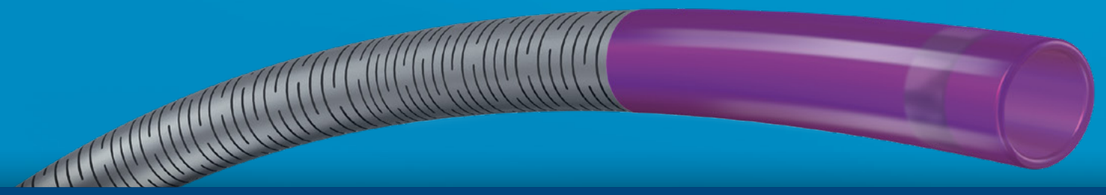
HANDLING THE **DIREXION**™ Torqueable Microcatheter

Boston Scientific
Advancing science for life™

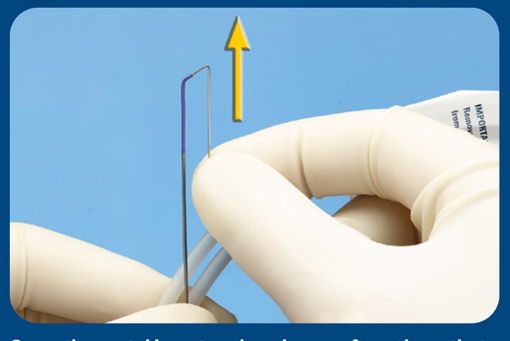


PACKAGING

1 Open Plastic Tray

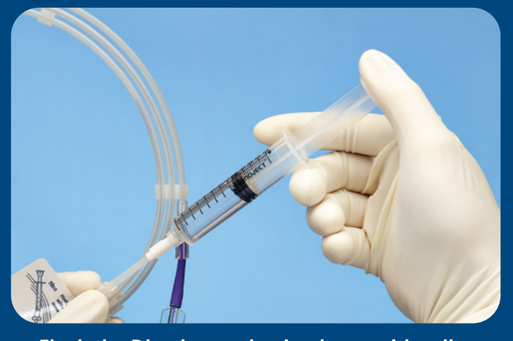
Open the plastic tray around Direxion's pre-shaped tip.

2 Remove Mandrel



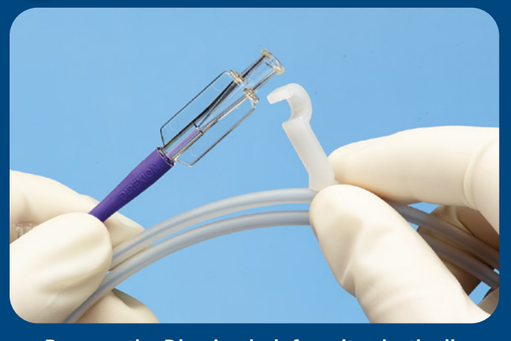
Grasp the metal insert and push away from the catheter tip to remove the Direxion shape-retention mandrel.

3 Flush Hoop



Flush the Direxion packaging hoop with saline prior to removal of the microcatheter.

4 Flush Microcatheter



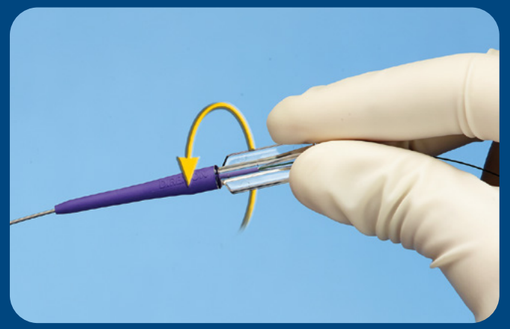
Remove the Direxion hub from its plastic clip and flush the inner lumen with saline.

PROCEDURE

Guidewire Support

Always insert a guidewire for support prior to advancing Direxion in the patient.

Rotate to Release Tension



Rotate Direxion in the opposite way to release tension if resistance is felt when torquing the hub.

Loosen RHV

Loosen the Y-adapter or rotating hemostatic valve (RHV) prior to advancing Direxion in the patient.

Don't Push Down at 90°

Do not press Direxion into the procedure bed during a hand injection.

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 preloaded 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 AB.6**

Boston Scientific
Advancing science for life™

Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

PI-277314-AB