Boston Scientific
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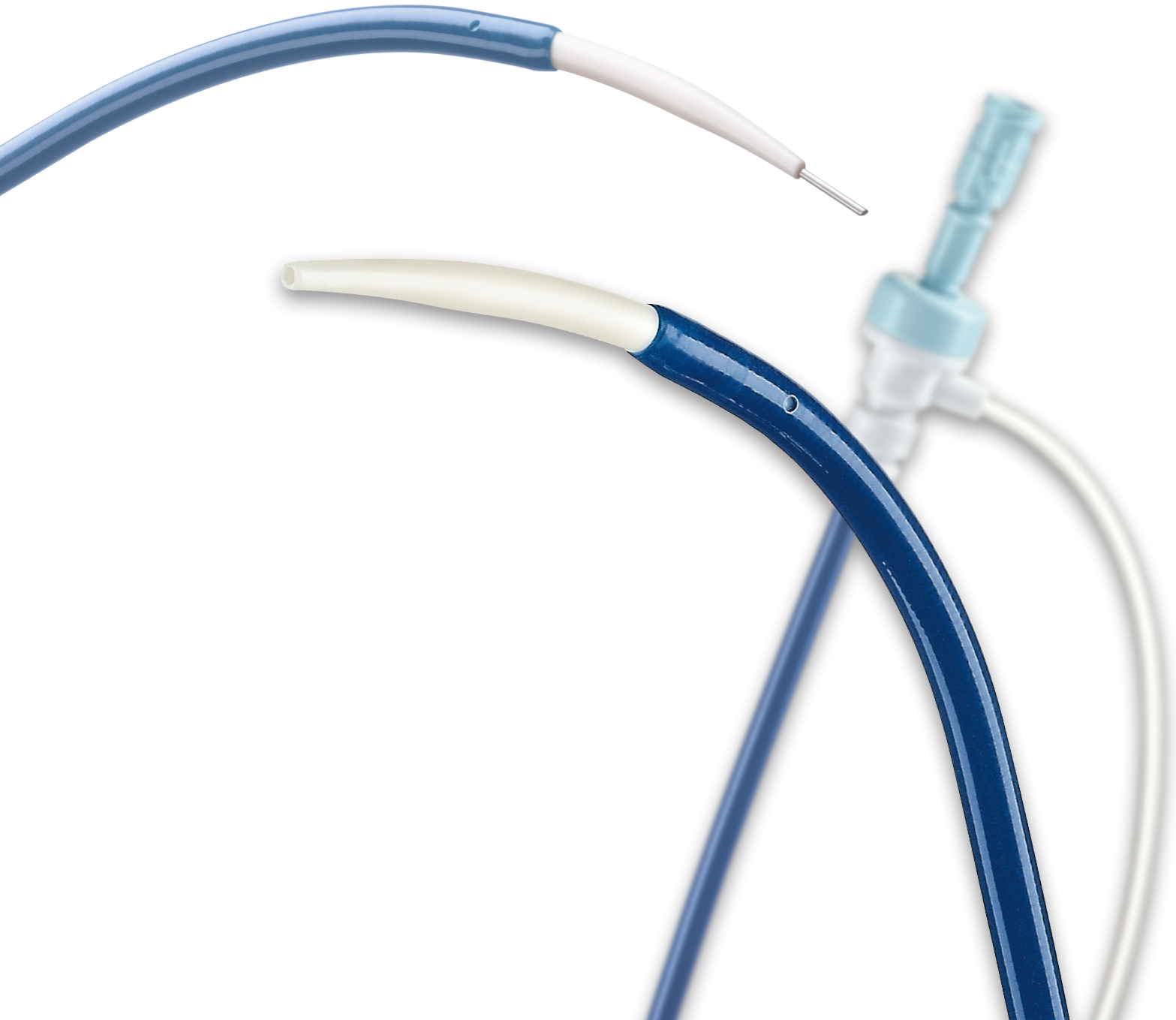
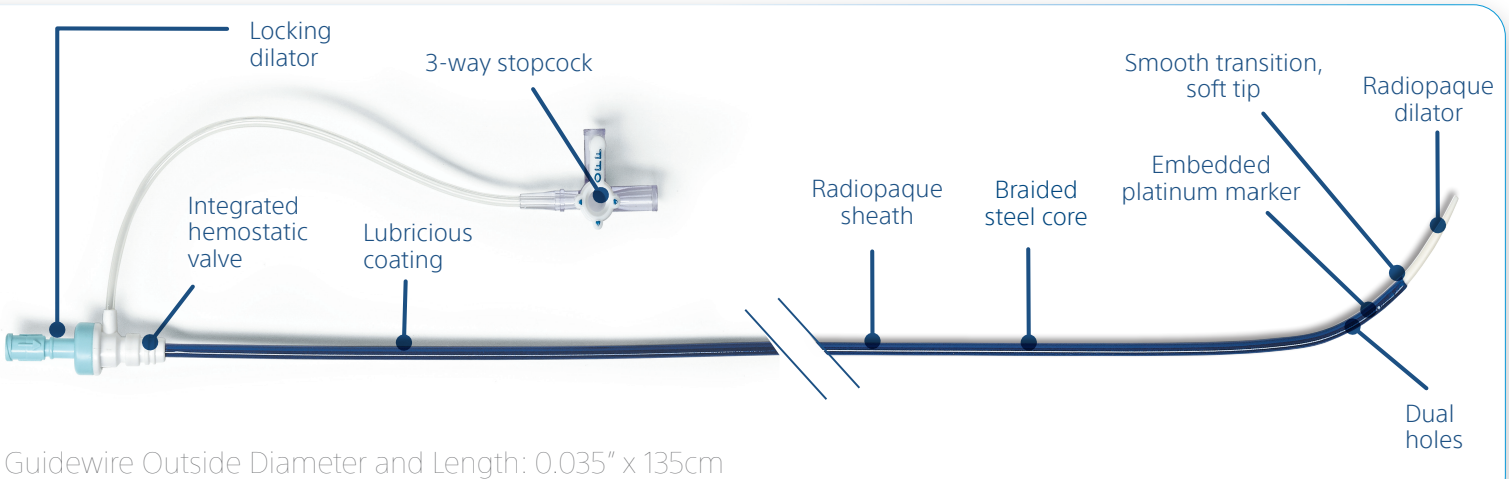
TSX™ Transseptal Delivery System

One Name. One Delivery. One Choice.



TSX™ Fixed Sheath



Guidewire Outside Diameter and Length: 0.035" x 135cm

Product Benefits

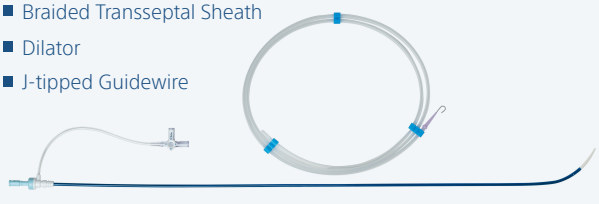
Braided steel core imparts excellent torqueability	Soft, atraumatic tip
Dual distal holes	Tapered dilator and tip geometry to facilitate tissue crossing
Radiopaque sheath and dilator enable in situ visualization	Lubricious coating inside and out
Snap-fit dilator locks in place	Embedded platinum marker

Order Information

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

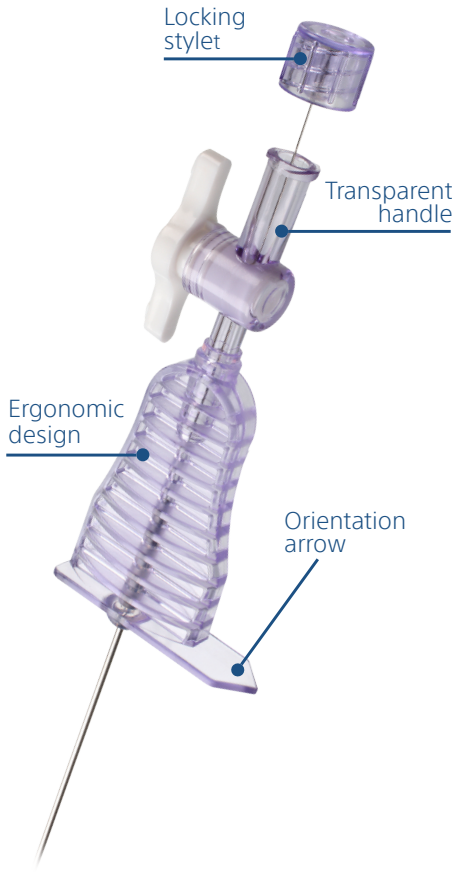
TSX Fixed Curve Sheath Kit Contains

- Braided Transseptal Sheath
- Dilator
- J-tipped Guidewire



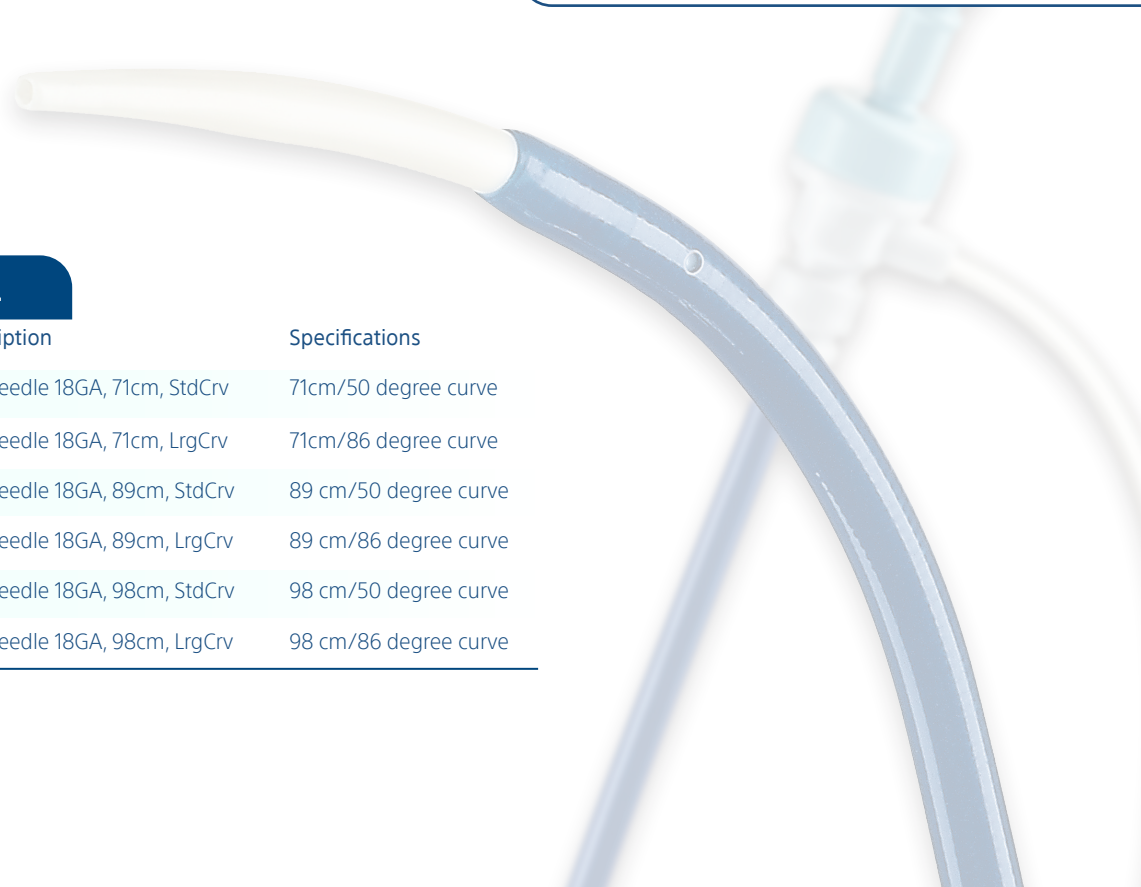
TSX™ Transseptal Needle

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

Model Number	Description	Specifications
M004TSXNEEDLE100	TSX Needle 18GA, 71cm, StdCrv	71cm/50 degree curve
M004TSXNEEDLE200	TSX Needle 18GA, 71cm, LrgCrv	71cm/86 degree curve
M004TSXNEEDLE300	TSX Needle 18GA, 89cm, StdCrv	89 cm/50 degree curve
M004TSXNEEDLE400	TSX Needle 18GA, 89cm, LrgCrv	89 cm/86 degree curve
M004TSXNEEDLE500	TSX Needle 18GA, 98cm, StdCrv	98 cm/50 degree curve
M004TSXNEEDLE600	TSX Needle 18GA, 98cm, LrgCrv	98 cm/86 degree curve

TSX™ Fixed 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:** 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

TSX™ Transseptal Needle

INDICATIONS FOR USE: The transseptal needle is used in conjunction with a transseptal catheter and/or introducer to create the puncture in the atrial septum to allow left heart catheterization procedure to occur through the right atrium. **CONTRAINDICATIONS:** Left atrial thrombus or tumor, Dilated aortic root, Continual anticoagulation , Inability to lie flat, Substantial deformity of the spine or chest, Marked atrial enlargement, Distorted anatomy due to congenital heart disease, Previous intra-septum patch. **WARNINGS:** 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, resterilization, or reuse. Only those physicians who specialize in the practice of invasive cardiology techniques should use this device. The device should be restricted for use by those specialists trained to perform transseptal procedures. Maintain continuous pressure monitoring and repeated biplane fluoroscopy during positioning. Caution should be used in patients with small left atrium, to avoid left atrial wall puncture. The transseptal needle should never be advanced until the catheter is positioned correctly on the atrial septum. Always ensure that the transseptal needle has clearly entered the left atrial cavity by confirming distinct left atrial pressure and fluoroscopy of the needle tip before advancing the dilator, sheath or catheter. 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. The device must be discarded after one use using acceptable medical practices and applicable local, state and federal laws and regulations. Follow instructions accompanying the transseptal introducers. **PRECAUTIONS:** Store in a cool, dark and dry place. Inspect all components prior to use. If resistance is met while advancing or withdrawing the introducer or guidewire, fluoroscopy should be used to determine the cause. Prior to use, ensure the appropriate catheter is being used with the transseptal needle. **ADVERSE EVENTS:** In addition to the complications associated with any cardiac catheterization, the following could occur during a transseptal catheterization: Inferior vena cava puncture, Aorta puncture, Atrial free wall puncture, Coronary sinus puncture, Arterial embolism from thrombus at the puncture site Tamponade, Residual atrial septal defects, Atrial arrhythmia. 90960897 REV AB

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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (2273422)
Customer Service:
1.888.272.1001

EP-308608-AD