Advisor™ FL Circular Mapping Catheter, Sensor Enabled™

 REF
 D-AVSE-D10-F20, D-AVSE-DF10-F20, D-AVSE-D10-F15, D-AVSE-DF10-F15

INSTRUCTIONS FOR USE
For U.S. – California Only:
Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

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Advisor™ FL Circular Mapping Catheter, Sensor Enabled™

Description
Advisor™ FL Circular Mapping Catheters, Sensor Enabled™ are steerable, flexible, insulated electrophysiology catheters constructed of thermoplastic elastomer material and noble metal electrodes. For both bi-directional and uni-directional catheters, the shaft curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve on the uni-directional catheter, push or pull the thumb control located on the handle. To adjust the curve on the bi-directional catheter, use the actuator to deflect the catheter in either direction. The distal loop is oriented counter-clockwise as viewed from the handle. See label for outer diameter and specific loop configuration.

Indications for Use
The Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ is a sensor-enabled steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial regions of the heart.

The catheter is used with the EnSite Precision™ System to combine and display magnetic processed patient positioning and navigation mapping information. The catheter is used with the MediGuide™ Technology system to enable real-time positioning and navigation. The MediGuide™ Technology system is indicated for use as an adjunct to fluoroscopy.

Contraindications
- The catheter is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transseptal approach.
- This device should not be used via retrograde approach.
- This device is not recommended for use in the ventricles.
- The device is not intended for transcatheter ablation.
- This device should not be used with patients with active systemic infections.

Warnings
- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of transvenous electrophysiology studies.
- Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid thromboembolism, cardiac damage, perforation, or tamponade. The induction of atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF) can be risks associated with electrical stimulation.
- Do not use force to advance or withdraw catheter when resistance is encountered.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury, and/or the communication of infectious disease(s) from one patient to another.

Caution
- United States law restricts this device to sale by or on order of a physician.
- Read directions prior to use.

Precautions
- Personnel handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode catheter integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter.
- Use care to isolate any unused connector pins of the electromag cable. This will reduce the chances of developing accidental current pathways to the heart.
- Always straighten the catheter before insertion or withdrawal.
- Catheter advancement must be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade. Compatible navigation and visualization systems may be used in conjunction with fluoroscopy.
- Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve.

Directions
1. Inspect the package prior to use. Do not use if the package is open, damaged, or expired.
2. Remove the catheter from its packaging.
   - Completely remove the tray from the pouch.
   - Remove the handle retainer from the tray before removing the catheter. See Figure 1 in the Packaging and Shelf-Life section.
   - To prevent potential damage to the loop, lift the catheter up and out of the tray.
3. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Insert the distal tip section of catheter into an 8F minimum introducer (not included) using the loop straightener.
   - Prior to insertion, deflect catheter shaft to straight position.
   - Slide the loop straightener over the distal loop section of catheter.
   - Insert the loop straightener with the catheter distal end into and through the hemostasis valve of the introducer (not included).
   - Insert catheter through the hemostasis valve.
   - After the catheter is inside the introducer, pull the loop straightener out from the hemostasis valve.
5. Never manipulate the loop or deflectable section of the shaft while within the introducer.
6. Connect to compatible systems using the appropriate cable. Refer to the cable's instructions for use.
7. If the loop is not perpendicular to the shaft when extended from the sheath, completely retract the loop into the sheath and re-extract catheter.
8. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy. Compatible navigation and visualization systems may be used in conjunction with fluoroscopy.
9. To adjust the curve of the distal tip on the uni-directional catheter, push or pull the thumb control located on the handle. To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction.

   **NOTE:** The bi-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. The amount of friction increases as the knob is rotated clockwise until it reaches the fully plus (+) position.

   **NOTE:** The uni-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. If necessary, the tension control knob may be rotated to increase or decrease the tension.

10. Prior to withdrawal, deflect catheter shaft to straight position. Re-insert the loop straightener into the hemostasis valve prior to removing the catheter from the introducer.

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

**Connection to Other Equipment**

The catheter may be connected to a commercially available EP recording system and navigation and visualization system using the connection cable. All systems must be patient isolated. For instructions regarding the use of these systems with the catheter, refer to the system’s instructions for use.

**Packaging and Shelf-Life**

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not re-sterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location. The instructions for use is recyclable. Dispose of used product and packaging following standard solid biohazard waste procedures.

To remove the catheter from its tray, remove the handle retainer from the tray then lift the catheter up and out of the tray. See Figure 1.

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**Warranty**

St. Jude Medical (SJM) warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the “Expiration” date stated on any product labeling. The authorized uses and approved methods of use of each of our products is set forth in the related “Instructions for Use” that accompany each product. SJM disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. SJM’s liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. SJM disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. SJM neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete SJM warranty policy available from SJM or on the back of an SJM invoice.

**Symbols**

*Note:* The symbols section contains all the symbols that may be used on product labels. Product is labeled as required.

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