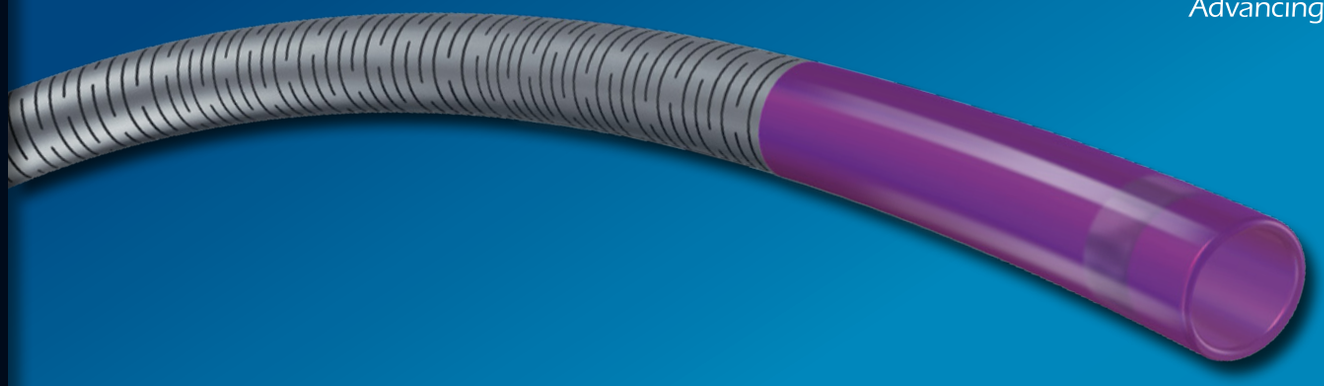
Boston Scientific

Advancing science for life™



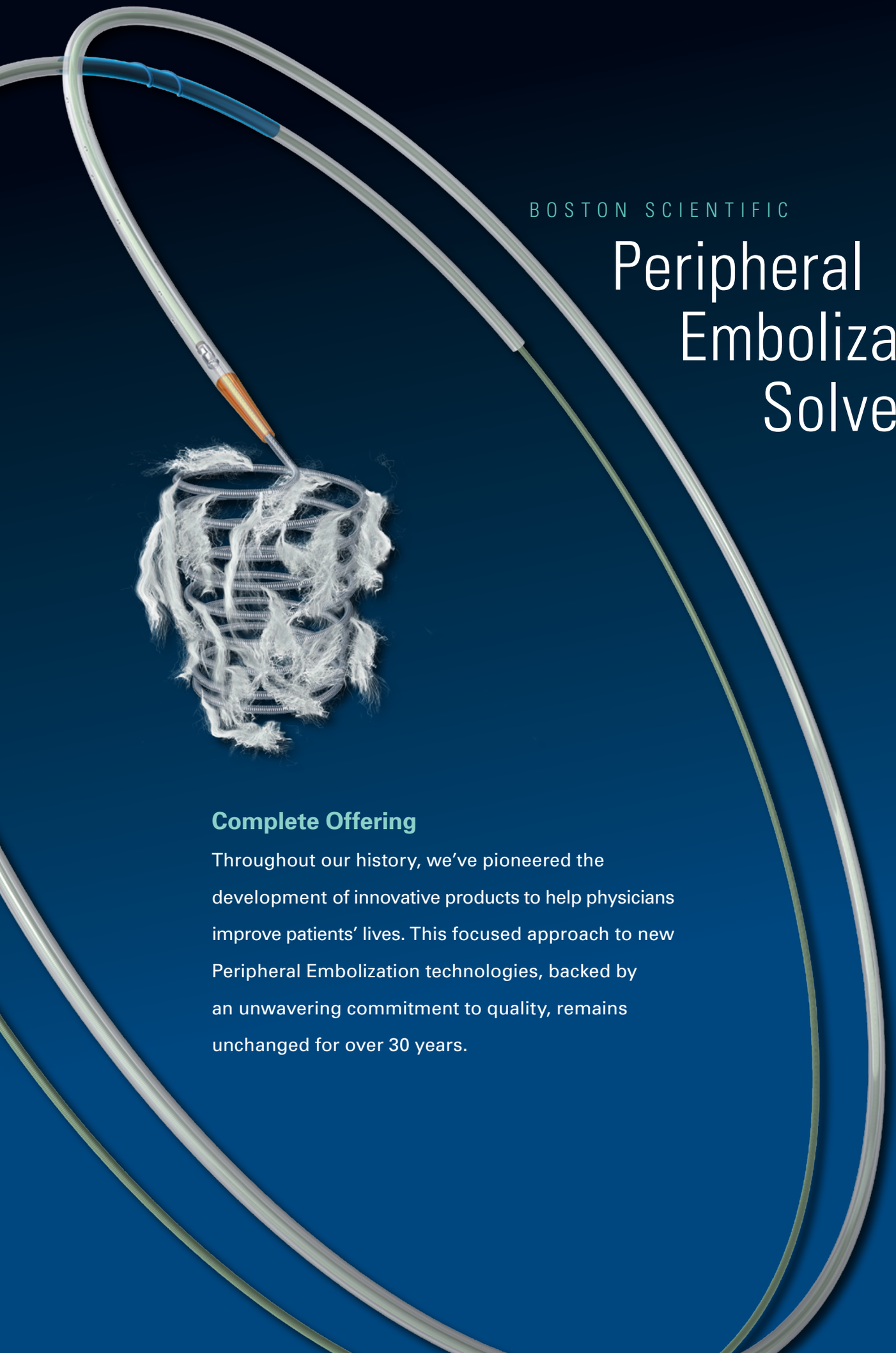
Peripheral Embolization Products

PRODUCT CATALOG AND ORDERING INFORMATION

Setting Standards. Exceeding Expectations.

BOSTON SCIENTIFIC

Peripheral Embolization Solved



Complete Offering

Throughout our history, we've pioneered the development of innovative products to help physicians improve patients' lives. This focused approach to new Peripheral Embolization technologies, backed by an unwavering commitment to quality, remains unchanged for over 30 years.

Guidewires

The Fathom™ Guidewires are designed to address a variety of clinical practice situations and are available in distinct profile configurations for challenging procedures. Available in 0.014" and 0.016" sizes, Fathom Guidewires combine a nitinol hypotube distal segment with advanced microfabrication technology, creating a design that revolutionizes access of the most tortuous vasculature.

Fathom Peripheral Embolization Guidewires

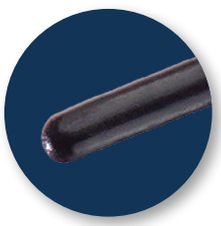
- Microfabricated nitinol hypotube designed for turn-for-turn torque
- Alternating microscopic channels balance support with flexibility
- Lubricious hydrophilic coating on distal segment and PTFE coating on stainless steel segment intended to facilitate guidewire placement and catheter tracking
- Highly visible, shapeable platinum/tungsten tip available in straight and angled profiles

Order Code	Total Length (cm)	Hypotube Length (cm)	Tip Length (cm)	Proximal/ Distal O.D. (in)	Tip Shape
M001508100	200	35	10	0.014	Straight
M001508110	200	35	10	0.014	Angled
M001508140	300	35	10	0.014	Straight
M001508150	300	35	10	0.014	Angled

Order Code	Total Length (cm)	Hypotube Length (cm)	Tip Length (cm)	Proximal/ Distal O.D. (in)	Tip Shape
M001509000	140	25	10	0.016	Straight
M001509010	140	35	20	0.016	Straight
M001509100	180	25	10	0.016	Straight
M001509110	180	35	20	0.016	Straight

Transend™ Peripheral Embolization Guidewires

- Scitanium alloy core provides excellent support
- Shapeable tungsten tip enables physicians to customize guidewire
- Lubricious ICE™ Hydrophilic Coating on distal segment, for enhanced catheter tracking
- A guidewire engineered to provide torque control and flexibility



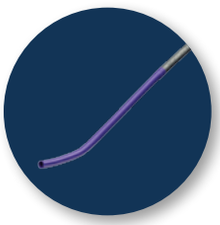
Order Code	Total Length (cm)	Shapeable Tip Length (cm)	Proximal O.D. (in)	Distal O.D. (in)
M001468100	135	2	0.014	0.014
M001468110	165	2	0.014	0.014
M001468010	190	2	0.014	0.014
M001468120	135	2	0.018	0.018
M001468130	165	2	0.018	0.018

Direxion™ Torquable Microcatheters

Direxion Microcatheter Family

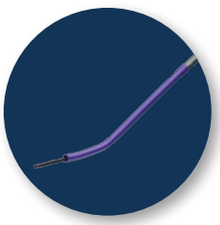
- 2.4 F distal OD with 0.021" PTFE inner lumen
- Straight, Bern, J, or Swan shape tip options
- 1 or 2 RO markers
- Compatible with all 0.018" coils, up to 700 micron sized spherical particles, and up to 500 micron sized non-spherical particles
- 1200 psi burst rating

Direxion Microcatheter



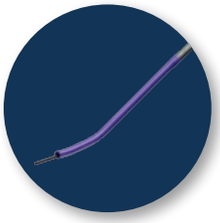
Order Code	Order Number	Usable Length (cm)	Tip Shape	RO Markers
M001195200	19-520	105	Straight	1
M001195210	19-521	130	Straight	1
M001195220	19-522	155	Straight	1
M001195230	19-523	105	Bern	1
M001195240	19-524	130	Bern	1
M001195250	19-525	155	Bern	1
M001195270	19-527	130	J	1
M001195300	19-530	130	Swan	1
M001195320	19-532	130	Straight	2
M001195340	19-534	130	Bern	2

Direxion Microcatheter Preloaded System with Fathom-16 Guidewire



Order Code	Order Number	Direxion Torqueable Microcatheter Usable Length (cm)	Direxion Torqueable Microcatheter Tip Shape	Fathom-16 Guidewire Overall Length (cm)
M001195610	19-561	130	Straight	180
M001195640	19-564	130	Bern	180

Direxion Microcatheter Preloaded System with Transend-14 Guidewire



Order Code	Order Number	Direxion Torqueable Microcatheter Usable Length (cm)	Direxion Torqueable Microcatheter Tip Shape	Transend-14 Guidewire Overall Length (cm)
M001195810	19-581	130	Straight	165
M001195840	19-584	130	Bern	165

The Direxion Microcatheter is the first microcatheter built using Boston Scientific's slotted nitinol hypotube technology. This technology maximizes torque transmission in the catheter shaft, giving the Direxion Microcatheter best-in-class torqueability while still maintaining excellent flexibility, trackability, and pushability. The Direxion Microcatheter is also available in six unique tip configurations as well as a full line of 0.021" and 0.027" lumen pre-loaded guidewire systems with your choice of a Fathom™-16 Guidewire, Transend™-14 Guidewire, or Transend-18 Guidewire.

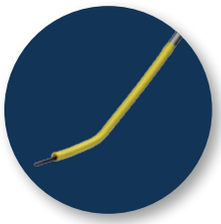
Direxion HI-FLO™ Microcatheter Family

- 2.8 F distal OD with 0.027" PTFE inner lumen
- Straight, Bern, J, or Swan shape tip options
- Compatible with up to 900 micron sized spherical particles, and up to 710 micron sized non-spherical particles
- 1200 psi burst rating

Direxion HI-FLO Microcatheter

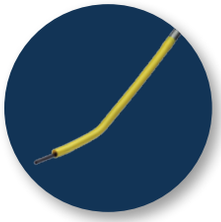
Order Code	Order Number	Usable Length (cm)	Tip Shape	RO Markers
M001195400	19-540	105	Straight	1
M001195410	19-541	130	Straight	1
M001195420	19-542	155	Straight	1
M001195430	19-543	105	Bern	1
M001195440	19-544	130	Bern	1
M001195450	19-545	155	Bern	1
M001195470	19-547	130	J	1
M001195500	19-550	130	Swan	1

Direxion HI-FLO Microcatheter Preloaded System with Fathom-16 Guidewire



Order Code	Order Number	Direxion Torqueable Microcatheter Usable Length (cm)	Direxion Torqueable Microcatheter Tip Shape	Fathom-16 Guidewire Overall Length (cm)
M001195710	19-571	130	Straight	180
M001195740	19-574	130	Bern	180

Direxion HI-FLO Microcatheter Preloaded System with Transend-18 Guidewire



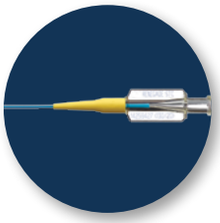
Order Code	Order Number	Direxion Torqueable Microcatheter Usable Length (cm)	Direxion Torqueable Microcatheter Tip Shape	Transend-18 Guidewire Overall Length (cm)
M001195910	19-591	130	Straight	165
M001195940	19-594	130	Bern	165

Renegade™ HI-FLO™ Microcatheters

Renegade HI-FLO Microcathether Family

Renegade HI-FLO Microcatheters

- 3 F proximal OD tapers to 2.8 F polished distal tip with RO marker
- Large 0.027" PTFE inner lumen and 800 psi burst pressure rating promotes exceptional flow rates
- Fiber and metal braid designed for excellent visibility without compromising kink resistance
- Compatible with up to 900 micron spherical particles and up to 710 micron non-spherical particles

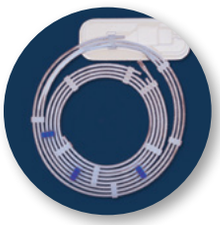


Order Code	Usable Length (cm)	Proximal/ Distal O.D. (F)	Distal I.D. (in)	Distal Tip Length (cm)	Tip Design
M001182840	105	3.0/2.8	0.027	10	Straight
M001182850	105	3.0/2.8	0.027	20	Straight
M001182860	115	3.0/2.8	0.027	10	Straight
M001182870	115	3.0/2.8	0.027	20	Straight
M001182880	135	3.0/2.8	0.027	10	Straight
M001182890	135	3.0/2.8	0.027	20	Straight
M001182900	150	3.0/2.8	0.027	10	Straight
M001182910	150	3.0/2.8	0.027	20	Straight

Recommended microcatheter for Contour Embolic Particles.

Renegade HI-FLO Fathom Kits (two hoops/one carton)

- Renegade HI-FLO Microcatheter paired with Fathom-16 Guidewire



Order Code	Fathom-16 Steerable Guidewire Overall Length (cm)	Fathom-16 Steerable Guidewire Tip Length (cm)	Renegade HI-FLO Microcatheter Usable Length (cm)	Renegade HI-FLO Microcatheter Tip Length (cm)
M001184580	140	10	105	10
M001184590	140	10	105	20
M001184600	140	10	115	10
M001184610	140	10	115	20
M001184620	180	10	135	10
M001184630	180	10	135	20
M001184640	180	10	150	10
M001184650	180	10	150	20

Boston Scientific's Renegade Hi-FLO Microcatheter Product Portfolio provides you with the options you need to address a wide variety of challenging interventions. With the trusted Renegade HI-FLO Microcatheter platform, this family of microcatheters gives you the confidence you need to access a variety of vasculature. The Renegade HI-FLO Fathom™ System combines the unique turn-for-turn, torque response, flexibility and high visibility of the Fathom-16 Guidewire with the clinically proven performance of the Renegade HI-FLO Microcatheter, all in one convenient platform. The combination of these custom-built technologies, available for the first time in one convenient package and eight configurations, provides physicians with advanced, simple solutions for their peripheral embolization needs.

Renegade HI-FLO Fathom Systems (one hoop/one carton)

- The Renegade HI-FLO Microcatheter is pre-loaded with a Fathom Guidewire
- Combined kit eliminates a prep-step
- The Diamond-cut nitinol hypotube of the Fathom Guidewire provides turn-for-turn torque for deft navigation of even the most tortuous vasculature
- The Renegade HI-FLO Microcatheter has a large 0.027" PTFE inner lumen, yet maintains a small 2.8 F distal tip, providing excellent deliverability, rail support, and flow rates

Order Code	Fathom-16 Steerable Guidewire Overall Length (cm)	Fathom-16 Steerable Guidewire Tip Length (cm)	Renegade HI-FLO Microcatheter Usable Length (cm)	Renegade HI-FLO Microcatheter Tip Length (cm)
M001184500	140	10	105	10
M001184510	140	10	105	20
M001184520	140	10	115	10
M001184530	140	10	115	20
M001184540	180	10	135	10
M001184550	180	10	135	20
M001184560	180	10	150	10
M001184570	180	10	150	20

Renegade HI-FLO Transend™ Kits (two hoops/one carton)

- Renegade HI-FLO Microcatheter paired with Transend-18 Guidewire

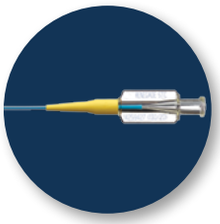
Order Code	Transend-18 Guidewire Usable Length (cm)	Transend-18 Guidewire Shapeable Tip Length (cm)	Renegade HI-FLO Microcatheter Usable Length (cm)	Renegade HI-FLO Microcatheter Tip Length (cm)
M001182980	135	2	105	10
M001182990	135	2	105	20
M001183000	135	2	115	10
M001183010	135	2	115	20
M001183020	165	2	135	10
M001183030	165	2	135	20

Renegade™ Microcatheters

Renegade Microcatheter Family

Renegade STC 18 Microcatheters

- 3 F proximal OD tapers to 2.4 F smooth distal tip with non-protruding RO marker and 0.021" PTFE inner lumen
- Angled and straight distal tip options, 20 and 30 cm lengths
- 1,000 psi burst pressure rating
- Compatible with all 0.018" coils, up to 700 micron sized spherical particles, and up to 500 micron non-spherical particles

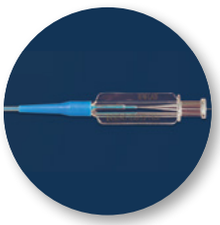


Order Code	Usable Length (cm)	Proximal/ Distal O.D. (F)	Distal I.D. (in)	Distal Tip Length (in)	Tip Design
M001181270	105	3.0/2.4	0.021	20	Angled
M001181280	105	3.0/2.4	0.021	30	Angled
M001181330	130	3.0/2.4	0.021	20	Angled
M001181340	130	3.0/2.4	0.021	30	Angled
M001181390	150	3.0/2.4	0.021	20	Angled
M001181400	150	3.0/2.4	0.021	30	Angled
M001181250	105	3.0/2.4	0.021	20	Straight
M001181260	105	3.0/2.4	0.021	30	Straight
M001181310	130	3.0/2.4	0.021	20	Straight
M001181320	130	3.0/2.4	0.021	30	Straight
M001181370	150	3.0/2.4	0.021	20	Straight
M001181380	150	3.0/2.4	0.021	30	Straight

Recommended microcatheter for Interlock™-18 Fibered Occlusion System and for all 0.018" pushable coils.

Renegade Fiber Braided Microcatheters

- 3 F proximal OD tapers to 2.5 F smooth distal tip with RO marker and 0.021" PTFE inner lumen
- 300 psi rated burst pressure
- VORTEC™ Fiber Braided Material intended to provide excellent flexibility
- Compatible with all 0.018" coils, up to 700 micron sized spherical particles, and up to 500 micron non-spherical particles



Order Code	Usable Length (cm)	Proximal/ Distal O.D. (F)	Distal I.D. (in)	Distal Tip Length (cm)
M001182520	130	3.0/2.5	0.021	20
M001182510	150	3.0/2.5	0.021	10
M001182530	150	3.0/2.5	0.021	20

FasTracker™-325 Microcatheters

FasTracker-325 Microcatheter Family

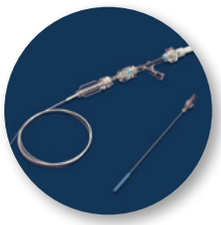
FasTracker-325 Infusion Catheters

- 3 F proximal OD tapers to 2.8 F smooth distal tip with RO marker and 0.024" PTFE inner lumen
- Hydrolene™ Hydrophilic Coating polymer surface for excellent tracking
- 300 psi burst pressure rating
- Compatible with all 0.018" pushable coils, non-spherical particles up to 500 microns and with spherical particles up to 900 microns

Order Code	Total Length (cm)	Proximal/ Distal O.D. (F)	Proximal/ Distal I.D. (F)	Catheter Distal Length (cm)
M0011611040	135	3.0/2.8	0.024	12
M0011611030	140	3.0/2.8	0.024	8

FasTracker-325 Systems (one tray/one carton)

- Either the Taper™ or Transend™ Guidewire pre-loaded in a FasTracker-325 Microcatheter



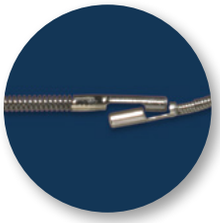
Order Code	Guidewire and Usable Length (cm)	FasTracker-325 Microcatheter Usable Length (cm)	FasTracker-325 Microcatheter Tip Length (cm)
M0015501010	Taper-14 Flex Tip/135	105	12
M0015501030	Taper-14 Flex Tip/155	125	12
M0015501040	Taper-14 Flex Tip/165	135	12
M0015502030	Taper-16/155	125	12
M0015502040	Taper-16/165	135	12
M0035503010	Transend-18/135	105	12
M0035503040	Transend-18/165	135	12

Interlock™ Fibered IDC™ Occlusion System

Interlock-18 Fibered IDC Occlusion Systems

- Available in 2D Helical and Diamond Coil shapes, maximizing your ability to tailor coil type to anatomical need
- Deliverable through a microcatheter with a inner diameter of 0.021"

2D Standard Length



Order Code	Description	Diameter (mm)	Length (cm)	Shape
M001361480	Interlock-18 Coil	2	4	2D
M001361490	Interlock-18 Coil	2	6	2D
M001361500	Interlock-18 Coil	3	6	2D
M001361510	Interlock-18 Coil	3	12	2D
M001361520	Interlock-18 Coil	4	8	2D
M001361530	Interlock-18 Coil	4	15	2D
M001361540	Interlock-18 Coil	5	8	2D
M001361550	Interlock-18 Coil	5	15	2D
M001361560	Interlock-18 Coil	6	10	2D
M001361570	Interlock-18 Coil	6	20	2D
M001361580	Interlock-18 Coil	8	20	2D
M001361590	Interlock-18 Coil	10	20	2D
M001361600	Interlock-18 Coil	10	30	2D
M001361610	Interlock-18 Coil	12	20	2D
M001361620	Interlock-18 Coil	12	30	2D
M001361630	Interlock-18 Coil	14	20	2D
M001361640	Interlock-18 Coil	14	30	2D

2D Long Length

Order Code	Description	Diameter (mm)	Length (cm)	Shape
M001361920	Interlock-18 Coil	10	50	2D
M001361930	Interlock-18 Coil	14	50	2D
M001361940	Interlock-18 Coil	18	50	2D
M001361950	Interlock-18 Coil	20	50	2D
M001361960	Interlock-18 Coil	22	60	2D

Diamond Configurations

Order Code	Description	Diameter (mm)	Length (cm)	Shape
M001361740	Interlock-18 Coil	2/3	2.3	Diamond
M001361750	Interlock-18 Coil	2/4	4.1	Diamond
M001361760	Interlock-18 Coil	2/5	5.8	Diamond
M001361770	Interlock-18 Coil	2/6	8.0	Diamond

The Interlock Fibered IDC Occlusion System features “interlocking arms” that allow the coil to be advanced and retracted before final placement in the vessel, thus aiding in a more controlled delivery. The long coil lengths and wide diameters provide increased procedural flexibility, helping you meet the challenges of vessel size and procedural variables.

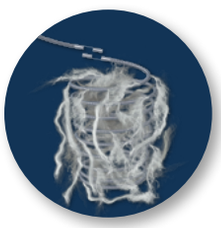
Interlock-35 Fibered IDC Occlusion Systems

- Available in 2D, Cube and Diamond Shapes
- Deliverable through a 5 F Imager™ II 0.035" or 0.038" guidewire compatible Diagnostic catheter

Cube

Order Code	Description	Diameter (mm)	Length (cm)	Shape
M001363700	Interlock-35 Coil	4	6	Cube
M001363720	Interlock-35 Coil	6	10	Cube
M001363730	Interlock-35 Coil	6	20	Cube
M001363760	Interlock-35 Coil	8	20	Cube
M001363790	Interlock-35 Coil	10	25	Cube
M001363800	Interlock-35 Coil	10	40	Cube
M001363810	Interlock-35 Coil	15	25	Cube
M001363820	Interlock-35 Coil	15	40	Cube
M001363830	Interlock-35 Coil	20	40	Cube

2D



Order Code	Description	Diameter (mm)	Length (cm)	Shape
M001363500	Interlock-35 Coil	3	4	2D
M001363520	Interlock-35 Coil	4	10	2D
M001363540	Interlock-35 Coil	6	10	2D
M001363550	Interlock-35 Coil	6	20	2D
M001363570	Interlock-35 Coil	8	10	2D
M001363580	Interlock-35 Coil	8	20	2D
M001363590	Interlock-35 Coil	8	40	2D
M001363600	Interlock-35 Coil	10	20	2D
M001363610	Interlock-35 Coil	10	40	2D
M001363620	Interlock-35 Coil	12	20	2D
M001363630	Interlock-35 Coil	12	40	2D
M001363640	Interlock-35 Coil	15	20	2D
M001363650	Interlock-35 Coil	15	40	2D
M001363660	Interlock-35 Coil	18	20	2D
M001363670	Interlock-35 Coil	18	40	2D

Diamond

Order Code	Description	Diameter (mm)	Length (cm)	Shape
M001363910	Interlock-35 Coil	4	4.5	Diamond
M001363920	Interlock-35 Coil	6	9.0	Diamond
M001363930	Interlock-35 Coil	8	14.0	Diamond

Pushable Platinum Coils

Pushable 0.018" Fibered Platinum Coils

- Boston Scientific's line of pushable 0.018" coils offer wide variety of shapes that have been designed to address the unpredictable challenges of the distal vasculature
- Pushable 0.018" coils can be used in conjunction with a small lumen microcatheter, such as the Renegade™ STC Microcatheter or Renegade-18 Microcatheter

VortX™ Diamond-18 Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013822031	3	3.3	23
M0013822041	4	3.7	41
M0013822051	5	5.5	58
M0013822061	6	6.7	80

VortX-18 Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013812031	3	2.5	22
M0013812041	4	4.0	42
M0013812051	5	5.5	60
M0013812061	6	6.5	85

Straight-18 Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013120021	Straight	2.0	2
M0013122051	Straight	5.0	5

Figure 8-18 Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013120211	2	5.0	10

With Boston Scientific, you can choose from a wide range of platinum coils, all engineered for enhanced visibility. All Boston Scientific platinum coils include dense Dacron™ Fibers intended to facilitate fast and complete occlusion, and rounded ball-weld ends designed for ease of use and to address the risk of vessel trauma.

Multi-Loop-18 Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013120431	4	7.0	30

Complex Helical-18 Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013120221	4	4.0	20
M0013120331	6	6.0	30
M0013120441	7	10.0	40
M0013120551	8	12.0	50
M0013120661	10	14.0	60
M0013120771	11	17.0	70

Pushable 0.035" Fibered Platinum Coils

- Boston Scientific's line of pushable 0.035" coils have been engineered to facilitate robust radial force
- Pushable 0.035" coils are designed with long, dense Dacron Fibers to facilitate vessel occlusion

0.035" Multi-Loop Fibered Platinum Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013723021	3	2.6	20
M0013723041	3	5.2	40
M0013724031	4	2.9	30
M0013725031	5	2.4	30
M0013725051	5	4.0	50
M0013726041	6	2.6	40
M0013727041	7	2.3	40
M0013729061	9	2.7	60

VortX-35 Vascular Occlusion Coils

Order Code	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)
M0013732041	4	4.0	30
M0013733051	5	4.5	35
M0013733061	6	5.0	53
M0013733071	7	5.5	67

Embolic Particles & Occlusion Balloons

Advancing vessel occlusion…Boston Scientific Occlusion Balloon Catheters are designed to provide the strength and reliability your procedures require. Occlusion Balloon Catheters are setting the standard in temporary vessel occlusion.

Contour™ Embolization Particles

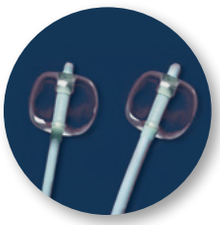
- PVA flakes that are indicated for the embolization of hypervascular tumors including leiomyoma uteri and arteriovenous malformations (AVM)
- Available in dry vials and a range of embolic sizes to help promote procedural flexibility

Order Code	Particle Size (microns)	Box (units)	Packaging
M0017600121	45-150	2	Vial
M0017600151	45-150	5	Vial
M0017600221	150-250	2	Vial
M0017600251	150-250	5	Vial
M0017600321	250-335	2	Vial
M0017600351	250-355	5	Vial
M0017600421	355-500	2	Vial
M0017600451	355-500	5	Vial
M0017600621	500-710	2	Vial
M0017600651	500-710	5	Vial
M0017600821	710-1000	2	Vial
M0017600851	710-1000	5	Vial
M0017601151	1000-1180	5	Vial

Occlusion Balloons

Standard Occlusion Balloons

- Soft, compliant latex material designed to increase balloon burst strength during multiple inflations
- Multiple shaft lengths designed to optimize procedural efficiency



Order Code	Size (F)	Lumens	Usable Length (cm)	Recommended Guidewire	Inflated Balloon Diameter (mm)
M001171020	7	2	65	0.038	11.5
M001171030	7	2	100	0.038	11.5

Berenstein Occlusion Balloons

- Compliant latex material allows for inflation to either 8.5 mm or 11.5 mm diameters
- Non-tapered catheter shaft designed to facilitate the coaxial use of small catheters or embolics

Order Code	Size (F)	Lumens	Usable Length (cm)	Recommended Guidewire	Inflated Balloon Diameter (mm)
M001173010	6	2	80	0.038	8.5/11.5

CONTOUR™ EMBOLIZATION PARTICLES

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use: The Contour Embolization Particles are used for the embolization of peripheral hypervascular tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

Contraindications for Use: *Contraindications Specific to All Peripheral Indications:* 1. Vascular anatomy or blood flow precludes stable, selective Contour Embolization Particles or catheter placement 2. Presence of vasospasm 3. Presence of hemorrhage 4. Presence of severe atheromatous disease 5. Presence of feeding arteries smaller than distal branches from which they emerge 6. Presence of collateral vessel pathways potentially endangering normal territories during embolization 7. Presence of arteries supplying the lesion not large enough to accept Contour Embolization Particles 8. Vascular resistance peripheral to the feeding arteries precluding passage of Contour Embolization Particles into the lesion 9. In large diameter arteriovenous shunts 10. In the pulmonary vasculature 11. Patient intolerance to occlusion procedures. *Contraindications Specific to Uterine Fibroid Embolization (UFE):* 1. Pregnant women 2. Suspected pelvic inflammatory disease or any other active pelvic infection 3. Any malignancy of the pelvic region 4. Endometrial neoplasia or hyperplasia 5. Presence of one or more submucosal fibroid(s) with more than 50% growth into the uterine cavity 6. Presence of pedunculated serosal fibroid as the dominant fibroid(s) 7. Fibroids with significant collateral feeding by vessels other than the uterine arteries. *Complications specific to embolization include, but may not be limited to:* 1. Foreign body reactions (i.e. pain, rash) necessitating medical intervention 2. Allergic reaction to contrast media 3. Infection necessitating medical intervention 4. Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgment, vasospasm and nerve and/or circulatory injuries, which may result in leg injury) 5. Undesirable reflux or passage of Contour Embolization Particles into arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds 6. Ischemia at an undesirable location 7. Incomplete occlusion of vascular beds or territories may give rise to the possibility of post procedural hemorrhage, development of alternative vascular pathways, recanalization or recurrence of symptoms 8. Vessel or lesion rupture and hemorrhage 9. Recurrent hemorrhage 10. Ischemic stroke or my cardial infarction 11. Death. *Potential Complications Specific to UFE*: 1. Postembolization syndrome 2. Vaginal discharge 3. Tissue passage, fibroid sloughing or fibroid expulsion post-UFE 4. Temporary or permanent stopping of menstrual bleeding 5. Infection of the pelvic region 6. Endometrial atrophy with amenorrhea despite normal ovarian function 7. Complications to pregnancy 8. Premature Ovarian Failure (i.e., menopause) 9. Uterine/Ovarian necrosis 10. Uterine rupture 11. Post-UFE intervention to remove necrotic fibroid tissue 12. Hysterectomy.

Warnings and Precautions: *Warnings Applicable to All Peripheral Indications* • PRIOR TO EMBOLIZATION, PROSPECTIVE PATIENTS OR THEIR REPRESENTATIVES MUST BE PROVIDED AN INFORMED CONSENT DESCRIBING THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE USE OF THIS DEVICE. WRITTEN ACKNOWLEDGMENT IS WARRANTED. • The safety and effectiveness of Contour Embolization Particles for neurovascular use have not been established. • As with any embolization device, patient injury, permanent disability or death may occur as a result of its use. • Vascular occlusion should only be performed by physicians possessing skilled interventional occlusion experience in the territory intended to be embolized. • A thorough evaluation of a patients medical condition, vascular pathways and the desired embolization goal is necessary to achieve successful occlusion. This evaluation should include baseline angiography to determine the presence of potentially dangerous collateral pathways. Postprocedural patient follow-up to assess the continued level of vascular occlusion is necessary. Angiography may be indicated. • Serious radiation induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's institutional protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients that may be at risk. • Onset of radiation-induced injury to the patient may be delayed. Patients should be counseled on potential radiation side effects and whom they should contact if they show symptoms. *Precautions Applicable to All Indications:* • Patients with known allergy to contrast medium may require pre-medication prior to embolization. • Additional evaluations or precautions may be necessary in managing periprocedural care for patients with the following conditions: a) Bleeding diathesis or hypercoagulative state; b) Immunocompromised. The use of sophisticated imaging equipment is necessary for successful embolization therapy. • Appropriate facilities should be available to treat potential complications of the procedure. • While it is anticipated that long-term embolization of vascular structures with Contour Embolization Particles will be achieved, no guarantee of permanence, cure or benefit can be made. *UFE Specific Warnings for Pregnancy (Specific for Treatment of Leiomyoma Uteri):* • UFE is not intended for women who desire future pregnancy. The effects of UFE on the ability to become pregnant and carry a fetus to term, and on the development of the fetus, have not been determined. Therefore, this procedure should only be performed on women who do not intend future pregnancy. • Women who become pregnant following UFE, should be aware that they may be at increased risk for preterm delivery, cesarean delivery, malpresentation (incorrect positioning of the baby), and postpartum hemorrhage (post-delivery bleeding). • Devascularization of uterine myometrium resulting from UFE may put women who become pregnant following UFE at increased risk of uterine rupture. *Other UFE Specific Warnings:* • Devascularization of uterine myometrium resulting from UFE may put women at increased risk of uterine rupture. • The diagnosis of uterine sarcoma could be delayed by taking a non-surgical approach (such as UFE), to treat uterine fibroids. Conduct a more thorough work-up for patients with warning signs for sarcoma (e.g., prior pelvic radiation, MRI findings, rapid tumor growth, postmenopausal with new uterine enlargement). Recurrent or continued tumor growth following UFE should be considered a potential warning sign for sarcoma and surgery should be considered. *UFE Specific Precautions:* • It is recommended that patients undergoing embolization of leiomyoma uteri be provided a clear understanding of who will provide post-procedure care prior to the embolization procedure. • UFE should only be performed by physicians who have received appropriate training for treatment of uterine leiomyomata (fibroids). • There is an increased chance of retro-migration of Contour Embolization Particles into unintended blood vessels as uterine artery flow diminishes. Embolization should be stopped when the vasculature surrounding the fibroid can no longer be visualized but before complete stasis in the uterine artery. Please refer to the "Directions for Use" for clinical data from the Boston Scientific Corporation Contour Embolization Particles UFE Clinical Study Summary prior to use of this product.

DIREXION™ AND DIREXION HI-FLO™ TORQUEABLE MICROCATHETERS

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications: The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

Contraindications: None known.

Adverse Events: The Adverse Events include, but are not limited to: Allergic reaction, Death, Embolism, Hemorrhage/Hematoma, Infection, Pseudoaneurysm, Stroke, Vascular thrombosis, Vessel occlusion, Vessel spasm, Vessel trauma (dissection, perforation, rupture)

Warning: Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation. Direxion Microcatheter family is not intended for use in the coronary vasculature or neurovasculature. The Direxion HI-FLO Microcatheter is not designed for the delivery of embolic coils. Use of excessive force to manipulate the microcatheter against resistance can cause a fracture in the nitinol shaft. Take care not to over-torque the microcatheter, and to relieve any tension before withdrawal by rotating the microcatheter in the opposite direction.

Precautions: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter. Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal. If other interventional devices are used with the microcatheter, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device. If other interventional devices are used with the microcatheter, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device. Always verify tip response under fluoroscopy and the position of the proximal portion of the microcatheter, to avoid shaft coiling and/or fracture. If resistance is felt during rotation of the microcatheter and there is no visible tip response, stop and rotate in the opposite direction to release tension. Should the shaft fracture under too much tension, attempt to advance a guidewire through the fracture point and past the distal lumen, or retract the microcatheter into the guiding catheter. Then withdraw the system in a smooth motion, minimizing any rotation and torquing.

FASTRACKER™-325 MICROCATHETER AND PRE-LOADED SYSTEM

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use: The FasTracker-325 Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be sued for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into the vessels. Diagnostic, embolic or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.

Contraindications for Use: None known.

Warning: The FasTracker-325 Microcatheters are not intended for use in the coronary or neurovasculature. Do not use a microcatheter that has been damaged in any way. Damaged microcatheters may rupture causing vessel trauma or tip detachment during steering maneuvers. Never advance or withdraw an intraluminal device against resistance. Movement of microcatheter or guidewire against resistance could dislodge a clot, perforate a vessel wall, or damage microcatheter and guidewire. In severe cases, tip separation of guidewire or microcatheter could occur. Do not exceed maximum infusion [pressure of 2070 kPa (300 psi)] for each microcatheter model. Infusion pressure in excess of this maximum may result in ruptured microcatheter or severed tip, possibly resulting in patient injury. Discontinue use of microcatheter for infusion if flow through the microcatheter becomes restricted. Restricted flow indicates possible blockage. Remove and replace blocked microcatheter immediately. DO NOT attempt to clear the microcatheter lumen by infusion. Doing so may cause the microcatheter to rupture, resulting in vascular damage or patient injury.

Potential Complications: *Potential complication include, but are not limited to:* • Vessel trauma/perforation • Embolism • Hemorrhage/hematoma • Vasospasm • Infection • Allergic reaction.

FATHOM™-14/16 STEERABLE GUIDEWIRE

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use: The Fathom-14 and Fathom-16 Steerable Guidewire families are intended for general intravascular use in the peripheral vasculature. They can be used to selectively introduce and position catheters and other interventional devices in the peripheral vasculature. This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures

Contraindications for Use: This guidewire is not intended for use in the coronary vasculature.

Potential Complications: *Potential complication include, but are not limited to:* • Allergic reaction • Death • Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism) • Hematoma at the puncture site • Infection • Pseudoaneurysm • Seizure/stroke • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel dissection • Vessel damage • Nerve injury • Perforation of the vessel • Hemorrhage • Bleeding • Failed treatment • Inability to position guidewire • Damage to the catheter. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTERLOCK™-18 AND INTERLOCK-35 FIBERED IDC™ OCCLUSION SYSTEMS

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Intended Use/Indications for Use: Interlock and Interlock-35 Fibered IDC Occlusion Systems are modified interlocking detachable coils indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. These devices are not intended for neurovascular use.

Contraindications: None known.

Warning: Compatibility with Magnetic Resonance Imaging (MRI) has not been established, and the degree of imaging distortion resulting from the coils has not been measured.

Adverse Events: • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and vessel dissection or perforation) • Pain • Hemorrhage • Infection necessitating medical intervention • Foreign body reactions necessitating medical intervention • Emboli • Ischemia • Vasospasm • Tissue necrosis • Undesirable clot formation of the vasculature • Claudication • Recanalization • Death • Temporary neurological deficit. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's instructions.

OCCLUSION BALLOON CATHETERS
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Intended Use/Indications for Use: Boston Scientific's Occlusion Balloon Catheters are designed for temporary vessel occlusion in application including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.
Contraindications: Boston Scientific Occlusion Balloon Catheters are not designed for use in embolectomy procedures. Boston Scientific Occlusion Balloon Catheters are not designed for use as vascular flow-directed catheters (Swan-Ganz type). Any use for procedures other than those indicated in the instructions is not recommended.
Warning: This product contains natural rubber latex which may cause allergic reactions. The recommended inflation media is contrast, diluted 50% with sterile saline. Failure to observe recommended inflation techniques may result in formation of contrast crystals which could prevent deflation. Bleed catheter of all air before use in the arterial system or in any situation where a balloon rupture could cause a dangerous air embolism.
Precautions: The recommended shelf life is as noted. As with all latex rubber, the latex used in the balloon suffers deterioration over time. Storage beyond the expiration date listed on the package may cause the balloon to deteriorate.

RENEGADE™ FIBER BRAIDED MICROCATHETER
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Indications for Use: The Renegade Fiber Braided Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be sued for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. Diagnostic, embolic or therapeutic agents to be used in accordance with specifications outlined by the manufacturer.
Contraindications for Use: None known.
Warning: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
Potential Complications: *Potential complication include, but are not limited to:* • Vessel trauma • Embolism • Hemorrhage/hematoma • Vasospas • Infection • Air embolism • Allergic reaction. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

RENEGADE HI-FLO™ FATHOM™ KIT/SYSTEM
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Indications for Use: The Renegade HI-FLO Fathom Kit/System is intended for peripheral vascular use. The Fathom Guidewire can be used to selectively introduce the Renegade HI-FLO Microcatheter in the peripheral vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels.
Contraindications for Use: None known.
Warning: The Renegade HI-FLO Fathom Kit/System is not intended for use in the coronary vasculature. This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
Potential Complications: *Potential complication include, but are not limited to:* • Allergic reaction • Death • Embolism • Hemorrhage/hematoma • Infection • Pseudoaneurysm • Stroke • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel trauma (dissection, perforation, trauma). Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

RENEGADE HI-FLO MICROCATHETER AND MICROCATHETER KIT
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Indications for Use: The Renegade HI-FLO Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be sued for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. Diagnostic, embolic or therapeutic agents to be used in accordance with specifications outlined by the manufacturer.
Contraindications for Use: None known.
Warning: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
Potential Complications: *Potential complication include, but are not limited to:* • Vessel trauma • Embolism • Hemorrhage/hematoma • Vasospasm • Infection • Air embolism • Allergic reaction. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

RENEGADE STC 18 MICROCATHETER WITH HYDROPASS™ HYDROPHILIC COATING
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Indications for Use: The Renegade STC 18 Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be sued for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. Diagnostic, embolic or therapeutic agents to be used in accordance with specifications outlined by the manufacturer.
Contraindications for Use: None known.
Warning: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
Potential Complications: *Potential complication include, but are not limited to:* • Vessel trauma • Embolism • Hemorrhage/hematoma • Vasospasm • Infection • Air embolism • Allergic reaction. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

TRANSEND™ GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Indications for Use: The Transend Guidewire is intended for general intravascular use, including the peripheral vasculature. They can be used to selectively introduce and position catheters and other interventional devices in the peripheral vasculature. This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
Contraindications for Use: This device is not intended for use in the coronary arteries.
Warning: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
Adverse Events: *Complications attributed to the guidewire are the following:* • Procedural related complications including but not limited to: • Vessel trauma • Death • Air embolism, thromboembolism • Hematoma at the puncture site • Infection • Post embolization syndrome (abdominal pain, fever and nausea/vomiting) • Vascular thrombosis • Vessel spasm • Vessel damage • Perforation of the vessel • Hemorrhage • Bleeding. • Failed treatment • Inability to position guidewire • Damage to the catheter • Excessive force against resistance may result in separation of the guidewire tip. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

VORTX™-18, VORTX, VORTX-35, DIAMOND-18, STRAIGHT-18, FIGURE 8-18, MULTI-LOOP-18, COMPLEX HELICAL-18 AND 2D HELICAL-35 FIBERED PLATINUM COILS
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Intended Use/Indications for Use: Boston Scientific's 0.018 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature.
Contraindications: None known.
Warning: Recanalization has been observed with the usage of some coils. Angiographic follow-up is recommended to ensure continued occlusion. To date, there have been no reports of adverse events associated with MRI procedures conducted on patients with platinum coils in their peripheral vasculature. However, compatibility with Magnetic Resonance Imaging (MRI) has not been established, and the degree of imaging distortion resulting from the coil has not been measured.
Adverse Events: *Potential complication include, but are not limited to:* • Hematoma at the site of entry • Vessel perforation • Emboli • Hemorrhage • Ischemia or Vasospasm • Clot formation at tip of catheter and subsequent dislodgement • Nerve and vessel dissection and perforation • Pain • Infection necessitating medical intervention • Claudication • Tissue necrosis • Undesirable clot formation of the vasculature • Foreign body reactions necessitating medical intervention. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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