



## **Instructions for Use Reprocessed LASSO® NAV eco and LASSO® 2515 NAV eco Variable Electrophysiology (EP) Catheter**

### ***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 Biosense Webster LASSO NAV eco and LASSO 2515 NAV eco Variable Catheter has been designed to facilitate electrophysiological mapping of the atria of the heart with the CARTO® 3 EP Navigation System and a reference device. It is deployed in the right or left atrium through an 8 F guiding sheath. The deflectable catheters consist of a 4.5 F (LASSO NAV eco) or 4 F (LASSO 2515 NAV eco Variable) circular spine on its distal tip, with platinum electrodes that can be used for stimulation and recording.

The Reprocessed LASSO 2515 NAV eco Variable Catheter features a Nitinol loop design that allows the expansion and contraction of the loop to custom-fit veins with different sizes, ranging from 25mm to 115mm diameter ( $\pm 15\%$ ).

The Reprocessed LASSO NAV eco Catheter is a fixed catheter with three fixed catheter sizes, namely 15, 20, 25 mm loop sizes to accommodate different vein sizes. Each loop size will be available with either 10 or 20 electrodes.

The catheter interfaces with standard recording equipment and CARTO 3 EP Navigation System equipment via interface cables with the appropriate connectors. Consult the local distributor or manufacturer for the appropriate interface cables.

For use in mapping procedures, refer to the instructions for the CARTO 3 EP Navigation System.

**For further description of the operation of the CARTO 3 EP Navigation System, refer to the operating instructions for the instrument.**

#### **INDICATIONS FOR USE**

##### **Reprocessed LASSO 2515 NAV eco Variable Catheter and Reprocessed LASSO NAV eco Catheter**

The Reprocessed LASSO 2515 NAV eco Variable Catheter and Reprocessed LASSO NAV eco Catheter are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. These catheters are designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed LASSO 2515 NAV eco Variable Catheter and Reprocessed LASSO NAV eco Catheter provide location information when used with compatible CARTO 3 EP Navigation Systems. (These catheters are not compatible with CARTO 3 EP Navigation Systems prior to Version 2.3.)

## **CONTRAINDICATIONS FOR USE**

- The Reprocessed LASSO NAV eco and LASSO 2515 NAV eco Variable Catheters have not been shown to be safe and effective for radio frequency (RF) ablation.
- Use of these catheters may not be appropriate for use in patients with prosthetic valves.
- A relative contraindication for cardiac catheter procedures is active systemic infection.
- The transeptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.
- The retrograde approach is contraindicated because of risk of entrapping the catheter in the left ventricle or valvular apparatus. The catheter is not recommended for use in the ventricles.

## **WARNINGS**

- 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.
- Careful consideration must be given for the use of this catheter in pregnant women.
- Do not immerse the proximal handle, pig tail or cable connector in fluids; electrical performance could be affected.
- Do not autoclave the catheter.
- 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. The loop should be fully relaxed (handle grip rotated fully to the left) to minimize tension applied to the Nitinol structure.
- Do not introduce the catheter tip folded into the guiding sheath.
- Catheter is recommended for use with an 8 F atraumatic soft tipped guiding sheath.  
**Note:** Do not use the catheter in conjunction with transeptal sheaths featuring side holes larger than 1.25 mm in diameter.
- Do not expose the catheter to organic solvents such as alcohol.
- Tactile feedback of reprocessed devices may vary during use.

## **PRECAUTIONS**

- 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.
- The standard transeptal procedure should be followed during mapping when moving the catheter from the right atrium to the left atrium.
- To prevent entanglement of the catheter with the valves and to prevent slippage of the catheter into the ventricles, care should be taken when using the catheter in or around the atrio-ventricular valve region.
- Prior to use, the physician should ensure that the intracardiac signals are recorded by all of the electrodes on the loop of the catheter.
- Do not use in the proximity of magnetic resonance imaging (MRI) equipment because the MRI equipment may induce movement of the catheter that could result in perforation.
- The catheter should be stored in its original packaging and in a cool, dry, dark place until it is used.
- Prior to connecting and attempting to operate the catheter, read and understand all accessory operating instructions and these Instructions for Use.
- Do not attempt to operate the catheter prior to completely reading and understanding these Instructions for Use.

**Instructions for Use: Reprocessed LASSO® NAV eco and LASSO® 2515 NAV eco Variable EP Catheter**

- 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. Do not use excessive force to advance or withdraw the catheter through the guiding sheath, when resistance is encountered. In addition, extra care should be taken while inserting, aspirating, and manipulating the guiding sheath.
- The sterile packaging and catheter should be inspected 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 straight position.
- To place the Reprocessed LASSO NAV eco Catheter, torque (or rotate) shaft in a clockwise motion only.
- Do not apply RF energy when the ablation catheter is in contact with one or more of the catheter electrodes.

**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
- Vascular 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 package is opened or damaged, or if the package was opened and the catheter unused, do not use the catheter. Return the catheter to Innovative Health for reprocessing. **Do not attempt to resterilize.**
- Remove the catheter from its package and place it in a sterile work area.
  - The Reprocessed LASSO NAV eco catheter is recommended for use with an 8 F atraumatic soft tipped sheath. Confirm compatibility of the catheter with the guiding sheath by fully inserting and withdrawing the catheter through the irrigated sheath before clinical use. If excessive force is required or interference between the catheter and sheath is observed, use an alternate guiding sheath to avoid damaging the catheter or sheath.
- Inspect the catheter for physical integrity and overall condition. Do not use the catheter if damage is observed. Return the catheter to Innovative Health.
- 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.

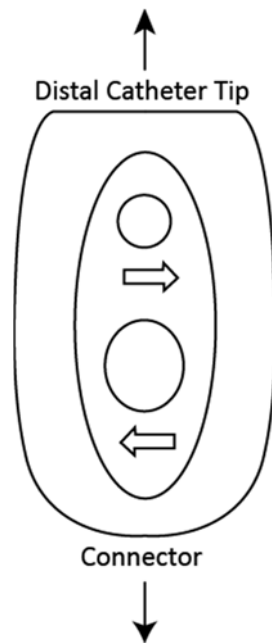
**Instructions for Use: Reprocessed LASSO® NAV eco and LASSO® 2515 NAV eco Variable EP Catheter**

**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.
- To place the Reprocessed LASSO NAV eco Catheter, torque (or rotate) shaft in a clockwise motion only.  
Pushing the thumbknob 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 thumbknob has been pulled back completely (tip straightened) and that the loop is in a fully relaxed position (handle grip fully rotated to the left). Remove the catheter through the guiding sheath and dispose of it in an appropriate manner.
- Remove the guiding sheath, vessel dilator and guidewire as a unit per its Instructions for Use.













**OPERATING INSTRUCTIONS FOR REPROCESSED LASSO 2515 NAV eco VARIABLE CATHETER**

To reduce the diameter of the loop, rotate the handle clockwise with the catheter pointing away from you. Rotating the handle counter-clockwise increases the loop diameter (see Figure 1). When the handle is fully rotated clockwise, the minimum 15mm diameter is attained. Pushing forward on the catheter thumbknob deflects the tip of the catheter. When the thumbknob is pulled back, the catheter tip straightens.



**Figure 1: Reprocessed LASSO 2515 NAV eco Variable Catheter**

**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
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	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 packaging have been sterilized with ethylene oxide gas (EO). 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 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.

LASSO® and CARTO® are registered trademarks of Biosense Webster, Inc.

Please refer to [www.innovative-health.com](http://www.innovative-health.com) for product warranty.