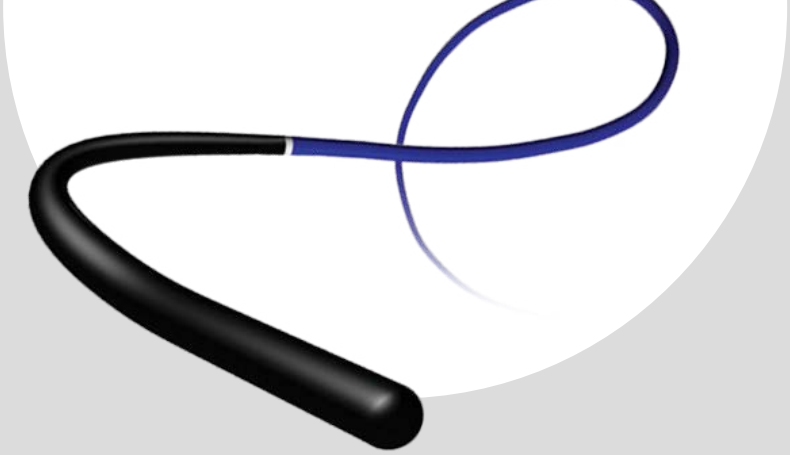
Medtronic

2022 catalog

Neurovascular

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

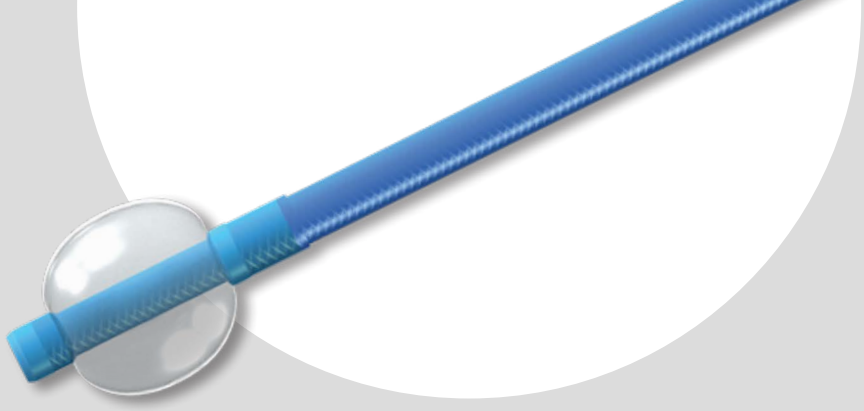
Mirage™ .008" Hydrophilic Guidewire

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

X-Pedion™ Hydrophilic Guidewire

Product Catalog Number	Diameter (in)	Total Length (cm)	Coil Length (cm)
103-0605-200	.012>.010	200	10

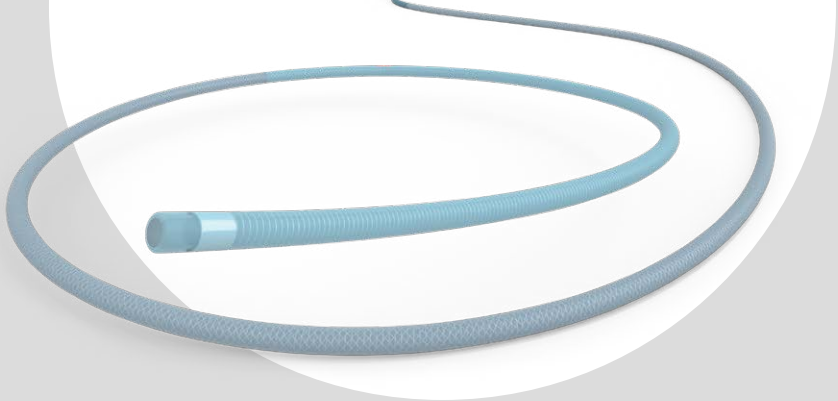
Balloon Guide Catheters



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



Phenom™ Plus Catheter

Product Catalog Number	Working Length (cm)	Proximal Outer Diameter (in)	Distal Outer Diameter (in)	Catheter Inner Diameter (in)
FG19120-1030-1S	120	0.061	0.055	0.0445

React™ 68 Catheter

Product Catalog Number	ID (in)	Max OD (in)	Working Length (cm)
REACT-68	0.068	0.083	132

React™ 71 Catheter

Product Catalog Number	ID (in)	Max OD (in)	Working Length (cm)
REACT-71	0.071	0.0855	132

1. Cathera Document ML-0001.A

Radial Access System

The Rist™ Radial Access System features the first guide catheter designed for the unique demands of accessing the neurovasculature through the radial pathway.[1-9]

Rist™ 079 Radial Access Guide Catheter[6,7]

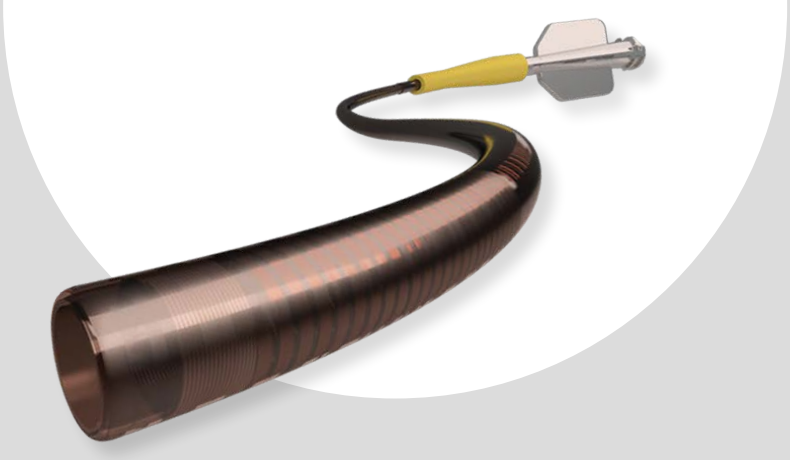
Product Catalog Number	Working Length (cm)	OD (in / F)	ID (in)	Hydrophilic Coating Length (cm)
107F-079-95	95	0.093 / 7F	0.079	25
107F-079-100	100	0.093 / 7F	0.079	25
107F-079-105	105	0.093 / 7F	0.079	25

Rist™ Radial Access Selective Catheter[8]

Product Catalog Number	Working Length (cm)	OD (in / F)	ID (in)	Tip Shapes
105F-BER-120	120	0.070 / 5.5F	0.040	Berenstein
105F-BER-130	130	0.070 / 5.5F	0.040	Berenstein
105F-SIM-120	120	0.070 / 5.5F	0.040	Sim2
105F-SIM-130	130	0.070 / 5.5F	0.040	Sim2

1. INC TR-12549
2. INC TR-12736
3. INC TR-13494
4. INC TR-13523
5. K191551
6. K201682
7. INC-11816
8. INC-11694
9. D00312142

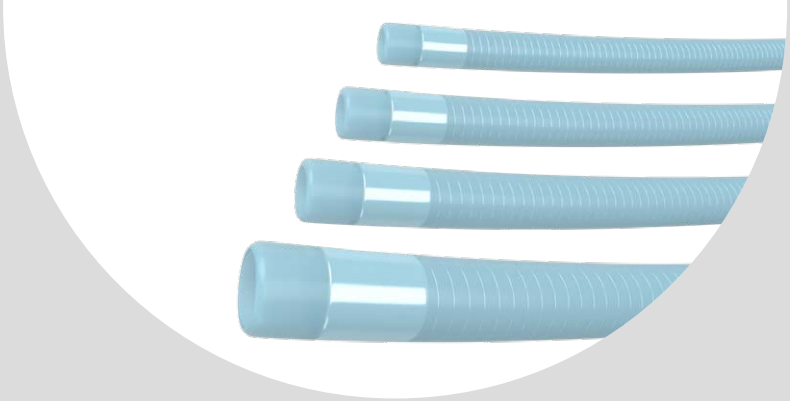
Intracranial Support Catheters



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°	0.038	8
RFX072-130-08	6 / 0.084	0.072	130	Straight	0.038	8
RFX072-130-08MP	6 / 0.084	0.072	130	Multi-Purpose 25°	0.038	8

Micro Catheters



Phenom™ 17 Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Working Length (cm)	Soft Distal Segment (cm)	Flexible Single Coil Segment (cm)	Tip Shape	Max. Guidewire (in)
FG11150-0615-2S	2.2>1.8	0.017	150	6	15	Straight	0.014
FG11150-0615-2J	2.2>1.8	0.017	150	6	15	J Curve	0.014
FG11150-0615-2X	2.2>1.8	0.017	150	6	15	45 Curve	0.014
FG11150-0615-2R	2.2>1.8	0.017	150	6	15	90 Curve	0.014

Phenom™ 21 Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Working Length (cm)	Soft Distal Segment (cm)	Flexible Single Coil Segment (cm)	Tip Shape	Max. Guidewire (in)
FG13150-0615-2S	2.6>2.3	0.021	150	6	15	Straight	0.018
FG13160-0615-1S	2.6>2.3	0.021	160	6	15	Straight	0.018

Phenom™ 27 Catheter

Product Catalog Number	Outer Diameter (F)	Inner Diameter (in)	Working Length (cm)	Soft Distal Segment (cm)	Flexible Single Coil Segment (cm)	Tip Shape	Max. Guidewire (in)
FG15150-0615-1S	3.1>2.8	0.027	150	6	15	Straight	0.025
FG15150-0630-1S	3.1>2.8	0.027	150	6	30	Straight	0.025
FG15160-0615-1S	3.1>2.8	0.027	160	6	15	Straight	0.025

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

Micro Catheters

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
105-5096-000	2.7 / 0.036	1.5 / 0.020	0.013	165	3.0	Straight	0.008 & 0.010 hydrophilic	> 0.20

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

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

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°

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	
Product Catalog Number	**Description**
105-7100-060	Onyx™ 18 LES
105-7100-080	Onyx™ 34 LES

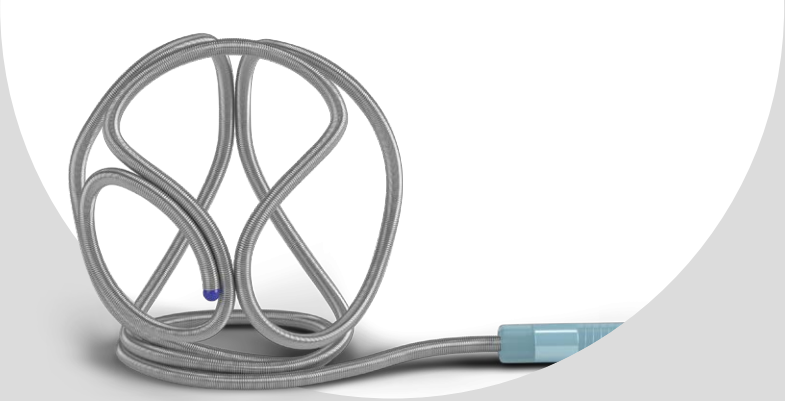
The Onyx™ 18 and 34 LES Kits contain[1]:

- 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)

Onyx™ LES Accessories	
Product Catalog Number	**Description**
103-1205-001	Vial Mixer

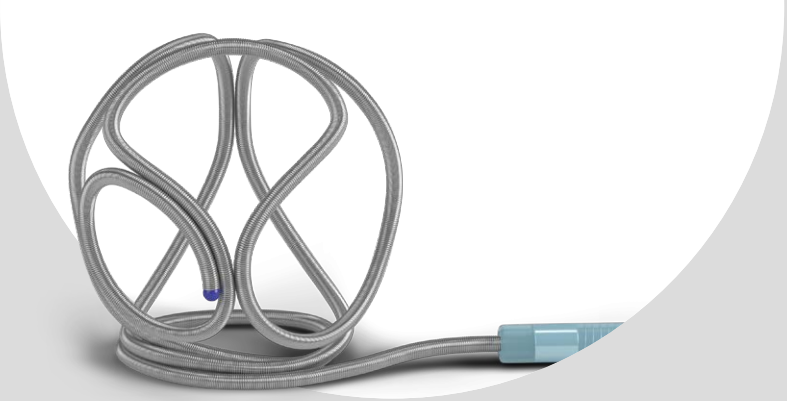
1. IFU 70862 Rev 10/13

3D Framing Detachable Coils



Axium™ Prime Detachable Coils (Frame)			
Product Catalog Number	**Diameter (mm)**	**Length (cm)**	**Progressive Coil Diameter (in)**
FC-3-6-3D	3	6	0.0115
FC-3-8-3D	3	8	0.0115
FC-3-10-3D	3	10	0.0115
FC-3.5-6-3D	3.5	6	0.0115
FC-3.5-8-3D	3.5	8	0.0115
FC-3.5-10-3D	3.5	10	0.0115
FC-4-6-3D	4	6	0.0125
FC-4-8-3D	4	8	0.0125
FC-4-10-3D	4	10	0.0125
FC-4-12-3D	4	12	0.0125
FC-4-15-3D	4	15	0.0125
FC-5-8-3D	5	8	0.0125
FC-5-10-3D	5	10	0.0125
FC-5-15-3D	5	15	0.0125
FC-5-20-3D	5	20	0.0125
FC-6-10-3D	6	10	0.0125
FC-6-15-3D	6	15	0.0125
FC-6-20-3D	6	20	0.0125
FC-6-25-3D	6	25	0.0125
FC-7-12-3D	7	12	0.0135
FC-7-15-3D	7	15	0.0135
FC-7-20-3D	7	20	0.0135
FC-7-30-3D	7	30	0.0135
FC-8-15-3D	8	15	0.0135
FC-8-20-3D	8	20	0.0135
FC-8-30-3D	8	30	0.0135

3D Framing Detachable Coils



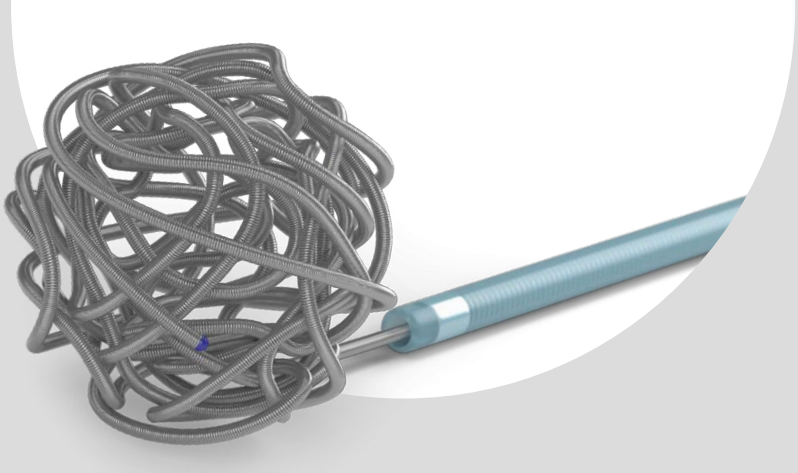
Axium™ Prime Detachable Coils (Frame)

Product Catalog Number	Diameter (mm)	Length (cm)	Progressive Coil Diameter (in)
FC-9-20-3D	9	20	0.0135
FC-9-30-3D	9	30	0.0135
FC-10-20-3D	10	20	0.0135
FC-10-30-3D	10	30	0.0135
FC-10-40-3D	10	40	0.0135
FC-12-30-3D	12	30	0.0145
FC-12-40-3D	12	40	0.0145
FC-12-50-3D	12	50	0.0145
FC-14-30-3D	14	30	0.0145
FC-14-40-3D	14	40	0.0145
FC-14-50-3D	14	50	0.0145
FC-16-40-3D	16	40	0.0145
FC-16-50-3D	16	50	0.0145
FC-18-40-3D	18	40	0.0145
FC-18-50-3D	18	50	0.0145
FC-20-50-3D	20	50	0.0145
FC-22-50-3D	22	50	0.0145
FC-25-50-3D	25	50	0.0145

ID Instant Detacher (5 Pack)

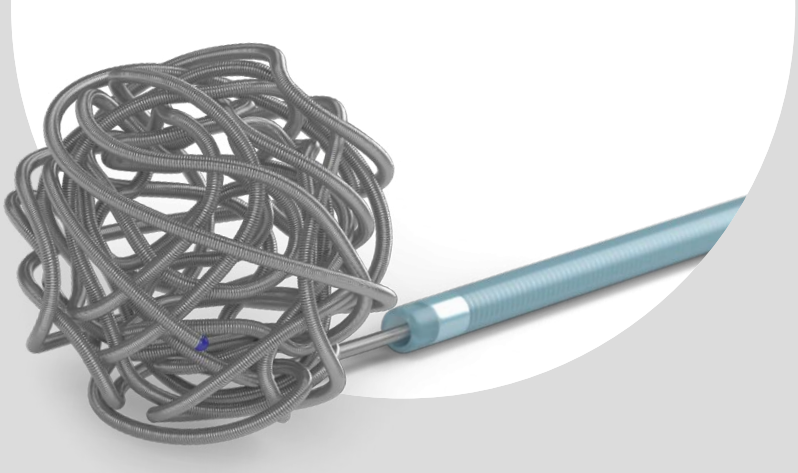
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

3D Soft Detachable Coils



Axium™ Prime 3D Detachable Coils (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 Soft Detachable Coils



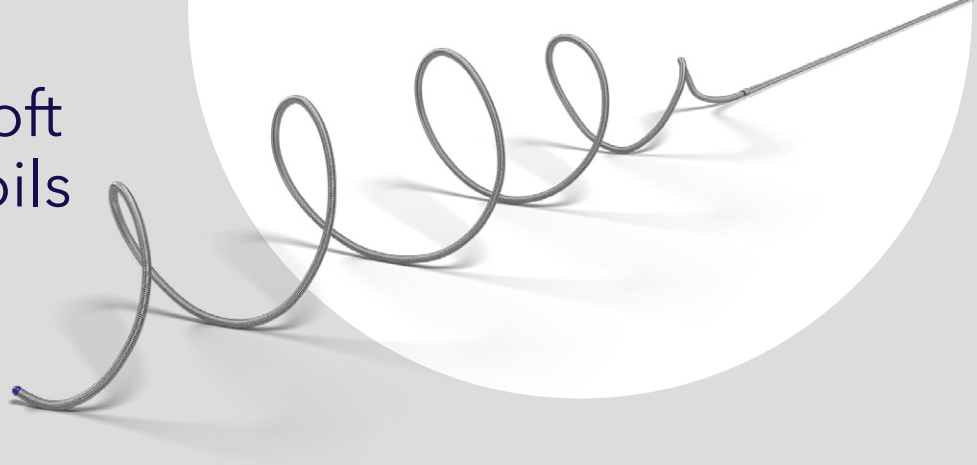
Axium™ Prime Helical Detachable Coils (Soft)			
Product Catalog Number	**Diameter (mm)**	**Length (cm)**	**Progressive Coil Diameter (in)**
APB-4-6-HX-SS	4	6	0.0115
APB-4-8-HX-SS	4	8	0.0115
APB-4-10-HX-SS	4	10	0.0115
APB-4-12-HX-SS	4	12	0.0115
APB-5-10-HX-SS	5	10	0.0115
APB-5-15-HX-SS	5	15	0.0115
APB-5-20-HX-SS	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 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 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

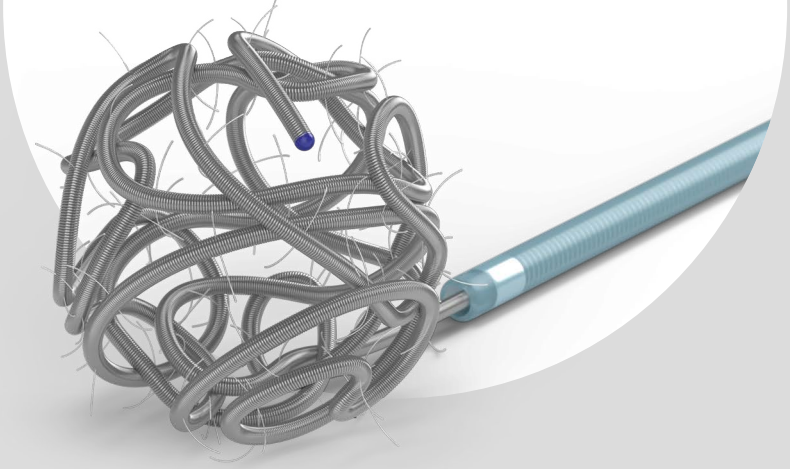
Axium™ Helical Detachable Coils

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)

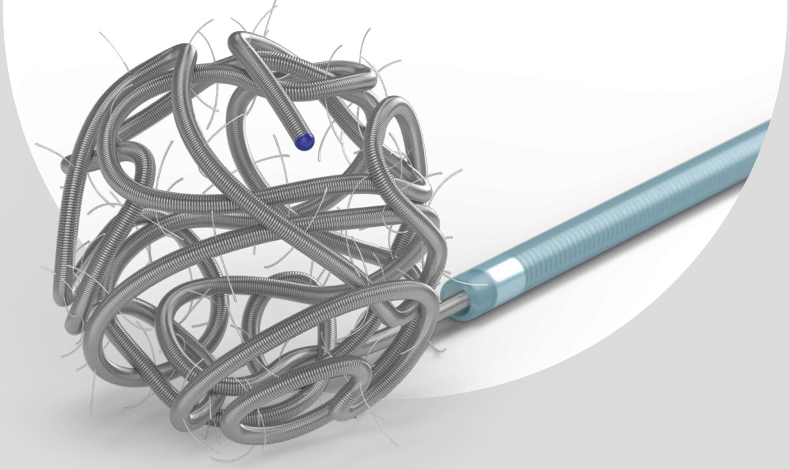
Product Catalog Number	Description
ID-1-5	Axium™ ID Instant Detacher

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

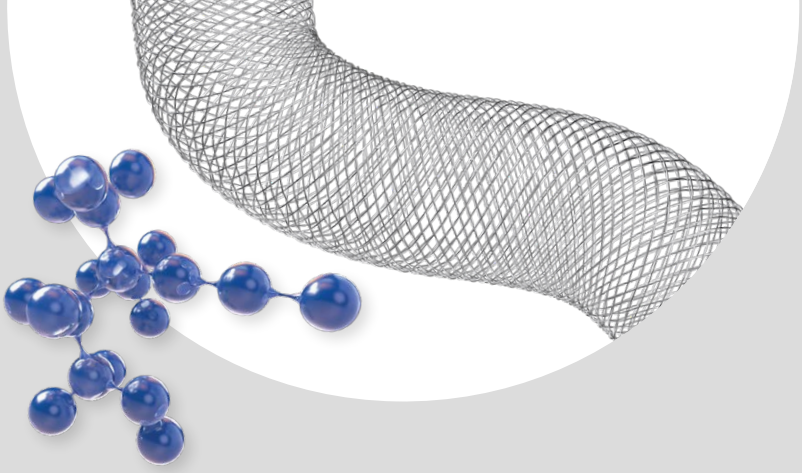
Axium™ MicroFX™ PGLA Helix Coils			
Product Catalog Number	**Diameter (mm)**	**Length (cm)**	**Progressive Coil Diameter (in)**
PC-2-1-HELIX	2	1	0.0115
PC-2-2-HELIX	2	2	0.0115
PC-2-3-HELIX	2	3	0.0115
PC-2-4-HELIX	2	4	0.0115
PC-2-6-HELIX	2	6	0.0115
PC-2-8-HELIX	2	8	0.0115
PC-3-4-HELIX	3	4	0.0115
PC-3-6-HELIX	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



Pipeline™ Flex Embolization Device with Shield Technology™ is designed to divert blood flow away from certain brain aneurysms. The device features a braided cylindrical mesh that is implanted across the base or neck of the aneurysm.[1] Shield Technology™ builds on the clinically proven Pipeline™ Flex Embolization Device[2] by introducing an innovative implant surface modification, designed to reduce material thrombogenicity.[3,4*]

Pipeline™ Flex Embolization Device with Shield Technology™

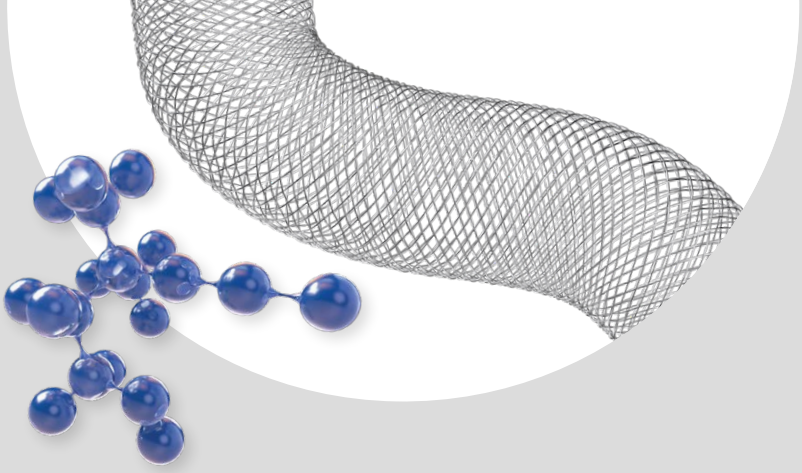
Product Catalog Number	Diameter (mm)	Length (mm)
PED2-250-10	2.50	10
PED2-250-12	2.50	12
PED2-250-14	2.50	14
PED2-250-18	2.50	18
PED2-275-12	2.75	12
PED2-275-16	2.75	16
PED2-300-10	3.00	10
PED2-300-12	3.00	12
PED2-300-14	3.00	14
PED2-300-20	3.00	20
PED2-325-12	3.25	12
PED2-325-14	3.25	14
PED2-325-16	3.25	16
PED2-325-20	3.25	20
PED2-350-12	3.50	12
PED2-350-14	3.50	14
PED2-350-16	3.50	16
PED2-350-18	3.50	18
PED2-350-20	3.50	20
PED2-375-10	3.75	10
PED2-375-12	3.75	12
PED2-375-14	3.75	14
PED2-375-16	3.75	16
PED2-375-18	3.75	18
PED2-375-20	3.75	20
PED2-375-25	3.75	25
PED2-400-12	4.00	12

*Data is derived from the referenced pre-clinical studies and may not be representative of clinical performance.

For information on additional sizes not listed above, contact your Medtronic Neurovascular representative.

1. M002318CDOC2_B. Pipeline Flex with Shield Technology IFU.
2. Kallmes, DF et al. International Retrospective Study of the Pipeline Embolization Device: A Multicenter Aneurysm Treatment Study, AJNR Published online, Oct 29, 2014.
3. Medtronic Internal Study, D00422708 Rev. A, Competitive Test Report - Material Thrombogenicity Evaluation of Flow Diversion Devices.
4. Girdhar G, Li J, Kostousov L, Wainwright J, Chandler WL. In-vitro thrombogenicity assessment of flow diversion and aneurysm bridging devices. J Thromb Thrombolysis. 2015 Nov;40(4):437-43. doi: 10.1007/s11239-015-1228-0. PMID: 25975924

Flow Diverters



Pipeline™ Flex Embolization Device with Shield Technology™

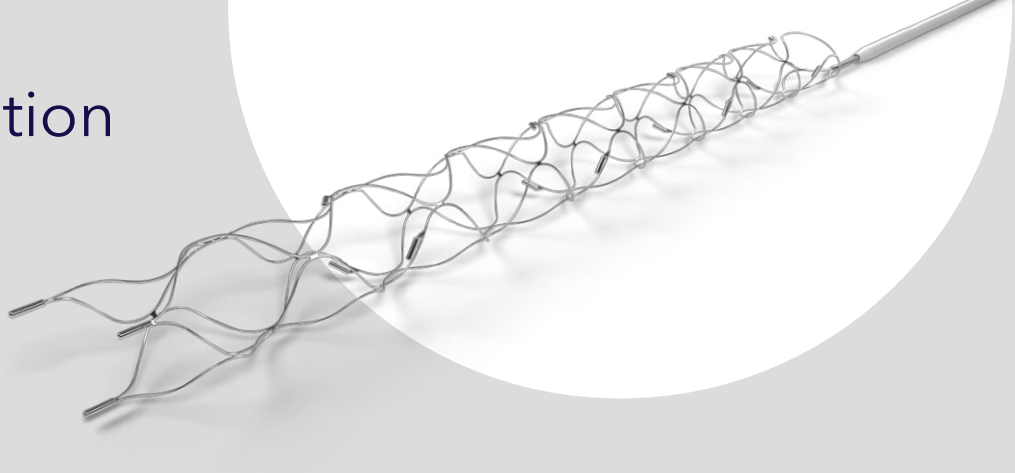
Product Catalog Number	Diameter (mm)	Length (mm)
PED2-400-14	4.00	14
PED2-400-16	4.00	16
PED2-400-18	4.00	18
PED2-400-20	4.00	20
PED2-400-30	4.00	30
PED2-425-12	4.25	12
PED2-425-14	4.25	14
PED2-425-16	4.25	16
PED2-425-18	4.25	18
PED2-425-20	4.25	20
PED2-425-25	4.25	25
PED2-450-12	4.50	12
PED2-450-14	4.50	14
PED2-450-16	4.50	16
PED2-450-18	4.50	18
PED2-450-20	4.50	20
PED2-450-25	4.50	25
PED2-450-35	4.50	35
PED2-475-12	4.75	12
PED2-475-14	4.75	14
PED2-475-16	4.75	16
PED2-475-20	4.75	20
PED2-475-30	4.75	30
PED2-500-12	5.00	12
PED2-500-14	5.00	14
PED2-500-16	5.00	16
PED2-500-18	5.00	18
PED2-500-20	5.00	20
PED2-500-25	5.00	25
PED2-500-30	5.00	30
PED2-500-35	5.00	35

*Data is derived from the referenced pre-clinical studies and may not be representative of clinical performance.

1. M002318CDOC2_B. Pipeline Flex with Shield Technology IFU.
2. Kallmes, DF et al. International Retrospective Study of the Pipeline Embolization Device: A Multicenter Aneurysm Treatment Study, AJNR Published online, Oct 29, 2014.
3. Medtronic Internal Study, D00422708 Rev. A, Competitive Test Report - Material Thrombogenicity Evaluation of Flow Diversion Devices.
4. Girdhar G, Li J, Kostousov L, Wainwright J, Chandler WL. In-vitro thrombogenicity assessment of flow diversion and aneurysm bridging devices. J Thromb Thrombolysis. 2015 Nov;40(4):437-43. doi: 10.1007/s11239-015-1228-0. PMID: 25975924

For information on additional sizes not listed above, contact your Medtronic Neurovascular representative.

Revascularization Devices



The Solitaire™ X Revascularization Device is a mechanical thrombectomy device designed to restore blood flow by removing thrombus to reduce disability in patients experiencing ischemic stroke due to large intracranial vessel occlusion.[1] The Solitaire™ X device is designed with an optimized delivery system – produces lower delivery force for improved procedural efficiency and smooth navigation through even the most complicated anatomy.[2,3]

Solitaire™ X Revascularization Device[3-5]

Product Catalog Number	Size (mm)	Recommended Vessel Diameter (mm)	Minimum Micro Catheter ID (in / mm)	Push Wire Length (cm)	# of Radiopaque Markers		Radiopaque Marker Spacing (mm)
					Distal End	Proximal End	
SFR4-3-20-10	3 x 20	1.5 – 3.0	0.017 / 0.43	200	3	1	10
SFR4-3-40-10	3 x 40	1.5 – 3.0	0.017 / 0.43	200	3	1	10
SFR4-4-20-05	4 x 20	1.5 – 4.0	0.021 / 0.53	200	3	1	5
SFR4-4-20-10	4 x 20	1.5 – 4.0	0.021 / 0.53	200	3	1	10
SFR4-4-40-10	4 x 40	1.5 – 4.0	0.021 / 0.53	200	3	1	10
SFR4-6-20-10	6 x 20	2.0 – 5.5	0.021 / 0.53	200	4	1	10
SFR4-6-24-06	6 x 24	2.0 – 5.5	0.021 / 0.53	200	4	1	6
SFR4-6-40-10	6 x 40	2.0 – 5.5	0.021 / 0.53	200	4	1	10

1. M003592CDOC2
2. TR-NV16168 Rev A
3. Compared to Solitaire™ Platinum
4. K203358
5. K193576

Aspiration

The React™ 68 Catheter and the React™ 71 Catheter feature a coil and braid design – easing navigation to the M1 and M2 segments. Combined with the Riptide™ Aspiration System, these catheters are designed to revascularize patients experiencing acute ischemic stroke.[1]

Riptide™ Aspiration System

Product Catalog Number	Description
MAP-1000	Riptide™ Aspiration System

Riptide™ Collection Canister & Intermediate Tubing

Product Catalog Number	Description	Volume (ml)
MAC-1200	Riptide™ Collection Canister & Intermediate Tubing	1200

Riptide™ Aspiration Tubing

Product Catalog Number	Description	Inner Diameter (in)	Tubing Length (in)	Distal Length (in)
MAT-110-110	Riptide™ Aspiration Tubing	0.110	112	7

Riptide™ Aspiration Catheters

Product Catalog Number	Description	Working Length (cm)	Max OD (in)	Max ID (in)
REACT-68	React™ 68 Catheter	132	0.083	0.068
REACT-71	React™ 71 Catheter	132	0.0855	0.071

1. M994065ADOC2

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

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

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™ Hydrophilic Guidewire
The Mirage™ 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 or diagnostic agents into the neuro, peripheral, and coronary vasculatures.

React™ 68 and 71 Catheter
The React™ Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Rist™ 079 Radial Access Guide Catheter
The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Rist™ Radial Access Selective Catheter

The Rist™ Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.

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.

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.

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™ Flow Directed Micro Catheter
The Marathon™ Flow Directed 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.

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.

Hyperform™ and HyperGlide™ Occlusion Balloon System
The Hyperform™ and HyperGlide™ 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.

Indications for use

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.

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 with Shield Technology™
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 for the Pipeline™ Flex Embolization Device with Shield Technology™ can be viewed at https://www.medtronic.com/manuals. Indications for Use: The Pipeline™ Flex Embolization Device with Shield Technology™ 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. The Pipeline™ Flex Embolization Device with Shield Technology™ is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm. Contraindications: 1) Patients with active bacterial infection. 2) Patients in whom dual antiplatelet and/or anticoagulation 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. 5) Patients in whom the parent vessel size does not fall within the indicated range. Warnings: 1) Pushing delivery wire without retracting the micro catheter at the same time will cause the open end braid to move distally in the vessel. This may cause damage to the braid or vessel. 2) Use in tortuous anatomy may result in difficulty or inability to deploy the Pipeline™ Flex embolization device with Shield Technology™ and can lead to damage to the Pipeline™ Flex Embolization Device with Shield Technology™ and microcatheter. To mitigate potential problems as a result of increased delivery forces, reduce the load in the system by: Unloading the microcatheter to the inner curves of vessel by pulling back on the system (i.e., the microcatheter and delivery wire together). Continue unloading the system until advancement of the device (inside the microcatheter) is observed, while minimizing the distal tip movement to prevent loss of position. Begin to re-advance the delivery wire while maintaining reduced load in the microcatheter. This process should be repeated until the device passes through tortuous area and the delivery force is decreased. 3) Resheathing of the Pipeline™ Flex Embolization Device with Shield Technology™ more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 4) 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 with Shield Technology™ implant. 5) Person with known allergy to tin, silver, stainless steel, or silicone elastomer may suffer an allergic reaction to the Pipeline™ Flex Embolization Device with Shield Technology™ Delivery System. 6) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection

Indications for use

and compromised device performance. 7) Post-procedural movement (migration and/or foreshortening) of the Pipeline™ Flex Embolization Device with Shield Technology™ implant may occur following implantation and can result in serious adverse events and/or death. 8) Factors which may contribute to post procedural device movement include (but are not limited to) the following: Failure to adequately size the implant (i.e., under sizing), Failure to obtain adequate wall apposition during the implant deployment, Implant stretching, Vasospasm, Severe vessel tapering, Tortuous anatomy 9) Delayed rupture may occur with large and giant aneurysms. 10) Placement of multiple Pipeline™ Flex Embolization Device with Shield Technology™ may increase the risk of ischemic complications. 11) Use in anatomy with severe tortuosity, stenosis or parent vessel narrowing may result in difficulty or inability to deploy the Pipeline™ Flex Embolization Device with Shield Technology™ and can lead to damage to the Pipeline™ Flex Embolization Device with Shield Technology™ and microcatheter. Advancement or retraction of the Pipeline™ Flex Embolization Device with Shield Technology™ against resistance may result in damage, including unintended device or component separation, fracture, or breakage of the delivery system due to inherent flexibility limits of device design. Device damage may result in patient injury or death. Refer to page 4 in the instructions for use for additional information. 12) Do not attempt to reposition the device after full deployment. 13) The benefits may not outweigh the risks of treatment of small and medium asymptomatic extradural intracranial aneurysms, including those located in the cavernous internal carotid artery. The risk of rupture for small and medium asymptomatic extradural intracranial aneurysms is very low if not negligible. 14) A decrease in the proportion of patients who achieve complete aneurysm occlusion without significant parent artery stenosis has been observed with the use of the device in the communicating segment (C7) of the internal carotid artery (47.4% (9/19 subjects in the PREMIER study at 1 year)), including those IAs fed by the posterior circulation or have retrograde filling. Ensure appropriate patient selection and weigh the benefits and risks of alternative treatments prior to use of this device for the treatment of intracranial aneurysms located in this region of the ICA. The following anatomical characteristics, associated with retrograde filling, should be carefully considered during procedural planning of C7 intracranial aneurysms: PComm of fetal origin (A PCA of fetal origin is defined as a small, hypoplastic, or absent P1 segment of the PCA with the PComm artery supplying a majority of blood flow to the ICA); PComm overlapping with the aneurysm neck; and/or PComm branch arising from the dome of the aneurysm. 15) The safety and effectiveness of this device for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient. Precautions: 1) The Pipeline™ Flex Embolization Device with Shield Technology™ should be used only by physicians trained in percutaneous, intravascular techniques, and procedures at medical facilities with the appropriate fluoroscopy equipment. 2) Physicians should undergo appropriate training prior to using the Pipeline™ Flex Embolization Device with Shield Technology™ in patients. 3) The Pipeline™ Flex Embolization Device with Shield Technology™ is intended for single use only. Store in a cool, dry place. 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. Do not use product if the sterile package is damaged. 4) Use the Pipeline™ Flex Embolization Device with Shield Technology™ system prior to the "Use By" date printed on the package. 5) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 6) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 7) 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. 8) The Pipeline™ Flex Embolization Device with Shield Technology™ may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment. 9) Take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible. 10) Carefully weigh the benefits of treatment vs. the risks associated with treatment using the device for each individual patient based on their medical health status and risks factors for intracranial aneurysm rupture during their expected life time such as age, medical comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefits of device use may not outweigh the risks associated with the device in certain patients; therefore, judicious patient selection is recommended. 11) The safety and effectiveness of the device has not been established for treatment of fusiform IAs. 12) There may be a decrease in effectiveness and increase in safety events when the device is used in patients ≥ 60 years old. 13) The safety and effectiveness of the device has not been evaluated or demonstrated for ruptured aneurysms. 14) If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient. Potential Complications: Potential complications of the device and the endovascular procedure include, but are not limited to, the following: Access site complications like hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; Adverse reaction to anti-platelet/anticoagulation agents, anesthesia, reactions due to radiation exposure (such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts and delayed neoplasia) or contrast media, including organ failure; Vascular Complications like vasospasm, stenosis, dissection, perforation, rupture, fistula formation, pseudo aneurysm, occlusion, thromboembolic complications including ischemia (to unintended territory); Device complications like fracture, breakage (including unintended device or component separation), misplacement, migration/delayed foreshortening or reaction to device materials may occur; Systemic Complications like: Infection, Pain, fever, allergic reactions, organ failure, nerve damage; Bleeding/hemorrhagic complication including retroperitoneal hemorrhage; Neurological Deficits or dysfunctions including Stroke, Infarction, Loss of vision, Seizures, TIA, Headache, Cranial Nerve Palsies, Confusion, Coma, Hand Dysfunction; Decreased therapeutic response including need for target aneurysm retreatment; Risks associated with visual symptoms include Amaurosis Fugax/transient blindness, Blindness, Diplopia, Reduced visual acuity/field, Retinal artery occlusion, Retinal ischemia, Retinal infarction, Vision impairment including scintillations, blurred vision, eye floaters; Intracranial Hemorrhage (including from Aneurysm Rupture) Brain Edema, Hydrocephalus, Mass Effect; Death.

Solitaire™ X Revascularization Device

The Solitaire™ X 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. The Solitaire™ X Revascularization Device is indicated 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 IV t-PA or who fail IV t-PA therapy are candidates for treatment. The Solitaire™ X 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (<70 cc by CTA or MRA,<25 cc by MR-DWI). Endovascular therapy with the device should start within 6-16 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Indications, contraindications, warnings and instructions for use for Solitaire™ X Revascularization Device can be viewed at www.medtronic.com/manuals.

Indications, contraindications, warnings and instructions for all other products can be found in the product labeling supplied with each device.

Riptide™ Aspiration System

The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral M1 and M2 segments, basilar, and vertebral arteries) 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.

Indication, contraindication, warnings and instructions for use for the Riptide™ Aspiration System can be viewed at www.medtronic.com/manuals.

Cadence™ Precision Injector

The Cadence Precision Injector is intended for the controlled delivery of fluids in the inflation and deflation of temporary occlusion balloons.

Medtronic

9775 Toledo Way
Irvine, CA 92618
USA
Tel 877.526.7890
Fax 763.526.7888

medtronicNV.com