

Guider Softip XF Guide Catheter

RX ONLY

See package insert for complete indications, contraindications, warnings and instructions for use.

Intended use/indications for use

Boston Scientific Guider Softip XF Guide Catheters are intended to facilitate the placement of interventional devices into the neurovascular system.

Contraindications

None known.

Adverse events

Potential adverse events that may result from the use of guide catheters include, but are not limited to, the following:

- Allergic reactions due to antiplatelet agents and/or contrast media
- Distal emboli (air, foreign material, tissue, or thrombus)
- Death
- Hematoma or Hemorrhage
- Infection
- Neurological deficits including stroke
- Pseudoaneurysm or Arteriovenous fistula formation
- Vascular occlusion or thrombosis
- Vessel dissection, perforation, rupture, spasm or damage

Preparations for use

Warnings

After removal from packaging, carefully inspect the guide catheter prior to use. Verify shape, size and conditions are suitable for the specific procedure.

Check that all fittings are secure and that gas has been removed from pressure bags so that air is not introduced into guide catheter during continuous flush.

Do not exceed maximum pressure of 2068 kPa (300 psi). Excessive pressure may result in a ruptured guide catheter or severed tip.

Precautions

This guide catheter is not recommended for routine arteriography.

Avoid damaging the guide catheter during removal from the package. Grasp the hub and gently withdraw the catheter. Rapid removal or jerking from the package may cause catheter damage.

Directions for use

Warnings

The percutaneous technique for catheter introduction should be undertaken only by physicians experienced in angiography. Due to variations in individual patient anatomy and individual physician techniques, the procedure may vary.

Due to the size and relative stiffness of guide catheters, extreme care must be taken to avoid damage to the vessel walls through which this catheter passes.

This catheter may occlude smaller vessels. Care must be taken not to completely block blood flow.

Never advance or withdraw an intraluminal device against resistance. If strong resistance is felt when removing an intraluminal device remove them as a unit to prevent damage to the intraluminal device, guide catheter, or blood vessel.

Precautions

Check the labeled diameter of both the Interventional device and guide catheter prior to use to ensure compatibility.

It is recommended that guidewires coated with materials to enhance lubricity be used with this guide catheter to ensure easy introduction of the catheter and removal of the guidewire.

Boston Scientific strongly advises that all guide catheters be inserted into the vasculature with the aid of a catheter introducer.

To control the proper introduction, movement, positioning and removal of the guide catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.

Store catheters in a cool, dry, dark area. Do not expose them to organic solvents or ionizing radiation. Rotate inventory so that catheters and other dated products are used prior to the "Use By" date shown on the package label. Excessive aging may cause the polymers used in these products to deteriorate.