



Instructions for Use Reprocessed PentaRay Nav eco High-Density Mapping 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 PentaRay Nav eco High-Density Mapping Catheter is designed to facilitate electrophysiological mapping of the heart with the Carto 3 EP Navigation System. It is designed for deployment in a heart chamber through an 8 F guiding sheath. This deflectable catheter consists of multiple 3F spines on its distal tip, each spine having multiple platinum electrodes that are used for stimulation and recording. A magnetic location sensor embedded in the deflectable tip transmits location information to the Carto 3 EP Navigation System. The catheter has two electrodes on the deflectable tip to provide for visualization of the tip when used with the Carto 3 EP Navigation System. Pushing forward on the catheter thumb knob deflects the tip; pulling back on the thumb knob straightens the tip. This device includes an irrigation lumen for connection to a source of continuous anticoagulant fluid

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

For use in mapping procedures, refer to the instructions for the Carto 3 EP Navigation System.

INDICATIONS FOR USE

The Reprocessed PentaRay Nav eco High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e. recording or stimulation only. The catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

The catheter provides location information when used with the compatible Carto 3 EP Navigation Systems. (This catheter is not compatible with Carto 3 EP Navigation Systems prior to Version 3.x.)

CONTRAINDICATIONS FOR USE

- The catheter has not been shown to be safe and effective for radiofrequency (RF) ablation.
- Do not use the catheter in patients with prosthetic valves. This patient population is subject to increased risk of embolization of components and resultant patient sequelae.
- Catheter ablation is contraindicated in patients with an active systemic infection because this may increase the risk of cardiac infection.
- The transseptal approach is contraindicated in patients with intracardiac thrombus or myxoma, or interatrial baffle or patch.

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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 the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure.
- Careful consideration must be given for the use of this catheter in pregnant women.
- Do not immerse the handle or the cable connector in fluids; electrical performance could be affected.
- Do not expose the catheter to organic solvents such as alcohol.
- Do not autoclave the catheter.
- Flush the catheter with heparinized saline prior to insertion into the body.
- Do not introduce the catheter into a guiding sheath with the catheter's distal spines folded backwards toward the handle. Collapse the spines together using the insertion tube prior to insertion.
- The catheter is recommended for use with an 8F guiding sheath because the distal spines may be damaged if used with a sheath that is not compatible. Do not use the catheter in conjunction with transseptal sheaths featuring side holes larger than 1.25 mm in diameter.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Do not attempt to operate the catheter prior to completely reading and understanding these Instructions for Use. The catheter should be stored in its original packaging and in a cool, dry place until used.
- Cardiac catheterization 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.
- Standard grounding procedures should be followed if electrosurgical instruments are used.
- 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 through a guiding sheath. In addition, extra care should be taken while inserting, aspirating, and manipulating the guiding sheath.
- Prior to removing or repositioning the catheter, use direct imaging guidance such as fluoroscopy to confirm that the spine assembly is not entangled with another catheter or with an anatomical structure.
- Exercise caution when maneuvering the catheter near the valvular apparatus to avoid entanglement or entrapment which may result in the need for surgical intervention.
- **Do not use excessive force to advance or withdraw the catheter through the guiding sheath when resistance is encountered.**
- Always pull the thumb knob of the catheter back before insertion or withdrawal to ensure that the catheter tip assumes its original shape.
- Flush the catheter with heparinized saline prior to insertion into the body. Always follow standard practices using a continuous drip of anticoagulant fluid under pressure through the proximal Luer connector when the device is in the body.

ADVERSE REACTIONS

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

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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.
- Follow standard practice for vessel puncture, guidewire insertion, and guiding sheath use and aspiration per its Instructions for Use.
- Connect the interface connectors to the Carto 3 EP Navigation System.
- Flush the catheter with heparinized saline prior to insertion into the body.
- Always follow standard practices of using a continuous drip of anticoagulant fluid under pressure through the proximal Luer connector when the device is in the body.
- Before insertion, confirm that the thumb knob is pulled back completely.
- Advance the insertion tube along the catheter shaft to collapse the spines together prior to insertion into the sheath (see Figure 1 below). Do not bend the spines backward. After insertion, slide the insertion tube back toward the handle.

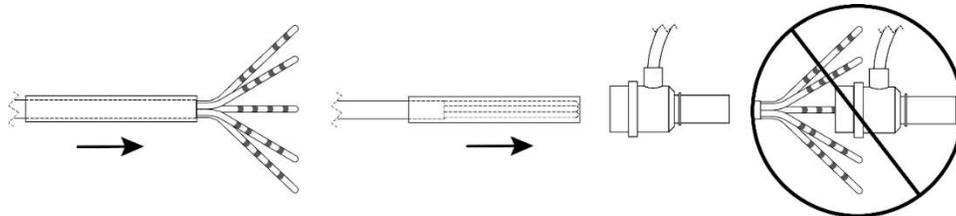


Figure 1: Insertion of Catheter Shaft / Spines into Sheath

- Advance the catheter through the guiding sheath to the area of the endocardium under evaluation. The spines will naturally return to their expanded pattern as they emerge from the tip of the guiding sheath. 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 curve; pulling the thumb knob back straightens the catheter tip.
- Under fluoroscopy, catheter spine “A” can be identified by the marker band near ring 2. Catheter spine “B” can be identified by the marker band near ring 8. Once spines A and B have been identified, all other spines and electrodes may be identified as follows:

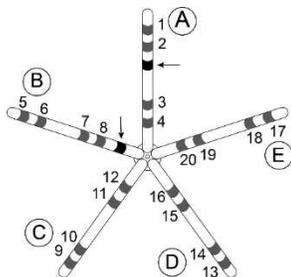


Figure 2: Identification of Spines

- Prior to removal of the catheter, confirm that the thumb knob has been pulled back completely to straighten the tip. Remove the catheter from the guiding sheath and dispose of it in an appropriate manner.

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Explanation of Symbols



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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



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.

PentaRay and Carto are trademarks of Biosense Webster, Inc.

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