Reprocessed by

stryker®

Sustainability Solutions

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

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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Catheter Description

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

Indications for Use

Reprocessed 3D Diagnostic Ultrasound Catheters are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® XP Navigation Systems, the SOUNDSTAR® 3D Catheter provides location information.

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.
- Ensure that the two articulation knobs are in the neutral position and the brake is released before advancing or withdrawing the diagnostic ultrasound catheter.
- For proper care and handling of the 3D Diagnostic Ultrasound Catheter, always hold the ultrasound catheter by the handle and support the catheter shaft. Avoid touching the 3D Diagnostic Ultrasound Catheter interconnect tab.
- Do not immerse the connectors in fluid.

Adverse Reactions

The following are known potential adverse reactions

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

Interfering substances 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

These Directions for Use relate only to the safe and effective use of the SOUNDSTAR® Catheter in conjunction with Biosense Webster CARTO® Systems with ultrasound capability. The Directions for Use do not include essential background, instructional, or handling information related to the ultrasound features of the SOUNDSTAR® Catheter, or when used with the ultrasound system only.

PROCEDURE PREPARATION

Before you begin the preparation procedures, power on the ultrasound system and the CARTO® System. To prepare the SOUNDSTAR® Catheter and SwiftLink* connector for use in an ultrasound exam:

1. Inspect the sterile package prior to catheter.
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. Using proper sterile technique, remove the SOUNDSTAR® Catheter from the sterile package. Place the SOUNDSTAR® Catheter in a sterile working area.
4. Inspect the entire SOUNDSTAR® Catheter for damage.
5. Inspect the extension cable to ensure that the sterility of the products or packaging have not been compromised. Inspect the location reference device for damage.
6. Rotate the steering knobs. The steering function should be smooth. The catheter tip should flex in a corresponding direction
7. Position the steering knobs in the neutral position by aligning the marks on the steering knobs to the marks on the housing.
8. Slip the sterile sheath over the SOUNDSTAR® Catheter interconnect tab until the sheath is appropriately seated, leaving the CARTO® connector uncovered.
9. Inspect the SwiftLink* connector for damage.
10. Lift the lever on the SwiftLink* connector. Slip the SwiftLink* connector on to the SOUNDSTAR® Catheter interconnect tab until the SwiftLink* connector is securely mated with the SOUNDSTAR® Catheter handle. Push the lever down, locking the SOUNDSTAR® Catheter to the SwiftLink* connector.
11. Carefully slip the sterile sheath over the SwiftLink* connector. Cover enough of the SwiftLink* connector cable such that it is outside the sterile field.
12. Connect the other end of the SwiftLink* connector to the ultrasound system. Ensure that the ultrasound image appears in the ultrasound system screen.
13. For connection to the CARTO® XP V9 System, connect the SOUNDSTAR® Catheter to the Patient Interface Unit (PIU) via a sterile extension cable, which has been connected to the QWIK port adaptor, as detailed in the CARTO® XP V9 System documentation (System Hardware section).
14. For connection to other CARTO® Systems, follow the operating instructions for the CARTO® System.

15. Connect the location reference device and ablation catheter, if required, following the CARTO® System documentation (System Hardware section).

DURING THE PROCEDURE

To conduct an ultrasound exam using the SOUNDSTAR® Catheter:

1. Create a vascular access with a catheter introducer (hemostatic) large enough to accommodate the SOUNDSTAR® Catheter with heparinized saline.
2. Before advancing or withdrawing the SOUNDSTAR® Catheter, ensure that the steering knobs are in the neutral position and that the tension control knob is released.
3. Advance the SOUNDSTAR® Catheter into the vasculature through the catheter introducer. Fluoroscopy can aid in advancing the catheter into the heart.
4. When the SOUNDSTAR® Catheter is inside the heart, use the steering knobs to direct the ultrasound transducer for visualization of the target cardiac anatomy.
5. For details on mapping with a SOUNDSTAR® Catheter during a CARTO® System study, refer to the documentation provided with the Ultrasound Image Integration Add-On Module.

Procedure Conclusion

To end a procedure using the SOUNDSTAR® Catheter:

1. Before withdrawing the SOUNDSTAR® Catheter, ensure that the steering knobs are in the neutral position and that the tension control knob is released.
2. Withdraw the SOUNDSTAR® Catheter from the patient.

Compatibility

Model #	Ultrasound Connector Type	CARTO™ Connector Type	Ultrasound Console Type
SNDSTR10	Swift-link	24-pin Hypertronic	Siemens / Acuson (Sequoia, Cypress, SC2000, X300, X700)
SNDSTR10G	Swift-link	24-pin Hypertronic	GE (Vivid *i*, Vivid *q*)

COMPATIBLE CARTO SYSTEMS

- CARTO® XP
- CARTO® 3

TRANSDUCER SURFACE SYSTEMS

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

Ultrasound System	TMM (Max Temp)
Sequoia*	42.1°C
Cypress*	42.1°C
X300*	41.8°C
SC2000	42.1°C

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)

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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