

Reprocessed by









Instructions for Use Reprocessed Diagnostic Electrophysiology Catheters

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**
- **NON-PYROGENIC**

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 Diagnostic Electrophysiology Catheters

Catheter Description

Diagnostic electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a handpiece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tips of deflectable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

Specific to Webster® 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

Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures. In addition, the LASSO® 2515 Variable Circular Mapping Catheter and the Reflexion Spiral™ Variable Radius Catheter are designed for electrophysiological mapping of the atria of the heart.

Contraindications for Use

Reprocessed diagnostic electrophysiology catheters may be contraindicated for:

- Use in patients with prosthetic valves.
- Use in patients with current or frequent systemic infection.
- Transseptal approach in certain patients (e.g., patients with left atrial thrombus or myxoma and patients with intra-atrial baffle or patch).
- Transcatheter ablation.
- Retrograde transaortic approach in certain patients (e.g., patients with aortic valve replacement).
- Use in coronary vasculature other than the coronary sinus ostium.
- Patients with acute conditions (including electrolyte abnormality, acute ischemia and drug toxicity) that could make the findings of the electrophysiological study unrepresentative of the patient's usual state.
- Patients with an underlying cardiac disease (i.e. acute myocardial infarction, unstable angina and hemodynamic instability) that would make induced arrhythmias extremely difficult to terminate and therefore could present a high risk of death.
- Use of the LASSO® 2515 Variable Circular Mapping Catheter and the Reflexion Spiral™ Variable Radius EP Catheter are not suggested for use in the heart ventricles.

Warnings

- EP catheters should be used only by or under the supervision of an appropriately trained physician using proper procedures and techniques.
- Do not exert excessive pressure during placement of catheter if unknown resistance is encountered.
- Vascular and/or cardiac damage, including perforation, is a small but inherent risk.
- EP studies present the potential for significant X-ray exposure due to fluoroscopic imaging. Consideration should be given to the possible effects of radiation exposure on certain patients (e.g., children and pregnant women).
- Do not autoclave catheter.
- Do not use for electrical ablation.
- If electrocardiogram equipment is used for placement of the catheter, the equipment must be front-end isolated or have an isolated patient cable. Current leakage from the electrocardiogram monitor must not exceed 10 microamps.
- Catheters or cables with unprotected male connectors, if inadvertently attached to power supply sockets of connectors, may present a risk of electrocution of the patient or operator. Use caution during device set-up.
- Serious complications can result from catheter and accessory misuse.
- Use only sterile saline or water to wipe the device.
- Do not introduce the tip folded into the guiding sheath.

Specific to LASSO® Catheters:

- Place the catheter by rotating the shaft in a clockwise motion only to reduce the risk of entrapping cardiac structures.
- Pull thumbknob back prior to insertion or withdrawal.
- Note: Do not use the catheter in conjunction with transseptal sheaths featuring side holes larger than 1.25mm in diameter.

Specific to the LASSO® 2515 Variable Circular Mapping Catheters:

- The catheter is recommended for use with the Biosense Webster PREFACE® Braided Guiding Sheath.
- Prior to insertion or withdrawal, the loop should be fully relaxed (handle grip rotated fully to the left) to reduce tension applied to the Nitinol structure.

Reprocessed Diagnostic Electrophysiology Catheters

Specific to the LASSO® 2515 Variable Circular Mapping Catheters and Reflexion Spiral™ Variable Radius EP Catheters:

- When provided, use the curve straightener when inserting the catheter into the introducer to maintain integrity of the loop.
- To avoid potential damage to anatomical structures, do not attempt to pull, insert or withdraw catheter into the sheath, with the loop in a contracted position.
- When not in regions intended for mapping, manipulate the catheter with the loop in the fully expanded position to further decrease the risk of entrapping cardiac structures.

Precautions

- Do not attempt to use the reprocessed EP catheter prior to completely reading and understanding the *Directions for Use*.
- Do not alter this device.
- Inspect the packaging and catheter for damage or defects prior to use.
- Avoid excessive torque, stretching, kinking and/or bending of catheter, as this may interfere with distal tip shaping or cause damage to internal electrode wires.
- Avoid manual pre-bending of distal curve, as this may damage steering mechanism of steerable catheters. Handle catheter with care to avoid improper electrical functioning.
- Standard electrical grounding precautions should be observed when using electrical recording or stimulation equipment.
- Avoid excessive contact of handpiece with fluids, as this could adversely affect the electrical performance of the catheter.
- Diagnostic EP catheters are not recommended for long-term pacing.
- Do not insert or withdraw the catheter without straightening the catheter tip.
- Do not use a catheter if the small vent area at the connector end of the handpiece is clogged, as air may be forced into the catheter lumen and into the bloodstream.
- Personnel handling EP catheters should wear protective gloves.
- This device should only be used with equipment that complies with international safety standards.
- This device should not be used with Magnetic Resonance Imaging (MRI) systems.
- Use fluoroscopic guidance during catheter positioning.
- Use the smallest dose of local anesthesia necessary to achieve the desired effect. Systemic levels of local anesthesia may result in electrophysiologic effects.
- Monitor patients with life threatening arrhythmias closely when antiarrhythmic drugs are discontinued.
- To avoid char formation on the LASSO® 2515 Variable Circular Mapping Catheter rings, do not apply RF energy when the ablation catheter is in contact with one or more of the LASSO® electrodes.

Adverse Reactions

The following are known potential adverse reactions:

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

Reprocessed Diagnostic Electrophysiology Catheters

Directions for Use

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. Do not attempt to resterilize.
3. Remove the catheter from the package and place it in a sterile work area using aseptic technique.
4. 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.
5. Create an appropriate vascular access using aseptic technique.
6. Using a standard technique, insert the catheter (through a suitable introducer sheath when indicated) and direct the catheter to the desired intracardiac site. Straighten deflectable catheter tips (with straightener, if provided) and relax variable catheter loops prior to insertion. For variable loop catheters:
Become thoroughly familiar with the operation of the actuator control located in the handle at the proximal end of the catheter and adjust it to manipulate the tip portion of the catheter. Never manipulate the deflectable section of the shaft or the spiral loop while the catheter is within the introducer.
 - a. For the LASSO® 2515 Variable Circular Mapping Catheter:
Catheter may be manipulated using the handle grip. Contract the loop by rotating the handle to the right, relax the loop by rotating the handle to the left. Curve the catheter tip by pushing the thumbknob forward, straighten the catheter tip by pulling the thumbknob back.
 - b. For the Reflexion Spiral™ Variable Radius EP Catheter:
Prior to insertion into the hemostasis introducer, advance the curve straightener over the distal tip of the catheter. Fully insert the curve straightener into the hemostasis valve prior to inserting the catheter into the introducer. Adjust the loop actuator mechanism to adjust the spiral loop: Move the loop actuator mechanism forward (distally) to contract loop. Move the loop actuator mechanism backwards (proximally) to relax the loop. Prior to actuating the shaft to the full 180° deflection, adjust the spiral loop to the fully closed position.
7. Use fluoroscopy and/or electrocardiogram for positioning and monitoring.
8. Connect the catheter to the corresponding cable connector.
9. Connect the cable to the correct electronic equipment for recording and/or sensing. Observe polarity of proximally located connector pins of the interface cable when connecting to the electronic equipment. Isolate any unused connector pins to reduce development of accidental current pathways to the heart.
10. Follow a suitable electrophysiology study protocol.
11. Prior to withdrawal, straighten catheter tip of deflectable catheters to avoid vascular injury.

Compatibility

- EP catheters are connected to standard electronic recording equipment using appropriate cable connectors.
- Temporary pacing connections:
 - “Distal” negative (-) electrode jack to negative (-) terminal of external pulse generator. Positive (+) electrode jack to positive (+) terminal of external pulse generator.
 - Shield remaining electrode jacks.
- Use the appropriate interface cables for the reprocessed EP catheter being utilized.

Storage and Handling

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

Reprocessed Diagnostic Electrophysiology Catheters

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.

LASSO®, PREFACE® and Carto® are registered trademarks of Biosense Webster, Inc.
Reflexion Spiral™ is a trademark of St. Jude Medical, Inc.