Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed Coronary Sinus Diagnostic Electrophysiology Catheter

Reprocessed Device for Single Use

- **STERILE**

Explanation of Symbols

℞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
	Date of Reprocessing
	Use by Date
REF	Catalogue Number
	Do Not Reuse
	See Instructions For Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	Non-pyrogenic
	Do not re-sterilize

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Reprocessed CS Diagnostic Electrophysiology Catheter

Catheter Description
The reprocessed WEBSTER® Coronary Sinus (CS) Diagnostic Electrophysiology Catheter is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The device has either a 6FR or 7FR with a usable length of 115 cm. The catheter has a high-torque shaft with a braided deflectable, Bi-Directional or Uni-directional tip section containing platinum electrodes that can be used for recording and stimulation. Four curve types, D/F, F/J, D, and F, for CS placement, are available.

Specific to Webster® CS Catheters with Auto ID Technology:
Each catheter is equipped with EEPROM (Electronically 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 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.
- Use of the catheter is contraindicated in patients with totally obstructed Coronary Sinus.
- 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 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.
- Tactile feedback of reprocessed devices may vary during use.

Adverse Reactions
The following are known potential adverse reactions:
- Pulmonary embolism
- Myocardial infarction
- Stroke
- Cardiac tamponade
- Arrhythmias
- Tamponade
- Thrombi
- Valvular damage
- Air embolism
- Pneumothorax
- Hemothorax
- Vascular bleeding
- Local hematomas
- Thrombosis
- Atrioventricular fistula
- Pseudoaneurysm
- Thromboembolism
- Vasovagal reactions
- Death
- Cardiac perforation

How Supplied

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

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 Stryker Sustainability Solutions.
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 Stryker Sustainability 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.

Advance the catheter to the region of the endocardium under investigation. Use both fluoroscopy and electrograms to assist in proper positioning.

8. 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.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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.

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