Instructions for Use
Reprocessed Deflectable Diagnostic Electrophysiology (EP) 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 (Webster) Deflectable Tip Electrode Catheter has been designed to facilitate electrophysiological mapping of the heart. The catheter has a high-torque shaft with a deflectable tip section containing an array of platinum electrodes that can be used for stimulation and recording. Several tip configurations are available. (Standard curve types are identified by a color band on the shaft near the proximal end.)

The catheter interfaces with standard recording equipment via interface cables with the appropriate connectors.

INDICATIONS FOR USE

The catheter is indicated for electrophysiological mapping of the cardiac structures of the heart, i.e. stimulation and recording only.

CONTRAINDICATIONS FOR USE

- The catheters have not been shown to be safe and effective for electrical ablation or for use in the coronary vasculature other than the coronary sinus ostium.
- The transseptal approach is contraindicated.
- Use of the catheter may not be appropriate for patients with prosthetic valves. A relative contraindication for cardiac catheter procedures is active systemic infection.

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 proximal handle or cable connector in fluids; electrical performance could be affected.
- Do not autoclave the catheter.
- Do not expose the catheter to organic solvents such as alcohol.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Do not attempt to operate the catheter prior to completely reading and understanding these direction for use.
- Store in a cool, dry place.
- Cardiac catheterization procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory.
- Careful 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 reactions have been documented for cardiac catheterization procedures including:

- Pulmonary Embolism
- Myocardial Infarction
- Stroke
- Cardiac Tamponade
- Death

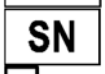
The following complications associated with cardiac catheterization have also been reported in the literature:

- Vascular Bleeding
- Local Hematomas
- Thrombosis
- AV Fistula
- Pseudoaneurysm
- Thromboembolism
- Vasovagal Reactions
- Cardiac Perforation
- Air Embolism
- Arrhythmias
- Vavular Damage
- Pneumothorax
- 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 and packaging to Innovative Health. **Do not attempt to resterilize**.
- Remove the catheter from its package and place it in a sterile work area.
- Inspect the catheter for physical integrity and overall condition. Do not use the catheter if damage is observed. Return the catheter to Innovative Health.
- 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.
- 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 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. Remove the catheter.

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
	Use by Date
	Do Not Reuse
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	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 gas (EO). 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.