1. Device Description

The POLARx™ Cryoablation Catheter System. The POLARSHEATH is non-pyrogenic. Use prior to the Use By date as labeled on the POLARSHEATH package.

POLARx™ Cryoablation Catheter System. The POLARSHEATH is compatible for use with the Boston Scientific POLAR™ Cryoablation Catheter System. The POLARSHEATH is non-pyrogenic.

1.1 Contents of Package

One (1) POLARx™ Steerable Sheath

One (1) Dilator

1.2 Have Supplied

The POLARSHEATH is supplied individually packaged within a pouch. Package contents are listed on the pouch and box labels. Do not use if labeling is illegible or incomplete.

2. Intended Use

The POLARSHEATH is intended to facilitate the placement of diagnostic and/or therapeutic intracardiac devices during percutaneous catheter ablation procedures. The sheath deflection facilitates catheter positioning.

3. Indications for use

The POLARSHEATH is indicated for left-sided procedures via a transseptal approach.

4. Contraindications

Use of the POLARSHEATH is contraindicated as follows:

• In patients with an active systemic infection as this may increase the risk of endocarditis and sepsis.

• In women where vascular access is unobtainable, or the femoral vein is known to be obstructed.

• In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event.

• During use of the device may lead to injury, illness or death of the patient.

5. Warnings

• Introducing catheters and sheaths into the circulatory system entails the risk of air emboli. Always advance/withdraw the POLARSHEATH slowly. Always advance/withdraw catheters slowly through the POLARSHEATH valve and minimizing blood loss. A side-port is integrated to allow continuous drip infusion, injection through the center lumen, flushing, aspiration, and blood sampling.

• A composite structured single lumen shaft, an ergonomic handle to provide torque and active deflection, and a hemostasis valve to allow safe introduction, withdrawal, and swapping of catheters and wires while preventing air ingress and minimizing blood loss. A side-port is integrated to allow continuous drip infusion, injection through the center lumen, flushing, aspiration, and blood sampling.

• The POLARSHEATH is compatible for use with the Boston Scientific POLAR™ Cryoablation Catheter System. The POLARSHEATH is non-pyrogenic.

6. Precautions

• Cardiac catheterization procedures should be performed only in a fully equipped facility.

• The POLARSHEATH and its accessories are to be used only by physicians, or under the supervision of physicians, trained in cardiac electrophysiology procedures in properly equipped facilities.

7. Potential Adverse Effects

Potential adverse events associated with cannulation of the peripheral vasculature and intracardiac placement of the POLARSHEATH and dilator may include the following conditions:

• Access site complications

• Anxiety

• Arhythmias

• Arteriovenous (AV) fistula

• Bleeding/hemorrhage

• Cardiac perforation

• Cardiac/pulmonary arrest

• Catheter entrapment

• Cerebral vascular accident (hemorrhagic or thrombotic)

• Chest pain/discomfort/pressure

• Cold feeling/shivering

• Complete heart block (transient or permanent)

• Coronary artery spasm

• Cough

• Death

• Diaphragm

• Dizziness or lightheadedness

• Edema

• Elevated cardiac enzymes

• Esophageal injury (including esophageal fistula)

• Embolism (air, gas, thrombo)

• Endocarditis

• Fatigue

• Fever

• Headache

• Heart failure/pump failure

8. Product Operation

8.1 Product Preparation

8.1.1.2 Check the expiration date.

8.1.3. Remove the POLARSHEATH and dilator from the packaging using sterile technique.

8.1.4. Inspect the integrity of the POLARSHEATH to verify no damage.

8.1.5. Attach a three-way stopcock to the side port.

8.1.6. Flush the POLARSHEATH side port and dilator lumen with sterile saline solution.

8.1.7. Place the dilator shaft with sterile saline solution before insertion through the hemostatic valve.

8.1.8. Insert the dilator into the valve and fully into the POLARSHEATH.

8.1.9. Insert the shaft of the POLARSHEATH with sterile saline solution.

8.1.10. Verify that the POLARSHEATH is in the neutral ( undeflected) position.

8.2 Product Operation

To use the POLARSHEATH, follow these steps:

8.2.1. Create the required vascular access in a large central vein (e.g. femoral vein) with an appropriate introducer.

8.2.2. Insert compatible guide wire through the vasculature and into the desired heart chamber.

8.2.3. Advance the dilator and the POLARSHEALTH over the wire and into the desired heart chamber.

8.2.4. Slowly remove the guide wire and dilator from the POLARSHEALTH.

8.2.5. Slowly aspirate and then flush the POLARSHEALTH, taking care to avoid introducing air bubbles.

8.2.6. Connect a continuous heparinized saline drip to maintain anticoagulation therapy per institutional protocol.

8.2.7. Turn the control knob to the right (clockwise) to deflect or steer the distal section of the POLARSHEALTH. Turn the control knob to the left (counter clockwise) to straighten the distal section of the POLARSHEALTH.

8.3 Removal

8.3.1. Before withdrawal, ensure that the POLARSHEALTH is in a neutral ( undeflected) position.

8.3.2. Ensure that catheters and guidewires have been removed from the POLARSHEALTH before removing the POLARSHEALTH from the patient.

8.3.3. Slowly retract the POLARSHEALTH from the body.

8.3.4. Use proper hemostasis techniques when removing the POLARSHEALTH from the femoral vein.

9. Device compatibility

The POLARSHEALTH is compatible for use with the Boston Scientific Cryoablation Catheter System.

10. Disposal

Used products are contaminated and must be handled and disposed as contaminated hospital waste.
11. Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath Overall Length</td>
<td>82 cm (32.3 in)</td>
</tr>
<tr>
<td>Sheath Usable Length</td>
<td>68 cm (26.8 in)</td>
</tr>
<tr>
<td>Sheath Inner Diameter</td>
<td>12.7 Fr</td>
</tr>
<tr>
<td>Sheath Outer Diameter</td>
<td>15.9 Fr</td>
</tr>
<tr>
<td>Usable Dilator Length</td>
<td>85 cm (33.5 in)</td>
</tr>
<tr>
<td>Radiopaque Markers</td>
<td>2.5mm proximal to sheath tip</td>
</tr>
<tr>
<td>Guidewire compatibility</td>
<td>0.81 mm (0.032 in) and 0.89 mm (0.035 in)</td>
</tr>
</tbody>
</table>

Environmental Parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage</td>
<td>15°C to 25°C (59°F to 77°F)</td>
</tr>
<tr>
<td>Transit</td>
<td>-30°C to 80°C (-22°F to 140°F), 15% to 90% relative humidity</td>
</tr>
<tr>
<td>Operation</td>
<td>15°C to 30°C (59°F to 86°F)</td>
</tr>
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12. Warranty

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.