NEUROVASCULAR
2018 PRICE LIST

Medtronic

TABLE OF CONTENTS

GUIDEWIRES

AVÍGO™ .014" HYDROPHILIC GUIDEWIRE

Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0606-200	.014	205	5

MIRAGE™ .008" HYDROPHILIC GUIDEWIRE

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

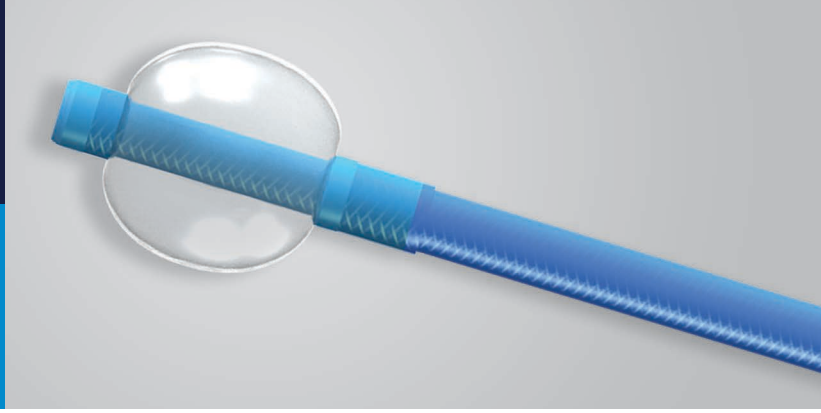
SILVERSPEED™ HYDROPHILIC GUIDEWIRE

Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0601-200	0.010	200	10
103-0602-175	0.014	175	20
103-0602-200	0.014	200	20
103-0603-200	0.016	200	20

X-PEDION™ HYDROPHILIC GUIDEWIRE

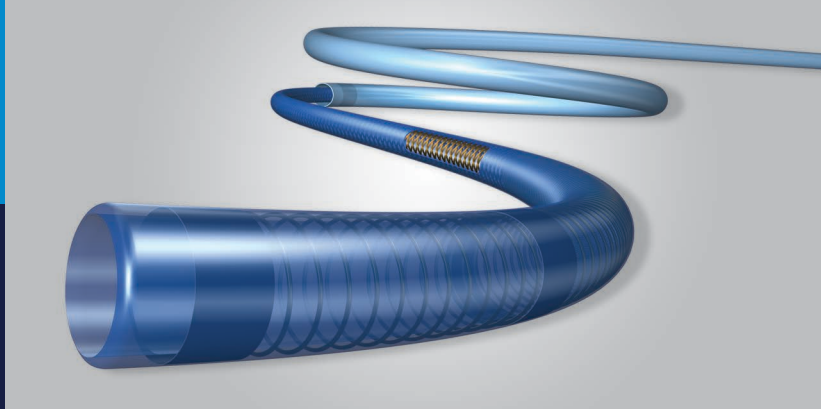
Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0605-200	0.010	200	10
203-0602-200	0.014	200	20

BALLOON GUIDE CATHETERS



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

DISTAL ACCESS CATHETERS



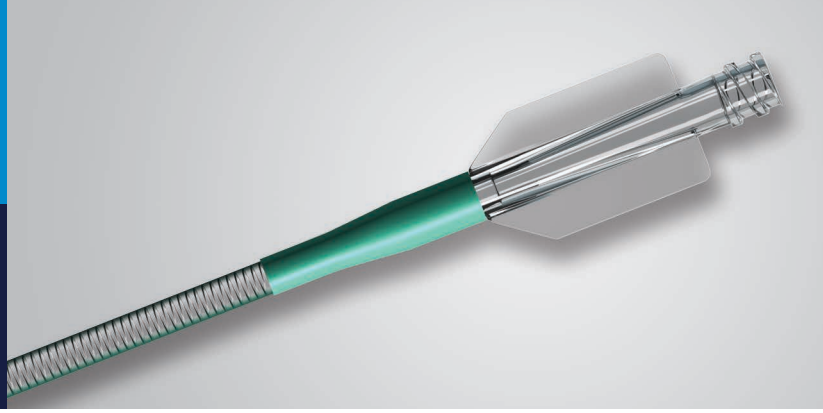
With features such as an elite composite shaft, proprietary inner lining, and a rounded distal tip, the **PHENOM™* FAMILY OF CATHETERS** are the ultimate delivery platform for coil and stent delivery.[1] Different clinical scenarios require variations in levels of support and navigation. With Phenom™* catheters, we provide various catheter specifications to meet your needs.

PHENOM™* PLUS CATHETER				
Product Catalog Number	Working Length (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Catheter Inner Diameter (in)
FG19105-0630-1S	105	0.061	0.055	0.0445
FG19120-1030-1S	120	0.061	0.055	0.0445

1. Cathera Document ML-0001.A

Phenom is a trademark of Cathera, Inc.

INTRACRANIAL SUPPORT CATHETERS



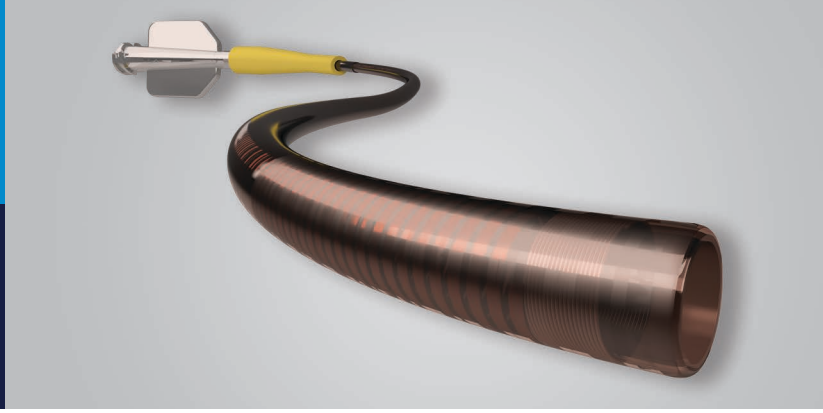
The **ARC™ INTRACRANIAL SUPPORT CATHETER** is indicated for the introduction of interventional devices into the peripheral and neurovasculature.[1]

ARC™ INTRACRANIAL SUPPORT CATHETER						
Product Catalog Number	Working Length (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Proximal Inner Diameter (in)	Distal Inner Diameter (in)	Max Wire Compatibility
ARC-132	132	0.080	0.069	0.069	0.061	0.038

ARC™ MINI INTRACRANIAL SUPPORT CATHETER						
Product Catalog Number	Working Length (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Proximal Inner Diameter (in)	Distal Inner Diameter (in)	Max Wire Compatibility
ARC-160	160	0.060	0.044	0.044	0.035	0.032

1. Indication from Arc™ Intracranial Support Catheter IFU 70885-001 Rev. 06/15

INTRACRANIAL SUPPORT CATHETERS



NAVIEN™ INTRACRANIAL SUPPORT CATHETER						
Product Catalog Number	Maximum Outer Diameter (F / in)	Inner Diameter (in)	Length (cm)	Tip Shape	Max Wire Compatibility (in)	Flexible Distal Length (cm)
RFX058-105-08	5 / 0.070	0.058	105	Straight	0.038	8
RFX058-115-08	5 / 0.070	0.058	115	Straight	0.038	8
RFX058-125-08	5 / 0.070	0.058	125	Straight	0.038	8
RFX058-130-08	5 / 0.070	0.058	130	Straight	0.038	8
RFX072-95-08	6 / 0.084	0.072	95	Straight	0.038	8
RFX072-95-08MP	6 / 0.084	0.072	95	Multi-Purpose 25°	0.038	8
RFX072-105-08	6 / 0.084	0.072	105	Straight	0.038	8
RFX072-105-08MP	6 / 0.084	0.072	105	Multi-Purpose 25°	0.038	8
RFX072-115-08	6 / 0.084	0.072	115	Straight	0.038	8
RFX072-115-08MP	6 / 0.084	0.072	115	Multi-Purpose 25°	0.038	8
RFX072-125-08	6 / 0.084	0.072	125	Straight	0.038	8
RFX072-125-08MP	6 / 0.084	0.072	125	Multi-Purpose 25°	0.039	8
RFX072-130-08	6 / 0.084	0.072	130	Straight	0.040	8
RFX072-130-08MP	6 / 0.084	0.072	130	Multi-Purpose 25°	0.041	8

MICRO CATHETERS

The **APOLLO™ ONYX™ DELIVERY MICRO CATHETER**, built on the proven Marathon™ micro catheter platform, combines exceptional navigation capabilities with a mechanically detachable tip.

APOLLO™ ONYX™ DELIVERY MICRO CATHETER

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

MARATHON™ FLOW DIRECTED MICRO CATHETER

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

REBAR™ 10 REINFORCED MICRO CATHETER

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)
105-5078-153*	2.3>1.7	.015	153	0.012

REBAR™ 14 REINFORCED MICRO CATHETER

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)
105-5080-153*	2.4>1.9	.017	153	0.014

REBAR™ 18 REINFORCED MICRO CATHETER

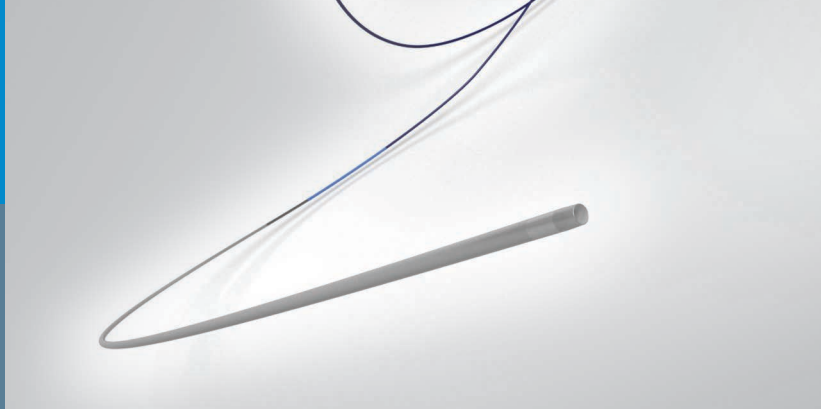
Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)
105-5081-153*	2.7>2.4	.021	153	0.018

REBAR™ 27 REINFORCED MICRO CATHETER

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

*Dual marker band

MICRO CATHETERS



MARKSMAN™ MICRO CATHETER

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

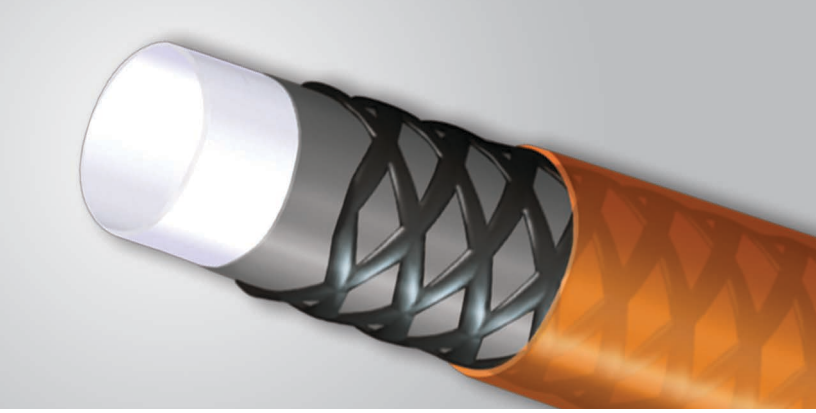
NAUTICA™ 14 XL REINFORCED MICRO CATHETER

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Usable Length (cm)	Max. Guidewire (in)
105-5094-153	2.8>2.2	.021>.018	150	0.016

ORION™ -21 MICRO CATHETER

Product Catalog Number	Proximal Outer Diameter (F)	Distal Outer Diameter (F)	Inner Diameter (in)	Length (cm)	Max. Guidewire (in)	Hypotube Length (cm)
105-5098-150	2.4	2.6	0.021	150	0.018	82

MICRO CATHETERS



ECHELON™ 10 MICRO CATHETER

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

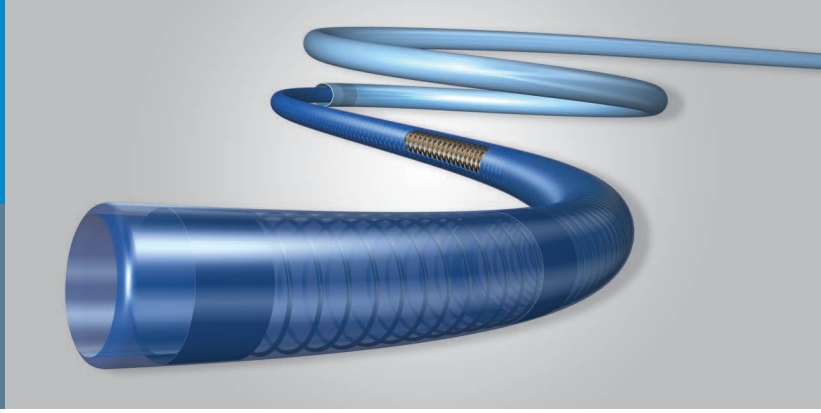
ECHELON™ 14 MICRO CATHETER

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

ECHELON™ SYRINGE ADAPTER

Product Catalog Number	Quantity	Units/Box
103-5095	1 Box	20

MICRO CATHETERS



With features such as an elite composite shaft, proprietary inner lining, and a rounded distal tip, the **PHENOM™* FAMILY OF CATHETERS** are the ultimate delivery platform for coil and stent delivery.[1] Different clinical scenarios require variation in levels of support and navigation. With Phenom™* catheters, we provide various catheter specifications to meet your needs.

PHENOM™* 017 CATHETER

Product Catalog Number	Tip Shape	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Catheter Inner Diameter (in)
FG11150-0615-2S	Straight	0.029	0.024	0.017
FG11150-0615-2J	J Curve	0.029	0.024	0.017
FG11150-0615-2X	45 Curve	0.029	0.024	0.017
FG11150-0615-2R	90 Curve	0.029	0.024	0.017

PHENOM™* 021 CATHETER

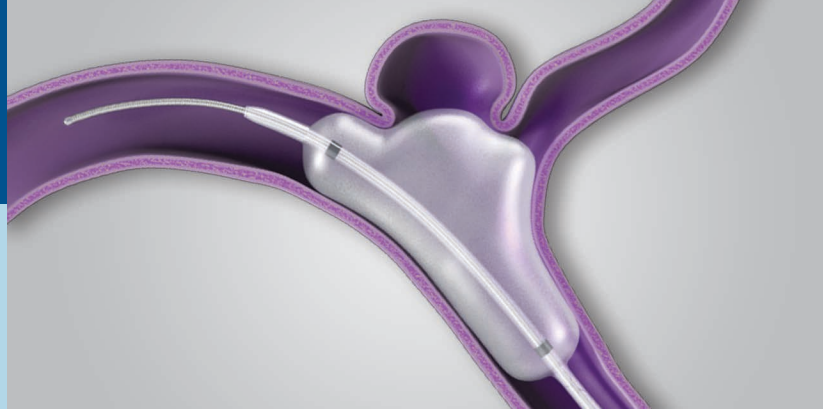
Product Catalog Number	Soft Distal Segment (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Catheter Inner Diameter (in)
FG13150-0615-2S	6	0.034	0.030	0.021
FG13150-1015-2S	10	0.034	0.030	0.021

PHENOM™* 027 CATHETER

Product Catalog Number	Flexible Single Coil Length (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Catheter Inner Diameter (in)
FG15150-0615-1S	15	0.040	0.036	0.027
FG15150-0630-1S	30	0.040	0.036	0.027

1. Cathera Document ML-0001.A

BALLOONS



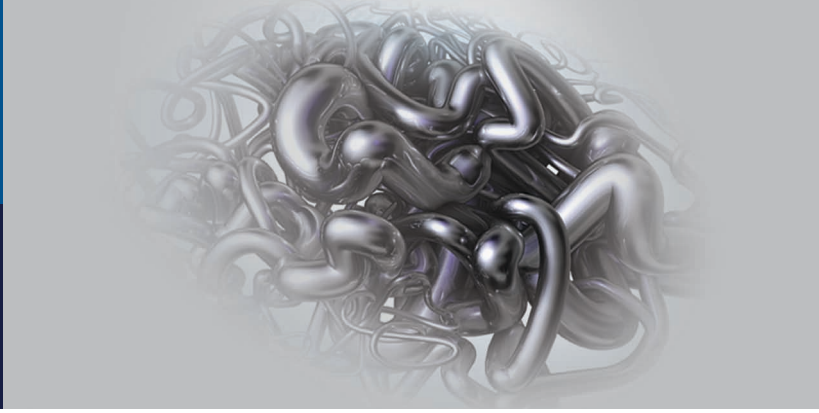
HYPERFORM™ OCCLUSION BALLOON SYSTEMS							
Product Catalog Number	Usable Length (cm)	Balloon Diameter (mm)	Balloon Length (mm)	Tip Length (mm)	Proximal OD (FR)	Distal OD (FR)	Guidewire (in)
104-4370	150	3	7	2	2.8	2.2	.010
104-4153	150	3	15	2	2.8	2.2	.010
104-4470	150	4	7	2	2.8	2.2	.010
104-4415	150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

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

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

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

LIQUID EMBOLICS



ONYX™ LIQUID EMBOLIC SYSTEM provides the advantage of time and the power of control for presurgical embolization of brain arterio-venous malformations (AVMs).[1] Onyx™ HD-500 liquid embolic system is for the treatment of intracranial, succulary sidewall aneurysms that present with a wide-neck (≥4mm) or with a dome-to-neck ratio <2 that are not amenable to treatment with surgical clipping.

ONYX™ LIQUID EMBOLIC SYSTEM	
Product Catalog Number	**Description**
105-7100-060	Onyx 18 LES
105-7100-080	Onyx 34 LES
105-8101-500	Onyx HD-500 LES

The Onyx™ 18 and 34 LES Kits contain:
- 1.5 ml vial of Onyx LES (1)
- 1.5 ml vial of DMSO (1)
- 1 ml DMSO syringe (1)
- 1 ml Onyx LES syringe (2)

The Onyx™ HD-500 LES Kits contain:
- 1.5 ml vial of Onyx HD-500 LES (1)
- 1.5 ml vial of DMSO (1)
- 1 ml DMSO syringe (1)
- 1 Quick Stop syringe (1)
- 1 Rebar™ 14 interface needle (1)

ONYX™ LES ACCESSORIES	
Product Catalog Number	**Description**
103-1205-001	Vial Mixer
103-1206-001	Vial Heater

1. IFU 70753 - OCI Rev. 03/14
2. IFU 70865 - OCI Rev. 9/14

3D FRAMING DETACHABLE COILS

AXIUM™ PRIME DETACHABLE COILS (FRAME)		
Product Catalog Number	Diameter (mm)	Length (cm)
FC-3-6-3D	3	6
FC-3-8-3D	3	8
FC-3-10-3D	3	10
FC-3.5-6-3D	3.5	6
FC-3.5-8-3D	3.5	8
FC-3.5-10-3D	3.5	10
FC-4-6-3D	4	6
FC-4-8-3D	4	8
FC-4-10-3D	4	10
FC-4-12-3D	4	12
FC-4-15-3D	4	15
FC-5-8-3D	5	8
FC-5-10-3D	5	10
FC-5-15-3D	5	15
FC-5-20-3D	5	20
FC-6-10-3D	6	10
FC-6-15-3D	6	15
FC-6-20-3D	6	20
FC-6-25-3D	6	25
FC-7-12-3D	7	12
FC-7-15-3D	7	15
FC-7-20-3D	7	20
FC-7-30-3D	7	30
FC-8-15-3D	8	15
FC-8-20-3D	8	20
FC-8-30-3D	8	30
FC-9-20-3D	9	20
FC-9-30-3D	9	30

3D FRAMING DETACHABLE COILS

AXIUM™ PRIME DETACHABLE COILS (FRAME)		
Product Catalog Number	Diameter (mm)	Length (cm)
FC-10-20-3D	10	20
FC-10-30-3D	10	30
FC-10-40-3D	10	40
FC-12-30-3D	12	30
FC-12-40-3D	12	40
FC-12-50-3D	12	50
FC-14-30-3D	14	30
FC-14-40-3D	14	40
FC-14-50-3D	14	50
FC-16-40-3D	16	40
FC-16-50-3D	16	50
FC-18-40-3D	18	40
FC-18-50-3D	18	50
FC-20-50-3D	20	50
FC-22-50-3D	22	50
FC-25-50-3D	25	50

ID INSTANT DETACHER (5 PACK)	
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

3D EXTRA SOFT DETACHABLE COILS

AXIUM™ PRIME 3D DETACHABLE COILS (EXTRA SOFT)			
Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-1-2-3D-ES	1	2	0.0108
APB-1-3-3D-ES	1	3	0.0108
APB-1-4-3D-ES	1	4	0.0108
APB-1.5-2-3D-ES	1.5	2	0.0108
APB-1.5-3-3D-ES	1.5	3	0.0108
APB-1.5-4-3D-ES	1.5	4	0.0108
APB-2-2-3D-ES	2	2	0.0108
APB-2-3-3D-ES	2	3	0.0108
APB-2-4-3D-ES	2	4	0.0108
APB-2.5-4-3D-ES	2.5	4	0.0108
APB-2.5-6-3D-ES	2.5	6	0.0108
APB-3-4-3D-ES	3	4	0.0108
APB-3-6-3D-ES	3	6	0.0108
APB-3-8-3D-ES	3	8	0.0108
APB-3.5-6-3D-ES	3.5	6	0.0108
APB-3.5-8-3D-ES	3.5	8	0.0108
APB-3.5-10-3D-ES	3.5	10	0.0108

HELICAL EXTRA SOFT DETACHABLE COILS

AXIUM™ PRIME HELICAL DETACHABLE COILS (EXTRA SOFT)			
Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-1-1-HX-ES	1	1	0.0108
APB-1-2-HX-ES	1	2	0.0108
APB-1-3-HX-ES	1	3	0.0108
APB-1.5-1-HX-ES	1.5	1	0.0108
APB-1.5-2-HX-ES	1.5	2	0.0108
APB-1.5-3-HX-ES	1.5	3	0.0108
APB-1.5-4-HX-ES	1.5	4	0.0108
APB-2-1-HX-ES	2	1	0.0108
APB-2-2-HX-ES	2	2	0.0108
APB-2-3-HX-ES	2	3	0.0108
APB-2-4-HX-ES	2	4	0.0108
APB-2-6-HX-ES	2	6	0.0108
APB-2-8-HX-ES	2	8	0.0108
APB-2.5-3-HX-ES	2.5	3	0.0108
APB-2.5-4-HX-ES	2.5	4	0.0108
APB-2.5-6-HX-ES	2.5	6	0.0108
APB-2.5-8-HX-ES	2.5	8	0.0108
APB-3-4-HX-ES	3	4	0.0108
APB-3-6-HX-ES	3	6	0.0108
APB-3-8-HX-ES	3	8	0.0108
APB-3-10-HX-ES	3	10	0.0108

ID INSTANT DETACHER (5 PACK)	
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

3D SUPER SOFT DETACHABLE COILS

AXIUM™ PRIME 3D DETACHABLE COILS (SUPER SOFT)			
Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-4-6-3D-SS	4	6	0.0115
APB-4-8-3D-SS	4	8	0.0115
APB-4-10-3D-SS	4	10	0.0115
APB-4-12-3D-SS	4	12	0.0115
APB-5-8-3D-SS	5	8	0.0115
APB-5-10-3D-SS	5	10	0.0115
APB-5-15-3D-SS	5	15	0.0115
APB-6-10-3D-SS	6	10	0.0115
APB-6-15-3D-SS	6	15	0.0115
APB-6-20-3D-SS	6	20	0.0115

HELICAL SUPER SOFT DETACHABLE COILS

AXIUM™ PRIME HELICAL DETACHABLE COILS (SUPER SOFT)			
Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
APB-4-6-HX-SS	4	6	0.0115
APB-4-8-HX-SS	4	8	0.0115
APB-4-10-HX-SS	4	10	0.0115
APB-4-12-HX-SS	4	12	0.0115
APB-5-10-HX-SS	5	10	0.0115
APB-5-15-HX-SS	5	15	0.0115
APB-5-20-HX-SS	5	20	0.0115
APB-6-12-HX-SS	6	12	0.0115
APB-6-20-HX-SS	6	20	0.0115

ID INSTANT DETACHER (5 PACK)	
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

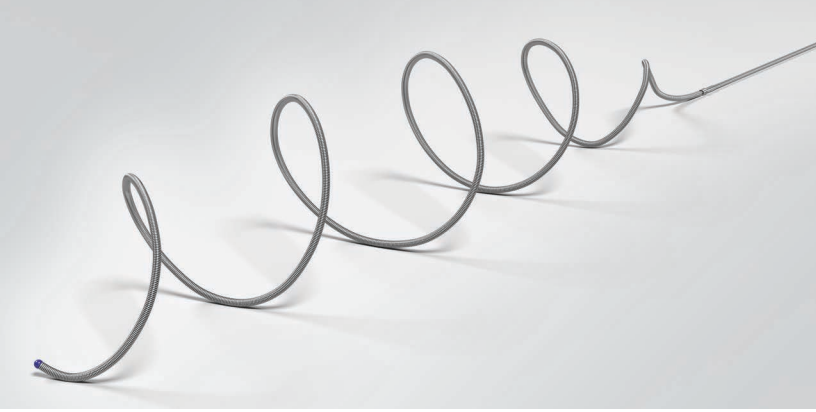
3D DETACHABLE COILS

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

3D DETACHABLE COILS

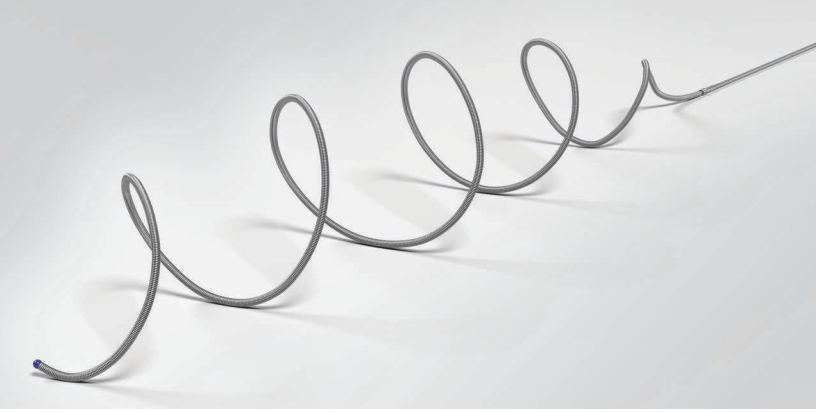
AXIUM™ 3D DETACHABLE COILS			
Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
QC-7-15-3D	7	15	0.0135
QC-7-20-3D	7	20	0.0135
QC-7-30-3D	7	30	0.0135
QC-8-15-3D	8	15	0.0135
QC-8-20-3D	8	20	0.0135
QC-8-30-3D	8	30	0.0135
QC-9-20-3D	9	20	0.0135
QC-9-30-3D	9	30	0.0135
QC-10-20-3D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

HELICAL DETACHABLE COILS



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

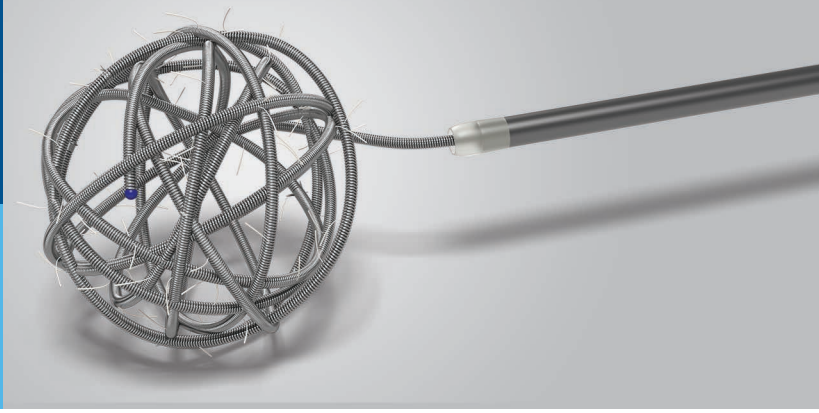
HELICAL DETACHABLE COILS



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

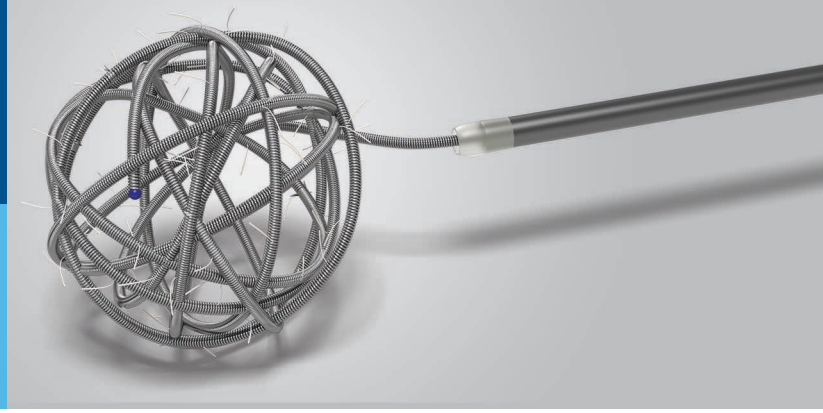
ID INSTANT DETACHER (5 PACK)	
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

PGLA 3D COILS



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

PGLA 3D COILS



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

PGLA HELICAL COILS

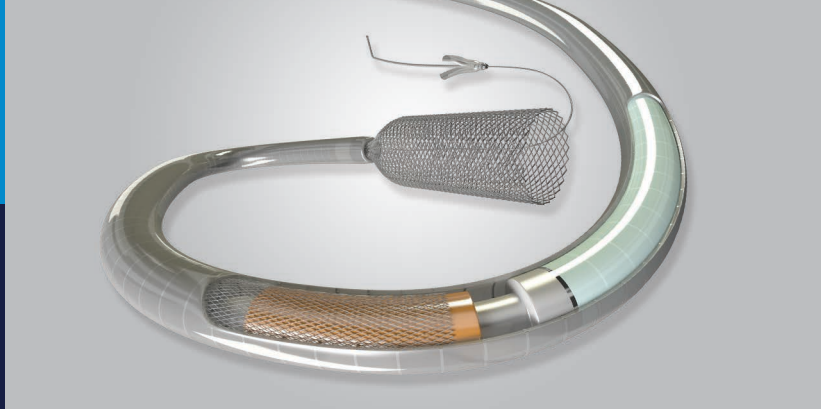
AXIUM™ MICROFX™ PGLA HELIX COILS			
Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
PC-2-1-HELIX	2	1	0.0115
PC-2-2-HELIX	2	2	0.0115
PC-2-3-HELIX	2	3	0.0115
PC-2-4-HELIX	2	4	0.0115
PC-2-6-HELIX	2	6	0.0115
PC-2-8-HELIX	2	8	0.0115
PC-3-4-HELIX	3	4	0.0115
PC-3-6-HELIX	3	6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

NYLON HELICAL COILS

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

ID INSTANT DETACHER (5 PACK)	
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

FLOW DIVERTERS

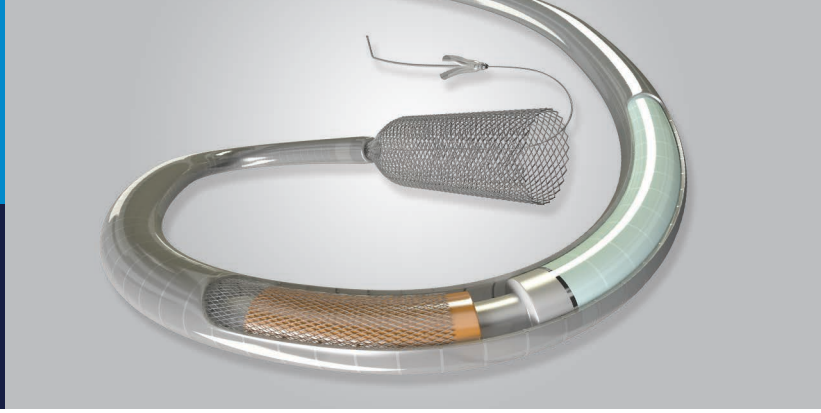


The **PIPELINE™ FLEX EMBOLIZATION DEVICE** features a clinically proven braid design for flexible conformity, and a redesigned, softer distal tip.[1] It's trackable through tortuosity, enables better vessel deflection, and allows for a controlled distal landing zone.[2] The Pipeline™ device is fully resheathable and can be repositioned and redeployed up to two times.[3]

PIPELINE™ FLEX EMBOLIZATION DEVICE		
Product Catalog Number	Diameter (mm)	Length (mm)
PED-250-10	2.50	10
PED-250-12	2.50	12
PED-250-14	2.50	14
PED-250-16	2.50	16
PED-250-18	2.50	18
PED-250-20	2.50	20
PED-275-10	2.75	10
PED-275-12	2.75	12
PED-275-14	2.75	14
PED-275-16	2.75	16
PED-275-18	2.75	18
PED-275-20	2.75	20
PED-300-10	3.00	10
PED-300-12	3.00	12
PED-300-14	3.00	14
PED-300-16	3.00	16
PED-300-18	3.00	18
PED-300-20	3.00	20
PED-300-25	3.00	25
PED-300-30	3.00	30
PED-300-35	3.00	35
PED-325-10	3.25	10
PED-325-12	3.25	12
PED-325-14	3.25	14
PED-325-16	3.25	16
PED-325-18	3.25	18
PED-325-20	3.25	20
PED-325-25	3.25	25
PED-325-30	3.25	30

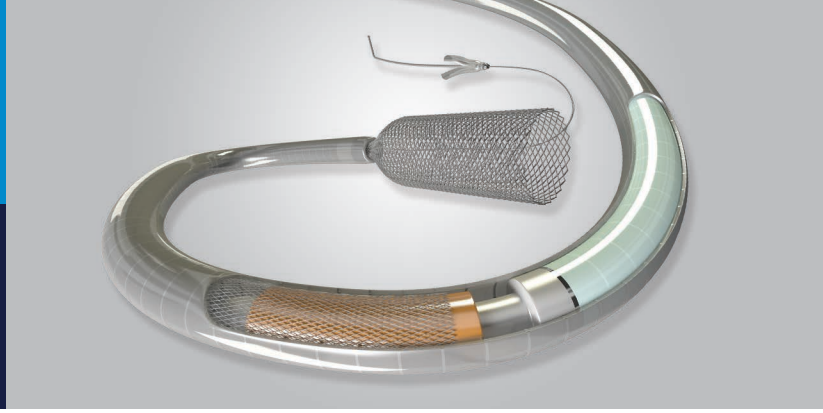
1. TR-NV10931/TR-NV11121. Rev. A.
2. TR-NV10931 Rev. A/TR-NV11121 Rev. A
3. TR-NV11534/TR-NV11121. Rev. A.

FLOW DIVERTERS



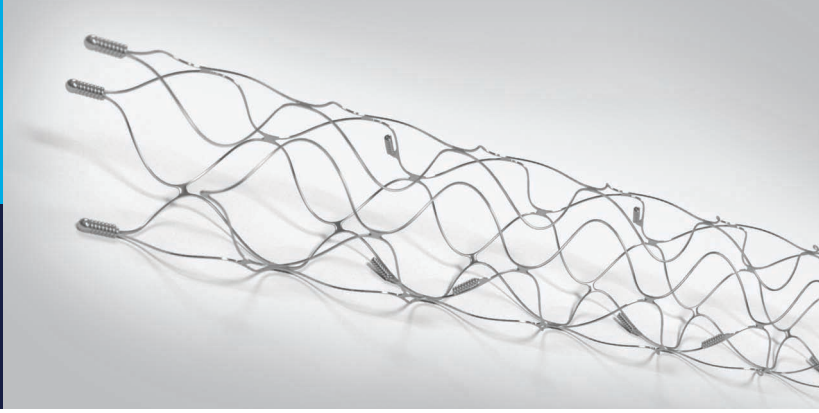
PIPELINE™ FLEX EMBOLIZATION DEVICE		
Product Catalog Number	Diameter (mm)	Length (mm)
PED-325-35	3.25	35
PED-350-10	3.50	10
PED-350-12	3.50	12
PED-350-14	3.50	14
PED-350-16	3.50	16
PED-350-18	3.50	18
PED-350-20	3.50	20
PED-350-25	3.50	25
PED-350-30	3.50	30
PED-350-35	3.75	35
PED-375-10	3.75	10
PED-375-12	3.75	12
PED-375-14	3.75	14
PED-375-16	3.75	16
PED-375-18	3.75	18
PED-375-20	3.75	20
PED-375-25	3.75	25
PED-375-30	3.75	30
PED-375-35	4.00	35
PED-400-10	4.00	10
PED-400-12	4.00	12
PED-400-14	4.00	14
PED-400-16	4.00	16
PED-400-18	4.00	18
PED-400-20	4.00	20
PED-400-25	4.00	25
PED-400-30	4.00	30
PED-400-35	4.00	35
PED-425-10	4.25	10
PED-425-12	4.25	12
PED-425-14	4.25	14
PED-425-16	4.25	16

FLOW DIVERTERS



PIPELINE™ FLEX EMBOLIZATION DEVICE		
Product Catalog Number	Diameter (mm)	Length (mm)
PED-425-18	4.25	18
PED-425-20	4.25	20
PED-425-25	4.25	25
PED-425-30	4.25	30
PED-425-35	4.25	35
PED-450-10	4.50	10
PED-450-12	4.50	12
PED-450-14	4.50	14
PED-450-16	4.50	16
PED-450-18	4.50	18
PED-450-20	4.50	20
PED-450-25	4.50	25
PED-450-30	4.50	30
PED-450-35	4.50	35
PED-475-10	4.75	10
PED-475-12	4.75	12
PED-475-14	4.75	14
PED-475-16	4.75	16
PED-475-18	4.75	18
PED-475-20	4.75	20
PED-475-25	4.75	25
PED-475-30	4.75	30
PED-475-35	4.75	35
PED-500-10	5.00	10
PED-500-12	5.00	12
PED-500-14	5.00	14
PED-500-16	5.00	16
PED-500-18	5.00	18
PED-500-20	5.00	20
PED-500-25	5.00	35
PED-500-30	5.00	30
PED-500-35	5.00	35

REVASCULARIZATION DEVICES



The **SOLITAIRE™ PLATINUM REVASCULARIZATION DEVICE** is a mechanical thrombectomy device designed to restore blood flow by removing thrombus in patients with ischemic stroke due to large intracranial vessel occlusion. This next generation device, with the addition of platinum markers, is designed to provide real time procedural feedback[1] when being used in the neurovasculature such as the Internal Carotid Artery, M1 and M2 segments of the Middle Cerebral Artery, Anterior Cerebral Artery, Basilar Artery, and Vertebral Arteries.[2]

SOLITAIRE™ PLATINUM REVASCULARIZATION DEVICE

Product Catalog Number	Size (mm)	Recommended Vessel Diameter (mm)	Minimum Micro Catheter ID (in)	Push Wire Length (cm)	# of Radiopaque Markers			Radiopaque Marker Spacing (mm)	Total # of Radiopaque Marker Rows
					Distal end	Proximal end	Stent body		
SFR3-4-20-05	4 x 20	2.0 – 4.0	0.021	180	3	1	12	5	5
SFR3-4-20-10	4 x 20	2.0 – 4.0	0.021	180	3	1	3	10	3
SFR3-4-40-10	4 x 40	2.0 – 4.0	0.021	180	3	1	3	10	5
SFR3-6-20-10	6 x 20	3.0 – 5.5	0.027	180	4	1	3	10	3
SFR3-6-24-06	6 x 24	3.0 – 5.5	0.027	180	4	1	12	6	5
SFR3-6-40-10	6 x 40	3.0 – 5.5	0.027	180	4	1	12	10	5

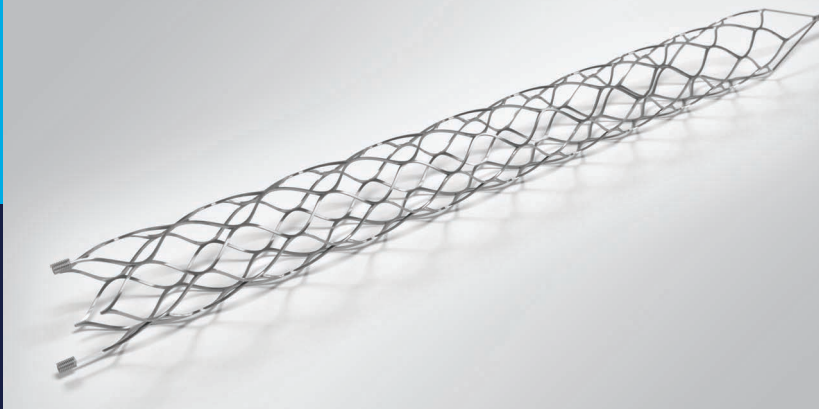
The **SOLITAIRE™ 2 REVASCULARIZATION DEVICE** is a mechanical thrombectomy device designed to restore blood flow by removing thrombus in patients with ischemic stroke due to large intracranial vessel occlusion. The device is designed to be used in the neurovasculature such as the Internal Carotid Artery, M1 and M2 segments of the Middle Cerebral Artery, Anterior Cerebral Artery, Basilar Artery, and Vertebral Arteries.[3]

SOLITAIRE™ 2 REVASCULARIZATION DEVICE

Product Catalog Number	Size (mm)	Recommended Vessel Diameter (mm)	Diameter (mm)	Minimum Micro Catheter ID (in)	Push Wire Length (cm)	Distal Markers	Proximal Markers	Usable Length (mm)	Total Length (mm)
SFR2-4-15	4 x 15	2.0 – 4.0	4	0.021	180	3	1	15	26
SFR2-4-20	4 x 20	2.0 – 4.0	4	0.021	180	3	1	20	31
SFR2-4-40	4 x 40	2.0 – 4.0	4	0.021	180	3	1	40	50
SFR2-6-20	6 x 20	3.0 – 5.5	6	0.027	180	4	1	20	31
SFR2-6-30	6 x 30	3.0 – 5.5	6	0.027	180	4	1	30	42

1. TR-NV12692 rev A.
2. Indication from Solitaire Platinum IFU 70927-001 Rev. 01/16.
3. Indication from Solitaire 2 IFU 70686-001 Rev. 09/12.

REVASCULARIZATION DEVICES



The **MINDFRAME CAPTURE™ LP REVASCULARIZATION DEVICE** is the only mechanical thrombectomy device compatible with a catheter in the 10/14 class. It is designed to navigate, access and treat distal zone occlusions. It features distal and proximal markers for accurate positioning and a proprietary cell geometry that minimizes deformation and maximizes entrapment.[1,2]

MINDFRAME CAPTURE™ LP REVASCULARIZATION DEVICE

Product Catalog Number	Size (mm)	Recommended Vessel Diameter (mm)	Total Length (mm)	Push Wire Length (cm)	Distal Markers	Proximal Markers	Minimum Micro Catheter ID[1] (in)
300015	4 x 23	2.5 – 4.0	30	178	2	1	0.017
300016	3 x 23	2.0 – 3.0	30	178	2	1	0.017
300017	4 x 15	2.5 – 4.0	20	178	2	1	0.017
300018	3 x 15	2.0 – 3.0	20	178	2	1	0.017

1. PR/TR13-011 and PR/TR13-017
2. PR/TR14-005 and PR/TR14-006

ACCESSORIES

The **CADENCE™ PRECISION INJECTOR** provides precision inflation of balloon catheters; 0.02 ml inflation per rotation offers tactile feedback.

CADENCE™ PRECISION INJECTOR ACCESSORY		
Product Catalog Number	Capacity (ml)	Quantity
103-0304	1	5

1 ML INJECTION SYRINGE		
Product Catalog Number	Capacity (ml)	Syringes/Box
103-1203	1	10

INDICATIONS FOR USE

Specifications Nominal

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

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

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

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

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

Arc™ and Arc™ Mini
The Arc™ and Arc™ Mini Intracranial Support Catheters are indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

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

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

Navien™ intracranial support catheter
The Navien™ intracranial support catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Apollo™ Onyx™ delivery micro catheter
This product is for the exclusive use by medical specialists experienced in angiographic and percutaneous neurointerventional procedures.

Indications For Use: The Apollo™ Onyx™ delivery micro catheter is intended to access the neuro vasculature for the controlled selective infusion of the Onyx™ liquid embolic system (LES).

Contraindications:

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

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

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

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

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

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

Orion™ -21 micro catheter
The Orion™ -21 micro catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

INDICATIONS FOR USE

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

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

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

Onyx™ liquid embolic system (AVM)
This product is for the exclusive use by medical specialists experienced in angiographic and percutaneous neurointerventional procedures.

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

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

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

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

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

Should catheter removal become difficult, the following will assist in catheter retrieval: Carefully pull the catheter to assess any resistance to removal. If resistance is felt, remove any "slack" in the catheter. Gently apply traction to the catheter (approximately 3-4 cm of stretch to the catheter). Hold this traction for a few seconds and release. Assess traction on vasculature to minimize risk of hemorrhage. This process can be repeated intermittently until catheter is retrieved.

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

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

Potential Complications: The following adverse events occurred using Onyx during a prospective, randomized, multi-center clinical trial for the presurgical treatment of bAVMs: Death, Headache +/- nausea and vomiting, Patient discomfort, Laboratory/Imaging abnormalities (Endocrine/Metabolic, Hematologic, Asymptomatic MRI/CT Findings, Respiratory/Pulmonary, General, Gastrointestinal (GI)), Worsening Neurologic Status (Persistent, Resolved), Hyperglycemia, Infection, Bleeding and/or Low Hct requiring transfusion (Surgical Bleeding, Decreased Hct Requiring Transfusion), Intracranial Hemorrhage, Medication reaction, Failed access, Access site bleeding, Fever, Delivery Catheter removal difficulty, Poor penetration/visualization, Hypotension, Stroke, Cardiac arrhythmia, Hydrocephalus, SIADH (Syndrome of inappropriate antidiuretic hormone secretion, dilutional hyponatremia), Vessel Dissection, Hypertension, Limb ischemia, Respiratory failure, Seizures, UTI (Urinary tract infection), Vasospasm, Vaso-vagal episode, catheter shaft rupture, delivery catheter rupture, fragmentation of the Onyx™ LES, hypoxia, laryngospasm, peptic ulcer disease, psychotic episode, pulmonary edema, skin abrasion, subintimal injection, tachypnea, and tongue swelling.

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

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

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

Onyx™ HD-500 liquid embolic system
Humanitarian Device. Authorized by Federal law for use in the intracranial, saccular, sidewall aneurysms that present with a wide neck (≥ 4 mm) or with a dome-to-neck ratio < 2 that are not amenable to treatment with surgical clipping. The effectiveness of this device for this use has not been demonstrated.

This device should be used only by physicians with a thorough understanding of angiography and percutaneous neurointerventional procedures.

Onyx™ HD-500 Liquid Embolic System must be used with appropriately designed DMSO compatible micro catheters, balloon catheters and syringes.

Indications For Use: Treatment of intracranial, saccular, sidewall aneurysms that present with a wide neck (≥ 4 mm) or with a dome-to-neck ratio < 2 that are not amenable to treatment with surgical clipping.

INDICATIONS FOR USE

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

- When optimal catheter placement is not possible.
- When vasospasm stops blood flow.

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

Precautions: 1) The safety and effectiveness has not been studied in the following patient populations: Pregnant and nursing women, individuals less than 18 years old, patients with intracranial stents and/or coils, individuals with significant impairment of liver and kidney function. 2) Some data indicates that dimethyl sulfoxide potentiates other concomitantly administered medications. 3) A garlic-like taste may be noted by the patient with use of Onyx™ HD-500 Liquid Embolic System due to the DMSO component. This taste may last several hours. An odor on the breath and skin may be present. 4) Inspect product packaging prior to use. Do not use if sterile barrier is open or damaged. 5) Use prior to expiration date. 6) Verify that the catheters and accessories (see Directions) used in direct contact with the Onyx™ HD-500 Liquid Embolic System polymer are clean and compatible with the material and do not trigger polymerization or degrade with contact. Use only Medtronic Neurovascular micro catheters indicated for use in the neurovasculature, e.g., Rebar™ and ev3 Neurovascular syringes. Other micro catheters or syringes may not be compatible with DMSO and their use can result in thromboembolic events due to catheter degradation. Refer to the Warnings and Directions sections.

Potential Complications: The following adverse events occurred using Onyx™ HD-500 Liquid Embolic System during a clinical study to evaluate the safety and probable benefit: Neurological (e.g., headache, visual impairment, ataxia/unsteady gait), Gastrointestinal (e.g., nausea/vomiting, constipation, heartburn), Vascular Complications (e.g., access site pain, hematoma, and bleeding), Pulmonary/Respiratory (e.g., pneumonia, respiratory failure, COPD exacerbation), Musculoskeletal (e.g., joint pain, misc. somatic pain, neck/back pain), Dermatological (e.g., skin bruising, urticaria/itching, alopecia), Cardiac (e.g., increased blood pressure, decreased blood pressure, arrthymias/bradycardia), Metabolic (e.g., electrolyte change), Constitutional (e.g. anemia, dehydration), Vasospasm, Protrusion in Parent Vessel, Stroke – Ischemic, Urogenital, Other – Misc., PAO – Partial, Distal Embolic Events, PAO – Complete, Death, PAO – Stent Induced, Perforations/Dissections, Stroke – Hemorrhagic, Hematological.

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

Axium™ and Axium™ Prime detachable coils

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

Pipeline™ Flex embolization device

The Pipeline™ Flex embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment.

Indications for Use: The Pipeline™ Flex embolization device is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments.

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

Warnings: 1) Resheathing of the Pipeline™ Flex embolization device more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 2) Persons with known allergy to platinum or cobalt/chromium alloy (including the major elements platinum, cobalt, chromium, nickel, molybdenum or tungsten) may suffer an allergic reaction to the Pipeline™ Flex embolization device implant. 3) Person with known allergy to tin, silver, stainless steel or silicone elastomer may suffer an allergic reaction to the Pipeline™ Flex embolization device delivery system. 4) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection and compromised device performance. 5) Delayed rupture may occur with large and giant aneurysms. 6) Placement of multiple Pipeline™ Flex embolization devices may increase the risk of ischemic complications.

Precautions: 1) Do not use product if the sterile package is damaged. 2) Do not use the Pipeline™ Flex embolization device in patients in whom angiography demonstrates inappropriate anatomy, such as severe pre- or post-aneurysmal narrowing. 3) The Pipeline™ Flex embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment. 4) Physicians should undergo appropriate training prior to using the Pipeline™ Flex embolization device in patients. 5) The Pipeline™ Flex embolization device is provided sterile for single use only. Store in a cool, dry place. 6) Carefully inspect the sterile package and device components prior to use to verify that they have not been damaged during shipping. Do not use kinked or damaged components. 7) Use the Pipeline™ Flex embolization device system prior to the "Use By" date printed on the package. 8) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 9) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 10) Do not attempt to reposition after deployment. 11) Do not use in patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to conditions such as severe intracranial vessel tortuosity or stenosis. 12) Use of implants with labeled diameter larger than the parent vessel diameter may result in decreased effectiveness and additional safety risk due to incomplete foreshortening resulting in an implant longer than anticipated.

Potential Complications: Potential complications, some of which could be fatal, include, but are not limited to the following: Adverse reaction to antiplatelet/ anticoagulation agents or contrast media, Blindness, Coma, Device fracture, Device migration or misplacement, Dissection of the parent artery, Embolism, Groin injury, Headache, Hemorrhage, Hydrocephalus, Infection, Intracerebral bleeding, Ischemia, Mass effect, Neurological deficits, Parent Artery Stenosis, Perforation, Perforator occlusion, Post- procedure bleeding, Ruptured or perforated aneurysm, Seizure, Stroke, Thromboembolism, Transient Ischemic Attack (TIA), Vasospasm, Vessel occlusion, Vessel perforation, Vision impairment.

Contraindications: The use of the Pipeline™ Flex embolization device is contraindicated for patients with any of the following conditions: 1) Patients with active bacterial infection. 2) Patients in whom dual antiplatelet therapy (aspirin and clopidogrel) is contraindicated. 3) Patients who have not received dual antiplatelet agents prior to the procedure. 4) Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location.

INDICATIONS FOR USE

Solitaire™ Platinum revascularization device
The Solitaire™ Platinum revascularization device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The Solitaire™ revascularization device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

Solitaire™ 2 revascularization device
The Solitaire™ 2 revascularization device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The Solitaire™ revascularization device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

Mindframe Capture™ LP revascularization device
The MindFrame Capture™ LP revascularization device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. This Device should only be used by physicians' trained in interventional neuroradiology and treatment of ischemic stroke.

Cadence™ precision injector
The Cadence precision injector is intended for the controlled delivery of fluids in the inflation and deflation of temporary occlusion balloons.

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