



## Instructions for Use

### Reprocessed Advisor High Density (HD) Grid Mapping Catheter, Sensor Enabled

#### *Reprocessed Device for Single Use*

**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**

#### **DEVICE DESCRIPTION**

The Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled, is an irrigated, steerable, flexible, insulated electrophysiology catheter constructed of thermoplastic elastomer material and noble metal electrodes. 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 catheter, use the actuator to deflect the catheter in either direction. The catheter is compatible with St. Jude Medical (Abbott) visualization and 3D navigation systems.

<b>System Device</b>	<b>Connect Via</b>	<b>System Software</b>
EnSite Velocity System	Sensor Enabled Diagnostic Catheter Cable (D-AVSE-CBL22)	v 5.2 or later
EnSite Precision System		v 2.2 or later

**Table 1:** Compatible Systems

#### **INDICATIONS FOR USE**

The Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

#### **CONTRAINDICATIONS FOR USE**

- 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 with patients with active systemic infections.
- The catheter is contraindicated in patients who cannot be anticoagulated or infused with heparinized saline.

#### **WARNINGS**

- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of percutaneous 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 device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade.

**Instructions for Use: Reprocessed Advisor High Density (HD) Grid High Density Mapping Catheter, Sensor Enabled**

- Risks associated with electrical stimulation may include, but are not limited to, the induction of arrhythmias, such as atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF).
- 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).
- Tactile feedback of reprocessed device may vary during use.

**PRECAUTIONS**

- Do not attempt to operate the catheter prior to completely reading and understanding these directions for use.
- Personnel handling the electrophysiology catheter should wear gloves.
- Excessive bending or kinking of the catheter may cause damage to the catheter.
- 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 and/or if any of the irrigation ports are blocked.
- Maintain an activated clotting time (ACT) within a target range of 250-350 seconds at all times during use of the catheter. This includes when the catheter is used in the right side of the heart.
- To prevent entanglement with concomitantly used catheters, use care when using the catheter in the proximity of the other catheters.
- Maintain constant irrigation to prevent coagulation on the distal paddle. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. If irrigation is interrupted, remove the catheter from the patient and inspect the catheter. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion.
- To maintain optimal patient safety and electrode catheter integrity, do not wipe this catheter with alcohol.
- Use care to isolate any unused connector pins of the electrogram 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.

**ADVERSE REACTIONS**

- None.

**DIRECTIONS**

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened, damaged. If the catheter is damaged or if the package is compromised or expired, do not use the catheter. Return the catheter to Innovative Health. **Do not attempt to resterilize.**
- Using proper sterile technique, remove the catheter from its package and place it in a sterile work area.
- To prevent potential damage to the distal paddle, lift the catheter up and out of the tray.
- Upon removal from packaging, inspect the electrodes and catheter carefully for integrity and overall condition.
- Connect a sterile luer lock syringe filled with saline mix to the luer connection of the catheter. Push the contents of the syringe into the catheter to confirm the irrigation port is open.
- Connect the catheter to the irrigation system using standard luer fittings. The pump must be able to operate at a minimum flow rate of 2ml/min.
- Flush the catheter with heparinized saline and purge the tubing and catheter of air bubbles before insertion.

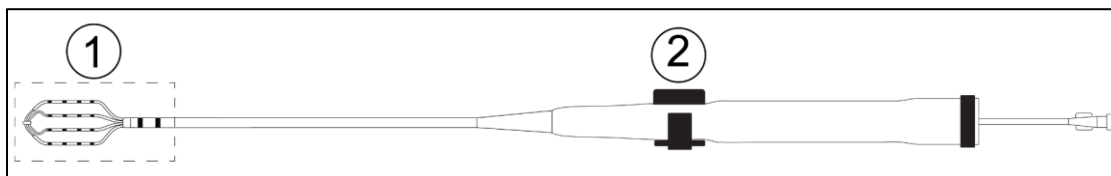
**Instructions for Use: Reprocessed Advisor High Density (HD) Grid High Density Mapping Catheter, Sensor Enabled**

- To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removal of the catheter from the body.
- Insert the distal tip section of catheter into an 8.5 F minimum introducer (not included) using the insertion tool:
  - Prior to insertion, deflect catheter shaft to straight position.
  - Slide the insertion tool over the distal paddle section of the catheter.
  - Insert the insertion tool 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 insertion tool out from the hemostasis valve.
- Never manipulate the deflectable section of the shaft while within the introducer.
- Connect to compatible systems using the appropriate cable. Refer to the SJM cable's instructions for use for information about connections.
- The catheter should be passed from a peripheral vessel to the desired position with the aid of fluoroscopy.
- To adjust the curve of the distal tip on the 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.
- Prior to withdrawal, deflect catheter shaft to straight position. Re-insert the insertion tool into the hemostasis valve prior to removing the catheter from the introducer.
- Upon use, please return the device per Innovative Health's Instructions.

**Electrode Identification**

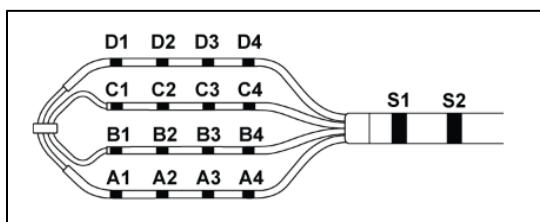
Orientation of the Electrodes



1. Distal paddle and shaft electrodes (see figures below for detailed view)
2. Tension Knob

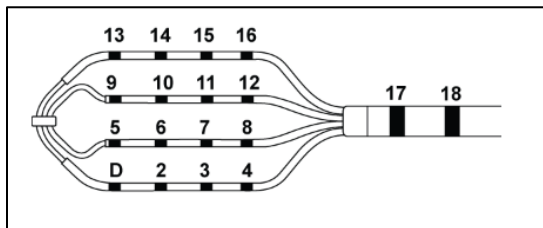
**Figure 1:** Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled

The EnSite Precision and EnSite Velocity Systems have two options for displaying the electrodes on the distal paddle and shaft. The figures below show electrode numbering in the different display views.



**Figure 2:** With the tension knob facing upwards, electrodes on the A spline are located on the bottom of the paddle.

**Instructions for Use: Reprocessed Advisor High Density (HD) Grid High Density Mapping Catheter, Sensor Enabled**



**Figure 3:** With the tension knob facing upwards, electrodes on the D through 4 spline are on the bottom of the paddle.

**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.

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**EXPLANATION OF SYMBOLS**



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Sterilized by Ethylene Oxide



Catalog Number



Serial Number



Lot Number



Use by Date



Do Not Reuse



Do Not Resterilize



Consult Instructions for Use



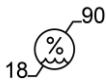
Do Not Use if Package is Damaged



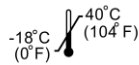
Keep Product Dry



Keep Away from Sunlight and Radioactive Sources



Humidity Limitation



Temperature Limits



Non-pyrogenic

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

**Sterilization:** This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

**Warning:** This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

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Please refer to [www.innovative-health.com](http://www.innovative-health.com) for product warranty.