Boston Scientific
Advancing science for life™

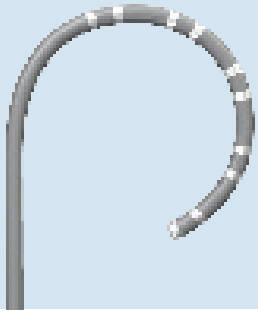
# POLARIS X™
## STEERABLE DIAGNOSTIC CATHETER

## Ergonomic Handling with Precise Maneuverability

## Technical Information

| Description | Specifications |
|---|---|
| Shaft Diameter | 6F |
| Usable Length | 105cm |
| Electrode Material | Platinum/Iridium |
| Curve Size | 270° standard |
| Curve Direction | Unidirectional |
| Configuration | Decapolar |

## 270° Standard Curve



Suggested catheter configurations are illustrative representations only and may not reflect actual performance.

## Ordering Information

Polaris X Steerable Diagnostic Catheter

| Model Number | Electrode Configuration | Electrode Spacing | Cable Model Number |
|---|---|---|---|
| M0047000D0 | Decapolar | 2.5mm | M0045454S0 |
| M0047001D0 | Decapolar | 5mm | M0045454S0 |
| M0047003D0 | Decapolar | 2.5/5/2.5mm | M0045454S0 |
| M0047004D0 | Decapolar | 2/8/2mm | M0045454S0 |
| M0047005D0 | Decapolar | 2/10/2mm | M0045454S0 |

**Polaris X Steerable Diagnostic Catheter from Boston Scientific**

**INDICATIONS FOR USE:** The Polaris X Steerable Diagnostic Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

**CONTRAINDICATIONS:** Caution should be exercised, in the use of this or any other catheter, in patients with prosthetic valves. Patients with recurrent sepsis or with hypercoaguable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation.

**WARNINGS:** The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used. Care must be taken to ensure that any equipment used in connection with the BSC Catheters be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with local regulatory requirements for the specified intended use. No modification of this equipment is allowed. The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets of connectors could result in electrocution of the patient or operator. Diagnostic electrophysiology involves x-ray exposure that present the potential risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam and intensity and duration of the fluoroscopic imaging. Steps should be taken to minimize this exposure as much as possible. Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. This catheter is not indicated for use in Cardiac Ablation or Coronary Artery Mapping.

**PRECAUTIONS:**

- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and/or electrical wires, and may cause patient injury.
- Before using, inspect for physical damage, including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.

**ADVERSE EVENTS:** The following potential risks or discomforts may be associated with diagnostic BSC procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

- Allergic reaction
- Arrhythmias
- Cardiac or respiratory arrest
- Cardiac valve damage
- Catheter entrapment/ entanglement
- Chest pain
- Damage to vessel intima or cardiac structures
- Death
- Embolus, air embolus
- Hematoma/ecchymosis
- Hemorrhage
- Hypotension
- Infection
- Myocardial infarction
- Perforation
- Pericardial effusion
- Pericarditis/pleuritis
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Sinus or AV node injury
- Stroke
- Tamponade
- Thrombosis
- Vasovagal reaction
- X-ray exposure

**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. 90960896 (Rev AB)

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