INSTRUCTIONS FOR USE

Reprocessed 3D Imaging Catheter

Control #: SMI-420-303 Rev. C

Reprocessed by:

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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The Reprocessed SOUNDSTAR® 3D and SOUNDSTAR® *eco* Diagnostic Ultrasound Catheters (hereinafter 3D and *eco* Diagnostic Ultrasound Catheter) 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 and *eco* Diagnostic Ultrasound Catheters provide location information when used with the CARTO® XP Version 9.0 or higher and CARTO ® 3 version 1.1 and higher EP Navigation System.

The Original Equipment Manufacturer (OEM) provided an "Instructions for Use" (IFU) document as well as a Compatibility Matrix Insert for the systems compatibility with the original device. The health institution who wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

The Sterilmed Reprocessed 3D and *eco* Diagnostic Ultrasound Catheters are designed to provide two-dimensional imaging using an ultrasound (ultrasonic phased-array) transducer and three-dimensional location information using a location sensor. Both the ultrasound transducer and location sensor are at the distal tip of the device and may be positioned within the target area by a steering mechanism which rotates the catheter tip and allows for variable deflection. The 3D and *eco* Diagnostic Ultrasound Catheters feature a hand piece, a flexible shaft, and a distal tip section containing the ultrasound transducer and location sensor. The 3D and *eco* Diagnostic Ultrasound Catheter 3D location sensor provides location information to the CARTO® XP and CARTO ® 3 EP Navigation Systems. The 3D and *eco* Diagnostic Ultrasound Catheters have a 10 French diameter and a 90 cm insertion length.

The 3D and *eco* Diagnostic Ultrasound Catheters have been cleaned, evaluated for continued integrity, and sterilized following a prior use. Devices are tracked throughout the reprocessing steps to monitor and ensure they do not exceed the specified number of reprocessing cycles.

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This device is provided **STERILE**.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

CONTRAINDICATIONS

1. This device is contraindicated in cases where vascular access is inadequate, or in the presence of conditions which create an unacceptable risk during cardiac catheterization, such as:
    a. Sepsis
    b. Major coagulation abnormalities
    c. Presence of any right sided intracardiac thrombus
    d. Presence of class IV angina or heart failure
    e. Deep vein thrombosis
    f. Significant peripheral vascular disease

2. ***Warning: This device is not intended for:***
    a. Use in the coronary vessels
    b. Insertion into the arterial system
    c. Fetal or pediatric uses

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of these devices as well as cardiac imaging procedures. All mapping procedures must be performed in fully equipped EP labs.
2. For ultrasound purposes, the Reprocessed 3D and *eco* Diagnostic Ultrasound Catheters are identical to the AcuNav™ 10F Catheter. Refer to the AcuNav™ Ultrasound Catheter User Manual supplied by the OEM.
3. Inspect the packaging and the imaging catheter prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
4. The device should only be used by physicians trained in cardiac catheterization and, preferably, in the placement and use of intracardiac imaging devices and the interpretation of the resulting ultrasound images.
5. Do not attempt to connect and operate the device before completely reading and understanding the instructions for use and system manual.
6. Carefully manipulate the catheter in order to avoid cardiac damage, perforation or tamponade.

7. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
8. Discontinue the procedure and determine the cause of resistance before proceeding if strong resistance is encountered during articulation of the catheter.
9. Perforation of the vasculature or cardiac structures is an inherent risk of any catheter placement.
10. Do not immerse or allow any fluid or moisture between the catheter connector and ultrasound catheter; the device may not function properly.
11. Regular visual inspection of the catheter connector is recommended. Replace a damaged catheter connector immediately.
12. Ensure the two articulation knobs are in the neutral position and the brake is released before advancing or withdrawing the diagnostic ultrasound catheter.
13. Excessive bending or kinking of the catheter may damage internal wires and/or distal tip articulating capabilities.

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with 3D Imaging Catheters. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

Several major adverse events have been documented for cardiac catheterization procedures including the following:

1. Death
2. Stroke
3. Cardiac tamponade
4. Myocardial infarction
5. Pulmonary embolism
6. Air embolism
7. AV fistula
8. Femoral artery or vein injury
9. Hemothorax
10. Perforation/Dissection
11. Pneumothorax
12. Pseudoaneurysm
13. Thrombosis
14. Valve or structural cardiac damage

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GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to Sterilmed.

DIRECTIONS FOR USE

1. Remove the catheter from the sterile packaging using proper sterile technique.
2. Check the device for any signs of damage and do not use catheter if damaged in any way.
3. Manipulate the steering control knobs to verify proper flexion of the catheter tip and place them in the neutral position.
4. Place the sterile sheath over the interconnect tab so it is fully seated onto the handle.
5. Mate the catheter connector with the steering handle making certain that the connector is locked in place.
6. Place the sterile sheath over the catheter connector in a manner which will allow the distal portion to be outside the sterile field.
7. Connect the end of the catheter connector to the ultrasound system using the appropriate SwiftLink™ Catheter connector and verify that the imaging screen appears.
8. Use the hypertonic catheter connector to connect the 3D and *eco* Diagnostic Ultrasound Catheter to the mapping system (if used).
9. When the 3D and *eco* Diagnostic Ultrasound Catheter is used in conjunction with the CARTO® XP and CARTO® 3 mapping system, connect the catheter to the Patient Interface Unit (PIU) using a sterile extension cable (not provided by Sterilmed, Inc.).

   Caution: Quick connection or disconnection of the 3D and *eco* Diagnostic Ultrasound Catheters may result in catheter damage, potentially causing procedural delay.

10. Connect the reference patch, such as REFSTAR® with QWIKPATCH®, to the appropriate operating system.
11. For use of the 3D and *eco* Diagnostic Ultrasound Catheter in mapping procedures, an additional external reference patch (not provided by Sterilmed, Inc.) is required for location reference position purposes. Connect the external reference patch (not provided by Sterilmed, Inc.) following the appropriate mapping system documentation.

12. Create a vascular access with an appropriate introducer sheath.
13. Advance the catheter into the vasculature though the introducer sheath under fluoroscopic guidance.
14. Manipulate steering knobs to direct the transducer inside the cardiac anatomy.
15. Release the tension control knob and return the steering knobs to the neutral position prior to withdrawal of the catheter.

INTERFERING SUBSTANCES OR DEVICES

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

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

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 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.

Instructions for Use can be found at www.sterilmed.com.

Further questions or concerns by the health practitioner can be addressed directly by contacting your Sterilmed Customer Service Associate and/or the Sterilmed Quality Department at 1-888-541-0078.

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Explanation of Symbols

	**Single patient use only**
	**Consult instructions for use**
	**Use by date**
	**Batch code**
	**(OEM) Catalog number**
	**Sterilized using ethylene oxide**
	**Non-sterile**
	**Do not use if package is damaged**
RxOnly	**Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).**
	**Latex free**

NOTE: Please refer to the package and labeling for applicable symbols.