PERIPHERAL U.S. PRODUCT CATALOG

August 2021

Medtronic
Further, Together

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DIRECTIONAL ATHERECTOMY SYSTEMS

HawkOne™
Directional Atherectomy
System

HawkOne™

Directional Atherectomy System

The versatile HawkOne™ device — the latest addition to the Medtronic directional atherectomy portfolio — restores blood flow in patients with peripheral arterial disease (PAD) by removing plaque from blocked arteries. The HawkOne device is a comprehensive system that treats all morphologies, including severe calcium, above and below the knee, and offers physicians the flexibility to create a channel or maximize luminal gain.

	Model Name	Reference Number	Vessel Diameter (mm)	Sheath Compatibility (F)	Crossing Profile (mm)	Working Length† (cm)	Effective Length** (cm)	Tip Length (cm)	Max. Cut Length (mm)	Packing Device
7 F	HawkOne LS | Standard Tip	H1-LS	3.5 to 7.0	7	2.6	114	107	6.6	50	■
7 F	HawkOne LX | Extended Tip	H1-LX	3.5 to 7.0	7	2.6	114	104	9.6	75	■
6 F	HawkOne M | Standard Tip	H1-M	3.0 to 7.0	6	2.2	135	129	5.9	40	■
6 F	HawkOne S | Extended Tip	H1-S	2.0 to 4.0	6	2.2	151	145	5.9	40	■

Max guidewire is 0.014″ for all HawkOne devices.

†Working length — distal end end of preloaded flush tool, in the proximal position, to the distal end of tip.
**Effective length — distal end of preloaded flush tool, in the proximal position, to the proximal end of cutter window.

TurboHawk™

Peripheral Plaque Excision System

The TurboHawk™ plaque excision system treats peripheral arterial disease (PAD) by removing soft to moderately calcified plaque buildup in leg arteries. This second–generation device uses a directional cutting blade to shave plaque from the vessel — maximizing luminal gain. The plaque is captured in the nosecone and safely removed from the vessel.

Product Name	Reference Number	Vessel Diameter (mm)	Sheath Compatibility† (F)	Crossing Profile (mm)	Working Length** (cm)	Effective Length†† (cm)	Tip Length (cm)	Max Cut Length (mm)	Packing Device
LX-M	TH-LX-M	3.5 to 7.0	7/8	2.7	113	104	9.0	75	■
SX-C	THS-SX-C	2.0 to 4.0	6	2.2	135	129	5.9	40	■
SS-CL	THS-SS-CL	2.0 to 4.0	6	2.2	149	145	3.9	20	

Max guidewire is 0.014" for all TurboHawk devices.

†Sheath compatibility — per the Instructions For Use, the large vessel devices with smooth cutter are compatible with 8 F sheaths. A physician survey of device usage indicated 7 F sheaths may have an internal diameter (ID) that will accommodate the crossing profile of the LX-M device. Data on file with manufacturer.
**Working length — distal end of strain relief to the distal end of tip.
††Effective length — distal end of strain relief to the proximal end of cutter window.

SilverHawk™

Peripheral Plaque Excision System

The first-generation SilverHawk™ plaque excision system treats peripheral arterial disease (PAD) by removing soft-to-mild plaque buildup in leg arteries. SilverHawk system technology uses a directional cutting blade to shave plaque from the vessel. The plaque is captured in the nosecone and safely removed from the vessel.

Product Name	Reference Number	Vessel Diameter (mm)	Sheath Compatibility (F)	Crossing Profile (mm)	Working Length† (cm)	Effective Length** (cm)	Tip Length (cm)	Max Cut Length (mm)	Packing Device
EXL	P4044	2.0 to 3.0	6	2.0	135	129	6.0	15	■
DS	P4028	1.5 to 2.0	6	1.9	135	132	2.6	10	

Max guidewire is 0.014" for all SilverHawk devices.

†Working length — distal end of strain relief to the distal end of tip.
**Effective length — distal end of strain relief to the proximal end of cutter window.

DRUG-COATED BALLOONS

IN.PACT™ Admiral™
Drug-Coated Balloon

IN.PACT™ AV
Drug-Coated Balloon

IN.PACT™ Admiral™

Drug-Coated Balloon

The IN.PACT™ Admiral™ Drug-Coated Balloon (DCB) is a clinically proven, primary endovascular therapy that treats femoropopliteal disease, reduces interventions, and preserves future treatment options.[1]

[1] Laird JA, Schneider PA, Jaff MR, et al. Long-Term Clinical Effectiveness of a Drug-Coated Balloon for the Treatment of Femoropopliteal Lesions. 5-year results from the IN.PACT SFA Trial. *Circ Cardiovasc Interv.* June 2019;12(6):e007702.

TECHNICAL SPECIFICATIONS

Paclitaxel drug dose	3.5 µg/mm^2
Excipient	Urea
Balloon diameters	4.0–7.0 mm
Balloon lengths	40, 60, 80, 120, 150, 200, 250 mm[†]
Balloon fold configuration	4.0 mm: 3 folds 5.0, 6.0, and 7.0 mm: 6 folds

Catheter design	Over the wire (OTW)
Catheter lengths	80, 130 cm
Guidewire compatibility	0.035"
Nominal balloon pressure	8 atm: 40, 60, 80, 120, and 150 mm 5 atm: 200 and 250 mm

[†]120, 150, 200, and 250 mm lengths are not offered on the 7.0 mm diameter balloon.

Reference Number Usable Length 80 cm	Reference Number Usable Length 130 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
ADM 040 040 08P	ADM 040 040 13P	4.0	40	5	8	14
ADM 040 060 08P	ADM 040 060 13P	4.0	60	5	8	14
ADM 040 080 08P	ADM 040 080 13P	4.0	80	5	8	14
ADM 040 120 08P	ADM 040 120 13P	4.0	120	5	8	14
ADM 040 150 08P	ADM 040 150 13P	4.0	150	5	8	14
ADM 040 200 08P	ADM 040 200 13P	4.0	200	5	5	11
ADM 040 250 08P	ADM 040 250 13P	4.0	250	5	5	11
ADM 050 040 08P	ADM 050 040 13P	5.0	40	6	8	14
ADM 050 060 08P	ADM 050 060 13P	5.0	60	6	8	14
ADM 050 080 08P	ADM 050 080 13P	5.0	80	6	8	14
ADM 050 120 08P	ADM 050 120 13P	5.0	120	6	8	14
ADM 050 150 08P	ADM 050 150 13P	5.0	150	6	8	14
ADM 050 200 08P	ADM 050 200 13P	5.0	200	6	5	11
ADM 050 250 08P	ADM 050 250 13P	5.0	250	6	5	11
ADM 060 040 08P	ADM 060 040 13P	6.0	40	6	8	14
ADM 060 060 08P	ADM 060 060 13P	6.0	60	6	8	14
ADM 060 080 08P	ADM 060 080 13P	6.0	80	6	8	14
ADM 060 120 08P	ADM 060 120 13P	6.0	120	6	8	14
ADM 060 150 08P	ADM 060 150 13P	6.0	150	6	8	14
ADM 060 200 08P	ADM 060 200 13P	6.0	200	6	5	11
ADM 060 250 08P	ADM 060 250 13P	6.0	250	6	5	11
ADM 070 040 08P	ADM 070 040 13P	7.0	40	7	8	14
ADM 070 060 08P	ADM 070 060 13P	7.0	60	7	8	14
ADM 070 080 08P	ADM 070 080 13P	7.0	80	7	8	14

IN.PACT™ AV

Drug-Coated Balloon

The IN.PACT AV Drug-Coated Balloon (DCB) is a clinically demonstrated endovascular therapy for AV fistula maintenance for patients with end-stage renal disease (ESRD). It delivers an antiproliferative drug (paclitaxel) to the vessel to inhibit AV fistula stenosis. The IN.PACT AV DCB may enable dramatically fewer AV fistula reinterventions, which could keep patients out of the hospital longer.[1] It can make an impact clinically, financially,[2] and emotionally.

[1] Lookstein RA, et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. *N Engl J Med.* 2020;383:733-42. DOI: 10.1056/NEJMoa1914617. Highlighted results reported at both 180 and 210 days.

[2] Thamer M, Lee TC, Wasse H, et al. Medicare Costs Associated With Arteriovenous Fistulas Among US Hemodialysis Patients. *Am J Kidney Dis.* July 1, 2018;72(1):10-18.

Ref. Number Usable Length 40 cm	Ref. Number Usable Length 80 cm	Ref. Number Usable Length 130 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
IAV04004004P	IAV04004008P	-	4.0	40	5	8	14
IAV04006004P	IAV04006008P	-	4.0	60	5	8	14
IAV04008004P	IAV04008008P	-	4.0	80	5	8	14
IAV04012004P	IAV04012008P	-	4.0	120	5	8	14
IAV05004004P	IAV05004008P	-	5.0	40	6	8	14
IAV05006004P	IAV05006008P	-	5.0	60	6	8	14
IAV05008004P	IAV05008008P	-	5.0	80	6	8	14
IAV05012004P	IAV05012008P	-	5.0	120	6	8	14
IAV06004004P	IAV06004008P	-	6.0	40	6	8	14
IAV06006004P	IAV06006008P	-	6.0	60	6	8	14
IAV06008004P	IAV06008008P	-	6.0	80	6	8	14
IAV06012004P	IAV06012008P	-	6.0	120	6	8	14
IAV07004004P	IAV07004008P	-	7.0	40	7	8	14
IAV07006004P	IAV07006008P	-	7.0	60	7	8	14
IAV07008004P	IAV07008008P	-	7.0	80	7	8	14
IAV08004004P	IAV08004008P	IAV08004013P	8.0	40	7	8	10
IAV08006004P	IAV08006008P	IAV08006013P	8.0	60	7	8	10
IAV08008004P	IAV08008008P	IAV08008013P	8.0	80	7	8	10
IAV09004004P	IAV09004008P	IAV09004013P	9.0	40	7	8	10
IAV09006004P	IAV09006008P	IAV09006013P	9.0	60	7	8	10
IAV09008004P	IAV09008008P	IAV09008013P	9.0	80	7	8	10
IAV10004004P	IAV10004008P	IAV10004013P	10.0	40	7	6	9
IAV12004004P	IAV12004008P	IAV12004013P	12.0	40	9	6	9

ENDOAVF

Ellipsys™
Vascular Access System

Ellipsys™

Vascular Access System

Designed for end-stage renal disease (ESRD) patients requiring hemodialysis, the Ellipsys system is a unique single-catheter, nonsurgical option for physicians to create an arteriovenous (AV) fistula, a traditionally invasive procedure that — until the advent of percutaneous AVF technology — had not changed in more than 50 years. It transforms the standard surgical AV fistula creation into a reproducible, minimally invasive procedure that requires no implant or suture, and allows patients to leave with just a single needle stick.[1]

[1] Hull JE, Jennings WC, Cooper RI, Waheed U, Schaefer ME, Narayan R. The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *J Vasc Interv Radiol.* February 2018;29(2):149-158.e5.

Reference Number	Description	Recommended Introducer Sheath (F)	Guidewire Compatibility (in)	Vessel Size (mm)
AMI 6005	Ellipsys catheter†	6**	0.014	2.0 +

†Requires AMI-1001 Ellipsys™ Power Controller (110-240v, 50/60HZ, reusable).

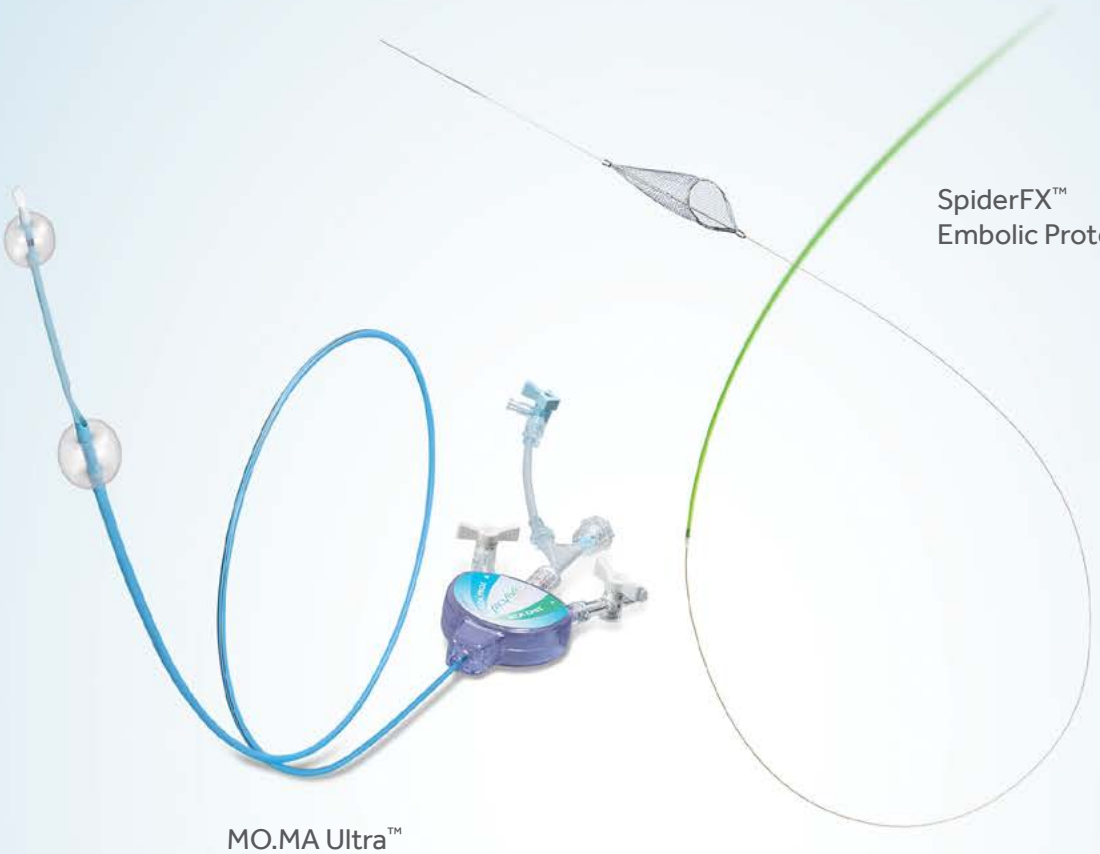
**Maximum sheath length 10 cm. Prior to using a specific sheath, ask your sales or clinical representative if the sheath is compatible with the Ellipsys catheter. Sheaths that are too long may cover the working portion at the device tip.

Ellipsys Vascular Access System Accessories

Reference Number	Description	Units per Pack
AMI1001	Ellipsys Power Controller	1 each
K21-00022	EndoAVF Access Kit Hydrophilic Sheath††	5 each

††Includes 21 ga x 7 cm echo-tip micropuncture needle, 0.018" guidewire, and 6F x 10 cm thin-walled radial artery sheath. Additional devices: Crossing Needle Model No. AMI-3000.

EMBOLIC PROTECTION



SpiderFX™
Embolic Protection Device

MO.MA Ultra™
Proximal Cerebral Protection Device

SpiderFX™

Embolic Protection Device

The SpiderFX™ device is used to capture and remove debris that becomes dislodged during an interventional procedure. The SpiderFX device can be delivered over any 0.014" or 0.018" guidewire, or through any 0.035" catheter.† The SpiderFX device has the broadest indication among distal embolic filters. It is indicated for use in carotid arteries, coronary saphenous vein bypass grafts, and lower extremity procedures.

†Lower extremity procedures.

			Capture Wire		Delivery End	Recovery End	Guide Catheter/ Sheath
Reference Number	Filter Size (mm)	Target Vessel Size (mm)	Wire Length OTW/RX (cm)	Wire Diameter (in/mm)	Crossing Profile (F)	Diameter (F)	Minimum ID (in)
SPD2-US-030-320	3.0	3.0 SVG & Carotid	320/190	0.014/0.36	3.2	4.2	0.066
SPD2-US-040-320	4.0	3.1–4.0 SVG & Carotid	320/190	0.014/0.36	3.2	4.2	0.066
SPD2-US-050-320	5.0	4.1–5.0 SVG & Carotid 3.0-4.0 Lower Extremity	320/190	0.014/0.36	3.2	4.2	0.066
SPD2-US-060-320	6.0	4.5–6.0 SVG & Carotid 3.5-5.0 Lower Extremity	320/190	0.014/0.36	3.2	4.2	0.066
SPD2-US-070-320	7.0	5.5–6.0 SVG 5.5–7.0 Carotid 4.5–6.0 Lower Extremity	320/190	0.014/0.36	3.2	4.2	0.066

The 320 cm wire lengths are scored to allow for snapping down to a 190 cm wire length if desired.

MO.MA Ultra™

Proximal Cerebral Protection Device

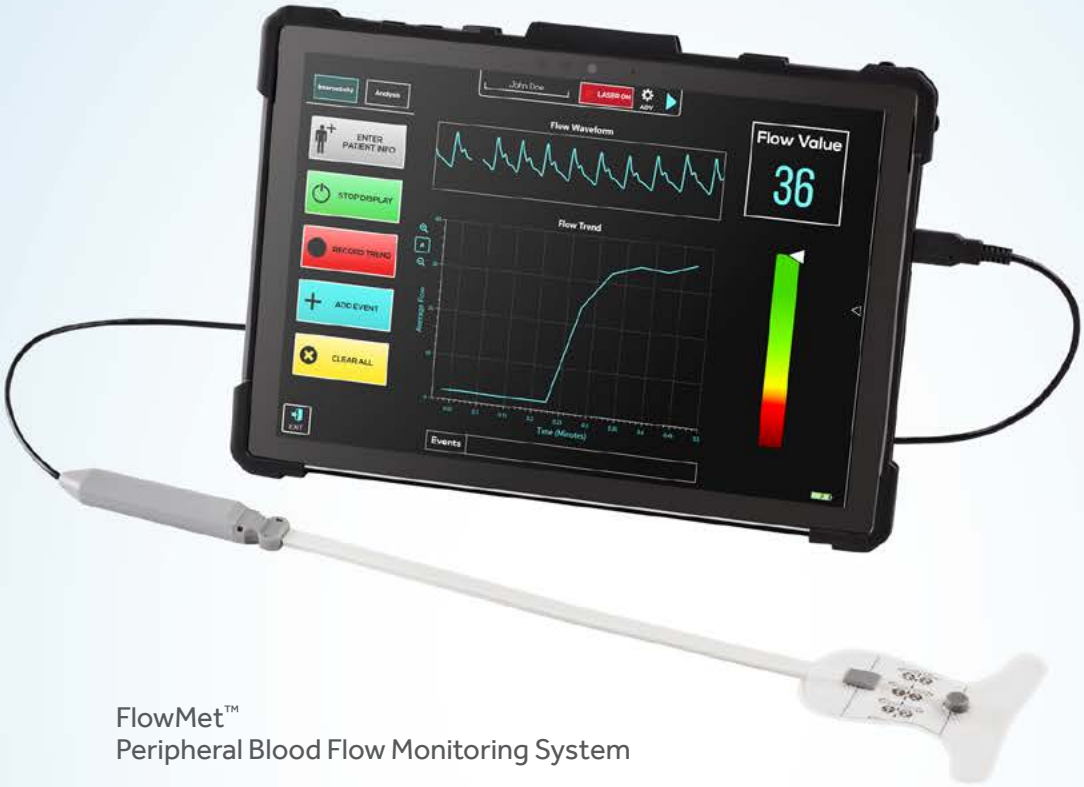
Use the MO.MA Ultra™ proximal cerebral protection device to contain and remove all sizes of debris that can dislodge during interventional procedures in the carotid arteries. The MO.MA Ultra device with double-occlusion balloon system allows for proximal embolic protection to be established prior to crossing a carotid lesion.

TECHNICAL SPECIFICATIONS

Balloon material	Compliant elastomeric rubber
Balloon marker distance	6 cm
Recommended guidewire	0.035" (0.89 mm)
Balloon occlusion range	5–13 mm diameter (CCA prox. balloon) 3–6 mm diameter (ECA dist. balloon)

Reference Number	Minimum Sheath Size (F)	Inner Diameter of the Working Channel
MUS0130069X6	9	0.083"/2.12 mm

INTRAPROCEDURAL
MONITORING



FlowMet™
Peripheral Blood Flow Monitoring System

FlowMet™

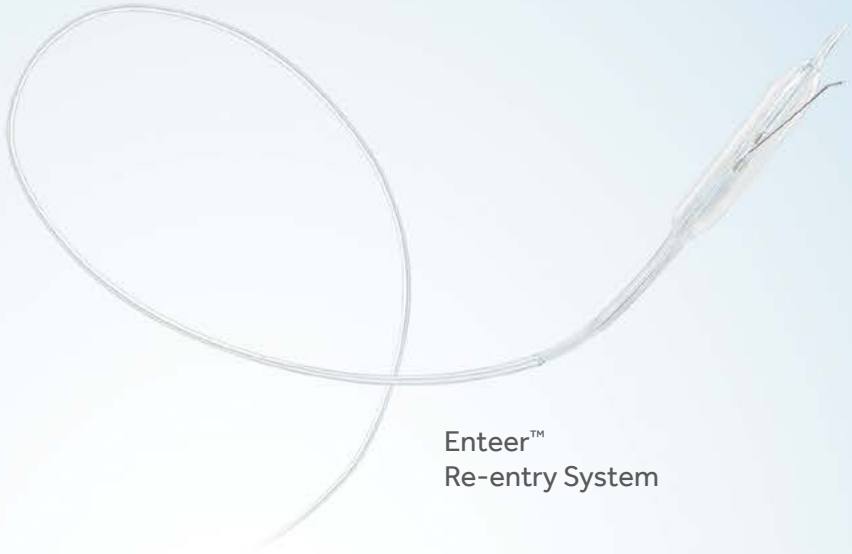
Peripheral Blood Flow Monitoring System

When it comes to gauging the impact of a peripheral arterial disease (PAD) revascularization, angiography cannot fully assess distal blood flow.[1,2] Is there a way to reduce procedural uncertainty by directly measuring blood flow? The FlowMet System provides continuous and objective blood flow measurements on the table, offering treating physicians a way to monitor changes throughout the intervention. The system supplements angiography for real-time procedural insight,[3] and is noninvasive, simple, and easy to use.

[1] Kim AH, Shevitz AJ, Morrow KL, et al. Characterizing tissue perfusion after lower extremity intervention using two-dimensional color-coded digital subtraction angiography. *J Vasc Surg.* November 2017;66(5):1464-1472.
[2] Lou W-S, Su H-B, Huang K-Y, et seq. Evaluation of Distal Hemodynamic Changes of Lower Extremity after Endovascular Treatment. *J Vasc Interv Radiol.* June 2016;27(6):852-858.
[3] Data on file at Medtronic.

Reference Number	Description	GTIN
FMET-IM-SYS	FlowMet Peripheral Blood Flow Monitoring System	00860001276121
FMET-IM-RSC	FlowMet Peripheral Blood Flow Monitoring System Reusable Cable	00860001276138
FMET-IM-SENS-5	FlowMet Peripheral Blood Flow Monitoring System Disposable Sensors (5 pack)	10860001276111

CTO DEVICES



Enteer™
Re-entry System

Viance™
Crossing Catheter

Viance™

Crossing Catheter

The Viance™ crossing catheter is designed to efficiently cross chronic total occulsions via the true lumen. The low-profile catheter, with its fast-spin torque handle, is designed to find small microchannels in a lesion, while leaving the control of crossing in the physician's hands.

Reference Number	Description	Working Length (cm)	Guidewire Compatibility (in)	Crossing Profile (max in)	Sheath Compatibility
VNC-FX-150	Flexible	150	0.014	0.038	5 F
VNC-SD-150	Standard	150	0.014	0.038	5 F

Enteer™ Re-entry System

The Enteer™ system, consisting of the Enteer re-entry balloon catheter and the Enteer guidewire, provides the physician with control to reliably target the true lumen from the subintimal channel above or below the knee. The Enteer catheter's unique balloon design self-orients toward the true lumen within the subintimal space when inflated. Offset exit ports are located on either side of the device, allowing the Enteer guidewire to reenter into the true lumen.

Re-entry Balloon Catheter

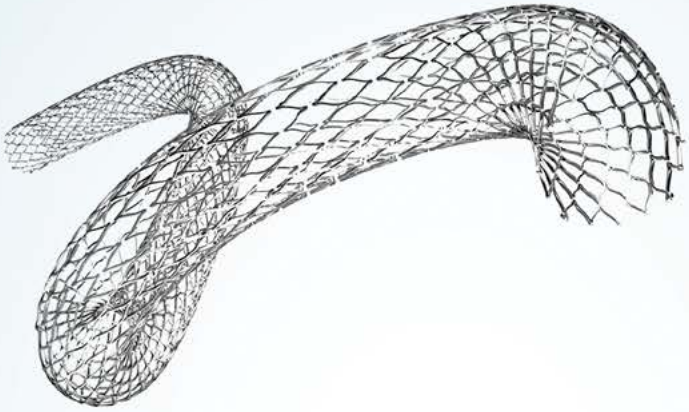
Reference Number		Balloon Size (W x H x L mm)	Working Length (cm)	Guidewire Compatibility (in)	Crossing Profile (max in)	Sheath Compatibility
ENB-375-20-135	ATK	3.75 x 1.5 x 20	135	≤ 0.018	0.066	5 F
ENB-275-20-150	BTK	2.75 x 1.0 x 20	150	≤ 0.018	0.066	5 F

Guidewire

Reference Number	Description	Diameter (in)	Length (cm)	Tip Reach (mm)
ENW-FX-014-300	Flexible	0.014	300	1.5
ENW-SD-014-300	Standard	0.014	300	1.5
ENW-SF-014-300	Stiff	0.014	300	2.5

STENTS

EverFlex™
Self-expanding Peripheral
Stent System



Visi-Pro™
Balloon-expandable Peripheral
Stent System

EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System

You asked for simple deployment with reduced variability — and we delivered. When you need to stent, trust the precision, strength, and flexibility of the #1 peripheral stent†: EverFlex self-expanding peripheral stent with Entrust delivery system. The Entrust™ system is a one-handed stent delivery system with a low 5 F profile. This low profile was achieved without compromising the design of the EverFlex™ stent or the 0.035" guidewire compatibility. The device was engineered specifically for control and accuracy[1] based on physician feedback during extensive interviews and procedural observations. The device is indicated for use in the superficial femoral artery and/or proximal popliteal arteries, and is available in lengths from 20 mm to 150 mm.

†EverFlex Self-expanding Peripheral Stent, U.S. only. DRG market share data for peripheral self-expanding bare metal stents.
[1] Data on file at Medtronic.

CATHETER LENGTH			STENT SIZE		COMPATIBILITY		
80 cm Reference Number	120 cm Reference Number	150 cm Reference Number	Diameter (mm)	Length (mm)	Recomm. Introducer Sheath (F)	Guidewire (in)	Recomm. Lumen Size (mm)
EVD35-06-020-080	EVD35-06-020-120	EVD35-06-020-150	6	20	5	0.035	4.5–5.5
EVD35-06-040-080	EVD35-06-040-120	EVD35-06-040-150	6	40	5	0.035	4.5–5.5
EVD35-06-060-080	EVD35-06-060-120	EVD35-06-060-150	6	60	5	0.035	4.5–5.5
EVD35-06-080-080	EVD35-06-080-120	EVD35-06-080-150	6	80	5	0.035	4.5–5.5
EVD35-06-100-080	EVD35-06-100-120	EVD35-06-100-150	6	100	5	0.035	4.5–5.5
EVD35-06-120-080	EVD35-06-120-120	EVD35-06-120-150	6	120	5	0.035	4.5–5.5
EVD35-06-150-080	EVD35-06-150-120	EVD35-06-150-150	6	150	5	0.035	4.5-5.5
EVD35-07-020-080	EVD35-07-020-120	EVD35-07-020-150	7	20	5	0.035	5.5–6.5
EVD35-07-040-080	EVD35-07-040-120	EVD35-07-040-150	7	40	5	0.035	5.5–6.5
EVD35-07-060-080	EVD35-07-060-120	EVD35-07-060-150	7	60	5	0.035	5.5–6.5
EVD35-07-080-080	EVD35-07-080-120	EVD35-07-080-150	7	80	5	0.035	5.5–6.5
EVD35-07-100-080	EVD35-07-100-120	EVD35-07-100-150	7	100	5	0.035	5.5–6.5
EVD35-07-120-080	EVD35-07-120-120	EVD35-07-120-150	7	120	5	0.035	5.5–6.5
EVD35-07-150-080	EVD35-07-150-120	EVD35-07-150-150	7	150	5	0.035	5.5–6.5
EVD35-08-020-080	EVD35-08-020-120	EVD35-08-020-150	8	20	5	0.035	6.5–7.5
EVD35-08-040-080	EVD35-08-040-120	EVD35-08-040-150	8	40	5	0.035	6.5–7.5
EVD35-08-060-080	EVD35-08-060-120	EVD35-08-060-150	8	60	5	0.035	6.5–7.5
EVD35-08-080-080	EVD35-08-080-120	EVD35-08-080-150	8	80	5	0.035	6.5–7.5
EVD35-08-100-080	EVD35-08-100-120	EVD35-08-100-150	8	100	5	0.035	6.5–7.5
EVD35-08-120-080	EVD35-08-120-120	EVD35-08-120-150	8	120	5	0.035	6.5–7.5
EVD35-08-150-080	EVD35-08-150-120	EVD35-08-150-150	8	150	5	0.035	6.5–7.5

Each system includes one stent and delivery catheter system.

EverFlex™

Self-expanding Peripheral Stent System

When you need to stent, trust the precision, strength, and flexibility of the EverFlex stent,[1,2] indicated for use in the superficial femoral and proximal popliteal arteries (SFA/PPA), common iliac, and/or external iliac arteries. The EverFlex stent is available in lengths from 20 to 200 mm (SFA/PPA) or 20–120 mm (iliac). The broad size matrix, all deliverable through a 6 F catheter, provides the most appropriate single-stent fit. Peak-to-peak connection nodes disperse force uniformly, enhancing durability, while the spiral-cell connection and three-wave peak design optimize flexibility.

[1] Data on file at Medtronic.

[2] Rocha-Singh KJ, Bosiers M, Schultz G, et al. A single stent strategy in patients with lifestyle limiting claudication: 3-year results from the Durability II trial. *Catheter Cardiovasc Interv.* July 2015;86(1):164-170.

CATHETER LENGTH		STENT SIZE		COMPATIBILITY		
Reference Number 80 cm	Reference Number 120 cm	Diameter (mm)	Length (mm)	Recomm. Introducer Sheath (F)	Guidewire (in)	Recomm. Lumen Size (mm)
PRB35-06-020-080	PRB35-06-020-120	6	20	6	0.035	4.5–5.5
PRB35-06-030-080	PRB35-06-030-120	6	30	6	0.035	4.5–5.5
PRB35-06-040-080	PRB35-06-040-120	6	40	6	0.035	4.5–5.5
PRB35-06-060-080	PRB35-06-060-120	6	60	6	0.035	4.5–5.5
PRB35-06-080-080	PRB35-06-080-120	6	80	6	0.035	4.5–5.5
PRB35-06-100-080	PRB35-06-100-120	6	100	6	0.035	4.5–5.5
PRB35-06-120-080	PRB35-06-120-120	6	120	6	0.035	4.5–5.5
PRB35-06-150-080	PRB35-06-150-120	6	150	6	0.035	4.5–5.5
N/A	PRB35-06-200-120	6	200	6	0.035	4.5–5.5
PRB35-07-020-080	PRB35-07-020-120	7	20	6	0.035	5.5–6.5
PRB35-07-030-080	PRB35-07-030-120	7	30	6	0.035	5.5–6.5
PRB35-07-040-080	PRB35-07-040-120	7	40	6	0.035	5.5–6.5
PRB35-07-060-080	PRB35-07-060-120	7	60	6	0.035	5.5–6.5
PRB35-07-080-080	PRB35-07-080-120	7	80	6	0.035	5.5–6.5
PRB35-07-100-080	PRB35-07-100-120	7	100	6	0.035	5.5–6.5
PRB35-07-120-080	PRB35-07-120-120	7	120	6	0.035	5.5–6.5
PRB35-07-150-080	PRB35-07-150-120	7	150	6	0.035	5.5–6.5
N/A	PRB35-07-200-120	7	200	6	0.035	5.5–6.5
PRB35-08-020-080	PRB35-08-020-120	8	20	6	0.035	6.5–7.5
PRB35-08-030-080	PRB35-08-030-120	8	30	6	0.035	6.5–7.5
PRB35-08-040-080	PRB35-08-040-120	8	40	6	0.035	6.5–7.5
PRB35-08-060-080	PRB35-08-060-120	8	60	6	0.035	6.5–7.5
PRB35-08-080-080	PRB35-08-080-120	8	80	6	0.035	6.5–7.5
PRB35-08-100-080	PRB35-08-100-120	8	100	6	0.035	6.5–7.5
PRB35-08-120-080	PRB35-08-120-120	8	120	6	0.035	6.5–7.5
PRB35-08-150-080	PRB35-08-150-120	8	150	6	0.035	6.5–7.5
N/A	PRB35-08-200-120	8	200	6	0.035	6.5–7.5

Each system includes one stent and delivery catheter system.

Protégé™ EverFlex™

Self-expanding Biliary Stent System

The Protégé™ EverFlex™ stent system is designed for the palliative treatment of malignant neoplasms in the biliary tree. The stent is made of nitinol and comes pre-mounted on an over-the-wire delivery system. The proximal and distal ends of the stent have tantalum radiopaque markers for enhanced visibility.

Reference Number	Unconstrained Stent Diameter (mm)	Unconstrained Stent Length (mm)	Rec. Lumen Size (mm)	Usable Length (cm)	Sheath Size (F)	Guidewire Acceptance (in)	Outside Diameter (in)
PRB35-05-020-080	5	20	3.5–4.5	80	6	0.035	0.079
PRB35-05-020-120	5	20	3.5–4.5	120	6	0.035	0.079
PRB35-05-030-080	5	30	3.5–4.5	80	6	0.035	0.079
PRB35-05-030-120	5	30	3.5–4.5	120	6	0.035	0.079
PRB35-05-040-080	5	40	3.5–4.5	80	6	0.035	0.079
PRB35-05-040-120	5	40	3.5–4.5	120	6	0.035	0.079
PRB35-05-060-080	5	60	3.5–4.5	80	6	0.035	0.079
PRB35-05-060-120	5	60	3.5–4.5	120	6	0.035	0.079
PRB35-05-080-080	5	80	3.5–4.5	80	6	0.035	0.079
PRB35-05-080-120	5	80	3.5–4.5	120	6	0.035	0.079
PRB35-05-100-080	5	100	3.5–4.5	80	6	0.035	0.079
PRB35-05-100-120	5	100	3.5–4.5	120	6	0.035	0.079
PRB35-05-120-080	5	120	3.5–4.5	80	6	0.035	0.079
PRB35-05-120-120	5	120	3.5–4.5	120	6	0.035	0.079

Each system includes one stent and delivery catheter system.

Protégé™ GPS™

Self-expanding Peripheral and Biliary Stent System

The Protégé™ GPS™ self-expanding peripheral and biliary stent system is a self-expanding, nitinol stent system indicated for the common and external iliac arteries (excluding 14 mm sizes), and designed for the palliative treatment of malignant neoplasms in the biliary tree. The stent is made of a nickel titanium alloy (nitinol) and comes pre-mounted on a 6 F over-the-wire delivery system. The stent is cut from a nitinol tube into an open lattice design and has tantalum radiopaque markers at the proximal and distal ends of the stent.

Reference Number	Unconstrained Stent Diameter (mm)	Unconstrained Stent Length (mm)	Rec. Lumen Size (mm)	Usable Length (cm)	Sheath Size (F)	Guidewire Acceptance (in)	Outside Diameter (in)
SERB65-09-20-80	9	20	7.5–8.5	80	6	0.035	0.079
SERB65-09-30-80	9	30	7.5–8.5	80	6	0.035	0.079
SERB65-09-40-80	9	40	7.5–8.5	80	6	0.035	0.079
SERB65-09-60-80	9	60	7.5–8.5	80	6	0.035	0.079
SERB65-09-80-80	9	80	7.5–8.5	80	6	0.035	0.079
SERB65-10-20-80	10	20	8.5–9.5	80	6	0.035	0.079
SERB65-10-30-80	10	30	8.5–9.5	80	6	0.035	0.079
SERB65-10-40-80	10	40	8.5–9.5	80	6	0.035	0.079
SERB65-10-60-80	10	60	8.5–9.5	80	6	0.035	0.079
SERB65-10-80-80	10	80	8.5–9.5	80	6	0.035	0.079
SERB65-12-20-80	12	20	9.5–11.0	80	6	0.035	0.079
SERB65-12-30-80	12	30	9.5–11.0	80	6	0.035	0.079
SERB65-12-40-80	12	40	9.5–11.0	80	6	0.035	0.079
SERB65-12-60-80	12	60	9.5–11.0	80	6	0.035	0.079
SERB65-12-80-80	12	80	9.5–11.0	80	6	0.035	0.079
SERB65-09-20-120	9	20	7.5–8.5	120	6	0.035	0.079
SERB65-09-30-120	9	30	7.5–8.5	120	6	0.035	0.079
SERB65-09-40-120	9	40	7.5–8.5	120	6	0.035	0.079
SERB65-09-60-120	9	60	7.5–8.5	120	6	0.035	0.079
SERB65-09-80-120	9	80	7.5–8.5	120	6	0.035	0.079
SERB65-10-20-120	10	20	8.5–9.5	120	6	0.035	0.079
SERB65-10-30-120	10	30	8.5–9.5	120	6	0.035	0.079
SERB65-10-40-120	10	40	8.5–9.5	120	6	0.035	0.079
SERB65-10-60-120	10	60	8.5–9.5	120	6	0.035	0.079
SERB65-10-80-120	10	80	8.5–9.5	120	6	0.035	0.079
SERB65-12-20-120	12	20	9.5–11.0	120	6	0.035	0.079
SERB65-12-30-120	12	30	9.5–11.0	120	6	0.035	0.079
SERB65-12-40-120	12	40	9.5–11.0	120	6	0.035	0.079
SERB65-12-60-120	12	60	9.5–11.0	120	6	0.035	0.079
SERB65-12-80-120	12	80	9.5–11.0	120	6	0.035	0.079
Biliary Only							
SERB65-14-20-80	14	20	11.5–13.0	80	6	0.035	0.079
SERB65-14-30-80	14	30	11.5–13.0	80	6	0.035	0.079
SERB65-14-40-80	14	40	11.5–13.0	80	6	0.035	0.079
SERB65-14-60-80	14	60	11.5–13.0	80	6	0.035	0.079
SERB65-14-80-80	14	80	11.5–13.0	80	6	0.035	0.079
SERB65-14-20-120	14	20	11.5–13.0	120	6	0.035	0.079
SERB65-14-30-120	14	30	11.5–13.0	120	6	0.035	0.079
SERB65-14-40-120	14	40	11.5–13.0	120	6	0.035	0.079
SERB65-14-60-120	14	60	11.5–13.0	120	6	0.035	0.079
SERB65-14-80-120	14	80	11.5–13.0	120	6	0.035	0.079

Each system includes one stent and delivery catheter system.

Protégé™ RX

Self-expanding Carotid Stent System

The Protégé™ RX stent system is designed for carotid artery stenting. The nitinol stent comes pre-mounted on a 6 F, 0.014" rapid exchange delivery system. The proximal and distal ends of the stent have tantalum radiopaque markers for enhanced visibility.

Reference Number	Unconstrained Stent Diameter (mm)	Unconstrained Stent Length (mm)	Recommended Lumen Size (mm)	Usable Catheter Length (cm)	Sheath Size (F)	Guidewire Acceptance (in)
Straight						
SECX-6-20-135	6	20	4.5–5.5	135	6	0.014
SECX-6-30-135	6	30	4.5–5.5	135	6	0.014
SECX-6-40-135	6	40	4.5–5.5	135	6	0.014
SECX-6-60-135	6	60	4.5–5.5	135	6	0.014
SECX-7-20-135	7	20	5.5–6.5	135	6	0.014
SECX-7-30-135	7	30	5.5–6.5	135	6	0.014
SECX-7-40-135	7	40	5.5–6.5	135	6	0.014
SECX-7-60-135	7	60	5.5–6.5	135	6	0.014
SECX-8-20-135	8	20	6.5–7.5	135	6	0.014
SECX-8-30-135	8	30	6.5–7.5	135	6	0.014
SECX-8-40-135	8	40	6.5–7.5	135	6	0.014
SECX-8-60-135	8	60	6.5–7.5	135	6	0.014
SECX-9-20-135	9	20	7.5–8.5	135	6	0.014
SECX-9-30-135	9	30	7.5–8.5	135	6	0.014
SECX-9-40-135	9	40	7.5–8.5	135	6	0.014
SECX-9-60-135	9	60	7.5–8.5	135	6	0.014
SECX-10-20-135	10	20	8.5–9.5	135	6	0.014
SECX-10-30-135	10	30	8.5–9.5	135	6	0.014
SECX-10-40-135	10	40	8.5–9.5	135	6	0.014
SECX-10-60-135	10	60	8.5–9.5	135	6	0.014
Tapered						
SECX-8-6-30-135	8/6	30	(6.5–7.5)–(4.5–5.5)	135	6	0.014
SECX-8-6-40-135	8/6	40	(6.5–7.5)–(4.5–5.5)	135	6	0.014
SECX-10-7-30-135	10/7	30	(8.5–9.5)–(5.5–6.5)	135	6	0.014
SECX-10-7-40-135	10/7	40	(8.5–9.5)–(5.5–6.5)	135	6	0.014

Each system includes one stent and delivery catheter system.

Visi-Pro™

Balloon-expandable Peripheral Stent System

The Visi-Pro™ stent system is indicated for use in the common and external iliac arteries. It is made from a stainless steel tube that is cut into an open lattice design and has tantalum radiopaque markers at the proximal and distal ends of the stent. The stent is mounted (crimped) onto a tightly folded balloon catheter and expanded and deployed by inflating the balloon.

CATHETER LENGTH		STENT SIZE		BALLOON	COMPATIBILITY	
Reference Number 80 cm	Reference Number 135 cm	Diameter (mm)	Length (mm)	Balloon Length (mm)	Rec. Introducer Sheath (F)	Guidewire (in)
PXB35-05-12-080	-	5	12	15	6†	0.035
PXB35-05-17-080	PXB35-05-17-135	5	17	20	6†	0.035
PXB35-05-27-080	PXB35-05-27-135	5	27	30	6†	0.035
PXB35-05-37-080	PXB35-05-37-135	5	37	40	6†	0.035
PXB35-05-57-080	PXB35-05-57-135	5	57	60	6†	0.035
PXB35-06-12-080	-	6	12	15	6†	0.035
PXB35-06-17-080	PXB35-06-17-135	6	17	20	6†	0.035
PXB35-06-27-080	PXB35-06-27-135	6	27	30	6†	0.035
PXB35-06-37-080	PXB35-06-37-135	6	37	40	6†	0.035
PXB35-06-57-080	PXB35-06-57-135	6	57	60	6†	0.035
PXB35-07-12-080	-	7	12	15	6†	0.035
PXB35-07-17-080	PXB35-07-17-135	7	17	20	6†	0.035
PXB35-07-27-080	PXB35-07-27-135	7	27	30	6†	0.035
PXB35-07-37-080	PXB35-07-37-135	7	37	40	6†	0.035
PXB35-07-57-080	PXB35-07-57-135	7	57	60	6†	0.035
PXB35-08-17-080	PXB35-08-17-135	8	17	20	6†	0.035
PXB35-08-27-080	PXB35-08-27-135	8	27	30	6†	0.035
PXB35-08-37-080	PXB35-08-37-135	8	37	40	6†	0.035
PXB35-08-57-080	PXB35-08-57-135	8	57	60	6†	0.035
PXB35-09-17-080	PXB35-09-17-135	9	17	20	7	0.035
PXB35-09-27-080	PXB35-09-27-135	9	27	30	7	0.035
PXB35-09-37-080	PXB35-09-37-135	9	37	40	7	0.035
PXB35-09-57-080	PXB35-09-57-135	9	57	60	7	0.035
PXB35-10-17-080	PXB35-10-17-135	10	17	20	7	0.035
PXB35-10-27-080	PXB35-10-27-135	10	27	30	7	0.035
PXB35-10-37-080	PXB35-10-37-135	10	37	40	7	0.035
PXB35-10-57-080	PXB35-10-57-135	10	57	60	7	0.035

†6 F = 0.085" I.D.

Each system includes one stent and delivery catheter system.

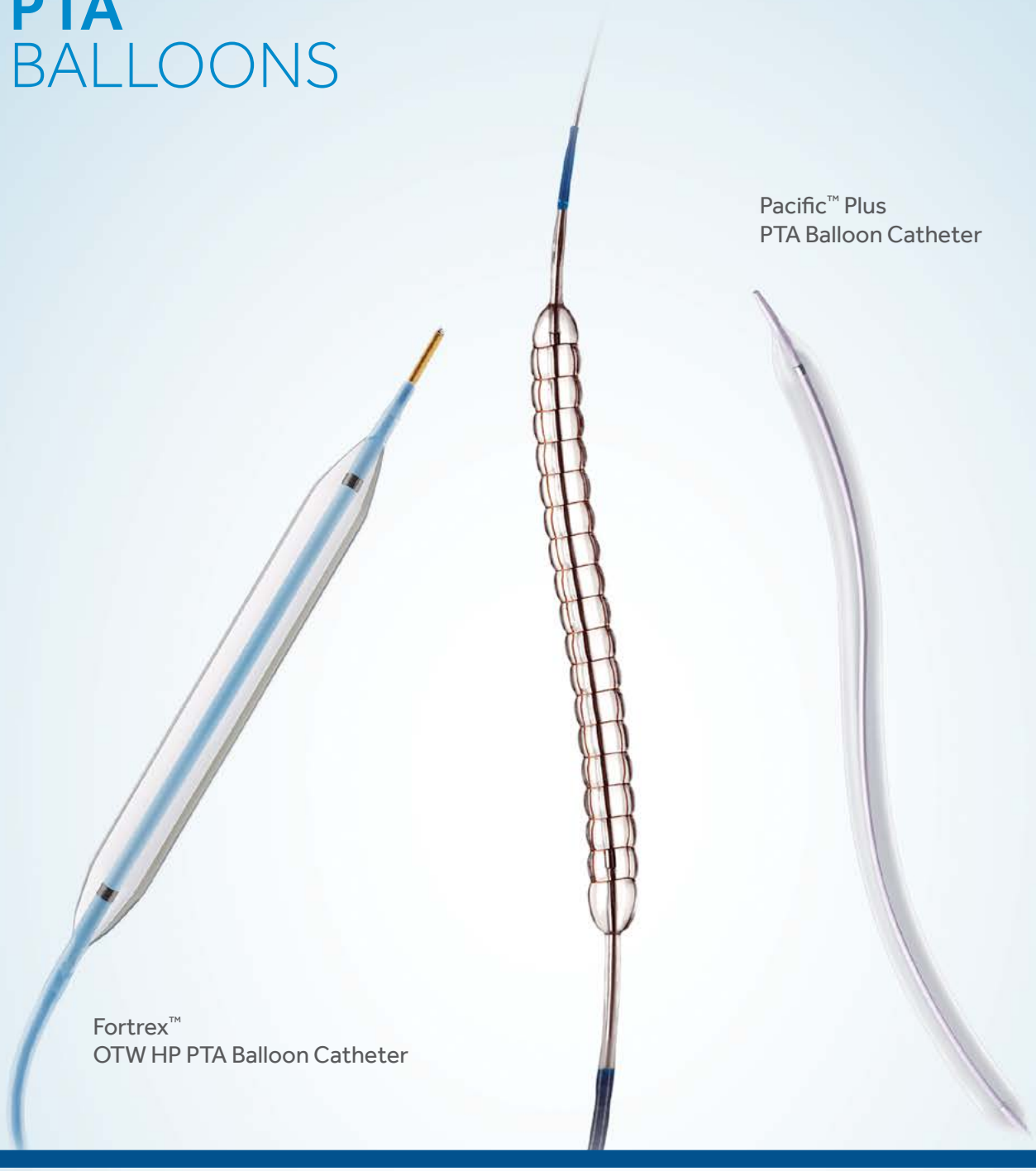
IntraStent™

Biliary Stent System

The IntraStent™ biliary stent system consists of unmounted large diameter stents designed for flexiblity and strength, while remaining low profile. These stents are designed to be manually crimped onto a noncompliant PTA balloon catheter that is indicated for biliary stent expansion.

Reference Number	UNEXPANDED STENT SIZE		EXPANDED STENT SIZE	
	Diameter (mm)	Length (mm)	Diameter (mm)	Length (mm)
IntraStent™ DoubleStrut LD Biliary Stent				
S15-16 (90-1431-000)	3.8	16.0	9, 10, 11, 12	16.0
S15-26 (90-1431-001)	3.8	26.0	9, 10, 11, 12	26.0
S15-36 (90-1431-002)	3.8	36.0	9, 10, 11, 12	36.0
S15-56 (90-1431-003)	3.8	56.0	9, 10, 11, 12	56.0
S15-76 (90-1431-004)	3.8	76.0	9, 10, 11, 12	76.0
IntraStent™ Mega LD Biliary Stent				
S17-16 (90-2313-000)	3.8	16.0	9, 10, 11, 12	16.0
S17-26 (90-2313-001)	3.8	26.0	9, 10, 11, 12	26.0
S17-36 (90-2313-002)	3.8	36.0	9, 10, 11, 12	36.0
IntraStent™ Max LD Biliary Stent				
S18-16 (90-2319-000)	4.5	16.0	12	16.0
S18-26 (90-2319-001)	4.5	26.0	12	26.0
S18-36 (90-2319-002)	4.5	36.0	12	36.0

PTA
BALLOONS



Pacific™ Plus
PTA Balloon Catheter

Fortrex™
OTW HP PTA Balloon Catheter

EverCross™

OTW PTA Balloon Catheter

The EverCross™ balloon catheter is a 0.035" balloon that is specially designed for optimal pushability, and it is available in a broad range of balloon sizes.

Reference Number Usable Length 40 cm	Reference Number Usable Length 80 cm	Reference Number Usable Length 135 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recomm. Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
-	AB35W03020080	AB35W03020135	3.0	20	5	10	20
-	AB35W03030080	AB35W03030135	3.0	30	5	10	20
-	AB35W03040080	AB35W03040135	3.0	40	5	10	20
-	AB35W03060080	AB35W03060135	3.0	60	5	10	20
-	AB35W03080080	AB35W03080135	3.0	80	5	10	20
-	AB35W03100080	AB35W03100135	3.0	100	5	10	20
-	AB35W03120080	AB35W03120135	3.0	120	5	10	20
-	AB35W03150080	AB35W03150135	3.0	150	5	10	20
-	AB35W03200080	AB35W03200135	3.0	200	5	10	20
-	AB35W04020080	AB35W04020135	4.0	20	5	10	20
-	AB35W04030080	AB35W04030135	4.0	30	5	10	20
-	AB35W04040080	AB35W04040135	4.0	40	5	10	20
-	AB35W04060080	AB35W04060135	4.0	60	5	10	20
-	AB35W04080080	AB35W04080135	4.0	80	5	10	20
-	AB35W04100080	AB35W04100135	4.0	100	5	10	20
-	AB35W04120080	AB35W04120135	4.0	120	5	10	20
-	AB35W04150080	AB35W04150135	4.0	150	5	10	20
-	AB35W04200080	AB35W04200135	4.0	200	5	10	20
AB35W05020040	AB35W05020080	AB35W05020135	5.0	20	5	10	20
AB35W05030040	AB35W05030080	AB35W05030135	5.0	30	5	10	20
AB35W05040040	AB35W05040080	AB35W05040135	5.0	40	5	10	20
AB35W05060040	AB35W05060080	AB35W05060135	5.0	60	5	10	20
AB35W05080040	AB35W05080080	AB35W05080135	5.0	80	5	10	20
-	AB35W05100080	AB35W05100135	5.0	100	5	10	20
AB35W05120040	AB35W05120080	AB35W05120135	5.0	120	5	10	16
-	AB35W05150080	AB35W05150135	5.0	150	5	10	16
-	AB35W05200080	AB35W05200135	5.0	200	5	10	16
AB35W06020040	AB35W06020080	AB35W06020135	6.0	20	5	8	14
-	AB35W06030080	AB35W06030135	6.0	30	5	8	14
AB35W06040040	AB35W06040080	AB35W06040135	6.0	40	5	8	14
-	AB35W06060080	AB35W06060135	6.0	60	5	8	14
AB35W06080040	AB35W06080080	AB35W06080135	6.0	80	5	8	14
-	AB35W06100080	AB35W06100135	6.0	100	5	8	14
AB35W06120040	AB35W06120080	AB35W06120135	6.0	120	5	8	12
-	AB35W06150080	AB35W06150135	6.0	150	5	8	12
-	AB35W06200080	AB35W06200135	6.0	200	6	8	11
AB35W07020040	AB35W07020080	AB35W07020135	7.0	20	5	7	14
-	AB35W07030080	AB35W07030135	7.0	30	5	7	14
AB35W07040040	AB35W07040080	AB35W07040135	7.0	40	5	7	14
AB35W07060040	AB35W07060080	AB35W07060135	7.0	60	6	7	14
-	AB35W07080080	AB35W07080135	7.0	80	6	7	14
-	AB35W07100080	AB35W07100135	7.0	100	6	7	14
-	AB35W07120080	AB35W07120135	7.0	120	6	7	10
-	AB35W07150080	AB35W07150135	7.0	150	6	7	10
-	AB35W07200080	AB35W07200135	7.0	200	6	7	10
AB35W08020040	AB35W08020080	AB35W08020135	8.0	20	6	7	14
-	AB35W08030080	AB35W08030135	8.0	30	6	7	14
AB35W08040040	AB35W08040080	AB35W08040135	8.0	40	6	7	14
AB35W08060040	AB35W08060080	AB35W08060135	8.0	60	6	7	14
-	AB35W08080080	AB35W08080135	8.0	80	6	7	14
-	AB35W09020080	AB35W09020135	9.0	20	6	7	12
-	AB35W09030080	AB35W09030135	9.0	30	6	7	12
-	AB35W09040080	AB35W09040135	9.0	40	6	7	12
-	AB35W09060080	AB35W09060135	9.0	60	6	7	12
-	AB35W09080080	AB35W09080135	9.0	80	6	7	12
-	AB35W10020080	AB35W10020135	10.0	20	6	7	11
-	AB35W10030080	AB35W10030135	10.0	30	6	7	11
-	AB35W10040080	AB35W10040135	10.0	40	6	7	11
-	AB35W10060080	AB35W10060135	10.0	60	7	7	11
-	AB35W12020080	AB35W12020135	12.0	20	7	7	10
-	AB35W12040080	AB35W12040135	12.0	40	7	7	10
-	AB35W12060080	AB35W12060135	12.0	60	7	7	10

Admiral Xtreme™

PTA Balloon Catheter OTW 0.035"

Treat longer peripheral arterial disease (PAD) lesions above the knee with Admiral Xtreme™ PTA balloon catheter. Offered in 250 and 300 mm lengths, with 0.035" guidewire compatibility, featuring large inflation lumen for rapid inflation and deflation.

TECHNICAL SPECIFICATIONS

Catheter design	Over the wire (OTW)
Balloon material	Flexitec™ Xtreme
Balloon marker	2 swaged (zero profile) platinum-iridium
Usable shaft lengths	80, 130 cm
Shaft diameter	5 F–5.3 F
Guidewire compatibility	0.035"

Reference Number Usable Length 80 cm	Reference Number Usable Length 130 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recom. Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
ADM 040 250 080	ADM 040 250 130	4.0	250	5	6	14
ADM 040 300 080	ADM 040 300 130	4.0	300	5	6	14
ADM 050 250 080	ADM 050 250 130	5.0	250	5	6	14
ADM 050 300 080 L	ADM 050 300 130 L	5.0	300	5	6	14
ADM 060 250 080 L	ADM 060 250 130 L	6.0	250	5	6	12
ADM 060 300 080 L	ADM 060 300 130 L	6.0	300	5	6	12
ADM 070 250 080	ADM 070 250 130	7.0	250	6	6	12

Fortrex™

0.035" OTW HP PTA Balloon Catheter

The Fortrex™ PTA balloon is the next-generation high pressure solution for AV access, and it is also intended for use in the peripheral vascular system. Engineered specifically for peak performance at rated burst pressure, the Fortrex balloon offers the deliverability, predictability, and procedural efficiency desired by physicians.

Reference Number Usable Length 40 cm	Reference Number Usable Length 80 cm	Reference Number Usable Length 135 mm	Balloon Diameter (mm)	Balloon Length (mm)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Recommended Introducer Sheath (F)
A35HPV04020040	A35HPV04020080	A35HPV04020135	4.0	20	12	24	6
A35HPV04040040	A35HPV04040080	A35HPV04040135	4.0	40	12	24	6
A35HPV04080040	A35HPV04080080	A35HPV04080135	4.0	80	12	24	6
A35HPV04100040	A35HPV04100080	A35HPV04100135	4.0	100	12	24	6
A35HPV05020040	A35HPV05020080	A35HPV05020135	5.0	20	12	24	6
A35HPV05040040	A35HPV05040080	A35HPV05040135	5.0	40	12	24	6
A35HPV05080040	A35HPV05080080	A35HPV05080135	5.0	80	12	24	6
A35HPV05100040	A35HPV05100080	A35HPV05100135	5.0	100	12	24	6
A35HPV06020040	A35HPV06020080	A35HPV06020135	6.0	20	12	24	6
A35HPV06040040	A35HPV06040080	A35HPV06040135	6.0	40	12	24	6
A35HPV06080040	A35HPV06080080	A35HPV06080135	6.0	80	12	23	6
A35HPV06100040	A35HPV06100080	A35HPV06100135	6.0	100	12	23	6
A35HPV07020040	A35HPV07020080	A35HPV07020135	7.0	20	9	20	6
A35HPV07040040	A35HPV07040080	A35HPV07040135	7.0	40	9	20	6
A35HPV07080040	A35HPV07080080	A35HPV07080135	7.0	80	9	20	6
A35HPV07100040	A35HPV07100080	A35HPV07100135	7.0	100	9	20	6
A35HPV08040040	A35HPV08040080	A35HPV08040135	8.0	40	9	20	6
A35HPV08080040	A35HPV08080080	A35HPV08080135	8.0	80	9	19	6
A35HPV08100040	A35HPV08100080	A35HPV08100135	8.0	100	9	18	6
A35HPV09040040	A35HPV09040080	A35HPV09040135	9.0	40	9	18	7
A35HPV09080040	A35HPV09080080	A35HPV09080135	9.0	80	9	18	7
A35HPV10040040	A35HPV10040080	A35HPV10040135	10.0	40	8	16	7
A35HPV10080040	A35HPV10080080	A35HPV10080135	10.0	80	8	16	7
A35HPV12040040	A35HPV12040080	A35HPV12040135	12.0	40	8	14	7
A35HPV12080040	A35HPV12080080	A35HPV12080135	12.0	80	7	12	7

Pacific™ Plus

PTA Catheter OTW 0.018"

Realize more access options when you choose the Pacific™ Plus PTA catheter OTW 0.018", with its versatile shaft lengths. The proprietary balloon technology allows for enhanced crossing for treating lesions and the improved shaft design speeds deflation following treatment.

TECHNICAL SPECIFICATIONS

Catheter design	Over the wire (OTW), coaxial shaft	Usable shaft lengths	90, 130, 150,180 cm
Balloon coating	Hydrophilic	Shaft diameter	4–5 F
Balloon marker	2 swaged, platinum-iridium	Maximum guidewire compatibility	0.018"

Reference Number Usable Length 90 cm	Reference Number Usable Length 130 cm	Reference Number Usable Length 150 cm	Reference Number Usable Length 180 cm	Balloon Diameter (mm)	Balloon Length (mm)	Minimum Sheath Inner Diameter (F)	Nominal Pressure (atm)	RBP (atm)
PCP 020 020 090	PCP 020 020 130	PCP 020 020 150	PCP 020 020 180	2.00	20	4	8	22
PCP 020 040 090	PCP 020 040 130	PCP 020 040 150	PCP 020 040 180	2.00	40	4	8	22
PCP 020 060 090	PCP 020 060 130	PCP 020 060 150	PCP 020 060 180	2.00	60	4	8	22
PCP 020 080 090	PCP 020 080 130	PCP 020 080 150	PCP 020 080 180	2.00	80	4	8	22
PCP 020 120 090	PCP 020 120 130	PCP 020 120 150	PCP 020 120 180	2.00	120	4	8	22
PCP 020 150 090	PCP 020 150 130	PCP 020 150 150	PCP 020 150 180	2.00	150	4	8	22
PCP 025 020 090	PCP 025 020 130	PCP 025 020 150	PCP 025 020 180	2.50	20	4	8	16
PCP 025 040 090	PCP 025 040 130	PCP 025 040 150	PCP 025 040 180	2.50	40	4	8	16
PCP 025 060 090	PCP 025 060 130	PCP 025 060 150	PCP 025 060 180	2.50	60	4	8	16
PCP 025 080 090	PCP 025 080 130	PCP 025 080 150	PCP 025 080 180	2.50	80	4	8	16
PCP 025 120 090	PCP 025 120 130	PCP 025 120 150	PCP 025 120 180	2.50	120	4	8	16
PCP 025 150 090	PCP 025 150 130	PCP 025 150 150	PCP 025 150 180	2.50	150	4	8	16
PCP 030 020 090	PCP 030 020 130	PCP 030 020 150	PCP 030 020 180	3.00	20	4	8	16
PCP 030 040 090	PCP 030 040 130	PCP 030 040 150	PCP 030 040 180	3.00	40	4	8	16
PCP 030 060 090	PCP 030 060 130	PCP 030 060 150	PCP 030 060 180	3.00	60	4	8	16
PCP 030 080 090	PCP 030 080 130	PCP 030 080 150	PCP 030 080 180	3.00	80	4	8	16
PCP 030 120 090	PCP 030 120 130	PCP 030 120 150	PCP 030 120 180	3.00	120	4	8	16
PCP 030 150 090	PCP 030 150 130	PCP 030 150 150	PCP 030 150 180	3.00	150	4	8	16
PCP 035 020 090	PCP 035 020 130	PCP 035 020 150	PCP 035 020 180	3.50	20	4	8	16
PCP 035 040 090	PCP 035 040 130	PCP 035 040 150	PCP 035 040 180	3.50	40	4	8	16
PCP 035 060 090	PCP 035 060 130	PCP 035 060 150	PCP 035 060 180	3.50	60	4	8	16
PCP 035 080 090	PCP 035 080 130	PCP 035 080 150	PCP 035 080 180	3.50	80	4	8	16
PCP 035 120 090	PCP 035 120 130	PCP 035 120 150	PCP 035 120 180	3.50	120	4	8	16
PCP 035 150 090	PCP 035 150 130	PCP 035 150 150	PCP 035 150 180	3.50	150	4	8	16
PCP 040 020 090	PCP 040 020 130	PCP 040 020 150	PCP 040 020 180	4.00	20	4	8	14
PCP 040 040 090	PCP 040 040 130	PCP 040 040 150	PCP 040 040 180	4.00	40	4	8	14
PCP 040 060 090	PCP 040 060 130	PCP 040 060 150	PCP 040 060 180	4.00	60	4	8	14
PCP 040 080 090	PCP 040 080 130	PCP 040 080 150	PCP 040 080 180	4.00	80	4	8	14
PCP 040 120 090	PCP 040 120 130	PCP 040 120 150	PCP 040 120 180	4.00	120	4	8	14
PCP 050 020 090	PCP 050 020 130	-	PCP 050 020 180	5.00	20	4	8	14
PCP 050 040 090	PCP 050 040 130	-	PCP 050 040 180	5.00	40	4	8	14
PCP 050 060 090	PCP 050 060 130	-	PCP 050 060 180	5.00	60	4	8	14
PCP 050 080 090	PCP 050 080 130	-	PCP 050 080 180	5.00	80	4	8	14
PCP 050 120 090	PCP 050 120 130	-	PCP 050 120 180	5.00	120	4	8	14
PCP 060 020 090	PCP 060 020 130	-	PCP 060 020 180	6.00	20	4	8	14
PCP 060 040 090	PCP 060 040 130	-	PCP 060 040 180	6.00	40	4	8	14
PCP 060 060 090	PCP 060 060 130	-	PCP 060 060 180	6.00	60	4	8	14
PCP 060 080 090	PCP 060 080 130	-	PCP 060 080 180	6.00	80	4	8	14
PCP 060 120 090	PCP 060 120 130	-	PCP 060 120 180	6.00	120	4	8	14
PCP 070 020 090	PCP 070 020 130	-	PCP 070 020 180	7.00	20	4	8	12
PCP 070 040 090	PCP 070 040 130	-	PCP 070 040 180	7.00	40	4	8	12
PCP 070 060 090	PCP 070 060 130	-	PCP 070 060 180	7.00	60	4	8	12
PCP 070 080 090	PCP 070 080 130	-	PCP 070 080 180	7.00	80	5	8	12
PCP 070 120 090	PCP 070 120 130	-	PCP 070 120 180	7.00	120	5	8	12

Pacific™ Xtreme

PTA Balloon Catheter OTW 0.018"

Treat longer lesions with the Pacific™ Xtreme PTA balloon catheter OTW 0.018" that is offered in lengths from 150 to 300 mm. These balloons are well-suited for use in treating long lesions in the femoral and popliteal vessels.

TECHNICAL SPECIFICATIONS

Catheter design	Over the wire (OTW), coaxial shaft
Balloon material	Flexitec™ Xtreme
Balloon coating	Hydrophilic
Balloon marker	2 swaged, platinum-iridium
Usable shaft lengths	90, 130 cm
Shaft diameter	3.9 F-4.2 F
Guidewire compatibility	0.018"

Reference Number Usable Length 90 cm	Reference Number Usable Length 130 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
PCU 040 150 090	PCU 040 150 130	4.0	150	4	6	14
PCU 040 200 090	PCU 040 200 130	4.0	200	4	6	14
PCU 040 250 090	PCU 040 250 130	4.0	250	4	6	14
PCU 040 300 090	PCU 040 300 130	4.0	300	4	6	14
PCU 050 150 090	PCU 050 150 130	5.0	150	4	6	14
PCU 050 200 090	PCU 050 200 130	5.0	200	4	6	14
PCU 050 250 090	PCU 050 250 130	5.0	250	5	6	14
PCU 050 300 090	PCU 050 300 130	5.0	300	5	6	14
PCU 060 150 090	PCU 060 150 130	6.0	150	5	6	12
PCU 060 200 090	PCU 060 200 130	6.0	200	5	6	12
PCU 060 250 090	PCU 060 250 130	6.0	250	5	6	12
PCU 060 300 090	PCU 060 300 130	6.0	300	5	6	12
PCU 070 150 090	PCU 070 150 130	7.0	150	5	6	12
PCU 070 200 090	PCU 070 200 130	7.0	200	5	6	12
PCU 070 250 090	PCU 070 250 130	7.0	250	5	6	12

NanoCross™ Elite

0.014" OTW PTA Balloon Dilatation Catheter

Go deeper into the anatomy and across difficult lesions with NanoCross™ Elite balloon catheter. Its seamless design from balloon to tip offers efficient energy transfer.

Reference Number Usable Length 90 cm	Reference Number Usable Length 150 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recomm. Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
AB14W015020090	AB14W015020150	1.5	20	4	8	14
AB14W015040090	AB14W015040150	1.5	40	4	8	14
AB14W020020090	AB14W020020150	2.0	20	4	8	14
AB14W020040090	AB14W020040150	2.0	40	4	8	14
AB14W020060090	AB14W020060150	2.0	60	4	8	14
AB14W020080090	AB14W020080150	2.0	80	4	8	14
AB14W020100090	AB14W020100150	2.0	100	4	8	14
AB14W020120090	AB14W020120150	2.0	120	4	8	14
AB14W020150090	AB14W020150150	2.0	150	4	8	14
AB14W020210090	AB14W020210150	2.0 (proximal)/1.5 (distal)	210	4	8	14
AB14W025020090	AB14W025020150	2.5	20	4	8	14
AB14W025040090	AB14W025040150	2.5	40	4	8	14
AB14W025060090	AB14W025060150	2.5	60	4	8	14
AB14W025080090	AB14W025080150	2.5	80	4	8	14
AB14W025100090	AB14W025100150	2.5	100	4	8	14
AB14W025120090	AB14W025120150	2.5	120	4	8	14
AB14W025150090	AB14W025150150	2.5	150	4	8	14
AB14W025210090	AB14W025210150	2.5 (proximal)/2.0 (distal)	210	4	8	14
AB14W030020090	AB14W030020150	3.0	20	4	8	14
AB14W030040090	AB14W030040150	3.0	40	4	8	14
AB14W030060090	AB14W030060150	3.0	60	4	8	14
AB14W030080090	AB14W030080150	3.0	80	4	8	14
AB14W030100090	AB14W030100150	3.0	100	4	8	14
AB14W030120090	AB14W030120150	3.0	120	4	8	14
AB14W030150090	AB14W030150150	3.0	150	4	8	14
AB14W030210090	AB14W030210150	3.0 (proximal)/2.5 (distal)	210	4	8	14
AB14W035020090	AB14W035020150	3.5	20	4	8	14
AB14W035040090	AB14W035040150	3.5	40	4	8	14
AB14W035060090	AB14W035060150	3.5	60	4	8	14
AB14W035080090	AB14W035080150	3.5	80	4	8	14
AB14W035100090	AB14W035100150	3.5	100	4	8	14
AB14W035120090	AB14W035120150	3.5	120	4	8	14
AB14W035150090	AB14W035150150	3.5	150	4	8	14
AB14W035210090	AB14W035210150	3.5 (proximal)/3.0 (distal)	210	4	8	14
AB14W040020090	AB14W040020150	4.0	20	4	8	14
AB14W040040090	AB14W040040150	4.0	40	4	8	14
AB14W040060090	AB14W040060150	4.0	60	4	8	14
AB14W040080090	AB14W040080150	4.0	80	4	8	14
AB14W040100090	AB14W040100150	4.0	100	4	8	14
AB14W040120090	AB14W040120150	4.0	120	4	8	14
AB14W040150090	AB14W040150150	4.0	150	4	8	14
AB14W040210090	AB14W040210150	4.0 (proximal)/3.5 (distal)	210	4	8	14
AB14W050020090	AB14W050020150	5.0	20	5	8	14
AB14W050040090	AB14W050040150	5.0	40	5	8	14
AB14W050060090	AB14W050060150	5.0	60	5	8	14
AB14W050080090	AB14W050080150	5.0	80	5	8	14
AB14W050100090	AB14W050100150	5.0	100	5	8	14
AB14W050120090	AB14W050120150	5.0	120	5	8	14
AB14W050150090	AB14W050150150	5.0	150	5	8	14
AB14W050200090	AB14W050200150	5.0	200	5	8	14
AB14W060020090	AB14W060020150	6.0	20	5	8	14
AB14W060040090	AB14W060040150	6.0	40	5	8	14
AB14W060060090	AB14W060060150	6.0	60	5	8	14
AB14W060080090	AB14W060080150	6.0	80	5	8	14
AB14W060100090	AB14W060100150	6.0	100	5	8	14
AB14W060120090	AB14W060120150	6.0	120	5	8	14
AB14W060150090	AB14W060150150	6.0	150	5	8	14
AB14W060200090	AB14W060200150	6.0	200	6	8	14

RapidCross™

PTA Rapid Exchange Balloon Dilatation Catheter

Reach for the RapidCross™ PTA rapid exchange balloon dilatation catheter when you need to reach more distal lesions in the small vessels below the knee. This catheter is the Medtronic solution for a rapid exchange balloon with 0.014" guidewire capability.

Reference Number Usable Length 90 cm	Reference Number Usable Length 170 cm	Balloon Diameter (mm)	Balloon Length (mm)	Recomm. Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
A14BX020020090	A14BX020020170	2.0	20	4	8	14
A14BX020040090	A14BX020040170	2.0	40	4	8	14
A14BX020060090	A14BX020060170	2.0	60	4	8	14
A14BX020080090	A14BX020080170	2.0	80	4	8	14
A14BX020100090	A14BX020100170	2.0	100	4	8	14
A14BX020120090	A14BX020120170	2.0	120	4	8	14
A14BX020150090	A14BX020150170	2.0	150	4	8	14
A14BX020210090	A14BX020210170	2.0 (proximal)/1.5 (distal)	210	4	8	14
A14BX025020090	A14BX025020170	2.5	20	4	8	14
A14BX025040090	A14BX025040170	2.5	40	4	8	14
A14BX025060090	A14BX025060170	2.5	60	4	8	14
A14BX025080090	A14BX025080170	2.5	80	4	8	14
A14BX025100090	A14BX025100170	2.5	100	4	8	14
A14BX025120090	A14BX025120170	2.5	120	4	8	14
A14BX025150090	A14BX025150170	2.5	150	4	8	14
A14BX025210090	A14BX025210170	2.5 (proximal)/2.0 (distal)	210	4	8	14
A14BX030020090	A14BX030020170	3.0	20	4	8	14
A14BX030040090	A14BX030040170	3.0	40	4	8	14
A14BX030060090	A14BX030060170	3.0	60	4	8	14
A14BX030080090	A14BX030080170	3.0	80	4	8	14
A14BX030100090	A14BX030100170	3.0	100	4	8	14
A14BX030120090	A14BX030120170	3.0	120	4	8	14
A14BX030150090	A14BX030150170	3.0	150	4	8	14
A14BX030210090	A14BX030210170	3.0 (proximal)/2.5 (distal)	210	4	8	14
A14BX035020090	A14BX035020170	3.5	20	4	8	14
A14BX035040090	A14BX035040170	3.5	40	4	8	14
A14BX035060090	A14BX035060170	3.5	60	4	8	14
A14BX035080090	A14BX035080170	3.5	80	4	8	14
A14BX035100090	A14BX035100170	3.5	100	4	8	14
A14BX035120090	A14BX035120170	3.5	120	4	8	14
A14BX035150090	A14BX035150170	3.5	150	4	8	14
A14BX035210090	A14BX035210170	3.5 (proximal)/3.0 (distal)	210	4	8	14
A14BX040020090	A14BX040020170	4.0	20	4	8	14
A14BX040040090	A14BX040040170	4.0	40	4	8	14
A14BX040060090	A14BX040060170	4.0	60	4	8	14
A14BX040080090	A14BX040080170	4.0	80	4	8	14
A14BX040100090	A14BX040100170	4.0	100	4	8	14
A14BX040120090	A14BX040120170	4.0	120	4	8	14
A14BX040150090	A14BX040150170	4.0	150	4	8	14
A14BX040210090	A14BX040210170	4.0 (proximal)/3.5 (distal)	210	4	8	14

PTA
SPECIALTY BALLOON

Chocolate™*
PTA Balloon Catheter

*Third party brands are trademarks of their respective owners.

Chocolate™*

PTA Balloon Catheter

The Chocolate™* PTA balloon is designed to minimize vessel trauma, dissections, and the need for bailout stenting above or below the knee. The balloon's unique nitinol constraining structure creates pillows and grooves that provide a predictable, uniform, and atraumatic dilatation.

Reference Number	Balloon Diameter (mm)	Balloon Length (mm)	Catheter Length (cm)	Guidewire (in)	Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
CB1415025040OTW	2.5	40	150	0.014"	5	9	14
CB1415025080OTW	2.5	80	150	0.014"	5	9	14
CB1415025120OTW	2.5	120	150	0.014"	5	9	14
CB1415030040OTW	3.0	40	150	0.014"	5	9	14
CB1415030080OTW	3.0	80	150	0.014"	5	9	14
CB1415030120OTW	3.0	120	150	0.014"	5	9	14
CB1413535040OTW	3.5	40	135	0.014"	5	9	14
CB1413535080OTW	3.5	80	135	0.014"	5	9	14
CB1413535120OTW	3.5	120	135	0.014"	5	9	14
CB1413540040OTW	4.0	40	135	0.014"	5	9	14
CB1413540080OTW	4.0	80	135	0.014"	5	9	14
CB1413540120OTW	4.0	120	135	0.014"	5	9	14
CB1812050040OTW	5.0	40	120	0.018"	6	6	12
CB1812050080OTW	5.0	80	120	0.018"	6	6	12
CB1812050120OTW	5.0	120	120	0.018"	6	6	12
CB1812060040OTW	6.0	40	120	0.018"	6	6	12
CB1812060080OTW	6.0	80	120	0.018"	6	6	12
CB1812060120OTW	6.0	120	120	0.018"	6	6	12

INFUSION THERAPY

Cragg-McNamara™
Valved Infusion Catheters

Cragg-McNamara™

Valved Infusion Catheter

Cragg-McNamara™ catheter is a 4 or 5 F single-lumen catheter with a proprietary valved tip, which gives the option to to infuse without a guidewire in place.

Reference Number	Diameter (mm)	Usable Length (cm)	Infusion Length (cm)	Max. Guidewire (in)
41032-01	4	40	10	0.035
41033-01	4	40	20	0.035
41034-01	4	65	5	0.035
41035-01	4	65	10	0.035
41036-01	4	65	20	0.035
41037-01	4	100	5	0.035
41038-01	4	100	10	0.035
41039-01	4	100	20	0.035
41040-01	4	135	5	0.035
41041-01	4	135	10	0.035
41042-01	4	135	20	0.035
41043-01	5	40	5	0.038
41044-01	5	40	10	0.038
41045-01	5	40	20	0.038
41046-01	5	65	5	0.038
41047-01	5	65	10	0.038
41048-01	5	65	20	0.038
41049-01	5	100	5	0.038
41050-01	5	100	10	0.038
41051-01	5	100	20	0.038
41052-01	5	100	30	0.038
41053-01	5	100	40	0.038
41054-01	5	100	50	0.038
41055-01	5	135	5	0.038
41056-01	5	135	10	0.038
41057-01	5	135	20	0.038
41058-01	5	135	30	0.038
41059-01	5	135	40	0.038
41060-01	5	135	50	0.038

SNARES

Amplatz Goose Neck™
Snare

Amplatz Goose Neck™

Snare Kit

The Amplatz Goose Neck™ snare kit is intended for use in the retrieval of atraumatic foreign bodies. Each kit contains one snare, one catheter, one introducer, and one torque device. The snare is constructed of nitinol cable and a gold-plated tungsten loop. Because of the snare's preformed loop and superelastic construction, it can be introduced through catheters without risk of snare deformation. The snare catheter has a platinum-iridium radiopaque marker band. The Amplatz Goose Neck snare kit is intended for the cardiovascular and peripheral vascular systems.

Reference Number	Loop Diameter (mm)	Snare Length (cm)	Catheter Size (F)	Catheter Length (cm)
GN500	5	120	4	102
GN1000	10	120	4	102
GN1001	10	65	4	48
GN1500	15	120	6	102
GN2000	20	120	6	102
GN2500	25	120	6	102
GN2501	25	65	6	48
GN3000	30	120	6	102
GN3500	35	120	6	102

Amplatz Goose Neck™

Microsnare Kit

The Amplatz Goose Neck™ microsnare kit is intended for the coronary and peripheral vascular systems and the extracranial neurovascular anatomy. Each kit contains one microsnare, one microsnare catheter, one introducer, and one torque device.

Reference Number	Loop Diameter (mm)	Snare Length (cm)	Catheter Size (F)	Catheter Length (cm)
SK200	2	175	2.3–3	150
SK201	2	200	2.3–3	175
SK400	4	175	2.3–3	150
SK401	4	200	2.3–3	175
SK700	7	175	2.3–3	150
SK701	7	200	2.3–3	175

GUIDEWIRES

Wholey™*
Guidewire System

Nitrex™
Guidewire

*Third party brands are trademarks of their respective owners.

Wholey™*

Guidewire System

The Wholey™* guidewire is intended to facilitate the placement and exchange of interventional devices during diagnostic or therapeutic interventional procedures. Wholey guidewires provide enhanced torqueability and lubricity, alllowing interventionalists to approach challenging cases with confidence. Each Wholey wire, excluding the extension system, is packaged with a torque device.

Reference Number	Description	Stiffness Profile	Tip Style	Size Outer Dia. (in)	Size Length (cm)	Quantity
WWFS35145	Floppy Tip, Extension Compatible	Floppy	Straight/Shapeable	0.035	145	3/Pkg
WWFS35175	Floppy Tip, Extension Compatible	Floppy	Straight/Shapeable	0.035	175	3/Pkg
WWFS35260	Floppy Tip, Exchange Length	Floppy	Straight/Shapeable	0.035	260	3/Pkg
WWFS35300	Floppy Tip, Exchange Length	Floppy	Straight/Shapeable	0.035	300	3/Pkg
WWIJ35145	Modified J Tip, Extension Compatible	Intermediate	Modified J/Shapeable	0.035	145	3/Pkg
WWIJ35175	Modified J Tip, Extension Compatible	Intermediate	Modified J/Shapeable	0.035	175	3/Pkg
WWIJ35260	Modified J Tip, Exchange Length	Intermediate	Modified J/Shapeable	0.035	260	3/Pkg
WWIJ35300	Modified J Tip, Exchange Length	Intermediate	Modified J/Shapeable	0.035	300	3/Pkg
WWSS35145	Standard Tip, Extension Compatible	Standard	Straight/Shapeable	0.035	145	3/Pkg
WWSS35175	Standard Tip, Extension Compatible	Standard	Straight/Shapeable	0.035	175	3/Pkg
WWSS35260	Standard Tip, Exchange Length	Standard	Straight/Shapeable	0.035	260	3/Pkg
WWSS35300	Standard Tip, Exchange Length	Standard	Straight/Shapeable	0.035	300	3/Pkg
WWES35001	Extension System	Standard	Straight/Shapeable	0.035	155	3/Pkg
WWTD35001	Kendall Torque Device	NA	NA	0.025"-0.038"		10/Pkg

Babywire™

Nitinol Guidewire

The Babywire™ guidewire assists in the placement of initial catheters and exchange of small vessel anatomy. Babywire guidewires are straight 0.012" nitinol guidewires designed with double-ended round tips and flexible ends. Babywire guidewires are kink-resistant and provide 1:1 torque.

Reference Number (10/Package)	Diameter (in)	Length (cm)
BW1200	0.012	18
BW1201	0.012	50

Nitrex™

Guidewire

Nitrex™ guidewires are kink-resistant and provide 1:1 torque. They are constructed of a superelastic nitinol core wire with a gold-plated tungsten coil for enhanced visualization. The wires have proprietary silicone coating for ease in placement. A torque device is packaged with 0.014" and 0.018" Nitrex guidewires. The 0.014" and 0.018" Nitrex guidewires are intended for use in the peripheral and coronary vasculatures. The 0.025" and 0.035" Nitrex guidewires are indicated for use in the peripheral vasculature.

Reference Number (3/Package)†	Diameter (in)	Length (cm)	Tip Style	Tip Length (cm)	Tip Shape	Tip Angle (°)
0.014"						
N140801	0.014	80	INT	5	A	15
N141802	0.014	180	INT	5	A	15
N143001	0.014	300	INT	5	A	15
0.018"						
N180601	0.018	60	INT	5	S	0
N180603	0.018	60	INT	7	S	0
N180801	0.018	80	STD	2	S	0
N180802	0.018	80	INT	5	A	15
N181804	0.018	180	STD	2	S	0
N181805	0.018	180	INT	5	A	15
N181806	0.018	180	Flop	20	A	15
N183001	0.018	300	STD	2	S	0
N183002	0.018	300	INT	5	A	15
0.025"						
N251801	0.025	180	INT	8	A	15
N251802	0.025	180	STD	2	S	0
N252601	0.025	260	INT	8	A	15
0.035" Flexible Shaft						
N351451	0.035	145	INT	15	S	0
N351452	0.035	145	INT	15	A	45
N351803	0.035	180	INT	15	S	0
N352601	0.035	260	INT	15	A	45
N354001	0.035	400	INT	15	S	0
0.035" Stiff Shaft						
N350801	0.035	80	INT	9	S	0
N351453	0.035	145	FLOP	14	A	45
N351454	0.035	145	INT	9	S	0
N351455	0.035	145	FLOP	14	S	0
N351804	0.035	180	INT	9	S	0
N351805	0.035	180	STD	4	A	45
N352602	0.035	260	FLOP	14	S	0
N352603	0.035	260	STD	4	A	45
N352604	0.035	260	INT	9	S	0
N353001	0.035	300	INT	9	S	0
N354002	0.035	400	INT	9	S	0

†Torque devices included on 0.014" and 0.018" wire sizes.

SUPPORT CATHETERS
AND GUIDE CATHETERS

TrailBlazer™
Angled Support Catheter

TrailBlazer™

Support Catheter

The TrailBlazer™ catheter is an over-the-wire, single-lumen, seamless catheter with three embedded radiopaque markers, an atraumatic tapered tip, and a 40 cm hydrophilic distal tip coating. The TrailBlazer catheter is designed for high visibility, optimal wire support, and ease of lesion entry for difficult-to-cross lesions.

Reference Number (5/Package)	Guidewire Compatibility	Working Length (cm)	Minimum Guide Sheath (F)	Minimum Introducer Sheath (F)	Marker Band Spacing (mm)
SC-014-135	0.014	135	5	4	15
SC-014-150	0.014	150	5	4	15
SC-018-090	0.018	90	5	4	15
SC-018-135	0.018	135	5	4	15
SC-018-150	0.018	150	5	4	15
SC-035-065	0.035	65	6	5	50
SC-035-090	0.035	90	6	5	50
SC-035-135	0.035	135	6	5	50
SC-035-150	0.035	150	6	5	50

TrailBlazer™

Angled Support Catheter

With an angled tip and braided shaft design, the TrailBlazer™ angled support catheter has exceptional pushability and directionality to reach and cross lesions.

Reference Number (5/Package)	Guidewire Compatibility	Working Length (cm)	Minimum Guide Sheath (F)	Minimum Introducer Sheath (F)	Marker Band Spacing (mm)
ASC-014-090	0.014	90	5	4	15
ASC-014-135	0.014	135	5	4	15
ASC-014-150	0.014	150	5	4	15
ASC-018-090	0.018	90	5	4	15
ASC-018-135	0.018	135	5	4	15
ASC-018-150	0.018	150	5	4	15
ASC-035-065	0.035	65	5	4	50
ASC-035-090	0.035	90	5	4	50
ASC-035-135	0.035	135	5	4	50
ASC-035-150	0.035	150	5	4	50

Launcher™

Peripheral Guide Catheter

The Launcher™ peripheral guide catheter is designed for multiple interventional approaches.

Reference Number	French Size (F)	Length (cm)	Curve Style
Renal Curve			
LA6PK1W	6	47	PK1
LA7PK1W	7	47	PK1
LA8PK1W	8	47	PK1
Hockey Stick			
LA6MPHK	6	55	MPH
LA7MPHK	7	55	MPH
LA8MPHK	8	55	MPH
Renal Double Curve			
LA6RDCK	6	55	RDC
LA7RDCK	7	55	RDC
LA8RDCK	8	55	RDC
Sheperd's Crook			
LA6SCR40K	6	55	SCR
LA7SCR40K	7	55	SCR
LA8SCR40K	8	55	SCR

Reference Number	French Size (F)	Length (cm)	Curve Style
Multipurpose			
LA6MP1K	6	55	MP1
LA7MP1K	7	55	MP1
LA8MP1K	8	55	MP1
Champ			
LA6CHAMP15K	6	55	Champ 1.5
LA7CHAMP15K	7	55	Champ 1.5
LA8CHAMP15K	8	55	Champ 1.5
LA6CHAMP20K	6	55	Champ 2.0
LA7CHAMP20K	7	55	Champ 2.0
LA8CHAMP20K	8	55	Champ 2.0
LA6CHAMP25K	6	55	Champ 2.5
LA7CHAMP25K	7	55	Champ 2.5
LA8CHAMP25K	8	55	Champ 2.5

BRIEF STATEMENTS AND REFERENCE STATEMENTS

Admiral™ Xtreme™ 0.035" PTA Balloon Catheter
Indications for Use: The Admiral Xtreme PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Test data is on file at Medtronic Inc.
Bench test results may not be indicative of clinical performance.

Chocolate™* PTA Balloon
Indications for Use: The Chocolate™ PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, iliofemoral, popliteal, infra-popliteal, and renal arteries.

Babywire™ Guidewire
Indications for Use: The Babywire™ Guidewire is intended for assisting in the placement of initial catheters and/or exchange in the small vessel anatomy. The Babywire Guidewire is compatible with a 24 gauge needle or 2.0 French catheter. The Babywire Guidewire is not indicated for coronary use.

Cragg-McNamara™ Valved Infusion Catheters
Indications for Use: The Cragg-McNamara™ Valved Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents or radiopaque contrast media into the general vasculature. All pharmacologic agents utilized with the Micro Therapeutics Infusion Catheter should be fully prepared and used according to the instructions for use of the specific pharmacologic agent. The Micro Therapeutics Infusion Catheter is not intended for coronary, pediatric, or neonatal use.

Ellipsys™ System
The Ellipsys™ system is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.
Contraindications: The Ellipsys™ system is contraindicated for use in patients with target vessels that are < 2 mm in diameter. The Ellipsys™ System is contraindicated for use in patients who have a distance between the target artery and vein > 1.5 mm.
Warnings
- The Ellipsys™ system has only been studied for the creation of an AV fistula using the proximal radial artery and the adjacent perforating vein. It has not been studied in subjects who are candidates for surgical fistula creation at other locations, including sites distal to this location.
- The Ellipsys™ system is not intended to treat patients with significant vascular disease or calcification in the target vessels.
- The Ellipsys™ system has only been studied in subjects who had a patent palmar arch and no evidence of ulnar artery insufficiency.
- Use only with the Ellipsys™ Power Controller, Model No. AMI-1001.
- The Ellipsys™ Catheter has been designed to be used with the 6 F Terumo Glidesheath Slender™*. If using a different sheath, verify the catheter can be advanced through the sheath without resistance prior to use.
- Use ultrasound imaging to ensure proper placement of the catheter tip in the artery before retracting the sheath, since once the distal tip of the catheter has been advanced into the artery, it cannot be easily removed without creation of the anastomosis. If the distal tip is advanced into the artery at an improper location, complete the procedure and remove the catheter as indicated in the directions for use. It is recommended that a follow-up evaluation of the patient is performed using appropriate clinical standards of care for surgical fistulae to determine if any clinically significant flow develops that require further clinical action.

Precautions
- This product is sterilized by ethylene oxide gas.
- Additional procedures are expected to be required to increase and direct blood flow into the AVF target outflow vein and to maintain patency of the AVF. Care should be taken to proactively plan for any fistula maturation procedures when using the device.
- In the Ellipsys™ study, 99% of subjects required balloon dilatation (PTA) to increase flow to the optimal access vessel and 62% of subjects required embolization coil placement in competing veins to direct blood flow to the optimal access vessel. Prior to the procedure, care should be taken to assess the optimal access vessel for maturation, the additional procedures that may be required to successfully achieve maturation, and appropriate patient follow-up. Please refer to the "Arteriovenous Fistula (AVF) Maturation" section of the labeling for guidance about fistula flow, embolization coil placement, and other procedures to assist fistula maturation and maintenance.
- The Ellipsys™ System is intended to only be used by physicians trained in ultrasound guided percutaneous endovascular interventional techniques using appropriate clinical standards for care for fistula maintenance and maturation including balloon dilatation and coil embolization.
- Precautions to prevent or reduce acute or longer-term clotting potential should be considered. Physician experience and discretion will determine the appropriate anticoagulant/antiplatelet therapy for each patient using appropriate clinical standards of care.

Potential Adverse Events: Potential complications that may be associated with creation and maintenance of an arteriovenous fistula include, but may not be limited to, the following:
- Total occlusion, partial occlusion or stenosis of the anastomosis or adjacent outflow vein
- Stenosis of the central AVF outflow requiring treatment per the treatment center's standard of care
- Failure to achieve fistula maturation
- Incomplete vessel ligation when using embolization coil to direct flow
- Steal Syndrome
- Hematoma
- Infection or other complications
- Need for vessel superficialization or other maturation assistance procedures.

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

Enteer™ Re-entry Catheter
Indications for Use: The Enteer™ Re-entry Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the peripheral vasculature. When used as part of the Peripheral System, the Enteer Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Enteer™ Re-entry Guidewire
Indications for Use: The Enteer™ Re-entry Guidewire is intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal angioplasty (PTA). The Enteer Guidewire is not to be used in cerebral blood vessels. When used as part of the Peripheral System, the Enteer Guidewire is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

EverCross™ 0.035" PTA Balloon Catheter
Indications for Use: The EverCross™ 0.035" OTW PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

EverFlex™ Self-expanding Peripheral Stent System
Indication: The EverFlex™ Self-Expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 180 mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm-7.5 mm. The EverFlex Self-Expanding Peripheral Stent System is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 4.5 mm-7.5 mm. The Protégé EverFlex Self-expanding Biliary Stent System is intended as a palliative treatment of malignant neoplasms in the biliary tree.
Contraindications: Use of the EverFlex™ Self-Expanding Peripheral Stent System is contraindicated in patients with known hypersensitivity to nickel titanium and in patients contraindicated for anticoagulant and/or antiplatelet 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.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Artery perforation or rupture, Bleeding requiring transfusion, Infection, Pseudoaneurysm, Restenosis, Stent collapse or fracture, Stent migration, Surgical or endovascular intervention, Thrombosis/occlusion of the stent.
See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events, and device information.

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

BRIEF STATEMENTS AND REFERENCE STATEMENTS

EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System
Indication: The EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 140 mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm-7.5 mm.
Contraindications: Use of the EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system. The EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System is contraindicated for use in the carotid artery.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Artery perforation or rupture, Bleeding requiring transfusion, Infection, Pseudoaneurysm, Restenosis, Stent collapse or fracture, Stent migration, Surgical or endovascular intervention, Thrombosis/occlusion of the stent.
See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events, and device information.

Fortrex™ 0.035" PTA Balloon Catheter
Indications for Use: The Fortrex™ 0.035" OTW PTA balloon catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

FlowMet™ System
Important: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.
Indications for Use: The FlowMet™ is a noninvasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

Goose Neck™ Microsnare
Indications for Use: The Amplatz Goose Neck microsnare kit is intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extracranial neurovascular anatomy.

Goose Neck™ Snare
Indications for Use: The Amplatz Goose Neck snare is intended for use in the cardiovascular system or hollow viscus to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.

HawkOne™ Directional Atherectomy System
Indications for Use: The HawkOne™ peripheral directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculatures.

IN.PACT™ Admiral™ Drug-Coated Balloon
Indications for Use: The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of *de novo,* restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
Contraindications
The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the *Instructions for Use* (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Effects
The potential adverse effects (e.g. complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.

Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.

Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.

Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

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

BRIEF STATEMENTS AND REFERENCE STATEMENTS

Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

IntraStent™ Biliary Stent System
Indications for Use: The stent is intended as a palliative treatment of malignant neoplasms in the biliary tree.
WARNING: The safety and effectiveness of this device for use in the vascular system have not been established.

Launcher™ Peripheral Guide Catheter
Indications for Use: The Launcher™ Peripheral Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.
WARNINGS
- For single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Cleaning, disinfection, and resterilization may compromise the essential material and design characteristics of the device leading to device failure.
- Do not use if package is opened or damaged.
- Due to the size and relative stiffness of the guiding catheters, extreme care must be taken to avoid damage to the wall of the vessels through which this catheter passes.
- Due to the size of the non-tapered tip, this catheter may occlude smaller vessels. Care must be taken not to completely block flow.
- When there is limited clearance between devices and the guide catheter lumen, devices must be advanced and withdrawn slowly with the valve open to reduce the risk of embolism.
- Use catheters prior to the expiration date specified on the package.

Precautions
- The large internal diameter of the catheter permits injection with little force being required on the syringe. Inject slowly whenever attempting to opacify the vessels via this catheter.
- Guiding Catheters are designed for use by physicians engaged in the practice of a specialized branch of medicine. Use of these devices should be restricted to those specialists trained to perform the procedure.
- This device has been delivered STERILE. Careful inspection prior to use should verify the size, shape, and condition of the catheter as suitable for the specific procedure.
- Store catheters straight in a cool, dark area. Do not expose catheters to solvents or ionizing radiation.
- If resistance is encountered at any time during the insertion of the interventional device through the lumen of the guiding catheter, do not force passage. Determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, remove the entire dilatation system.
- If the guide catheter is torqued when kinked, it may cause damage that could result in separation along the catheter shaft. In the event the catheter shaft becomes kinked, withdraw the guide catheter, guidewire, and catheter sheath introducer.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Adverse effects
Use of Guiding Catheters may give rise to the following complications:
- Hemorrhage or Hematoma
- Allergic reaction to contrast medium
- Infection
- Embolism
- Vessel or heart dissection, perforation
- Vessel spasm
- Thrombosis
- Myocardial infarction
- Stroke
- Death
- Vascular occlusion

IN.PACT™ AV Paclitaxel-coated PTA Balloon
INDICATIONS FOR USE: The IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.
CONTRAINDICATIONS:
The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure

WARNINGS:
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulae. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options for their specific disease/condition with their patients.**
- Use the product prior to the Use-by date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT AV DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 15,105 µg paclitaxel has not been evaluated clinically.

PRECAUTIONS:
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure. This product is not intended for the expansion or delivery of a stent.
- Do not use the IN.PACT AV DCB for pre-dilatation or for post-dilatation.
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilatation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

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

BRIEF STATEMENTS AND REFERENCE STATEMENTS

POTENTIAL ADVERSE EFFECTS: Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following: abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hematoma, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the dilated vessel, shock, stroke, vessel spasms or recoil.
Potential complications of peripheral balloon catheterization include, but are not limited to, the following: balloon rupture, detachment of a component of the balloon and/or catheter system, failure of the balloon to perform as intended, failure to cross the lesion. These complications may result in adverse effects.
Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/arthralgia, myelosuppression, peripheral neuropathy.
Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Mo.Ma™ Ultra Cerebral Protection Device
Indications for Use: The Mo.Ma™ Ultra Proximal Cerebral Protection Device is indicated as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures involving lesions of the internal carotid artery and/or the carotid bifurcation.
The reference diameter of the external carotid artery should be between 3-6 mm and the reference diameter of the common carotid artery should be between 5-13 mm.
Test data is on file at Medtronic Inc.
Bench test results may not be indicative of clinical performance

NanoCross™ Elite 0.014" PTA Balloon Catheter
Indications for Use: The NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Nitrex™ Guidewire
Indications for Use: The 0.014 in. (0.36 mm) and 0.018 in. (0.46 mm) diameter NITREX Nitinol Guidewires are intended for use in the peripheral and coronary vasculature. The 0.025 in. (0.64 mm) and 0.035 in. (0.89 mm) diameter NITREX Nitinol Guidewires are indicated for use in the peripheral vasculature.

Pacific™ Plus 0.018" PTA Balloon Catheter
Indications for Use: The Pacific Plus PTA Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries; and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
WARNING:
- Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings, and precautions.
- Do not exceed the rated burst pressure.

CAUTION: Larger models of the Pacific™ Plus PTA catheter may exhibit slower deflation times, particularly on long catheter shafts.
Potential Adverse Events: Possible adverse events associated with use of the Pacific™ Plus PTA Catheter include, but are not limited to, complications related to puncture such as, but not limited to, local hematoma, infection and hemorrhage; dilatation related complications including, but not limited to, dissection, perforation and restenosis; angiography related complications such as, but not limited to, hypotension, drug/allergic reactions, and death.
Test data is on file at Medtronic Inc.
Bench test results may not be indicative of clinical performance.

Pacific™ Xtreme™ 0.018" PTA Balloon Catheter
Indications for Use: The PACIFIC XTREME™ PTA Balloon Dilatation Catheter in 150 mm, 200 mm, 250 mm, and 300 mm balloon length is intended to dilate stenoses in femoral, popliteal, and infrapopliteal arteries.
Test data is on file at Medtronic Inc.
Bench test results may not be indicative of clinical performance.

Protégé™ GPS™ Self-expanding Peripheral and Biliary Stent System
Indication: The Protégé™ GPS™ Self-Expanding Peripheral Stent Systems is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with reference vessel diameters of 7.5-11 mm. The stent is intended as a palliative treatment of malignant neoplasms in the biliary tree.
Contraindications: Use of the Protégé™ GPS™ Self-Expanding Peripheral Stent System is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the common and/or external iliac arteries include, but are not limited to: Abrupt or sub-acute closure, Allergic reaction to device materials or procedure medications, Allergic reaction to Nitinol, Amputation, Aneurysm, Angina, Arrhythmia, Arterio-venous fistula, Artery injury (e.g., dissection, perforation, or rupture), Bleeding requiring transfusion, Bruising, Contrast medium reaction/renal Failure, Death, Device breakage, Edema, Embolism, Failure to deploy stent, Fever, Gastrointestinal bleeding due to Anticoagulation, Hematoma, Hypertension/Hypotension, Infection, Inflammation, Intraluminal thrombus, Myocardial infarction Pain, Partial stent deployment, Pseudoaneurysm, Renal failure, Renal insufficiency, Restenosis, Sepsis, Shock, Stent collapse or fracture, Stent migration, Stent misplacement, Stroke, Surgical or endovascular Intervention, Thrombosis/occlusion of the stent, Transient ischemic attack, Venous thromboembolism, Vessel spasm, Worsening claudication or rest, pain.
See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events, and device information.

Protégé™ RX Self-expanding Carotid Stent System
Indications: The Protégé™ RX Carotid Stent System, when used in conjunction with the ev3 embolic protection system, is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require percutaneous carotid revascularization and meet the following criteria: 1. Patients with carotid artery stenosis (≥ 50% for symptomatic patients by ultrasound or angiography or ≥ 80% for asymptomatic patients by ultrasound or angiography) of the Common or Internal Carotid Artery, AND 2. Patients must have a reference vessel diameter within the range of 4.5 mm and 9.5 mm at the target lesion.
Contraindications: Use of the Protégé RX Carotid Stent System is contraindicated under these circumstances: Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs is contraindicated; patients with vascular tortuosity or anatomy, which precludes the safe introduction of the sheath, guide catheter, embolic protection system, or stent system; patients with known hypersensitivity to nickel-titanium; patients with uncorrected bleeding
disorders; lesions in the ostium of the common carotid artery.
WARNING: Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the carotid arteries include, but are not limited to: Abrupt closure, Allergic reactions to procedural medications, contrast dye or device materials, Amaurosis fugax, Aneurysm, Angina/coronary ischemia, Arrhythmia, Arterial occlusion or thrombosis at puncture site or remote site, Arteriovenous fistula, Bacteremia or septicemia, Bleeding from anticoagulant or antiplatelet medications, Bleeding, with or without transfusion, Cerebral edema, Cerebral hemorrhage, Cerebral ischemia or transient ischemic attack

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

BRIEF STATEMENTS AND REFERENCE STATEMENTS

(TIA), Congestive heart failure (CHF), Death, Detachment of a component of the device system, Embolism (air, tissue, thrombus), Emergent or urgent endarterectomy surgery (CEA), Fever, Filter thrombosis or occlusion, Fluid overload, Groin hematoma, with or without surgical repair, Hemorrhage, with or without transfusion, Hyperperfusion syndrome, Hypotension or hypertension, Infection and/or pain at the puncture site, Ischemia or infarction of tissue/organ, Myocardial infarction (MI), Pain (head, neck), Pseudoaneurysm (femoral), Renal failure/insufficiency (new or worsening), Restenosis of stented segment, Seizure, Severe unilateral headache, Slow/no flow during procedure, Stent/filter collapse or fracture, Stent/filter entanglement or damage, Stent/filter failure to deploy, Stent embolization, migration, or misplacement, Stent or vessel thrombosis/occlusion, Stroke/cerebrovascular accident (CVA), Total occlusion of carotid artery, Vessel dissection, flap, perforation, or rupture, Vessel spasm or recoil.

RapidCross™ 0.014" Rapid Exchange PTA Balloon Catheter
Indications for Use: The RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

SilverHawk™ Plaque Excision System
Indications for Use: The SilverHawk™ Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

SpiderFX™ Embolic Protection Device
Indications for Use: Lower Extremity (LE) Interventions
The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.
Carotid Interventions
The SpiderFX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 7.0 mm.
Saphenous Vein Graft (SVG) Interventions
The SpiderFX Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 mm to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

TrailBlazer™ Support Catheter
Indications for Use: TrailBlazer™ Support Catheters are percutaneous, single-lumen catheters designed for use in the peripheral vascular system. TrailBlazer™ Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TrailBlazer™* Angled Support Catheter
Indications for Use: TrailBlazer™ Angeled Support Catheters are percutaneous, single-lumen catheters designed for use in the peripheral vascular system. TrailBlazer™ Support Catheters are intended to guide and support a guide-wire during access of the vasculature, allow for wire exchanges, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TurboHawk™ Plaque Excision System
Indications for Use: The TurboHawk™ Peripheral Plaque Excision System is intended for use in the atherectomy of the peripheral vasculature. The TurboHawk catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature. The TurboHawk Catheter is indicated for use in conjunction with the SpiderFX™ Embolic Protection Device in the treatment of severely calcified lesions (LS-C and LX-C only).

Viance™ Crossing Catheter
Indications for Use: The Viance™ Catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. When used as part of the Peripheral System, the Viance Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Visi-Pro™ Balloon-expandable Peripheral Stent System
Indications: The Visi-Pro™ Balloon-expandable Peripheral Stent System is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to 100 mm in length, with a reference vessel diameter of 5 to 10 mm. The Visi-Pro™ Balloon-expandable Biliary Stent System is intended as a palliative treatment of malignant neoplasms in the biliary tree.
Contraindications: Use of the Visi-Pro™ Balloon-expandable Peripheral Stent System is contraindicated in patients with known hypersensitivity to stainless steel or its components; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who exhibit persistent acute intraluminal thrombus of the proposed lesion site; perforation at the angioplasty site; aneurysm of the artery to be treated. All of the customary contraindications for PTA.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the Iliac arteries include, but are not limited to: Abrupt or sub-acute closure, Allergic reaction to 316L stainless steel, Allergic reaction to device materials or procedure medications Amputation, Aneurysm, Angina, Arrhythmia, Arterio-venous fistula, Artery injury (e.g., dissection, perforation or rupture), Bleeding requiring transfusion, Contrast medium reaction/renal failure, Death Device breakage, Embolism, Failure to deploy stent, Fever, Gastrointestinal bleeding due to anticoagulation, Hematoma, Hypertension/Hypotension, Infection, Inflammation, Intraluminal thrombus, Myocardial infarction , Pain, Partial stent deployment, Pseudoaneurysm, Renal insufficiency, Restenosis, Sepsis, Shock, Stent collapse or fracture, Stent migration, Stent misplacement, Stroke, Surgical or endovascular intervention, Thrombosis/occlusion of the stent, Transient increase in glomerular filtration rate, Transient ischemic attack, Venous thromboembolism, Vessel spasm, Worsening claudication or rest pain.
See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events, and device information.

Wholey™ Guidewire System
Indications for Use: The Wholey™ guidewire system is intended to facilitate the placement and exchange of interventional devices during diagnostic or therapeutic interventional procedures. The guidewire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches.

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

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