

Reprocessed by









Instructions for Use Reprocessed 3D Diagnostic Ultrasound 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 3D Diagnostic Ultrasound Catheters

Catheter Description

The reprocessed SOUNDSTAR™ 3D Diagnostic Ultrasound Catheters (hereinafter 3D Diagnostic Ultrasound Catheter) are specially designed catheters that provide two-dimensional imaging using an ultrasound transducer and three-dimensional location information using a location sensor. The ultrasound transducer and location sensor are at the distal tip of the catheter and can be positioned for ultrasound imaging and 3D mapping by a steering mechanism that rotates the catheter tip to variable deflections. 3D Diagnostic Ultrasound Catheters incorporate a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer and a location sensor. The 3D Diagnostic Ultrasound Catheter 3-D location sensor provides location information to the CARTO® XP EP Navigation System (mapping system). The 3D Diagnostic Ultrasound Catheter is 10 French with a 90 cm insertion length.

Indications for Use

Reprocessed 3D Diagnostic Ultrasound Catheters are indicated for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The 3D Diagnostic Ultrasound Catheter provides location information when used with the CARTO® XP EP Navigation System Version 9 or greater.

Contraindications for Use

3D Diagnostic Ultrasound Catheters are contraindicated for:

- Presence of conditions that create unacceptable risk during cardiac catheterization.
- Inadequate vascular access.
- Sepsis
- Major coagulation abnormalities
- Presence of any right-heart intracardiac thrombus
- Presence of class IV angia or heart failure
- Deep vein thrombosis
- Significant peripheral vascular disease
- Use in coronary vessels
- Insertion into the arterial system
- Pediatric or fetal use in coronary vessels

Warnings

- 3D Diagnostic Ultrasound 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 damage, including perforation, is a small but inherent risk.
- Carefully manipulate the catheter in order to avoid cardiac damage, perforation or tamponade.
- If encountering strong resistance during catheter articulation, discontinue the procedure and determine the cause of the resistance before proceeding.

Precautions

- Do not attempt to use the 3D Diagnostic Ultrasound Catheter prior to completely reading and understanding the *Directions for Use* and related user manuals for the ultrasound and mapping system.
- Inspect the packaging and catheter for damage or defects prior to use.
- Avoid excessive kinking or bending of catheter, as this may interfere with distal tip shaping or cause damage to internal electrode wires.
- Ensure that the two articulation knobs are in the neutral position and the brake is released before advancing or withdrawing the diagnostic ultrasound catheter.
- Do not immerse the connectors in fluid.

Adverse Reactions

The following are known potential adverse reactions:

1. Pulmonary embolism
2. Myocardial infarction
3. Stroke
4. Tamponade

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5. Death
6. Femoral artery or vein injury
7. Thrombosis
8. Pseudoaneurysm
9. AV fistula
10. Cardiac perforation
11. Air embolism
12. Valve or structural cardiac damage
13. Pneumothorax
14. Hemothorax

Interfering substances or devices

- Immediately discontinue the use of the 3D Diagnostic Ultrasound Catheter if it interferes with the function of the patient's pacemaker.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Turn the ultrasound and mapping system on. Verify incoming main voltage is 120 VAC.
3. 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 (EtO) gas.
4. Do not attempt to resterilize.
5. Remove the catheter from the package and place it in a sterile work area using aseptic technique.
6. Inspect the catheter for overall condition and physical integrity. Do not use the catheter if any damage is noted. If such problems exist, return the catheter and packaging to Ascent Healthcare Solutions.
7. Rotate the steering control knobs. The function should be smooth and the catheter tip should flex in a corresponding direction up to 160°. The tension control knob is completely released by rotating fully counter clockwise.
8. Position the control knobs in the neutral position by aligning the marks on the knobs to the marks on the housing.
NOTE: If the tip does not return to neutral position, release the tension by rotating the tension control knob in a counterclockwise direction.
9. Slip the sterile sheath over the interconnect tab until it is fully seated on to the handle.
10. Lift the lever on the connector, slipping it onto the catheter interconnect tab until fully mated with the steering handle. Push the lever down, locking it into place.
11. Carefully slip the sterile sheath over the catheter connector, covering a sufficient length so that it is out of the sterile field.
12. Use the appropriate SwiftLink™ Catheter connector to connect the 3D Diagnostic Ultrasound Catheter to the ultrasound system. Ensure that the imaging screen appears.
13. Use the hypertonic catheter connector to connect the 3D diagnostic ultrasound catheter to the mapping system.
14. When the 3D Diagnostic Ultrasound Catheter is used in conjunction with the CARTO® XP mapping system, connect the catheter to the Patient Interface Unit (PIU) using a sterile extension cable (not provided by Ascent Healthcare Solutions).
15. Connect the reference patch, such as the RAFSTAR® with QWIKPATCH®, to the appropriate operating system.
15. For use of the 3D Diagnostic Ultrasound Catheter in mapping procedures, an additional external reference patch (not provided by Ascent Healthcare Solutions) is required for location reference position purposes. Connect the external reference patch (not provided by Ascent Healthcare Solutions) following the appropriate mapping system documentation.
16. Create a vascular access with a catheter introducer sheath (hemostatic) large enough to accommodate the catheter with heparinized saline.
17. Verify the steering knobs are in the neutral position and the tension control knob is released, before advancing the catheter into the vasculature through the catheter introducer sheath. Fluoroscopy may aid in advancing the catheter into the heart.
18. Once inside the heart, use the steering knobs to direct the ultrasound transducer to visualize the desired cardiac anatomy.
19. Prior to device withdrawal, release the tension control knob and return the steering knobs to the neutral position.
20. Remove the catheter at the end of the evaluation.

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Compatibility

- 3D Diagnostic Ultrasound catheters are connected to standard ultrasound equipment using appropriate connectors.

Storage and Handling

- Store 3D Diagnostic Ultrasound Catheters in a cool, dry place.
- Air freight only in pressurized cargo.
- Relative humidity: Up to 90% non-condensing.
- Temperature: Maximum 50°C (122°F), Minimum 10°C (14°F)

Reprocessed 3D Diagnostic Ultrasound 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.

SOUNDSTAR™ and CARTO® are trademarks of Biosense Webster, Inc.
SwiftLink™ is a trademark of Siemens Medical Solutions USA, Inc.

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