



Instructions for Use

Reprocessed SoundStar 3D Diagnostic Ultrasound Catheter

Reprocessed Device for Single Use

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

DEVICE DESCRIPTION

The Reprocessed SoundStar 3D Diagnostic Ultrasound Catheters (hereinafter Catheter) is an imaging catheter. The distal end of the catheter has an ultrasound transducer providing two-dimensional imaging and a three-dimensional location sensor providing location information to compatible CARTO EP Navigation Systems with ultrasound capability. A steering mechanism controls the image plane orientation by rotating both the catheter tip and the variable deflection.

The catheter is validated for use with Siemens and GE ultrasound systems and compatible CARTO EP Navigation Systems with ultrasound capability. Refer to the Original Manufacturer compatibility matrix insert for information about compatible ultrasound and CARTO systems.

Use the appropriate Swiftlink Catheter connector to connect the SoundStar catheter to the ultrasound system. Use the Hypertonic catheter connector to connect the SoundStar Catheter to the CARTO System.

For use of the SoundStar catheter in mapping procedures, an additional location reference device is required for location reference position purposes. Refer to the documentation provided with the CARTO system.

For ultrasound purposes, the SoundStar Catheter is identical to the Siemens AcuNav 10F Catheter. Refer to the AcuNav Ultrasound Catheter User Manual supplied by Siemens Ultrasound ICE option.

INDICATIONS FOR USE

The Reprocessed SoundStar 3D Diagnostic Ultrasound Catheter is 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.

The SoundStar 3D Diagnostic Ultrasound Catheter provides location information when used with the CARTO EP Navigation Systems.

CONTRAINDICATIONS FOR USE

Use of the catheter is contraindicated under conditions where the cardiac catheterization process would cause unacceptable risk to the patient. Contraindicated conditions include, but are not limited to, cases where vascular access is inadequate. Known contraindicated conditions include: sepsis, major coagulation abnormalities, presence of any intracardiac thrombus, presence of class IV angina or heart failure, deep vein thrombosis, and significant peripheral vascular disease. The catheter is not for fetal or pediatric use or for use in coronary vessels.

WARNINGS

- Diagnostic Ultrasound Catheters should be used only by or under the supervision of physicians well trained in cardiac catheterization including the placement and use of intracardiac imaging devices and the interpretation of the resulting ultrasound images. Physicians must be appropriately trained and familiar with the techniques for cardiac mapping procedures. All mapping procedures must be performed in a fully equipped electrophysiology laboratory.
- Do not use the connector if the connector appears damaged in any way. Using a damaged connector can result in patient or user injury.
- Do not immerse the connector in fluid of any kind. Moisture trapped between the connector and the catheter can damage the connector and/or the catheter, causing possible patient or user injury or death. Do not use the connector if the connector appears wet.
- Do not use the catheter if the packaging is open or damaged. Using a catheter that has been stored in an open or damaged package can result in patient or user injury.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Excessive bending or kinking of the catheter can damage internal wires and/or distal tip articulating capabilities.
- Completely read and understand the User Manual and your ultrasound system user documentation before you attempt to connect the catheter to any ultrasound system and operate the catheter. Failure to completely read and understand the catheter User Manual and your ultrasound system user documentation can result in patient injury.
- Prior to connecting and attempting to operate the catheter, read and understand all accessory operating instructions and these Instructions for Use.

ADVERSE REACTIONS

Adverse events related to cardiac catheterization include (but are not limited to):

- | | |
|---------------------------------|--------------------------------------|
| • Femoral Artery or Vein Injury | • Myocardial Infarction |
| • Thrombosis | • Valve or Structural Cardiac Damage |
| • Pseudoaneurysm | • Cardiac Tamponade |
| • Cardiac Perforation | • Pneumothorax |
| • Air Embolism | • Hemothorax |
| • Pulmonary Embolism | • Death |

DIRECTIONS

The package label is detachable and may be affixed to the medical record of the patient.

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. For this information refer to the OM AcuNav Ultrasound Catheter User Manual.

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

- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the catheter. Return the catheter to Innovative Health for reprocessing. **Do not attempt to resterilize.**
- Using proper sterile technique, remove the catheter from its package and place it in a sterile work area.
- Inspect the catheter for physical integrity and overall condition. Do not use the catheter if damage is observed. Return the catheter to Innovative Health.
- Rotate the steering knobs. The steering function should be smooth. The catheter tip should flex in a corresponding direction.

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NOTE: If the catheter 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 counter-clockwise direction.

- Position the steering knobs in the neutral position by aligning the marks on the steering knobs to the marks on the housing.
- Slip the sterile sheath over the catheter interconnect tab until the sheath is appropriately seated, leaving the CARTO connector uncovered.
- Inspect the SwiftLink Connector for damage.
- Lift the lever on the connector. Slip the connector on to the catheter interconnect tab until the connector is securely mated with the catheter handle. Push the lever down, locking the catheter to the connector.
- Carefully slip the sterile sheath over the connector. Cover enough of the connector cable such that it is outside the sterile field.
- Connect the other end of the connector to the ultrasound system. Ensure that the ultrasound image appears in the ultrasound system screen.
- For connection to CARTO systems, follow the operating instructions for the CARTO system.
- Create a vascular access with a catheter introducer (hemostatic) large enough to accommodate the catheter with heparinized saline.
- Before advancing or withdrawing the catheter, ensure that the steering knobs are in the neutral position and that the tension control knob is released.
- Advance the catheter into the vasculature through the catheter introducer. Fluoroscopy can aid in advancing the catheter into the heart.
- Do not use excessive force to advance or withdraw the catheter. Using excessive force can result in patient injury or death.
- 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 catheter.
 - If you encounter strong resistance during catheter navigation, discontinue the procedure.
 - Withdraw and redirect the catheter as needed.
- Manipulate the catheter carefully in order to avoid cardiac damage, entanglement, perforation or tamponade.
- When the catheter is inside the heart, use the steering knobs to direct the ultrasound transducer for visualization of the target cardiac anatomy.
- Before withdrawing the catheter, ensure that the steering knobs are in the neutral position and that the tension control knob is released.
- Withdraw the catheter from the patient.
- Upon use, please return the device per Innovative Health's instructions.

Interfering Substances or Devices

It is imperative that you are aware of the pacemaker needs of the patient. If use of the catheter interferes with the function of the patient's pacemaker, immediately discontinue use of the catheter.



Explanation of Symbols

R_X only

STERILE EO

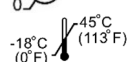
REF

SN

LOT



IPX8



Federal Law in the USA restricts this device to sale by or on the order of a physician

Sterilized by Ethylene Oxide Gas

Catalog Number

Serial Number

Lot Number

Use by Date

Do Not Reuse

Do Not Resterilize

Consult Instructions for Use

Do Not Use if Package is Damaged

Defibrillator-proof type CF applied part

Keep Product Dry

Keep Away from Sunlight

Manufacturer

Non-pyrogenic

Fragile

Liquid-tight (catheter shaft only)

Relative Humidity up to 90%, noncondensing

Temperature Limits

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide (EO) gas. 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 EO. The packaging may expose you to EO, 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. AcuNav and SwiftLink are trademarks of Siemens Medical Solutions.

Please refer to www.innovative-health.com for product warranty.



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