

Reprocessed by









Instructions for Use
Reprocessed Coronary Sinus Diagnostic Electrophysiology Catheter
with EZ STEER™ Technology

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **Non-pyrogenic**
- **STERILE**

Explanation of Icons

	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
	Ascent Product Code
	Do Not Reuse
	See Instructions For Use

Reprocessed CS Diagnostic Electrophysiology Catheter

Catheter Description

The reprocessed WEBSTER® Coronary Sinus (CS) Diagnostic Electrophysiology Catheter (hereinafter CS Bi-Directional Diagnostic 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 115 cm. The catheter has a high-torque shaft with a braided bi-directional deflectable tip section containing platinum electrodes that can be used for recording and stimulation. Two asymmetric curve types, DF and FJ, are available providing two 180° opposed, single plane curves. The rocker lever located on the handpiece is used to deflect the tip section. The high torque shaft allows the plane of the curved tip to rotate, enabling accurate positioning of the catheter tip at the preferred site.

Specific to Webster® CS Catheters with Auto ID Technology:

Each catheter is equipped with EEPROM (Electrically Erasable Programmable Read Only Memory), which is used to save unique catheter identification information. CARTO® EP Navigation Systems equipped with Auto ID Technology can access the saved information and automatically recognize the catheter information.

Indications for Use

The Reprocessed 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 this device:

- Through the transseptal approach in patients with left atrial thrombus or myxoma or interatrial baffle or patch;
- Through the retrograde approach in patients with aortic valve replacement.

Warnings and Precautions

- Take all appropriate measures to minimize x-ray exposure to 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. Therefore, careful consideration must be given for the use of the catheter in prepubescent children and pregnant women.
- Do not attempt to operate the catheter prior to completely reading and understanding the applicable Instructions for Use.
- Do not submerge 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 device.
- Do not use excessive force to advance or withdraw the catheter. Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade.
- Use both fluoroscopy and electrograms to monitor the advancement of the device to the area of the endocardium under investigation to avoid vascular or cardiac damage.

Adverse Reactions

The following are known potential adverse reactions:

- | | | |
|-------------------------|---------------------|----------------------------|
| • Pulmonary embolism | • Valvular damage | • Atrioventricular fistula |
| • Myocardial infarction | • Air embolism | • Pseudoaneurysm |
| • Stroke | • Pneumothorax | • Thromboembolism |
| • Cardiac tamponade | • Hemothorax | • Vasovagal reactions |
| • Arrhythmias | • Vascular bleeding | • Death |
| • Tamponade | • Local hematomas | • Cardiac perforation |
| • Thrombi | • Thrombosis | |

How Supplied

- The available curves include DF and FJ.
- Appropriate interface cables are supplied separately.

Reprocessed CS Diagnostic Electrophysiology Catheter

Directions for Use

Physician Training - 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.

Compatible Accessories: Use appropriate Biosense Webster accessory cables to connect the Catheter to standard recording equipment.

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect the catheter and package before opening. The contents of the package are sterile unless the package is opened or damaged. If the package is damaged or if it was opened and the catheter not used, do not use the catheter. Return the catheter and packaging to Ascent Healthcare Solutions for resterilization by ethylene oxide (EO) gas.
3. Do not attempt to resterilize.
4. Remove the catheter from the package and place it in a sterile work area using aseptic technique.
5. Inspect the catheter for overall condition and physical integrity. Do not use the catheter if electrodes appear loose or if any damage is noted. If such problems exist, return the catheter and packaging to Ascent Healthcare Solutions.
6. Create a vascular access in a large central vessel using aseptic techniques and insert the catheter.
7. Connect the catheter to the interface cables and standard recording equipment using the appropriate interface cables.
8. Advance the catheter to the region of the endocardium under investigation. Use both fluoroscopy and electrograms to assist in proper positioning.
9. 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. Return the Rocker Lever to neutral position to straighten the tip.

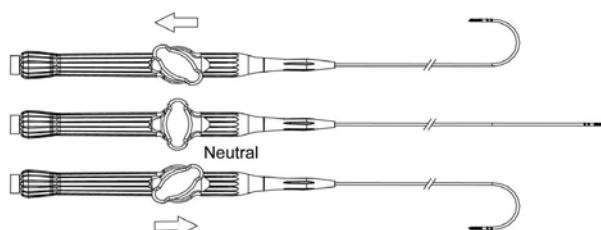


Figure 1

An adjustable friction control, located on the handle, 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 tip. The amount of friction increases as the Friction Control Knob is rotated clockwise until it reaches the fully “on” position.

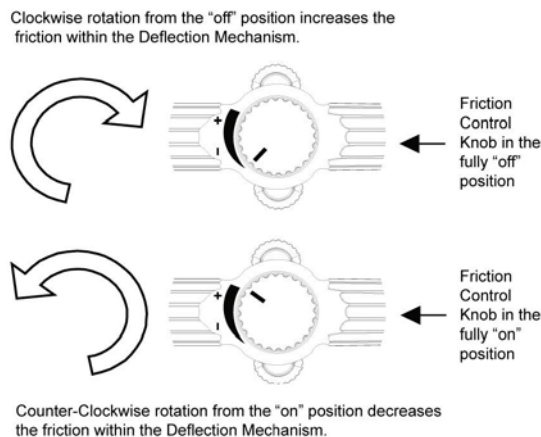


Figure 2

10. Verify that the electrodes are in stable contact with the intended mapping site.

Storage and Handling

- Prior to use, store reprocessed EP catheters in a cool, dry, dark place.

Reprocessed CS Diagnostic Electrophysiology Catheter

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

BIOSENSE WEBSTER, EZ STEER, WEBSTER and Carto® are trademarks of Biosense Webster, Inc.