Instructions for Use
Reprocessed Webster® CS Uni-Directional Diagnostic Electrophysiology Catheter with Auto ID Technology

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 Coronary Sinus (CS) Diagnostic Electrophysiology (EP) Catheter is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The device is a 6FR catheter with a usable length of 115cm. 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.

Standard features of this catheter include a braided 6 FR deflectable tip section with an array of platinum electrodes that includes a 2mm tip dome. The braided tip is controlled by a proximal hand piece that features a thumb operated sliding piston and is offered in various curve types. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

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 CARTO EP Navigation Systems equipped with Auto ID Technology via interface cables with the appropriate connectors.

INDICATIONS FOR USE

The Reprocessed Webster CS Uni-Directional Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording only. The catheter is designed for use in the coronary sinus.

CONTRAINDICATIONS FOR USE

- The catheter has not been shown to be safe and effective for electrical ablation.
- Use of the catheter may not be appropriate for patients with prosthetic valves.
- A relative contraindication for cardiac catheter procedures is active systemic infection.
- Do not use the catheter via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.
- Do not use the catheter via the retrograde transaortic approach in patients with aortic valve replacement.
- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.

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WARNINGS

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- Take all appropriate measures to minimize x-ray exposure to both patients and clinical staff. Significant x-ray exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the x-ray beam intensity and duration of the fluoroscopic imaging. The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children and pregnant women.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Always ensure that the thumb knob is pulled back completely to straighten the catheter tip before insertion or withdrawal of the catheter.
- Do not use excessive force to advance or withdraw the catheter. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid vascular or cardiac damage.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Do not attempt to use the reprocessed EP catheter prior to completely reading and understanding the *Directions for use.*
- Inspect the packaging and catheter for damage or defects prior to use.
- Use only sterile saline or water to wipe the catheter.
- The catheter is equipped with a cable connector; use with the appropriate cable.
- Excessive bending, torqueing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.

ADVERSE REACTIONS

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

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

- Vascular Bleeding
- Local Hematomas
- Thrombosis
- AV Fistula
- Pseudoaneurysm
- Thromboembolism
- Vasovagal Reactions
- Cardiac Perforation
- Tamponade
- Thrombi
- Air Embolism
- Arrhythmias
- Valvular 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 to Innovative Health. **Do not attempt to resterilize**.
- Physicians must be familiar with the techniques and appropriately trained for cardiac mapping procedures. All mapping procedures must be performed in a fully equipped electrophysiology laboratory.
- Remove the catheter from its package using aseptic technique and place it in a sterile work area.
- Inspect the electrodes and catheter for integrity, continuity of leads and overall condition. Do not use the catheter if damage is observed. Return any damaged catheter to Innovative Health.

- **Compatible Accessories**: Use appropriate Biosense Webster accessory cables to connect the catheter to appropriate standard recording equipment.
- Create a vascular access in a large central vessel using aseptic techniques and insert the catheter.
- 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 thumb knob is pulled back completely before insertion (catheter in straight position).
- 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.
- Prior to removal of the catheter, confirm that the thumb knob has pulled back completely (straightened).

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.