Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed SOUNDSTAR® *eco* Diagnostic Ultrasound 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 Symbols

℞Only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Catalogue Number
	Do Not Reuse
	See Instructions For Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	Non-Pyrogenic

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1810 W Drake Dr.
Tempe AZ, 85283
sustainability.stryker .com
888.888.3433

Catheter Description

The Reprocessed SOUNDSTAR® *eco* Diagnostic Ultrasound Catheter is a sterile, single-use, disposable imaging catheter. The distal end of the catheter has an ultrasound transducer providing 2D imaging and 3D location sensor providing location information to compatible CARTO® 3 EP Navigation Systems with ultrasound capability. A steering mechanism controls the image plane orientation by rotating both the Reprocessed SOUNDSTAR® *eco* catheter tip and the variable deflection.

The Reprocessed SOUNDSTAR® *eco* incorporates a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer and location sensor. The Reprocessed SOUNDSTAR® *eco* provides location information to the CARTO® 3 EP Navigation Systems with ultrasound capability. The Reprocessed SOUNDSTAR® *eco* is 8 French or 10 French with 90 cm insertion length.

Indications for Use

Reprocessed SOUNDSTAR® *eco* devices 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. When utilized with compatible CARTO® 3 EP Navigation Systems, the Reprocessed SOUNDSTAR® *eco* provides location information. Please refer to the applicable Biosense Webster Compatibility Matrix Insert for Compatible CARTO® 3 Systems as each catheter is compatible with a specific version of CARTO® 3 and is not backwards compatible with previous versions of CARTO® 3 EP Navigation Systems.

Contraindications for Use

Reprocessed SOUNDSTAR® *eco* are contraindicated for:

- Presence of conditions that create unacceptable risk during cardiac catheterization
- Inadequate vascular access
- Sepsis
- Major coagulation abnormalities
- Presence of class IV angina or heart failure
- 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

Warnings

- Reprocessed SOUNDSTAR® eco devices should be used only by or under the supervision of any appropriately trained physician using proper procedures and techniques.
- Failure to completely read and understand the device literature could result in patient injury.
- Do not use the Reprocessed SOUNDSTAR® eco if the packaging is opened or damaged.
- Do not use the Reprocessed SOUNDSTAR® eco if it is damaged.
- Do not use the SwiftLink® connector if it appears to be damaged.
- Do not immerse the SwiftLink® connector in fluid of any kind.
- Moisture trapped between the SwiftLink® connector and the SOUNDSTAR® eco Catheter can damage the SwiftLink® connector and/or the SOUNDSTAR® eco Catheter.
- Do not use excessive force to advance or withdraw the Reprocessed SOUNDSTAR® eco.
- If you encounter strong resistance during catheter navigation, discontinue the procedure. Withdraw and redirect the Reprocessed SOUNDSTAR® eco as needed.
- Carefully manipulate the Reprocessed SOUNDSTAR® eco in order to avoid cardiac damage, entanglement, perforation or tamponade.

Precautions

- Do not attempt to use the Reprocessed SOUNDSTAR® eco prior to completely reading and understanding the Directions for Use.
- 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.
- Use the appropriate SwiftLink® Catheter connector to connect the Reprocessed SOUNDSTAR® eco catheter to the

ultrasound system. All reprocessed device models connect to CARTO® 3 using the multipin SOUNDSTAR® eco cable.
- Excessive bending or kinking of the Reprocessed SOUNDSTAR® eco can damage internal wires and/or distal tip articulating capabilities.
- To help prevent excessive force ensure that both steering knobs are in the neutral position, and that the tension control knob is released before advancing or withdrawing the Reprocessed SOUNDSTAR® eco.
- For proper care and handling of the Reprocessed SOUNDSTAR® eco, always hold the Reprocessed SOUNDSTAR® eco by the handle and support the catheter shaft. Avoid touching the ultrasound catheter interconnect tab.
- Quick connection or disconnection of the Reprocessed SOUNDSTAR® eco may result in catheter damage, potentially causing procedural delay.
- It is imperative that you are aware of the pacemaker needs of the patient. If use of the Reprocessed SOUNDSTAR® eco interferes with the function of the patient's pacemaker, immediately discontinue use of the Reprocessed SOUNDSTAR® eco.
- The intracardiac ultrasound image will disappear if the CARTO® 3 EP Navigation System power is disrupted and this may present a safety issue if the EP is using the ultrasound to monitor the patient during the EP procedure. The ultrasound image will not reappear until the CARTO® 3 System is restored.

Adverse Reactions

Adverse events related to cardiac catheterization have been documented and include, but are not limited to:

- Femoral artery or vein injury
- Thrombosis
- Pseudoaneurysm
- Cardiac perforation
- Air embolism
- Pulmonary embolism
- Myocardial infarction
- Valve or structural cardiac damage
- Cardiac tamponade
- Pneumothorax
- Hemothorax
- Stroke
- AV fistula
- Death

Directions for Use

1. The Reprocessed SOUNDSTAR® *eco* is intended for use during single patient procedure.
2. Do not attempt to resterilize. Stryker will not accept Reprocessed SOUNDSTAR® *eco* for reprocessing that have been reprocessed and sterilized by other facilities.
3. The package label is detachable and may be affixed to the medical r*eco*rd of the patient.
4. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
5. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the Reprocessed SOUNDSTAR® *eco* if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the Reprocessed SOUNDSTAR® *eco* and the package to Stryker.
6. Using proper sterile technique, remove the Reprocessed SOUNDSTAR® *eco* from the package and place it in a sterile work area.
7. Inspect the Reprocessed SOUNDSTAR® *eco* for overall condition and physical integrity. Do not use the Reprocessed SOUNDSTAR® *eco* if any damage is noted. Return the Reprocessed SOUNDSTAR® *eco* and packaging to Stryker if it is not in acceptable condition for the procedure.
8. Rotate the steering knobs. The steering function should be smooth. The catheter tip should flex in a corresponding direction. If the Reprocessed SOUNDSTAR® *eco* tip does not return to the neutral position after you release the steering knobs, ensure that the tension control knob is completely released. Release the tension by rotating the tension control knob completely in a counterclockwise direction.
9. Position the steering knobs in the neutral position by aligning the marks on the steering knobs to the marks on the housing.

10. Inspect the SwiftLink® connector for damage.
11. If using two narrow sterile sleeves, lift the lever on the SwiftLink® ® connector. Slip the SwiftLink® connector on to the Reprocessed SOUNDSTAR® *eco* interconnect tab until the SwiftLink® connector is securely mated with the Reprocessed SOUNDSTAR® *eco* handle. Push the lever down, locking the Reprocessed SOUNDSTAR® *eco* to the SwiftLink® connector
12. Carefully slip the sterile sleeve over the SwiftLink® connector. Cover enough of the SwiftLink® connector as such that it is outside the sterile field.
13. Using a s*eco*nd narrow sterile sleeve for the CARTO® Systems connector, slip the sterile sleeve over the Reprocessed SOUNDSTAR® *eco* interconnect tab until the sleeve is appropriately seated.
14. Connect the other end of the SwiftLink® connector to the ultrasound system. Ensure that the ultrasound image appears in the ultrasound system screen.
15. Slowly slip the Reprocessed SOUNDSTAR® *eco* extension cable onto the Reprocessed SOUNDSTAR® *eco* interconnect tab until the connector is securely mated with the Reprocessed SOUNDSTAR® *eco* handle.
16. Carefully slip the sterile sleeve over the cable. Cover enough of the Reprocessed SOUNDSTAR® *eco* cable such that it is outside the sterile field.
17. Connect the other end of the Reprocessed SOUNDSTAR® *eco* cable to the CARTO® System PIU.
18. Carefully slip the sterile sleeve over both cables. Cover enough of the cables such that the uncovered portions are outside the sterile field.
19. Connect the other end of the cables to their respective systems.
20. Connect the location reference patches and ablation catheter, if required, following the CARTO® system documentation.
21. Create a vascular access with a catheter introducer sheath (hemostatic) large enough to accommodate the Reprocessed SOUNDSTAR® *eco* with heparinized saline. Fluoroscopy may aid in advancing the catheter into the heart.
22. Before advancing or withdrawing the Reprocessed SOUNDSTAR® *eco*, ensure the steering knobs are in the neutral position and that the tension control knob is released.
23. Advance the Reprocessed SOUNDSTAR® *eco* into the vasculature through the catheter introducer. Fluoroscopy can aid in advancing the catheter into the heart.
24. Once inside the heart, use the steering knobs to direct the ultrasound transducer for visualization of the target cardiac anatomy.
25. Remove the catheter at the end of the evaluation.

Compatibility

The Reprocessed SOUNDSTAR® *eco* is connected to standard ultrasound equipment using appropriate connectors.

Model #	CARTO® Connector Type	Ultrasound Console Type
10439236	33-pin *eco* Connector	GE (Vivid *i*, Vivid *q*)
10439072	33-pin *eco* Connector	GE (Vivid *i*, Vivid *q*)
10439011	33-pin *eco* Connector	Siemens / Acuson (Sequoia, Cypress, SC2000, X300, X700)
10438577	33-pin *eco* Connector	Siemens / Acuson (Sequoia, Cypress, SC2000, X300, X700)

COMPATIBLE CARTO® SYSTEMS

- CARTO® 3

TRANSDUCER SURFACE SYSTEMS

The following table provides the maximum surface temperature of the SOUNDSTAR® *eco* Catheter with the relevant ultrasound system. The tissue mimicking material (TMM) temperature is displayed in accordance with IEC 60601-2-37 requirements.

Storage and Handling

- Store Reprocessed SOUNDSTAR® eco 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)

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 LAIBLE 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.

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.

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