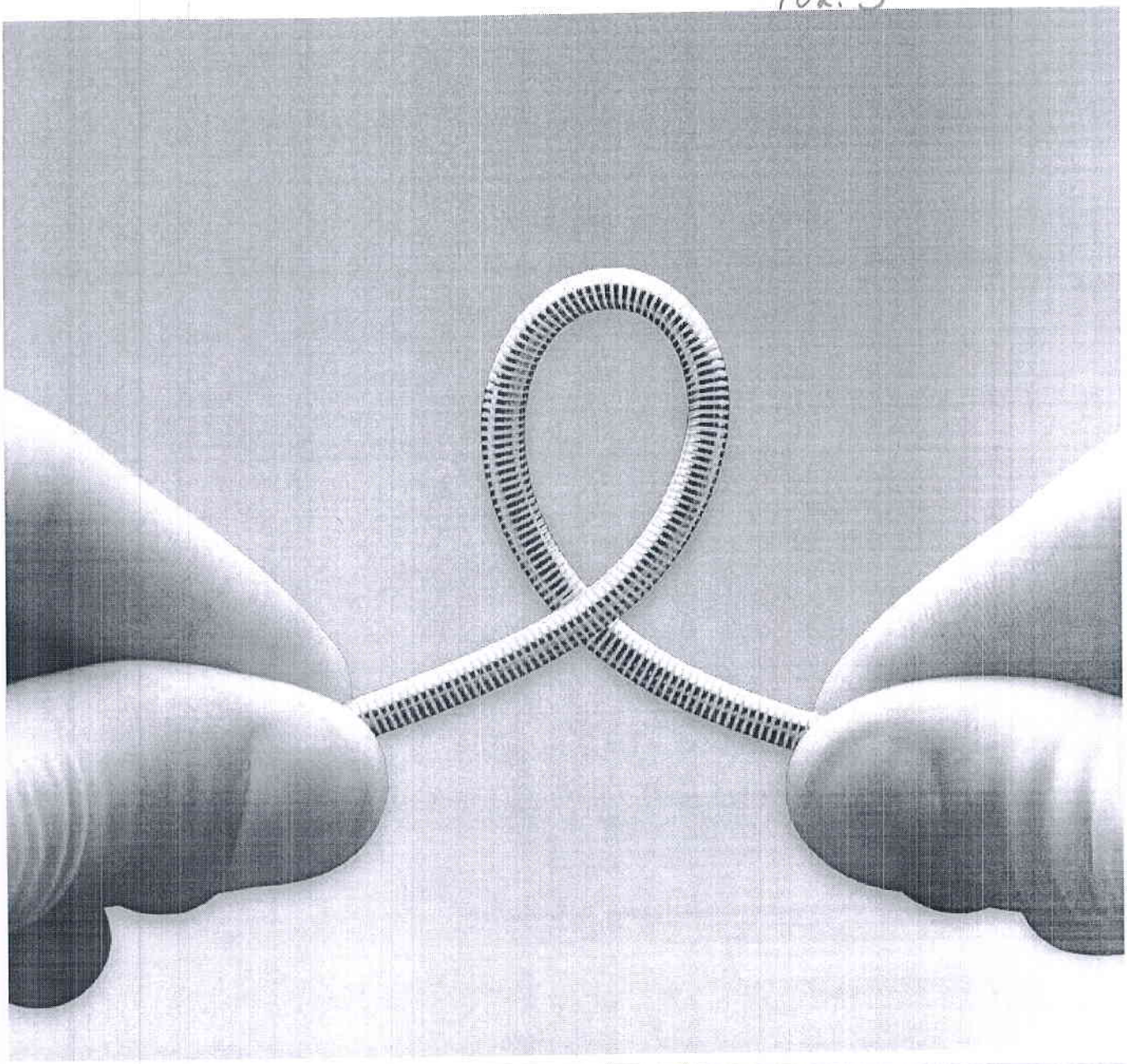
Poz. 3



SUPER ARROW-FLEX® SHEATH INTRODUCER

Flexibility you can see. Strength you can feel.

Teleflex

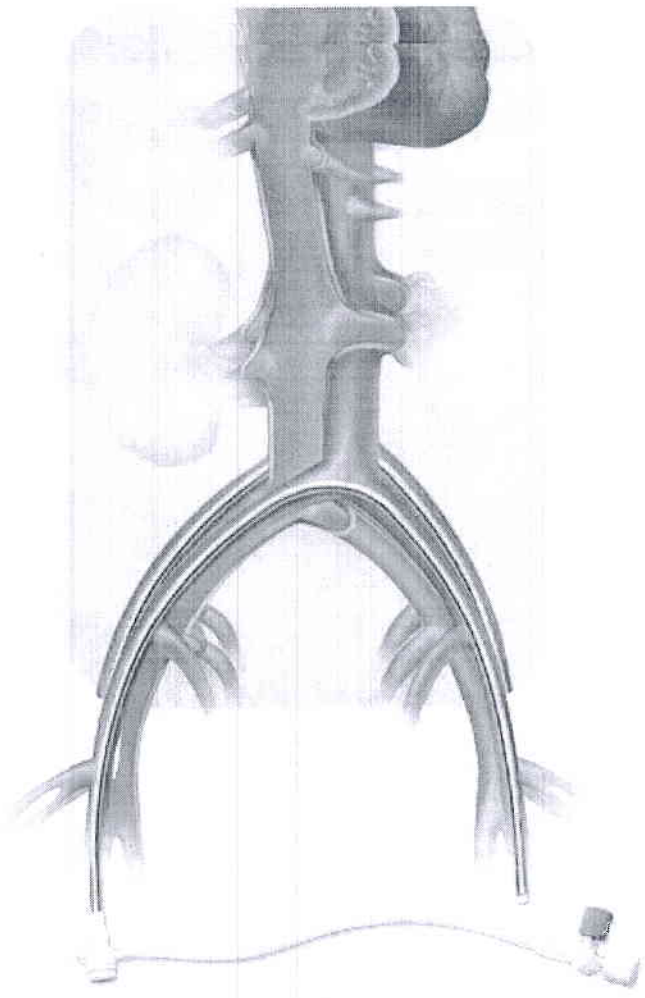
COMPLETE VASCULAR ACCESS WITHOUT KINKING OR COLLAPSING

THE FLEXIBLE, KINK-RESISTANT SUPER ARROW-FLEX SHEATH INTRODUCER

The ARROW brand of Teleflex sheath introducers continues to be the choice of many clinicians who require flexibility in sheath design in many areas of the world. Super Arrow-Flex gives you complete vascular access, thanks to its wire-reinforced design and construction. From easy insertion and handling to the highly visible radiopaque tip*, Super Arrow-Flex is designed to deliver optimal performance from start to finish. And with a wide range of sheath sizes and lengths, Super Arrow-Flex gives you flexibility of choice for multiple vascular applications.

RANGE OF PRODUCTS FOR INTERVENTIONAL PROCEDURES

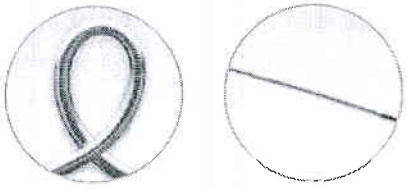
- specific designs suitable for renal, carotid, and transseptal procedures
- wide range of products provides reliable access during crossover, TIPS, and antegrade brachial procedures
- variety of product options from 5 Fr. to 11 Fr. and 7.5 cm to 100 cm
- sheath available with and without guide wire
- colour coded for convenience



*35 cm and longer, except 5 Fr.

MAXIMUM EFFECTIVENESS EVEN IN THE MOST CHALLENGING CASES

- exclusive coil-wire design allows the sheath to flex at any point and in any direction without kinking or losing support
- excellent steerability helps negotiate tortuous anatomies
- tapered dilator provides exceptional pushability to the contralateral leg and the superficial femoral artery (SFA)
- increased patient comfort and reduced back pain post-procedures due to the flexible design[1]



[1] *Waksman et al. Randomized comparison of flexible versus nonflexible femoral sheaths on patient comfort after angioplasty. American Heart Journal. 131:6. 1076-1078.*

SUPER ARROW-FLEX SHEATH INTRODUCER SETS WITH WIRE GUIDES

5-10 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CP-07511-P	5 Fr.	7.5 cm	grey	10
CP-07511	5 Fr.	11 cm	grey	10
CP-07611-P	6 Fr.	7.5 cm	green	10
CP-07611	6 Fr.	11 cm	green	10
CP-07711	7 Fr.	11 cm	orange	10
CP-07811	8 Fr.	11 cm	blue	10
CP-07911	9 Fr.	11 cm	black	10
CP-07011	10 Fr.	11 cm	white	10

EACH "CP" SET INCLUDES:

- Super Arrow-Flex sheath with integral side port/ haemostasis valve and attached 3-way stopcock
- 17 3/4" (45 cm) long dual purpose "J" tip spring-wire guide in holder with tip straightener. Short-length sheath set (P) has .021"-dia. and all others have .035"-dia. wire guide
- vessel dilator with snap-lock feature
- obturator cap

SUPER ARROW-FLEX SHEATH INTRODUCER SETS WITHOUT WIRE GUIDES

5 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-07511	5 Fr.	11 cm		10
CL-07524	5 Fr.	24 cm		5
CL-07545	5 Fr.	45 cm	grey	5
CL-07565	5 Fr.	65 cm		5
CL-07590	5 Fr.	90 cm		2

6 FR. INTRODUCERS

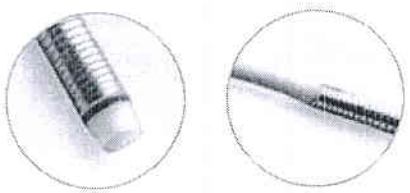
REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-07611	6 Fr.	11 cm		10
CL-07624	6 Fr.	24 cm		5
CL-07635	6 Fr.	35 cm		5
CL-07645	6 Fr.	45 cm	green	5
CR-07645*	6 Fr.	45 cm (renal)		5
CL-07665	6 Fr.	65 cm		5
CL-07690	6 Fr.	90 cm		2

7 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-07711	7 Fr.	11 cm		10
CL-07724	7 Fr.	24 cm		5
CL-07735	7 Fr.	35 cm		5
CL-07745	7 Fr.	45 cm		5
CR-07745*	7 Fr.	45 cm (renal)		5
CR-07745-NT**	7 Fr.	45 cm (renal)	orange	5
CL-07765	7 Fr.	65 cm		5
CL-07780	7 Fr.	80 cm		2
CL-07790-R*	7 Fr.	90 cm (carotid)		2
CL-07700	7 Fr.	100 cm		2

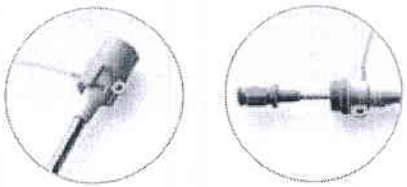
EASY PLACEMENT AND INSERTION

- radiopaque tip marker enhances visualisation during insertion and enables precise deployment of a catheter just beyond the sheath tip
- highly radiopaque sheath, yet spacing between coils enables visualisation
- smooth transition between sheath and dilator helps prevent peel-back
- hydrophilic surface facilitates smooth insertion
- valve lubrication eases catheter placement through the sheath



SAFETY AND PEACE OF MIND

- capability to be used as a guiding sheath may eliminate the need for a guiding catheter (includes obturator cap)
- colour-coded hubs for easy identification of sheath sizes
- tri-cuspid haemostasis valve facilitates catheter manipulation with minimal bleed-back
- sheath and dilator lock together to enable simultaneous and secure insertion



8 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-07811	8 Fr.	11 cm		10
CL-07824	8 Fr.	24 cm		5
CL-07835	8 Fr.	35 cm		5
CL-07845	8 Fr.	45 cm		5
CT-07860	8 Fr.	60 cm (transseptal)	blue	2
CL-07865	8 Fr.	65 cm		5
CL-07880	8 Fr.	80 cm		2
CL-07890-R*/***	8 Fr.	90 cm (carotid)		2
CL-07800	8 Fr.	100 cm		2

9 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-07911	9 Fr.	11 cm		10
CL-07924	9 Fr.	24 cm		5
CL-07965	9 Fr.	65 cm	black	5
CL-07980	9 Fr.	80 cm		2
CL-07900	9 Fr.	100 cm		2

10 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-07011	10 Fr.	11 cm		10
CL-07024	10 Fr.	24 cm		5
CL-07035	10 Fr.	35 cm	white	5
CL-07045	10 Fr.	45 cm		5
CL-07065	10 Fr.	65 cm		5
CL-07080	10 Fr.	80 cm		2

11 FR. INTRODUCERS

REF.	SHEATH SIZE	SHEATH LENGTH	COLOUR CODED HUB	SETS/ CASE
CL-71165	11 Fr.	65 cm		5
CL-71180	11 Fr.	80 cm	yellow	2

EACH "CL" SET INCLUDES:

- Super Arrow-Flex sheath with integral side port/ haemostasis valve and attached 3-way stopcock
- vessel dilator with snap-lock feature
- obturator cap

* *These products include a special Tuohy-Borst "Y" adapter with side arm extension.*

** *Tuohy-Borst "Y" adapter is not included with this product.*

*** *Contact your* ARROW *representative to check availability.*

Teleflex is a leading global provider of specialty medical devices used for diagnostic and therapeutic procedures in critical care, urology and surgery. Our mission is to provide solutions that enable healthcare providers to improve outcomes and enhance patient and provider safety.
We specialise in devices for general and regional anaesthesia, cardiac care, respiratory care, urology, vascular access and surgery and we serve healthcare providers in more than 130 countries. Teleflex also provides specialty products for medical device manufacturers.

Teleflex global operations: Austria, Belgium, Canada, China, Czech Republic, France, Germany, Greece, India, Ireland, Italy, Japan, Malaysia, Mexico, Netherlands, Portugal, Singapore, Slovak Republic, South Africa, Spain, Switzerland, United Kingdom, Uruguay and USA.

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For detailed information see www.teleflex.com

The products in this catalogue may not be available in all countries.
Please contact your local representative. All data current at time of printing (02/2013).
Subject to technical changes without further notice.

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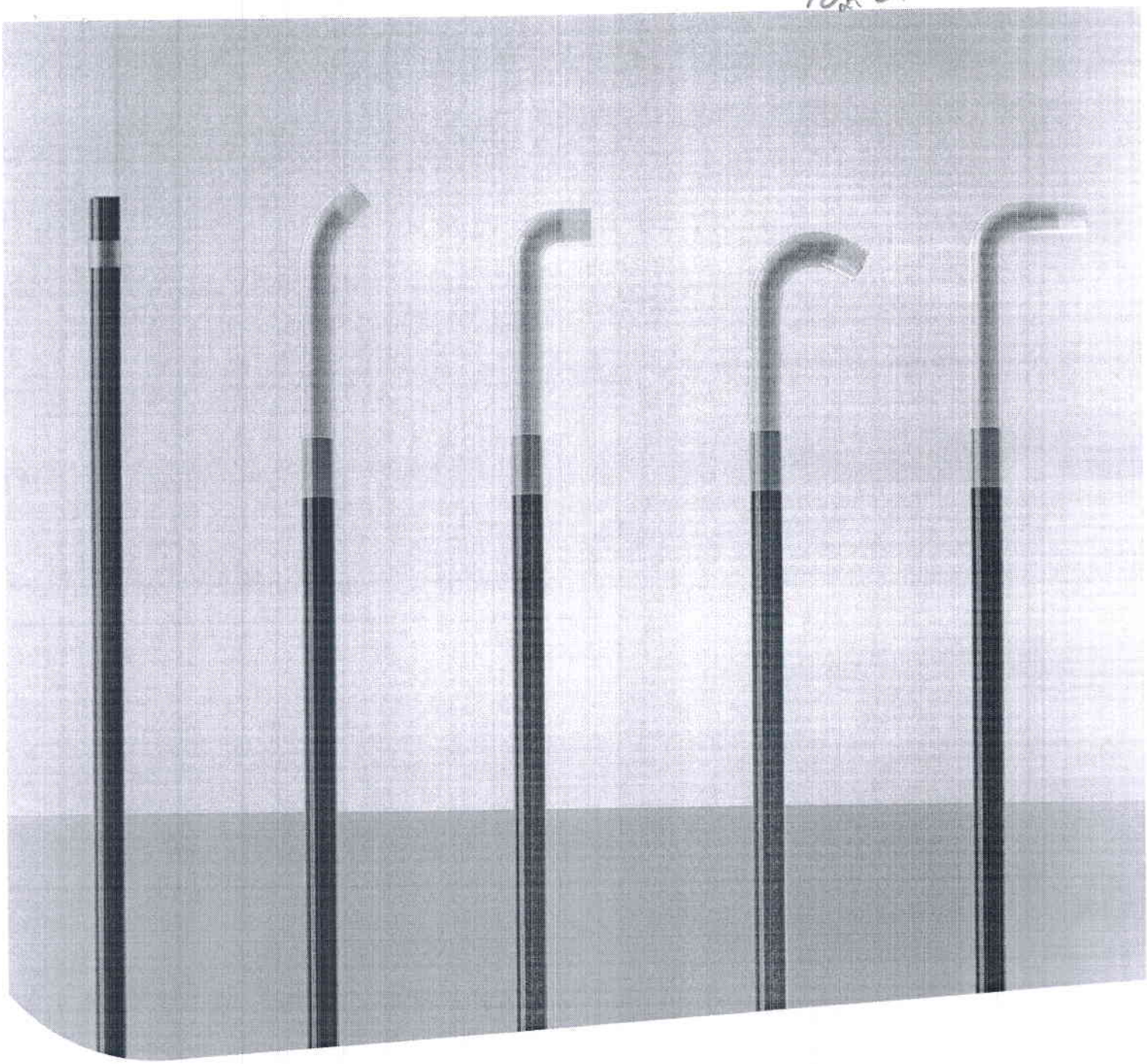
Teleflex

Pox 5.



SuperCross Microcatheters

Superb Crossability in Tortuous Anatomy

Teleflex

Superb Crossability in Challenging Cases

SuperCross Microcatheters provide support in tortuous anatomy and navigating bifurcated vessels.

XT=90° Extended Tip for Secure Cannulation

Angled Tip Catheters

Dual Coil Shaft Construction
Provides excellent torque response, flexibility, pushability and kink resistance

PTFE Inner Layer
Allows for outstanding guidewire movement and delivery

Hydrophilic Coating on the Distal 80 cm
Enables exceptional trackability around tight bends and tortuous anatomy

Embedded Platinum/Tungsten Coil
Provides enhanced visibility along the entire angled tip

Straight | Flexible Tip (FT) Catheters

Stainless Steel Braid
For flexibility, pushability and kink resistance

Straight Tip Version
Stiffer tip for more supportive delivery and increased pushability to access complex anatomy

Flexible Tip (FT) Version
For increased trackability through tortuous anatomy

Ordering Information

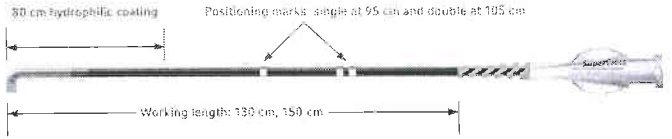
SuperCross Microcatheters

The SuperCross Microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.

MODEL	GUIDEWIRE COMPATIBILITY	DISTAL TIP	WORKING LENGTH	SHAFT CONSTRUCTION	DISTAL O.D.	PROXIMAL O.D.	DISTAL I.D.	PROXIMAL I.D.	HYDROPHILIC COATING
5302	0.014"	45°	130 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5303	0.014"	45°	150 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5304	0.014"	90°	130 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5305	0.014"	90°	150 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5306	0.014"	120°	130 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5307	0.014"	120°	150 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5308	0.014"	90° XT	130 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm
5309	0.014"	90° XT	150 cm	Coiled	2.4 Fr. 0.79 mm / 0.031"	3.2 Fr. 1.07 mm / 0.042"	0.017" (0.43 mm)	0.018" (0.46 mm)	Distal 80 cm

Packaged in quantities of 1 unit per box.

ANGLED TIP



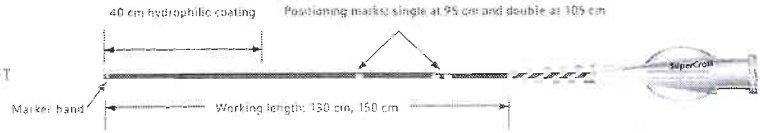
SuperCross Microcatheters—Straight | FT

The SuperCross Microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.

MODEL	GUIDEWIRE COMPATIBILITY	DISTAL TIP	WORKING LENGTH	SHAFT CONSTRUCTION	DISTAL O.D.	PROXIMAL O.D.	DISTAL I.D.	PROXIMAL I.D.	HYDROPHILIC COATING
5300	0.014"	Straight	130 cm	Braided	1.8 Fr. 0.61 mm / 0.024"	2.5 Fr. 0.84 mm / 0.033"	0.017" (0.43 mm)	0.021" (0.53 mm)	Distal 40 cm
5301	0.014"	Straight	150 cm	Braided	1.8 Fr. 0.61 mm / 0.024"	2.5 Fr. 0.84 mm / 0.033"	0.017" (0.43 mm)	0.021" (0.53 mm)	Distal 40 cm
5340	0.014"	FT	130 cm	Braided	1.8 Fr. 0.61 mm / 0.024"	2.5 Fr. 0.84 mm / 0.033"	0.017" (0.43 mm)	0.021" (0.53 mm)	Distal 40 cm
5341	0.014"	FT	150 cm	Braided	1.8 Fr. 0.61 mm / 0.024"	2.5 Fr. 0.84 mm / 0.033"	0.017" (0.43 mm)	0.021" (0.53 mm)	Distal 40 cm

Packaged in quantities of 1 unit per box.
FT=Flexible Tip

STRAIGHT | FT



Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose-driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow, Deknatel, Hudson RCI, LMA, Pilling, Rüsch, UroLift, and Weck – trusted brands united by a common sense of purpose.

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South Africa +27 (0)11 807 4887
Spain +34 918 300 451
Switzerland +41 (0)31 818 40 90
United Kingdom +44 (0)1494 53 27 61
For more information, please visit teleflex.com.

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Information in this material is not a substitute for the product Instructions for Use. Not all products may be available in all countries. Please contact your local representative. Revised: 07/2018.

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Teleflex

Poz. 6

scoreflex™ NC

Coronary Dilatation Catheter

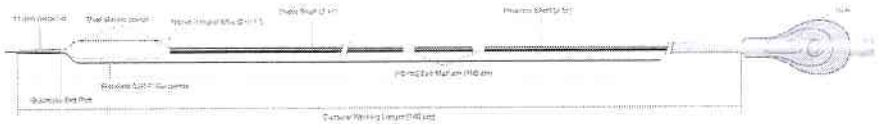
Ordering Information

Ø (mm)	Length (mm)		
	10	15	20
1.75	617-104-1	617-154-1	617-204-1
2.00	620-104-1	620-154-1	620-204-1
2.25	622-104-1	622-154-1	622-204-1
2.50	625-104-1	625-154-1	625-204-1
2.75	627-104-1	627-154-1	627-204-1
3.00	630-104-1	630-154-1	630-204-1
3.50	635-104-1	635-154-1	635-204-1
4.00	640-104-1	640-154-1	640-204-1

Technical Specifications

Scoreflex NC	
Catheter Type	Rapid exchange
Guidewire Lumen Diameter	0.014"
Balloon Material	Nylon blend
Balloon Compliance	Non-compliant
Coating (distal shaft and tip)	Hydro-X hydrophilic coating
Coating (guidewire lumen)	Invio hydrophobic coating
Crossing Profile*	0.0313" / 0.79 mm
Nominal Pressure	12 atm
Rated Burst Pressure	20 atm

* (2.5 mm diameter balloon)



For more information please visit our website at **www.OrbusNeich.com** or contact us:

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* Only for Belgium, Denmark, France, Germany, Ireland, Netherlands, Norway, Sweden and UK

G-70-0598 Rev.01

OrbusNeich™
Pioneers

scoreflex™ NC
Coronary Dilatation Catheter

Focused Force Angioplasty for

Non-compliant Lesion Preparation

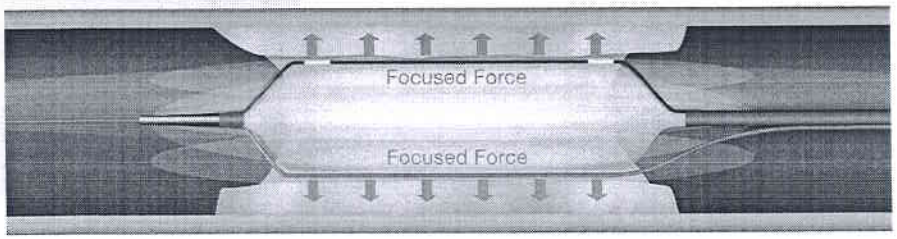
OrbusNeich™
Pioneers

scoreflex NC

Coronary Dilatation Catheter

Focused Force Angioplasty for
Safe and Controlled Dilatation

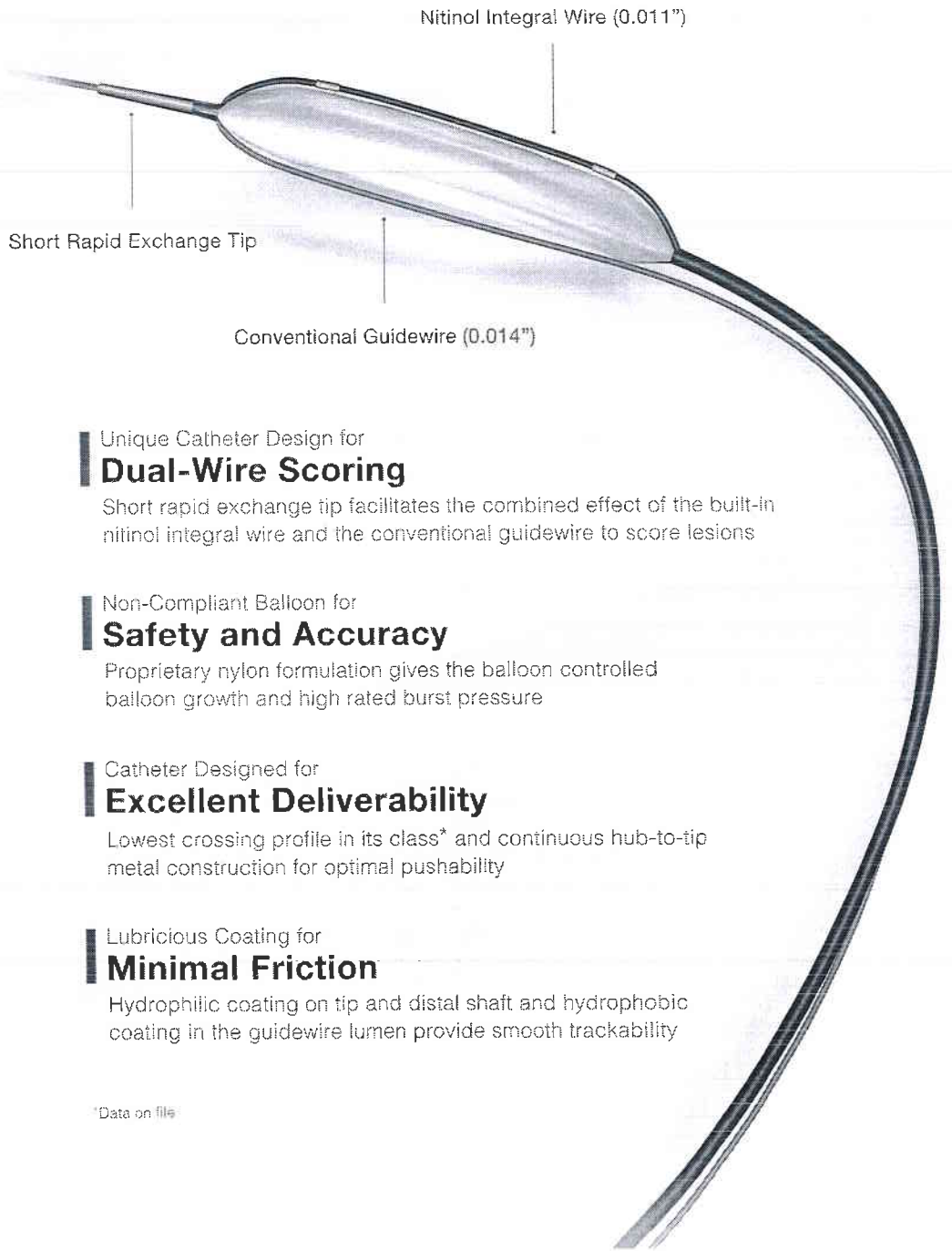
Scoreflex NC is a focused force dilatation balloon with a dual-wire system which creates a focal stress pattern to facilitate safe and controlled plaque modification at lower resolution pressure



Scoreflex NC
Recommended Applications

Coronary Applications

- Lesion preparation for stents, scaffolds, drug-coated balloons
- Calcified and fibrotic lesions
- Ostial lesions
- Bifurcation lesions
- Long diffused lesions
- Small lesions without need of stenting
- In-stent restenosis



Unique Catheter Design for
Dual-Wire Scoring

Short rapid exchange tip facilitates the combined effect of the built-in nitinol integral wire and the conventional guidewire to score lesions

Non-Compliant Balloon for
Safety and Accuracy

Proprietary nylon formulation gives the balloon controlled balloon growth and high rated burst pressure

Catheter Designed for
Excellent Deliverability

Lowest crossing profile in its class* and continuous hub-to-tip metal construction for optimal pushability

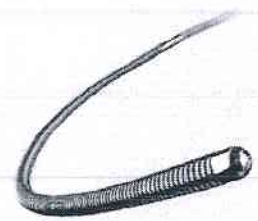
Lubricious Coating for
Minimal Friction

Hydrophilic coating on tip and distal shaft and hydrophobic coating in the guidewire lumen provide smooth trackability

*Data on file

Pos 13

PressureWire™ X Guidewire
FFR Measurement System



Product Benefits

- New flat corewire design for a softer, more durable tip with excellent shapeability, re-shapeability and shape retention*
- Hydrophilic coating with reduced friction for improved device delivery and compatibility**
- Proprietary, high-fidelity sensor technology for measurement of intravascular pressure
- Wireless radio technology for easier maneuverability and reduced clutter across the sterile field
- Hydrophilic-coated polymer sleeve protects cabling and electronics from fluids
- With the proximal transmitter removed, the wireless PressureWire™ guidewire acts as a standard 0.014" guidewire enabling balloon and stent placement***
- Multiple platform compatibility, including hemodynamic recording systems (via PressureWire™ Receiver) and St. Jude Medical™ PCI systems

*St. Jude Medical, Data on File, Report [illegible]
**St. Jude Medical, Data on File, [illegible]
***Refer to instructions for use.

Product Specifications

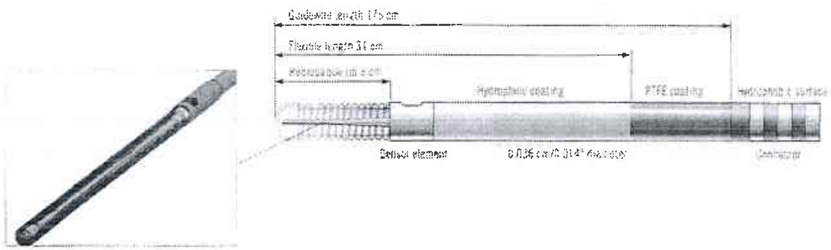
Specifications
0.014" pressure guidewire with medium weight support

Pressure

Operating pressure range:	-30 to +300 mmHg
Frequency response:	DC to 25 Hz

Transmission For Wireless Configuration

Radio range:	5 m
Battery time transmitter:	3 hours
Frequency range:	2.4000–2.4835 GHz (ISM band)
Radio type:	Frequency hopping spread spectrum (FHSS)
Radio power:	1 mW peak, 70 µW average
Total signal time delay	< 28 ms



St. Jude Medical

Ordering Information

Reorder Number	Description
C12059	PressureWire™ X Wireless FFR Guidewire, 175 cm
C12009	PressureWire™ X Cabled FFR Guidewire, 175 cm

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

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St. Jude Medical Brasil Ltda.
Rua Itapeva, 538
5º ao 8º andares
01332-000 – São Paulo – SP
Brazil
T +55 11 5080 5400 | F +55 11 5080 5423

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
T +852 2996 7688 | F +852 2956 0622

St. Jude Medical Japan Co., Ltd.
Shiodome City Center 15F
1-5-2, Higashi Shinbashi, Minato-ku
Tokyo 105-7115
Japan
T +81 3 6255 6370 | F +81 3 6255 6371

St. Jude Medical Australia Pty. Ltd.
17 Orion Road
Lane Cove, NSW 2066
Australia
T +61 2 9936 1200 | F +61 2 9936 1222

SJMprofessional.com

SJM-PW-0416-0015(1) Item approved for international use only.

St. Jude Medical

SJM Declaration of Conformity PressureWire

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address: St. Jude Medical
5050 Nathan Lane North
Plymouth, Minnesota 55442 USA

European Representative: St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type: Guidewire mounted sensor

Product Name(s): PressureWire Diagnostic Guidewire

Model Number(s): See Attachment 1

Classification: Class III per Annex IX, Rule 7

GMDN Code(s): 15071 Catheter-tip transducer, pressure
35094 Cardiac catheter guidewire, single use

Original CE Mark Date: See Attachment 1.

Certificate No and expiration date: Certificate No: CE 597699 – Annex II.3 (FQA)
Expiration Date: 15 May 2023

Certificate No: CE 623075 – Annex II.4 (DE)
Expiration Date: 13 April 2019

Applicable Quality System Standards: ISO 13485 and EN ISO 13485:2012

Notified Body: BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keynes
MK5 8PP UK

Notified Body Number: 0086

Manufacturing Facilities: St. Jude Medical Costa Rica LTDA
Zona Franca Coyol S.A.
Edifico #44B, Calle 0, Avenida 2, Coyol
Alajuela Costa Rica

Signature:

Marlene Peterson
Regulatory Affairs Manager

16 May 2019
Issue Date

ST. JUDE MEDICAL

90183871 Rev. M
Declaration of Conformity

SJM Declaration of Conformity PressureWire

Attachment 1. PressureWire Model Numbers

Product Description	Model Number	Original CE Mark Date
PressureWire Certus, Agile Tip, 175cm	C12008	18 December 2014*
PressureWire Certus, Agile Tip, 300cm	C12308	18 December 2014*
PressureWire Aeris, Agile Tip, 175cm	C12058	18 December 2014*
PressureWire Aeris, Agile Tip, 300cm	C12358	18 December 2014*
PressureWire X, 175cm, cabled connection	PWX175C	15 April 2016
PressureWire X, 300cm, cabled connection	PWX300C	15 April 2016
PressureWire X, 175cm, wireless connection	PWX175W	15 April 2016
PressureWire X, 300cm, wireless connection	PWX300W	15 April 2016
PressureWire X, 175cm, cabled connection	C12009	2 August 2016
PressureWire X, 300cm, cabled connection	C12309	2 August 2016
PressureWire X, 175cm, wireless connection	C12059	2 August 2016
PressureWire X, 300cm, wireless connection	C12359	2 August 2016

*Date reflects original CE Mark through BSI, as denoted on Annex II.4 certificate, CE 62305. Previously CE marking was through Intertek (Certus and Aeris only) in 2009, and through Dekra (for Certus only) in 2006.

Signature:

Marlene Peterson
Regulatory Affairs Manager

16 May 2019
Issue Date

bsi.

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 623075**

Issued To: **St. Jude Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

PressureWire Diagnostic Guidewire

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **18 December 2014** Date: **02 August 2016** Expiry Date: **13 April 2019**

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EC Design-Examination Certificate

Supplementary Information to CE 623075

Issued To: **St. Jude Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Product: PressureWire Certus, PressureWire Aeris

Model Number	Product Name
C12008	PressureWire Certus, Agile Tip, 175 cm
C12308	PressureWire Certus Agile Tip, 300 cm
C12058	PressureWire Aeris Agile Tip, 175 cm
C12358	PressureWire Aeris Agile Tip, 300 cm

Product: PressureWire X

Model Number	Product Name
PWX175C, C12009	PressureWire X, 175 cm, cabled connection
PWX300C, C12309	PressureWire X, 300 cm, cabled connection
PWX175W, C12059	PressureWire X, 175 cm, wireless connection
PWX300W, C12359	PressureWire X, 300 cm, wireless connection

First Issued: **18 December 2014** Date: **02 August 2016** Expiry Date: **13 April 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Poz. 15

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EC Design-Examination Certificate

Supplementary Information to CE 623075

Issued To:

St. Jude Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
18 December 2014	10152648	First Issue. Mirror certificate to CE 620481.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
15 April 2016	10162099	Addition of PressureWire X models.
03 May 2016	10163009	Correction of typographical error in product table.
02 August 2016	10164104	Changes for PressureWire X products: Shelf life extension to 2 years, addition of hydrophilic PEG coating over sensor, changes to labeling and IFU, addition of alternate model numbers.

First Issued: **18 December 2014** Date: **02 August 2016** Expiry Date: **13 April 2019**

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PORTICO

PRODUCT CATALOG

PORTICO™ TRANSCATHETER AORTIC VALVE

PRODUCT HIGHLIGHTS

- Large open-cell geometry preserves coronary access for future interventions[1]
- Intra-annular position provides earlier leaflet functionality[2]
- No need for rapid pacing during deployment[3,4]
- Experience controlled, relaxed deployment thanks to continuous hemodynamic stability[5]
- Recapturable, repositionable and retrievable for optimal placement[1]
- Simple prep consisting of two short 10-second rinses (total 20 seconds)[6]

ORDERING INFORMATION

Portico Transcatheter Aortic Valve System

Model Number	Valve Size (mm)	Annulus Range (mm)	Area Range (mm²)	Perimeter Range (mm)
PRT-23	23	19-21	277-346	60-66
PRT-25	25	21-23	338-415	66-73
PRT-27	27	23-25	405-491	72-79
PRT-29	29	25-27	479-573	79-85

PORTICO™ TRANSFEMORAL DELIVERY SYSTEM

PRODUCT HIGHLIGHTS

- Tackle every case with the most complete portfolio of deliverable valves on the market
- Experience responsive delivery at every turn with optimized trackability and flexibility[1]
- Lowest profile delivery system[1]
- Gradual, controlled deployment gives more time to assess valve placement[1]

ORDERING INFORMATION

Portico Transfemoral Delivery System

Model Number	Distal Outer Diameter (F)	Proximal Outer Diameter (F)	Working Length (cm)
PRT-DS-TF-18F	18	13	110
PRT-DS-TF-19F	19	13	110

*Valid fully deployed.

Information contained herein for **DISTRIBUTION** outside of the U.S. **ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Abbott

PORTICO

PRODUCT CATALOG

PORTICO™ VALVE LOADING SYSTEM

PRODUCT HIGHLIGHTS

- The Portico™ valve loading systems facilitate valve preparation and loading onto the Portico delivery systems. Each loading system includes a loading base, loading funnel, loading tube, base insert and two leaflet testers (Figures 1 and 2).

ORDERING INFORMATION

Transfemoral/Alternative Access Loading System

Model Number
PRT-LS-TF/ALT-18F
PRT-LS-TF/ALT-19F

FIGURE 1: 18 F 23/25 MM VALVES

FIGURE 2: 19 F 27/29 MM VALVES

ULTIMUM™ EV INTRODUCER

ORDERING INFORMATION

Model Number	Insertion Profile (I.D.)
C407698	18 F
C407699	19 F

PORTICO SOLO™ INTRODUCER

ORDERING INFORMATION

Model Number	Insertion Profile (I.D.)
PRTSOLO-19	11 F
PRTSOLO-20	12 F

REFERENCES
1. [illegible] et al. Portico TF EU [illegible] 2. Portico [illegible] How Portico helps solve challenging cases: [illegible] Webinar March 4, 2016. 4. Data on file. Document No. [illegible]

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. [illegible] where CE marking is not the regulation in force.

CAUTION: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use inside the product carton (when available) or at manuals [illegible] for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott
Park Lane, Culliganlaan 2b, 1831 Diegem, Belgium, Tel: [illegible]
www.Abbott.com

Abbott

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 578287**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

In respect of:

Design and manufacture of Mechanical and Tissue Heart Valves, Transcatheter Heart Valves, Pericardial Patches, Valved Grafts, Annuloplasty Rings and Related Accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Pietro Foschi - Strategic Delivery Director

First Issued: **30 January 2012** Date: **01 December 2014** Expiry Date: **15 December 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
Abbyland PorkPak Inc. 539 North Meridian Street Curtiss Wisconsin 54422 USA	**Animal substances**
BRF - Brasil Foods S.A. Rua Senador Atilio Fontana, 86, Concordia/SC Brasil	**Animal substances**
Frigoestrela S.A. Estrada Vicinal Romão Lopes Martins, S/N - KM 0+700M, Jardim Marabá, Tupã/SP Brasil	**Animal substances**
Frigorifico Argus Ltda BR 376 KM 621, São José do Pinhais/PR Brasil	**Animal substances**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: CE 578287

Date: 01 December 2014

Issued To: St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
Frigorifico Miolar Ltda Estrada para Fazenda Mazurana S/N, Dois Vizinhos/PR Brasil	**Animal substances**
Frimesa Cooperativa Central Rua Bahia, 159, Medianeira/PR Brasil	**Animal substances**
Heraeus Medical Components 5030 Centerville Road St. Paul Minnesota 55127-2203 USA	**Manufacture**
InterVascular SAS Z.1 Athelia 1 13705 La Ciotat Cedex France	**Manufacture**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
JBS Aves Ltda Rua João Andriolllo, 1167, Ana Rech Caxias do Sul/RS Brasil	**Animal substances**
JBS S.A. Parque Industrial S/N Distrito Industrial, LINS/SP Brasil	**Animal substances**
JBS S.A. Rodovia, GO 164, Km 167 S/N, Zona Rural, Mozarlândia/GO Brasil	**Animal substances**
JBS S.A. Rua Principal S/N, Vila Miisa, Ituiutaba/MG Brasil	**Animal substances**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: CE 578287

Date: 01 December 2014

Issued To: St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
Mac Frios Rod. Antônio de Paiva Cantelmo, PR 566- KM 02, Zona Rural, Francisco Beltrão/PR Brasil	**Animal substances**
Maquet Cardiovascular 45 Barbour Pond Drive Wayne NJ 07470 USA	**Animal substances** **Manufacture**
Marcho Farms Inc. 519 Allentown Road Franconia Pennsylvania 18924 USA	**Animal substances**
Oakey Abattoir Lot 1, Oakey Connection Road, Oakey QLD 4401 Australia	**Animal substances**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
Phillips Plastics Corporation Phillips Medical New Richmond 705 Wisconsin Drive New Richmond Wisconsin 54017 USA	**Manufacture**
Rio Branco Alimentos S.A. (Pif Paf) BR 365 Km 455, Patrocínio/MG Brasil	**Animal substances**
Seara Alimentos Ltda Rua Tranquilo Damo, 209 -Santo Antonio, Frederico Westphalen/RS Brasil	**Animal substances**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: CE 578287

Date: 01 December 2014

Issued To: St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 51250 USA	**Animal substances**
St. Jude Medical Brasil Ltda. Rua Professor Jose Vieira de Mendonca, 1301 Bairro Engenho Nogueira Belo Horizonte Minas Gerais 33.310-260 Brasil	**Manufacture**
St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2, Zona Franca Coyol El Coyol Alajuela Costa Rica	**Manufacture**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 and 21 Caguas 00726 Puerto Rico	**Final Inspection** **Manufacture** **Moist Heat Sterilization**
St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park Arecibo PR 00612 USA	**ETO Sterilization**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
St. Jude Medical 177 County Road B East St. Paul Minnesota 55117 USA	**Distribution** **Final Inspection** **Labelling** **Manufacture** **Moist Heat Sterilization** **Packaging**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative**
Steris Corporation Isomedix Services State Road 690 KM1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	**Gamma Irradiation**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
STERIS Isomedix Services, Inc. 2072 Southport Road Spartanburg SC 29306 USA	**ETO Sterilization**
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
Teys Australia Southern, Tamworth Phoenix street Tamworth, NSW 2340 Australia	**Animal substances**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: CE 578287

Date: 01 December 2014

Issued To: St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:	Service(s) supplied
Vascutek Limited Newmains Avenue Inchinnan Renfrewshire Scotland PA4 9RR United Kingdom	**Animal substances Manufacture**
W & G Marketing Co. 2824 Northridge Drive Sidney, IA USA	**Animal substances**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance System
Certificate History

Certificate No: **CE 578287**

Date: **01 December 2014**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Date	Reference Number	Action
30 January 2012	7727627	First issue of mirror certificate to CE 544668
8 June 2012	7816634	Addition of significant subcontractor for sterilization to St Jude Medical Puerto Rico LLC for VAVGJ devices.
16 November 2012	7910273	Transcatheter valves added to the scope. Addition of St Jude Medical (Minnetonka), St Jude Medical (Maple Grove), Marcho Farms and Abbyland PorkPak to the list of subcontractors.
13 December 2012	7930677	Update to subcontractor address St Jude Medical PR LLC.
16 January 2013	7943381	St Jude Medical (Costa Rica) added to the list of subcontractors.
18 April 2013	7984806	St Jude Medical (Maple Grove) removed from the list of subcontractors.
10 November 2013	8071312	Addition of significant subcontractor InterVascular SAS (Maquet) La Ciotat France facility as a fabric supplier for SJM Mechanical Heart Valves, Valved Grafts and Annuloplasty Rings.
19 November 2014	8245105	Certificate renewal.
01 December 2014	8194269	Tissue valves and pericardial patches added to the scope (transferred from another Notified Body). St Jude Medical Brasil, Phillips Plastics and bovine porcine abattoirs added to the list of subcontractors.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK

Annex II
Declaration of Conformity

St. Jude Medical (SJM), Cardiovascular and Ablation Technologies Division hereby declares that the following products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC, as amended by 2007/47/EC; and Regulation (EU) 722/2012 (for the valve).

Manufacturer Address:
St. Jude Medical
177 County Road B East
St. Paul, MN 55117
U.S.A.

European Representative:
St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem Belgium

Product Type:
Transcatheter Heart Valve, Delivery System and Loading System

Product Name
Portico™ Transcatheter Heart Valve
Portico™ Transfemoral Delivery System
Portico™ Transfemoral Loading System

Model Numbers
PRT-23; Transcatheter Heart Valve (23mm)
PRT-25; Transcatheter Heart Valve (25mm)
PRT-27; Transcatheter Heart Valve (27mm)
PRT-29; Transcatheter Heart Valve (29mm)
PRT-DS-TF-18F; Transfemoral Delivery System
PRT-LS-TF/ALT-18F; Transfemoral Loading System
PRT-DS-TF-19F; Transfemoral Delivery System
PRT-LS-TF/ALT-19F; Transfemoral Loading System

Classification:
Class III per Annex IX, Rule 17 and Rule 6

GMDN Codes:
60245 (Transcatheter Heart Valve)
10760 (Delivery system)
58987 (Loading System)

Signature: _____
Jeff Sturm
Sr. Manager, Regulatory Affairs

Issue Date: 14 December 2017

90113141 Ver P

Annex II, Clause 3:	Certificate No.: 578287 Expiration Date: 15 December 2019
EC Design Examination Certificate	Certificate No.: 585003 Expiration Date: 15 November 2022
Applicable Quality System Standards:	ISO 13485:2003
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes, MK5 8 PP United Kingdom
Notified Body Number:	0086
Original CE Mark Date:	16 November 2012
Manufacturing Facilities:	St. Jude Medical 177 County Road B East St. Paul, MN 55117 U.S.A. St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345 U.S.A. St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica

Signature: _____

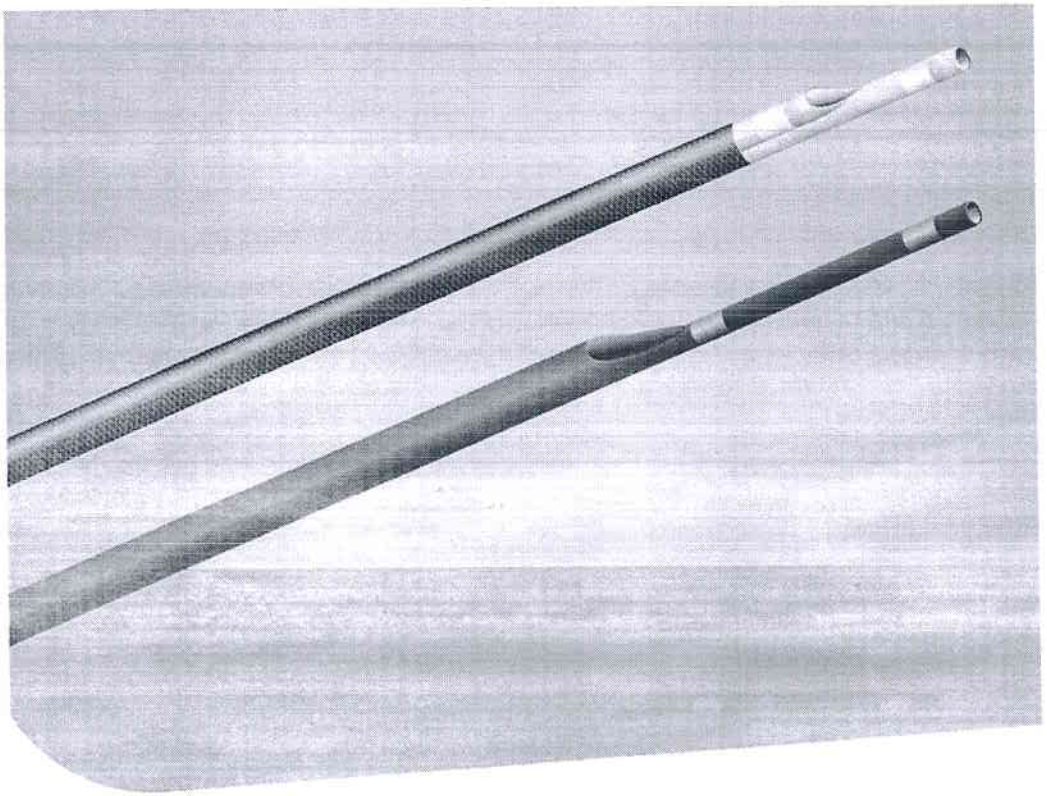
Jeff Sturm
Sr. Manager, Regulatory Affairs

Issue Date: 14 December 2017

90113141 Ver. P

Poz 16

Twin-Pass
dual access catheter



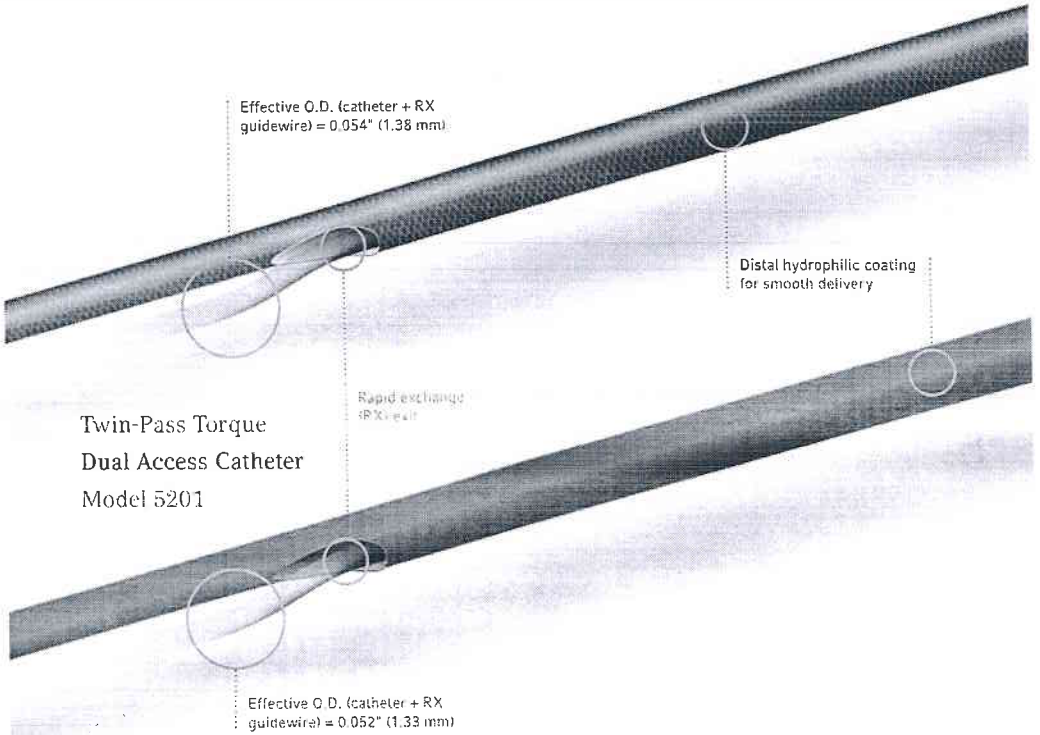
Twin-Pass® Dual Access Catheters

A Second Lumen When and Where It's Needed

Teleflex®

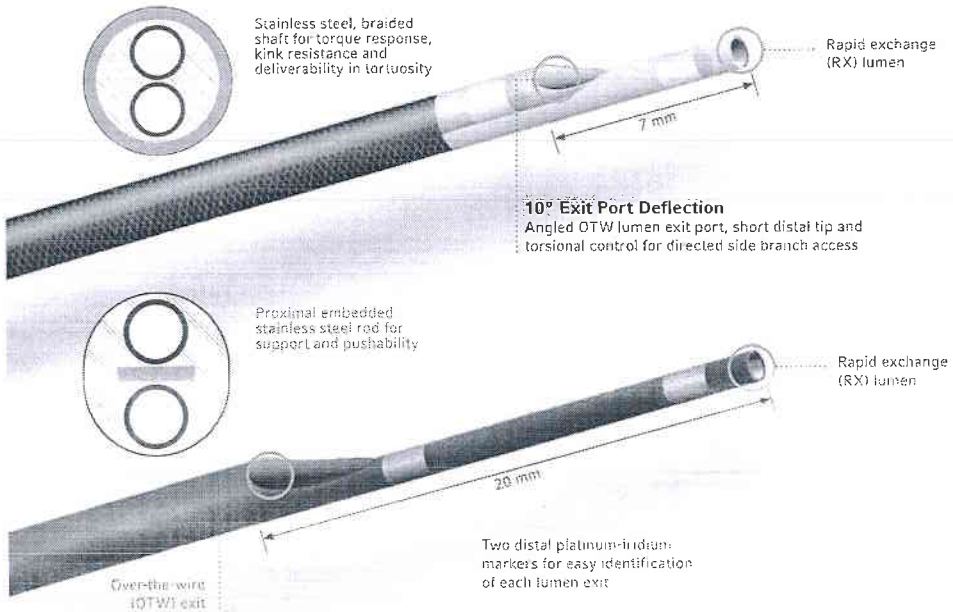
Access or Delivery While Maintaining Wire Position

The Twin-Pass® Dual Access Catheter offers the convenience of an over-the-wire lumen and a rapid exchange lumen in a single catheter. This unique design allows the guidewire to remain in place while the second lumen is used for advancement of a second 0.014" guidewire, or subselective delivery of contrast or medication.



Twin-Pass Torque
Dual Access Catheter
Model 5201

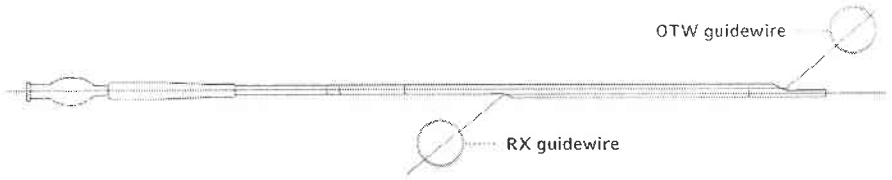
Twin-Pass Dual
Access Catheter
Model 5200



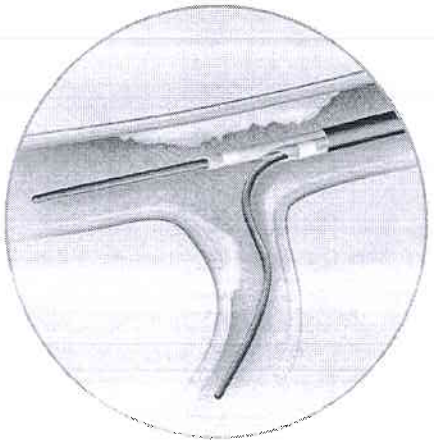
Simple Deployment in a Dual-Lumen Design

RX lumen is delivered over in-place guidewire

OTW lumen is used for subsequent delivery of a second guidewire or fluid injection

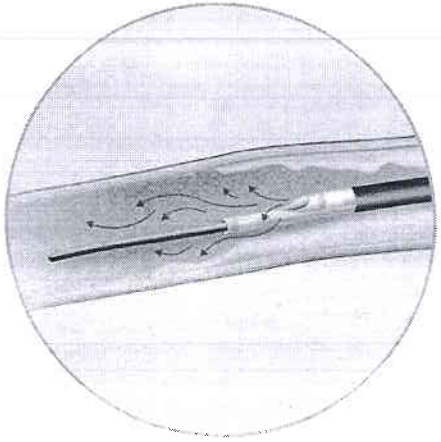


Supportive Access for Bifurcations and Wire Exchanges



With the Twin-Pass Catheter over the RX guidewire in the main branch, the OTW lumen can be used to advance a guidewire into a side branch or for guidewire exchange.

Targeted Delivery of Medication or Contrast



The RX guidewire can remain while the OTW lumen is used to deliver medication or contrast to the desired distal vessel segment.

	Twin-Pass Torque Dual Access Catheter 5201	Twin-Pass Dual Access Catheter 5200
Primary clinical usage	Procedures requiring a dual-lumen with torque response for precise angle alignment into side branches	Procedures requiring a dual-lumen for convenient rapid fluid delivery or a second guidewire in the same vessel
OTW lumen exit port deflection angle	10°	0°
Shaft construction	Stainless steel braid	Stainless steel rod
Distal tip length	7 mm	20 mm
Dual-lumen outer diameter (Crossing Profile)	3.5 Fr. x 3.5 Fr.	3.4 Fr. x 2.7 Fr.

Ordering Information

Twin-Pass® Torque Dual Access Catheter Model 5201

The Twin-Pass Torque Catheter is intended to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.

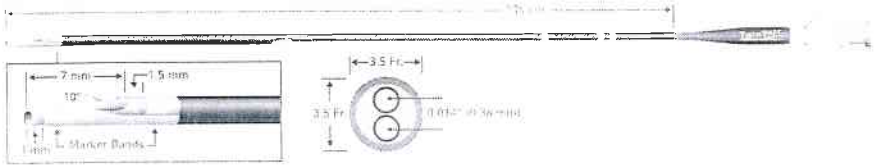
Twin-Pass® Dual Access Catheter Model 5200

The Twin-Pass Catheters are intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, and for use during two guidewire procedures. The Twin-Pass catheter is also used to subselectively infuse/deliver diagnostic or therapeutic agents.

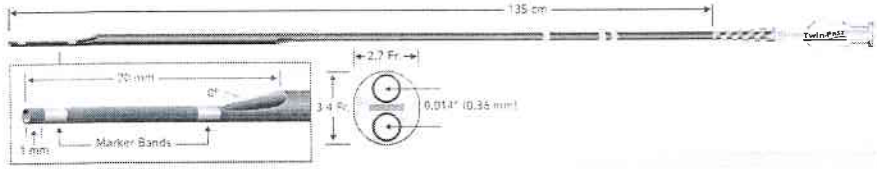
SPECIFICATIONS	TWIN-PASS TORQUE DUAL ACCESS CATHETER MODEL 5201	TWIN-PASS DUAL ACCESS CATHETER MODEL 5200
Guide catheter compatibility	≥5 Fr. (≥0.056" / 1.42 mm I.D.)	≥5 Fr. (≥0.056" / 1.42 mm I.D.)
Guidewire compatibility	≤0.014" / 0.36 mm	≤0.014" / 0.36 mm
OTW lumen O.D.	0.040" / 1.02 mm	0.038" / 0.97 mm
Dual-lumen O.D.	3.5 Fr. x 3.5 Fr. (1.17 mm / 0.046")	3.4 Fr. x 2.7 Fr. (1.14 mm / 0.045" x 0.91 mm / 0.036")
Distal tip O.D.	2.1 Fr. (0.71 mm / 0.028")	2 Fr. (0.66 mm / 0.026")
Working length	135 cm	135 cm
RX lumen length	22 cm	21 cm
Distal tip length	7 mm	20 mm
Hydrophilic coating	Distal 25 cm	Distal 18 cm
Positioning marks	95 cm (single) and 105 cm (double) from distal tip	95 cm (single) and 105 cm (double) from distal tip
OTW lumen exit port deflection angle	10°	0°

Packaged in quantities of 1 unit per box

Twin-Pass® Torque
Dual Access Catheter
Model 5201



Twin-Pass® Dual
Access Catheter
Model 5200



Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rüsch®, and Weck® – trusted brands united by a common sense of purpose.

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Spain +34 918 300 451
Switzerland +41 (0)31 818 40 90
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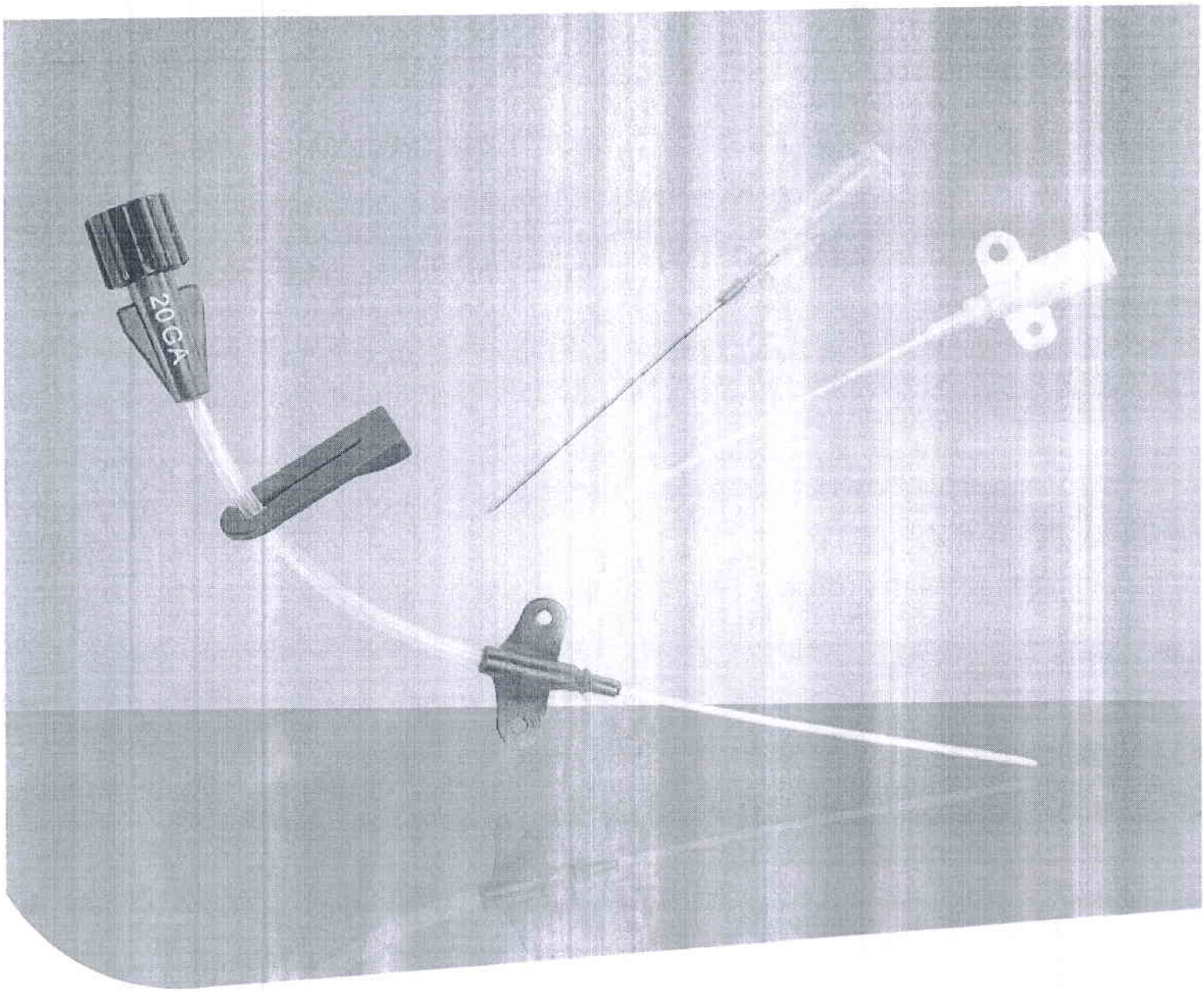
For more information, please visit teleflex.com.

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Teleflex®

Poz. 18

ARROW



Arrow

Arterial access

Reliability counts

Teleflex

Teleflex - Because Reliability Counts

Teleflex - high quality medical supplies - all from a single source

Teleflex - your strong and cost-efficient partner. With reliable brands, on the basis of solid tradition and with focus on patient safety, we apply all of our innovation capacity on supporting you to minimise risks and maximise treatment results for your patients. Therefore we have developed a unique product portfolio based on your requirements.

As a leading manufacturer of high-quality medical products we, Teleflex, are at your disposal worldwide and at any time.

With its Arrow products, Teleflex sets benchmarks in this field. We help you undertake life-saving treatments while adhering to important health directives.

You can find further details and technical specifications of our products within this brochure.

Reliable Haemodynamic Monitoring

Standard Seldinger Technique

The design of the Standard Seldinger Technique components minimize infection while providing increased access options. Features such as flexible suture wings and the hydrophilic coating help increase positive outcomes.

Integrated Seldinger Technique

A milestone in arterial catheterization by offering the first integrated design. Enables quick and easy insertions with high success rates. Reduced risk of contamination and blood contact.

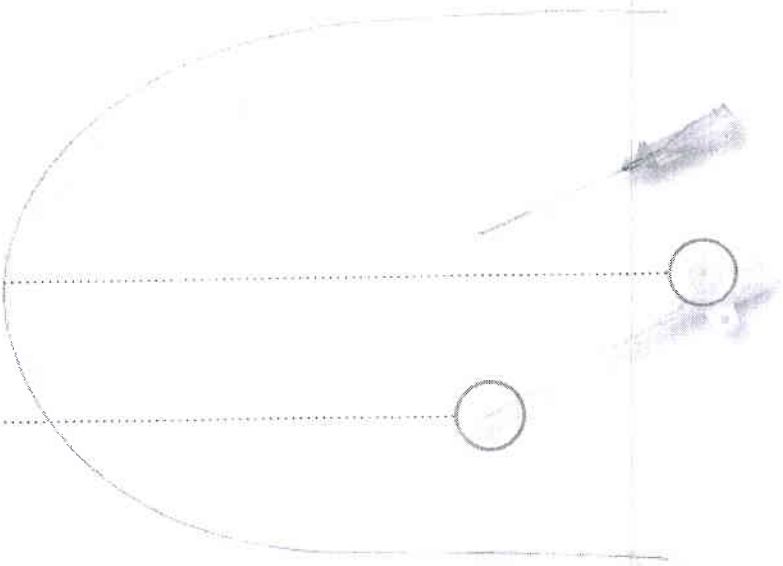
QuickFlash System

Combines the ease of use of a peripheral I.V. with the advantages of an integrated Seldinger device. The QuickFlash System allows for a rapid identification of blood return with arterial puncture.

Arterial Access Catheterisation Sets

Seldinger technique I, II 3-5
Modified Seldinger 6
QuickFlash 7

Standard Seldinger Technique I



Flexible, angled suture wings with low profile
allow a variety of fixation options

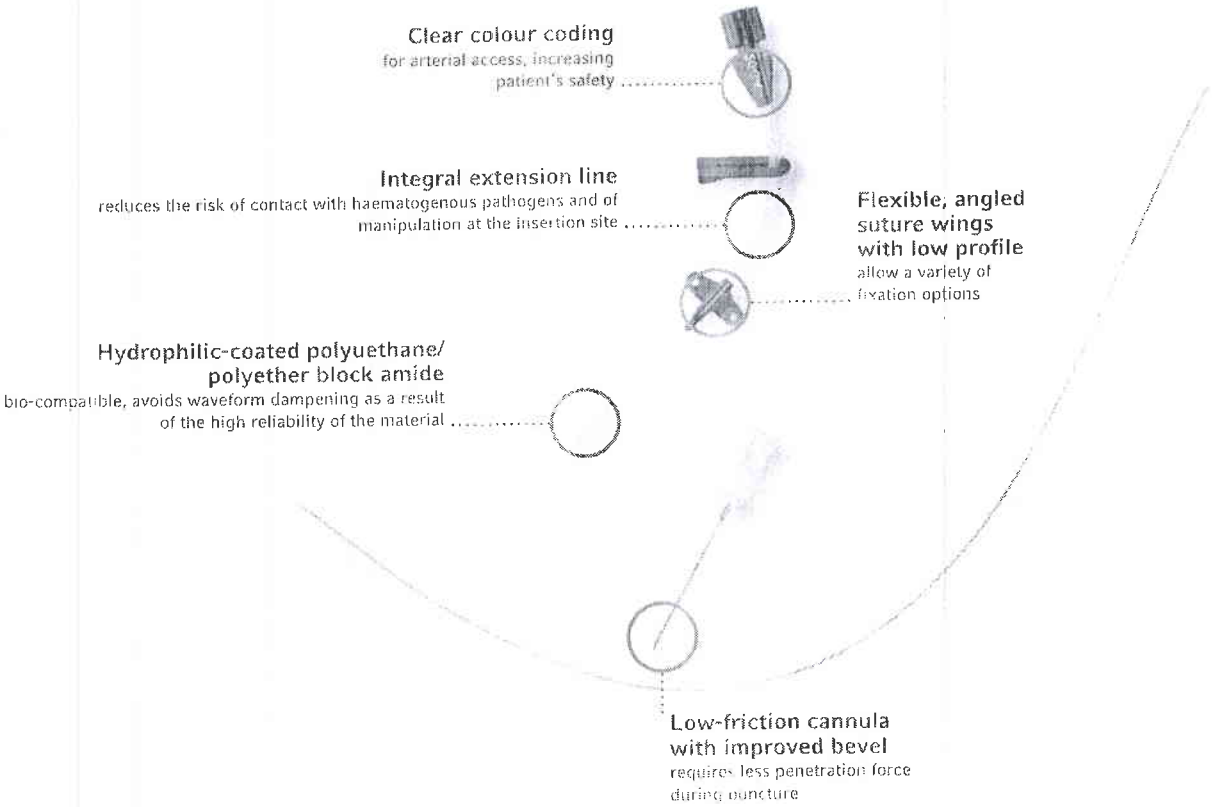
Hydrophilic-coated polyurethane
Bio-compatible, avoids waveform dampening as a result of the high reliability of the material

Seldinger Technique

Sets for the Standard Seldinger Technique I

	CATHETER			GUIDEWIRE			CANNULA		SYRINGE	
ART. NO.	Ø	LENGTH	MATERIAL	LENGTH	Ø	TIP	LENGTH	Ø		QTY
GH-04124	24 G	4.13 cm	PUR	18 cm	0.46 mm (.018")	straight/straight	3.81 cm	22 G²	3 ml LS	10
GH-04122	22 G	3.49 cm	PUR	25 cm	0.46 mm (.018")	straight/straight	3.81 cm	21 G²		25
GH-04120	20 G	6.35 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	3.81 cm	20 G²		25
GH-04120-E	20 G	7.78 cm	PUR	19 cm	0.53 mm (.021")	straight/straight	3.81 cm	20 G²		10
GH-04125	20 G	7.78 cm	PUR	25 cm	0.64 mm (.025")	straight/straight	3.81 cm	20 G²		50
GH-04150	20 G	20 cm	PUR	45 cm	0.64 mm (.025")	J-tip/straight	6.35 cm	18 G²		10
CK-04018	18 G	12 cm	PUR	45 cm	0.64 mm (.025")	J-tip/straight	6.35 cm and 3.81 cm	18 G² and 20 G¹		25

Standard Seldinger Technique II (SAC)

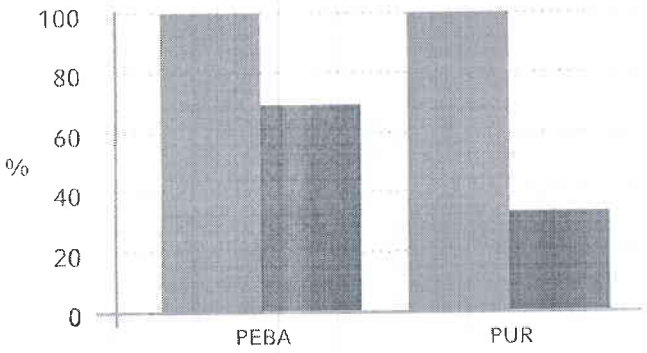


Sets for the Standard Seldinger Technique II (SAC) – Polyurethane

	CATHETER			GUIDEWIRE					CANNULA		
ART. NO.	Ø	LENGTH	MATERIAL	LENGTH	Ø	TIP	EXIT MARKING	REFERENCE	LENGTH	Ø	QTY
SAC-00324	24 G	2.5 cm	PUR	25 cm	0.46 mm (.018")	straight/straight	•		Cannula 24 G/1.9 mm over needle 26 G		10
SAC-00524	24 G	5 cm	PUR	25 cm	0.46 mm (.018")	straight/straight	•		Cannula 24 G/1.9 mm over needle 26 G		10
SAC-00522	22 G	5 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	22 G¹	10
SAC-00822	22 G	8 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	22 G¹	10
SAC-01222	22 G	12 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	22 G¹	10
SAC-00520	20 G	5 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	20 G¹	10
SAC-00820	20 G	8 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	20 G¹	10
SAC-01220	20 G	12 cm	PUR	35 cm	0.53 mm (.021")	straight/straight	•		7 cm	20 G¹	10
SAC-01620	20 G	16 cm	PUR	50 cm	0.53 mm (.021")	straight/straight	•		7 cm	20 G¹	10
SAC-00818	18 G	8 cm	PUR	33 cm	0.64 mm (.025")	straight/straight	•		5 cm	18 G¹	10
SAC-01218	18 G	12 cm	PUR	33 cm	0.64 mm (.025")	straight/straight	•		5 cm	18 G¹	10
SAC-01618	18 G	16 cm	PUR	45 cm	0.64 mm (.025")	J-tip/straight		Arrow Advancer	7 cm	18 G¹	10
SAC-02318	18 G	23 cm	PUR	60 cm	0.64 mm (.025")	J-tip/straight		Arrow Advancer	7 cm	18 G¹	10

Stiffness of Catheter Body

■ At Room Conditions (25 °C)
■ Dwelled in Vessels (37 °C)



Note: 100% stiffness relates to ambient room conditions.

- The PEBA Seldinger Arterial Catheter uses material Poly-Ether Block Amide (PEBA) of high endurance to flexure, despite changes from room to body temperature.
- This makes the catheter stable no matter if still being inserted or dwelling in a vessel

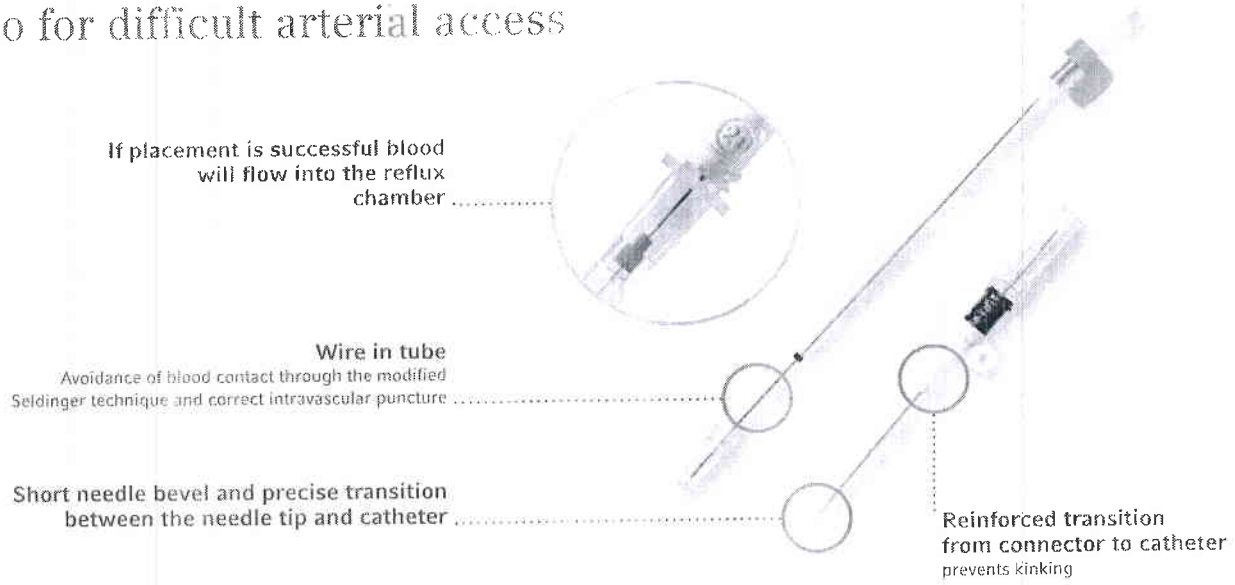
Sets for the Standard Seldinger Technique II (SAC) – Polyether Block Amide

	CATHETER			GUIDEWIRE					CANNULA		
ART. NO.	Ø	LENGTH	MATERIAL	LENGTH	Ø	TIP	EXIT MARKING	REFERENCE	LENGTH	Ø	QTY
SAC-00324-PBX	24 G	2.5 cm	PEBA	25 cm	0.46 mm (.018")	straight/straight	•		Cannula 24 G/1.9 mm over needle 26 G		10
SAC-00524-PBX	24 G	5 cm	PEBA	25 cm	0.46 mm (.018")	straight/straight	•		Cannula 24 G/1.9 mm over needle 26 G		10
SAC-00522-PBX	22 G	5 cm	PEBA	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	22 G[1]	10
SAC-00822-PBX	22 G	8 cm	PEBA	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	22 G[1]	10
SAC-01222-PBX	22 G	12 cm	PEBA	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	22 G[1]	10
SAC-00520-PBX	20 G	5 cm	PEBA	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	20 G[1]	10
SAC-00820-PBX	20 G	8 cm	PEBA	35 cm	0.53 mm (.021")	straight/straight	•		4 cm	20 G[1]	10
SAC-01220-PBX	20 G	12 cm	PEBA	35 cm	0.53 mm (.021")	straight/straight	•		7 cm	20 G[1]	10
SAC-01620-PBX	20 G	16 cm	PEBA	50 cm	0.53 mm (.021")	straight/straight	•		7 cm	20 G[1]	10
SAC-00818-PBX	18 G	8 cm	PEBA	33 cm	0.64 mm (.025")	straight/straight	•		5 cm	18 G[1]	10
SAC-01218-PBX	18 G	12 cm	PEBA	33 cm	0.64 mm (.025")	straight/straight	•		5 cm	18 G[1]	10
SAC-01618-PBX	18 G	16 cm	PEBA	45 cm	0.64 mm (.025")	J-tip/straight		Arrow Advancer	7 cm	18 G[1]	10
SAC-02318-PBX	18 G	23 cm	PEBA	60 cm	0.64 mm (.025")	J-tip/straight		Arrow Advancer	7 cm	18 G[1]	10

[1] *XTW = Extra Thin Wall* [2] *TW = Thin Wall* [3] *RW = Standard Wall*

Modified Seldinger Technique

Also for difficult arterial access



Sets for the Modified Seldinger Technique/A. Radialis

	CATHETER			GUIDEWIRE				CANNULA		
ART. NO.	Ø	LENGTH	MATERIAL	LENGTH	Ø	TIP	REFERENCE	LENGTH	Ø	QTY
RA-04022	22 G	4.45 cm	FEP	14 cm	0.46 mm (.018")	straight	Spring-Wire Guide/* Tube Assembly	7 cm	25 G[2]	50
RA-04122	22 G	3.49 cm	PUR	12.5 cm	0.38 mm (.015")	straight	Spring-Wire Guide/ Tube Assembly	6.35 cm	23 G	50
RA-04020	20 G	4.45 cm	PUR		0.46 mm (.018")	straight	Integral Spring-Wire Guide	9.17 cm	22 G[1]	50
RA-04120	20 G	3.81 cm	PUR		0.46 mm (.018")	straight	Integral Spring-Wire Guide	9.17 cm	22 G[1]	50
RA-04018	18 G	4.45 cm	FEP		0.64 mm (.025")	straight	Integral Spring-Wire Guide	7 cm	20 G[1]	50

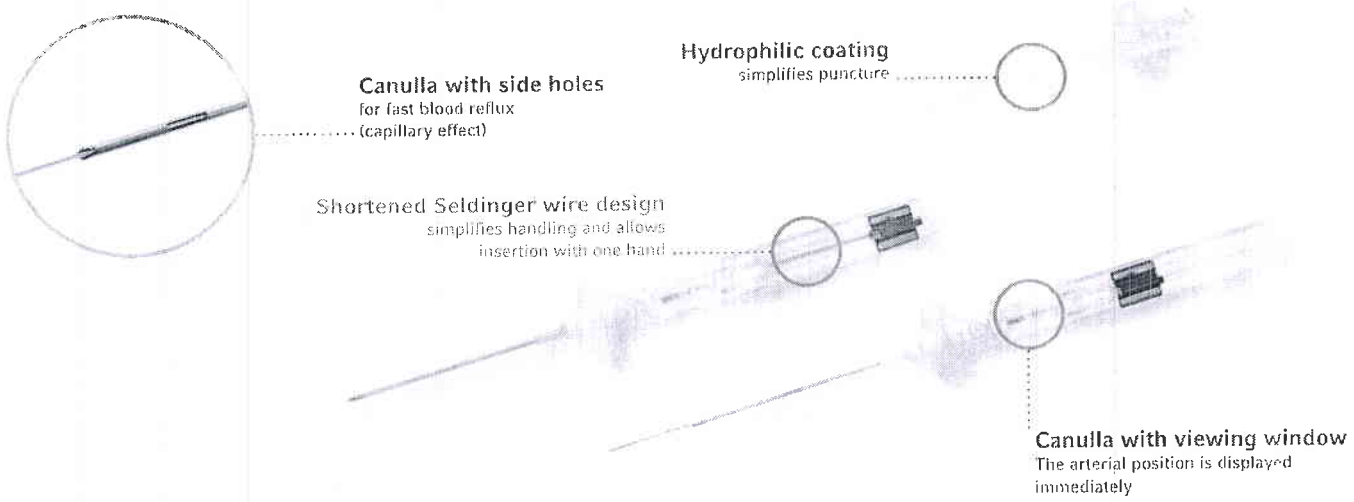
Sets for the Modified Seldinger Technique

	CATHETER			GUIDEWIRE				CANNULA		
ART. NO.	Ø	LENGTH	MATERIAL	LENGTH	Ø	TIP	REFERENCE	LENGTH	Ø	QTY
FA-04020	20 G	10.8 cm	PUR	24 cm	0.46 mm (.018")	straight	Spring-Wire Guide/ Tube Assembly	13.3 cm	22 G[2]	25
FA-04018	18 G	10.8 cm	PUR	24.5 cm	0.64 mm (.025")	straight	Spring-Wire Guide/ Tube Assembly	13.3 cm	20 G[2]	25

** can only be inserted through the introducer catheter*

QuickFlash

Direct arterial placement with the advantages of the Seldinger technique, but even safer and more reliable.



Sets with QuickFlash catheter

	CATHETER			GUIDEWIRE			CANNULA		
ART. NO.	Ø	LENGTH	MATERIAL	Ø	TIP	REFERENCE	LENGTH	Ø	QTY
RA-04220 (without wings)	20 G	3.81 cm	PUR	0.46 mm (.018")	straight	Integral Spring-Wire Guide	6.35 cm	21 G[2]	50
RA-04220-W (with wings)	20 G	3.81 cm	PUR	0.46 mm (.018")	straight	Integral Spring-Wire Guide	6.35 cm	21 G[2]	50

[1] *XTW = Extra Thin Wall* [2] *TW = Thin Wall* [3] *RW = Standard Wall*

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