Endovascular Catalog - U.S.

Cordis®
A Cardinal Health company

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Cordis is a worldwide leader in the development and manufacture of interventional vascular technology with a more than 50-year history of delivering pioneering products to treat millions of patients.

Our focus is in cardiology and endovascular platforms, with high-quality products such as diagnostic and interventional catheters, balloons, self-expanding stents, guide wires, and vascular closure devices. Working with our customers, we identify solutions that provide the best possible results for both physicians and patients.

We will continue to build on our rich history as part of Cardinal Health, a company with complementary skills and expertise. By leveraging Cordis' deep experience in product innovation and Cardinal Health's business and operational expertise, we are uniquely positioned to continue meeting the evolving needs of our customers and their patients – and remain at the forefront of change in healthcare.

To learn more visit cordis.com

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Access Portfolio

AVANTI®+ Sheath Introducer

The Cordis AVANTI®+ Sheath Introducer is the pioneer of catheter sheath introducer technology. Featuring a patented SLIX™ Valve, the AVANTI®+ Sheath Introducer provides smooth transitions, monitoring capabilities and exceptional performance for your procedural success, as well as:

- A hexacuspid design that provides a balance between catheter maneuverability and hemostasis.
- A rotating suture collar that facilitates procedural flexibility. It stays in place and allows patient movement.
- A kink-resistant cannula design integrating a soft, flexible inner layer with a stiffer outer layer for excellent bendability and support. It is also cost-effective and reliable.
- Atraumatic tip transitions for both the sheath and the vessel dilator are uniquely tapered and manicured. This results in smooth insertions and may help lessen damage upon entry.

Learn more on page 6.

BRITE TIP® Catheter Sheath Introducer

The Cordis BRITE TIP® Catheter Sheath Introducer provides flexibility and control with a kink resistant cannula and patented SLIX™ Valve, as well as:

- A unique dual layer cannula offering the flexibility and support to access tortuous vessels.
- A thicker cannula wall for excellent kink resistance.
- A silicone coated cannula for lubricious, anti-thrombogenic vessel entry.
- A patented SLIX valve with a six-cut spiral design for hemostasis, minimizing blood reflux and air aspiration.

Learn more on page 7.

Obturators

- Flexible shaft helps prevent kinking of the sheath when the sheath is used in a patient for a long period of time without a product in place.
- Easy French size identification provided by a color coding system and the number on the hub*.
- Easy to store boxes with small dimensions.
- Ease of insertion through the sheath and minimal vessel damage due to the rounded atraumatic distal tip.
- No "backing out" of the obturator by the secure snap fit between obturator and sheath.
- Low profile hub to ease placement and manipulation.

Learn more on page 8.

Vessel Dilators

- Secure snap to prevent "backing out" of the dilator
- Easy insertion due to lubricious SLX™ coating
- Minimal tissue trauma due to optimized tapering

Learn more on page 9.

* 4F-red, 5F-grey, 6F-green, 7F-orange, 8F-blue, 9F-black, 10F-magenta, 11F-yellow.

AVANTI®+ Sheath Introducer

The Cordis AVANTI®+ Sheath Introducer is the pioneer of catheter sheath introducer technology. Featuring a patented SLIX™ Valve, the AVANTI®+ introducer provides smooth transitions, monitoring capabilities and exceptional performance for your procedural success

Vessel Dilator

CSI

Mini-Guidewire

Key Features

- .035" guidewire compatible
- Unique SLIX™ valve for uncompromised valve hemostasis
- Flexible and kink resistant
- Excellent OD/ID ratio
- Smooth insertion
- Units per package: 5

		Brachial / Pediatric 5.5cm Cannula		Mid-length 11cm Cannula		Standard 23cm Cannula
French Size (F)	**Color Code**	**With Mini-Guidewire**	**Without Mini-Guidewire**	**With Mini-Guidewire**	**Without Mini-Guidewire**	**Without Mini-Guidewire**
4		402604P		402604X	402604A	
5		402605P		402605X	402605A	402605T
5.5				402655X		
6		402606P	402-606R	402606X	402606A	402606T
6.5				402656X		
7		402607P	402-607R	402607X	402607A	
8				402608X	402608A	402608T
9				402609X	402609A	402609T
10				402610X	402610A	
11				402611X		

For information on indications, contraindications, warnings, and precautions, see page 87.

BRITE TIP® Catheter Sheath Introducer

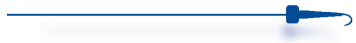
Provides excellent visualization of the tungsten-filled radiopaque tip, which facilitates exact location of the sheath's distal tip for accurate positioning. Longer lengths are available for a wide variety of interventional procedures.

Key Features

- Co-extruded kink resistant cannula
- Unique SLIX™ valve for excellent valve hemostasis
- 3mm atraumatic, and radiopaque distal tip for precise placement
- Smooth transition between cannula and dilator
- Excellent kink resistance and back up support
- 5 units per package for 5.5cm, 11cm and 23cm lengths
- 2 units per package for 35cm or longer lengths

vessel dilator

CSI



mini-guidewire

French Size (F)	Color Code	Dilator Tip	5.5cm Cannula With mini-guidewire	11cm cannula With mini-guidewire	23cm cannula Without mini-guidewire	35cm cannula Without mini-guidewire	45cm cannula Without mini-guidewire	55cm cannula Without mini-guidewire	90cm cannula Without mini-guidewire
4		25		401411M	401423M				
5		25		401511M	401523M	401535M	401545M	401555M	
6		35	401605M	401611M	401623M	401635M	401645M	401655M	401690M
7		35	401705M	401711M	401723M	401735M	401745M	401755M	401790M
8		35	401805M	401811M	401823M	401835M	401845M	401855M	401890M
9		35		401911M	401923M	401935M	401945M	401955M	
10		45		401011M	401023M				
11		45		401111M	401123M				

For information on indications, contraindications, warnings, and precautions, see page 87.

Obturators

Key Features

- Flexible shaft helps prevent kinking of the sheath when the sheath is used in a patient for a long period of time without a product in place
- Easy French size identification provided by a color coding system and the number on the hub
- Easy to store boxes with small dimensions
- Ease of insertion through the sheath and minimal vessel damage thanks to the rounded atraumatic distal tip
- No "backing out" of the obturator by the secure snap fit between obturator and sheath
- Low profile hub to ease placement and manipulation
- Units per package: 10

French Size (F)	Color Code	13cm Cannula	23cm cannula
4		502188	502189
5		502190	502196
6		502191	502197
7		502192	502198
8		502194	
9			502200

Vessel Dilators

Key Features

- Facilitate the percutaneous entry of angiographic catheters
- With Luer hubs
- Units per package: 10

French Size (F)	Color Code	Guidewire compatibility (inch)	Usable length (cm)	Product Code
4		.021"	12	504504S
4		.035"	16	504404X
5		.021"	12	504505S
5		.035"	16	504405X
5		.038"	17	504505X
6		.021"	13	504506S
6		.035"	17	504406X
6		.038"	17	504506X
7		.035"	17	504407X
7		.038"	17	504507X
8		.035"	17	504408X
8		.038"	17	504508X
9		.035"	17	504409X
9		.038"	17	504509X

Diagnostic Portfolio

Diagnostic Guidewires

EMERALD® Diagnostic Guidewire

Intended for percutaneous entry and guidance of catheters, the Cordis EMERALD® Diagnostic Guidewire complements our diagnostic catheter and catheter sheath introducer lines. Performance, endurance and safety are built into each EMERALD® Guidewire with solid tensile strength to minimize the likelihood of stretching or fracturing.

Learn more on page 11.

Diagnostic Catheters

SUPER TORQUE® Diagnostic Catheter

Used in coronary angioplasty. Constructed from polyurethane to deliver exceptional responsiveness and flow rates, optimal torque, and shape retention

- Braided Polyurethane body
- High flow rates
- Excellent torque response
- 1200 psi pressure limit (4F, 6F)
- 1050 psi pressure limit (5F)

Learn more on page 15.

TEMPO® Diagnostic Catheter

Providing a unique combination of support and shape options to enable a tailored approach to tough lesions:

- Braided nylon body
- Neon TIP (tungsten filled radiopaque tip)
- High flow rates
- 1200 psi pressure limit
- Lipiodol resistant hub
- Micro-catheter compatibility
- SLX™ coating

Learn more on page 15.

TEMPO AQUA® Diagnostic Catheter

An angiographic catheter providing excellent flow rates, optimal contrast delivery and vessel opacification.

- Braided Nylon body
- Neon TIP (tungsten filled radiopaque tip)
- Lipiodol resistant hub
- Micro-catheter compatibility
- Hydrophilically coated distal shaft

Learn more on page 15.

NYLEX® Diagnostic Catheter

- Non-braided Nylon body
- High flow rates
- 1050 psi pressure limit
- One piece construction

Learn more on page 15.

Diagnostic Guidewires General Information

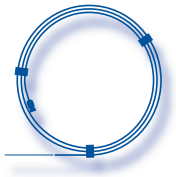
Inch	.018"	.021"	.025"	.032"	.035"	.038"	.065"
EMERALD® Diagnostic Guidewire	X	X	X	X	X	X	X

EMERALD® Diagnostic Guidewire

Intended for percutaneous entry and guidance of catheters, the Cordis EMERALD® Diagnostic Guidewire complements our diagnostic catheter and catheter sheath introducer lines. Performance, endurance and safety are built into each EMERALD® Guidewire with solid tensile strength to minimize the likelihood of stretching or fracturing.

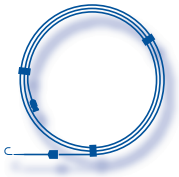
Amplatz

- For percutaneous entry and guidance of angiographic catheters
- Units per package: 5



PTFE-Coated Straight Tip

Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.035	150		502581A

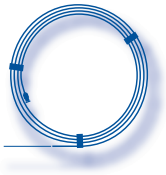


PTFE-Coated J-Curve

Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.038	150	3	502570A
.035	150	3	502571A

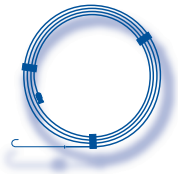
Amplatz Super Stiff

- For percutaneous entry and guidance of angiographic catheters
- Units per package: 5



PTFE-Coated Straight Tip

Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.035	150		502726
.035	180		502728



PTFE-Coated J-Curve

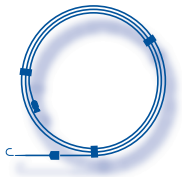
Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.035	150	3	502731
.035	180	3	502733
.035	260	3	502735

For information on indications, contraindications, warnings, and precautions, see page 90.

EMERALD® Diagnostic Guidewire, *continued*

Rosen Heavy Duty

- For percutaneous entry and guidance of angiographic catheters
- Atraumatic end
- Units per package: 5

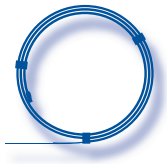


PTFE-Coated J-Curve

Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.035	180	1.5	502717

Fixed-Core

- For percutaneous entry and guidance of angiographic catheters
- Units per package: 5



PTFE-Coated Straight Tip

Diameter (inch)	Length (cm)	Flexible End (cm)	Product Code
.018	150	7	502704
.021	150	7	502703
.025	150	7	502549
.032	150	7	502548
.035	150	7	502542
.035	150	10	502544*
.035	150	20	502560
.038	150	7	502541

PTFE-Coated Double-Ended

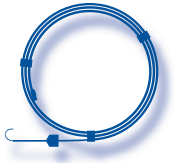
3cm straight / 7cm J-curve

Diameter (inch)	Length (cm)	Flexible End (cm)	J-Radius (mm)	Product Code
.035	150	3/7	2	502563

* Newton LT.

For information on indications, contraindications, warnings, and precautions, see page 90.

EMERALD® Diagnostic Guidewire, *continued*



PTFE-Coated J-Curve

Diameter (inch)	Length (cm)	Flexible End (cm)	J-Radius (mm)	Description	Product Code
.025	150	7	3		502524
.025	150	7	15		502536
.030	150	7	3	Heavy duty, high strength	502522
.032	150	7	3		502526
.035	80	7	3		502701
.035	150	7	1.5		502531
.035	175	7	1.5	High strength	502534
.035	150	7	3		502521
.035	150	10	3		502587*
.035	175	7	3		502585
.035	150	7	6		502589
.035	150	7	15		502535
.035	150	10	15		502576*
.038	150	7	3		502520
.038	175	7	3		502584
.038	150	7	6		502588
.065	150	10	6		502530*

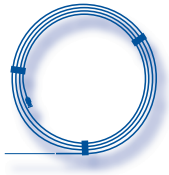
* Newton LT.

For information on indications, contraindications, warnings, and precautions, see page 90.

EMERALD® Diagnostic Guidewire, *continued*

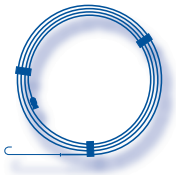
Fixed-Core Exchange

- For use in percutaneous entry, guidance and exchange of angiographic catheters
- Units per package: 5



PTFE-Coated Straight Tip

Diameter (inch)	Length (cm)	Flexible End (cm)	Product Code
.032	260	7	502554
.035	220	7	502558
.035	260	7	502555
.038	260	7	502553

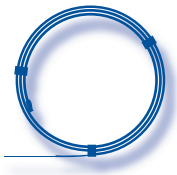


PTFE-Coated J-Curve

Diameter (inch)	Length (cm)	Flexible End (cm)	J-Radius (mm)	Product Code
.018	260	7	3	502456
.025	260	7	3	502452
.032	260	7	3	502454
.035	260	7	3	502455
.038	260	7	3	502453

Movable-core

- For percutaneous entry and guidance of angiographic catheters
- With 4 cm handle
- Units per package: 5



PTFE-Coated Straight Tip

Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.035	150		502581
.038	150		502580

PTFE-Coated J-Curve

Diameter (inch)	Length (cm)	J-Radius (mm)	Product Code
.035	150	3	502571
.038	150	3	502570

* Newton LT.

For information on indications, contraindications, warnings, and precautions, see page 90.

Cordis
A Cardinal Health company

Flush Catheters

Flow Rate Chart (ml/s)

Selective Catheters Lengths (cm)	65	90	100	110
SUPER TORQUE® Catheter 4F	20	17	16	15
SUPER TORQUE® Catheter 5F	19	16	15	14
SUPER TORQUE® Catheter 6F	33	29	28	26
TEMPO® Catheter 4F	23	20	19	18
TEMPO® Catheter 5F	31	27	25	24
TEMPO AQUA® Catheter 4F	21	18	17	16
TEMPO AQUA® Catheter 5F	33	28	26	24

Inner Diameter Specifications

Selective Catheters Lengths (cm)	ID Body (inches)	ID Tip (inches)	Guidewire Acceptance (inches)
SUPER TORQUE® Catheter 4F, 5F	.0395	.0395	.035
SUPER TORQUE® Catheter 6F	.051	.0435*	.038
TEMPO® Catheter 4F	.042	.042**	.035
TEMPO® Catheter 5F	.048	.043	.035
TEMPO AQUA® Catheter 4F	.040	.042	.035
TEMPO AQUA® Catheter 5F	.050	.038	.035

* .042" for pigtail. ** .038" for pigtail. For information on indications, contraindications, warnings, and precautions, see page 94, page 116, and page 117.

Flush Catheters

SUPER TORQUE® Catheter 4F, 5F, 6F

- Braided Polyurethane body
- High flow rates
- 1200 psi pressure limit (4F-6F)
- 1050 psi pressure limit (5F) Diagnostic Catheters

TEMPO® Catheter 4F, 5F

- Braided Nylon body
- Neon TIP (tungsten filled radiopaque tip)
- High flow rates. 1200 psi pressure limit
- SLX™ coating

NYLEX® Catheter 4F, 5F

- Non-braided nylon body
- High flow rates
- 1050 psi pressure limit
- One piece construction

	4F	5F	6F	4F	5F	4F	5F
Length (cm)	SUPER TORQUE® Catheter	SUPER TORQUE® Catheter	SUPER TORQUE® Catheter	TEMPO® Catheter	TEMPO® Catheter	NYLEX® Catheter	NYLEX® Catheter
	Side Holes / Pro. Code	Side Holes / Pro. Code	Side Holes / Pro. Code	Side Holes / Pro. Code	Side Holes / Pro. Code	Side Holes / Pro. Code	Side Holes / Pro. Code
Pigtail (PIG)							
65	8 / 532410T	8 / 532524V8	12 / 455610T	5 / 451403 V5	5 / 451503 V5	8 / 526410	8 / 526510
65				451402 V5	5 / 451502 V5	8 / 526430	8 / 526530
90	8 / 532411T	8 / 532539F8	12 / 455611T	5 / 451403 F5	5 / 451503 F5	8 / 526411	8 / 526511
90						8 / 526431	
100	8 / 532412T	8 / 532555H8		5 / 451403 H5	5 / 451503 H5	8 / 526412	8 / 526512
110	8 / 532413T		8 / 455613E	5 / 451403 L5	5 / 451503 L5		
Universal Flush (UNIV)							
65				5 / 451404V5	5 / 451504V5	8 / 526440	8 / 526540
90				5 / 451404F5	5 / 451504F5		
100							
110					5 / 451504L5		
Straight (STR)							
65	8 / 532420T	8 / 532564V8		5 / 451401V5	5 / 451501V5	8 / 526420	8 / 526520
90	8 / 532421T			5 / 451401F5	5 / 451501F5	8 / 526421	8 / 526521
100	8 / 532422T	8 / 532569H8		5 / 451401H5	5 / 451501H5	8 / 526422	8 / 526522
110				5 / 451401L5	5 / 451501L5		8 / 526523

SH = Side Holes. For information on indications, contraindications, warnings, and precautions, see page 94, page 116, and page 117.

Flow Rate Chart (ml/s)

Selective Catheters Lengths (cm)	65	80	100	125
SUPER TORQUE® Catheter 4F	20	18	16	14
SUPER TORQUE® Catheter 5F	25	22	19	17
SUPER TORQUE® Catheter 6F	35	32	28	25
TEMPO® Catheter 4F	22	20	17	16
TEMPO® Catheter 5F	30	27	24	23
TEMPO AQUA® Catheter 4F	22	20	17	16
TEMPO AQUA® Catheter 5F	30	27	24	23

Inner Diameter Specifications

Selective Catheters Lengths (cm)	ID Body (inches)	ID Tip (inches)	Guidewire Acceptance (inches)
SUPER TORQUE® Catheter 4F, 5F	.0395	.0395	.035
SUPER TORQUE® Catheter 6F	.051	.0435	.038
TEMPO® Catheter 4F	.042	.042	.038
TEMPO® Catheter 5F	.048	.043	.038
TEMPO AQUA® Catheter 4F	.042	.042	.038
TEMPO AQUA® Catheter 5F	.048	.043	.038

For information on indications, contraindications, warnings, and precautions, see page 94, page 116, and page 117.

Selective Multipurpose Catheters

SUPER TORQUE® Catheter 4F, 5F, 6F

- Braided polyurethane body
- Excellent torque response
- High flow rates

TEMPO® Catheter 4F, 5F

- Braided nylon body
- Neon TIP (tungsten filled radiopaque tip)
- Lipiodol resistant hub
- Micro-catheter compatibility
- SLX™ coating

TEMPO AQUA® Catheter 4F, 5F

- Braided nylon body
- Neon TIP (tungsten filled radiopaque tip)
- Lipiodol resistant hub
- Micro-catheter compatibility
- Hydrophilically coated distal shaft

	4F		5F		6F		4F		5F		4F		5F	
Length (cm)	**SUPER TORQUE® Catheter**		**SUPER TORQUE® Catheter**		**SUPER TORQUE® Catheter**		**TEMPO® Catheter**		**TEMPO® Catheter**		**TEMPO AQUA® Catheter**		**TEMPO AQUA® Catheter**	
	Side Holes	**Pro. Code**	**Side Holes**	**Pro. Code**	**Side Holes**	**Pro. Code**	**Side Holes**	**Pro. Code**	**Side Holes**	**Pro. Code**	**Side Holes**	**Pro. Code**	**Side Holes**	**Pro. Code**
Multipurpose Small														
65								451406V0		451506V0				
80										451506S0				
80	2	532432	2	532506			2	451406S2	2	451506S2				
100		532430						451406H0		451506H0				
100	2	532482	2	532507					2	451506H2				
125		532431						451406P0		451506P0				
125	2	532457	2	532508					2	451506P2				
Multipurpose Adult														
65								451407V0		451507V0				
80				532579		455623								
80					2	455636	2	451407S2	2	451507S2				
100				532578								452407H0		452507H0
100					2	455637	2	451407H2	2	451507H2				
Multipurpose (Subintimal Recanalization)														
65				532576										

SH = Side Holes. For information on indications, contraindications, warnings, and precautions, see page 94, page 116, and page 117.

Selective Visceral Catheters

Length (cm)	4F SUPER TORQUE® Catheter		5F SUPER TORQUE® Catheter		6F SUPER TORQUE® Catheter		4F TEMPO® Catheter		5F TEMPO® Catheter		4F TEMPO AQUA® Catheter		5F TEMPO AQUA® Catheter	
	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code
Renal Double Curve Small														
65	2	532462	2	532510					2	451546V2				
80								451446S0		451546S0				
80	2	532478	2	532511										
Renal Double Curve Adult														
80				532509		455686		451447S0		451547S0				
80					2	455689			2	451547S2				
Cobra - Child 1 (C1)														
65		532440		532512				451442V0		451542V0		452442V0		452542V0
65	2	532441	2	532515			2	451442V2	2	451542V2				
Cobra - Small Adult (C2)														
65		532442		532513		455671		451443V0		451543V0		452443V0		452543V0
65	2	532443	2	532516			2	451443V2	2	451543V2				
80												452443S0		SRD6677
100								451443H0		451543H0				
Cobra - Normal Adult (C3)														
65		532444		532514		455672		451444V0		451544V0				
65	2	532445	2	532517					2	451544V2				

SH = Side Holes.

Selective Visceral Catheters

Length (cm)	4F SUPER TORQUE® Catheter		5F SUPER TORQUE® Catheter		6F SUPER TORQUE® Catheter		4F TEMPO® Catheter		5F TEMPO® Catheter		4F TEMPO AQUA® Catheter		5F TEMPO AQUA® Catheter	
	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code
Shepherd Hook I														
			0.8cm-radius											
65		532473						451449V0		451549V0				
Shepherd Hook II														
			1.0cm-radius											
65		532474		532519				451450V0		451550V0				
Celiac Trunk														
80				532567										
Uni Select I														
80								451418S0		451518S0				
J-Curve I														
			Large - radius 1.4cm											
65		532447						451455V0		451555V0				
J-Curve I I														
			Medium - radius 1.1cm											
65		532448		532522				451456V0		451556V0				
J-Curve I I I														
			Small - radius 0.6cm											
65		532449		532523				451457V0		451557V0				

SH = Side Holes.

Selective Cerebral Catheters

Length (cm)	4F SUPER TORQUE® Catheter		5F SUPER TORQUE® Catheter		6F SUPER TORQUE® Catheter		4F TEMPO® Catheter		5F TEMPO® Catheter		4F TEMPO AQUA® Catheter		5F TEMPO AQUA® Catheter	
	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code
Sidewinder Simmons Technique I (SIM1)														
100		532414		532501		455660		451430H0		451530H0		452430H0		452530H0
100					2	455660D			2	451530H2				
Sidewinder Simmons Technique I I (SIM2)														
100		532415		532502		455661		451431H0		451531H0		452431H0		452531H0
100				532547					2	451531H2				
Sidewinder Simmons Technique I I I (SIM3)														
100				532503		455662		451432H0		451532H0				
100									2	451532H2				
Sidewinder Simmons Technique I V (SIM4)														
100						455663								

SH = Side Holes.

Selective Cerebral Catheters

Length (cm)	4F SUPER TORQUE® Catheter Side Holes	4F SUPER TORQUE® Catheter Pro. Code	5F SUPER TORQUE® Catheter Side Holes	5F SUPER TORQUE® Catheter Pro. Code	6F SUPER TORQUE® Catheter Side Holes	6F SUPER TORQUE® Catheter Pro. Code	4F TEMPO® Catheter Side Holes	4F TEMPO® Catheter Pro. Code	5F TEMPO® Catheter Side Holes	5F TEMPO® Catheter Pro. Code	4F TEMPO AQUA® Catheter Side Holes	4F TEMPO AQUA® Catheter Pro. Code	5F TEMPO AQUA® Catheter Side Holes	5F TEMPO AQUA® Catheter Pro. Code
Headhunter I (H1)														
100		532461		532504		455665		451435H0		451535H0		452-435H0		452535H0
100						455666**								
125												SRD6107		
Headhunter I I I (H3)														
100								451439H0		451539H0				
Newton III (HN3)														
100										451520H0				
Newton I V (HN4)														
100				532520				451421H0		451521H0				
Mani (MAN)														
100		532470		532571						451512H0				

SH = Side Holes.
** Headhunter I Hilal Modified

Selective Cerebral Catheters

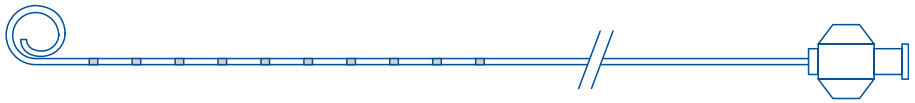
Length (cm)	SUPER TORQUE® Catheter 4F		SUPER TORQUE® Catheter 5F		SUPER TORQUE® Catheter 6F		TEMPO® Catheter 4F		TEMPO® Catheter 5F		TEMPO AQUA® Catheter 4F		TEMPO AQUA® Catheter 5F	
	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code	Side Holes	Pro. Code
Berenstein (BERN)														
65								451413V0		451513V0				
100								451413H0		451513H0		452413H0		452513H0
Berenstein I I														
40										451515T0				
65								451415V0		451515V0				
100								451415H0		451515H0				
Bentson-Hanafee-Wilson I (JB1)														
100		532436		532541H0				451423H0		451523H0				
Bentson-Hanafee-Wilson I I (JB2)														
100		532437		532543H0				451424H0		451524H0				
Bentson-Hanafee-Wilson I I I (JB3)														
100		532438								451525H0				
Vertebral (VERT)														
100		532497		532549H0				451414H0		451514H0		452414H0		452514H0
65												SRD6912		SRD6906
125												SRD6108		

Calibration Catheters

Flow Rate Chart (ml/s)

Selective Catheters Lengths (cm)	French	65 (20 Gold)	70 (2 Gold)	110 (10 Gold)	110 (20 Gold)
SUPER TORQUE® Marker Bands	5F	23	22	18	18

SUPER TORQUE® Marker Bands



		10 Gold-Alloy Marker Bands		20 Gold-Alloy Marker Bands	
Length (cm)	Size (F)	Side Holes	Pro. Code	Side Holes	Pro. Code
65	5			8	532598C
110	5	6	532598A	6	532598B

Crossing Portfolio

OUTBACK® Elite Re-Entry Catheter

Enables re-entry of a guidewire from the subintimal space back into true lumen of the vessel:

- Ergonomic handle for excellent control
- Highly visible "L" and "T" markers orient the re-entry cannula toward the true lumen easily, eliminating the need for additional visualization equipment.
- Helps reduce time under fluoroscopy as compared to traditional guidewire techniques[1]
- Braided catheter shaft provides effective torque control and helps easy and quick positioning of the OUTBACK® Elite Re-Entry Catheter towards the target re-entry site.

Learn more on page 26.

ELITECROSS™ Support Catheter

Providing a unique combination of support and shape options to enable a tailored approach to tough lesions:

- Unparalleled support[2]
- Unparalleled pushability[2]
- Enhanced steerability[2]
- Extra large inner lumen can accommodate .014" support catheter systems
- Tapered tip and lubricious hydrophilic coating enhance deliverability

Learn more on page 27.

FRONTRUNNER® XP CTO Catheter

High success rates when conventional guidewire techniques have failed.[3] It creates a microchannel through a CTO facilitating guidewire placement.

- Low profile shapeable, atraumatic actuating distal blunt tip is designed to minimize risk of vessel perforation and helps create a pathway for the ELITECROSS™ Support Catheter.
- Integrated system approach: the advancing and retracting of the ELITECROSS™ Support Catheter provides variable support to the FRONTRUNNER® CTO Catheter in order to successfully engage the CTO.
- Braided catheter shaft for effective torque control to enhance maneuverability and steerability.

Learn more on page 28.

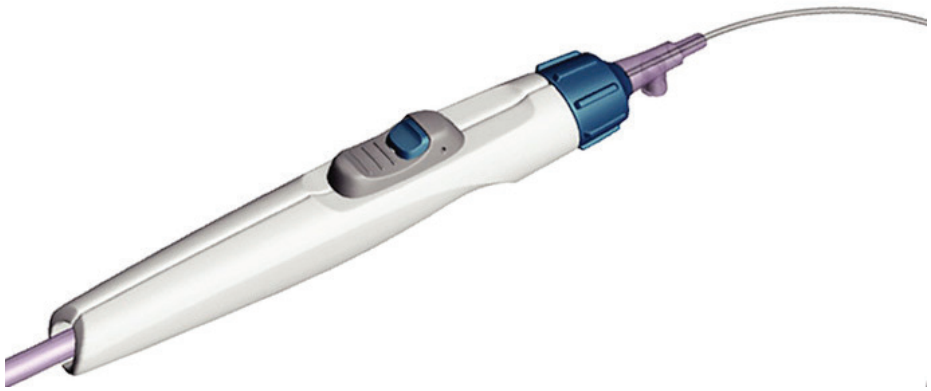
[1] Gandini, R., Fabiano, S., Spano, S., Volpi, T., Morosetti, D., Chiaravalloti, A., Nano, G. and Simonetti, G. (2013), Randomized control study of the Outback LTD reentry catheter versus manual reentry for the treatment of chronic total occlusions in the superficial femoral artery. Cathet. Cardiovasc. Intervent., 82: 485–492.
[2] Cordis internal testing reports. Data on file at Cordis.
[3] Shetty R, et al. Safety and Efficacy of the Frontrunner® XP Catheter for Recanalization of Chronic Total Occlusion of the Femoropopliteal Arteries. J. Invasive Cardiol 2013;25(7):344-347

OUTBACK® Elite Re-Entry Catheter

Enables re-entry of a guidewire from the subintimal space back into true lumen of the vessel.

Key Features

- Unique re-entry technology
- Highly visible "L" and "T" markers
- Helps reduce time under fluoroscopy as compared to traditional guidewire techniques[1]
- Braided catheter shaft



Usable Length (cm)	Sheath Compatibility (F)	Crossing Profile (F)	Product Code
80	6	5.9	OTB59080A
120	6	5.9	OTB59120A

Recommended OUTBACK® Elite Re-Entry Catheter compatible .014" guidewires

Product Name	Total Length (cm)	Tip Flexibility	Tip Shape	Product Code
ATW™ All Track Wire*	300	Floppy	Straight	595EX014
ATW™ All Track Wire*	300	Floppy	J-Curve	595EY014
ATW™ Steerable Guidewire*	195	Floppy	Straight	595014
ATW™ Steerable Guidewire*	195	Floppy	J-Curve	595J014
STABILIZER® Plus Guidewire**	300	Supersoft	Straight	507114X
STABILIZER® Plus Guidewire**	300	Supersoft	J-Curve	507114Y
STABILIZER® Support Guidewire**	180	Supersoft	Straight	507180S
STABILIZER® Extra Support Guidewire**	180	Supersoft	Straight	527180E

[1] Gandini, R., Fabiano, S., Spano, S., Volpi, T., Morosetti, D., Chiaravalloti, A., Nano, G. and Simonetti, G. (2013), Randomized control study of the Outback LTD reentry catheter versus manual reentry for the treatment of chronic total occlusions in the superficial femoral artery. Cathet. Cardiovasc. Intervent., 82: 485–492. doi: 10.1002/ccd.24742

* Packaged 1 per box. Order in quantities of one each. ** Packaged 5 per box. Order in quantities of five each.

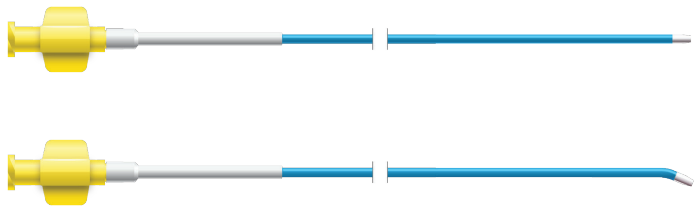
For information on indications, contraindications, warnings, and precautions, see page 99.

ELITECROSS™ Support Catheter

Provides a unique combination of support and shape options to enable a tailored approach to tough lesions.

Key Features

- Unparalleled Support*
- Unparalleled Pushability*
- Enhanced Steerability*
- Extra Large Inner Lumen can accommodate .014" support catheter systems
- Tapered tip and lubricious hydrophilic coating enhance deliverability



Usable Length (cm)	Shape	Sheath Compatibility (F)	Product Code
82	Straight	5	MGC39090X
82	Angled	5	MGC39090A
132	Straight	5	MGC39140X
132	Angled	5	MGC39140A

* Cordis internal testing reports. Data on file at Cordis.
For information on indications, contraindications, warnings, and precautions, see page 89.

FRONTRUNNER® XP CTO Catheter

High success rates when conventional guidewire techniques have failed.* It creates a microchannel through a CTO facilitating guidewire placement. Low profile shapeable, atraumatic actuating distal blunt tip is designed to minimize risk of vessel perforation and helps create a pathway for the ELITECROSS™ Support Catheter.

Key Features

- Low profile shapeable, atraumatic, actuating distal blunt tip
- Braided catheter shaft
- Integrated shaft
- Compatible with Elitecross™ Support Catheter

Usable Length (cm)	Sheath Compatibility (F)	Crossing Profile (F)	Product Code
90	6F	3.1	FBS3990
140	6F	3.1	FBP39140

* Shetty R, et al. Safety and Efficacy of the Frontrunner® XP Catheter for Recanalization of Chronic Total Occlusion of the Femoropopliteal Arteries. J. Invasive Cardiol 2013;25(7):344-347. For information on indications, contraindications, warnings, and precautions, see page 92.

Interventional Portfolio

Guiding Catheters

VISTA BRITE TIP® Guiding Catheter

Guiding catheters have extra large lumen and are available in different shapes for precise placement. Cordis has also introduced the extra large lumen 6F .070"ID VISTA BRITE TIP® Guiding Catheter. It provides value to physicians by having a larger lumen while maintaining the 6F OD and performance characteristics of the VISTA BRITE TIP® Guiding Catheter.

Learn more on page 32.

VISTA BRITE TIP® IG Guiding Catheter

Combines the guiding qualities and handling of the VISTA BRITE TIP® guiding catheter with the sheath introducer advantages of the AVANTI®+ Sheath Introducer in one unique device.

Learn more on page 32.

Steerable Guidewires

AQUATRACK® Hydrophilic Nitinol Guidewire

Facilitates access to the most tortuous anatomy, providing the control, visibility, and exceptional design symmetry that enable you to torque and maneuver through difficult lesions.

Learn more on page 37.

STORQ® Steerable Guidewire

An ideal steerable guidewire for interventional procedures using .035" devices. This precision tool helps to enable access to difficult to reach arteries.

Learn more on page 38.

SV Steerable Guidewire

Small diameter interventional wires that give you support to perform procedures with a .018" device.

Learn more on page 40.

ATW™ and ATW™ Marker Wire Steerable Guidewires

Intermediate support .014" workhorse wires for .014" devices.. The ATW™ Marker Wire Steerable Guidewire provides 4 equally spaced marker bands (10mm) for secure measurements of lesion length.

Learn more on page 41.

STABILIZER® Plus and STABILIZER® XS Steerable Guidewires

High support .014" wires that provides balanced support and flexibility for greater guidewire demands.

Learn more on page 43.

JINDO® Steerable Guidewire

A steerable wire with a soft and atraumatic .022" tip and a very supportive .035" shaft allowing physicians to complete renal procedures with a single guidewire. The distal part is covered with a PTFE sleeve to maximize lubricity while keeping excellent wire control. Three different taper lengths allow you to choose the right configuration for any situation.

Learn more on page 39.

PTA Balloons .035" Guidewire Compatibility

POWERFLEX® Pro PTA Dilatation Catheter

For lower extremity vessels

- Wide range of lengths and diameters
- Fast deflation time*
- Excellent profile and atraumatic flexible tip

Learn more on page 46.

POWERFLEX® P3 PTA Dilatation Catheter

For iliac, femoral, ilio-femoral, popliteal, infrapopliteal, renal arteries and obstructive lesions of native or synthetic arteriovenous dialysis fistulae needs

- Low profile, high pressure balloon
- MDX coated shaft
- Rapid inflation and deflation time*

Learn more on page 47

* Data on file at Cordis.

Interventional Portfolio

POWERFLEX® Extreme PTA Dilatation Catheter

For ilio-femoral, femoro-popliteal and dialysis fistulas needs

- High pressure balloon for challenging procedures
- Excellent abrasion resistance
- Atraumatic flexible tip

Learn more on page 48

OPTA® Pro PTA Dilatation Catheter

For iliac, femoral, ilio-femoral, popliteal, infrapopliteal, renal arteries and obstructive lesions of native or synthetic arteriovenous dialysis fistulae needs

- Low profile, moderate pressure balloon
- Outstanding delivery through a 6F sheath introducer (select sizes)
- Flexible, tapered tip

Learn more on page 49

MAXI LD® PTA Dilatation Catheter

For the dilatation of iliac arteries (14 - 15mm sizes) and for dilatation of strictures of the esophagus (16 - 25mm sizes).

- Large diameter balloon (up to 25mm)
- Short shoulders designed to minimize vessel straightening
- Braided inner body for excellent stability

Learn more on page 50.

* Data on file at Cordis.

PTA Balloons .018" Guidewire Compatibility

SABER™ PTA Dilatation Catheter

For iliac, femoral, ilio-femoral, popliteal, infrapopliteal, renal, and obstructive lesions of native or synthetic arteriovenous dialysis fistulae needs

- Wide range of sizes
- Designed with more crossability
- Higher rated burst pressure
- Fast deflation time*
- Balloon lengths up to 300mm

Learn more on page 51.

SLALOM® PTA Dilatation Catheter

For ilio-femoral, femoro-popliteal, infra-popliteal, renal and dialysis fistulas

- SLX™ coated shaft for excellent trackability
- Small to medium low profile balloon
- Optimized ratio pressure/profile

Learn more on page 53.

SAVVY® and SAVVY® Long PTA Dilatation Catheters

For femoro-popliteal and infra-popliteal needs

- Small to medium low profile balloons
- Lubricious coating on balloon and shaft for outstanding crossability
- Wide range of lengths and diameters

Learn more on page 54.

PTA Balloons .014" Guidewire Compatibility

AVIATOR® Plus PTA Dilatation Catheter

For carotid and renal needs

- Ultra low profile balloon
- Shaft designed for excellent pushability
- Smooth tip-to-wire transition

Learn more on page 58.

SLEEK® RX and SLEEK® OTW PTA Dilatation Catheters

For infra-popliteal needs

- Low profile rapid exchange .014" PTA system
- Long balloon lengths (up to 280 mm)
- Smooth tip-to-wire transition

Learn more on page 57.

Interventional Portfolio

Self-Expanding Stents

S.M.A.R.T.® Vascular Stent System

When outcomes matter, design matters. For superficial femoral artery (SFA) and iliac lesions.

Learn more on page 59.

S.M.A.R.T.® Control Vascular Stent System

The delivery system offers two deployment mechanisms for both rapid delivery and true placement accuracy.

Learn more on page 59.

Vena Cava Filters

OPTEASE® Retrievable Vena Cava Filter

An innovative option for prevention of recurrent pulmonary embolism. It offers the strengths of the Cordis TRAPEASE® Permanent Vena Cava Filter plus the additional option of retrieval.

Learn more on page 80.

TRAPEASE® Permanent Vena Cava Filter

Offers a range of unique advantages including double-basket design with dual-layer filtration.

Learn more on page 81.

Balloon Expandable Stents

PALMAZ® Balloon-Expandable Stent

Utilizes FlexSegment Technology that is designed to improve flexibility, reduce shortening, and improve scaffolding in a bend.

Learn more on page 75.

PALMAZ BLUE® Transhepatic Biliary Stent

Utilizes advanced L605 cobalt chromium technology with the proven PALMAZ design to offer increased radiopacity, low profiles and superior flexibility and deliverability.

Learn more on page 66

PALMAZ GENESIS® Transhepatic Biliary Stent

The Genesis family is designed according to the PALMAZ™ Stent heritage with one piece laser cut stainless steel slotted tube (no welds) and a closed-cell design.

Learn more on page 68

Carotid Systems

PRECISE PRO RX® Carotid Stent System

A unique design for enhanced contourability, increased longitudinal stability and uniform scaffolding.

Learn more on page 76.

ANGIOGUARD® RX Emboli Capture Guidewire System

With its Rapid Exchange System is easy to use, providing optimal protection while maintaining blood flow.

Learn more on page 78.

* Nitinol Constraining Structure

VISTA BRITE TIP® Guiding Catheter

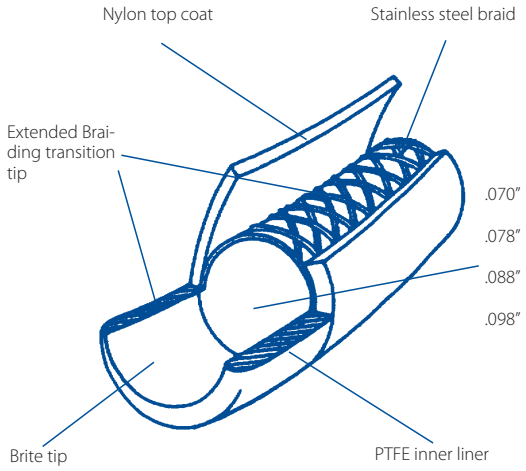
Guiding catheters have extra large lumen and are available in different shapes for precise placement. Cordis has also introduced the extra large lumen 6F .070"ID VISTA BRITE TIP® Guiding Catheter. It provides value to physicians by having a larger lumen while maintaining the 6F OD and performance characteristics of the VISTA BRITE TIP® Guiding Catheter.

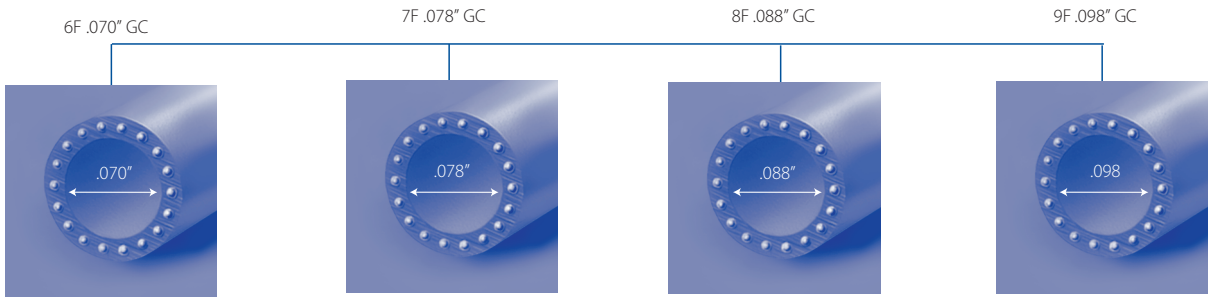
VISTA BRITE TIP® IG Guiding Catheter

Combines the guiding qualities and handling of the VISTA BRITE TIP® guiding catheter with the sheath introducer advantages of the AVANTI®+ Sheath Introducer in one unique device.

General Information

Extended Braiding





- Lengths: 55cm/90cm/95cm/125cm
- 1 unit per package.

For information on indications, contraindications, warnings, and precautions, see page 118.

VISTA BRITE TIP® Guiding Catheter

- Braided shaft
- Extra large lumen
- Suitable for tortuous vessels
- Reliable tip shape memory
- Highly radiopaque distal tip
- Different shapes available

VISTA BRITE TIP® IG Guiding Catheter

- Hybrid between a guiding catheter and a sheath introducer
- Braided shaft
- Sheathless insertion possible-allows for smaller puncture size
- Unique SLIX™ valve for uncompromised valve hemostasis
- Extra large lumen
- Suitable for tortuous vessels

Length (cm)	6F .070" VISTA BRITE TIP® Guiding Catheter	7F .078" VISTA BRITE TIP® Guiding Catheter	7F .078" VISTA BRITE TIP® IG Guiding Catheter	8F .088" VISTA BRITE TIP® Guiding Catheter	8F .088" VISTA BRITE TIP® IG Guiding Catheter	9F .098" VISTA BRITE TIP® Guiding Catheter	9F .098" VISTA BRITE TIP® IG Guiding Catheter	10F VISTA BRITE TIP® Guiding Catheter
Straight (Str)								
55	67028055	77828055		588843P	4038553S	598943P		
80								511040P
90	67028090	77828090		588844P		598944P		
95					4038953S			
Multipurpose								
55	67027055	77827055	4037553M	588840P	4038553M			
90	67027090	77827090		588842P		598942P		
95					4038953M		4039953M	
Multipurpose (MPC)								
95				5888206*		598-9206		
Multipurpose (MPD)								
95				5888207*				

* For carotid indications. For information on indications, contraindications, warnings, and precautions, see page 118.

Length (cm)	6F .070" VISTA BRITE TIP® Guiding Catheter	7F .078" VISTA BRITE TIP® Guiding Catheter	7F .078" VISTA BRITE TIP® IG Guiding Catheter	8F .088" VISTA BRITE TIP® Guiding Catheter	8F .088" VISTA BRITE TIP® IG Guiding Catheter
Hockey Stick					
55	67027855	77827855	4037553H	588841P	4038553H
Renal Curve I (Small)					
55	67021055	77821055	4037553R	588845P	4038553R
Renal Curve (Adult)					
55	67021255	77821255	4037553A	588846P	4038553A
J-Curve					
55	67021455	77821455			
Contralateral I					
55		77822255	4037553C	588857P	4038553C
Contralateral I I					
55		77822455		588858P	
Vertebral					
90		77821690		588847P	

Length (cm)	6F .070" VISTA BRITE TIP® Guiding Catheter	7F .078" VISTA BRITE TIP® Guiding Catheter	7F .078" VISTA BRITE TIP® IG Guiding Catheter	8F .088" VISTA BRITE TIP® Guiding Catheter	8F .088" VISTA BRITE TIP® IG Guiding Catheter
Modified Cerebral Burke (CBL) 					
55	67021890	77825090		588848P	
95					4038953B
Headhunter (H1) 					
95				5888202*	
Judkins Right 4 (JR4) 					
55	67008255				
Internal Mammary 					
55	67019055				

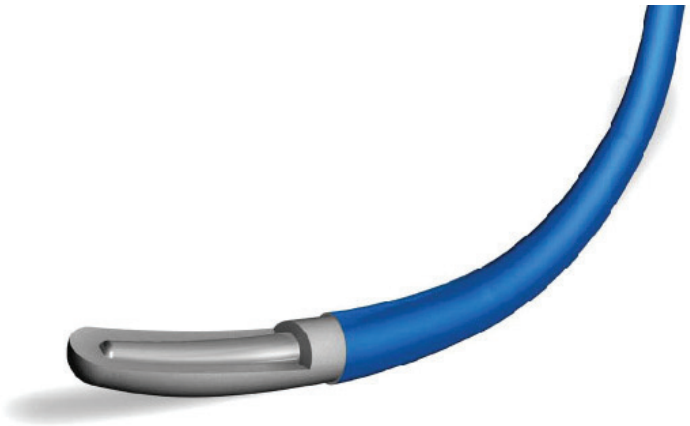
* For carotid indications.

General Information

Inch	.014"	.018"	.035"	.035" > .022"
AQUATRACK® Hydrophilic Nitinol Guidewire			X	
SV Steerable Guidewire		X		
JINDO® Steerable Guidewire				X
STORQ® Steerable Guidewire			X	
ATW™ Steerable Guidewires	X			
ATW™ Marker Wire Steerable Guidewire	X			
STABILIZER® Plus Steerable Guidewires	X			
STABILIZER® XS Steerable Guidewires	X			

AQUATRACK® Hydrophilic Nitinol Guidewire

Facilitates access to the most tortuous anatomy, providing the control, visibility and exceptional design symmetry that enable you to torque and maneuver through difficult lesions.



Key Features

- .035" platform. 150cm, 180cm, and 260cm lengths
- Angled and straight tips
- Regular and stiff configurations
- Nitinol core wire
- Torque device included with each wire
- Units per package: 5

Regular - Wire Tapers Over 8"

Length (cm)	Stiffness	Taper	Tip	Product Code
150	Regular	Short	Angled	C3515RSA
150	Regular	Short	Straight	C3515RSS
180	Regular	Short	Angled	C3518RSA
180	Regular	Short	Straight	C3518RSS
260	Regular	Short	Angled	C3526RSA

Stiff - Wire Tapers Over 5"

Length (cm)	Stiffness	Taper	Tip	Product Code
150	Stiff	Short	Angled	C3515SSA
180	Stiff	Short	Angled	C3518SSA
260	Stiff	Short	Angled	C3526SSA
260	Stiff	Short	Straight	C3526SSS

For information on indications, contraindications, warnings, and precautions, see page 86.

STORQ® Steerable Guidewire

A broad range of wires for .035" interventional procedures - standard, soft and super soft tips with straight, angled and modified J configurations.

Key Features

- .035" platform. 180cm and 300cm lengths
- Stainless steel core wire
- With SLX™ coating
- Torque device included with each wire
- Units per package: 5

Super Soft Tip

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.035	Straight	180	503256
.035	Angled	180	503256J

Soft Tip

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.035	Straight	180	503356
.035	Angled	180	503356J
.035	Modified J	180	503356MJ
.035	Straight	300	503356X
.035	Angled	300	503356Y
.035	Modified J	300	503356MY

Standard Tip

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.035	Straight	180	503456
.035	Angled	180	503456J
.035	Modified J	180	503456MJ
.035	Straight	300	503456X
.035	Angled	300	503456Y
.035	Modified J	300	503456MY

For information on indications, contraindications, warnings, and precautions, see page 116.

JINDO® Steerable Guidewire

A steerable wire with a soft and atraumatic .022″ tip and a very supportive .035″ shaft allowing physicians to complete renal procedures with a single guidewire.

Key Features

- .035″ - .022″
- Distal part covered with PTFE sleeves
- Straight shapeable radiopaque tip
- Units per package: 5

Standard Tip

Diameter (inch)	Sleeve	Taper	Length (cm)	Product Code
.035	Short	Short	180	503452
.035	Long	Short	300	503453
.035	Long	Intermediate	300	503553

For information on indications, contraindications, warnings, and precautions, see page 86.

SV Steerable Guidewire

Small diameter interventional wires that give you support to perform procedures with a .018" device.

Key Features

- .018" platform. 180cm and 300cm lengths
- Tip shape: straight (shapeable)
- Proximal shaft coating: blue PTFE spray
- Radiopaque coil length
- Units per package: 5

5cm Distal Taper Configuration

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.018	Straight	180	503558
.018	Straight	300	503558X

8cm Distal Taper Configuration

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.018	Straight	180	503658
.018	Straight	300	503658X

For information on indications, contraindications, warnings, and precautions, see page 86.

ATW™ Steerable Guidewire

Designed to give you precise steerability for lesion access and excellent flexibility for tracking in tortuous vessels. ATW™ Guidewire is an intermediate support .014" wire that is a workhorse wire for .014" devices.

Key Features

- Guidewire OD: .014"
- Intermediate support wire
- Coating: Duraglide/PTFE
- Distal Tip Radiopacity: 3cm
- Tip Flexibility: floppy
- Units per package: 1

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.014	Straight	195	595014
.014	J-curve	195	595J014

ATW™ Eco Pacs Steerable Guidewire

Key Features

- Intermediate support wire
- Coating: Duraglide/PTFE
- Distal Tip Radiopacity: 3cm
- Tip Flexibility: floppy
- Units per package: 5

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.014	Straight	195	595E014
.014	J-curve	195	595EJ014

For information on indications, contraindications, warnings, and precautions, see page 86.

ATW™ Marker Wire Steerable Guidewire

An intermediate support wire with four markers that span 30mm in 10mm increments. It is useful for discerning most lesion lengths and provides accuracy in selecting device length.

Key Features

- Intermediate support wire
- Coating: Duraglide/PTFE
- 4 radiopaque markers spaced 10mm apart
- Tip Flexibility: floppy

Units per package: 1

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.014	Straight	195	595M014
.014	J-curve	195	595MJ014

Units per package: 5

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.014	Straight	195	595ME014
.014	J-curve	195	595MEJ014

For information on indications, contraindications, warnings, and precautions, see page 86.

STABILIZER® Plus Steerable Guidewire

A high support .014" wire that provides balanced support for the delivery of advanced peripheral devices in complex and tortuous anatomy.

Key Features

- Coating: Duraglide / PTFE
- Balanced performance steerable guidewire
- Distal tip radiopacity: 3cm
- Supersoft tip configuration
- Units per package: 5
- Compatible with Outback® Elite Re-Entry Catheter

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.014	Straight	180	507180S
.014	Straight	300	507300S

For information on indications, contraindications, warnings, and precautions, see page 86.

STABILIZER® Extra Support Guidewire

A .014 wire with a higher level of support for the most challenging peripheral interventions.

Key Features

- Coating: Duraglide / PTFE
- Balanced performance steerable guidewire
- Distal tip radiopacity: 3cm
- Supersoft tip configuration
- Units per package: 5
- Compatible with Outback® Elite Re-Entry Catheter

Diameter (inch)	Tip Shape	Length (cm)	Product Code
.014	Straight	180	527180E
.014	Straight	300	527300E

For information on indications, contraindications, warnings, and precautions, see page 86.

PTA Balloons

The CORDIS® PTA Balloon Portfolio is comprised of .035 PTA Balloons, .018 PTA Balloons, .014 PTA Balloons, and Specialty PTA Balloons to help you treat routine and challenging cases. In addition to featuring Cordis' renowned quality, each balloon incorporates a specific set of characteristics that optimizes the outcomes of the applications.

Many Cordis PTA balloons are made out of DURALYN™, a unique balloon material with these characteristics:

- High puncture resistance: for stent placement or post-dilatation of stent as well as for dilating hard lesions
- Versatile high-strength balloon material: provides you with a complete range of products with different profiles and pressure capabilities
- Great flexibility: balloon conforms to tortuous vessels and crosses difficult-to-reach lesions
- Low crossing profiles and exceptional rewrap characteristics: well suited for primary and secondary profiles
- Soft material: friendly to the vessel wall and for creating smooth transitions
- Reputable durability: enabling you to use the same balloon multiple times during the same procedure while keeping the same secondary profile.

Product	Type	Guidewire Compatibility (inch)	Balloon Diameter (mm)	Rated Burst Pressure (atm)	Balloon Material	Shaft Construction
POWERFLEX® Pro	Over-The-Wire	.035	3-12	8-18	DURALYN™	Dual-Lumen
POWERFLEX® P3	Over-The-Wire	.035	4-10, 12	up to 15	Nylon	Dual-Lumen
POWERFLEX® Extreme	Over-The-Wire	.035	4-10	20, 17	DURALYN™	Dual-Lumen
OPTA® Pro	Over-The-Wire	.035	3-12	10, 6	DURALYN™	Dual-Lumen
MAXI LD®	Over-The-Wire	.035	14-25	6, 5	DURALYN™	Coaxial
SABER™	Over-The-Wire	.018	2-10	10, 18	DURALYN™	Coaxial
SLALOM®	Over-The-Wire	.018	3-8	14, 12, 10	DURALYN™	Dual-Lumen
SAVVY®	Over-The-Wire	.018	2-6	10	DURALYN™	Coaxial
SAVVY® Long	Over-The-Wire	.018	2-6	up to 10	Nylon	Coaxial
SLEEK® OTW	Over-The-Wire	.014	1.25-5	up to 16	Nylon	Coaxial
SLEEK® RX	Rapid Exchange	.014	2-4	up to 16	Nylon	RX Dual-Lumen
AVIATOR® Plus	Rapid Exchange	.014	4-7	up to 14	DURALYN™	RX Coaxial

Product Code Composition

Example 1 - MAXI LD™

Balloon Type code		OD x length		Shaft length
416	-	15	20	S

also Valid for
POWERFLEX™ EXTREME - SLALOM™

Example 2 - SAVVY®

Balloon Type code		OD x length		Shaft length
435	-	50	2	S

POWERFLEX® Pro PTA Dilatation Catheter

A .035" workhorse solution that delivers advanced crossing ability and remarkable versatility for treating diffuse or challenging lesions.

Key Features

- Dual lumen shaft
- Atraumatic tip
- RBP up to 18 ATM
- Extended product range
- One piece hub
- Inner and outer (30cm distal) MDX coating

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (80cm)	Shaft Length (135cm)
3	20	18	5	4400302S	4400302X
3	40	18	5	4400304S	4400304X
3	60	18	5	4400306S	4400306X
3	80	18	5	4400308S	4400308X
3	100	18	5	4400310S	4400310X
3	120	18	5	4400312S	4400312X
3	150	18	5	4400315S	4400315X
3	220	18	5	4400322S	4400322X
4	20	18	5	4400402S	4400402X
4	40	18	5	4400404S	4400404X
4	60	18	5	4400406S	4400406X
4	80	18	5	4400408S	4400408X
4	100	18	5	4400410S	4400410X
4	120	18	5	4400412S	4400412X
4	150	18	5	4400415S	4400415X
4	220	18	5	4400422S	4400422X
5	20	15	5	4400502S	4400502X
5	40	15	5	4400504S	4400504X
5	60	15	5	4400506S	4400506X
5	80	15	5	4400508S	4400508X
5	100	15	5	4400510S	4400510X
5	120	15	5	4400512S	4400512X
5	150	15	5	4400515S	4400515X
5	220	15	5	4400522S	4400522X
6	20	15	5	4400602S	4400602X
6	40	15	5	4400604S	4400604X
6	60	15	5	4400606S	4400606X
6	80	15	5	4400608S	4400608X
6	100	15	5	4400610S	4400610X
6	120	15	5	4400612S	4400612X
6	150	15	5	4400615S	4400615X
6	220	15	5	4400622S	4400622X
7	20	15	5	4400702S	4400702X
7	40	15	5	4400704S	4400704X
7	60	12	5	4400706S	4400706X
7	80	12	5	4400708S	4400708X
7	100	12	6	4400710S	4400710X
8	20	12	5	4400802S	4400802X
8	40	12	5	4400804S	4400804X
8	60	12	5	4400806S	4400806X
8	80	12	5	4400808S	4400808X
8	100	12	5	4400810S	4400810X
9	20	12	6	4400902S	4400902X
9	40	12	6	4400904S	4400904X
9	60	12	6	4400906S	4400906X
9	80	12	7	4400908S	4400908X
9	100	12	7	4400910S	4400910X
10	20	12	6	4401002S	4401002X
10	40	12	6	4401004S	4401004X
10	60	12	7	4401006S	4401006X
10	80	12	7	4401008S	4401008X
10	100	12	7	4401010S	4401010X
12	20	8	7	4401202S	4401202X
12	40	8	7	4401204S	4401204X
12	60	8	7	4401206S	4401206X

For information on indications, contraindications, warnings, and precautions, see page 105.

POWERFLEX® P3 PTA Dilatation Catheter

A .035" over the wire PTA balloon catheter for challenging leg interventions.

Key Features

- Low profile, high pressure balloon
- MDX coated shaft
- Rapid inflation and deflation time*
- Dual lumen
- Flexible tapered tip

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (40cm)	Shaft Length (80cm)	Shaft Length (110cm)	Shaft Length (135cm)
4	20	15	5	4204020T	4204020S	4204020L	4204020X
4	40	15	5	4204040T	4204040S	4204040L	4204040X
4	60	15	5		4204060S		
4	80	15	5		4204080S	4204080L	
4	100	15	5		4204000S	4204000L	
5	20	15	5	4205020T	4205020S	4205020L	4205020X
5	30	15	5		4205030S		
5	40	15	5	4205040T	4205040S	4205040L	4205040X
5	60	15	5		4205060S	4205060L	
5	80	15	6		4205080S	4205080L	
5	100	15	6		4205000S	4205000L	
6	20	15	5	4206020T	4206020S	4206020L	4206020X
6	30	15	5		4206030S		4206030X
6	40	15	5	4206040T	4206040S	4206040L	4206040X
6	60	15	6		4206060S		
6	80	15	6		4206080S	4206080L	
6	100	15	6		4206000S	4206000L	
7	20	15	6	4207020T	4207020S	4207020L	4207020X
7	30	15	6		4207030S		
7	40	15	6	4207040T	4207040S	4207040L	4207040X
7	60	15	6		4207060S		
7	80	15	6		4207080S	4207080L	
7	100	15	7		4207000S	4207000L	
8	20	15	6	4208020T	4208020S	4208020L	4208020X
8	30	15	6		4208030S		
8	40	15	6	4208040T	4208040S	4208040L	4208040X
8	60	15	7		4208060S	4208060L	
8	80	15	7		4208080S		
8	100	15	8		4208000S		
9	20	14	7		4209020S	4209020L	4209020X
9	40	14	7		4209040S	4209040L	4209040X
9	60	14	7		4209060S		
10	20	14	7		4200020S	4200020L	4200020X
10	40	14	7		4200040S	4200040L	4200040X
10	60	14	7		4200060S		
10	80	14	8		4200080S		
12	20	8	7		4202020S	4202020L	
12	40	8	7		4202040S	4202040L	

* Data on file at Cordis. For information on indications, contraindications, warnings, and precautions, see page 104.

POWERFLEX® Extreme PTA Dilatation Catheter

A high pressure .035" balloon with high abrasion resistance and atraumatic flexible tip for ilio-femoral, femoro-popliteal lesions and dialysis fistulas needs.

.035" High Pressure Balloon

- Dual lumen 5F over-the-wire shaft
- Atraumatic tip
- Very high rated burst pressure (20atm)
- Extended product range
- One piece hub
- Inner (whole length) and outer (30 distal cm) SLX™ coating

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (40cm)	Shaft Length (80cm)
4	20	20	5	4154020T	4154020S
4	40	20	5	4154040T	4154040S
4	60	20	5		4154060S
5	20	20	6	4155020T	4155020S
5	40	20	6	4155040T	4155040S
5	60	20	6		4155060S
6	20	20	6	4156020T	4156020S
6	40	20	6	4156040T	4156040S
6	60	20	6		4156060S
7	20	20	6	4157020T	4157020S
7	40	20	6	4157040T	4157040S
7	60	20	7		4157060S
8	20	20	7		4158020S
8	40	20	7	4158040T	4158040S
8	60	20	7		4158060S
9	20	17	7		4159020S
9	40	17	7	4159040T	4159040S
10	20	17	7		4150020S
10	40	17	9	4150040T	4150040S
10	60	17	9		4150060S

For information on indications, contraindications, warnings, and precautions, see page 104.

OPTA® Pro PTA Dilatation Catheter

The everyday choice for efficient leg intervention.

.035" Low profile, moderate pressure balloon

- .035" PTA Balloon
- Outstanding delivery through a 6F sheath introducer (select sizes)
- 5F dual-lumen shaft
- Optimal-rated burst pressure: 10atm (3mm-10mm) and 6atm
- Flexible, tapered tip

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (80cm)	Shaft Length (110cm)	Shaft Length (135cm)
3	40	10	5	4193040S	4193040L	4193040X
3	80	10	5	4193080S	4193080L	4193080X
4	20	10	5	4194020S	4194020L	4194020X
4	40	10	5	4194040S	4194040L	4194040X
4	60	10	5		4194060L	
4	80	10	5	4194080S	4194080L	
4	100	10	5	4194000S	4194000L	
5	20	10	5	4195020S	4195020L	4195020X
5	30	10	5	4195030S		
5	40	10	5	4195040S	4195040L	4195040X
5	60	10	5		4195060L	
5	80	10	5	4195080S	4195080L	
5	100	10	5	4195000S	4195000L	
6	20	10	5	4196020S	4196020L	4196020X
6	30	10	5	4196030S		
6	40	10	5	4196040S	4196040L	4196040X
6	60	10	5	4196060S	4196060L	
6	80	10	6	4196080S	4196080L	
6	100	10	6	4196000S	4196000L	
7	20	10	5	4197020S	4197020L	4197020X
7	30	10	5	4197030S		
7	40	10	5	4197040S	4197040L	4197040X
7	60	10	6	4197060S	4197060L	
7	80	10	6	4197080S	4197080L	
7	100	10	6	4197000S	4197000L	
8	20	10	6	4198020S	4198020L	4198020X
8	30	10	6	4198030S		
8	40	10	6	4198040S	4198040L	4198040X
8	60	10	6	4198060S	4198060L	
8	80	10	6	4198080S	4198080L	
8	100	10	7	4198000S		
9	20	10	6	4199020S	4199020L	
9	30	10	6	4199030S		
9	40	10	6	4199040S	4199040L	
9	60	10	6	4199060S		
10	20	10	6	4190020S	4190020L	4190020X
10	30	10	6	4190030S		
10	40	10	6	4190040S	4190040L	4190040X
10	60	10	7	4190060S		
12	20	6	7	4192020S	4192020L	
12	30	6	7	4192030S		
12	40	6	7	4192040S	4192040L	

For information on indications, contraindications, warnings, and precautions, see page 95.

MAXI LD® PTA Dilatation Catheter

A .035" large diameter PTA balloon catheter indicated for PTA of iliac arteries and for dilatation of strictures of the esophagus.

Key Features

- Coaxial 7F over-the-wire shaft
- Braided inner body
- 5 and 6atm rated burst pressure
- Large product range
- One piece hub

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Indications	Shaft Length (80cm)	Shaft Length (110cm)
14	40	6	8	Iliac	4171440S	4171440L
14	60	6	8	Iliac	4171460S	4171460L
15	20	6	9	Iliac	4171520S	4171520L
15	40	6	9	Iliac	4171540S	4171540L
15	60	6	9	Iliac	4171560S	4171560L
16	40	6	10	Esophageal	4171640S	4171640L
16	60	6	10	Esophageal	4171660S	4171660L
18	40	6	10	Esophageal	4171840S	4171840L
18	60	6	10	Esophageal	4171860S	4171860L
20	40	6	11	Esophageal	4172040S	4172040L
20	60	6	11	Esophageal	4172060S	4172060L
22	40	5	12	Esophageal	4172240S	4172240L
25	40	5	12	Esophageal	4172540S	4172540L

For information on indications, contraindications, warnings, and precautions, see page 92.

SABER® PTA Dilatation Catheter

A next-generation, high-performance workhorse .018" PTA balloon catheter

.018" Low Profile Balloon

- Coaxial shaft 3.9F / 4.7F
- RBP: Up to 18 ATM
- Dual layer hydrophilic coating on the balloon and distal part of the shaft

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (90cm)	Shaft Length (150cm)
2	20	18	4	48002002S	48002002X
2	30	18	4	48002003S	48002003X
2	40	18	4	48002004S	48002004X
2	60	18	4	48002006S	48002006X
2	80	18	4	48002008S	48002008X
2	100	18	4	48002010S	48002010X
2	150	18	4	48002015S	48002015X
2	200	18	4	48002020S	48002020X
2	250	18	4	48002025S	48002025X
2	300	18	4	48002030S	48002030X
2.5	20	18	4	48002502S	48002502X
2.5	30	18	4	48002503S	48002503X
2.5	40	18	4	48002504S	48002504X
2.5	60	18	4	48002506S	48002506X
2.5	80	18	4	48002508S	48002508X
2.5	100	18	4	48002510S	48002510X
2.5	150	18	4	48002515S	48002515X
2.5	200	18	4	48002520S	48002520X
2.5	250	18	4	48002525S	48002525X
2.5	300	18	4	48002530S	48002530X

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (90cm)	Shaft Length (150cm)
3	20	18	4	48003002S	48003002X
3	30	18	4	48003003S	48003003X
3	40	18	4	48003004S	48003004X
3	60	18	4	48003006S	48003006X
3	80	18	4	48003008S	48003008X
3	100	18	4	48003010S	48003010X
3	150	14	4	48003015S	48003015X
3	200	14	4	48003020S	48003020X
3	250	14	4	48003025S	48003025X
3	300	14	4	48003030S	48003030X
3.5	20	18	4	48003502S	48003502X
3.5	30	18	4	48003503S	48003503X
3.5	40	18	4	48003504S	48003504X
3.5	60	18	4	48003506S	48003506X
3.5	80	18	4	48003508S	48003508X
3.5	100	18	4	48003510S	48003510X
3.5	150	14	4	48003515S	48003515X
3.5	200	14	4	48003520S	48003520X
3.5	250	14	4	48003525S	48003525X
3.5	300	14	4	48003530S	48003530X

For information on indications, contraindications, warnings, and precautions, see page 111.

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (90cm)	Shaft Length (150cm)
4	20	18	4	48004002S	48004002X
4	30	18	4	48004003S	48004003X
4	40	18	4	48004004S	48004004X
4	60	18	4	48004006S	48004006X
4	80	18	4	48004008S	48004008X
4	100	18	4	48004010S	48004010X
4	150	14	4	48004015S	48004015X
4	200	14	4	48004020S	48004020X
4	250	14	4	48004025S	48004025X
4	300	14	4	48004030S	48004030X
5	20	16	4	48005002S	48005002X
5	30	16	4	48005003S	48005003X
5	40	16	4	48005004S	48005004X
5	60	16	4	48005006S	48005006X
5	80	16	4	48005008S	48005008X
5	100	16	4	48005010S	48005010X
5	150	14	5	48005015S	48005015X
5	200	14	5	48005020S	48005020X
5	250	14	5	48005025S	48005025X
5	300	14	5	48005030S	48005030X
6	20	16	4	48006002S	48006002X
6	30	16	4	48006003S	48006003X
6	40	16	4	48006004S	48006004X
6	60	16	4	48006006S	48006006X
6	80	16	5	48006008S	48006008X
6	100	16	5	48006010S	48006010X
6	150	14	5	48006015S	48006015X
6	200	14	5	48006020S	48006020X
6	250	14	6	48006025S	48006025X
6	300	14	6	48006030S	48006030X

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (90cm)	Shaft Length (150cm)
7	20	14	4	48007002S	48007002X
7	30	14	4	48007003S	48007003X
7	40	14	4	48007004S	48007004X
7	60	14	5	48007006S	48007006X
7	80	14	5	48007008S	48007008X
7	100	14	5	48007010S	48007010X
8	20	12	4	48008002S	48008002X
8	30	12	4	48008003S	48008003X
8	40	12	4	48008004S	48008004X
8	60	12	5	48008006S	48008006X
8	80	12	5	48008008S	48008008X
8	100	12	5	48008010S	48008010X
9	20	10	5	48009002S	
9	30	10	5	48009003S	
9	40	10	5	48009004S	
9	60	10	5	48009006S	
9	80	10	6	48009008S	
9	100	10	6	48009010S	
10	20	10	5	48010002S	
10	30	10	5	48010003S	
10	40	10	5	48010004S	
10	60	10	6	48010006S	
10	80	10	6	48010008S	
10	100	10	6	48010010S	

SLALOM® PTA Dilatation Catheter

A .018" PTA balloon catheter that delivers the high-pressure strength and accuracy crucial for renal procedures.

.018" Small-to-Medium Balloon

- Dual lumen over-the-wire shaft (3.7 F - up to 6mm Ø, 4 F - 7-8mm Ø)
- High rated burst pressure (14-10atm)
- One piece hub
- Inner (whole length) and outer (30 distal cm) SLX™ coating

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (80cm)	Shaft Length (120cm)	Shaft Length (135cm)
3	20	14	4/6	4383020S		4383020X
3	40	14	4/6	4383040S	4383040M	4383040X
4	20	14	4/6	4384020S	4384020M	4384020X
4	40	14	4/6	4384040S	4384040M	4384040X
5	20	14	5/6	4385020S	4385020M	4385020X
5	40	14	5/6	4385040S	4385040M	4385040X
6	20	12	5/6	4386020SP	4386020MP	4386020XP
6	40	12	5/6	4386040SP	4386040MP	4386040XP
7	20	12	6/7	4387020S	4387020M	4387020X
7	40	12	6/7	4387040S	4387040M	4387040X
8	20	10	6/8	4388020S	4388020M	4388020X
8	40	10	6/8	4388040S		4388040X

For information on indications, contraindications, warnings, and precautions, see page 113.

SAVVY® PTA Dilatation Catheters

A .018" PTA balloon catheter for femoro-popliteal and infra-popliteal needs.

.018" Low Profile Balloons

- High rated burst pressure
- Lubricious coating on the balloon and delivery system

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (80cm)	Shaft Length (120cm)	Shaft Length (150cm)
2	20	10	4	435202S	435202L	435202X
2	30	10	4		435203L	
2	40	10	4	435204S	435204L	435204X
2	60	10	5	435206S	435206L	
2	100	10	5	435200S	435200L	435200X
2.5	20	10	4	435252S	435252L	435252X
2.5	40	10	4	435254S	435254L	435254X
2.5	60	10	5	435256S	435256L	
2.5	100	10	5	435250S	435250L	
3	20	10	4	435302S	435302L	435302X
3	30	10	4		435303L	
3	40	10	4	435304S	435304L	435304X
3	60	10	5	435306S	435306L	
3	100	10	5	435300S	435300L	435300X
3.5	20	10	4	435352S	435352L	435352X
3.5	40	10	4	435354S	435354L	435354X
3.5	60	10	5		435356L	
3.5	100	10	5		435350L	

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (80cm)	Shaft Length (120cm)	Shaft Length (150cm)
4	20	10	4	435402S	435402L	435402X
4	30	10	4		435403L	
4	40	10	4	435404S	435404L	435404X
4	60	10	5	435406S	435406L	
4	100	10	5	435400S	435400L	435400X
4.5	20	10	4	435452S	435452L	
4.5	40	10	5	435454S	435454L	
4.5	60	10	5		435456L	
5	20	10	4	435502S	435502L	
5	40	10	4	435504S	435504L	
5	60	10	5	435506S	435506L	
5	100	10	5	435500S	435500L	
5.5	20	10	4	435552S		
5.5	40	10	4	435554S		
6	20	10	4	435602S	435602L	
6	40	10	4	435604S	435604L	
6	60	10	5	435606S	435606L	
6	100	10	5	435600S	435600L	

For information on indications, contraindications, warnings, and precautions, see page 111.

SAVVY® Long PTA Dilatation Catheters

A .018" PTA balloon catheter for femoro-popliteal and infra-popliteal needs.

.018" Low Profile Balloons

- High rated burst pressure
- Lubricious coating on the balloon and delivery system

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (120cm)	Shaft Length (150cm)
2	120	10	4	4362012L	4362012X
2	150	10	4	4362015L	4362015X
2	220	10	4	4362022L	4362022X
2.5	120	10	4	4362512L	4362512X
2.5	150	10	4	4362515L	4362515X
2.5	220	10	4	4362522L	4362522X
3	120	10	4	4363012L	4363012X
3	150	10	4	4363015L	4363015X
3	220	10	4	4363022L	4363022X
3.5	120	10	4		4363512X
3.5	150	10	4		4363515X
3.5	220	10	4		4363522X
4	120	10	4	4364012L	4364012X
4	150	10	4	4364015L	4364015X
4	220	10	4	4364022L	4364022X
5	120	10	4	4365012L	
5	150	10	4	4365015L	
5	220	10	4	4365022L	
6	120	10	4	4366012L	
6	150	10	4	4366015L	
6	220	10	4	4366022L	

For information on indications, contraindications, warnings, and precautions, see page 112.

SLEEK® OTW PTA Dilatation Catheter

Designed for infrapopiteal vessels. Delivers precision, speed and control.

.014" Over-The-Wire

- Coaxial
- High rated burst pressure (up to 16atm)
- Long Balloon lengths (1.5-28cm)

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (150cm)
1.25	15	14	4	4261201X
1.5	15	14	4	4261501X
1.5	20	16	4	4261502X
1.5	40	16	4	4261504X
1.5	80	16	4	4261508X
1.5	100	16	4	4261510X
1.5	120	16	4	4261512X
2	20	16	4	4262002X
2	40	16	4	4262004X
2	80	15	4	4262008X
2	100	15	4	4262010X
2	120	15	4	4262012X
2	150	15	4	4262015X
2	220	15	4	4262022X
2	280	15	4	4262028X
2.5	20	16	4	4262502X
2.5	40	16	4	4262504X
2.5	80	15	4	4262508X
2.5	100	15	4	4262510X
2.5	120	15	4	4262512X
2.5	150	15	4	4262515X
2.5	220	15	4	4262522X
2.5	280	15	4	4262528X
3	20	16	4	4263002X
3	40	16	4	4263004X
3	80	15	4	4263008X
3	100	15	4	4263010X
3	120	15	4	4263012X
3	150	15	4	4263015X
3	220	15	4	4263022X
3	280	15	4	4263028X
3.5	20	16	4	4263502X
3.5	40	16	4	4263504X
3.5	80	15	4	4263508X
3.5	100	15	4	4263510X
3.5	120	15	4	4263512X
3.5	150	15	4	4263515X
3.5	220	15	4	4263522X
3.5	280	15	4	4263528X
4	20	16	4	4264002X
4	40	16	4	4264004X
4	80	15	4	4264008X
4	100	15	4	4264010X
4	120	15	4	4264012X
4	150	15	4	4264015X
4	220	15	4	4264022X
4	280	15	4	4264028X
5	20	14	4	4265002X
5	40	14	4	4265004X
5	80	13	4	4265008X
5	100	13	4	4265010X
5	120	13	4	4265012X
5	150	10	4	4265015X
5	220	10	4	4265022X
5	280	10	4	4265028X

SLEEK® RX PTA Dilatation Catheter

Designed for infrapopiteal vessels. Delivers precision, speed and control.

.014" Rapid Exchange Balloon

- Dual-lumen rapid exchange shaft
- High rated burst pressure (16-15atm)
- Long balloon lengths (4-22cm)

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (150cm)	Shaft Length (155cm)
2	40	16	4	4252004X	
2	80	15	4	4252008X	
2	100	15	4	4252010X	
2	120	15	4	4252012X	
2	150	15	4		4252015X
2	220	15	4		4252022X
2.5	40	16	4	4252504X	
2.5	80	15	4	4252508X	
2.5	100	15	4	4252510X	
2.5	120	15	4	4252512X	
2.5	150	15	4		4252515X
2.5	220	15	4		4252522X
3	40	16	4	4253004X	
3	80	15	4	4253008X	
3	100	15	4	4253010X	
3	120	15	4	4253012X	
3	150	15	4	4253015X	
3	220	15	4	4253022X	
3.5	40	16	4	4253504X	
3.5	80	15	4	4253508X	
3.5	100	15	4	4253510X	
3.5	120	15	4	4253512X	
3.5	150	15	4		4253515X
3.5	220	15	4		4253522X
4	40	16	4	4254004X	
4	80	15	4	4254008X	
4	100	15	4	4254010X	
4	120	15	4	4254012X	
4	150	15	4		4254015X
4	220	15	4		4254022X

For information on indications, contraindications, warnings, and precautions, see page 115.

AVIATOR® Plus PTA Catheters

.014" rapid exchange PTA balloon catheters for carotid and renal needs.

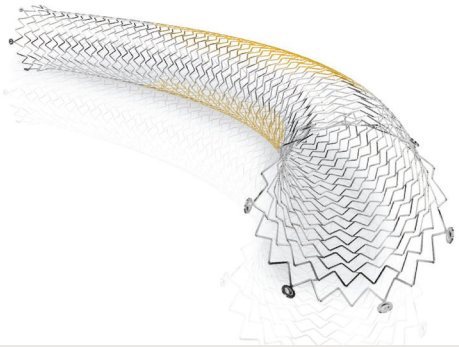
.014" Rapid Exchange Balloons

- Coaxial rapid exchange shaft
  - 3.3F distally (25cm length)
  - 3.3F proximal with stiffening wire
- High rated burst pressure (14-12atm)

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (142cm)
4	15	14	4	4244015W
4	20	14	4	4244020W
4	30	14	4	4244030W
4	40	14	4	4244040W
4.5	15	14	4	4244515W
4.5	20	14	4	4244520W
4.5	30	14	4	4244530W
4.5	40	14	4	4244540W
5	15	14	4	4245015W
5	20	14	4	4245020W
5	30	14	4	4245030W
5	40	14	4	4245040W

Balloon Diameter (mm)	Balloon Length (mm)	Rated Burst Pressure (atm)	Sheath Fit (F)	Shaft Length (142cm)
5.5	15	14	4	4245515W
5.5	20	14	4	4245520W
5.5	30	14	4	4245530W
5.5	40	14	4	4245540W
6	15	14	4	4246015W
6	20	14	4	4246020W
6	30	14	4	4246030W
6	40	14	4	4246040W
7	15	12	5	4247015W
7	20	12	5	4247020W
7	30	12	5	4247030W
7	40	12	5	4247040W

For information on indications, contraindications, warnings, and precautions, see page 87.



S.M.A.R.T.® Vascular Stent System

Key Features

Scaffolding
Smaller cell size and uniform coverage can help prevent vessel prolapse

Longitudinal stability
Excellent stability minimizes stretching at deployment, thereby increasing placement accuracy

Radial force
The stent's ability to resist compression maintains luminal gain

High primary patency rate maintained out to 3 years in the STROLL Study with the S.M.A.R.T.® Vascular Stent Systems*

Product Description

Type	MicroMesh geometry, segmented design
Material	Nitinol, with MicroMarker™ Technology
Stent diameters	6-10mm
Stent delivery system working lengths	80cm (S suffix) & 120cm (M suffix)
Stent delivery systems	Delivery handle: 20-100mm stent lengths Pin and pull: 120 and 150mm stent lengths
Maximum guidewire	.035"
Stent lengths	120 - 150mm
Sheath compatibility	6F (6-10mm)
Guide catheter compatibility	8F (6-10mm)

S.M.A.R.T.® Control Vascular Stent System

Key Features

Scaffolding
Smaller cell size and uniform coverage can help prevent vessel prolapse

Longitudinal stability
Excellent stability minimizes stretching at deployment, thereby increasing placement accuracy

Radial force
The stent's ability to resist compression maintains luminal gain.

High primary patency rate maintained out to 3 years in the STROLL Study with the S.M.A.R.T.® Vascular Stent Systems*

Product Description

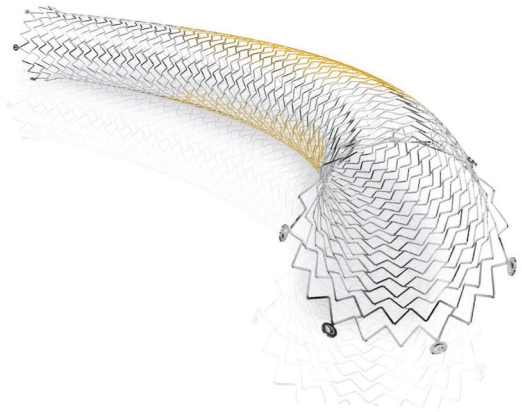
Type	MicroMesh geometry, segmented design, with delivery handle
Material	Nitinol, with MicroMarker™ Technology
Stent diameters	6-10mm
Stent delivery system working lengths	80cm (S suffix) & 120cm (M suffix)
Stent delivery systems	Delivery handle: 20-100mm stent lengths Pin and pull: 120 and 150mm stent lengths
Maximum guidewire	.035"
Stent lengths	20 - 100mm
Sheath compatibility	6F (6-10mm)
Guide catheter compatibility	8F (6-10mm)

* Data on file at Cordis. For information on indications, contraindications, warnings, and precautions, see page 109.

Product Code			Stent		
80cm Usable Length	120cm Usable Lenth	Indication	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Size (mm)
C06020SL	C06020ML	Iliac SFA	6	20	4-5
C06030SL	C06030ML	Iliac SFA	6	30	4-5
C06040SL	C06040ML	Iliac SFA	6	40	4-5
C06060SL	C06060ML	Iliac SFA	6	60	4-5
C06080SL	C06080ML	Iliac SFA	6	80	4-5
C06100SL	C06100ML	Iliac SFA	6	100	4-5
C06120SL	C06120ML	SFA	6	120	4-5
C06150SL	C06150ML	SFA	6	150	4-5
C07020SL	C07020ML	Iliac SFA	7	20	5-6
C07030SL	C07030ML	Iliac SFA	7	30	5-6
C07040SL	C07040ML	Iliac SFA	7	40	5-6
C07060SL	C07060ML	Iliac SFA	7	60	5-6
C07080SL	C07080ML	Iliac SFA	7	80	5-6
C07100SL	C07100ML	Iliac SFA	7	100	5-6
	C07120ML	SFA	7	120	5-6
	C07150ML	SFA	7	150	5-6
C08020SL	C08020ML	Iliac SFA	8	20	6-7
C08030SL	C08030ML	Iliac SFA	8	30	6-7
C08040SL	C08040ML	Iliac SFA	8	40	6-7
C08060SL	C08060ML	Iliac SFA	8	60	6-7
C08080SL	C08080ML	Iliac SFA	8	80	6-7
C08100SL	C08100ML	Iliac SFA	8	100	6-7
	C08120ML	SFA	8	120	6-7
	C08150ML	SFA	8	150	6-7
C09020SL	C09020ML	Iliac	9	20	7-8
C09030SL	C09030ML	Iliac	9	30	7-8
C09040SL	C09040ML	Iliac	9	40	7-8
C09060SL	C09060ML	Iliac	9	60	7-8
C10020SL	C10020ML	Iliac	10	20	8-9
C10030SL	C10030ML	Iliac	10	30	8-9
C10040SL	C10040ML	Iliac	10	40	8-9
C10060SL	C10060ML	Iliac	10	60	8-9

S.M.A.R.T.® Biliary Stent System

When physicians think of nitinol stents, they think of Cordis. The S.M.A.R.T.® Stents are cut from a single piece of nitinol without rough or cutting edges.



Key Features

Super-elastic nitinol
- Crush-recoverable
- Thermally self-expanding at body temperature
- Highly flexible before and after deployment

Micromesh design
- High radial resistive force*
- Excellent strength
- Chronic outward force
- Minimal shortening

Delivery system
- Accurate placement and ease of use
- Treats range of lengths and diameters
- Atraumatic
- Available in 120mm and 150mm lengths
- Sheath compatibility - 6F

Product Code	Stent Length	Expanded Stent Diameter (mm)	SDS Length (cm)	Recommended Vessel Size (mm)
C06120MB	120	6	120	4-5
C06150MB	150	6	120	4-5
C07120MB	120	7	120	5-6
C07150MB	150	7	120	5-6
C08120MB	120	8	120	6-7
C08150MB	150	8	120	6-7

* Data on file at Cordis. For information on indications, contraindications, warnings, and precautions, see page 109.

S.M.A.R.T.® Control Biliary Stent

Offering two deployment mechanisms for both rapid delivery and true placement accuracy.

Key Features

- Deployment Lever – Slide down for rapid deployment
- Tuning Dial – Advance for more controlled deployment
- Offers one-handed operation for stent delivery
- Uses perpendicular applied force to reduce unintentional stent movement
- Allows user to adjust stent position prior to vessel wall apposition
- Maintains tactile feel via fine adjustment and controlled deployment
- Unique TRUMARK® Technology innercoil throughout the length of the catheter reduces delivery system compression and movement during deployment
- More flexible tapered tip enhances crossability
- 6F sheath compatible delivery system improves trackability
- MicroMarker® Technology aids in visualization at any angle. The Cordis Marker Securement System of laser-cutting a solid tube of Nitinol and coning the markers ensures marker security

Product Description

Type	MicroMesh geometry, segmented design
Material	Nitinol, with MicroMarker™ Technology
Stent diameters	6-10mm (stent diameter should be 1-2mm greater than vessel diameter)
Stent delivery system working lengths	80cm (S suffix) & 120cm (M suffix)
Stent delivery systems	Delivery Handle: 20-100mm Stent lengths.
	Pin and Pull: 120 and 150mm Stent Lengths
Maximum guidewire	.035"
Stent lengths	30-80mm
Sheath compatibility	6F (6-10mm), 7F(12 - 14mm)
Guide catheter compatibility	8F (6-10mm), 9F(12-14mm)

80cm Usable Length	120cm Usable Lenth	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Size (mm)
C09080SB	C09080MB	9	80	7-8
C10080SB	C10080MB	10	80	8-9
C12030SB	C12030MB	12	30	10-11
C12040SB	C12040MB	12	40	10-11
C12060SB	C12060MB	12	60	10-11
C12080SB	C12080MB	12	80	10-12
C14030SB	C14030MB	14	30	12-13
C14040SB	C14040MB	14	40	12-13
C14060SB	C14060MB	14	60	12-13
C14080SB	C14080MB	14	80	12-13

For information on indications, contraindications, warnings, and precautions, see page 109.

S.M.A.R.T.® Flex Biliary Stent

The S.M.A.R.T.® Flex Biliary Stent builds on the strength of our proven S.M.A.R.T.® Stent and is engineered with outstanding flexibility, making it fully connected yet highly flexible.

Key Features

- Built upon the PALMAZ® Stent heritage with a tissue-to-metal ratio of 80% to 90% and high radial strength
- Easy, accurate placement due to low deployment forces* and fully connected architecture
- Superior* longitudinal stability from a fully connected design
- Optimal, closed-cell scaffolding with uniform coverage

Product Description

Type	Fully connected yet flexible stent design
Material	Nitinol, with tantalum markers on stent ends
Maximum Guidewire	.035"
Stent Lengths:	30 - 150mm
Sheath Compatibility:	6F
Stent Diameters:	5-10mm (stent diameter should be 0.5-1.5mm greater than vessel diameter)
Stent Delivery System Working Lengths	80cm (S suffix) and 120cm (M suffix)

Product Code	Product Code	Stent			Delivery System	
80cm Usable Length	120cm Usable Length	Stent Diameter (mm)	Stent Length (mm)	Recommended Lumen Size (mm)	Recommended Sheath Introducer Size (F)	Guidewire Acceptance
	SF05030MB	5	30	3.5-4.5	6	.035"
	SF05040MB	5	40	3.5-4.5	6	.035"
	SF05060MB	5	60	3.5-4.5	6	.035"
	SF05080MB	5	80	3.5-4.5	6	.035"
	SF05100MB	5	100	3.5-4.5	6	.035"
	SF05120MB	5	120	3.5-4.5	6	.035"
	SF06030MB	6	30	4.5-5.5	6	.035"
	SF06040MB	6	40	4.5-5.5	6	.035"
	SF06060MB	6	60	4.5-5.5	6	.035"
	SF06080MB	6	80	4.5-5.5	6	.035"
	SF06100MB	6	100	4.5-5.5	6	.035"
	SF06120MB	6	120	4.5-5.5	6	.035"

*Data on File, Cordis Corporation. For information on indications, contraindications, warnings, and precautions, see page 109.

S.M.A.R.T.® Flex Biliary Stent, *continued*

Product Code	Product Code	Stent			Delivery System	
80cm Usable Length	120cm Usable Length	Stent Diameter (mm)	Stent Length (mm)	Recommended Lumen Size (mm)	Recommended Sheath Introducer Size (F)	Guidewire Acceptance
	SF06150MB	6	150	4.5-5.5	6	.035"
	SF07030MB	7	30	5.5-6.5	6	.035"
	SF07040MB	7	40	5.5-6.5	6	.035"
	SF07060MB	7	60	5.5-6.5	6	.035"
	SF07080MB	7	80	5.5-6.5	6	.035"
	SF07100MB	7	100	5.5-6.5	6	.035"
	SF07120MB	7	120	5.5-6.5	6	.035"
	SF07150MB	7	150	5.5-6.5	6	.035"
SF08030SB	SF08030MB	8	30	6.5-7.5	6	.035"
SF08040SB	SF08040MB	8	40	6.5-7.5	6	.035"
SF08060SB	SF08060MB	8	60	6.5-7.5	6	.035"
SF08080SB	SF08080MB	8	80	6.5-7.5	6	.035"
SF08100SB	SF08100MB	8	100	6.5-7.5	6	.035"
	SF08120MB	8	120	6.5-7.5	6	.035"
	SF08150MB	8	150	6.5-7.5	6	.035"
SF09030SB	SF09030MB	9	30	7.5-8.5	6	.035"
SF09040SB	SF09040MB	9	40	7.5-8.5	6	.035"
SF09060SB	SF09060MB	9	60	7.5-8.5	6	.035"
SF09080SB	SF09080MB	9	80	7.5-8.5	6	.035"
SF09100SB	SF09100MB	9	100	7.5-8.5	6	.035"
SF10030SB	SF10030MB	10	30	8.5-9.5	6	.035"
SF10040SB	SF10040MB	10	40	8.5-9.5	6	.035"
SF10060SB	SF10060MB	10	60	8.5-9.5	6	.035"
SF10080SB	SF10080MB	10	80	8.5-9.5	6	.035"
SF10100SB	SF10100MB	10	100	8.5-9.5	6	.035"

For information on indications, contraindications, warnings, and precautions, see page 109.

PRECISE® RX Transhepatic Biliary Stent

This landmark stent has several key features, including minimal stent shortening and high radial strength.

Key Features

- .014" rapid exchange
- MicroMesh geometry, segmented design
- Nitinol
- Length of delivery system: 135cm, Rapid Exchange
- Maximum guidewire: .014"
- Sheath compatibility: 5F (5-7mm diameters), 6F (8-10mm diameters)
- Guide catheter compatibility: 7F (5-7mm diameters), 8F (8-10mm diameters)

Diameter X Length (mm)	Recommended Duct Size (mm)	Sheath/Guide Compatibility	Product Code
5 x 20	3-4	5/7	P05020RXB
5 x 30	3-4	5/7	P05030RXB
5 x 40	3-4	5/7	P05040RXB
6 x 20	4-5	5/7	P06020RXB
6 x 30	4-5	5/7	P06030RXB
6 x 40	4-5	5/7	P06040RXB
7 x 30	5-6	5/7	P07030RXB
7 x 40	5-6	5/7	P07040RXB
8 x 30	6-7	6/8	P08030RXB
8 x 40	6-7	6/8	P08040RXB
9 x 30	7-8	6/8	P09030RXB

For information on indications, contraindications, warnings, and precautions, see page 108.

PALMAZ BLUE® Transhepatic Biliary Stent

Utilizes advanced L605 cobalt chromium technology with the proven PALMAZ design to offer increased radiopacity, low profiles and superior flexibility and deliverability.

Key Features

Radiopacity
- Better fluoroscopic visibility*
- Less ferromagnetism means more MRI compatible*

Strength
- Improved radial strength*
- Landmark design

Deliverability
- Ultra-low profile*
- More flexible and deliverable*

Product Description

Type	Closed cell, FLEXSEGMENT™ Technology
Material	L605 cobalt chromium alloy
Stent Diameters (Expanded)	4-7mm
Stent Lengths (Unexpanded)	12mm, 15mm, 18mm, 24mm
Balloon/SDS	SLALOM® Catheters
Nominal/RBP	Nominal pressure: 12/10 Rated burst: 14/12
Maximum Guidewire	.018"
Sheath Introducer	5F
Guide Catheter Compatibility	6F
Usable length	80cm (S suffix) or 135cm (X suffix)

80cm Shaft Length - .018" Over-The-Wire

Product Code	Balloon Diameter (mm)	Balloon Length (mm)	Expanded Stent Length (mm)
PB1240BSS	4	15	12
PB1250BSS	5	15	11
PB1260BSS	6	15	10
PB1270BSS	7	15	11
PB1540BSS	4	17	15
PB1550BSS	5	17	14
PB1560BSS	6	17	14
PB1570BSS	7	17	14
PB1840BSS	4	20	17
PB1850BSS	5	20	18
PB1860BSS	6	20	17
PB1870BSS	7	20	18
PB2440BSS	4	25	23
PB2450BSS	5	25	24
PB2460BSS	6	25	23
PB2470BSS	7	25	24

* All comparisons are to Cordis PALMAZ® GENESIS® Transhepatic Biliary Stent

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ BLUE® Transhepatic Biliary Stent,
continued

135cm Shaft Length - .018" Over-The-Wire

Product Code	Balloon Diameter (mm)	Balloon Length (mm)	Expanded Stent Length (mm)
PB1240BSX	4	12	12
PB1250BSX	5	12	11
PB1260BSX	6	12	10
PB1270BSX	7	12	11
PB1540BSX	4	15	15
PB1550BSX	5	15	14
PB1560BSX	6	15	14
PB1570BSX	7	15	14
PB1840BSX	4	18	17
PB1850BSX	5	18	18
PB1860BSX	6	18	17
PB1870BSX	7	18	18
PB2440BSX	4	24	23
PB2450BSX	5	24	24
PB2460BSX	6	24	23
PB2470BSX	7	24	24

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ GENESIS® Transhepatic Biliary Stent

Medium Stents on Cordis SLALOM® PTA Dilatation Catheter - .018"

Product Description

Type	Closed cell, FLEXSEGMENT™ Technology
Material	316L stainless steel
Stent Diameters (Expanded)	3mm, 8mm
Stent Lengths (Unexpanded)	12mm, 15mm, 18mm, 24mm
Balloon/SDS	SLALOM® Catheters
Nominal/RBP	Nominal pressure: 12/10/8atm; Rated burst: 14/12/10atm
Maximum Guidewire	.018"
Sheath Introducer	5F, 6F
Guide Catheter Compatibility	6F, 7F, 8F
Usable length	80cm (S suffix) or 135cm (X suffix)

Product Code		Balloon		
80cm Shaft Length	**135cm Shaft Length**	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Expanded Stent Length (mm)**
PG1230BSS		3	15	12
PG1280BSS	PG1280BSX	8	15	10
PG1530BSS	PG1530BSX	3	17	15
PG1580BSS	PG1580BSX	8	17	13
PG1830BSS	PG1830BSX	3	20	18
PG1880BSS	PG1880BSX	8	20	16
	PG2430BSX	3	25	24
PG2480BSS	PG2480BSX	8	25	23

For information on indications, contraindications, warnings, and precautions, see page 102.

PALMAZ GENESIS® Transhepatic Biliary Stent
continued

Large Stents on Cordis SLALOM® PTA Dilatation Catheter - .018"

Product Description

Type	Closed cell, FLEXSEGMENT™ Technology
Material	316L Stainless Steel
Stent Diameters (Expanded)	5-8mm
Stent Lengths (Unexpanded)	29mm, 39mm
Balloon/SDS	SLALOM® Catheters
Nominal/RBP	Nominal: 10/8atm; Rated: 14/12/10atm
Maximum Guidewire	.018"
Sheath Introducer	5F, 6F
Guide Catheter Compatibility	7F, 8F
Usable Length	80cm (S suffix) or 135cm (X suffix)

Product Code		Balloon		
80cm Shaft Length	**135cm Shaft Length**	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Expanded Stent Length (mm)**
	PG2950BSX	5	30	28
PG2960BSS	PG2960BSX	6	30	27
PG2970BSS	PG2970BSX	7	30	26
PG2980BSS	PG2980BSX	8	30	26
PG3950BSS	PG3950BSX	5	40	39
PG3960BSS	PG3960BSX	6	40	38
PG3970BSS	PG3970BSX	7	40	36
PG3980BSS	PG3980BSX	8	40	36

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ GENESIS® Transhepatic Biliary Stent
continued

Large Stents on Cordis OPTA® Pro PTA Dilatation Catheter - .035”

Product Description

Type	Closed cell, FLEXSEGMENT™ Technology
Material	316L Stainless Steel
Stent Diameters (Expanded)	5-10mm
Stent Lengths (Unexpanded)	19mm, 29mm, 39mm, 59mm, 79mm
Balloon/SDS	OPTA® Pro Catheters
Nominal/RBP	8atm/10atm
Maximum Guidewire	.035”
Sheath Introducer	6F, 6.5F, 7F
Guide Catheter Compatibility	8F, 9F
Usable Length	80cm (S suffix) or 135cm (X suffix)

Product Code		Balloon		
80cm Shaft Length	**135cm Shaft Length**	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Expanded Stent Length (mm)**
PG1990BPS	PG1990BPX	9	20	17
PG1910BPS	PG1910BPX	10	20	16
PG2950BPS	PG2950BPX	5	30	28
PG2960BPS	PG2960BPX	6	30	27
PG2970BPS	PG2970BPX	7	30	26
PG2980BPS	PG2980BPX	8	30	26
PG2990BPS	PG2990BPX	9	30	25
PG2910BPS	PG2910BPX	10	30	24
PG3950BPS	PG3950BPX	5	40	39

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ GENESIS® Transhepatic Biliary Stent

continued

Large Stents on Cordis OPTA® Pro PTA Dilatation Catheter - .035”

Product Code		Balloon		
80cm Shaft Length	135cm Shaft Length	Balloon Diameter (mm)	Balloon Length (mm)	Expanded Stent Length (mm)
PG3960BPS	PG3960BPX	6	40	38
PG3970BPS	PG3970BPX	7	40	36
PG3980BPS	PG3980BPX	8	40	36
PG3990BPS	PG3990BPX	9	40	35
PG3910BPS	PG3910BPX	10	40	32
PG5950BPS	PG5950BPX	5	60	59
PG5960BPS	PG5960BPX	6	60	59
PG5970BPS	PG5970BPX	7	60	57
PG5980BPS	PG5980BPX	8	60	56
PG5990BPS	PG5990BPX	9	60	53
PG5910BPS	PG5910BPX	10	60	53
PG7950BPS	PG7950BPX	5	80	79
PG7960BPS	PG7960BPX	6	80	79
PG7970BPS	PG7970BPX	7	80	78
PG7980BPS	PG7980BPX	8	80	76
PG7990BPS	PG7990BPX	9	80	75
PG7910BPS	PG7910BPX	10	80	73

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ GENESIS® Transhepatic Biliary Stent
continued

Medium Stents on Cordis OPTA® Pro PTA Dilatation Catheter - .035"

Product Description

Type	Closed cell, FLEXSEGMENT™ Technology
Material	316L stainless steel
Stent Diameters (Expanded)	4-8mm
Stent Lengths (Unexpanded)	12mm, 15mm, 18mm, 24mm
Balloon/SDS	OPTA® Pro Catheters
Nominal/RBP	8atm/10atm
Maximum Guidewire	.035"
Sheath Introducer	6F
Guide Catheter Compatibility	8F
Usable Length	80cm (S suffix) or 135cm (X suffix)

Product Code		Balloon		
80cm Shaft Length	**135cm Shaft Length**	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Expanded Stent Length (mm)**
PG1240BPS		4	15	11
PG1250BPS	PG1250BPX	5	15	11
PG1260BPS	PG1260BPX	6	15	11
PG1270BPS	PG1270BPX	7	15	11
PG1280BPS	PG1280BPX	8	15	11
PG1540BPS		4	17	14
PG1550BPS	PG1550BPX	5	17	14
PG1560BPS	PG1560BPX	6	17	14
PG1570BPS	PG1570BPX	7	17	14

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ GENESIS® Transhepatic Biliary Stent,
continued

Medium Stents on Cordis OPTA® Pro PTA Dilatation Catheter - .035"

Product Code		Balloon		
80cm Shaft Length	**135cm Shaft Length**	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Expanded Stent Length (mm)**
PG1580BPS	PG1580BPX	8	17	14
PG1840BPS		4	20	17
PG1850BPS	PG1850BPX	5	20	17
PG1860BPS	PG1860BPX	6	20	17
PG1870BPS	PG1870BPX	7	20	17
PG1880BPS	PG1880BPX	8	20	17
PG2440BPS		4	25	23
PG2450BPS	PG2450BPX	5	25	23
PG2460BPS	PG2460BPX	6	25	23
PG2470BPS	PG2470BPX	7	25	23
PG2480BPS	PG2480BPX	8	25	23

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ GENESIS® Transhepatic Biliary Stent (Unmounted)

Product Description	Medium	Large	XD
Type	Closed cell, FLEXSEGMENT™ Technology	Closed cell, FLEXSEGMENT™ Technology	Closed Cell, FLEXSEGMENT™ Technology
Material	316L stainless steel	316L stainless steel	316L stainless steel
Stent Diameters (Expanded)	5-8mm	5-10mm	10-12mm (10mm only for 59mm)
Stent Lengths (Unexpanded)	12mm, 15mm, 18mm, 24mm	29mm, 39mm, 59mm, 79mm	19mm, 25mm, 29mm, 39mm, 59mm
Recommended PTA Dilatation Catheter	OPTA® Pro Catheters	OPTA® Pro Catheters	OPTA® Pro Catheters
Sheath Introducer	6F	7F, 7.5F	8F

Unmounted Medium

Product Code	Expansion Diameter (mm)	Unexpanded Stent Length (mm)
PG124B	5-8	12
PG154B	5-8	15
PG184B	5-8	18
PG244B	5-8	24

Unmounted Large

Product Code	Expansion Diameter (mm)	Unexpanded Stent Length (mm)
PG295B	5-10	29
PG395B	5-10	39
PG595B	5-10	59
PG795B	5-10	79

Unmounted XD (Extra Diameter)

Product Code	Expansion Diameter (mm)	Unexpanded Stent Length (mm)
PG1910B	10-12	19
PG2510B	10-12	25
PG2910B	10-12	29
PG3910B	10-12	39
PG5910B	10	59

For information on indications, contraindications, warnings, and precautions, see page 101.

PALMAZ® Balloon-Expandable Stent (unmounted)

Utilizes FlexSegment Technology that is designed to improve flexibility, reduce shortening, and improve scaffolding in a bend.

Product Description

Type	Closed cell
Material	316L stainless steel
Stent Diameters (Expanded)	4-12mm
Stent Lengths (Unexpanded)	15mm, 20mm, 29mm, 30mm
Recommended PTA Dilatation Catheter	POWERFLEX® PRO
Sheath Introducer	6F, 7F

Medium

Product Code	Expansion Diameter (mm)	Unexpanded Stent Length (mm)
P154M	6 - 8 iliac, 4 - 8 renal	15
P204M	6 - 8 iliac, 4 - 8 renal	20
P294M	6 - 8 iliac	29
P394M	4 - 9 biliary	39

Large

Product Code	Expansion Diameter (mm)	Unexpanded Stent Length (mm)
P308M	8 - 12 iliac	30

For information on indications, contraindications, warnings, and precautions, see page 100.

PALMAZ® XL Transhepatic Biliary Stent (Unmounted)

Product Description

Type	Closed cell
Material	316L stainless steel
Stent Diameters (Expanded)	10mm
Stent Lengths (Unexpanded)	30mm, 40mm, 50mm
Sheath Introducer	10F

Product Code	Expansion Diameter (mm)	Unexpanded Stent Length (mm)
P3110	10	30
P4010	10	40
P5010	10	50

For information on indications, contraindications, warnings, and precautions, see page 101.

PRECISE PRO RX® Carotid Stent System

.014" Stent Delivery System (Carotid Stent System) Nitinol

- Laser cut from a Nitinol hypotube (no welds)
- Micromesh design
- Multi segmental construction
- High radial resistive force
- 8% maximum foreshortening (for all sizes)
- Crush-recoverable
- Carotid indication
- Length of delivery system: 135cm

Product Code	Diameter X Length (mm)	Recommended Vessel Size (mm)	Sheath/Guide Compatibility
PC0520RXC	5 x 20	3-4	5/7
PC0530RXC	5 x 30	3-4	5/7
PC0540RXC	5 x 40	3-4	5/7
PC0620RXC	6 x 20	4-5	5/7
PC0630RXC	6 x 30	4-5	5/7
PC0640RXC	6 x 40	4-5	5/7
PC0720RXC	7 x 20	5-6	5/7
PC0730RXC	7 x 30	5-6	5/7
PC0740RXC	7 x 40	5-6	5/7
PC0820RXC	8 x 20	6-7	5/7

Product Description

Type	MicroMesh geometry, segmented design
Clinical Use	Carotid artery stenting
Material	Nitinol
Distal outer diameter	5F (5-8mm), 6F (9-10mm)
Stent Delivery System	135cm, Rapid Exchange
Maximum Guidewire	.014"
Sheath Compatibility	5F (5-8mm diameters), 6F (9-10mm diameters)
Guide Catheter Compatibility	7F (5-8mm diameters), 8F (9-10mm diameters)
Recommended Embolic Protection Device	ANGIOGUARD® RX Emboli Capture Guidewire System

Product Code	Diameter X Length (mm)	Recommended Vessel Size (mm)	Sheath/Guide Compatibility
PC0830RXC	8 x 30	6-7	5/7
PC0840RXC	8 x 40	6-7	5/7
PC0920RXC	9 x 20	7-8	6/8
PC0930RXC	9 x 30	7-8	6/8
PC0940RXC	9 x 40	7-8	6/8
PC1020RXC	10 x 20	8-9	6/8
PC1030RXC	10 x 30	8-9	6/8
PC1040RXC	10 x 40	8-9	6/8

For information on indications, contraindications, warnings, and precautions, see page 106.

PRECISE® OTW Carotid Stent System

Features

- Stent Diameters: 5-10mm (stent diameter should be 1-2mm greater than vessel diameter.
- Stent Delivery System: 135cm. Over the wire.
- Maximum Guidewire: .018"
- Sheath Compatability: 5.5F (5-8mm diameters), 8F (9-10mm diameters)

Product Code	Diameter X Length (mm)	Recommended Vessel Size (mm)	Sheath/Guide Compatibility
P05020XC	5 x 20	(3-4)	(6/7)
P05030XC	5 x 30	(3-4)	(6/7)
P05040XC	5 x 40	(3-4)	(6/7)
P06020XC	6 x 20	(4-5)	(6/7)
P06030XC	6 x 30	(4-5)	(6/7)
P06040XC	6 x 40	(4-5)	(6/7)
P07020XC	7 x 20	(5-6)	(6/7)
P07030XC	7 x 30	(5-6)	(6/7)
P07040XC	7 x 40	(5-6)	(6/7)
P08020XC	8 x 20	(6-7)	(6/7)
P08030XC	8 x 30	(6-7)	(6/7)
P08040XC	8 x 40	(6-7)	(6/7)
P09020XC	9 x 20	(7-8)	(6/8)
P09030XC	9 x 30	(7-8)	(6/8)
P09040XC	9 x 40	(7-8)	(6/8)
P10030XC	10 x 30	(8-9)	(6/8)
P10040XC	10 x 40	(8-9)	(6/8)

For information on indications, contraindications, warnings, and precautions, see page 106.

ANGIOGUARD® RX Emboli Capture Guidewire System

With its Rapid Exchange System is easy to use, providing optimal protection while maintaining blood flow.

Ease of Use

Medium & Extra Support Wires
- .014" compatible wire available in medium and extra support for lesion specific access and support of interventional devices

Excellent crossability
- Easy to cross tortuous anatomies with a crossing profile from as low as 3.2F

Rapid Exchange System
- Simplified deployment with peel away deployment sheath
- Easy capture of filter with rapid exchange capture sheath
- Single operator
- Faster procedure
- Enhanced wire control

Capture Effectiveness

- Effective capture of clinically relevant emboli with 100µ pore sizes filter
- Optimal wall apposition

Safety

- Continuous perfusion throughout the procedure
- Excellent visualisation and optimal control
  - 4 radiopaque markers on the basket
  - Proximal and distal markerbands
- Effect sealing of the vessel preventing migration of emboli (when properly sized)
- Designed to minimize vessel trauma
  - Tapered delivery and capture sheaths
  - Coil nosecone to improve wire transition

Ordering Information

- Guidewire length: 180cm
- .014"Wire
- Guiding catheter compatibility: 8F
- Sheath Compatibility: 6F

Product Code Medium Support	Product Code Extra Support	Guidewire Diameter (in)	System Length (cm)	Filter Basket Diameter (mm)	Recommended Vessel Diameter For Placement (mm)	Crossing Profile (F)
401814RMC		.014	180	4	3 to < 3.5	3.2
501814RMC	501814REC	.014	180	5	3.5 to < 4.5	3.3
601814RMC	601814REC	.014	180	6	4.5 to < 5.5	3.5
701814RMC	701814REC	.014	180	7	5.5 to < 6.5	3.7
801814RMC	801814REC	.014	180	8	6.5 to < 7.5	3.9
403014MC		.014	300	4	3 to < 3.5	3.2
503014MC		.014	300	5	3.5 to < 4.5	3.3
603014MC		.014	300	6	4.5 to < 5.5	3.5
703014MC		.014	300	7	5.5 to < 6.5	3.7
803014MC		.014	300	8	6.5 to < 7.5	3.9

For information on indications, contraindications, warnings, and precautions, see page 86.

The CORDIS® Vena Cava filters with nitinol technology feature a double-basket, self-centering design, offering dual-layer filtration for excellent capturing capacity. The closed cage structure is designed to eliminate risk of caval perforation and strut embolization. Self-centering side struts help reduce the risk of tilting while fixation barbs minimize migration to maintain clot capture efficiency.

There are many benefits to CORDIS® Vena Cava filters:

- Maximum cava diameter of 30 mm
- Excellent caval coverage for optimal clot capturing efficiency
- Double basket to maximize clot capture efficiency
- Nitinol technology for easy and reliable filter placement & MRI safe (tested under 3 Tesla)
- 6 options for access sites
- Self centering design aids to avoid tilting and allow for reliable filter placement

OPTEASE® Retrievable Vena Cava Filter

Retrievable Vena Cava filter
Offers all the benefits of the TRAPEASE® Vena Cava Filter, with the option of retrieval. This filter can be either retrieved within 23 days or left implanted permanently.

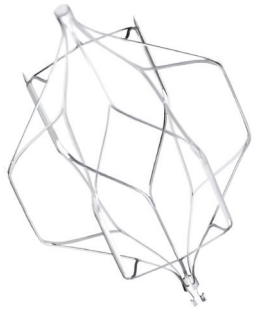
Angiographic Vessel Dilator
With an open end, side holes, and radiopaque marker bands at 30mm (end-to-end) distance, the angiographic vessel dilator references the maximum indicated inferior vena cava diameter.

TRAPEASE® Permanent Vena Cava Filter

Permanent Vena Cava filter
A unique permanent Vena Cava filter with proven design strength.

OPTEASE® Retrievable Vena Cava Filter

In PE cases that may require the need for filter retrieval, the OPTEASE® Retrievable Vena Cava Filter is designed to deliver performance, stability, and safety for every patient.



Key Features

- Nitinol construction
- Closed cage design
- Low profile 6F sheath
- Maximum cava diameter of 30mm
- Long side struts to enable self-centering
- Femoral/jugular/antecubital vein placement
- Fixation barbs to minimize migration
- Dual Prong Caudal Hook for easier capture with any appropriate endovascular snare
- Retrieval window up to 23 days

Kit Components

- OPTEASE® Filter in storage tube
- Obturator
- BRITE TIP® Catheter Sheath Introducer
- Angiographic Vessel Dilator
- Patient information brochure

Description	Access Site	Product Code
Cordis OPTEASE® Vena Cava Filter and Introduction Kit (55cm)	Femoral	466F230AF
Cordis OPTEASE® Vena Cava Filter and Introduction Kit (55cm)	Jugular	466F230AJ
Cordis OPTEASE® Vena Cava Filter and Introduction Kit (90cm)	Antecubital, Jugular	466F230BJ
Cordis OPTEASE® Retrieval Catheter with Radiopaque Tip (80cm, 10F)	Femoral	466C220F

WARNING: Implant of the OPTEASE® Vena Cava Filter with the hook oriented in the cranial direction can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures and ineffective pulmonary embolism prevention. For information on indications, contraindications, warnings, and precautions, see page 95.

TRAPEASE® Permanent Vena Cava Filter

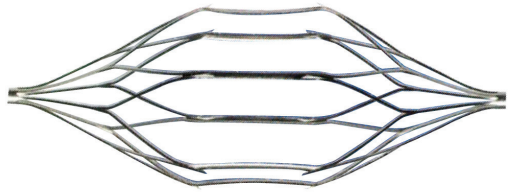
In PE cases that require permanent placement of an IVC filter, the TRAPEASE® Vena Cava Filter offers a solution proven with design strength.

Key Features

- Nitinol construction
- Closed cage design
- Low profile 6F sheath
- Maximum cava diameter of 30mm
- Long side struts to enable self-centering
- Femoral/jugular/antecubital vein placement
- Opposing cranial and caudal fixation barbs to reduce migration

Kit Components

- TRAPEASE® Filter in storage tube
- Obturator
- BRITE TIP® Catheter Sheath Introducer
- Angiographic Vessel Dilator
- Patient information brochure



Description	Access Site	Product Code
Cordis TRAPEASE® Vena Cava Filter and Introduction Kit (55cm)	Jugular, Femoral	466P306AU
Cordis TRAPEASE® Vena Cava Filter and Introduction Kit (90cm)	Antecubital, Jugular, Femoral	466P306BU

For information on indications, contraindications, warnings, and precautions, see page 117.

Closure Portfolio

Our closure portfolio includes the MYNX CONTROL™, MYNXGRIP®, and EXOSEAL® Vascular Closure Devices. MYNX CONTROL™ and MYNXGRIP® Vascular Closure Devices utilize the proprietary GRIP™ sealant to seal the arteriotomy. The GRIP™ sealant, comprised of Polyethylene Glycol (PEG), grips the artery, providing a secure close. The sealant dissolves within 30 days, leaving nothing permanently behind but a healed artery. MYNX® Closure Devices treat a wide range of patients and clinical scenarios including punctures at or below the bifurcation and antegrade punctures. The versatile design provides options in challenging anatomies.

MYNXGRIP® Vascular Closure Device

The MYNXGRIP® Closure Device offers a patient-friendly closure option with no cinching, suturing, or metal implants. Learn more on page 83.

MYNX CONTROL™ Vascular Closure Device

The innovative design and predictable deployment of MYNX CONTROL™ Vascular Closure Device (VCD) delivers outstanding performance and control, for consistently secure arterial closures. Learn more on page 84.

EXOSEAL® Vascular Closure Device

Combining safety and ease-of-use, the Cordis EXOSEAL® Vascular Closure Device means a more confident close and improved patient outcomes. Learn more on page 85.

1. Fargen KM, Hoh Bl, Mocco J. J NeuroIntervent Surg, 2011

MYNXGRIP® Vascular Closure Device

The MYNXGRIP® Device provides secure mechanical closure with the safety of an extravascular sealant. The MYNXGRIP® Device contains the proprietary GRIP™ Sealant which actively adheres to and seals the arteriotomy or venotomy while expanding to fill the tissue tract. The MYNXGRIP® Device offers a patient-friendly closure option with no cinching, suturing, or metal implants. The GRIP™ sealant dissolves within 30 days leaving nothing permanently behind but a healed artery. The MYNXGRIP® Device is indicated to close femoral arterial and venous access sites utilizing a 5F, 6F, or 7F procedural sheath.

Ordering Information

The MYNXGRIP® Vascular Closure Device includes:

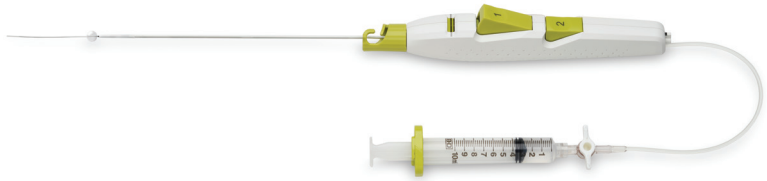
- Balloon catheter with integrated sealant
- 10 ml locking syringe
- Units per package: 10

Product	Size	Product Code
MYNXGRIP® Vascular Closure Device	5F	MX5021
MYNXGRIP® Vascular Closure Device	6F/7F	MX6721

MYNXGRIP® Vascular Closure Devices are manufactured by Cardinal Health and are part of the Cordis portfolio.
For information on indications, contraindications, warnings, and precautions, see page 94.

MYNX CONTROL™ Vascular Closure Device (VCD)

The MYNX CONTROL™ VCD integrates active extravascular sealing and resorbability properties with a next-generation delivery system to maximize predictability, safety, and ease of use in sealing 5-7F femoral arterial access sites. The new deployment system is purpose-designed to enhance safety and deliver reliable performance. The GRIP™ sealant securely adheres to the arteriotomy and dissolves within 30 days, leaving nothing permanently behind but a healed artery. The MYNX CONTROL™ Device is indicated to close femoral arterial access sites utilizing a 5F, 6F, or 7F procedural sheath.



Ordering Information

The MYNX CONTROL™ VCD includes:

- (1) MYNX CONTROL™ VCD including balloon catheter and integrated polyethylene glycol sealant
- (1) 10 ml locking syringe
- Units per package: 10

Product	Size	Order Number
MYNX CONTROL™ Vascular Closure Device (VCD)	5F	MX5060
	6F/7F	MX6760

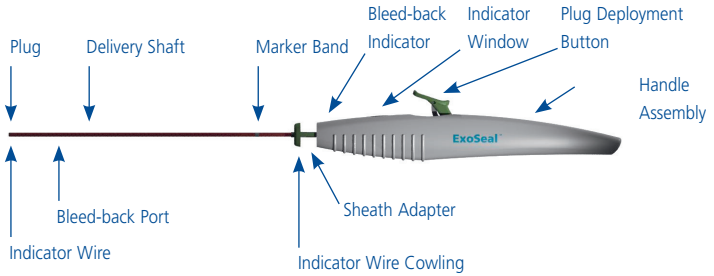
* Data on file at Cardinal Health. MYNX CONTROL™ VCD is manufactured by Cardinal Health and is part of the Cordis portfolio.
For information on indications, contraindications, warnings, and precautions, see page 94.

EXOSEAL® Vascular Closure Device

The EXOSEAL® Vascular Closure Device is indicated for femoral artery puncture site closure, reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional catheterization procedures using a standard 5F, 6F, or 7F vascular sheath introducer with up to a 12-cm working length. The EXOSEAL® Vascular Closure Device is designed for a safe, simple, and secure close.

Key Features

- No anchor left inside the artery
- Two unique visual indicators enable precise positioning
- Easy-to-learn deployment helps efficiently achieve procedural success
- Simple 3-step procedure
- Available in 3 French sizes



Product	Size	Order Number
EXOSEAL® Vascular Closure Device	5F	EX500
EXOSEAL® Vascular Closure Device	6F	EX600
EXOSEAL® Vascular Closure Device	7F	EX700

For information on indications, contraindications, warnings, and precautions, see page 90.

ANGIOGUARD® RX Emboli Capture Guidewire System

Indications
The Cordis ANGIOGUARD® RX Emboli Capture Guidewire System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5mm (see Instructions for Use for basket/vessel sizing).

Contraindications
- Patients in whom antiplatelet and or anticoagulation therapy is contraindicated.
- Patients in whom the guide catheter is unable to be placed.
- Patients with uncorrected bleeding disorders.
- Patients with known allergies to nitinol.
- Lesions in the ostium of the common carotid artery.

Warnings
- Only physicians who have received appropriate training for carotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
- The safety and effectiveness of this device as an emboli protection system has not been established in the coronary, cerebral, or peripheral vasculature, other than carotid arteries.
- The safety and efficacy of the ANGIOGUARD® RX Guidewire System have not been demonstrated with stent systems other than the PRECISE® Stent System.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- Patient ACT of >300 seconds needs to be maintained during ANGIOGUARD® RX Guidewire System deployment.

AQUATRACK® Hydrophilic Nitinol Guidewire, ATW™ Steerable Guidewire, ATW™ Marker Wire, STABILIZER® Plus Steerable Guidewire, STABILIZER® XS Steerable Guidewire, JINDO® Steerable Guidewire, SV Steerable Guidewire

Indications
Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.

Contraindications
Cordis Steerable Guidewires are contraindicated for use in chronic total occlusions.

Contraindications for interventional devices are described in the instructions supplied with the respective device.

Warnings
Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. All parts are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Cordis Corporation will not be responsible for any direct, incidental or consequential damages resulting from reuse of the product.

Guidewires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guidewire carefully for coil separation, bends, or kinks. Do not use a guidewire that shows signs of damage. Damage will prevent the guidewire from performing with accurate torque response and control.

- Guidewire manipulation/torquing should always be performed under fluoroscopic guidance.
- Never push, auger, withdraw, or torque a guidewire that meets resistance. First, using fluoroscopy, determine the cause of resistance and take any necessary remedial action. Torquing or pushing a guidewire against resistance may cause guidewire damage, and/or guidewire tip separation, or direct damage to the vessel. Resistance may be felt and/or observed (via fluoroscopy) by noting any buckling of the guidewire tip. If guidewire tip prolapse is observed, DO NOT allow the tip to remain in a prolapsed position; otherwise damage to the guidewire may occur.
- If any resistance is felt, i.e., due to vessel spasm, bent guidewire, or guidewire entrapment, while manipulating or removing the guidewire in the blood vessel: STOP the procedure. DO NOT move or torque the guidewire. Using fluoroscopy, first determine the cause of the resistance, then take appropriate remedial action. If the guidewire is moved excessively, it may break or become damaged. This may cause blood vessel injury or result in fragments being left inside the vessel.
- Should torque control/tip response be compromised during use, confirm tip integrity using fluoroscopy. LOSS OF TORQUE CONTROL MAY BE DUE TO CORE WIRE FRACTURE. Under fluoroscopic guidance, advance the balloon catheter to the distal end of the guidewire and

remove the balloon catheter/guidewire system as a unit.

Precautions
- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage the guidewire.
- Do not expose to organic solvents.
- Movement of torque device or metal insertion tool on a guidewire's coating may compromise the integrity of the coating.

Complications
Procedures requiring percutaneous guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during or after the procedure.

Possible complications include, but are not limited to:

- Air embolism
- Hematoma at the puncture site
- Infection
- Perforation of the heart or vessel wall
- Tip fractures have been reported in procedures involving guidewire entrapment, total occlusions, highly tortuous vasculature, and small side branches.

- For guidewire tip retrieval, please refer to the referenced publications for recommended techniques.

AVANTI®+ Sheath Introducer, BRITE TIP® Catheter Sheath Introducer

Indications
The CSI is indicated for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices.

Contraindications
None known.

Warnings
For one use only. Do not resterilize or reuse. Structural integrity and/or function may be impaired through cleaning, resterilization or reuse and may cause adverse patient reactions. Accordingly, Cordis will not be responsible for any direct or consequential damages or expenses resulting from reuse of the CSI.

Do not use with Ethiodol™ or Lipiodol™ contrast media, or other such contrast media, which incorporate the components of these agents.

Do not leave a CSI in place for extended periods of time without a catheter or an obturator to support the cannula wall.

Precautions
- Store in a dry, dark, cool place.
- Do not use if package is open or damaged.
- Note "Use Before" or "Use By" date prior to using product.
- Do not resterilize. Exposure to temperatures above 54°C (130°F) may damage the catheter sheath and components.
- Do not expose to organic solvents, e.g. alcohol.
- If increased resistance is felt upon insertion of the CSI, investigate the cause before continuing. If the cause of the resistance cannot be determined and corrected, discontinue the procedure and withdraw the CSI.

Complications
Possible complications include, but are not limited to:

- air embolism
- infection
- intimal tear
- hematoma at the puncture site
- perforation of the vessel wall
- thrombus formation.

AVIATOR® Plus PTA Dilatation Catheter

Indications For Use
The Cordis AVIATOR PLUS PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for postdilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Contraindications
The Cordis AVIATOR® PLUS PTA Balloon Dilatation Catheter is contraindicated for use in coronary arteries. Generally, further contraindications include, but may not be limited to:

- Patients with highly calcified lesions resistant to PTA.

- Patients with a target lesion with a large amount of adjacent acute or subacute thrombus.
- Patients with uncorrected bleeding disorders.

Warnings

- Store in a cool, dark and dry place.
- Do not use if inner package is opened or damaged.
- Exposure to temperatures above 54°C (130°F) may damage the device.
- Do not expose the device to organic solvents (e.g. alcohol).
- Do not use Ethiodol™ or Lipiodol™ contrast media.
- This product contains no detectable latex.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may increase the risk of inappropriate resterilization and cross contamination and compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death.
- To reduce the potential for vessel damage or the risk of dislodgement of particles it is very important that the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the lesion. The balloon dimensions are printed on the product label and hub identification band. The compliance table printed on the box label and packaged with the product illustrates how the balloon diameter increases with increasing pressure.
- Do not retract the catheter unless the balloon is fully deflated under vacuum.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the rated burst pressure recommended on the label. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure-monitoring device is recommended to prevent over-pressurization.
- Use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon.
- Use the device prior to the "Use By" date specified on the package.
- Maintain a snug seal with the hemostasis valve over the balloon catheter during advancement to prevent introduction of air into the sheath or guiding catheter. Without a snug seal, a tight fit between the balloon section of the balloon catheter and the sheath or guiding catheter may cause a risk for introduction of air and air entrainment during advancement of the balloon catheter through the sheath or guiding catheter.

Precautions

- The device should only be used by physicians who are trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty in the indicated arteries.
- Prior to use, the device should be examined to verify functionality and integrity, and ensure that its size is suitable for the specific procedure. Before and during the procedure, appropriate anticoagulant/antiplatelet therapy should be provided to the patient, as needed.
- Consider the use of systemic heparinization by flushing the devices with sterile heparinized saline or similar isotonic solution.
- Ensure that the devices are prepared according to the steps outlined in Preparation.
- The minimal acceptable sheath introducer / guiding catheter size is printed on the package label. Do not attempt to pass the balloon catheter through a smaller size sheath introducer / guiding catheter than indicated on the label. Use of a smaller than indicated accessory device can lead to introduction of air into that device as the balloon catheter is advanced, which may not be removed during air aspiration.
- Prior to use, ensure all devices have been flushed and air is removed from the system according to standard medical practice. Failure to do so could result in air entering the vascular system.
- When the catheter is exposed to the vascular system, it should be manipulated only under fluoroscopy.
- Caution should be taken when treating patients with poor renal function who, in the physician's opinion, may be at risk for contrast-induced nephropathy.
- During the procedure remove blood or any other residues from the devices, using a heparinized-saline soaked gauze.
- In case of post dilatation of a balloon-expandable or self-expanding stent, the applicable stent Instructions for Use should be consulted.
- Crossing a partially or fully deployed stent with adjunct devices must be performed with extreme caution.
- Distal protection is recommended when using the balloon catheter in a carotid or renal angioplasty procedure. If a distal protection device is used, follow the applicable instructions for use.

Potential Complications

Potential complications, which may lead to additional intervention, include, but are not limited to:

- Abrupt closure
- Acute myocardial infarction

- Allergic reaction (device, contrast medium and medications)
- Amputation
- Aneurysm
- Angina
- Arrhythmias (major, minor), including ventricular fibrillation
- Arteriovenous fistula
- Coma
- Death
- Embolism
- Hematoma
- Hemorrhage, including bleeding at puncture site
- Hypotension / hypertension
- Ischemia
- Necrosis
- Nephropathy
- Neurological events, including peripheral nerve injury and neuropathies
- Organ failure (single, multiple)
- Paralysis
- Pyrogenic reaction
- Renal failure
- Restenosis
- Seizures
- Sepsis / infection / inflammation
- Shock
- Stroke
- Thrombosis
- Transient Ischemic Attack
- Vascular Complications (e.g. intimal tear, dissection, pseudoaneurysm,
- perforation, rupture, spasm, occlusion)
- Weakness.

ELITECROSS™ Support Catheter

Indications

The Cordis ELITECROSS™ Support Catheter is intended to facilitate the intraluminal placement of diagnostic/interventional devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention, and to deliver saline or contrast medium. Additionally, ELITECROSS™ can be used as an accessory with the FRONTRUNNER® XP CTO Catheter.

Contraindications

The ELITECROSS™ Support Catheter is not intended for use in the cerebral or coronary vasculature.

Warnings

- Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For Single use. Do not resterilize.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not manipulate catheter through a metal sheath as it may result in damage and/or separation of the hydrophilic coating requiring retrieval.
- Do not advance or torque the catheter in the vascular system or into a stenotic lesion (chronic total occlusion) unless the distal end is supported by an ancillary device.
- Do not use with Ethiodol or Lipiodol* contrast media, or other such contrast media which incorporates the components of these agents.
- Do not expose to organic solvents (e.g., alcohol).
- Do not exceed maximum pressure rating printed on product label.
- If damage is detected in the catheter at any time, replace with an undamaged catheter.

Precautions

- Store in a cool, dark, dry place.
- Do not use if package is opened or damaged.
- Use prior to the "Use By" date.
- Exposure to temperatures above 60°C (140°F) may damage the catheter.
- The catheter should only be used by physicians trained in percutaneous interventional techniques in a fully equipped catheterization laboratory.
- Do not use without completely reading and understanding this document.
- To prevent damage to the catheter during removal from the package, grasp the hub and withdraw the catheter.
- Inspect the catheter before use to verify that its size, shape and condition are suitable for the specific procedure.
- If strong resistance is met during manipulation, determine the cause of resistance before proceeding.
- Torquing the catheter excessively may cause damage to the product and/or, specifically, result in possible separation along the catheter shaft.
- Withdraw the catheter if it becomes kinked, or if binding occurs between the catheter and ancillary device.
- Before use, flush all devices entering a blood vessel with sterile heparinized saline or a similar isotonic solution.

- Keep the catheter filled with either flushing solution or contrast medium while the catheter is in the vascular system and consider the use of systemic heparinization
- Advancement, manipulation and withdrawal of the catheter should always be performed under fluoroscopic guidance..

Complications
This product is designed for use by physicians trained in and familiar with percutaneous interventional techniques. Complications may occur at any time during or after the procedure.

Possible complications may include, but are not limited to, the following:

- air embolism
- hematoma at the puncture site
- vessel damage, dissection, perforation, or injury
- vasospasm
- vascular thrombosis
- pseudoaneurysm
- embolism
- infection and/or sepsis
- reaction to contrast media
- death

EMERALD® Diagnostic Guidewire

Indications
Cordis Guidewires are intended for use in the percutaneous introduction of catheters.

Contraindications
None known.

Warnings
Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. All parts are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Accordingly, Cordis Corporation will not be responsible for any direct, incidental or consequential damages resulting from reuse of the product.

Precautions
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" date.
- Do not expose to organic solvents.
- Exposure to temperatures above 54°C (130°F) may damage the components.
- Do not withdraw a PTFE coated guidewire through a metal-cannula needle. Withdrawal may damage the guidewire coating.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter and guidewire.

Complications
Procedures requiring percutaneous catheter/guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to:

- air embolism
- hematoma at the puncture site
- infection
- perforation of the vessel wall.

EXOSEAL® Vascular Closure Device

Indication for Use
The EXOSEAL® Vascular Closure Device is indicated for femoral artery puncture site closure, reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional catheterization procedures using a standard 5F, 6F, or 7F vascular sheath introducer with up to a 12cm working length. Additionally, the EXOSEAL® Vascular Closure Device is indicated to reduce times to hemostasis and ambulation in patients who have undergone interventional catheterization procedures, using a standard 6F vascular sheath introducer up to a 12cm working length, who have received preprocedural and/or intraprocedural glycoprotein (GP) IIb-IIIa inhibitor therapy.

Contraindications
There are no contraindications to the use of this device. Attention is drawn to the Warnings, Precautions, and Special Patient Populations.

Warnings
- Do not use the EXOSEAL® Vascular Closure Device if the package is damaged or any portion of the package has been previously opened.
- Do not use the EXOSEAL® Vascular Closure Device if the device appears damaged or defective in any way.
- Do not use the EXOSEAL® Vascular Closure Device if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred; a broken sterile field may result in infection.

- For SINGLE USE ONLY. Do not resterilize or reuse. 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. Use aseptic technique when handling the product.
- Do not use the EXOSEAL® Vascular Closure Device in patients with known allergy to polyglycolic acid.

Precautions

- Serious adverse events might result with the use of the EXOSEAL® Vascular Closure Device in vessels not suitable for the use of the device. Avoid the use of the EXOSEAL® Vascular Closure Device in patients with arteriotomies created in areas of calcified plaque or in vessels with diameters < 5mm.
- With antegrade puncture (restricted to peripheral vascular catheterization procedures), the ability to accurately assess vessel size or extraluminal device position may be limited.
- The EXOSEAL® Vascular Closure Device procedure should be performed by physicians who have expertise in the techniques of vascular catheterization (or other health care professionals authorized by, or under the direction of, such physicians) and possess adequate training in the use of the device, eg, participation in an EXOSEAL® Vascular Closure Device training program.
- Observe sterile technique at all times when using the EXOSEAL® Vascular Closure Device. Employ proper groin management postprocedure and posthospital discharge to prevent infection.
- The vascular sheath introducer and/or EXOSEAL® Vascular Closure Device should not be advanced or withdrawn when resistance is met without first determining the cause by fluoroscopic examination. Using excessive force to advance or torque the EXOSEAL® Vascular Closure Device may lead to arterial damage and/or breakage of the device, which may necessitate interventional and/or surgical removal of the device and arterial repair.
- If for any reason it is desired to abort the procedure once the EXOSEAL® Vascular Closure Device has been introduced into the bloodstream, remove the EXOSEAL® Vascular Closure Device and vascular sheath introducer as a unit. Do not attempt to withdraw the EXOSEAL® Vascular Closure Device from the vascular sheath introducer, as Plug dislodgement may occur.
- Pulsatile flow is necessary for proper positioning. If pulsatile flow is not observed from the Bleed-Back Indicator, discontinue the procedure.
- Do not remove the EXOSEAL® Vascular Closure Device from the vascular sheath introducer after removal from the patient; discard the EXOSEAL® Vascular Closure Device with the Delivery Shaft still locked inside the vascular sheath introducer.
- In patients undergoing interventional endovascular procedures, ambulation less than 2 hours after EXOSEAL® Vascular Closure Device use increases the risk of oozing or rebleeding after initial hemostasis and should be done only after all clinical factors have been considered.

Special Patient Population

The safety and effectiveness of the EXOSEAL® Vascular Closure Device has not been established in the following patient populations:

- Patients with acure ST-elevation myocardial infarction ≤ 48 hours prior to the cardiac or peripheral catheterization
- Patients with uncontrolled hypertension at time of closure (BP ≥180/110 mmHg)
- Patients who bruise or bleed easily or with a history of significant bleeding or platelet disorders, such as thrombocytopenia (with < 100,000 platelet count), Von Willebrand's disease, anemis (Hgb < 10 g/dL, Hct < 30%), thrombasthenia, decreased fibrinogen (<200 mg/dl), and Factory V deficiency
- Patients with prior femoral vascular surgery or vascular graft in region of access site
- Patients with pre-existing systemic or cutaneous infection
- Patients who are known to be pregnant or who are lactating
- Patients on thrombolytic (e.g. streptokinase, urokinase, t-PA) ≤ 24 hours prior to the catheterization procedure
- Patients on Angiomax (bivalirudin) or other thrombin-specific anticoagulants or low molecular weight heparin ≤ 24 hours prior to the cardiac or peripheral catheterization procedure
- Patients with a BMI > 40 Kg/m2
- Patients with symptomatic leg ischemia in the target vessel limb including severe claudication (, 30.48 meters / < 100 feet) or weak/absent pulse
- Patients with planned arterial access at the same access site ≤ 30 days following the femoral artery closure procedure
- Patients undergoing arterial puncture in the femoral artery or both legs
- Patients with prior target artery closure with any closure device, or closure with manual compression ≤ 30 days prior to the cardia or peripheral catheterization procedure
- Patients with prior or recent use of an intra-aortic balloon pump through the arterial access site
- Patients with evidence of a preexisting hematoma, arteriovenous fistula, or pseudoaneurysm at the access site prior to start of femoral artery closure procedure

- Patients with a tortuous targeted femoral artery
- Patients who within ≤ 1cm of the puncture site have fluoroscopically visible calcium, atherosclerotic disease, or a stent
- Patients with a targeted femoral artery diameter stenosis ≥ 50%
- Patients with arteriotomies in vessels with diameters < 5mm
- Patients where there is difficulty in obtaining vascular access resulting in multiple arterial punctures and/or posterior arterial puncture
- Patients with antegrade puncture
- Heparinized patients with elevated pre-closure ACT level: . 250 seconds with GP IIb/IIIa inhibitor, > 300 seconds without GP IIb/IIIa inhibitor
- Patients experiencing cardiogenic shock (hemodynamic instability requiring intravenous medications or mechanical support) during or immediately post-catheterization

FRONTRUNNER® XP CTO Catheter

Indications
The FRONTRUNNER® XP CTO Catheter is intended to facilitate the intraluminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Contraindications
This device is not intended for use in the cerebral vasculature.

Warnings
- Single use only. Do not resterilize, autoclave, or reuse.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after internal use
- Reuse of this product, including after reprocessing and/or resterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety
- Do not use this device to cross a lesion within a stent
- Do not use if package is opened or damaged
- Do not use after the last day of the month of the "Use By" date on the package
- Do not use this device in the coronary vasculature

Precautions
- This catheter should only be used by physicians trained in percutaneous interventional techniques in a fully equipped catheterization laboratory or vascular surgery suite
- Do not use without completely reading and understanding this document
- Store in a cool, dark, dry place
- Do not expose the catheter to organic solvents (e.g., alcohol)
- Excessive bending or kinking of the catheter may affect performance
- Torquing the catheter excessively may cause damage to the product. Withdraw the catheter should it become kinked
- If strong resistance is felt during manipulation, determine the cause of the resistance before proceeding further. If the cause cannot be determined, withdraw the catheter.

Potential Complications
This product is designed for use by physicians trained in and familiar with percutaneous interventional techniques. Possible complications may include, but are not limited to, the following:

- Vessel dissection, perforation, or injury
- Vascular thrombosis
- Vessel spasm
- Embolism
- Pseudoaneurysm
- Infection and/or sepsis

MAXI LD® Large Diameter PTA Dilatation Catheter (14 - 15 mm diameter sizes)

Indications
The MAXI LD® PTA catheter is intended to dilate stenoses in iliac arteries.

Contraindications
The MAXI LD® PTA catheter is contraindicated for use in coronary arteries. No additional contraindications are known for PTA procedures.

Warnings
- This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.

- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9% of the balloons, (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.

Precautions

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty. Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.
- Not intended for precise arterial blood pressure monitoring.

Adverse Effects

Possible adverse effects include, but are not limited to, the following:

- air embolism
- aneurysm
- hematoma at the puncture site
- perforation of the vessel wall

MAXI LD® Large Diameter Balloon Dilatation Catheter (16 - 25 mm diameter sizes)

Indications

The MAXI LD® large diameter balloon dilatation catheter is intended for use in the dilatation of strictures of the esophagus.

Contraindications

None known.

Warnings

- This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- When the catheter is exposed to the esophagus, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons, (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.

Precautions

- Prior to use, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by or under supervision of physicians thoroughly trained in wire guided esophageal balloon dilatation. A thorough understanding of the technical principles, clinical application, and risks associated with balloon dilatation of the esophagus is necessary before using these devices.
- The minimal acceptable French size is printed on the package label. Do not attempt to pass the catheter through a smaller size introducer than indicated on the label.

Adverse Effects
Possible adverse effects include, but are not limited to, the following:

- hemorrhage
- hematoma
- perforation
- septicemia/infection
- allergic reaction to contrast medium
- rupture
- hematemesis

MYNX CONTROL™ VCD Indications For Use

Indications for Use:
The MYNX CONTROL VCD is indicated for use to seal femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath.

Contraindications
There are no known contraindications for the MYNX CONTROL VCD.

Warnings
Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened. DO NOT REUSE OR RESTERILIZE. The MYNX CONTROL VCD is for single use only. The catheter is loaded with a single Hydrogel sealant. Reuse of the device would result in no delivery of Hydrogel sealant. Do not use the MYNX CONTROL VCD if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and/or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma/bleed. Perform a femoral angiogram to verify the location of the puncture site. Do not use the MYNX CONTROL VCD if the puncture is through the posterior wall or if there are multiple punctures, as such punctures may result in a retroperitoneal hematoma/bleed.

Precautions
The MYNX CONTROL VCD should only be used by a trained licensed physician or healthcare professional. The MYNX CONTROL VCD should not be used in patients with a known allergy to PEG.

Potential Adverse Events
See IFU for a list of Potential Adverse Events.

MYNXGRIP® Vascular Closure Device

Indications For Use
The MYNXGRIP® Device is indicated for use to seal femoral arterial and femoral venous access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath.

Contraindications
There are no known contraindications for MYNXGRIP®

Precautions
The MYNXGRIP® Device should only be used by a trained licensed physician or healthcare professional. The MYNXGRIP® Device should not be used in patients with a known allergy to PEG.

Warnings
Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened. DO NOT REUSE OR RESTERILIZE. The MYNXGRIP® Device is for single use only. The balloon catheter is loaded with a single hydrogel sealant. Reuse of the device would result in no delivery of hydrogel sealant. Do not use the MYNXGRIP® Device if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) (for arterial application) and/or above the inguinal ligament based upon osseus landmarks, since such a puncture site may result in a retroperitoneal hematoma/bleed. Perform a femoral angiogram or venogram to verify the location of the puncture site. Do not use the MYNXGRIP® Device if the puncture is through the posterior wall or if there are multiple punctures, as such punctures may result in a retroperitoneal hematoma/bleed.

Potential Adverse Events
In addition to the complications noted in the MYNX® Device clinical trial, the following potential complications, which may be related to the endovascular procedure or the vascular closure, may occur: allergic reaction, ecchymosis, superficial vein thrombosis, foreign body/ local reaction, retroperitoneal bleed, vessel occlusion, pulmonary embolism, or death. See IFU for complete information.

NYLEX® Diagnostic Catheter, TEMPO® Diagnostic Catheter , TEMPO AQUA® Diagnostic Catheter

Indications
Cordis catheters are designed to deliver radiopaque contrast medium to selected sites in the vascular system.

Contraindications
None known.

Complications
Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to the following:

- Air embolism
- Hematoma at the puncture site
- Infection
- Perforation of the vessel wall

OPTA® Pro PTA Dilatation Catheter

Indications
The OPTA® PRO PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications
None known for PTA procedure. The OPTA® PRO PTA catheter is contraindicated for use in coronary arteries.

Warnings
- This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization. Use only the recommended balloon inflation medium.
- Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.

Precautions
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.
- Not intended for precise arterial blood pressure monitoring.

Adverse Effects
Possible adverse effects include, but are not limited to, the following:

- air embolism
- aneurysm
- hematoma at the puncture site
- perforation of the vessel wall.

OPTEASE® Retrievable Vena Cava Filter

Jugular Approach

Indications
The OPTEASE® Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed, or is contraindicated.

Contraindications
Vena cava filters should not be implanted in:

- Patients with risk of septic embolism.
- Patients with uncontrolled infectious disease.
- Patients with an IVC diameter larger than 30mm.
- Patients contraindicated for procedures under fluoroscopy.
- Patients with demonstrated hypersensitivity to one of the components of the OPTEASE® Filter.

There are no known contraindications for use of the Angiographic Vessel Dilator.

Warnings
For Filter Placement:

- Retrieval of the OPTEASE® Filter is possible only from femoral vein approach. Do not implant the filter with the intention to retrieve using the jugular access.
- All components in the OPTEASE® Introduction Kit with Angiographic Vessel Dilator are for single use only. Do not resterilize or reuse. Structural integrity and/or function may be impaired through cleaning, resterilization, or reuse and may cause adverse patient reactions. Accordingly, Cordis will not be responsible for any direct or consequential damages or expenses resulting from reuse of any of the components in the OPTEASE® Introduction Kit.
- When injecting contrast medium through the Angiographic Vessel Dilator, do not exceed maximum pressure rating of 800 psi. Ensure that a high-pressure connection line is used.
- After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded.
- The OPTEASE® Filter is supplied constrained in a plastic storage tube indicating the appropriate orientation for jugular approach. Never reload a fully ejected or partially ejected OPTEASE® Filter into the storage tube as this could result in incorrect orientation for the selected access site. Never reload a fully ejected or partially ejected OPTEASE® Filter into the storage tube as this could affect its shape, and function.
- Implant of the OPTEASE® Filter with the hook oriented in the cranial direction can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death.
- Filter fracture is a potential complication of vena cava filters. Anatomic locations that create concentrated stress points from filter deformation (for example, deployment at apex of scoliosis, overlapping of either of the renal ostia, or placement adjacent to a vertebral osteophyte) may contribute to fracture of a particular
- filter strut. However, reports of adverse clinical sequelae from filter fractures are rare.
- The OPTEASE® Filter should only be used by physicians who are trained in diagnostic and percutaneous interventional techniques, for instance placement of vena cava filters.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- In patients with acute pulmonary embolism in which the OPTEASE® Filter is inserted as an alternative to anticoagulation therapy, a conventional course of anticoagulation therapy should be started if the risk of bleeding resolves.
- Where practicable, a retrievable filter should be removed if a conventional course of anticoagulation therapy can be started, or if the underlying reason for indication is resolved.

For Optional Filter Retrieval

- Excessive force should not be used to retrieve the filter.
- Retrieval of the Filter should not be attempted if thrombus is present in the filter and/or caudal to the filter.
- Available data from retrievals in a 21 patient study and a 40 patient retrospective chart review suggest that the OPTEASE® Filter can be safely retrieved (mean of 11.1 days, range 5–14 days and mean of 16.4 days, range 3–48 days, respectively). Please refer to the Clinical Experience section of this IFU. The OPTEASE® Filter is considered a permanent filter if it is not retrieved within a clinically suitable time period.
- Where practicable, a retrievable filter should be removed if a conventional course of anticoagulation therapy can be started, or if the underlying reason for indication is resolved.
- The OPTEASE® Filter must be implanted with the fixation barbs to the cranial end and retrieval hook to the caudal end of the filter.
- Retrieval of the OPTEASE® Filter is possible only from femoral vein approach. Before attempting retrieval of the OPTEASE® Filter from the femoral access site, verify that the filter retrieval hook is at the caudal end of the filter, i.e. caudal orientation in the IVC. The retrieval hook at the caudal end of the filter is the location for endovascular snare engagement.
- Retrieval of the OPTEASE® Filter with a filter fracture present may result in complications.
- Retrieval of the OPTEASE® Filter should only be performed by physicians who are trained in percutaneous interventional techniques.

- Never redeploy a retrieved filter.
- Please refer to Section IX labeled Optional Procedure for Filter Retrieval.

Precautions

- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" date.
- Do not resterilize.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose to organic solvents.
- The OPTEASE® Filter has been tested and qualified with the accompanying accessories. The use of any other accessory could result in complications and/or an unsuccessful procedure.
- Advancement, manipulation and withdrawal of the OPTEASE® Filter or its accessories should always be performed under fluoroscopic control.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding. It is the responsibility of the physician to use his/her judgment, based on patient safety and clinical experience, regarding the acceptability level of any resistance and/or whether to continue or abort the retrieval attempt.
- The safety and effectiveness of the OPTEASE® Filter has not been established in patients who are known to be pregnant or who are lactating.

Jugular / Antecubital Approach

Indications

The OPTEASE® Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed, or is contraindicated.

The OPTEASE® Filter may be retrieved according to the instructions supplied in the Section labeled: Optional Procedure for Filter Retrieval.

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the vena cava.

Contraindications

Vena cava filters should not be implanted in:

- Patients with risk of septic embolism.
- Patients with uncontrolled infectious disease.
- Patients with an IVC diameter larger than 30mm.
- Patients contraindicated for procedures under fluoroscopy.
- Patients with demonstrated hypersensitivity to one of the components of the OPTEASE® Filter.

There are no known contraindications for use of the Angiographic Vessel Dilator.

Warnings

For Filter Placement:

- Retrieval of the OPTEASE® Filter is possible only from femoral vein approach. Do not implant the filter with the intention to retrieve using the jugular access.
- All components in the OPTEASE® Introduction Kit with Angiographic Vessel Dilator are for single use only. Do not resterilize or reuse. Structural integrity and/or function may be impaired through cleaning, resterilization, or reuse and may cause adverse patient reactions. Accordingly, Cordis will not be responsible for any direct or consequential damages or expenses resulting from reuse of any of the components in the OPTEASE® Introduction Kit.
- When injecting contrast medium through the Angiographic Vessel Dilator, do not exceed maximum pressure rating of 800 psi. Ensure that a high-pressure connection line is used.
- After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded.
- The OPTEASE® Filter is supplied constrained in a plastic storage tube indicating the appropriate orientation for jugular/antecubital approaches. Never reload a fully ejected or partially ejected OPTEASE® Filter into the storage tube as this could result in incorrect orientation for the selected access site. Never reload a fully ejected or partially ejected OPTEASE® Filter into the storage tube as this could affect its shape, and function.
- Implant of the OPTEASE® Filter with the hook oriented in the cranial direction can result in life threatening or serious injury including, but not limited to dissection,

vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death.
- Filter fracture is a potential complication of vena cava filters. Anatomic locations that create concentrated stress points from filter deformation (for example, deployment at apex of scoliosis, overlapping of either of the renal ostia, or placement adjacent to a vertebral osteophyte) may contribute to fracture of a particular filter strut. However, reports of adverse clinical sequelae from filter fractures are rare.
- The OPTEASE® Filter should only be used by physicians who are trained in diagnostic and percutaneous interventional techniques, for instance placement of vena cava filters.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- In patients with acute pulmonary embolism in which the OPTEASE® Filter is inserted as an alternative to anticoagulation therapy, a conventional course of anticoagulation therapy should be started if the risk of bleeding resolves.
- Where practicable, a retrievable filter should be removed if a conventional course of anticoagulation therapy can be started, or if the underlying reason for indication is resolved.

Precautions
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" date.
- Do not resterilize.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose to organic solvents.
- The OPTEASE® Filter has been tested and qualified with the accompanying accessories. The use of any other accessory could result in complications and/or an unsuccessful procedure. Advancement, manipulation and withdrawal of the OPTEASE® Filter or its accessories should always be performed under fluoroscopic control.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding. It is the responsibility of the physician to use his/her judgment, based on patient safety and clinical experience, regarding the acceptability level of any resistance and/or whether to continue or abort the retrieval attempt.
- The safety and effectiveness of the OPTEASE® Filter has not been established in patients who are known to be pregnant or who are lactating

Femoral Approach

Indications
The OPTEASE® Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed, or is contraindicated.

Contraindications
Vena cava filters should not be implanted in:

- Patients with risk of septic embolism.
- Patients with uncontrolled infectious disease.
- Patients with an IVC diameter larger than 30mm.
- Patients contraindicated for procedures under fluoroscopy.
- Patients with demonstrated hypersensitivity to one of the components of the OPTEASE® Filter.

There are no known contraindications for use of the Angiographic Vessel Dilator.

Warnings
For Filter Placement:

- Retrieval of the OPTEASE® Filter is possible only from femoral vein approach. Do not implant the filter with the intention to retrieve using the jugular access.
- All components in the OPTEASE® Introduction Kit with Angiographic Vessel Dilator are for single use only. Do not resterilize or reuse. Structural integrity and/or function may be impaired through cleaning, resterilization, or reuse and may cause adverse patient reactions. Accordingly, Cordis will not be responsible for any direct or consequential damages or expenses resulting from reuse of any of the components in the OPTEASE® Introduction Kit.
- When injecting contrast medium through the Angiographic Vessel Dilator, do not exceed maximum

pressure rating of 800 psi. Ensure that a high-pressure connection line is used. After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded.
- The OPTEASE® Filter is supplied constrained in a plastic storage tube indicating the appropriate orientation for femoral approach.
- Never reload a fully ejected or partially ejected OPTEASE® Filter into the storage tube as this could result in incorrect orientation for the selected access site. Never reload a fully ejected or partially ejected OPTEASE® Filter into the storage tube as this could affect its shape, and function.
- Implant of the OPTEASE® Filter with the hook oriented in the cranial direction can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death.
- Filter fracture is a potential complication of vena cava filters. Anatomic locations that create concentrated stress points from filter deformation (for example, deployment at apex of scoliosis, overlapping of either of the renal ostia, or placement adjacent to a vertebral osteophyte) may contribute to fracture of a particular filter strut. However, reports of adverse clinical sequelae from filter fractures are rare.
- The OPTEASE® Filter should only be used by physicians who are trained in diagnostic and percutaneous interventional techniques, for instance placement of vena cava filters.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- In patients with acute pulmonary embolism in which the OPTEASE® Filter is inserted as an alternative to anticoagulation therapy, a conventional course of anticoagulation therapy should be started if the risk of bleeding resolves. Where practicable, a retrievable filter should be removed if a conventional course of anticoagulation therapy can be started, or if the underlying reason for indication is resolved.

Precautions
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" date.
- Do not resterilize.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose to organic solvents.
- The OPTEASE® Filter has been tested and qualified with the accompanying accessories. The use of any other accessory could result in complications and/or an unsuccessful procedure.
- Advancement, manipulation and withdrawal of the OPTEASE® Filter or its accessories should always be performed under fluoroscopic control.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding. It is the responsibility of the physician to use his/her judgment, based on patient safety and clinical experience,regarding the acceptability level of any resistance and/or whether to continue or abort the retrieval attempt.
- The safety and effectiveness of the OPTEASE® Filter has not been established in patients who are known to be pregnant or who are lactating

OUTBACK® Elite Re-Entry Catheter

Indications
The OUTBACK® Elite Re-Entry Catheter is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The OUTBACK® Elite Re-Entry Catheter is not intended for use in the coronary or cerebral vasculature.

Contraindications
This device is not intended for use in the coronary or cerebral vasculature.

Warnings
- Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For single use only. Do not resterilize
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after internal use. Reuse of this product, including after reprocessing and/or resterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose the OUTBACK® Elite Re-Entry Catheter to organic solvents (e.g., alcohol).
- Do not use if package is opened or damaged
- Do not use after the last day of the month of the "Use By" date on the package

Precautions

- Store in a cool, dark, dry place
- This catheter should only be used by physicians trained in peripheral percutaneous interventional techniques in a fully equipped catheterization laboratory
- Do not use without completely reading and understanding this document
- The OUTBACK® Elite Re-Entry Catheter should be kept straight flushing, preparation steps and during guidewire loading. A sterile gauze sponge with heparinized saline may be used to wipe the catheter 9with the cannula in the retracted position) going from the proximal hub to the distal tip. Do not tug or otherwise overstretch the catheter to straighten it.
- Always confirm visualization of the targeted distal vessel via contrast injection and fluoroscopy before using the catheter. Avoid contrast injection in the sub-intimal space
- Minimize sub-intimal dissection tract beyond point of reconstitution
- To maintain guide wire position during device exchanges, and exchangeable length guide wire is recommended
- Prior to use, carefully read the instructions packaged with the guide wires. Failure to use recommended guide wire may result in damage to the guide wire, such as abrasion of the hydrophilic coating, release of polymer fragments, separation of the wire, or inability to withdraw the OUTBACK® Elite Re-Entry Catheter over the guide wire.
- Always visualize tracking of the catheter tip over the aorto-iliac bifurcation
- If strong resistance is felt during catheter manipulation/ delivery, determine the cause of the resistance before proceeding further. Consider using a 3-4mm balloon at the low ATM to dilate points of resistance, as needed, along delivery track. If the cause cannot be determined, withdraw the OUTBACK® Elite Re-Entry Catheter.
- Excessive rotation, bending or kinking of the OUTBACK® Elite Re-Entry Catheter may affect its performance. Withdraw the OUTBACK® Elite Re-Entry Catheter if it becomes excessively kinked.
- If the guide wire kins, carefully attempt to remove the wires and replace with a new one. Stop if any resistance is felt when removing wire from the OUTBACK® Elite Re-Entry Catheter. If resistance is encountered, retract the cannula tip back into the shaft and then remove the OUTBACK® Elite Re-Entry Catheter and wire together from the vasculature.
- Excessive calcification at the site of re-entry may impair performance

Potential Complications

This product is designed for use by physicians trained in and familiar with peripheral percutaneous interventional techniques. Possible complications may include, but are not limited to, the following:

- Vessel dissection, perforation, or injury
- Embolism
- Vessel spasm
- Pseudoaneurysm
- Vascular thrombosis
- Hemorrhage
- Ischemia

PALMAZ® Balloon-Expandable Stent

Indications

The Cordis PALMAZ® Balloon-Expandable Transhepatic Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

Contraindications

Contraindications associated with the use of transhepatic biliary endoprostheses include:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.
- Patients with uncorrected bleeding disorders.
- Severe ascites.

Warnings

- The safety and effectiveness of the PALMAZ® Balloon-Expandable Transhepatic Biliary Stent System for use in the vascular system have not been established.
- Do not use if the inner package is opened or damaged.
- The PALMAZ® Balloon-Expandable Transhepatic Biliary Stent System is intended for single use only. Do not resterilize and/or reuse the device.
- Store in a cool, dark, dry place.
- Use the stent prior to the "Use By" date printed on the product label.
- The device should only be used by physicians who are trained in interventional techniques, placement of stents and transhepatic access. Crimping tube sizes and crimping tool sizes are not interchangeable.
- Use only the recommended balloon dilatation catheters.
- When using the POWERFLEX® PLUS balloon cathether, use the crimping tube that is packaged with the balloon catheter.
- Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.
- The delivery system is not designed for use with power injection systems.
- Do not exceed the rated burst pressure recommended on the catheter label.

- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different metals in tandem where overlap or contact is possible, with an exception: stents made of 316L stainless steel are compatible with stents made of nickel titanium alloy. Do not attempt to remove or readjust the stent once crimped on the delivery system.
- Persons with allergic reactions to stainless steel may suffer an allergic response to this implant.
- Any secondary expansion of the biliary stent should be performed with a device indicated for biliary stent placement.

Potential Complications
Potential complications associated with the use of transhepatic biliary endoprostheses implantation may include, but are not limited to, the following:

- Cholangitis
- Hemobilia
- Peritonitis
- Abscess
- Stent migration
- Rupture, overstretching of duct
- Sepsis/infection
- Stent obstruction secondary to tumor growth through the stent
- Tumor overgrowth at the stent ends
- Pancreatitis
- Bile duct perforation
- Parenchymal hemorrhage

PALMAZ BLUE® Transhepatic Biliary Stent

Indications
The Cordis PALMAZ BLUE® .018 Transhepatic Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

Contraindications
Contraindications associated with the use of transhepatic biliary endoprostheses include:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.
- Patients with uncorrected bleeding disorders.
- Severe ascites.

Warnings
The safety and effectiveness of the PALMAZ BLUE® .018 Transhepatic Biliary Stent System for use in the vascular system have not been established.

- Do not use if the inner package is opened or damaged.
- The PALMAZ BLUE® .018 Transhepatic Biliary Stent System is intended for single use only. Do not resterilize and/or reuse the device, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- Store in a cool, dark, dry place.
- Inflation at a high rate may damage the balloon.
- Use the stent and delivery system prior to the "Use By" date specified on the package.
- Use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon.
- Do not use Ethiodol™ or Lipiodol™ contrast medium.
- Do not expose the delivery system to organic solvents (e.g. alcohol).
- Exposure to temperatures above 54°C (130°F) may damage the catheter.
- Persons with allergic reactions to a cobalt-chromium alloy, whose main constituents are cobalt, chromium, tungsten, and nickel, may suffer an allergic response to this implant.
- Once fully deployed, the stent cannot be repositioned.
- Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.
- Any secondary expansion of the biliary stent should be performed with a device indicated for Biliary stent placement.

Precautions
- The device should only be used by physicians who are trained in interventional techniques, placement of stents and transhepatic access.
- Prior to stenting, the PALMAZ BLUE® .018 Transhepatic Biliary Stent System should be examined to verify functionality and integrity.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with extreme caution.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different metals in tandem where overlap or contact is possible, with an exception: stents made of cobalt-chromium alloy conforming to ASTM F90 (L605) are compatible with stents made of 316L stainless steel and nickel titanium alloy.
- Do not attempt to remove or readjust the stent on the delivery system.
- To assure full expansion, inflate to at least the recommended nominal pressure as shown on the label.
- Do not exceed the rated burst pressure recommended on the label. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons

(with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the delivery system through a smaller size sheath introducer than indicated on the label.

Potential Complications
Potential complications associated with transhepatic biliary endoprostheses implantation may include, but are not limited to, the following:

- Sepsis/infection
- Stent migration
- Stent obstruction secondary to tumor growth through the stent
- Tumor overgrowth at the stent ends
- Bile duct occlusion/obstruction
- Pancreatitis
- Bile duct perforation
- Parenchymal hemorrhage
- Hemobilia
- Peritonitis
- Abscess
- Rupture, overstretching of duct
- Cholangitis.

PALMAZ GENESIS® Transhepatic Biliary Stent

Indications
The Cordis PALMAZ GENESIS® Transhepatic Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

Contraindications
Contraindications associated with the use of transhepatic biliary endoprostheses include:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.
- Patients with uncorrected bleeding disorders
- Severe ascites.

Warnings
- The safety and effectiveness of the PALMAZ GENESIS® Transhepatic Biliary Stent System for use in the vascular system have not been established.
- Do not use if the inner package is opened or damaged.
- The PALMAZ GENESIS® Transhepatic Biliary Stent System is intended for single use only. Do not resterilize and/or reuse the device, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- Store in a cool, dark, dry place.
- Inflation at a high rate may damage the balloon.
- Use the stent and delivery system prior to the "Use By" date specified on the package.
- Use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon. • Do not use Ethiodol™ or Lipiodol™ contrast medium.
- Do not expose the delivery system to organic solvents (e.g. alcohol).
- Exposure to temperatures above 54°C (130°F) may damage the catheter.
- Persons with allergic reactions to a cobalt-chromium alloy, whose main constituents are cobalt, chromium, tungsten, and nickel, may suffer an allergic response to this implant.
- Once fully deployed, the stent cannot be repositioned.
- Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.
- Any secondary expansion of the biliary stent should be performed with a device indicated for Biliary stent placement.

Precautions
- The device should only be used by physicians who are trained in interventional techniques, placement of stents and transhepatic access.
- Prior to stenting, the PALMAZ GENESIS® Transhepatic Biliary Stent System should be examined to verify functionality and integrity.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with extreme caution.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different metals in tandem where overlap or contact is possible, with an exception: stents made of cobalt-chromium alloy conforming to ASTM F90 (L605) are compatible with stents made of 316L stainless steel and nickel titanium alloy.
- Do not attempt to remove or readjust the stent on the delivery system.
- To assure full expansion, inflate to at least the recommended nominal pressure as shown on the label.
- Do not exceed the rated burst pressure recommended on the label. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons

(with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the delivery system through a smaller size sheath introducer than indicated on the label.

Potential Complications
Potential complications associated with transhepatic biliary endoprostheses implantation may include, but are not limited to, the following:

- Sepsis/infection
- Stent migration
- Stent obstruction secondary to tumor growth through the stent
- Tumor overgrowth at the stent ends
- Bile duct occlusion/obstruction
- Pancreatitis
- Bile duct perforation
- Parenchymal hemorrhage
- Hemobilia
- Peritonitis
- Abscess
- Rupture, overstretching of duct
- Cholangitis

PALMAZ® XL Transhepatic Biliary Stent

Indications
The PALMAZ® XL Balloon-Expandable Transhepatic Biliary Stent is indicated for palliation of malignant neoplasms in the biliary tree.

Contraindications
Contraindications associated with the use of transhepatic biliary endoprostheses include:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.
- Patients with bleeding disorders.
- Severe ascites.

Warnings
The safety and effectiveness of this device for use in the vascular system have not been established.

- The PALMAZ® XL Balloon-Expandable Transhepatic Biliary Stent is intended for single use only. Do not resterilize and/or reuse the device.
- Do not use if the inner pouch is opened or damaged.
- Store in a cool, dark, dry place.
- Use the stent prior to the "Use By" date specified on the package.
- Once fully deployed, the stent cannot be repositioned.
- Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.
- Persons with allergic reactions to stainless steel may suffer an allergic response to this implant.
- Any secondary expansion of the biliary stent should be performed with a device indicated for biliary stent placement.

Precautions
- The device should only be used by physicians who are trained in interventional techniques such as percutaneous transluminal angioplasty, placement of stents and transhepatic access.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- To avoid the possibility of dissimilar metal corrosion do not implant stents of different metals in tandem where overlap or contact is possible, with an exception, stents made of 316L stainless steel are compatible with stents made of nickel titanium alloy.
- Plastic crimping tubes and metal introducer tubes are not interchangeable.
- Do not attempt to remove or readjust the stent once crimped on the delivery system.
- To assure full expansion, inflate to at least the nominal pressure recommended on the catheter label.
- Do not exceed the rated burst pressure (RBP) recommended on the catheter label.
- Crimping tool must always be used in preparation of stent delivery catheter.

Potential Complications
Potential complications associated with the use of transhepatic biliary endoprostheses may include, but are not limited to, the following:

- Sepsis/infection
- Stent migration
- Stent obstruction secondary to tumor growth through the stent
- Tumor overgrowth at the stent ends
- Bile duct occlusion/obstruction
- Pancreatitis

- Bile duct perforation
- Parenchymal hemorrhage
- Hemobilia
- Peritonitis
- Abscess
- Rupture, overstretching
- Cholangitis

POWERFLEX® Extreme PTA Dilatation Catheter

Indications
The Cordis POWERFLEX® Extreme Dilatation Catheter is intended for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries.

Contraindications

None known for PTA procedure. The POWERFLEX® Extreme PTA Catheter is contraindicated for use in coronary arteries.

Warnings
- The POWERFLEX® Extreme PTA Dilatation Catheters are not intended for stent expansion.
- This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.

Precautions
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.
- Not intended for precise arterial blood pressure monitoring.

Adverse Effects
Possible adverse effects include, but are not limited to, the following:

- Air embolism
- Aneurysm
- Hematoma at the puncture site
- Perforation of the vessel wall

POWERFLEX® P3 PTA Dilatation Catheter

Indications
The POWERFLEX® P3 PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications
None known for PTA procedure. The POWERFLEX® P3 PTA catheter is contraindicated for use in coronary arteries.

Warnings
- This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated.

- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.

Precautions
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.
- Not intended for precise arterial blood pressure monitoring.

Adverse Effects
Possible adverse effects include, but are not limited to, the following:

- air embolism
- aneurysm
- hematoma at the puncture site
- perforation of the vessel wall.

POWERFLEX® Pro PTA Catheter

Indications
The POWERFLEX® PRO PTA Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilation of balloon-expandable and selfexpanding stents in the peripheral vasculature.

Contraindications
- None known for PTA procedure.
- The POWERFLEX® PRO PTA catheter is contraindicated for use in coronary arteries.

Warnings
- This device is intended for one time use only.
- DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.

Precautions
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.

Adverse Effects
Possible adverse effects include, but are not limited to, the following:

- Air embolism
- Aneurysm
- Hematoma at the puncture site
- Perforation of the vessel wall
- Vascular Complications (e.g. intimal tear, dissection, pseudoaneurysm, perforation, rupture, spasm, occlusion)
- Embolism
- Allergic reaction (device, contrast medium and medications)
- Pyrogenic reaction
- Hemorrhage, including bleeding at puncture site
- Hypotension / hypertension
- Ischemia
- Necrosis
- Thrombosis

PRECISE PRO RX® Carotid Stent

Indications
The Cordis PRECISE PRO RX® Carotid Stent System, used in conjunction with the Cordis ANGIOGUARD® RX Emboli Capture Guidewire System, is indicated for treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the following criteria:

- Patients with neurological symptoms and > 50% stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and > 80% stenosis of the common or internal carotid artery by ultrasound or angiogram.
- Patients must have a vessel diameter of 4-9mm at the target lesion. The vessel distal to the target lesion must be within the range of 3mm and 7.5mm to allow for placement of the ANGIOGUARD® RX Guidewire System.

Contraindications
- Patients in whom antiplatelet and or anticoagulation therapy is contraindicated.
- Patients in whom the guide catheter is unable to be placed.
- Patients with uncorrected bleeding disorders.
- Patients with known allergies to nitinol.
- Lesions in the ostium of the common carotid artery.

Warnings
- Only physicians who have received appropriate training for carotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
- The safety and efficacy of the PRECISE® Stent System have not been demonstrated with embolic protection systems other than the ANGIOGUARD® RX Guidewire System.
- The long-term performance (>3 years) of carotid stents has not yet been established.
- As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
- The stent may cause a thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
- Appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure.
- In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.
- Safety and effectiveness of the Cordis PRECISE PRO RX® Carotid Stent System has NOT yet been established in patients with the characteristics noted below:

Lesion Characteristics
- Patients with evidence of intraluminal thrombus thought to increase the risk of plaque fragmentation and distal embolization.
- Patients whose lesion(s) may require more than two stents.
- Patients with total occlusion of the target vessel.
- Patients with lesions of the ostium of the common carotid.
- Patients with highly calcified lesions resistant to PTA.
- Concurrent treatment of bilateral lesions.

Patient Characteristics
- Patients at low-to-moderate risk for adverse events from carotid endarterectomy.
- Patients experiencing acute ischemic neurologic stroke or who experienced a stroke within 48 hours.
- Patients with an intracranial mass lesion (i.e., abscess, tumor, or infection) or aneurysm (>9mm).

- Patients with arterio-venous malformations in the territory of the target carotid artery.
- Patients with coagulopathies.
- Patients with poor renal function, who, in the physician's opinion, may be at high risk for a reaction to contrast medium.
- Patients with perforated vessels evidenced by extravasation of contrast media.
- Patients with aneurysmal dilation immediately proximal or distal to the lesion.
- Pregnant patients or patients under the age of 18.

Access Characteristics

- Patients with known peripheral vascular, supra-aortic or internal carotid artery tortuosity that would preclude the use of catheter-based techniques.
- Patients in whom femoral or brachial access is not possible.
- Risk of distal embolization may be higher if the Cordis PRECISE PRO RX® Carotid Stent System device cannot be used in conjunction with the ANGIOGUARD® RX Guidewire System during the carotid stenting procedure.
- The black dotted pattern on the gray temperature exposure indicator found on the pouch must be clearly visible. Do not use if entire circle is completely black as the preprogrammed stent diameter may have been compromised.
- Do not use the device if there are abnormalities in the sterile barrier (e.g. broken seal, torn or breached barrier) or product.
- Do not reuse.
- Do not use with Ethiodol™ or Lipiodol™ contrast media, which may adversely affect the stent delivery system.
- Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and/or function of the device may be impaired.
- The stent is not designed for dragging or repositioning.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
- As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudo aneurysm or rupture.

Precautions

- Venous access should be available during carotid stenting in order to manage bradycardia and/or hypotension by pharma ceutical intervention or placement of a temporary pacemaker.
- Catheters in the body should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
- The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance.
- If resistance is met during delivery system introduction, the system should be withdrawn and another system used.
- Prior to stent deployment, remove all slack from the catheter delivery system.
- When treating multiple lesions, the distal lesion should be initially stented, followed by the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent, reducing the chance for dislodging stents that have already been placed.
- Overlap of sequential stents is necessary, but the amount of overlap should be kept to a minimum (approximately 5mm). In no instance should more than 2 stents overlap.
- Recrossing a deployed stent with adjunct devices must be performed with caution.
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- Fractures of this stent may occur. Fractures may also occur with the use of multiple overlapping stents. In the PRECISE Stent, they have been reported most often in clinical uses for which the safety and effectiveness have not been established. The causes and clinical implications of stent fractures are not well characterized. Care should also be taken when deploying the stent as excessive force could, in rare instances, lead to stent deformation and/or fracture.
- The Cordis PRECISE Stent was evaluated through bench testing and has been shown to be MR safe at field strengths of 1.5 Tesla or less, with a maximum spatial gradient of 3 T/m, gradient magnetic fields of 33 mT/m or less, a temporal magnetic field gradient (dB/dt) of 80 T/m/s, and a maximum whole body averaged specific absorption rate (SAR) of 1.33 W/kg for 16:40:00 min of MR imaging. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the PRECISE Stent. The PRECISE Stent has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.

Potential Adverse Events
Possible adverse events include, but are not limited to:

- Air embolism
- Allergic/anaphylactoid reaction
- Aneurysm
- Angina/coronary ischemia
- Arrhythmia (including bradycardia possibly requiring need for a temporary or
- permanent pacemaker)
- Arterial occlusion/vessel restenosis
- Arterial occlusion/thrombus at and remote from puncture site
- Arteriovenous fistula
- Bacteremia or septicemia
- Cerebral edema
- Damage to emboli capture device
- Death
- Embolization (stent or arterial)
- Emergent repeat hospital intervention

PRECISE® Transhepatic Biliary Stent

Indications
The Cordis PRECISE Nitinol Stent Transhepatic Biliary System is indicated for palliation of malignant neoplasms in the biliary tree.

Contraindications
Contraindications associated with the use of transhepatic biliary endoprostheses include:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis
- Patients with bleeding disorders
- Severe ascites

Warnings
- The safety and effectiveness of this device for use in the vascular system have not been established.
- Persons with allergic reactions to nickel titanium (nitinol) may suffer an allergic response to this implant.
- The Cordis PRECISE Nitinol Stent Transhepatic Biliary System is intended for single use only. DO NOT resterilize and/or reuse the device.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- The black dotted pattern on the grey temperature exposure indicator, found on the pouch, must be clearly visible. Do not use if entire temperature exposure indicator is completely black as the unconstrained stent diameter may have been compromised.
- Do not use if the pouch is opened or damaged.
- Use the stent system prior to the "Use By" date specified on the package.
- Do not use with Ethiodol™ or Lipiodol™ contrast media.
- Do not expose the delivery system to organic solvents (e.g. alcohol).
- The stent is not designed for repositioning or recapturing.
- Stenting across a major bile duct branch could lead to compromised future diagnostic or therapeutic procedures.
- Any secondary expansion of the biliary stent should be performed with a device indicated for biliary stent placement.

Precautions
- The device is intended for use by physicians who have received appropriate training.
- The delivery system is not designed for use with power injection systems.
- When catheters are in the body, they should be manipulated only under fluoroscopy.
- Radiographic equipment that provides high quality images is needed.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- The PRECISE Nitinol Stent Transhepatic Biliary System is shipped with the Tuohy Borst valve in the OPEN position (see "Preparation of the Stent Delivery System") on the 5.5F stent delivery system only.
- Prior to stent deployment remove all slack from the catheter delivery system (see "Stent Deployment").
- Fractures of this stent may occur. Fractures may also occur with the use of multiple overlapping stents. In the PRECISE stent, they have been reported most often in clinical uses for which the safety and effectiveness have not been established. The causes and clinical implications of stent fractures are not well characterized. Care should also be taken when deploying the stent as excessive force could, in rare instances, lead to stent deformation and/or fracture.
- Store in a cool, dark, dry place.

Potential Complications
Potential complications associated with the use of transhepatic biliary endoprostheses may include, but are not limited to:

- Sepsis/infection
- Stent misplacement
- Stent migration

- Stent obstruction secondary to tumor ingrowth through the stent
- Tumor overgrowth at the stent ends
- Sludge occlusion
- Pancreatitis
- Bile duct perforation
- Parenchymal hemorrhage
- Liver abscess

S.M.A.R.T.® Flex Biliary Stent

Indication
The S.M.A.R.T.® Flex Biliary Stent System is indicated for use in the palliation of malignant strictures in the biliary tree.

Contraindications
- Stent of a duct with total biliary occlusion which cannot be crossed by the delivery catheter
- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis
- Patients with bleeding disorders
- Severe ascites

General Warnings / Precautions
- The safety and effectiveness of this device for use in the vascular system have not been established .
- Store at ambient room conditions out of direct sunlight.
- The device is provided STERILE and is intended for single use only. Do Not Resterilize the device and / or reuse the device. Do not autoclave.
- Do not use beyond the "Use By" date.
- Carefully inspect the sterile packaging and device prior to use. Do not use if it appears damaged.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to the stent or lumen.
- If resistance occurs during movement through the sheath, carefully withdraw the stent system.
- Do not expose the delivery system to organic solvents.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to the stent or lumen.
- If resistance occurs during movement through the sheath, carefully withdraw the stent system.
- If resistance is felt when initially retracting the outer deployment sheath, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- Persons allergic to nitinol (nickel titanium) may suffer an allergic reaction to this implant.
- This product should only be used by physicians trained and experienced in diagnostic and interventional techniques.
- Standard techniques for interventional procedures should be employed.
- Do not use power injection systems with the delivery system.
- Use in patients with a history of contrast sensitivity is not recommended unless the patient can be adequately premedicated.
- The system is not designed for stent repositioning or recapturing.
- Use caution when crossing a deployed stent with any adjunct device.

Potential Adverse Events
Potential hazards and side effects include, but are not limited to:

- Infection secondary to contamination of the stent may lead to cholangitis, hemobilia, peritonitis, or abscess.
- Pancreatitis.
- Overstretching of the duct may result in rupture leading to infection or death.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- Drug reaction to contrast media.
- Tumor overgrowth at the stent ends.
- Intervention due to: stent migration, unintentional placement of stent, partial stent deployment, or stretched and/or damaged stents.

S.M.A.R.T.® Vascular Stent System, S.M.A.R.T. CONTROL® Vascular Stent System

Indications
The Cordis S.M.A.R.T. CONTROL® / S.M.A.R.T.® Vascular Stent System is indicated for use to improve luminal diameter in the treatment of patients with de novo or restenotic native lesion(s) of the superficial femoral artery and/or proximal popliteal artery with total length up to 150mm and with a reference vessel diameter ranging from 4mm to 7mm.

Contraindications
- Patients with a known hypersensitivity to nickel titanium
- Patients who cannot receive antiplatelet or anticoagulation therapy.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

Warnings

- It is not recommended that stents be used in patients with a history of contrast media allergy/intolerance not amenable to pretreatment with steroids and/or antihistamines.
- Safety and effectiveness has not been demonstrated in patients with:
  - Lesions that are either totally or densely calcified
  - Patients with uncontrollable hypercoagulability and/or other coagulopathy
  - Patients with confirmed pregnancy
  - Pediatric patients
- Caution should be taken when stenting patients with poor renal function who, in the physician's opinion, may experience further deterioration of renal function.
- It is important to use the correct stent size, as recommended in the Stent Size Selection Table (Table 2 provided in Section X –Instructions for Use). The stent may cause a thrombus or distal embolization, or it may migrate from the site of an implant down the arterial lumen.
- The device should only be used by physicians who are trained in such interventional techniques as percutaneous transluminal angioplasty and placement of intravascular stents.
- When catheters are in the body, they should be manipulated only under fluoroscopy.
- Failure to pre-dilate the lesion may impair the ability to remove the stent system after stent deployment.
- Before insertion of the primary dilatation catheter, the appropriate antiplatelet and anticoagulant therapy should be administered.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different metals in tandem where overlap or contact is possible, with an exception of stents made of 316L stainless steel which are compatible with stents made of nickel titanium alloy.
- The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- Do not use the delivery system with a power injection system.

Stent Storage and Preparation

- The Cordis S.M.A.R.T. CONTROL® / S.M.A.R.T.® Vascular Stent System is designed and intended for single use only. DO NOT re-sterilize and/or reuse the device.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information, all of which present a potential risk to patient safety.
- Store in a cool, dark, dry place.
- Do not use if the entire temperature exposure indicator is completely black as the unconstrained stent diameter may have been compromised. The black dotted pattern on the gray temperature exposure indicator found on the pouch must be clearly visible.
- Do not use if the pouch is opened or damaged. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- Use the stent system prior to the "Use By" date specified on the package.

Stent Handling

- Do not use if the stent is partially deployed upon removal from the package, or before starting the deployment procedure.
- Avoid contaminating the stent. As with any type of vascular implant, infection, secondary to contamination of the stent, may lead to thrombosis or pseudoaneurysm.
- Do not use with Ethiodol or Lipiodol1 contrast media to avoid possible damage to the stent delivery system components.
- Do not expose the delivery system to organic solvents (e.g. alcohol).

Stent Placement

- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to stent or vessel. Carefully withdraw the stent system without deploying the stent.
- If resistance is felt when beginning deployment, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- The stent is not designed to be lengthened or shortened past its nominal length. Excessive stent lengthening or shortening may increase the risk of stent fracture.
- Do not attempt to drag or reposition the stent, as this may result in unintentional stent deployment.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system. Do not attempt to recapture the stent once the stent is partially deployed.
- Avoid stent placement that may obstruct access to a vital side branch.
- Overstretching of the artery may result in rupture and life threatening bleeding. Do not overstretch the stent.
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- When treating multiple lesions, the most distal lesion should be stented first followed by the stenting of proximal lesions. Stenting in this order eliminates the need to cross and reduces the chance of dislodging

stents which have already been placed. Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum.

Stent/System Removal
- In the event of complications such as infections, pseudoaneurysm or fistulization, surgical removal of the stent may be required. Standard surgical procedure is appropriate.

Post Implant
- Re-crossing a stent with adjunct devices must be performed with caution to avoid stent damage or migration.
- In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
- Antiplatelet therapy should be maintained for at least three months post-procedure.

Complications
The following complications may be associated with intravascular stent implantation:

- Abrupt closure
- Access failure
- Allergic / anaphylactoid reaction to anticoagulant and/or antithrombotic therapy or contrast medium
- Allergic reaction to nitinol
- Amputation
- Anemia
- Aneurysm
- Angina / coronary ischemia / myocardial infarction
- Arrhythmia
- Arterial occlusion / thrombus
- Arterial restenosis
- Arterial spasm
- Arterial stenosis, or dissection
- Arteriosclerosis
- Arteriovenous fistula
- Blue toe syndrome
- Bradycardia
- Worsened claudication or rest pain
- Death
- Disseminated intravascular coagulation
- Edema, peripheral
- Embolism
- Emergent repeat hospital intervention
- Encephalopathy (new or worse)
- Fever
- Fistulization
- Gangrene
- Gastrointestinal bleed from anticoagulation/antiplatelet medication
- Hematoma/hemorrhage
- Hypotension / hypertension
- Infection/ abscess at insertion site
- Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- Multi-organ failure
- Muscle hemorrhage
- Pain
- Pseudoaneurysm
- Renal failure
- Respiratory arrest
- Septicemia / bacteremia (sepsis)
- Stent embolization
- Stent migration
- Stent occlusion
- Tissue necrosis
- Trauma to adjacent structures
- Stroke /TIA (hemorrhagic/embolic)

SABER® PTA Dilatation Catheter

Indications
The SABER® PTA Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
The device is also indicated for post-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Contraindications
- None known for PTA procedure.
- The SABER® PTA Balloon Dilatation Catheter is contraindicated for use in coronary arteries.

Warnings
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may increase the risk of inappropriate resterilization and cross contamination and compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death.
- Exposure to temperatures above 54°C (130°F) may damage the device.
- Do not expose the device to organic solvents (e.g. alcohol).
- Do not use Ethiodol™ or Lipiodol™ contrast media.
- Store in a cool, dark, dry place.
- Use the catheter prior to the "Use By" date specified on the package.
- Do not use if inner package is opened or damaged.
- Prior to angioplasty, the catheter should be examined to verify functionality and integrity, and ensure that its size and shape are suitable for the specific procedure

for which it is to be used. Do not use if product damage is suspected or evident.
- To reduce the potential for vessel damage or the risk of dislodgement of particles it is very important that the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the lesion. The balloon dimensions are printed on the product label. The compliance table incorporated with the product shows how balloon diameter increases as pressure increases.
- Do not exceed the rated burst pressure recommended on the label. The rated burst pressure is based on the results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent overpressurization
- Pressure in excess of the rated burst pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath. Balloon rupture can cause vessel damage and the need for additional intervention.
- Use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.
- 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.
- 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. Forceful handling can result in catheter separation and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces.
- Always verify integrity of the catheter after removal.

SAVVY® Long PTA Dilatation Catheter

Indications
The SAVVY® Long Percutaneous Transluminal Angioplasty (PTA) Peripheral Catheter family is intended for balloon dilatation of the femoral, popliteal and infra-popliteal arteries.

Contraindications
- Contraindicated for use in coronary arteries.

Warnings
- For single use only. DO NOT resterilize and/or reuse.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Caution
- Do not exceed the rated burst pressure. A syringe with pressure gauge is recommended to monitor pressure. Pressure in excess of the rated burst pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
- In PTA, the dilated balloon should not markedly exceed the diameter of the vessel lying just proximal to the stenosis.
- Use only an 20ml or larger syringe for inflation.
- Do not advance the guidewire, balloon dilatation catheter, or any 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.

Precautions
- Dilation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- For use only by appropriately trained physicians.
- Careful attention must be paid to the maintenance of tight catheter connections to avoid the introduction of air into the system.
- 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 gently twisting motion combined with traction.
- Before removing catheter from 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

Adverse Events
Possible adverse events include, but are not limited to:

- Vessel perforation
- Vessel spasm
- Haemorrhage
- Haematoma
- Hypotension
- Pain and tenderness
- Arrhythmias
- Sepsis/infection
- Systemic embolization
- Endocarditis
- Short-term hemodynamic deterioration
- Death
- Vascular thrombosis
- Drug reactions, allergic reaction to contrast media
- Pyrogenic reaction
- Arteriovenous fistula
- Thromboembolic episodes
- Vessel dissection
- Potential balloon separation following rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces

SAVVY® PTA Dilatation Catheter

Indications
The SAVVY® PTA Dilatation Catheter is intended for balloon dilatation of lesions in peripheral arteries (iliac, renal, popliteal, infra-popliteal, femoral and ilio-femoral) and is also intended to treat obstructive lesions of native or syntetic arteriovenous dialysis fistulae.

Contraindications
- None known for PTA procedure.
- Contraindicated for use in coronary arteries.

Warnings
- For single use only. DO NOT resterilize and/or reuse.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be used while under high-quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Precautions
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- For use only by appropriately trained physicians.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or a similar isotonic solution.
- Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.
- Not intended for precise arterial pressure monitoring

Adverse Events
Possible adverse events include, but are not limited to:

- Hemorrhage/hematoma
- Perforation of the vessel wall
- Embolism
- Intimal tear
- Arteriovenous fistula
- Total occlusion
- Pseudoaneurysm formation
- Restenosis of the dilated artery
- Thrombus

SLALOM® PTA Dilatation Catheter

Indications
The Cordis SLALOM® PTA Dilatation Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications
- None known for PTA procedure.
- The SLALOM® Catheter is contraindicated for use in coronary arteries.

Warnings
- For single use only. DO NOT resterilize and/or reuse.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be used while under high-quality fluoroscopic observation.

- Do not advance or retract the catheter unless the balloon is fully deflated.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon

Precautions
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- For use only by appropriately trained physicians.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or a similar isotonic solution.
- Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label.
- Not intended for precise arterial pressure monitoring

Adverse Events
Possible adverse events include, but are not limited to:

- Air embolism
- Aneurysm
- Hematoma at the puncture site
- Perforation of the heart or vessel wall

SLEEK® OTW PTA Dilatation Catheter

Indications
The SLEEK® OTW catheters are intended for balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Warnings
- Contents supplied STERILE using ethylene oxide (EO). Non-pyrogenic. Do not reuse, reprocess or resterilize.
- Reuse, resterilization, reprocessing and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.
- Visually inspect the packaging to verify that the sterile barrier is intact. Do not use if the sterile barrier is opened or damaged.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- Do not exceed the rated burst pressure. A syringe with pressure gauge is recommended to monitor pressure. Pressure in excess of the rated burst pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
- Use a 20 ml or larger syringe for inflation.
- Use the catheter prior to the "Use By" date specified on the package.
- Do not advance the guidewire, balloon dilation catheter, or any 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.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.

Precautions
- Dilation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Carefully inspect the catheter prior to use to verify that the catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident.
- Careful attention must be paid to the maintenance of tight catheter connections to avoid the introduction of air into the system. If resistance is felt upon removal, then the balloon, guidewire and the sheath/guide catheter 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/guide

catheter as a unit and withdrawing both together, using a gently twisting motion combined with traction.
- Before removing catheter from sheath/guide catheter 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.
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Adverse Events
Possible adverse effects include, but are not limited to, the following:

- Vessel perforation
- Vessel spasm
- Haemorrhage
- Haematoma
- Hypotension
- Pain and tenderness
- Arrhythmias
- Sepsis/infection
- Systemic embolization
- Endocarditis

SLEEK® RX PTA Dilatation Catheter

Indications
The Sleek® PTA Rx Balloon Dilatation Catheter is intended for balloon dilatation of the femoral, popliteal and infra popliteal arteries.

Contraindications
Contraindicated for use in coronary arteries.

Warnings
- For single use only. DO NOT resterilize and/or reuse.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Caution
- Do not exceed the rated burst pressure. A syringe with pressure gauge is recommended to monitor pressure. Pressure in excess of the rated burst pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
- In PTA, the dilated balloon should not markedly exceed the diameter of the vessel lying just proximal to the stenosis.
- Use only an endoflator or 20ml syringe for inflation.
- Do not advance the guidewire, balloon dilatation catheter, or any 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.

Precautions
- Dilation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- For use only by appropriately trained physicians
- Careful attention must be paid to the maintenance of tight catheter connections to avoid the introduction of air into the system.
- 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 gently twisting motion combined with traction.
- Before removing catheter from 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

ADVERSE EVENTS
Possible adverse events include, but are not limited to:

- Vessel perforation
- Vessel spasm
- Heamorrhage
- Heamatoma
- Hypotension
- Pain and tenderness
- Arrhythmias
- Sepsis/infection
- Systemic embolization
- Endocarditis
- Short-term hemodynamic deterioration
- Death
- Vascular thrombosis
- Drug reactions, allergic reaction to contrast media
- Pyrogenic reaction
- Arteriovenous fistula
- Thromboembolic episodes
- Vessel dissection
- Potential balloon separation following rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces

STORQ® Steerable Guidewire

The STORQ® Steerable Guidewire has been designed to provide torque response and steerable control. The distal tip of the guidewire is shapeable and radiopaque.

Indications
Cordis Steerable Guidewires are intended to be used in angiographic procedures to introduce and position catheters within the vasculature.

Contraindications
None known.

Warnings
Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. All parts are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Accordingly, Cordis Corporation will not be responsible for any direct, incidental or consequential damages resulting from reuse of the product.

Precautions
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" date.
- Do not expose to organic solvents.
- Do not resterilize. Exposure to temperatures above 54ºC (130ºF) may damage the components.
- Do not withdraw a PTFE* coated guidewire through a metal-cannula needle. Withdrawal may damage the guidewire coating.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter and guidewire.

Complications
Procedures requiring percutaneous catheter/guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to:

- Air embolism
- Hematoma at the puncture site
- Infection
- Perforation of the vessel wall

SUPER TORQUE® Diagnostic Catheter, SUPER TORQUE® Plus Diagnostic Catheter

Indications
Cordis Angiographic Catheters with Marker Bands are designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.

Contraindications
None known.

Warnings
- Failure to observe these instructions may result in damage, breakage or separation of the catheter or the markerbands, which may necessitate additional intervention.
- Manipulation of the catheter under excessive friction due to interaction with other devices or while trapped in the vasculature, can lead to stretching or elongation of the catheter.
- Stretching or elongation of the catheter during endovascular procedures could result in the marker bands moving along the catheter. In extreme cases, marker bands may come off the catheter and dislodge into the vascular system.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose to organic solvents.
- Do not exceed maximum pressure rating printed on label and hub.

Precautions
- Avoid entrapment of the catheter between other endovascular devices and the vessel wall.
- Avoid excessive friction on the catheter; avoid simultaneous introduction of the catheter and aortic graft devices through the same sheath.
- Store in cool, dark, dry place.
- Do not use if the package is open or damaged.
- Do not use the catheter if the "Use By" date on the package label has expired.
- Do not resterilize.
- Exposure to temperatures above 54°C (130°F) may damage the catheter.

Complications
Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure. Possible complications include, but are not limited to, the following: air embolism, hematoma at the puncture site, infection, thrombosis, hemorrhage, dissection, perforation or other damage of the vessel wall. Movement of the marker bands along the catheter can result in inaccurate reference and device sizing. Dislodgement of the marker bands into the vascular system can result in additional intervention, embolism, thrombosis or other vascular complications.

TRAPEASE® Permanent Vena Cava Filter

Indications
The TRAPEASE® Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy in thromboembolic diseases.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the vena cava.

Contraindications
The TRAPEASE® Filter should not be implanted in:

- Patients with risk of septic embolism.
- Patients with uncontrolled infectious disease.
- Patients with an IVC diameter larger than 30mm.
- Patients contraindicated for procedures under fluoroscopy
- Patients with demonstrated hypersensitivity to one of the components of the TRAPEASE® Filter.

There are no known contraindications for use of the Angiographic Vessel Dilator.

Warnings
- Risk of re-use. This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use. Reuse of this product, including after reprocessing and/ or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- When injecting contrast medium through the Angiographic Vessel Dilator, do not exceed the maximum pressure rating of 800 psi. Ensure that a high-pressure connection line is used.
- After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded.
- The TRAPEASE® Filter is supplied constrained in a plastic storage tube. Never reload a (partially) ejected filter into the tube as this could affect its shape and function. Accordingly, Cordis will not be responsible for any direct, incidental or consequential damages resulting from replacement of the TRAPEASE® Filter in the plastic storage tube.
- Filter fracture is a potential complication of vena cava filters. Anatomic locations that create concentrated stress points from filter deformation (for example, deployment at apex of scoliosis, overlapping of either of the renal ostia, or placement adjacent to a vertebral osteophyte) may contribute to fracture of a particular filter strut. However, reports of adverse clinical sequelae from filter fractures are rare.
- The TRAPEASE® Filter should only be used by physicians who are trained in diagnostic and percutaneous interventional techniques, for instance placement of vena cava filters. Accordingly, Cordis will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.

Precautions
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged
- Usepriorto"UseBy"date.
- Do not resterilize by any other method. Do not expose to temperatures above 54°C (130°F) for any length of time.
- Do not expose to organic solvents.
- The TRAPEASE® Filter has been tested and qualified with the accompanying accessories. The use of any other accessory could result in complications and/or an unsuccessful procedure.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding.

- The TRAPEASE® Filter has been shown to be MRI safe at field strengths of 3.0 Tesla or less, a maximum gradient of 5 T/m, and a maximum whole body averaged specific absorption rate (SAR) of 4 W/Kg for 15 minutes of MRI through non-clinical testing. The TRAPEASE® Filter should not migrate in this MRI environment. MRI at 3 Tesla or less may be performed immediately following the implantation of the filter. Non-clinical testing has not been performed to rule out the possibility of filter migration at field strengths higher than 3 Tesla. In testing, filters produced a temperature rise of less than 1.8°C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/ Kg for 15 minutes of MRI. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the filter.

Complications
Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during the procedure.

Possible procedure complications include, but are not limited to, the following:

- air embolism
- hematoma at the puncture site
- incorrect positioning of the filter
- perforation of the vessel wall
- restriction of blood flow
- occlusion of small vessel
- distal embolization
- infection
- intimal tear
- filter fracture
- thrombus formation.

VISTA BRITE TIP® Guiding Catheter, VISTA BRITE TIP® IG Guiding Catheter

Indications
The guiding catheter is intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

Contraindications
None known for guiding catheters.

Warnings
Risk of reuse: This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.

Do not use with Ethiodol™ or Lipiodol™ contrast media, or other such contrast media which incorporates the components of these agents.

Precautions
- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the "Use By" date.
- Do not resterilize.
- Do not expose to organic solvents.
- Inspect the guiding catheter before use to verify that its size, shape and condition are suitable for the specific procedure.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause of the resistance before proceeding. If the cause of the resistance can not be determined, withdraw the catheter.
- Torquing the guiding catheter excessively while kinked may cause damage which could result in possible separation along the catheter shaft. Should the guiding catheter shaft become severely kinked, withdraw the entire system (guiding catheter, guidewire and catheter sheath introducer).
- Advancement, manipulation and withdrawal of the guiding catheter should always be performed under fluoroscopic guidance.
- Extreme care must be taken to avoid damage to the vasculature through which the guiding catheter passes. The guiding catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.
- Large internal lumen guiding catheters require less force on the syringe during injection.

Complications
Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during or after the procedure.

Possible complications include, but are not limited to the following:

- air embolism
- hematoma at the puncture site
- infection
- perforation of the heart
- vessel damage, dissection or perforation
- vasospasm
- ischemia
- hemorrhage
- arrhythmia
- reaction to contrast media
- death

U.S. Headquarters

5452 Betsy Ross Dr
Santa Clara, CA 95054

Customer Service Center

Phone: 1.800.327.7714 (toll-free, continental U.S.)
Fax: 800.997.1122

Attn: Customer Contact Center
14201 Northwest 60th Ave
Miami Lakes, FL 33014

Technical Information

1.800.327.7714 (toll-free, continental US)

All orders should be directed to the Customer Service Center by fax, EDI, or telephone. The Customer Service Center is open weekdays (excluding US national holidays) between the hours of 7:30 AM and 9:00 PM EST/EDT. Emergency order service is also available 24 hours a day.

Terms

Net 30 days. Normal delivery second day A.R.O., F.O.B. shipping point with freight prepaid. Standing order shipments are F.O.B. shipping point with freight prepaid. Prices are subject to change without notice.

Disclaimer of warranty and limitation of remedy

There is no express or implied warranty, including any implied warranty of merchantability of fitness for a particular purpose, including the products described in this publication. Under no circumstances shall Cordis be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind Cordis to any representation or warranty except as specifically set forth herein.

Standing Purchase Orders

Cordis encourages standing purchase orders. Standing purchase orders are agreements to purchase specific quantities of product for delivery on a specific, predetermined schedule. To establish a standing purchase order, telephone the Customer Contact Center at 1.800.327.7714 option 1, or contact your local Cordis Sales Representative.

Intended Product Usage/Storage

- **Usage:** Most products in this catalog are supplied sterile and nonpyrogenic. Do not use any products if their sterile package is damaged. Discard catheters and single-use accessories after one procedure. All parts are extremely difficult to clean. DO NOT REUSE OR RESHAPE. DO NOT AUTOCLAVE SINGLE-USE PRODUCTS. Structural integrity and/or function may be impaired through reuse, reshaping, and cleaning. ACCORDINGLY, CORDIS CORPORATION WILL NOT BE RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM REUSE OF CATHETERS AND ACCESSORIES. Prior to use, refer to the instructions accompanying the product.
- **Storage:** Store products in a cool, dark, dry place. Use sterile products prior to the "Use By" date. Do not expose to organic solvents.
- **Caution:** Federal (USA) law restricts these devices to sale by or on the order of a physician.

Return Policy

Products on consignment are not returnable for credit under this policy. To return any product on consignment, you must contact your local Sales Representative for instructions.

Return Authorization

To return other Cordis products you must contact the Customer Service Center at 1.800.327.7714 option 2 or your local sales representative for a return goods authorization. You must also provide information about the acquisition method (e.g. purchase, consignment, or evaluation) for the product being returned.

Credits

Full Credit of the invoice price will be issued on products returned within 180 days from the date of invoice. Full Credit of the invoice price, less a 10% restocking charge, will be issued on products returned later than 180 days from the date of invoice with the exception of EXOSEAL® Vascular Closure Device.

Partial credit will be issued for product returned in quantities less than the full 10 pack for EXOSEAL® Vascular Closure Device when returned within 365 days.

Credit will not be issued for products returned greater than 365 days from the date of invoice. Additionally, credit will not be issued for product meeting the following conditions:

- Discontinued from sale
- Modified products ("Specials")
- Packaging is opened
- Modified product/trays
- Modified instruments
- Damaged
- Used
- Less than full shipping unit
- Stickers, markings, or any changes made to blister package or packaging in general

Return Logistics

All products should be returned with freight prepaid by the customer within five (5) business days of receiving Return Authorization approval. All returned products must be accompanied with the Return Authorization Confirmation in its proper protective packaging along with the Return Authorization Number written on the packaging and sent to:

Cordis Returned Goods
8640 Nail Road, Suite 115
Olive Branch, MS 38654

All returns due to Cordis should use the merchandise pick-up process. Contact Customer Service at 1.800.327.7714 option 1, and they will have our Transportation Department arrange for the carrier to pick up the order error for return.

Product Complaints

This policy does not address product complaints. All product complaints should be handled by calling Customer Service at 1.800.327.7714.

Trademarks

CORDIS, the Cordis LOGO, and the trademarks listed below are trademarks of Cardinal Health and may be registered in the US and/or in other countries.. All other marks are the property of their respective owners. The MYNX ACE® Vascular Closure Device and the MYNXGRIP® Vascular Closure Device are manufactured by Cardinal Health and are part of the Cordis portfolio.

- CORDIS
- The Cordis LOGO
- ANGIOGUARD® RX Emboli Capture Guidewire System
- AQUATRACK® Hydrophilic Guidewire
- AQUATRACK® Hydrophilic Nitinol Guidewire
- ATW™ Marker Wire Steerable Guidewire
- ATW™ Steerable Guidewire
- AVANTI®+ Sheath Introducer
- AVIATOR® PTA Dilatation Catheter
- AVIATOR® Plus PTA Dilatation Catheter
- BRITE TIP® Catheter Sheath Introducer
- ELITECROSS™ Support Catheter
- EMERALD® Diagnostic Guidewire
- EXOSEAL® Vascular Closure Device
- FRONTRUNNER® XP CTO Catheter
- JINDO® Steerable Guidewire
- MAXI LD® PTA Dilatation Catheter
- MYNX CONTROL™ Vascular Closure Device
- MYNXGRIP® Vascular Closure Device
- NYLEX® Diagnostic Catheter
- OPTA® Pro PTA Dilatation Catheter
- OPTEASE® Retrievable Vena Cava Filter
- OUTBACK® Elite Re-Entry Catheter
- PALMAZ BLUE® Transhepatic Biliary Stent
- PALMAZ GENESIS® Transhepatic Biliary Stent
- PALMAZ® Balloon-Expandable Stent
- POWERFLEX® Extreme PTA Dilatation Catheter
- POWERFLEX® P3 PTA Dilatation Catheter
- POWERFLEX® Pro PTA Catheter
- PRECISE PRO RX® Carotid Stent
- PRECISE® OTW Carotid Stent
- PRECISE® Transhepatic Biliary Stent
- S.M.A.R.T.® Control Flex Biliary Stent
- S.M.A.R.T.® Flex Biliary Stent
- S.M.A.R.T.® Vascular Stent System
- SABER® PTA Dilatation Catheter
- SAVVY® Long PTA Dilatation Catheter
- SAVVY® PTA Dilatation Catheter
- SLALOM® PTA Dilatation Catheter
- SLEEK® OTW PTA Dilatation Catheter
- SLEEK® RX PTA Dilatation Catheter
- STABILIZER® Plus Steerable Guidewire
- STABILIZER® XS Steerable Guidewire
- STORQ® Steerable Guidewire
- SUPER TORQUE® Diagnostic Catheter
- SUPER TORQUE® Plus Diagnostic Catheter
- TEMPO AQUA® Diagnostic Catheter
- TEMPO® Diagnostic Catheter
- TRAPEASE® Permanent Vena Cava Filter
- VISTA BRITE TIP® Guiding Catheter
- VISTA BRITE TIP® IG Guiding Catheter

For customer service, call 1.800.327.7714. To learn more, visit cordis.com.
CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.
See package insert for full product information. All claim data is on file at Cordis.

100538299 05/2019