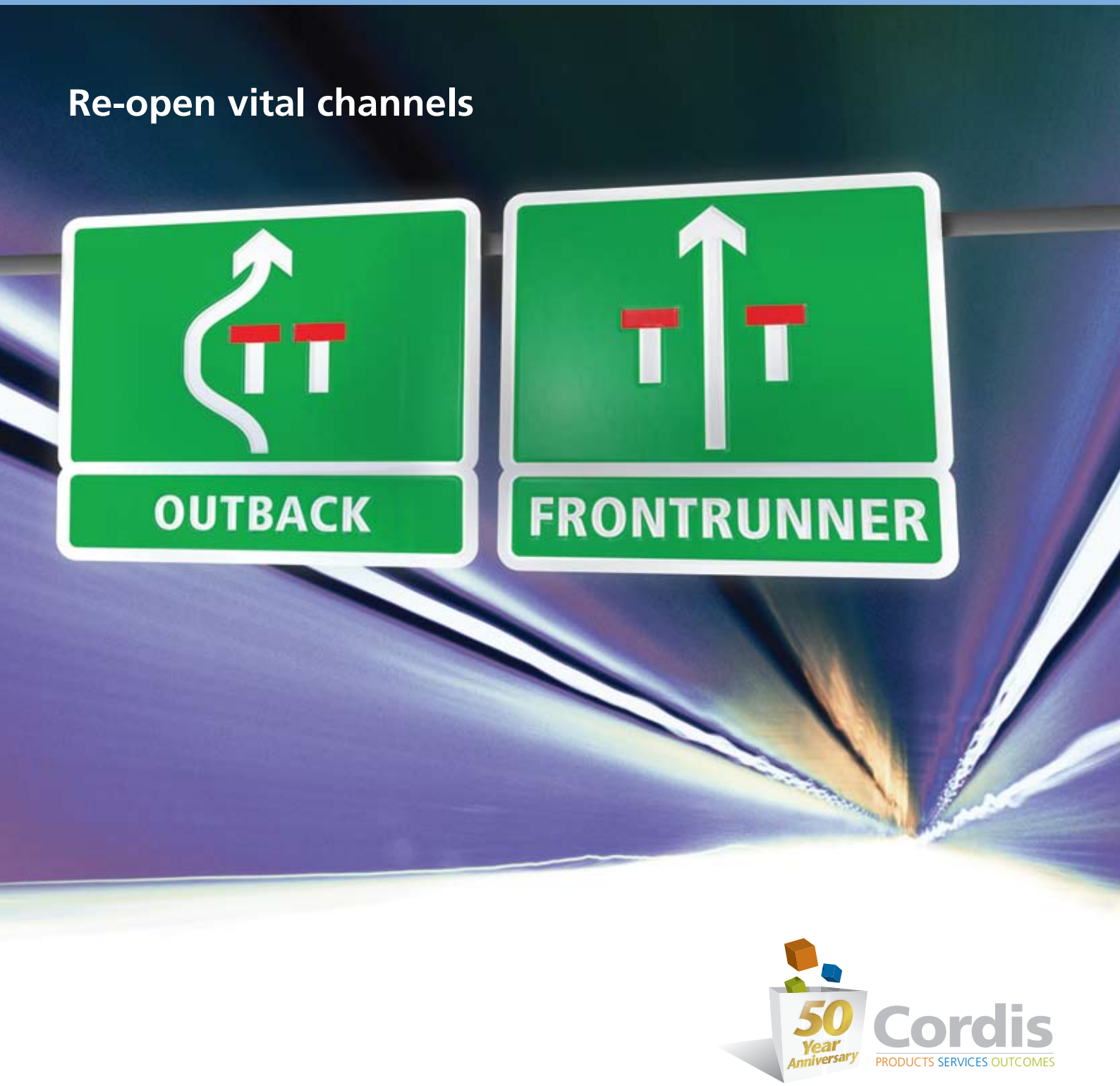
Cordis®
a Johnson & Johnson company

Ground breaking, Life changing™

Endovascular

Chronic Total Occlusion (CTO) Technologies

Re-open vital channels



50 Year Anniversary

Cordis
PRODUCTS SERVICES OUTCOMES

OUTBACK® LTD™ Re-Entry Catheter

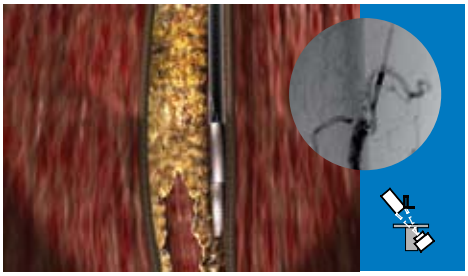
True Lumen Re-Entry Technology

Get back into the true lumen with ease and precision

"There are a number of challenging arterial occlusions where the Outback re-entry catheter has proved indispensable" *Dr. Amman Bolia, Leicester Royal Infirmary, UK*

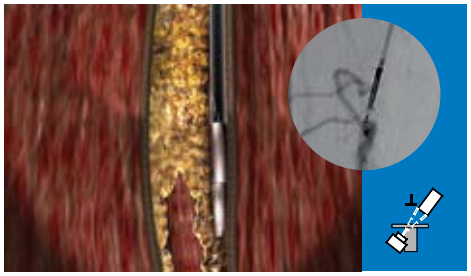
Precise and predictable orientation and deployment of the re-entry cannula towards the true lumen at the reconstitution point to ensure optimal patient outcomes.

No need for additional visualization equipment.



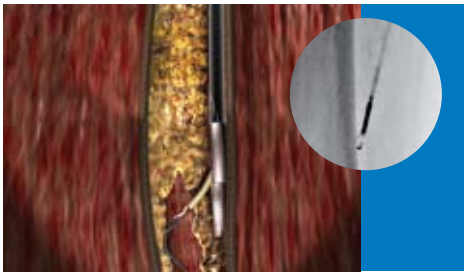
Locate

Correct positioning and orientation of the nitinol cannula towards the true lumen at the right location is straightforward with the highly visible **"L"** shaped radiopaque marker.



Tune

Confirmation of the desired alignment at the re-entry site is provided by the **"T"** shaped radiopaque marker (visualized from 90 degree orthogonal view). For simple and accurate adjustment of orientation *in vivo* the catheter provides one-to-one torque response.



Deploy

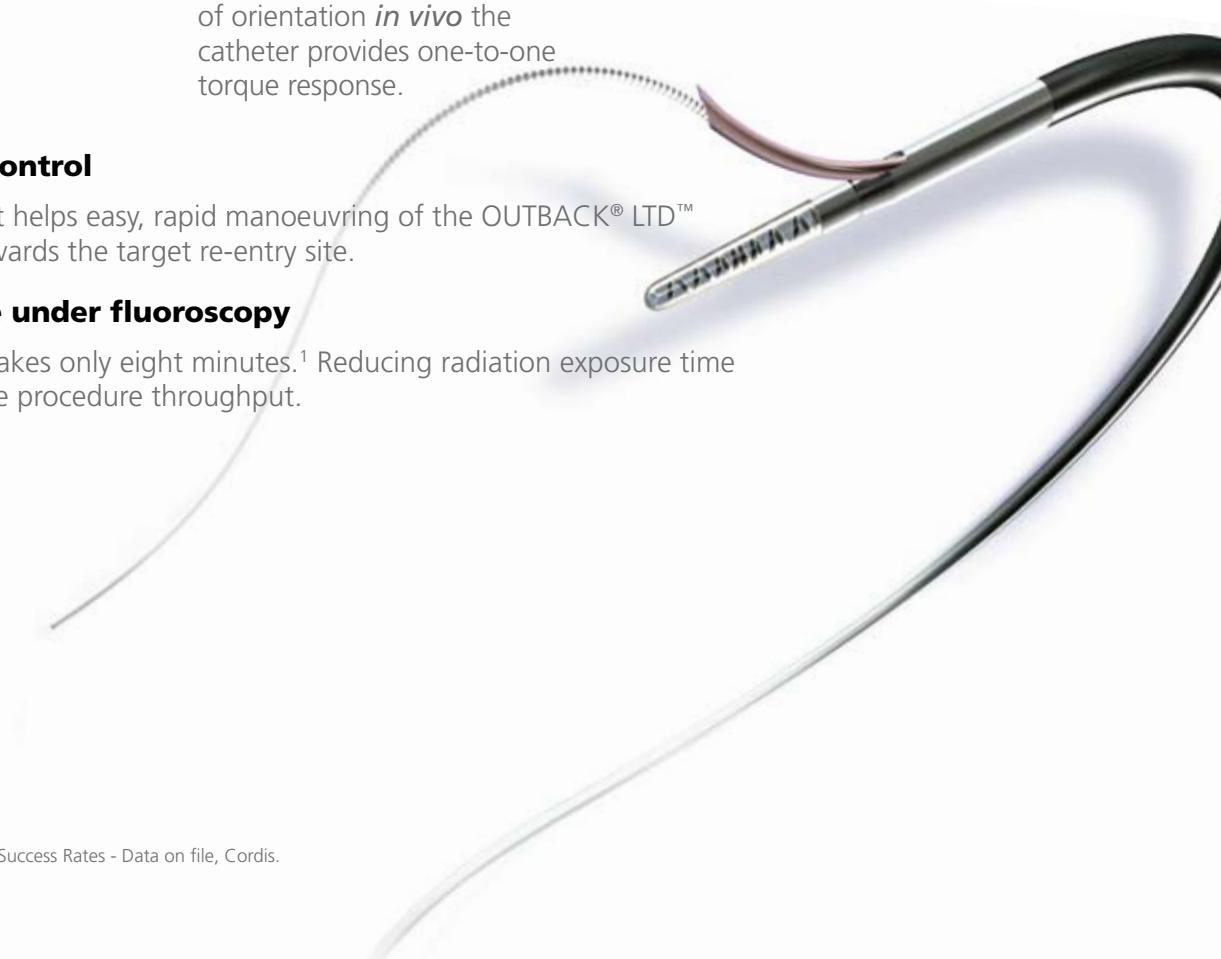
Single-handed actuator simplifies deployment of the 22-gauge nitinol cannula for re-entry back into the true lumen at the reconstitution point.

Effective torque control

Braided catheter shaft helps easy, rapid manoeuvring of the OUTBACK® LTD™ Re-Entry Catheter towards the target re-entry site.

Helps reduce time under fluoroscopy

On average re-entry takes only eight minutes.[1] Reducing radiation exposure time may also help increase procedure throughput.



Reference:
1. Outback Catheter - Procedural Success Rates - Data on file, Cordis.

FRONTRUNNER® XP CTO Catheter

Chronic Total Occlusion (CTO) Crossing Technology

Cross CTOs with confidence

Controlled blunt micro-dissection (BMD) technology creates a microchannel through a CTO and enables fast, safe and effective penetration and crossing of CTOs.

Facilitating guidewire placement.

Step 1

FRONTRUNNER® XP is easily delivered to the CTO, using the Micro Guide Catheter. The blunt tip engages the CTO, penetrating its proximal cap. The actuating jaws of the FRONTRUNNER® XP CTO Catheter delivers enough force to microdissect the plaque, minimalizing embolisation.

Step 2

Supported by the Micro Guide Catheter, the FRONTRUNNER® XP continues separating plaque to create a channel through the occlusion.

Step 3

Once a channel has been established, the Micro Guide Catheter allows a conventional guidewire to be placed across the CTO.

Minimizes risk of vessel perforation

A pathway for the Micro Guide Catheter (MGC) through the CTO is created by the FRONTRUNNER® XP's shapeable, atraumatic, actuating distal blunt tip.

Integrated system approach

Variable support is provided by advancing and retracting 4.5F Micro Guide Catheter.

Effective torque control

Braided catheter shaft enhances manoeuvrability and steerability.

Facilitating device delivery

Cordis **STABILIZER® guidewires**

The guidewires of choice for use with OUTBACK® LTD™

Versatility

Easy device deliverability and compatibility with the OUTBACK® LTD™ Re-Entry Catheter are assured by broad transitions and secure tip attachment.

Enhanced Lubricity

Exceptional surface lubricity is provided by the proximal DURAGLIDE™ PTFE Spray and distal PTFE Sleeve.

Atraumatic vessel entry and navigation

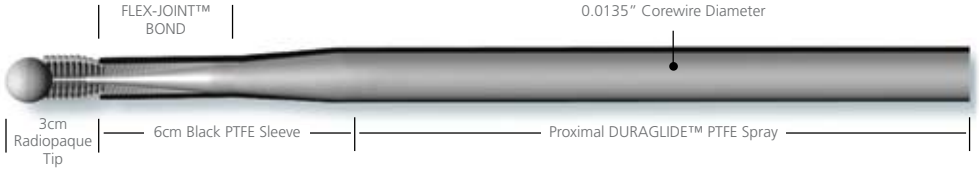
SuperSoft tip flexibility ensures that Stabilizer® is atraumatic in use.

Cordis **STABILIZER® Support Guidewire**

Support for the delivery of advanced peripheral devices in complex and tortuous anatomy

Cordis **STABILIZER® Extra-Support Guidewire**

When a higher level of support is needed for the most challenging peripheral interventions



Cordis **MICRO GUIDE CATHETER**

Providing the support for the FRONTRUNNER® XP

Excellent support

The torquable sheath provides support and facilitates delivery of the FRONTRUNNER® XP and guidewire to and from the occlusion.

Easy guide tip location

Clear positioning is provided by an atraumatic radiopaque distal tip with a fluoroscopic marker band.

Easy delivery

With a 4.5F crossing profile, delivery through the guiding catheter, sheath or vasculature is aided by the Micro Guide Catheter's torquable braided shaft with hydrophilic coating.

Meeting the challenges of longer femoropopliteal CTOs

SAVVY® LONG PTA Balloon Catheter

Easy navigation of the SFA and infrapopliteal vessels

- Low profile .018" balloons and tapered shaft (3.5F to 3.0F) for treating long diffuse lesions
- 4F sheath introducer compatibility on sizes up to 5x120mm
- Up to 220mm length balloons
- Lubricious silicone coating on catheter shaft, inner lumen and balloon
- Smooth TRANSTAPER™ tip-to-wire transition

The strength to handle calcified lesions

- High rated burst pressure (up to 15atm) for treating resistant calcified lesions
- Quadflex® balloon material that combines flexibility and durability

LONG S.M.A.R.T.® Nitinol Self-expanding Stent

S.M.A.R.T.® patients go the distance

- The lowest published binary restenosis data of any self-expanding nitinol stent in SFA at 4-year follow-up, leading to the highest patency rates
  - 79% of patients TLR free after 4 years
  - 59% of patients Binary Restenosis free after 4 years[2]
- Enhanced placement accuracy
  - 1mm flared ends for immediate wall appositioning
  - TruMark™ coil construction with counteractive compression forces
- Increasing, the length, increasing the legacy
  - Up to 150mm in length

Reference:
2. Duda et al. Sirocco 4 year results Presented at EuroPCR 200805.

Excellent clinical outcomes

With OUTBACK® LTD™

Jacobs et al.[3] published a retrospective analysis of the use of true lumen re-entry devices in 24 patients in whom the true lumen could not be re-entered using standard catheter and wire techniques. The true lumen re-entry device (either an OUTBACK® Catheter or a Pioneer™ Catheter) was used if access to the true lumen failed after 10 minutes of manipulation. True lumen re-entry was successful in all cases.

The total time of catheter manipulation required to achieve re-entry was <10 minutes and was routinely accomplished in <3 minutes. Overall mean fluoroscopy time was 38 minutes. All occlusions were stented and no cases required open repair.

According to the authors, their initial experience with true lumen re-entry catheters for treatment of CTOs suggests that the technical success rate for endovascular treatment of these lesions is enhanced by the use of these devices, particularly in the complex iliac occlusions. Precision and ease of treatment are important secondary benefits. They believe these devices are essential tools in their toolbox for endovascular treatment of patients with lower-extremity occlusive disease.

With FRONTRUNNER® XP

Mossop et al.[4] reported on a prospective study on 44 lesions in 36 patients using the FRONTRUNNER® XP catheter. Successful recanalization (defined as: restoration of lower limb perfusion and <30% residual stenosis of the arterial lumen) was achieved in 91% of cases (40/44). The four procedural failures occurred due to inability to access an iliac CTO due to excessive vessel tortuosity.

The time from the initial introduction of the guidewire to its removal or successful placement across the CTO was an average of 22 ± 24 minutes (range, 2-130 minutes).

In conclusion, the technique of Controlled Blunt Microdissection (CMD) is safe and effective for recanalizing resistant peripheral CTOs, of varying length, location, and degree of calcification, with a high procedural success rate. This provides an attractive solution to the problem posed by symptomatic CTOs that are refractory to revascularization with conventional endoluminal techniques, obviating the need for bypass surgery in these patients.

Reference:

3. Jacobs DL, Motaganahalli RL, Cox DE, True lumen re-entry devices facilitate subintimal angioplasty and stenting of total chronic occlusions: Initial report. *J Vasc Surg*. 2006;43(6):1291-6.
4. Mossop PJ, Amukotuwa SA and Whitbourn RJ. Controlled blunt microdissection for percutaneous recanalization of lower limb arterial chronic total occlusion: A single center experience. *Cath and Cardio Interv*. 2006;68:304-10.

Commitment to Professional Education

CCVI (Cordis Cardiac & Vascular Institute) www.ccvi-online.com

CCVI offers simulator and hands-on workshops, technology forums and scientific symposia promoting the treatment and understanding of Peripheral Vascular Disease (PVD). CCVI also offers access to the exclusive CTO training modules on select simulators. Please contact your local representative for more information.

CTO e-Learning module on CCVI-online www.ccvi-online.com

This online CTO programme will help you become familiar with two Cordis tools for treating chronic total occlusions (CTOs):

- The FRONTRUNNER® XP CTO Catheter, with MICRO GUIDE CATHETER
- The OUTBACK® LTD™ Re-Entry Catheter

You will also find case studies that offer clinical examples of how these devices have helped both patients and physicians. Finally, simulations will provide an opportunity to practice using the devices online.

ACTION (Atherosclerosis and Circulation-Training InformatiOn Network)

The **ACTION** programme is aimed at increasing the awareness and detection of PVD in clinical practice, as well as increasing the awareness of this condition amongst the general public. **ACTION** is being developed in association with vascular specialists and is supported by an educational grant from Cordis Endovascular.

Cordis offers a complete range of products with proven clinical evidence for the minimally-invasive treatment of lower limb disease. Our aim is to optimize outcomes for you and your patients.

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Ground breaking, Life changing™

Chronic Total Occlusion (CTO) Technologies

Re-open vital channels

Ordering information

OUTBACK® LTD™ Re-Entry Catheter			
Product code	Usable length (cm)	Sheath compatibility (f)	Crossing profile (f)
OTB42120	120	6	5.9

Cordis Stabilizer® Support Guidewire				
Product code	Diameter (inches)	Tip flexibility	Length (cm)	Tip shape
507 - 180S	0.014	SuperSoft	180	Straight
507 - 300S	0.014	SuperSoft	300	Straight

Cordis Stabilizer® Extra Support Guidewire				
Product code	Diameter (inches)	Tip flexibility	Length (cm)	Tip shape
527 - 180E	0.014	SuperSoft	180	Straight
527 - 300E	0.014	SuperSoft	300	Straight

FRONTRUNNER® XP CTO Catheter			
Product code	Usable length (cm)	Sheath compatibility (f)	Crossing profile (f)
FBS 3990	90	6	3.1
FBP 39140	140	6	3.1

Micro Guide Catheter				
Product code	Overall length	Usable length (cm)	Sheath compatibility (f)	Crossing profile (f)
MGC 3990	82	76	6	4.5
MGX 39140	132	126	6	4.5

SAVVY® LONG					
Product code	Balloon OD x length (mm x cm)	Rated burst pressure (atm)	Recommended sheath fit (F)	Shaft length (cm)	
				80	120
436-2012	2 x 12	15	4	S	L
436-2015	2 x 15	15	4	S	L
436-2022	2 x 22	15	4	S	L
436-2512	2.5 x 12	15	4	S	L
436-2512	2.5 x 15	15	4	S	L
436-2525	2.5 x 22	15	4	S	L
436-3012	3 x 12	15	4	S	L
436-3015	3 x 15	15	4	S	L
436-3022	3 x 22	15	4	S	L
436-3512	3.5 x 12	15	4	S	L
436-3515	3.5 x 15	15	4	S	L
436-3522	3.5 x 22	15	4	S	L
436-4012	4 x 12	15	4	S	L
436-4015	4 x 15	15	4	S	L
436-4022	4 x 22	15	4	S	L
436-5012	5 x 12	13	4	S	L
436-5015	5 x 15	13	4	S	L
436-5022	5 x 22	13	5	S	L
436-6012	6 x 12	12	4	S	L
436-6015	6 x 15	12	4	S	L
436-6022	6 x 22	12	4	S	L

LONG S.M.A.R.T.®				
Product code (Delivery system length: 120cm)	Stent configuration (D x L, mm)	Expanded stent diameter (mm)	Expanded stent length (mm)	Min-max vessel diameter (mm)
C06120MV	6 x 120	6	120	4-5
C07120MV	7 x 120	7	120	5-6
C08120MV	8 x 120	8	120	5-6
C06150MV	6 x 150	6	150	4-5
C07150MV	7 x 150	7	150	5-6
C081520MV	8 x 150	8	150	5-6

Important Information:
Prior to use, refer to the "Instructions for use" supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions. As part of the Cordis policy of continuous product development we reserve the right to change product specifications without prior notification.

Not for distribution in the USA

50 Year Anniversary

Cordis
PRODUCTS SERVICES OUTCOMES

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