



Instructions for Use Reprocessed Webster® CS Bi-directional Diagnostic Electrophysiology Catheter with EZ Steer 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 7FR catheter with a usable length of 115cm. The catheter has a high-torque shaft with a bi-directional 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 bi-directional deflectable tip section with an array of platinum electrodes that includes a 2mm tip dome. Additionally, two asymmetric curve types are available providing two 180° opposed, single plane curves. The curve types include DF and FJ. A Rocker Lever is used to deflect the tip. 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.

For Devices with Auto ID Technology:

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 Bi-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 patch.
- Do not use the catheter via the retrograde transaortic approach in patients with aortic valve replacement.
- Use of the catheter is contraindicated in patients with totally obstructed Coronary Sinus.

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- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.
- Electrophysiology studies are contraindicated when reversible factors make the findings unrepresentative of the patient's disease state (e.g. electrolyte imbalance).

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 place the Rocker Lever in the neutral position 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 | • Tamponade |
| • Local Hematomas | • Thrombi |
| • Thrombosis | • Air Embolism |
| • AV Fistula | • Arrhythmias |
| • Pseudoaneurysm | • Valvular Damage |
| • Thromboembolism | • Pneumothorax |
| • Vasovagal Reactions | • Hemothorax |
| • Cardiac Perforation | |

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.**

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- Remove the catheter from its package using appropriate sterile 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 catheter to the interface cables and standard recording equipment using the appropriate interface cables.
- Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning.
- Use the Rocker Lever to deflect the catheter tip (**Figure 1**). When the lever is pulled back from neutral, the tip will deflect relative to the direction of rotation. The amount of deflection is relative to the amount of lever rotation. When the lever is pushed forward, the tip will deflect in the opposite direction. To straighten the tip, return the Rocker Lever to neutral position.

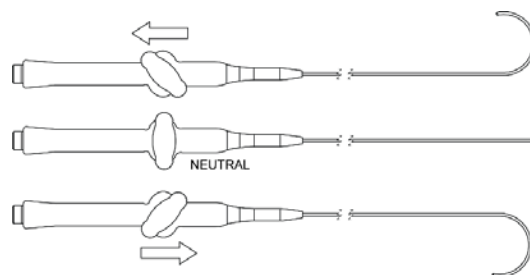


Figure 1

- The handle has an adjustable friction control that allows the operator to use the Rocker Lever and deflecting tip in a “free” state or adjust the friction to where the Rocker Lever and tip curve are “locked” in place (**Figure 2**). This knob is located on the opposite side of the Rocker Lever. Out of the package, the knob will be in the “off” position which allows free movement for the lever and deflecting top. The amount of friction increases as the Friction Control Knob is rotated clockwise until it reaches the full “on” position.

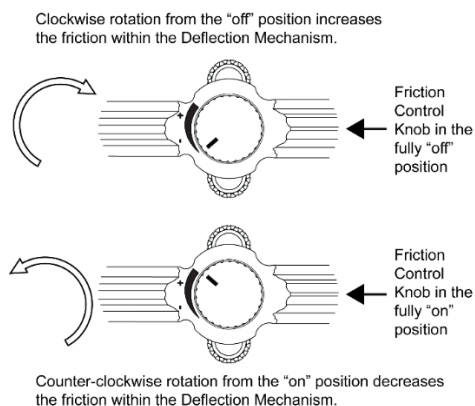















Figure 2

- Determine that the electrodes are in stable contact with the intended 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
	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.

Biosense Webster EZ Steer, CARTO and Webster are trademarks of Biosense Webster, Inc.

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