Boston Scientific
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Sept. 15, 2014

Head Technologist, Radiology Department/Special Procedures
Hospital/Medical Center
Address
City, State ZIP

Dear Valued Customer,

Recently, BSC has brought to market the Direxion™ Torqueable Microcatheter. Prior to commercial release, Boston Scientific tested Direxion to ensure its compatibility with common toxic substances to which exposure during procedures is common, including DMSO, Cyanoacrylate, ethanol, and ethiodol/lipiodol. Direxion passed all such tests regarding the material integrity of the catheter and catheter hub. Parameters used to assess these results were: microcatheter distal joint integrity, hub/shaft tensile strength, maximum infusion pressure, and freedom from liquid leakage. All catheters were exposed to these chemicals by an injection of approximately 3 cc into the catheter to ensure that the catheter's inner lumen was full of liquid. Each catheter was then flushed with heparinized saline and stored in water for further testing parameters.

This letter is being provided to describe the testing. In the event that you have any additional questions, or if you would like additional information on the specific compatibility data filed in tech report #90873359, please contact your local Boston Scientific sales representative.

Kind Regards,

Cameron Kittle
Product Manager, Microcatheters & Guidewires

Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752

DIREXION™ DIREXION HI FLO™

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)