Instructions for Use
Reprocessed DecaNav Diagnostic Electrophysiology Catheter

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 DecaNav Catheter has been designed to be used with the Carto 3 Navigation System (a magnetic field location technology) to facilitate electrophysiological mapping of the heart. The catheter has a high-torque shaft with a deflectable tip section containing an array of platinum/iridium electrodes that can be used for stimulation and recording of cardiac electrical signals. The catheter has a single proximal electrode that can be used for unipolar recording signals.

The catheter tip deflection is controlled by a proximal hand piece that features a thumb operated sliding piston and is offered in various curve types. The plane of the curved tip can be rotated during use.

This catheter interfaces with standard recording equipment and the Carto 3 EP Navigation System via interface cables with the appropriate connectors.

For further description of the Carto 3 EP Navigation system, please refer to the operating instructions for the system.

INDICATIONS FOR USE

The Reprocessed DecNav Catheter is indicated for electrophysiological mapping of cardiac structures i.e., recording and stimulation, including in the Coronary Sinus.

The catheter provides tip location information when used with the compatible Carto 3 EP Navigation Systems.

CONTRAINDICATIONS FOR USE

- The catheter is not for radiofrequency ablation or for use in the coronary arteries. Electrophysiology studies are contraindicated when reversible factors make the findings unrepresentative of the patient's disease state (e.g. electrolyte imbalance).
- The use of the catheter is contraindicated for use in patients with a high risk of death (e.g. acute stroke, acute myocardial infarction, unstable angina, hemodynamic instability).
- The use of the catheter is contraindicated in patients with totally obstructed Coronary Sinus.
- A relative contraindication for cardiac catheter procedures is active system infection.
- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.

WARNINGS

- 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.
- Cardiac catheterization should only be performed after adequate attention has been given to potential radiation exposure associated with the procedure, and steps taken to minimize this exposure.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Catheter advancement and placement should be done under fluoroscopic guidance.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Excessive force may cause dissection and/or perforation of Coronary Sinus or other cardiac structures.
- Do not expose the catheter to organic solvents such as alcohol.
- 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.
- The catheter should be stored in its original packaging and in a cool, dry place until used.
- Cardiac catherization procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory.
- The sterile packaging and catheter should be inspected prior to use.
- Do not immerse the handle or cable connector in fluids; electrical performance could be affected.
- Continually monitor the catheter tip position for movement and dislodging from the Coronary Sinus. See the Carto 3 EP Navigation System user manual for location and reference applications.
- Electromagnetic interference (EMI) produced by other electrical equipment in the Electrophysiology laboratory during normal operation may affect the performance of the catheter.
- Attention should be given to assure adequate anti-coagulation during the procedure.

ADVERSE REACTIONS

A number of serious adverse reaction have been documented for cardiac catheterization procedures including pulmonary embolism, myocardial infraction, stroke, cardiac tamponade, and death.

The following complications associated with cardiac catheterization have also been reported in the literature: vascular bleeding, local hematomas, thrombosis, AV fistula, pseudoaneurysm, thromboembolism, vasovagal reactions, cardiac perforation, air embolism, arrhythmias, valvular damage, pneumothorax and hemothorax.

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.
- Inspect the electrodes and catheter carefully for integrity, continuity of leads and overall condition.
- Create a vascular access in a large peripheral vein using aseptic techniques and insert a compatible catheter sheath introducer (at a minimum, sheath should be half a French size larger than the catheter French size).
- Connect the interface connectors to the Carto 3 EP Navigation System interface equipment.

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- Confirm that the thumb knob is pulled back completely before insertion (catheter in straight position).
- Insert the catheter into the catheter sheath introducer.
- Advance the catheter into the Coronary Sinus. Use both fluoroscopy and electrograms to aid in proper positioning.
- Adjust the radius of curvature as necessary by manipulating the thumb knob. Pushing the thumb knob forward causes the catheter tip to bend (curve); when the knob is pulled back, the tip straightens.
- Use the catheter features as required during the procedure.
- Prior to removal of the catheter, confirm that the thumb knob has been pulled back completely (straightened). Remove the catheter from the guiding sheath.

Explanation of Symbols

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from Sunlight
	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.