



Instructions for Use Reprocessed LASSO® Circular Mapping Diagnostic 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 2515 Variable Circular Mapping Catheter has been designed to facilitate electrophysiological mapping of the atria of the heart. It is deployed in the right or left atrium through an 8F guiding sheath. The deflectable catheter consists of a 4F circular spine on its distal tip, with platinum electrodes that can be used for stimulation and recording. By pushing forward on the catheter thumbknob, the tip is deflected; when the thumbknob is pulled back, the catheter tip straightens.

The Reprocessed LASSO 2515 Variable Circular Mapping 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 15mm diameter ($\pm 15\%$).

The Reprocessed Biosense Webster LASSO Deflectable Circular Mapping Catheter has been designed to facilitate electrophysiological mapping of the atria of the heart. It is deployed in the right or left atrium through an 8F guiding sheath. The deflectable catheter consists of a 3F circular spine on its distal tip, with platinum electrodes that can be used for stimulation and recording. By pushing forward on the catheter thumbknob, the tip is deflected; when the thumbknob is pulled back, the catheter tip straightens.

The LASSO 2515 Variable and LASSO Deflectable catheters interface with standard recording equipment via interface cables with appropriate connectors.

The Reprocessed Biosense Webster LASSO Deflectable Circular Mapping Catheter (with Auto ID Technology) has been designed to facilitate electrophysiological mapping of the atria of the heart. It is deployed in the right or left atrium through an 8F guiding sheath. The deflectable catheter consists of a 3F or 4F circular spine on its distal tip, with platinum electrodes that can be used for stimulation and recording. By pushing forward on the catheter thumbknob, the tip is deflected; when the thumbknob is pulled back, the catheter tip straightens. The catheter is equipped with Electronically Erasable Programmable Read Only Memory (EEPROM) which is used to store unique catheter identification. CARTO EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize the catheter information.

The LASSO Deflectable (with Auto ID Technology) catheter interfaces with CARTO EP Navigation Systems equipped with Auto ID Technology via interface cables with the appropriate connectors.

INDICATIONS FOR USE

Instructions for Use: Reprocessed LASSO Circular Mapping Diagnostic EP Catheter

The catheter is 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.

CONTRAINDICATIONS FOR USE

- The 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 transseptal 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

- Specific to the LASSO 2515 Variable Catheter:
 - To reduce the risk of entrapping cardiac structures in the mapping-electrode portion of the catheter, place the LASSO 2515 Variable Catheter by torqueing (or rotating) the shaft in a clockwise motion only. When not in regions intended for mapping, manipulate the catheter with the loop in the fully expanded (i.e. 25mm diameter) position to further reduce the risk of entrapping cardiac structures.
 - 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.
- 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 or cable connector in fluids; electrical performance could be affected.
- Do not autoclave the catheter.
- Do not introduce the catheter tip folded into the guiding sheath.
- Catheter is recommended for use with the Biosense Webster PREFACE® Braided Guiding Sheath.
Note: Do not use the catheter in conjunction with transseptal 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

- Read all accessory operation instructions prior to connection of the catheter. Do not attempt to operate the catheter prior to completely reading and understanding 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. 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.

Instructions for Use: Reprocessed LASSO Circular Mapping Diagnostic EP Catheter

- Always pull the thumbknob of the catheter back before insertion or withdrawal to assure that the catheter tip assumes its original shape.
- To place catheter, torque (or rotate) shaft in a clockwise motion only.
- To avoid char formation on the LASSO 2515 Variable Catheter rings, do not apply RF energy when the ablation catheter is in contact with one or more of the LASSO 2515 Variable Catheter electrodes.
- The catheter should be stored in its original packaging and in a cool, dry, dark place until it is used.
- The sterile packaging and catheter should be inspected prior to use. **Do not use if the package is open or damaged.**

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

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 and packaging to Innovative Health. **Do not attempt to resterilize.**
- Remove the catheter from its package and place it in a sterile work area.
- 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.
NOTE: Read pacing and recording equipment operator manual for proper set up and operation.
- Specific to catheters with Auto ID Technology:
 - Connect the interface cable to the Patient Interface Unit of the appropriate CARTO EP Navigation System and connect the catheter to the interface cable.
- Specific to LASSO 2515 Variable Catheter:
 - 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. By rotating the handle grip to the right, the loop contracts; by rotating the grip to the left, the loop expands (see Figure 1). Contract the loop by rotating the handle to the right, relax/expand the loop by rotating the handle to the left. (see Figure 1).

Instructions for Use: Reprocessed LASSO Circular Mapping Diagnostic EP Catheter

- Confirm that the thumbknob is pulled back completely before insertion. Advance the catheter through the guiding sheath to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning.
- Adjust the radius of curvature as necessary by manipulating the thumbknob. Pushing the thumbknob forward causes the catheter tip to bend (curve); when the knob is pulled back, the tip straightens.
- 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.
- Remove the guiding sheath, vessel dilator and guidewire as a unit per its Instructions for Use.

OPERATING INSTRUCTIONS FOR REPROCESSED LASSO 2515 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 counter-clockwise, the maximum diameter of 25mm is attained. 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.

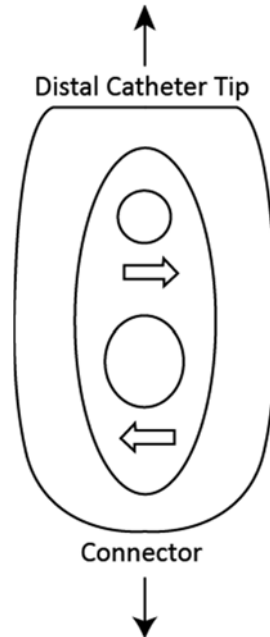


Figure 1: Reprocessed LASSO 2515 Variable Catheter

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



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 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 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, LASSO, CARTO, and PREFACE are trademarks of Biosense Webster, Inc.

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