

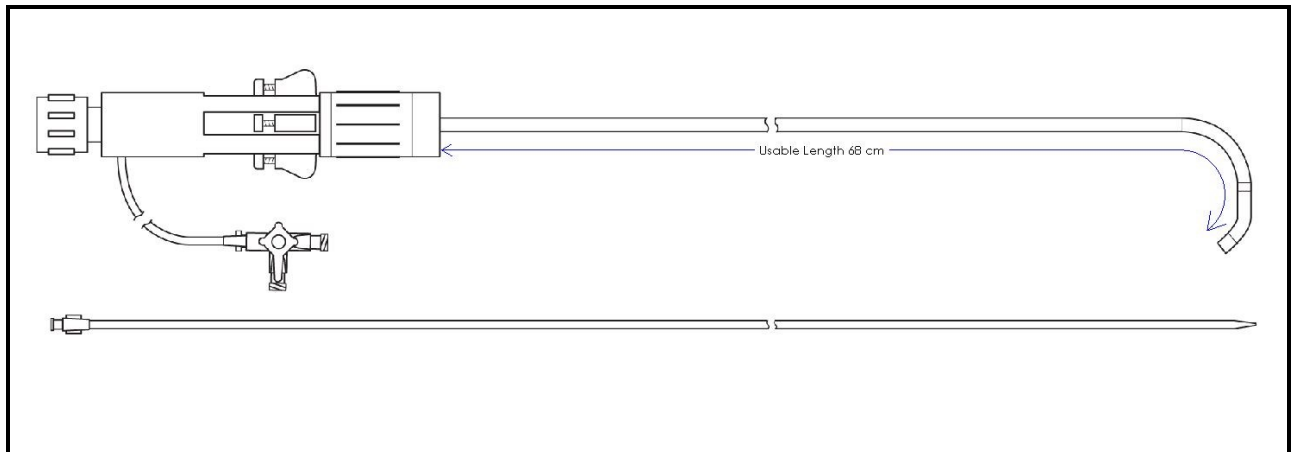


VIZARAMED, INC.
MULTI*flex*™ Steerable Sheath

Instructions for Use

Model

VIZ175 (17.5F/5.84 mm)



*** WARNING: ENSURE YOU ARE FAMILIAR WITH THIS DOCUMENT AND DEVICE PRIOR TO USE.**

CONTENTS

1 – 17.5F Sheath, 1 - Dilator

DEVICE DESCRIPTION

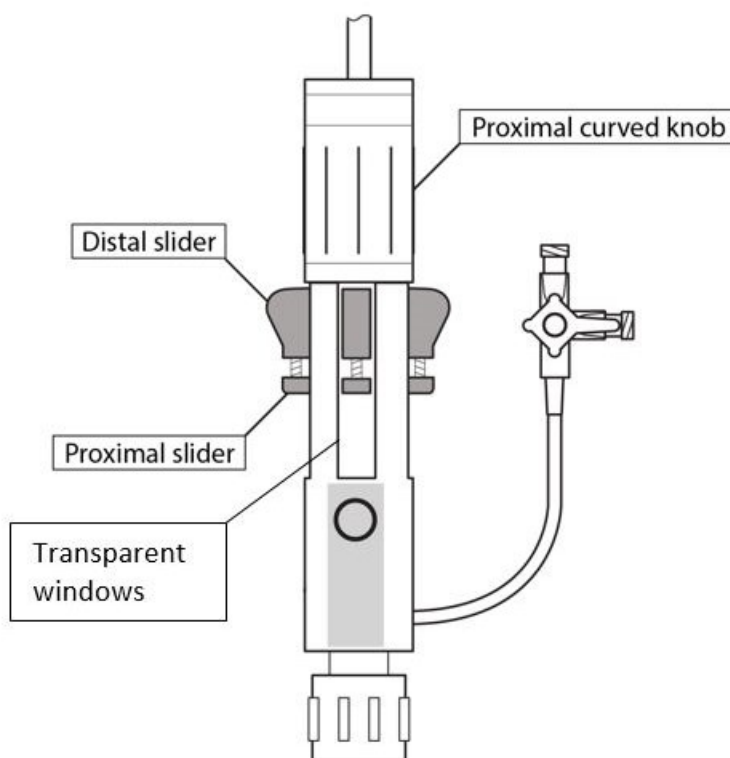
The VizaraMed MULTI*flex*™ Steerable Sheath is a deflectable, sterile, single-use, percutaneous sheath with a dilator used to facilitate the placement of various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath consists of a steerable shaft capable of complex three-dimensional shapes, a handle with lockable steering controls, a Tuohy-Borst adapter with a hemostasis valve, a side port with three-way stopcock, and atraumatic soft distal tip. The shaft is radio-opaque for easy visualization under fluoroscopy.

Included in the sterile packaging is a dilator designed to accommodate a 0.038" guidewire (not included). The dilator is made of material for optimal rigidity and pushability. The dilator conveniently snaps securely into the sheath.

The 17.5F sheath will accommodate devices sized 3F (0.039") - 17.5F (0.230").

The proximal unidirectional deflectable curve is designed to span across the right to left side of the heart through a transseptal puncture. The proximal curve is actuated by the rotating knob found near the top of the handle. The direction of deflection will be on the same side of the sideport.



The distal portion of sheath can deflect in four (4) directions along two perpendicular planes (see below). These are controlled by the four slider mechanisms located in the mid portion of the handle. Each of these actuators contains a proximal slider and distal slider. A desired deflection can be achieved by pulling the distal slider down with the thumb. The curve will be automatically locked at the position. To release the curve, push on the proximal slider.

	Inward distal deflection in the same plane as the proximal curve
	Outward distal deflection in the same plane as the proximal curve
	Distal deflection out of the plane of proximal curve Towards the user
	Distal deflection out of the plane of proximal curve Away from the user

Caution: The diagonally opposite slider actuates the distal curve in the opposite direction. Release one side before actuating the opposite side.

Note: Complex deflection geometry can be achieved by movement of adjacent sliders.

INDICATIONS FOR USE

The VizaraMed MULTIflex™ Steerable Sheath is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS

- Previous intra-atrial septal patch.
- Known or suspected atrial myxoma.
- Patients who do not tolerate anticoagulation therapy.
- Presence of atrial thrombus.
- Patients with an active infection.

WARNINGS

- Do not reuse.
- Do not resterilize. Resterilization might compromise the integrity of the device.
- This device should only be used by a physician trained in the use of this device.
- Do not insert a catheter that exceeds the indicated lumen size.
- Manipulate under fluoroscopy.
- Maintain continuous hemodynamic monitoring throughout the procedure.
- Maintain continuous heparinized fluid infusion throughout the procedure.
- Fibrin sleeves might develop during use and should be carefully removed.
- Ensure device compatibility prior to use.

PRECAUTIONS

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Store in a cool, dark, dry place.
- Inspect packaging and device prior to use. Do not use if damaged.
- Careful review of this document should be performed prior to use of this device.
- Ensure the device is not deflected while inserting or removing the device from the body.
- If resistance is encountered, determine cause before advancing or removing the device.
- The French size specifies the outer diameter of the sheath.
- Familiarize oneself with the device prior to inserting.
- Ensure compatibility of devices prior to insertion into this sheath.

POTENTIAL COMPLICATIONS

- Air embolism
- Infection
- Perforation
- Access site hematoma

- Access site laceration or dissection
- Access site local infection
- Retroperitoneal bleeding
- Intimal tear
- Dissection
- Catheter entrapment
- Thrombus
- Vascular occlusion
- Cardiac or/and lower extremity thromboembolic events
- Stroke
- Vessel spasm
- Pericardial effusion
- Myocardial infarction
- Arrhythmia
- Valvular damage
- Septal tear
- Prolonged bleeding

INSTRUCTIONS FOR USE

Before introducing the MULTIflex™ Steerable Sheath into the patient, test the deflection mechanisms to ensure they are operational.

PRECAUTION:

- **DO NOT ACTUATE DISTAL CONTROLS THAT ARE 180° APART SIMULTANEOUSLY.**

1. Assemble the sheath and dilator together. Flush the sheath side port and dilator lumen with sterile saline solution. Ensure that the sheath is in the neutral (non-deflected) position and wet the dilator shaft with sterile saline solution. Loosen the Touhy-Borst adaptor. Insert the distal tip of the dilator straight through the center of the valve and fully into the sheath until the dilator hub snaps into the sheath hub. Tighten the Touhy-Borst adaptor to seal around the dilator. Wet the shaft of the steerable sheath with sterile saline solution.
2. Using an aseptic technique, create a vascular access with an appropriate introducer.
3. If left heart chamber access is needed, perform transseptal puncture using an appropriate tool kit and institutional standard practice
4. After access, administer anticoagulation therapy during and post-procedure according to institutional standards.
5. Insert a compatible guide wire (maximum size 0.038") through the vasculature and position the guide wire using standard vascular access techniques.
6. Insert the dilator and sheath over the guide wire and advance into the desired position.
7. Slowly remove the guide wire and dilator from the sheath. Slowly aspirate blood through the sideport and then flush the sheath, taking care to prevent bubbles.
8. Once the sheath is positioned, manage flushing and/or continuous drip according to institutional standards.

9. Insert and position the therapeutic device or implant delivery catheter. Slowly aspirate and flush the sheath.
10. Advance the device making sure not to introduce any air. Air bubbles can be observed in the clear lower part of the sheath handle. If any air bubbles are present, stop advancing the therapeutic device and aspirate the sheath to remove the air bubbles.
11. By manipulating the proximal and distal curves of the tip of the MULTIflex™ Steerable Sheath can be aligned to the target therapeutic site.
12. Adjacent distal curve controls can be used in concert to move the distal tip to desired orientation without torquing the sheath.
13. Perform therapy or implant as directed by the instructions for the use of such devices.
14. After successful completion of the therapy or implantation, ensure that the sheath is in the neutral (non-deflected) position prior to withdrawal.
15. Slowly withdraw the sheath from the body and obtain appropriate hemostasis according to institutional standards or consensus statements.
16. After use, dispose of the device in accordance with hospital, administrative, and/or local governmental policy.

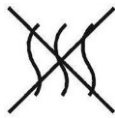
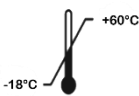
USA ONLY

STATE OF CALIFORNIA (USA ONLY)

WARNING: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

MULTIflex™ Steerable Sheath is covered by US Pat 11,344,702 B2 and other pending patents.

SYMBOLS

	Do not re-use
	Consult instructions for use
	Keep away from heat
	Keep dry
	Use by date
LOT	Batch code
STERILE EO	Sterilized using ethylene oxide
REF	Catalog number
	Do not re-sterilize
	Do not use if package is damaged
Rx ONLY	Prescription only
	Latex Free
	Non-pyrogenic
	Store between 18°C and +60°C



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