Instructions for Use
Reprocessed Webster Fixed Curve and Webster Fixed Curve with Auto ID 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 Fixed Curve Diagnostic Electrophysiology (EP) Catheter has been designed to facilitate electrophysiological mapping of cardiac structures. The catheter has a high-torque shaft with an array of platinum electrodes at the distal tip that can be used for stimulation and recording. (Standard curve types are identified by a color band on the shaft near the proximal end – please refer to OM Catalog.)

The high-torque shaft allows the plane of the distal curve to be manually rotated to assist in positioning the catheter tip at the desired site**.**

Specific to Webster Fixed Curve with Auto ID:
The catheter is equipped with Electronically Erasable Programmable 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 standard recording equipment or Carto EP Navigation Systems (for devices with Auto ID) 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.
- Use of the catheter may not be appropriate for patients with prosthetic valves.
- A relative contraindication for cardiac catheter procedures is active system 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.

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- 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

- Do not attempt to operate the catheter prior to completely reading and understanding these directions for use.
- Cardiac catheterization procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory.
- 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.
- Store in a cool, dry place.

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. If the catheter is packaged with a curve retainer, remove the curve retainer before use.
- 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 lead pins or connectors to the appropriate recording equipment.
- **Specific to Webster Fixed Curve with Auto ID:**
    - Connect the interface cable to the Patient Interface Unit of the appropriate Carto EP Navigation System and connect the catheter to the interface cable.
- Advance the catheter to the area of the endocardium under investigation.
- Use both fluoroscopy and electrograms to aid in proper positioning.
- The electrode catheter shaft may be gently hand rotated to facilitate positioning at the desired mapping site.

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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
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	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.