CHANNEL™ STERABLE SHEATH

Right Place, Right Time, Right Sheath – Every Time.
Introducing the CHANNEL Steerable Sheath

The Sheath for Every Ablation Case

- **Hemostasis Valve**: Prevents back-bleed
- **Side Port**: Allows for flushing and aspiration
- **CurveLock™ Technology**: Designed to remain in the precise position once
- **Hemostasis Valve**: Prevents back-bleed
The CHANNEL Steerable Sheath... Versatile, Consistent and Dependable

Right Place, Right Time, Right Sheath – Every Time.

Use with 89cm TSX™ Transseptal Needle

- Ergonomic handle design
- Tapered tip transition
- Item number 2001398

Flush Holes
Allows for continuous heparin delivery

Radiopaque Marker Band
Convenient visualization

Braided Shaft
The exclusive shaft features optimal torque and kink resistance

0 to 180° steerability with active straightening

Inner PTFE Liner
Allows for smooth advance of devices

The pin-point control and stability of the Channel Steerable Sheath provide critical capabilities for a successful case.
Channel™ Steerable Sheath

INDICATIONS FOR USE The Boston Scientific Channel Steerable Sheath is intended to be used to facilitate the placement of interventional devices into the peripheral and coronary systems. The steerable sheath system is intended for single use only. CONTRAINDICATIONS The following are contraindications for use of the steerable sheath: Use of the steerable sheath is contraindicated in patients with obstructed or inadequate vasculature. WARNINGS and PRECAUTIONS Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. Transvenous device compatibility – Use the steerable sheath only with compatible transvenous devices. Use the appropriate size sheath for the size of the transvenous device being utilized. Consequences of using the steerable sheath with incompatible devices may include the inability to deliver the transvenous device or damage to the transvenous device during delivery. Inspecting the sterile package - Inspect the package prior to opening. Contact Boston Scientific or your distributing representative with the part number and lot number from the package label if the seal or package is damaged or if there are any concerns regarding product integrity. Do not use the product after its Use Before Date. The storage temperature for this product is at or below 40°C. The steerable sheath has been sterilized with ethylene oxide prior to shipment. If the integrity of the sterile package has been compromised, DO NOT USE. Handling the steerable sheath - Handle the steerable sheath with care at all times. Before removing the steerable sheath, straighten the distal section as much as possible to avoid damage during removal. Refer to “Deflecting and straightening the steerable sheath” for instructions. Do not kink, stretch, or severely bend the steerable sheath. Do not use surgical instruments to grasp the steerable sheath. Do not use excessive force when inserting a steerable sheath into a vessel. Do not force the steerable sheath assembly if significant resistance is encountered during insertion or passage. Do not wipe the sheath with chlorofluorocarbon based solvents. Ensure the steerable sheath is thoroughly flushed and free of air prior to use. Avoid contact with liquids other than isopropyl alcohol, blood, saline, or contrast solution. To ensure retention of desired deflection position(s) avoid contact with the button ‘locking’ mechanism that may cause the sheath to change deflected shape. An unsupported sheath (without a device or dilator) may be susceptible to kinking during advancement or torsional manipulation. Vessel and tissue damage – Use care when passing the steerable sheath through vessels and tissue. Avoid damaging vessels and cardiac tissue, such as perforations and dissections, during steerable sheath passage and positioning. The sheath will deflect at the speed which the slide is advanced. Avoid rapid deflection that may cause vessel damage. Flushing the steerable sheath – Use the side flush port to inject contrast solution or flush the steerable sheath. The steerable sheath must be thoroughly flushed with either saline or heparinized saline and free of air prior to use to avoid air embolism to the patient. Flush through the infusion port on the side of the sheath or if supplied with a luer fitting from the luer fitting at the proximal end of the fitting. The steerable sheath must be thoroughly flushed and free of air prior to use. Do not use a power injection syringe to inject contrast solution. Do not aspirate steerable sheath with a guidewire in place through the hemostasis valve. Aspiration with the guidewire through the valve may cause an air embolism which can result in significant morbidity or death. Necessary Hospital equipment – Keep external defibrillation equipment nearby for immediate use during insertion, placement, acute lead system testing, or whenever arrhythmias are possible or intentionally induced. If the patient has left bundle branch block, back up pacing should be readily available during insertion of the steerable sheath assembly. Use of the steerable sheath assembly may cause heart block. ADVERSE EVENTS Adverse events related to the use of the steerable sheath may include, but are not limited to, the following. Air Embolism, Allergic reaction to contrast media, Arteriovenous fistula formation, Bleeding at the insertion site, Brachial plexus injury, Cardiac tamponade, Dislodgement, Dissection, Endocarditis, Heart block, Hematoma formation, Hemothorax, Infection, Irregular heart beat, Mediastinal widening, Perforation, Pneumothorax, Subclavian artery puncture, Thrombophlebitis, Thrombosis, Valve damage, Vascular occlusion, Vessel damage.

Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>8Fr CHANNEL Steerable Sheath</th>
<th>9Fr CHANNEL Steerable Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item Number</td>
<td>M004CS100</td>
<td>M004CS200</td>
</tr>
<tr>
<td>French Size Compatibility</td>
<td>8F</td>
<td>9F</td>
</tr>
<tr>
<td>Sheath Inner Diameter (ID)</td>
<td>8.3F / 2.8mm</td>
<td>9.8F / 3.3mm</td>
</tr>
<tr>
<td>Sheath Outer Diameter (OD)</td>
<td>11.4F / 3.8mm</td>
<td>12.6F / 4.2mm</td>
</tr>
<tr>
<td>Sheath Usable Length</td>
<td>67cm</td>
<td>67cm</td>
</tr>
<tr>
<td>Sheath Radiopaque Marker</td>
<td>0.25in / 6.35mm from tip</td>
<td>0.25in / 6.35mm from tip</td>
</tr>
<tr>
<td>Sheath Turning Range</td>
<td>0 to 180°</td>
<td>0 to 180°</td>
</tr>
<tr>
<td>Dilator Usable Length</td>
<td>86cm</td>
<td>86cm</td>
</tr>
<tr>
<td>Transseptal Needle Compatibility</td>
<td>89cm needle</td>
<td>89cm needle</td>
</tr>
<tr>
<td>Dilator ID Compatibility</td>
<td>0.038in / 1mm</td>
<td>0.038in / 1mm</td>
</tr>
</tbody>
</table>

Channel Steerable Sheath is a registered or unregistered trademark of Boston Scientific or its affiliates. All other trademarks are property of their respective owners.

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.