Instructions for Use
Reprocessed Advisor VL Circular 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 VL Circular Mapping Catheters, Sensor Enabled, are steerable, flexible, insulated electrophysiology catheters constructed of thermoplastic elastomer material and noble metal electrodes. The shaft curvature is manipulated by the shaft deflection mechanism located on the handle at the catheter's proximal end. 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. The loop is deflected by the actuator located on the handle at the catheter's proximal end. To adjust the loop diameter, rotate the loop actuator in either direction. The catheter features a variable loop design that is intended to accommodate vein sizes ranging from 25mm to 15mm in diameter.

Table 1. Compatible Systems

System Device	Connect via	System Software
EnSite Precision ™ System	Sensor Enabled ™ Diagnostic Catheter Cable (D-AVSE-CBL22)	V 2.2 or later

INDICATIONS FOR USE

The Reprocessed Advisor VL Circular Mapping Catheter is a steerable electrophysiology catheter with integrated sensors. The catheter is 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.

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 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.
- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.

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

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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. To unentangle the catheter, fully open the loop and straighten the catheter shaft, then rotate the handle clockwise.
- 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.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Do not attempt to operate the catheter prior to completely reading and understanding these directions for use.
- Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter.
- 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.
- 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 or if there is difficulty deflecting the loop. Do not use if the catheter does not hold its loop diameter.

ADVERSE REACTIONS

None.

DIRECTIONS

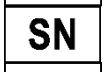
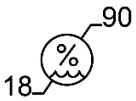
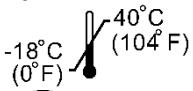
- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the 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 loop, lift the catheter up and out of the tray.
- Inspect the electrodes and catheter carefully for integrity and overall condition prior to use.
- Insert the distal tip section of the catheter into an 8F minimum introducer (not included):
    - Prior to insertion, deflect catheter shaft to straight position and open the loop.
    - Insert catheter through the hemostasis valve.
- Never manipulate the loop or 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.

- If the loop is not perpendicular to the shaft when extended from the sheath, completely retract the loop into the sheath and re-extend catheter.
- 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.
- To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction. To adjust the loop diameter, rotate the loop actuator.
  NOTE: The catheter handle has an adjustable tension lock 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 lock knob may be rotated to increase or decrease the tension.
- Prior to withdrawal, deflect catheter shaft to straight position and open the loop completely.
- Upon use, please return the device per Innovative Health's instructions.

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.

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 Gas
	Catalog Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	Relative Humidity up to 90%, noncondensing
	Temperature Limits
	Do Not Use if Package is Damaged
	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.

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

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