

# TSX™

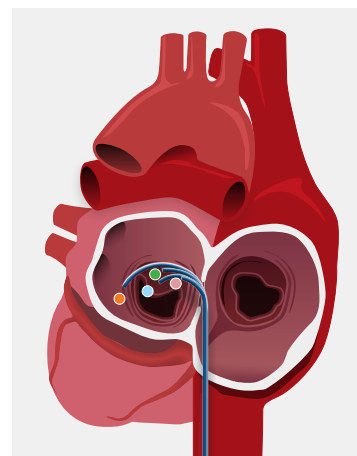
## TRANSEPTAL DELIVERY SYSTEM

### Left Atrium

- TSXFS 8.5F 150i°
- TSXFS 8.5F 90°
- TSXFS 8.5F 120L°
- TSXFS 8.5F 55°

#### Fixed Curve Sheath Suggested Curve Placements

Sheath curve (Degree)	Cardiac Anatomy
55	Pulmonary Veins, Fossa Ovalis
90	Pulmonary Veins, Fossa Ovalis
120 L	Left Pulmonary Veins, Mitral Isthmus Area
150 i	Mitral isthmus area

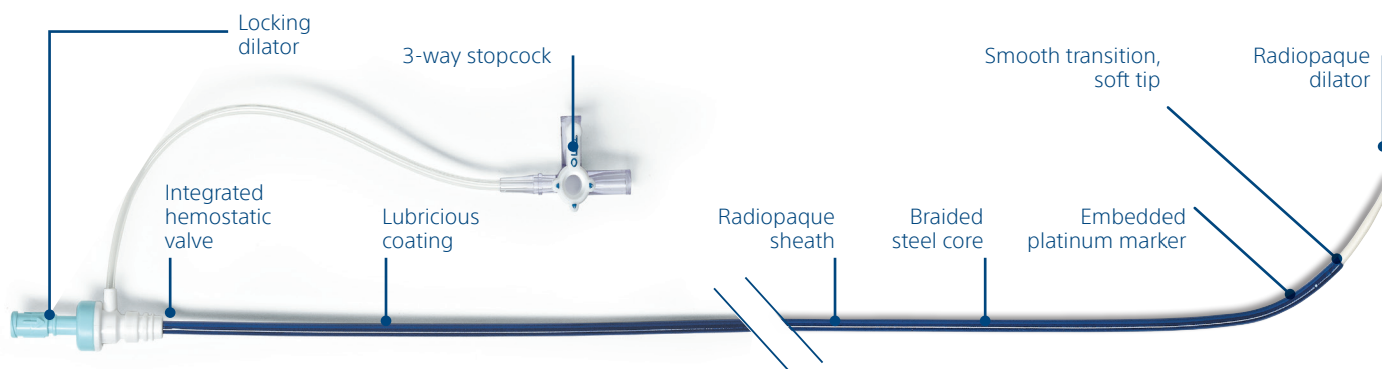
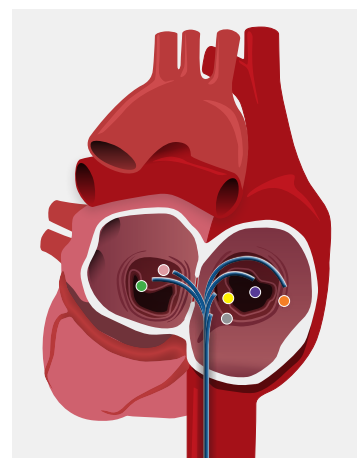


### Right Atrium

- TSXFS 8.5F 150i°
- TSXFS 8.5F 90°
- TSXFS 8.5F 120s°
- TSXFS 8.5F 55°
- TSXFS 8.5F 30°
- TSXFS 8.5F 15°

#### Fixed Curve Sheath Suggested Curve Placements

Sheath curve (Degree)	Cardiac Anatomy
15	IVC, SVC, Right Atrium
30	IVC, SVC, Right Atrium
55	All right atrial anatomy, RVOT
90	Crista Terminalis, Right Atrium, Septum
120S	Right Atrial Isthmus
150 i	Right Atrial Isthmus



Guidewire Outside Diameter and Length: 0.035" x 135cm  
0.035" = 0.89mm

# TSX™ TRANSEPTAL DELIVERY SYSTEM

## Product Benefit

Braided steel core imparts excellent torqueability	Soft, atraumatic tip
Radiopaque sheath and dilator enable in situ visualization	Lubricious coating inside and out
Dual distal holes	Tapered dilator and tip geometry to facilitate tissue crossing
Snap-fit dilator locks in place	Embedded platinum marker

Model Number	French Size	Length	Curve Degree
M004TSXSHEATH100	8.5F (2.83 mm)	60 cm	15
M004TSXSHEATH200	8.5F (2.83 mm)	60 cm	30
M004TSXSHEATH300	8.5F (2.83 mm)	60 cm	55
M004TSXSHEATH400	8.5F (2.83 mm)	60 cm	120 Small
M004TSXSHEATH500	8.5F (2.83 mm)	60 cm	120 Large
M004TSXSHEATH600	8.5F (2.83 mm)	60 cm	150
M004TSXSHEATH700	8.5F (2.83 mm)	79.4 cm	15
M004TSXSHEATH800	8.5F (2.83 mm)	79.4 cm	55
M004TSXSHEATH900	8.5F (2.83 mm)	79.4 cm	90
M004TSXSHEATH1100	8.5F (2.83 mm)	79.4 cm	120 Large

### TSX™ Fixed Curve Transept Sheath

**INDICATIONS FOR USE:** For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture. **WARNINGS:** 1. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. 2. For single 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. This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy, system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization, or reuse. 3. 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. 4. When the sheath is left in the vessel, a continuous heparinized infusion under pressure is strongly recommended through the sheath sideport. 5. Infusion through the sideport should only be done after all air is removed from the unit. 6. 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. 7. 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. 8. 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. 9. 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. 10. 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:** 1. Aspiration and Flushing of the sheath, dilator, and catheter should be performed frequently to help minimize the potential for air embolism. 2. Indwelling sheaths should be internally supported by a catheter, electrode, or dilator. 3. Never advance, torque, or withdraw guidewire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action. 4. 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. 5. 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) 6. Care should be taken to avoid excessive bending of the sheath and/or dilator before and during use. 7. 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. 8. Fluoroscopic guidance should be used when advancing the TSX Transseptal Sheath and/or dilator. When advancing the sheath and/or dilator across a valve, a guidewire or pigtail should be used. 9. The sheath, dilator, and guidewire are designed for single use only. Reuse may expose the patient to communicable disease and/or injury. 10. Arrhythmias may occur during the use of any intracardiac device. Careful monitoring and availability of emergency equipment are mandatory. 11. 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. 90960898 (Rev AB)

**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.

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