The POLARMAP is to be used only by physicians. Do not use if the sterile barrier is damaged. If damage is found, contact your Boston Scientific representative.

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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

1. Catheter Description

The POLARMAP™ Circular Mapping Catheter (POLARMAP) is a single use, multi-electrode catheter designed to record intracardiac electrogams and provide pacing stimulation during electrophysiology procedures. The POLARMAP connects to electrophysiology lab recording systems via an EP Electrical Cable (not included). The POLARMAP is compatible for use with the Boston Scientific POLAR™ Cryoablation Catheter System. The POLARMAP is non-pyrogenic.

1.1 Package Contents

One (1) POLARMAP Circular Mapping Catheter

1.2 How Supplied

The POLARMAP is supplied in one carton that contains one sterile pouch. Package contents are listed on the carton and pouch labels. Do not use if labeling is illegible or incomplete.

2. Intended Use

The POLARMAP is intended to obtain electrograms and provide pacing in cardiac structures in the atrial regions of the heart.

3. Indications for Use

The POLARMAP is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

4. Contraindications

Use of the POLARMAP is contraindicated as follows:

- In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis.
- In patients with a myxoma or an intracardiac thrombus as the POLARMAP could precipitate an embolic event.
- In patients with a prosthetic heart valve (mechanical or tissue).
- In the ventricle of the heart where the POLARMAP may become entrapped in a valve or chordae structures.
- In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event.
- In patients with pulmonary vein stents as the POLARMAP could dislodge or damage the stent.
- In patients with cryoglobulinemia as the cryoablation application may lead to vascular injury.
- In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis.
- In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event.
- In patients with pulmonary vein stents as the POLARMAP could dislodge or damage the stent.
- In patients with cryoglobulinemia as the cryoablation application may lead to vascular injury.

5. Warnings

Introducing catheters into the circulatory system entails risk of air embolism. Always advance and withdraw the POLARMAP slowly. Minimize catheter exchanges and follow with proper flushing.

Administer appropriate peri-procedural anticoagulation therapy per standard of care for patients undergoing electrophysiology procedures. Administer anticoagulation therapy during and post-procedure according to the Institution’s standards.

Catheter procedures may introduce life threatening arrhythmias.

Do not use the POLARMAP if it is functionally or physically damaged. If the POLARMAP becomes damaged while in the patient, remove and replace the POLARMAP.

POLARMAP placement and manipulation should be performed under fluoroscopy. Exercise care and attention when manipulating the POLARMAP within the heart. Do not apply excessive force or torque to the POLARMAP, especially if resistance is encountered. Always rotate the POLARMAP clockwise. Inappropriate POLARMAP manipulation may result in cardiac injury such as perforation or tamponade or device damage.

Avoid positioning the POLARMAP around the chordae tendineae as this increases the likelihood of entrapment within the heart.

Do not navigate the POLARMAP through a prosthetic valve (mechanical or tissue). Avoid proximity to all valves whenever possible. Manipulation of the POLARMAP across these structures may result in entanglement and damage to the valve.

Do not allow the patient to contact grounded equipment that might produce electrical current leakage during ablation or Direct Current Cardioversion (DCCV). This may result in induced arrhythmias that could result in patient death.

Do not connect the POLARMAP to a radiofrequency (RF) generator or use it to deliver RF energy. This may result in patient harm or device malfunction.

Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARMAP, or patient injury or death may occur.

Do not allow leakage current from any devices connected to the patient to exceed 10µA under any circumstances.

Do not use the POLARMAP if the package is open and/or the sterile barrier is broken.

Use prior to the Use By date as labeled on the POLARMAP package label.

Use caution when manipulating the POLARMAP in patients with intracardiac devices (catheters, implants, wires, etc). Entanglement with intracardiac devices may require surgical intervention.

6. Precautions

It is the user’s responsibility to ensure that the equipment used with the POLARMAP meets all local applicable electrical safety requirements.

Disconnect the POLARMAP from the EP Electrical Cable prior to cardioversion or defibrillation. Failure to do so may result in damage to any connected EP recording system or equipment.

Do not attempt to preshape the POLARMAP shaft or electrode loop. Do not scrub the catheter or electrode surface. Do not apply organic solvents such as alcohol.

If using the POLAR™ Cryoablation Balloon Catheter, loosen the Tuohy valve prior to removal of the POLARMAP to prevent damage to the POLARMAP.

The POLARMAP should only be used with a compatible EP recording system and in a fully equipped electrophysiology lab.

Do not immerse the POLARMAP handle or cable connector in fluids; electrical performance could be affected.

The POLARMAP is to be used only by physicians, or under the supervision of physicians, trained in cardiac electrophysiology procedures in properly equipped facilities.

Use the POLARMAP only with the EP Electrical Cable and a compatible EP recording system. Use the POLARMAP within a compatible catheter with minimum internal diameter of 1.12 mm.

7. Potential Adverse Effects

- Access site complications
- Anemia
- Anxiety
- Arhythmias
- Arteriovenous (AV) fistula
- Bleeding/hemorrhage
- Cardiac perforation
- Cardiac/pulmonary arrest
- Catheter entrapment
- Cerebral vascular accident (hemorrhagic or thromboembolic)
- Chest pain/discomfort/pressure
- Cold feeling/shivering
- Complete heart block (transient or permanent)
- Coronary artery spasm
- Cough
- Death
- Diarrhea
- Dizziness or lightheadedness
- Edema
- Elevated cardiac enzymes
- Esophageal injury (including esophageal fistula)
- Embolism (air, gas, thrombo)
- Endocarditis
- Fatigue
- Fever
- In conditions where insertion or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event.
- In patients with intra-atrial septal patch or other surgical intervention in or adjacent to the intra-atrial septum.
- In patients with a contraindication to an invasive procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe.

8. How Supplied

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9. Contraindications

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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.

8. Instructions for Use

Carefully read all instructions prior to use and observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction.

8.1 Product Preparation

8.1.1. Inspect the sterile packaging for any breach that may cause contamination of the components.

8.1.2. Check the Use By date.

8.1.3. Inspect the integrity of the POLARMAP to verify no damage.

8.1.4. Remove the POLARMAP from the packaging following sterile technique.

8.1.5. Make the electrical connections from the handle of the POLARMAP to the EP Electrical Cable and from the EP Electrical Cable to the EP Recording System.

NOTE: A sterile protective sleeve may be used if the connections cross into the sterile field.

NOTE: Pins 9 and 10 of the EP Electrical Cable are not used when connecting the POLARMAP.

8.2 Product Insertion and Operation

8.2.1. Rinse the POLARMAP circular loop and wipe the POLARMAP body with sterile, heparinized saline.

8.2.2. Slide the introducer over the distal loop.

8.2.3. Insert the POLARMAP through a compatible catheter until the circular loop exits the distal tip of the catheter system.

8.2.4. Advance the POLARMAP to the desired position.

NOTE: POLARMAP manipulation and positioning should be performed under fluoroscopy.

NOTE: Exercise care and attention when manipulating the POLARMAP to avoid tissue injury and POLARMAP damage.

NOTE: Always rotate the POLARMAP in a clockwise direction while positioning the circular loop to avoid tissue injury.

8.2.5. Perform recording and pacing functions.

NOTE: Refer to instructions for use appropriate for the connected EP Recording System.

9. Device Compatibility

The POLARMAP may only be used with the EP Electrical Cable and a compatible EP recording system. Use the POLARMAP within a compatible catheter with minimum internal diameter of 1.12 mm. The POLARMAP 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>POLARMAP Shaft Size</th>
<th>3.3 Fr (1.1 mm or 0.043 inches)</th>
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</thead>
<tbody>
<tr>
<td>Compatible Mating Device</td>
<td>3.4 Fr (1.12 mm or 0.044 inches)</td>
</tr>
<tr>
<td>Minimum Internal Diameter</td>
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<tr>
<td>Loop Diameter</td>
<td>20 mm (0.79 inches)</td>
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<tr>
<td>POLARMAP Shaft Length</td>
<td>Overall: 166 cm</td>
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<tr>
<td>Effective</td>
<td>149 cm</td>
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<tr>
<td>Electrodes</td>
<td>8 electrodes</td>
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<tr>
<td>Electrode Size</td>
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<td>Electrode Spacing</td>
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<tr>
<td>Environmental Parameters</td>
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<tr>
<td>Storage</td>
<td>15°C to 25°C (59°F to 77°F)</td>
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<tr>
<td>Transit</td>
<td>-30°C to 60°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>
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</tbody>
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