HANDLING THE DIREXION™ Torqueable Microcatheter

**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 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, or vessel perforation. • Do not introduce the microcatheter without guidewire support as this may damage the proximal shaft of the catheter. • Do not introduce the microcatheter without guidewire support as this may cause damage to the peripheral vessels. • Use of excessive force to manipulate the microcatheter against resistance can cause a fracture in the nitinol shaft. • Use care not to overtorque 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 properly 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 this microcatheter may be advanced into superior or inferior vasculature, repeatedly assure that the microcatheter has not been advanced too far to interfere with its removal. • Adverse Events: The Adverse Events include, but are not limited to: • Allergic reaction • Death • Embolization • Hemorrhage/hematoma • Infection • Nerve irritation • Pseudoaneurysm • Stroke • Thrombosis • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel trauma (dissection, perforation, rupture)