	SA6SL30
SL3.5	SA5SL35	SA6SL35
SL4.0	SA5SL40	SA6SL40
SL4.5	SA5SL45	SA6SL45
SL5.0	SA5SL50	SA6SL50
SL6.0	SA5SL60	SA6SL60

CORONARY GUIDE CATHETERS

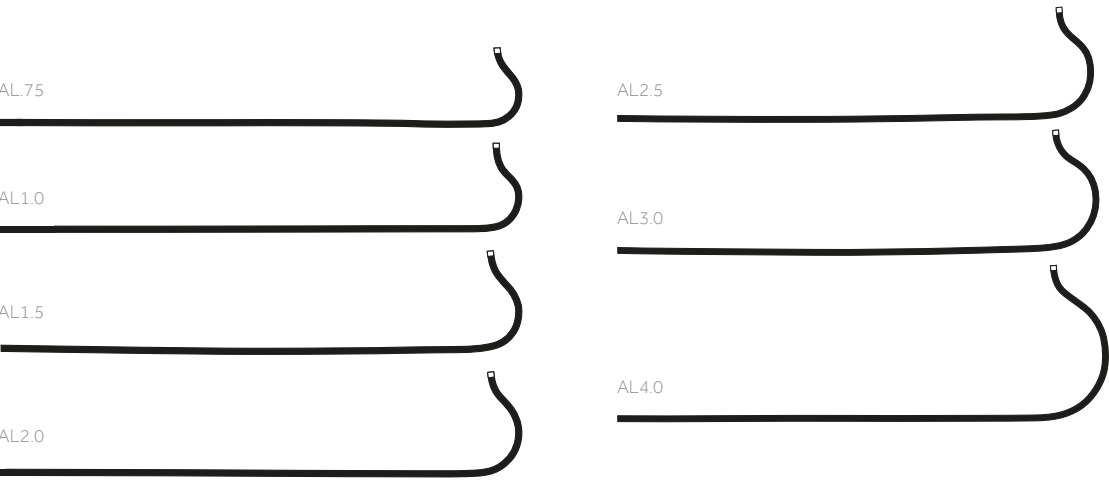
Sherpa NX™ Active Amplatz Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



AMPLATZ LEFT

	5F ACTIVE CODE	6F ACTIVE CODE
AL.75	SA5AL75	SA6AL75
AL1.0	SA5AL10	SA6AL10
AL1.5	SA5AL15	SA6AL15
AL2.0	SA5AL20	SA6AL20
AL2.5	SA5AL25	SA6AL25
AL3.0	SA5AL30	SA6AL30
AL4.0	SA5AL40	SA6AL40

CORONARY GUIDE CATHETERS

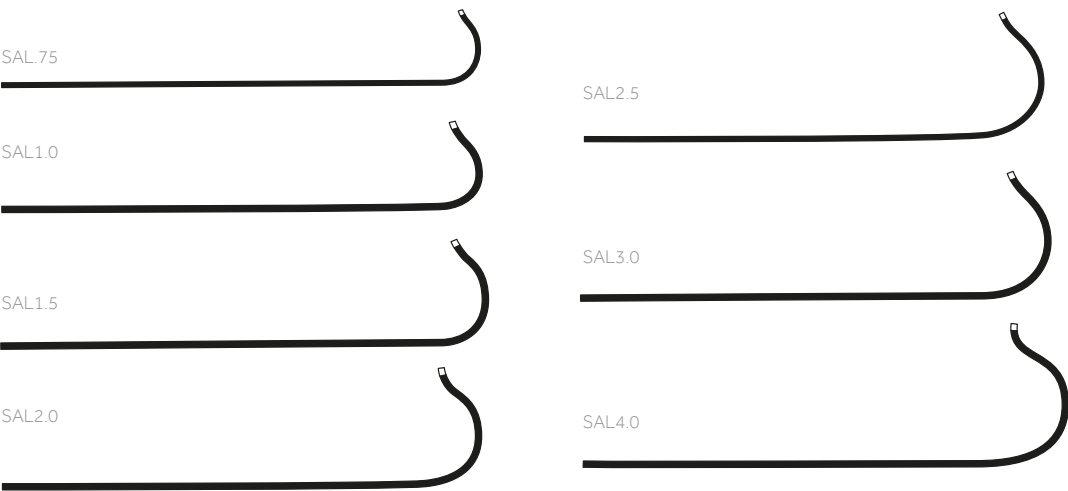
Sherpa NX™ Active Short Amplatz Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT AMPLATZ
LEFT

	5F ACTIVE CODE	6F ACTIVE CODE
SAL75	SA5SAL75	SA6SAL75
SAL1.0	SA5SAL10	SA6SAL10
SAL1.5	SA5SAL15	SA6SAL15
SAL2.0	SA5SAL20	SA6SAL20
SAL2.5	SA5SAL25	SA6SAL25
SAL3.0	SA5SAL30	SA6SAL30
SAL4.0	SA5SAL40	SA6SAL40

CORONARY GUIDE CATHETERS

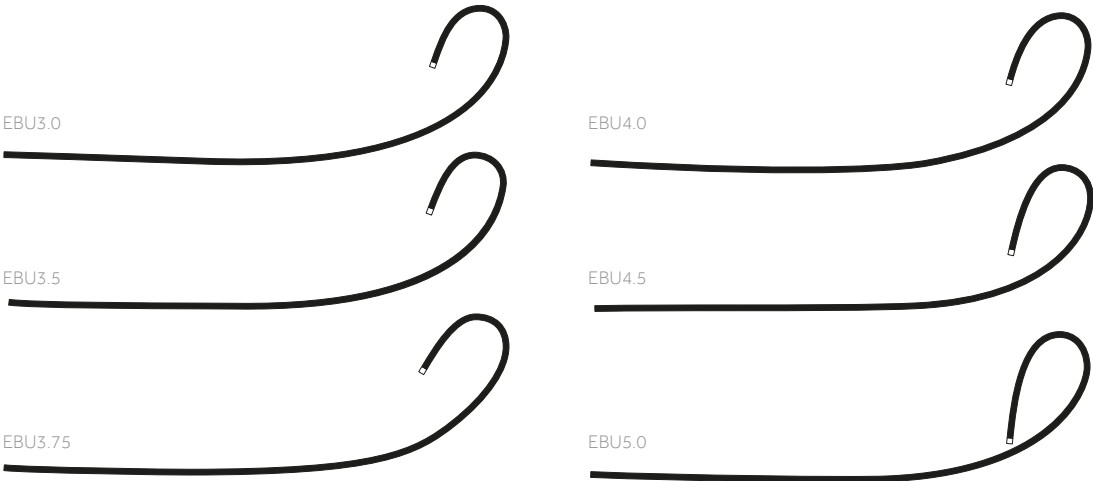
Sherpa NX™ Active Left Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



EBU
(EXTRA BACKUP)

	5F ACTIVE CODE	6F ACTIVE CODE
EBU3.0	SA5EBU30	SA6EBU30
EBU3.5	SA5EBU35	SA6EBU35
EBU3.75	SA5EBU375	SA6EBU375
EBU4.0	SA5EBU40	SA6EBU40
EBU4.5	SA5EBU45	SA6EBU45
EBU5.0	SA5EBU50	SA6EBU50

CORONARY GUIDE CATHETERS

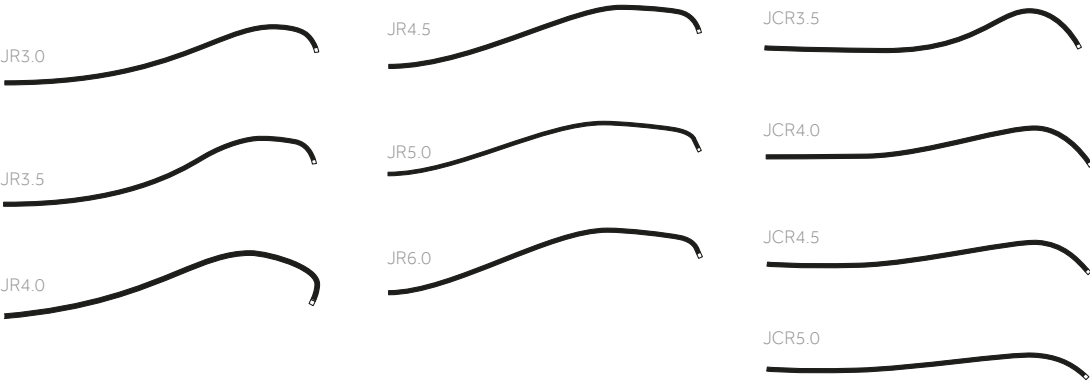
Sherpa NX™ Active Right Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



RIGHT STANDARD

	5F ACTIVE CODE	6F ACTIVE CODE
JR3.0	SA5JR30	SA6JR30
JR3.5	SA5JR35	SA6JR35
JR4.0	SA5JR40	SA6JR40
JR4.5	SA5JR45	SA6JR45
JR5.0	SA5JR50	SA6JR50
JR6.0	SA5JR60	SA6JR60
JCR3.5	SA5JCR35	SA6JCR35
JCR4.0	SA5JCR40	SA6JCR40
JCR4.5	SA5JCR45	SA6JCR45
JCR5.0	SA5JCR50	SA6JCR50

CORONARY GUIDE CATHETERS

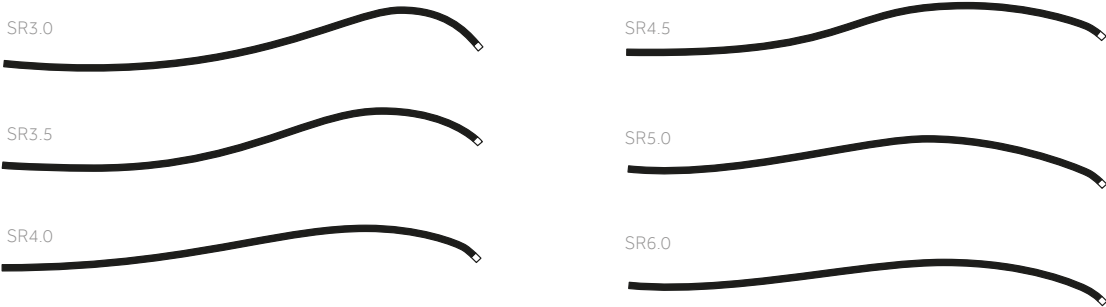
Sherpa NX™ Active Short Right Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT RIGHT

	5F ACTIVE CODE	6F ACTIVE CODE
SR3.0	SA5SR30	SA6SR30
SR3.5	SA5SR35	SA6SR35
SR4.0	SA5SR40	SA6SR40
SR4.5	SA5SR45	SA6SR45
SR5.0	SA5SR50	SA6SR50
SR6.0	SA5SR60	SA6SR60

CORONARY GUIDE CATHETERS

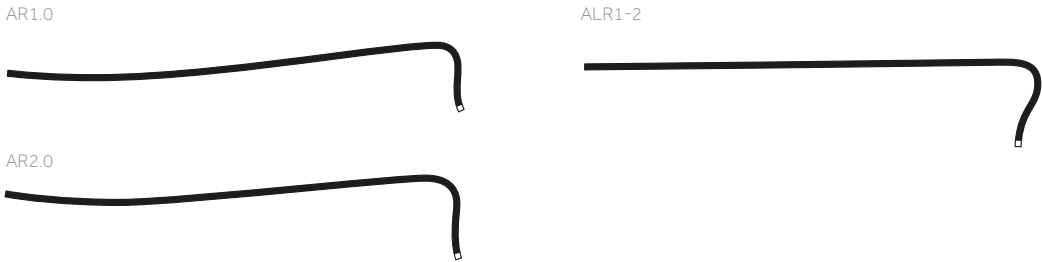
Sherpa NX™ Active
Amplatz Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



AMPLATZ RIGHT

	5F ACTIVE CODE	6F ACTIVE CODE
AR1.0	SA5AR10	SA6AR10
AR2.0	SA5AR20	SA6AR20
ALR1-2	SA5ALR12	SA6ALR12

CORONARY GUIDE CATHETERS

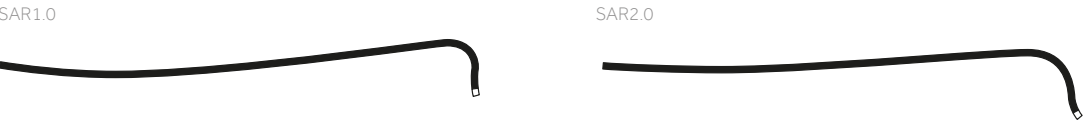
Sherpa NX™ Active
Short Amplatz Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT AMPLATZ
RIGHT

	5F ACTIVE CODE	6F ACTIVE CODE
SAR1.0	SA5SAR10	SA6SAR10
SAR2.0	SA5SAR20	SA6SAR20

CORONARY GUIDE CATHETERS

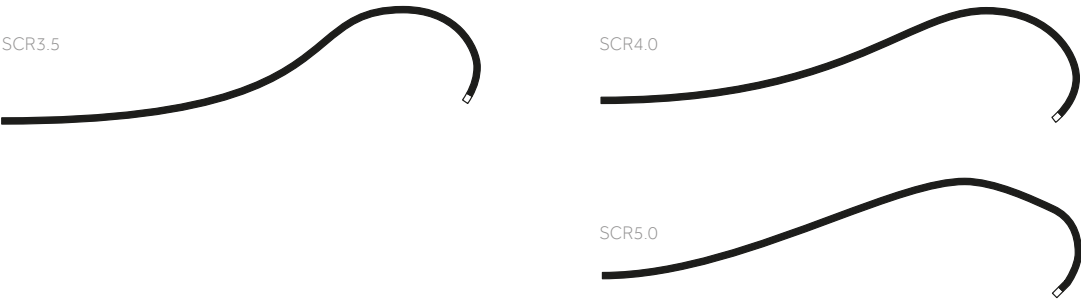
Sherpa NX™ Active
Shepherd’s Crook Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHEPHERD’S
CROOK RIGHT

	5F ACTIVE CODE	6F ACTIVE CODE
SCR3.5	SA5SCR35	SA6SCR35
SCR4.0	SA5SCR40	SA6SCR40
SCR5.0	SA5SCR50	SA6SCR50

CORONARY GUIDE CATHETERS

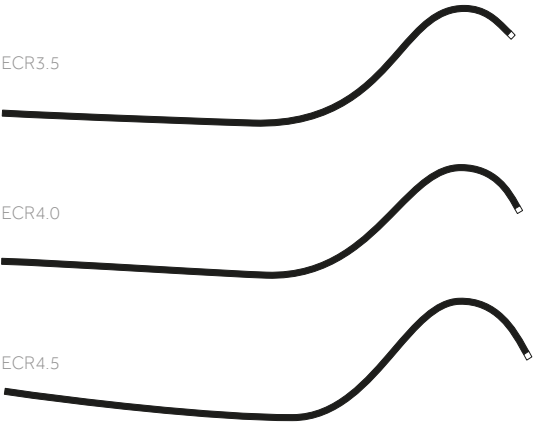
Sherpa NX™ Active
Right Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



ECR CURVES

	5F ACTIVE CODE	6F ACTIVE CODE
ECR 3.5	SA5ECR35	SA6ECR35
ECR 4.0	SA5ECR40	SA6ECR40
ECR 4.5	SA5ECR45	SA6ECR45

CORONARY GUIDE CATHETERS

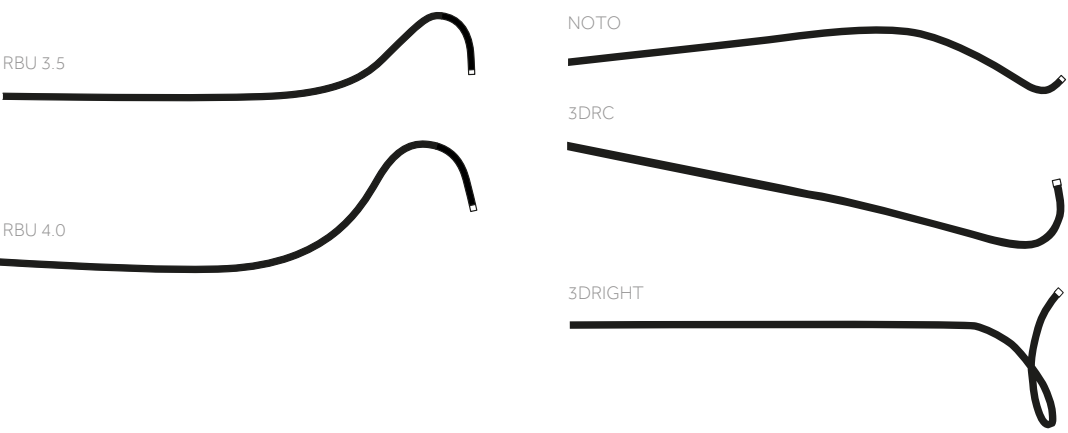
Sherpa NX™ Active Right Coronary Backup Support

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



BACKUP SUPPORT CURVES

	5F ACTIVE CODE	6F ACTIVE CODE
RBU 3.5	SA5RBU35	SA6RBU35
RBU 4.0	SA5RBU40	SA6RBU40
3DRC		SA63DRC
3DRIGHT	SA53DRIGHT	SA63DRIGHT
NOTO	LA5NOTO	LA6NOTO

CORONARY GUIDE CATHETERS

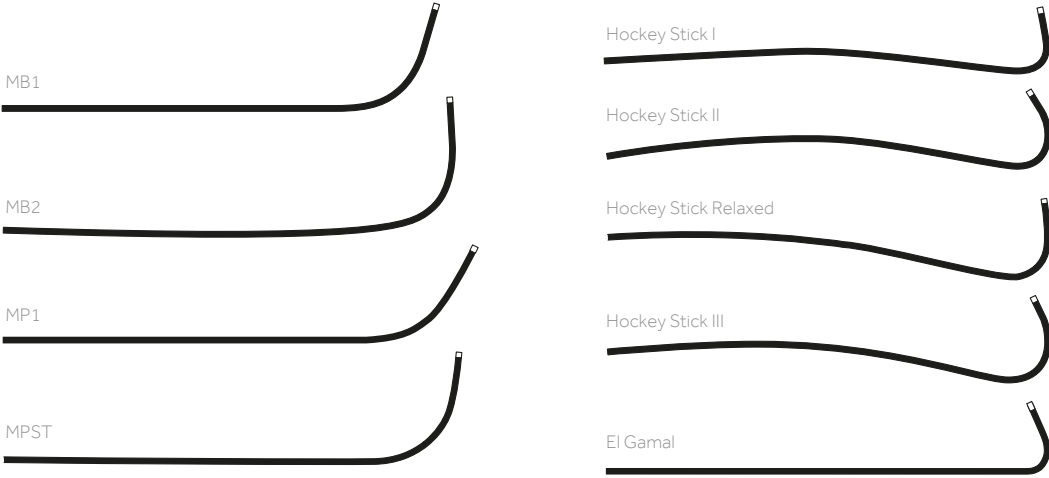
Sherpa NX™ Active Multipurpose Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



MULTIPURPOSE

	5F ACTIVE CODE	6F ACTIVE CODE
MB1	SA5MB1	SA6MB1
MB2	SA5MB2	SA6MB2
MB Short Tip	SA5MPST	SA6MPST
MP1	SA5MP1	SA6MP1
MP2	SA5MP2	SA6MP2
Hockey Stick I	SA5HSI	SA6HSI
Hockey Stick II	SA5HSII	SA6HSII
HS II Relaxed	SA5RMHSII	SA6RMHSII
Hockey Stick III	SA5HSIII	SA6HSIII
El Gamal	SA5ELGAMAL	SA6ELGAMAL

CORONARY GUIDE CATHETERS

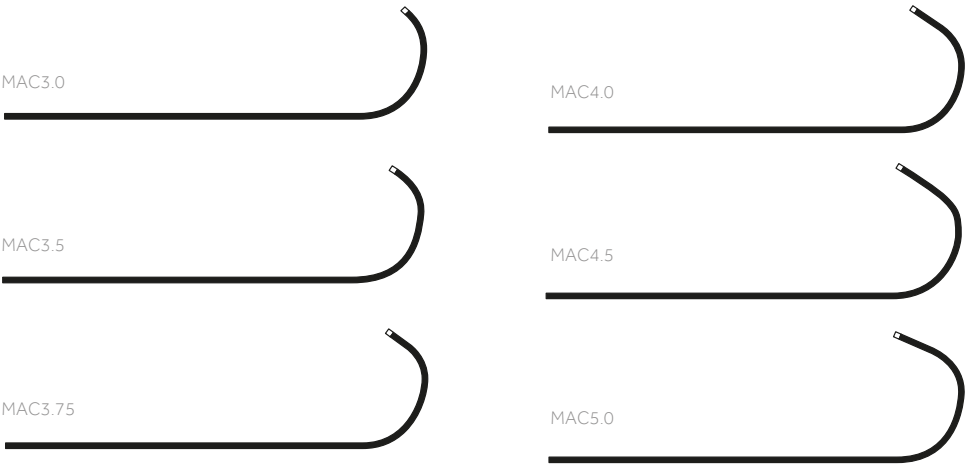
Sherpa NX™ Active Other Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



MAC (MULTI- AORTIC CURVES)

	5F ACTIVE CODE	6F ACTIVE CODE
MAC3.0	SA5MAC30	SA6MAC30
MAC3.5	SA5MAC35	SA6MAC35
MAC3.75	SA5MAC375	SA6MAC375
MAC4.0	SA5MAC40	SA6MAC40
MAC4.5	SA5MAC45	SA6MAC45
MAC5.0	SA5MAC50	SA6MAC50

CORONARY GUIDE CATHETERS

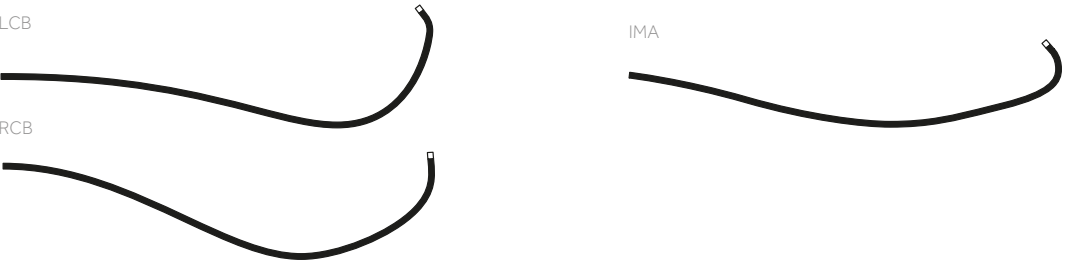
Sherpa NX™ Active Bypass Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



BYPASS CURVES

	5F ACTIVE CODE	6F ACTIVE CODE
LCB	SA5LCB	SA6LCB
LCB (90 cm)	SA5LCBD	SA6LCBD
RCB	SA5RCB	SA6RCB
RCB (90 cm)	SA5RCBD	SA6RCBD
IMA	SA5IMA	SA6IMA
IMA (90 cm)	SA5IMAD	SA6IMAD

CORONARY GUIDE CATHETERS

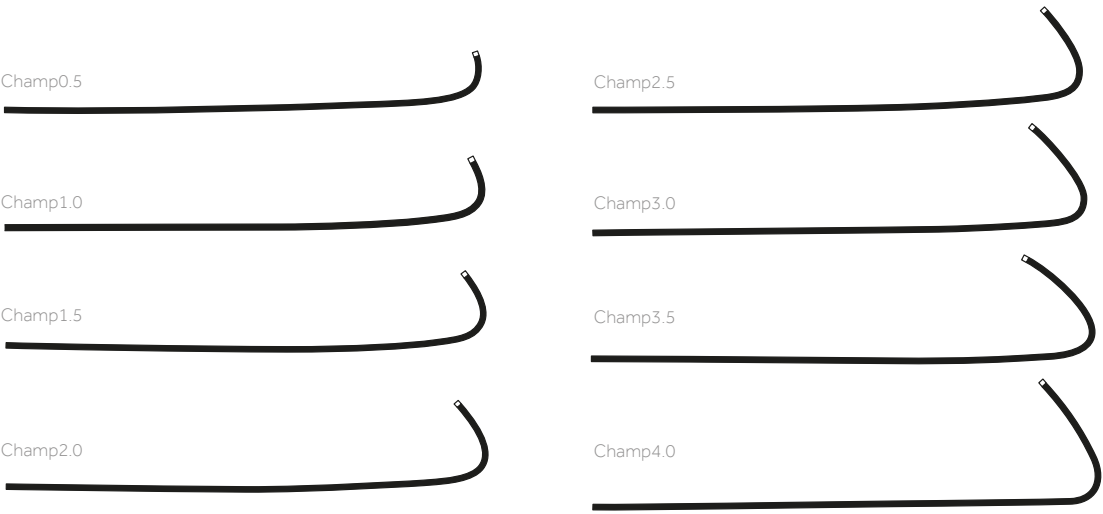
Sherpa NX™ Active Other Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



CHAMP	5F ACTIVE CODE	6F ACTIVE CODE
CHAMP 0.5	SA5CHAMP05	SA6CHAMP05
CHAMP 10	SA5CHAMP10	SA6CHAMP10
CHAMP 15	SA5CHAMP15	SA6CHAMP15
CHAMP 20	SA5CHAMP20	SA6CHAMP20
CHAMP 25	SA5CHAMP25	SA6CHAMP25
CHAMP 30	SA5CHAMP30	SA6CHAMP30
CHAMP 35	SA5CHAMP35	SA6CHAMP35
CHAMP 40	SA5CHAMP40	SA6CHAMP40

CORONARY GUIDE CATHETERS

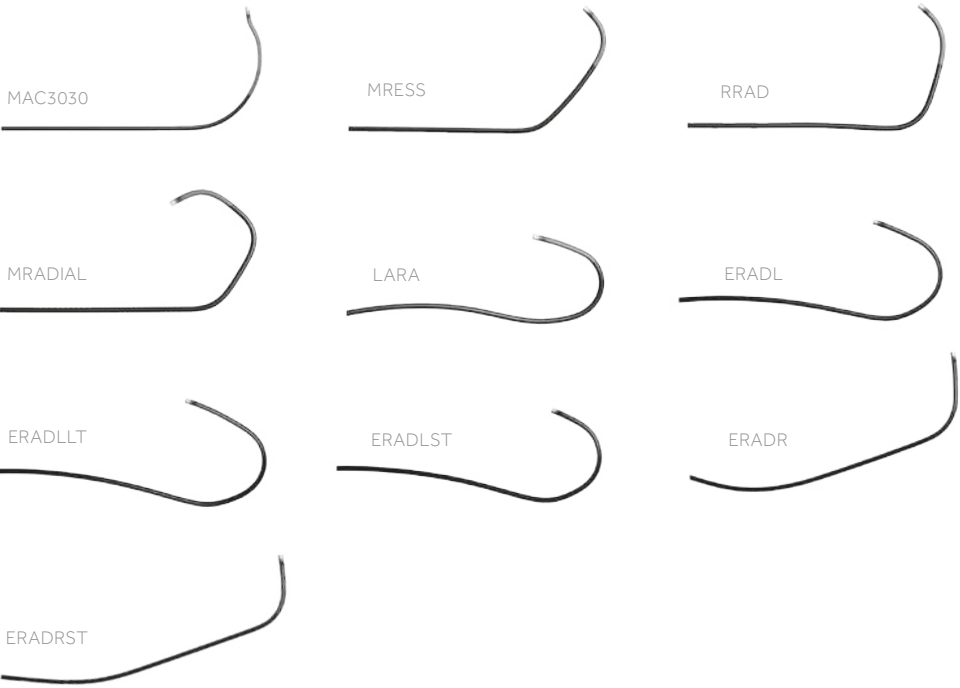
Sherpa NX™ Active Radial Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 5F = Grey, 6F = Green
- Lumen inner diameter: 5F = 0.058", 6F 0.070"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



RADIAL CURVES	5F ACTIVE CODE	6F ACTIVE CODE
MRADIAL	SA5MRADIAL	SA6MRADIAL
MRESS	SA5MRESS	SA6MRESS
RIGHT RADIAL	SA5RRAD	SA6RRAD
ERADL	SA5ERADL	SA6ERADL
ERADLLT	SA5ERADLLT	SA6ERADLLT
ERADLST	SA5ERADLST	SA6ERADLST
ERADR	SA5ERADR	SA6ERADR
ERADRST	SA5ERADRST	SA6ERADRST
MAC3030	SA5MAC30303	SA6MAC30303

CORONARY GUIDE CATHETERS

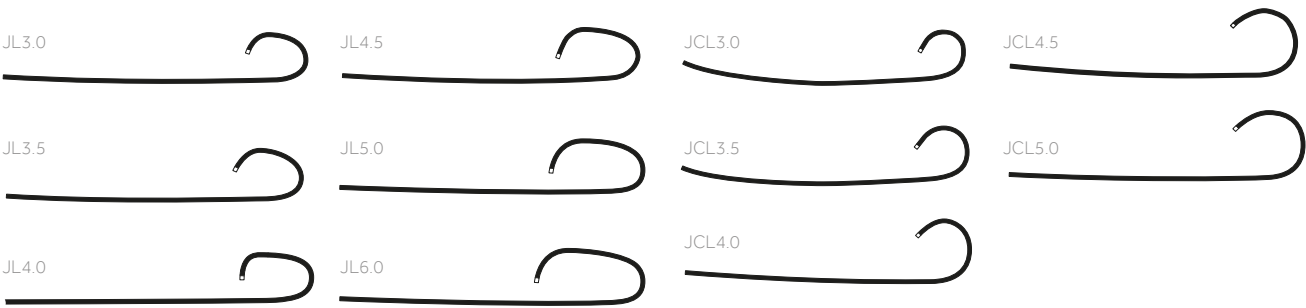
Sherpa NX™ Balanced Left Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



LEFT STANDARD

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
JL3.0	SB6JL30	SB7JL30	SB8JL30
JL3.5	SB6JL35	SB7JL35	SB8JL35
JL4.0	SB6JL40	SB7JL40	SB8JL40
JL4.5	SB6JL45	SB7JL45	SB8JL45
JL5.0	SB6JL50	SB7JL50	SB8JL50
JL6.0	SB6JL60	SB7JL70	SB8JL70
JCL3.0	SB6JCL30	SB7JCL30	SB8JCL30
JCL3.5	SB6JCL35	SB7JCL35	SB8JCL35
JCL4.0	SB6JCL40	SB7JCL40	SB8JCL40
JCL4.5	SB6JCL45	SB7JCL45	SB8JCL45
JCL5.0	SB6JCL50	SB7JCL50	SB8JCL50

CORONARY GUIDE CATHETERS

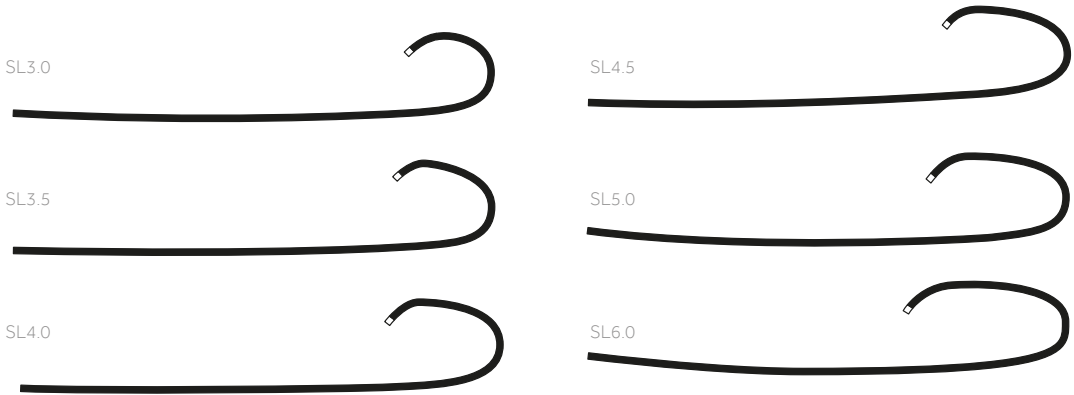
Sherpa NX™ Balanced Short Left Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT LEFT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
SL3.0	SB6SL30	SB7SL30	SB8SL30
SL3.5	SB6SL35	SB7SL35	SB8SL35
SL4.0	SB6SL40	SB7SL40	SB8SL40
SL4.5	SB6SL45	SB7SL45	SB8SL45
SL5.0	SB6SL50	SB7SL50	SB8SL50
SL6.0	SB6SL60	SB7SL70	SB8SL70

CORONARY GUIDE CATHETERS

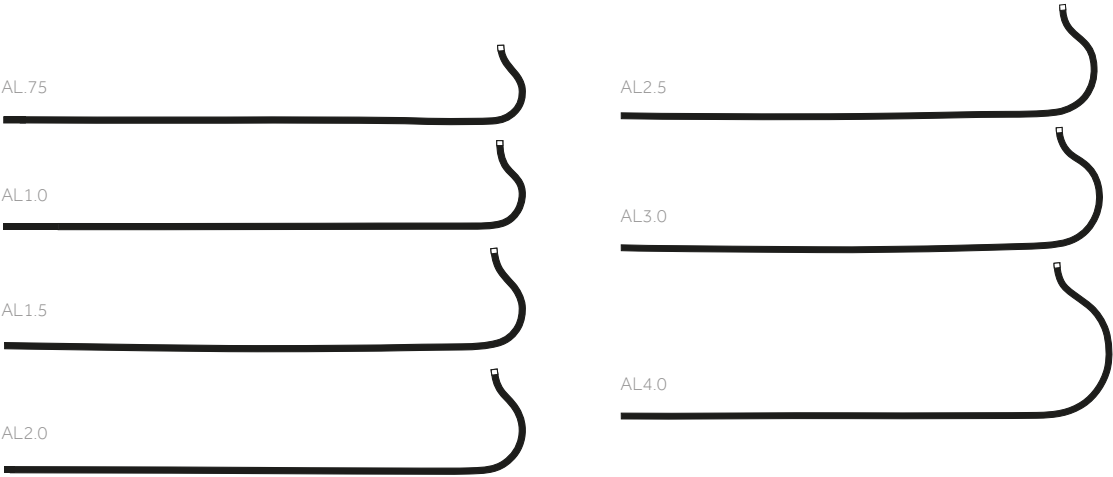
Sherpa NX™ Balanced Amplatz Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



AMPLATZ LEFT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
AL.75	SB6AL75	SB7AL75	SB8AL75
AL.1.0	SB6AL10	SB7AL10	SB8AL10
AL.1.5	SB6AL15	SB7AL15	SB8AL15
AL.2.0	SB6AL20	SB7AL20	SB8AL20
AL.2.5	SB6AL25	SB7AL25	SB8AL25
AL.3.0	SB6AL30	SB7AL30	SB8AL30
AL.4.0	SB6AL40	SB7AL40	SB8AL40

CORONARY GUIDE CATHETERS

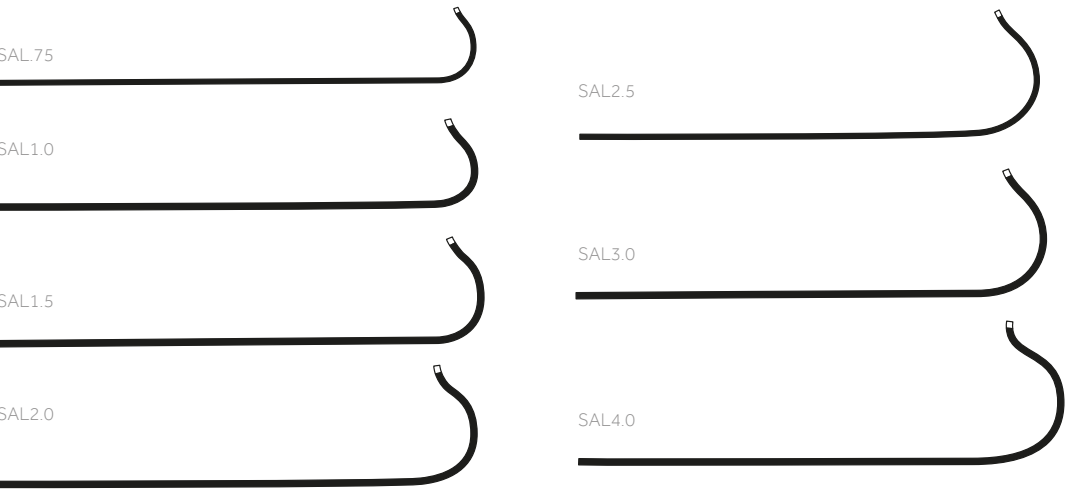
Sherpa NX™ Balanced Short Amplatz Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT AMPLATZ
LEFT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
SAL.75	SB6SAL75	SB7SAL75	SB8SAL75
SAL.1.0	SB6SAL10	SB7SAL10	SB8SAL10
SAL.1.5	SB6SAL15	SB7SAL15	SB8SAL15
SAL.2.0	SB6SAL20	SB7SAL20	SB8SAL20
SAL.2.5	SB6SAL25	SB7SAL25	SB8SAL25
SAL.3.0	SB6SAL30	SB7SAL30	SB8SAL30
SAL.4.0	SB6SAL40	SB7SAL40	SB8SAL40

CORONARY GUIDE CATHETERS

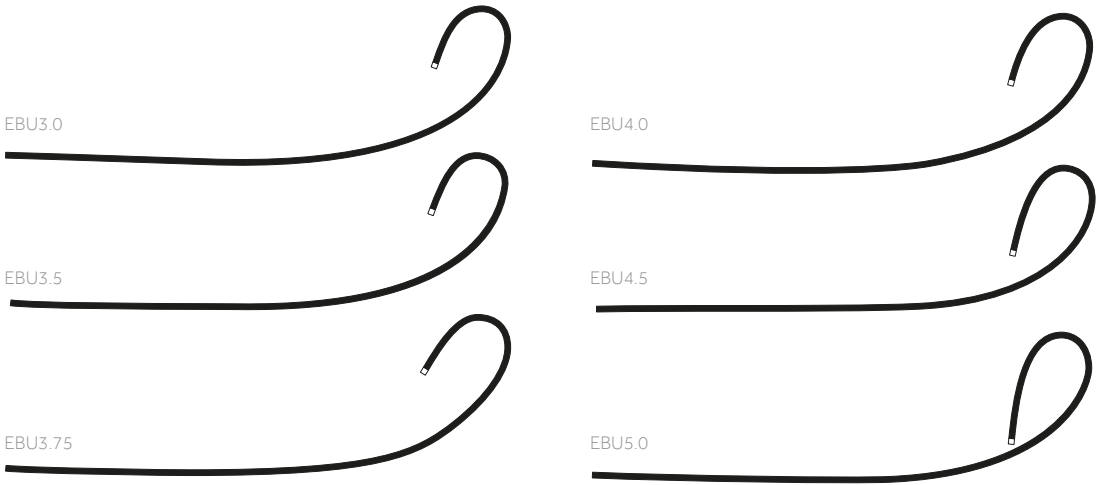
Sherpa NX™ Balanced Left Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



EBU
(EXTRA BACKUP)

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
EBU3.0	SB6EBU30	SB7EBU30	SB8EBU30
EBU3.5	SB6EBU35	SB7EBU35	SB8EBU35
EBU3.75	SB6EBU375	SB7EBU375	SB8EBU375
EBU4.0	SB6EBU40	SB7EBU40	SB8EBU40
EBU4.5	SB6EBU45	SB7EBU45	SB8EBU45
EBU5.0	SB6EBU50	SB7EBU50	SB8EBU50

CORONARY GUIDE CATHETERS

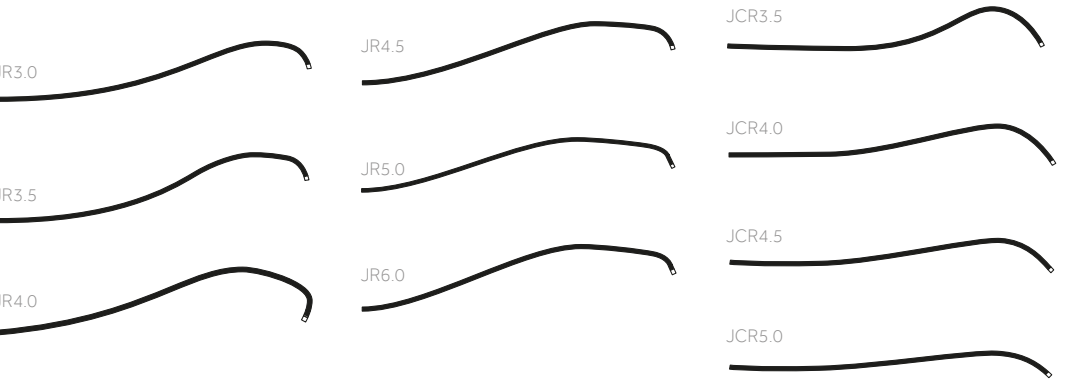
Sherpa NX™ Balanced Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



RIGHT STANDARD

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
JR3.0	SB6JR30	SB7JR30	SB8JR30
JR3.5	SB6JR35	SB7JR35	SB8JR35
JR4.0	SB6JR40	SB7JR40	SB8JR40
JR4.5	SB6JR45	SB7JR45	SB8JR45
JR5.0	SB6JR50	SB7JR50	SB8JR50
JR6.0	SB6JR60	SB7JR70	SB8JR70
JCR3.5	SB6JCR35	SB7JCR35	SB8JCR35
JCR4.0	SB6JCR40	SB7JCR40	SB8JCR40
JCR4.5	SB6JCR45	SB7JCR45	SB8JCR45
JCR5.0	SB6JCR50	SB7JCR50	SB8JCR50

CORONARY GUIDE CATHETERS

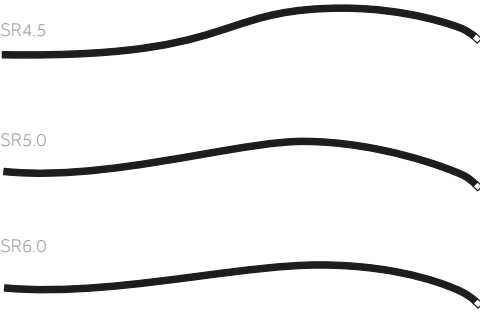
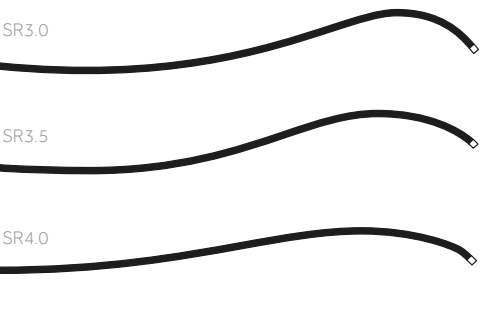
Sherpa NX™ Balanced Short Right Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



SHORT RIGHT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
SR3.0	SB6SR30	SB7SR30	SB8SR30
SR3.5	SB6SR35	SB7SR35	SB8SR35
SR4.0	SB6SR40	SB7SR40	SB8SR40
SR4.5	SB6SR45	SB7SR45	SB8SR45
SR5.0	SB6SR50	SB7SR50	SB8SR50
SR6.0	SB6SR60	SB7SR70	SB8SR70

CORONARY GUIDE CATHETERS

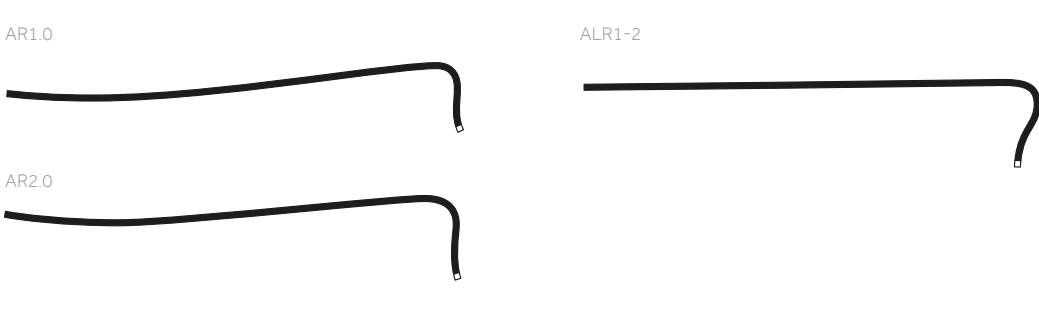
Sherpa NX™ Balanced Amplatz Right Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



AMPLATZ RIGHT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
AR1.0	SB6AR10	SB7AR10	SB8AR10
AR2.0	SB6AR20	SB7AR20	SB8AR20
ALR1-2	SB6ALR12	SB7ALR12	SB8ALR12

CORONARY GUIDE CATHETERS

Sherpa NX™ Balanced
Short Amplatz Right Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage

SAR1.0



SAR2.0



SHORT AMPLATZ RIGHT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
SAR1.0	SB6SAR10	SB7SAR10	SB8SAR10
SAR2.0	SB6SAR20	SB7SAR20	SB8SAR20

CORONARY GUIDE CATHETERS

Sherpa NX™ Balanced
Shepherd's Crook Right Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage

SCR3.5



SCR4.0



SCR5.0



SHEPHERD'S CROOK RIGHT

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
SCR3.5	SB6SCR35	SB7SCR35	SB8SCR35
SCR4.0	SB6SCR40	SB7SCR40	SB8SCR40
SCR5.0	SB6SCR50	SB7SCR50	SB8SCR50

CORONARY GUIDE CATHETERS

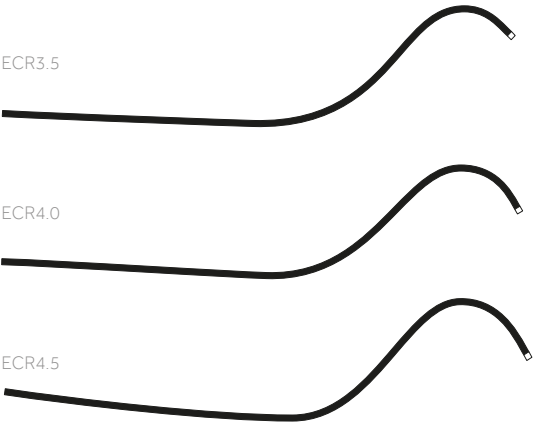
Sherpa NX™ Balanced Right Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



ECR CURVES

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
ECR 3.5	SB6ECR35	SB7ECR35	SB8ECR35
ECR 4.0	SB6ECR40	SB7ECR40	SB8ECR40
ECR 4.5	SB6ECR45	SB7ECR45	SB8ECR45

CORONARY GUIDE CATHETERS

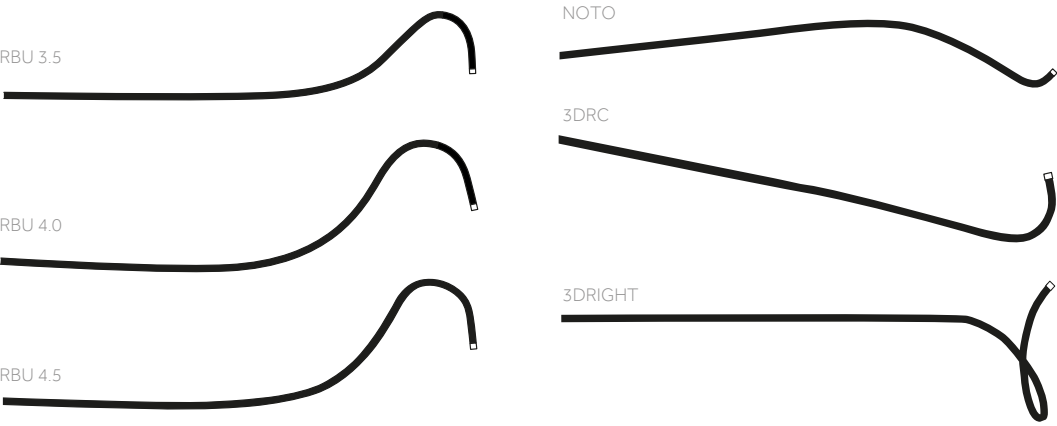
Sherpa NX™ Balanced Right Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



BACKUP SUPPORT
CURVES

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
RBU 3.5	SB6RBU35	SB7RBU35	SB8RBU35
RBU 4.0	SB6RBU40	SB7RBU40	SB8RBU40
RBU 4.5	SB6RBU45	SB7RBU45	SB8RBU45
3DRC	SB63DRC	SB73DRC	SB83DRC
3DRIGHT	SB63DRIGHT	SB73DRIGHT	SB83DRIGHT
NO TORQUE Right	SB6NOTO	SB7NOTO	

CORONARY GUIDE CATHETERS

Sherpa NX™ Balanced Multipurpose Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



MULTIPURPOSE

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
MB1	SB6MB1	SB7MB1	SB8MB1
MB2	SB6MB2	SB7MB2	SB8MB2
MB Short Tip	SB6MPST	SB7MPST	SB8MPST
MP1	SB6MP1	SB7MP1	SB8MP1
MP2	SB6MP2	SB7MP2	SB8MP2
Hockey Stick I	SB6HSI	SB7HSI	SB8HSI
Hockey Stick II	SB6HSII	SB7HSII	SB8HSII
HS II Relaxed	SB6RMHSII	SB7RMHSII	SB8RMHSII
Hockey Stick III	SB6HSIII	SB7HSIII	SB8HSIII
El Gamal	SB6ELGAMAL	SB7ELGAMAL	SB8ELGAMAL

CORONARY GUIDE CATHETERS

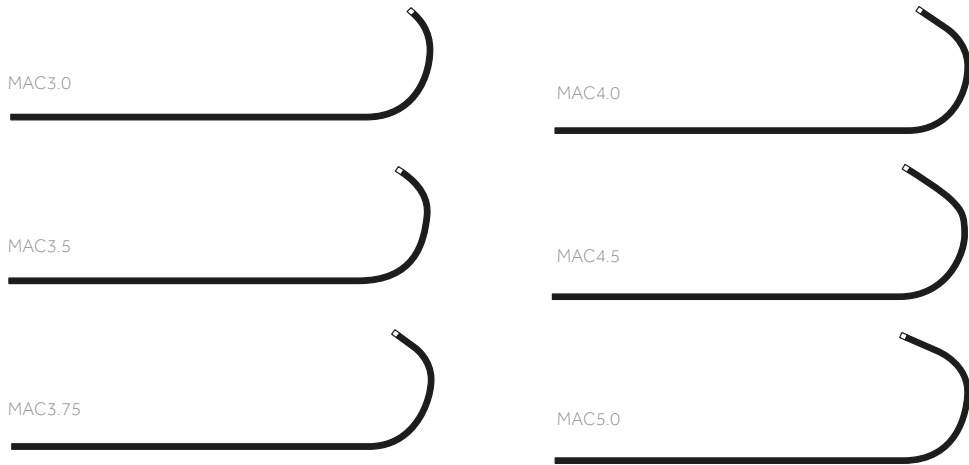
Sherpa NX™ Balanced Other Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



MAC (MULTI-AORTIC CURVES)

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
MAC3.0	SB6MAC30	SB7MAC30	SB8MAC30
MAC3.5	SB6MAC35	SB7MAC35	SB8MAC35
MAC3.75	SB6MAC375	SB7MAC375	SB8MAC375
MAC4.0	SB6MAC40	SB7MAC40	SB8MAC40
MAC4.5	SB6MAC45	SB7MAC45	SB8MAC45
MAC5.0	SB6MAC50	SB7MAC50	SB8MAC50

CORONARY GUIDE CATHETERS

Sherpa NX™ Balanced Bypass Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage

LCB

RCB

IMA

BYPASS CURVES

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
LCB	SB6LCB	SB7LCB	SB8LCB
LCB (90 cm)	SB6LCBD	SB7LCBD	SB8LCBD
RCB	SB6RCB	SB7RCB	SB8RCB
RCB (90 cm)	SB6RCBD	SB7RCBD	SB8RCBD
IMA	SB6IMA	SB7IMA	SB8IMA
IMA (90 cm)	SB6IMAD	SB7IMAD	SB8IMAD

CORONARY GUIDE CATHETERS

Sherpa NX™ Balanced Other Curves

GENERAL CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage

Champ0.5

Champ1.0

Champ1.5

Champ2.0

Champ2.5

Champ3.0

Champ3.5

Champ4.0

CHAMP

	6F BALANCED CODE	7F BALANCED CODE	8F BALANCED CODE
CHAMP 0.5	SB6CHAMP05	SB7CHAMP05	SB8CHAMP05
CHAMP 10	SB6CHAMP10	SB7CHAMP10	SB8CHAMP10
CHAMP 15	SB6CHAMP15	SB7CHAMP15	SB8CHAMP15
CHAMP 20	SB6CHAMP20	SB7CHAMP20	SB8CHAMP20
CHAMP 25	SB6CHAMP25	SB7CHAMP25	SB8CHAMP25
CHAMP 30	SB6CHAMP30	SB7CHAMP30	SB8CHAMP30
CHAMP 35	SB6CHAMP35	SB7CHAMP35	SB8CHAMP35
CHAMP 40	SB6CHAMP40	SB7CHAMP40	SB8CHAMP40

CORONARY GUIDE CATHETERS

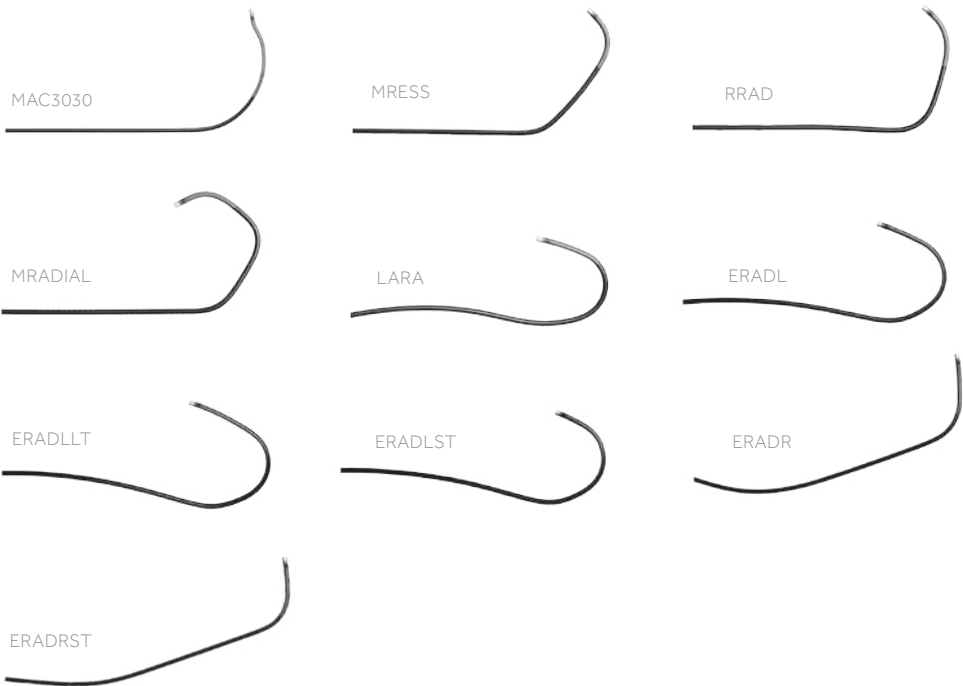
Sherpa NX™ Balanced Radial Curves

GENERAL
CHARACTERISTICS

- Supplied sterile, Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 6F = 0.070", 7F = 0.080", 8F = 0.088"

PRODUCT
DESCRIPTION

Soft tip and distal sleeve to facilitate ease of engagement. Advanced HDPE liner for smooth, low friction device passage



RADIAL CURVES

	6F BALANCED CODE	7F BALANCED CODE
MRADIAL	SB6MRADIAL	SB7MRADIAL
MRESS	SB6MRESS	SB7MRESS
RIGHT RADIAL	SB6RRAD	SB7RRAD
ERADL	SB6ERADL	
ERADLLT	SB6ERADLLT	
ERADLST	SB6ERADLST	
ERADR	SB6ERADR	
ERADRST	SB6ERADRST	

CORONARY GUIDE CATHETERS

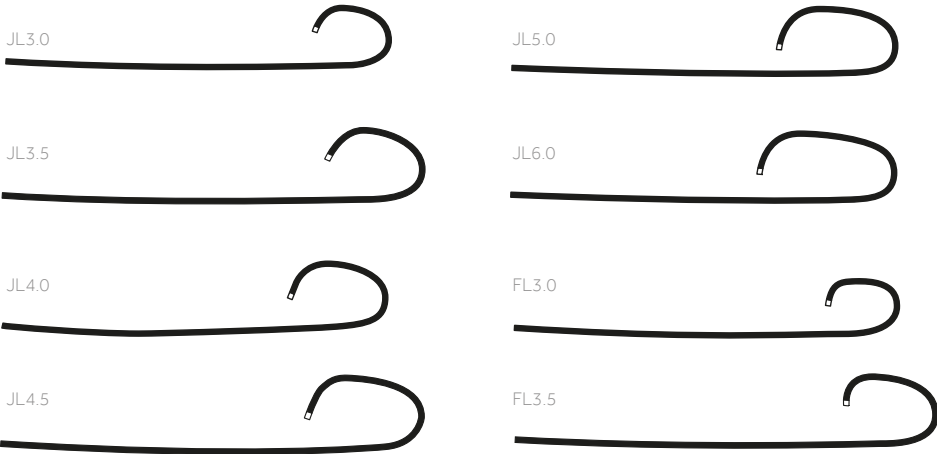
Zuma2™ Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



LEFT CORONARY

	5F CODE	6F CODE	7F CODE	8F CODE
JL3.0	ZM5JL30	Z26JL30	Z27JL30	Z28JL30
JL3.5	ZM5JL35	Z26JL35	Z27JL35	Z28JL35
JL4.0	ZM5JL40	Z26JL40	Z27JL40	Z28JL40
JL4.5	ZM5JL45	Z26JL45	Z27JL45	Z28JL45
JL5.0	ZM5JL50	Z26JL50	Z27JL50	Z28JL50
JL6.0	ZM5JL60	Z26JL60	Z27JL60	Z28JL60
FL3.0	ZM5FL30	Z26FL30	Z27FL30	Z28FL30
FL3.5	ZM5FL35	Z26FL35	Z27FL35	Z28FL35

CORONARY GUIDE CATHETERS

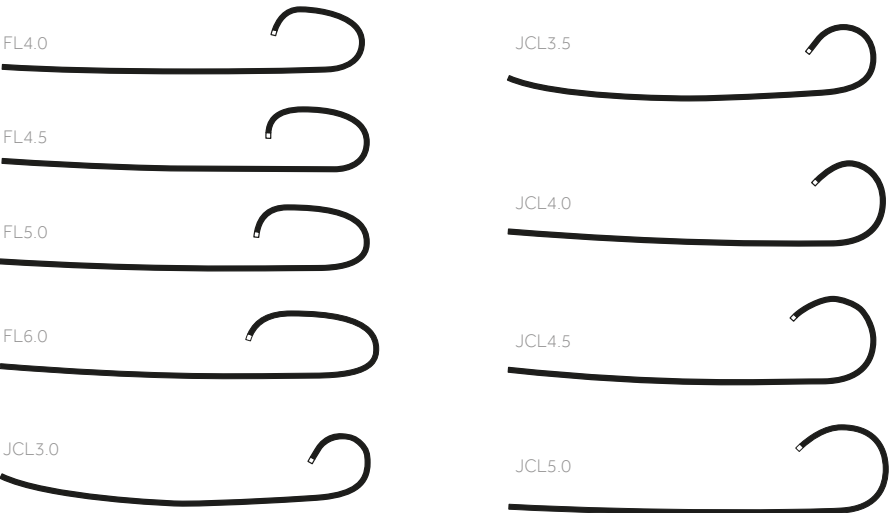
Zuma2™
Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



LEFT CORONARY

	5F CODE	6F CODE	7F CODE	8F CODE
FL4.0	ZM5FL40	Z26FL40	Z27FL40	Z28FL40
FL4.5	ZM5FL45	Z26FL45	Z27FL45	Z28FL45
FL5.0	ZM5FL50	Z26FL50	Z27FL50	Z28FL50
FL6.0	ZM5FL60	Z26FL60	Z27FL60	Z28FL60
JCL3.0	ZM5JCL30	Z26JCL30	Z27JCL30	Z28JCL30
JCL3.5	ZM5JCL35	Z26JCL35	Z27JCL35	Z28JCL35
JCL4.0	ZM5JCL40	Z26JCL40	Z27JCL40	Z28JCL40
JCL4.5	ZM5JCL45	Z26JCL45	Z27JCL45	Z28JCL45
JCL5.0	ZM5JCL50	Z26JCL50	Z27JCL50	Z28JCL50

CORONARY GUIDE CATHETERS

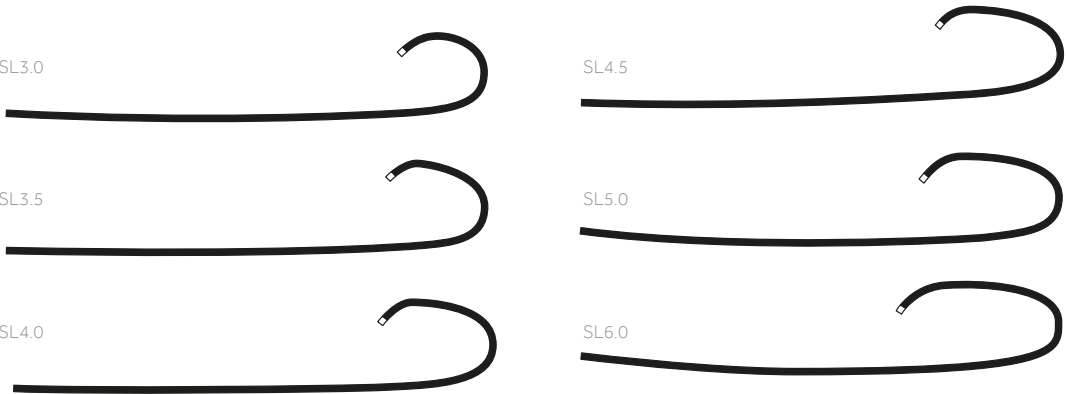
Zuma2™
Short Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



SHORT TIP LEFT
CORONARY

	5F CODE	6F CODE	7F CODE	8F CODE
SL3.0	ZM5SL30	Z26SL30	Z27SL30	Z28SL30
SL3.5	ZM5SL35	Z26SL35	Z27SL35	Z28SL35
SL4.0	ZM5SL40	Z26SL40	Z27SL40	Z28SL40
SL4.5	ZM5SL45	Z26SL45	Z27SL45	Z28SL45
SL5.0	ZM5SL50	Z26SL50	Z27SL50	Z28SL50
SL6.0	ZM5SL60	Z26SL60	Z27SL60	Z28SL60

CORONARY GUIDE CATHETERS

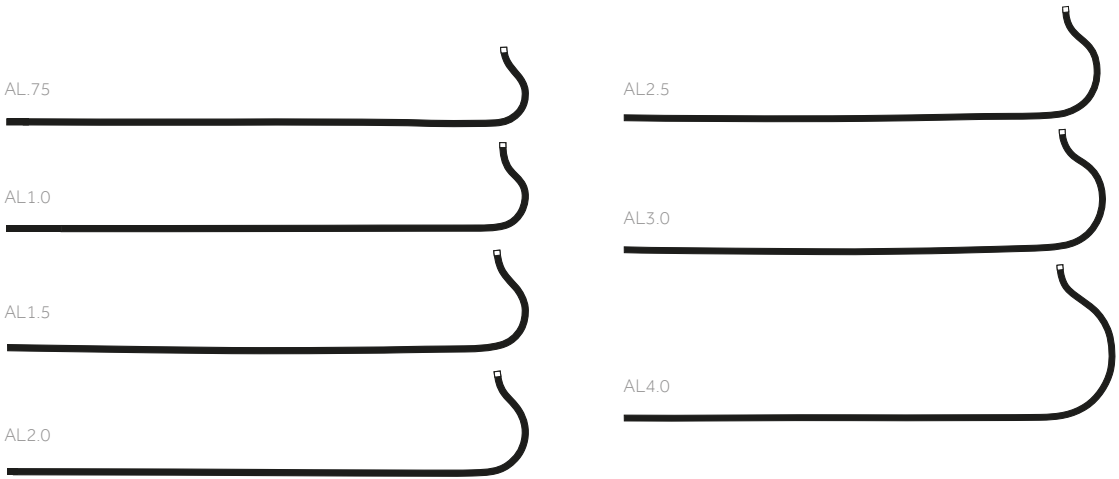
Zuma2™ Amplatz Left Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



AMPLATZ LEFT

	5F CODE	6F CODE	7F CODE	8F CODE
AL75	ZM5AL75	Z26AL75	Z27AL75	Z28AL75
AL1.0	ZM5AL10	Z26AL10	Z27AL10	Z28AL10
AL1.5	ZM5AL15	Z26AL15	Z27AL15	Z28AL15
AL2.0	ZM5AL20	Z26AL20	Z27AL20	Z28AL20
AL2.5	ZM5AL25	Z26AL25	Z27AL25	Z28AL25
AL3.0	ZM5AL30	Z26AL30	Z27AL30	Z28AL30
AL4.0	ZM5AL40	Z26AL40	Z27AL40	Z28AL40

CORONARY GUIDE CATHETERS

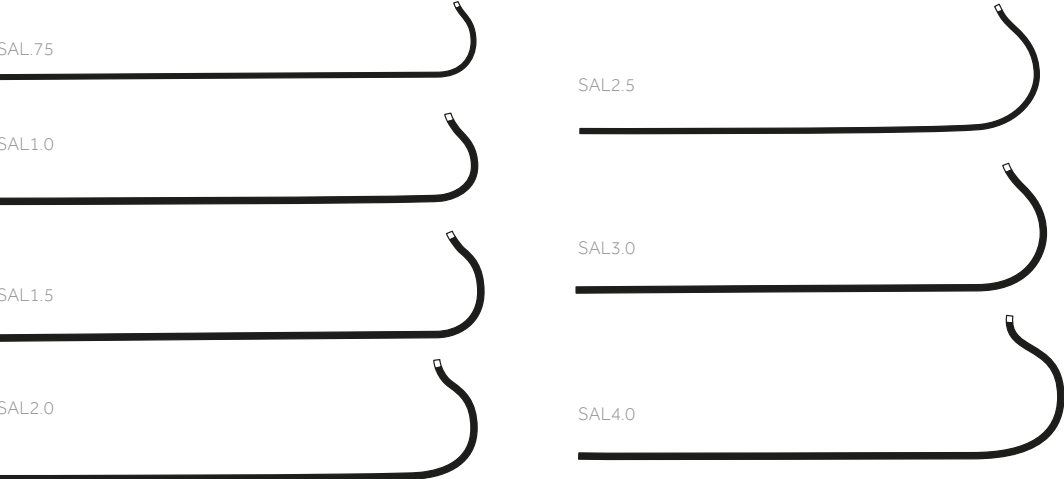
Zuma2™ Short Amplatz Left Coronary Curve

GENERAL CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



SHORT TIP AMPLATZ LEFT

	5F CODE	6F CODE	7F CODE	8F CODE
SAL75	ZM5SAL75	Z26SAL75	Z27SAL75	Z28SAL75
SAL1.0	ZM5SAL10	Z26SAL10	Z27SAL10	Z28SAL10
SAL1.5	ZM5SAL15	Z26SAL15	Z27SAL15	Z28SAL15
SAL2.0	ZM5SAL20	Z26SAL20	Z27SAL20	Z28SAL20
SAL2.5	ZM5SAL25	Z26SAL25	Z27SAL25	Z28SAL25
SAL3.0	ZM5SAL30	Z26SAL30	Z27SAL30	Z28SAL30
SAL4.0	ZM5SAL40	Z26SAL40	Z27SAL40	Z28SAL40

CORONARY GUIDE CATHETERS

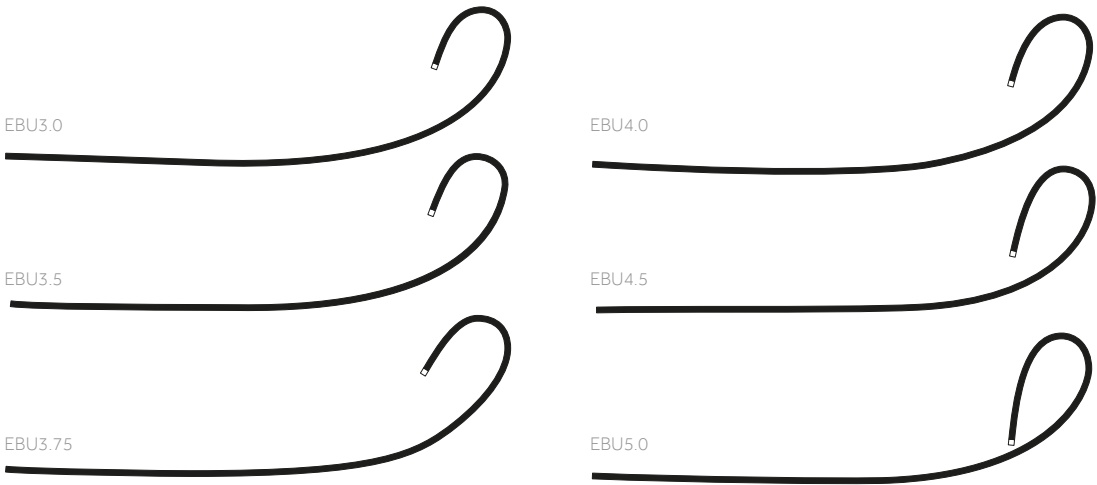
Zuma2™
Left Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



EBU
(EXTRA BACKUP)

	5F CODE	6F CODE	7F CODE	8F CODE
EBU3.0	ZM5EBU30	Z26EBU30	Z27EBU30	Z28EBU30
EBU3.5	ZM5EBU35	Z26EBU35	Z27EBU35	Z28EBU35
EBU3.75	ZM5EBU375	Z26EBU375	Z27EBU375	Z28EBU375
EBU4.0	ZM5EBU40	Z26EBU40	Z27EBU40	Z28EBU40
EBU4.5	ZM5EBU45	Z26EBU45	Z27EBU45	Z28EBU45
EBU5.0	ZM5EBU50	Z26EBU50	Z27EBU50	Z28EBU50

CORONARY GUIDE CATHETERS

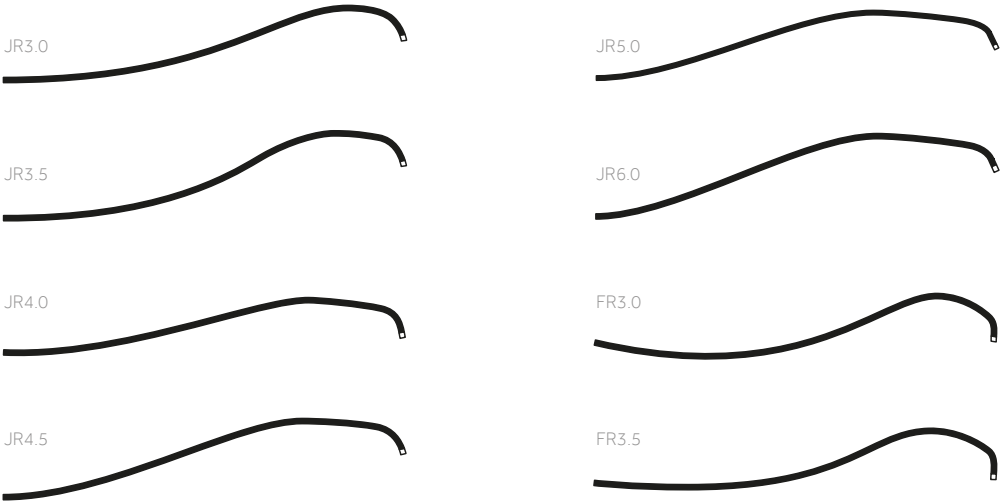
Zuma2™
Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



RIGHT CORONARY
CURVE

	5F CODE	6F CODE	7F CODE	8F CODE
JR3.0	ZM5JR30	Z26JR30	Z27JR30	Z28JR30
JR3.5	ZM5JR35	Z26JR35	Z27JR35	Z28JR35
JR4.0	ZM5JR40	Z26JR40	Z27JR40	Z28JR40
JR4.5	ZM5JR45	Z26JR45	Z27JR45	Z28JR45
JR5.0	ZM5JR50	Z26JR50	Z27JR50	Z28JR50
JR6.0	ZM5JR60	Z26JR60	Z27JR60	Z28JR60
FR3.0	ZM5FR30	Z26FR30	Z27FR30	Z28FR30
FR3.5	ZM5FR35	Z26FR35	Z27FR35	Z28FR35

CORONARY GUIDE CATHETERS

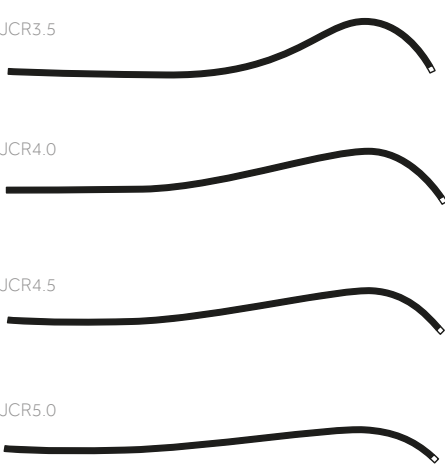
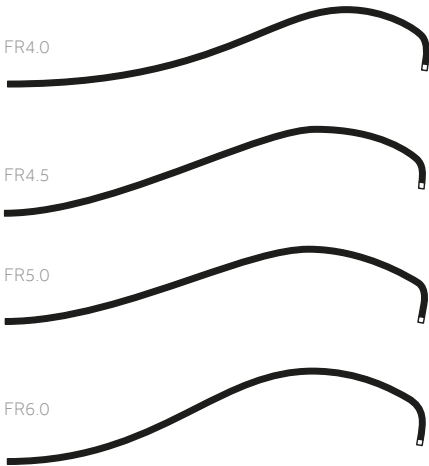
Zuma2™ Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



RIGHT CORONARY
CURVE

	5F CODE	6F CODE	7F CODE	8F CODE
FR4.0	ZM5FR40	Z26FR40	Z27FR40	Z28FR40
FR4.5	ZM5FR45	Z26FR45	Z27FR45	Z28FR45
FR5.0	ZM5FR50	Z26FR50	Z27FR50	Z28FR50
FR6.0	ZM5FR60	Z26FR60	Z27FR60	Z28FR60
JCR3.5	ZM5JCR35	Z26JCR35	Z27JCR35	Z28JCR35
JCR4.0	ZM5JCR40	Z26JCR40	Z27JCR40	Z28JCR40
JCR4.5	ZM5JCR45	Z26JCR45	Z27JCR45	Z28JCR45
JCR5.0	ZM5JCR50	Z26JCR50	Z27JCR50	Z28JCR50

CORONARY GUIDE CATHETERS

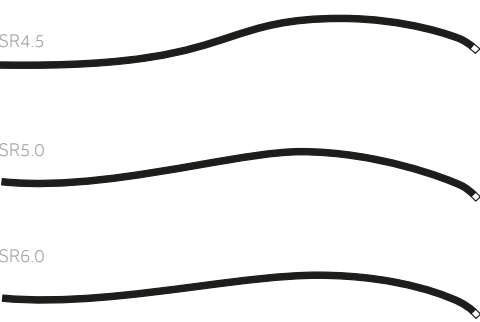
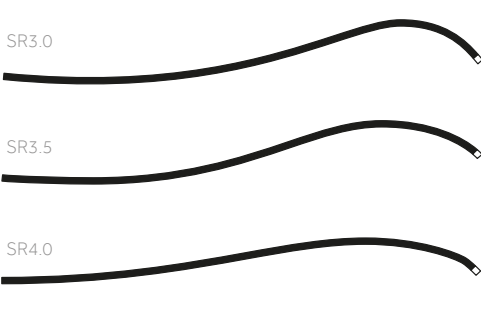
Zuma2™ Short Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



SHORT TIP RIGHT
CORONARY

	5F CODE	6F CODE	7F CODE	8F CODE
SR3.0	ZM5SR30	Z26SR30	Z27SR30	Z28SR30
SR3.5	ZM5SR35	Z26SR35	Z27SR35	Z28SR35
SR4.0	ZM5SR40	Z26SR40	Z27SR40	Z28SR40
SR4.5	ZM5SR45	Z26SR45	Z27SR45	Z28SR45
SR5.0	ZM5SR50	Z26SR50	Z27SR50	Z28SR50
SR6.0	ZM5SR60	Z26SR60	Z27SR60	Z28SR60

CORONARY GUIDE CATHETERS

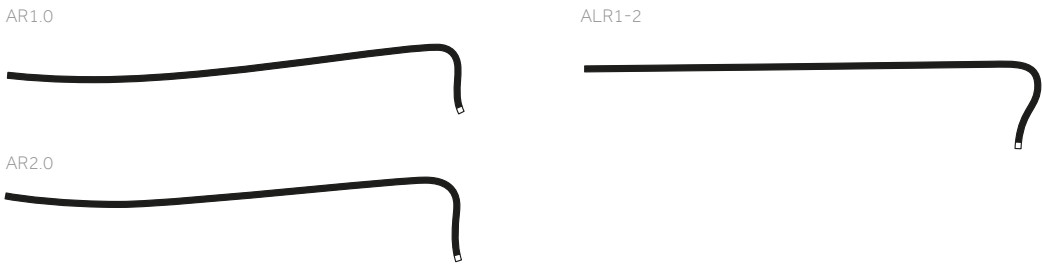
Zuma2™
Amplatz Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



AMPLATZ RIGHT

	5F CODE	6F CODE	7F CODE	8F CODE
AR1.0	ZM5AR10	Z26AR10	Z27AR10	Z28AR10
AR2.0	ZM5AR20	Z26AR20	Z27AR20	Z28AR20
ALR1-2	ZM5ALR12	Z26ALR12	Z27ALR12	Z28ALR12

CORONARY GUIDE CATHETERS

Zuma2™
Short Amplatz Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



SHORT TIP
AMPLATZ
RIGHT

	5F CODE	6F CODE	7F CODE	8F CODE
SAR1.0	ZM5SAR10	Z26SAR10	Z27SAR10	Z28SAR10
SAR2.0	ZM5SAR20	Z26SAR20	Z27SAR20	Z28SAR20

CORONARY GUIDE CATHETERS

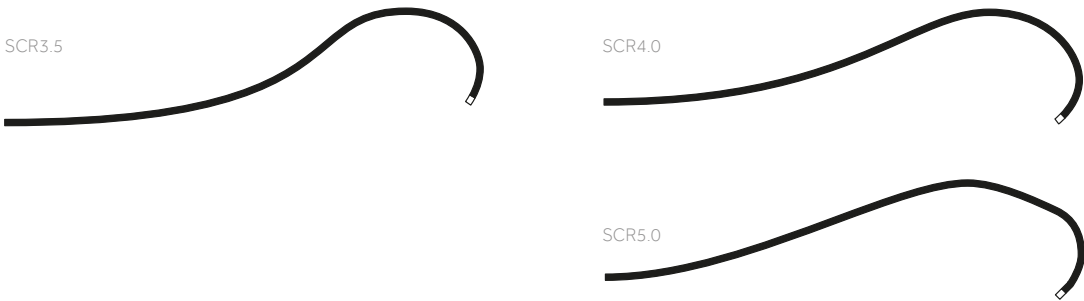
Zuma2™
Shepherd’s Crook Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



SHEPHERD’S
CROOK
RIGHT

	5F CODE	6F CODE	7F CODE	8F CODE
SCR3.5	ZM5SCR35	Z26SCR35	Z27SCR35	Z28SCR35
SCR4.0	ZM5SCR40	Z26SCR40	Z27SCR40	Z28SCR40
SCR5.0	ZM5SCR50	Z26SCR50	Z27SCR50	Z28SCR50

CORONARY GUIDE CATHETERS

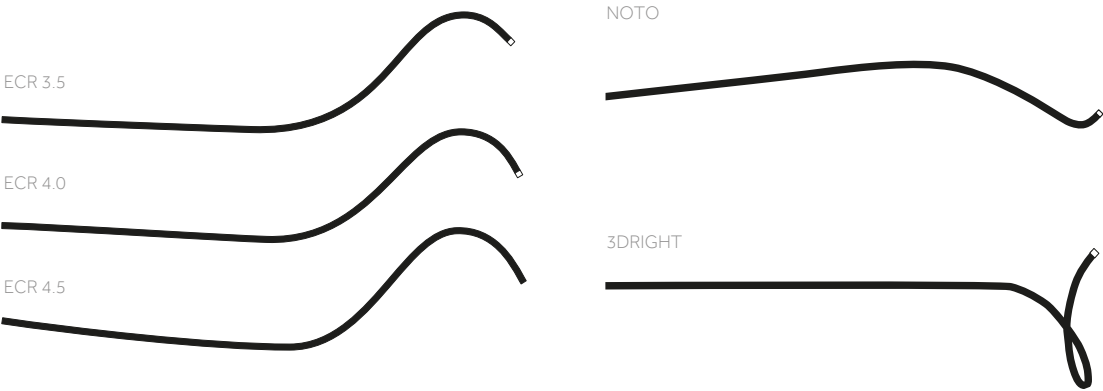
Zuma2™
Right Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



ECR CURVES

	5F CODE	6F CODE	7F CODE	8F CODE
ECR 3.5		Z26ECR35	Z27ECR35	Z28ECR35
ECR 4.0		Z26ECR40	Z27ECR40	Z28ECR40
ECR 4.5		Z26ECR45	Z27ECR45	Z28ECR45
3D RIGHT	-	Z263DRIGHT		
NO TORQUE Right	ZM5NOTO	Z26NOTO	Z27NOTO	Z28NOTO

CORONARY GUIDE CATHETERS

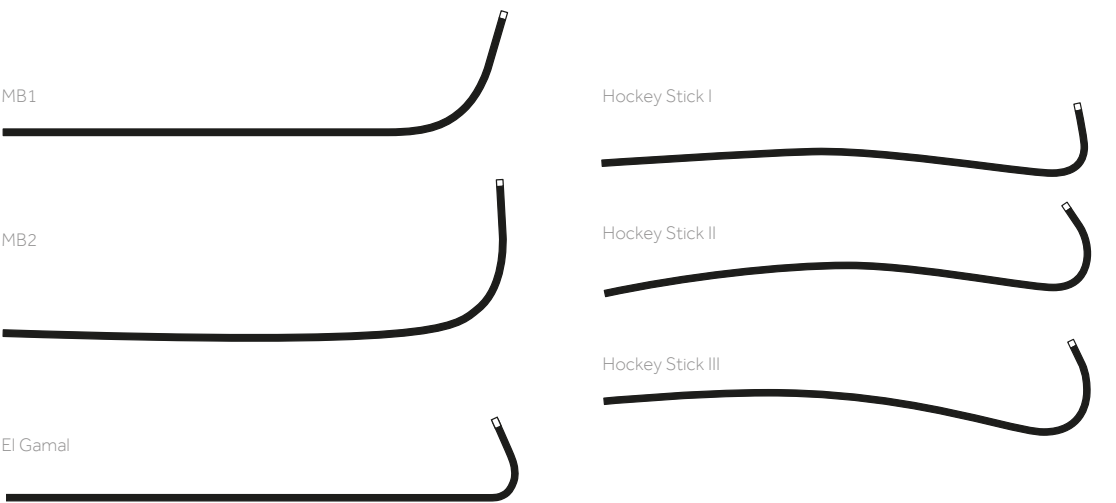
Zuma2™ Multipurpose Curves

GENERAL CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



MULTIPURPOSE

	5F CODE	6F CODE	7F CODE	8F CODE
MB1	ZM5MB1	Z26MB1	Z27MB1	Z28MB1
MB2	ZM5MB2	Z26MB2	Z27MB2	Z28MB2
Hockey Stick I	ZM5HSI	Z26 HSI	Z27 HSI	Z28 HSI
Hockey Stick II	ZM5HSII	Z26HSII	Z27HSII	Z28HSII
Hockey Stick III	ZM5HSIII	Z26HSIII	Z27HSIII	Z28HSIII
El Gamal	ZM5ELGAMAL	Z26ELGAMAL	Z27ELGAMAL	Z28ELGAMAL

CORONARY GUIDE CATHETERS

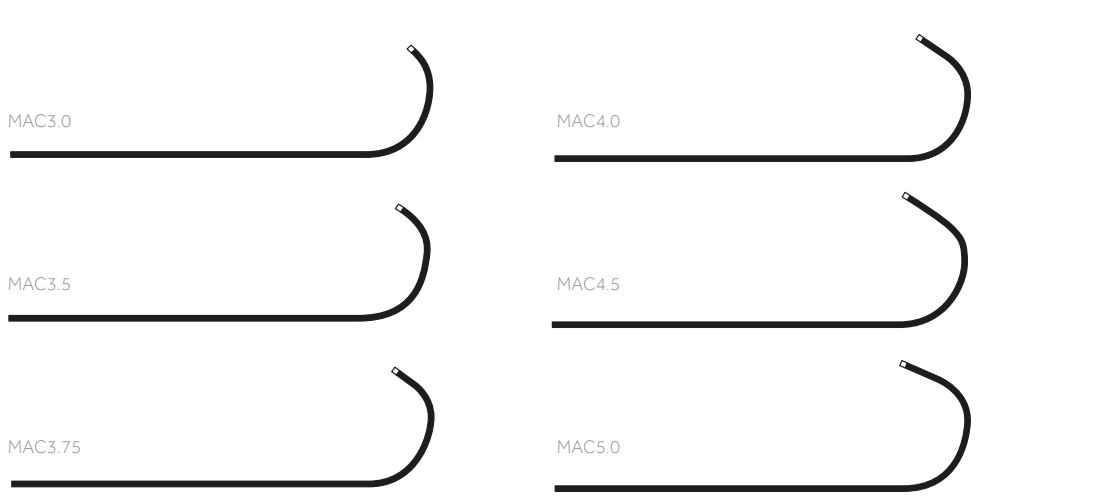
Zuma2™ Other Curves

GENERAL CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



MAC (MULTI- AORTIC CURVES)

	5F CODE	6F CODE	7F CODE	8F CODE
MAC3.0	ZM5MAC30	Z26MAC30	Z27MAC30	Z28MAC30
MAC3.5	ZM5MAC35	Z26MAC35	Z27MAC35	Z28MAC35
MAC3.75	ZM5MAC375	Z26MAC375	Z27MAC375	Z28MAC375
MAC4.0	ZM5MAC40	Z26MAC40	Z27MAC40	Z28MAC40
MAC4.5	ZM5MAC45	Z26MAC45	Z27MAC45	Z28MAC45
MAC5.0	ZM5MAC50	Z26MAC50	Z27MAC50	Z28MAC50

CORONARY GUIDE CATHETERS

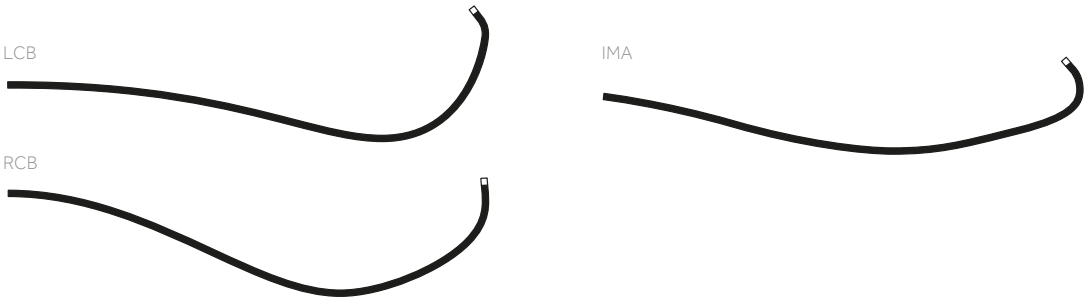
Zuma2™ Bypass Curves

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



BYPASS GRAFTS

	5F CODE	6F CODE	7F CODE	8F CODE
LCB	ZM5LCB	Z26LCB	Z27LCB	Z28LCB
RCB	ZM5RCB	Z26RCB	Z27RCB	Z28RCB
RCB (90 cm)	ZM5RCBD	Z26RCBD	Z27RCBD	Z28RCBD
IMA	ZM5IMA	Z26IMA	Z27IMA	Z28IMA
IMA (90 cm)	ZM5IMAD	Z26IMAD	Z27IMAD	Z28IMAD

CORONARY GUIDE CATHETERS

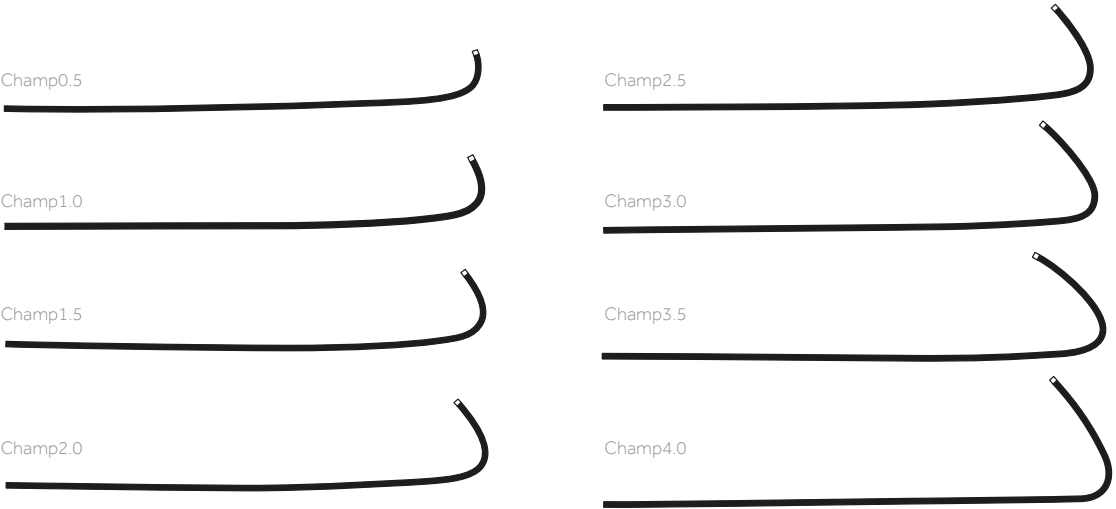
Zuma2™ Other Curves

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 5F = Grey, 6F = Green, 7F = Orange, 8F = Blue
- Lumen inner diameter: 5F = 0.058", 6F = 0.070", 7F = 0.081", 8F = 0.091"

PRODUCT
DESCRIPTION

Soft, flexible distal segment for atraumatic engagement. Soft tip polymer construction to minimize vessel trauma.



CHAMP

	5F CODE	6F CODE	7F CODE	8F CODE
CHAMP 0.5	ZM5CHAMP05	Z26CHAMP05	Z27CHAMP05	Z28CHAMP05
CHAMP 10	ZM5CHAMP10	Z26CHAMP10	Z27CHAMP10	Z28CHAMP10
CHAMP 15	ZM5CHAMP15	Z26CHAMP15	Z27CHAMP15	Z28CHAMP15
CHAMP 20	ZM5CHAMP20	Z26CHAMP20	Z27CHAMP20	Z28CHAMP20
CHAMP 25	ZM5CHAMP25	Z26CHAMP25	Z27CHAMP25	Z28CHAMP25
CHAMP 30	ZM5CHAMP30	Z26CHAMP30	Z27CHAMP30	Z28CHAMP30
CHAMP 35	ZM5CHAMP35	Z26CHAMP35	Z27CHAMP35	Z28CHAMP35
CHAMP 40	ZM5CHAMP40	Z26CHAMP40	Z27CHAMP40	Z28CHAMP40

CORONARY GUIDE CATHETERS

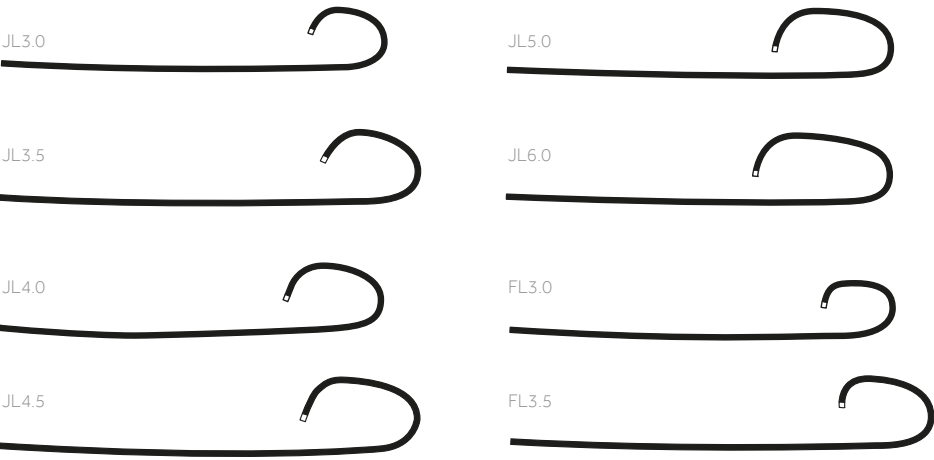
Zuma™
Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



LEFT CORONARY

	6F CODE	7F CODE	8F CODE	9F CODE
JL3.0	ZM6JL30	ZT7JL30	ZS8JL30	ZM9JL30
JL3.5	ZM6JL35	ZT7JL35	ZS8JL35	ZM9JL35
JL4.0	ZM6JL40	ZT7JL40	ZS8JL40	ZM9JL40
JL4.5	ZM6JL45	ZT7JL45	ZS8JL45	ZM9JL45
JL5.0	ZM6JL50	ZT7JL50	ZS8JL50	ZM9JL50
JL6.0	ZM6JL60	ZT7JL60	ZS8JL60	ZM9JL60
FL3.0	ZM6FL30	ZT7FL30	ZS8FL30	ZM9FL30
FL3.5	ZM6FL35	ZT7FL35	ZS8FL35	ZM9FL35

CORONARY GUIDE CATHETERS

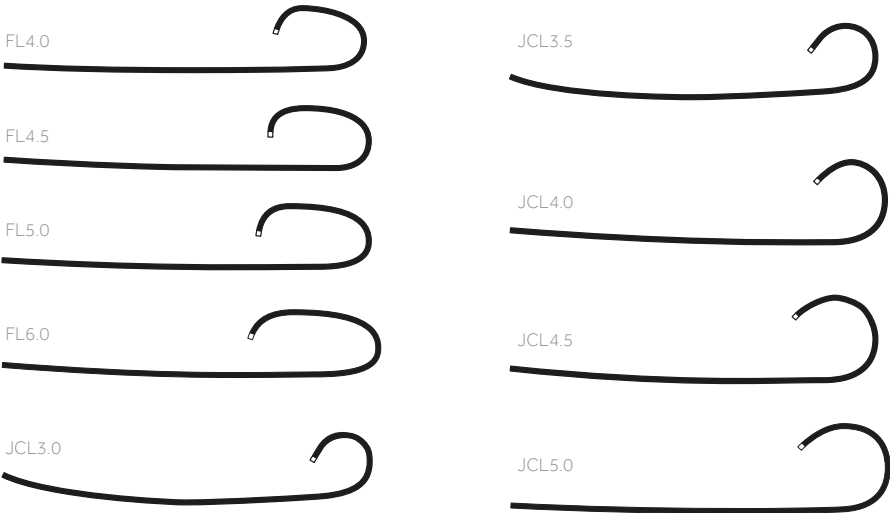
Zuma™
Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



LEFT CORONARY

	6F CODE	7F CODE	8F CODE	9F CODE
FL4.0	ZM6FL40	ZT7FL40	ZS8FL40	ZM9FL40
FL4.5	ZM6FL45	ZT7FL45	ZS8FL45	ZM9FL45
FL5.0	ZM6FL50	ZT7FL50	ZS8FL50	ZM9FL50
FL6.0	ZM6FL60	ZT7FL60	ZS8FL60	ZM9FL60
JCL3.0	ZM6JCL30	ZT7JCL30	ZS8JCL30	ZM9JCL30
JCL3.5	ZM6JCL35	ZT7JCL35	ZS8JCL35	ZM9JCL35
JCL4.0	ZM6JCL40	ZT7JCL40	ZS8JCL40	ZM9JCL40
JCL4.5	ZM6JCL45	ZT7JCL45	ZS8JCL45	ZM9JCL45
JCL5.0	ZM6JCL50	ZT7JCL50	ZS8JCL50	ZM9JCL50

CORONARY GUIDE CATHETERS

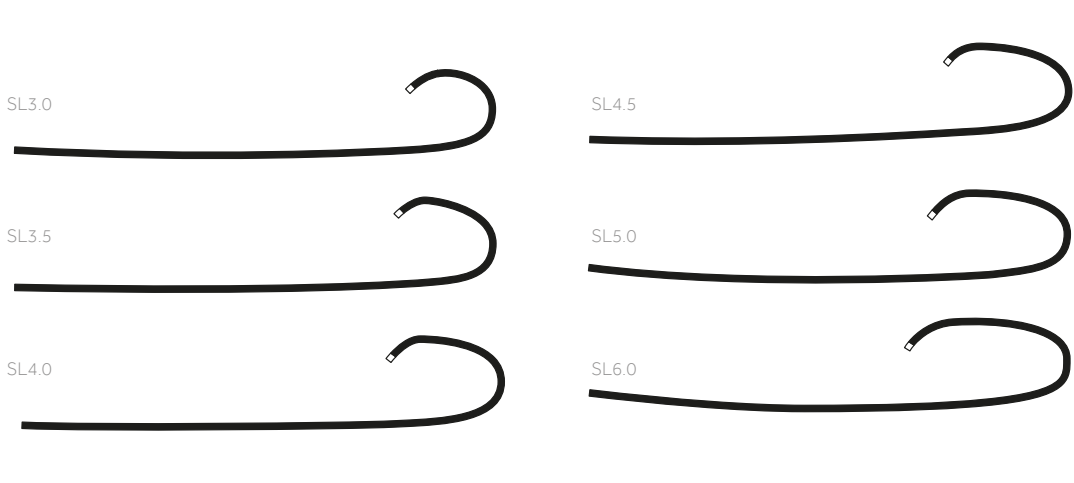
Zuma™
Short Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



SHORT TIP LEFT
CORONARY

	6F CODE	7F CODE	8F CODE	9F CODE
SL3.0	ZM6SL30	ZT7SL30	ZS8SL30	ZM9SL30
SL3.5	ZM6SL35	ZT7SL35	ZS8SL35	ZM9SL35
SL4.0	ZM6SL40	ZT7SL40	ZS8SL40	ZM9SL40
SL4.5	ZM6SL45	ZT7SL45	ZS8SL45	ZM9SL45
SL5.0	ZM6SL50	ZT7SL50	ZS8SL50	ZM9SL50
SL6.0	ZM6SL60	ZT7SL60	ZS8SL60	ZM9SL60

CORONARY GUIDE CATHETERS

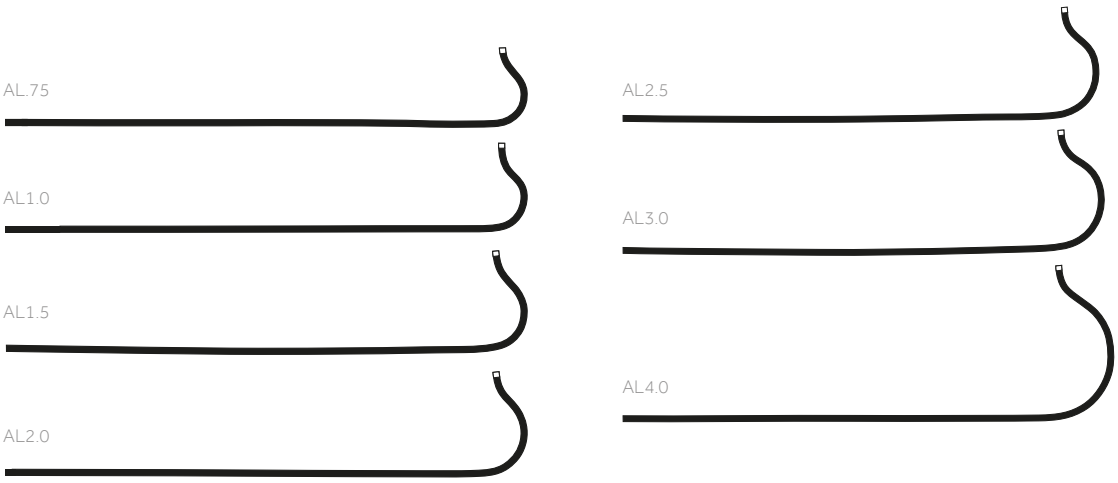
Zuma™
Amplatz Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



AMPLATZ LEFT

	6F CODE	7F CODE	8F CODE	9F CODE
AL75	ZM6AL75	ZT7AL75	ZS8AL75	ZM9AL75
AL1.0	ZM6AL10	ZT7AL10	ZS8AL10	ZM9AL10
AL1.5	ZM6AL15	ZT7AL15	ZS8AL15	ZM9AL15
AL2.0	ZM6AL20	ZT7AL20	ZS8AL20	ZM9AL20
AL2.5	ZM6AL25	ZT7AL25	ZS8AL25	ZM9AL25
AL3.0	ZM6AL30	ZT7AL30	ZS8AL30	ZM9AL30
AL4.0	ZM6AL40	ZT7AL40	ZS8AL40	ZM9AL40

CORONARY GUIDE CATHETERS

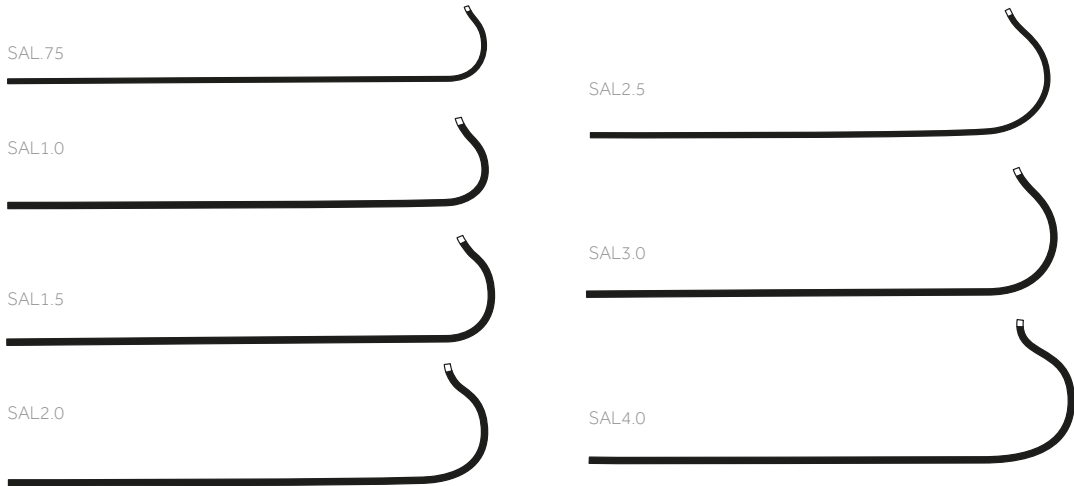
Zuma™
Short Amplatz Left Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



SHORT TIP
AMPLATZ LEFT

	6F CODE	7F CODE	8F CODE	9F CODE
SAL75	ZM6SAL75	ZT7SAL75	ZS8SAL75	ZM9SAL75
SAL1.0	ZM6SAL10	ZT7SAL10	ZS8SAL10	ZM9SAL10
SAL1.5	ZM6SAL15	ZT7SAL15	ZS8SAL15	ZM9SAL15
SAL2.0	ZM6SAL20	ZT7SAL20	ZS8SAL20	ZM9SAL20
SAL2.5	ZM6SAL25	ZT7SAL25	ZS8SAL25	ZM9SAL25
SAL3.0	ZM6SAL30	ZT7SAL30	ZS8SAL30	ZM9SAL30
SAL4.0	ZM6SAL40	ZT7SAL40	ZS8SAL40	ZM9SAL40

CORONARY GUIDE CATHETERS

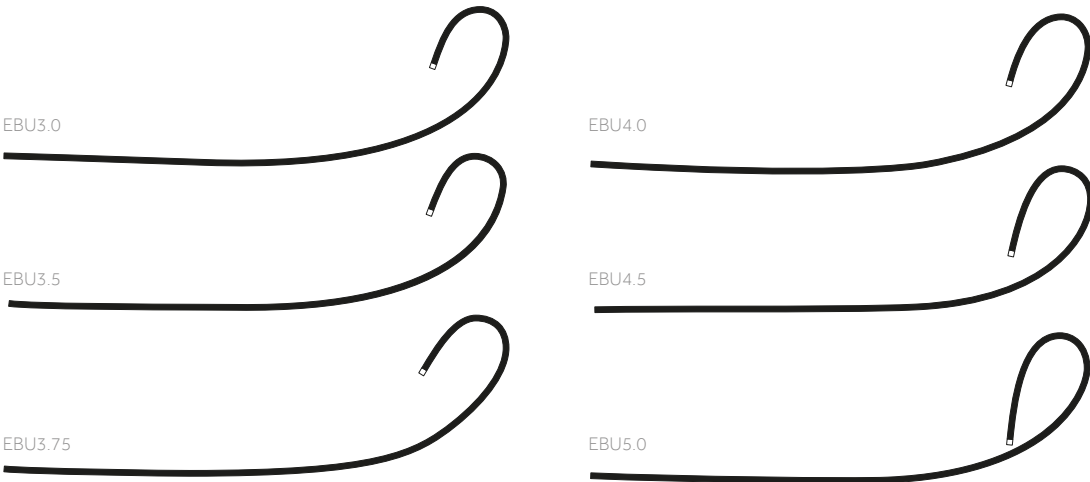
Zuma™
Left Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



EBU (EXTRA
BACKUP)

	6F CODE	7F CODE	8F CODE	9F CODE
EBU3.0	ZM6EBU30	ZT7EBU30	ZS8EBU30	ZM9EBU30
EBU3.5	ZM6EBU35	ZT7EBU35	ZS8EBU35	ZM9EBU35
EBU3.75	ZM6EBU375	ZT7EBU375	ZS8EBU375	ZM9EBU375
EBU4.0	ZM6EBU40	ZT7EBU40	ZS8EBU40	ZM9EBU40
EBU4.5	ZM6EBU45	ZT7EBU45	ZS8EBU45	ZM9EBU45
EBU5.0	ZM6EBU50	ZT7EBU50	ZS8EBU50	ZM9EBU50

CORONARY GUIDE CATHETERS

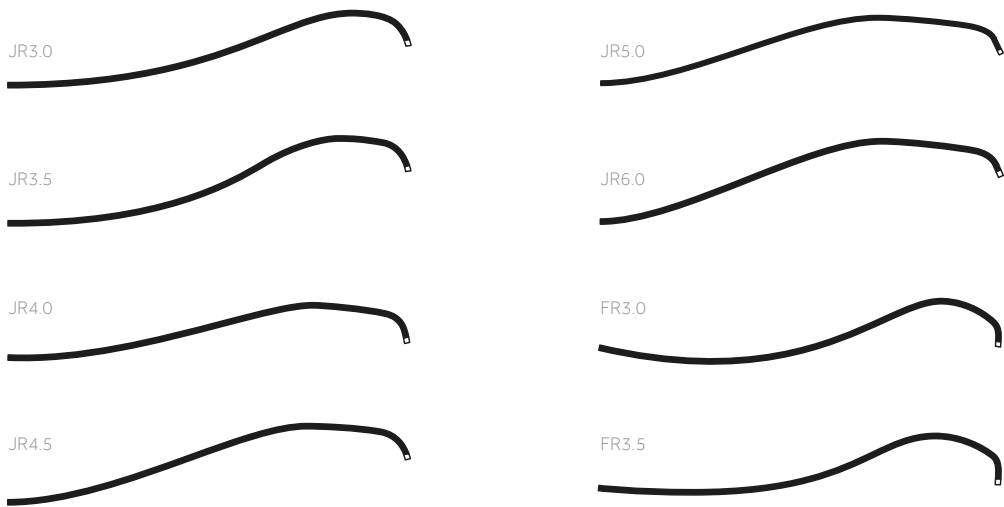
Zuma™
Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



RIGHT CORONARY
CURVE

	6F CODE	7F CODE	8F CODE	9F CODE
JR3.0	ZM6JR30	ZT7JR30	ZS8JR30	ZM9JR30
JR3.5	ZM6JR35	ZT7JR35	ZS8JR35	ZM9JR35
JR4.0	ZM6JR40	ZT7JR40	ZS8JR40	ZM9JR40
JR4.5	ZM6JR45	ZT7JR45	ZS8JR45	ZM9JR45
JR5.0	ZM6JR50	ZT7JR50	ZS8JR50	ZM9JR50
JR6.0	ZM6JR60	ZT7JR60	ZS8JR60	ZM9JR60
FR3.0	ZM6FR30	ZT7FR30	ZS8FR30	ZM9FR30
FR3.5	ZM6FR35	ZT7FR35	ZS8FR35	ZM9FR35

CORONARY GUIDE CATHETERS

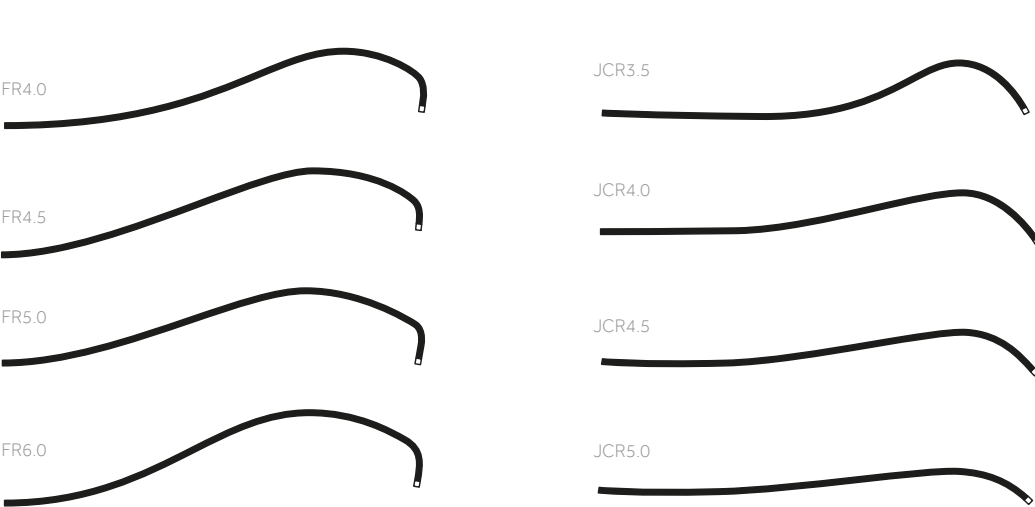
Zuma™
Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



RIGHT CORONARY
CURVE

	6F CODE	7F CODE	8F CODE	9F CODE
FR4.0	ZM6FR40	ZT7FR40	ZS8FR40	ZM9FR40
FR4.5	ZM6FR45	ZT7FR45	ZS8FR45	ZM9FR45
FR5.0	ZM6FR50	ZT7FR50	ZS8FR50	ZM9FR50
FR6.0	ZM6FR60	ZT7FR60	ZS8FR60	ZM9FR60
JCR3.5	ZM6JCR35	ZT7JCR35	ZS8JCR35	ZM9JCR35
JCR4.0	ZM6JCR40	ZT7JCR40	ZS8JCR40	ZM9JCR40
JCR4.5	ZM6JCR45	ZT7JCR45	ZS8JCR45	ZM9JCR45
JCR5.0	ZM6JCR50	ZT7JCR50	ZS8JCR50	ZM9JCR50

CORONARY GUIDE CATHETERS

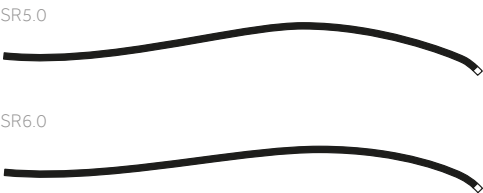
Zuma™
Short Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



SHORT TIP RIGHT
CORONARY

	6F CODE	7F CODE	8F CODE	9F CODE
SR3.0	ZM6SR30	ZT7SR30	ZS8SR30	ZM9SR30
SR3.5	ZM6SR35	ZT7SR35	ZS8SR35	ZM9SR35
SR4.0	ZM6SR40	ZT7SR40	ZS8SR40	ZM9SR40
SR4.5	ZM6SR45	ZT7SR45	ZS8SR45	ZM9SR45
SR5.0	ZM6SR50	ZT7SR50	ZS8SR50	ZM9SR50
SR6.0	ZM6SR60	ZT7SR60	ZS8SR60	ZM9SR60

CORONARY GUIDE CATHETERS

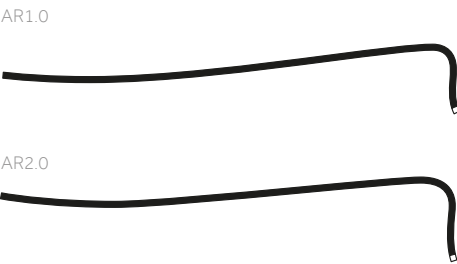
Zuma™
Amplatz Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



AMPLATZ RIGHT

	6F CODE	7F CODE	8F CODE	9F CODE
AR1.0	ZM6AR10	ZT7AR10	ZS8AR10	ZM9AR10
AR2.0	ZM6AR20	ZT7AR20	ZS8AR20	ZM9AR20
ALR1-2	ZM6ALR12	ZT7ALR12	ZS8ALR12	ZM9ALR12

CORONARY GUIDE CATHETERS

Zuma™
Short Amplatz Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use

SAR1.0



SAR2.0



SHORT TIP
AMPLATZ RIGHT

	6F CODE	7F CODE	8F CODE	9F CODE
SAR1.0	ZM6SAR10	ZT7SAR10	ZS8SAR10	ZM9SAR10
SAR2.0	ZM6SAR20	ZT7SAR20	ZS8SAR20	ZM9SAR20

CORONARY GUIDE CATHETERS

Zuma™
Shepherd’s Crook Right Coronary Curve

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use

SCR3.5



SCR4.0



SCR5.0



SHEPHERD’S
CROOK
RIGHT

	6F CODE	7F CODE	8F CODE	9F CODE
SCR3.5	ZM6SCR35	ZT7SCR35	ZS8SCR35	ZM9SCR35
SCR4.0	ZM6SCR40	ZT7SCR40	ZS8SCR40	ZM9SCR40
SCR5.0	ZM6SCR50	ZT7SCR50	ZS8SCR50	ZM9SCR50

CORONARY GUIDE CATHETERS

Zuma™
Right Coronary Backup Support

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



LEFT CORONARY

	6F CODE	7F CODE	8F CODE	9F CODE
NO TORQUE Right	ZM6NOTO	ZT7NOTO	ZS8NOTO	ZM9NOTO

CORONARY GUIDE CATHETERS

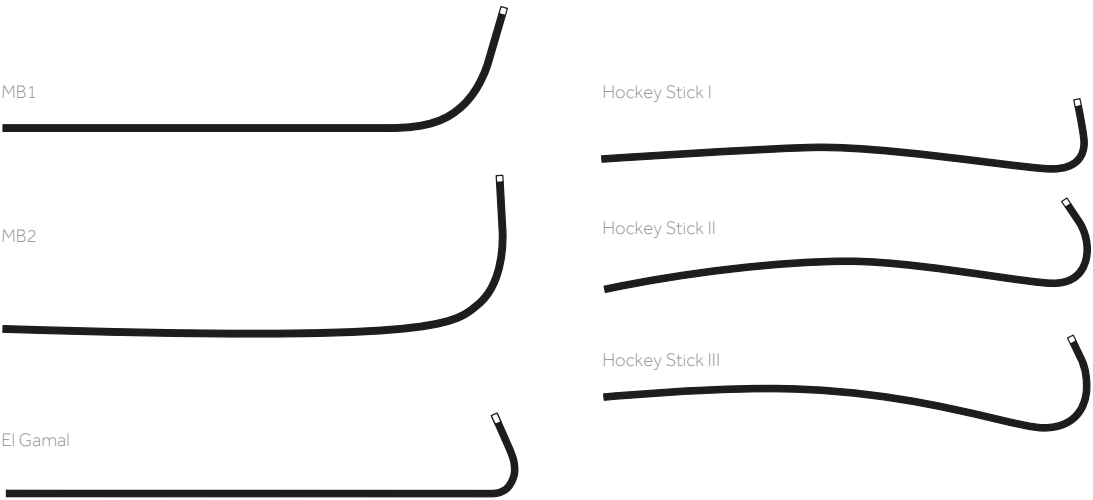
Zuma™
Multipurpose Curves

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



MULTIPURPOSE

	6F CODE	7F CODE	8F CODE	9F CODE
MB1	ZM6MB10	ZT7MB1	ZS8MB1	ZM9MB1
MB2	ZM6MB2	ZT7MB2	ZS8MB2	ZM9MB2
Hockey Stick I	ZM6HSI	ZT7HSI	ZS8HSI	ZM9HSI
Hockey Stick II	ZM6HSII	ZT7HSII	ZS8HSII	ZM9HSII
Hockey Stick III	ZM6HSIII	ZT7HSIII	ZS8HSIII	ZM9HSIII
El Gamal	ZM6ELGAMAL	ZT7ELGAMAL	ZS8ELGAMAL	ZM9ELGAMAL

CORONARY GUIDE CATHETERS

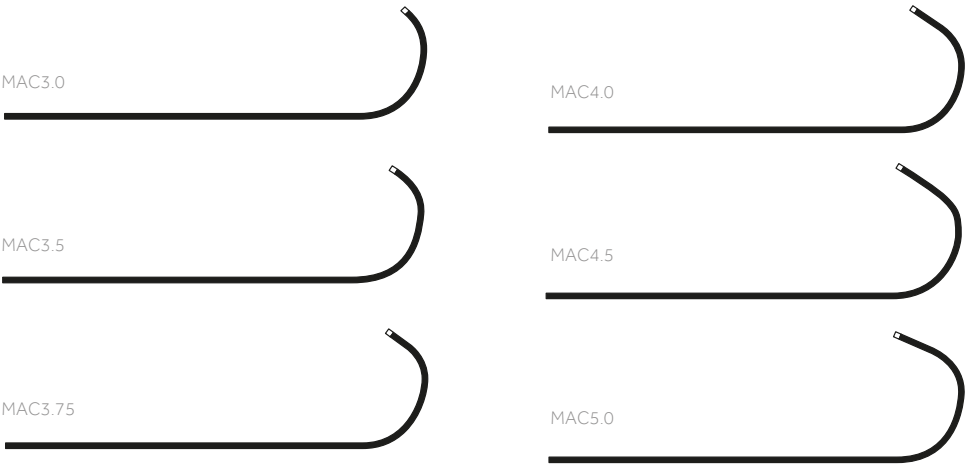
Zuma™
Other Curves

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



MAC (MULTI-
AORTIC CURVES)

	6F CODE	7F CODE	8F CODE	9F CODE
MAC3.0	ZM6MAC30	ZT7MAC30	ZS8MAC30	ZM9MAC30
MAC3.5	ZM6MAC35	ZT7MAC35	ZS8MAC35	ZM9MAC35
MAC3.75	ZM6MAC375	ZT7MAC375	ZS8MAC375	ZM9MAC375
MAC4.0	ZM6MAC40	ZT7MAC40	ZS8MAC40	ZM9MAC40
MAC4.5	ZM6MAC45	ZT7MAC45	ZS8MAC45	ZM9MAC45
MAC5.0	ZM6MAC50	ZT7MAC50	ZS8MAC50	ZM9MAC50

CORONARY GUIDE CATHETERS

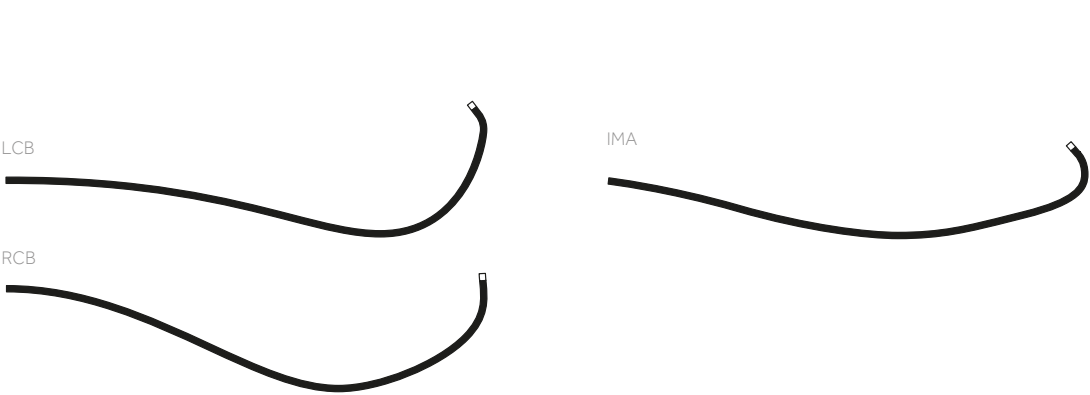
Zuma™
Bypass Curves

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey,
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

Supportive stiff guide for passive use



BYPASS GRAFTS

	6F CODE	7F CODE	8F CODE	9F CODE
LCB	ZM6LCB	ZT7LCB	ZS8LCB	ZM9LCB
RCB	ZM6RCB	ZT7RCB	ZS8RCB	ZM9RCB
RCB (90 cm)	ZM6RCBD	ZT7RCBD	ZS8RCBD	ZM9RCBD
IMA	ZM6IMA	ZT7IMA	ZS8IMA	ZM9IMA
IMA (90 cm)	ZM6IMAD	ZT7IMAD	ZS8IMAD	ZM9IMAD

CORONARY GUIDE CATHETERS

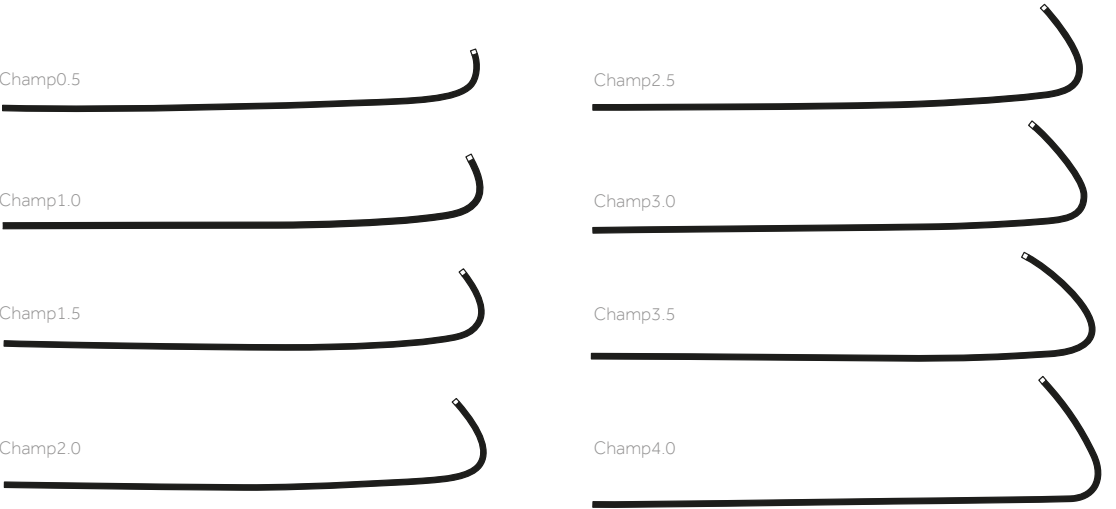
Zuma™
Other Curves

GENERAL
CHARACTERISTICS

- Supplied sterile Items per box: 1
- Label colour: 6F = Green, 7F = Orange, 8F = Blue, 9F = Grey.
- Lumen inner diameter: 6F = 0.068", 7F = 0.081", 8F = 0.091", 9F = 0.103"

PRODUCT
DESCRIPTION

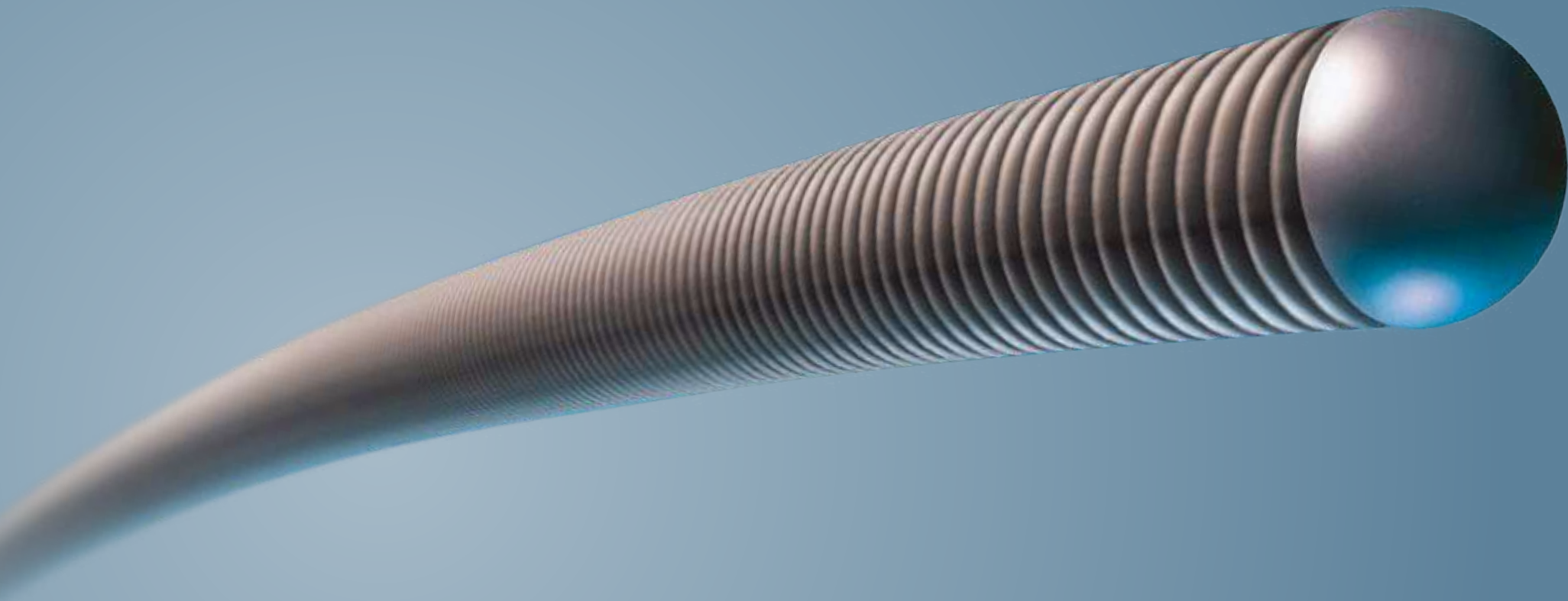
Supportive stiff guide for passive use



CHAMP

	6F CODE	7F CODE	8F CODE	9F CODE
CHAMP 0.5	Z26CHAMP05	ZT7CHAMP05	ZS8CHAMP05	ZM9CHAMP05
CHAMP 10	Z26CHAMP10	ZT7CHAMP10	ZS8CHAMP10	ZM9CHAMP10
CHAMP 15	Z26CHAMP15	ZT7CHAMP15	ZS8CHAMP15	ZM9CHAMP15
CHAMP 20	Z26CHAMP20	ZT7CHAMP20	ZS8CHAMP20	ZM9CHAMP20
CHAMP 25	Z26CHAMP25	ZT7CHAMP25	ZS8CHAMP25	ZM9CHAMP25
CHAMP 30	Z26CHAMP30	ZT7CHAMP30	ZS8CHAMP30	—
CHAMP 35	Z26CHAMP35	ZT7CHAMP35	ZS8CHAMP35	ZM9CHAMP35
CHAMP 40	Z26CHAMP40	ZT7CHAMP40	ZS8CHAMP40	ZM9CHAMP40

INTERVENTIONAL GUIDEWIRES



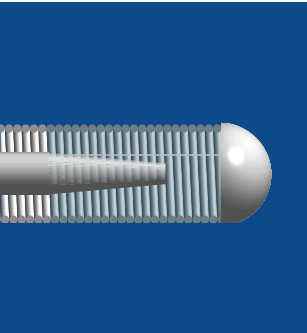
CONTENTS	1. DRUG ELUTING STENTS	2. DRUG METAL STENTS	3. BALLOON DILATION CATHETERS	4. DRUG ELUTING BALLOONS	5. GUIDE CATHETER FAMILY	6. INTERVENTIONAL GUIDEWIRES	7. ASPIRATION CATHETERS	8. ANGIOGRAPHIC CATHETERS AND WIRES	9. INTRODUCERS	10. INTERVENTIONAL ACCESSORIES	11. PEDIATRIC AND TRANSSEPTAL PRODUCTS	12. RENAL DENERVATION
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GUIDEWIRE FAMILY

Medtronic offers a wide array of guidewires to support different clinical needs

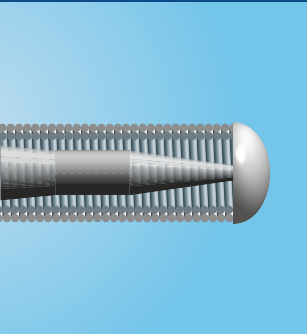
ZINGER™ Stainless steel workhorse guidewire

- When you need steerability and torque control
- Stainless steel core wire provides torque transmission for advanced steerability and control. Available in a range of support levels for a variety of clinical situations: light, marker, medium and support.



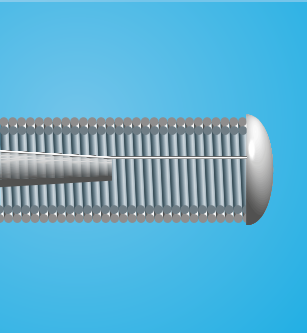
INTUITION™ Advanced workhorse guidewire

- Confidently cross your more challenging workhorse cases
- Torque performance and one-gram tip weight give you precision and confidence during your more difficult workhorse cases. Accu-Core Technology provides torque and improved crossability.



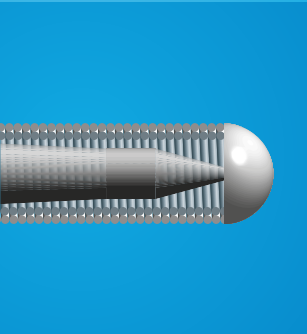
COUGAR™ Nitinol workhorse guidewire

- When you need trackability for distal and tortuous access
- Nitinol core wire provides steerability and support through tortuous anatomy and for multivessel treatment. Double coil tip is soft and atraumatic for shape retention.



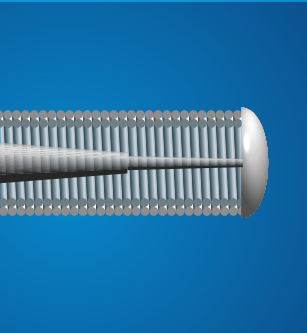
PROVIA™ Crossing guidewire

- Designed to cross your most demanding lesions
- Available in a wide range of weights and lengths. Accu-Core Technology offers torque performance, tactile feel, improved lesion penetration and a 1-mm nonhydrophilic tip.



THUNDER™ Extra-support guidewire

- When you need extra support
- Stainless steel, core-to-tip design provides torque, tip control and steering for situations requiring extra support.



INTERVENTIONAL GUIDEWIRES

Zinger™ Light
Stainless steel workhorse guidewire

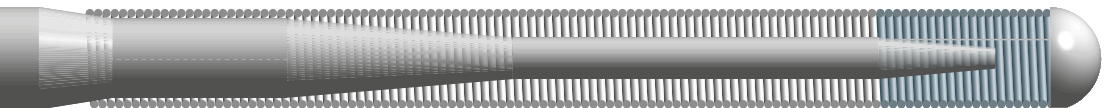
GENERAL CHARACTERISTICS

• Supplied sterile • Items per box: 5

PRODUCT DESCRIPTION

The Zinger™ line of guidewires is the latest advancement in highly trackable guidewires with excellent torque control.

- Available with Pro/Pel™ silicone coating or Hydro-Track™ hydrophilic coating for more treatment strategies.
- Zinger™ is available in various support levels as well as a marker version to meet your preference and clinical challenge.
- 2-cm radiopaque tip for visibility.
- Zinger™ Light is a highly trackable light support guidewire with floppy tip for tortuous anatomy.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
ZINGER LS	ZNGRLS180HS	180	Hydro-Track	Straight tip
ZINGER LS	ZNGRLS180S	180	Pro/Pel	Straight tip
ZINGER LS	ZNGRLS180HJ	180	Hydro-Track	J-tip
ZINGER LS	ZNGRLS180J	180	Pro/Pel	J-tip
ZINGER LS	ZNGRLS300HS	300	Hydro-Track	Straight tip
ZINGER LS	ZNGRLS300S	300	Pro/Pel	Straight tip
ZINGER LS	ZNGRLS300HJ	300	Hydro-Track	J-tip
ZINGER LS	ZNGRLS300J	300	Pro/Pel	J-tip

Tip style:	Forming ribbon
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness	Support
	

INTERVENTIONAL GUIDEWIRES

Zinger™ Marker Stainless steel workhorse guidewire

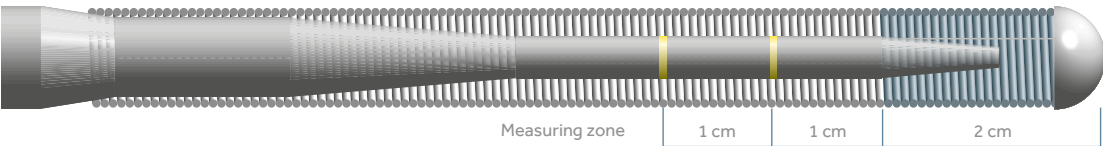
GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 5

PRODUCT DESCRIPTION

The Zinger™ line of guidewires is the latest advancement in highly trackable guidewires with excellent torque control.

- The Hydro-track hydrophilic coating offers optimal lubricity and durability.
- Zinger™ is available in various support levels as well as a marker version to meet your preference and clinical challenge.
- Zinger™ Marker is a light support guidewire with two radiopaque markers for reference measure of vessels and lesions.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
ZINGER MK	ZNGRMK180HS	180	Hydro-Track	Straight tip
ZINGER MK	ZNGRMK180S	180	Pro/Pel	Straight tip
ZINGER MK	ZNGRMK180HJ	180	Hydro-Track	J-tip
ZINGER MK	ZNGRMK180J	180	Pro/Pel	J-tip
ZINGER MK	ZNGRMK300HS	300	Hydro-Track	Straight tip
ZINGER MK	ZNGRMK300S	300	Pro/Pel	Straight tip
ZINGER MK	ZNGRMK300HJ	300	Hydro-Track	J-tip
ZINGER MK	ZNGRMK300J	300	Pro/Pel	J-tip

Tip style:	Forming ribbon
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness Support



INTERVENTIONAL GUIDEWIRES

Zinger™ Medium Stainless steel workhorse guidewire

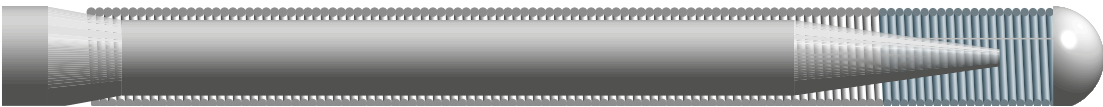
GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 5

PRODUCT DESCRIPTION

The Zinger™ line of guidewires is the latest advancement in highly trackable guidewires with excellent torque control.

- The Hydro-track hydrophilic coating offers optimal lubricity and durability.
- Zinger™ is available in various support levels as well as a marker version to meet your preference and clinical challenge.
- Zinger™ Medium is a medium weight "workhorse" wire, ideal for general use in varied anatomy.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
ZINGER MS	ZNGRMS180HS	180	Hydro-Track	Straight tip
ZINGER MS	ZNGRMS180S	180	Pro/Pel	Straight tip
ZINGER MS	ZNGRMS180HJ	180	Hydro-Track	J-tip
ZINGER MS	ZNGRMS180J	180	Pro/Pel	J-tip
ZINGER MS	ZNGRMS300HS	300	Hydro-Track	Straight tip
ZINGER MS	ZNGRMS300S	300	Pro/Pel	Straight tip
ZINGER MS	ZNGRMS300HJ	300	Hydro-Track	J-tip
ZINGER MS	ZNGRMS300J	300	Pro/Pel	J-tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness Support



INTERVENTIONAL GUIDEWIRES

Zinger™ Support Stainless steel workhorse guidewire

GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 5

PRODUCT DESCRIPTION

The Zinger™ line of guidewires is the latest advancement in highly trackable guidewires with excellent torque control.

- The Hydro-track hydrophylic coating offers optimal lubricity and durability.
- Zinger™ is available in various support levels as well as a marker version to meet your preference and clinical challenge.
- Zinger™ Support is designed with added support for stent placement, yet trackable.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
ZINGER S	ZNGRS180HS	180	Hydro-Track	Straight tip
ZINGER S	ZNGRS180S	180	Pro/Pel	Straight tip
ZINGER S	ZNGRS180HJ	180	Hydro-Track	J-tip
ZINGER S	ZNGRS180J	180	Pro/Pel	J-tip
ZINGER S	ZNGRS300HS	300	Hydro-Track	Straight tip
ZINGER S	ZNGRS300S	300	Pro/Pel	Straight tip
ZINGER S	ZNGRS300HJ	300	Hydro-Track	J-tip
ZINGER S	ZNGRS300J	300	Pro/Pel	J-tip

Tip style:	Forming ribbon
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness



Support



INTERVENTIONAL GUIDEWIRES

Intuition™ Advanced workhorse guidewire

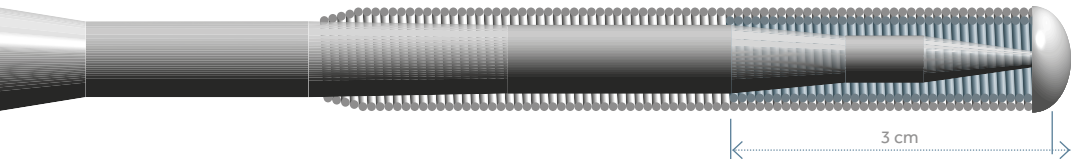
GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 5

PRODUCT DESCRIPTION

The Intuition™ guidewire offers torque performance and one-gram tip weight to give precision and confidence during more difficult workhorse cases.

- Rounded tip and body provide control.
- Accu-Core technology provides torque performance to control and direct the wire.
- Femoral (proximal) markers on wire, 90 cm and 100 cm from distal tip.
- Available with Pro/Pel™ silicone coating or Hydro-Track™ hydrophilic coating for more treatment strategies.
- 3-cm radiopaque tip for visibility.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
Intuition	INTU180HS	180	Hydro-Track	Straight tip
Intuition	INTU180SS	180	Pro/Pel	Straight tip
Intuition	INTU300HS	300	Hydro-Track	Straight tip
Intuition	INTU300SS	300	Pro/Pel	Straight tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness



Support



INTERVENTIONAL GUIDEWIRES

Cougar™ LS Nitinol workhorse guidewire

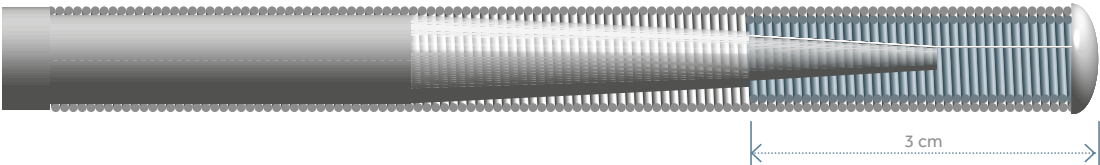
GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 5

PRODUCT DESCRIPTION

The Cougar™ Steerable Guidewire offers the performance and support required for workhorse cases.

- Nitinol core wire
- Double coil tip design offers a soft tip with outstanding tip shape retention.
- Available in Hydro-Track™ hydrophilic or Pro/Pel™ silicone coating. The Hydro-Track hydrophilic coating offers optimal lubricity and durability.
- The Pro/Pel silicone coating offers traditional performance for situations that require reduced lubricity.
- 3-cm radiopaque tip for visibility.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
Cougar LS	CGRLS190HS	190 cm	Hydro-Track	Straight tip
Cougar LS	CGRLS190S	190 cm	Pro/Pel	Straight tip
Cougar LS	CGRLS190HJ	190 cm	Hydro-Track	J-tip
Cougar LS	CGRLS190J	190 cm	Pro/Pel	J-tip
Cougar LS	CGRLS300HS	300 cm	Hydro-Track	Straight tip
Cougar LS	CGRLS300S	300 cm	Pro/Pel	Straight tip
Cougar LS	CGRLS300HJ	300 cm	Hydro-Track	J-tip
Cougar LS	CGRLS300J	300 cm	Pro/Pel	J-tip

Tip style:	Forming ribbon
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness Support



INTERVENTIONAL GUIDEWIRES

Cougar™ XT Nitinol workhorse guidewire

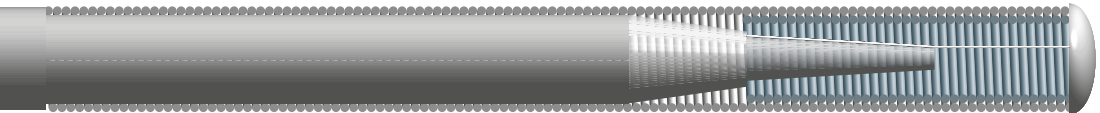
GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 5

PRODUCT DESCRIPTION

The Cougar™ Steerable Guidewire offers the performance and support required for workhorse cases.

- Nitinol core wire
- Double coil tip design offers a soft tip with outstanding tip shape retention.
- Available in Hydro-Track™ hydrophilic or Pro/Pel™ silicone coating. The Hydro-Track hydrophilic coating offers optimal lubricity and durability.
- The Pro/Pel silicone coating offers traditional performance for situations that require reduced lubricity.
- 3-cm radiopaque tip for visibility.



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
Cougar XT	CGRXT190HS	190 cm	Hydro-Track	Straight tip
Cougar XT	CGRXT190S	190 cm	Pro/Pel	Straight tip
Cougar XT	CGRXT190HJ	190 cm	Hydro-Track	J-tip
Cougar XT	CGRXT190J	190 cm	Pro/Pel	J-tip
Cougar XT	CGRXT300HS	300 cm	Hydro-Track	Straight tip
Cougar XT	CGRXT300S	300 cm	Pro/Pel	Straight tip
Cougar XT	CGRXT300HJ	300 cm	Hydro-Track	J-tip
Cougar XT	CGRXT300J	300 cm	Pro/Pel	J-tip

Tip style:	Forming ribbon
Outer coating:	Hydro-Track or Pro/Pel

Tip Stiffness Support



INTERVENTIONAL GUIDEWIRES

ProVia™ Crossing guidewire

GENERAL CHARACTERISTICS

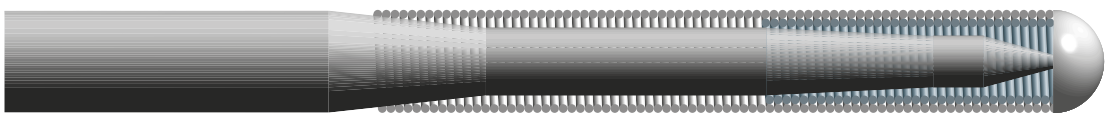
- Supplied sterile
- Items per box: 5

PRODUCT DESCRIPTION

- The ProVia™ Crossing Guidewire is designed to cross demanding lesions.
- Accu-Core wire technology is designed to provide torque performance to control and direct the wire.
 - Rounded tip and body provide control.
 - Tapered tip on ProVia™ 9 and 12 wires.
 - 1-mm noncoated tip on the hydrophilic version.
 - Femoral (proximal) markers on wire, 90 cm and 100 cm from distal tip.
 - Available in Hydro-Track™ hydrophilic or Pro/Pel™ silicone coating. The Hydro-Track hydrophilic coating offers optimal lubricity and durability.
 - The Pro/Pel silicone coating offers traditional performance for situations that require reduced lubricity.
 - 3-cm radiopaque tip for visibility

ProVia™ 3

Straight tip (0.014 in.)



ORDERING INFORMATION

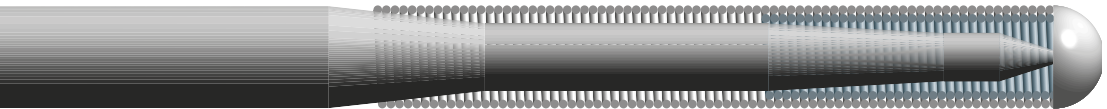
PRODUCT	PRODUCT CODE	SIZE (G)	LENGTH (CM)	COATING	TIP
ProVia 3	3PROV180HS	3	180	Hydro-Track	Straight tip
ProVia 3	3PROV180SS	3	180	Pro/Pel	Straight tip
ProVia 3	3PROV300HS	3	300	Hydro-Track	Straight tip
ProVia 3	3PROV300SS	3	300	Pro/Pel	Straight tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel



ProVia™ 6

Straight tip (0.014 in.)



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	SIZE (G)	LENGTH (CM)	COATING	TIP
ProVia 6	6PROV180HS	6	180	Hydro-Track	Straight tip
ProVia 6	6PROV180SS	6	180	Pro/Pel	Straight tip
ProVia 6	6PROV300HS	6	300	Hydro-Track	Straight tip
ProVia 6	6PROV300SS	6	300	Pro/Pel	Straight tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel



INTERVENTIONAL GUIDEWIRES

ProVia™ Crossing guidewire

GENERAL CHARACTERISTICS

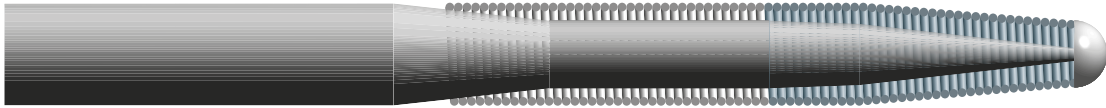
- Supplied sterile
- Items per box: 5

PRODUCT DESCRIPTION

- The ProVia™ Crossing Guidewire is designed to cross demanding lesions.
- Accu-Core wire technology is designed to provide torque performance to control and direct the wire.
 - Rounded tip and body provide control.
 - Tapered tip on ProVia™ 9 and 12 wires.
 - 1-mm noncoated tip on the hydrophilic version.
 - Femoral (proximal) markers on wire, 90 cm and 100 cm from distal tip.
 - Available in Hydro-Track™ hydrophilic or Pro/Pel™ silicone coating. The Hydro-Track hydrophilic coating offers optimal lubricity and durability.
 - The Pro/Pel silicone coating offers traditional performance for situations that require reduced lubricity.
 - 3-cm radiopaque tip for visibility

ProVia™ 9

Tapered tip (0.009 in.)



ORDERING INFORMATION

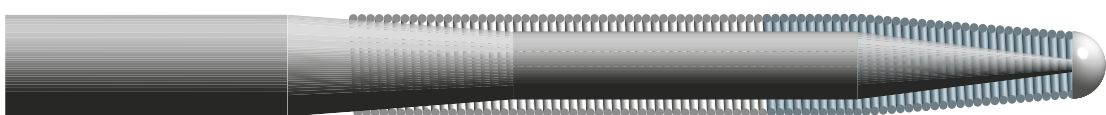
PRODUCT	PRODUCT CODE	SIZE (G)	LENGTH (CM)	COATING	TIP
ProVia 9	9PROV180HS	9	180	Hydro-Track	Tapered tip
ProVia 9	9PROV180SS	9	180	Pro/Pel	Tapered tip
ProVia 9	9PROV300HS	9	300	Hydro-Track	Tapered tip
ProVia 9	9PROV300SS	9	300	Pro/Pel	Tapered tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel



ProVia™ 12

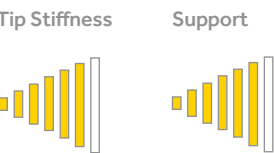
Tapered tip (0.009 in.)



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	SIZE (G)	LENGTH (CM)	COATING	TIP
ProVia 12	12PROV180HS	12	180	Hydro-Track	Tapered tip
ProVia 12	12PROV180SS	12	180	Pro/Pel	Tapered tip
ProVia 12	12PROV300HS	12	300	Hydro-Track	Tapered tip
ProVia 12	12PROV300SS	12	300	Pro/Pel	Tapered tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel



INTERVENTIONAL GUIDEWIRES

ProVia™ Crossing guidewire

GENERAL CHARACTERISTICS

• Supplied sterile • Items per box: 5

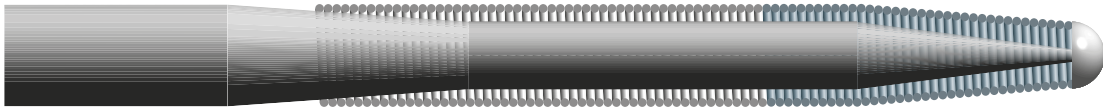
PRODUCT DESCRIPTION

The ProVia™ Crossing Guidewire is designed to cross demanding lesions.

- Accu-Core wire technology is designed to provide torque performance to control and direct the wire.
- Rounded tip and body provide control.
- Tapered tip on ProVia™ 9 and 12 wires.
- 1-mm noncoated tip on the hydrophilic version.
- Femoral (proximal) markers on wire, 90 cm and 100 cm from distal tip.
- Available in Hydro-Track™ hydrophilic or Pro/Pel™ silicone coating. The Hydro-Track hydrophilic coating offers optimal lubricity and durability.
- The Pro/Pel silicone coating offers traditional performance for situations that require reduced lubricity.
- 3-cm radiopaque tip for visibility

ProVia™ 15

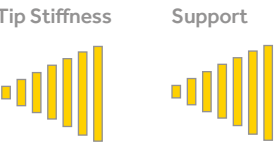
Tapered tip (0.009 in.)



ORDERING INFORMATION

PRODUCT	PRODUCT CODE	SIZE (G)	LENGTH (CM)	COATING	TIP
ProVia 15	15PROV180HS	15	180	Hydro-Track	Tapered tip
ProVia 15	15PROV180SS	15	180	Pro/Pel	Tapered tip
ProVia 15	15PROV300HS	15	300	Hydro-Track	Tapered tip
ProVia 15	15PROV300SS	15	300	Pro/Pel	Tapered tip

Tip style:	Core-to-tip
Outer coating:	Hydro-Track or Pro/Pel



INTERVENTIONAL GUIDEWIRES

Thunder™ Extra-Support guidewire

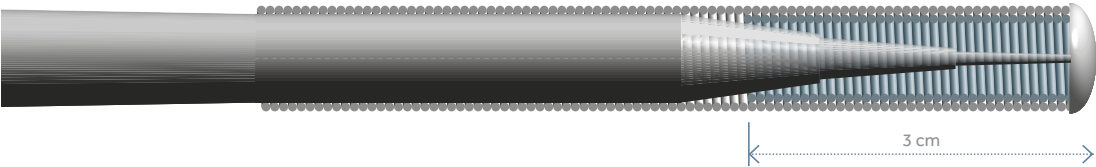
GENERAL CHARACTERISTICS

• Supplied sterile • Items per box: 5 • Label color: Silver

PRODUCT DESCRIPTION

The Thunder™ Guidewire has a stainless steel core-to-tip design which provides enhanced support and stability while maintaining excellent torque characteristics with precise tip control and steering.

- 11 cm transition zone (rail) which provides support for accurate device placement
- Available in Pro/Pel Silicone coating for track ability and smooth device delivery
- 3 cm Radiopaque Tip for visibility

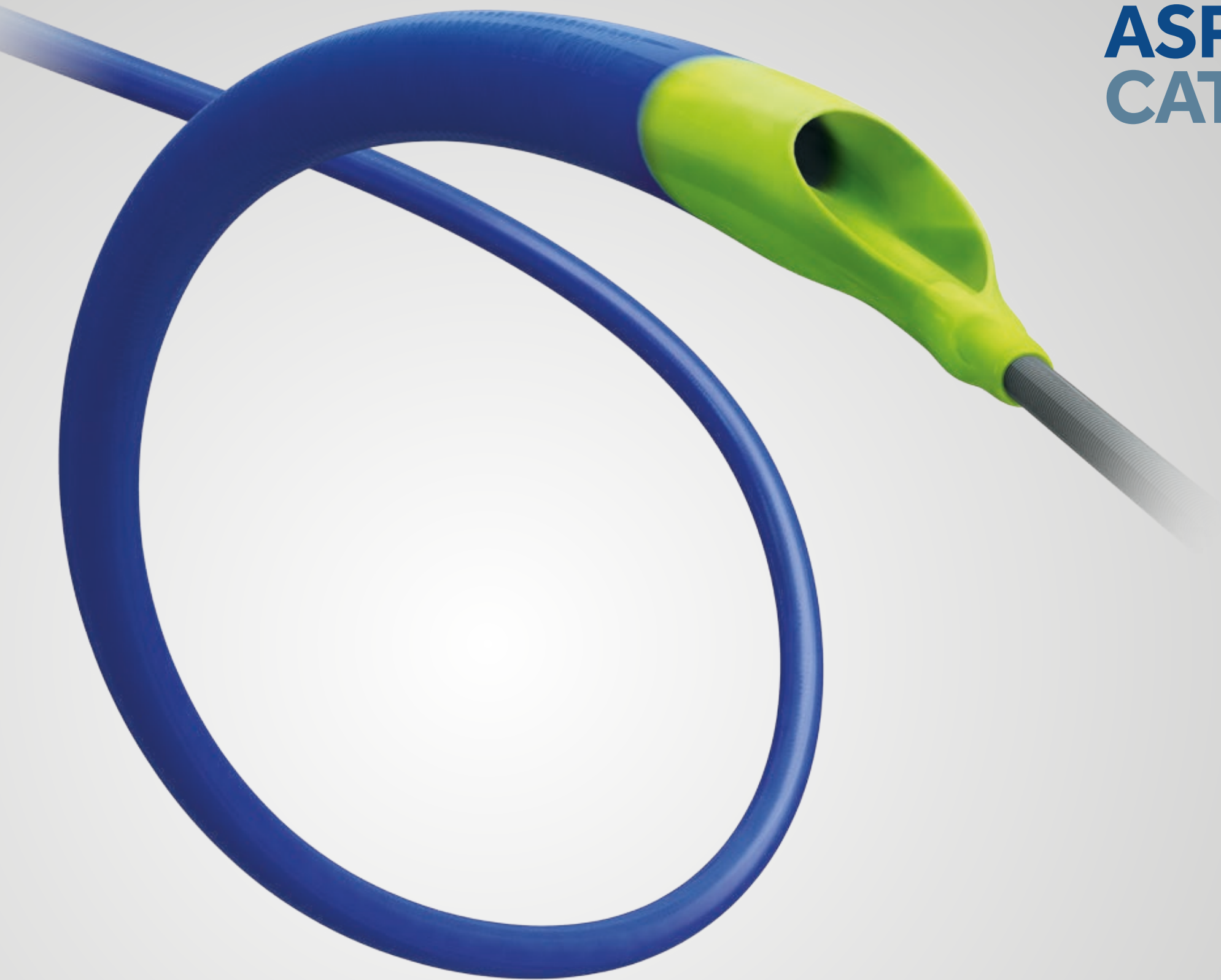


ORDERING INFORMATION

PRODUCT	PRODUCT CODE	LENGTH (CM)	COATING	TIP
THUNDER	THNDR190S	190	Pro/Pel	Straight tip
THUNDER	THNDR190J	190	Pro/Pel	J-tip
THUNDER	THNDR300S	300	Pro/Pel	Straight tip
THUNDER	THNDR300J	300	Pro/Pel	J-tip

Tip style:	Core-to-tip
Outer coating:	Pro/Pel





ASPIRATION CATHETERS

ASPIRATION CATHETERS

Export Advance™

GENERAL CHARACTERISTICS

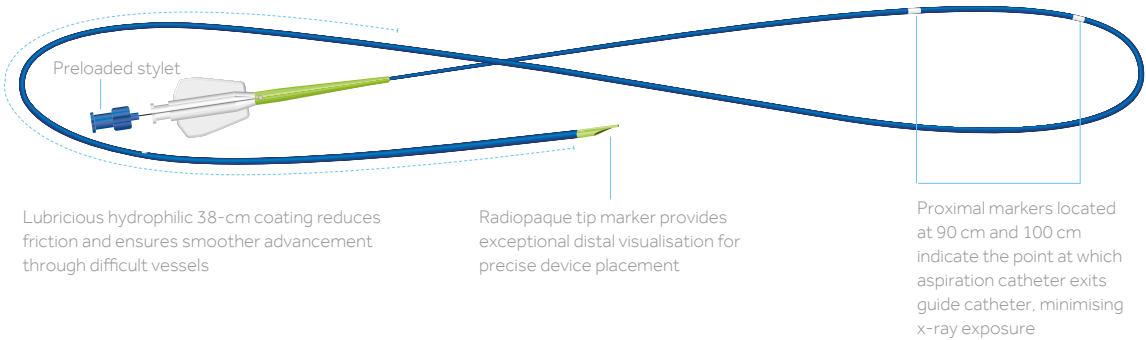
- Supplied sterile
- Items per box: 1
- Includes two syringes, one filter cup and extension line with stopcock.

PRODUCT DESCRIPTION

The Export Advance™ aspiration catheter features a preloaded stylet and manual locking syringe to remove embolic material throughout the arterial system.

FEATURES

- Full Wall Variable Braiding Technology shaft construction
- Preloaded stylet
- Buddy wire compatibility
- Large extraction lumen (0.044" proximal; 0.043" distal)
- Soft, short, forward-facing tip



TECHNICAL INFORMATION

Distal O.D. (in.)	0.067
Lumen I.D. (in.)	0.043 (distal), 0.044 (proximal)
Length (cm)	140
Braiding	Variable, hub to tip
Tip design	Soft, short, beveled tip
Coating	Hydrophilic (38 cm)
Syringe (cc)	2 x 30
Product code	ADVANCECE

ASPIRATION CATHETERS

Export™ AP

GENERAL CHARACTERISTICS

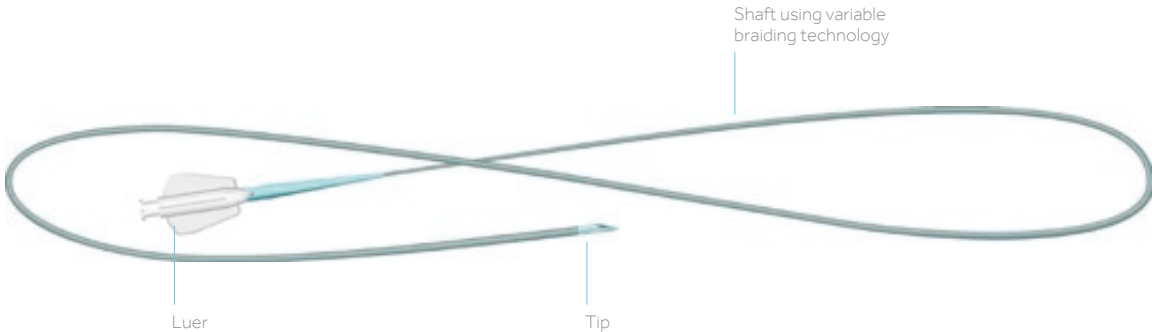
- Supplied sterile
- Items per box: 1
- Includes two syringes, one filter cup and extension line with stopcock.

PRODUCT DESCRIPTION

The Export™ AP aspiration catheter uses a manual locking syringe to remove embolic material throughout the arterial system.

FEATURES

- Full Wall Variable Braiding Technology shaft construction
- Extended hydrophilic coating (40 cm)
- Forward-facing atraumatic tip



TECHNICAL INFORMATION

Lumen I.D. (in.)	0.043
Lumen O.D. (in.)	0.068
Guide catheter compatibility (in.)	6F (min ID 0.070)
Guide wire compatibility (in.)	0.014
Delivery System	Rapid Exchange
Length (cm)	140
Radio-opaque marker	1.5 mm from distal tip
Product code	EXPORTAPCE

ASPIRATION CATHETERS

Export™ 7 F

GENERAL CHARACTERISTICS

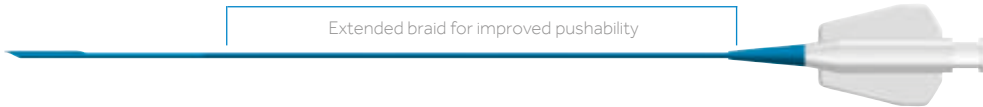
- Supplied sterile.
- Includes two syringes and two filters.

PRODUCT DESCRIPTION

The Export™ Aspiration Catheter uses a manual locking syringe to remove embolic material throughout the arterial system. Export™ 7 French delivers double the aspiration power.

FEATURES

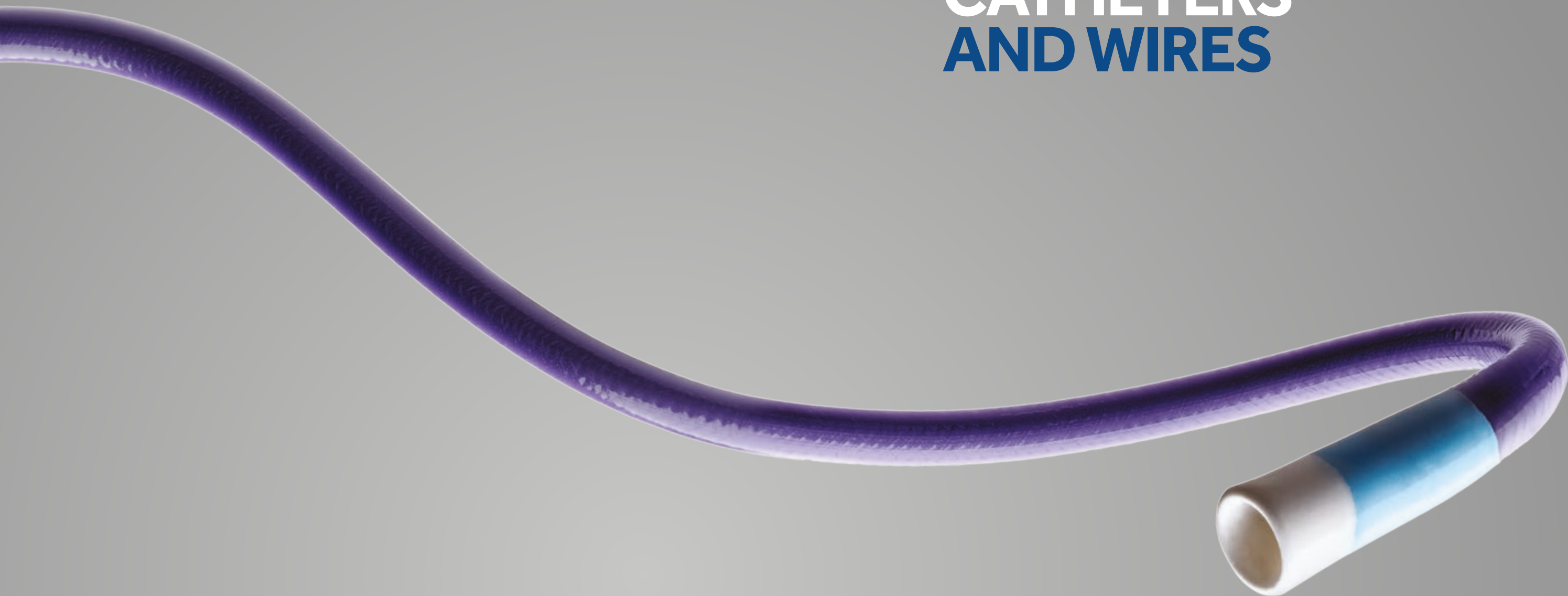
- Distal lumen (in.) 0.050
- Lumen O.D. (in) 0.078
- Guide catheter compatibility (in.) 7F (min ID 0.080)



TECHNICAL INFORMATION

PRODUCT CODE	GUIDE COMPATIBILITY (IN.)	WIRE COMPATIBILITY (IN.)	LENGTH (CM)
GEZ62007B	7F min. guide I.D. 0.080	0.014	145

ANGIOGRAPHIC CATHETERS AND WIRES



CORONARY DIAGNOSTIC CATHETERS

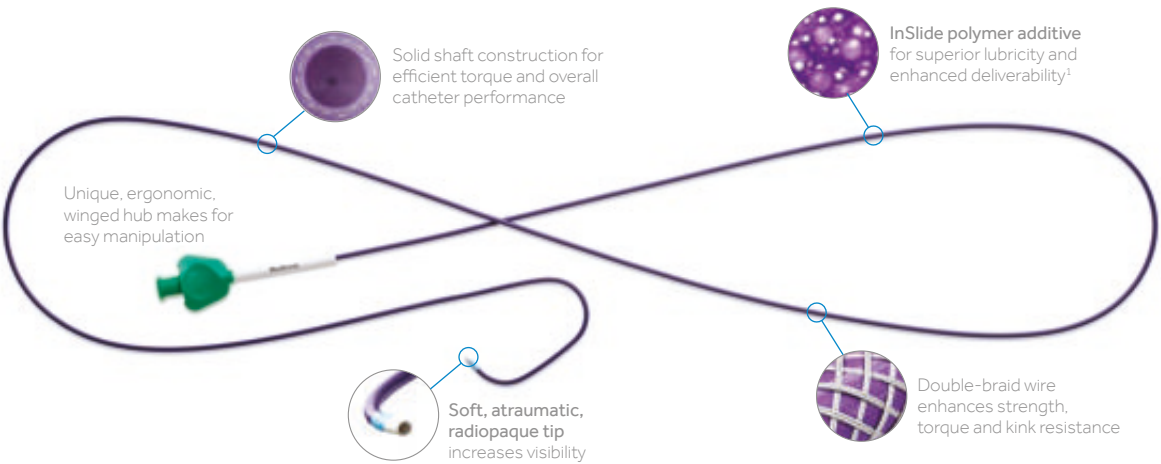
DxTerity™

PRODUCT DESCRIPTION

Features Full-Wall Technology: a proprietary extrusion process that melts layers together to form a solid shaft. This construction process is applied from hub to tip, providing the DxTerity diagnostic catheter with superior torque and lubricity for precise manipulation and enhanced deliverability.

PRODUCT FEATURES

- Enhanced deliverability:**
- InSlide™ polymer additive for superior lubricity to reduce friction and enhance deliverability
- Precise manipulation:**
- Unique, ergonomic, winged hub design for easy manipulation
 - Double-braid wire applied from hub to tip enhances strength, torque and kink resistance
- Excellent image quality:**
- Soft, atraumatic radiopaque tip allows for increased visibility
 - Large lumen enables high flow of contrast media to increase visualization
- Broad catheter portfolio:**
- Optimized for both radial and femoral procedures
 - Wide range of shapes and sizes
 - Includes expanded offerings of long (125 cm) lengths



TECHNICAL SPECIFICATIONS

	5F		6F	
Catheter O.D. (in)	0.066		0.079	
Lumen I.D. (in)	0.047		0.056	
Braiding	Hub to tip		Hub to tip	
Dye flow rate at:	600 psi	1200 psi	600 psi	1200 psi
(mL/sec)	19	27	28	40

1. Based on bench test data comparing leading competitors. Bench test data may not be indicative of clinical performance.

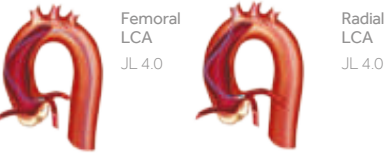
CORONARY DIAGNOSTIC CATHETERS

DxTerity™
Standard Curve Selection

LEFT CURVES

Judkins Left

Available in: 3.5, 4.0, 4.5, 5.0, 6.0



Amplatz Left

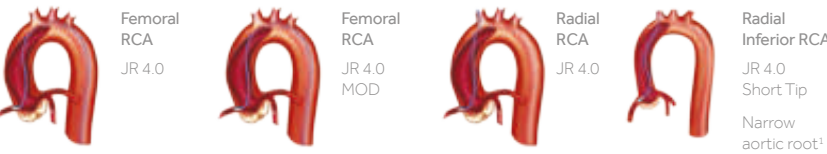
Available in: 1.0, 2.0, 3.0



RIGHT CURVES

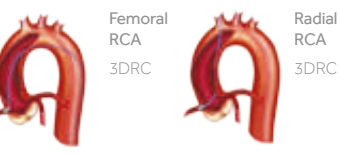
Judkins Right

Available in: 3.5, 4.0, 4.0 ST, 4.0 MOD, 5.0, 6.0



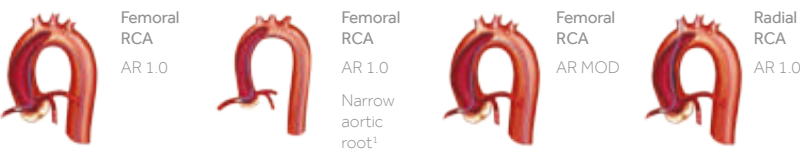
3DRC

One size



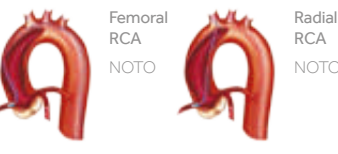
Amplatz Right

Available in: 1.0, 2.0, MOD



NOTO

One size



MULTIPURPOSE CURVES

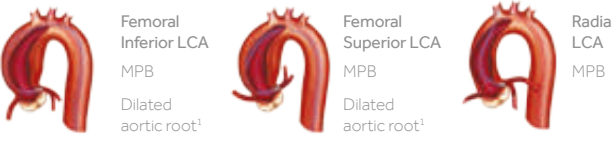
MPA

One size fits all



MPB

One size fits all



Normal anatomy is shown unless otherwise indicated.

1. In porcine models. Based on preclinical data on file at Medtronic.

CORONARY DIAGNOSTIC CATHETERS

DxTerity™
Standard Curve Selection

BYPASS CURVES

RCB
One size



Femoral SVG to RCA
RCB



Radial SVG to RCA
RCB

LCB
One size



Femoral SVG to LCX
LCB



Radial SVG to LCX
LCB

IMA
One size



Femoral IMA TO LAD
IMA



Radial IMA to LAD
IMA

PIGTAIL CURVES

Straight



Femoral Pigtail Straight



145°



Femoral Pigtail 145°



Radial Pigtail 145°

155°



Femoral Pigtail 155°



Radial Pigtail 155°

CORONARY DIAGNOSTIC CATHETERS

DxTerity™
Universal Radial Curve Selection

UNIVERSAL RADIAL CURVES

TRApease curve

Relaxed secondary curve allows for easy engagement of the coronary artery ostia. Includes additional tertiary curve for additional support.



TRAnsformer curve

Provides excellent support from theortic root and offers more reach to engage thcoronary artery ostia.



TRActive curve

30-degree soft tip after the primary curve, allowing it to engage the coronary artery ostia.



TRAcker curve

Provides excellent support from the contrateral wall and aortic root leverage.



TRApease Curve
Available in: 3.5, 4.0, 4.5

Radial LCA
TRApease 4.0



Radial RCA
TRApease 4.0



TRAnsformer Curve
Available in: 3.5, 4.0, 4.5

Radial LCA
TRAnsformer 3.5



Radial RCA
TRAnsformer 3.5



TRActive Curve
One size fits all

Radial LCA
TRActive



Radial RCA
TRActive



TRAcker Curve
One size fits all

Radial LCA
TRAcker



Radial RCA
TRAcker



1. Normal aortic root, 3.5–4.0 cm; narrow aortic root, <3.5 cm; dilated aortic root > 4.0 cm.

CORONARY DIAGNOSTIC CATHETERS

DxTerity™ Standard Curves

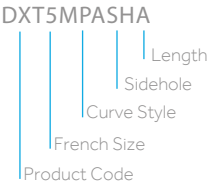
GENERAL CHARACTERISTICS

- 5 catheters per box • Supplied sterile • Color-coded hub and packaging
- Maximum guidewire: 5F = 0.038"; 6 F = 0.038"

PRODUCT DESCRIPTION

Features Full-Wall Technology: a proprietary extrusion process that melts layers together to form a solid shaft. This construction process is applied from hub to tip, providing the DxTerity diagnostic catheter with superior torque and lubricity for precise manipulation and enhanced deliverability.

PRODUCT CODE



ORDERING INFORMATION

CURVE STYLE	CURVE SIZE	LENGTH (CM)	5F PRODUCT CODE	6F PRODUCT CODE	SIDEHOLES
Judkins Left	JL3.5	100	DXT5JL35	DXT6JL35	0
	JL4.0	100	DXT5JL40	DXT6JL40	0
	JL4.0	125	DXT5JL40X	DXT6JL40X	0
	JL4.5	100	DXT5JL45	DXT6JL45	0
	JL4.5	125	DXT5JL45X	DXT6JL45X	0
	JL5.0	100	DXT5JL50	DXT6JL50	0
	JL5.0	125	DXT5JL50X	DXT6JL50X	0
	JL6.0	100	DXT5JL60	DXT6JL60	0
Judkins Right	JR3.5	100	DXT5JR35	DXT6JR35	0
	JR3.5	125	DXT5JR35X	DXT6JR35X	0
	JR4.0	100	DXT5JR40	DXT6JR40	0
	JR4.0	125	DXT5JR40X	DXT6JR40X	0
	JR4.0 MOD	100	DXT5JR4M	DXT6JR4M	0
	JR4.0 ST	100	DXT5JR4ST	DXT6JR4ST	0
	JR5.0	100	DXT5JR50	DXT6JR50	0
	JR5.0	125	DXT5JR50X	DXT6JR50X	0
Amplatz Left	JR6.0	100	DXT5JR60	DXT6JR60	0
	AL1.0	100	DXT5AL10	DXT6AL10	0
	AL2.0	100	DXT5AL20	DXT6AL20	0
Amplatz Right	AL3.0	100	DXT5AL30	DXT6AL30	0
	AR1.0	100	DXT5AR10	DXT6AR10	0
	AR2.0	100	DXT5AR20	DXT6AR20	0
	AR MOD	100	DXT5ARM	DXT6ARM	0
Multipurpose	MPA	100	DXT5MPA	DXT6MPA	0
	MPA	110	DXT5MPAA	DXT6MPAA	0
	MPA	100	DXT5MPASH	DXT6MPASH	2
	MPA	110	DXT5MPASHA	DXT6MPASHA	2
	MPB	100	DXT5MPB	DXT6MPB	0
	MPB	110	DXT5MPBA	DXT6MPBA	0
	MPB	100	DXT5MPBSH	DXT6MPBSH	2
	MPB	110	DXT5MPBSHA	DXT6MPBSHA	2
Specialty	NOTO	100	DXT5NOTO	DXT6NOTO	0
	3DRC	100	DXT53DRC	DXT63DRC	0
	RCB	100	DXT5RCB	DXT6RCB	0
	LCB	100	DXT5LCB	DXT6LCB	0
	IMA	100	DXT5IMA	DXT6IMA	0
Pigtails	PIG STR	110CM	DXT5PIGSTA	DXT6PIGSTA	6
	PIG STR	125CM	DXT5PIGSTX	DXT6PIGSTX	6
	PIG 145	110CM	DXT5PIG45A	DXT6PIG45A	6
	PIG 155	110CM	DXT5PIG55A	DXT6PIG55A	6

CORONARY DIAGNOSTIC CATHETERS

Packaging options for DxTerity™ Angio-kits Standard curve

GENERAL CHARACTERISTICS

- 5 catheters per box • Supplied sterile • Maximum guidewire: 5F = 0.038"; 6 F = 0.038"

PRODUCT DESCRIPTION

- Angio-kit contains:
- One Judkins Left 4.0 catheter (JL4.0)
 - One Judkins Right 4.0 catheter (JR 4.0)
 - One Straight or Angled Pigtail catheter

ORDERING INFORMATION

PRODUCT CODE	CURVES	LENGTH (CM)	SIZE
AKSTAN501	Judikins Left 4.0	100	5F
	Judkins Right 4.0	100	5F
	Straight Pigtail	110	5F
AKSTAN502	Judikins Left 4.0	100	5F
	Judkins Right 4.0	100	5F
	145 Pigtail	110	5F
AKSTAN601	Judikins Left 4.0	100	6F
	Judkins Right 4.0	100	6F
	Straight Pigtail	110	6F
AKSTAN602	Judikins Left 4.0	100	6F
	Judkins Right 4.0	100	6F
	145 Pigtail	110	6F

CORONARY DIAGNOSTIC CATHETERS

DxTerity™ Universal Radial Curves

GENERAL CHARACTERISTICS

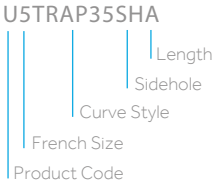
• 5 catheters per box • Supplied sterile • Color-coded hub and packaging • Maximum guidewire: 5F = 0.038"; 6 F = 0.038"

PRODUCT DESCRIPTION

Features Full-Wall Technology: a proprietary extrusion process that melts layers together to form a solid shaft. This construction process is applied from hub to tip, providing the DxTerity diagnostic catheter with superior torque and lubricity for precise manipulation and enhanced deliverability.

DxTerity™ TRA diagnostic catheters are specifically adapted for radial use, offering four universal radial curve shapes to engage both coronaries without catheter exchange.

PRODUCT CODE



ORDERING INFORMATION

	CURVE STYLE	CURVE SIZE	LENGTH (CM)	5F PRODUCT CODE	6F PRODUCT CODE	SIDEHOLES
TRApease	TRAP	3.5	100	U5TRAP35	U6TRAP35	0
		3.5	100	U5TRAP35SH	U6TRAP35SH	2
		3.5	110	U5TRAP35SHA	U6TRAP35SHA	2
		4.0	100	U5TRAP40	U6TRAP40	0
		4.0	100	U5TRAP40SH	U6TRAP40SH	2
		4.0	110	U5TRAP40SHA	U6TRAP40SHA	2
		4.5	100	U5TRAP45	U6TRAP45	0
		4.5	100	U5TRAP45SH	U6TRAP45SH	2
		4.5	110	U5TRAP45SHA	U6TRAP45SHA	2
TRAnsformer	TRAN	3.5	100	U5TRAN35	U6TRAN35	0
		3.5	100	U5TRAN35SH	U6TRAN35SH	2
		3.5	110	U5TRAN35SHA	U6TRAN35SHA	2
		4.0	100	U5TRAN40	U6TRAN40	0
		4.0	100	U5TRAN40SH	U6TRAN40SH	2
		4.0	110	U5TRAN40SHA	U6TRAN40SHA	2
		4.5	100	U5TRAN45	U6TRAN45	0
		4.5	100	U5TRAN45SH	U6TRAN45SH	2
		4.5	110	U5TRAN45SHA	U6TRAN45SHA	2
TRAcker	TRACK	100	100	U5TRACK	U6TRACK	0
		100	100	U5TRACKSH	U6TRACKSH	2
		110	100	U5TRACKSHA	U6TRACKSHA	2
TRActive	TRACT	100	100	U5TRACT	U6TRACT	0
		100	100	U5TRACTSH	U6TRACTSH	2
		110	100	U5TRACTSHA	U6TRACTSHA	2

CORONARY DIAGNOSTIC CATHETERS

Packaging options for DxTerity™ Angio-kits Universal Radial Curves

GENERAL CHARACTERISTICS

• 5 catheters per box • Supplied sterile • Maximum guidewire: 5F = 0.038"; 6 F = 0.038"

PRODUCT DESCRIPTION

Angio-kit contains:

- One Universal Radial Curve with sideholes (TRAP4.0 o TRAN3.5)
- One Straight or Angled Pigtail catheter

ORDERING INFORMATION

PRODUCT CODE	CURVES	LENGTH (CM)	SIZE
AKUNIV501	TRApease 4.0 SH	100	5F
	Straight Pigtail	110	5F
AKUNIV502	TRApease 4.0 SH	100	5F
	145 Pigtail	110	5F
AKUNIV503	TRAnsformer 3.5 SH	100	5F
	Straight Pigtail	110	5F
AKUNIV504	TRAnsformer 3.5 SH	100	5F
	145 Pigtail	110	5F
AKUNIV601	TRApease 4.0 SH	100	6F
	Straight Pigtail	110	6F
AKUNIV602	TRApease 4.0 SH	100	6F
	145 Pigtail	110	6F
AKUNIV603	TRAnsformer 3.5 SH	100	6F
	Straight Pigtail	110	6F
AKUNIV604	TRAnsformer 3.5 SH	100	6F
	145 Pigtail	110	6F

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style A Standard

GENERAL CHARACTERISTICS

- Supplied sterile • Maximum guidewire: 7F, 7.5F and 8F standard: 0.035" 7F and 8 F Hi-Flow: 0.038"
- Items per box: 10

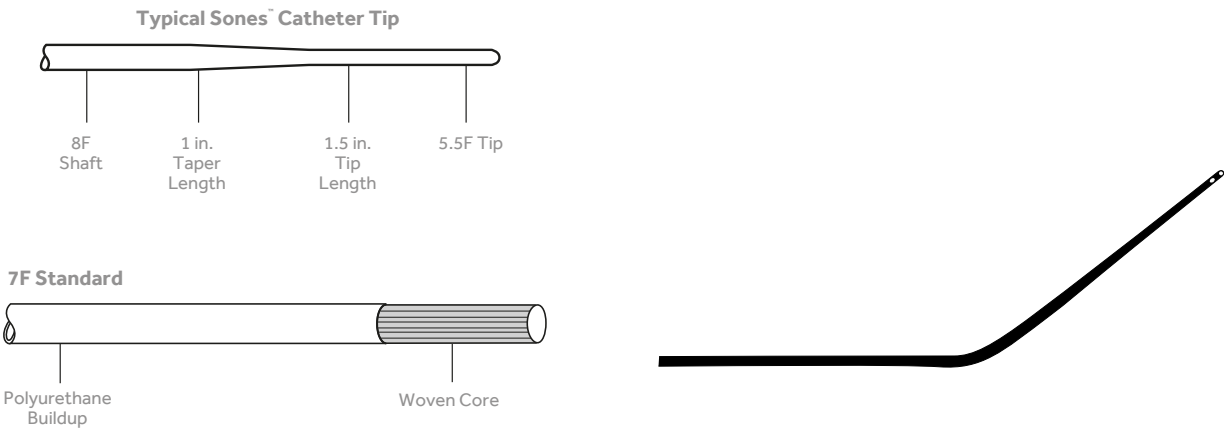
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE A STANDARD

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
007764	7	80	1.5	0.036	Extra stiffness—tip & shaft
007536	7	100	1.5	0.036	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style A Hi-Flow

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

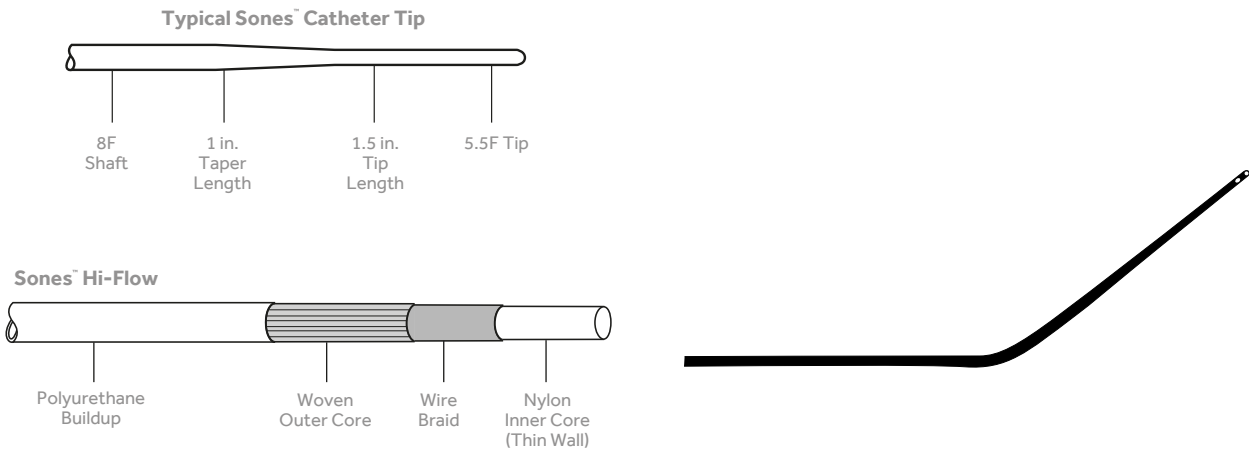
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE A HI-FLOW

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008976	7	80	1.5	0.040	
008977	7	100	1.5	0.040	
008718	8	80	1.5	0.040	
008971	8	100	1.5	0.040	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style A Standard Nylon Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

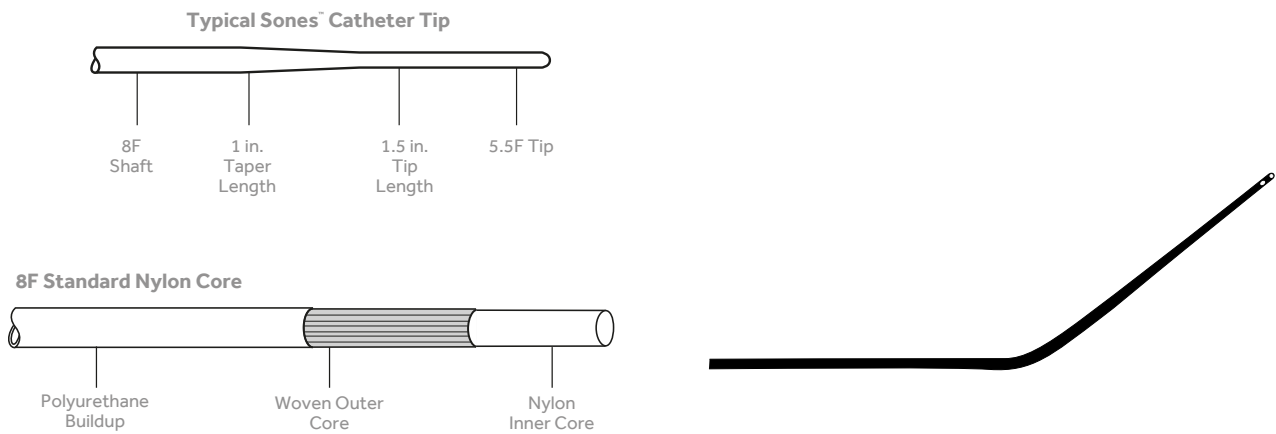
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE A STANDARD NYLON CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
007538	8	80	1.5	0.036	
007539	8	100	1.5	0.036	
007766	8	80	1.5	0.036	Extra stiffness—tip & shaft
007540	8	125	1.5	0.036	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style A Positrol™ Nylon Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

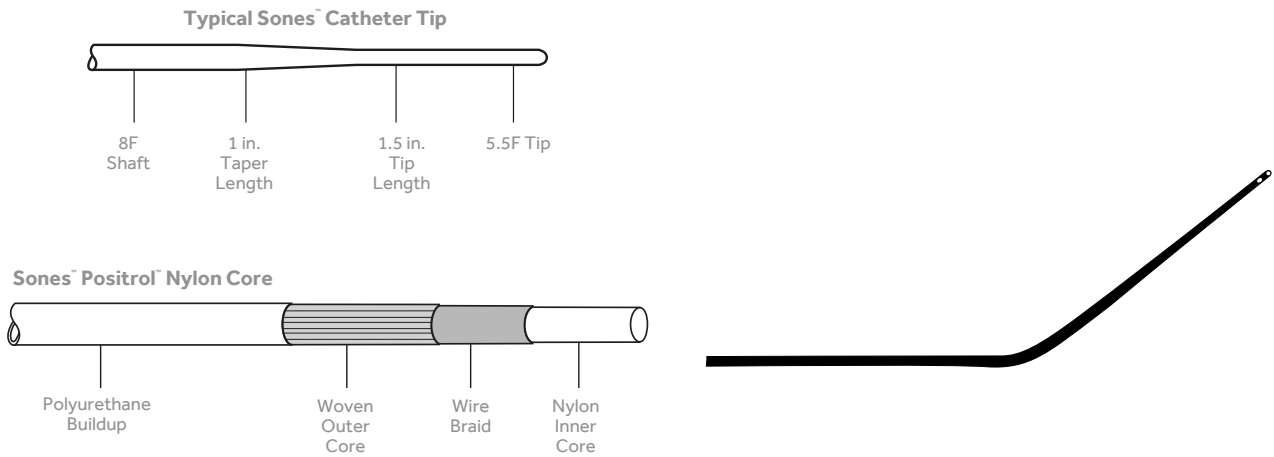
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE A POSITROL™ NYLON CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008541	7.5	100	1.5	0.036	Extra stiffness—shaft

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style B Standard

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

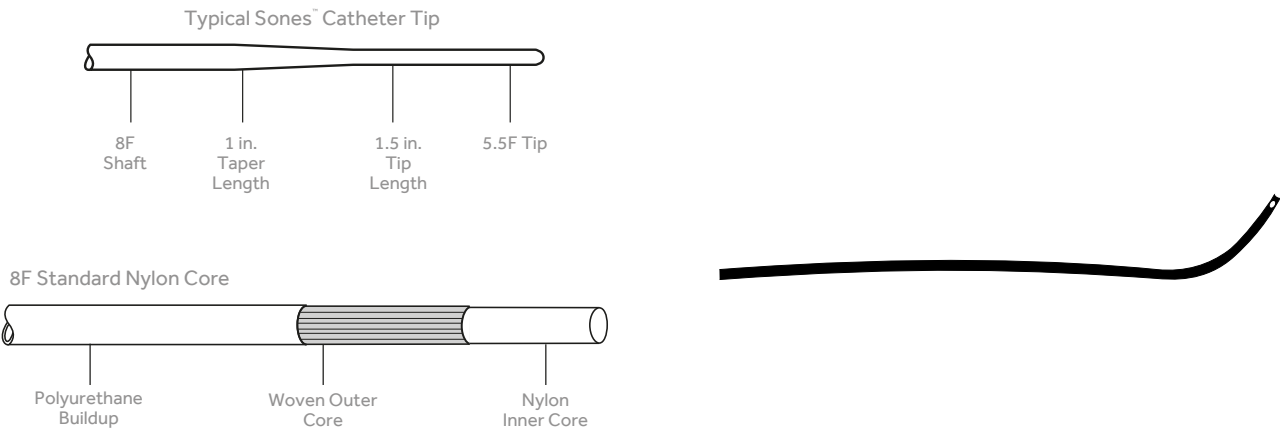
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE B STANDARD

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
007548	7	100	1.5	0.036	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style B Hi-Flow

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

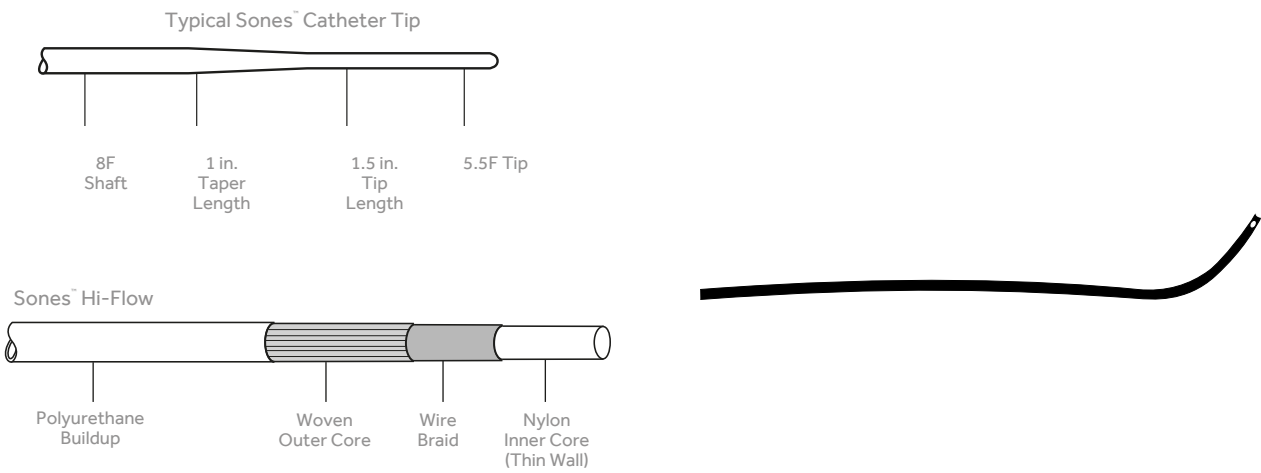
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE B HI-FLOW

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008978	7	80	1.5	0.040	
008979	7	100	1.5	0.040	
008719	8	80	1.5	0.040	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style B Standard Nylon Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

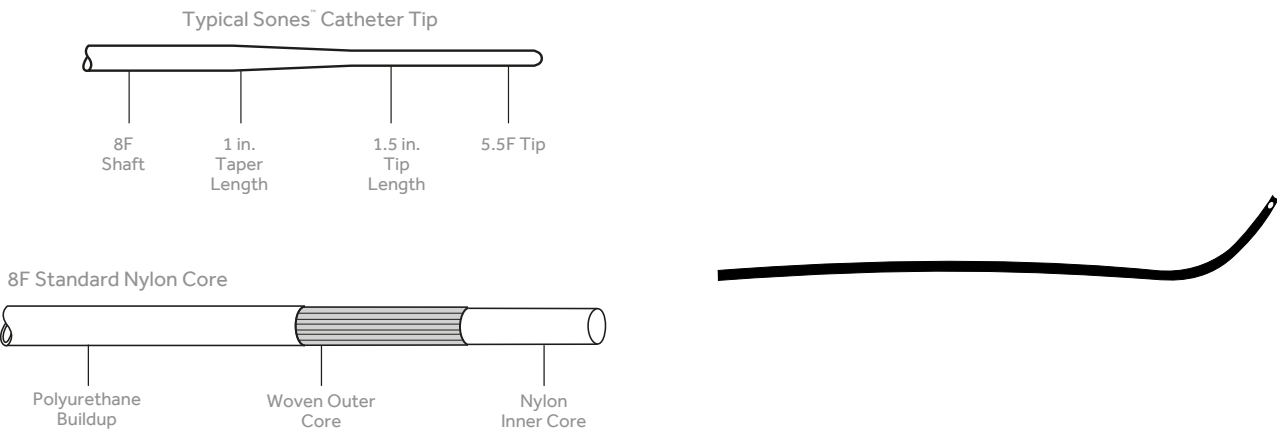
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE B STANDARD NYLON CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
007550	8	80	1.5	0.036	
007551	8	100	1.5	0.036	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style B Positrol™ Woven Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

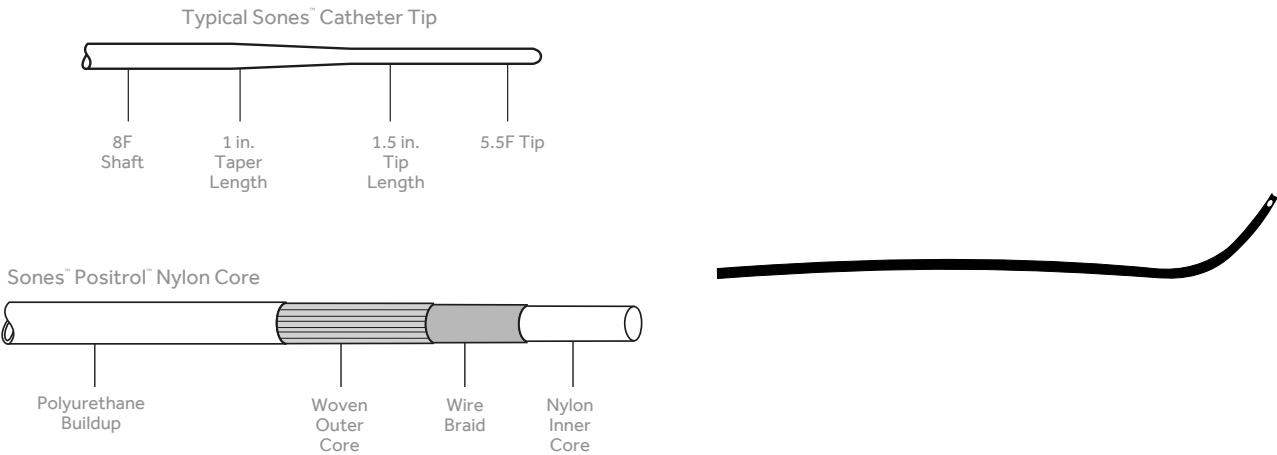
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE B POSITROL™ WOVEN CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
007561	7.5	80	1.5	0.036	Wire-reinforced
007562	7.5	100	1.5	0.036	Wire-reinforced

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style B Positrol™ Nylon Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

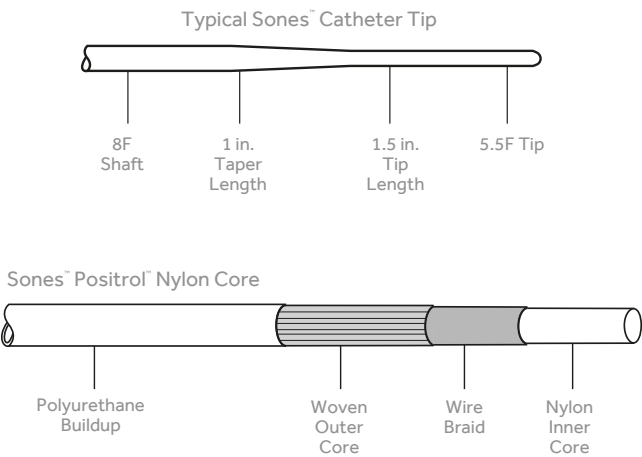
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE B POSITROL™ NYLON CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008554	7.5	100	1.5	0.036	Extra stiffness—shaft

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style C Hi-Flow

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

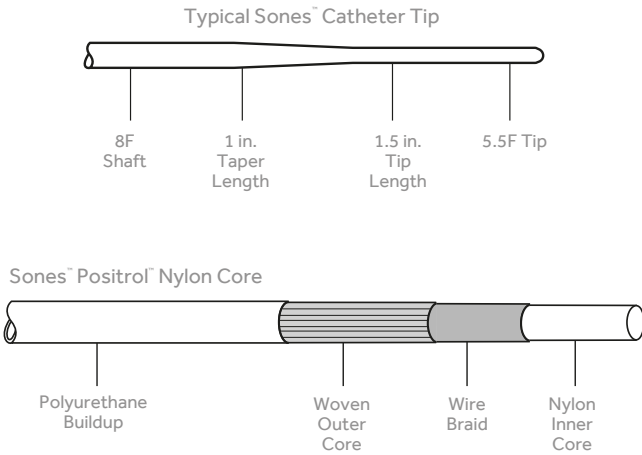
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE C HI-FLOW

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008980	7	80	1.5	0.040	
008981	7	100	1.5	0.040	
008720	8	80	1.5	0.040	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Curve Style C Positrol™ Nylon Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

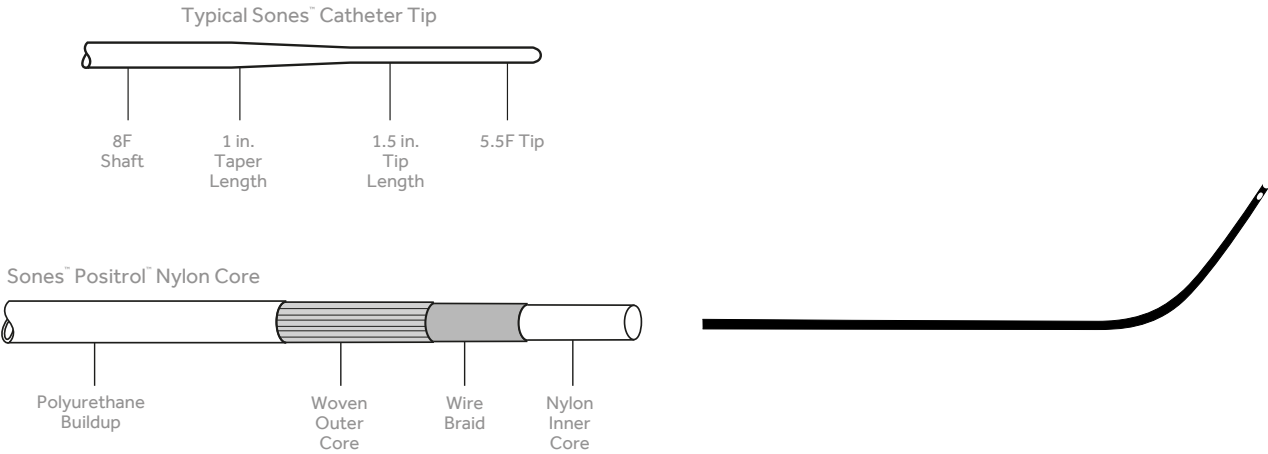
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



CURVE STYLE C POSITROL™ NYLON CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008538	7.5	80	1.5	0.036	
008539	7.5	100	1.5	0.036	
008356	8	80	1.5	0.036	Standard nylon core

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Brachial LTX-S

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

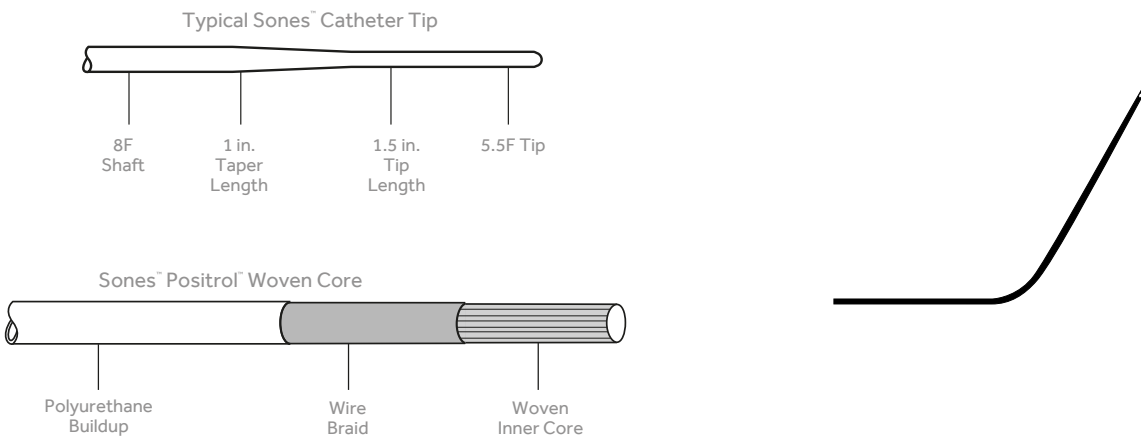
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



BRACHIAL LTX-S

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
007770	8	80	Long tip	0.036	
007771	8	100	Long tip	0.036	

ANGIOGRAPHIC CATHETERS

Sones™ Woven Coronary Catheters Standard Nylon Core

GENERAL CHARACTERISTICS

- Supplied sterile. • Maximum guidewire: 7F, 7.5F & 8F Standard: 0.035"; 7F & 8F Hi-Flow: 0.038"
- Items per box: 10 • All tips taper to 5.5F

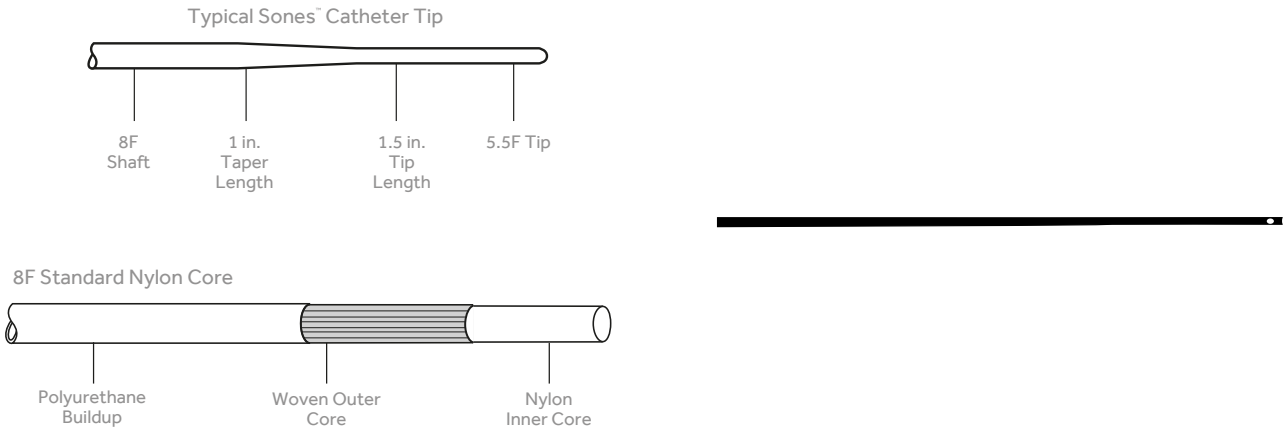
PRODUCT DESCRIPTION

The Sones™ coronary catheter was developed with F. Mason Sones, MD, to meet the evolving clinical needs of the brachial angiographer.

Two Unique Design Features:

- The woven core provides excellent torque control.
- The tapered tip easily adapts to anatomical variations.

Medtronic supplies a variety of catheter constructions and curve style tips as illustrated.



STANDARD NYLON CORE

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	TIP LENGTH (IN.)	MINIMUM TIP I.D. (IN.)	COMMENTS
008358	8	80	1.5	0.036	Straight tip
008359	8	100	1.5	0.036	Straight tip

ANGIOGRAPHIC CATHETERS

NIH Woven Coronary catheters High-Volume

GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 10 • Nylon core • Closed end • Six sideholes • Thin-wall construction

PRODUCT DESCRIPTION

The NIH catheter is designed with a thin wall and nylon core construction to provide maximum flow rates and catheter stability.

The flexible tip makes positioning in the cardiopulmonary system easier. This catheter is used to visualize the aorta, ventricles, pulmonary vasculature and the great veins.



NIH

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	LENGTH (CM)
001348 	5	Thin wall	50
001353 	6	Thin wall	80
 Pediatric item			

ANGIOGRAPHIC CATHETERS

Pediatric NIH Woven Coronary catheters High-Volume

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 10 • Closed end • Six sideholes (4F catheter has four sideholes) • Thin-wall construction

PRODUCT DESCRIPTION

This thin-walled catheter is designed to provide maximum flow and flexibility.
The catheter can be used for aortic, ventricular, pulmonary and large-vein contrast studies.



PEDIATRIC NIH

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	SIDEHOLES	LENGTH (CM)
001375 	4	Thin wall	4	50
001377 	5	Thin wall	6	50
001378 	5	Thin wall	6	80
001380 	6	Thin wall	6	50
001381 	6	Thin wall	6	80
001382 	6	Thin wall	6	100
 Pediatric item				

ANGIOGRAPHIC CATHETERS

Pediatric NIH with Cardio-Marker Image Bands Woven Coronary catheters High-Volume

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 5 • Closed end • Six sideholes • Thin-wall construction • Band width: 1mm

PRODUCT DESCRIPTION

This thin-walled catheter is designed to provide maximum flow and flexibility. The catheter can be used for aortic, ventricular, pulmonary and large-vein contrast studies.
Bandwidth: 1 mm;two marker bands 1 cm apart +/-0.5 mm (leading edge to leading edge)



PEDIATRIC NIH WITH CARDIO-MARKER IMAGE BANDS

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	LENGTH (CM)
010010 	5	Thin wall	010010 - 65
010011 	6	Thin wall	010011 - 80
010012 	7	Thin wall	010012 - 80
 Pediatric item			

ANGIOGRAPHIC CATHETERS

Pediatric Curved NIH Woven Coronary catheters High-Volume

GENERAL CHARACTERISTICS

▪ Supplied sterile. ▪ Items per box: 10 ▪ Closed end ▪ Six sideholes ▪ Thin-wall construction

PRODUCT DESCRIPTION

This thin-walled catheter is designed to provide maximum flow and flexibility.
The catheter can be used for aortic, ventricular, pulmonary and large-vein contrast studies.



PEDIATRIC CURVED NIH

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	LENGTH (CM)
008761 	5	Thin wall	65
008762 	6	Thin wall	65
008763 	7	Thin wall	80
 Pediatric item			

ANGIOGRAPHIC CATHETERS

Lehman™ Ventriculography Woven Coronary catheters High-Volume

GENERAL CHARACTERISTICS

▪ Supplied sterile. ▪ Items per box: 10 ▪ Closed end ▪ Four sideholes ▪ Thin-wall construction

PRODUCT DESCRIPTION

J.S. Lehman, MD, developed the Lehman™ ventriculography catheter. This catheter is specifically designed to be placed easily into the left ventricle via the aorta. The flexible, tapered distal tip is slightly curved to assist passage through the aortic valve and to sit freely in the contour of the left ventricle.

The location of the four sideholes enables the angiographer to record proximal aortic pressures without removing the tip from the aortic valve. This catheter provides excellent flow rates and catheter stability due to its thin-wall construction.



LEHMAN™ VENTRICULOGRAPHY

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	LENGTH (CM)	COMMENTS
001415	7	Thin wall	100	Closed end

ANGIOGRAPHIC CATHETERS

Gensini™ Catheter Woven Coronary Catheters High-Volume

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10
- Open end
- Six sideholes
- Thin-wall construction

PRODUCT DESCRIPTION

Goffredo G. Gensini, MD, is responsible for the first designed catheter with an open end hole. This catheter has a tapered tip that fits securely over a guidewire for percutaneous introduction.

The six sideholes and thin-wall construction provide maximum flow rates. The catheter is used for aortic, ventricular, pulmonary, and large-venous contrast studies.



GENSINI™ PERCUTANEOUS

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	LENGTH (CM)	COMMENTS
001323 ⚠	5	Thin wall	0.026	100	Use with 0.025 in. guidewire
001339 ⚠	6	Thin wall	0.036	80	Use with 0.035 in. guidewire
⚠ Pediatric item					

ANGIOGRAPHIC CATHETERS

Gensini™ Catheter Woven Coronary catheters General Purpose and Transvalvular

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10
- Open end
- No sideholes
- Standard wall construction

PRODUCT DESCRIPTION

Designed by Andre Cournand, MD, in 1939, the Cournand™ Catheter was the first to be manufactured specifically for use in the heart. The gradually curved tip facilitates easy access to the right heart. The Cournand™ catheter is used for blood sampling and pressure measurements.

The general construction of these catheters consists of a woven outer core and a high-density polyurethane coating.



COURNAND™ CATHETER

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	LENGTH (CM)
001433	6	Standard wall	0.036	100
001434	6	Standard wall	0.036	125
007455	7	Standard wall	0.046	100
007456	7	Standard wall	0.046	125

ANGIOGRAPHIC CATHETERS

Lehman™ Catheter Woven Coronary catheters General Purpose and Transvalvular

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10
- Open end
- No sideholes
- Thin-wall construction

PRODUCT DESCRIPTION

J.S. Lehman, MD, designed a catheter for right heart studies similar to the Cournand™ catheter. However, the Lehman™ catheter has a thin-wall construction that maximizes catheter flexibility and flow rates.

The general construction of these catheters consists of a woven outer core and a high-density polyurethane coating.



LEHMAN™ CATHETER

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	LENGTH (CM)
001253 	5	Thin wall	0.032	50
001254 	5	Thin wall	0.032	80
001263	7	Thin wall	0.055	100
001264	7	Thin wall	0.055	125
 Pediatric item				

ANGIOGRAPHIC CATHETERS

Goodale-Lubin™ Catheter Woven Coronary catheters General Purpose and Transvalvular

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10
- Open end
- Two laterally opposed sideholes
- Thin-wall or standard-wall construction.

PRODUCT DESCRIPTION

The general construction of these catheters consists of a woven outer core and a high-density polyurethane coating.

Walter T. Goodale, MD, and Martin Lubin, MD, developed standard-wall and thin-wall catheters similar to the Cournand™ and Lehman™ catheters in construction and tip curve.

The additional feature of the Goodale-Lubin™ catheter is the two laterally opposed sideholes just proximal to the tip for improved disbursement of contrast during right heart angiography.



Thin Wall



Standard Wall

GOODALE-LUBIN™ CATHETER

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	LENGTH (CM)
001279 	5	Thin wall	0.032	80
001453 	5	Standard wall	0.026	50
001284	6	Thin wall	0.043	100
001288	7	Thin wall	0.055	100
007459	7	Standard wall	0.046	100
007460	7	Standard wall	0.046	125
 Pediatric item				

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Fixed Core Straight Tip

GENERAL CHARACTERISTICS

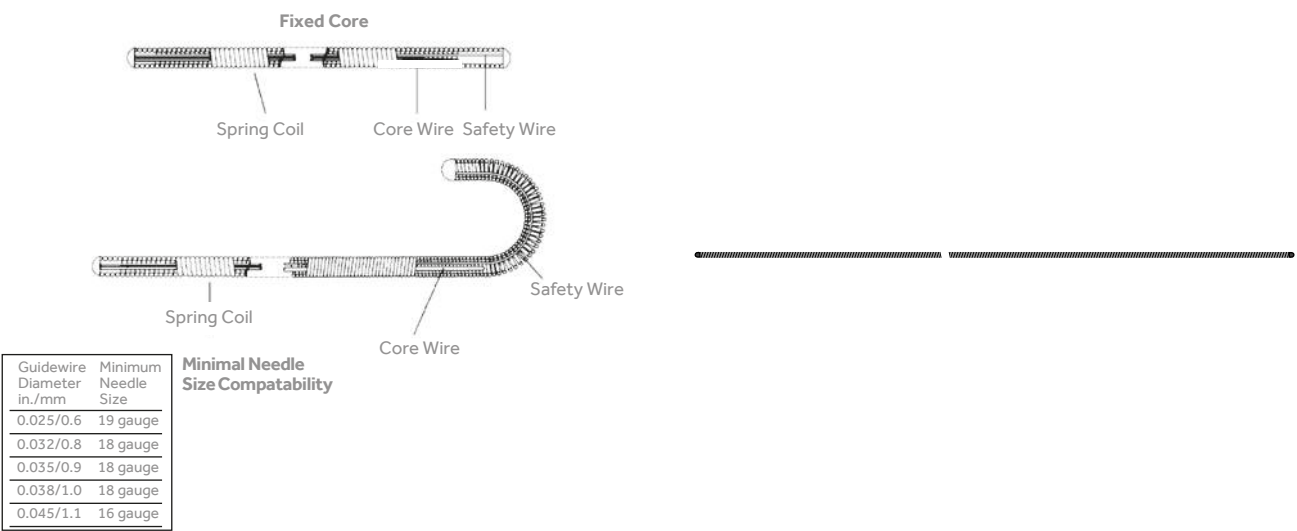
- Supplied sterile.
- Packaged in coiled hoops.
- Items per box: 10

PRODUCT DESCRIPTION

This design has a gradually tapered core that minimizes trauma to the vessel. Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique 'J' tip configuration is available on the fixed core wires. This 'J' tip can be "fingertip-straightened" from virtually any point of the wire shaft. This built-in convenience eliminates the need for a 'J' straightening tool for wire loading.

Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and 'J'. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



STRAIGHT TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
007468	0.035/0.9	145	Extra long taper core 15 cm
007643	0.038/1.0	145	Extra long taper core 15 cm
007467	0.035/0.9	145	Long taper core 10 cm
007642	0.038/1.0	145	Long taper core 10 cm
007641	0.025/0.6	120	Standard taper core 6 cm
010387	0.025/0.6	145	Standard taper core 6 cm
007644	0.032/0.8	120	Standard taper core 6 cm
007645	0.032/0.8	145	Standard taper core 6 cm
007045	0.035/0.9	120	Standard taper core 6 cm
007046	0.035/0.9	145	Standard taper core 6 cm
008629	0.035/0.9	175	Standard taper core 6 cm
007048	0.038/1.0	145	Standard taper core 6 cm

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Fixed Core 1.5-mm 'J' Tip

GENERAL CHARACTERISTICS

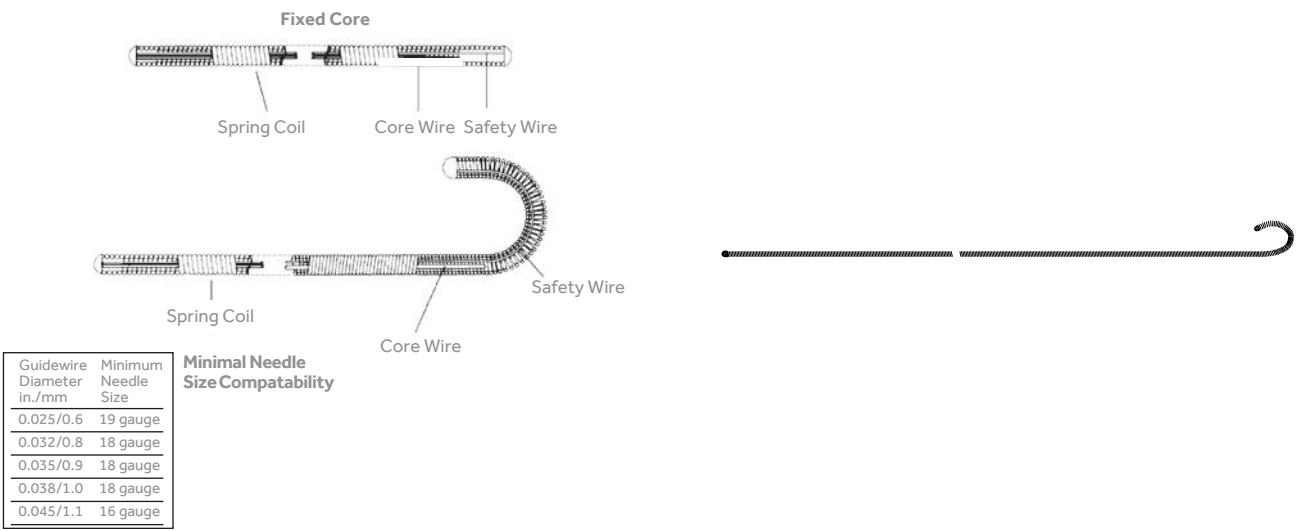
- Supplied sterile.
- Packaged in coiled hoops.
- Items per box: 10

PRODUCT DESCRIPTION

This design has a gradually tapered core that minimizes trauma to the vessel. Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique 'J' tip configuration is available on the fixed core wires. This 'J' tip can be "fingertip-straightened" from virtually any point of the wire shaft. This built-in convenience eliminates the need for a 'J' straightening tool for wire loading.

Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and 'J'. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



1.5-MM 'J' TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
008944	0.035/0.9	175	Rosen guidewire
008945	0.038/1.0	175	Rosen guidewire

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Fixed Core 3-mm 'J' Tip

GENERAL CHARACTERISTICS

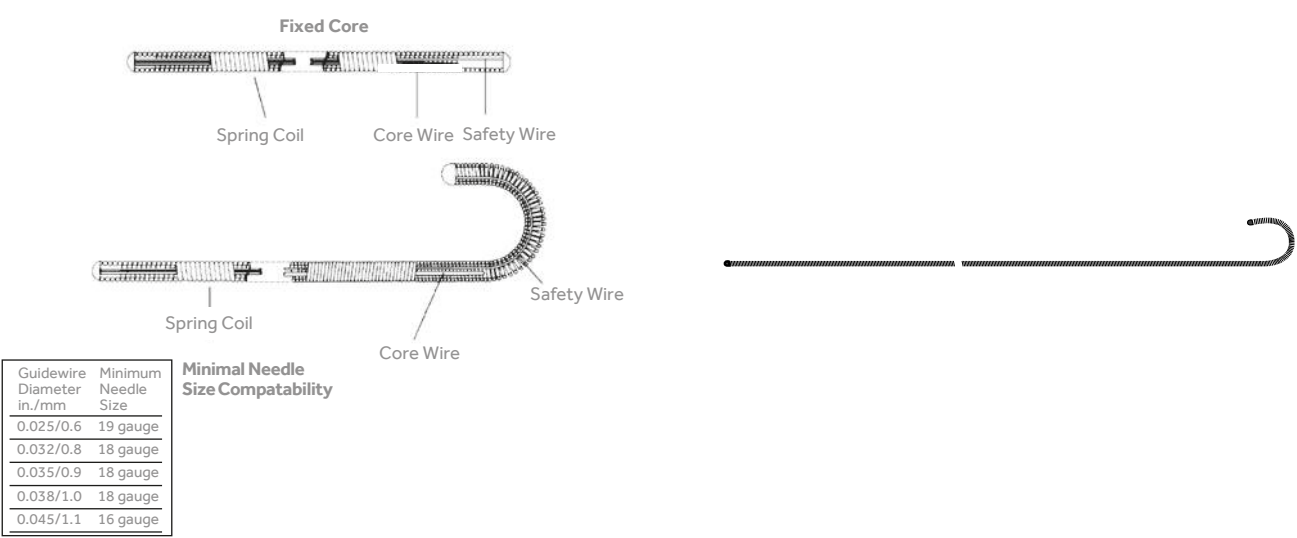
- Supplied sterile.
- Packaged in coiled hoops.
- Items per box: 10

PRODUCT DESCRIPTION

This design has a gradually tapered core that minimizes trauma to the vessel. Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique 'J' tip configuration is available on the fixed core wires. This 'J' tip can be “fingertip-straightened” from virtually any point of the wire shaft. This built-in convenience eliminates the need for a 'J' straightening tool for wire loading.

Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and 'J'. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



3-MM 'J' TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
010388	0.025/0.6	145	Standard taper core 6 cm
008952	0.028/0.7	145	Standard taper core 6 cm
008953	0.032/0.8	145	Standard taper core 6 cm
007041	0.035/0.9	120	Standard taper core 6 cm
007042	0.035/0.9	145	Standard taper core 6 cm
008627	0.035/0.9	175	Standard taper core 6 cm
007044	0.038/1.0	145	Standard taper core 6 cm
008628	0.038/1.0	175	Standard taper core 6 cm
010003	0.035/0.9	145	Long taper core 10 cm
010004	0.038/1.0	145	Long taper core 10 cm

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Fixed Core 6-mm 'J' Tip

GENERAL CHARACTERISTICS

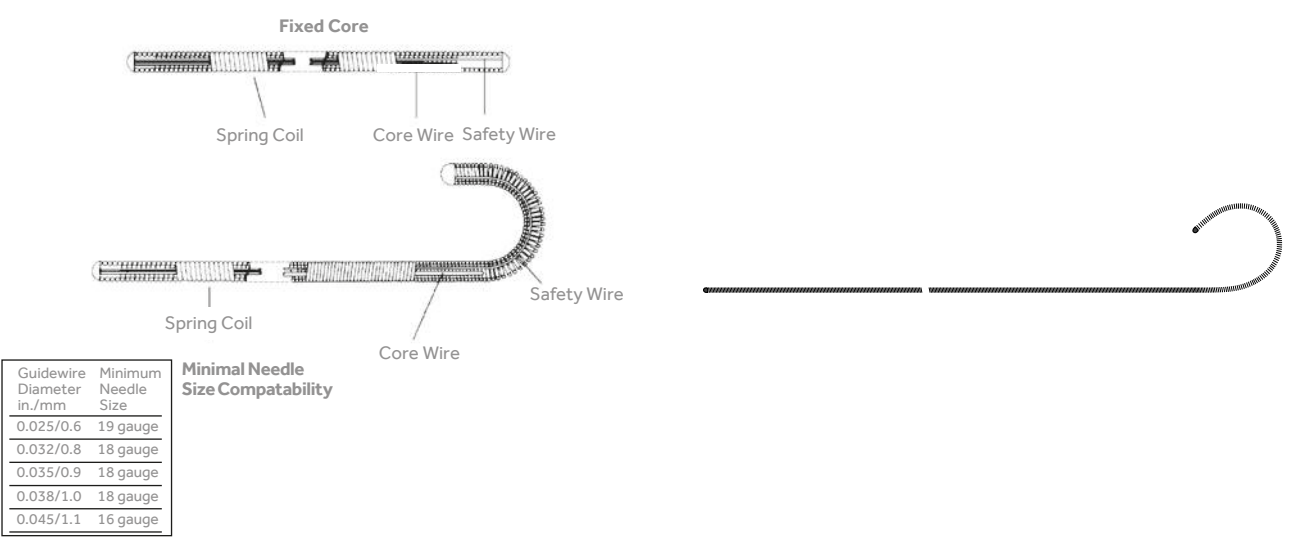
- Supplied sterile.
- Packaged in coiled hoops.
- Items per box: 10

PRODUCT DESCRIPTION

This design has a gradually tapered core that minimizes trauma to the vessel. Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique 'J' tip configuration is available on the fixed core wires. This 'J' tip can be “fingertip-straightened” from virtually any point of the wire shaft. This built-in convenience eliminates the need for a 'J' straightening tool for wire loading.

Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and 'J'. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



6-MM 'J' TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
007441	0.035/0.9	145	Standard taper core 6 cm
007443	0.038/1.0	145	Standard taper core 6 cm

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Fixed Core 15-mm ‘J’ Tip

GENERAL CHARACTERISTICS

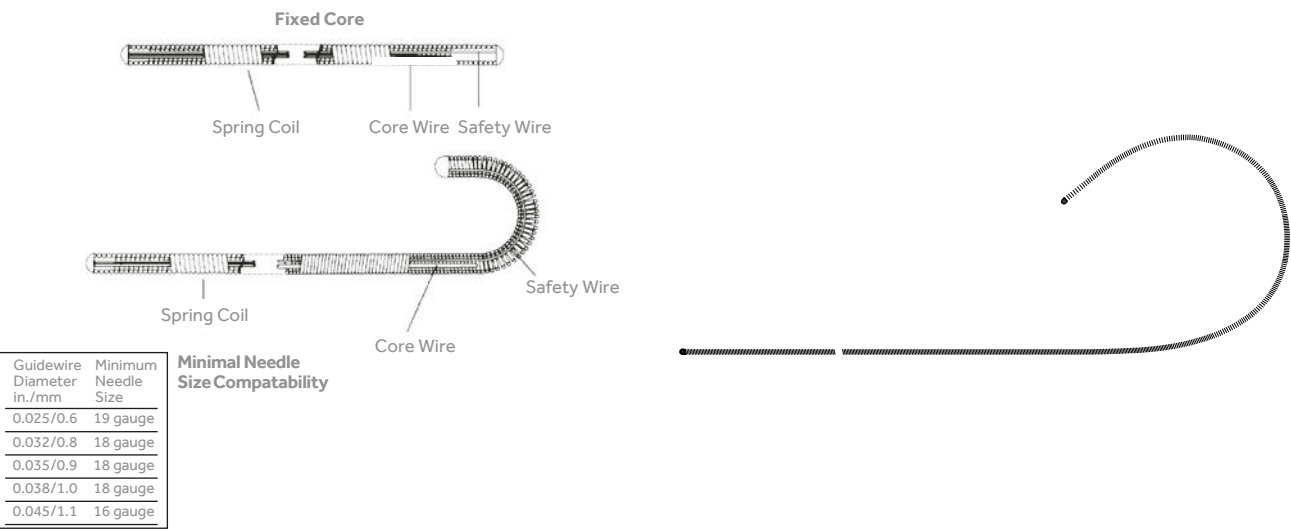
- Supplied sterile.
- Packaged in coiled hoops.
- Items per box: 10

PRODUCT DESCRIPTION

This design has a gradually tapered core that minimizes trauma to the vessel. Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique ‘J’ tip configuration is available on the fixed core wires. This ‘J’ tip can be “fingertip-straightened” from virtually any point of the wire shaft. This built-in convenience eliminates the need for a ‘J’ straightening tool for wire loading.

Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and ‘J’. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



15-MM ‘J’ TIP

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)	COMMENTS
007471	0.035/0.9	145	Standard taper core 6 cm
007472	0.038/1.0	145	Standard taper core 6 cm

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Movable Core Straight Tip

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- Variable stiffness.
- Items per box: 10

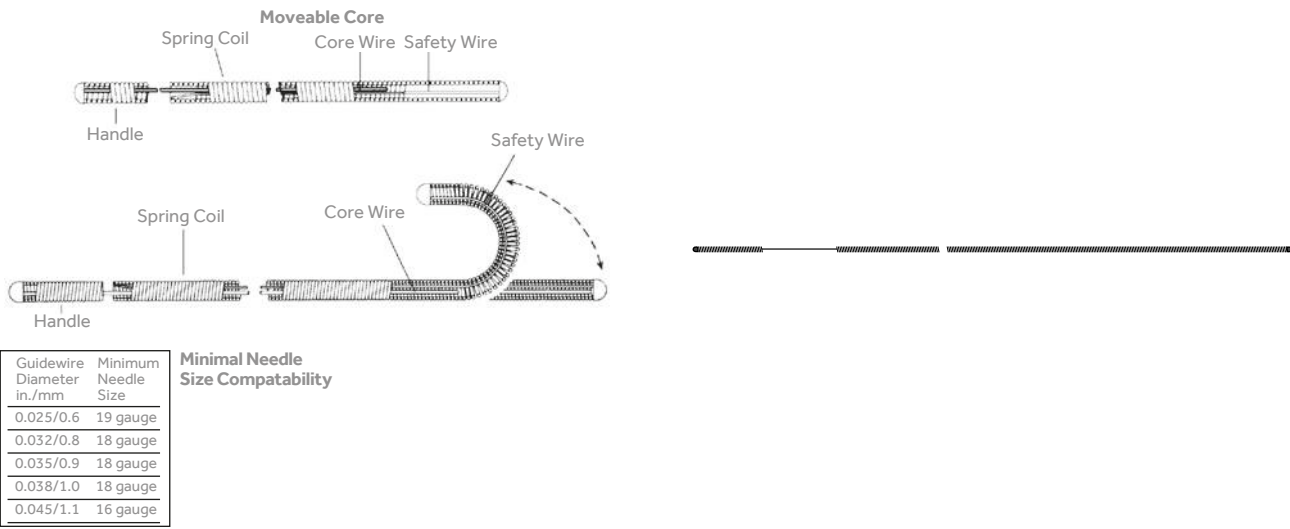
PRODUCT DESCRIPTION

This design allows the wire softness to be adjusted manually by moving the core wire back and forth, allowing the operator to lengthen or shorten at will.

Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique ‘J’ tip configuration is available on the movable core wires. This ‘J’ tip can be “fingertipstraightened” from virtually any point of the wire shaft.

This built-in convenience eliminates the need for a ‘J’ straightening tool for wire loading. Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and ‘J’. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



STRAIGHT TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)
007647	0.032/0.8	145
007051	0.035/0.9	145
007053	0.038/1.0	145

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Movable Core 3-mm 'J' Tip

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- Variable stiffness.
- Items per box: 10

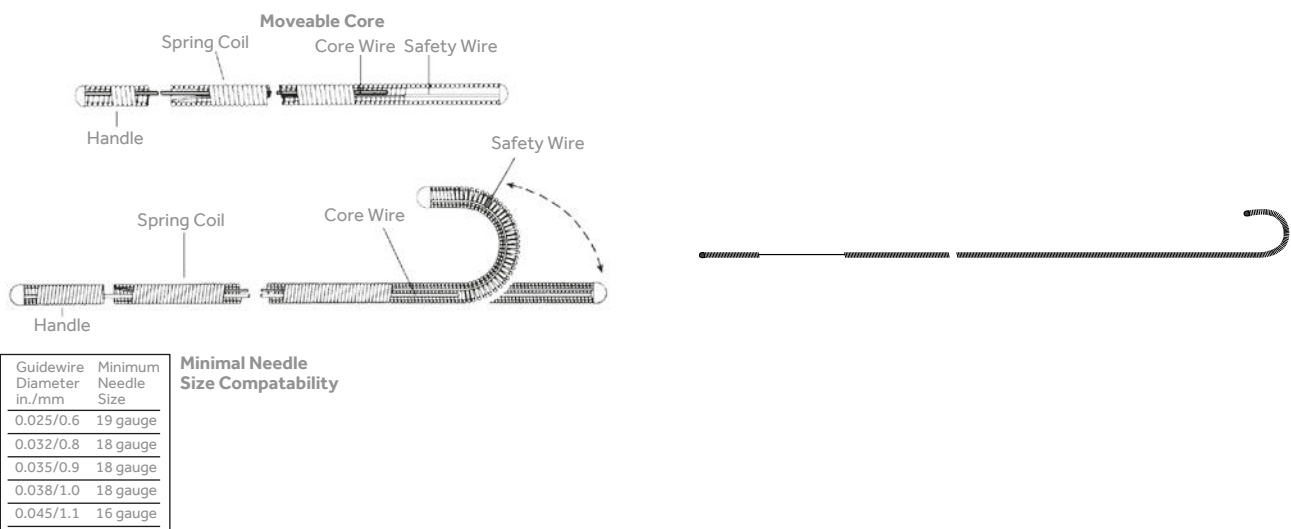
PRODUCT DESCRIPTION

This design allows the wire softness to be adjusted manually by moving the core wire back and forth, allowing the operator to lengthen or shorten at will.

Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique 'J' tip configuration is available on the movable core wires. This 'J' tip can be "fingertipstraightened" from virtually any point of the wire shaft.

This built-in convenience eliminates the need for a 'J' straightening tool for wire loading. Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and 'J'. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



3-MM 'J' TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)
007648	0.032/0.8	120
007649	0.032/0.8	145
007446	0.035/0.9	120
007447	0.035/0.9	145
007054	0.038/1.0	145

ANGIOGRAPHIC WIRES

PTFE-Coated Guidewires: Movable Core 6-mm 'J' Tip

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- Variable stiffness.
- Items per box: 10

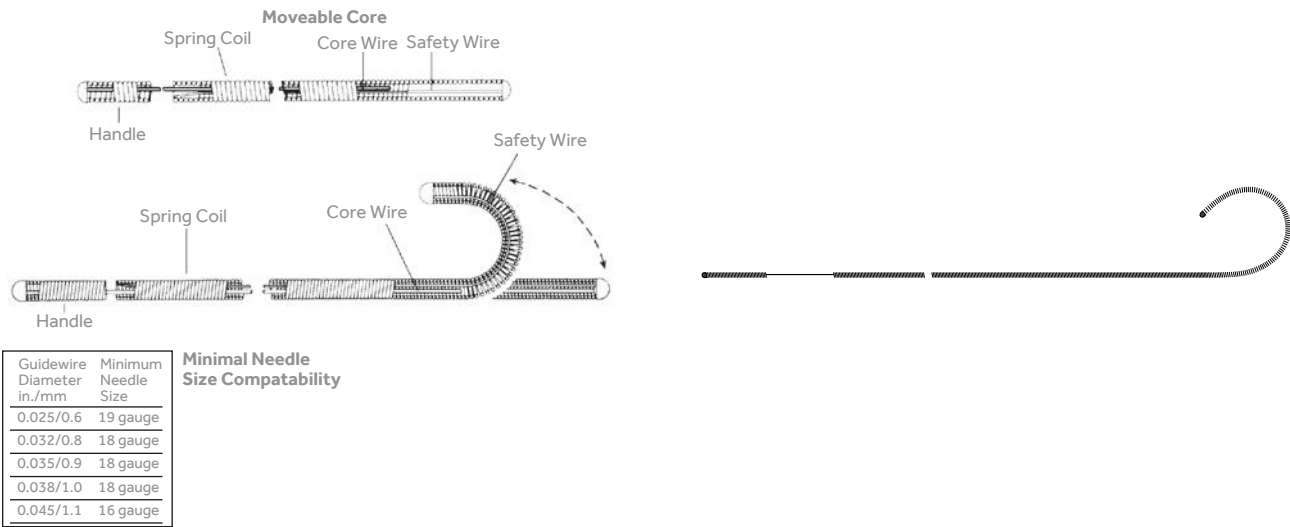
PRODUCT DESCRIPTION

This design allows the wire softness to be adjusted manually by moving the core wire back and forth, allowing the operator to lengthen or shorten at will.

Angiography guidewires come with a PTFE coating applied over the entire core, enabling free movement and a smooth sliding action.

A unique 'J' tip configuration is available on the movable core wires. This 'J' tip can be "fingertipstraightened" from virtually any point of the wire shaft.

This built-in convenience eliminates the need for a 'J' straightening tool for wire loading. Medtronic offers a variety of tip configurations, sizes and styles. The two most common tip configurations are straight and 'J'. Medtronic guidewires are available in a range of diameters and are compatible with the minimal needle sizes noted in the table.



6-MM 'J' TIP

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)
007445	0.035/0.9	145

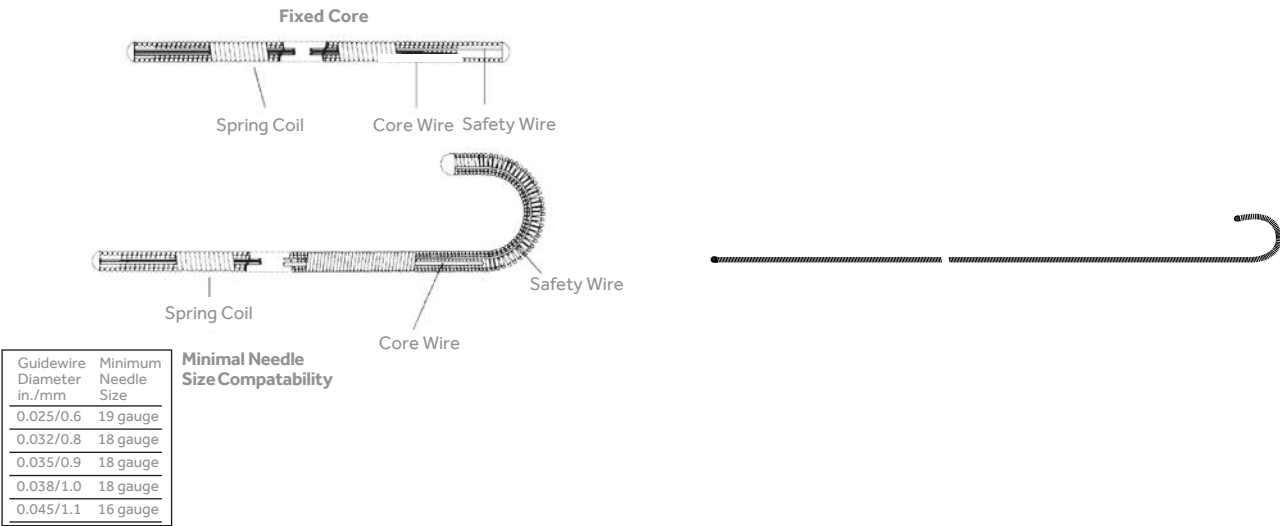
ANGIOGRAPHIC WIRES

Support and Exchange wires 3-mm 'J' Tip Exchange Wire: Fixed Core

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- PTFE coated.
- Items per box: 10

PRODUCT DESCRIPTION



3-MM 'J' TIP EXCHANGE WIRE: FIXED CORE

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
008631	0.035/0.9	260	Standard taper core 6 cm
008634	0.038/1.0	260	Standard taper core 6 cm

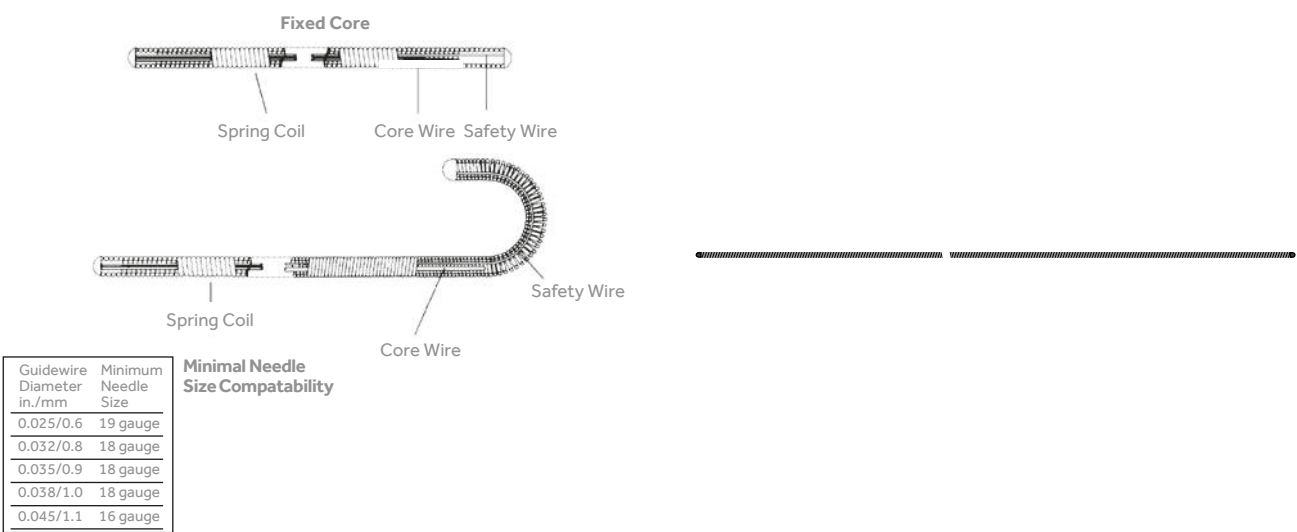
ANGIOGRAPHIC WIRES

Support and Exchange wires Straight Tip Exchange Wire: Fixed Core

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- PTFE coated.
- Items per box: 10

PRODUCT DESCRIPTION



STRAIGHT TIP EXCHANGE WIRE: FIXED CORE

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
008633	0.035/0.9	260	Standard taper core 6 cm
008632	0.038/1.0	260	Standard taper core 6 cm

ANGIOGRAPHIC WIRES

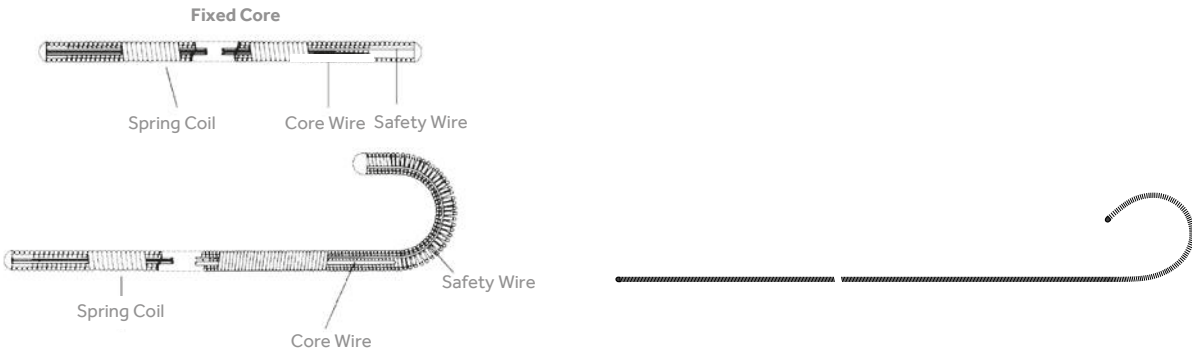
Support and Exchange wires
PTFE-Coated 0.063” Guidewire

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- PTFE coated.
- Items per box: 10

PRODUCT DESCRIPTION

For placement of guiding catheter (flexible distal tip, fixed core)



PTFE-COATED 0.063” GUIDEWIRE

PRODUCT CODE	TIP	DIAMETER (IN.)	LENGTH (CM)
008418	6-mm 'J'	0.063	160

ANGIOGRAPHIC WIRES

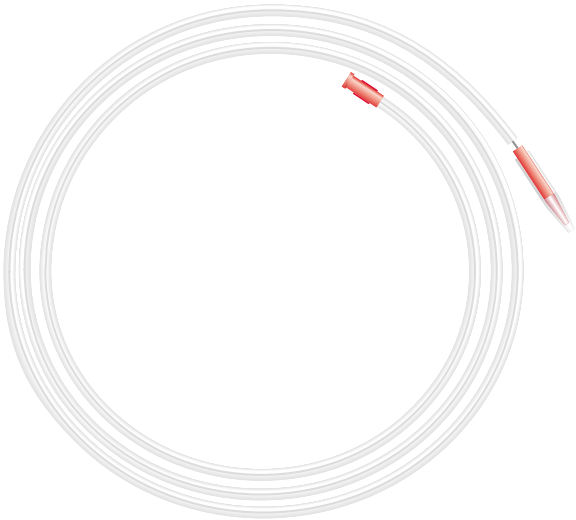
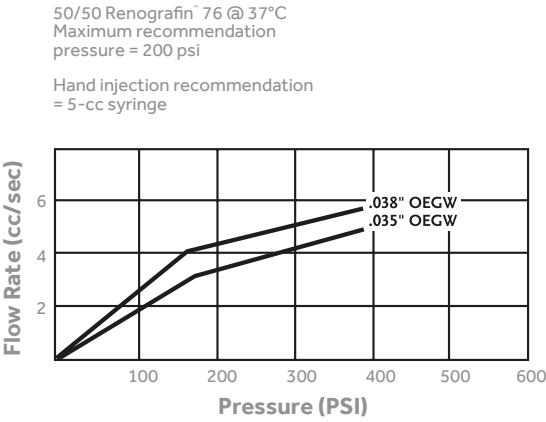
Specialty Guidewires
Sos Open-Ended Guidewire

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- Items per box: 10

PRODUCT DESCRIPTION

Movable/removable core wire is packaged with removable luer lock hub, product code 006210



SOS OPEN-ENDED GUIDEWIRE

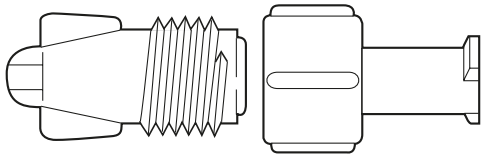
PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
006203	0.035/0.9	145	Standard taper core 6 cm
006200	0.038/1.0	145	Standard taper core 6 cm
006204	0.035/0.9	145	Long taper core 10 cm
006201	0.038/1.0	145	Long taper core 10 cm
Renografin® is a registered trademark of Olin Mathieson Chemical Corporation.			

ANGIOGRAPHIC WIRES

Specialty Guidewires
Removable Luer Lock Hub

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10



REMOVABLE LUER LOCK HUB

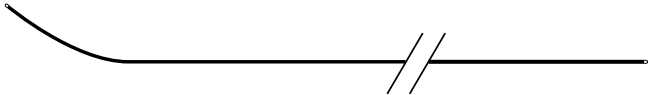
PRODUCT CODE	SIZE IN./MM	FOR USE WITH
006210	Fits all sizes	Sos Open-Ended Guidewire

ANGIOGRAPHIC WIRES

Specialty Guidewires
Steerable Guidewire with Steering Handle

GENERAL CHARACTERISTICS

- Supplied sterile.
- Packaged in coiled hoops.
- PTFE coated.
- Items per box: 5



STEERABLE GUIDEWIRE WITH STEERING HANDLE

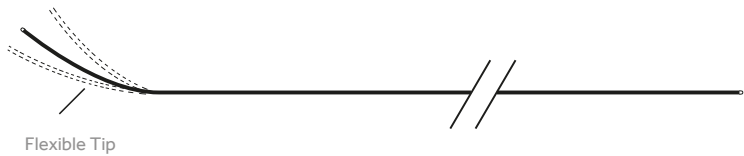
PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
010037	0.035/0.9	145	3 cm flexible tip
010038	0.038/1.0	145	3 cm flexible tip

ANGIOGRAPHIC WIRES

Specialty Guidewires Softwire

GENERAL CHARACTERISTICS

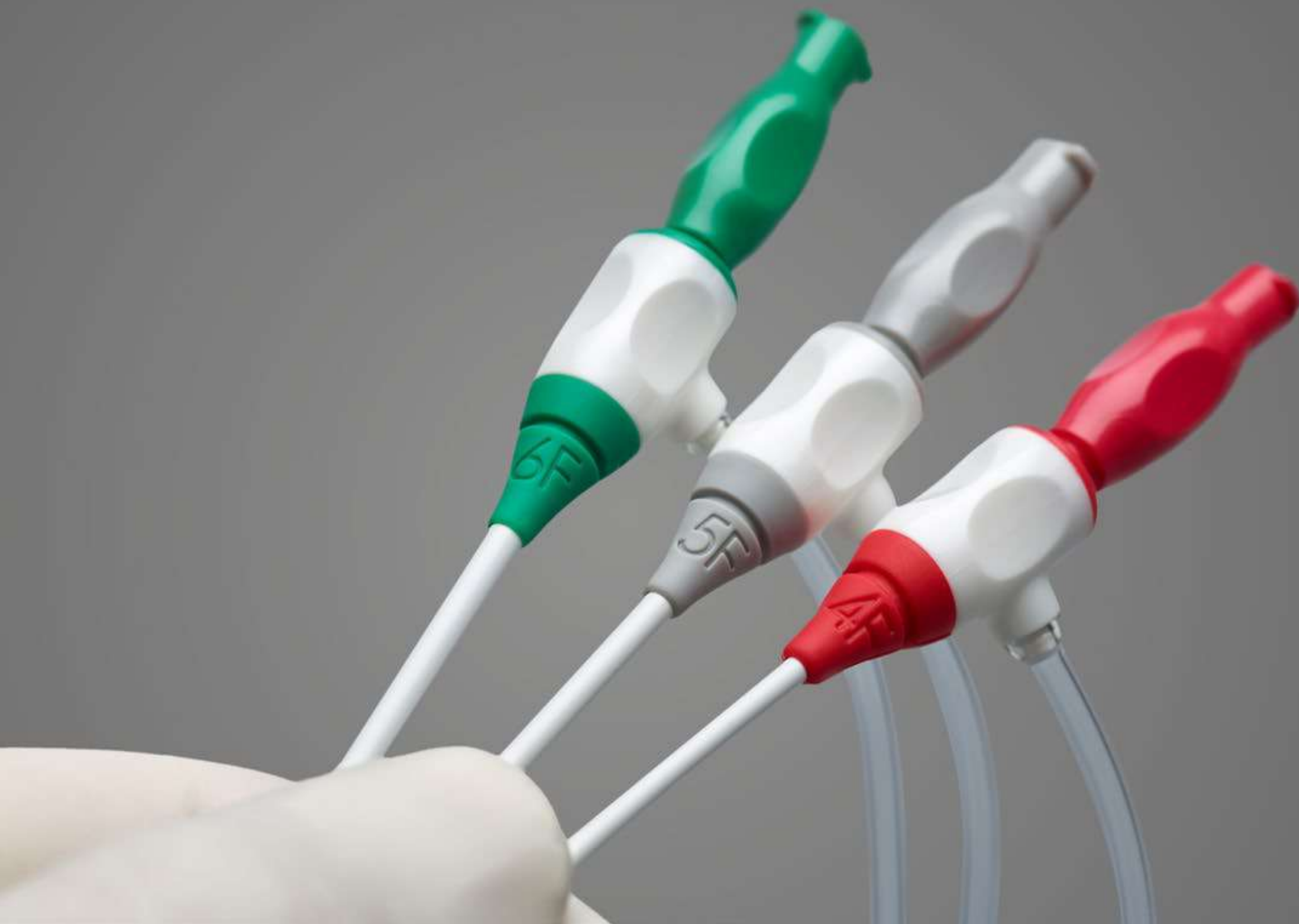
- Supplied sterile.
- Packaged in coiled hoops.
- PTFE coated.
- Items per box: 10



SOFTWARE

PRODUCT CODE	SIZE IN./MM	LENGTH (CM)	COMMENTS
006305	0.035/0.9	145	Extra long taper core 15 cm
006307	0.038/1.0	145	Extra long taper core 15 cm

INTRODUCERS



CONTENTS
1. DRUG-ELUTING STENTS
2. DRUG-ELUTING STENTS
3. BALLOON DILATION CATHETERS
4. DRUG-ELUTING BALLOONS
5. GUIDE CATHETER FAMILY
6. INTERVENTIONAL GUIDEWIRES
7. ASPIRATION CATHETERS
8. ANGIOGRAPHIC CATHETERS AND WIRES
9. INTRODUCERS
10. INTERVENTIONAL ACCESSORIES
11. PEDIATRIC AND TRANSCATHETER PRODUCTS
12. RENAL DENERVATION

RADIAL INTRODUCERS

InTRaKit™
Access Kit

GENERAL CHARACTERISTICS

• Items per box: 5 • Supplied sterile

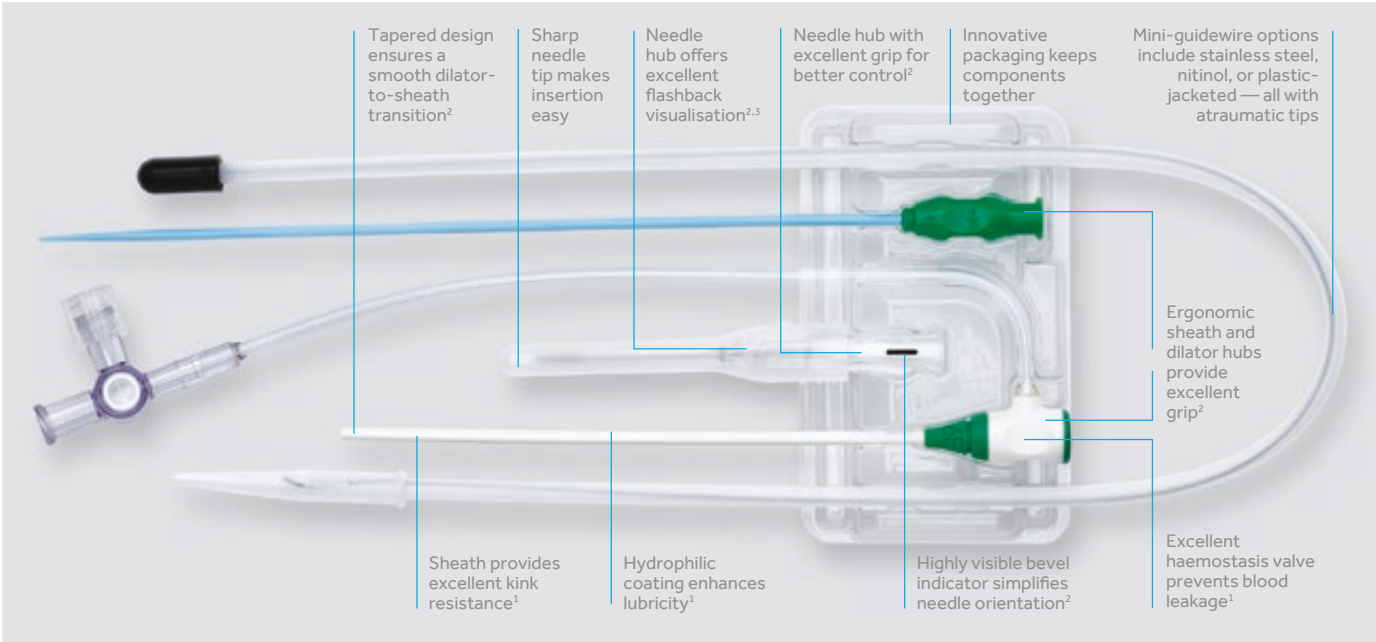
PRODUCT DESCRIPTION

- InTRaKit™ access kit delivers excellent components for the transradial approach:
- IV catheter and micropuncture needles feature sharp tips for easy insertion
 - Needle hubs offer excellent flashback visualization and excellent grip
 - Mini-guidewire options include stainless steel, nitinol, or plastic- jacketed — all with atraumatic tips
 - Tapered design ensures a smooth dilator-to-sheath transition
 - Hydrophilic coating for enhanced lubricity
 - Sheath provides excellent kink resistance

PRODUCT CODE

INT4F07A1

Wire Type
Needle Type
Sheath Length (cm)
French Size (F)
Product code



ORDERING INFORMATION

SHEATH THICKNESS	FRENCH SIZE (F)	SHEATH LENGTH (CM)	NEEDLE TYPE	WIRE TYPE
Standard	4)	07	A: IV Cath 22G	1: Stainless steel 45 cm
	5	11	B: IV Cath 20G	2: Nitinol 45 cm
	6	23	C: Micropuncture 21 G	3: Plastic-jacketed 45 cm
			D: Micropuncture 18 G	4: Stainless steel 80 cm

RADIAL INTRODUCERS

InTRaKit™
Access Kit

ORDERING INFORMATION

4 FRENCH ORDER CODES (CFN)					
CFN	Sheath Length	Needle Size	Needle Type	Wire Type	Wire Length
INT4F07B1	7 cm	20 G	IV Catheter	Stainless steel	45 cm
INT4F07B3	7 cm	20 G	IV Catheter	Plastic-jacketed	45 cm
INT4F07C1	7 cm	21 G	Micropuncture	Stainless steel	45 cm
INT4F11A3	11 cm	22 G	IV Catheter	Plastic-jacketed	45 cm
INT4F11B1	11 cm	20 G	IV Catheter	Stainless steel	45 cm
INT4F11B3	11 cm	20 G	IV Catheter	Plastic-jacketed	45 cm
INT4F11C1	11 cm	21 G	Micropuncture	Stainless steel	45 cm
INT4F11C2	11 cm	21 G	Micropuncture	Nitinol	45 cm
INT4F23B4	23 cm	20 G	IV Catheter	Stainless steel	80 cm
INT4F23C4	23 cm	21 G	Micropuncture	Stainless steel	80 cm

5 FRENCH ORDER CODES (CFN)					
CFN	Sheath Length	Needle Size	Needle Type	Wire Type	Wire Length
INT5F07B1	7 cm	20 G	IV Catheter	Stainless steel	45 cm
INT5F07B2	7 cm	20 G	IV Catheter	Nitinol	45 cm
INT5F07B3	7 cm	20 G	IV Catheter	Plastic-jacketed	45 cm
INT5F07C1	7 cm	21 G	Micropuncture	Stainless steel	45 cm
INT5F07C2	7 cm	21 G	Micropuncture	Nitinol	45 cm
INT5F07D1	7 cm	18 G	Micropuncture	Stainless steel	45 cm
INT5F07D2	7 cm	18 G	Micropuncture	Nitinol	45 cm
INT5F11A3	11 cm	22 G	IV Catheter	Plastic-jacketed	45 cm
INT5F11B1	11 cm	20 G	IV Catheter	Stainless steel	45 cm
INT5F11B2	11 cm	20 G	IV Catheter	Nitinol	45 cm
INT5F11B3	11 cm	20 G	IV Catheter	Plastic-jacketed	45 cm
INT5F11C1	11 cm	21 G	Micropuncture	Stainless steel	45 cm
INT5F11C2	11 cm	21 G	Micropuncture	Nitinol	45 cm
INT5F11D1	11 cm	18 G	Micropuncture	Stainless steel	45 cm
INT5F11D2	11 cm	18 G	Micropuncture	Nitinol	45 cm
INT5F23B4	23 cm	20 G	IV Catheter	Stainless steel	80 cm
INT5F23C4	23 cm	21 G	Micropuncture	Stainless steel	80 cm
INT5F23D4	23 cm	18 G	Micropuncture	Stainless steel	80 cm

6 FRENCH ORDER CODES (CFN)					
CFN	Sheath Length	Needle Size	Needle Type	Wire Type	Wire Length
INT6F07B1	7 cm	20 G	IV Catheter	Stainless steel	45 cm
INT6F07B2	7 cm	20 G	IV Catheter	Nitinol	45 cm
INT6F07B3	7 cm	20 G	IV Catheter	Plastic-jacketed	45 cm
INT6F07C1	7 cm	21 G	Micropuncture	Stainless steel	45 cm
INT6F07C2	7 cm	21 G	Micropuncture	Nitinol	45 cm
INT6F07D1	7 cm	18 G	Micropuncture	Stainless steel	45 cm
INT6F11A3	11 cm	22 G	IV Catheter	Plastic-jacketed	45 cm
INT6F11B1	11 cm	20 G	IV Catheter	Stainless steel	45 cm
INT6F11B2	11 cm	20 G	IV Catheter	Nitinol	45 cm
INT6F11B3	11 cm	20 G	IV Catheter	Plastic-jacketed	45 cm
INT6F11C1	11 cm	21 G	Micropuncture	Stainless steel	45 cm
INT6F11C2	11 cm	21 G	Micropuncture	Nitinol	45 cm
INT6F11D1	11 cm	18 G	Micropuncture	Stainless steel	45 cm
INT6F23B4	23 cm	20 G	IV Catheter	Stainless steel	80 cm
INT6F23C4	23 cm	21 G	Micropuncture	Stainless steel	80 cm
INT6F23D4	23 cm	18 G	Micropuncture	Stainless steel	80 cm

1. Bench test data on file at Medtronic. Bench test data may not be indicative of clinical results.

2. Based on physician feedback during preclinical study and compared to participants' current clinical experience; data on file at Medtronic.

3. Preclinical studies on file at Medtronic. Preclinical data may not be indicative of clinical performance.

FEMORAL INTRODUCERS

Input™ TS Introducer Sheath

GENERAL CHARACTERISTICS

• Supplied sterile. • Maximum guidewire: 0.038" • Items per box: 5

PRODUCT DESCRIPTION

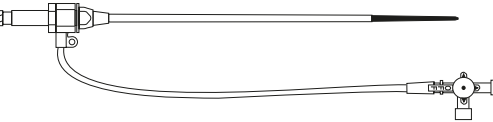
- FEP sheath with silicone coating.
- Silicone hemostasis valve.
- Polyethylene dilator with silicone coating.
- Double distal 'J' stainless steel guidewire (included in 7-cm and 11-cm sheaths only).
- See obturators, dilators and sterile sleeves.



Input TS Introducer Sheath Dilator



Input TS Introducer Sheath



Input TS Introducer Sheath with Dilator

INPUT™ TS INTRODUCER SHEATH

PRODUCT CODE	FRENCH SIZE	OBTURATOR INCLUDED	COLOR CODE	LENGTH (CM)	DILATOR LENGTH (CM)	WIRE STYLE (IN.)
040028A	5	No	Gray	7	13	0.038 DDJ
040031A	6	No	Green	7	13	0.038 DDJ
040035A	7	No	Orange	7	13	0.038 DDJ
051101A	5	No	Gray	11	17	0.038 DDJ
061101A	6	No	Green	11	17	0.038 DDJ
071101A	7	No	Orange	11	17	0.038 DDJ
081101A	8	No	Blue	11	17	0.038 DDJ
091101A	9	No	Gray	11	17	0.038 DDJ
010101A	10	No	Dk Blue	11	17	0.038 DDJ
011101A	11	No	Red	11	17	0.038 DDJ
060037A	6	Yes	Green	23	29	N/A
070037A	7	Yes	Orange	23	29	N/A
080037A	8	Yes	Blue	23	29	N/A
090037A	9	Yes	Gray	23	29	N/A

FEMORAL INTRODUCERS

Input™ TS Introducer Sheath with Needle and Guidewire

GENERAL CHARACTERISTICS

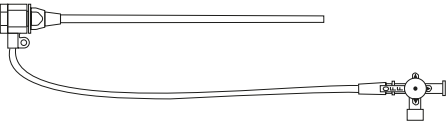
• Supplied sterile. • Maximum guidewire: 0.038" • Items per box: 5

PRODUCT DESCRIPTION

- FEP sheath with silicone coating.
- Silicone hemostasis valve.
- Polyethylene dilator with silicone coating.
- Double distal 'J' stainless steel guidewire (included in 7-cm and 11-cm sheaths only).
- See obturators, dilators and sterile sleeves.



Input TS Introducer Sheath Dilator



Input TS Introducer Sheath



Input TS Introducer Sheath with Dilator

INPUT™ TS INTRODUCER SHEATH WITH NEEDLE AND GUIDEWIRE

PRODUCT CODE	FRENCH SIZE	SHEATH LENGTH (CM)	NEEDLE LENGTH (CM)	NEEDLE GAUGE
051102A	5	11	7	18
061102A	6	11	7	18
071102A	7	11	7	18
081102A	8	11	7	18
091102A	9	11	7	18

FEMORAL INTRODUCERS

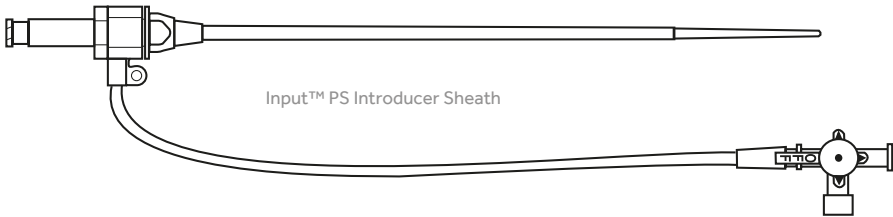
Input™ PS Introducer Sheath

GENERAL CHARACTERISTICS

- Supplied sterile.
- Maximum guidewire: 0.038"
- Items per box: 5

PRODUCT DESCRIPTION

- Pebax™ sheath.
- Silicone hemostasis valve.
- Polyethylene dilator.
- Double distal ‘J’ stainless steel guidewire (included in 11-cm sheaths only).
- Hydro/Pel™ hydrophilic coating: water-activated, super-lubricious coating on the distal portions of the sheath assembly allows for easy insertion.
- See obturators, dilators, sterile sleeves.



INPUT™ PS INTRODUCER SHEATH

PRODUCT CODE	FRENCH SIZE	OBTURATOR INCLUDED	COLOR CODE	SHEATH LENGTH (CM)	DILATOR LENGTH (CM)	WIRE STYLE (IN.)
050011	5	No	Gray	11	17	0.038 DDJ
060011	6	No	Green	11	17	0.038 DDJ
070011	7	No	Orange	11	17	0.038 DDJ
080011	8	No	Blue	11	17	0.038 DDJ
060023	6	Yes	Green	23	31	N/A
070023	7	Yes	Orange	23	39	N/A
080023	8	Yes	Blue	23	39	N/A
863311	6	No	Green	11	17	N/A
873311	7	No	Orange	11	17	N/A
883311	8	No	Blue	11	17	N/A
Pebax™ is a registered trademark of Atofina Corporation France.						

FEMORAL INTRODUCERS

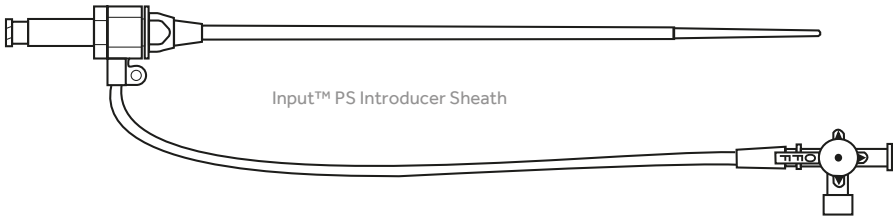
Input™ PS Introducer Sheath with Needle and Guidewire

GENERAL CHARACTERISTICS

- Supplied sterile.
- Maximum guidewire diameter: 0.038"
- Items per box: 5
- Color code: see chart below

PRODUCT DESCRIPTION

- Pebax™ sheath.
- Silicone hemostasis valve.
- Polyethylene dilator.
- Double distal "J" stainless steel guidewire (included in 11-cm sheaths only).
- Hydro/Pel™ hydrophilic coating: water-activated, super-lubricious coating on the distal portions of the sheath assembly allows for easy insertion.
- See obturators, dilators, sterile sleeves.



INPUT™ PS INTRODUCER SHEATH WITH NEEDLE AND GUIDEWIRE

PRODUCT CODE	FRENCH SIZE (F)	SHEATH LENGTH (CM)	NEEDLE LENGTH (CM)	NEEDLE GAUGE	COLOUR CODE
553311	5	11	7	18	Gray
563311	6	11	7	18	Green
573311	7	11	7	18	Orange
583311	8	11	7	18	Blue
Pebax™ is a registered trademark of Atofina Corporation France.					

FEMORAL INTRODUCERS

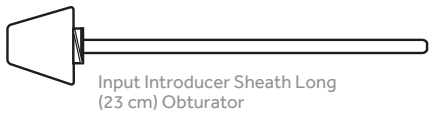
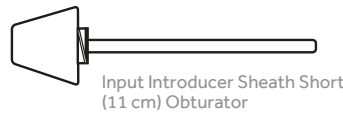
Input™ Accessories Obturator

GENERAL CHARACTERISTICS

- Supplied sterile.
- Color-coded for easy identification of compatible sheath.
- Items per box: 10

PRODUCT DESCRIPTION

- Helps maintain sheath patency and protects from outside contamination.
- Twist 'N Shut locking system locks obturator in place to prevent backout from sheath.
- Inserted into the introducer sheath when placement of the transvenous temporary pacing electrode or intravascular catheter is delayed or removed.



INPUT™PS INTRODUCER SHEATH OBTURATOR

PRODUCT CODE	USE WITH INTRODUCER	COLOR CODE	OBTURATOR I.D. (F)	OBTURATOR O.D. (F)	OBTURATOR LENGTH (CM)
205211	050011	Gray	5	4	11
206211	060011	Green	6	5	11
207211	070011	Orange	7	6	11
209223	090023	Gray	9	8	23

FEMORAL INTRODUCERS

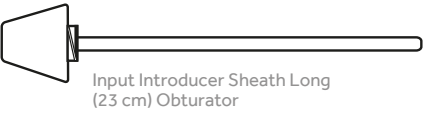
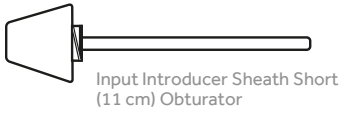
Input™ Accessories Obturator

GENERAL CHARACTERISTICS

- Supplied sterile.
- Color-coded for easy identification of compatible sheath.
- Items per box: 10

PRODUCT DESCRIPTION

- Helps maintain sheath patency and protects from outside contamination.
- Twist 'N Shut locking system locks obturator in place to prevent backout from sheath.
- Inserted into the introducer sheath when placement of the transvenous temporary pacing electrode or intravascular catheter is delayed or removed.



INPUT™TS INTRODUCER SHEATH OBTURATOR

PRODUCT CODE	USE WITH INTRODUCER	COLOR CODE	OBTURATOR I.D. (F)	OBTURATOR O.D. (F)	OBTURATOR LENGTH (CM)
206211A	061101A	Green	6	6	11
207211A	071101A	Orange	7	7	11
209223A	090037A	Gray	9	9	23

FEMORAL INTRODUCERS

Input™ Accessories
Vessel Dilator

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10

PRODUCT DESCRIPTION

- For use in arterial or venous applications.
- Polyethylene dilator.



Input Introducer Sheath Vessel Dilator

INPUT™PS INTRODUCER SHEATH VESSEL DILATOR

PRODUCT CODE	FRENCH SIZE	COLOR CODE	MAXIMUM WIRE SIZE (IN.)	DILATOR LENGTH (CM)
653311	5	Gray	0.038	17
673311	7	Orange	0.038	17
673323	7	Orange	0.038	Double 39

FEMORAL INTRODUCERS

Input™ Accessories
Vessel Dilator

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10

PRODUCT DESCRIPTION

- For use in arterial or venous applications.
- Polyethylene dilator.



Input Introducer Sheath Vessel Dilator

INPUT™TS INTRODUCER SHEATH VESSEL DILATOR

PRODUCT CODE	FRENCH SIZE	COLOR CODE	MAXIMUM WIRE SIZE (IN.)	DILATOR LENGTH (CM)
040037A	5	Gray	0.038	17
040042A	6	Green	0.038	17
040044A	7	Orange	0.038	17
040049A	9	Gray	0.038	17

FEMORAL INTRODUCERS

Input™ Accessories Sterile Sleeve

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10

PRODUCT DESCRIPTION

- Maintains sterility of indwelling catheter shaft proximal to the introducer hub.
- Twist 'N Shut locking system locks sleeve into input hub.



Input Introducer Sheath Sterile Sleeve

INPUT™ INTRODUCER SHEATH STERILE SLEEVE

PRODUCT CODE	LENGTH (CM)	FOR USE WITH
026000	26	Input™ Introducer Sheaths
060000	60	Input™ Introducer Sheaths

FEMORAL INTRODUCERS

Mullins Transseptal Catheter Introducer Sheath

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 1

PRODUCT DESCRIPTION

Sets include one sheath and one dilator. Used with Brockenbrough™ needle, except where noted.



Mullins Transseptal Catheter Introducer Sheath

MULLINS TRANSSEPTAL CATHETER INTRODUCER SHEATH

PRODUCT CODE	FRENCH SIZE	MAXIMUM WIRE SIZE (IN.)	SHEATH LENGTH (CM)	DILATOR LENGTH (CM)
008550	6	0.032	59	67
008551	7	0.032	59	67
008552	8	0.032	59	67

FEMORAL INTRODUCERS

Pediatric Mullins Transseptal Catheter Introducer Sheath

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 1

PRODUCT DESCRIPTION

Sets include one sheath and one dilator. Used with Brockenbrough™ needle, except where noted.



Mullins Transseptal Catheter Introducer Sheath

MULLINS
TRANSSEPTAL
CATHETER
INTRODUCER
SHEATH

PRODUCT CODE	FRENCH SIZE	MAXIMUM WIRE SIZE (IN.)	SHEATH LENGTH (CM)	DILATOR LENGTH (CM)
008530 	6	0.025	44	52
008531 	7	0.025	44	52
008532 	8	0.025	44	52
 Pediatric item				

FEMORAL INTRODUCERS

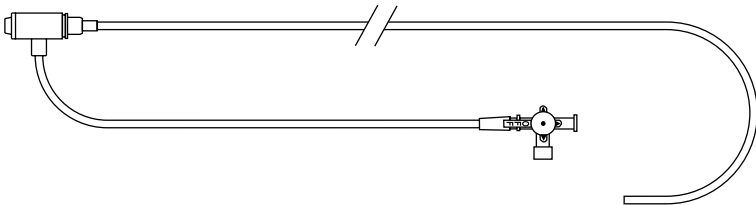
Mullins Transseptal Catheter Introducer Sheath with Hemostasis Valve

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 1

PRODUCT DESCRIPTION

Sets include one sheath and one dilator. Used with Brockenbrough™ needle.
Transseptal catheter introducer sheath has attached sidearm with stopcock and hemostasis valve.



Transseptal Catheter Introducer Sheath with Hemostasis Valve

TRANSSEPTAL
CATHETER
INTRODUCER
SHEATH WITH
HEMOSTASIS
VALVE

PRODUCT CODE	FRENCH SIZE	MAXIMUM WIRE SIZE (IN.)	SHEATH LENGTH (CM)	DILATOR LENGTH (CM)
008591	8	0.032	59	67

INTERVENTIONAL ACCESSORIES



INTERVENTIONAL ACCESSORIES

TRAcelet™ Hemostasis Device

GENERAL CHARACTERISTICS

- Items per box: 5
- Supplied sterile

PRODUCT DESCRIPTION

- The TRAcelet™ compression device is an innovative solution for simplified pressure control.
- Its dual-compression balloon system uniformly delivers pressure to the access site to stop bleeding, while maintaining radial artery patency.
- In the cath lab: use the syringe provided with the TRAcelet™ compression device for pressure optimization.
- In the recovery area: use the dial-based system for controlled pressure adjustments without the need for a syringe.



TECHNICAL SPECIFICATIONS

INFLATION VOLUME NUMBERS (CC)	
Nominal	13
Maximum	18

STRAP LENGTHS (CM)	
Regular	19.2
Large	25.2

CFN	STRAP LENGTHS (CM)
TRACR	Regular
TRACL	Large

1. Data on file at Medtronic.
2. Bench test data on file at Medtronic.

INTERVENTIONAL ACCESSORIES

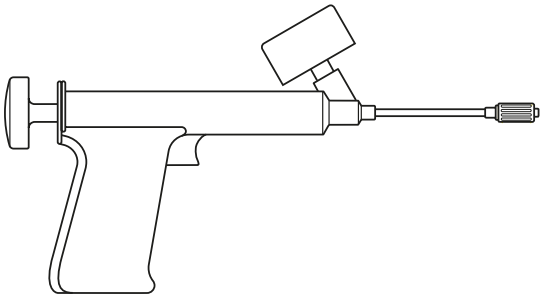
Everest™ Disposable Inflation Device and Accessories

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 1
- Kits per box: 1

PRODUCT DESCRIPTION

- Available with a 3-way stopcock.
- The pistol-grip fits comfortably in either hand and its trigger mechanism is easy to use for all operators.
- A 20-cc syringe capacity provides rapid negative pressures to speed deflation times.
- The 20 atm/bar and 30 atm/bar luminescent gauges are easy to read under low light conditions. Accurate readings within +/- 3% of gauge full scale.



EVEREST INFLATION DEVICE

PRODUCT CODE	DESCRIPTION	PACKAGED WITH
AC2200	Everest20 Inflation Device	1 three-way stopcock
AC3200	Everest30 Inflation Device	1 three-way stopcock
AC2205P	Everest20 Survival Kit	1 Everest20 atm inflation device, 1 three-way stopcock, Piton™ Y-adapter, guidewire insertion tool, and torque handle
AC3205P	Everest30 Survival Kit	1 Everest30 atm inflation device, 1 three-way stopcock, Piton™ Y-adapter, guidewire insertion tool, and torque handle

INTERVENTIONAL ACCESSORIES

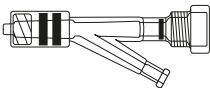
Piton™ Disposable PTCA Y-Adaptor and Y-Adaptor Kits

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 5

PRODUCT DESCRIPTION

- Designed for today's smaller shafted balloon catheters.
- Large, ridged cap and extra length simplify handling.
- Cap won't fall off.
- Lubricious gasket allows better maneuverability.



Piton™ Y-Adaptor



Insertion Tool

PITON™ Y-ADAPTOR

PRODUCT CODE	COLOR	LUMEN I.D. (IN.)	PACKAGED WITH
AC4001M	Clear/Blue	0.110	1 Piton™ Y-Adaptor, 1 insertion tool

INTERVENTIONAL ACCESSORIES

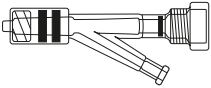
Piton™ Disposable PTCA Y-Adaptor and Y-Adaptor Kits

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 5

PRODUCT DESCRIPTION

- Designed for today's smaller shafted balloon catheters.
- Large, ridged cap and extra length simplify handling.
- Cap won't fall off.
- Lubricious gasket allows better maneuverability.



Piton™ Y-Adaptor



Insertion Tool



Torque Handle

PITON™ Y-ADAPTOR KIT

PRODUCT CODE	LUMEN I.D. (IN.)	PACKAGED WITH
AC4003M	0.110	1 Piton™ Y-Adaptor, 1 insertion tool, 1 torque handle

INTERVENTIONAL ACCESSORIES

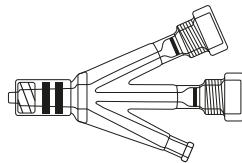
Piton™ Disposable PTCA Y-Adaptor and Y-Adaptor Kits

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 5

PRODUCT DESCRIPTION

- Designed for today's smaller shafted balloon catheters.
- Large, ridged cap and extra length simplify handling.
- Cap won't fall off.
- Lubricious gasket allows better maneuverability.



Piton™ Tri-Adaptor



Insertion Tool

PITON™ TRI-ADAPTORS

PRODUCT CODE	LUMEN I.D. (IN.)	PACKAGED WITH
AC4002M	0.110	1 Piton™ Tri-Adaptor, 1 insertion tool

INTERVENTIONAL ACCESSORIES

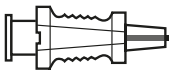
Metal guidewire insertion tool

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 5

PRODUCT DESCRIPTION

For use with Piton™ Y-Adaptors and Tri-Adaptors.



Stretch Insertion Tool

STRETCH INSERTION TOOL

PRODUCT CODE	DESCRIPTION
006073	Stretch insertion tool

INTERVENTIONAL ACCESSORIES

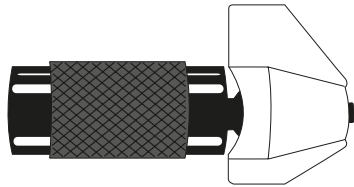
Steering Handle

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 5

PRODUCT DESCRIPTION

For use with PTCA guidewires.
Plastic nut with metal jaws.



STEERING HANDLE

PRODUCT CODE
008958

HEMODYNAMIC MONITORING CATHETERS

Pulmonary Wedge Pressure (PWP) Catheter

GENERAL CHARACTERISTICS

- Supplied sterile.
- For single use.
- Maximum guidewire: 0.038"
- Items per box: 5
- Packaged with balloon inflation syringe.

PRODUCT DESCRIPTION

- Provides rapid and accurate placement for hemodynamic pressure readings.
- Large lumen for blood sampling and excellent pressure tracings.



PULMONARY WEDGE PRESSURE (PWP) CATHETER

PRODUCT CODE	FRENCH SIZE	LENGTH (CM)
150075	7	110



PEDIATRIC AND TRANSSEPTAL PRODUCTS

CONTENTS
1. DRUG ELUTING STENTS
2. STENT PETAL STENTS
3. BALLOON DILATATION CATHETERS
4. DRUG ELUTING BALLOONS
5. GUIDE CATHETER FAMILY
6. INTERVENTIONAL GUIDEWIRES
7. ASPIRATION CATHETERS
8. ANGIOGRAPHIC CATHETERS AND WIRES
9. INTRODUCERS
10. INTERVENTIONAL ACCESSORIES
11. PEDIATRIC AND TRANSSEPTAL PRODUCTS
12. RENAL DENERVATION

PEDIATRIC PRODUCTS

Lehman™ Catheter Pediatric Woven Coronary Catheters

GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 10 • Maximum guidewire equals minimum tip I.D. • Closed end.
- Thin-wall construction.

PRODUCT DESCRIPTION

J.S. Lehman, MD, developed the Lehman™ ventriculography catheter. This catheter is specifically designed to be placed easily into the left ventricle via the aorta. The flexible, tapered distal tip is slightly curved to assist passage through the aortic valve and to sit freely in the contour of the left ventricle. This catheter provides excellent flow rates and catheter stability due to its thin-wall construction.



LEHMAN™ CATHETER

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	LENGTH (CM)	COMMENTS
001253 	5	Thin wall	0.032	50	No sideholes
001254 	5	Thin wall	0.032	80	No sideholes
 Pediatric item					

PEDIATRIC PRODUCTS

Goodale-Lubin™ Catheter Pediatric Woven Coronary Catheters

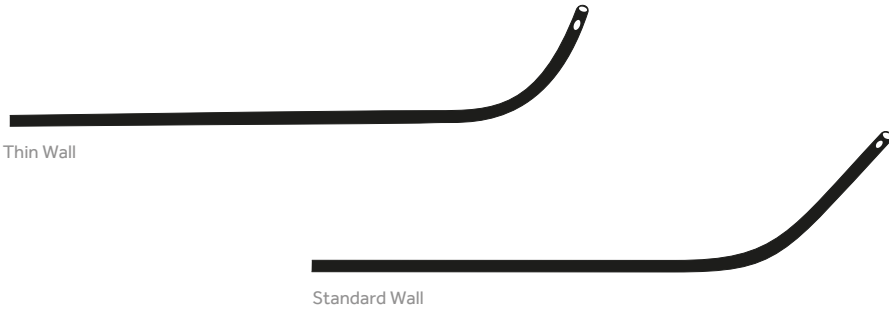
GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 10 • Maximum guidewire equals minimum tip I.D. • Open end.
- Two laterally opposed sideholes. • Thin-wall or standard-wall construction.

PRODUCT DESCRIPTION

Walter T. Goodale, MD, and Martin Lubin, MD, developed standard-wall and thin-wall catheters similar to the Cournand™ and Lehman™ catheters in construction and tip curve.

The additional feature of the Goodale-Lubin™ catheter is the two laterally opposed sideholes just proximal to the tip for improved disbursement of contrast during right heart angiography.



GOODALE-LUBIN™ CATHETER

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	SIDEHOLES	LENGTH (CM)
001279 	5	Thin wall	0.032	2	80
001453 	5	Standard wall	0.026	2	50
 Pediatric item					

PEDIATRIC PRODUCTS

Gensini™ Percutaneous Catheter Pediatric Woven Coronary Catheters

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10
- Maximum guidewire equals minimum tip I.D.
- Open end.
- Six sideholes.
- Thin-wall construction.

PRODUCT DESCRIPTION

Goffredo G. Gensini, MD, is responsible for the first designed catheter with an open end hole. This catheter has a tapered tip that fits securely over a guidewire for percutaneous introduction.

The six sideholes and thin-wall construction provide maximum flow rates. The catheter is used for aortic, ventricular, pulmonary and large-venous contrast studies.



GENSINI™ PERCUTANEOUS CATHETER

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	MINIMUM TIP I.D. (IN.)	LENGTH (CM)	COMMENTS
001323 	5	Thin wall	0.026	100	Use with 0.025 in. guidewire
001339 	6	Thin wall	0.036	80	Use with 0.035 in. guidewire
 Pediatric item					

PEDIATRIC PRODUCTS

NIH Pediatric Woven NIH Catheters

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 10
- Maximum guidewire equals minimum tip I.D.
- Nylon core.
- Closed end.
- Six sideholes.
- Thin-wall construction.

PRODUCT DESCRIPTION

The NIH (National Institutes of Health) catheter is designed with a thin wall and nylon core construction to provide maximum flow rates and catheter stability.

The flexible tip makes positioning in the cardiopulmonary system easier. This catheter is used to visualize the aorta, ventricles, pulmonary vasculature and the great veins.

The flexible tip makes positioning in the cardiopulmonary system easier. This catheter is used to visualize the aorta, ventricle, pulmonary vasculature and the great veins.



NIH

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	SIDEHOLES	LENGTH (CM)
001348 	5	Thin wall	6	50
001353 	6	Thin wall	6	80
 Pediatric item				

PEDIATRIC PRODUCTS

Pediatric NIH Pediatric Woven NIH Catheters

GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 10 • Maximum guidewire equals minimum tip I.D. • Nylon core.
- Closed end. • Six sideholes (4F Catheter has four sideholes). • Thin-wall construction.

PRODUCT DESCRIPTION

This thin-walled catheter is designed to provide maximum flow and flexibility. The catheter can be used for aortic, ventricular, pulmonary and large-vein contrast studies.

The flexible tip makes positioning in the cardiopulmonary system easier. This catheter is used to visualize the aorta, ventricle, pulmonary vasculature and the great veins.



PEDIATRIC NIH

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	SIDEHOLES	LENGTH (CM)
001375 	4	Thin wall	4	50
001377 	5	Thin wall	6	50
001378 	5	Thin wall	6	80
001380 	6	Thin wall	6	50
001381 	6	Thin wall	6	80
001382 	6	Thin wall	6	100
 Pediatric item				

PEDIATRIC PRODUCTS

Pediatric Curved NIH Pediatric Woven NIH Catheters

GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 10 • Maximum guidewire equals minimum tip I.D. • Nylon core.
- Closed end. • Six sideholes. • Thin-wall construction.

PRODUCT DESCRIPTION

This thin-walled catheter is designed to provide maximum flow and flexibility. The catheter can be used for aortic, ventricular, pulmonary and large-vein contrast studies.

The flexible tip makes positioning in the cardiopulmonary system easier. This catheter is used to visualize the aorta, ventricle, pulmonary vasculature and the great veins.



PEDIATRIC CURVED NIH

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	LENGTH (CM)
008761 	5	Thin wall	65
008762 	6	Thin wall	65
008763 	7	Thin wall	80
 Pediatric item			

PEDIATRIC PRODUCTS

Pediatric NIH with Cardio-Marker Image Bands Pediatric Woven NIH Catheters

GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 5 • Maximum guidewire equals minimum tip I.D. • Closed end.
- Six sideholes • Thin-wall construction.

PRODUCT DESCRIPTION

This thin-walled catheter is designed to provide maximum flow and flexibility. The catheter can be used for aortic, ventricular, pulmonary and large-vein contrast studies.

Band width: 1 mm.

Two marker bands 1 cm apart +- 1/2 mm (leading edge to leading edge).



PEDIATRIC NIH WITH CARDIO-MARKER IMAGE BANDS

PRODUCT CODE	FRENCH SIZE	DESIGN STYLE	SIDEHOLES	LENGTH (CM)
010010 	5	Thin wall	6	65
010011 	6	Thin wall	6	80
010012 	7	Thin wall	6	80
 Pediatric item				

PEDIATRIC PRODUCTS

Rashkind™ Recessed Balloon Catheter Pediatric Septostomy Balloon Catheters

GENERAL CHARACTERISTICS

- Supplied sterile. • Items per box: 1

PRODUCT DESCRIPTION

- Woven shaft design
- Shaft length: 50 cm



RASHKIND™ RECESSED BALLOON CATHETER

PRODUCT CODE	SHAFT SIZE (F)	RECOMMENDED INFLATED BALLOON DIAMETER (MM)	RECOMMENDED INTRODUCER (F)	COMMENTS
008764 	6	14	6	Single lumen
 Pediatric item				
Rashkind® is a registered trademark of William J. Rashkind, M.D.				

PEDIATRIC PRODUCTS

Rashkind™ Balloon Catheter Single Lumen Pediatric Septostomy Balloon Catheters

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 1

PRODUCT DESCRIPTION

- Woven shaft design
- Shaft length: 50 cm



RASHKIND™ BALLOON CATHETER SINGLE LUMEN

PRODUCT CODE	SHAFT SIZE (F)	RECOMMENDED INFLATED BALLOON DIAMETER (MM)	RECOMMENDED INTRODUCER (F)	COMMENTS
007161 	4	11	7	Single lumen
007160 	5	12	8	Single lumen
 Pediatric item				
Rashkind® is a registered trademark of William J. Rashkind, M.D.				

PEDIATRIC PRODUCTS

Rashkind™ Balloon Catheter Double Lumen Pediatric Septostomy Balloon Catheters

GENERAL CHARACTERISTICS

• Supplied sterile. • Items per box: 1

PRODUCT DESCRIPTION

- Woven shaft design
- Shaft length: 50 cm



RASHKIND™ BALLOON CATHETER DOUBLE LUMEN

PRODUCT CODE	SHAFT FRENCH SIZE	RECOMMENDED INFLATED BALLOON DIAMETER (MM)	RECOMMENDED INTRODUCER (F)	COMMENTS
007158	5.5	14	9	Double lumen
 Pediatric item				

PEDIATRIC PRODUCTS

Pediatric Mullins Transseptal Catheter Introducer Sheath

GENERAL CHARACTERISTICS

• Supplied sterile. • Maximum guidewire: 0.025" • Items per box: 1

PRODUCT DESCRIPTION

- Sets include one sheath and one dilator.
- For use with Pediatric Brockenbrough™ Needle.



Mullins Transseptal Catheter Introducer Sheath

PEDIATRIC MULLINS TRANSSEPTAL INTRODUCER SHEATH

PRODUCT CODE	FRENCH SIZE	MAXIMUM WIRE SIZE (IN.)	SHEATH LENGTH (CM)	DILATOR LENGTH (CM)
008530 	6	0.025	44	52
008531 	7	0.025	44	52
008532 	8	0.025	44	52
 Pediatric item				

TRANSSEPTAL PRODUCTS & ACCESSORIES

Mullins Transseptal Catheter Introducer Sheath

GENERAL CHARACTERISTICS

• Not supplied sterile. • Single-use device. • Items per box: 1

PRODUCT DESCRIPTION

Sets include one sheath and one dilator. Used with Brockenbrough™ needle, except where noted.
For use with Brockenbrough™ Needle.

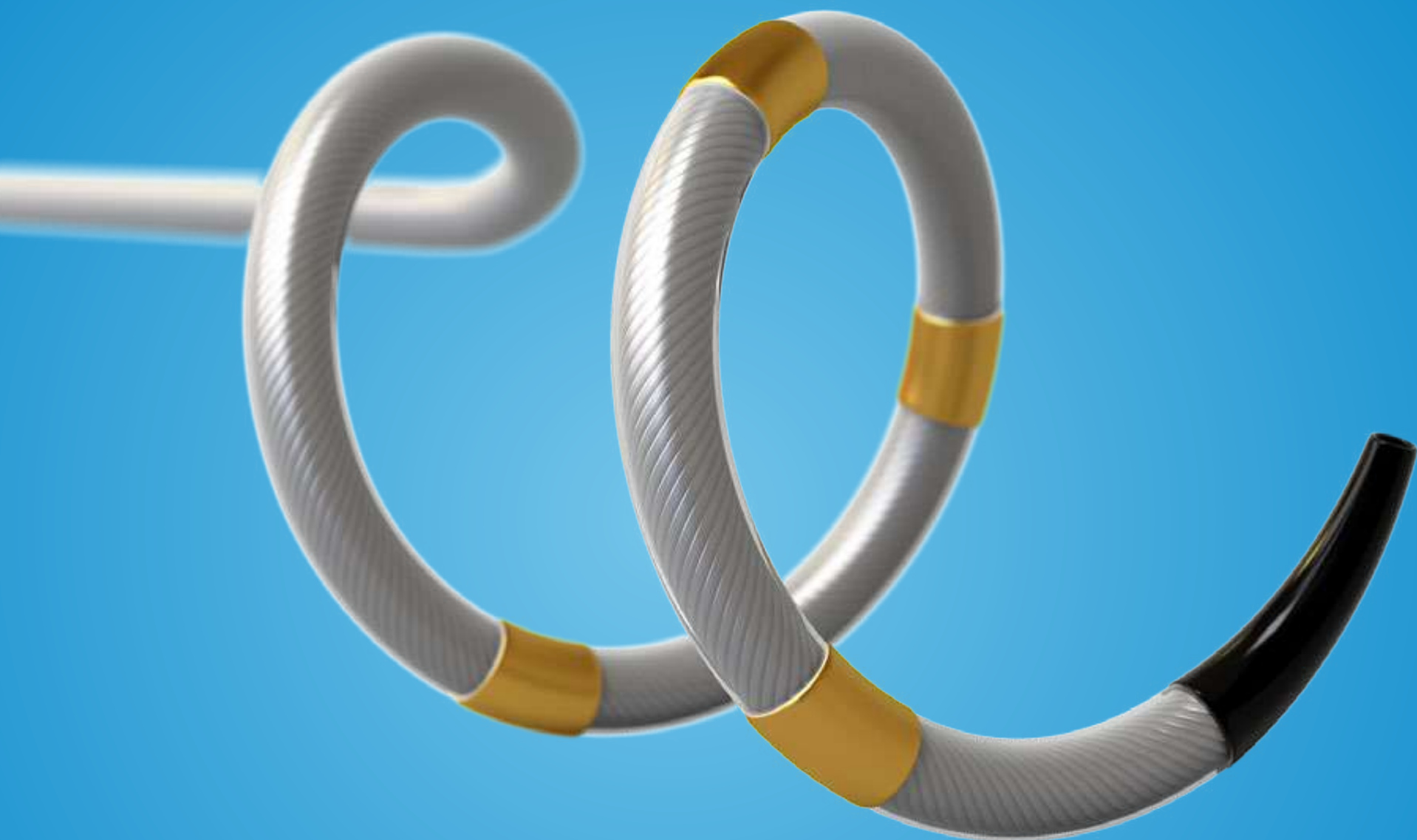


Mullins Transseptal Catheter Introducer Sheath

MULLINS TRANSSEPTAL CATHETER INTRODUCER SHEATH

PRODUCT CODE	FRENCH SIZE	MAXIMUM WIRE SIZE (IN.)	SHEATH LENGTH (CM)	DILATOR LENGTH (CM)
008550	6	0.032	59	67
008551	7	0.032	59	67
008552	8	0.032	59	67
For use with Brockenbrough™ Needle.				

RENAL DENERVATION CATHETERS



RENAL DENERVATION

Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter

GENERAL CHARACTERISTICS

▪ Supplied sterile ▪ Items per box: 1 ▪ Label color: Orange.

PRODUCT DESCRIPTION

The Symlicity Spyral™ Multi-Electrode Catheter offers an improved renal denervation procedure. Consistent four-quadrant ablation pattern, self-expanding helical design conforms to a wide range of artery shapes and sizes (3-8mm) and a low 6F guide catheter compatibility, delivered over a standard 0.014" guidewire with rapid exchange system.



ORDERING CHART

CATALOG NUMBER	PRODUCT
RDN016	Symlicity Spyral™ Catheter
RDN017	Symlicity G3™ Generator, supplied standard with remote control
RDN019	Cart, Symlicity G3™ Generator Component
RDN012	Replacement foot switch
PRT075-XX	Replacement power cable (country-specific) (Contact Medtronic representative for catalog number)

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LIFE IS DIFFERENT



CoreValve™
Evolut™ R

Transcatheter Aortic
Valve Replacement
(TAVR) Platform

Medtronic

BUILT ON A PROVEN FOUNDATION

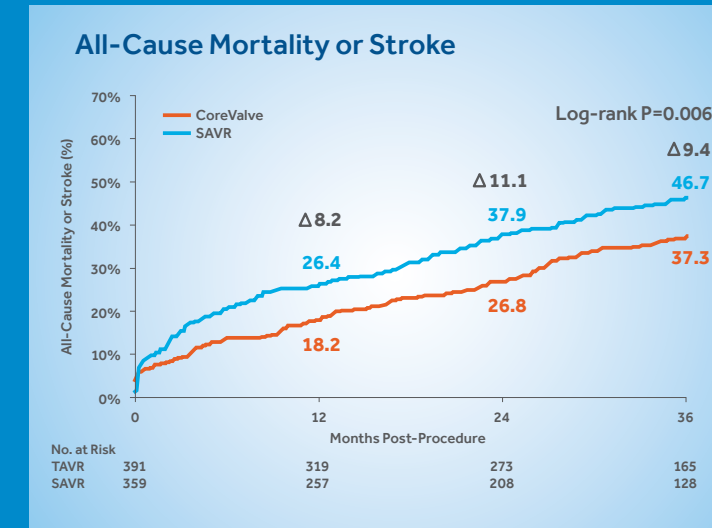
SUPERIOR LONG-TERM CLINICAL OUTCOMES



The CoreValve™ System continues to demonstrate exceptional outcomes — and we've taken what we've learned from the design of that platform and applied it to the Evolut™ R System.

Supra-annular Valve Design
Self-expanding Nitinol Frame
Porcine Pericardial Tissue
Low Delivery Profile

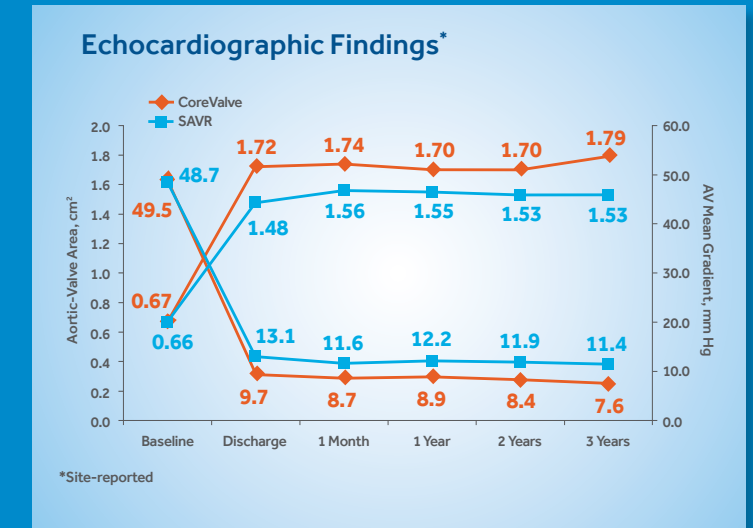
Lower Rate of Mortality or Stroke



The CoreValve™ Platform shows superior outcomes vs. surgery.¹

1. CoreValve™ US Pivotal High Risk Trial 3-year Outcomes Presented at ACC 2016.

Unsurpassed Sustained Hemodynamic Performance



CoreValve™ system had significantly better valve performance over SAVR at all follow-up visits (P<0.001)¹

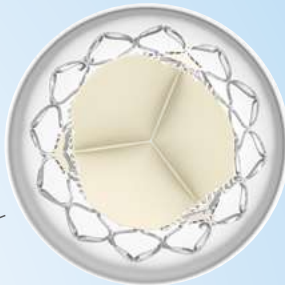
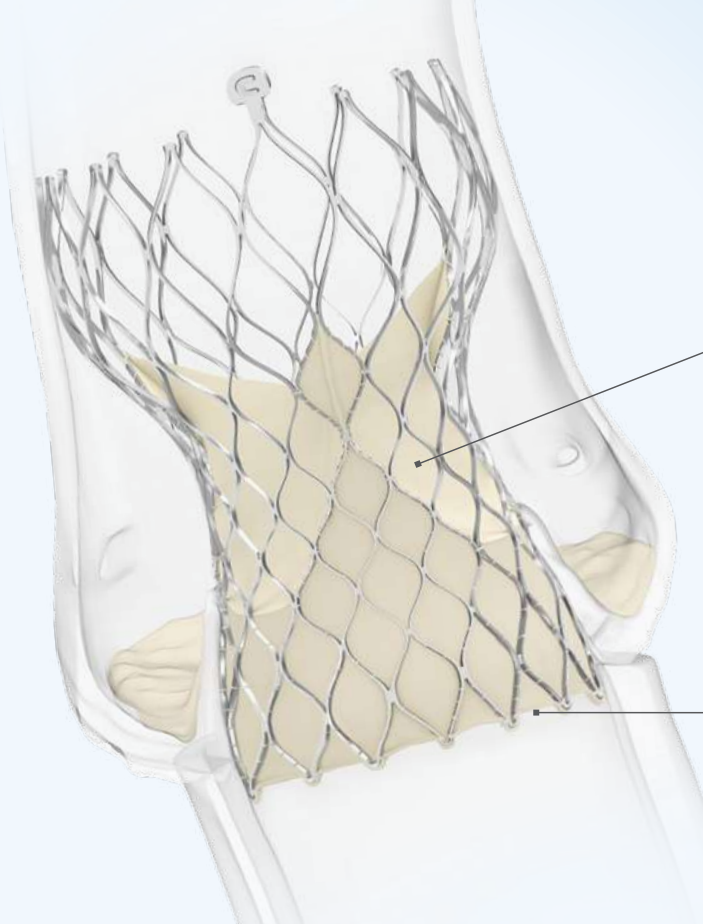
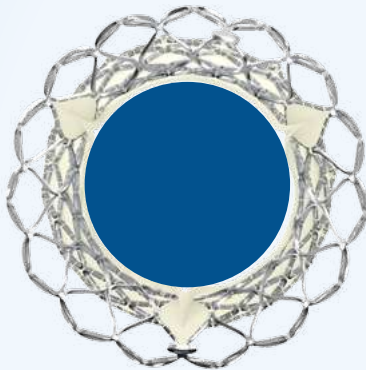
UNSURPASSED HEMODYNAMICS



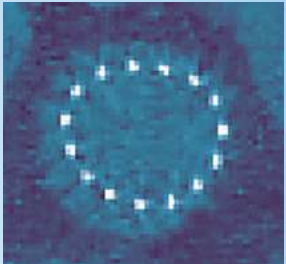
Supra-annular valve design maximizes leaflet coaptation and promotes single digit gradients and large EOA's.

7.5 mm Hg
single digit
gradients

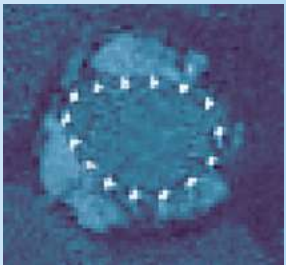
2.0 cm²
Large EOA



Supra-annular Valve | Optimizes coaptation in non-circular anatomy with supra-annular valve position



Annulus | Conforms to the native annulus

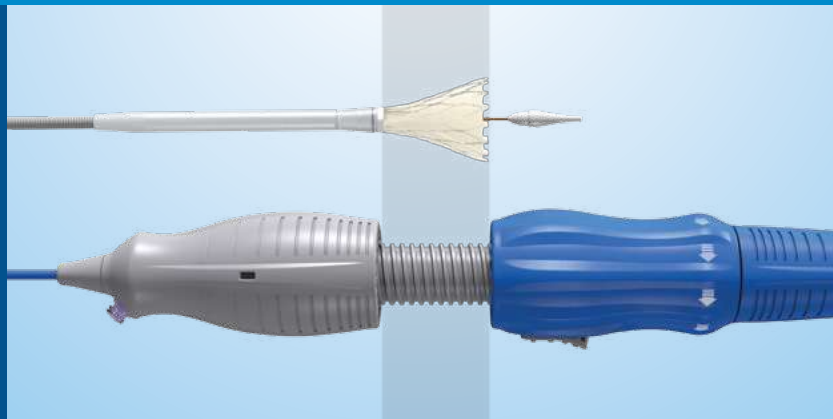


**Exceptional
Survival
98.8%**

CONTROL DURING DEPLOYMENT

ACCURATE POSITIONING

1:1 response provides immediate feedback between the deployment knob and the movement of the capsule



RECAPTURE AND REPOSITION

EnVeo™ R provides option to recapture and reposition for accurate placement.

[†] Up to 80% deployment.

Tactile Indicator
~ 2/3 Deployment

Just Prior to Point
of No Recapture[†]

ACCESS MORE PATIENTS



BROADEST ANNULUS RANGE ON THE MARKET**

The only TAVR platform indicated to treat annulus up to 30 mm

17[‡]/18



23 mm Valve



26 mm Valve



29 mm Valve



34 mm Valve

30 mm

LOWEST DELIVERY PROFILE

The only TAVR system with a vessel indication down to 5.0 mm***



** Broadest annulus range based on CT derived diameters

[‡] Measurement for TAV-in-SAV only.

*** Evolut™ R 23, 26 and 29 mm valves. 34 mm valve minimum vessel indication ≥ 5.5 mm

During Use: For direct aortic and subclavian access procedures, care must be exercised when using the retrieval mechanism to ensure adequate clearance to avoid advancement of the catheter tip through the bioprosthetic leaflets during device closure. For direct aortic access procedures, use a separate introducer sheath; do not use the Envivo R1 line sheath. Adequate rinsing of the catheter is required to prevent thrombus formation. Do not touch the catheter or the catheter handle to the catheter, do not touch the leaflets or squeeze the bioprosthetic. If a capsule becomes damaged during loading or the capsule fails to close, replace the entire system (bioprosthetic, catheter, and CLS). Do not use a catheter with a damaged capsule. After a bioprosthetic is deployed, do not touch the catheter or the catheter handle to the catheter. Only the catheter handle should be used to deploy the catheter. Only during implantation, if resistance to deployment is encountered (e.g., the micro knob starts clicking or is tight or stuck), apply upward pressure to the macro slider while turning the micro knob. If the bioprosthetic still does not deploy, remove it from the patient and use another system. AccurTrack DCS Only: Once the catheter is deployed, return the catheter to the bioprosthetic from the patient and use the catheter handle to deploy the catheter. Do not touch the catheter or the catheter handle to the catheter. Only the catheter handle should be used to deploy the catheter.

For EnVeo R DCS: For transfemoral access, use caution in patients who present with multipplanar curvature of the aorta, acute angulation of the aortic arch, an ascending aortic aneurysm, or severe calcification in the aorta and/or vasculature. If ≥2 of these factors are present, consider an alternative access route to prevent vascular complications. There will be some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and investigate the cause of the resistance. For example, if the area of resistance is before proceeding, consider force passage. For long passage could cause the risk of vascular complications (for example, vessel dissection). Persistent resistance could cause the catheter to kink, which could increase the risk of vascular complications (for example, vessel dissection or rupture).

POTENTIAL ADVERSE EVENTS Potential risks associated with the implantation of the CoreValve or CoreValve Evolut R transcatheter aortic valve may include, but are not limited to, the following: • death • myocardial infarction, cardiac arrest, cardiogenic shock, cardiac tamponade • coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) • cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricular myocardium, or valvular structures that may require intervention) • emergent surgical or transcatheter intervention (for example, aortic valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon aortic valvuloplasty) • prosthetic valve dysfunction (regurgitation or stenosis) due to fracture, bending (out-of-round configuration) of the valve frame, underexpansion of the valve frame, calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-pannus mismatch); malposition (either too high or too low)/malplacement • prosthetic valve migration/embolization • prosthetic valve endocarditis • prosthetic valve thrombosis • delivery catheter system malfunction resulting in the need for additional re-crossing of the aortic valve and prolonged procedural time • aortic dissection or rupture • stroke • peripheral embolization • acute kidney injury • acute heart failure • acute pulmonary embolism or other neurological deficits • heart failure • cardiac failure or low cardiac output • ancillary device embolization • individual organ (for example, cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure • major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) • vascular access-related complications (eg, dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, stenosis) • mitral valve regurgitation or injury • conduction system disturbances (for example, atrioventricular block, left-bundle branch block, asystole), which may require a permanent pacemaker • infection (including endocarditis) • pericardial effusion • tamponade • hemolysis • hematuria • hemoglobinuria • electrolyte imbalance • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

CAUTION Federal law (USA) restricts this device to sale by or on the order of a physician.

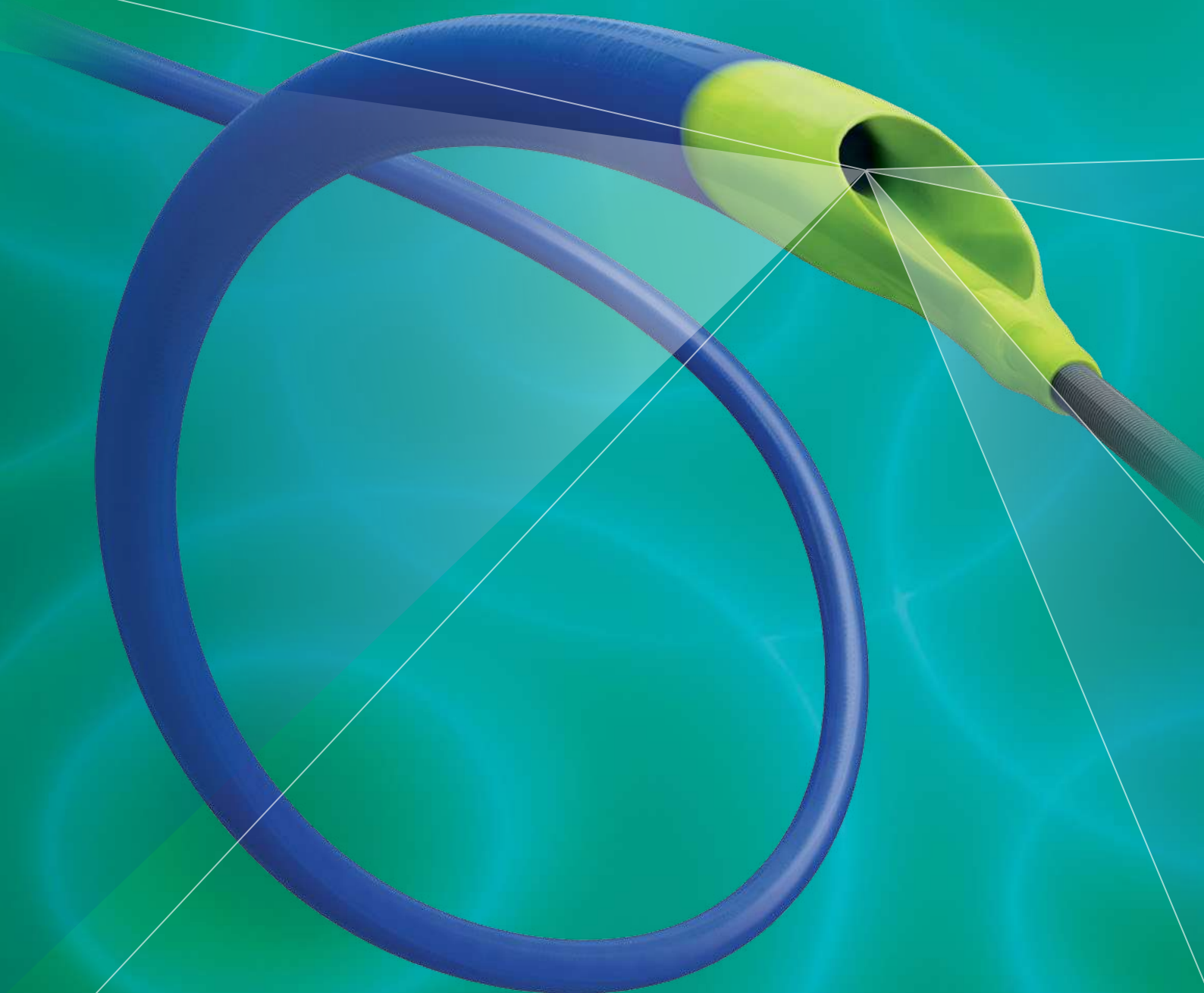
UC:201704294 FN 10/2016

medtronic.com



Export **Advance**[™]

ASPIRATION CATHETER



Advancing Performance



Medtronic

Export Advance™

ASPIRATION CATHETER

The Export Advance™ aspiration catheter delivers consistent, high-performing aspiration power when it matters most—restoring flow and protecting patients.

1 Superior Deliverability* and Kink Resistance

Combining innovative technology with precision and performance, the Export Advance catheter confidently delivers in a wide range of anatomies.

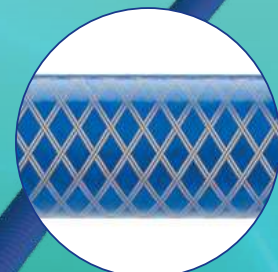
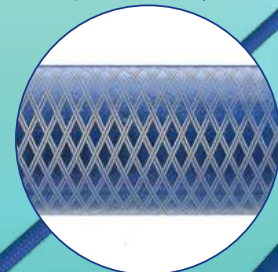
Full Wall Variable Braiding Technology shaft construction provides variable levels of stiffness without joints for optimal catheter performance

Preloaded stylet facilitates dependable delivery to target aspiration site

- Stylet enhances stiffness[†] in the shaft during catheter delivery, boosting kink resistance, trackability and pushability

Buddy wire compatibility allows for extra support, when needed, in demanding cases

Proximal shaft braiding enhances pushability



Distal shaft braiding increases flexibility

Preloaded stylet facilitates delivery



Dependable, High-Performing Aspiration Power

2

When every second counts, the Export Advance catheter's sleek design effectively extracts thrombus.

- Large extraction lumen (0.044" proximal; 0.043" distal) increases aspiration power
- Optimised hub geometry provides improved flow
- Soft, short, forward-facing tip design permits excellent particle capture



3

More Than 1,000,000 Export™ Patients Treated

Medtronic engineered the first aspiration catheter in 2003 and continues to be the worldwide leader in aspiration catheters.‡

The Export™ family of aspiration catheters demonstrates a statistically significant reduction of cardiac death at one year in STEMI patients§



*Data on file at Medtronic, Inc. Based on bench test studies.

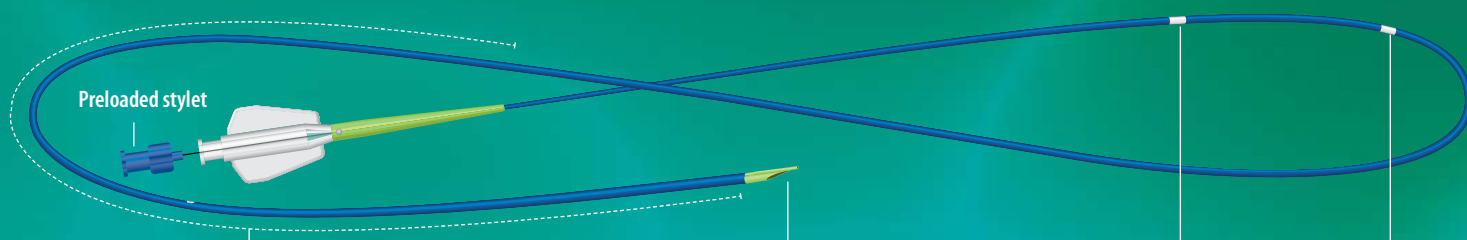
†Based on animal studies compared with Export™ AP aspiration catheter without stylet.

‡Data on file at Medtronic, Inc. Based on 2003–2013 sales data.

§Vlaar PJ et al. Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study. *The Lancet*. 2008;371:1915–1920. Post hoc analysis, not adjusted for multiplicity.

Export Advance™

ASPIRATION CATHETER



Lubricious hydrophilic 38-cm coating reduces friction and ensures smoother advancement through difficult vessels

Radiopaque tip marker provides exceptional distal visualisation for precise device placement

Proximal markers located at 90 cm and 100 cm indicate point at which aspiration catheter exits guide catheter, minimising X-ray exposure

Product Code	Guide Compatibility (in.)	Wire Compatibility (in.)	Length (cm)
ADVANCECE	6 F min. guide I.D. 0.070	0.014	140

Indications for Use

The Export™ aspiration catheter is indicated for use in the central and peripheral circulatory system, including saphenous vein grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty, percutaneous transluminal angioplasty and/or stenting procedures, and
- To subselectively infuse/deliver diagnostic or therapeutic fluids with or without vessel occlusion.

Important Information

Prior to use, refer to the product *Instructions for Use* supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

Trademarks may be registered and are the property of their respective owners. For distribution only in markets where Export Advance™ aspiration catheter has been approved. Not for distribution in the USA, Japan or France.

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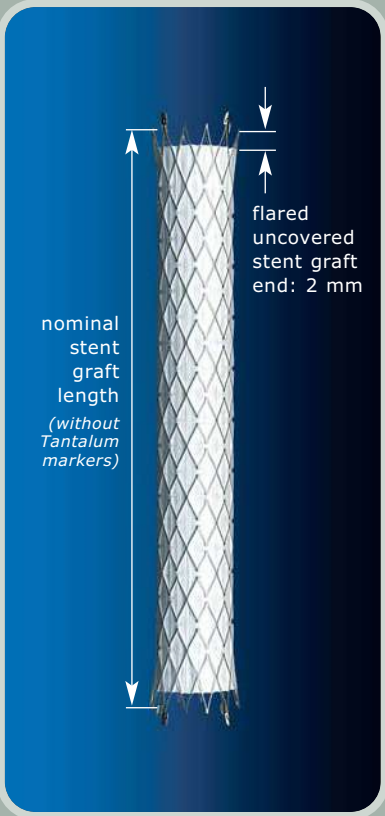
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3750 NW 87th Avenue, Suite 700
Miami, FL 33178
USA
Tel: 305.500.9328
Fax: 786.709.4244



Vascular Stent Graft

Deployment system working length
80 cm and 117 cm, Guidewire 0.035 in



PULL-BACK DEVICE 				
Deployment system working length:		80 cm	117 cm	
Expanded Stent Graft Diameter [mm]	Stent Graft Length [mm]	Delivery System Diameter [F]	Order No.	Order No.
5	20	8	FVM05020	FVL05020
	30	8	FVM05030	FVL05030
	40	8	FVM05040	FVL05040
	60	8	FVM05060	FVL05060
	80	8	FVM05080	FVL05080
	100	8	FVM05100	FVL05100
6	120	8	FVM05120	FVL05120
	20	8	FVM06020	FVL06020
	30	8	FVM06030	FVL06030
	40	8	FVM06040	FVL06040
	60	8	FVM06060	FVL06060
	80	8	FVM06080	FVL06080
7	100	8	FVM06100	FVL06100
	120	8	FVM06120	FVL06120
	20	8	FVM07020	FVL07020
	30	8	FVM07030	FVL07030
	40	8	FVM07040	FVL07040
	60	8	FVM07060	FVL07060
8	80	9	FVM07080	FVL07080
	100	9	FVM07100	FVL07100
	120	9	FVM07120	FVL07120
	20	9	FVM08020	FVL08020
	30	9	FVM08030	FVL08030
	40	9	FVM08040	FVL08040
9	60	9	FVM08060	FVL08060
	80	9	FVM08080	FVL08080
	100	9	FVM08100	FVL08100
	120	9	FVM08120	FVL08120
	30	9	FVM09030	FVL09030
	40	9	FVM09040	FVL09040
10	60	9	FVM09060	FVL09060
	80	9	FVM09080	FVL09080
	100	9	FVM09100	FVL09100
	120	9	FVM09120	FVL09120
	30	9	FVM10030	FVL10030
	40	9	FVM10040	FVL10040
12	60	9	FVM10060	FVL10060
	80	9	FVM10080	FVL10080
	100	9	FVM10100	FVL10100
	120	9	FVM10120	FVL10120
	30	10	FVM12030	FVL12030
	40	10	FVM12040	FVL12040
13,5	60	10	FVM12060	FVL12060
	80	10	FVM12080	FVL12080
	100	10	FVM12100	FVL12100
	120	10	FVM12120	FVL12120
	30	10	FVM14030	FVL14030
	40	10	FVM14040	FVL14040
	60	10	FVM14060	FVL14060
	80	10	FVM14080	FVL14080
	100	10	FVM14100	FVL14100
	120	10	FVM14120	FVL14120

Minimum order quantity: 1 unit

Not For Distribution in the U.S. or to any U.S. customer.
Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and directions for use.

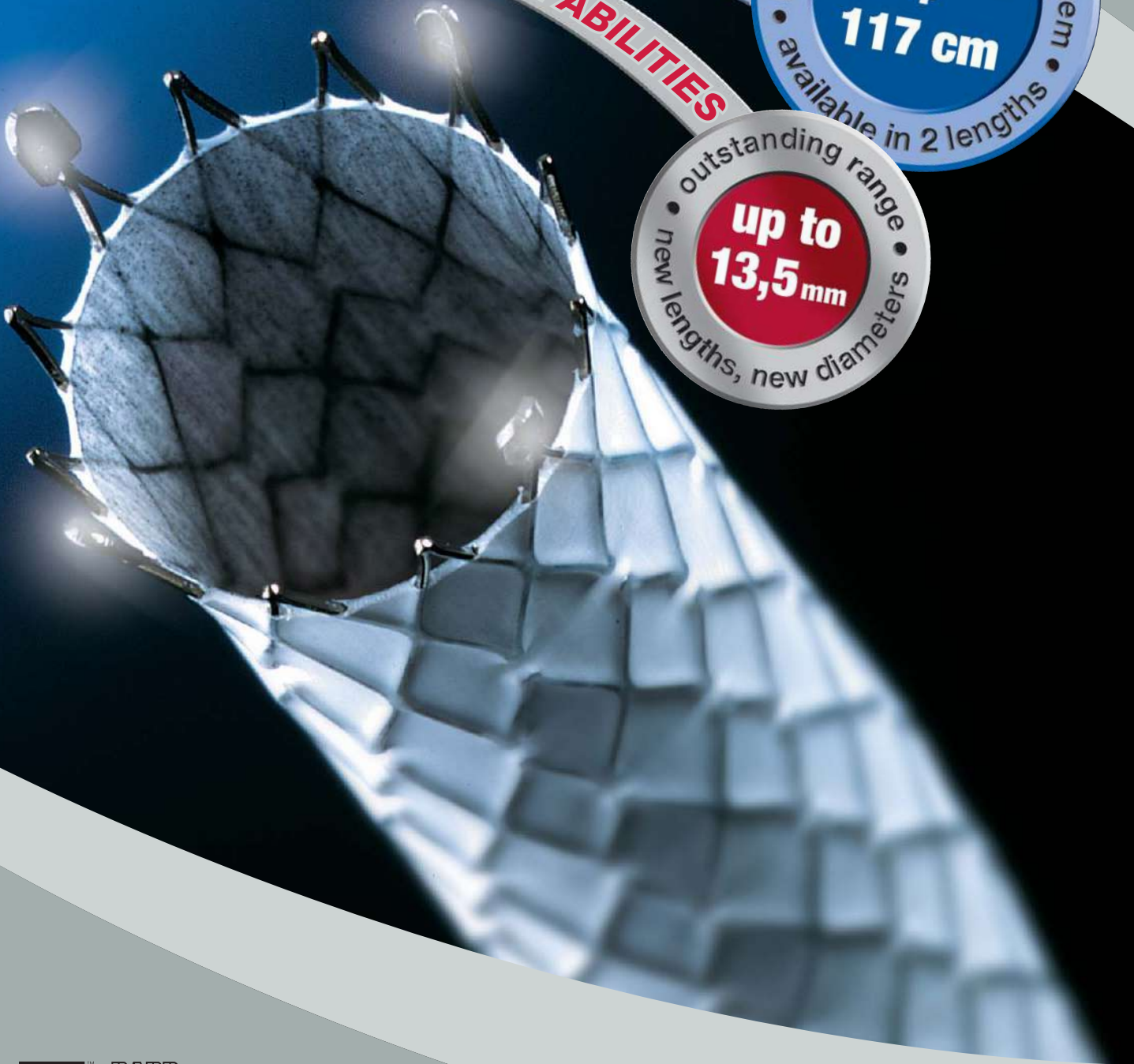
angiomed

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TEL: ++ 49 721 9445-0 • FAX: ++ 49 721 9445-393



VASCULAR
STENT GRAFT

EXPANDING PERFORMANCE
EXTENDING CAPABILITIES



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fluency[®] plus

VASCULAR STENT GRAFT

● The **FLUENCY[®] Plus** Stent Graft consists of a self-expanding Nitinol skeleton, encapsulated with two ultrathin layers of ePTFE

● The luminal surface of the ePTFE is impregnated with Carbon

● Highly radiopaque PUZZLE™ Tantalum Markers provide superior fluoroscopic visualization during the entire Stent Graft placement procedure

● The excellent radial expansion force and the 2mm flared bare Stent Graft ends minimize the risk of dislocation

● Minimal Stent Graft foreshortening during deployment further contributes to placement accuracy

● **FLUENCY[®] Plus** Stent Grafts are MRI safe and compatible

● Proprietary PUZZLE™ Tantalum Marker technology provides superior visibility of stent graft ends

Patient with iliac artery occlusion

After implantation of a FLUENCY[®] Plus Vascular Stent Graft (8 mm diameter/40 mm length)

Continuing the innovation, the **FLUENCY[®] Plus** Stent Graft now features the **BARD S.A.F.E.[®] DELIVERY SYSTEM** including the unique catheter tip, which is formed from the outer sheath. During deployment the new tip disappears from the distal end of the deployment system. During the retraction there is no tip visible on the inner catheter. The tip of the **BARD S.A.F.E.[®] DELIVERY SYSTEM** is retracted as part of the outer sheath.

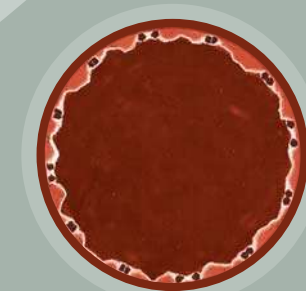
This proprietary delivery system technology features a multifunction braided catheter with optimal balance between shaft **Pushability** and progressive **Flexibility** at the catheter tip, providing excellent **Trackability** to the target lesion site.

- Unique Catheter Tip Design
- Multifunctional Braided Catheter
- Low profile 8F, 9F and 10F delivery systems reduce trauma to the patient

● The soft and atraumatic tip is tapered to fit 0.035 in guide wires

● The "tipless inner catheter" reduces the risk of catheter entanglement post stent graft deployment

● A radiopaque marker band is integrated into the outer sheath and moves towards the handle during stent graft deployment substantially contributing to placement control



Cross section of 8 mm diameter FLUENCY[®] Plus Vascular Stent Graft at 1 mm oversizing (in-vitro)



INSTRUCȚIUNI DE UTILIZARE

Bobina detașabilă AXIUM™

și

I.D. (dispozitiv de decuplare instantanee)



CUPRINSUL

Bobina detaşabilă AXIUM™ şi I.D. (dispozitiv de decuplare instantanee)

English	3
Francais.....	5
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Glosar de simboluri	39

Română

RO

Instrucțiuni de utilizare

ATENȚIE

- Legea federală (SUA) restricționează acest dispozitiv la vânzarea, distribuția și utilizare de către, sau la ordinul unui medic.
- Acest dispozitiv trebuie utilizat numai de către medici care au o înțelegere aprofundată a angiografiei și a procedurilor neuro-intervenționale percutanate.

DESCRIERE

Bobina detașabilă AXIUM™ constă dintr-o bobină de embolizare de platină atașată la un împingător compozit pentru plantarea a implantului ce are un marker de poziționare radioopac și un dispozitiv de decuplare instantanee (I.D.) care, atunci când este activat, detașează bobina de vârful împingătorului. Unele dintre bobinele detașabile AXIUM™ sunt îmbinate cu microfibramente PGLA sau microfibramente din nailon. I.D. se vinde separat.

OMPATIBILITATEA DISPOZITIVULUI

Pentru utilizarea sistemului cu bobină detașabilă AXIUM™ sunt necesare următoarele dispozitive:

	Tipul	Diametrul (mm)	Diametrul interior minim al micro-cateterului (in)	Decuplare
AXIUM™ Bobine detașabile	Neizolat	Toate	0.0165	I.D.
AXIUM™ Bobine detașabile	PGLA	De la 2 la 10	0.0165	I.D.
AXIUM™ Bobine detașabile	PGLA	De la 12 în sus	0.020	I.D.
AXIUM™ Bobine detașabile	Nailon	De la 2 la 4	0.0165	I.D.
AXIUM™ Bobine detașabile	Nailon	De la 5 în sus	0.020	I.D.

Alte produse accesorii (necesare pentru executarea unei proceduri)

Cateter de ghidaj 6-8F *

Microcateter cu două bandelete de marcare (vezi mai sus*)

Fire de ghidaj compatibile cu microcateterul*

Set infuzie continuă de soluție salină /heparină *

Supape hemostatice rotative (RHHV)*

Robinet cu trei căi*

Robinet cu o cale*

Stativ IV*

Teacă femurală*

* Nu este livrat ca parte a sistemului; este ales pe baza experienței și preferințelor medicului.

INDICAȚII DE UTILIZARE

Bobinele detașabile AXIUM™ sunt destinate embolizării endovasculare a anevrismelor intracraniene. Bobinele detașabile AXIUM™ sunt, de asemenea, destinate embolizării altor anomalii neuro-vasculare, cum ar fi malformațiile arteriovenoase și fistulele arteriovenoase.

COMPLICAȚII POSIBILE

Complicațiile potențiale includ, dar nu se limitează la acestea:

- Hematom la locul de intrare
 - Perforarea vasului sanguin
 - Spasmul vascular
 - Hemoragie
- Episoade trombo-embolice
 - Deficite neurologice, inclusiv accident vascular cerebral și deces
 - Tromboză vasculară
 - Ischemie

AVERTIZĂRI

- Bobina detașabilă AXIUM™, piesa de livrare și teaca introductoare sunt furnizate într-un pachet steril și nepirogen, nedeschis și nedeteriorat. Pachetul trebuie verificat pentru eventuale deteriorări. Bobinele detașabile AXIUM™ deteriorate nu trebuie utilizate, deoarece aceasta poate duce la rănierea pacientului.
- Bobinele detașabile AXIUM™ sunt de unică folosință. I.D. furnizat steril și poate fi utilizat doar la un singur pacient. După utilizare, nu reutilizați și / sau refoșiți. Reprocesarea sau resterilizarea pot compromite integritatea structurală a dispozitivului și / sau pot duce la defectarea dispozitivului care, la rândul său, poate duce la rănierea pacientului, la boală sau deces.

- Nu utilizați dacă ambalajul steril a fost compromis sau deteriorat.

- Împingătorul și / sau bobinele de plantare a implantului deteriorate pot afecta desfășurarea bobinei și stabilitatea în interiorul vasului sau anevrismului, ceea ce poate duce la migrarea sau extravazarea bobinei.

- Nu rotiți împingătorul implantului în timpul sau după plantare bobinei în anevrism. Rotirea împingătorului după livrarea bobinei în anevrism poate duce la întinderea bobinei sau la detașarea prematură a bobinei de la împingător, ceea ce ar putea duce la migrarea bobinei.
- Nu utilizați dispozitive hemostatice pentru a avansa împingătorul. Acest lucru poate duce la îndoierea împingătorului, ceea ce poate duce la detașarea prematură a bobinei.

- Înainte de detașarea bobinei detașabile AXIUM™ verificați ca axul distal al microcateterului să nu fie tensionat.. Compresia axială sau forțele de întindere ar putea fi acumulate în microcateter, provocând mișcarea vârfului în timpul plantării bobinei detașabile AXIUM™. Mișcarea vârfului microcateterului poate provoca ruperea anevrismului sau a vasului.

- Avansarea împingătorului dincolo de vârful microcateterului, după ce bobina a fost desfășurată și detașată, implică riscul de rupere a anevrismului sau de perforație a vasului.

AVERTIZĂRI

- Dacă sub imagistica fluoroscopică este observată o mișcare anormală a bobinei detașabile AXIUM™ după plantarea bobinei și înainte de detașare, scoateți bobina și înlocuiți-o cu o altă bobină detașabilă AXIUM™ de dimensiuni mai adecvate. Mișcarea bobinei poate indica faptul că bobina ar putea migra, după ce este detașată. De asemenea, trebuie efectuate controalele angiografice înainte de detașarea bobinei, pentru a se asigura că masa bobinei nu extravazează din vasul principal.

- Maparea fluoroscopică digitală de înaltă calitate este obligatorie pentru a realiza cateterizarea sigură a anevrismului sau a vasului, și pentru plasarea corectă a primei bobine. În cazul anevrismelor mai mici, acesta este un pas deosebit de important.

- Dacă este necesară re poziționarea bobinei detașabile AXIUM™, aveți grijă deosebită să retrageți bobina sub fluoroscopie într-o mișcare unu-la-unu cu împingătorul implantului. Dacă bobina nu se mișcă cu manevra unu-la-unu sau re poziționarea este dificilă, bobina a fost întinsă și s-ar putea rupe. Scoateți-le lent și aruncați atât cateterul, cât și bobina

- Datorită naturii delicate a bobinei detașabile AXIUM™, în căilor vasculare sinuoase către anumite anevrisme și vase, și datorită morfologiilor variate ale anevrismelor intracraniene, bobina se poate întinde ocazional în timp ce este manevrată. Întinderea este un precursor al unor potențiale defecțiuni, cum ar fi spargerea bobinei și migrarea sa.

- Dacă, în timpul retragerii bobine detașabile AXIUM™ care se află într-un unghi acut față de vârful cateterului, operatorul simte rezistență, prin re poziționarea cu atenție a vârfului distal al cateterului la ostiumul anevrismului, sau doar ușor în interiorul arterei de bază, este posibil să se evite întinderea sau ruperea bobinei.

- Aveți grijă să nu înțeptați mânușile sau drapajele sterile în timp ce manipulați împingătorul implantului.

- Pentru a obține occluzia necesară în unele anevrisme sau vase, poate fi necesară plantarea mai multor bobine detașabile AXIUM™.

- Efectul pe termen lung al acestui produs asupra țesuturilor extravasculare nu a fost stabilit, așa că trebuie să aveți grijă ca dispozitivul să rămână în spațiul intravascular

- Acest dispozitiv este furnizat STERIL numai pentru o singură utilizare. Nu reutilizați și nu sterilizați. Reutilizarea și sterilizarea cresc riscul infecției pacientului și compromit performanțele dispozitivului.

PRECAUȚII

- Manipulați bobina detașabilă AXIUM™ cu grijă, pentru a evita deteriorarea, înainte sau în timpul tratamentului.
- Nu avansați bobina detașabilă AXIUM™ dacă simțiți rezistență, ci doar după ce cauza rezistenței a fost eliminată sub vizualizare fluoroscopică. Avansarea bobinei în astfel de situații poate duce la distrugerea acesteia și /sau a cateterului, sau la perforarea vasului.
- Este esențial să confirmați compatibilitatea cateterului cu bobina detașabilă AXIUM™. Diametrul exterior al bobinei detașabile AXIUM™ trebuie verificat pentru vă asigura că bobina nu va bloca cateterul.
- Pista dispensatorului, teaca introductorului și dispozitivul I.D. nu sunt destinate contactului cu pacientul.
- Nu utilizați bobina detașabilă AXIUM™ și I.D. după data de expirare tipărită pe eticheta produsului.
- Pentru a obține o performanță optimă a bobinei detașabile AXIUM™, și pentru a reduce riscul de complicații tromboembolice, este esențial să se mențină perfuzarea continuă a unei soluție de spălare adecvată.
- Avansați și retrageți bobinele detașabile AXIUM™ încet și lin, în special în anatomia sinuoasă. Scoateți bobina dacă se observă o frecare neobișnuită sau „zgâriere”. Dacă se observă fricțiune într-o a doua bobină, examinați cu atenție atât bobina, cât și cateterul, pentru a observa posibile deteriorări, cum ar fi flambarea sau înclinarea axului cateterului, sau o îmbinare fuzionată necorespunzător.
- Dacă se observă flambarea sau înclinarea împingătorului, apucați partea cea mai distală a împingătorului, distală față de zona de flambare, blocare sau rupere și scoateți-l din microcateter.
- Nu avansați forțat bobina dacă aceasta s-a așezat în interiorul sau în afara microcateterului. Identificați rezistențe și, dacă este necesar, scoateți sistemul.
- Dacă se simte rezistență la retragerea dispozitivului de împingere a implantului, trageți simultan cateterul de perfuzie până când dispozitivul de împingere poate fi îndepărtat fără rezistență.
- Dacă se simte rezistență în timpul livrării bobinei, scoateți sistemul și verificați dacă există deteriorări ale cateterului.

PĂSTRARE

Păstrați bobinele detașabile AXIUM™ în încăperi răcoroase și uscate.

Unele dintre bobinele detașabile AXIUM™ sunt îmbinate cu microfibramente PGLA. Păstrați și aceste configurații într-un loc răcoros și uscat, cu o temperatură maximă de depozitare care nu depășește 50 °C (122 °F). Un indicator de temperatură este amplasat pe fiecare cutie și punăgă pentru configurațiile PGLA ale bobinei detașabile AXIUM™. Dacă produsul a fost expus la temperaturi mai mari de 50 ° C (122 ° F), indicatorul de temperatură de pe cutie și/sau punăgă se va schimba în roșu.

AVERTIZARE

- Nu utilizați produsul dacă indicatorul de temperatură de pe punăgă sau din cutie este roșu. Indicatorul roșu înseamnă că produsul a fost expus la o temperatură mai mare de 50 °C (122 °F). Utilizarea produsului care a fost expus la temperaturi mai mari de 50 ° C (122 ° F) poate compromite siguranța pacientului.

PREGĂTIREA PENTRU UTILIZARE

1. Pentru a obține o funcționare optimă a bobinei detașabile AXIUM™, și pentru a reduce riscul de complicații tromboembolice, este recomandat să se mențină spălarea continuă cu soluție salină a) teaca femurală și cateterul de ghidaj, b) microcateterul și cateterul de ghidaj și c) microcateter și dispozitivul de împingere a implantului și bobina detașabilă AXIUM™.
 2. Introduceți cateterul de ghidaj corespunzător, urmând procedurile recomandate. Conectați o supapă hemostatică rotativă (RHHV) la butucul cateterului de ghidaj. Atașați un robinet cu 3 căi la brațul lateral al RHHV, apoi conectați o linie pentru spălarea continuă.
 3. Atașați un al doilea RHHV la butucul microcateterului. Atașați un robinet cu sens unic la brațul lateral al RHHV, apoi conectați o linie pentru spălare continuă.
- Pentru bobinele detașabile AXIUM™:** se recomandă o picătură din punga de presiune la fiecare 3-5 secunde.
- Pentru bobine detașabile AXIUM™ din microfilament PGLA sau Nylon:** se recomandă o picătură din punga de presiune la fiecare 1-3 secunde.
4. Verificați toate armăturile astfel încât să vă asigurați că nu a intrat aer în cateterul de ghidaj, sau în microcateter, în timpul spălării continue.

IMAGISTICA RMN DE DIAGNOSTIC

Testarea non-clinică a demonstrat că bobinele detașabile AXIUM™ sunt utilizabile cu imagistică RMN în anumite condiții. Bobinele detașabile AXIUM™ pot fi scanate în siguranță în următoarele condiții:

- Câmp magnetic static de 3-Tesla sau mai puțin
- Gradientul câmpului spațial de 720 Gauss/cm sau mai puțin
- Rata medie specific de absorbție (SAR) de 3 W/kg, la 15 minute de scaneare.

În testele non-clinice, bobinele detașabile AXIUM™ au produs o creștere de 0,6 °C a temperaturii, la o rată maximă medie de absorbție specifică (SAR) de 3 W/kg la 15 minute de scaneare RMN, într-un sistem de scaneare MR 3-Tesla (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

INDICAȚII DE UTILIZARE

- 1. Îndepărtați încet și simultan bobina detașabilă AXIUM™ și teaca introductoare din calea de acces. Verificați împingătorul proximal al implantului pentru nereguli. Dacă există nereguli, înlocuiți cu o nouă bobină detașabilă AXIUM™.
- 2. Avansați lent bobina detașabilă AXIUM™ în afara teacii introductoare, în palma mării înmănușate, și verificați dacă există posibile nereguli ale bobinei sau ale zonei de detașare. Datorită riscului potențial de deteriorare, trebuie să existe verificare vizuală. Dacă există probleme, înlocuiți cu o nouă bobină detașabilă AXIUM™.

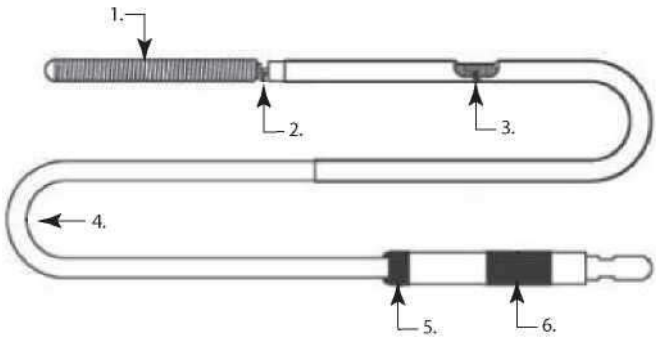


Figura 1

- 1. Implant
- 2. Zonă de detașare
- 3. Marker aliniere bobină
- 4. Împingător
- 5. Indicator rupere hipotub (HBI)
- 6. Indicator de încărcare pozitivă

- 3. Scufundați lent bobina detașabilă AXIUM™ și zona de detașare a acesteia în soluție salină heparinizată. Aveți grijă să nu întindeți bobina în timpul acestei proceduri, pentru a putea păstra memoria bobinei. În timp ce elementele sunt încă scufundate în soluția salină heparinizată, așezați teaca introductoare, la verticală, în soluție salină, și trageți ușor vârful distal al bobinei în teaca introductoare.
- 4. Introduceți capătul distal al teacii introductoare prin supapa hemostatică rotativă (RHV) și în butucul microcateterului până când teaca este așezată ferm. Strângeți RHV în jurul teacii, pentru a preveni întoarcerea fluxului sanguin, dar nu atât de strâns încât să deterioreze bobina în timpul introducerii sale în cateter.
- 5. Transferați bobina detașabilă AXIUM™ în microcateter, avansând lent și continuu împingătorul implantului, (curse de 1-2 cm). Odată ce porțiunea flexibilă a dispozitivului de împingere a implantului a intrat în axul cateterului, slăbiți RHV și îndepărtați teaca introductoare peste capătul proximal al dispozitivului de împingere a implantului. Nu încercați să avansați întregul dispozitiv de împingere în teaca introductoare, deoarece aceasta poate cauza îndoirea proximală a dispozitivului de împingere. Opriti-vă la aproximativ 15 cm de capătul distal al împingătorului. Odată finalizat, strângeți RHV în jurul împingătorului. Dacă veți lăsa teaca introductoare în poziție, aceasta va întrerupe infuzia normală de soluție de spălare, și va permite fluxul de sânge să revină înapoi în microcateter.
- 6. Verificați vizual dacă soluția de spălare este perfuzată normal. Odată confirmat, slăbiți RHV suficient pentru a avansa împingătorul implantului, dar nu suficient pentru a permite flux de sânge înapoi în împingătorul.
- 7. Avansați bobina detașabilă AXIUM™, sub vizualizare fluoroscopică, și poziționați-o cu atenție în locul dorit. Dacă plasarea bobinei nu este satisfăcătoare, retrageți-o lent, trăgând de împingătorul implantului, apoi avansați din nou, încet, pentru a re poziționa bobina. Dacă dimensiunea bobinei nu este adecvată, scoateți-o și înlocuiți-o cu o bobină de dimensiuni adecvate.
 - a. Dacă se observă flambarea sau încovoierea împingătorului, apucați partea cea mai distală a acestuia, distal față de zona de încovoiere, flambare sau rupere, și scoateți-l din microcateter.

AVERTIZARE

Nu utilizați dispozitive hemostatice pentru a încerca să avansați împingătorul. Acest lucru poate îndoi împingătorul, ceea ce poate duce la detașare prematură a bobinei.

- 8. Continuați să avansați bobina detașabilă AXIUM™ până când markerul de aliniere cu bobina al împingătorului este aproape distal față de markerul proximal al microcateterului (vedeți figura 2).
 - b. Avansați markerul de aliniere a bobinei imediat dincolo de banda de marcare din zona proximală a cateterului, apoi retrageți împingătorul până când markerul de aliniere a bobinei creează un „T” cu banda proximală de marcare a cateterului, sub vizualizare fluoroscopică. Această manevră scade presiunea la înaintare, care poate duce la detașarea falsă pozitivă a bobinei.

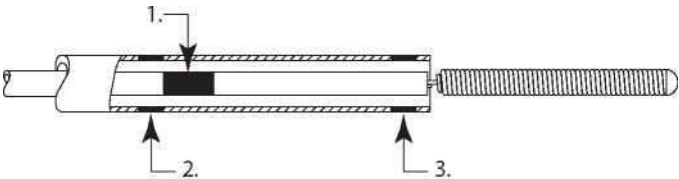


Figura 2

- 1. Marker aliniere bobină
- 2. Bandă marcare cateter proximal
- 3. Bandă marcare cateter distal

- 9. Strângeți RHV pentru a preveni deplasarea împingătorului.
- 10. Scoateți I.D. din ambalajul său protector și așezați-l în câmpul steril. I.D. este ambalat separat, ca dispozitiv steril, și este destinat utilizării pe un singur pacient.
- 11. Confirmați din nou, sub vizualizare fluoroscopică, că markerul de aliniere a bobinei împingătorului este în „T” cu markerul proximal al microcateterului.

- 12. Înainte de a atașa I.D., verificați dacă RHV este corect blocat în jurul împingătorului implantului, pentru a vă asigura că bobina nu se mișcă în timpul procesului de conectare. Asigurați-vă că împingătorul implantului este liniar între RHV și I.D. Îndreptarea acestei secțiuni a împingătorului optimizează alinierea la I.D.
- 13. Țineți capătul proximal al împingătorului la capătul distal al indicatorului de încărcare. Avansați I.D. peste capătul proximal al împingătorului, până când indicatorul de încărcare intră complet în orbită și împingătorul este așezat ferm în actuator (vezi Figura 3)..

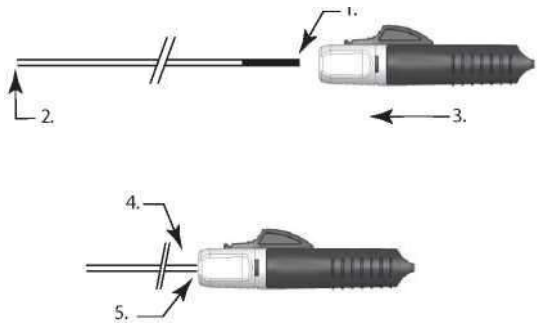


Figura 3

- 4. Gata de detașare
- 5. RHV și împingătorul implantului sunt în linie dreaptă, iar capătul distal al indicatorului de încărcare este complet introdus în butucul I.D.

- 1. Indicator de limită proximală de încărcare
- 2. Apucați împingătorul aici atunci când avansați I.D. peste împingătorul implantului.
- 3. Avansați I.D. peste împingător.

Notă: Dacă banda indicatoare este în continuare afișată (așa ca în Figura 4 de mai jos), I.D. trebuie avansat mai mult, până când împingătorul implantului este așezat complet în butuc, așa ca în Figura 3 de mai sus.



Figura 4

- 1. nu este încărcat complet
- 14. Pentru a detașa bobina, puneți I.D. în palmă și retrageți glisorul cu degetul mare, până când se oprește și face clic, apoi lăsați lent glisorul pentru să revină la poziția inițială. Demontați I.D.

Notă: I.D. poate fi, de asemenea, îndepărtat la sfârșitul cursei, dacă se dorește. Pentru a îndepărta I.D.) la sfârșitul cursei, țineți glisorul cu degetul mare în poziția cea mai anterioară și scoateți I.D. (vezi Figura 5).

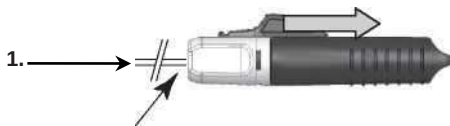


Figura 5

- 1. Gata pentru detașare 2. Capătul distal al indicatorului de încărcare este intrat complet în butucul I.D.

- 15. Detașare completă a bobinei trebuie verificată prin monitorizare fluoroscopică, pentru a putea confirma că bobina s-a desprins. Trageți încet împingătorul în timp ce îl urmăriți fluoroscopic, pentru a vă asigura că bobina nu se mișcă. În cazul, puțin probabil, că bobina se mișcă, repetați pașii 12-14. Dacă este necesar, avansați împingătorul implantului pentru a restabili alinierea markerului bobinei cu cateterul. Verificați detașarea bobinei așa cum am descris mai sus.
- 16. Dacă doriți să confirmați detașarea, apucați indicatorul de încărcare pozitivă între degetul mare și arătătorul mâinii stângi și capătul proximal al împingătorului de livrare a implantului cu degetul mare și arătătorul mâinii drepte. Trageți ușor de capătul proximal al împingătorului. Dacă se deplasează liber prin tub, sistemul este detașat corect. Dacă nu, repetați pașii 13-15.
- Notă:** Dacă bobina nu se desprinde după 3 încercări, eliminați I.D. și înlocuiți-l cu un nou ID.
- 17. În cazul, foarte rar, în care bobina nu se desprinde și nu poate fi scoasă din dispozitivul de împingere a implantului, urmați pașii de mai jos pentru detașare.
 - a. Prindeți hipotubul la aproximativ 5 cm distal față de indicatorul de sarcină pozitivă, la indicatorul de rupere a hipotubului, și îndoiți împingătorul - doar distal față de HBI, la 180°.
 - b. Îndreptați apoi împingătorul spre înapoi, și continuați îndoirea și îndreptarea până când tubul împingătorului se deschide expunând elementul de eliberare (Figura 6).

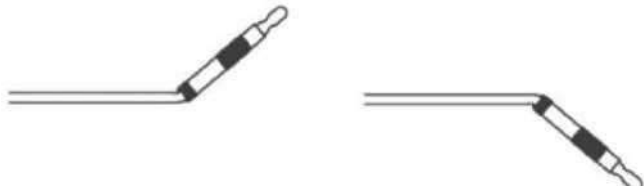


Figura 6

- c. Separați lent capetele proximale și distale ale împingătorului deschis. Apoi, sub fluoroscopie, trageți porțiunea proximală a împingătorului implantului aproximativ 2-3 cm, pentru a confirma detașarea implantului, conform instrucțiunilor de utilizare a acestuia (Figura 7).



Figura 7

18. Odată ce a fost detectată detașarea bobinei și confirmată fluoroscopic, retrageți încet împingătorul din microcateter.

AVERTIZARE

În cazul în care:

- a. În cazul unei detașări fals pozitive (încercarea de detașare a eșuat), scoateți bobina din zona de tratare și din microcateter, și înlocuiți-o cu o nouă bobină detașabilă AXIUM™.
- b. În cazul unei detașări fals negative (bobina se detașează prematur), îndepărtați împingătorul implantului și:
 - i) Avansați bobină cea nouă în așa fel încât să împingă coada rămasă a bobinei detașate prematur în zona de tratament.
 - ii) Scoateți bobina detașată prematur, cu ajutorul dispozitivului de recuperare corespunzător.

19. Dacă este necesară plantarea unei bobine suplimentare, repetați pașii 1-18,.
20. După finalizarea procedurii, eliminați I.D.

AVERTIZARE

- Nu resterilizați I.D. Acesta poate fi utilizat pe un singur pacient.
- I.D. este proiectat pentru un maxim de 25 de cicluri.

GLOSAR DE SIMBOLURI
INTERNAȚIONALE

STERILE EO	Sterilizare cu oxid de etilenă		Limită superioară de temperatură
2	O singură utilizare		Evitați temperaturile extreme
Rx ONLY	Atenție: Legea federală (SUA) restricționează vânzarea acestui dispozitiv de către, sau la ordinul unui medic		
2 STERILIZE	Nu resteriliza		
!	Atenție, consultați documentele însoțitoare		
MR	Utilizare condiționată cu RMN	REF	Număr de catalog
			Producător
			Folosiți înainte de data...
	Nepirogen	LOT	Număr lot
		CONTENTS	Conținutul ambalajului
	Păstrați uscat		

Detachment Tips

Suboptimal Conditions Indication

Verify under fluoroscopy that the coil has detached by slowly pulling back on the delivery wire and monitoring the fluoro image to ensure the coil does not move. If the coil moves, check marker band alignment with microcatheter, check and adjust flush, and flush the system to remove contrast, then repeat detachment process.

Patient Needs Grounding

The InZone® System detected a Legacy GDC® or Matrix2® Detachable Coil. The patient needs to be grounded using the IZDS® Connecting Cable and a sterile 20- or 22-gauge uncoated stainless steel hypodermic needle. When a complete circuit is detected, the amber light will stop blinking and become steady and the OK indicator will show a solid green light accompanied by a single beep. When the detach button is pressed and released, the GROUNDING indicator will turn off.

If the GROUNDING indicator is still blinking after following the grounding instructions, verify that the IZDS Connecting Cable is securely connected, the needle is uncoated, the coil is properly aligned, and that the coil has not detached. If the GROUNDING indicator continues to blink, the IZDS Connecting Cable and/or needle may need to be replaced.

Grounding Indicator Illuminated While Using Target® Detachable Coil

Remove the InZone Detachment System completely from the delivery wire and reinsert the wire in the InZone Detachment System. If after several insertion attempts the device fails to recognize the Target® Detachable Coil, replace the device and notify your Stryker Neurovascular representative.

Grounding Indicator Not Illuminated While Using Legacy Coil

Remove the InZone Detachment System completely from the delivery wire and reinsert the wire in the InZone Detachment System. If after several insertion attempts the device fails to recognize a Legacy GDC or Matrix2 Detachable Coil, replace the device and notify your Stryker Neurovascular representative.

InZone Detachment System Will Not Power On

If the InZone Detachment System remains powered off for more than one second, remove the system completely from the delivery wire and reinsert the wire in the InZone Detachment System, allowing the system one second to power on. If after several insertion attempts there is still no power, replace the device and notify your Stryker Neurovascular representative.

InZone Detachment System Sounds a Single Beep and No Indicator Light is Illuminated

The delivery wire was incompletely inserted, was removed, or lost electrical contact before the detachment cycle was completed. To restart detachment, simply reinsert the wire to establish the contact connection and begin the detachment process.

InZone Detachment System Will Not Come Out of Sleep Mode

If pressing the DETACHMENT BUTTON does not bring the system out of Sleep Mode, the coil delivery wire has lost contact with the InZone Detachment System. Remove the InZone Detachment System completely from the delivery wire and reinsert the wire in the InZone Detachment System to reset the system.



THE UPGRADED
InZone®
DETACHMENT SYSTEM

LED Summary

	SYSTEM READY	Solid Green 1 Beep	Ready to Detach
	CURRENT FLOW	Solid Green No Sound	Current Flowing (Do Not Remove)
	CYCLE COMPLETE	Solid Green 3 Short Beeps: <10 second cycle	Detachment Detected*
		Flashing Green 1 Long Beep: 10 second cycle	Second Detach Cycle is Recommended* (Suboptimal Conditions)
	GROUNDING	Flashing Amber 1 Beep	Patient Needs Grounding
		Solid Amber 1 Beep	Patient Grounding Complete
	LOW BATTERY	Flashing Amber No Sound	System Battery is Low (Replace Device)

**Verify detachment under fluoro*

Target® Detachable Coil Accessories

Description	Product Number
InZone Detachment System	451009-5
IZDS® Connecting Cable	451102-5

stryker®
Neurovascular

Stroke: Our Only Focus. Our Ongoing Promise.

InZone® Detachment System

See package insert for complete indications, contraindications, warnings and instructions for use.

INDICATIONS FOR USE

The InZone Detachment System is intended for use with all versions of Stryker Neurovascular detachable coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

CONTRAINDICATIONS

None known.

POTENTIAL ADVERSE EVENTS

No adverse events are associated with the use of the InZone Detachment System as a stand alone device. Failure to detach might result in prolongation of the procedure or additional intervention. Refer to Stryker Neurovascular Detachable Coil Directions for Use for adverse events associated with the use of Stryker Neurovascular detachable coils. Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected associated with the use of this device. Please make every attempt to retain any suspect device, its associated

components and their packaging for return to Stryker Neurovascular.

WARNINGS

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.
- The InZone Detachment System can only be used with Stryker Neurovascular detachable coils (Target®, GDC®, and Matrix²®) and the IZDS® Connecting Cable. DO NOT SUBSTITUTE any components or devices from other manufacturers or injury to the patient or user could result.

- Advancing the coil delivery wire beyond the microcatheter tip once the coil has detached may increase the risk of aneurysm or vessel rupture.
- Sliding the detachment system with too much force or failing to tighten the microcatheter RHV prior to detachment may cause the delivery wire to kink or result in displacement of the coil and/or microcatheter tip in the vessel, which could lead to failed detachment, suboptimal coil position postdetachment, vessel perforation, aneurysm perforation, pseudoaneurysm, or aneurysm rupture. Do not advance the InZone Detachment System over the coil delivery wire against significant resistance.
- After use, the InZone Detachment System (excluding packaging) should be handled and processed as biohazardous material. After use, dispose of the InZone Detachment System unit in accordance with hospital, administrative, and/or local government policy for the handling, processing, and disposal of biohazardous materials. Dispose of packaging, delivery wires, introducer sheaths, IZDS Connecting Cable (UPN M00345110250, if applicable), and needle (if applicable) in accordance with hospital, administrative, and/or local government policy.
- The use of cables and/or other medical devices other than the IZDS Connecting Cable specified may result in increased emissions or decreased immunity of the InZone Detachment System.
- The InZone Detachment System should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary,

the InZone Detachment System should be observed to verify normal operation in the configuration in which it will be used.

- No modification of the equipment is allowed.

CAUTIONS:

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Prior to beginning a procedure, confirm that there are enough detachment systems on the shelf to complete the anticipated number of detachments required. In addition, one extra InZone® Detachment System is required as backup for all procedures. Verify that the InZone Detachment Systems to be used are within their indicated shelf life.
- One extra IZDS® Connecting Cable (UPN M00345110250) and sterile 20- or 22-gauge uncoated stainless steel hypodermic needle are required as backup for all procedures using the InZone Detachment System to detach GDC® or Matrix²® Detachable Coils. Verify that the cables and needles to be used are within their indicated shelf life.
- While it is essential to sufficiently tighten the microcatheter RHV around the coil delivery wire prior to using the InZone Detachment System, over-tightening the RHV could cause the delivery wire to kink.
- Batteries are pre-loaded into the InZone Detachment System. Do not attempt to replace batteries or open the enclosure.
- Increased detachment times may occur when:
 - Other embolic agents are present.

- Detachment zone is in contact with the coil mass.
- Delivery wire and microcatheter markers are not properly aligned.
- Thrombus is present on the coil detachment zone.
- The IZDS Connecting Cable has been resterilized. The IZDS Connecting Cable is supplied for one use only and should be discarded after each procedure (Only applicable when detaching GDC or Matrix² Detachable Coils).
- If device is set down, take care to gently place it in a stable position so that it does not slide off of the delivery wire during detachment. If device is held, take care to gently hold it in a stable position so that it does not slide off of the delivery wire during detachment.
- In some ECG equipment, perturbations may be observed immediately before illumination of the CYCLE COMPLETE indicator on the InZone Detachment System.

- Because coils are not always detached following completion of a cycle, ALWAYS verify under fluoroscopy that the coil has detached by slowly pulling back on the delivery wire while monitoring the fluoro image to make sure there is no movement of the coil. In the unlikely event the coil moves (indicating it is still attached to the delivery wire), check and adjust the flush system, flush the system to clear any contrast that may exist around the detachment zone, check and adjust the grounding setup (only applicable when detaching GDC or Matrix² Detachable Coils), realign the delivery wire with the microcatheter, tighten the RHV, and repeat the detachment procedure.
- Needle must not be coated.
- If the patient experiences pain at the site of the needle, or if detachment times are increasing, replace the needle with a new needle at a new insertion site.

- The IZDS Connecting Cable is intended for single patient use only. Do not resterilize and/or reuse. Resterilization could corrode the connecting cable, resulting in increased detachment times.
- Disconnection or poor connection of any part of the grounding setup after the detachment system indicates SYSTEM READY may result in an inability to detach GDC or Matrix² Detachable Coils.
- The safety and performance characteristics of the InZone Detachment System when used with another manufacturer's devices (whether coils, coil delivery devices, catheters, guidewires and/or other accessories), have NOT been established. Due to the potential incompatibility of non-Stryker Neurovascular components with the InZone Detachment System, the use of another manufacturer's device(s) with the InZone Detachment System is not recommended.

- The InZone Detachment System needs special precautions regarding EMC. Use of the InZone Detachment System should be according to the EMC information provided within the Directions for Use.
- Portable and mobile RF communications equipment may affect the performance of the InZone Detachment System.

EC	REP
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France

C E 0344

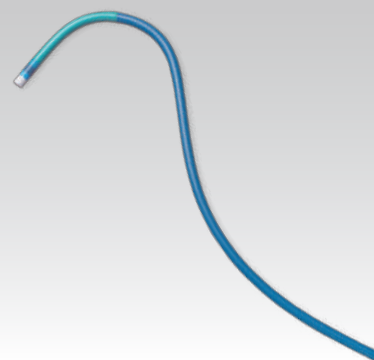
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Date of Release: 30/SEP/2013





ACTIVE
FLEXIBILITY

SUPPORTIVE
SECONDARY
CURVE

BALANCED PERFORMANCE THAT'S AHEAD OF THE CURVE

The Launcher™ guide catheter offers you a blend of flexibility, support and visualisation — the capability you need to respond to your challenging cases.

Advanced Platform Designed for Multiple Interventional Approaches

- Designed for radial and femoral approaches
- Soft distal segment enables you to actively engage the guide for backup support
- Full-Wall Technology construction provides kink resistance and stable torque control

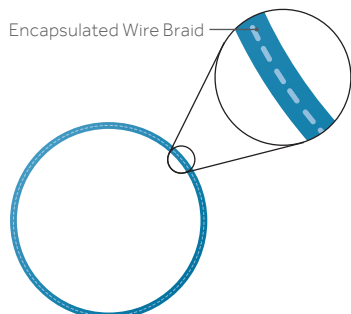
Enhanced Visualisation

- Large 5 F I.D. (0.058 inches) allows for increased contrast flow for enhanced visualisation
- Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity

Full Range of Traditional and Specialty Curves

- Extensive collection of specialty transradial and brachial curves

Encapsulated Wire Braid



MEDTRONIC FULL-WALL TECHNOLOGY:

Encapsulated flat-wire braid enables thinner, more robust walls without compromising support, retention, or torque response.

LAUNCHER™ 5 F GUIDE CATHETERS

LEFT CORONARY CURVES					Backup Support Left
Left Standard	Short Left	JCL	Amplatz Left	Short Amplatz Left	EBU
LA5JL20	LA5SL30	LA5JCL15	LA5AL75	LA5SAL75	LA5EBU20
LA5JL30	LA5SL35	LA5JCL30	LA5AL10	LA5SAL10	LA5EBU30
LA5JL35	LA5SL40	LA5JCL35	LA5AL15	LA5SAL15	LA5EBU35
LA5JL40	LA5SL45	LA5JCL40	LA5AL20	LA5SAL20	LA5EBU375
LA5JL45	LA5SL50	LA5JCL45	LA5AL25	LA5SAL25	LA5EBU40
LA5JL50	LA5SL50	LA5JCL50	LA5AL30	LA5SAL30	LA5EBU45
LA5JL60	LA5SL60		LA5AL40	LA5SAL40	LA5EBU50
RIGHT CORONARY CURVES					
Right Standard	Short Right	JCR	Amplatz Right	Shepherd's Crook Right	Backup Support Right
LA5JR30	LA5SR30	LA5JCR35	LA5AR10	LA5SCR35	LA5RBU35
LA5JR35	LA5SR35	LA5JCR40	LA5AR20	LA5SCR40	LA5RBU40
LA5JR40	LA5SR40	LA5JCR45	LA5ALR12	LA5SCR50	
LA5JR45	LA5SR50	LA5JCR50			ECR
LA5JR50	LA5SR60		Short Amplatz Right		LA5ECR35
LA5JR60			LA5SAR10		LA5ECR40
			LA5SAR20		LA5ECR45
					3-Dimensional
					LA53DRIGHT
OTHER CURVES					
Multipurpose	MAC (Multi-Aortic)	Bypass	Champ	Radial Specialty	NOTO
LA5MB1	LA5MAC30	LA5IMA	LA5CHAMP05	LA5LARA	LA5NOTO
LA5MB2	LA5MAC35	LA5LCB	LA5CHAMP10	LA5MRADIAL	
LA5MPST	LA5MAC375	LA5RCB	LA5CHAMP15	LA5MRESS	
LA5HSI	LA5MAC40	LA5RCBII	LA5CHAMP20	LA5RRAD	
LA5HSII	LA5MAC45		LA5CHAMP25		EL GAMAL
LA5HSIII	LA5MAC50		LA5CHAMP30		LA5ELGAMAL
LA5HSREL			LA5CHAMP35		
			LA5CHAMP40		

Shaft Diameter: 5 F Inner Diameter: 0.058 in. 5 packs available in select curves

Indications for Use: The Medtronic Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.
Important Information: Refer to *Instructions for Use* supplied with the device for indications, warnings, precautions, and adverse effects.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
The curve recommendations in this guide are not meant to replace patient-specific clinical judgement.

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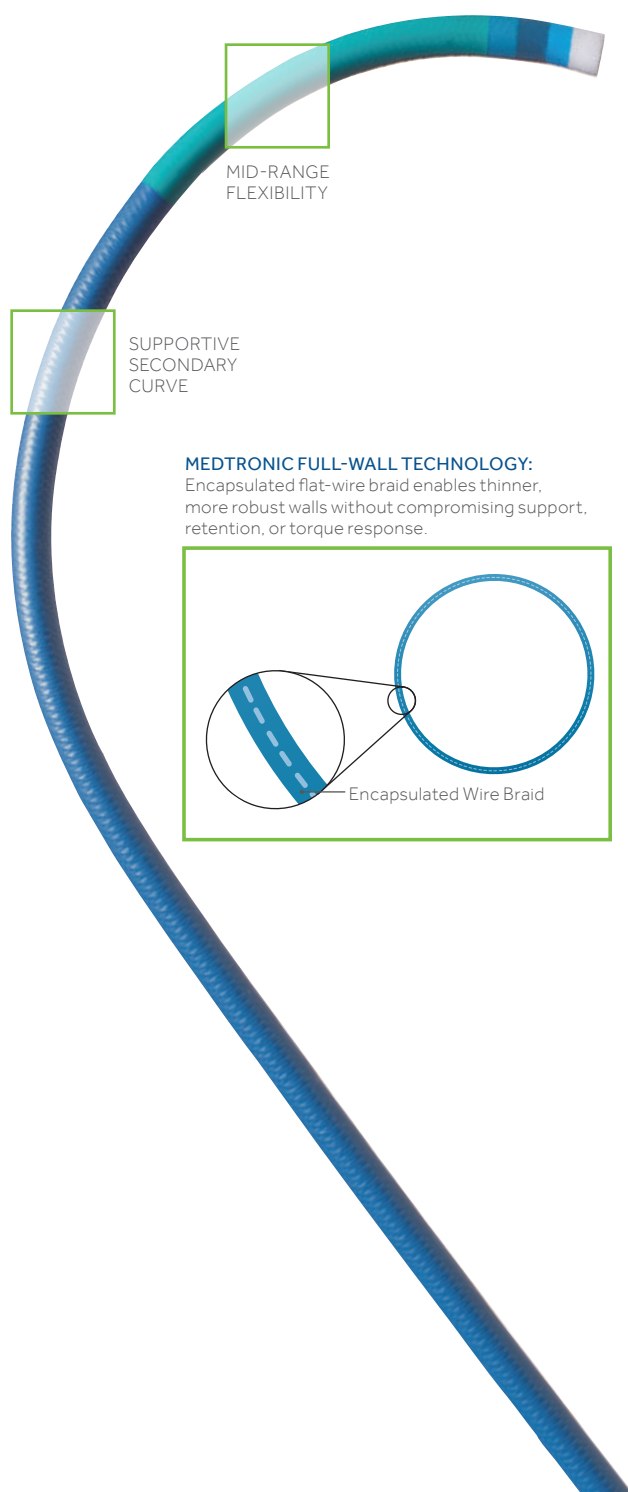
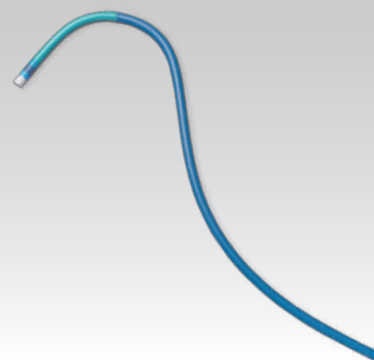
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Launcher™

Guide Catheter



MID-RANGE
FLEXIBILITY

SUPPORTIVE
SECONDARY
CURVE

MEDTRONIC FULL-WALL TECHNOLOGY:

Encapsulated flat-wire braid enables thinner, more robust walls without compromising support, retention, or torque response.

Encapsulated Wire Braid

BALANCED PERFORMANCE THAT'S AHEAD OF THE CURVE

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Advanced Platform Designed for Multiple Interventional Approaches

- Designed for radial and femoral approaches
- Flexible distal segment enables you to engage the guide for backup support
- Full-Wall Technology construction provides kink resistance and stable torque control
- Supportive secondary curve for increased backup support and curve retention

Enhanced Visualisation

- Large 6 F I.D. (0.071 inches) allows for increased contrast flow for enhanced visualisation
- Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity

Full Range of Traditional and Specialty Curves

- Extensive collection of traditional and specialty coronary curves available

LAUNCHER™ 6 F GUIDE CATHETERS

LEFT CORONARY CURVES					Backup Support Left
Left Standard (JL)	Short Left (SL)	JCL	Amplatz Left	Short Amplatz Left	EBU
LA6JL25	LA6SL30	LA6JCL30	LA6AL75	LA6SAL75	LA6EBU30
LA6JL30	LA6SL35	LA6JCL35	LA6AL10	LA6SAL10	LA6EBU325
LA6JL35	LA6SL40	LA6JCL40	LA6AL15	LA6SAL15	LA6EBU35
LA6JL40	LA6SL45	LA6JCL45	LA6AL175	LA6SAL20	LA6EBU375
LA6JL40P^	LA6SL50	LA6JCL50	LA6AL20	LA6SAL25	LA6EBU40
LA6JL45	LA6SL60		LA6AL25	LA6SAL30	LA6EBU45
LA6JL50			LA6AL30	LA6SAL40	LA6EBU50
LA6JL60			LA6AL40		
			LA6AL50		
Left Standard (FL)	Short Left (FLST)				
LA6FL35	LA6FL35ST				
LA6FL40	LA6FL40ST				
LA6FL40G^^	LA6FL45ST				
LA6FL40P^	LA6FL50ST				
RIGHT CORONARY CURVES					
Right Standard	Short Right	JCR	Amplatz Right	Shepherd's Crook Right	Backup Support Right
LA6JR30	LA6SR30	LA6JCR35	LA6AR10	LA6SCR35	LA6RBU35
LA6JR35	LA6SR35	LA6JCR40	LA6AR20	LA6SCR40	LA6RBU40
LA6JR40	LA6SR40	LA6JCR45	LA6ALR12	LA6SCR50	LA6RBU45
LA6JR40P^	LA6SR45	LA6JCR50			
LA6JR45	LA6SR50		Short Amplatz Right		ECR
LA6JR50	LA6SR60		LA6SAR10		LA6ECR30
LA6JR60			LA6SAR20		LA6ECR35
					LA6ECR40
Right Standard (FR)					LA6ECR45
LA6FR35					
LA6FR40					3-Dimensional
					LA63DRC
					LA63DRIGHT
OTHER CURVES					
Multipurpose	MAC (Multi-Aortic)	Bypass	Champ	Peripheral	Radial Specialty
LA6MB1	LA6MAC30	LA6LCB	LA6CHAMP05	LA6CHAMP15K+	LA6LARA
LA6MB2	LA6MAC35	LA6LCBD*	LA6CHAMP10	LA6CHAMP20K+	LA6MRADIAL
LA6MP1	LA6MAC375	LA6RCB	LA6CHAMP15	LA6CHAMP25K+	LA6MRESS
LA6MP2	LA6MAC40	LA6RCBD*	LA6CHAMP20	LA6IMAK+	LA6RRAD
LA6MPST	LA6MAC45	LA6RCBII	LA6CHAMP25	LA6JR40K+	
LA6HSI	LA6MAC50	LA6IMA	LA6CHAMP30	LA6MP1K+	NOTO
LA6HSII		LA6IMAD*	LA6CHAMP35	LA6MPHK+	LA6NOTO
LA6RMHSII			LA6CHAMP40	LA6PK1W++	
LA6HSIII				LA6RDCK+	EL GAMAL
					LA6ELGAMAL

D* = 90 cm shaft length Shaft Diameter: 6 F K+ = 55 cm shaft length Inner Diameter: 0.071 in. W++ = 47 cm shaft length P^ = Posterior
To order curves with sideholes, please add "SH" to end of model number G^^ = Anterior 5 packs available in select curves

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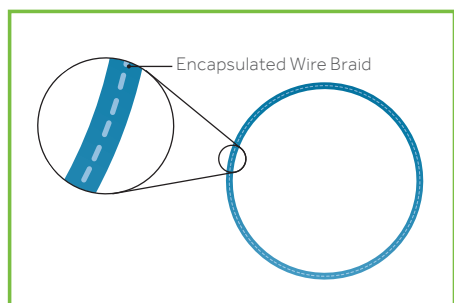
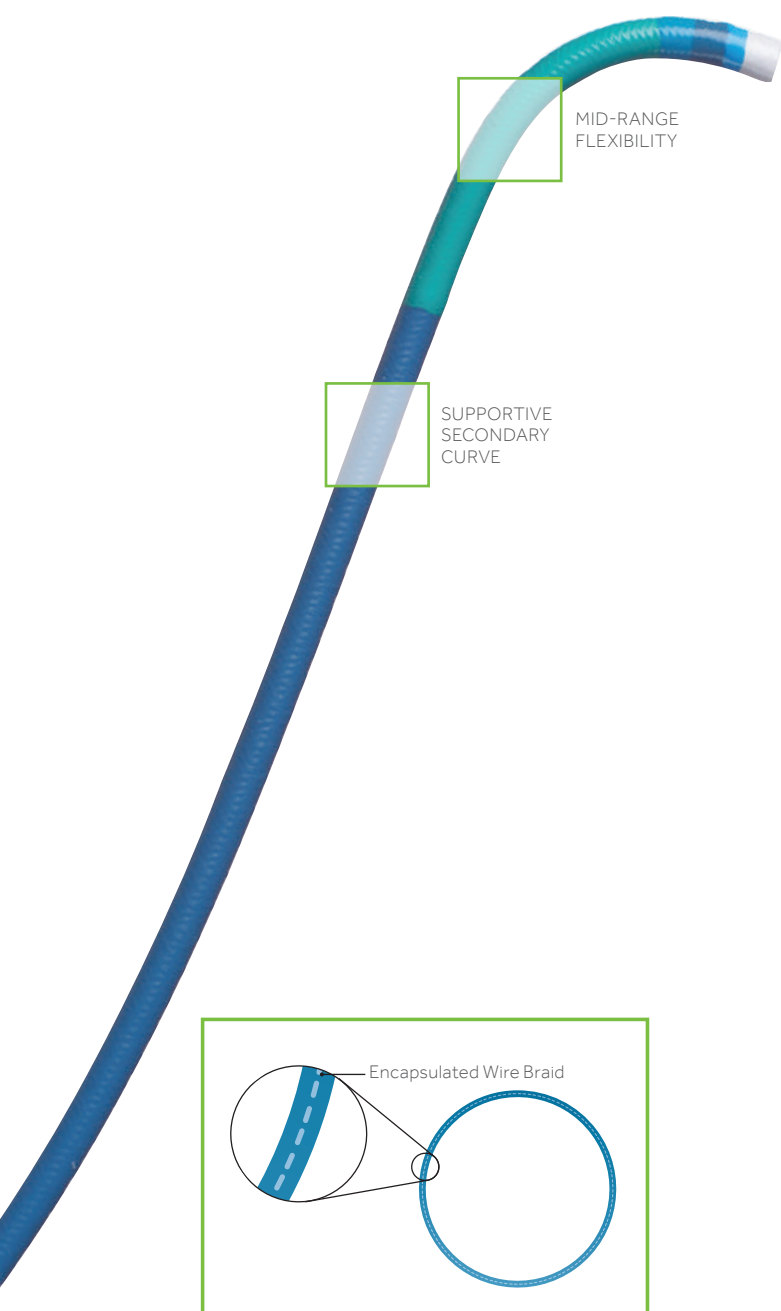
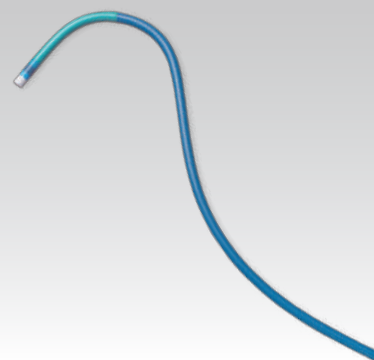
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MEDTRONIC FULL-WALL TECHNOLOGY:
Encapsulated flat-wire braid enables thinner, more robust walls without compromising support, retention, or torque response.

BALANCED PERFORMANCE THAT'S AHEAD OF THE CURVE

The Launcher™ guide catheter offers you a blend of flexibility, support and visualisation — the capability you need to respond to your challenging cases.

Optimal Balance Between Flexibility and Support

- Flexible distal segment enables you to engage the guide for backup support
- Full-Wall Technology construction provides kink resistance and stable torque control
- Supportive secondary curve for backup support when delivering larger profile devices

Enhanced Visualisation

- Large 7 F I.D. (0.081 inches) allows for increased contrast flow for enhanced visualisation
- Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity
- Radiopaque marker band facilitates tip orientation for ostial engagement

Full Range of Traditional and Specialty Curves

- Extensive collection of traditional and specialty coronary curves available

LAUNCHER™ 7 F GUIDE CATHETERS

LEFT CORONARY CURVES					Backup Support Left
Left Standard (JL)	Short Left (SL)	JCL	Amplatz Left	Short Amplatz Left	EBU
LA7JL30	LA7SL30	LA7JCL30	LA7AL75	LA7SAL75	LA7EBU30
LA7JL35	LA7SL35	LA7JCL35	LA7AL10	LA7SAL10	LA7EBU30D*
LA7JL35G^^	LA7SL40	LA7JCL40	LA7AL10D*	LA7SAL15	LA7EBU35
LA7JL35P^	LA7SL45	LA7JCL45	LA7AL15	LA7SAL20	LA7EBU35D*
LA7JL40	LA7SL50	LA7JCL50	LA7AL20	LA7SAL25	LA7EBU375
LA7JL40D*	LA7SL60		LA7AL20D*	LA7SAL30	LA7EBU40
LA7JL40G^^			LA7AL25	LA7SAL40	LA7EBU40D*
LA7JL40P^			LA7AL30		LA7EBU45
LA7JL45			LA7AL40		LA7EBU50
LA7JL50					
LA7JL60					
Left Standard (FL)					
LA6FL35					
LA6FL40					
LA6FL40G^^					
LA6FL40P^					
RIGHT CORONARY CURVES					
Right Standard	Short Right	JCR	Amplatz Right	Shepherd's Crook Right	Backup Support Right
LA7JR30	LA7SR30	LA7JCR35	LA7AR10	LA7SCR35	LA7RBU35
LA7JR35	LA7SR35	LA7JCR40	LA7AR10D*	LA7SCR40	LA7RBU40
LA7JR40	LA7SR40	LA7JCR45	LA7AR20	LA7SCR50	
LA7JR40D*	LA7SR45	LA7JCR50	LA7AR20D*		
LA7JR40P^	LA7SR50		LA7ALR12		ECR
LA7JR45	LA7SR60				LA7ECR35
LA7JR50					LA7ECR40
LA7JR60			Short Amplatz Right		LA7ECR45
			LA7SAR10		
			LA7SAR20		
FCR					
LA7FCR35					3-Dimensional
LA7FCR40					LA73DRC
					LA73DRIGHT
OTHER CURVES					
Multipurpose	MAC (Multi-Aortic)	Bypass	Champ	Peripheral	NOTO
LA7HSI	LA7MAC30	LA7IMA	LA7CHAMP05	LA7CHAMP15K+	LA7NOTO
LA7HSII	LA7MAC35	LA7IMAD*	LA7CHAMP05D*	LA7CHAMP20K+	
LA7RMHSII	LA7MAC375	LA7LCB	LA7CHAMP10	LA7CHAMP25K+	
LA7HSIII	LA7MAC40	LA7LCBD*	LA7CHAMP10D*	LA7IMAK+	EL GAMAL
LA7HSIV	LA7MAC45	LA7RCB	LA7CHAMP15	LA7JR40K+	LA7ELGAMAL
LA7MB1	LA7MAC50	LA7RCBD*	LA7CHAMP20	LA7MPHK+	
LA7MB2		LA7RCBII	LA7CHAMP25	LA7MP1K+	
LA7MP1			LA7CHAMP30	LA7MPHK+	
LA7MP1D*			LA7CHAMP35	LA7PK1W++	
LA7MPST			LA7CHAMP40	LA7RDCK+	
				LA7SCR40K+	
				LA7STRD*	

D* = 90 cm shaft length Shaft Diameter: 7 F K+ = 55 cm shaft length Inner Diameter: 0.081 in. W++=47 cm shaft length P^= Posterior
To order curves with sideholdes, please add "SH" to end of model number G^^= Anterior 5 packs available in select curves

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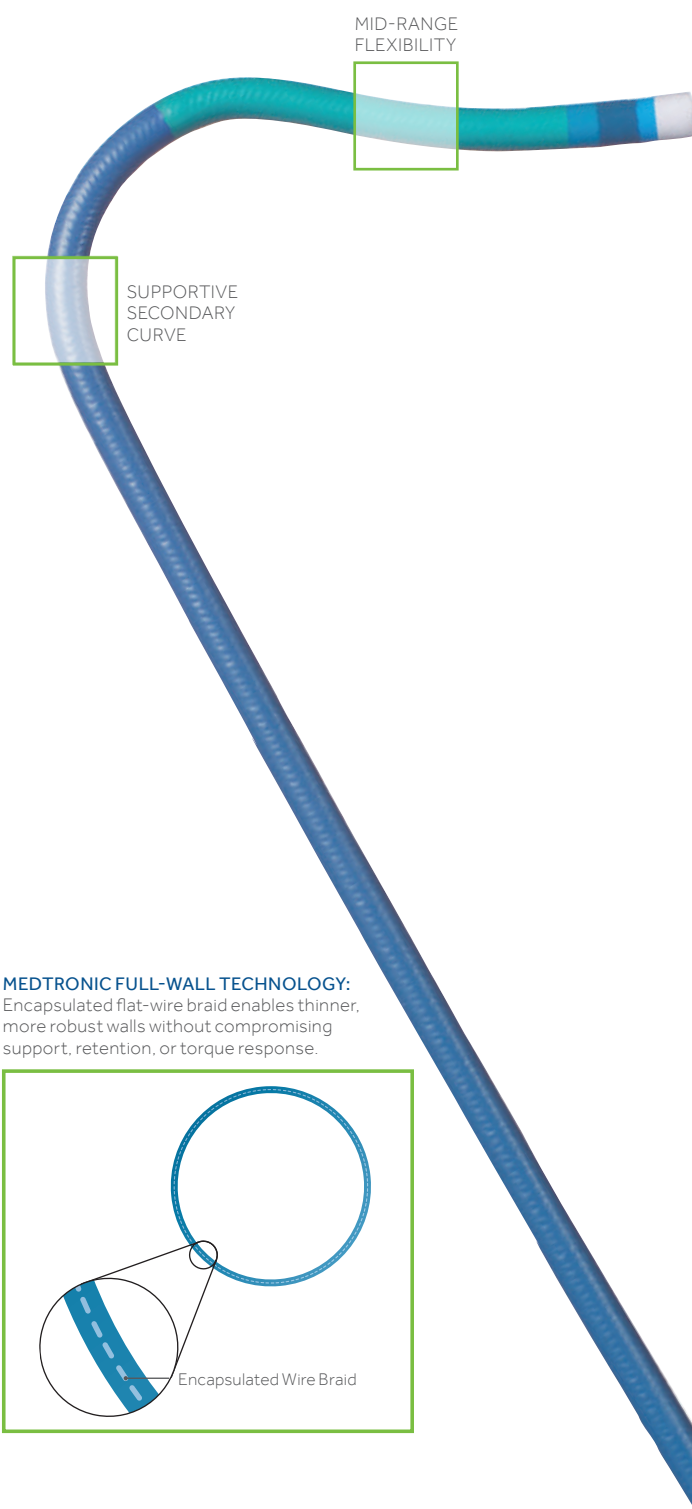
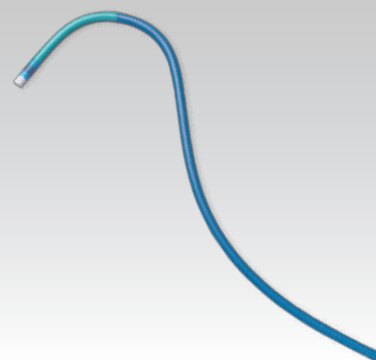
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FLEXIBILITY

SUPPORTIVE
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Optimal Balance Between Flexibility and Support

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- Full-Wall Technology construction provides kink resistance and stable torque control
- Supportive secondary curve for backup support when delivering larger profile devices

Enhanced Visualisation

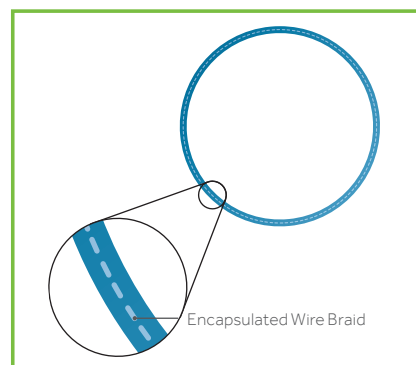
- Large 8 F I.D. (0.090 inches) allows for enhanced vessel visibility and device passage
- Vest-Tech Nylon outer jacket provides excellent hub to tip radiopacity
- Radiopaque marker band facilitates tip orientation for ostial engagement

Full Range of Traditional and Specialty Curves

- Extensive collection of traditional and specialty coronary curves available
- 90 cm length catheters available for your specialty cases

MEDTRONIC FULL-WALL TECHNOLOGY:

Encapsulated flat-wire braid enables thinner, more robust walls without compromising support, retention, or torque response.



LAUNCHER™ 8 F GUIDE CATHETERS

LEFT CORONARY CURVES					Backup Support Left
Left Standard (JL)	Short Left (SL)	JCL	Amplatz Left	Short Amplatz Left	EBU
LA8JL30	LA8SL30	LA8JCL30	LA8AL75	LA8SAL75	LA8EBU30
LA8JL35	LA8SL35	LA8JCL35	LA8AL10	LA8SAL10	LA8EBU35
LA8JL40	LA8SL40	LA8JCL35D*	LA8AL10D*	LA8SAL15	LA8EBU35D*
LA8JL40D*	LA8SL45	LA8JCL40	LA8AL15	LA8SAL20	LA8EBU375
LA8JL45	LA8SL50	LA8JCL40D*	LA8AL20	LA8SAL25	LA8EBU40
LA8JL50	LA8SL60	LA8JCL45	LA8AL20D*	LA8SAL30	LA8EBU40D*
LA8JL60		LA8JCL45D*	LA8AL25	LA8SAL40	LA8EBU45
LA8JL70		LA8JCL50	LA8AL30		LA8EBU50
LA8JL80			LA8AL40		
			LA8AL40D*		
			LA8AL50		
RIGHT CORONARY CURVES					
Right Standard	Short Right	JCR	Amplatz Right	Shepherd's Crook Right	Backup Support Right
LA8JR30	LA8SR30	LA8JCR35	LA8AR10	LA8SCR35	LA8RBU35
LA8JR35	LA8SR35	LA8JCR40	LA8AR20	LA8SCR40	LA8RBU40
LA8JR35D	LA8SR40	LA8JCR45	LA8ALR12	LA8SCR50	LA8RBU40D
LA8JR40	LA8SR45	LA8JCR50			
LA8JR40D	LA8SR50				ECR
LA8JR45	LA8SR60				LA8ECR35
LA8JR50					LA8ECR40
LA8JR60			Short Amplatz Right		LA8ECR45
			LA8SAR10		
			LA8SAR20		
					3-Dimensional
					LA83DRC
OTHER CURVES					
Multipurpose	MAC (Multi-Aortic)	Bypass	Champ	Peripheral	NOTO
LA8HSI	LA8MAC30	LA8IMA	LA8CHAMP05	LA8CARL3D*	LA8NOTO
LA8HSII	LA8MAC35	LA8IMAD*	LA8CHAMP10	LA8CARLD*	
LA8RMSHII	LA8MAC375	LA8LCB	LA8CHAMP15	LA8CHAMP15K+	
LA8HSIII	LA8MAC40	LA8LCBD*	LA8CHAMP20	LA8CHAMP20K+	
LA8MB1	LA8MAC45	LA8RCB	LA8CHAMP25	LA8CHAMP25K+	
LA8MB1D*	LA8MAC50	LA8RCBD*	LA8CHAMP30	LA8IMAK+	
LA8MB2		LA8RCBII	LA8CHAMP35	LA8JR40K+	
LA8MB2D*			LA8CHAMP40	LA8MP1K+	EL GAMAL
LA8MP1				LA8MPHK+	LA8ELGAMAL
LA8MPST				LA8PK1W++	LA8ELGAMAL2
				LA8RDCK+	LA8ELGAMAL3
				LA8SCR40K+	
				LA8STRD*	
				LA8STRK+	
				LA8SW1	
				LA8SW1D*	

D* = 90 cm shaft length Shaft Diameter: 8 F K+ = 55 cm shaft length Inner Diameter: 0.090 in. W++=47 cm shaft length
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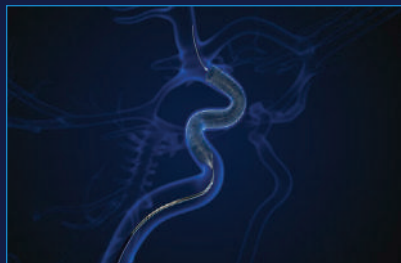
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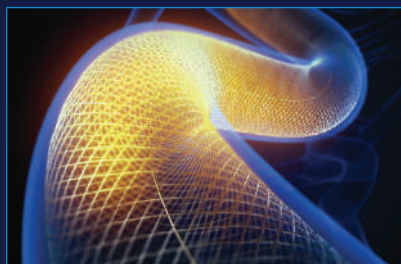
COMPATIBLE
WITH PHENOM™ 21
AND 27 CATHETERS



48 AND 64 WIRE
DFT BRAIDS

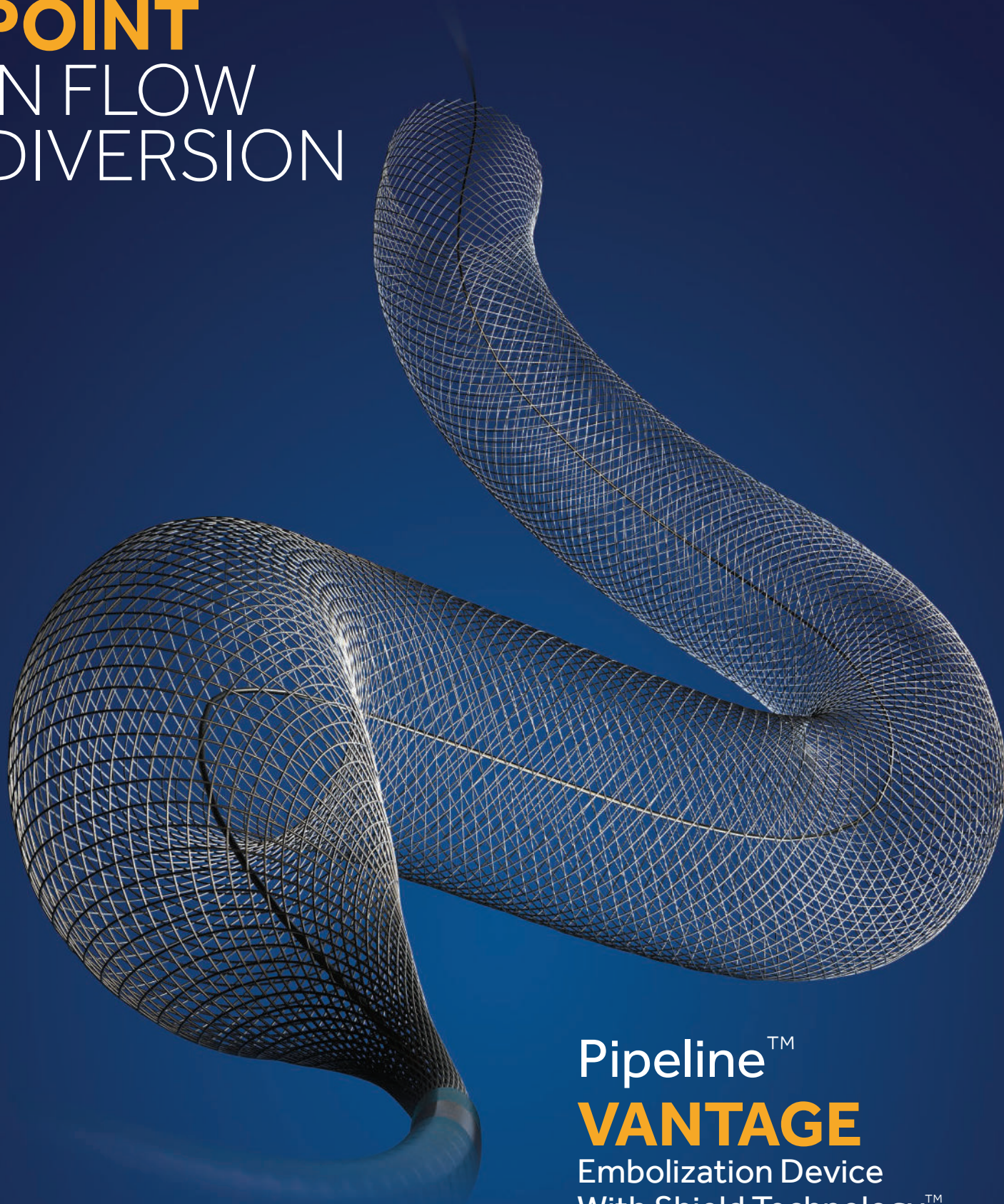


REDESIGNED
RESHEATHING
MECHANISM



FEATURING
SHIELD TECHNOLOGY™

THE VANTAGE POINT IN FLOW DIVERSION



Pipeline™
VANTAGE
Embolization Device
With Shield Technology™

Medtronic

Pipeline™ VANTAGE

Embolization Device With Shield Technology™

ENHANCED

- Distal opening
- Wall apposition

IMPROVED

- Delivery force
- Resheathing force

OPTIMIZED

- Pore density
- Implant wall thickness

Medtronic

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medtronic.eu

The Pipeline™ Vantage Embolization Device with Shield Technology™ is intended for endovascular treatment of adults (22 years of age or older) with wide-necked intracranial aneurysms located in the internal carotid artery (up to the terminus). Phenom™ catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu

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Product Catalog Number	Diameter (mm)	Length (mm)
COMMERCIALLY AVAILABLE SIZES		
PED3-021-250-10	250	10
PED3-021-250-12	250	12
PED3-021-250-14	250	14
PED3-021-250-20	250	20
PED3-021-300-12	300	12
PED3-021-300-14	300	14
PED3-021-300-20	300	20
PED3-021-350-12	350	12
PED3-021-350-14	350	14
PED3-021-350-16	350	16
PED3-021-350-20	350	20
PED3-021-350-25	350	25
PED3-027-350-12	350	12
PED3-027-350-14	350	14
PED3-027-350-16	350	16
PED3-027-350-20	350	20
PED3-027-350-25	350	25
PED3-027-400-12	400	12
PED3-027-400-14	400	14
PED3-027-400-16	400	16
PED3-027-400-20	400	20
PED3-027-400-25	400	25
PED3-027-400-30	400	30
PED3-027-450-12	450	12
PED3-027-450-14	450	14
PED3-027-450-16	450	16
PED3-027-450-20	450	20
PED3-027-450-25	450	25
PED3-027-450-30	450	30
PED3-027-450-40	450	40
PED3-027-500-14	500	14
PED3-027-500-16	500	16
PED3-027-500-20	500	20
PED3-027-500-25	500	25
PED3-027-500-30	500	30
PED3-027-500-40	500	40
PED3-027-550-20	550	20
PED3-027-550-40	550	40
PED3-027-550-50	550	50
PED3-027-600-20	600	20
PED3-027-600-40	600	40
PED3-027-600-50	600	50
SHIP TO ORDER SIZES		
PED3-021-275-12	275	12
PED3-021-275-14	275	14
PED3-021-275-16	275	16
PED3-021-275-20	275	20
PED3-021-325-12	325	12
PED3-021-325-14	325	14
PED3-021-325-16	325	16
PED3-021-325-20	325	20
PED3-027-550-16	550	16
PED3-027-550-30	550	30
PED3-027-600-16	600	16
PED3-027-600-30	600	30

INTERVENTIONAL ACCESSORIES

TRAcelet™ Hemostasis Device

GENERAL CHARACTERISTICS

- Items per box: 5
- Supplied sterile

PRODUCT DESCRIPTION

- The TRAcelet™ compression device is an innovative solution for simplified pressure control.
- Its dual-compression balloon system uniformly delivers pressure to the access site to stop bleeding, while maintaining radial artery patency.
- In the cath lab: use the syringe provided with the TRAcelet™ compression device for pressure optimization.
- In the recovery area: use the dial-based system for controlled pressure adjustments without the need for a syringe.



TECHNICAL SPECIFICATIONS

INFLATION VOLUME NUMBERS (CC)	
Nominal	13
Maximum	18

STRAP LENGTHS (CM)	
Regular	19.2
Large	25.2

CFN	STRAP LENGTHS (CM)
TRACR	Regular
TRACL	Large

1. Data on file at Medtronic.
2. Bench test data on file at Medtronic.

INTERVENTIONAL ACCESSORIES

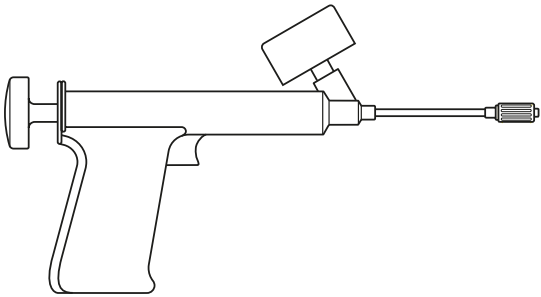
Everest™ Disposable Inflation Device and Accessories

GENERAL CHARACTERISTICS

- Supplied sterile.
- Items per box: 1
- Kits per box: 1

PRODUCT DESCRIPTION

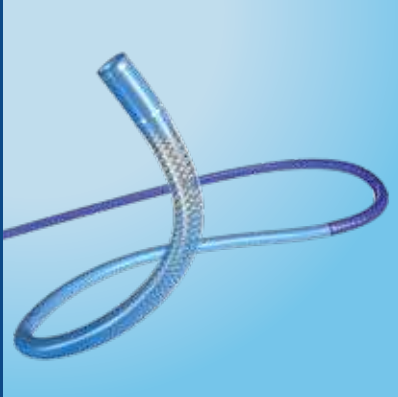
- Available with a 3-way stopcock.
- The pistol-grip fits comfortably in either hand and its trigger mechanism is easy to use for all operators.
- A 20-cc syringe capacity provides rapid negative pressures to speed deflation times.
- The 20 atm/bar and 30 atm/bar luminescent gauges are easy to read under low light conditions. Accurate readings within +/- 3% of gauge full scale.



EVEREST INFLATION DEVICE

PRODUCT CODE	DESCRIPTION	PACKAGED WITH
AC2200	Everest20 Inflation Device	1 three-way stopcock
AC3200	Everest30 Inflation Device	1 three-way stopcock
AC2205P	Everest20 Survival Kit	1 Everest20 atm inflation device, 1 three-way stopcock, Piton™ Y-adapter, guidewire insertion tool, and torque handle
AC3205P	Everest30 Survival Kit	1 Everest30 atm inflation device, 1 three-way stopcock, Piton™ Y-adapter, guidewire insertion tool, and torque handle

MICRO CATHETERS



Echelon™ Micro Catheter

The Echelon™ micro catheter is a steam shapeable micro catheter with variable nitinol braiding and a flexible distal tip for optimal device delivery. The Echelon™ micro catheter is DMSO compatible.

PRODUCT NAME	PRODUCT CATALOGUE NO.	OUTER DIAMETER (FR)	DISTAL INNER DIAMETER (IN)	TOTAL LENGTH (CM)	USABLE LENGTH (CM)	MAX GUIDEWIRE (IN)	TIP LENGTH (MM)	TIP SHAPE
Echelon™ 10	105-5091-150	2.1-1.7	0.017	155	150	0.014	-	Straight
	145-5091-150	2.1-1.7	0.017	155	150	0.014	2.5	45°
	190-5091-150	2.1-1.7	0.017	155	150	0.014	5	90°
Echelon™ 14	105-5092-150	2.4-1.9	0.017	155	150	0.014	-	Straight
	145-5092-150	2.4-1.9	0.017	155	150	0.014	2.5	45°
	190-5092-150	2.4-1.9	0.017	155	150	0.014	5	90°

INDICATIONS: The Echelon™ micro catheter is intended to access peripheral and neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.

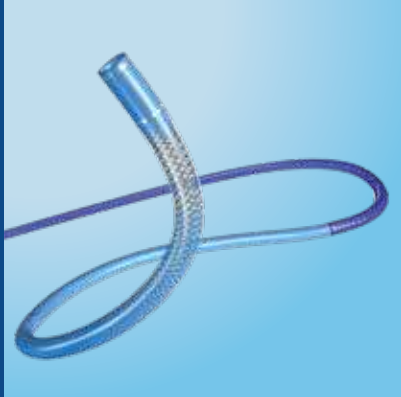
Marksman™ Micro Catheter

All Marksman™ micro catheters are specially designed for the optimal and safe delivery of the Pipeline™ embolization device except Marksman™ 160 micro catheter specially designed for Stroke. Proximally the design is offering a stainless steel coil and a stainless steel braiding for optimised handling and support. The Marksman™ catheter has a high kink resistant stainless steel braiding for a smooth device delivery.

PRODUCT CATALOGUE NO.	OUTER DIAMETER DISTAL/PROXIMAL (FR)	INNER DIAMETER (IN)	WORKING LENGTH (CM)	DISTAL FLEXIBLE LENGTH (CM)
FA-55105-1015	2.8/3.2	0.027	105	10
FA-55135-1030	2.8/3.2	0.027	135	10
FA-55150-1030	2.8/3.2	0.027	150	10
FA-55160-1030	2.8/3.2	0.027	160	10

INDICATIONS : The Marksman™ micro catheter is intended for the introduction of interventional and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculature.

MICRO CATHETERS



Rebar™ Reinforced Micro Catheter

Rebar™ micro catheter is a stainless steel coil reinforced micro catheter offering high kink resistance for optimal device delivery. Rebar™ micro catheter is compatible with Onyx™ liquid embolic system.

PRODUCT NAME	PRODUCT CATALOGUE NO.	OUTER DIAMETER (FR)	DISTAL INNER DIAMETER (IN)	TOTAL LENGTH (CM)	USABLE LENGTH (CM)	MAX GUIDEWIRE (IN)	MARKER BANDS
Rebar™ 10	105-5078-153	2.3-1.7	0.015	158	153	0.012	1
	105-5078-153C	2.3-1.7	0.015	158	153	0.012	2
Rebar™ 18	105-5081-153	2.7-2.4	0.021	158	153	0.018	2
Rebar™ 27	105-5082-130	2.8-2.8	0.027	135	130	0.021	1

INDICATIONS: The Rebar™ micro catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

TECHNICAL FEATURES

Technical Features	Telescope™ GEC
Catheter length	150 cm
Distal extension length	25 cm
Marker band material	Platinum iridium
Marker band lengths and locations	1 mm long, 2 mm from distal tip 3 mm long, spade-shaped at entry port
Coating	Hydrophilic, outer layer of distal 21 cm
Pushwire length	125 cm
Tapered pushwire portion	10 cm
On-ramp length	4 cm
On-ramp material	Nylon-based polymer
TruFlex™ tip	2 mm
Shelf life	2 years

DIMENSIONAL COMPARISON

French Size (F)	GEC Name	I.D. (in)	O.D. (in)	Required GC I.D. (in)
5.5	GuideLiner™* V3 GEC ⁶	0.051	0.063	6 F ≥ 0.066
6	Telescope™ GEC	0.056	0.067	6 F ≥ 0.070
6	GuideLiner™* V3 GEC ⁶	0.056	0.067	6 F ≥ 0.070
6	Guidezilla™* II GEC ⁷	0.057	0.067	6 F ≥ 0.070
7	Telescope™ GEC	0.062	0.075	7 F ≥ 0.078
7	GuideLiner™* V3 GEC ⁶	0.062	0.075	7 F ≥ 0.078
7	Guidezilla™* II GEC ⁷	0.063	0.073	7 F ≥ 0.078

Important Information
Prior to use, refer to the product Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings, and precautions.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner. See package inserts for full product information.

ORDERING INFORMATION

French Size (F)	CFN
6	TELE6F

French Size (F)	CFN
7	TELE7F



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AN EXTENSION OF YOU

Telescope™ Guide Extension Catheter

THE PERFORMANCE YOU WANT FOR
YOUR COMPLEX CLINICAL PRACTICE

Today's PCIs are becoming increasingly complex. In difficult cases, guide extension catheters provide additional backup support and improve access to distal lesions.¹

Medtronic
Further, Together

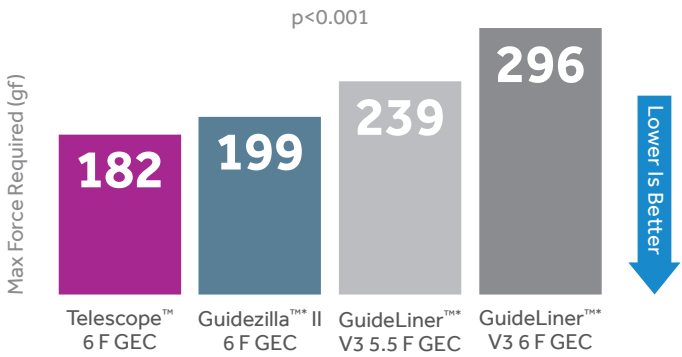
TELESCOPE™ GEC
AN EXTENSION
OF YOU



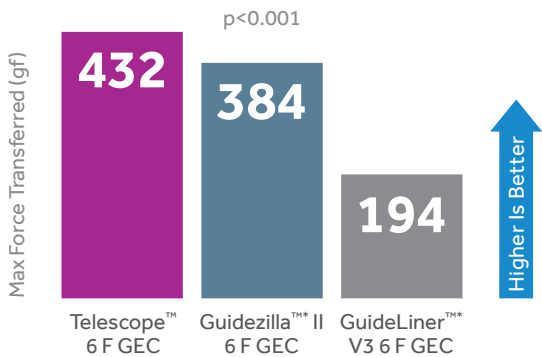
SUPERIOR
DELIVERABILITY²

Strong pushwire³ and coil-reinforced distal segment enhance performance.

Deliverability



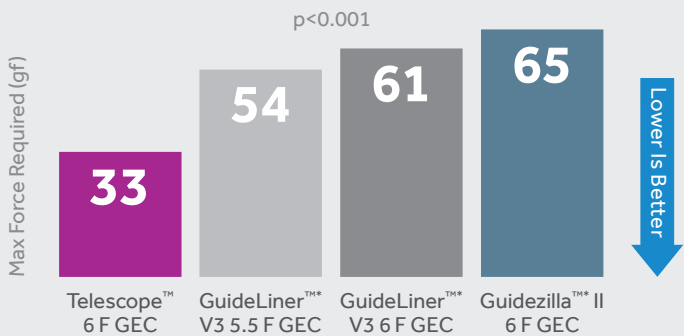
Pushability



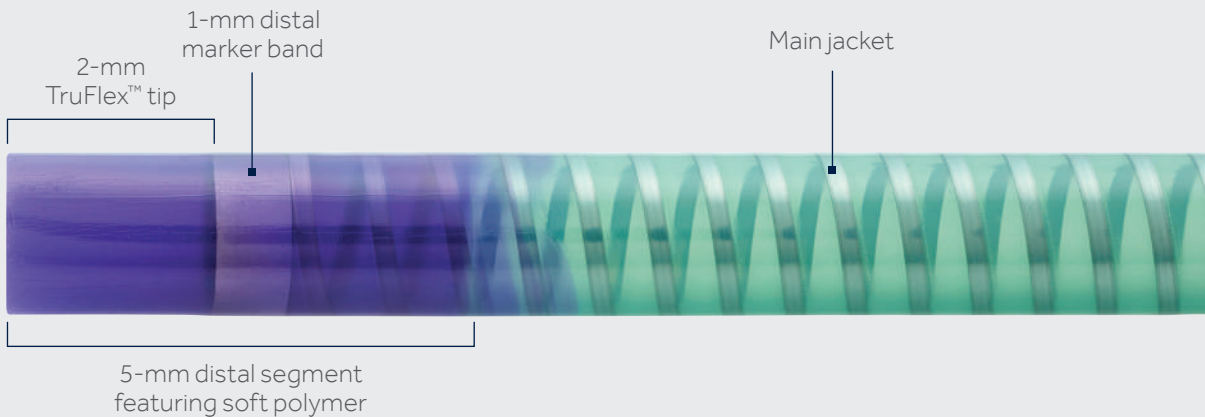
SOFTTEST⁴ TIP

Our extruded TruFlex™ soft⁴ polymer tip responsively deflects and provides flexibility.

Soft Tip Compression

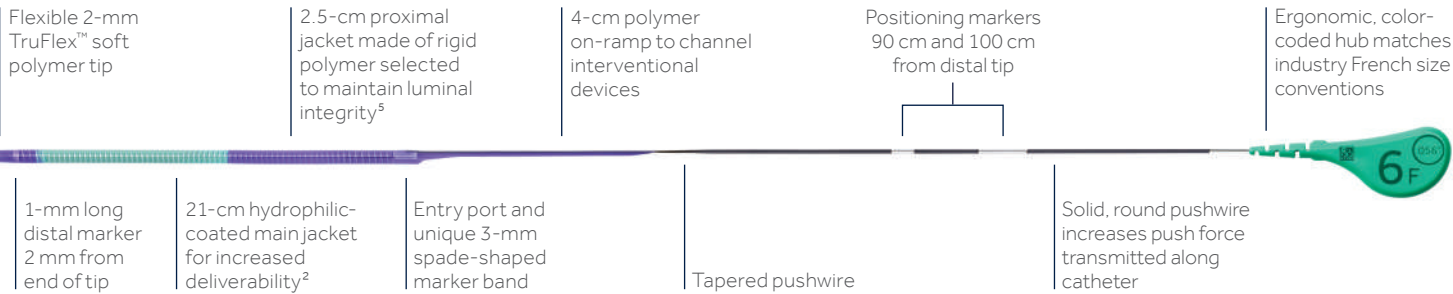
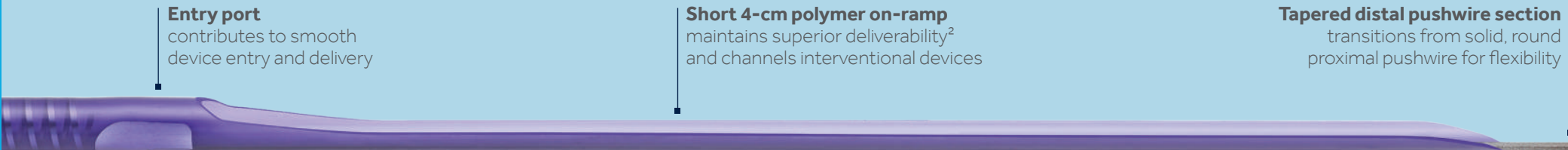


The TruFlex™ tip required at least **39% less force** to deflect.⁴



SMOOTHPASS
TECHNOLOGY

SmoothPass Technology includes three components that work together to smoothly channel interventional devices.



¹ Sambu N, Fernandez J, Shah NC, O’Kane P. The Guideliner®: an interventionalist’s experience of their first 50 cases: “the mostly good, rarely bad, beware of the ugly!” *Interv. Cardiol.* 2013;5(4):389-404.

² Deliverability bench testing: Telescope™ 6 F GEC vs. GuideLiner™ V3 5.5 F/6 F GEC vs. Guidezilla™ II 6 F GEC. Differences among the means are significant if p < 0.05. N = 8 for each GEC tested. 10 test cycles per GEC. Results measure maximum force.

³ Pushability bench testing: Telescope™ 6 F GEC vs. GuideLiner™ V3 6 F GEC vs. Guidezilla™ II 6 F GEC. Differences among the means are significant if p < 0.05. N = 8 for each GEC tested. Results measure maximum force.

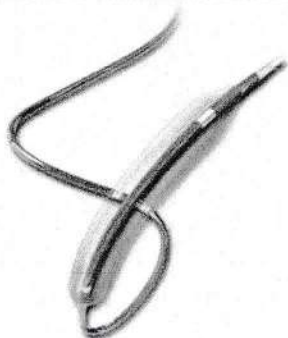
⁴ Soft tip compression bench testing: Telescope™ 6 F GEC vs. GuideLiner™ V3 5.5 F/6 F GEC vs. Guidezilla™ II 6 F GEC. Differences among the means are significant if p < 0.05. N = 8 for each GEC tested. Results measure maximum force.

⁵ Details on luminal integrity are in the Telescope™ GEC design freeze document (internal design document).

⁶ GuideLiner™ V3 GEC measurements are from the product brochure.

⁷ Guidezilla™ II GEC measurements are from the product brochure.

Bench test data may not be indicative of clinical performance.

CATETER CU BALON DE
DILATARE NON-COMPLIANT

Caracteristici și beneficii

- Durabile, cu capacitatea de reumflare de până la 10 ori, fără a se sparge
- Capacitate de înaintare și retragere îmbunătățite¹
- Profil redus de creștere²

Matrice de dimensiuni

Diametru Balon (mm)	Lungime balon (mm)					
	06	08	12	15	20	27
2.00	NCSLC2006X	NCSLC2008X	NCSLC2012X	NCSLC2015X	NCSLC2020X	—
2.25	NCSLC22506X	—	NCSLC22512X	—	NCSLC22520X	—
2.50	NCSLC2506X	NCSLC2508X	NCSLC2512X	NCSLC2515X	NCSLC2520X	NCSLC2527X
2.75	NCSLC27506X	NCSLC27508X	NCSLC27512X	NCSLC27515X	NCSLC27520X	—
3.00	NCSLC3006X	NCSLC3008X	NCSLC3012X	NCSLC3015X	NCSLC3020X	NCSLC3027X
3.25	NCSLC32506X	NCSLC32508X	NCSLC32512X	NCSLC32515X	NCSLC32520X	—
3.50	NCSLC3506X	NCSLC3508X	NCSLC3512X	NCSLC3515X	NCSLC3520X	NCSLC3527X
3.75	NCSLC37506X	NCSLC37508X	NCSLC37512X	NCSLC37515X	NCSLC37520X	—
4.00	NCSLC4006X	NCSLC4008X	NCSLC4012X	NCSLC4015X	NCSLC4020X	NCSLC4027X
4.50	—	NCSLC4508X	NCSLC4512X	NCSLC4515X	NCSLC4520X	—
5.00	—	NCSLC5008X	NCSLC5012X	NCSLC5015X	—	—

Lungimi de înlocuire: înlocuirea baloanelor NC Sprinter™ de 9mm cu baloane de 8mm și înlocuirea baloanelor NC Sprinter™ de 21mm cu baloane de 20mm
Culoarea portocalie = dimensiune suplimentară peste matricea de balon NC Sprinter™

Îmbunătățiri tehnice

Caracteristici Tehnice	Cateter cu balon de dilatare non-compliant NC Solarice™	Cateter cu balon de dilatare non-compliant NC Sprinter™
Presiune nominală (atm)	12	10
Presiune de spargere (RBP) (atm)	20	18
Capacitate de depreciere a materialului (cicluri până la RBP)	10	10
Cateter distal O.D. (F) 2.00 mm-3.75 mm 4.00 mm-5.00 mm	Uniform 2.5 F Uniform 2.7 F	2.6 F la denivelări și 2.4 F Uniform 3.0 F
Material bandă marcaj	Platină Iridiu	Aur
Profil de intrare în leziune (in.)	0.015	0.016

Modificări ale
Caracteristicilor Tehnice

Caracteristici tehnice	Balon NC Solarice™	Balon NC Sprinter™
Material balon	Brevetată, pe bază de nailon	Soft Fulcrum™ Plus
Înveliș hidrofil	Nicio modificare	Selective Dura-Trac
Lungime cateter (cm)	Nicio modificare	142
Balon MiniWrap 2.00 mm-3.75 mm 4.00 mm-5.00 mm	Nicio modificare Nicio modificare	3 pliuri 5 pliuri
MGC ID pentru balon 2.00-4.00-mm	Nicio modificare	1.42 mm/0.056"
MGC ID pentru balon 4.00-5.00-mm	Nicio modificare	1.68 mm/0.066"

Testare competitivă față de baloanele* NC Trek™ și NC Quantum Apex™.
Testare competitivă față de baloanele* NC Quantum Apex™.
Datele de testare pe banc pot să nu fie elocvente pentru performanța clinică.

Medtronic

MINISTERUL JUSTIȚIEI
LAMBRU ISABELA-RAISA
TRADUCĂTOR AUTORIZAT
NR. 34612/2012
ENGLEZĂ - SPANIOLĂ

CATETER CU BALON DE DILATARE NON-COMPLIANT NC Solarice™

Date de complianță

Presiune kPa (atm)	Diametru mediu balon (mm)										
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
608 (6)	1.89	2.12	2.35	2.54	2.77	2.94	3.13	3.43	3.67	4.09	4.64
709 (7)	1.91	2.15	2.37	2.57	2.80	2.97	3.17	3.47	3.72	4.14	4.71
811 (8)	1.93	2.17	2.40	2.60	2.84	3.01	3.22	3.51	3.78	4.19	4.79
912 (9)	1.95	2.19	2.43	2.63	2.87	3.06	3.27	3.56	3.84	4.25	4.86
1013 (10)	1.97	2.21	2.46	2.66	2.91	3.10	3.32	3.61	3.90	4.31	4.92
1115 (11)	1.98	2.23	2.48	2.69	2.94	3.14	3.37	3.66	3.95	4.37	4.95
1216 (12) ¹	1.99 ¹	2.25 ¹	2.50 ¹	2.71 ¹	2.97 ¹	3.18 ¹	3.41 ¹	3.70 ¹	3.99 ¹	4.42 ¹	5.00 ¹
1317 (13)	2.00	2.26	2.51	2.73	2.99	3.21	3.44	3.73	4.03	4.47	5.04
1419 (14)	2.02	2.28	2.53	2.75	3.01	3.23	3.47	3.76	4.07	4.51	5.08
1520 (15)	2.03	2.29	2.54	2.77	3.03	3.26	3.50	3.78	4.10	4.54	5.12
1621 (16)	2.04	2.30	2.56	2.78	3.05	3.28	3.52	3.81	4.13	4.58	5.15
1723 (17)	2.05	2.31	2.58	2.80	3.07	3.30	3.55	3.83	4.15	4.60	5.19
1824 (18)	2.06	2.33	2.59	2.81	3.09	3.33	3.57	3.86	4.18	4.63	5.23
1925 (19)	2.07	2.34	2.61	—	3.11	3.35	3.59	3.88	4.21	4.66	5.27
2027 (20) ¹	2.09 ¹	2.36 ¹	2.63 ¹	2.84 ¹	3.13 ¹	3.37 ¹	3.62 ¹	3.91 ¹	4.24 ¹	4.69 ¹	5.30 ¹
2128 (21)	2.10	2.37	2.65	2.86	3.15	3.39	3.64	3.93	4.28	4.72	5.35
2229 (22)	2.12	2.39	2.66	2.88	3.17	3.41	3.66	3.96	4.31	4.75	5.39
2330 (23)	2.14	2.40	2.68	2.90	3.20	3.43	3.69	3.99	4.34	4.78	—
2432 (24)	2.15	2.42	2.71	2.92	3.22	—	3.71	—	—	4.81	—
2533 (25)	—	2.44	—	2.94	3.25	—	3.74	—	—	4.84	—

Presiune nominală¹ Presiune de spargere²
¹Presiune nominală: presiunea la care balonul atinge diametrul de pe etichetă.
²Presiunea de spargere — a nu se depăși. Presiunea de spargere: presiunea maximă la care un balon este proiectat să fie umflat.

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L6Y 0R3 Canada
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Fax: 905.460.3998
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Medtronic medtronic.com

Subsemnata, **Lambru Isabela Raisa**, traducător autorizat de Ministerul de Justiție din România cu autorizația numărul 34612/2012, certific exactitatea traducerii în limba română cu înscrisul în limba engleză, care a fost vizat de mine.

TRADUCĂTOR,

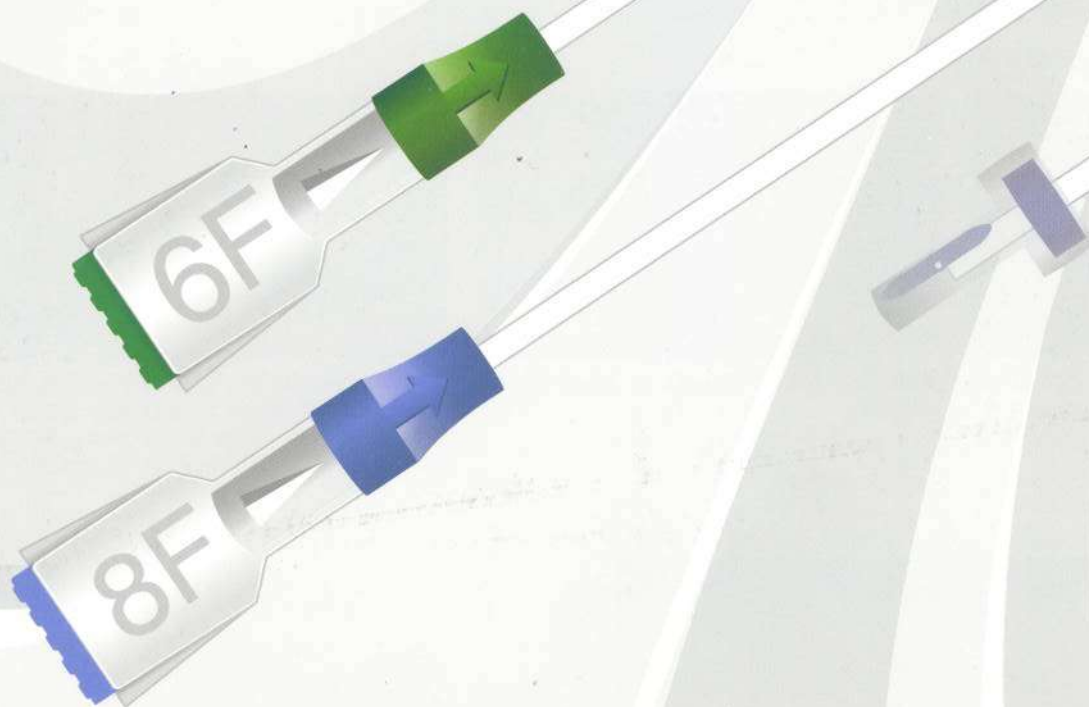
MINISTERUL JUSTITIEI
LAMBRU ISABELA-RAISA
TRADUCĂTOR AUTORIZAT
NR. 34612/2012
ENGLEZĂ - SPANIOLĂ

Meril

ObturaTM

Vascular Closure Device

Assured Closure. Delivered !



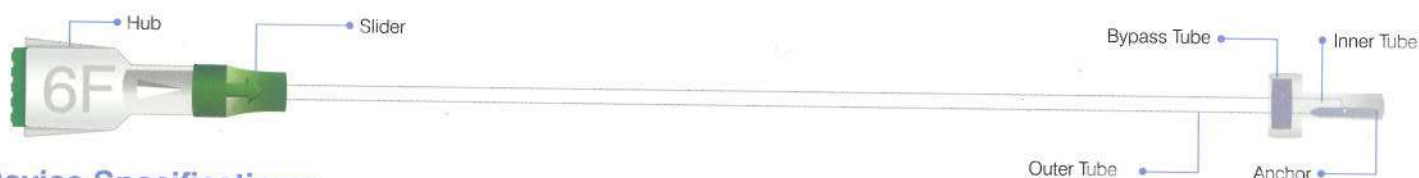
ObturaTM

Vascular Closure Device

Meril

The ObturaTM Vascular Closure Device is a mechanical closure system which provides an unassailable sealing of the arterial puncture without exchanging Introducer Sheath making it easy to use and providing rapid hemostasis.

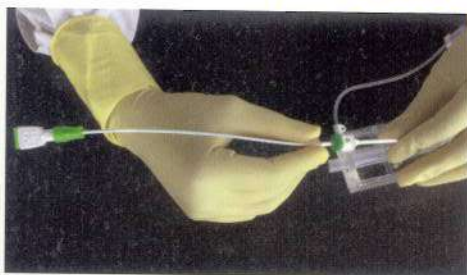
- NO exchange of Introducer Sheath
- Less procedural time
- Rapid Hemostasis and less blood loss
- 90 days absorption
- Easy to use Mechanical technique



Device Specifications:

Parameter	Specification
Device Size (F)	6 and 8
Device Total Length (mm)	205
Device Effective Length(mm)	155
Complete Degradation Period* (days)	90
Device Size Compatibility	6F device compatible with 6F & 7F Introducer Sheath 8F device compatible with 8F & 9F Introducer Sheath
Introducer Sheath Compatibility	Medtronic: InPut Introducer Sheath Cordis Corporation: AVANTI TM Introducer Sheath Terumo Corporation: PINNACLE Introducer Sheath Oscor Inc: Adelante Meril Medical: Prelude
Compatible Introducer Sheath Length(cm)	12

Simple Three Step Procedure:



Step 1: Grasp the device at Bypass tube between two fingers like a pen such that size indicator 6F/8F on Hub and Arrow mark on Slider Hub appears upwards.



Step 2: Pull the Hub until the Black Marker appears.



Step 3: Grasping the three components Hub, Slider Hub and Hub of the Introducer Sheath in palm, retract the entire device along with the introducer sheath. Keep the tension on Suture.

Ordering Information:

Reference Number	French Size
OBT6F	6F
OBT8F	8F

ObturaTM

Vascular Closure Device

Meril

The ObturaTM Vascular Closure Device is a mechanical closure system which provides an unassailable sealing of the arterial puncture without exchanging Introducer Sheath making it easy to use and providing rapid hemostasis.

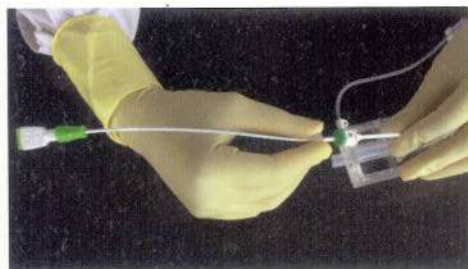
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Ordering Information:

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OBT6F	6F
OBT8F	8F

RIGHT CASE
RIGHT TIME
PREVAIL

Prevail™
Paclitaxel Coated PTCA
Balloon Catheter



Medtronic

Prevail

Paclitaxel Coated PTCA
Balloon Catheter

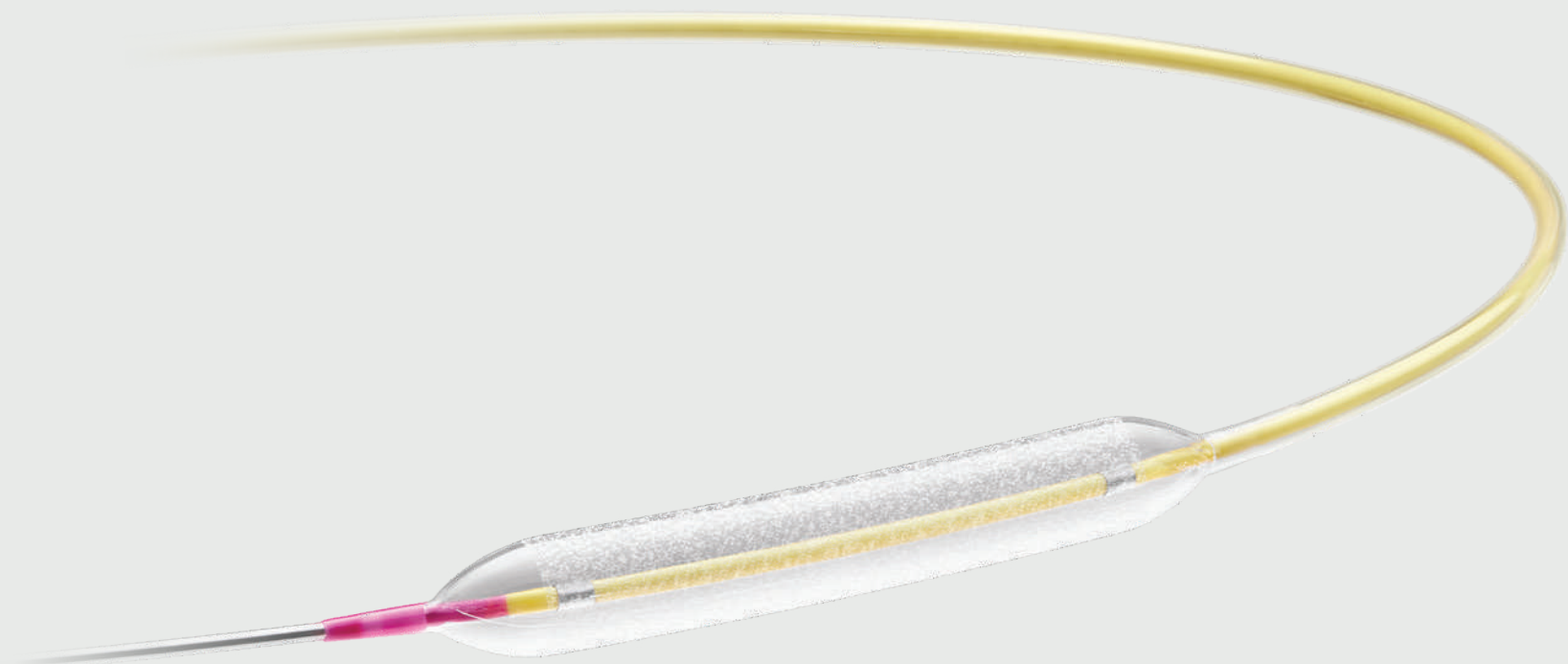


Performance you want for treating complex lesions¹:

- **Superior deliverability^{†2}** — deliberately designed to maximise pushability
- **Rapid absorption of paclitaxel¹** — facilitated by biocompatible urea excipient³
- **Excellent safety and efficacy** — demonstrated in the IN.PACT Falcon clinical program; confirmed by the PREVAIL Study⁴

SUPERIOR DELIVERABILITY^{†2}

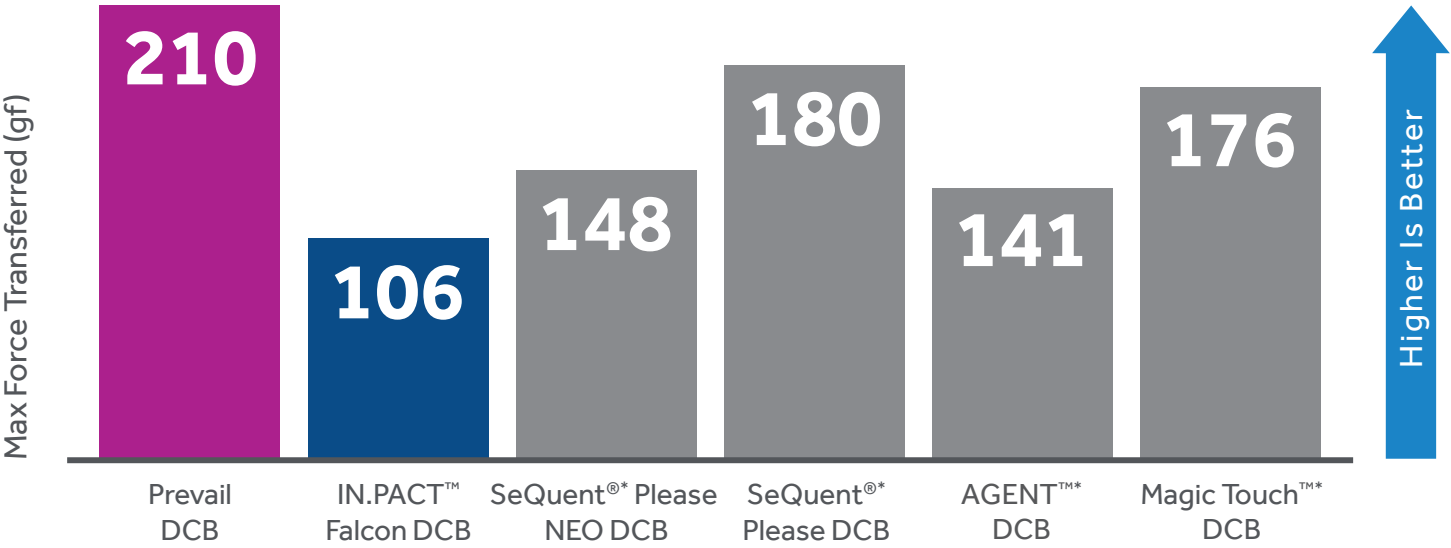
PowerTrac™ technology
and a hydrophilic coating
facilitate superior
deliverability and device
performance.^{†2}



2x

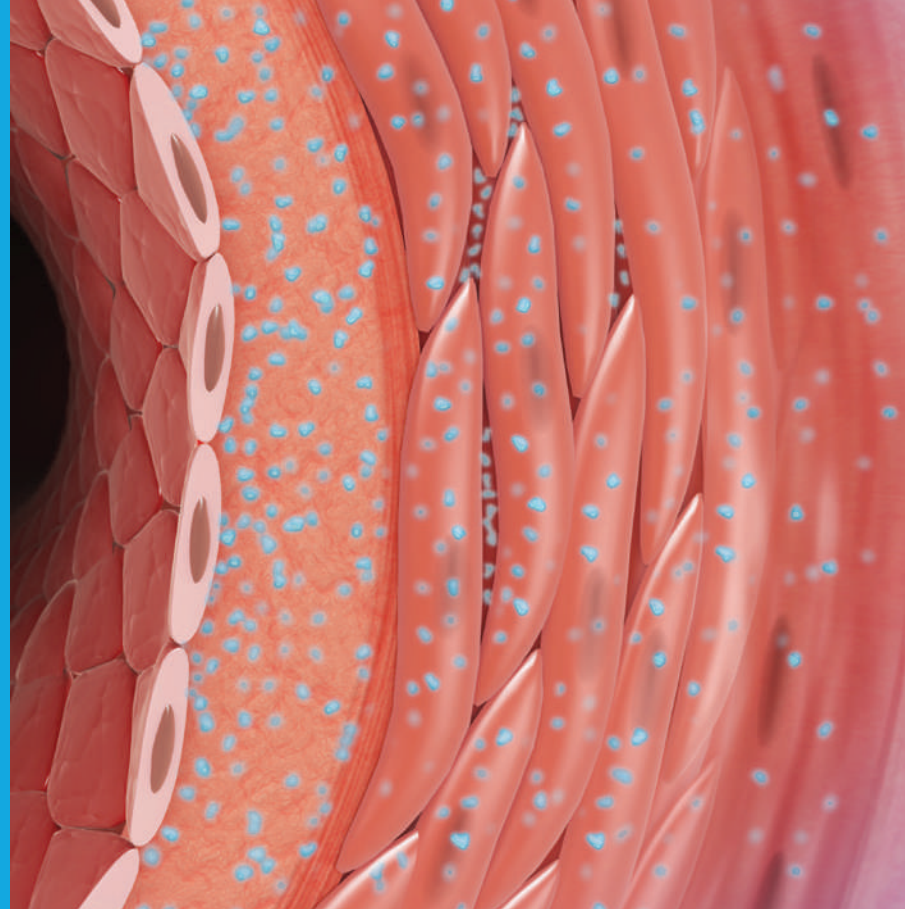
Prevail DCB is 2x more
pushable vs. IN.PACT
Falcon DCB⁵

PUSHABILITY



RAPID ABSORPTION OF PACLITAXEL¹

FreePac™ coating combines
two proven components that
work together.⁶



Paclitaxel — potent
antirestenotic drug that
remains in tissue throughout
the healing process^{7,8}

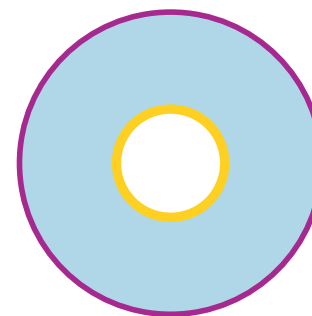


Urea — biocompatible
excipient that enables
rapid drug delivery within
30–60 seconds^{1,3}

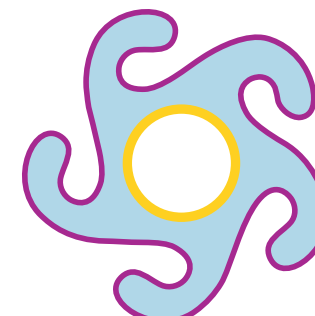
Open coating process provides for reliable, uniform
FreePac coating.[†]

— FreePac coating

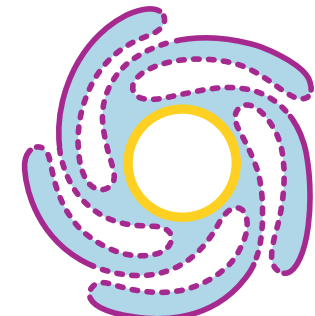
- - - Protected FreePac coating



Balloon open while FreePac
coating is applied



Balloon folding



**65% of drug is protected
within the folds⁹**

EXCELLENT SAFETY AND EFFICACY

As demonstrated in the
**IN.PACT Falcon clinical
program:**

 10 trials

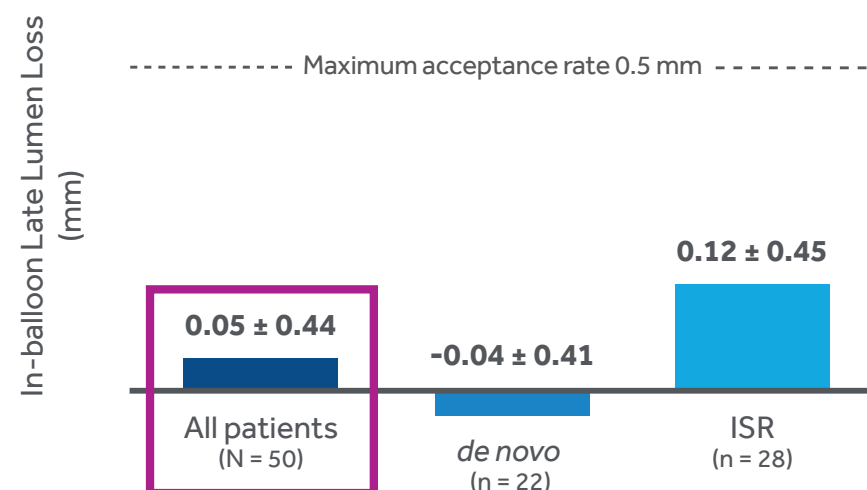
 > 1400 patients



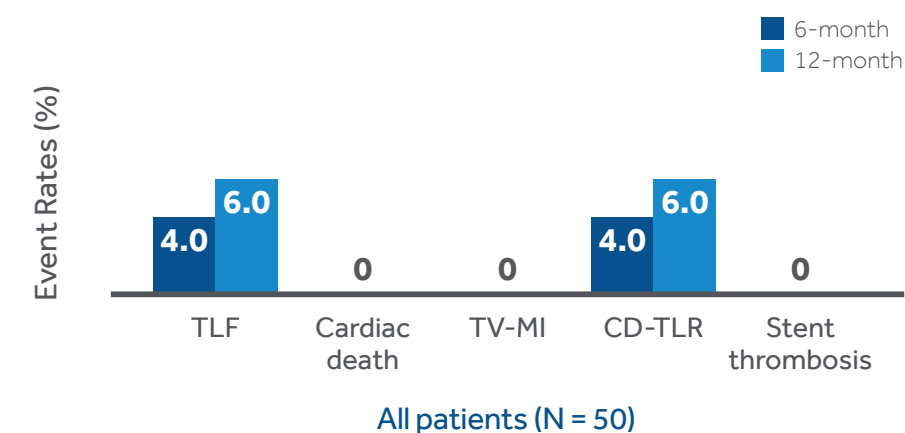
And **confirmed in the
PREVAIL Study⁴:**

- Includes complex lesions
- 54.7% ISR
- 75% small vessel in *de novo* lesions

VERY LOW LATE LOSS IN ALL PATIENTS AT 6 MONTHS⁴

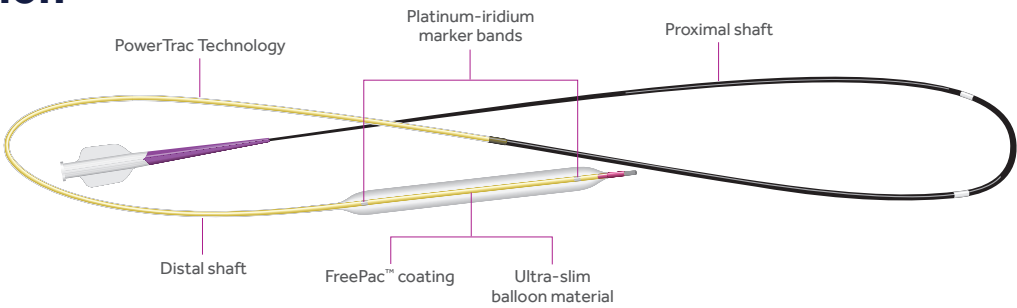
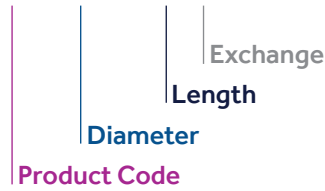


0% STENT THROMBOSIS, TV-MI, OR CARDIAC DEATH FOR ALL PATIENTS



Ordering Information

PRV025010RX



Balloon Diameter (mm)	Balloon Length (mm)				
	10	15	20	25	30
2.00	PRV020010RX	PRV020015RX	PRV020020RX	PRV020025RX	PRV020030RX
2.25	PRV022510RX	PRV022515RX	PRV022520RX	PRV022525RX	—
2.50	PRV025010RX	PRV025015RX	PRV025020RX	PRV025025RX	PRV025030RX
2.75	PRV027510RX	PRV027515RX	PRV027520RX	PRV027525RX	—
3.00	PRV030010RX	PRV030015RX	PRV030020RX	PRV030025RX	PRV030030RX
3.50	PRV035010RX	PRV035015RX	PRV035020RX	PRV035025RX	PRV035030RX
4.00	PRV040010RX	PRV040015RX	PRV040020RX	PRV040025RX	PRV040030RX

Compliance Data

Pressure kPa (atm)	Average Balloon Diameter (mm)						
	2.00	2.25	2.50	2.75	3.00	3.50	4.00
608 (6)	2.03	2.27	2.50	2.70	2.92	3.39	3.88
709 (7)	2.05	2.30	2.52	2.73	2.95	3.43	3.93
811 (8)	2.07	2.32	2.55	2.77	2.99	3.48	3.99
912 (9)	2.09	2.35	2.58	2.80	3.03	3.53	4.04
1013 (10)	2.12	2.38	2.61	2.84	3.06	3.58	4.10
1115 (11)	2.14	2.41	2.64	2.87	3.10	3.62	4.14
1216 (12)	2.17	2.43	2.67	2.91	3.14	3.67	4.19
1317 (13)	2.19	2.46	2.70	2.94	3.17	3.71	4.23
1419 (14)	2.22	2.49	2.73	2.98	3.21	3.76	4.28
1520 (15)	2.25	2.52	2.76	3.02	3.25	3.81	4.33
1621 (16)	2.28	2.56	2.79	3.06	3.29	3.86	4.38
1723 (17)	—	2.60	2.83	3.11	3.34	3.91	4.43

Nominal pressure Rated burst pressure — do not exceed.

¹Third-party brands are trademarks of their respective owners.
²Based on bench test data. Bench test data may not be indicative of clinical performance.
³Prevail Instructions for Use.
⁴Compared with IN.PACT Falcon DCB, SeQuent® Please NEO DCB, Agent™ DCB, and MagicTouch™ DCB. Deliverability defined as pushability. Based on bench test data, 2020.
⁵Barrett BJ. Contrast nephrotoxicity. *J Am Soc Nephrol.* August 1994;5(2):125-137.
⁶Latib A, et al. PREVAIL Study, presented at PCR 2020, results through 12 months. IN.PACT Falcon DCB and Prevail DCB use the same FreePac™ coating. PREVAIL study did not have powered endpoints.
⁷99% improved push force compared to IN.PACT Falcon DCB.
⁸Virmani R. Arterial wall response to drug-coated balloons. *Confluence.* September 2016;13:15-19.
⁹Cremers B, Clever Y, Schaffner S, Speck U, Böhm M, Scheller B. Treatment of coronary in-stent restenosis with a novel paclitaxel urea coated balloon. *Minerva Cardioangiol.* October 2010;58(5):583-588.
¹⁰PS762 preclinical study report: An Evaluation of the Medtronic Drug Coated IN.PACT™ Euphoro™ Coronary Balloon Catheter in a Porcine Artery Model, 2016. On file at Medtronic.
¹¹Depending on DCB fold configuration. D00277875 report on file at Medtronic.

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Caracteristici și beneficii

- Livrare îmbunătățită¹ — capacitate de înaintare mărită
- Forțe necesare scăzute pentru înaintare și retragere printr-un cateter de ghidaj de 6F^{1,2}
- Benzi de marcaj cu profil redus — traversabilitate îmbunătățită¹

Matrice de dimensiuni

Diametru balon (mm)	Lungime balon (mm)						
	06	10	12	15	20	25	30
1.50	SLC1506X	SLC1510X	SLC1512X	SLC1515X	SLC1520X	—	—
2.00	SLC2006X	SLC2010X	SLC2012X	SLC2015X	SLC2020X	SLC2025X	SLC2030X
2.25	SLC22506X	SLC22510X	SLC22512X	SLC22515X	SLC22520X	SLC22525X	—
2.50	SLC2506X	SLC2510X	SLC2512X	SLC2515X	SLC2520X	SLC2525X	SLC2530X
2.75	SLC27506X	—	SLC27512X	SLC27515X	SLC27520X	SLC27525X	—
3.00	SLC3006X	SLC3010X	SLC3012X	SLC3015X	SLC3020X	SLC3025X	SLC3030X
3.25	—	—	SLC32512X	SLC32515X	SLC32520X	—	—
3.50	SLC3506X	SLC3510X	SLC3512X	SLC3515X	SLC3520X	SLC3525X	SLC3530X
3.75	—	—	SLC37512X	SLC37515X	SLC37520X	—	—
4.00	SLC4006X	SLC4010X	SLC4012X	SLC4015X	SLC4020X	SLC4025X	SLC4030X

Îmbunătățiri tehnice

Caracteristici tehnice	Cateter cu balon de dilatare semi-compliant Solarice™	Cateter cu balon de dilatare semi-compliant Sprinter™ Legend™
Presiune nominală (atm)	8	1.25 mm: 12 1.50 mm: 6 2.00-4.00 mm: 8
Presiune de spargere (RBP) (atm)	1.50-4.00 mm: 14	1.25-1.50 mm: 12 2.00-4.00 mm: 14
Capacitate de deprecieri a materialului (cicluri până la RBP)	10	10
Dimensiunea axului Proximal	1.50-3.50 mm: 0.69 mm (2.1 F)	1.25-3.50 mm: RX 1.9 F; OTW 3.2 F
Dimensiunea axului Distal	0.84 mm (2.5 F)	2.4 F/2.6 F
Dimensiunea axului Proximal	3.75 mm-4.00 mm: 0.69 mm (2.1 F)	3.75 mm-4.00 mm: RX 1.9 F; OTW 3.2 F
Dimensiunea axului Distal	0.91 mm (2.7 F)	2.5 F/2.7 F
Material bandă marcaj	Nicio modificare	Platină Iridiu
Profil de intrare în leziune (in.)	Nicio modificare	0.016

Modificări ale Caracteristicilor Tehnice

Caracteristici tehnice	Balon Solarice™	Balon Sprinter™
Material balon	Fulcrum™ Lite	Fulcrum™
Înveliș hidrofil	Nicio modificare	Selective Dura-Trac
Lungime cateter (cm)	Nicio modificare	142
Balon MiniWrap	1.50 mm: 2 pliuri 2.00 mm-3.50 mm: 3 pliuri 3.75 mm-4.00 mm: 5 pliuri	1.25 mm: 0 pliuri 1.50 mm: 2 pliuri 2.00 mm-3.75 mm: 3 pliuri 4.00 mm: 5 pliuri
MGC ID pentru balon 1.50-4.00-mm	Nicio modificare	1.42 mm/0.056"

¹Testare comparativă față de baloanele Trek™, Emerge™, Sprinter™ Legend™ și Ryuji™ Plus. Testare cu baloane 2.50-mm x 15-mm.

²Pe baza testării 6 F KBT.

Datele de testare pe banc pot să nu fie elocvente pentru performanța clinică.

Medtronic

MINISTERUL JUSTIȚIEI
LAMBRU ISABELA-RAISA
TRADUCĂTOR AUTORIZAT
NR. 34612/2012
ENGLEZĂ - SPANIOLĂ

Cateter cu balon de dilatare semi-compliant Solarice™

Date de Complanță

Presiune kPa (atm)	Diametru mediu balon (mm)									
	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
608 (6)	1.49	2.03	2.27	2.50	2.70	2.92	3.17	3.39	3.66	3.88
709 (7)	1.51	2.05	2.30	2.52	2.73	2.95	3.21	3.43	3.70	3.93
811 (8) ¹	1.52 ¹	2.07 ¹	2.32 ¹	2.55 ¹	2.77 ¹	2.99 ¹	3.25 ¹	3.48 ¹	3.75 ¹	3.99 ¹
912 (9)	1.54	2.09	2.35	2.58	2.80	3.03	3.30	3.53	3.80	4.04
1013 (10)	1.55	2.12	2.38	2.61	2.84	3.06	3.34	3.58	3.85	4.10
1115 (11)	1.57	2.14	2.41	2.64	2.87	3.10	3.38	3.62	3.90	4.14
1216 (12)	1.58	2.17	2.43	2.67	2.91	3.14	3.42	3.67	3.95	4.19
1317 (13)	1.60	2.19	2.46	2.70	2.94	3.17	3.46	3.71	4.00	4.23
1419 (14) ²	1.61 ²	2.22 ²	2.49 ²	2.73 ²	2.98 ²	3.21 ²	3.51 ²	3.76 ²	4.05 ²	4.28 ²
1520 (15)	1.62	2.25	2.52	2.76	3.02	3.25	3.56	3.81	4.10	4.33
1621 (16)	1.64	2.28	2.56	2.79	3.06	3.29	3.61	3.86	4.16	4.38
1723 (17)	1.65	—	2.60	2.83	3.11	3.34	3.66	3.91	4.22	4.43

Presiune nominală¹ Presiune de spargere²

¹Presiune nominală: presiunea la care balonul atinge diametrul de pe etichetă.

²Presiunea de spargere— a nu se depăși. Presiunea de spargere: presiunea maximă la care un balon este proiectat să fie umflat.

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Pentru distribuire strict pe piețele unde cateterul cu balon de dilatare semi-compliant Solarice™ a fost aprobat. UC201707863 ML 03/2020

Medtronic medtronic.com

Subsemnata, **Lambru Isabela Raisa**, traducător autorizat de Ministerul de Justiție din România cu autorizația numărul 34612/2012, certific exactitatea traducerii în limba română cu înscrisul în limba engleză, care a fost vizat de mine.

TRADUCĂTOR,

MINISTERUL JUSTIȚIEI
LAMBRU ISABELA-RAISA
TRADUCĂTOR-AUTORIZAT
NR. 34612/2012
ENGLEZĂ - SPANIOLĂ

Synchro² Support Guidewires

Product number	Description	Total length	Distal segment	Proximal/Distal OD
S2SPS14215	Access Length, Support	215cm	35cm	.014in (0.36mm)
S2SPP14215	Access Length, Support, Pre-shaped	215cm	35cm	.014in (0.36mm)
S2SPS14300	Exchange Length, Support	300cm	35cm	.014in (0.36mm)
S2SPP14300	Exchange Length, Support, Pre-shape	300cm	35cm	.014in (0.36mm)

Synchro² Soft, Standard and Support Guidewires

See package insert for complete indications, contraindications, warnings and instructions for use.

Indications for use

The Synchro² Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

This document is intended solely for the use of healthcare professionals.

A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

strykerneurovascular.com

Date of Release: APR/2020

EX_EN_IL

stryker

Synchro²™ Support
Guidewire
Start with more.

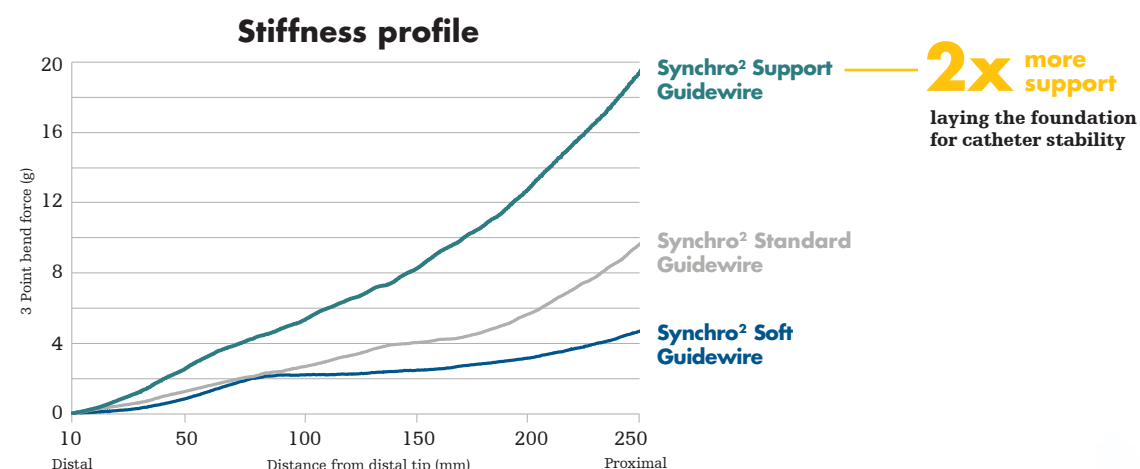


Start with **more.**

Built on the trusted 0.014in Synchro² Guidewire platform, Synchro² Support provides more support with uncompromised distal access designed to improve navigation of large-bore catheters to the clot.

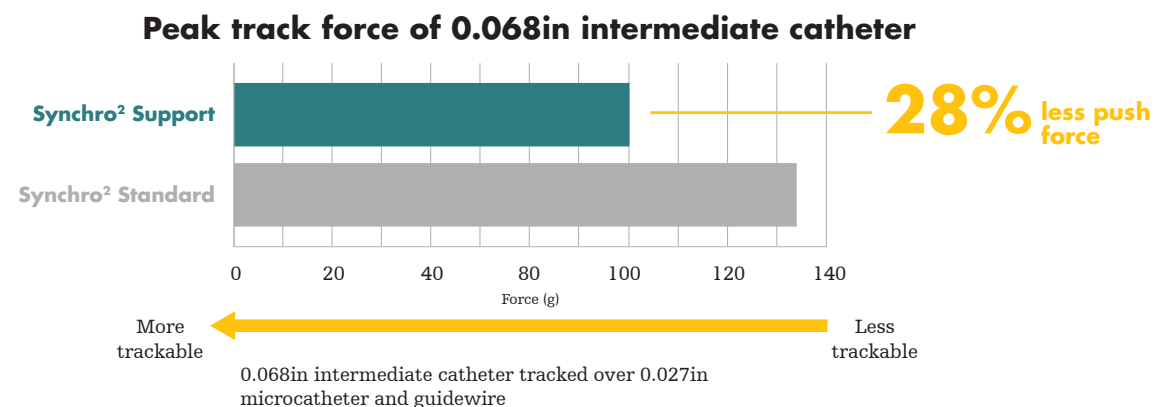
More **distal support**

Achieved with a more robust core wire



More **trackability** of large bore catheters

Makes it easier to navigate through tortuosity



More **length** to accommodate a triaxial set up

With longer 215cm length



Trusted Synchro² Guidewire construction

Enhanced features for proven performance



Pushability and torque control
from the microfabricated nitinol distal hypotube

Dependable distal access
Consistent 0.014in tip-to-end diameter

0.014in diameter

Gentle vessel contact
with Synchro² GentleTip Technology offered in straight and pre-shaped tips

Testing performed by Stryker. Data on file at Stryker.
Bench test results may not necessarily be indicative of clinical performance.

Synchro²™ Support
Guidewire

Selection Guide

Synchro²™ Guidewires

Hydrophilic				
Product Number	Description	Total Length	Distal Segment	Proximal/Distal OD
M00326010	Access Length, Soft	200cm	35cm	.014in (0.36mm)
M00326110	Access Length, Soft, Pre-shaped	200cm	35cm	.014in (0.36mm)
M00326410	Access Length, Standard	200cm	35cm	.014in (0.36mm)
M00326420	Access Length, Standard, Pre-shaped	200cm	35cm	.014in (0.36mm)
M00326310	Exchange Length, Soft	300cm	35cm	.014in (0.36mm)
M00326320	Exchange Length, Soft, Pre-shaped	300cm	35cm	.014in (0.36mm)
M00326510	Exchange Length, Standard	300cm	35cm	.014in (0.36mm)
M00326520	Exchange Length, Standard, Pre-shaped	300cm	35cm	.014in (0.36mm)

Original Synchro™-14 Guidewires

Hydrophilic				
Product Number	Description	Total Length	Distal Segment	Proximal/Distal OD
M00313010	Access Length	200cm	35cm	.014in (0.36mm)
M00313020	Access Length	200cm	45cm	.014in (0.36mm)
M00313310	Exchange Length	300cm	35cm	.014in (0.36mm)
M00313320	Exchange Length	300cm	45cm	.014in (0.36mm)
M00313410	Support Access	200cm	35cm	.014in (0.36mm)

Synchro-10 Guidewires

Hydrophilic				
Product Number	Description	Total Length	Distal Segment	Proximal/Distal OD
M00316310	Access Length	200cm	55cm	.012in/.010in (0.30mm/0.25mm)
M00316330	Exchange Length	300cm	55cm	.012in/.010in (0.30mm/0.25mm)

Synchro™ Neuro Guidewire

See package insert for complete indications, contraindications, warnings and instructions for use.

INDICATIONS FOR USE

The Synchro Neuro Guidewire series is intended for neurovascular use. It can be used to selectively introduce and position catheters and other interventional devices within the neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

THIS DOCUMENT IS INTENDED SOLELY FOR THE USE OF HEALTHCARE PROFESSIONALS.

A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area. The Stryker products listed above are CE marked according to the Medical Device Directive 93/42/EEC.

EC	REP
----	-----

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stryker.com/neurovascular
stryker.com/emea/neurovascular

Date of Release: JAN/2014

EX_EN_IL



Synchro™
GUIDEWIRES

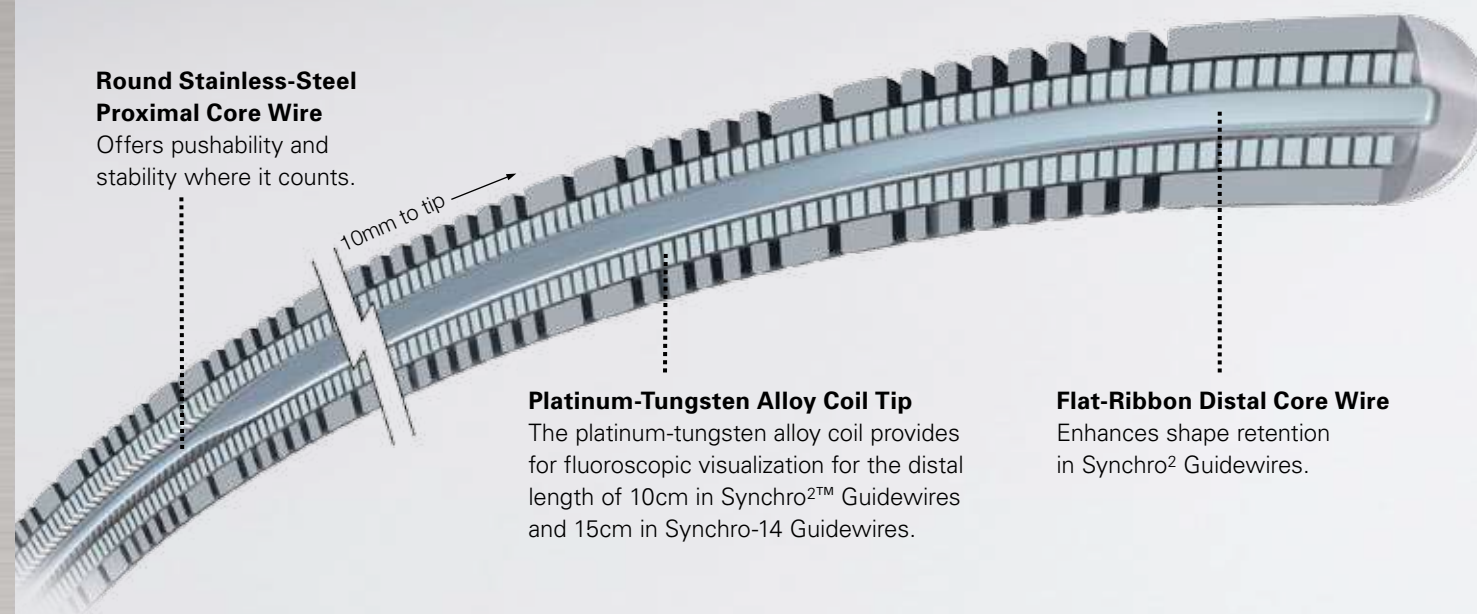
Advanced Design for Access

Synchro™

GUIDEWIRES

Access Transformed

- Designed for Torque Control
- Intended for reliable Stability and Flexibility
- Offered in both Shapeable Tip and Pre-shaped
- Presented with Standard and Soft Tip options



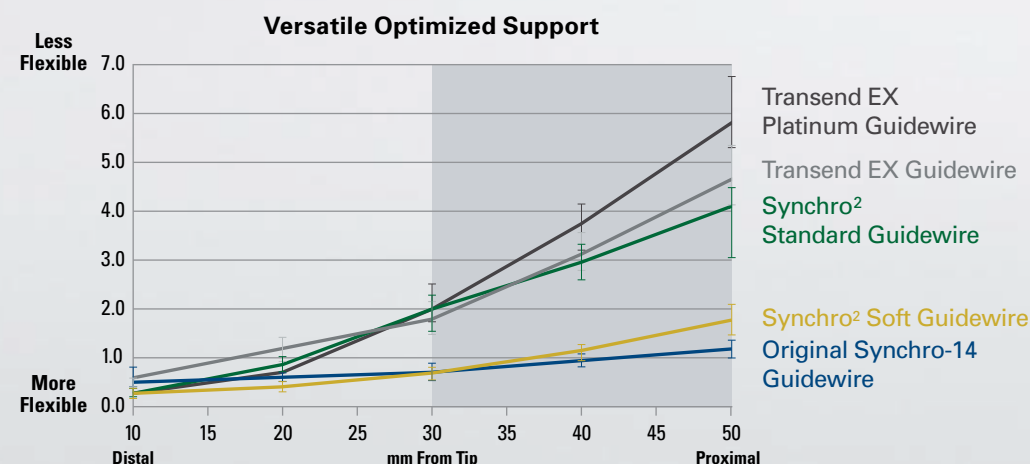
Distal Support Profiles*

Synchro² Soft Guidewires with Floppy Body

Comparable to original Synchro-14 Guidewires

Synchro² Guidewires with Standard Body

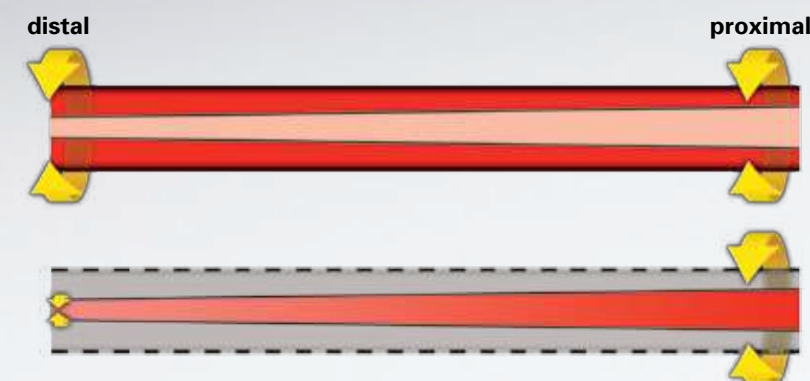
Comparable to Transend™ EX Guidewires and Transend EX Platinum Guidewires



*Ten samples of each wire were tested using a cantilever beam test method. Stiffness is measured in EI (10⁻⁴ in⁴2-lb). Error bars represent minimum and maximum observed values to provide an indication of data variability.

Bench testing conducted by Stryker Neurovascular. Data on file.
Bench test results are not necessarily indicative of clinical performance.

Established Synchro™ Guidewire Technology

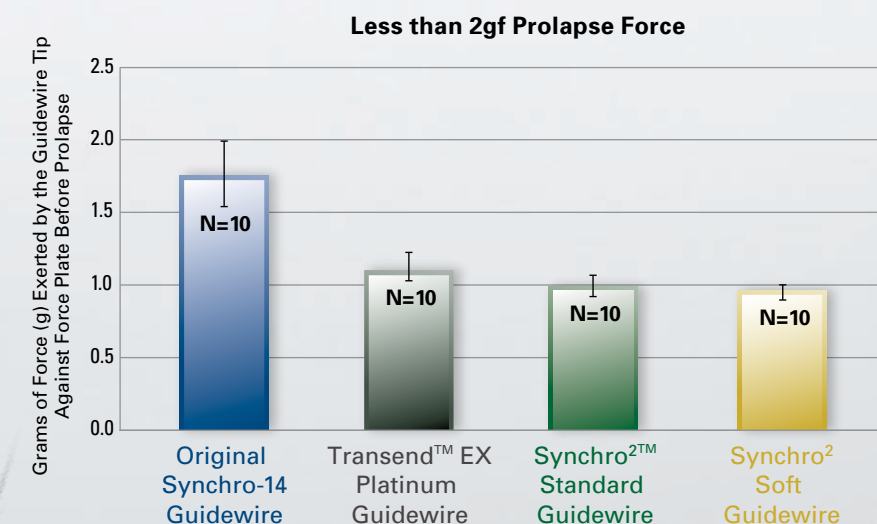


Microfabricated Nitinol Distal Hypotube

Transmits torque efficiently from proximal end to distal tip and engineered to provide standard and soft tip options.

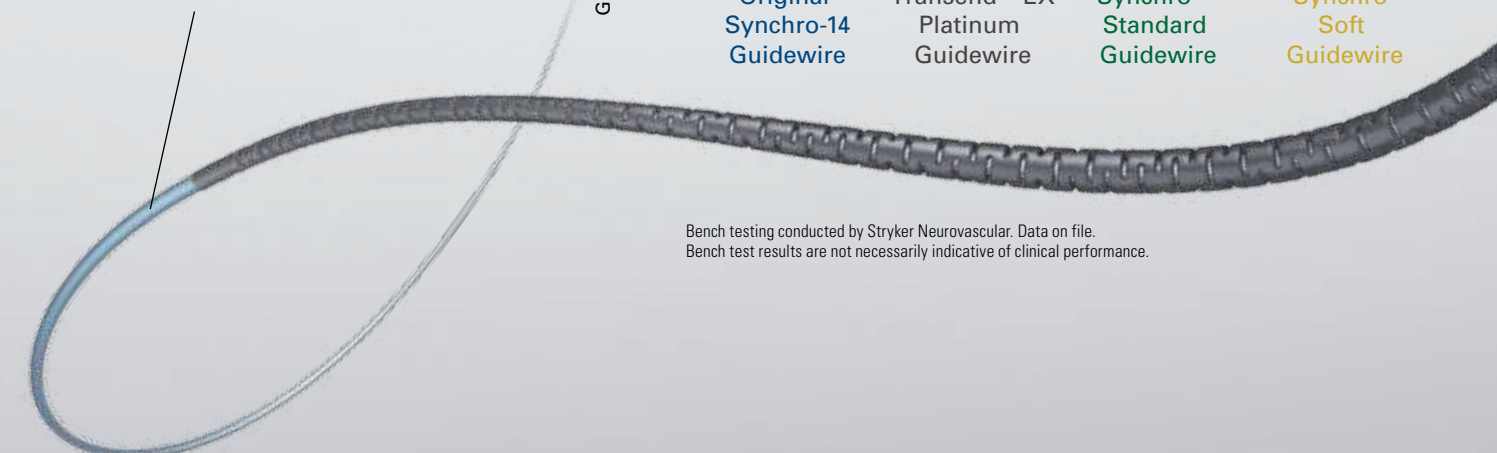


Variety of Soft Atraumatic Tips



PTFE-Coated Proximal Shaft

The proximal shaft features a PTFE coating engineered to enhance tracking and manipulation of the guidewire within the microcatheter.



Bench testing conducted by Stryker Neurovascular. Data on file.
Bench test results are not necessarily indicative of clinical performance.

Target™ 360

DETACHABLE COILS

Conformability from frame to finish

Open loop configuration designed to conform to different aneurysm shapes, fill uniformly, and minimize compartmentalization.



Target™ 3D

DETACHABLE COILS

Consistent framing

Alternating large and small loops are designed to create a stable frame.



Target XL™

DETACHABLE COILS

Larger and longer

Target XL™ Coils provide two times more fill and 40% more width than Target 10-size coils. All deliverable through Excelsior™ SL-10™ and XT-17™ Microcatheters.



Target™ Nano™

DETACHABLE COILS

Beyond soft

2x softer than Target™ Ultra Coils with advanced microcatheter stability. Designed to fill small spaces and conform to the final spaces within aneurysms.



InZone™

DETACHMENT SYSTEM

Smarter detachment

Electrolytic detachment affords a small and flexible coil junction, enhancing coil delivery.



Target™ Detachable Coil

See package insert for complete indications, contraindications, warnings and instructions for use.

INTENDED USE / INDICATIONS FOR USE

Target Detachable Coils are intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.

Target Detachable Coils are indicated for endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

InZone™ Detachment System

See package insert for complete indications, contraindications, warnings and instructions for use.

INDICATIONS FOR USE

The InZone Detachment System is intended for use with all versions of Stryker Neurovascular detachable coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

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A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area. The Stryker products listed above are CE marked according to the Medical Device Directive 93/42/EEC.

Smooth and stable.



stryker®
Neurovascular

Purposeful innovation in mind.

Target™
DETACHABLE COILS

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strykerneurovascular.com
Date of Release: JUN/2016
EX_EN_IL

Selection Guide



360 shape



3D shape



Helical shape

Target XL™ 360 Standard Coils			Target™ 360 Standard Coils			Target™ 360 Soft Coils			Target™ 360 Nano™ Coils			
Secondary diameter (mm)	Length in introducer (cm)	Product number	Secondary diameter (mm)	Length in introducer (cm)	Product number	Secondary diameter (mm)	Length in introducer (cm)	Product number	Secondary diameter (mm)	Length in introducer (cm)	Product number	
6	20	M003 6106200	3	6	M003 5463060	2	4	M003 5472040	1	2	M003 5421020	
7	20	M003 6107200		8	M003 5463080	3	6	M003 5473060		3	M003 5421030	
8	30	M003 6108300		8	M003 5464080		8	M003 5473080		2	M003 5421520	
9	30	M003 6109300	4	10	M003 5464100		10	M003 5473100	3	M003 5421530		
10	40	M003 6101040		15	M003 5464150	3.5	10	M003 5473510	4	M003 5421540		
12	45	M003 6101240	5	15	M003 5465150		6	M003 5474060	2	3	M003 5442030	
14	50	M003 6101450		20	M003 5465200	4	8	M003 5474080		4	M003 5442040	
16	50	M003 6101650		15	M003 5466150		10	M003 5474100	2.5	4	M003 5442540	
18	50	M003 6101850	6	20	M003 5466200		15	M003 5474150	3	4	M003 5443040	
20	50	M003 6102050		30	M003 5466300	4.5	12	M003 5474510		6	M003 5443060	
22	50	M003 6102250		7	15		M003 5467150	10	M003 5475100	3.5	6	M003 5443560
24	50	M003 6102450	20		M003 5467200	5	15	M003 5475150	Target™ 360 Ultra Coils			
Target XL™ 360 Soft Coils			30		M003 5467300		20	M003 5475200				
			8	20	M003 5468200		10	M003 5476100	6	15	M003 5476150	2
30	M003 5468300	20		M003 5476200	20	M003 5476300	4	M003 5422040				
Secondary diameter (mm)	Length in introducer (cm)	Product number	9	30	M003 5469200	30	M003 5476300	7		15	M003 5477150	
2	3	M003 6122030		30	M003 5469300	15	M003 5477150		4	M003 5422540		
2	6	M003 6122060	10	30	M003 5461030	8	20		M003 5477200	2.5	4	M003 5423040
3	6	M003 6123060	11	30	M003 5461130		30	M003 5477300	6		M003 5423060	
3	9	M003 6123090	12	30	M003 5461230		30	M003 5477300	8		M003 5423080	
4	8	M003 6124080	13	30	M003 5461330	9	20	M003 5478200	3	10	M003 5423100	
4	12	M003 6124120	14	30	M003 5461430		30	M003 5478300		8	M003 5423580	
5	10	M003 6125100	15	40	M003 5461540		30	M003 5479200		10	M003 5424060	
5	15	M003 6125150	10	30	M003 5461030	30	M003 5479300	3.5	8	M003 5424080		
6	20	M003 6126200				30	M003 5471030		8	M003 5424100		
7	20	M003 6127200				30	M003 5471130		10	M003 5424150		
8	30	M003 6128300	11	30	M003 5461130	12	M003 5471230	4	15	M003 5424510		
9	30	M003 6129300				13	M003 5471330		15	M003 5425100		
10	40	M003 6121040				14	M003 5471430		15	M003 5425150		
12	45	M003 6121240	12	30	M003 5461230	14	30	M003 5471430	4.5	10	M003 5425100	
14	50	M003 6121450								15	M003 5425150	
16	50	M003 6121650										
18	50	M003 6121850										
20	50	M003 6122050										

† Comparable to Soft Coils
Not all products are available for sale in all countries.

Target™ 3D Detachable Coils		
Secondary diameter (mm)	Length in introducer (cm)	Product number
3	6	M003 6153060
4	8	M003 6154080
5	10	M003 6155100
6	15	M003 6156150
7	15	M003 6157150
8	25	M003 6158250
10	30	M003 6151030

Target XL™ Helical Soft Coils		
Secondary diameter (mm)	Length in introducer (cm)	Product number
5	15†	M003 6115150
6	20†	M003 6116200
7	20†	M003 6117200
8	30†	M003 6118300
9	30†	M003 6119300
10	40†	M003 6111040
12	50†	M003 6111250
14	50†	M003 6111450

Target XL™ Helical Standard Coils		
Secondary diameter (mm)	Length in introducer (cm)	Product number
16	50	M003 6111650
18	50	M003 6111850
20	50	M003 6112050
22	50	M003 6112250
24	50	M003 6112450

Target™ Helical Nano Coils		
Secondary diameter (mm)	Length in introducer (cm)	Product number
1	1	M003 5431010
	2	M003 5431020
	3	M003 5431030
1.5	1	M003 5431510
	2	M003 5431520
	3	M003 5431530
2	4	M003 5431540
	2	M003 5452020
	3	M003 5452030
	4	M003 5452040
2.5	6	M003 5452060
	3	M003 5452530
	4	M003 5452540
3	6	M003 5452560
	4	M003 5453040
	6	M003 5453060
	8	M003 5453080

Target™ Helical Ultra Coils		
Secondary diameter (mm)	Length in introducer (cm)	Product number
2	1	M003 5432010
	2	M003 5432020
	3	M003 5432030
	4	M003 5432040
	6	M003 5432060
2.5	8	M003 5432080
	3	M003 5432530
	4	M003 5432540
	6	M003 5432560
3	4	M003 5433040
	6	M003 5433060
	8	M003 5433080
	10	M003 5433100
3.5	6	M003 5433560
4	6	M003 5434060
	8	M003 5434080
	15	M003 5434150
4.5	8	M003 5434580

Target™ Coil Accessories	
Description	Product number
InZone™ Detachment System	M003 45100950
IZDS™ Connecting Cable	M003 45110250

Target™
DETACHABLE COILS

Smooth and stable

Consistently smooth deployment and exceptional microcatheter stability.



PACIFIC™ XTREME

ORDER INFORMATION

REF. N° USABLE LENGTH 90CM	REF. N° USABLE LENGTH 130CM	REF. N° USABLE LENGTH 180CM	BALLOON Ø (MM)	BALLOON LENGTH (MM)	RECOM. INTRODUCER SHEATH (F)	NOMINAL PRESSURE (BAR)	RBP (BAR)
PCF 040 150 090	PCF 040 150 130	PCF 040 150 180	4.0	150	4	6	14
PCF 040 200 090	PCF 040 200 130		4.0	200	4	6	14
PCF 040 250 090	PCF 040 250 130		4.0	250	4	6	14
PCF 040 300 090	PCF 040 300 130		4.0	300	4	6	14
PCF 050 150 090	PCF 050 150 130	PCF 050 150 180	5.0	150	4	6	14
PCF 050 200 090	PCF 050 200 130		5.0	200	4	6	14
PCF 050 250 090	PCF 050 250 130		5.0	250	5	6	14
PCF 050 300 090	PCF 050 300 130		5.0	300	5	6	14
PCF 060 150 090	PCF 060 150 130		6.0	150	5	6	12
PCF 060 200 090	PCF 060 200 130		6.0	200	5	6	12
PCF 060 250 090	PCF 060 250 130		6.0	250	5	6	12
PCF 060 300 090	PCF 060 300 130		6.0	300	5	6	12
PCF 070 150 090	PCF 070 150 130		7.0	150	5	6	12
PCF 070 200 090	PCF 070 200 130		7.0	200	5	6	12
PCF 070 250 090	PCF 070 250 130		7.0	250	5	6	12

TECHNICAL SPECIFICATIONS

CATHETER DESIGN	Over the wire (OTW), coaxial shaft
BALLOON MATERIAL	Flexitec Xtreme
BALLOON COATING	LFC Hydrophilic
BALLOON MARKER	2 swaged, Platinum Iridium
SHAFT DIAMETER	3.9F – 4.2F
USABLE SHAFT LENGTHS	90, 130, 180cm
GUIDEWIRE COMPATIBILITY	0.018"

PACIFIC™ PLUS

ORDER INFORMATION

REF. N° USABLE LENGTH 90CM	REF. N° USABLE LENGTH 130CM	REF. N° USABLE LENGTH 180CM	BALLOON Ø (MM)	BALLOON LENGTH (MM)	RECOM. INTRODUCER SHEATH (F)	NOMINAL PRESSURE (BAR)	RBP (BAR)
PCE 020 020 090	PCE 020 020 130		2.0	20	4	8	22
PCE 020 040 090	PCE 020 040 130	PCE 020 040 180	2.0	40	4	8	22
PCE 020 060 090	PCE 020 060 130		2.0	60	4	8	22
PCE 020 080 090	PCE 020 080 130	PCE 020 080 180	2.0	80	4	8	22
PCE 020 120 090	PCE 020 120 130	PCE 020 120 180	2.0	120	4	8	22
PCE 020 150 090	PCE 020 150 130	PCE 020 150 180	2.0	150	4	8	22
PCE 025 020 090	PCE 025 020 130		2.5	20	4	8	16
PCE 025 040 090	PCE 025 040 130	PCE 025 040 180	2.5	40	4	8	16
PCE 025 060 090	PCE 025 060 130		2.5	60	4	8	16
PCE 025 080 090	PCE 025 080 130	PCE 025 080 180	2.5	80	4	8	16
PCE 025 120 090	PCE 025 120 130	PCE 025 120 180	2.5	120	4	8	16
PCE 025 150 090	PCE 025 150 130	PCE 025 150 180	2.5	150	4	8	16
PCE 030 020 090	PCE 030 020 130		3.0	20	4	8	16
PCE 030 040 090	PCE 030 040 130	PCE 030 040 180	3.0	40	4	8	16
PCE 030 060 090	PCE 030 060 130		3.0	60	4	8	16
PCE 030 080 090	PCE 030 080 130	PCE 030 080 180	3.0	80	4	8	16
PCE 030 120 090	PCE 030 120 130	PCE 030 120 180	3.0	120	4	8	16
PCE 030 150 090	PCE 030 150 130	PCE 030 150 180	3.0	150	4	8	16
PCE 035 020 090	PCE 035 020 130		3.5	20	4	8	16
PCE 035 040 090	PCE 035 040 130		3.5	40	4	8	16
PCE 035 060 090	PCE 035 060 130		3.5	60	4	8	16
PCE 035 080 090	PCE 035 080 130		3.5	80	4	8	16
PCE 035 120 090	PCE 035 120 130		3.5	120	4	8	16
PCE 035 150 090	PCE 035 150 130		3.5	150	4	8	16
PCE 040 020 090	PCE 040 020 130		4.0	20	4	8	14
PCE 040 040 090	PCE 040 040 130	PCE 040 040 180	4.0	40	4	8	14
PCE 040 060 090	PCE 040 060 130		4.0	60	4	8	14
PCE 040 080 090	PCE 040 080 130	PCE 040 080 180	4.0	80	4	8	14
PCE 040 120 090	PCE 040 120 130	PCE 040 120 180	4.0	120	4	8	14
PCE 050 020 090	PCE 050 020 130		5.0	20	4	8	14
PCE 050 040 090	PCE 050 040 130	PCE 050 040 180	5.0	40	4	8	14
PCE 050 060 090	PCE 050 060 130	PCE 050 060 180	5.0	60	4	8	14
PCE 050 080 090	PCE 050 080 130	PCE 050 080 180	5.0	80	4	8	14
PCE 050 120 090	PCE 050 120 130	PCE 050 120 180	5.0	120	4	8	14
PCE 060 020 090	PCE 060 020 130		6.0	20	4	8	14
PCE 060 040 090	PCE 060 040 130	PCE 060 040 180	6.0	40	4	8	14
PCE 060 060 090	PCE 060 060 130		6.0	60	4	8	14
PCE 060 080 090	PCE 060 080 130	PCE 060 080 180	6.0	80	4	8	14
PCE 060 120 090	PCE 060 120 130	PCE 060 120 180	6.0	120	4	8	14
PCE 070 020 090	PCE 070 020 130		7.0	20	4	8	12
PCE 070 040 090	PCE 070 040 130	PCE 070 040 180	7.0	40	4	8	12
PCE 070 060 090	PCE 070 060 130		7.0	60	4	8	12
PCE 070 080 090	PCE 070 080 130	PCE 070 080 180	7.0	80	5	8	12
PCE 070 120 090	PCE 070 120 130	PCE 070 120 180	7.0	120	5	8	12

TECHNICAL SPECIFICATIONS

CATHETER DESIGN	Over the Wire (OTW), Coaxial Shaft
BALLOON MATERIAL	Proprietary
BALLOON COATING	Hydrophilic Coating
BALLOON MARKER	2 Swaged, Platinum Iridium
SHAFT DIAMETER	4.0F
USABLE SHAFT LENGTHS	90, 130, 180cm
MAXIMUM GUIDEWIRE COMPATIBILITY	0.018"

Only for distribution in markets where Pacific™ Plus is approved for commercial sale.

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medtronic.eu
medtronic.com/peripheral

PACIFIC™ PLUS

PTA Catheter OTW 0.018"

PACIFIC™ XTREME

PTA Balloon Catheter
OTW 0.018"



Medtronic
Further. Together

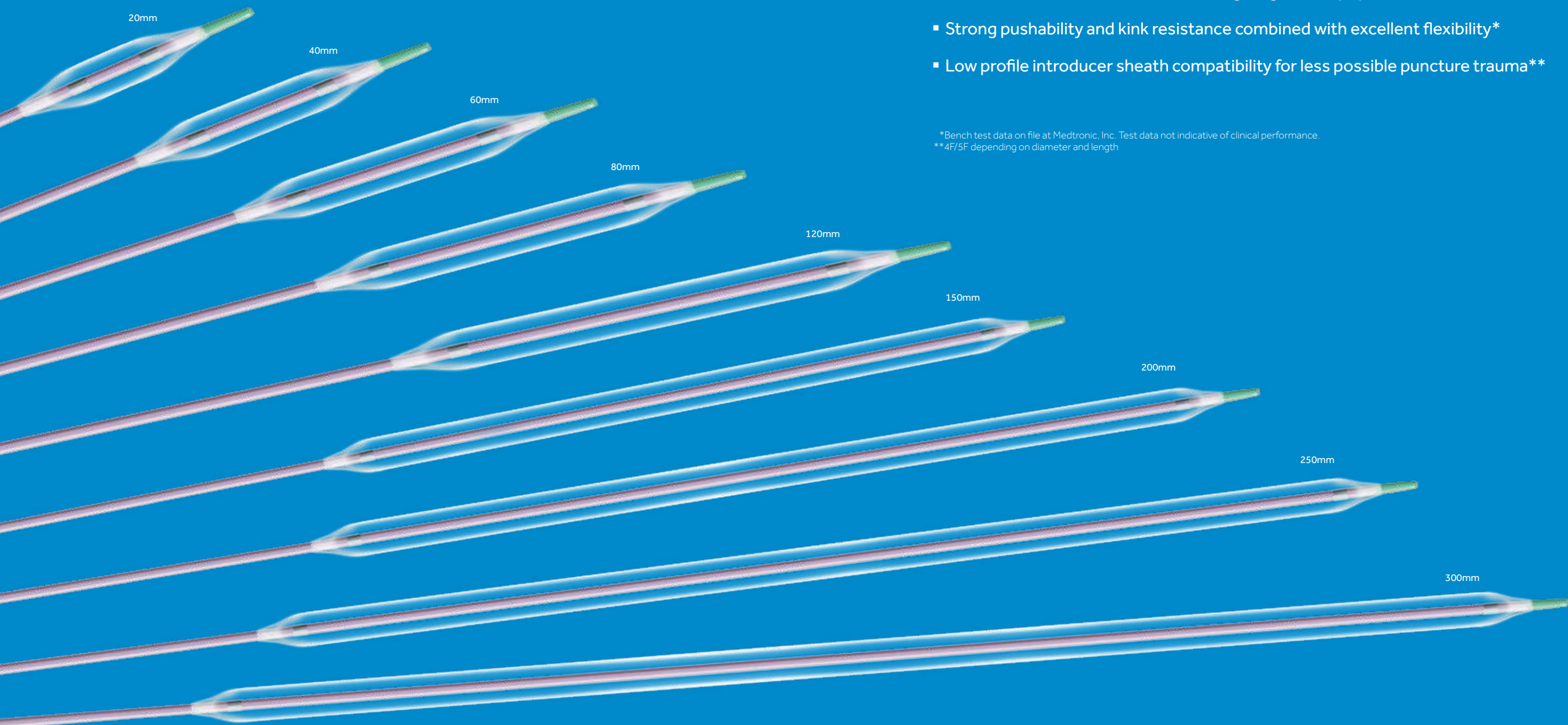
THE PACIFIC™ FAMILY OF BALLOON CATHETERS OFFERS COMPLEMENTARY OPTIONS FOR EVERYDAY USE AND GOING TO EXTREME LENGTHS

PACIFIC™ XTREME

DEFINING PERFORMANCE IN LOWER LIMB INTERVENTIONS

- Balloons from 150–300 mm for treating long femoropopliteal lesions
- Strong pushability and kink resistance combined with excellent flexibility*
- Low profile introducer sheath compatibility for less possible puncture trauma**

*Bench test data on file at Medtronic, Inc. Test data not indicative of clinical performance.
**4F/5F depending on diameter and length

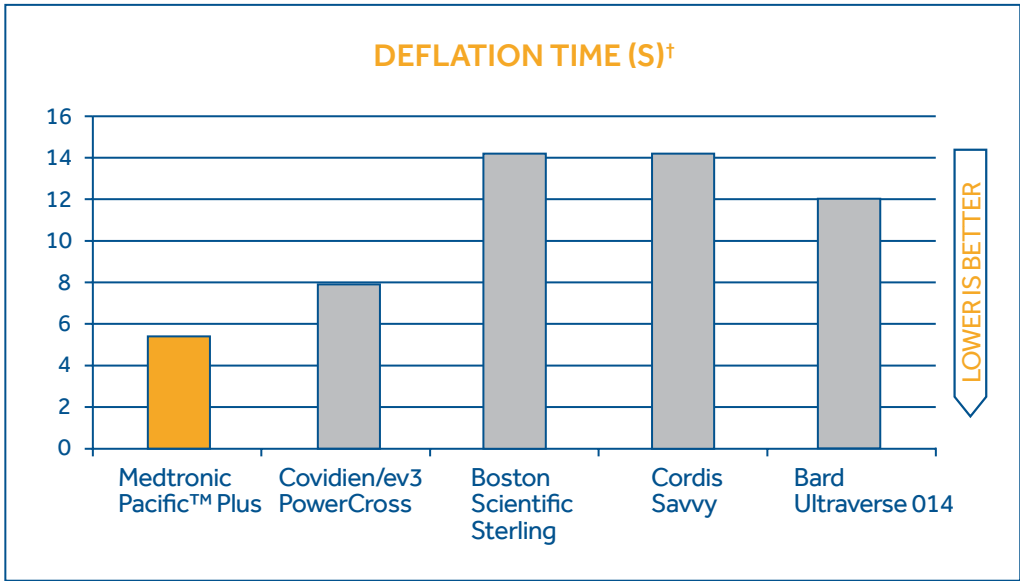
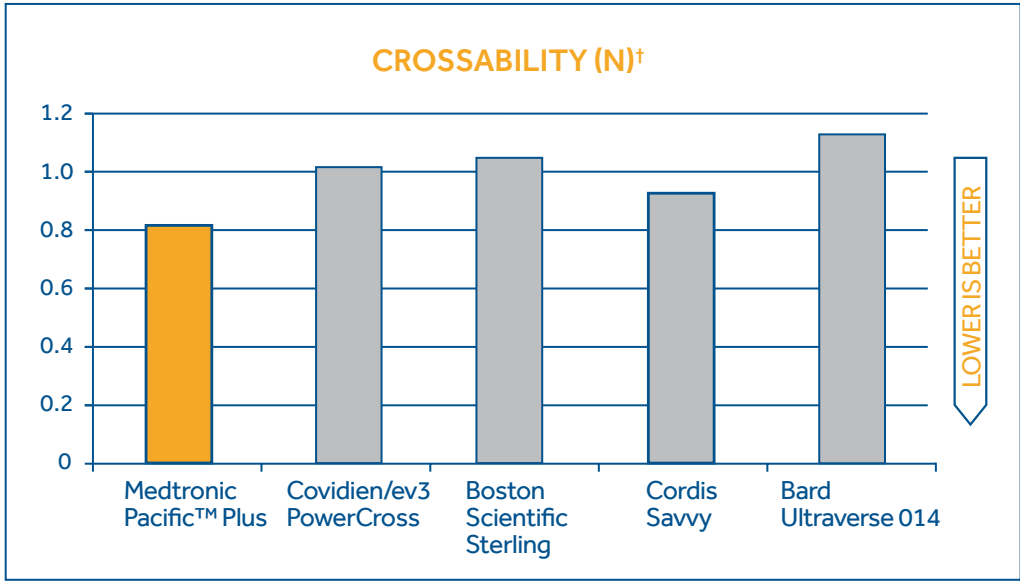


Actual size

PACIFIC™ PLUS

VERSATILITY FOR EVERYDAY AND BEYOND

- Versatile shaft lengths and guidewire compatibility for more access options
- Proprietary balloon technology allows for great crossability*
- Improved shaft design for faster deflation*



†Six samples of each brand tested, 5 mm x 40 mm. Medtronic data on file. Bench test results may not be indicative of clinical performance.



Features and Benefits

- Durable with ability to reinflate up to 10 times without bursting
- Enhanced pushability and trackability*
- Low growth profile†

Size Matrix

Balloon Diameter (mm)	Balloon Length (mm)					
	06	08	12	15	20	27
2.00	NCSLC2006X	NCSLC2008X	NCSLC2012X	NCSLC2015X	NCSLC2020X	—
2.25	NCSLC22506X	—	NCSLC22512X	—	NCSLC22520X	—
2.50	NCSLC2506X	NCSLC2508X	NCSLC2512X	NCSLC2515X	NCSLC2520X	NCSLC2527X
2.75	NCSLC27506X	NCSLC27508X	NCSLC27512X	NCSLC27515X	NCSLC27520X	—
3.00	NCSLC3006X	NCSLC3008X	NCSLC3012X	NCSLC3015X	NCSLC3020X	NCSLC3027X
3.25	NCSLC32506X	NCSLC32508X	NCSLC32512X	NCSLC32515X	NCSLC32520X	—
3.50	NCSLC3506X	NCSLC3508X	NCSLC3512X	NCSLC3515X	NCSLC3520X	NCSLC3527X
3.75	NCSLC37506X	NCSLC37508X	NCSLC37512X	NCSLC37515X	NCSLC37520X	—
4.00	NCSLC4006X	NCSLC4008X	NCSLC4012X	NCSLC4015X	NCSLC4020X	NCSLC4027X
4.50	—	NCSLC4508X	NCSLC4512X	NCSLC4515X	NCSLC4520X	—
5.00	—	NCSLC5008X	NCSLC5012X	NCSLC5015X	—	—

Replacement lengths: 8-mm balloon replacing 9-mm NC Sprinter™ balloon and 20-mm balloon replacing 21-mm NC Sprinter balloon

Orange color = new size over NC Sprinter balloon matrix

Technical Improvements

Technical Feature	NC Solarice™ Balloon	NC Sprinter Balloon
Nominal pressure (atm)	12	10
Rated burst pressure (RBP) (atm)	20	18
Fatigue capability (cycles to RBP)	10	10
Catheter distal O.D. (F) 2.00 mm–3.75 mm 4.00 mm–5.00 mm	Straight 2.5 F Straight 2.7 F	Bumped 2.6 F and 2.4 F Straight 3.0 F
Marker band material	Platinum iridium	Gold
Lesion entry profile (in.)	0.015	0.016

Changes in Selected Technical Features

Technical Feature	NC Solarice Balloon	NC Sprinter Balloon
Balloon material	Proprietary nylon-based	Soft Fulcrum™ Plus
Hydrophilic coating	No change	Selective Dura-Trac
Catheter length (cm)	No change	142
Balloon MiniWrap 2.00 mm–3.75 mm 4.00 mm–5.00 mm	No change No change	3 folds 5 folds
MGC ID for 2.00–4.00-mm balloon	No change	1.42 mm/0.056"
MGC ID for 4.00–5.00-mm balloon	No change	1.68 mm/0.066"

*Competitive testing vs. NC Trek and NC Quantum Apex™ balloons.

†Competitive testing vs. NC Quantum Apex balloon.

Bench test data may not be indicative of clinical performance.

Compliance Data

Pressure kPa (atm)	Average Balloon Diameter (mm)										
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
608 (6)	1.89	2.12	2.35	2.54	2.77	2.94	3.13	3.43	3.67	4.09	4.64
709 (7)	1.91	2.15	2.37	2.57	2.80	2.97	3.17	3.47	3.72	4.14	4.71
811 (8)	1.93	2.17	2.40	2.60	2.84	3.01	3.22	3.51	3.78	4.19	4.79
912 (9)	1.95	2.19	2.43	2.63	2.87	3.06	3.27	3.56	3.84	4.25	4.86
1013 (10)	1.97	2.21	2.46	2.66	2.91	3.10	3.32	3.61	3.90	4.31	4.92
1115 (11)	1.98	2.23	2.48	2.69	2.94	3.14	3.37	3.66	3.95	4.37	4.95
1216 (12)	1.99	2.25	2.50	2.71	2.97	3.18	3.41	3.70	3.99	4.42	5.00
1317 (13)	2.00	2.26	2.51	2.73	2.99	3.21	3.44	3.73	4.03	4.47	5.04
1419 (14)	2.02	2.28	2.53	2.75	3.01	3.23	3.47	3.76	4.07	4.51	5.08
1520 (15)	2.03	2.29	2.54	2.77	3.03	3.26	3.50	3.78	4.10	4.54	5.12
1621 (16)	2.04	2.30	2.56	2.78	3.05	3.28	3.52	3.81	4.13	4.58	5.15
1723 (17)	2.05	2.31	2.58	2.80	3.07	3.30	3.55	3.83	4.15	4.60	5.19
1824 (18)	2.06	2.33	2.59	2.81	3.09	3.33	3.57	3.86	4.18	4.63	5.23
1925 (19)	2.07	2.34	2.61	—	3.11	3.35	3.59	3.88	4.21	4.66	5.27
2027 (20)	2.09	2.36	2.63	2.84	3.13	3.37	3.62	3.91	4.24	4.69	5.30
2128 (21)	2.10	2.37	2.65	2.86	3.15	3.39	3.64	3.93	4.28	4.72	5.35
2229 (22)	2.12	2.39	2.66	2.88	3.17	3.41	3.66	3.96	4.31	4.75	5.39
2330 (23)	2.14	2.40	2.68	2.90	3.20	3.43	3.69	3.99	4.34	4.78	—
2432 (24)	2.15	2.42	2.71	2.92	3.22	—	3.71	—	—	4.81	—
2533 (25)	—	2.44	—	2.94	3.25	—	3.74	—	—	4.84	—

Nominal pressure **Rated burst pressure***

*Rated burst pressure—do not exceed.

Nominal pressure: the pressure at which the balloon reaches its labeled diameter

Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated

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Features and Benefits

- Enhanced deliverability*—improved pushability
- Low insertion and retraction forces through a 6 F guide catheter*†
- Low-profile marker bands—improved crossability*

Size Matrix

Balloon Diameter (mm)	Balloon Length (mm)						
	06	10	12	15	20	25	30
1.50	SLC1506X	SLC1510X	SLC1512X	SLC1515X	SLC1520X	—	—
2.00	SLC2006X	SLC2010X	SLC2012X	SLC2015X	SLC2020X	SLC2025X	SLC2030X
2.25	SLC22506X	SLC22510X	SLC22512X	SLC22515X	SLC22520X	SLC22525X	—
2.50	SLC2506X	SLC2510X	SLC2512X	SLC2515X	SLC2520X	SLC2525X	SLC2530X
2.75	SLC27506X	—	SLC27512X	SLC27515X	SLC27520X	SLC27525X	—
3.00	SLC3006X	SLC3010X	SLC3012X	SLC3015X	SLC3020X	SLC3025X	SLC3030X
3.25	—	—	SLC32512X	SLC32515X	SLC32520X	—	—
3.50	SLC3506X	SLC3510X	SLC3512X	SLC3515X	SLC3520X	SLC3525X	SLC3530X
3.75	—	—	SLC37512X	SLC37515X	SLC37520X	—	—
4.00	SLC4006X	SLC4010X	SLC4012X	SLC4015X	SLC4020X	SLC4025X	SLC4030X

Technical Improvements

Technical Feature	Solarice™ Balloon	Sprinter™ Legend™ Balloon
Nominal pressure (atm)	8	1.25 mm: 12 1.50 mm: 6 2.00–4.00 mm: 8
Rated burst pressure (RBP) (atm)	1.50–4.00 mm: 14	1.25–1.50 mm: 12 2.00–4.00 mm: 14
Fatigue capability (cycles to RBP)	10	10
Shaft dimensions Proximal Distal	1.50–3.50 mm: 0.69 mm (2.1 F) 0.84 mm (2.5 F)	1.25–3.50 mm: RX 1.9 F; OTW 3.2 F 2.4 F/2.6 F
Shaft dimensions Proximal Distal	3.75 mm–4.00 mm: 0.69 mm (2.1 F) 0.91 mm (2.7 F)	3.75 mm–4.00 mm: RX 1.9 F; OTW 3.2 F 2.5 F/2.7 F
Marker band material	No change	Platinum iridium
Lesion entry profile (in.)	No change	0.016

Changes in Selected Technical Features

Technical Feature	Solarice Balloon	Sprinter Balloon
Balloon material	Fulcrum™ Lite	Fulcrum™
Hydrophilic coating	No change	Selective Dura-Trac
Catheter length (cm)	No change	142
Balloon MiniWrap	1.50 mm: 2 folds 2.00 mm–3.50 mm: 3 folds 3.75 mm–4.00 mm: 5 folds	1.25 mm: Zerofold 1.50 mm: 2 folds 2.00 mm–3.75 mm: 3 folds 4.00 mm: 5 folds
MGC ID for 1.50–4.00-mm balloon	No change	1.42 mm/0.056"

*Bench testing vs. Trek, Emerge™, Sprinter Legend and Ryuji™ Plus balloons. 2.50 mm x 15 mm balloons tested.

†Based on 6 F KBT testing.

Bench test data may not be indicative of clinical performance.

Compliance Data

Pressure kPa (atm)	Average Balloon Diameter (mm)									
	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
608 (6)	1.49	2.03	2.27	2.50	2.70	2.92	3.17	3.39	3.66	3.88
709 (7)	1.51	2.05	2.30	2.52	2.73	2.95	3.21	3.43	3.70	3.93
811 (8)	1.52	2.07	2.32	2.55	2.77	2.99	3.25	3.48	3.75	3.99
912 (9)	1.54	2.09	2.35	2.58	2.80	3.03	3.30	3.53	3.80	4.04
1013 (10)	1.55	2.12	2.38	2.61	2.84	3.06	3.34	3.58	3.85	4.10
1115 (11)	1.57	2.14	2.41	2.64	2.87	3.10	3.38	3.62	3.90	4.14
1216 (12)	1.58	2.17	2.43	2.67	2.91	3.14	3.42	3.67	3.95	4.19
1317 (13)	1.60	2.19	2.46	2.70	2.94	3.17	3.46	3.71	4.00	4.23
1419 (14)	1.61	2.22	2.49	2.73	2.98	3.21	3.51	3.76	4.05	4.28
1520 (15)	1.62	2.25	2.52	2.76	3.02	3.25	3.56	3.81	4.10	4.33
1621 (16)	1.64	2.28	2.56	2.79	3.06	3.29	3.61	3.86	4.16	4.38
1723 (17)	1.65	—	2.60	2.83	3.11	3.34	3.66	3.91	4.22	4.43

Nominal pressure

Rated burst pressure*

Nominal pressure: the pressure at which the balloon approximates its labeled diameter

Rated burst pressure: the maximum pressure to which a balloon is designed to be inflated

*Rated burst pressure—do not exceed.

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Resolute *Onyx*[™]

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM



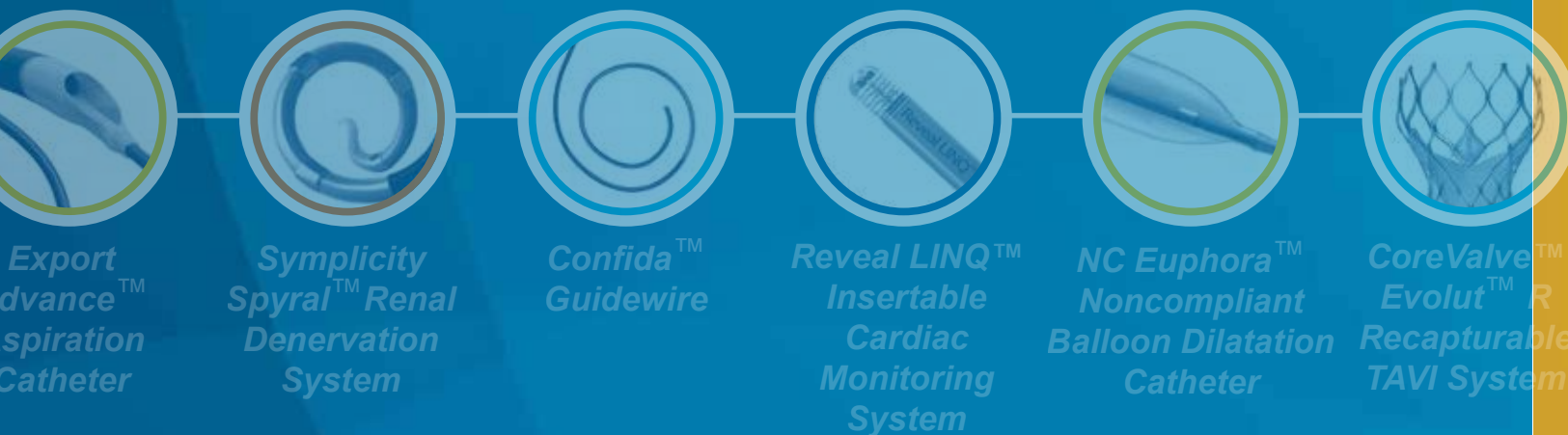
THE ADVANCED
WORKHORSE

POWERED BY

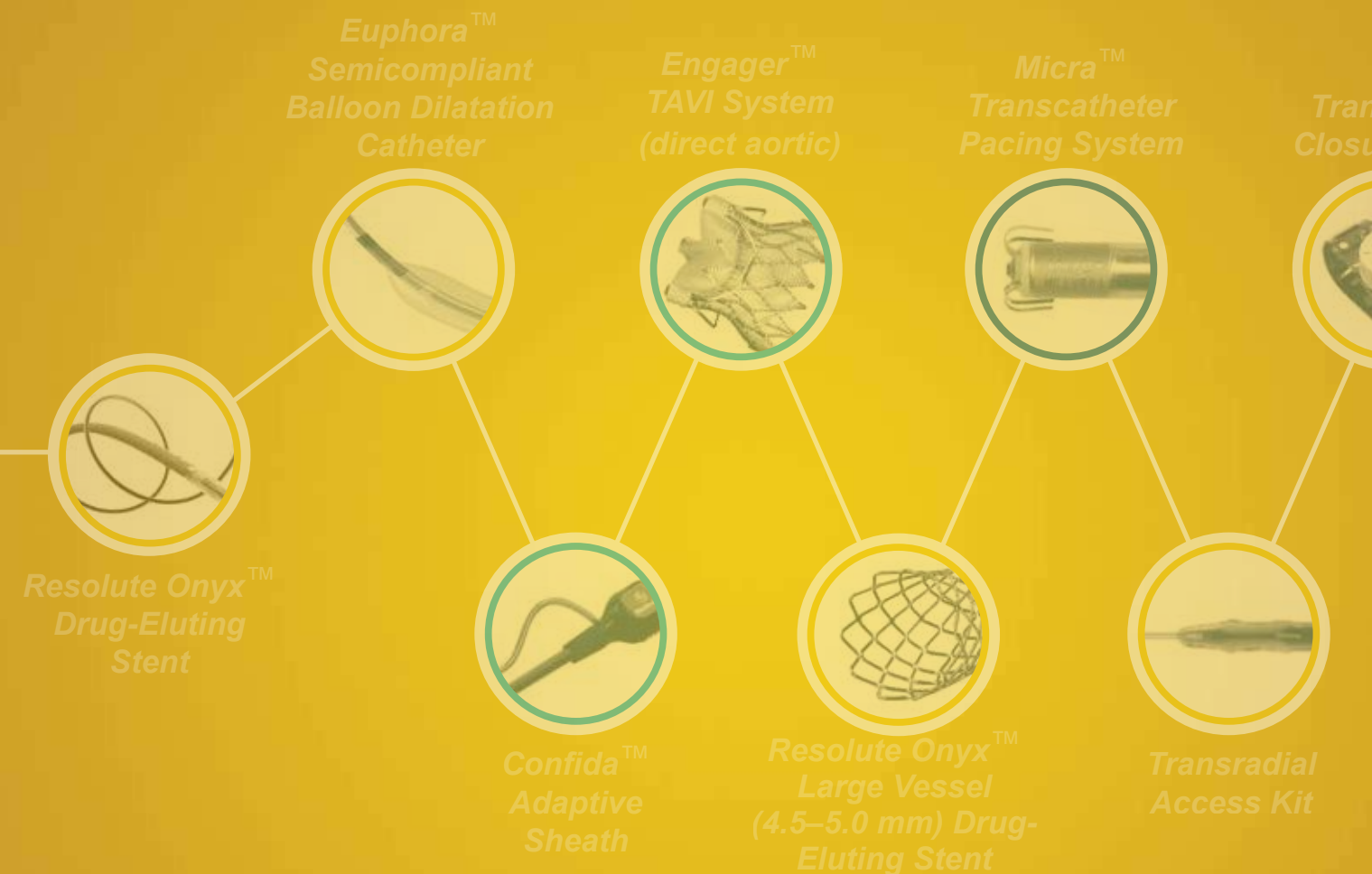




Medtronic



With an impressive series of product introductions planned over the next two years, the **Medtronic Interventional Portfolio** brings unmatched innovation today and tomorrow.



Introducing Resolute Onyx™ DES

The latest stent addition to the Medtronic Interventional Portfolio.

THE ADVANCED
WORKHORSE

POWERED BY

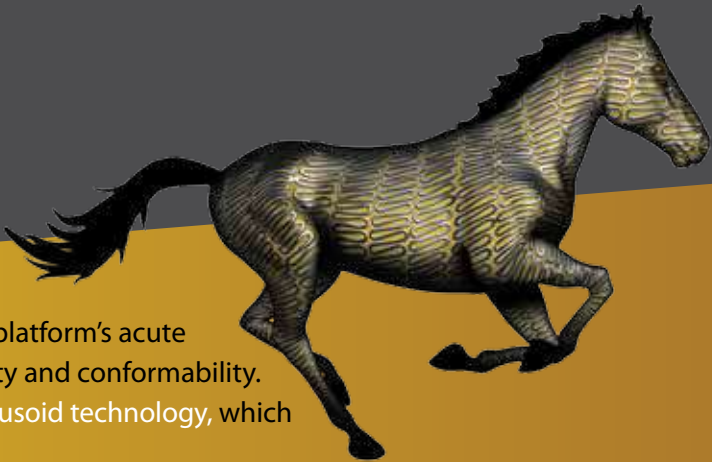


THE MOST DELIVERABLE DES¹

Featuring Core Wire Technology



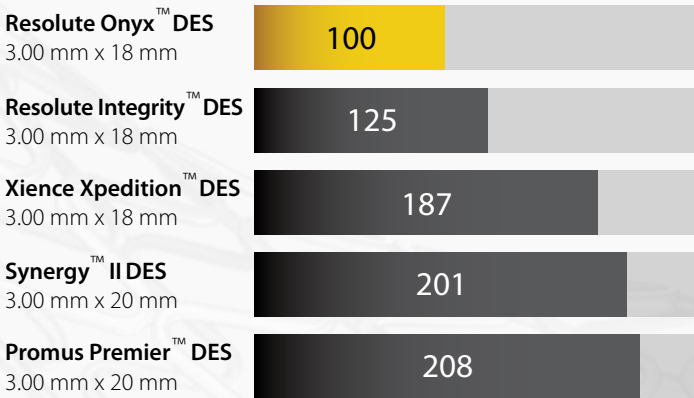
PROCEDURAL
SUCCESS



Resolute Onyx DES builds on the Integrity™ platform's acute procedural success² for even greater flexibility and conformability. The Integrity platform utilises continuous sinusoid technology, which offers key performance attributes.

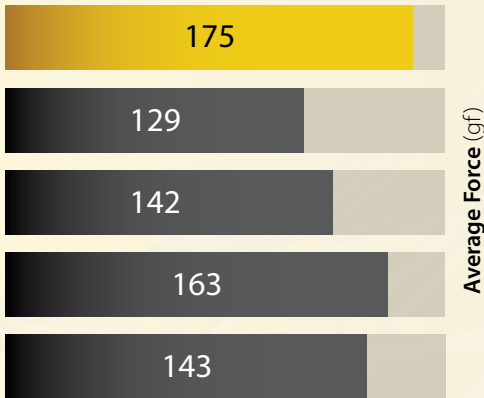
EVEN GREATER DELIVERABILITY AND PUSHABILITY

MOST DELIVERABLE³



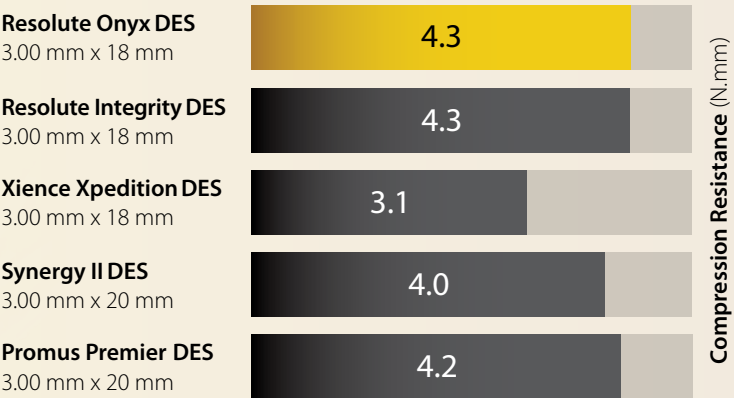
Lower Is Better

MOST PUSHABLE³



Higher Is Better

SUSTAINED RADIAL STRENGTH⁴



Higher Is Better



CORE WIRE TECHNOLOGY ENABLES:

- Increased deliverability
- Thinner struts with enhanced radiopacity
- No compromise to structural strength



Helical wrap



Laser-fused



Fluid range of motion

CONTINUOUS SINUSOID TECHNOLOGY

Resolute Onyx DES is manufactured from a single strand of core wire into a continuous sinusoidal wave form to provide a fluid range of motion.

^{1,3} Based on bench test data vs. Promus Premier DES, Synergy II DES, Xience Xpedition DES and Resolute Integrity DES.

² DELIVER study

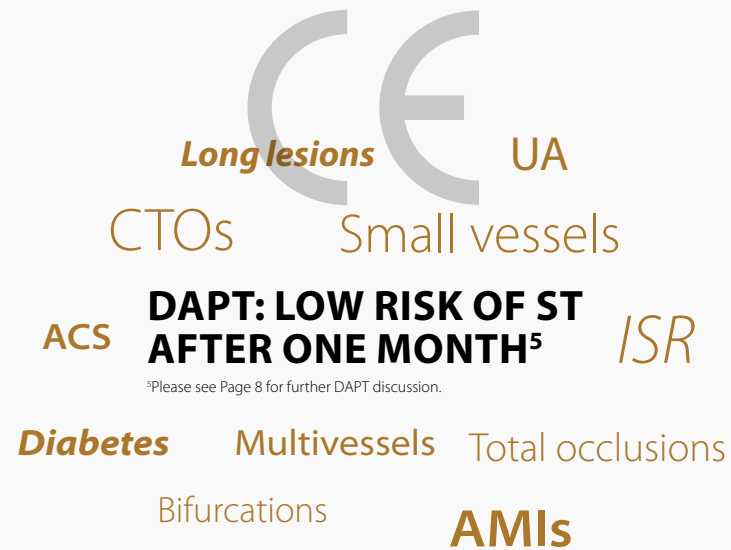
⁴ Bench test data of 3.00-mm stents on file at Medtronic, Inc.

BROADEST SIZE MATRIX

To Optimise Treatment of Complex Clinical Scenarios



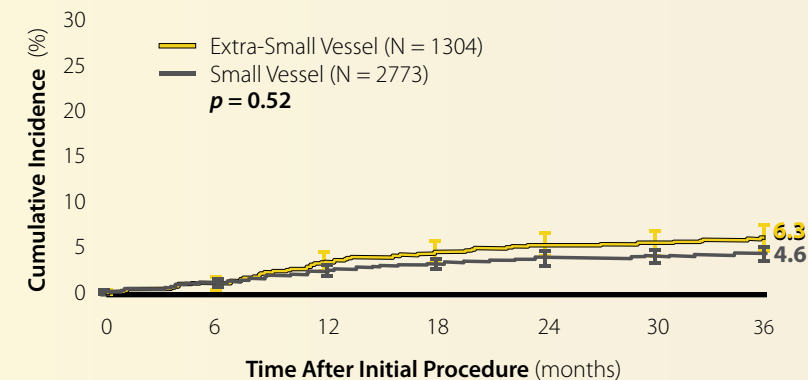
COMPLEX
CASES



Resolute Onyx DES offers meaningful new sizes to address extra-small vessels and long lesions, expanding treatment opportunities for patients with diabetes and diffuse disease.

EXCELLENT RESULTS IN EXTRA-SMALL-VESSEL (RVD ≤ 2.25 mm) PATIENTS⁶

RESOLUTE Pooled—Extra-Small Vessel
(RVD ≤ 2.25 mm) vs. Small Vessel (RVD > 2.25 mm
but ≤ 2.75 mm) Stenting TLR at 3 Years

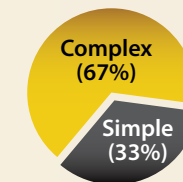


EXCELLENT PERFORMANCE IN COMPLEX PATIENTS⁷

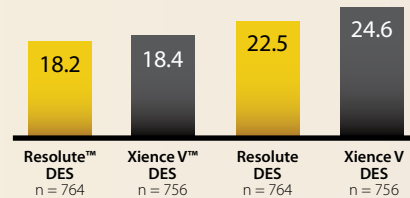
All Patients
N = 1520/2292

TLF (%) $p = 0.95$

MACE (%) $p = 0.36$



Almost 70% of
RESOLUTE All Comers
Patients Are Complex



Featuring a **2.00-mm** diameter
and longer stent lengths

⁶Post-hoc RESOLUTE Pooled analysis was not powered for the analysis shown.

RESOLUTE FIM, RESOLUTE All Comers, RESOLUTE International, RESOLUTE US, RESOLUTE US 38 mm, RESOLUTE Japan, RESOLUTE China RCT, RESOLUTE China Registry, Resolute Asia, RESOLUTE Japan SVS

⁷Including AMI (within 72 hours), multivessel treatment (> 2), renal insufficiency, ISR, bifurcation, bypass graft, LVEF $< 30\%$, long lesion (> 27 mm), total occlusion, > 1 lesion per vessel, thrombus lesion.

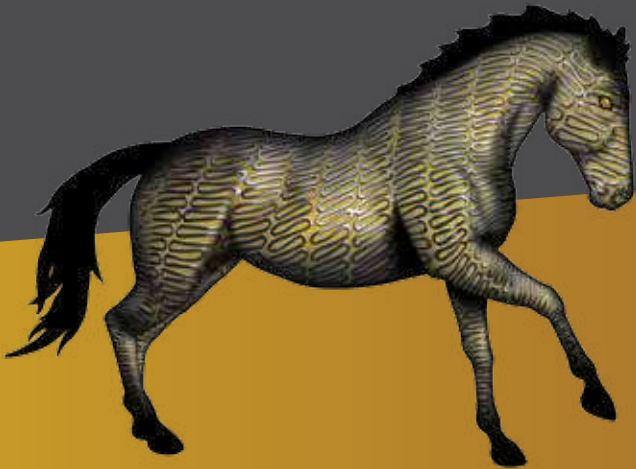
RESOLUTE All Comers was not powered for the analysis shown.

PROVEN LONG-TERM SAFETY AND EFFICACY

Demonstrated in the Global RESOLUTE Program



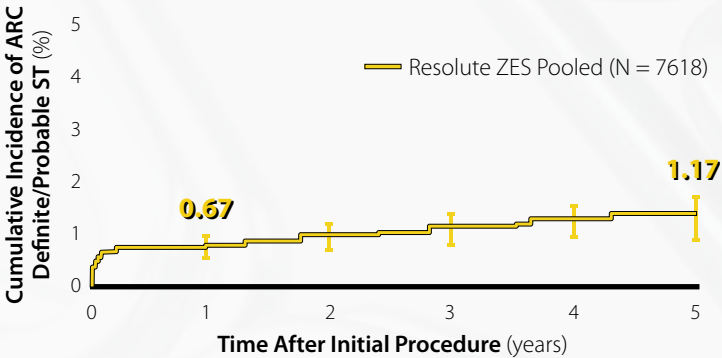
SAFETY
ASSURED



Comprehensive, unique Global RESOLUTE Program with more than **7500** patients enrolled.

SUSTAINED SAFETY OF 1.2% ST THROUGH FIVE YEARS IN MORE THAN 7500 PATIENTS⁸

RESOLUTE Pooled Stent Thrombosis (ARC Definite/Probable) at 5 Years



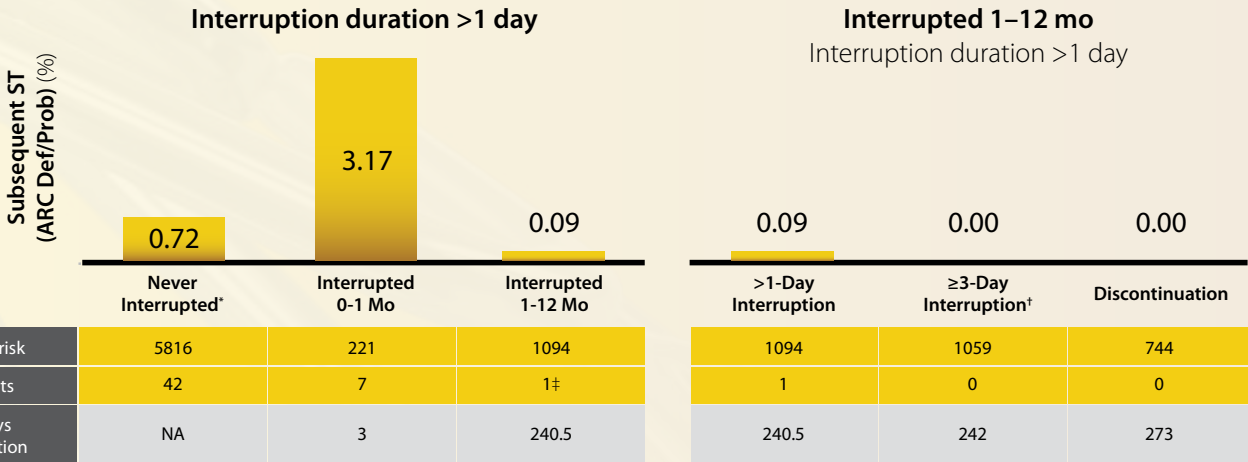
No. at risk	7618	7610	6908	5425	4244	2087
% CI	0.08	0.67	0.84	0.96	1.08	1.17

One year data from the RESOLUTE Clinical Program indicates low stent thrombosis rates for those that interrupted or discontinued DAPT any time after one month. While physicians should adhere to current ESC or ACC/AHA/SCAI guidelines for PCI, patients who interrupt or discontinue DAPT medication one month or more after stent implantation are considered at low risk and showed no increased risk for stent thrombosis. Early discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, MI or death.

—DAPT language in CE Mark IFU

NO INCREASED RISK FOR ST WITH INTERRUPTION OR DISCONTINUATION OF DAPT AFTER ONE MONTH⁹

Timing of First DAPT Interruption and ST Through 1 Year



Three-year follow-up was available in almost 5000 patients and showed no increased ST risk in patients interrupting beyond one month⁸. (R-China, R-Japan SVS, R-Asia, R-US 38 mm and China Registry have not completed follow-up beyond one year and will be included in future analyses).

Bhatt. Relation of stent thrombosis to interruption of dual antiplatelet therapy after Resolute zotarolimus-eluting stent implantation. TCT 2013. Kandhari. Pharmacodynamic considerations and clinical impact of dual antiplatelet therapy interruption after Resolute zotarolimus-eluting stent implantation. ACC 2014. Post-hoc RESOLUTE Pooled DAPT analysis was not powered for the analysis shown.

*Including patients with no DAPT interruption except for ST while on DAPT through 12 months.

†Three-day cutoff selected because studies have shown that discontinuation of at least three days is necessary for platelet function recovery in most individuals.

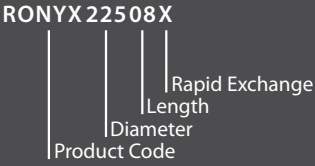
‡Patient with a history of thrombosis was on DAPT at the time of ST event but had interrupted DAPT for two consecutive days prior to the event.

§Kirtane. Long-term impact of antiplatelet therapy interruption on ST following PCI with the Resolute zotarolimus-eluting stent.

TCT 2013. ESC guidelines recommend DAPT duration of 6-12 months after DES implantation in all patients and one year after ACS, irrespective of the type of implanted stent.

⁸Di Mario C. Safety update and long-term clinical outcomes from all studies in the RESOLUTE Global Clinical Program. EuroPCR. 2014. Post-hoc RESOLUTE Pooled analysis was not powered for the analysis shown. RESOLUTE FIM, RESOLUTE All Comers, RESOLUTE International, RESOLUTE US, RESOLUTE US 38 mm, RESOLUTE Japan, RESOLUTE China RCT, RESOLUTE China Registry, RESOLUTE Asia, RESOLUTE Japan SVS
⁹Silber S et al. Eur Heart J. 2014;35(29):1949-1956.

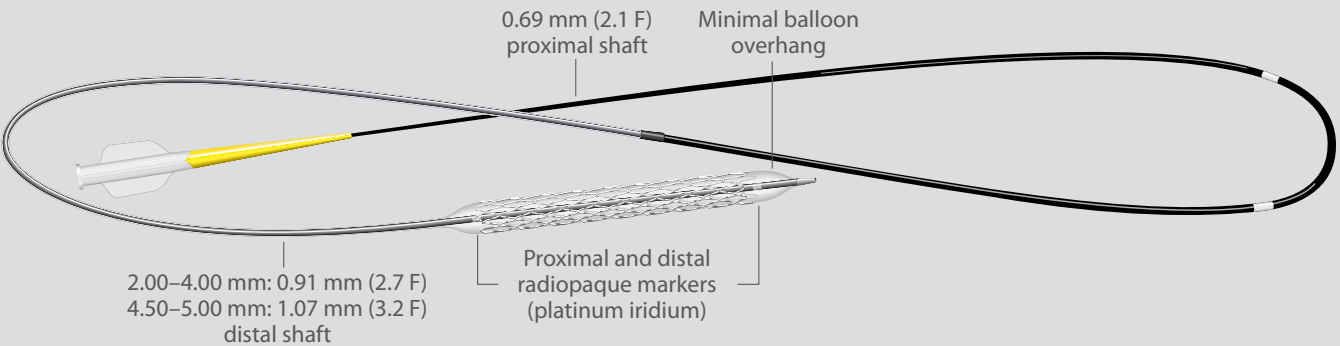
PRODUCT INFORMATION



Ordering Information

Stent Diameter (mm)	Stent Length (mm)								
	8	12	15	18	22	26	30	34	38
2.00	RONYX20008X	RONYX20012X	RONYX20015X	RONYX20018X	RONYX20022X	RONYX20026X	RONYX20030X	—	—
2.25	RONYX22508X	RONYX22512X	RONYX22515X	RONYX22518X	RONYX22522X	RONYX22526X	RONYX22530X	RONYX22534X	RONYX22538X
2.50	RONYX25008X	RONYX25012X	RONYX25015X	RONYX25018X	RONYX25022X	RONYX25026X	RONYX25030X	RONYX25034X	RONYX25038X
2.75	RONYX27508X	RONYX27512X	RONYX27515X	RONYX27518X	RONYX27522X	RONYX27526X	RONYX27530X	RONYX27534X	RONYX27538X
3.00	RONYX30008X	RONYX30012X	RONYX30015X	RONYX30018X	RONYX30022X	RONYX30026X	RONYX30030X	RONYX30034X	RONYX30038X
3.50	RONYX35008X	RONYX35012X	RONYX35015X	RONYX35018X	RONYX35022X	RONYX35026X	RONYX35030X	RONYX35034X	RONYX35038X
4.00	RONYX40008X	RONYX40012X	RONYX40015X	RONYX40018X	RONYX40022X	RONYX40026X	RONYX40030X	RONYX40034X	RONYX40038X
4.50	—	RONYX45012X	RONYX45015X	RONYX45018X	RONYX45022X	RONYX45026X	RONYX45030X		
5.00	—	RONYX50012X	RONYX50015X	RONYX50018X	RONYX50022X	RONYX50026X	RONYX50030X		

● Indicates new sizes



Compliance Data

Pressure kPa (atm)	Stent Diameter Deployed Stent I.D. (mm)								
	2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50	5.00
709 (7)	1.85	2.05	2.25	2.45	2.75	3.05	3.60	4.10	4.55
811 (8)	1.90	2.10	2.30	2.55	2.80	3.15	3.70	4.20	4.65
912 (9)	1.90	2.15	2.35	2.60	2.90	3.25	3.80	4.30	4.80
1013 (10)	1.95	2.20	2.45	2.65	2.95	3.35	3.85	4.40	4.90
1115 (11)	2.00	2.25	2.50	2.70	3.00	3.40	3.95	4.45	4.95
1216 (12)	2.05	2.30	2.55	2.75	3.05	3.45	4.00	4.50	5.05
1317 (13)	2.05	2.35	2.55	2.80	3.10	3.50	4.05	4.55	5.10
1419 (14)	2.10	2.35	2.60	2.80	3.10	3.55	4.05	4.60	5.15
1520 (15)	2.10	2.35	2.60	2.85	3.15	3.55	4.10	4.65	5.20
1621 (16)	2.15	2.40	2.65	2.90	3.20	3.60	4.15	4.70	5.25
1723 (17)	2.15	2.40	2.70	2.90	3.20	3.65	4.20	4.80	5.30
1824 (18)	2.20	2.45	2.70	2.95	3.25	3.70	4.25	4.85	5.35
1925 (19)	2.20	2.45	2.75	3.00	3.30	3.75	4.30	—	—
2027 (20)	2.25	2.50	2.75	3.00	3.35	3.80	4.35	—	—
2128 (21)	2.25	2.50	2.80	3.05	3.40	3.80	4.40	—	—
MSID	3.25*	3.25*	3.25*	3.75*	3.75*	4.75*	4.75*	5.75*	5.75*

Nominal pressure	Rated burst pressure [†]	Maximum stent I.D.
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*Do not postdilate greater than listed value.

[†]Do not exceed rated burst pressure.

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www.medtronicstents.com

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Bioprosthesis



Evolut R
23 mm Valve

Model Number:
EvolutR-23



EVOLUTR- 23



Evolut R
26 mm Valve

Model Number:
EvolutR-26



EVOLUTR- 26



Evolut R
29 mm Valve

Model Number:
EvolutR-29



EVOLUTR- 29

Loading System

EnVeo PRO Loading System

23, 26, 29 mm TAV



Model Number: L-ENVPRO-14

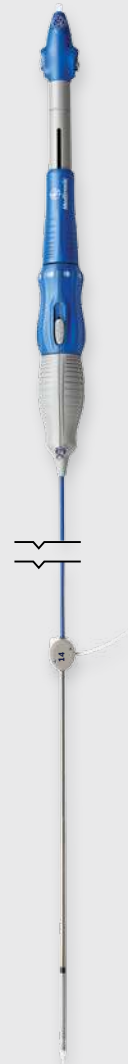


L- ENVPRO- 14

Catheter

EnVeo PRO Delivery Catheter System with InLine Sheath

14 Fr Equivalent



Model Number: ENVPRO-14



ENVPRO- 14

Medtronic

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Symlicity Spyral™

Multi-Electrode Renal Denervation Catheter

TECHNICAL SPECIFICATIONS



As a recognised leader in renal denervation innovation, we partner with industry experts who share our commitment to fighting hypertension and sustaining health. Our Symlicity Spyral™ catheter and Symlicity G3™ generator offer a sophisticated multi-electrode helical solution that smoothly moves through vessels and conforms naturally to a broad range of patient anatomies. Four electrodes deliver radiofrequency (RF) energy simultaneously to the treatment site over a 0.014" guidewire, providing exceptional delivery with reduced procedural time.

PRODUCT DESCRIPTION

The Symlicity Spyral™ catheter consists of:

- Catheter: 6 F guide catheter-compatible
- Electrodes: 4 RF monopolar, gold, radio-opaque, 1.50-mm length
- Thermocouple: T-type
- Tip marker: Platinum/Iridium alloy
- Handle: injection molded
- Integrated extension cable for connection with the Symlicity G3™ generator



MATERIALS

HANDLE

- ABS, thermoplastic elastomer overmold

CATHETER

- Proximal shaft: polyether block amide laminated over stainless steel
- Intermediate shaft: polyether block amide with braided stainless steel
- Distal electrode array jacket: thermoplastic urethane
- Tip: thermoplastic urethane
- Guidewire lumen: high-density polyethylene liner
- Spiral shaping element: nickel/titanium
- Guidewire loading tool: thermoplastic vulcanisates

THERMOCOUPLE

- T-type

SIZES

CATHETER

- 117-cm length-compatible with 100 cm or shorter guide catheters
- 6 F guide catheter-compatible
- 0.054" maximum profile

PERFORMANCE

CATHETER

- RX design compatible with 0.014" guidewire
- Guidewire retraction used to deploy the spiral electrode array
- RX joint: 30 cm from distal tip
- Vessel diameter treatment range: 3–8 mm
- Four independently controlled RF monopolar gold electrodes, spaced 6.5 mm apart
- Treatment length: 17–21 mm if all electrodes are activated
- Tip length: 5 mm
- Tip marker: 1 mm proximal of distal tip
- Femoral shaft marker: 55 cm from distal tip

STERILISATION PROCESS

- E-beam and 10⁻⁶ SAL

SHELF LIFE

- 1 year

LATEX

- Not present

PHTHALATE

- Not present

ANIMAL SUBSTANCE

- Not present

Refer to the *Instructions for Use (IFU)* for full product information.

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Symlicity Spyral™

Multi-Electrode Renal Denervation Catheter



Symlicity Spyral™
multi-electrode renal
denervation catheter

PERFORM WITH ACCURACY. DELIVER WITH CONSISTENCY.

Built on Symlicity™ technology by Medtronic, the Symlicity Spyral™ catheter offers an improved¹ renal denervation procedure to help bring your hypertension patients under control.

Consistent four-quadrant ablation pattern

- Helical four-electrode design delivers energy simultaneously
- Fast 60-second ablation time

Treats a wide range of anatomies

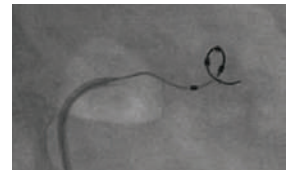
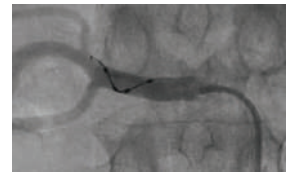
- The self-expanding helical design conforms to a wide range of artery shapes and sizes
- Single catheter can treat 3–8-mm diameter arteries

Exceptional deliverability²

- Exceptional deliverability with low 4 F profile catheter
- Delivery over a standard 0.014" guidewire with rapid exchange system



Helical ablation pattern:



SYMPPLICITY G3™ RENAL DENERVATION RF GENERATOR

Symlicity G3™ generator algorithm for patient safety

- Touchscreen interface allows for customisation of electrodes
- Fully visible electrode monitoring
- Remote control (right) and foot switch (not shown) enable easy activation



Symlicity G3™ renal
denervation RF generator



Remote control for
Symlicity G3™ RF
generator

¹Compared to Symlicity Flex™ catheter
²Data on file at Medtronic.

Symlicity Spyral™

Multi-Electrode Renal Denervation Catheter

Symlicity™ Renal Denervation System Components

DESCRIPTIONS

- Symlicity Spyral™ multi-electrode renal denervation catheter: single-use RDN catheter for use only with the Symlicity G3™ generator with remote control and DVI-D output
- Symlicity G3™ renal denervation RF generator: reusable RF generator for use with the Symlicity Spyral™ and Symlicity Flex™ catheters
- Symlicity G3™ generator component; cart
- Foot switch: used to activate generator
- Power cable: supplies power to generator unit

Ordering Information

CATALOG NUMBER	PRODUCT
RDN016	Symlicity Spyral™ catheter
RDN017	Symlicity G3™ generator; supplied standard with remote control
RDN019	Symlicity G3™ generator component; cart
RDN012	Replacement foot switch
PRT075-XX	Replacement power cable (country-specific) (Contact Medtronic representative for catalog number.)
THND190S	Thunder™ guidewire
SA6RDND1K	Sherpa NX™ Active 6 F 55-cm guide catheter with RDND1 curve
SB6RDND1K	Sherpa NX™ Balanced 6 F 55-cm guide catheter with RDND1 curve
LA6IMAK	Launcher™ 6 F 55-cm guide catheter with IMA curve
SA6IMAK	Sherpa NX™ Active 6 F 55-cm guide catheter with IMA curve
SB6IMAK	Sherpa NX™ Balanced 6 F 55-cm guide catheter with IMA curve

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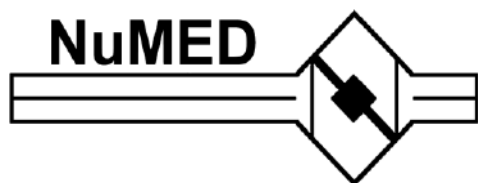
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Z-5TM

ATRIOSEPTOSTOMY CATHETER

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CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.



Instructions for Use

INDICATIONS

Recommended for balloon atrioseptostomy, an accepted technique in most pediatric cardiology centers for the palliation of several congenital cardiac defects. Balloon atrioseptostomy is performed in conjunction with diagnostic cardiac catheterization and has been carried out after the diagnosis of several congenital cardiac defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum. The **SPT002 - 9.5mm** is primarily for infants less than 2 kg.

CATHETER DESCRIPTION

The NuMED Atrioseptostomy Catheter is a new balloon catheter designed for the neonate with congenital heart disease requiring septostomy. It is a dual lumen catheter, 50cm in length. The **SPT002** has a 9.5mm $\pm$ 0.5mm non-compliant balloon, at 1.0cc volume, on the distal end. The **SPT003** has a 13.5mm $\pm$ 0.5mm non-compliant balloon, at 2.0cc volume, on the distal end. The **SPT002 - 9.5mm** catheter also features an end hole that will accommodate an 0.014" guidewire, the **SPT003 - 13.5mm** catheter also features an end hole that will accommodate an 0.018" to 0.021" guidewire. The inflated geometry of the balloon is a sphere. There is an imaging band under the balloon for balloon positioning in the left atrium. The catheter tip is angled at 35° to facilitate passage through the interatrial opening in the left atrium. To inflate the balloon of the **SPT002 - 9.5mm** catheter to its maximum diameter, 1cc of diluted contrast media is pushed into the balloon extension after purging. To inflate the balloon of the **SPT003 - 13.5mm** catheter to its maximum diameter, 2cc of diluted contrast media is pushed into the balloon extension after purging. Catheters are supplied with a one way stopcock for balloon sealing.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

WARNING

- CAUTION: Do not exceed the rated volume of 1cc for the **SPT002 - 9.5mm** Catheter. Over inflation may cause balloon rupture.
- CAUTION: Do not exceed the rated volume of 2cc for the **SPT003 - 13.5mm** Catheter. Over inflation may cause balloon rupture.
- Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
- Use only a 3cc inflation device with pressure gauge for inflation.
- Use a 3cc inflation device with pressure gauge for deflation. (For faster deflation, up to a 10cc inflation device with pressure gauge may be used).
- Do not exceed an injection pressure of 300 psi for the **SPT002 - 9.5mm** Catheter.
- Do not exceed an injection pressure of 600 psi for the **SPT003 - 13.5mm** Catheter.
- Do not advance the guidewire, septostomy catheter, or any other component if resistance is met, without first determining the cause and taking remedial action.
- This catheter is not recommended for pressure measurement or fluid injection.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination.
- The use of excessive force to pull the balloon across the atrial septum must be avoided.

PRECAUTIONS

- NuMED recommends the **SPT002 - 9.5mm** catheter be used with a 5F introducer to insure admittance.
- NuMED recommends the **SPT003 - 13.5mm** catheter be used with a 6F introducer to insure admittance.
- Balloon atrioseptostomy should not be performed for infants older than six weeks. These infants will have thick atrial septums. Reference AHA/ACC guidelines.
- Dilation procedures should be conducted under fluoroscopic/MRI guidance with appropriate x-ray equipment.
- Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight catheter connections and by aspiration before proceeding to avoid air introduction into the system.
- Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy/MRI and action taken to remedy the problem.
- If resistance is felt upon removal, then the balloon, guidewire and the sheath should be removed together as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
- Before removing the catheter from the sheath it is very important that the balloon is completely deflated.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.

	MRI Safety Information
Non-clinical testing has demonstrated that NuMED's Balloon Catheter Systems are MR Conditional. The following labeling is specific to NuMED's catheters and does not apply to guidewires or other accessories used in combination with NuMED's Balloon Catheter Systems. Users should consult the instructions for use and MRI safety information of other accessory devices used with NuMED's catheters. NuMED's Balloon Catheter Systems may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.	
Parameter	Condition
Device Name	NuMED's Balloon Catheter Systems
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
Maximum Spatial Field Gradient	19 T/m (1,900 G/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2.0 W/kg
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF scanning
Image Artifact	The presence of a NuMED Balloon Catheter in combination with an 0.035" MR Conditional guidewire may produce a radial image artifact of 1.8 cm.

POTENTIAL COMPLICATIONS

Potential complications & adverse effects associated with device use and indication include:

- Infection
- Inflammation
- Thromboembolic Events
- Air embolism
- Potential balloon separation with subsequent need of snare
- Vascular perforation requiring surgical repair
- Rhythm and conduction disturbances
- Perforation of the left atrial appendage
- Damage to the vascular intima
- Bleeding
- Hematoma Formation
- Conduction system Injury
- Death

Any serious incident that has occurred in relation to the device should be reported to NuMED & the Competent Authority in the country of use.

INSPECTION AND PREPARATION

1. Insert guidewire through the distal tip until guidewire exceeds proximal port.
2. Remove balloon protector. Inspect the catheter for damage prior to insertion.
3. Attach a 3cc inflation device with pressure gauge half filled with normal saline and attach it to the stopcock, already attached to the balloon port.
4. Purge and flush the catheter through lumen thoroughly, observing for leaks.
5. Point inflation device with pressure gauge nozzle downward, aspirate until all air is removed from the balloon, and bubbles no longer appear in the contrast medium.
6. Turn the stopcock off to maintain the vacuum in the balloon.
7. Remove guidewire.

INSERTION: VASCULAR

1. Prepare a 30% mixture by volume of contrast medium and normal saline.
2. Prepare the subject for the procedure.
3. Catheters may be introduced by percutaneous approach or by transumbilical vein. The **SPT002 - 9.5mm** catheter requires a 5F introducer sheath, the **SPT003 - 13.5mm** catheter requires a 6F introducer sheath (see Precautions) when utilizing this approach. In case of failure of this access technique, venous cutdown may be used.
4. The placement of the catheter can be accomplished under fluoroscopic/MRI guidance or under special conditions using two-dimensional echocardiographic guidance. Once through the sheath the catheter is passed to the inferior vena cava and into the right atrium. The angled tip facilitates passage across the interarterial opening to the left atrium. In case of difficulty in positioning a 0.014" guidewire for the **SPT002 - 9.5mm** catheter, or a 0.021" guidewire for the **SPT003 - 13.5mm** catheter may be used to achieve safe positioning. The guidewire should be pulled back into the catheter shaft or removed completely before proceeding with septostomy.
5. Balloon septostomy is most safely performed under fluoroscopy, MRI or 2-D echo. The balloon must be well identified in the left atrium. The balloon of the **SPT002 - 9.5mm** catheter is inflated with 1cc of fluid, the balloon of the **SPT003 - 13.5mm** catheter is inflated with 2cc of fluid and the stopcock is closed. CAUTION: Do not exceed the 1cc volume for the **SPT002 - 9.5mm** catheter or the 2cc volume for the **SPT003 - 13.5mm** catheter. Over-inflation may cause balloon rupture. The balloon is then pulled into the right atrium with a fast, snapping motion. This pulling maneuver must be stopped at the inferior vena cava-right atrial junction and the balloon rapidly readvanced into the right atrium (since balloon is non-compliant, it will not conform to the shape of the IVC and tearing is a possibility). Immediately deflate the balloon by applying negative pressure to the inflation device with pressure gauge (a 3cc is recommended unless faster deflation is needed, then up to a 10cc inflation device with pressure gauge may be used).

The use of excessive force to pull the balloon across the atrial septum must be avoided. Specifically, the physician should avoid using the entire arm when pulling the balloon across the septum and should instead use only the motion of the wrist. If the balloon does not easily cross the septum using this method, it is recommended that a smaller volume of fluid be used initially. The amount of fluid can then be gradually increased in volume until the desired result is achieved. If the first two steps are not successful, consider static balloon dilation of the atrial septum.

If necessary the catheter can be repositioned in the left atrium and the process can be repeated. The number of repeated septostomies performed during one catheterization is determined by the clinical state of the patient and the estimation of effective palliation.

6. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal, then the balloon, guidewire, and the sheath should be removed together as a unit under fluoroscopic/MRI guidance, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
7. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.
8. Dispose of device after use according to standard hospital protocol for biohazardous devices.

WARNING: NuMED catheters are placed in the extremely hostile environment of the human body. Catheters may fail to function for a variety of causes including, but not limited to, medical complications or failure of catheters by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, catheters may be easily damaged before, during, or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of catheters will not occur or that the body will not react adversely to the placement of catheters or that medical complications will not follow the use of catheters.

NuMED cannot warrant or guarantee NuMED accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

Warranty and Limitations

Catheters and accessories are sold in an 'as is' condition. The entire risk as to the quality and performance of the catheter is with the buyer. NuMED disclaims all warranties, expressed or implied, with respect to catheters and accessories, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. NuMED shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any catheter or accessory or caused by any defect, failure, or malfunction of any catheter or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind NuMED to any representation or warranty with respect to catheters and accessories.

Z-5™ Balloon Sizing Chart
SPT002 - 9.5mm Balloon Sizing Chart

Injected Volume	Resultant Balloon Diameter	Injected Volume	Resultant Balloon Diameter
0.7 cc	7.95mm ± 0.5mm	0.9 cc	8.65mm ± 0.5mm
0.8 cc	8.00mm ± 0.5mm	1.0 cc	9.35mm ± 0.5mm

SPT003 - 13.5mm Balloon Sizing Chart

Injected Volume	Resultant Balloon Diameter	Injected Volume	Resultant Balloon Diameter
0.5 cc	8.0mm ± 0.5mm	1.5 cc	12.0mm ± 0.5mm
1.0 cc	10.5mm ± 0.5mm	2.0 cc	13.5mm ± 0.5mm

FRANÇAIS

Mode d'emploi

INDICATIONS

Recommandé pour l'atrioseptostomie au ballon, une technique acceptée dans la plupart des centres de cardiologie pédiatrique pour pallier plusieurs anomalies cardiaques congénitales. L'atrioseptostomie au ballon est effectuée en conjonction avec la cathétérisation cardiaque de diagnostic ; cette technique a été utilisée après le diagnostic de plusieurs anomalies cardiaques congénitales : transposition des gros vaisseaux, drainage veineux pulmonaire anormal total sans obstruction pulmonaire, atrésie tricuspide, sténose mitrale, atrésie mitrale et atrésie pulmonaire avec septum ventriculaire intact. Le **SPT002 - 9,5 mm** est essentiellement destiné aux enfants de moins de 2 kg.

DESCRIPTION DU CATHÉTER

Le cathéter d'atrioseptostomie NuMED est un nouveau cathéter à ballon conçu pour les nouveaux-nés souffrant d'une maladie cardiaque congénitale nécessitant une septostomie. Il s'agit d'un cathéter à double lumière d'une longueur de 50 cm. Le **SPT002** est pourvu d'un ballon non-compliant de 9,5 mm ± 0,5 mm, à un volume de 1,0 cm³, à l'extrémité distale. Le **SPT003** est pourvu d'un ballon non-compliant de 13,5 mm, à un volume de 2,0 cm³, à l'extrémité distale. De plus, l'orifice distal du cathéter **SPT002 - 9,5 mm** permet d'utiliser un guide métallique de 0,014 po. ; l'orifice distal du **SPT003 - 13,5 mm** permet d'utiliser un guide métallique de 0,018 à 0,021 po. Une fois gonflé, le ballon a la forme d'une sphère. Une bande d'imagerie située sous le ballon permet de le positionner dans l'oreillette gauche. Courbée, l'extrémité du cathéter forme un angle de 35° pour faciliter son passage dans l'ouverture interatriale de l'oreillette gauche. Un cm³ du médium de contraste dilué est poussé dans l'extension du ballon après la purge afin de gonfler le ballon du cathéter **SPT002 - 9,5 mm** à son diamètre maximum. Deux cm³ du médium de contraste dilué sont poussés dans l'extension du ballon après la purge afin de gonfler le ballon du cathéter **SPT003 - 13,5 mm** à son diamètre maximum. Les cathéters sont fournis avec un robinet à une voie assurant leur fermeture hermétique.

CONTENU DE L'EMBALLAGE

Fourni stérilisé à l'oxyde d'éthylène. Stérile et apyrogène si l'emballage n'a pas été ouvert ou endommagé. Ne pas utiliser en cas de doute sur la stérilité du produit. Éviter une exposition prolongée à la lumière. Examiner le produit après l'avoir sorti de son emballage pour s'assurer qu'il n'a pas été endommagé.

AVERTISSEMENT

- **MISE EN GARDE** : ne dépassez pas le volume maximal de 1 cm³ avec le cathéter **SPT002 - 9,5 mm**. Le gonflement excessif du ballon risque de provoquer sa rupture.
- **MISE EN GARDE** : ne dépassez pas le volume maximal de 2 cm³ avec le cathéter **SPT003 - 13,5 mm**. Le gonflement excessif du ballon risque de provoquer sa rupture.
- Utilisez exclusivement un médium approprié pour gonfler le ballon. N'utilisez pas d'air ni de médium gazeux pour gonfler le ballon.
- Utilisez un dispositif de gonflage de 3 cm³ avec un capteur de pression pour le gonflage.
- Utilisez un dispositif de gonflage de 3 cm³ avec un capteur de pression pour le dégonflage. (Un dispositif de gonflage de 10 cm³ peut également être utilisé pour accélérer le processus de dégonflage.)
- Ne dépassez pas la pression d'injection de 300 psi avec le cathéter **SPT002 - 9,5 mm**.
- Ne dépassez pas la pression d'injection de 600 psi avec le cathéter **SPT003 - 13,5 mm**.
- En cas de résistance, ne faites avancer ni le guide métallique, ni le cathéter de septostomie, ni aucun autre composant avant d'avoir déterminé la cause de la résistance et d'avoir remédié à celle-ci.
- Ce cathéter n'est pas recommandé pour les mesures de pression ni pour les injections de fluide.
- Ce dispositif est prévu pour une seule utilisation. Ne pas restériliser ni réutiliser, au risque de compromettre les performances du dispositif et d'augmenter le risque de contamination croisée.
- Évitez d'exercer une force excessive pour tirer le ballonnet à travers le septum interauriculaire.

PRÉCAUTIONS

- NuMED recommande d'utiliser un introducteur 5F avec le cathéter **SPT002 - 9,5 mm** afin d'assurer son admission.
- NuMED recommande d'utiliser un introducteur 6F avec le cathéter **SPT003 - 13,5 mm** afin d'assurer son admission.
- N'effectuez pas d'atrioseptostomie au ballon sur les enfants de plus de six semaines. Ces enfants ont des septums atriaux épais. Directives AHA/ACC de référence.
- La procédure de dilatation doit être effectuée sous guidage fluoroscopique/IRM avec les équipements radiographiques appropriés.
- Les guides métalliques sont des instruments délicats. Manipulez-les avec soin pour éviter de les briser.
- Avant d'entamer la procédure, vérifiez avec soin que les connexions et l'aspiration du cathéter sont étanches afin d'éviter que de l'air soit introduit dans le système.
- En cas de résistance ne faire avancer une partie du système de cathéter en cas de résistance. Identifier la cause de la résistance par fluoroscopie/IRM et prendre les mesures nécessaires pour remédier au problème.
- En cas de résistance lors du retrait, retirez le ballon, le guide métallique et la gaine en tant qu'une seule unité, notamment si vous savez ou suspectez que le ballon est rompu ou fuit. Ceci s'effectue en saisissant fermement le cathéter à ballon et la gaine en tant qu'une seule unité, puis en les retirant simultanément à l'aide d'une traction combinée à une légère rotation.

- Il est très important que le ballon soit complètement dégonflé avant de retirer le cathéter de la gaine.
- Le bon fonctionnement du cathéter dépend de son intégrité. Manipulez le cathéter avec précaution. Vous risquez d'endommager le cathéter si vous le pliez, l'étirez ou l'essuyez avec force.

Informations concernant la sécurité de l'IRM	
Des tests non cliniques ont démontré que les systèmes de cathéter à ballonnet de NuMED sont compatibles avec l'IRM sous certaines conditions. L'étiquette suivante est spécifique aux cathéters NuMED et ne s'applique pas aux guides ou aux autres accessoires utilisés en combinaison avec les systèmes de cathéter à ballonnet de NuMED. Les utilisateurs doivent consulter le mode d'emploi et les informations concernant la sécurité de l'IRM des autres accessoires utilisés avec les cathéters NuMED. Les systèmes de cathéter à ballonnet de NuMED peut être scannés sans risque n'importe où dans le corps à 1,5 T et 3,0 T dans les conditions suivantes : Le non-respect de ces conditions peut entraîner des blessures.	
Paramètre	Condition
Nom du dispositif	Les systèmes à cathéter à ballonnet de NuMED
Champ magnétique statique (B0)	1,5 T et 3 T
Type de scanner IRM	Cylindrique
Champ à gradient spatial maximum	19 T/m (1.900 gauss/cm)
Excitation RF	Polarisé de manière circulaire (PC)
Type d'antenne d'émission RF	Antenne d'émission intégrée corps entier
Mode de fonctionnement	Mode de fonctionnement normal
Conditions RF	DAS maximum corps entier : 2,0 W/kg
Durée d'acquisition	Débit d'absorption spécifique (DAS) moyenné pour le corps entier de 2 W/kg pendant 60 minutes d'acquisition RF continue
Artefact d'image	La présence d'un cathéter à ballonnet NuMED en combinaison avec un guide de 0,035 po (0,889 mm) compatible avec l'IRM sous certaines conditions peut produire un artefact d'image de 1,8 cm.

COMPLICATIONS ÉVENTUELLES

Parmi les complications et les effets indésirables potentiels associés à l'utilisation du dispositif et les indications, on citera les points suivants :

- Infection
- Inflammation
- Événements thromboemboliques
- Embolie gazeuse
- Séparation éventuelle du ballon, puis nécessité d'utiliser une anse métallique
- Perforation vasculaire nécessitant une réfection chirurgicale
- Perturbations du rythme et de la conduction
- Perforation de l'appendice auriculaire gauche
- Lésions de l'intima vasculaire
- Saignement
- Formation d'hématome
- Lésion du système de conduction
- Décès

Tout incident grave survenant en rapport avec le dispositif doit être signalé à NuMED et à l'autorité compétente du pays où il est utilisé.

INSPECTION ET PRÉPARATION

1. Insérez le guide métallique dans la partie distale jusqu'à ce qu'il dépasse le port proximal.
2. Retirez la protection du ballon. Inspectez le cathéter avant de l'insérer afin de vérifier qu'il n'est pas endommagé.
3. Utilisez un dispositif de gonflage de 3 cm³ avec capteur de pression, à demi rempli de solution saline normale, et attachez-le au robinet déjà attaché au port du ballon.
4. Purgez et rincez abondamment le cathéter par sa lumière en vérifiant qu'il ne fuit pas.
5. Placez le dispositif de gonflage de manière à ce que le bec du capteur de pression soit orienté vers le bas, et aspirez jusqu'à ce que tout l'air ait été retiré du ballon et que plus aucune bulle n'apparaisse dans le médium de contraste.
6. Fermez le robinet pour conserver le vide dans le ballon.
7. Retirez le guide métallique.

INSERTION : VASculaire

1. Préparez une solution saline à 30 % (par rapport au volume) de médium de contraste.
2. Préparez le sujet pour la procédure.
3. Les cathéters peuvent être introduits par voie percutanée ou transombilicale (veine). Le cathéter **SPT002 - 9,5 mm** nécessite une gaine d'introduction 5F, et le cathéter **SPT003 - 13,5 mm** nécessite une gaine d'introduction 6F (reportez-vous aux précautions) lorsque cette approche est utilisée. La technique de dissection veineuse peut être utilisée en cas d'échec de la technique d'accès mentionnée ci-dessus.
4. La mise en place du cathéter peut être accomplie sous guidage fluoroscopique/IRM ou dans des conditions spéciales sous guidage échocardiographique bi-dimensionnel. Une fois sorti de la gaine, le cathéter est acheminé dans la veine cave inférieure et dans l'oreillette droite. L'extrémité angulée facilite le passage au travers de l'ouverture interauriculaire vers l'oreillette gauche. En cas de difficulté lors du positionnement, un guide de 0,014 po pour le cathéter **SPT002 - 9,5 mm**, ou un guide de 0,021 po pour le cathéter **SPT003 - 13,5 mm** peut être utilisé pour assurer un positionnement sûr. Le guide doit être ramené dans le corps du cathéter ou retiré complètement avant de procéder à la réalisation d'une septostomie.
5. Pour assurer une sécurité optimale, réaliser une septostomie à ballonnet par fluoroscopie, sous IRM ou à l'aide d'une échocardiographie 2D. Le ballonnet doit être clairement identifié dans l'oreillette gauche. Le ballonnet du cathéter **SPT002 - 9,5 mm** est gonflé avec 1 cc de liquide, le ballonnet du cathéter **SPT003 - 13,5 mm** est gonflé avec 2 cc de liquide et le robinet est fermé. MISE EN GARDE : Ne pas dépasser le volume de 1 cc pour le cathéter **SPT002 - 9,5 mm** ou le volume de 2 cc pour le cathéter **SPT003 - 13,5 mm**. Un gonflage excessif du ballonnet peut provoquer sa rupture. Le ballonnet est tiré ensuite dans l'oreillette droite d'un mouvement sec et rapide. Cette manœuvre de traction doit être interrompue au niveau de la jonction entre la veine cave inférieure et l'oreillette droite, et le ballonnet doit être avancé de nouveau dans l'oreillette droite (comme le ballonnet non-compliant, il ne s'adapte pas à la forme de la VCI et une déchirure est possible). Dégonfler immédiatement le ballonnet en appliquant une pression négative au dispositif de gonflage à l'aide d'un manomètre (un dispositif de gonflage de 3 cc est recommandé sauf si un dégonflage plus rapide est requis ; dans ce cas, un dispositif de gonflage de 10 cc maximum muni d'un manomètre peut être utilisé).

L'utilisation d'une force excessive pour tirer le ballonnet au travers du septum inter-auriculaire doit être évitée. Spécifiquement, le médecin doit éviter d'utiliser le bras entier en tirant le ballonnet au travers du septum et doit utiliser uniquement un mouvement du poignet. Si le ballonnet ne franchit pas facilement le septum en employant cette méthode, il est recommandé d'utiliser un volume de liquide plus petit au départ. Il est possible d'augmenter ensuite progressivement le volume de liquide jusqu'à ce que le résultat souhaité soit obtenu. Si les deux premières étapes ne sont pas réussies, envisager la dilatation statique par ballonnet du septum inter-auriculaire.

Si nécessaire, le cathéter peut être repositionné dans l'oreillette gauche et le processus répété. Le nombre de septostomies

répétées réalisées pendant un cathétérisme est déterminé par l'état clinique du patient et une estimation de l'efficacité des soins palliatifs.

- Retirer délicatement le cathéter. Lorsque le ballonnet quitte le vaisseau, exercer un léger mouvement, doux et constant. En cas de résistance lors du retrait, retirer le ballonnet, le guide et la gaine d'un seul tenant sous guidage fluoroscopique/IRM, notamment en cas de rupture ou de fuite suspectée ou avérée du ballonnet. Cette opération peut être réalisée en saisissant fermement le cathéter à ballonnet et la gaine d'un seul tenant pour les retirer simultanément par une traction associée à une légère rotation.
- Appliquez une pression sur le site d'insertion conformément à la pratique standard ou au protocole hospitalier applicable aux procédures vasculaires percutanées.
- Éliminer le dispositif après l'emploi conformément au protocole standard de l'hôpital pour les dispositifs présentant un danger biologique.

AVERTISSEMENT : Les cathétères NuMED sont placés dans un environnement extrêmement hostile du corps humain. Il est possible que les cathétères ne fonctionnent pas correctement pour les raisons les plus diverses dont, sans toutefois s'y limiter, des complications médicales ou leur rupture. De plus, malgré le contrôle rigoureux appliqué durant les phases de conception, de sélection des composants, de fabrication et de tests préalables à la vente, les cathétères peuvent s'endommager facilement avant, pendant ou après leur insertion s'ils sont manipulés de manière inadéquate ou dans d'autres circonstances d'origine extérieure. Par conséquent, aucune déclaration ni aucune garantie indiquant que la défaillance ou la cessation du fonctionnement des cathétères ne se produira pas, que le corps ne réagira pas de manière indésirable ou encore que des complications médicales ne se produiront pas après l'utilisation des cathétères, ne sont émises.

NuMED ne peut pas assurer ni garantir les accessoires NuMED, car la structure des accessoires peut être endommagée s'ils sont manipulés de manière inappropriée avant ou pendant leur utilisation. Par conséquent, aucune déclaration ni aucune garantie ne sont émises à leur égard.

Garantie et limitations

Les cathétères et les accessoires sont vendus "en l'état". L'intégralité du risque relatif à la qualité et aux performances du cathéter est assumé par l'acheteur. NuMED dénie toutes les garanties, expresses ou implicites, quant aux cathétères et aux accessoires, dont, sans toutefois s'y limiter, toutes les garanties de qualité commerciale ou d'adaptation à un objectif particulier. NuMED ne peut être tenu responsable envers quiconque de tout frais médical ou de tout dommage direct ou indirect résultant de l'utilisation de quelque cathéter ou accessoire que ce soit ou encore provoqué par tout défaut, défaillance ou fonctionnement incorrect de quelque cathéter ou accessoire que ce soit, que la déclaration desdits dommages soit basée sur une garantie, un contrat, un acte délictuel ou autre. Aucun individu n'a l'autorité nécessaire pour obliger NuMED à assumer quelque déclaration ou garantie que ce soit ayant trait aux cathétères et accessoires.

**Tableau des dimensions des ballons Z-5™
Tableau des dimensions des ballons du SPT002 - 9,5 mm**

Volume Injecté	Diamètre de ballon résultant	Volume Injecté	Diamètre de ballon résultant
0,7 cc (0,7 cm³)	7,95 mm ± 0,5 mm	0,9 cc (0,9 cm³)	8,65 mm ± 0,5 mm
0,8 cc (0,8 cm³)	8,00 mm ± 0,5 mm	1,0 cc (1,0 cm³)	9,35 mm ± 0,5 mm

Tableau des dimensions des ballons du SPT003 - 13,5 mm

Volume Injecté	Diamètre de ballon résultant	Volume Injecté	Diamètre de ballon résultant
0,5 cc (0,5 cm³)	8,0 mm ± 0,5 mm	1,5 cc (1,5 cm³)	12,0 mm ± 0,5 mm
1,0 cc (1,0 cm³)	10,5 mm ± 0,5 mm	2,0 cc (2,0 cm³)	13,5 mm ± 0,5 mm

ITALIANO

Istruzioni per l'uso

INDICAZIONI

Consigliato per atriosettostomia con palloncino, una tecnica accettabile nella maggior parte dei centri cardiaci pediatrici per l'attenuazione di diversi difetti cardiaci congeniti. L'atriosettostomia con palloncino viene condotta insieme alla caterizzazione cardiaca diagnostica ed eseguita in seguito alla diagnosi di numerosi difetti cardiaci congeniti: trasposizione delle grandi arterie, completo drenaggio venoso polmonare anormale in assenza di ostruzione polmonare, atresia tricuspidale, stenosi mitrale, atresia mitrale e atresia polmonare con setto ventricolare intatto. **SPT002 - 9,5mm** è adatto principalmente ai neonati con peso inferiore ai 2 Kg.

DESCRIZIONE DEL CATETERE

Il catetere per atriosettostomia NuMED è un nuovo catetere con palloncino ideato per i neonati con malattia cardiaca congenita che richiede settostomia. È un catetere a lume doppio, lungo 50 cm. L'**SPT002** è dotato di un palloncino non conforme da 9,5mm ± 0,5mm al volume di 1 cc, sull'estremità distale. L'**SPT003** è dotato di un palloncino non conforme da 13,5 mm ± 0,5 mm, a 2 cc di volume, sull'estremità distale. Il catetere **SPT002 - 9,5mm** inoltre ha un foro all'estremità per la guida angiografica da 0,014". Anche il catetere **SPT003 - 13,5mm** è dotato di un foro all'estremità per una guida angiografica da 0,018" a 0,021". La forma geometrica del palloncino gonfiato è una sfera. Sotto al palloncino c'è un insieme di immagini che serve per posizionare il palloncino nell'atrio sinistro. La punta del catetere ha un angolo di 35° che facilita il passaggio lungo l'apertura interatriale nell'atrio sinistro. Per gonfiare il palloncino del catetere **SPT002 - 9,5mm** al massimo diametro, dopo lo spurgo nell'estensione del palloncino viene spinto 1 cc di mezzo di contrasto diluito. Per gonfiare il palloncino del catetere **SPT003 - 13,5mm** al massimo diametro, dopo lo spurgo nell'estensione del palloncino vengono spinti 2 cc di mezzo di contrasto diluito. I cateteri sono forniti con un rubinetto a unica direzione come sigillo del palloncino.

MODALITÀ DI FORNITURA

Fornito sterilizzato mediante ossido di etilene. Sterile e non pirogenico se la confezione è chiusa e integra. Non utilizzare il prodotto in caso di dubbi sulla sua sterilità. Evitare l'esposizione prolungata alla luce. Dopo averlo tolto dalla confezione, esaminare il prodotto per verificare che non abbia subito danni.

AVVERTENZA

- ATTENZIONE: per il catetere **SPT002 - 9,5mm** non superare il volume nominale di 1 cc. Un gonfiaggio eccessivo potrebbe causare la rottura del palloncino.
- ATTENZIONE: per il catetere **SPT003 - 13,5mm** non superare il volume nominale di 2 cc. Un gonfiaggio eccessivo potrebbe causare la rottura del palloncino.
- Usare solo il liquido di gonfiaggio del palloncino appropriato. Non usare aria o mezzi gassosi.
- Per il gonfiaggio usare solamente un dispositivo da 3 cc con indicatore di pressione.
- Per lo sgonfiaggio usare un dispositivo da 3 cc con indicatore di pressione (per uno sgonfiaggio più veloce è possibile usare un dispositivo di gonfiaggio da 10 cc con indicatore di pressione).
- Per il catetere **SPT002 - 9,5 mm** non superare la pressione di iniezione di 300 psi.
- Per il catetere **SPT003 - 13,5 mm** non superare la pressione di iniezione di 600 psi.
- In caso di resistenza, non fare avanzare la guida angiografica, il catetere per settostomia o alcun altro componente, senza aver prima determinato la causa dell'ostacolo e avervi posto rimedio.
- Non si consiglia di usare questo catetere per misurare la pressione o per iniettare fluido.
- Questo dispositivo è esclusivamente monouso. Per evitare prestazioni inadeguate e un maggior rischio di contaminazione crociata, non risterilizzare e/o riutilizzare il dispositivo.
- Evitare di applicare una eccessiva forza durante la fase di passaggio del palloncino attraverso il setto atriale.

PRECAUZIONI

- NuMED consiglia di usare il catetere **SPT002 - 9,5mm** con un introduttore vasale 5F per garantirne l'introduzione.
- NuMED consiglia di usare il catetere **SPT003 - 13,5mm** con un introduttore vasale 6F per garantirne l'introduzione.
- Non eseguire l'atriosettostomia nei neonati con più di sei settimane di vita in quanto il loro setto atriale è più spesso. Consultare le norme AHA/ACC.
- Eseguire la procedura di dilatazione sotto osservazione fluoroscopica/RM con apparecchiature adatte.
- Le guide angiografiche sono strumenti delicati. Per evitarne possibili rotture, fare molta attenzione durante il trattamento.
- Per evitare l'introduzione di aria nel sistema, prima di procedere eseguire con cura la manutenzione delle fisse connessioni del catetere e di aspirazione.
- Non forzare in nessun caso l'avanzamento di alcuna porzione del catetere. Identificare la causa della resistenza tramite fluoroscopia/RM e adottare le procedure più indicate per risolvere il problema.
- Se si osserva resistenza al momento della rimozione, togliere il palloncino, la guida angiografica e la guaina come unica unità, particolarmente se si sospetta o si è osservata una lesione o una perdita del palloncino. Allo scopo afferrare fermamente il catetere del palloncino e la guaina come unica unità e farli fuoriuscire insieme, con un movimento delicato e ruotante abbinato a trazione.
- Prima di rimuovere il catetere dalla guaina, accertarsi che il palloncino sia completamente sgonfio.
- L'integrità del catetere è essenziale per garantirne il funzionamento corretto. Trattare con cura il dispositivo in quanto eventuali attorcigliamenti, prolungamenti o puliture del catetere eseguite con forza possono causare danni.

Informazioni sulla sicurezza in ambiente RM	
Prove non cliniche hanno dimostrato che i sistemi con catetere a palloncino NuMED sono a compatibilità RM condizionata. L'etichettatura seguente è specifica per i cateteri NuMED e non si applica alle guide o agli altri accessori usati insieme ai sistemi con catetere a palloncino NuMED. Gli operatori devono consultare le istruzioni per l'uso e le informazioni sulla sicurezza in ambiente RM degli altri dispositivi accessori utilizzati con i cateteri NuMED. I sistemi con catetere a palloncino NuMED in qualsiasi parte del corpo possono essere sottoposti a scansione in sicurezza a 1,5 T o 3,0 T alle condizioni seguenti. Il mancato rispetto delle condizioni indicate può essere causa di lesioni.	
Parametro	Condizione
Nome dispositivo	Sistemi con catetere a palloncino NuMED
Intensità di campo magnetico statico (B0)	1,5 T e 3 T
Tipo di scanner RM	Cilindrico
Massimo gradiente spaziale di campo	19 T/m (1.900 G/cm)
Eccitazione RF	Polarizzazione circolare (CP)
Tipo di bobina trasmittente RF	Bobina trasmittente a corpo intero integrata
Modalità operativa	Modalità operativa normale
Condizioni RF	SAR massimo sul corpo intero 2,0 W/kg
Durata scansione	SAR mediato sul corpo intero di 2 W/kg per 60 minuti di scansione continua
Artefatto d'immagine	La presenza di un catetere a palloncino NuMED abbinato a una guida a compatibilità RM condizionata da 0,035 pollici (0,889 mm) può causare un artefatto d'immagine radiale di 1,8 cm.

POTENZIALI COMPLICAZIONI

Le complicanze e gli effetti avversi potenziali associati all'uso del dispositivo e alla sua indicazione includono:

- Infezione
- Infiammazione
- Eventi tromboembolici
- Embolia
- Potenziale separazione del palloncino con successiva necessità di cappio
- Perforazione vascolare che richiede un intervento chirurgico
- Disturbi ritmici e di conduzione
- Perforazione dell'appendice atriale sinistra
- Danno alla parete vascolare profonda
- Emorragia
- Formazione di ematoma
- Lesione del sistema di conduzione
- Morte

Gli incidenti gravi verificatisi con l'uso del dispositivo devono essere segnalati a NuMED e all'autorità competente del Paese di utilizzo.

ISPEZIONE E PREPARAZIONE

- Inserire la guida angiografica lungo la punta distale fino a che la guida non supera la porta prossimale.
- Rimuovere la protezione del palloncino. Prima di inserire il catetere controllarlo al fine di verificare che non sia danneggiato.
- Attaccare il dispositivo di gonfiaggio da 3 cc con l'indicatore di pressione riempito a metà di soluzione salina normale e collegarlo al rubinetto già attaccato alla porta del palloncino.
- Purgare e sciacquare il catetere accuratamente lungo il lume ed osservare se vi siano delle perdite.
- Puntare il dispositivo di gonfiaggio con il becco dell'indicatore di pressione rivolto verso il basso, aspirare fino a che non si è rimossa tutta l'aria dal palloncino e non appaiono più bolle nel mezzo di contrasto.
- Spegnerne il rubinetto per mantenere il vuoto nel palloncino.
- Rimuovere la guida angiografica.

INSERIMENTO: VASCOLARE

1. Preparare una miscela con volume al 30% di mezzo di contrasto e di soluzione salina normale.
2. Preparare il soggetto per la procedura.
3. È possibile inserire i cateteri per via percutanea o per vena transumbilicale. In questi casi il catetere **SPT002 - 9,5 mm** richiede l'uso di una guaina per introduttore vasale 5F, il catetere **SPT003 - 13,5 mm** richiede l'uso di una guaina per introduttore vasale 6F (vedere Precauzioni). Nel caso in cui questa tecnica non funzioni, si possono provare vie venose.
4. Il catetere può essere posizionato sotto osservazione fluoroscopica/RM o in condizioni speciali impiegando l'ecocardiografia 2D. Dopo aver oltrepassato la guaina, introdurre il catetere nella vena cava inferiore e successivamente nell'atrio destro. La punta angolata ne agevola il passaggio attraverso l'apertura interatriale fino all'atrio sinistro. Se si riscontra difficoltà, per un posizionamento sicuro si può utilizzare una guida da 0,014 pollici per il catetere **SPT002 da 9,5 mm** o una guida da 0,021 pollici per il catetere **SPT003 da 13,5 mm**. La guida deve essere ritirata nello stelo del catetere oppure rimossa completamente prima di eseguire la settostomia.
5. Per eseguire in sicurezza la settostomia mediante palloncino, avvalersi della fluoroscopia, della RM o dell'ecocardiografia 2D. Il palloncino deve essere chiaramente visibile nell'atrio sinistro. Gonfiare il palloncino del catetere **SPT002 da 9,5 mm** con 1 cc di liquido; gonfiare il palloncino del catetere **SPT003 da 13,5 mm** con 2 cc di liquido e chiudere il rubinetto. **ATTENZIONE:** non superare il volume di 1 cc per il catetere **SPT002 da 9,5 mm** e il volume di 2 cc per il catetere **SPT003 da 13,5 mm**, poiché il gonfiaggio eccessivo del palloncino può causarne la rottura. Tirare poi il palloncino nell'atrio destro con uno scatto rapido. Interrompere la manovra di trazione in corrispondenza della giunzione della vena cava inferiore con l'atrio destro; fare avanzare nuovamente e rapidamente il palloncino. Dato che il palloncino non è compliant, non assumerà la forma della vena cava inferiore, pertanto esiste il rischio che si laceri. Sgonfiare immediatamente il palloncino applicando pressione negativa con il dispositivo di gonfiaggio dotato di manometro. Si consigliano 3 cc, a meno che non sia necessario sgonfiare più rapidamente il palloncino; si possono usare fino a 10 cc se si utilizza un dispositivo di gonfiaggio dotato di manometro.
Evitare di tirare con forza eccessiva il palloncino attraverso il setto atriale. Nello specifico, il medico non deve usare tutto il braccio per tirare il palloncino attraverso il setto: deve usare invece solo il movimento del polso. Se con questo metodo il palloncino non attraversa con facilità il setto, si consiglia di impiegare inizialmente un volume di liquido minore. Il volume di liquido può poi essere aumentato gradatamente fino a ottenere il risultato desiderato. Se i primi due passaggi non riescono, prendere in considerazione la dilatazione del setto atriale con il palloncino in posizione statica.
Se necessario, il catetere può essere riposizionato nell'atrio sinistro e il procedimento può essere ripetuto. Il numero di settostomie eseguite durante un intervento di cateterismo dipende dallo stato clinico del paziente e dalla stima dell'effetto palliativo.
6. Ritirare delicatamente il catetere. Man mano che il palloncino fuoriesce dal vaso sanguigno, impartire un movimento costante, delicato e uniforme. Se si incontra resistenza al momento della rimozione, estrarre insieme il palloncino, la guida e la guaina come unica unità sotto osservazione fluoroscopica/RM, soprattutto in caso di rottura o perdita dal palloncino, sospetta o accertata. Per fare ciò, afferrare saldamente il catetere a palloncino e la guaina come unica unità e ritirarli insieme associando alla trazione un delicato movimento di rotazione.
7. Esercitare pressione al sito di penetrazione seguendo la pratica standard o il protocollo ospedaliero relativo alle procedure vascolari percutanee.
8. Smaltire il dispositivo dopo l'uso attenendosi al protocollo ospedaliero standard sui dispositivi biopericolosi.

AVVERTENZA: i cateteri NuMED vengono usati in parti del corpo umano che sono estremamente ostili per cui potrebbero non funzionare a causa di diversi motivi, tra cui possibili complicazioni mediche o il mancato funzionamento del dispositivo a causa di una rottura. Inoltre, nonostante il design dettagliato, la selezione accurata dei componenti e della produzione e il collaudo prima della vendita, i cateteri potrebbero danneggiarsi facilmente prima, durante o dopo inserimento a causa di un uso scorretto o della presenza di altri fattori. Di conseguenza non viene data alcuna rappresentanza o garanzia dell'assenza di eventuali guasti o di interruzioni di funzionamento o che il corpo non funzionerà in modo avverso all'inserimento del catetere o che non vi saranno complicazioni dovute all'uso dei cateteri.

NuMED non garantisce gli accessori NuMED poiché la struttura potrebbe essere stata danneggiata a causa di un trattamento scorretto prima o durante l'uso. Di conseguenza non viene data alcuna rappresentanza o garanzia a riguardo.

Garanzia e limitazioni

I cateteri e gli accessori vengono venduti come sono. Il rischio della qualità e delle prestazioni del catetere sono esclusivamente dell'acquirente. NuMED non offre alcuna garanzia, espressa o implicita, dei cateteri e degli accessori, tra cui eventuali garanzie implicite di commerciabilità o adeguatezza per un certo scopo. NuMED non è da ritenersi responsabile nei confronti di alcuna persona o di eventuali spese mediche o di danni diretti o conseguenti che risultano dall'uso di un catetere o accessorio o che sono causati da difetti, mancato funzionamento del catetere o dell'accessorio, sia che il reclamo si basi su garanzia, contratto, torto o altra forma. Nessuno ha alcuna autorità di vincolare NuMED a rappresentare o garantire i cateteri e gli accessori.

**Tabella delle dimensioni del palloncino dello Z-5™
SPT002 - 9,5 mm Tabella delle dimensioni del palloncino**

Volume inserito	Diametro del palloncino che ne risulta	Volume inserito	Diametro del palloncino che ne risulta
0,7 cc	7,95 mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00 mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

SPT003 - 13,5 mm Tabella delle dimensioni del palloncino

Volume inserito	Diametro del palloncino che ne risulta	Volume inserito	Diametro del palloncino che ne risulta
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

Gebrauchsanweisung

INDIKATION

Für Ballonatrioseptostomie, eine in den meisten Kardiologiezentren zur Behandlung bestimmter angeborener Herzfehler bei Kindern angewendete Technik empfohlen. Ballonatrioseptostomie wird in Verbindung mit diagnostischer Katheterisierung und nach der Diagnose verschiedener angeborener Herzfehler durchgeführt: Transposition der großen Arterien, totale Lungenvenenfehlmündung ohne Lungenobstruktion, Trikuspidalatresie, Mitralstenose, Mitralatresie und Pulmonalatresie mit intaktem Ventrikelseptum. Der Katheter **SPT002 - 9,5 mm** ist vor allem für Säuglinge unter 2 kg vorgesehen.

KATHETERBESCHREIBUNG

Der NuMED Atrioseptostomie-Katheter ist ein neuer Ballonkatheter, der für Neugeborene mit einer angeborenen Herzkrankheit konzipiert ist, die eine Septostomie erfordert. Es handelt sich um einen 50 cm langen Zwei-Lumen-Katheter. Der Katheter **SPT002** ist am distalen Ende mit einem nicht dehnbaren Ballon (9,5 mm $\pm$ 0,5 mm bei einem Volumen von 1,0 cc) versehen. Der Katheter **SPT003** ist am distalen Ende mit einem nicht dehnbaren Ballon (13,5 mm $\pm$ 0,5 mm bei einem Volumen von 2 cc) versehen. Der Katheter **SPT002 - 9,5 mm** verfügt auch über eine Endöffnung für einen Führungsdraht mit einem Durchmesser von 0,014 Zoll (0,0356 cm), während der Katheter **SPT003 - 13,5 mm** eine Endöffnung für einen Führungsdraht mit einem Durchmesser von 0,018 bis 0,021 Zoll (0,046 cm bis 0,053 cm) aufweist. Der aufgeblasene Ballon ist kugelförmig. Unter dem Ballon befindet sich ein bildgebendes Band zur Positionierung des Ballons im linken Vorhof. Die Katheterspitze ist abgewinkelt (35°), damit sie durch die interatriale Öffnung im linken Vorhof geschoben werden kann. Zum Aufblasen des Ballons des Katheters **SPT002 - 9,5 mm** auf den maximalen Durchmesser wird nach dem Entfernen der Luft 1 cc verdünntes Kontrastmittel in die Ballonverlängerung eingefüllt. Zum Aufblasen des Ballons des Katheters **SPT003 - 13,5 mm** auf den maximalen Durchmesser werden nach dem Entfernen der Luft 2 cc verdünntes Kontrastmittel in die Ballonverlängerung eingefüllt. Im Lieferumfang der Katheter ist ein Einwegabsperrrhahn zum Verschließen des Ballons enthalten.

LIEFERFORM

Bei Lieferung steril und pyrogenfrei, sofern die Verpackung ungeöffnet und unbeschädigt ist. Sterilisiert mit Ethylenoxid-Gas. Das Produkt nicht anwenden, wenn Zweifel darüber bestehen, ob das Produkt steril ist. Längere Lichteinwirkung vermeiden. Das Produkt nach dem Entfernen aus der Verpackung auf mögliche Beschädigungen überprüfen.

WARNUNG:

- **ACHTUNG:** Beim Katheter **SPT002 - 9,5 mm** darf das Nennvolumen von 1 cc nicht überschritten werden. Wenn der Ballon zu stark aufgeblasen wird, kann ein Riss entstehen.
- **ACHTUNG:** Beim Katheter **SPT003 - 13,5 mm** darf das Nennvolumen von 2 cc nicht überschritten werden. Wenn der Ballon zu stark aufgeblasen wird, kann ein Riss entstehen.
- Verwenden Sie nur eine geeignete Ballonfüllung. Verwenden Sie zum Aufblasen des Ballons weder Luft noch ein gasförmiges Mittel.
- Verwenden Sie zum Aufblasen nur einen 3-cc-Inflator mit Druckmesser.
- Verwenden Sie zur Deflation einen 3-cc-Inflator mit Druckmesser. (Zur schnelleren Deflation kann ein Inflator bis zu 10 cc mit Druckmesser verwendet werden.)
- Beim Katheter **SPT002 - 9,5 mm** darf der Einspritzdruck von 300 psi nicht überschritten werden.
- Beim Katheter **SPT003 - 13,5 mm** darf der Einspritzdruck von 600 psi nicht überschritten werden.
- Führen Sie den Führungsdraht, den Septostomie-Katheter bzw. andere Komponenten nicht ein, wenn Widerstand zu spüren ist, ohne vorher die Ursache zu ermitteln und geeignete Gegenmaßnahmen zu ergreifen.
- Dieser Katheter sollte nicht zur Druckmessung oder zum Einspritzen von Flüssigkeit verwendet werden.
- Dieses Produkt ist nur zum Einmalgebrauch vorgesehen. Nicht resterilisieren und/oder wiederverwenden, da sonst die Produktleistung beeinträchtigt werden kann und ein erhöhtes Kreuzkontaminationsrisiko besteht.
- Den Ballon nicht mit Gewalt über das Vorhofseptum ziehen.

VORSICHTSMASSNAHMEN

- NuMED empfiehlt, den Katheter **SPT002 - 9,5 mm** mit einer 5F-Einführschleuse zu verwenden, um das Einführen zu erleichtern.
- NuMED empfiehlt, den Katheter **SPT003 - 13,5 mm** mit einer 6F-Einführschleuse zu verwenden, um das Einführen zu erleichtern.
- Die Ballonatrioseptostomie sollte nur bei Säuglingen bis zum Alter von sechs Wochen durchgeführt werden. Diese Säuglinge haben ein dickes Vorhofseptum. Siehe Richtlinien der AHA/ACC.
- Die Dilatation sollte bei gleichzeitigem Durchleuchten/MRT mit einer geeigneten Vorrichtung erfolgen.
- Ein Führungsdraht ist ein zerbrechliches Instrument. Bei der Verwendung ist äußerste Vorsicht geboten, damit der Führungsdraht nicht bricht.
- Vor der Verwendung sind die Katheteranschlüsse auf ihre Dichtheit zu überprüfen und die gesamte Luft abzusaugen, damit keine Luft in das System gelangt.
- Unter keinen Umständen darf irgendein Teil des Kathetersystems eingeführt werden, wenn Widerstand zu spüren ist. Die Ursache für den Widerstand sollte per Durchleuchtung/MRT festgestellt werden. Anschließend sind die entsprechenden Maßnahmen zur Behebung des Problems zu ergreifen.
- Wenn beim Entfernen Widerstand zu spüren ist, sollte der Ballon samt Führungsdraht und Hülle herausgezogen werden. Dies empfiehlt sich vor allem dann, wenn der Ballon einen Riss hat oder undicht ist bzw. wenn dies der Fall sein könnte. Fassen Sie den Ballonkatheter samt Hülle fest an und ziehen Sie beides durch leichtes Drehen und gleichzeitiges Ziehen heraus.
- Vor dem Herausziehen des Katheters aus der Hülle muss der Ballon ganz entleert werden.
- Der Katheter funktioniert nur dann richtig, wenn er vollkommen intakt ist. Bei der Verwendung des Katheters ist Vorsicht geboten. Der Katheter kann durch Knicken, Dehnen oder zu starkes Abwischen beschädigt werden.



Angaben zur MRT-Sicherheit

Nichtklinische Tests haben gezeigt, dass die Ballonkathetersysteme von NuMED bedingt MR-sicher sind. Die folgende Kennzeichnung ist spezifisch für die Katheter von NuMED und gilt nicht für Führungsdrähte oder andere Zubehöriteile, die in Kombination mit den Ballonkathetersystemen von NuMED verwendet werden. Anwender sollten die Gebrauchsanweisung und die MRT-Sicherheitsinformationen anderer Zusatzprodukte, die mit den Kathetern von NuMED verwendet werden, konsultieren. Die Ballonkathetersysteme von NuMED können unter den folgenden Bedingungen bei 1,5 T oder 3,0 T an beliebigen Körperstellen gefahrlos gescannt werden. Nichteinhaltung dieser Bedingungen kann zu Verletzungen führen.

Parameter	Bedingung
Name des Produkts	Ballonkathetersysteme von NuMED
Statische Magnetfeldstärke (B0)	1,5 T und 3 T
Typ des MR-Scanners	Zylindrisch

Maximaler Raumfeldgradient	19 T/m (1900 G/cm)
HF-Anregung	Zirkuläre Polarisation (CP)
Typ der HF-Sendespule	Integrierte Ganzkörper-Sendespule
Betriebsmodus	Normaler Betriebsmodus
HF-Bedingungen	Maximale Ganzkörper-SAR: 2,0 W/kg
Scandauer	Ganzkörpergemittelte SAR von 2 W/kg während eines kontinuierlichen HF-Scans von 60 Minuten
Bildartefakte	Das Vorhandensein eines NuMED Ballonkatheters in Kombination mit einem bedingt MR-sicheren Führungsdraht von 0,035 Inch (0,889 mm) kann ein radiales Bildartefakt von 1,8 cm hervorrufen.

MÖGLICHE KOMPLIKATIONEN

Zu den möglichen Komplikationen und unerwünschten Nebenwirkungen im Zusammenhang mit der Anwendung und der Indikation gehören:

- Infektion
- Entzündung
- Thromboembolien
- Luftembolie
- Ballonabtrennung, die die anschließende Verwendung einer Schlinge erfordert.
- Gefäßperforation, die einen chirurgischen Eingriff erfordert.
- Rhythmus- und Leitungsstörungen
- Perforation des linken Vorhofanhangs
- Verletzung der Gefäßintima
- Blutung
- Blutergussbildung
- Verletzung des Reizleitungssystems
- Tod

Jeder schwerwiegende Vorfall, der im Zusammenhang mit dem Gerät aufgetreten ist, sollte NuMED und der zuständigen Behörde des Landes, in dem das Gerät verwendet wird, gemeldet werden.

ÜBERPRÜFUNG UND VORBEREITUNG

1. Führen Sie den Führungsdraht durch die distale Spitze ein, bis der Führungsdraht über den proximalen Anschluss hinausreicht.
2. Entfernen Sie den Ballonschutz. Überprüfen Sie den Katheter vor der Einführung auf etwaige Schäden.
3. Schließen Sie einen mit normaler Salzlösung halb gefüllten 3-cc-Inflator mit Druckmesser an den Absperrhahn an, der bereits am Ballonanschluss angebracht ist.
4. Entfernen Sie die Luft und spülen Sie den Durchlass des Katheters gründlich aus, und achten Sie dabei auf etwaige undichte Stellen.
5. Halten Sie den Inflator mit der Druckmesserdüse nach unten und saugen Sie die ganze Luft aus dem Ballon ab, bis im Kontrastmittel keine Blasen mehr zu sehen sind.
6. Drehen Sie den Absperrhahn zu, um das Vakuum im Ballon aufrechtzuerhalten.
7. Entfernen Sie den Führungsdraht.

EINFÜHRUNG: VASKULÄR

1. Bereiten Sie eine Mischung aus 30 % Kontrastmittel und normaler Salzlösung zu.
2. Bereiten Sie den Patienten für den Eingriff vor.
3. Katheter können perkutan oder über die Nabelvene eingeführt werden. Bei einem derartigen Eingriff ist für den Katheter **SPT002 - 9,5 mm** eine 5F-Einführschleusenhülle und für den Katheter **SPT003 - 13,5 mm** eine 6F-Einführschleusenhülle erforderlich (siehe Vorsichtsmaßnahmen). Wenn diese Methode nicht funktioniert, kann eine Venensektion durchgeführt werden.
4. Die Platzierung des Katheters kann unter Durchleuchtung/MRT-Führung oder unter besonderen Bedingungen unter zweidimensionaler echokardiographischer Führung erfolgen. Durch die Schleuse wird der Katheter in die untere Hohlvene und in den rechten Vorhof eingeführt. Die abgewinkelte Spitze erleichtert die Passage über die interatriale Öffnung zum linken Atrium. Bei Schwierigkeiten bei der Positionierung, kann ein 0,355 mm-Führungsdraht für den **SPT002 - 9,5 mm** Katheter oder ein 0,533 mm-Führungsdraht für den **SPT003 - 13,5 mm** Katheter verwendet werden, um eine sichere Positionierung zu erreichen. Der Führungsdraht sollte in den Katheterschaft zurückgezogen oder vollständig entfernt werden, bevor mit der Septostomie fortgefahren wird.
5. Die Ballon-Septostomie wird am sichersten unter Durchleuchtung, MRT oder 2-D-Echo durchgeführt. Der Ballon muss im linken Atrium gut identifiziert werden. Der Ballon des **SPT002 - 9,5 mm** Katheters wird mit 1cc Flüssigkeit aufgeblasen, der Ballon des **SPT003 - 13,5 mm** Katheters wird mit 2cc Flüssigkeit aufgeblasen und der Absperrhahn wird geschlossen. VORSICHT: Überschreiten Sie nicht das Volumen von 1cc für den **SPT002 - 9,5 mm** Katheter oder das Volumen von 2cc für den **SPT003 - 13,5 mm** Katheter. Übermäßiges Aufblasen kann zum Aufreißen des Ballons führen. Der Ballon wird dann mit einer schnellen, schnappenden Bewegung in den rechten Vorhof gezogen. Dieses Zugmanöver muss an der Verbindung zwischen der unteren Hohlvene und dem rechten Vorhof gestoppt und der Ballon schnell in den rechten Vorhof zurückgeführt werden (da der Ballon nicht konform ist, passt er sich nicht an die Form der IVC an und es besteht die Möglichkeit, dass er reißt). Entleeren Sie den Ballon sofort, indem Sie die Aufblasvorrichtung mit Manometer mit Unterdruck beaufschlagen (empfohlen werden 3cc, es sei denn, es wird eine schnellere Entleerung benötigt, dann kann eine Aufblasvorrichtung mit Manometer auf bis zu 10cc Druck verwendet werden).
Die Anwendung von übermäßiger Kraft, um den Ballon über die Vorhofscheidewand zu ziehen, muss vermieden werden. Insbesondere sollte der Arzt beim Ziehen des Ballons über das Septum nicht den gesamten Arm benutzen, sondern nur die Bewegung des Handgelenks. Wenn der Ballon bei dieser Methode das Septum nicht leicht durchquert, wird empfohlen, zunächst ein kleineres Flüssigkeitsvolumen zu verwenden. Die Flüssigkeitsmenge kann dann allmählich im Volumen erhöht werden, bis das gewünschte Ergebnis erreicht ist. Wenn die ersten beiden Schritte nicht erfolgreich sind, erwägen Sie eine stationäre Ballondilatation in der Vorhofscheidewand.
Bei Bedarf kann der Katheter im linken Atrium neu positioniert und der Vorgang wiederholt werden. Die Anzahl der wiederholten Septostomien, die während einer Katheterisierung durchgeführt werden, wird durch den klinischen Zustand des Patienten und die Abschätzung der effektiven Palliation bestimmt.
6. Den Katheter vorsichtig entfernen. Beim Austritt des Ballons aus dem Gefäß ist eine leichte, sanfte, gleichmäßige Bewegung anzuwenden. Wenn beim Entfernen Widerstand zu spüren ist, sollte der Ballon samt Führungsdraht und Schleuse unter Durchleuchtungs-/MRT-Führung herausgezogen werden. Dies empfiehlt sich vor allem dann, wenn der Ballon einen Riss hat oder undicht ist bzw. wenn dies der Fall sein könnte. Hierzu Ballonkatheter und Schleuse fest anfassen und mit einer leichten Drehbewegung zusammen herausziehen.
7. Üben Sie entsprechend dem Standardverfahren bzw. Krankenhausprotokoll für perkutane Gefäßeingriffe auf die Einführstelle Druck aus.
8. Entsorgen Sie das Gerät nach dem Gebrauch gemäß dem Standard-Krankenhausprotokoll für biogefährdende Geräte.

WARNUNG: NuMED Katheter kommen in einer äußerst aggressiven Umgebung im menschlichen Körper zum Einsatz. Katheter können aus verschiedenen Gründen wie beispielsweise aufgrund medizinischer Komplikationen oder infolge eines Katheterbruchs ausfallen. Außerdem können Katheter trotz sorgfältigster Konzeption, Komponentenauswahl, Fertigung und Erprobung vor dem Verkauf leicht vor, während oder nach der Einführung durch unsachgemäße Handhabung oder andere Eingriffe beschädigt werden. Folglich werden keinerlei Zusicherungen oder Garantien abgegeben, dass es zu keinem Versagen oder Ausfall des Katheters kommt.

oder dass durch Verwendung von Kathetern keine Nebenwirkungen oder medizinischen Komplikationen auftreten.

NuMED kann für NuMED Zubehörteile keinerlei Garantie gewähren, da die Zubehörteile durch unsachgemäße Handhabung vor oder während der Verwendung beschädigt werden können. Aus diesem Grund werden für Zubehörteile keinerlei Zusicherungen oder Garantien abgegeben.

Garantie und Haftungsbeschränkung

Katheter und Zubehörteile werden ohne Gewähr verkauft. Der Käufer trägt das gesamte Risiko hinsichtlich der Qualität und Leistungsfähigkeit der Katheter. NuMED schließt alle ausdrücklichen oder stillschweigenden Garantien im Zusammenhang mit den Kathetern und Zubehörteilen einschließlich, aber nicht beschränkt auf die Gewährleistung der Eignung für den gewöhnlichen Gebrauch oder der Eignung für einen bestimmten Zweck aus. NuMED übernimmt keinerlei Haftung für medizinische Ausgaben bzw. unmittelbare Schäden oder Folgeschäden, die durch die Verwendung eines Katheters bzw. Zubehörteils oder einen Defekt, einen Ausfall oder eine Funktionsstörung eines Katheters oder Zubehörteils entstehen, wobei es keine Rolle spielt, ob sich eine etwaige Schadenersatzforderung auf die Garantie, einen Vertrag, eine unerlaubte Handlung oder sonstiges bezieht. Niemand ist berechtigt, im Namen von NuMED im Zusammenhang mit Kathetern und Zubehörteilen verbindliche Zusicherungen oder Garantien abzugeben.

Z-5™ Ballongrößentabelle
SPT002 - 9,5 mm - Ballongrößentabelle

Einspritz-Volumen	Entsprechender Ballondurchmesser	Einspritz- Volumen	Entsprechender Ballondurchmesser
0,7 cc	7,95 mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00 mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

SPT003 - 13,5 mm - Ballongrößentabelle

Einspritz-Volumen	Entsprechender Ballondurchmesser	Einspritz- Volumen	Entsprechender Ballondurchmesser
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

ESPAÑOL

Instrucciones de utilización

INDICACIONES

Recomendado para atrioseptostomía con balón, una técnica aceptada en la mayoría de los centros pediátricos para la mitigación de varias cardiopatías congénitas. La atrioseptostomía con balón se realiza en conjunto con la cateterización cardiaca de diagnóstico y se ha llevado a cabo después del diagnóstico de varias cardiopatías congénitas: transposición de las arterias principales, drenaje venoso pulmonar totalmente anómalo sin obstrucción pulmonar, atresia tricúspide, estenosis mitral, atresia mitral y atresia pulmonar con septo ventricular intacto. El catéter **SPT002 - 9,5 mm** está primordialmente diseñado para bebés con un peso inferior a 2 kg.

DESCRIPCIÓN DEL CATÉTER

El catéter de atrioseptostomía NuMED es un nuevo catéter de balón diseñado para niños recién nacidos con cardiopatías congénitas que requieren septostomía. Es un catéter de dos vías, de 50 cm de longitud. El catéter **SPT002** tiene un balón no amoldable de 9,5 mm ± 0,5 mm, a un volumen de 1,0 cc, en el extremo distal. El catéter **SPT003** tiene un balón no amoldable de 13,5 mm ± 0,5 mm, a 2,0 cc de volumen, en el extremo distal. El catéter **SPT002 - 9,5 mm** tiene también un orificio terminal que admite una guía de 0,014" (0,3556 mm), y el catéter **SPT003 - 13,5 mm** tiene un orificio terminal adecuado para una guía de 0,018" (0,4572 mm) a 0,021" (0,5334 mm). La forma geométrica del balón inflado es una esfera. Hay una franja de imagen debajo del balón para su ubicación en la aurícula izquierda. La punta del catéter forma un ángulo de 35° para facilitar su paso a través de la abertura interatrial en la aurícula izquierda. Para inflar el balón del catéter **SPT002 - 9,5 mm** hasta su diámetro máximo, se introduce 1 cc de medio de contraste diluido en la extensión del balón después del vaciado. Para inflar el balón del catéter **SPT003 - 13,5 mm** hasta su diámetro máximo, se introducen 2 cc de medio de contraste diluido en la extensión del balón después del vaciado. Los catéteres se suministran con una llave de paso de una vía para el sellado del balón.

CÓMO SE SUMINISTRA

Se suministra esterilizado con gas de óxido de etileno. Estéril y apirógeno si el paquete está sin abrir y sin daños. No usar el producto si existe la duda de si está esterilizado. Evitar la exposición prolongada a la luz. Después de sacarlo del paquete, inspeccionar el producto para asegurarse de que no se ha producido daño alguno.

ADVERTENCIA

- ATENCIÓN: No exceda del volumen nominal de 1 cc para el catéter **SPT002 - 9,5 mm**. El inflado excesivo puede producir la rotura del balón.
- ATENCIÓN: No exceda del volumen nominal de 2 cc para el catéter **SPT003 - 13,5 mm**. El inflado excesivo puede producir la rotura del balón.
- Utilice sólo el medio de inflado adecuado para el balón. No utilice aire o un medio gaseoso para inflar el balón.
- Utilice sólo un dispositivo de inflado de 3 cc con indicador de presión para inflar el balón.
- Utilice sólo un dispositivo de inflado de 3 cc con indicador de presión para desinflar el balón. (Para desinflar más rápidamente el balón se puede utilizar un dispositivo de inflado de hasta 10 cc con indicador de presión).
- No sobrepase una presión de inyección de 300 psi para el catéter **SPT002 - 9,5 mm**.
- No sobrepase una presión de inyección de 600 psi para el catéter **SPT003 - 13,5 mm**.
- Si siente resistencia, no haga avanzar la guía, el catéter de septostomía o cualquier otro componente sin determinar primero la causa y tomar las medidas necesarias para resolver el problema.
- No se recomienda utilizar este catéter para medición de presión o inyección de fluidos.
- Este dispositivo es de un solo uso. No lo reesterilice ni reutilice, ya que puede poner en peligro el rendimiento del dispositivo y aumentar el riesgo de contaminaciones.
- Debe evitarse aplicar demasiada fuerza para empujar el globo por el tabique interauricular.

PRECAUCIONES

- NuMED recomienda utilizar el catéter **SPT002 - 9,5 mm** con un introductor de 5F para asegurar el acceso.

- NuMED recomienda utilizar el catéter **SPT003 - 13,5 mm** con un introductor de 6F para asegurar el acceso.
- No se debe realizar atroseptostomía de balón en bebés mayores de seis semanas. Estos bebés tienen septos auriculares gruesos. Consulte las normas de la AHA/ACC.
- Los procedimientos de dilatación se deben realizar bajo radioscopia o imagen por RM con equipos adecuados.
- Las guías son instrumentos delicados. Se debe tener mucho cuidado al manipularlas para evitar posibles roturas.
- Se debe prestar especial atención al mantenimiento de conexiones de catéter ajustadas y a la aspiración antes de seguir con el procedimiento para evitar la entrada de aire en el sistema.
- Bajo ninguna circunstancia se debe hacer avanzar ninguna parte del sistema del catéter si se siente resistencia. Se debe identificar la causa de la resistencia mediante radioscopia o imagen por RM y adoptar medidas para resolver el problema.
- Si se siente resistencia durante la extracción, se deben extraer el balón, la guía y la funda como una unidad, especialmente si se ha detectado o se sospecha una posible rotura o fuga del balón. Eso se puede realizar tomando con firmeza el catéter de balón y la funda como una unidad y retirándolos juntos, aplicando un suave movimiento de torsión combinado con tracción.
- Para extraer el catéter de la funda es muy importante que el balón esté completamente desinflado.
- El funcionamiento adecuado del catéter depende de su integridad. Se debe tener cuidado al manipular el catéter. Se pueden producir daños al doblar, estirar o frotar con fuerza el catéter.

	Información de seguridad sobre la resonancia magnética
Las pruebas no clínicas han demostrado que los sistemas de catéter balón de NuMED son compatibles con RM bajo ciertas condiciones. El siguiente etiquetado es específico para los catéteres de NuMED y no se aplica a las guías u otros accesorios utilizados en combinación con los sistemas de catéter balón de NuMED. Los usuarios deben consultar las instrucciones de uso y la información de seguridad de RM de otros productos complementarios utilizados con los catéteres de NuMED. Los sistemas de catéter balón de NuMED pueden escanearse de forma segura en cualquier lugar del cuerpo a 1,5 T o 3,0 T, en las siguientes condiciones. El incumplimiento de estas condiciones puede dar lugar a lesiones.	
Parámetro	Condición
Nombre del producto	Sistemas de catéter balón de NuMED
Intensidad de campo magnético estático (B0)	1,5 T y 3 T
Tipo de escáner de RM	Cilíndrico
Gradiente de campo espacial máximo	19 T/m (1900 G/cm)
Excitación por RF	Circular polarizada (CP)
Tipo de bobina de transmisión de RF	Bobina de transmisión de cuerpo entero integrada
Modo de funcionamiento	Modo de funcionamiento normal
Condiciones de RF	SAR de cuerpo entero máximo: 2,0 W/kg
Duración de la exploración	SAR promedio de cuerpo entero de 2 W/kg durante 60 minutos de exploración de RF continua
Artefactos de imagen	La presencia de un catéter balón de NuMED en combinación con una guía de 0,035" (0,889 mm) segura bajo ciertas condiciones de la resonancia magnética puede producir un artefacto radial en la imagen de 1,8 cm.

COMPLICACIONES POTENCIALES

Posibles complicaciones y efectos adversos asociados con el uso y las indicaciones del producto:

- Infección
- Inflamación
- Episodios tromboembólicos
- Embolia aérea
- Posible separación del balón con necesidad posterior de aplicar un procedimiento de extracción con cordón metálico
- Perforación vascular que requiera corrección quirúrgica
- Alteraciones de ritmo y conducción
- Perforación del apéndice auricular izquierdo
- Lesión de la íntima vascular
- Hemorragia
- Formación de hematomas
- Lesión del sistema de conducción
- Muerte

Cualquier incidente grave que haya ocurrido en relación con el producto debe notificarse a NuMED y a la autoridad competente en el país donde se utilice el producto.

INSPECCIÓN Y PREPARACIÓN

- Inserte la guía a través del extremo distal hasta que sobrepase el puerto próximo.
- Extraiga el protector del balón. Inspeccione el catéter para descartar daños antes de la inserción.
- Coloque un dispositivo de inflado de 3 cc con indicador de presión lleno hasta la mitad con solución salina normal en la llave de paso, ya colocada en el puerto del balón.
- Vacíe y enjuague el catéter a fondo a través de la vía, para detectar fugas.
- Orienté el dispositivo de inflado con la boquilla del indicador de presión hacia abajo, aspire hasta eliminar todo el aire del balón y ya no aparezcan burbujas en el medio de contraste.
- Cierre la llave de paso para mantener el vacío dentro del balón.
- Extraiga la guía.

INSERCIÓN: VASCULAR

- Prepare una mezcla al 30% del volumen de medio de contraste y solución salina normal.
- Prepare al paciente para el procedimiento.
- Los catéteres se pueden introducir por método percutáneo o a través de la vena transumbilical. El catéter **SPT002 - 9,5 mm** requiere una funda de introductor de 5F, el catéter **SPT003 - 13,5 mm** requiere una funda de introductor de 6F (consulte la sección Precauciones) si se utiliza este método. Si esta técnica de acceso fallara, podría realizarse un corte venoso.
- La colocación del catéter puede realizarse bajo radioscopia o imagen por RM, o en condiciones especiales mediante guiado ecocardiográfico bidimensional. Una vez que el catéter esté colocado en la vaina, se hace pasar a la vena cava inferior y a la aurícula derecha. La punta en ángulo facilita el paso a través de la abertura interauricular a la aurícula izquierda. Si hay dificultades durante la colocación, puede utilizarse una guía de 0,035 cm (0,014") para el catéter **SPT002 de 9,5 mm** o una guía de 0,053 cm (0,021") para el catéter **SPT003 de 13,5 mm** para lograr una colocación segura. La guía debe retraerse hacia atrás al interior del cuerpo del catéter, o debe retirarse por completo antes de continuar con la septostomía.
- La septostomía con balón se realiza con mayor seguridad bajo radioscopia, RM o ecografía 2D. El balón debe estar bien identificado en la aurícula izquierda. El balón del catéter **SPT002 de 9,5 mm** se infla con 1 cc de líquido y el balón del catéter **SPT003 de 13,5 mm** se infla con 2 cc de líquido, y se cierra la llave de paso. AVISO: No exceda el volumen de 1 cc para el catéter **SPT002 de 9,5 mm** o el volumen de 2 cc para el catéter **SPT003 de 13,5 mm**. Un inflado excesivo puede producir la ruptura del balón. A continuación, el balón se introduce en la aurícula derecha con un movimiento rápido de encaje. Esta maniobra de tracción debe detenerse en la unión entre la vena cava inferior y la aurícula derecha, y el balón debe hacerse avanzar de nuevo rápidamente dentro de la aurícula derecha (dado que el balón no es distensible, no se ajustará a la forma de la VCI y es posible que se rompa). Desinfele el balón inmediatamente aplicando presión negativa al dispositivo de inflado con un

manómetro (se recomienda un volumen de 3 cc a menos que sea necesario un desinflado más rápido; después puede utilizarse un volumen de 10 cc si se utiliza un dispositivo de inflado con manómetro).

Se debe evitar aplicar una fuerza excesiva para tirar del balón a través del tabique auricular. En concreto, el médico debe evitar usar todo su brazo al tirar del balón a través del tabique; en su lugar, debe utilizar solo el movimiento de la muñeca. Si el balón no cruza fácilmente el tabique con este método, se recomienda utilizar un volumen menor de líquido al inicio. El volumen de líquido puede aumentarse gradualmente hasta que se logre el resultado deseado. Si los dos primeros pasos no tienen éxito, considere realizar una dilatación estática con balón del tabique auricular.

Si es necesario, el catéter puede recolocarse en la aurícula izquierda y el proceso puede repetirse. El número de septostomías repetidas realizadas durante un cateterismo viene determinado por el estado clínico del paciente y la estimación de la terapia efectiva.

- Extraiga con cuidado el catéter. A medida que el balón vaya saliendo del vaso, utilice un movimiento suave, cuidadoso y continuo. Si se siente resistencia durante la extracción, debe extraerse conjuntamente el balón, la guía y la vaina mediante radioscopia o imagen por RM, especialmente si se ha detectado o se sospecha una posible rotura o fuga del balón. Para extraerlos, sujete con firmeza el catéter balón y la vaina y retírelos juntos, aplicando un suave movimiento de torsión combinado con tracción.
- Aplique presión en el sitio de inserción según la práctica estándar o el protocolo hospitalario para procedimientos vasculares percutáneos.
- Deseche el dispositivo después de utilizarlo de acuerdo con el protocolo estándar del hospital relativo a productos que presenten un riesgo biológico.

ADVERTENCIA: Los catéteres NuMED se colocan en el entorno extremadamente hostil del cuerpo humano. El funcionamiento de los catéteres puede fallar debido a varias razones, entre las que se incluyen, entre otras, las complicaciones médicas o el fallo de los catéteres por rotura. Además, aun cuando se apliquen las máximas precauciones en cuanto al diseño, selección de componentes, fabricación y ensayos antes de la venta, los catéteres se pueden dañar con facilidad antes, durante o después de la inserción debido a una manipulación incorrecta u otras acciones. En consecuencia, no se declara ni se garantiza que no se producirá fallo o parada de funcionamiento de los catéteres, o que el cuerpo no reaccionará de forma adversa frente a la colocación de catéteres, o que no se producirán complicaciones médicas después de su utilización.

NuMED no puede garantizar los accesorios NuMED debido a que la estructura de los accesorios se puede dañar por manipulación no adecuada antes o durante su utilización. Por lo tanto, no se hacen declaraciones ni se concede garantía con relación a los accesorios.

Garantía y limitaciones

Los catéteres y accesorios se venden "tal cual están". El comprador asume completamente el riesgo con relación a la calidad y rendimiento del catéter. NuMED no concede ningún tipo de garantía, tanto expresa como implícita, con relación a los catéteres y accesorios, incluyendo, entre otras, toda garantía implícita de comerciabilidad o aptitud para un propósito determinado. NuMED no se hará responsable ante ninguna persona de ningún gasto médico, daño directo o perjuicio resultante de la utilización de un catéter o accesorio, o causados por defectos, fallos o por el mal funcionamiento de un catéter o accesorio, sin tener en cuenta si la demanda por tales daños y perjuicios se basa en garantías, contratos, agravios u otro motivo. Ninguna persona tendrá autoridad para vincular a NuMED con relación a declaraciones o garantías sobre catéteres o accesorios.

Tabla de medidas del balón Z-5™
Tabla de medidas del balón SPT002 - 9,5 mm

Volumen inyectado	resultante del balón Diámetro	inyectado Volumen	resultante del balón Diámetro
0,7 cc	7,95 mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00 mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

Tabla de medidas del balón SPT003 - 13,5 mm

Volumen inyectado	resultante del balón Diámetro	inyectado Volumen	resultante del balón Diámetro
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

SVENSKA

Bruksanvisning

INDIKATIONER

Rekommenderas för ballongatriseptostomi, som utgör ett accepterat förfarande vid de flesta pediatriiska kardiologiceentra för lindring av flera olika medfödda hjärtdefekter. Ballongatriseptostomi utförs tillsammans med diagnostisk hjärkatetrisering, och har genomförts efter diagnos av flera medfödda hjärtdefekter: transposition av de stora artärerna, fullständigt onormalt venöst lungdränage utan pulmonär obstruktion, trikuspidalatri, mitral stenos, mitral atri och pulmonär atri med intakt ventrikulär septum. **SPT002 - 9,5 mm** är i första hand avsedd för spädbarn som väger mindre än 2 kg.

KATETERBESKRIVNING

NuMED:s atrioseptostomikateter är en ny ballongkateter, som är avsedd för neonatala patienter med medfödd hjärtsjukdom som kräver septostomi. Det är en dubbellumenkateter med en längd på 50 cm. **SPT002** har en icke-eftergivlig ballong på 9,5 mm ± 0,5 mm, vid en volym på 1,0 cc, i den distala änden. **SPT003** har en icke-eftergivlig ballong på 13,5 mm ± 0,5 mm, vid en volym på 2,0 cc, i den distala änden. **SPT002 - 9,5 mm**-katetern har dessutom ett ändhål dimensionerat för en ledare på 0,014 tum, och **SPT003 - 13,5 mm**-katetern har dessutom ett ändhål dimensionerat för en ledare på 0,018-0,021 tum. Efter uppblåsning är ballongen sfärisk. Det finns ett avbildningsband under ballongen för ballongplacering i vänster förmak. Kateterspetsen är vinklad i 35° för att underlätta passage genom den interatriella öppningen i vänster förmak. För att blåsa upp ballongen på **SPT002 - 9,5 mm**-katetern till dess maximala diameter trycks 1 cc utspätt kontrastmedel in i ballongförlängningen efter luftning. För att blåsa upp ballongen på **SPT003 - 13,5 mm**-katetern till dess maximala diameter trycks 2 cc utspätt kontrastmedel in i ballongförlängningen efter luftning. Kateterna är försedda med en envägskran för ballongtätning.

PRODUKTFINFORMATION

Produkten levereras steriliserad med etylenoxid. Steril och icke-pyrogen om förpackningen är öppnad och oskadad. Använd inte produkten om det råder tveksamhet om dess sterilitet. Undvik längre exponering för ljus. Granska produkten i samband med uppackningen för att säkerställa att den inte skadats.

VARNING

- FÖRSIKTIGHET: Överskrid inte den nominella volymen 1 cc för **SPT002 - 9,5 mm-** katetern. Överupplåsning kan leda till ballongbristning.
- FÖRSIKTIGHET: Överskrid inte den nominella volymen 2 cc för **SPT003 - 13,5 mm-** katetern. Överupplåsning kan leda till ballongbristning.
- Använd endast det ballongupplåsningsmedel som rekommenderas. Blås aldrig upp ballongen med luft eller något medel i gasform.
- Använd endast en upplåsningsanordning på 3 cc med tryckmätare för upplåsningen.
- Använd en upplåsningsanordning på 3 cc med tryckmätare för tömningen. (För snabbare tömning kan en upplåsningsanordning på upp till 10 cc användas.)
- Överskrid inte ett ijiceringsstryck på 300 psi för **SPT002 - 9,5 mm-**katetern.
- Överskrid inte ett ijiceringsstryck på 600 psi för **SPT003 - 13,5 mm-**katetern.
- För inte fram ledaren, septostomikatetern eller någon annan komponent om ett motstånd kan kännas, utan att först ta reda på orsken till motståndet och vidta åtgärder.
- Denna kateter rekommenderas inte för tryckmätning eller vätskeinjektion.
- Denna anordning är endast avsedd för engångsbruk. Får ej resteriliseras och/eller återanvändas eftersom detta potentiellt kan leda till att anordningens funktion äventyras samt ökad risk för korskontamination.
- Undvik att använda alltför stark kraft för att dra ballongen över förmaksstillväggen.

FÖRSIKTIGHETSÅTGÄRDER

- NuMED rekommenderar att **SPT002 - 9,5 mm-**katetern används med en 5F-introducer för att säkerställa tillträde.
- NuMED rekommenderar att **SPT003 - 13,5 mm-**katetern används med en 6F-introducer för att säkerställa tillträde.
- Ballongatrioseptostomi ska inte utföras på barn som är äldre än sex veckor, eftersom sådana barn har grova atriella septum. Se AHA / ACC-riktlinjerna.
- Dilatationsprocedurer ska utföras under fluoroskopisk/MRT-vägledning med lämplig utrustning.
- Ledare är känsliga instrument. Var försiktig vid hanteringen så att de inte går sönder.
- Var noga med att kontrollera att alla kateteranslutningar är åtdragna, och med aspiration, före förfarandet så att det inte kommer in luft i systemet.
- Ingen del av katetersystemet får under några som helst förhållanden föras fram mot ett motstånd. Orsaken till motståndet ska fastställas med fluoroskopi/MRT och åtgärder ska vidtas för att avhjälpa problemet.
- Om ett motstånd kan kännas vid uttagning ska ballongen, ledaren och skyddet tas ut tillsammans som en enhet, i synnerhet vid ballongbristning eller ballongläckage, eller om bristning eller läckage misstänks. Det gör man genom att ta ett stadigt tag om ballongen och skyddet tillsammans, och sedan ta ut båda tillsammans med en lätt vridrörelse samtidigt som man drar.
- Det är viktigt att ballongen är helt tömd innan den tas ut ur skyddet.
- För att katetern ska fungera på avsett sätt måste den vara hel. Var försiktig vid hantering av katetern. Skador kan uppkomma till följd av böjning eller sträckning av katetern, eller på grund av kraftig avtorkning av den.

 MR-säkerhetsanvisningar	
Icke-kliniska tester har visat att ballongkatetersystem från NuMED är MR-villkorliga. Följande märkning gäller endast för katetrar från NuMED och gäller inte ledare eller andra tillbehör som används tillsammans med ballongkatetersystem från NuMED. Användare ska läsa bruksanvisningarna och MR-säkerhetsanvisningarna till andra tillbehörsenheter som används tillsammans med katetrar från NuMED. Ballongkatetersystem från NuMED kan säkert skannas överallt i kroppen vid 1,5 T eller 3,0 T under följande villkor. Om dessa villkor inte följs kan det resultera i skada.	
Parameter	Tillstånd
Produktnamn	Ballongkatetersystem från NuMED
Statisk magnetisk fältstyrka (B0)	1,5 T och 3 T
Typ av MR-skanner	Cylindrisk
Maximal spatial fältgradient	19 T/m (1 900 G/cm)
RF Excitation	Cirkulärt polariserad (CP)
Typ av RF-överföringsspole	Integrerad överföringsspole för helkropp
Driftläge	Normalt driftläge
RF-villkor	Maximal helkropp-SAR: 2,0 W/kg
Skanningsduration	2 W/kg genomsnittlig specifik absorptionsnivå (SAR) för hela kroppen under 60 minuters kontinuerlig RF-skanning
Bildartefakt	Förekomsten av en NuMED-ballongkateter i kombination med en 0,035 tum (0,089 cm) MR-villkorad ledare kan ge en radial bildartefakt på 1,8 cm.

MÖJLIGA KOMPLIKATIONER

Möjliga komplikationer och biverkningar i samband med användning av enheten och dess indikationer omfattar:

- Infektion
- Inflammation
- Tromboemboliska händelser
- Luftemboli
- Potentiell ballongseparation som medför att snara behöver användas
- Vaskulär perforation som kräver kirurgisk reparation
- Rytm- och ledningsstörningar
- Perforation av vänster atriella bihang
- Skada på den vaskulära intiman
- Blödning
- Hematombildning
- Skador på ledningssystemet
- Dödsfall

Alla allvariga händelser som har inträffat i samband med enheten ska rapporteras till NuMED och till behörig myndighet i det land där den använts.

BESIKTNING OCH FÖRBEDRANDE

- För in ledaren genom den distala spetsen tills den kommer ut genom den proximala utgången.
- Ta bort ballongskyddet. Besiktiga katetern med avseende på skador innan den förs in.
- Anslut en upplåsningsanordning på 3 cc med tryckmätare, till hälften fylld med normal saltlösning. Anslut den till kranen som redan anslutits till ballongutgången.
- Lufta och spola katetern omsorgsfullt fenom lumen och kontrollera om det förekommer några läckor.
- Vänd munstycket på upplåsningsanordningen med tryckmätare nedåt och aspirera tills all luft är borta från ballongen, och det

- inte längre finns några bubblor i kontrastmedlet.
6. Stäng kranen för att bibehålla vakuumet i ballongen.
7. Ta bort ledaren.

INFÖRANDE: VASKULÄRT:

1. Gör iordning en 30-procentig (volymprocent) blandning av kontrastmedel och vanlig saltlösning.
2. Förbered patienten för förbandet.
3. Katetrar kan införas med perkutana metoder eller via transumbilikalvenen. **SPT002 – 9,5 mm**-katetrar kräver ett införingsskydd på 5F och **SPT003 – 13,5 mm**-katetrar kräver ett införingsskydd på 6F (se Försiktighetsåtgärder) när denna metod används. Om denna åtkomstteknik misslyckas kan ett venöst snitt användas.
4. Placeringen av katetern kan åtföljas av fluoroskopisk/MRT-vägledning eller, under vissa omständigheter, med tvådimensionell ekokardiografisk vägledning. När katetern är igenom hylsan förs den in i den nedre hälven och in i höger förmak. Den vinklade spetsen underlättar passagen genom öppningen mellan förmaken och in till vänster förmak. Om det är svårt att placera, kan säker placering uppnås genom att använda en 0,014 inch (0,035 cm) ledare för katetern **SPT002 – 9,5 mm** eller en 0,021 inch (0,053 cm) ledare för katetern **SPT003 – 13,5 mm**. Ledaren ska dras tillbaka in i kateterskaflet eller avlägsnas helt innan man fortsätter med septostomi.
5. Ballongseptostomi utförs säkrast under fluoroskopi, MRT eller 2D-eko. Ballongen måste vara tydligt identifierad i vänster förmak. Ballongen på katetern **SPT002 – 9,5 mm** fylls med 1 ml vätska, ballongen på katetern **SPT003 – 13,5 mm** fylls med 2 ml vätska och kranen stängs. VAR FÖRSIKTIG! Överskrid inte volymen 1 ml för katetern **SPT002 – 9,5 mm** eller volymen 2 ml för katetern **SPT003 – 13,5 mm**. Överfyllning kan göra att ballongen spricker. Ballongen dras sedan in i höger förmak med en snabb, snäppande rörelse. Den här dragrörelsen måste stoppas vid förbindningen mellan den nedre hälven och höger förmak och ballongen snabbt åter förs fram in i höger förmak (eftersom ballongen inte är eftergivlig kommer den inte att anpassas till den nedre hälvens form och det finns risk för revor). Töm ballongen omedelbart genom att applicera undertryck i påfyllningsenheten med tryckmanometer (3 ml rekommenderas såvida inte snabbare tömning krävs, i vilket fall en påfyllningsenhet med tryckmanometer på upp till 10 ml kan användas).
För stor kraft när ballongen dras genom förmaksseptum måste undvikas. I synnerhet måste kirurgen undvika att använda hela armen när ballongen dras genom septum och ska i stället endast använda handledens rörelse. Om ballongen inte passerar lätt igenom septum med den här metoden rekommenderas att en mindre vätskevolym används initialt. Mängden vätska kan sedan gradvis ökas tills önskat resultat uppnått. Om de första två stegen inte lyckas ska statisk ballongdilatation av förmaksseptum övervägas.
Om så krävs kan katetern placeras om i vänster förmak och proceduren upprepas. Antalet upprepade septostomier som kan utföras under en kateterisering bestäms av patientens kliniska status och hur effektiv lindringen uppskattas vara.
6. Avlägsna försiktigt katetern. Använd en jämn, mjuk, stadig rörelse medan ballongen kommer ut ur kärlet. Om ett motstånd känns av vid avlägsnandet ska ballongen, ledaren och hylsan avlägsnas tillsammans som en enda enhet under fluoroskopisk/MRT-vägledning, i synnerhet om man vet eller misstänker att ballongen har brutit eller läcker. Detta kan göras genom att fatta ett stadigt tag om ballongkatetern och hylsan som en enda enhet och sedan avlägsna dem båda tillsammans, med en lätt vridrörelse i kombination med dragning.
7. Applicera ett tryck mot införingspunkten enligt sjukhusets normala principer för perkutana vaskulärförfaranden.
8. Kassera enheten enligt normala sjukhusrutiner för biologiskt avfall efter användning.

VARNING: NuMED:s katetrar placeras i den extremt förtäta miljö som människokroppen utgör. Det finns många orsaker till att katetrar inte fungerar, däribland, men inte begränsat till, medicinska komplikationer eller kateterbrott. Trots att tillämplig omsorg vid konstruktion, komponentval, tillverkning och testning före försäljningen kan katetrar lätt skadas före, under och efter införande till följd av felaktig hantering eller andra mellankommande skeenden. Därför lämnas inga utfästelser eller garantier om att katetrar eventuellt inte fungerar, eller upphör att fungera, eller om att kroppen inte kommer att reagera negativt på placering av katetrar, eller om att medicinska komplikationer inte kommer att följa på användning av katetrar.

NuMED lämnar inga garantier för NuMED-tillbehören eftersom tillbehörens strukturer kan skadas av felaktig hantering före eller under användning. Därför lämnas inga garantier med avseende på dem.

Garanti och garantibegränsningar

Katetrarna och tillbehören säljs i "befintligt skick". Köparen tar hela risken med avseende på katetrarnas kvalitet och prestanda. NuMED fransäger sig därför allt ansvar, uttryckligt eller underförstått, med avseende på katetrar och tillbehör, innefattande men inte begränsat till varje underförstått ansvar med avseende på säljarjet eller lämplighet för en viss användning. NuMED är inte ansvariga gentemot någon person för eventuella sjukvårdskostnader, eller för direkta skador eller följdskador, som uppkommer till följd av användning av en kateter eller ett tillbehör, eller som orsakats av en defekt, ett fel eller en felfunktion hos en kateter eller ett tillbehör, vare sig sådant ersättningsanspråk grundar sig på garanti, kontrakt, otillåten handling eller någonting annat. Ingen person äger rätt att binda NuMED till någon garanti eller framställning med avseende på katetrar och tillbehör.

Z-5™ - ballongstorleksdiagram
SPT002 - 9,5 mm - ballongstorleksdiagram

Injicerad volym	Resulterande ballong- diameter	Injicerad volym	Resulterande ballong- diameter
0,7 cc	7,95 mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00 mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

SPT003 - 13,5 mm - ballongstorleksdiagram

Injicerad volym	Resulterande ballong- diameter	Injicerad volym	Resulterande ballong- diameter
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

Brugsanvisning

INDIKATIONER

Anbefalet til ballon-atrieseptostomi – en accepteret teknik i de fleste pædiatrisk kardiologiske afdelinger til lindring af forskellige medfødte hjertedefekter. Ballon-atrieseptostomi udføres sammen med diagnostisk hjertekateterisation og er blevet udført efter diagnose af forskellige medfødte hjertedefekter: transposition af de store arterier, total anomal lungenevnedrænage uden pulmonal obstruktion, trikuspidalatri, mitral stenose, mitral atresi og pulmonal atresi med intakt ventrikulær septum. Et **SPT002 - 9,5 mm** er primært til nyfødte, der vejer mindre end 2 kg.

KATETERBESKRIVELSE

NuMED atriaseptostomikatetret er et nyt ballonkatetret designet til nyfødte med medfødte hjertesygdomme, der kræver septostomi. Det er et duallumen katetret, 50 cm langt. **SPT002** katetret har en 9,5 mm $\pm$ 0,5 mm non-compliant ballon med en volumen på 1,0 cc (1 cm³) i den distale ende. **SPT003** katetret har en 13,5 mm $\pm$ 0,5 mm non-compliant ballon med en volumen på 2,0 cc (2 cm³) i den distale ende. **SPT002 - 9,5 mm** katetret er udstyret med et endehul til en 0,014" (0,3556 mm) guidewire, **SPT003 - 13,5 mm** katetret er udstyret med et endehul til en 0,018 til 0,021" (0,4572 mm til 0,5334 mm) guidewire. Den insufflerede ballon har form som en sfære. Der findes et billeddannende bånd under ballonen til placering af ballonen i venstre atrium. Kateterspidsen er drejet til en vinkel på 35° for at gøre indføring i den interatriale åbning i venstre atrium lettere. Ballonen i **SPT002 - 9,5 mm** katetret insuffleres til den maksimale diameter ved at skubbe 1,0 cc (1 cm³) fortyndet kontrastmiddel ind i ballonforlængelsen efter udtømmning. Ballonen i **SPT003 - 13,5 mm** katetret insuffleres til den maksimale diameter ved at skubbe 2,0 cc (2 cm³) fortyndet kontrastmiddel ind i ballonforlængelsen efter udtømmning. Katetrene er udstyret med en envejsstopphane til ballon.

LEVERES

Leveres steriliseret med etylenoxidgas. Steril og ikke-pyrogen, hvis emballagen er uåbnet og ubeskadiget. Produktet må ikke bruges, hvis der er tvivl om dets sterilitet. Undgå længere udsættelse for lys. Efter produktet er taget ud af emballagen, skal det inspiceres for at sikre, at det ikke er blevet beskadiget.

ADVARSEL

- **FORSIGTIG:** Den nominelle volumen på 1 cc (1 cm³) for **SPT002 - 9,5 mm** katetret må ikke overstiges. Overdreven insufflering kan forårsage ballonruptur.
- **FORSIGTIG:** Den nominelle volumen på 2 cc (2 cm³) for **SPT003 - 13,5 mm** katetret må ikke overstiges. Overdreven insufflering kan forårsage ballonruptur.
- Der bør kun anvendes passende ballon-insuffleringsmiddel. Anvend ikke luft eller et gasformigt middel til insufflering af ballonen.
- Anvend kun et 3 cc (3 cm³) insuffleringsapparat med trykmåler.
- Et 3 cc (3 cm³) insuffleringsapparat med trykmåler skal anvendes til desufflering. (Ønskes hurtigere desufflering, kan insuffleringsudstyr med trykmåler op til 10 cc (10 cm³) anvendes).
- Overstig ikke et injektionstryk på 300 psi for **SPT002 - 9,5 mm** katetret.
- Overstig ikke et injektionstryk på 600 psi for **SPT003 - 13,5 mm** katetret.
- Fremfør ikke guidewiren, septostomikatetret eller nogen anden del under modstand uden først at bestemme og afhjælpe årsagen.
- Dette kateter anbefales ikke til trykmåling eller væskeinjektion.
- Dette instrument er kun beregnet til engangsbrug. Det må ikke steriliseres igen og/eller genbruges, da dette kan medføre en kompromitteret ydeevne og øge risikoen for krydskontaminering.
- Det skal undgås at bruge voldsom kraft til at trække ballonen på tværs af atriaseptum.

FORHOLDSREGLER

- NuMED anbefaler, at **SPT002 - 9,5 mm** katetret anvendes med en 5F introducer for at sikre indlæggelsen.
- NuMED anbefaler, at **SPT003 - 13,5 mm** katetret anvendes med en 6F introducer for at sikre indlæggelsen.
- Ballon-atrieseptostomi bør ikke udføres på nyfødte, der er ældre end seks uger. Disse nyfødte har tyk atriaseptum. Se AHA/ACC retningslinjerne.
- Dilatationsprocedurer bør kun foretages under fluoroskopisk/MR-vejledning med passende udstyr.
- Guidewirer er sarte instrumenter. Man skal udvise forsigtighed ved håndtering for at undgå at beskadige dem.
- Man skal være særlig opmærksom på vedligeholdelsen af tætte kateterlislutninger og aspiration, før man fortsætter, så luftindtag i systemet kan undgås.
- Ingen del af katetersystemet må under nogen omstændigheder fremføres under modstand. Årsagen til modstanden skal identificeres med fluoroskopi/MR-scanning, og problemet skal afhjælpes.
- Hvis der opstår modstand under fjernelsen, skal ballon, guidewire og sheath fjernes samlet som en enhed, især hvis der er mistanke om eller kendt ballonruptur eller lækage. Det kan udføres ved at gribe ballonkatetret og sheathen som en enhed med et fast tag og udtække begge samlet med en forsigtig drejende bevægelse, mens man trækker.
- Før katetret fjernes fra sheathen, er det yderst vigtigt, at ballonen er fuldstændigt desuffleret.
- Korrekt funktion af katetret afhænger af dets integritet. Man skal være forsigtig, når man håndterer katetret. Snoning, strækning eller for kraftig afføring af katetret kan forårsage beskadigelse.



Oplysninger om sikkerhed af MR-scanning

Ikke-klinisk testning har påvist, at NuMED's ballonkatetersystemer kan scannes under visse betingelser (MR Conditional). Følgende mærkning er specifik for NuMED's katetre og gælder ikke guidewirer eller andet tilbehør, der anvendes i kombination med NuMED's ballonkatetersystemer. Brugere skal konsultere brugsanvisningen og sikkerhedsinformationen vedrørende MR-scanning for andet tilbehørsudstyr, der anvendes sammen med NuMED's katetre. NuMED's ballonkatetersystem kan scannes sikkert hvor som helst i kroppen ved 1,5 T eller 3,0 T under følgende betingelser. Manglende overholdelse af disse betingelser kan medføre personskade.

Parameter	Betingelse
Udstyrets navn	NuMED's ballonkatetersystemer
Statisk magnetfeltstyrke (B0)	1,5 T og 3 T
MR-scannertype	Cylindrisk
Maksimal rumlig feltgradient	19 T/m (1.900 G/cm)
RF-magnetisering	Cirkulært polariseret (CP)
RF-transmitter spoletype	Integreret helkrops transmitterspole
Driftstilstand	Normal driftstilstand
RF-betingelser	Maksimal helkrops SAR: 2,0 W/kg
Scanningsvarighed	2 W/kg helkrops gennemsnitlig SAR i 60 minutters kontinuerlig RF-scanning

Billedartefakt	Tilstedeværelsen af et NuMED ballonkateter i kombination med en 0,035" (0,889 mm) MR-betinget guidewire kan producere et radialt billedartefakt på 1,8 cm.
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POTENTIELLE KOMPLIKATIONER

Potentielle komplikationer og bivirkninger forbundet med brug af udstyret og indikationen herfor omfatter:

- Infektion
- Inflammation
- Tromboemboliske hændelser
- Luftemboli
- Potentiel ballonadskillelse med efterfølgende behov for snare.
- Vaskulær perforation der kræver kirurgisk ophealing.
- Rytme- og overledningsforstyrrelser
- Perforering af venstre atriums aurikel
- Beskadigelse af karrets intima
- Blødning
- Hæmatomdannelse
- Beskadigelse af ledningssystemet
- Død

Alle alvorlige hændelser, der er forekommet i relation til udstyret, skal indberettes til NuMED og den kompetente myndighed i brugslandet.

INSPEKTION OG FORBEREDELSE

1. Indfør guidewiren gennem den distale spids, indtil guidewiren overskrider den proksimale studs.
2. Fjern ballonbeskyttelseshylstre. Inspicér katetret for beskadigelse før indføring.
3. Fastgør et 3 cc (3 cm³) insuffleringsapparat med trykmåler, halvfylt med fysiologisk saltvand, til stophanen på ballonstudsens.
4. Udtøm og skyl katetret grundigt gennem lumen for at kontrollere for lækage.
5. Ret insuffleringsudstyret med trykmålerstudsens nedad og aspirer, indtil al luften er fjernet fra ballonen, og der ikke længere fremkommer bobler i kontrastmidlet.
6. Luk på stophanen for at vedligeholde vakuumet i ballonen.
7. Fjern guidewiren.

INDFØRING: VASKULÆRT

1. Klargør en blanding med 30 % kontrastmiddel i fysiologisk saltvand.
2. Forbered emnet til proceduren.
3. Katetre kan indføres perkutant eller i transumbilikal vene. **SPT002 - 9,5 mm** katetret kræver en 5F introducer sheath, **SPT003 - 13,5 mm** katetret kræver en 6F introducer sheath (se Forholdsregler), når denne metode anvendes. Hvis denne teknik ikke er mulig, kan venøs nedskæring anvendes.
4. Anlæggelsen af katetret kan ske under fluoroskopisk/MR-vejledning eller, under særlige forhold, under todimensional ekkokardiografisk vejledning. Når katetret er passeret igennem sheathen, føres det videre til vena cava inferior og ind i højre atrium. Den vinklede spids letter passage hen over den interatriale åbning til venstre atrium. Hvis der er vanskeligheder med placeringen, kan en 0,014 tomme guidewire anvendes til **SPT002 - 9,5 mm** katetret, eller en 0,021 tomme guidewire anvendes til **SPT003 - 13,5 mm** katetret, for at foretage sikker placering. Guidewiren skal trækkes tilbage og ind i kateterskaffet eller fjernes fuldstændigt før der forsættes med septostomi.
5. Det er mest sikkert at udføre ballon-septostomi under fluoroskopi, MR-scanning eller 2D ekko. Ballonen skal være vel identificeret i venstre atrium. Ballonen til **SPT002 - 9,5 mm** katetret inflateres med 1 ml væske, mens ballonen til **SPT003 - 13,5 mm** katetret inflateres med 2 ml væske, og stophanen lukkes. FORSIGTIG: Overstig ikke mængden på 1 ml til **SPT002 - 9,5 mm** katetret eller mængden på 2 ml til **SPT003 - 13,5 mm** katetret. Overinflation kan få ballonen til at bryde. Ballonen trækkes derefter ind i højre atrium med en hurtig, rykkende bevægelse. Denne trækmanøvre skal stoppes ved overgangen mellem vena cava inferior og højre atrium, hvorpå ballonen hurtigt igen føres frem og ind i højre atrium (da ballonen ikke er eftergivelig, vil den ikke tilpasse sig vena cava inferiors facon, og der kan være risiko for bristning). Deflater straks ballonen ved at danne vakuum i inflationsanordningen med trykmåler (en inflationsanordning på 3 ml anbefales, men hvis der er behov for hurtigere tømming, kan en inflationsanordning på 10 ml anvendes, hvis den har en trykmåler).

Undgå at bruge for stor kraft til at trække ballonen hen over atriaseptum. Nærmere bestemt skal lægen undgå at bruge hele armen, når ballonen trækkes hen over septum, men skal i stedet blot bruge en håndledsbevægelse. Hvis ballonen ikke krydser let over septum med denne metode, anbefales de indledningsvist at bruge en mindre mængde væske. Mængden af væske kan derefter øges gradvist, indtil det ønskede resultat opnås. Hvis de to første trin ikke lykkes, kan statisk ballondilatation af atriaseptum overvejes.

Hvis det er nødvendigt, kan katetret placeres i venstre atrium igen, og processen gentages. Antallet af gentagne septostomier, der udføres i løbet af en kateterisering, bestemmes ud fra patientens kliniske tilstand og en vurdering af lindrings effektivitet.

6. Træk forsigtigt katetret tilbage. Ballonen skal føres ud af karret med en jævn, forsigtig, og rolig bevægelse. Hvis der opstår modstand under fjernelsen, skal ballon, guidewire og sheath fjernes samlet som en enhed under fluoroskopisk/MR-vejledning, især hvis der er mistanke om eller kendt ballonruptur eller lækage. Det kan udføres ved at gribe ballonkatetret og sheathen som en enhed med et fast tag og udtække begge samlet med en forsigtigt drejende bevægelse, mens man trækker.
7. Påfør tryk på indføringsstedet i overensstemmelse med standardpraksis eller hospitalets protokol for perkutane, vaskulære procedurer.
8. Bortskaf enheden efter brug i henhold til standard hospitalsretningslinjer for biologisk farligt udstyr

ADVARSEL: NuMED-katetre placeres i et ekstremt aggressivt miljø i den menneskelige krop. Katetre kan svigte af flere forskellige årsager, inklusive men ikke kun, medicinske komplikationer eller katetersvigt efter beskadigelse. Derudover, og selv om der udvises den største omhyggelighed i design, udvælgelse af bestanddele, fremstilling, og testning før salg, kan katetre let beskadiges før, under eller efter indføring ved forkert håndtering eller andre indgribende handlinger. Konsekvensen deraf er, at der ikke fin des erklæringer om eller garantier for, at svigt eller funktionsophør ikke kan opstå, eller at kroppen ikke reagerer mod placeringen af katetret, eller at der ikke opstår medicinske komplikationer som følge af brugen af katetret.

NuMED kan ikke garantere NuMED tilbehør, da strukturen af tilbehøret kan beskadiges ved forkert håndtering før eller under brug. Derfor fremsættes der ingen erklæringer om eller garantier for det.

Garanti og garantibegrænsninger

Katetre og tilbehør sælges "som de er". Hele risikoen omkring katetrets kvalitet og ydelse ligger hos kunden. NuMED fralægger sig alle garantier, udtrykt eller implicit, med hensyn til katetre og tilbehør, deriblandt, men ikke begrænset til, alle implicite garantier omkring salgbarehed eller egnethed til et specifikt formål. NuMED kan ikke holdes ansvarlig for nogen persons medicinske udgifter eller andre direkte eller følgende beskadigelser forårsaget af brugen – eller forårsaget af defekt, svigt eller fejlfunktion – af et hvilket som helst kateter eller tilbehør, uanset om et krav for sådanne skader er baseret på garantier, kontrakter, erstatningsforpligtende retsbrud eller andet. Ingen person har autoritet til at forpligte NuMED til erklæringer om eller garantier for katetre og tilbehør.

Z-5™ Oversight over ballonstørrelser
SPT002 - 9,5 mm Oversight over ballonstørrelser

Injiceret volumen	Resulterende ballondiameter	Injiceret volumen	Resulterende ballondiameter
0,7 cc (0,7 cm³)	7,95 mm ± 0,5 mm	0,9 cc (0,9 cm³)	8,65 mm ± 0,5 mm
0,8 cc (0,8 cm³)	8,00 mm ± 0,5 mm	1,0 cc (1,0 cm³)	9,35 mm ± 0,5 mm

SPT003 - 13,5 mm Oversight over ballonstørrelser

Injiceret volumen	Resulterende ballondiameter	Injiceret volumen	Resulterende ballondiameter
0,5 cc (0,5 cm³)	8,0 mm ± 0,5 mm	1,5 cc (1,5 cm³)	12,0 mm ± 0,5 mm
1,0 cc (1,0 cm³)	10,5 mm ± 0,5 mm	2,0 cc (2,0 cm³)	13,5 mm ± 0,5 mm

NETERLANDS

Gebruiksaanwijzing

INDICATIES

Aanbevolen voor ballonatrioseptostomie, een in het merendeel van de cardiologiecentra voor kindergeneeskunde aanvaarde techniek voor de palliatieve behandeling van ernstige aangeboren hartaandoeningen. Ballonatrioseptostomie wordt in conjunctie met een diagnostische hartkatheterisatie verricht, en werd uitgevoerd na diagnose van verscheidene aangeboren hartaandoeningen: transpositie van de grote arteriën, totale abnormale pulmonale veneuze return in de afwezigheid van pulmonale obstructie, tricuspidalisatresie, mitralisstenose, mitralisatresie en pulmonalisatresie bij een intact ventrikelseptum. De **SPT002 – 9,5 mm** is voornamelijk bestemd voor zuigelingen van minder dan 2 kg.

BESCHRIJVING VAN DE KATHETER

De NuMED atrioseptostomiekatheter is een nieuwe ballonkatheter, ontworpen voor neonaten met aangeboren hartaandoeningen die septostomie vereisen. Het is een 50 cm lange katheter met dubbel lumen. De **SPT002** is op het distale uiteinde voorzien van een niet-rekbare ballon van 9,5 mm ± 0,5 mm bij een volume van 1,0 cc. De **SPT003** is op het distale uiteinde voorzien van een niet-rekbare ballon van 13,5 mm ± 0,5 mm bij een volume van 2,0 cc. De **SPT002 - 9,5 mm** katheter is ook voorzien van een opening aan het einde, om een voederraad van 0,014" (0,36 mm) te kunnen bevatten; de **SPT003 - 13,5 mm** katheter is ook voorzien van een opening aan het einde, om een voederraad van 0,018" tot 0,021" (0,46 mm tot 0,53 mm) te kunnen bevatten. De configuratie van de gevulde ballon is bolvormig. Er is een beeldvormingsstrook onder de ballon om hem in de linkerboezem te helpen plaatsen. De kathetertip is onder een hoek van 35° om doorgang door de interarteriële opening in de linkerboezem te vergemakkelijken. Om de ballon van de **SPT002 - 9,5 mm** katheter tot zijn maximale diameter te vullen, wordt 1 cc verdund contrastmiddel na het spoelen in het ballonverlengstuk geduwd. Om de ballon van de **SPT003 - 13,5 mm** katheter tot zijn maximale diameter te vullen, worden 2 cc verdund contrastmiddel na het spoelen in het ballonverlengstuk geduwd. De katheters worden geleverd met een eenwegafsluitkraan voor ballonverzegeling.

HOE WORDT HET PRODUCT GELEVERD?

Gesteriliseerd met behulp van ethyleenoxide. Steriel en niet-pyrogeen indien verpakking ongeopend en onbeschadigd is. Het product niet gebruiken indien er twijfel bestaat of het product steriel is. Vermijd langdurige blootstelling aan licht. Inspecteer het product als het uit de verpakking wordt gehaald om het te controleren op beschadiging.

WAARSCHUWING

- LET OP: U mag het nominale volume van 1 cc voor de **SPT002 - 9,5 mm** katheter niet overschrijden. Overmatig vullen kan de ballon doen breken.
- LET OP: U mag het nominale volume van 2 cc voor de **SPT003 - 13,5 mm** katheter niet overschrijden. Overmatig vullen kan de ballon doen breken.
- Gebruik uitsluitend een geschikt ballonvulmiddel. Gebruik geen lucht of een gasvormig vulmiddel om de ballon te vullen.
- Gebruik voor het vullen uitsluitend een vulinstrument van 3 cc, voorzien van een drukmeter.
- Gebruik voor het legen uitsluitend een vulinstrument van 3 cc, voorzien van een drukmeter. (Om het legen sneller te doen verlopen, mag een vulinstrument van maximaal 10 cc voorzien van een drukmeter worden gebruikt).
- De injectiedruk voor de **SPT002 - 9,5 mm** katheter mag 300 psi niet overschrijden.
- De injectiedruk voor de **SPT003 - 13,5 mm** katheter mag 600 psi niet overschrijden.
- Voer de voederraad, de septostomiekatheter of enig ander onderdeel niet op als u weerstand ondervindt, zonder er eerst de oorzaak van te achterhalen en de nodige maatregelen te treffen.
- Deze katheter is niet bestemd om de druk te meten, of vloeistof te injecteren.
- Dit hulpmiddel is uitsluitend bestemd voor eenmalig gebruik. Het mag niet opnieuw worden gesteriliseerd en/of opnieuw gebruikt, aangezien dit de prestaties van het hulpmiddel kan aantasten en kan leiden tot een verhoogd risico op kruisbesmetting.
- Vermijd het gebruik van overmatige kracht om de ballon langs het atriumseptum te trekken.

VOORZORGSMAATREGELEN

- NuMED raadt aan een introducer van 5 F met de **SPT002 - 9,5 mm** katheter te gebruiken, om de toegang te verzekeren.
- NuMED raadt aan een introducer van 6 F met de **SPT003 - 13,5 mm** katheter te gebruiken, om de toegang te verzekeren.
- Ballonatrioseptostomie mag niet worden verricht bij zuigelingen van meer dan 6 weken oud. Deze zuigelingen hebben dikke boezemsepten. Raadpleeg de AHA/ACC richtlijnen.
- De dilatatieprocedure moet onder doorlichting/MRI-visualisatie worden uitgevoerd met gebruik van passende apparatuur.
- Voedraden zijn delicate instrumenten. Ze dienen met zorg te worden gehanteerd om de kans op breuk te helpen vermijden.
- Er dient, alvorens verder te gaan, zorgvuldige aandacht te worden besteed aan het behoud van nauwsluitende kathetaraansluitingen en aan het opzuigen, om luchttoetreding in het systeem te voorkomen.
- Onder geen beding mag een onderdeel van het kathetersysteem worden opgevoerd tegen weerstand in. De oorzaak van het weerstand moet worden vastgesteld door middel van doorlichting/MRI en er moeten maatregelen worden getroffen om het probleem te verhelpen.
- Als er bij het verwijderen weerstand ondervonden wordt, moeten de ballon, de voederraad en de huls samen als een geheel worden verwijderd, vooral als er breuk of lekkage van de ballon vastgesteld is, of vermoed wordt. Om dit te doen neemt u de

ballonkatheter en de huls als een geheel stevig vast, en trekt u ze beide tezamen terug, met een voorzichtig draaiende en tegelijkertijd trekkende beweging.

- Alvorens de katheter uit de huls te verwijderen is het uitermate belangrijk dat de ballon volledig leeggelopen is.
- Een goede werking van de katheter is afhankelijk van zijn integriteit. De katheter dient met zorg te worden gehanteerd. Door knikken, uittrekken of met overmatige kracht afvegen kan de katheter beschadigd worden.

 MRI-veiligheidsinformatie	
Door middel van niet-klinische tests is aangetoond dat de ballonkathetersystemen van NuMED onder bepaalde voorwaarden veilig voor MRI zijn. De onderstaande documentatie geldt specifiek voor de katheters van NuMED en is niet van toepassing op voedraden of andere accessoires die in combinatie met de ballonkathetersystemen van NuMED worden gebruikt. Gebruikers moeten de gebruiksaanwijzing en MRI-veiligheidsinformatie raadplegen van andere accessoirehulpmiddelen die samen met de katheters van NuMED worden gebruikt. De ballonkathetersystemen van NuMED kunnen om het even waar in het lichaam onder de volgende voorwaarden bij 1,5 T of 3,0 T worden gescand. Nalatigheid in het volgen van deze voorwaarden kan leiden tot letsel.	
Parameter	Voorwaarde
Naam hulpmiddel	Ballonkathetersystemen van NuMED
Sterkte statisch magnetisch veld (B0)	1,5 T en 3 T
Type MRI-scanner	Cilinder
Maximale ruimtelijke gradiënt van veld	19 T/m (1900 G/cm)
RF-excitatie	Circulair gepolariseerd (CP)
Type RF-zendspoel	Geïntegreerde zendspoel over het hele lichaam
Bedrijfsmodus	Normale bedrijfsmodus
RF-voorwaarden	Maximale SAR over het gehele lichaam: 2,0 W/kg
Scanduur	2 W/kg over het gehele lichaam gemiddelde SAR gedurende 60 minuten continu RF-scanning
Beeldartefact	De aanwezigheid van een NuMED-ballonkatheter in combinatie met een 0,035 inch (0,889 mm) voedraad die onder bepaalde voorwaarden veilig voor MRI is, kan een radiaal beeldartefact produceren van 1,8 cm.

MOGELIJKE COMPLICATIES

Mogelijke complicaties en ongewenste effecten in verband met het gebruik en het voorschrijven van het hulpmiddel zijn onder meer:

- Infectie
- Inflammatie
- Trombo-embolie
- Luchtembolie
- Mogelijk losraken van de ballon en de daaropvolgende noodzaak een strik te gebruiken
- Vaatperforatie die operatieve herstelling vereist
- Ritme- en geleidingsstoornissen
- Perforatie van het linker hartoor
- Beschadiging van de vaatwanden
- Bloeding
- Hematoomvorming
- Letsel van het geleidingssysteem
- Overlijden

Elk ernstig incident dat zich heeft voorgedaan in verband met het hulpmiddel, moet worden gemeld aan NuMED en aan de bevoegde autoriteit in het land waar het wordt gebruikt.

INSPECTEREN EN PREPAREREN

1. Breng de voedraad door de distale tip in, totdat de voedraad uit de proximale poort komt.
2. Verwijder de ballonbeschermers. Controleer de katheter op beschadiging alvorens hem in te brengen.
3. Bevestig een vulinstrument van 3 cc, voorzien van een drukmeter, half gevuld met fysiologische zoutoplossing, en bevestig het aan de afsluitkraan die reeds aan de ballonpoort bevestigd is.
4. Purgeer en spoel het doorvoeren van de katheter grondig, en kijk na of er geen lekken zijn.
5. Houd het vulinstrument met de drukmeteruit naarwaarts gericht, en zuig aan tot al de lucht uit de ballon verwijderd is, en er geen belletjes meer in het contrastmiddel te zien zijn.
6. Draai de afsluitkraan naar de stand "off" om het vacuüm in de ballon te behouden.
7. Verwijder de voedraad.

INBRENGEN: VASCULAIR

1. Prepareer een mengsel van 30 volumeprocent contrastmiddel en normale fysiologische zoutoplossing.
2. Prepareer de patiënt voor de ingreep.
3. Katheters kunnen percutaan ofwel via de vena umbilicalis worden ingebracht. Bij gebruik van deze benadering vereist de **SPT002 - 9,5 mm** katheter een introducerhuls van 5 F, en vereist de **SPT003 - 13,5 mm** katheter een introducerhuls van 6 F (zie Voorzorgsmaatregelen). Als deze toegangstechniek faalt, kan een venapunctie worden uitgevoerd.
4. Plaatsing van de katheter kan onder doorlichting/MRI-visualisatie geschieden, of onder bijzondere omstandigheden met behulp van tweedimensionale echocardiografische visualisatie. Na het passeren van de sheath wordt de katheter opgevoerd naar de v. cava inferior en het rechter atrium in. De hoektip vergemakkelijkt het doorvoeren door de interatriale opening naar het linker atrium. Bij moeilijkheden bij het positioneren kan voor de **SPT002 - 9,5 mm**-katheter een voedraad van 0,36 mm (0,014 inch), of voor de **SPT003 - 13,5 mm**-katheter een voedraad van 0,53 mm (0,021 inch) worden gebruikt om een veilige plaatsing te verkrijgen. De voedraad moet worden teruggetrokken in de katheterschacht of volledig worden verwijderd voordat u overgaat tot septostomie.
5. De veiligste manier om ballonseptostomie uit te voeren, is onder doorlichting, MRI-visualisatie of 2D-echografie. De ballon moet duidelijk herkenbaar zijn in het linker atrium. De ballon van de **SPT002 - 9,5 mm**-katheter wordt gevuld met 1 ml vloeistof, de ballon van de **SPT003 - 13,5 mm**-katheter wordt gevuld met 2 ml vloeistof en de afsluitkraan wordt gesloten. LET OP: Gebruik niet meer dan het volume van 1 ml voor de **SPT002 - 9,5 mm**-katheter of het volume van 2 ml voor de **SPT003 - 13,5 mm**-katheter. Overmatig vullen kan leiden tot scheuren van de ballon. Vervolgens wordt de ballon met een snelle rukbeweging in het rechter atrium getrokken. Dit trekmanoeuvre moet worden gestopt bij de overgang tussen de v. cava inferior en het rechter atrium en de ballon moet dan snel opnieuw worden opgevoerd in het rechter atrium (omdat de ballon niet-compliant is, vormt hij niet de vorm van de v. cava inferior en bestaat er kans op scheuren). Leeg de ballon onmiddellijk door onderdruk uit te oefenen op het vulinstrument met de manometer (een instrument van 3 ml wordt aanbevolen tenzij sneller legen vereist is; in dat geval kan een vulinstrument van maximaal 10 ml met een manometer worden gebruikt).

Gebruik van overmatige kracht om de ballon door het atriale septum te trekken moet worden vermeden. In het bijzonder moet de arts niet de gehele arm gebruiken wanneer de ballon door het septum wordt getrokken; in plaats hiervan moet slechts een polsbeweging worden gebruikt. Als de ballon het septum niet gemakkelijk passeert met deze methode, wordt aanbevolen om aanvankelijk een kleiner vloeistofvolume te gebruiken. Het vloeistofvolume kan dan geleidelijk worden opgevoerd totdat het gewenste resultaat is verkregen. Als de eerste twee stappen niet het gewenste resultaat opleveren, overweeg dan statische ballondilatatie van het atriale septum.

Zo nodig kan de katheter opnieuw worden gepositioneerd in het linker atrium en kan het proces worden herhaald. Het aantal

herhaalde septostomieën dat bij één katheterisatie wordt uitgevoerd, wordt bepaald door de klinische toestand van de patiënt en de inschatting van effectieve palliatie.

6. Trek de katheter voorzichtig terug. Terwijl de ballon uit het vat komt, gebruikt u een soepele, voorzichtige, constante beweging. Als bij de verwijdering weerstand wordt gevoeld, moeten de ballon, voerdraad en sheath samen als één geheel onder doorlichting/MRI-visualisatie worden verwijderd, met name als de ballon zeker of vermoedelijk gescheurd is of lekt. Hiertoe pakt u de ballonkatheter en de sheath stevig als één geheel vast en trekt u ze samen terug, waarbij u tegelijkertijd voorzichtig draait en trekt.
7. Oefen druk uit op de inbrengplaats, volgens de standaardpraktijken of volgens het protocol van het ziekenhuis voor percutane vasculaire operaties.
8. Voer het hulpmiddel na het gebruik af volgens het standaardprotocol van het ziekenhuis voor biologisch gevaarlijke hulpmiddelen.

WAARSCHUWING: NuMED katheters worden in een uiterst onvriendelijk milieu in het menselijke lichaam geplaatst. Katheters kunnen om verscheidene redenen falen zoals o.a. wegens medische complicaties of faling van de katheter ten gevolge van breuk. Ondanks de uiterste zorg besteed bij het ontwerp, de selectie van de onderdelen, de fabricage en het testen kunnen katheters bovendien wegens onjuiste hantering of andere voorvallen voor, tijdens of na het inbrengen gemakkelijk beschadigd raken. Bijgevolg wordt geen enkele bewering gemaakt, noch garantie gegeven dat de katheters niet zullen falen of stoppen te werken, of dat het lichaam niet slecht zal reageren op de plaatsing van de katheters, of dat er zich geen medische complicaties zullen voordoen na gebruik van de katheters.

NuMED kan geen garantie geven of de NuMED accessoires garanderen aangezien de accessoires kunnen worden beschadigd door onjuiste hantering voor of tijdens gebruik ervan. Om die reden worden omtrent deze accessoires geen beweringen gemaakt, noch garanties gegeven.

Garantie en beperkingen

De katheters en accessoires worden verkocht in hun huidige conditie. Het gehele risico betreffende de kwaliteit en de prestaties van de katheter berust bij de koper. NuMED wijst alle uitdrukkelijke of stilzwijgende garanties met betrekking tot de katheters en de accessoires af, met inbegrip van, maar niet beperkt tot enige stilzwijgende garantie van verkoopbaarheid of geschiktheid voor een bepaald doel. NuMED zal niet aansprakelijk worden gesteld t.o.v. enige persoon voor medische kosten of enige directe of gevolgschade voortvloeiende uit het gebruik van enige katheter of accessoire of veroorzaakt door enig defect, faling of slechte werking van enige katheter of accessoire, ongeacht of dergelijke vordering gebaseerd is op een garantie, contract, onrechtmatige daad, of anderszins. Geen enkele persoon heeft machtiging om NuMED aan enige bewering of garantie te binden met betrekking tot de katheters en accessoires.

Tabel met Z-5™ ballonmaten
Tabel met SPT002 - 9,5 mm ballonmaten

Geïnjecteerd volume	Resulterende ballon-diameter	Geïnjecteerd volume	Resulterende ballon-diameter
0,7 cc	7,95 mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00 mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

Tabel met SPT003 - 13,5 mm ballonmaten

Geïnjecteerd volume	Resulterende ballon-diameter	Geïnjecteerd volume	Resulterende ballon-diameter
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

PORTUGUÊS

Instruções de utilização

INDICAÇÕES

Recomendado para atrioseptostomia com balão, uma técnica aceita na maior parte dos centros de cardiologia pediátrica para o alívio de diversos defeitos cardíacos congênitos. A atrioseptostomia com balão é efectuada em conjunto com a cateterização cardíaca de diagnóstico e tem sido feita após o diagnóstico de diversos defeitos cardíacos congênitos: transposição das grandes artérias, drenagem venosa pulmonar anómala total sem obstrução pulmonar, atresia tricúspide, estenose mitral, atresia mitral e atresia pulmonar com septo ventricular intacto. O **SPT002 - 9,5mm** destina-se principalmente a crianças com menos de 2 kg.

DESCRIÇÃO DO CATETER

O cateter de atrioseptostomia NuMED é um novo cateter de balão concebido para neonatos com cardiopatia congénita que necessitem de septostomia. É um cateter de dois lúmens com 50cm de comprimento. O **SPT002** tem um balão não deformável de 9,5mm ± 0,5mm, com volume de 1,0cc, na ponta distal. O **SPT003** tem um balão não deformável de 13,5mm ± 0,5mm, com volume de 2,0cc, na ponta distal. O cateter **SPT002 - 9,5mm** também inclui um orifício terminal que irá acomodar um fio-guia de 0,014" (0,36 mm); o cateter **SPT003 - 13,5mm** também inclui um orifício terminal que irá acomodar um fio-guia de 0,018" a 0,021" (0,46 a 0,53 mm). A geometria insuflada do balão é uma esfera. Existe uma faixa de imagiologia sob o balão para posicionar o balão na aurícula esquerda. A ponta do cateter faz um ângulo de 35° para facilitar a passagem através da abertura interauricular na aurícula esquerda. Para insuflar o balão do cateter **SPT002 - 9,5mm** até ao diâmetro máximo, é introduzido 1cc de meio de contraste diluído na extensão do balão após a purga. Para insuflar o balão do cateter **SPT003 - 13,5mm** até ao diâmetro máximo, são introduzidos 2cc de meio de contraste diluído na extensão do balão após a purga. Os cateteres são fornecidos com uma torneira de uma via para selagem do balão.

COMO É FORNECIDO

É fornecido esterilizado a gás de óxido de etileno. Estéril e apirrogénico se a embalagem não estiver aberta nem danificada. Não use o produto se tiver dúvidas se está ou não esterilizado. Evite a exposição prolongada à luz. Depois de retirar da embalagem, inspecione o produto para garantir que não está danificado.

AVISO

- **ATENÇÃO:** Não exceda o volume nominal de 1cc para o Cateter **SPT002 - 9,5mm**. A sobre-insuflação pode provocar a ruptura

do balão.

- **ATENÇÃO:** Não exceda o volume nominal de 2cc para o Cateter **SPT003 - 13,5mm**. A sobre-insuflação pode provocar a ruptura do balão.
- Utilize apenas o meio adequado de insuflação do balão. Não utilize ar ou meios gasosos para insuflar o balão.
- Utilize apenas um dispositivo de insuflação de 3cc com manómetro de pressão para a insuflação.
- Utilize um dispositivo de insuflação de 3cc com manómetro de pressão para a desinsuflação. (Para uma desinsuflação mais rápida, é possível utilizar um dispositivo de desinsuflação até 10cc com manómetro de pressão).
- Não exceda a pressão de injeção de 300 psi para o Cateter **SPT002 - 9,5mm**.
- Não exceda a pressão de injeção de 600 psi para o Cateter **SPT003 - 13,5mm**.
- Não faça avançar o fio-guia, o cateter de septostomia nem qualquer outro componente se encontrar resistência, sem primeiro determinar a causa e tomar medidas para a resolver.
- Este cateter não é recomendado para medição de pressão ou injeção de fluidos.
- Este dispositivo destina-se apenas a uma única utilização. Não o reesterilizar e/ou reutilizar, uma vez que tal poderá resultar potencialmente num desempenho comprometido do dispositivo e num risco acrescido de contaminação cruzada.
- Deve-se evitar a utilização de força excessiva para puxar o balão através do septo auricular.

PRECAUÇÕES

- A NuMED recomenda a utilização do cateter **SPT002 - 9,5mm** com um introdutor 5F para assegurar a entrada.
- A NuMED recomenda a utilização do cateter **SPT003 - 13,5mm** com um introdutor 6F para assegurar a entrada.
- A atioseptostomia com balão não deve ser efectuada em crianças com mais de seis semanas. Estas crianças têm septos auriculares espessos. Consulte as directivas AHA/ACC.
- Os processos de dilatação devem ser efectuados sob orientação fluoroscópica/RMN com equipamento adequado.
- Os fios-guia são instrumentos delicados. Deve ter-se muito cuidado ao manusear os mesmos, para evitar a possibilidade de ruptura.
- É necessário ter muita atenção à manutenção das ligações de cateteres estanques e aspiração antes de prosseguir, para evitar a entrada de ar no sistema.
- Em situação alguma se deve fazer avançar alguma parte do sistema de cateter quando for sentida resistência. A causa da resistência deve ser identificada com fluoroscopia/RMN e devem ser tomadas medidas para resolver o problema.
- Se for encontrada resistência durante a remoção, o balão, fio-guia e bainha devem ser retirados em conjunto como uma só unidade, especialmente se tiver ocorrido ou se suspeitar de ruptura ou fugas no balão. É possível fazê-lo agarrando firmemente no cateter do balão e na bainha como uma só unidade e retirando ambos ao mesmo tempo, utilizando um ligeiro movimento de torção associado à tracção.
- Antes de remover o cateter da bainha, é muito importante verificar se o balão está completamente esvaziado.
- O funcionamento correcto do cateter depende da respectiva integridade. Deve ter-se cuidado ao manusear o cateter. Podem resultar danos de nós, estiramentos ou da limpeza forçada do cateter.

 Informação sobre segurança em RMN	
Testes não clínicos demonstraram que os sistemas de cateter de balão da NuMED são MR Condicional (pode ser submetido a exames de RM sob determinadas condições). A rotulagem seguinte é específica para os cateteres da NuMED e não se aplica a fios-guia ou outros acessórios utilizados em combinação com os sistemas de cateteres de balão da NuMED. Os utilizadores devem consultar as instruções de utilização e as informações de segurança em RMN de outros dispositivos acessórios utilizados com os cateteres da NuMED. Os sistemas de cateteres de balão da NuMED podem ser submetidos com segurança a um exame em qualquer parte do corpo a 1,5 T ou 3,0 T sob as seguintes condições. O não cumprimento destas condições pode resultar em lesões.	
Parâmetro	Condição
Nome do dispositivo	Sistemas de cateteres de balão da NuMED
Força de campo magnético estático (B0)	1,5 T e 3 T
Tipo de scanner de RMN	Cilíndrico
Gradiente de campo espacial máximo	19 T/m (1.900 G/cm)
Excitação por RF	Polarizado circularmente (CP)
Tipo de bobina de transmissão por RF	Bobina de transmissão para todo o corpo integrada
Modo de funcionamento	Modo de funcionamento normal
Condições de RF	SAR máxima para todo o corpo: 2,0 W/kg
Duração da varredura	2 W/kg de SAR média para todo o corpo durante 60 minutos de varredura contínua por RF
Artefacto de imagem	A presença de um cateter de balão NuMED em combinação com um fio-guia de 0,035" (0,889 mm) condicional para RM pode produzir um artefacto de imagem radial de 1,8 cm.

COMPLICAÇÕES POTENCIAIS

As potenciais complicações e efeitos adversos associados à utilização e indicação do dispositivo incluem:

- Infecção
- Inflamação
- Tromboembolias
- Embolia gasosa
- Potencial separação do balão com necessidade subsequente de extracção por gancho
- Perfuração vascular com necessidade de reparação cirúrgica
- Perturbações de ritmo e condução
- Perfuração do apêndice auricular esquerdo
- Lesões na íntima vascular
- Hemorragias
- Formação de hematomas
- Lesões no sistema condutor
- Morte

Qualquer incidente grave que tenha ocorrido relacionado com o dispositivo deve ser notificado à NuMED e à autoridade competente do país de utilização.

INSPECÇÃO E PREPARAÇÃO

1. Insira o fio-guia através da ponta distal até o fio-guia exceder o orifício proximal.
2. Remova a protecção do balão. Verifique se o cateter apresenta danos antes da inserção.
3. Anexe um dispositivo de insuflação de 3cc com manómetro de pressão meio cheio com soro fisiológico normal e ligue-o à torneira, já ligada ao orifício do balão.
4. Efectue a purga e irrigue bem o lúmen directo do cateter, verificando se existem fugas.
5. Aponte o dispositivo de insuflação com o bocal do manómetro de pressão para baixo, aspire até todo o ar ser removido do balão e não aparecerem mais bolhas no meio de contraste.
6. Rode a torneira para a fechar e manter o vácuo no balão.

7. Retire o fio-guia.

INSERÇÃO: VASCULAR

1. Prepare uma mistura de 30% por volume de meio de contraste e soro fisiológico normal.
2. Prepare o indivíduo para o procedimento.
3. Os cateteres podem ser introduzidos por abordagem percutânea ou pela veia transumbilical. Ao utilizar esta abordagem, o cateter **SPT002 - 9,5mm** necessita de uma bainha introdutora 5F; o cateter **SPT003 - 13,5mm** necessita de uma bainha introdutora de 6F (consulte as Precauções). No caso de esta técnica de acesso falhar, é possível utilizar um corte venoso.
4. A colocação do cateter pode ser concretizada sob orientação fluoroscópica/RMN ou em condições especiais, utilizando orientação ecocardiográfica bidimensional. Uma vez através da bainha, o cateter é passado para a veia cava inferior e para a aurícula direita. A ponta angulada facilita a passagem através da abertura interauricular para a aurícula esquerda. Em caso de dificuldade no posicionamento, pode ser utilizado para conseguir um posicionamento seguro um fio-guia de 0,014 polegadas para o cateter **SPT002 (9,5 mm)** e o fio-guia de 0,021 polegadas para o cateter **SPT003 (13,5 mm)**. O fio-guia deve ser puxado para trás para o corpo do cateter ou removido completamente antes de prosseguir com a septostomia.
5. A septostomia com balão é realizada com mais segurança sob fluoroscopia, RMN ou eco 2-D. O balão deve ser bem identificado na aurícula esquerda. O balão do cateter **SPT002 (9,5 mm)** é cheio com 1 ml de fluido, o balão do cateter **SPT003 (13,5 mm)** é cheio com 2 ml de fluido e a torneira é fechada. **ATENÇÃO:** Não exceda o volume de 1 ml para o cateter **SPT002 (9,5 mm)** e os 2 ml para o cateter **SPT003 (13,5 mm)**. O excesso de enchimento pode causar a rutura do balão. O balão é então puxado para a aurícula direita com um movimento rápido e instantâneo. Esta manobra de puxar para trás deve ser interrompida na junção auricular da veia cava inferior direita e o balão rapidamente avançado de novo na aurícula direita (uma vez que o balão não é complacente, este não se ajustará à forma da VCI e a rutura é uma possibilidade). Esvazie imediatamente o balão aplicando uma pressão negativa no dispositivo de enchimento com manómetro (recomenda-se 3 ml, a menos que seja necessária esvaziar mais rapidamente, onde então pode ser utilizado um dispositivo de enchimento de 10 ml com manómetro).
A utilização de força excessiva para puxar o balão através do septo auricular deve ser evitada. Especificamente, o médico deve evitar utilizar o braço inteiro ao puxar o balão através do septo e, em vez disso, deve utilizar apenas o movimento do pulso. Se o balão não atravessar facilmente o septo utilizando este método, recomenda-se que um volume menor de fluido seja utilizado inicialmente. A quantidade de fluido pode ser aumentada gradualmente em volume até que o resultado desejado seja alcançado. Se os dois primeiros passos não forem bem-sucedidos, considere a dilatação por balão estático do septo auricular.
Se necessário, o cateter pode ser reposicionado na aurícula esquerda e o processo pode ser repetido. O número de septostomias repetidas realizadas durante um cateterismo é determinado pelo estado clínico do doente e pela estimativa de palição eficaz.
6. Retire o cateter com cuidado. À medida que o balão sai do vaso, realize um movimento suave, ligeiro, firme. Se for sentida resistência ao retirar, o balão, o fio-guia e a bainha devem ser retirados em conjunto como uma única unidade com orientação fluoroscópica/RMN, especialmente se tiver ocorrido ou se suspeitar de rutura ou fugas no balão. É possível fazê-lo agarrando firmemente o cateter de balão e a bainha como uma única unidade e retirando ambos ao mesmo tempo, utilizando um ligeiro movimento de torção associado à tração.
7. Aplique pressão no local de inserção segundo as práticas padrão ou o protocolo hospitalar para procedimentos vasculares percutâneos.
8. Elimine o dispositivo após a utilização, de acordo com o protocolo padrão do hospital para dispositivos com risco biológico.

AVISO: Os cateteres NuMED são colocados no ambiente extremamente hostil do corpo humano. As falhas de funcionamento dos cateteres podem ter uma variedade de causas, incluindo, entre outras, complicações médicas ou avaria dos cateteres por rutura. Para além disso, apesar de todo o cuidado tido na concepção, selecção de componentes, fabrico e testes anteriores às vendas, os cateteres podem facilmente ser danificados antes, durante ou após a inserção, devido a manuseamento incorrecto ou a outras acções. Assim, não há qualquer declaração ou garantia de que os cateteres não avariarem ou deixem de funcionar, de que o corpo não reaja de forma adversa à colocação de cateteres ou de que não haja complicações médicas devidas à utilização de cateteres.

A NuMED não pode oferecer garantias sobre os acessórios NuMED porque a estrutura dos acessórios pode ser danificada devido a manuseamento incorrecto antes ou durante a utilização. Consequentemente, não se emitem quaisquer declarações ou garantias em relação aos mesmos.

Garantia e limitações

Os cateteres e acessórios são vendidos 'tal como estão'. Todos os riscos relacionados com a qualidade e funcionamento do cateter são assumidos pelo comprador. A NuMED não se responsabiliza por quaisquer garantias, expressas ou implícitas, no que diz respeito a cateteres e acessórios, incluindo, entre outras, qualquer garantia implícita de comercialização ou adequação a um objectivo em particular. A NuMED não se responsabiliza por pessoa alguma relativamente a despesas médicas ou quaisquer danos directos ou consequentes resultantes da utilização de qualquer cateter ou acessório ou provocados por quaisquer defeitos, avarias ou mau funcionamento de qualquer cateter ou acessório, seja a reclamação por tais danos feita com base na garantia, contrato, prejuízo ou outros. Nenhuma pessoa tem autoridade para sujeitar a NuMED a qualquer obrigação legal relativamente a declarações ou garantias no que diz respeito a cateteres e acessórios.

**Gráfico de calibração do balão Z-5™
Gráfico de dimensões do balão SPT002 - 9,5mm**

Volume Injectado	Diâmetro resultante do balão	Volume Injectado	Diâmetro resultante do balão
0,7 cc	7,95mm ± 0,5mm	0,9 cc	8,65mm ± 0,5mm
0,8 cc	8,00mm ± 0,5mm	1,0 cc	9,35mm ± 0,5mm

Gráfico de dimensões do balão SPT003 - 13,5mm

Volume Injectado	Diâmetro resultante do balão	Volume Injectado	Diâmetro resultante do balão
0,5 cc	8,0mm ± 0,5mm	1,5 cc	12,0mm ± 0,5mm
1,0 cc	10,5mm ± 0,5mm	2,0 cc	13,5mm ± 0,5mm

Kullanım Talimatları

ENDİKASYONLARI

Bazı doğumsal kalp hastalıklarının tedavisi amacı ile birçok pediatrik kardiyoloji merkezinde kabul edilmiş bir tekniktir. Balon Atriöseptostomi işlemi, bazı doğumsal kalp hastalıklarını ortaya çıkaran diagnostik kardiyak kateterizasyon işlemi ile birlikte gerçekleştirilmelidir. Bu hastalıklar büyük arterlerin transpozisyonu, pulmoner obstrüksiyon olmaksızın total anormal pulmoner venöz boşalım, triküspid atrezi, mitral darlık, mitral atrezi ve bozulmamış ventriküler septum ile birlikte pulmoner atrezi. **SPT002 - 9,5 mm** öncelikle 2 kg altındaki bebekler için kullanılır.

AÇIKLAMA

NuMED atriöseptostomi kateteri, septostomi işlemi gerektiren doğumsal kalp hastalığına sahip yenidoğanlarda kullanılmak üzere dizayn edilmiş yeni bir balon katetertir. 50 cm uzunluğunda dual lümen bir katetertir. **SPT002**, distal ucunda 1,0 cc'lik 9,5 mm $\pm$ 0,5 mm komplan olmayan bir balona sahiptir. **SPT003**, distal ucunda 2,0 cc'lik 13,5 mm $\pm$ 0,5 mm komplan olmayan bir balona sahiptir. **SPT002 - 9,5 mm**'lik kateterin ucu delik olup içinden 0,014 inç çapında kılavuz tel geçer. **SPT003 - 13,5 mm**'lik kateterin ucu delik olup içinden 0,018 inç ile 0,021 inç arasında kılavuz tel geçer. Şişirilmiş balon, küre şeklindedir. Sol atriumda balonun pozisyonlandırılmasına olanak sağlamak için balonun altında bir marker (işaretleyici) bulunur. 1 cc seyreltilmiş kontrast madde ile şişirildiğinde **SPT002 - 9,5 mm**'lik balon maksimum çapına erişilir. 2 cc seyreltilmiş kontrast madde ile şişirildiğinde **SPT002 - 13,5 mm**'lik balon maksimum çapına erişilir. Kateterler tek yönlü musluk ile birliktedir.

TEDARİK ŞEKLİ

Etilen oksitle sterilize edilmiş şekilde tedarik edilir. Ambalaj açılmamışsa ve hasar görmemişse sterildir ve pirojenik değildir. Ürünün steril olup olmadığı ile ilgili tereddütünüz varsa ürünü kullanmayın. Uzun süre ışığa maruz bırakmaktan kaçının. Ambalajdan çıkardıktan sonra herhangi bir hasar olup olmadığından emin olmak için ürünü inceleyin.

UYARILAR

- DİKKAT: **SPT002 - 9,5 mm**'lik balon için nominal şişirme hacmi olan 1 cc'yi aşmayınız. Daha fazla şişirme balonun patlamasına sebep olabilir.
- DİKKAT: **SPT003 - 13,5 mm**'lik balon için nominal şişirme hacmi olan 2 cc'yi aşmayınız. Daha fazla şişirme balonun patlamasına sebep olabilir.
- Uygun balon şişirme malzemesi kullanınız. Hava veya gaz ile şişirmeyiniz.
- Balonu şişirmek için üzerinde basınç göstergesi olan 3 cc'lik şişirme aleti kullanınız.
- Balonu indirmek için üzerinde basınç göstergesi olan 3 cc'lik şişirme aleti kullanınız. (Daha hızlı indirme işlemi için üzerinde basınç göstergesi olan 10 cc'lik şişirme aleti kullanınız.)
- **SPT002 - 9,5 mm**'lik kateter için 300 psi enjeksiyon basıncını aşmayınız.
- **SPT003 - 13,5 mm**'lik kateter için 600 psi enjeksiyon basıncını aşmayınız.
- İşlem sırasında herhangi bir direnç karşılaşırsa kılavuz tel, septostomi kateteri veya herhangi diğer komponenti ilerletmeyiniz. Önce sebebini bulunuz ve gerekli önlemleri alınız.
- Bu kateterle basınç ölçülmesi veya sıvı enjeksiyonu yapılması tavsiye edilmez.
- Bu cihaz sadece tek kullanımlıktır. Yeniden sterilize etmeyin ve/veya yeniden kullanmayın çünkü bu büyük olasılıkla cihazın performansını etkileyebilir ve çapraz bulaşma riskini artırabilir.
- Balonu atriyal septum boyunca çekmek için aşırı kuvvet uygulamaktan kaçınılmalıdır.

ÖNEMLER

- NuMED, **SPT002 - 9,5 mm**'lik kateter ile birlikte 5F kalınlığında kılıf kullanılması tavsiye eder.
- NuMED, **SPT003 - 13,5 mm**'lik kateter ile birlikte 6F kalınlığında kılıf kullanılması tavsiye eder.
- Balon atriöseptostomi işlemi 6 haftalık küçük çocuklarda yapılmamalıdır. Bu çocuklar kalın bir atrial septuma sahip olacaklardır. Referans: AHA/ACC kılavuzları
- Dilatasyon işlemi floroskopi/MRG altında uygun cihaz ile yapılmalıdır.
- Kılavuz teller kolayca zarar görebilir. Kırılmayı önlemek için özen gösteriniz.
- Kateter bağlantılarının özenle yapılması ve işlem öncesi sistemde hava bulunmasını önleme amacı ile aspirasyon yapınız.
- Hiçbir koşulda kateter sisteminin herhangi bir kısmı dirence karşı ilerletilmemelidir. Direncin nedeni floroskopi/MRG ile tespit edilmeli ve sorunu gidermek için önlem alınmalıdır.
- Kateteri geri çekerken herhangi bir direnç karşılaşıldığında balon, kılavuz tel ve kılıf hep birlikte aynı anda geri çekilmelidir. Bu işlem balonun patlaması veya sızıntı durumu halinde de uygulanmalıdır. Çekme işlemi sırasında hafifçe rotasyon işlemi yapılmalıdır.
- Kateteri kılıftan çıkarmadan önce balonun tamamen indirilmiş olduğundan emin olunmalıdır.
- Uygun kateterizasyon işlemi için kateteri dikkatle tutmak gerekir. Kateterin bükülmesi, çekiştirilmesi, silerken üzerine fazla kuvvet uygulanması zarar verebilir.

	MRG Güvenlik Bilgisi
	Klinik olmayan testler NuMED Balon Kateter Sistemleri'nin MR Koşullu olduğunu göstermiştir. Aşağıdaki etiketlendirme NuMED kateterlerine özgüdür ve NuMED Balon Kateter Sistemleri ile birlikte kullanılan kılavuz teller ve diğer aksesuarlar için geçerli değildir. Kullanıcılar NuMED kateterleri ile birlikte kullanılan diğer aksesuar cihazların kullanım talimatına ve MRG güvenlik bilgilerine bakmalıdır. NuMED Balon Kateter Sistemleri, aşağıdaki koşullarda 1,5 T veya 3,0 T'de vücudun herhangi bir yerinde güvenli kullanılabilir. Bu koşullara uyulmaması yaralanmaya neden olabilir.
Parametre	Koşul
Cihaz Adı	NuMED Balon Kateter Sistemleri
Statik Manyetik Alan Gücü (B0)	1,5 T ve 3 T
MR Tarayıcı Tipi	Silindirik
Maksimum Uzamsal Alan Gradyanı	19 T/m (1.900 G/cm)
RF Uyarımı	Dairesel Polarize (CP)
RF İletim Bobini Tipi	Entegre Tam Vücut İletim Bobini
Çalışma Modu	Normal Çalışma Modu
RF Koşulları	Maksimum Tam Vücut SAR değeri: 2,0 W/kg
Tarama Süresi	60 dakikalık sürekli RF taraması için 2 W/kg tam vücut ortalama SAR değeri
Görüntü Artefaktı	0,035 inç (0,889 mm) MR Koşullu kılavuz tel ile kombinasyon halinde bir NuMED Balon Kateterinin varlığı, 1,8 cm'lik bir radyal görüntü artefaktı oluşturabilir.

POTANSİYEL KOMPLİKASYONLAR

Cihazın kullanımı ve endikasyonu ile ilişkili olası komplikasyonlar ve advers etkiler şunları içerir:

- Enfeksiyon
- İnflamasyon
- Tromboembolik olaylar
- Hava embolisi
- Balon yırtılması
- Cerrahi onarım gerektiren damar yırtılması
- Ritim ve iletim rahatsızlığı
- Sol atriyal ekin yırtılması
- Damar intimasının hasarı
- Kanama
- Hematom oluşması
- İletim sistemi hasarı
- Ölüm

Cihazla ilişkili herhangi bir ciddi olay meydana geldiyse bu durum NuMED ve cihazın kullanıldığı ülkede Uyum Yetkilisine bildirilmelidir.

KONTROL VE HAZIRLAMA

1. Kılavuz teli kateterin proximal ucundan çıkıncaya kadar distal ucundan sokunuz.
2. Balon koruyucuyu çıkarınız ve kateteri kullanmadan önce katelerde kırılma ve bükülme olup olmadığını kontrol ediniz.
3. İçinde yarı yarıya normal salin solüsyonu dolu olan basınç göstergeli 3 cc'lik şişirme aletini kateterin balon lümenine bağlı olan musluğa bağlayınız.
4. Kateter lümeninin içine vererek sızıntı olup olmadığını gözleyiniz.
5. Şişirme aletinin pistonunu geri çekerek balondaki tüm havayı alınız.
6. Balonun içindeki vakumu koruyacak şekilde musluğu kapatınız.
7. Kılavuz teli çıkarınız.

DAMARA YERLEŞTİRME

1. %30 kontrast madde ile normal salin solüsyonu karışımı hazırlayınız.
2. İşlem için gerekli olan malzemeleri hazırlayınız.
3. Kateterler perkütan yaklaşım veya transubimalal yoldan gönderilebilir. Bu yaklaşımlarda **SPT002 - 9,5 mm** kateter ile 5F kalınlığında klif, **SPT003 - 13,5 mm**'lik kateter ile 6F kalınlığında klif kullanılmıdır. Bu giriş tekniklerinin güçlüğünde veya yetersizliğinde venöz cutdown tekniği kullanılabilir.
4. Kateterin yerleştirilmesi, floroskopi/MRG kılavuzluğunda veya özel durumlarda 2 boyutlu ekokardiografi rehberliğinde yapılabilir. Kateter, klifin içinden ilerletilerek inferior vena cava'dan geçerek sağ atriyağa gönderilir. Kateterin ucunun açılı olması interatriyal açıklıktan sol atriyağa geçişi kolaylaştırır. Pozisyonlandırmada zorluk halinde, **SPT002 - 9,5 mm**'lik kateter için 0,014 inç kalınlığında ve **SPT003 - 13,5 mm**'lik kateter için 0,021 inç kalınlığında kılavuz tel, emin ve daha rahat pozisyonlandırma için kullanılabilir. Septostomi işleminden önce kılavuz tel kateter şaftı içine çekilmelidir veya tamamen geri çekilip çıkarılmalıdır.
5. Balon septostomi işlemi en emin şekilde floroskopi, MRG veya 2-D eko eşliğinde yapılır. Balon sol atriyağın içinde iyi bir şekilde tespit edilmelidir. **SPT002 - 9,5 mm**'lik kateterin balonu 1 cc hacminde sıvı ile, **SPT003 - 13,5 mm**'lik kateterin balonu 2 cc'lik sıvı ile şişirilir ve musluk kapatılır. DKKAT: **SPT002 - 9,5 mm**'lik kateterin balonu için 1 cc ve **SPT003 - 13,5 mm**'lik kateterin balonu için 2 cc şişirme hacmini aşmayınız. Daha fazla şişirme balonun patlamasına sebep olabilir. Balon sonra ani ve hızlı bir şekilde sağ atriyağa çekilir. Bu çekme işlemi inferior vena cava-sağ atriyal bağlantısında durdurulmalı ve balon hızlı bir şekilde tekrar sağ atriyağa doğru itilmelidir (balon uyumlu olmadığı için IVC'nin şekline uymayacak ve balonun yırtılma olasılığı olacaktır). Balonu basınç göstergeli bir şişirme cihazına negatif basınç uygulayarak hemen söndürün (daha hızlı bir şekilde söndürülmesi gerekmiyorsa 3 cc önerilir, aksi takdirde basınç göstergeli, en fazla 10 cc'lik bir şişirme cihazı kullanılabilir).

Balonu atriyal septumdan çekmek için aşırı güç kullanımından kaçınılmalıdır. Özellikle, doktor, balonu septumdan çekerken tüm kol gücünü kullanmaktan kaçınmalı ve yalnızca bilek hareketiyle çekmelidir. Bu yöntem kullanıldığında balon septumdan kolayca çekilemezse, öncelikle az miktarda sıvı kullanılması önerilir. Daha sonra istenen sonuç elde edilene kadar sıvı miktarı yavaş yavaş artırılabilir. Bu ilk iki adım başarılı olmazsa, atriyal septuma statik balon dilasyonu işlemi uygulamayı göz önünde bulundurun.

Gerekli olduğu halde kateter, tekrar sol atriyağa pozisyonlandırılarak işlem tekrarlanabilir. Tek bir kateterizasyon işlemi sırasında gerçekleştirilen tekrarlı septostomi işlemi sayısı hastanın klinik durumu ve tedavinin etkinliği ile belirlenir.

6. Kateteri yavaşça geri çekin. Balon damardan çıkarken düzgün, yavaş ve düzenli bir hareket gerçekleştirin. Çıkarma sırasında direnç karşılaşırsa ve özellikle balonun patladığı veya sızıntı bulunduğu biliniyor veya buralardan şüpheleniliyorsa balon, kılavuz tel ve klif floroskopi/MRG kılavuzluğu altında bir ünite halinde birlikte çıkarılmalıdır. Bu, balon kateteri ve klifi bir ünite olarak sıkıca kavrayıp hafif bir çermine hareketiyle traksiyon kullanırken kişi beraber geri çekerek gerçekleştirebilir.
7. Perkütan Vasküler işlemlerde hastane protokolü veya standart uygulamalara uygun olarak giriş bölgesine basınç uygulayınız.
8. Cihazı kullandıktan sonra hastanenin biyolojik olarak tehlikeli cihazlar için olan standart protokolüne göre atınız.

UYARI: NuMED kateterleri insan vücudunun yabancı maddeye en fazla direnç gösteren bölgesine yerleştirilirler. Kateterler, tıbbi komplikasyonlar veya kateterin kırılmasını da kapsayan fakat bunlarla sınırlı olmayan bir çok nedenle beklenen fonksiyonu göstermeyebilirler. Buna ek olarak, dizayn, kullanılacak parçaların seçimi, üretim ve satış öncesi testi konularında gösterilen zorunluluğu olan dikkatin gösterilmesi rağmen kateterler vücuda sokulmadan önce, vücuda sokulma sırasında veya vücuda sokulduktan sonra yanlış tutma veya diğer girişim yanlışlıkları nedenleriyle zarar görebilirler. Dolayısıyla, hiçbir temsil veya garanti kateterin kullanımında başarısız olunmayacak veya kateterin fonksiyonunu yerine getirmesinde engellemeyecek, vücut kateterin yerleştirilmesinde engel olacak tepki vermeyecek veya kateter kullanımının akabinde tıbbi komplikasyon olmayacak demek değildir.

NuMED aksesuarları, kullanımından önce veya kullanımı sırasında yanlış tutulma nedeniyle yapısal zarar görebileceğinden NuMED tarafından garanti edilmemektedir. Bu nedenle, aksesuarlarla ilgili hiçbir beyan veya garanti verilmemektedir.

Garanti ve Sınırlamalar

Kateterler ve aksesuarları "olduğu gibi" satılırlar. Kalitesiyle ve performansıyla ilgili riskler alıcıya aittir. NuMED kateter ve aksesuarlarıyla ilgili her türlü ticari ve belirlir bir amaca uygunluk garantisi dahil ancak bunlarla sınırlı kalmamak üzere, açık veya zımnı her türlü garantiyi reddeder. NuMED, kateterin ve aksesuarının kullanılmasından ya da kateter veya aksesuarındaki bir aksaklık, arıza veya hatalı çalışmadan doğan doğrudan veya bunlara bağlı olarak oluşan hasarlardan (söz konusu hasar tazminatı garanti, sözleşme, haksız fil veya başka bir gerekçeye dayansa da) veya tıbbi masraflardan sorumlu tutulamaz. Hiç kimsenin kateter ve aksesuarlarına ilişkin bir temsil veya garanti konusunda NuMED'i bağlayıcı yetkisi yoktur.

Z-5™ Balon Ölçüleri Çizelgesi
SPT002 - 9,5 mm Balon Ölçüleri Çizelgesi

Enjekte edilen hacim	Sonuçta Oluşan Balon Çapı	Enjekte edilen hacim	Sonuçta Oluşan Balon Çapı
0,7 cc	7,95mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

SPT003 - 13,5 mm Balon Ölçüleri Çizelgesi

Enjekte edilen hacim	Sonuçta Oluşan Balon Çapı	Enjekte edilen hacim	Sonuçta Oluşan Balon Çapı
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

ΕΛΛΗΝΙΚΑ

Οδηγίες χρήσης

ΕΝΔΕΙΞΕΙΣ

Συνιστάται για κολπική διαφραγματοστομία με μπαλόνι, μια αποδεκτή τεχνική στα περισσότερα παιδοκαρδιολογικά κέντρα για την ανακουφιστική αγωγή διαφόρων συγγενών καρδιακών ελλειμμάτων. Η κολπική διαφραγματοστομία με μπαλόνι πραγματοποιείται σε συνδυασμό με διαγνωστικό καρδιακό καθετήριασμό και έχει πραγματοποιηθεί μετά τη διάγνωση διαφόρων καρδιακών ελλειμμάτων: μετάθεση των μεγάλων αρτηριών, ολική ανώμαλη εκβολή των πνευμονικών φλεβών χωρίς πνευμονική απόφραξη, ατρησία τριγλώχινας, στένωση μιτροειδούς, ατρησία μιτροειδούς και ατρησία πνευμονικής με ακραίο μεσοκοιλιακό διαφράγμα. Ο **SPT002 - 9,5 mm** προορίζεται κυρίως για βρέφη κάτω των 2 kg.

ΠΕΡΙΓΡΑΦΗ ΤΟΥ ΚΑΘΗΤΗΡΑ

Ο καθετήρας κολπικής διαφραγματοστομίας NuMED είναι ένας νέος καθετήρας με μπαλόνι σχεδιασμένος για νεογνά με συγγενή καρδιοπάθεια που χρήζουν διαφραγματοστομίας. Είναι ένας καθετήρας δύο αυλών, μήκους 50 cm. Ο **SPT002** έχει ένα μη ενδοτικό μπαλόνι 9,5 mm ± 0,5, σε όγκο 1,0 cc, στο περιφερικό άκρο. Ο **SPT003** έχει ένα μη ενδοτικό μπαλόνι 13,5 mm ± 0,5, σε όγκο 2,0 cc, στο περιφερικό άκρο. Ο καθετήρας **SPT002 - 9,5 mm** διαθέτει επίσης μια τελική στή που μπορεί να δεχτεί οδηγό σύρμα 0,014", ο καθετήρας **SPT003 - 13,5 mm** διαθέτει επίσης μια τελική στή που μπορεί να δεχτεί οδηγό σύρμα 0,018" έως 0,021". Η γεωμετρία του πληρωμένου μπαλονιού είναι σφαιρική. Υπάρχει μια ταϊνία απεικόνισης κάτω από το μπαλόνι, για την τοποθέτηση του μπαλονιού στον αριστερό κόλπο. Το άκρο του καθετήρα σχηματίζει γωνία 35°, για τη διευκόλυνση της διέλευσης διαμέσου του ανοίγματος μεταξύ της αορτής και της πνευμονικής αρτηρίας στον αριστερό κόλπο. Για τη διόγκωση του μπαλονιού του καθετήρα **SPT002 - 9,5 mm** στη μέγιστη διάμετρό του, ωθήστε 1 cc αραιωμένου σκιαγραφικού μέσου στην προέκταση του μπαλονιού μετά την εκκένωση του. Για τη διόγκωση του μπαλονιού του καθετήρα **SPT003 - 13,5 mm** στη μέγιστη διάμετρό του, ωθήστε 2 cc αραιωμένου σκιαγραφικού μέσου στην προέκταση του μπαλονιού μετά την εκκένωσή του. Οι καθετήρες παρέχονται με μονόδρομη στρόφιγγα, για στεγανοποίηση του μπαλονιού.

ΤΡΟΠΟΣ ΔΙΑΘΕΣΗΣ

Παρέχεται αποστειρωμένο με αέριο αιθυλενοξείδιο. Αποστειρωμένο και μη πυρετογόνο εάν η συσκευασία δεν έχει ανοιχτεί ή δεν έχει υποστεί ζημία. Μη χρησιμοποιείτε το προϊόν εάν υπάρχει αμφιβολία ως προς τη στεριότητα του προϊόντος. Αποφύγετε την παρατεταμένη έκθεση σε φως. Αφού το αφαιρέσετε από τη συσκευασία, ελέγξτε το προϊόν για να βεβαιωθείτε ότι δεν έχει προκληθεί ζημία.

ΠΡΟΕΙΔΟΠΟΙΗΣΗ

- **ΠΡΟΣΟΧΗ:** Μην υπερβαίνετε τον ονομαστικό όγκο του 1 cc για τον καθετήρα **SPT002 - 9,5 mm**. Η υπερβολική διόγκωση μπορεί να προκαλέσει ρήξη του μπαλονιού.
- **ΠΡΟΣΟΧΗ:** Μην υπερβαίνετε τον ονομαστικό όγκο των 2 cc για τον καθετήρα **SPT003 - 13,5 mm**. Η υπερβολική διόγκωση μπορεί να προκαλέσει ρήξη του μπαλονιού.
- Χρησιμοποιείτε μόνο το εγκεκριμένο μέσο διόγκωσης μπαλονιών. Μη χρησιμοποιείτε αέρα ή άλλο αέριο μέσο για να διογκώσετε το μπαλόνι.
- Χρησιμοποιήστε μόνο συσκευή διόγκωσης 3 cc με μανόμετρο για τη διόγκωση.
- Χρησιμοποιήστε μόνο συσκευή διόγκωσης 3 cc με μανόμετρο για τη σύμπτυξη. (Για ταχύτερη σύμπτυξη, μπορεί να χρησιμοποιηθεί συσκευή διόγκωσης έως και 10 cc).
- Μην υπερβαίνετε την πίεση έγχυσης των 300 psi για τον καθετήρα **SPT002 - 9,5 mm**.
- Μην υπερβαίνετε την πίεση έγχυσης των 600 psi για τον καθετήρα **SPT003 - 13,5 mm**.
- Μην προωθείτε το οδηγό σύρμα, τον καθετήρα κολπικής διαφραγματοστομίας ή οποιοδήποτε άλλο εξάρτημα αν συναντήσετε αντίσταση, χωρίς πρώτα να προσδιορίσετε την αιτία και να λάβετε διορθωτικά μέτρα.
- Αυτός ο καθετήρας δεν συνιστάται για μέτρηση πίεσης ή έγχυση υγρού.
- Αυτή η συσκευή προορίζεται για μία χρήση μόνο. Μην την επαναποστερίωνετε ή/και επαναχρησιμοποιείτε, καθώς κάτι τέτοιο μπορεί δυνητικά να υποβαθμίσει την απόδοση της συσκευής και να αυξήσει τον κίνδυνο διασταυρούμενης μόλυνσης.
- Η χρήση υπερβολικής πίεσης για την έλξη του μπαλονιού επί του μεσοκοιλιακού διαφράγματος πρέπει να αποφεύγεται.

ΠΡΟΦΥΛΑΞΕΙΣ

- Η NuMED συνιστά τη χρήση του καθετήρα **SPT002 - 9,5 mm** με εισαγωγή 5 F, για τη διασφάλιση της εισόδου.
- Η NuMED συνιστά τη χρήση του καθετήρα **SPT003 - 13,5 mm** με εισαγωγή 6 F, για τη διασφάλιση της εισόδου.
- Δεν θα πρέπει να πραγματοποιείται κολπική διαφραγματοστομία με μπαλόνι για βρέφη ηλικίας άνω των έξι εβδομάδων. Αυτά τα βρέφη έχουν μεσοκοιλιακά διαφράγματα μεγάλου πάχους. Ανατρέξτε στις κατευθυντήριες οδηγίες των AHA/ACC.
- Η διαδικασία διαστολής θα πρέπει να διεξάγεται υπό ακτινοσκοπική καθοδήγηση/καθοδήγηση με μαγνητική τομογραφία με κατάλληλο ακτινογραφικό εξοπλισμό.
- Τα οδηγία σύρματα είναι ευαίσθητα εργαλεία. Θα πρέπει να δίδεται προσοχή κατά τον χειρισμό ώστε να αποφευχθεί η πιθανότητα θραύσης.
- Πριν προχωρήσετε, πρέπει να επαληθεύσετε με προσοχή ότι οι συνδέσεις του καθετήρα είναι σφικτές και υπάρχει αναρρόφηση για την αποφυγή εισαγωγής αέρα στο σύστημα.
- Σε καμία περίπτωση δεν θα πρέπει να προωθήσετε οποιοδήποτε τμήμα του συστήματος του καθετήρα εάν συναντήσετε

αντίσταση. Θα πρέπει να προσδιοριστεί η αιτία της αντίστασης με ακτινοσκόπηση/μαγνητική τομογραφία και να ληφθούν μέτρα για την αποκατάσταση του προβλήματος.

- Εάν συναντήσετε αντίσταση κατά την αφαίρεση, τότε το μταλόνι, το οδηγό σύρμα και το θηκάρι θα πρέπει να αφαιρεθούν μαζί ως ενιαία μονάδα, ιδιαίτερα εάν είναι γνωστή η ύπαρξη υποψία ρήξης ή διαρροής του μταλονιού. Αυτό μπορεί να επιτευχθεί κρατώντας σταθερά τον καθετήρα με μταλόνι και το θηκάρι ως ενιαία μονάδα και αποσύροντας και τα δύο μαζί, χρησιμοποιώντας ήπια περιστροφική κίνηση σε συνδυασμό με έλξη.
- Πριν από την αφαίρεση του καθετήρα από το θηκάρι, είναι πολύ σημαντικό το μταλόνι να έχει συμπιχθεί πλήρως.
- Η σωστή λειτουργία του καθετήρα εξαρτάται από την ακεραιότητά του. Θα πρέπει είστε προσεκτικοί κατά τον χειρισμό του καθετήρα. Μπορεί να προκληθεί ζημία από στρέβλωση, τάνυση ή έντονο σκούπισμα του καθετήρα.



Πληροφορίες ασφάλειας για μαγνητική τομογραφία

Μη κλινικές δοκιμές έχουν καταδείξει ότι τα συστήματα καθετήρων με μταλόνι της NuMED είναι ασφαλή για χρήση σε μαγνητική τομογραφία υπό προϋποθέσεις. Η παρακάτω επισήμανση είναι ειδική για τους καθετήρες της NuMED και δεν εφαρμόζεται στα οδηγιά σύρματα ή σε άλλα παρελκόμενα που χρησιμοποιούνται σε συνδυασμό με τα συστήματα καθετήρων με μταλόνι της NuMED. Οι χρήστες θα πρέπει να συμβουλευθούν τις οδηγίες χρήσης και τις πληροφορίες ασφάλειας για μαγνητική τομογραφία άλλων παρελκόμενων τεχνολογικών προϊόντων που χρησιμοποιούνται με τους καθετήρες της NuMED. Τα συστήματα καθετήρων με μταλόνι της NuMED μπορούν να σωθούν οπουδήποτε στο σώμα σε 1,5 T ή 3,0 T κάτω από τις ακόλουθες προϋποθέσεις. Η μη τήρηση αυτών των προϋποθέσεων μπορεί να οδηγήσει σε τραυματισμό.

Παράμετρος	Προϋπόθεση
Όνομα Προϊόντος	Συστήματα καθετήρων με μταλόνι της NuMED
Ένταση Στατικού Μαγνητικού Πεδίου (B0)	1,5 T και 3 T
Τύπος Σπρωχτής Μαγνητικής Τομογραφίας	Κυλινδρικός
Πεδίο Μέγιστης Χωρικής Βαθμίδωσης	19 T/m (1.900 G/cm)
Διέγερση λόγω Ραδιοσυνοχής	Κυκλικά Πολωμένο (Circularly Polarized - CP)
Τύπος Πηλίου Μετάδοσης Ραδιοσυνοχής	Ενσωματωμένο Πηλίο Ολοσωματικής Μετάδοσης
Τρόπος Λειτουργίας	Κανονικός Τρόπος Λειτουργίας
Προποθέσεις Ραδιοσυνοχής	Μέγιστος Ρυθμός Ειδικής Ολοσωματικής Απορρόφησης: 2,0 W/kg
Διάρκεια Σάρωσης	Μέγιστος ρυθμός ειδικής ολοσωματικής απορρόφησης 2 W/kg για 60 λεπτά σάρωσης ραδιοσυνοχής
Τέχνημα Εικόνας	Η παρουσία καθετήρα με μταλόνι της NuMED σε συνδυασμό με οδηγό σύρμα 0,035" (0,889 mm) ο οποίος είναι ασφαλής για μαγνητική τομογραφία υπό προϋποθέσεις μπορεί να παράγει ένα ακινικό τέχνημα εικόνας των 1,8 cm.

ΔΥΝΗΤΙΚΕΣ ΕΠΙΠΛΟΚΕΣ

Στις δυνητικές επιπλοκές και ανεπιθύμητα συμβάντα που σχετίζονται με τη χρήση και την ένδειξη του τεχνολογικού προϊόντος συγκαταλέγονται τα εξής:

- Λοίμωξη
- Φλεγμονή
- Θρομβοεμβολικά συμβάντα
- Εμβολή αέρα
- Δυνητικός διαχωρισμός του μταλονιού με επακόλουθη ανάγκη χρήσης βρόχου
- Αγγειακή διάτρηση που χρήζει χειρουργικής αποκατάστασης
- Διαταραχές του ρυθμού και της αγωγιμότητας
- Διάτρηση του ωτίου του αριστερού κόλπου
- Ζημία στον εσωτερικό αγγειακό χιτώνα
- Αιμορραγία
- Δημιουργία αιματώματος
- Τραυματισμός του συστήματος αγωγής
- Θάνατος

Οποιοδήποτε σοβαρό συμβάν που έχει παρουσιαστεί σε σχέση με αυτό το τεχνολογικό προϊόν θα πρέπει να αναφέρεται στη NuMED και στην αρμόδια αρχή της χώρας χρήσης.

ΕΠΙΔΕΥΣΗ ΚΑΙ ΠΡΟΕΤΟΙΜΑΣΙΑ

- Εισαγάγετε οδηγό σύρμα διαμέσου του περιφερικού άκρου, μέχρι το οδηγό σύρμα να εξέλθει από την εγγύς θύρα.
- Αφαιρέστε το προστατευτικό κάλυμμα του μταλονιού. Επιστρώστε τον καθετήρα για ζημία πριν από την εισαγωγή.
- Προσάρτηστε μια συσκευή διόγκωσης 3 cc με μανόμετρο, πληρωμένη μέχρι τη μέση με φυσιολογικό ορό και προσαρτήστε τη στη στρόφιγγα που είναι ήδη προσαρτημένη στη θύρα του μταλονιού.
- Εξερεώστε και εκπλύνετε τον καθετήρα διαμέσου του αυλού πλήρως, παρατηρώντας για τυχόν διαρροές.
- Στρέψτε τη συσκευή διόγκωσης με το ακροφύσιο να μονομέτρου προς τα κάτω, αναρροφήστε μέχρι να αφαιρεθεί όλος ο αέρας από το μταλόνι και να μην εμφανίζονται πλέον φυσαλίδες αέρα στο σκιαγραφικό μέσο.
- Κλείστε τη στρόφιγγα, για να διατηρηθεί το κενό στο μταλόνι.
- Αφαιρέστε το οδηγό σύρμα.

ΕΙΣΑΓΩΓΗ: ΑΓΓΕΙΑΚΗ

- Παρασκευάστε ένα μείγμα 30% κατ' όγκον σκιαγραφικού μέσου και φυσιολογικού ορού.
- Προετοιμάστε τον ασθενή για τη διαδικασία.
- Είναι δυνατή η εισαγωγή καθετήρων μέσω διαδερμικής προσπέλασης ή μέσω της ομφαλικής φλέβας. Ο καθετήρας **SPT002 - 9,5 mm** απαιτεί θηκάρι εισαγωγέα 5 F, ο καθετήρας **SPT003 - 13,5 mm** απαιτεί θηκάρι εισαγωγέα 6 F (βλέπε Προφυλάξεις) κατά τη χρήση αυτής της προσπέλασης. Σε περίπτωση αποτυχίας αυτής της τεχνικής προσπέλασης, μπορεί να χρησιμοποιηθεί φλεβοτομία.
- Η τοποθέτηση του καθετήρα μπορεί να επιτευχθεί υπό ακτινοσκοπική καθοδήγηση/καθοδήγηση με μαγνητική τομογραφία ή υπό ειδικές συνθήκες με χρήση ηχοκαρδιογραφικής καθοδήγησης δύο διαστάσεων. Μόλις εισέλθει μέσα από το θηκάρι, ο καθετήρας διέρχεται προς την κάτω κοίλη φλέβα και στον δεξιό κόλπο. Το γυναικό άκρο διευκολύνει τη διέλευση διαμέσου του μεσοκοιλιακού ανόligματος στον αριστερό κόλπο. Σε περίπτωση δυσκολίας τοποθέτησης, μπορεί να χρησιμοποιηθεί οδηγό σύρμα 0,36 mm (0,014") για τον καθετήρα **SPT002 - 9,5 mm** ή οδηγό σύρμα 0,53 mm (0,021") για τον καθετήρα **SPT003 - 13,5 mm** για την επίτευξη ασφαλούς τοποθέτησης. Το οδηγό σύρμα θα πρέπει να αποσύρεται στο στέλεχος του καθετήρα ή να αφαιρείται πλήρως προτού προχωρήσετε στην κολπική διαφραγμαστομία.
- Η κολπική διαφραγμαστομία με μταλόνι πραγματοποιείται με ασφάλεια υπό ακτινοσκόπηση, μαγνητική τομογραφία ή διαδίστατο υπερηχογράφημα. Το μταλόνι πρέπει να αναγνωρίζεται σαφώς στον αριστερό κόλπο. Το μταλόνι του καθετήρα **SPT002 - 9,5 mm** διογκώνεται με 1 cc υγρού, το μταλόνι του καθετήρα **SPT003 - 13,5 mm** διογκώνεται με 2 cc υγρού και τη στρόφιγγα κλείνει. ΠΡΟΣΟΧΗ: Μην υπερβείτε τον όγκο του 1 cc για τον καθετήρα **SPT002 - 9,5 mm** ή τον όγκο των 2 cc για τον καθετήρα **SPT003 - 13,5 mm**. Η υπερβολική διόγκωση μπορεί να προκαλέσει ρήξη του μταλονιού. Το μταλόνι κατόπιν αποσύρεται στον δεξιό κόλπο με γρήγορη, χαλαρή κίνηση. Αυτός ο χειρισμός απόσυρσης πρέπει να διακόπτεται στη συμβολή κάτω κοίλης φλέβας-δεξιού κόλπου και το μταλόνι να επαναρπρωθεί ταχέως στον δεξιό κόλπο (καθώς το μταλόνι είναι μη ενδοτικό, δεν θα προσαρμωθεί στο σχήμα της ΚΚΦ και υπάρχει ενδεχόμενο ρήξης). Συμπύκτε το μταλόνι εφαρμόζοντας αρνητική πίεση στη συσκευή διόγκωσης με μανόμετρο (συνιστάται συσκευή των 3 cc εκτός εάν απαιτείται ταχύτερη σύμπτυξη, κατόπιν μπορεί να χρησιμοποιηθεί συσκευή διόγκωσης με μανόμετρο έως και 10 cc).

Η χρήση υπερβολικής πίεσης για την έλξη του μπαλονιού επί του μεσοκολπικού διαφράγματος πρέπει να αποφεύγεται.

Συγκεκριμένα, ο ιατρός θα πρέπει να αποφεύγει τη χρήση όλου του βραχίονα κατά την απόσυρση του μπαλονιού επί του διαφράγματος και θα πρέπει να χρησιμοποιεί μόνο την κίνηση του καρπού. Εάν το μπαλόνι δεν μπορεί να διέλθει εύκολα από το διάφραγμα με τη χρήση αυτής της μεθόδου, συνιστάται η αρχική χρήση μικρότερου όγκου υγρού. Η ποσότητα του υγρού μπορεί κατόπιν να αυξηθεί σταδιακά σε όγκο, μέχρι την επίτευξη του επιθυμητού αποτελέσματος. Εάν τα πρώτα δύο βήματα δεν είναι επιτυχή, εξετάστε το ενδεχόμενο χρήσης διαστολής με στατικό μπαλόνι του μεσοκολπικού διαφράγματος.

Εάν είναι απαραίτητο, ο καθετήρας μπορεί να επαναποποθεθεί στον αριστερό κόλπο και η διαδικασία μπορεί να επαναληφθεί. Ο αριθμός των επαναλήψεων των διαφραγματισοσυσμών που πραγματοποιούνται κατά τη διάρκεια ενός καθετηριασμού προσδιορίζεται από την κλινική κατάσταση του ασθενούς και την εκτίμηση της αποτελεσματικής ανακουφιστικής αγωγής.

6. Αποσύρετε με ήπιες κινήσεις τον καθετήρα. Όσο εξέρχεται το μπαλόνι από το αγγείο, χρησιμοποιήστε ομαλή, ήπια, σταθερή κίνηση. Εάν συναντήσετε αντίσταση κατά την αφαίρεση, τότε το μπαλόνι, το οδηγό σύρμα και το θηκάρι θα πρέπει να αφαιρεθούν μαζί ως ενιαία μονάδα, υπό ακτινοσκοπική καθοδήγηση/καθοδήγηση με μαγνητική τομογραφία, ιδιαίτερα εάν είναι γνωστή ή υπάρχει υποψία ρήξης ή διαρροής του μπαλονιού. Αυτό μπορεί να επιτευχθεί κρατώντας σταθερά τον καθετήρα με μπαλόνι και το θηκάρι ως ενιαία μονάδα και αποσύροντας και τα δύο μαζί, χρησιμοποιώντας ήπια περιστροφική κίνηση σε συνδυασμό με έλξη.
7. Εφαρμόστε πίεση στο σημείο εισαγωγής σύμφωνα με την τυπική πρακτική ή το πρωτόκολλο του νοσοκομείου για διαδερμικές αγγειακές διαδικασίες.
8. Απορρίψτε το τεχνολογικά προϊόν μετά τη χρήση σύμφωνα με το πρωτόκολλο του νοσοκομείου για βιολογικά επικινδύνα τεχνολογικά προϊόντα

ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Οι καθετήρες NuMED τοποθετούνται στο εξαιρετικά εχθρικό περιβάλλον του ανθρώπινου σώματος. Οι καθετήρες μπορεί να μη λειτουργήσουν για διάφορες αιτίες που περιλαμβάνουν, μεταξύ άλλων, ιατρικές επιπλοκές ή αστοχία των καθετήρων λόγω θραύσης. Επιπλέον, παρά την απαιτούμενη προσοχή που έχει δοθεί κατά τον σχεδιασμό, την επιλογή εξαρτημάτων, την κατασκευή και τη δοκιμή πριν από την πώληση, οι καθετήρες μπορούν εύκολα να υποστούν ζημιά πριν, κατά τη διάρκεια ή μετά την εισαγωγή, λόγω ακατάλληλου χειρισμού ή άλλης παρεμβατικής ενέργειας. Συνεπώς, δεν παρέχεται καμία δήλωση ή εγγύηση ότι δεν θα προκύψει βλάβη ή διακοπή της λειτουργίας των καθετήρων ή ότι το σώμα δεν θα αντιδράσει δυσμενώς στην τοποθέτηση καθετήρων ή ότι μετά τη χρήση των καθετήρων δεν θα εμφανιστούν ιατρικές επιπλοκές.

Η NuMED δεν μπορεί να παράσχει εγγύηση για παρελκόμενα NuMED, επειδή η δομή των παρελκόμενων ενδέχεται να υποστεί ζημιά λόγω ακατάλληλου χειρισμού πριν ή κατά τη διάρκεια της χρήσης. Ως εκ τούτου, δεν παρέχονται δηλώσεις ή εγγυήσεις σχετικά με αυτά.

Εγγύηση και περιορισμοί

Οι καθετήρες και τα παρελκόμενα πωλούνται σε κατάσταση «ως έχουν». Ο αγοραστής αναλαμβάνει όλους τους κινδύνους που σχετίζονται με την ποιότητα και την απόδοση του καθετήρα. Η NuMED αποποιείται κάθε εγγύηση, ρητή ή σιωπηρή, όσον αφορά τους καθετήρες και τα παρελκόμενα, συμπεριλαμβανομένων, μεταξύ άλλων, κάθε σιωπηρής εγγύησης εμπιστευσιμότητας ή καταλληλότητας για συγκεκριμένο σκοπό. Η NuMED δεν φέρει ευθύνη έναντι οποιουδήποτε ατόμου για οποιεσδήποτε ιατρικές δαπάνες ή οποιεσδήποτε άμεσες ή επακόλουθες ζημιές που προκύπτουν από τη χρήση οποιουδήποτε καθετήρα ή παρελκόμενου, ανεξάρτητα από το αν η αξίωση για τέτοιου είδους ζημιές βασίζεται σε εγγύηση, σύμβαση, αδικοπράξια ή άλλως. Κανένα άτομο δεν έχει την άδεια να δεσμεύσει την NuMED σε οποιαδήποτε δήλωση ή εγγύηση όσον αφορά τους καθετήρες και τα παρελκόμενα.

Διάγραμμα προσδιορισμού μεγέθους μπαλονιού Z-5™
Διάγραμμα προσδιορισμού μεγέθους μπαλονιού SPT002 - 9,5 mm

Όγκος που εγχύθηκε	Διάμετρος μπαλονιού που προκύπτει	Όγκος που εγχύθηκε	Διάμετρος μπαλονιού που προκύπτει
0,7 cc	7,95 mm ± 0,5 mm	0,9 cc	8,65 mm ± 0,5 mm
0,8 cc	8,00 mm ± 0,5 mm	1,0 cc	9,35 mm ± 0,5 mm

Διάγραμμα προσδιορισμού μεγέθους μπαλονιού SPT003 - 13,5 mm

Όγκος που εγχύθηκε	Διάμετρος μπαλονιού που προκύπτει	Όγκος που εγχύθηκε	Διάμετρος μπαλονιού που προκύπτει
0,5 cc	8,0 mm ± 0,5 mm	1,5 cc	12,0 mm ± 0,5 mm
1,0 cc	10,5 mm ± 0,5 mm	2,0 cc	13,5 mm ± 0,5 mm

	Do Not Reuse Ne pas réutiliser Non riutilizzare Nicht wiederverwenden No reutilizar Får ej återanvändas	Må ikke genbruges Niet hergebruken Nào Reutilizar Tekrar Kullanmayın Μην επαναχρησιμοποιείτε		Catalogue Number Número de catalogue Numero di catalogo Katalognummer Número de catálogo Katalognummer	Katalognummer Catalogusnummer Número de Catálogo Katalog Numarası Αριθμός καταλόγου
	Batch Code Code du lot Codice del lotto Chargencode Código del lote Sändningskod	Partikode Partijcode Código do Lote Parti Kodu Κωδικός παρτίδας		Use By À utiliser avant Utilizzare entro Verwendbar bis Usar antes de Använd senast	Anvendes inden Gebruiken voor Usar Até Son Kullanma Tarihi Ημερομηνία λήξης
	Do not resterilize Ne pas restériliser Non ristabilizzare Nicht reesterilisieren No reesterilizar Får inte omsteriliseras	Må ikke resteriliseres Niet hersteriliseren Nào reesterilizar Yeniden sterilize etmeyin Μην επανοστεριζώνεστε		Temperature Limitation Limite de température Limitazione di temperatura Temperaturbegrenzung Limitación de la temperatura Temperaturbegrensning	Temperaturbegrensning Temperaturbeperking Limite de Temperatura Isi Sınırlaması Περιορισμός θερμοκρασίας
	Consult Instructions for Use Consulter le mode d'emploi Consultare le istruzioni per l'uso Gebruiksaanwijzing beachten Consultar las instrucciones de uso Läs bruksanvisningen			Konsultér brugsanvisningen Gebruiksaanwijzing raadplegen Consultar as instruções de utilização Kullanım talimatına bakın Συμβουλευτείτε τις οδηγίες χρήσης	
	Keep Away From Sunlight Garder à l'abri de la lumière du soleil Proteggere dai raggi solari Sonnenstrahlung vermeiden Mantener alejado de la luz solar Exponera inte för direkt solljus			Holdes væk fra sollys Uit direct zonlicht houden Mantem Afastado da Luz Solar Güneş Işığından Uzak Tutun Διατηρείτε μακριά από ηλιακό φως	
	Manufacturer / Date of Manufacture Fabricant / Date de fabrication Produttore / Data di fabbricazione Hersteller / Herstellungsdatum Fabricante / Fecha de fabricación Tilvarekare / Tilværkningsdatum			Producent / fremstillingsdato Fabrikant / Productiedatum Fabricante / Data de Fabrico Üretici / Üretim Tarihi Κατασκευαστής / Ημερομηνία κατασκευής	
	Double Sterile Barrier System Système de double barrière stérile Sistema di barriera sterile doppia Doppeltes Sterilbarriersystem Sistema de doble barrera estéril Dubbelt sterilit barriärsystem			Dobbelt sterilit barriersystem Systeem met dubbele steriele barrière Sistema de barreira dupla estéril Çift steril bariyer sistemi Διπλά αποστειρωμένο σύστημα φραγμού	
	Sterilized Using Ethylene Oxide Stérilisé à l'oxyde d'éthylène Sterilizzato con ossido di etilene Sterilisiert mit Ethylenoxid Esterilizado con óxido de etilen Steriliserad med etylenoxid			Steriliseret med ethylenoxid Gesteriliseerd met ethyleenoxide Esterilizado Usando Óxido de Etileno Etilen Oksit Kullanılarak Sterilize Edilmiştir Αποστειρώθηκε με χρήση οξείδιου του αιθυλενίου	
	Authorised Representative in the European Community Représentant autorisé dans la Communauté européenne Rappresentante autorizzato nella Comunità Europea Autorisierter Vertreter in der Europäischen Gemeinschaft Representante autorizado en la Comunidad Europea Autoriserad representant inom EU			Autoriseret repræsentant i Det Europæiske Fællesskab Gevollmachtigd vertegenwoordiger in de Europese Gemeenschap Representante Autorizado na Comunidade Europeia Avrupa Topluluğunda Yetkili Temsilci Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα	
	Do not use if package is damaged and consult instructions for use Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi Non usare se la confezione è danneggiata e consultare le istruzioni per l'uso Bei beschädigter Verpackung nicht verwenden und Gebrauchsanweisung beachten No utilizar si el envase está dañado y consultar las instrucciones de uso Får ej användas om förpackningen är skadad och se bruksanvisningen			Må ikke anvendes, hvis emballagen er beskadiget. Konsultér brugsanvisningen Niet gebruiken als de verpakking is beschadigd en gebruiksaanwijzing raadplegen Não utilizar se a embalagem estiver danificada e consultar as instruções de utilização Paket hasarlıysa kullanmayın ve kullanım talimatına bakın Μην χρησιμοποιείτε, ένα η συσκευασία έχει υποστεί ζημιά και συμβουλευτείτε τις οδηγίες χρήσης	
	MR Conditional Utilisable(s) en environnement RM sous certaines conditions A compatibilità RM condizionata Bedingt MR-sicher Producto seguro bajo ciertas condiciones de la resonancia magnética Vilkorligt godkänd för MR			Betinget MR-sikker MRI-veilig onder bepaalde voorwaarden MR Conditional (pode ser submetido a exames de RM sob determinadas condições) MR Kogullu Ασφαλές για μαγνητική τομογραφία υπό προϋποθέσεις	
	Medical Device Dispositif Médical Dispositivo medico Medizinprodukt Producto sanitario Medicinteknisk produkt			Medicinsk udstyr Medisch hulpmiddel Dispositivo médico Tıbbi Cihaz Ιατροτεχνολογικό προϊόν	

IFU-210CE-21



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RM0344-05K

03 February 2022