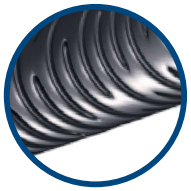
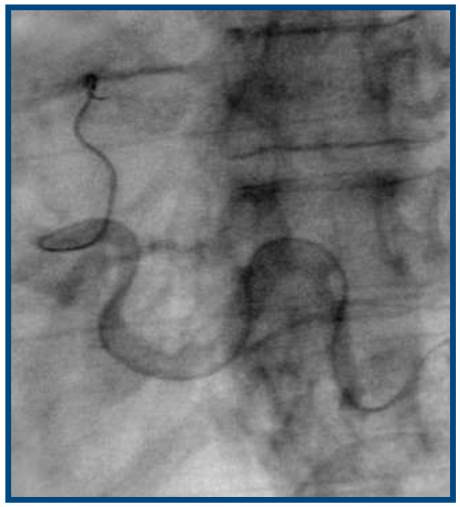
FATHOM™ and TRANSEND™ Steerable Guidewires



Hydrophilic coating on distal segment for smooth tracking within vessels

Laser-cut Nitinol maximizes torque transmission

Alternating pattern of microscopic channels designed to provide outstanding flexibility



AVAILABLE IN BOTH 0.014" AND 0.016" PLATFORMS AND LENGTH OPTIONS UP TO 300 CM

TRANSEND GUIDEWIRE

- Shapeable Tungsten tip enables physicians to customize guidewire tips
- Engineered to provide torque control and flexibility
- Available in both 0.014" and 0.018" platforms

DIREXION™ AND DIREXION HI-FLO™
Torqueable Microcatheter Family

Direxion Microcatheter						
UPN	Order Number	Usable Length (cm)	Proximal/ Distal O.D. (F)	I.D. (in)	Tip Shape	RO Markers
M001195200	19-520	105	2.7/2.4	0.021	Straight	1
M001195210	19-521	130	2.7/2.4	0.021	Straight	1
M001195220	19-522	155	2.7/2.4	0.021	Straight	1
M001195230	19-523	105	2.7/2.4	0.021	Bern	1
M001195240	19-524	130	2.7/2.4	0.021	Bern	1
M001195250	19-525	155	2.7/2.4	0.021	Bern	1
M001195260	19-526	105	2.7/2.4	0.021	J	1
M001195270	19-527	130	2.7/2.4	0.021	J	1
M001195280	19-528	155	2.7/2.4	0.021	J	1
M001195290	19-529	105	2.7/2.4	0.021	Swan	1
M001195300	19-530	130	2.7/2.4	0.021	Swan	1
M001195310	19-531	155	2.7/2.4	0.021	Swan	1
M001195320	19-532	130	2.7/2.4	0.021	Straight	2
M001195330	19-533	155	2.7/2.4	0.021	Straight	2
M001195340	19-534	130	2.7/2.4	0.021	Bern	2
M001195350	19-535	155	2.7/2.4	0.021	Bern	2

Direxion HI-FLO Microcatheter						
UPN	Order Number	Usable Length (cm)	Proximal/ Distal O.D. (F)	I.D. (in)	Tip Shape	RO Markers
M001195400	19-540	105	3.0/2.8	0.027	Straight	1
M001195410	19-541	130	3.0/2.8	0.027	Straight	1
M001195420	19-542	155	3.0/2.8	0.027	Straight	1
M001195430	19-543	105	3.0/2.8	0.027	Bern	1
M001195440	19-544	130	3.0/2.8	0.027	Bern	1
M001195450	19-545	155	3.0/2.8	0.027	Bern	1
M001195470	19-547	130	3.0/2.8	0.027	J	1
M001195480	19-548	155	3.0/2.8	0.027	J	1
M001195500	19-550	130	3.0/2.8	0.027	Swan	1
M001195510	19-551	155	3.0/2.8	0.027	Swan	1

DIREXION™
Microcatheters Systems and Kits

Direxion Microcatheter Pre-Loaded System with Fathom™-16 Guidewire				
UPN	Order Number	Direxion Usable Length (cm)	Direxion Tip Shape	Guidewire Length (cm)
M001195610	19-561	130	Straight	180
M001195620	19-562	155	Straight	180
M001195640	19-564	130	Bern	180
M001195650	19-565	155	Bern	180
M001195660	19-566	130	Straight (2RO)	180
M001195670	19-567	130	Bern (2RO)	180
M001195980*	19-598	155	Straight	200
M001195990*	19-599	155	Bern	200

Direxion HI-FLO Microcatheter Pre-Loaded System with Fathom-16 Guidewire				
UPN	Order Number	Direxion Usable Length (cm)	Direxion Tip Shape	Guidewire Length (cm)
M001195710	19-571	130	Straight	180
M001195720	19-572	155	Straight	180
M001195740	19-574	130	Bern	180
M001195750	19-575	155	Bern	180
M001195960*	19-596	155	Straight	200
M001195970*	19-597	155	Bern	200
Direxion Microcatheter Pre-Loaded System with Transend™-14 Guidewire				
M001195810	19-581	130	Straight	165
M001195840	19-584	130	Bern	165
M001195850	19-585	155	Bern	190
Direxion HI-FLO Microcatheter Pre-Loaded System with Transend-18 Guidewire				
M001195910	19-591	130	Straight	165
M001195940	19-594	130	Bern	165

***New radial length pre-loaded system**

All Direxion and Direxion HI-FLO Torqueable Microcatheters are compatible with most chemotherapy agents, alcohol, and DMSO. All Direxion and Direxion HI-FLO Torqueable Microcatheters have dynamic burst pressures of 1200 PSI.

RENEGADE™ AND RENEGADE™ HI-FLO™
Microcatheter Family

Renegade Fiber Braided Microcatheters					
UPN	Order Number	Usable Length (cm)	Proximal/ Distal O.D. (F)	I.D. (in)	Distal Tip Length (cm)
M001182510	18-251	150	3.0/2.5	0.021	10
M001182520	18-252	130	3.0/2.5	0.021	20
M001182530	18-253	150	3.0/2.5	0.021	20

Renegade STC 18 Microcatheters						
UPN	Order Number	Usable Length (cm)	Proximal/ Distal O.D. (F)	I.D. (in)	Distal Tip Length (in)	Tip Shape
M001181250	18-125	105	3.0/2.4	0.021	20	Straight
M001181260	18-126	105	3.0/2.4	0.021	30	Straight
M001181270	18-127	105	3.0/2.4	0.021	20	Angled
M001181280	18-128	105	3.0/2.4	0.021	30	Angled
M001181310	18-131	130	3.0/2.4	0.021	20	Straight
M001181320	18-132	130	3.0/2.4	0.021	30	Straight
M001181330	18-133	130	3.0/2.4	0.021	20	Angled
M001181340	18-134	130	3.0/2.4	0.021	30	Angled
M001181370	18-137	150	3.0/2.4	0.021	20	Straight
M001181380	18-138	150	3.0/2.4	0.021	30	Straight
M001181390	18-139	150	3.0/2.4	0.021	20	Angled
M001181400	18-140	150	3.0/2.4	0.021	30	Angled

RENEGADE™ AND RENEGADE HI-FLO™
Microcatheter Family

Renegade HI-FLO Microcatheters					
UPN	Order Number	Usable Length (cm)	Proximal/ Distal O.D. (F)	I.D. (in)	Distal Tip Length (cm)
M001182840	18-284	105/10	3.0/2.8	.027	10
M001182850	18-285	105/20	3.0/2.8	.027	20
M001182860	18-286	115/10	3.0/2.8	.027	10
M001182870	18-287	115/20	3.0/2.8	.027	20
M001182880	18-288	135/10	3.0/2.8	.027	10
M001182890	18-289	135/20	3.0/2.8	.027	20
M001182900	18-290	150/80	3.0/2.8	.027	10
M001182910	18-291	150/80	3.0/2.8	.027	20

RENEGADE™
Microcatheters Systems and Kits

Renegade HI-FLO Microcatheter Pre-Loaded System with Fathom™-16 Guidewire				
UPN	Order Number	Microcatheter Usable Length (cm)	Microcatheter Distal Tip Length (cm)	Guidewire Length (cm)
M001184500	18-450	105	10	140
M001184510	18-451	105	20	140
M001184520	18-452	115	10	140
M001184530	18-453	115	20	140
M001184540	18-454	135	10	180
M001184550	18-455	135	20	180
M001184560	18-456	150	10	180
M001184570	18-457	150	20	180
Renegade HI-FLO Transend™ Kits with Transend-18 Guidewires				
UPN	Order Number	Microcatheter Usable Length (cm)	Microcatheter Distal Tip Length (cm)	Guidewire Length (cm)
M001182980	18-298	105	10	135
M001182990	18-299	105	20	135
M001183000	18-300	115	10	135
M001183010	18-301	115	20	135
M001183020	18-302	135	10	165
M001183030	18-303	135	20	165

TRUSELECT™
Microcatheters

TruSelect Microcatheters					
UPN	Usable Length (cm)	Proximal/ Distal O.D. (F)	I.D. (in)	Distal Tip Length (in)	Tip Shape
M001394101050	105	2.8/2.0	0.021	30	Straight
M001394111050	105	2.8/2.0	0.021	30	Bern
M001394101300	130	2.8/2.0	0.021	30	Straight
M001394111300	130	2.8/2.0	0.021	30	Bern
M001394101550	155	2.8/2.0	0.021	30	Straight
M001394111550	155	2.8/2.0	0.021	30	Bern
M001394101750	175	2.8/2.0	0.021	30	Straight
M001394111750	175	2.8/2.0	0.021	30	Bern

FATHOM™
Steerable Guidewires

Fathom-16 Steerable Guidewires						
UPN	Order Number	Total Length (cm)	Nitinol Tip Length (cm)	Distal Floppy Tip Length (cm)	O.D. (in)	Tip Shape
M001509000	50-900	140	25	10	0.016	Straight
M001509010	50-901	140	35	20	0.016	Straight
M001509100	50-910	180	25	10	0.016	Straight
M001509110	50-911	180	35	20	0.016	Straight
M001509120	50-912	180	25	10	0.016	Angled
M001509200	50-920	200	25	10	0.016	Straight
M001509210	50-921	200	25	10	0.016	Angled
M001509300	50-930	215	25	10	0.016	Straight
M001509310	50-931	215	25	10	0.016	Angled
Fathom-14 Steerable Guidewires						
M001508100	50-810	200	35	10	0.014	Straight
M001508110	50-811	200	35	10	0.014	Angled
M001508140	50-814	300	35	10	0.014	Straight
M001508150	50-815	300	35	10	0.014	Angled

TRANSEND™
Steerable Guidewires

Transend-14 Steerable Guidewires					
UPN	Order Number	Total Length (cm)	Shapeable Total Length (cm)	Proximal/ Distal O.D. (in)	Proximal/ Distal O.D. (in)
M001468100	46-810	135	2	0.014	0.014
M001468110	46-811	165	2	0.014	0.014
M001468010	46-801	190	2	0.014	0.014
Transend-18 Steerable Guidewires					
M001468120	46-812	135	2	0.018	0.018
M001468130	46-813	165	2	0.018	0.018

DIREXION™ AND DIREXION HI-FLO™ TORQUEABLE MICROCATHETERS

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE**: 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. **WARNINGS:** • 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. • This 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. **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)
90960724 Rev/Ver AB.6

FATHOM-14 STEERABLE GUIDEWIRE

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The FATHOM-14 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures. **CONTRAINDICATIONS:** None known. **WARNINGS:** The FATHOM Steerable Guidewire is not intended for use in the coronary vasculature or the neuro vasculature. **ADVERSE EVENTS:** Complications attributed to endovascular procedures are the following: • Vessel trauma • Vessel damage • Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism) • Pseudoaneurysm • Seizure/stroke • Vessel dissection • Hematoma at the puncture site • Nerve injury • Infection • Perforation of the vessel • Vessel spasm • Hemorrhage • Vascular thrombosis • Vessel occlusion • Death • Bleeding • Failed treatment • Inability to position guidewire • Damage to the catheter. **92289647 Rev/Ver A.1**

FATHOM-16 STEERABLE GUIDEWIRE

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The FATHOM-16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures. **CONTRAINDICATIONS:** None known. **WARNINGS:** The FATHOM Steerable Guidewire is not intended for use in the coronary vasculature or the neuro vasculature. **ADVERSE EVENTS:** Complications attributed to endovascular procedures are the following: • Vessel trauma • Vessel damage • Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism) • Pseudoaneurysm • Seizure/stroke • Vessel dissection • Hematoma at the puncture site • Nerve injury • Infection • Perforation of the vessel • Vessel spasm • Hemorrhage • Vascular thrombosis • Vessel occlusion • Death • Bleeding • Failed treatment • Inability to position guidewire • Damage to the catheter **92289650 Rev/Ver A.1**

RENEGADE FIBER BRAIDED MICROCATHETER and RENEGADE HI-FLO MICROCATHETER

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The Renegade STC 18 Microcatheter, Renegade Fiber Braided Microcatheter, and the Renegade HI-FLO Microcatheter are 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 used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Diagnostic, embolic, therapeutic agents to be used in accordance with specifications outlined by the manufacturer. **CONTRAINDICATIONS:** None Known. **WARNING:** The Renegade STC 18 Microcatheter, Renegade Fiber Braided Microcatheter, and the Renegade HI-FLO Microcatheter are not intended for use in the coronary vasculature or the neurovasculature. **PRECAUTIONS:** • This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. • Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in separation of the microcatheter or guidewire tip, damage to the microcatheter or guidewire tip, or vessel perforation.
• Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal. **ADVERSE EVENTS:** The Adverse Events include, but are not limited to: • Vessel trauma • Embolism • Hemorrhage/Hematoma • Vasospasm • Infection • Air embolism • Allergic reaction **91059028 Rev/Ver AB.3**

RENEGADE HI-FLO FATHOM KIT

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructionsl **INTENDED USE/INDICATIONS FOR USE:** The Renegade HI-FLO FATHOM Kit is intended for peripheral vascular use. The FATHOM Guidewire can be used to selectively introduce and position the Renegade HI-FLO Microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. **CONTRAINDICATIONS:** None Known. **WARNINGS:** Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation. Renegade™ HI-FLO™ FATHOM™ Kit is not intended for use in the coronary vasculature or the neurovasculature. The Renegade HI-FLO microcatheter is not designed for delivery of embolic coils. **PRECAUTIONS:** This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal. **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) **90960756 Rev/Ver AB.4**

TRANSEND™ GUIDEWIRE WITH ICE™ HYDROPHILIC COATING

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE**: The Transend Guidewire is intended for general intravascular use, including the peripheral vasculature. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. **CONTRAINDICATIONS:** This device is not intended for use in coronary arteries. **PRECAUTIONS:** • This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. **ADVERSE EVENTS:** Complications attributed to guidewire applications are the following:
• Procedural related complications including but not limited to: • Vessel trauma • Vessel damage • Air embolism, thromboembolism • Post embolization syndrome (abdominal pain, fever, and nausea/vomiting) • Hematoma at the puncture site • Infection • Perforation of the vessel • Vessel spasm • Hemorrhage • Vascular thrombosis • Death • Bleeding • Failed treatment • Inability to position guidewire • Damage to catheter • Excessive force against resistance may result in separation of the guidewire tip
90960885 Rev/Ver AB.4

TRUSELECT™ MICROCATHETER

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions **INTENDED USE:** The TRUSELECT Microcatheters are intended for peripheral vascular use. The microcatheter can be used for selective infusion of diagnostic, embolic, or therapeutic materials into the vessel. **CONTRAINDICATIONS:** None known. **WARNINGS:** • 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. • TRUSELECT™ Microcatheter is not intended for use in the coronary vasculature or neurovasculature. **PRECAUTIONS:** • This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. • Diagnostic, embolic, or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer. • 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. **ADVERSE EVENTS:** The Adverse Events include, but are not limited to: • Allergic reaction (to drug, contrast, device or other) • Cerebrovascular accident (CVA), stroke, transient ischemic attack (TIA) • Death • Embolism (air, plaque, thrombus, device or other) • Hemorrhage/Hematoma • Infection/sepsis • Need for urgent intervention or surgery • Thrombus/thrombosis • Vasospasm • Vessel occlusion • Vessel trauma (perforation, injury, rupture, dissection, pseudoaneurysm) **92567338 A.1**

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