

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed 2515 NAV and 2515 NAV eco Variable Electrophysiology Catheter


Reprocessed Device for Single Use


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

- **STERILE**

Explanation of Icons

 Sterilized by Ethylene Oxide Gas


 Non-Pyrogenic

 Date of Reprocessing

 Use by Date

 Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed 2515 NAV and 2515 NAV eco Variable Electrophysiology Catheter

Catheter Description

The Reprocessed 2515 NAV and 2515 NAV eco Variable Electrophysiology (EP) Catheter are specially designed for electrophysiological mapping of the atria of the heart when used with the CARTO[®] 3 EP Navigation System and a reference device. The 2515 NAV and 2515 NAV eco Variable EP Catheter have platinum electrodes positioned on the distal end that can be used for stimulation and recording. The Nitinol loop design allows for the expansion and contraction of the loop to fit veins ranging from 25mm to 15mm diameter ($\pm 15\%$).

Indications for Use

The Reprocessed 2515 NAV and 2515 NAV eco Variable EP Catheter are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Reprocessed 2515 NAV and 2515 NAV eco Variable EP Catheter are designed to obtain electrograms in the atrial regions of the heart. The Reprocessed 2515 NAV Variable EP Catheter provides location information when used with compatible CARTO[®] EP Navigation Systems version 1.0 or higher.

The Reprocessed 2515 NAV eco Variable EP Catheter provides location information when used with compatible CARTO[®] EP Navigation Systems version 2.3 or higher.

Contraindications for Use

Reprocessed 2515 NAV and 2515 NAV eco Variable EP Catheter may be contraindicated for:

- Use in patients with prosthetic valves.
- Use in patients with current active systemic infection.
- Transseptal approach in certain patients (e.g., patients with left atrial thrombus or myxoma, and patients with interatrial baffle or patch).
- Use of retrograde approach in certain patients because of risk of entrapping the catheter in the left ventricle or valvular apparatus. Catheter is not suggested for use in the ventricles.
- Radio frequency (RF) ablation; catheter has not been shown to be safe and effective for RF ablation.

Operating Instructions

To reduce the diameter of the loop, rotate the handle clockwise with the catheter pointing away from you. To increase the loop diameter rotate the handle counter-clockwise (see Figure 1). The maximum diameter of 25mm is attained when the handle is fully rotated counter-clockwise. Likewise, when the handle is fully rotated clockwise, the minimum attained diameter is 15mm. To deflect the tip of the catheter push forward on the catheter thumbknob. To straighten the tip, pull the thumbknob back.

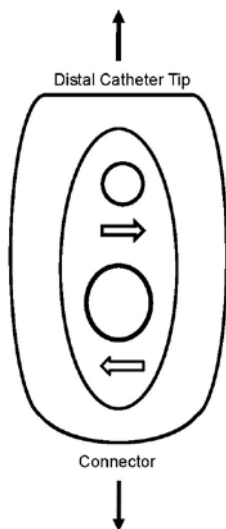


Figure 1: Reprocessed 2515 NAV and 2515 NAV eco Variable EP Catheter

The catheter interfaces with standard recording equipment and CARTO[®] 3 EP Navigation System equipment via interface cables with the appropriate connectors. Refer to the operating instructions for further description of the operation of the CARTO[®] 3 EP Navigation System.

Warnings and Precautions

- 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.
- In pregnant women, careful consideration must be given for the use of this catheter.
- Electrical performance could be affected if the proximal handle, pig tail or cable connector are immersed in fluids.
- Do not autoclave.
- To avoid potential damage to anatomical structures, do not attempt to pull the catheter, or withdraw it into the sheath, with the loop in a contracted position. To minimize tension applied to the Nitinol structure, the loop should be fully relaxed (handle grip rotated fully to the left).
- Do not introduce the catheter's tip folded into the guiding sheath.
- Catheter is recommended for use with an 8F guiding sheath. Do not use the catheter in conjunction with transeptal sheaths featuring side holes larger than 1.25mm in diameter.
- **Place the catheter by rotating (or torquing) the shaft in a clockwise motion only to reduce the risk of entrapping cardiac structures in the mapping electrode portion of the catheter.**
- **When not in regions intended for mapping, manipulate the catheter with the loop in the fully expanded (i.e. 25 mm diameter) position to further decrease the risk of entrapping cardiac structures.**
- Do not use in the proximity of magnetic resonance imaging (MRI) equipment because the MRI equipment may induce movement of the catheter, resulting in perforation.
- Until used, the catheter should be stored in its original packaging and in a cool, dry place.
- Prior to connecting and attempting to operate the Catheter, read and understand all accessory operating instructions and these Instructions for Use.
- Cardiac catheterization procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory.
- Careful manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement and placement should be done under fluoroscopic guidance through a guiding sheath. When resistance is encountered, do not use excessive force to advance or withdraw the catheter through the guiding sheath. In addition, extra care should be taken while inserting, aspirating and manipulating the guiding sheath.
- Inspect the sterile packaging and catheter prior to use. **Do not use if the package is open or damaged.**
- The catheter is intended for single patient use only.
- Always pull the thumbknob of the catheter back before insertion or withdrawal to assure that the catheter tip assumes its original shape.
- Do not apply RF energy when the ablation catheter is in contact with one or more of the Reprocessed 2515 NAV Variable EP Catheter electrodes.
For Reprocessed 2515 NAV eco Variable Electrophysiology Catheter:
- The standard transeptal procedure should be followed during mapping when moving the catheter from the right atrium to the left atrium.
- Take care when using the catheter in or around the atrio-ventricular valve region to prevent entanglement of the catheter with the valves and to prevent slippage of the catheter into the ventricles.
- Prior to mapping, the physician should ensure that the intracardiac signals are recorded by all of the electrodes on the loop of the catheter.

Directions for Use

- 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 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 for resterilization by ethylene oxide (EO) gas. Do not attempt to resterilize.
- Remove the catheter from its package and place it in a sterile work area using aseptic technique.
- 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.
- Follow standard practice for vessel puncture, guidewire insertion and guiding sheath use and aspiration per its Instructions for Use.
- Connect the interface connectors to the appropriate recording equipment.

- **NOTE: Read pacing and recording equipment operator manual for proper set up and operation.**
- Confirm that the thumbknob is pulled back completely before insertion and that the loop-contraction mechanism is not activated, ensuring minimal tension to the Nitinol loop.
- Adjust the loop diameter with the handle grip. Contract the loop by rotating the handle to the right, relax/expand the loop by rotating the handle to the left. (see Figure 1).
- Adjust the radius of curvature as necessary by manipulating the thumbknob. Curve the catheter tip by pushing the thumbknob forward, straighten the catheter tip by pulling the thumbknob back.
- Prior to removal of the catheter, confirm that the thumbknob has been pulled back completely and that the loop is in a fully relaxed position (handle grip rotated fully to the left). Remove the catheter through the guiding sheath and dispose of it in an appropriate manner. Remove the guiding sheath, guidewire and vessel dilator as a unit per its Instructions for Use.
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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
- Valvular Damage
- Pneumothorax
- Hemothorax

Reprocessed 2515 NAV and 2515 NAV eco Variable Electrophysiology Catheter

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.

Reprocessed 2515 NAV and 2515 NAV eco Variable Electrophysiology Catheter

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.

CARTO[®] is a registered trademark of Biosense Webster, Inc.

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