

## Fixed Curve Braided Transseptal Sheath

### INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications. Merit Medical Systems, Inc. relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.

#### For U.S.-California Only.

Proposition 65, a State of California voter initiative, requires the following notice:

**WARNING:** This product and its packaging have been sterilized with ethylene oxide. This 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.

#### CAUTION:

- Federal (USA) law restricts this device to sale by or on the order of a physician. This device should be used only by physicians thoroughly trained in percutaneous procedures.
- Do not alter this device in anyway.
- This device is supplied sterile and intended for one-time use only. Do not use any unit if its package is opened or damaged. Do not resterilize and/or reuse.

#### HOW SUPPLIED:

Sterile: Sterilized with ethylene oxide gas. Non-pyrogenic.

**Contents:** One (1) Radiopaque Sheath, one (1) Radiopaque Dilator, one (1) 0.032" x 180 cm Guidewire

**NOTE:** Sheath Length, Diameter, and Curve configurations are indicated on the product label.

#### DESCRIPTION:

The Braided Transseptal Sheath is designed to provide a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations. It provides support for positioning and maintaining the position of catheters at specific locations in the heart. The sheath may be used for percutaneous entry.

The kit consists of three components: a sheath, a dilator, and a J-tipped guidewire.

The sheath has a radiopaque marker band which aids in defining the location of the tip, an atraumatic soft tip, and a lubricious coating on the inner and outer surface.

The dilator is designed to conform to the inner diameter and curve of the sheath, and has a tapered tip.

To facilitate access to a variety of cardiac structures and sites, the sheaths are available in various sizes, lengths and tip curve configurations.

#### INDICATIONS:

For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture.

#### STORAGE:

Store in a cool, dark, dry place.

#### WARNINGS:

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The device(s) should be used by physicians engaged in the practice of specialized invasive cardiology techniques. Use of the device should be restricted to those physicians specifically trained in the approach to be used.
- When the sheath is left in the vessel, a continuous heparinized infusion under pressure is strongly recommended through the sheath sideport.
- Infusion through the sideport should only be done after all air is removed from the unit.
- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve components resulting in blood flow through the valve, as well as cause a vacuum which may allow air to enter the sheath.
- Aspiration of the side port is recommended when withdrawing the catheter, probe, or dilator to remove any fibrin deposition which may have accumulated in or on the tip of the sheath.
- Careful sheath manipulation must be performed in the presence of an implantable cardiac device of any kind to minimize the potential to displace or dislodge lead placement.
- Direct percutaneous insertion of the sheath requires the use of the dilator to minimize the potential risk of vessel injury due to a flared tip.
- Fluoroscopic monitoring of the location of the distal tip of the sheath using the radiopaque marker, especially when used in a transseptal approach, is recommended.

#### PRECAUTIONS:

- Aspiration and flushing of the sheath, dilator, and catheter should be performed frequently to help minimize the potential for air embolism.
- Indwelling sheaths should be internally supported by a catheter, electrode, or dilator.
- Never advance, torque, or withdraw guidewire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.
- Use the sideport for injection or aspiration of sheath and sideport assembly. Assure that stopcock is in the closed position after flushing, to prevent back-bleeding.
- The following conditions require that special care be taken when using this product involving the transseptal approach.
  - enlarged aortic root
  - marked right atrial enlargement
  - small left atrium
  - marked distortion of the thoracic configuration (e.g. kyphosis or scoliosis)
- Care should be taken to avoid excessive bending of the sheath and/or dilator before and during use.
- Fluoroscopic procedures involve exposure to ionizing radiation by the patient and staff. Precautions to minimize exposure should be taken and protective equipment should be used.
- Fluoroscopic guidance should be used when advancing the Braided Transseptal Sheath and/or dilator. When advancing the sheath and/or dilator across a valve, a guidewire or pigtail should be used.
- The sheath, dilator, and guidewire are designed for single use only. Reuse may expose the patient to communicable disease and/or injury.
- Arrhythmias may occur during the use of any intracardiac device. Careful monitoring and availability of emergency equipment are mandatory.
- When using the Braided Transseptal Sheath in the presence of radio frequency ablation, care must be taken to assure all ablating elements are outside the sheath.

#### ADVERSE REACTIONS:

Adverse reactions to cannulation of the peripheral vasculature and intracardiac placement of the sheath and dilator may include, but are not limited to:

- infection
- local nerve damage
- perforation
- dissection
- AV fistula formation
- pseudoaneurysm formation
- arrhythmias
- hematoma
- hemorrhage
- thromboembolic events
- catheter entrapment
- valve damage
- pacemaker/defibrillator lead displacement
- air embolus
- vasovagal reaction
- vessel trauma
- vessel spasm
- atrial septal defect
- aortic puncture
- perforation and/or tamponade
- coronary artery spasm and/or damage
- stroke
- myocardial infarction
- pericardial/pleural effusion
- pulmonary edema

#### REQUIRED EQUIPMENT:

Carefully read the instructions for each accessory before use.

Needle

Heparinized Normal Saline

#### INSPECTION PRIOR TO USE:

Carefully inspect the package for any breach of the sterile barrier or damage to the contents prior to use.

#### USE STERILE TECHNIQUE:

Suggested Procedure

- Open package and place contents on sterile field.
- Prep skin and drape in area of anticipated vein-puncture as desired.
- Perform skin wheal using 25 gauge needle (not supplied).
- Locate vessel using small gauge needle and syringe.
- Insert Introducer Needle (not supplied) into vessel. Look for blood return to confirm proper needle position.
- Insert soft tip of guidewire through Introducer Needle into vessel. Advance guidewire to required depth. At no time should the guidewire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding.
- Hold guidewire in place and remove Introducer Needle. Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.
- Enlarge cutaneous puncture site with scalpel.
- Assemble dilator and sheath together until the dilator hub locks into the sheath hub. Thread the dilator/sheath assembly over the guidewire, using a slight twisting motion. The Braided Transseptal Sheath may now be positioned to deliver catheters to desired locations.
- Aspirate all air from the sheath valve assembly by using a syringe connected to the sideport. Flush the sheath through the sideport. If transseptal puncture is required, continue with steps below.

#### Suggested Procedure

- Advance the Braided Transseptal Sheath and Dilator assembly to the superior vena cava (SVC) just above the right atrium.
- Separate the dilator and sheath hub approximately 1cm while slowly advancing the sheath over the dilator. This will aid the introduction of the curved transseptal needle (not supplied).
- While the sheath and dilator hubs are separated, slowly remove the guidewire from the dilator. Remove all air from the dilator by slowly aspirating blood. After making certain no air is in the dilator, flush the dilator.
- Completely flush the transseptal needle.
- Introduce the needle into the dilator hub. Carefully advance the curved section of the needle into the dilator, being certain not to restrict the movement of the needle.
- Withdraw the sheath approximately one centimeter while maintaining the dilator position. Re-attach the dilator and sheath hubs.
- While maintaining the sheath's position, slowly advance the curved section of the needle until it is about to protrude from the dilator tip.
- Monitor the right atrial pressure by connecting the needle hub to pressure monitoring equipment. Good right atrial pressure should be observed before proceeding.
- Position the needle and sheath set in the right atrium. Verify position using fluoroscopy.
- Position the unit (dilator and needle point) against the atrial septum in the region of the fossa ovale by gradually rotating the needle posteriorly and toward the left scapula during withdraw. Use continual pressure monitoring and repeated anterior-posterior and lateral visualization of the tip under fluoroscopy during all positioning procedures.
- After confirming the position of the dilator tip and needle point against the atrial septum, advance the needle and complete the transseptal puncture. Successful needle entry into the left atrium is confirmed by pressure monitoring and a sudden reduction in resistance. It is critical that acceptable left atrial pressure monitoring immediately after the needle penetration is felt through the interatrial septum. Do not advance the dilator if acceptable pressure is not seen. Disconnect the pressure monitoring line from the needle. This will show the location of the needle. Reconnect the pressure monitoring line to the needle.
- Advance the dilator with the needle in place through the septum. Acceptable left atrial pressure should be continually observed. A sequential increase in resistance to movement followed by a sharp decrease in resistance will indicate location of the dilator in the left atrium.
- Withdraw the needle point even with the dilator tip. The dilator with the needle point within should be freely located in the left atrium. Verify with fluoroscopy.
- Advance the sheath slowly over the dilator-needle combination until it is in the left atrium. A slow rotating motion of the sheath as firm pressure is applied will aid in this procedure. The sheath will be in position when a sharp reduction of resistance is felt.
- Advance the sheath approximately 2 cm into the left atrium while maintaining the dilator needle position.
- Disconnect the pressure monitoring line from the needle.
- Slowly remove the needle from the dilator.
- Slowly remove the dilator from the sheath.
- Attach the sheath sideport to the monitoring line. Gently aspirate blood through the side arm for sampling and to be sure the sheath is clear of air.
 

Caution: Remove the dilator slowly to reduce the possibility of creating a vacuum in the sheath. Blood should aspirate freely through the sideport. If not, withdraw the sheath 0.5-1.0 cm (sheath tip may be resting against the wall of the atrium or a pulmonary vein). Note: Do not apply strong vacuum.
- In order to maintain the location of the sheath in the left atrium, monitor the location of the radiopaque tip marker frequently under the fluoroscopy.
- Introduce the properly prepared catheter through the hemostatic valve into the left atrium. Improved catheter manipulation may be obtained by withdrawing the sheath into the right atrium. The sheath should be returned to the left atrium over the catheter prior to removing the catheter. Location of sheath can be confirmed by comparison to position established in step 20.
- After removal of the sheath, use standard technique to achieve hemostasis.


⚠ Caution: Consult accompanying documents

📦 Contents

⊖ Inner diameter

⊕ Outer diameter

☒ Non-pyrogenic

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