PRECAUTIONS: - Aspiration and flushing of the sheath, dilator, and guide wire should be performed frequently to help minimize the potential for air embolism.

- Indicator needles should be internally supported by a catheter, electrode, or dilator.

- Never advance, rotate, or aspirate guidewires or sheaths when resistance is met. Determine cause by fluoroscopy and take remedial action.

- Use the sideport for injection or aspiration of sheath and sheath assembly. Ensure 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:

  • Atrial septal defects
  
  • Atrial arrhythmia.

- Do not remove a dilator, sheath or catheter that has been inadvertently advanced into the pericardial space until the patient is in surgery.

- Do not reuse this device.

- Only those physicians who specialize in the practice of invasive cardiology are recommended.

- Fluoroscopic procedures involve exposure to ionizing radiation by the patient and staff. Precations to minimize exposure should be taken and protective equipment should be used.

- Fluoroscopic guidance should be used when advancing the TSX Transseptal Sheath and/or dilator.

- Fluoroscopy and take remedial action.

- 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.

ADVERSE REACTIONS: - Adverse reactions to cannulation of the peripheral vasculature are not rare. Place of the sheath and dilator may include, but are not limited to:

  • Infection
  
  • Local nerve damage
  
  • Perforation
  
  • Pseudoaneurysm formation
  
  • Arthritis/arthralgia
  
  • Hemorrhage
  
  • Hematoma
  
  • Vasovagal reaction
  
  • Myocardial infarction
  
  • Stroke
  
  • Coronary artery spasm and/or damage
  
  • Nerve damage
  
  • Hypertrophic infection
  
  • Pseudoaneurysm formation
  
  • Pulmonary edema

TSX™ Transseptal Delivery System

Customer Service: 1-888-272-1001

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The TSX Transseptal Needle combines advances in materials along with an ergonomic design engineered to enhance tactile and visual feedback during the transseptal puncture.

**Product Benefits**
- Transparent Handle: To allow direct visualization of bubbles before they travel distally
- Ergonomic Handle: Excellent handling characteristics

**Order Information**

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Guidewire Outside Diameter and Length: 0.035” x 135cm

**Product Benefits**
- Soft,atraumatic tip
- Tapered dilator and tip geometry to facilitate tissue crossing
- Lubricious coating inside and out
- Embedded platinum marker

**Order Information**

<table>
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TSX Fixed Curve Sheath Kit Contains
- Braided Transseptal Sheath
- Dilator
- J-tipped Guidewire

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