Instructions for Use
Reprocessed Halo® XP
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 Deflectable Tip Halo XP Diagnostic Electrophysiology (EP) Catheters have been designed for electrophysiological mapping of the heart, in particular, the tricuspid annulus. The catheters have a high-torque shaft with a halo-shaped tip section containing ten pairs of platinum electrodes that can easily be seen under fluoroscopy. The tip section also contains a radiopaque mark in the center of the electrode array. The halo-shaped tip section has a preformed curve which can be positioned around the atrial aspect of the tricuspid annulus. The catheters facilitate simultaneous local electrograms spanning the tricuspid annulus, from the midseptal to anterior to lateral to posterolateral. The catheter interfaces with standard recording equipment. Recordings of the entire annulus can be obtained without repositioning the catheter tip. The tip is packaged with a plastic tip protector.

A piston in the handpiece is attached to an internal puller wire which changes the radius of curvature. When the piston is pushed forward, the radius of curvature of the preformed loop is reduced; when the thumbknob is pulled back, the radius of the curvature is increased until the tip section returns to the preformed shape. The high torque shaft allows the plane of the curve to be maneuvered in order to facilitate accurate positioning.

For Devices with Auto ID Technology:
The catheter is equipped with Electronically Erasable Programable Read Only Memory (EEPROM) which is used to store unique catheter identification information. CARTO EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize the catheter information.

The catheter interfaces with CARTO EP Navigation Systems equipped with Auto ID Technology via interface cables with appropriate connectors.

INDICATIONS FOR USE

The Reprocessed Halo XP Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording only. The catheters' preformed halo shape of the tip section is designed specifically for the tricuspid annulus.

CONTRAINDICATIONS FOR USE

- The catheter has not been shown to be safe and effective for electrical ablation or for use in the coronary vasculature other than the coronary sinus ostium.
- Do not use the catheter via the transseptal approach.
- Use of the catheter may not be appropriate for patients with prosthetic valves.
- 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 clinically adequate ACT levels**.**

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WARNINGS

- The device(s) should be used by physicians thoroughly trained in the techniques of transvenous 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. 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 consideration which therefore be given for the use of this catheter in pregnant women.
- Vascular perforation is an inherent risk of any electrode placement. Do not force the catheter through the vessel.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- 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 direction for use.
- Personnel handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- 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. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Always pull the thumbknob of the catheter back before insertion or withdrawal to assure that the catheter tip assumes its original shape.

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 central vessel using aseptic techniques and insert the catheter.
- Connect the interface connectors to the appropriate recording equipment.
- For devices with Auto ID technology: connect the interface cable to the Patient Interface Unit of the appropriate CARTO EP Navigation System and connect the catheter to the interface cable.
- Confirm that the thumbknob is pulled back completely before insertion. Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper

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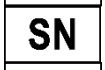
positioning. Adjust the radius of curvature as necessary by manipulating the thumbknob. Pushing the thumbknob forward causes the catheter tip to bend (curve); when the knob is pulled back, the tip straightens.

- Prior to removal of the catheter, confirm that the thumbknob has been pulled back completely.

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
	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.