Instructions for Use
Reprocessed Advisor High Density (HD) Grid X 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 X Mapping Catheter, Sensor Enabled, is a sterile, 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 includes a fluid lumen extension with a luer for saline irrigation during the diagnostic procedure. The catheter connects to navigation systems via Sensor Enabled diagnostic catheter cables and commercially available compatible irrigation systems via the catheter fluid lumen extension. The Reprocessed Advisor HD Grid X Mapping Catheter, Sensor Enabled also has a straightener intended to compress and guide the distal paddle into, and withdraw from, the hemostasis valve of an 8.5F minimum introducer sheath.

CONNECTION TO OTHER EQUIPMENT

The reprocessed catheter may be connected to a commercially available EP mapping, navigation and visualization system using a connection cable listed in the Compatible Systems table. All systems must be patient isolated. The catheter must be connected to a commercially available irrigation system using standard luer fittings. The irrigation system must be capable of a 2.0 ml/minute minimum flow rate. The catheter is compatible with an 8.5F minimum introducer sheath. To use the Sensor Enabled functionality of the Advisor HD Grid X catheter, it must be connected to the EnSite X EP System. For compatible devices, refer to the EnSite X EP System instructions for use for their direction and safety information.

System Device	Connect Via	System Software
EnSite X EP System	Advisor HD Grid X Sensor Enabled 32 pin EnSite X Cable (D-ENS-AVHDX-CBL)	v 3.1 or later

Table 1: Compatible Systems

INDICATIONS FOR USE

The Reprocessed Advisor HD Grid X 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

- 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.
- Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation.

WARNINGS

- Persons with a known history of allergies to any of the materials listed below may suffer an allergic reaction to this device. Before use, counsel the patient on the materials contained in the device and discuss a thorough history of allergies. Per the Original Manufacturer, this device contains:
  - Acrylonitrile-butadiene-styrene (ABS - Cycolac)
  - Loctite Adhesive
  - Pellethane
  - Platinum Iridium alloy
  - Polyimide
  - Polyether block amide (PEBAX)
  - Polyethylene (High Density Polyethylene, HDPE)
  - Titanium
- Misuse of this device may result in serious complications.
- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of percutaneous electrophysiology studies in a fully equipped operational electrophysiology laboratory.
- 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.
- The safety and effectiveness of the device has not been established in pregnant women or prepubescent children. Careful consideration must therefore be given for the use of this device in pregnant women or prepubescent children.
- 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.
- 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.
- 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.
- 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.
- 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 electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.
- Use the straightener during the insertion process to avoid damage to the hemostasis valve. 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 real time visualization systems may also be considered.
- 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.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- One or more components of this device may contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: N-methyl-2-pyrrolidone (NMP): Chemical Abstracts Service (CAS) No. 872-50-4; EC No. 212-828-1. Based on a quantitative toxicological assessment it has been determined that NMP released from this device is unlikely to cause adverse reproductive effects.

ADVERSE REACTIONS

Complications related to the use of the device include, but are not limited to, the following:

- New or worsening of existing arrhythmia
  - Atrial fibrillation
  - Ventricular tachycardia requiring cardioversion
  - Supraventricular tachycardia (SVT)
  - Ventricular fibrillation
- Cardiac perforation
  - Pericardial effusion
  - Cardiac tamponade
- Bleeding, including access site
  - Hemorrhage/bleeding
  - Ecchymosis
  - Hematoma
- Vascular access complication/peripheral vascular injury
  - Femoral artery dissection
  - Dissection
  - Arteriovenous fistula
  - Pseudoaneurysm formation
- Pulmonary vein stenosis
- Heart failure
- Volume overload
- Hypotension
- Embolism
- Cerebrovascular accident (CVA)/ stroke
- Infection
- Pneumonia
- Pulmonary edema
- Immunological reaction
- Pain
- Pericarditis

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.

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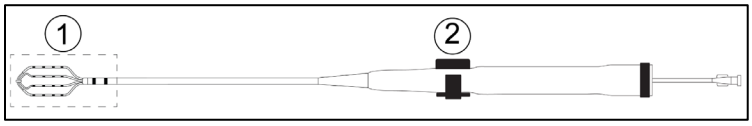
  - To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removal of the catheter from the body.
- Insert the distal tip section of catheter into an 8.5 F minimum introducer (not included) using the straightener:
  - Prior to insertion, deflect catheter shaft to straight position.
  - Slide the straightener over the distal paddle section of the catheter.
  - Insert the 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, remove the straightener 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 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 straightener 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 X Mapping Catheter, Sensor Enabled

The compatible mapping systems, listed in Table 1 above, have two options for displaying the electrodes on the distal paddle and shaft. The figures below show electrode numbering in the different display views.

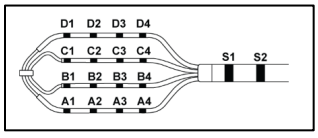


Figure 2: With the tension knob facing upwards, electrodes on the A spline are located on the bottom of the paddle.

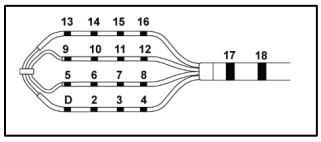


Figure 3: With the tension knob facing upwards, electrodes on the D through 4 spline are on the bottom of the paddle.

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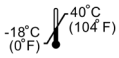
EXPLANATION OF SYMBOLS

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	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
	Manufacturer
	Humidity Limitation
	Temperature Limits
	Non-pyrogenic
	Contains hazardous substances (N-methyl-2-pyrrolidone CAS No. 872-50-4)

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.

Advisor, Sensor Enabled, and EnSite, are registered trademarks of the Abbott group of companies.

Please refer to www.innovative-health.com for product warranty.