Instructions for Use
Reprocessed SoundStar *eco* 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 *eco* Diagnostic Ultrasound Catheter (hereinafter SoundStar) 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 3 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 only with certain ultrasound systems and the compatible CARTO 3 EP Navigation Systems with ultrasound capability. Please 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 multipin SoundStar *eco* cable to connect the SoundStar catheter to the CARTO System.

For use of the SoundStar catheter in mapping procedures, additional location reference patches are 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 Catheter. Refer to the AcuNav Ultrasound Catheter User Manual supplied by the Original Manufacturer.

The SoundStar *eco* 8F catheter will be able to generate ultrasound images within the Stereotaxis NIOBE Remote Magnetic System without impacting the location or image quality.

INDICATIONS FOR USE

The Reprocessed SoundStar *eco* 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.

The SoundStar *eco* Diagnostic Ultrasound Catheter provides location information when used with the compatible CARTO 3 EP Navigation Systems. Please refer to the 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

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 or 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 or 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.
- Quick connection or disconnection of the catheter may result in catheter damage, potentially causing procedural delay.

ADVERSE REACTIONS

A number of adverse reactions have been documented for electrophysiology procedures including:

Heart block, pulmonary vein stenosis, esophageal fistula and/or injury, stroke (cerebrovascular accident), other arrhythmias (outside diagnosis), life threatening arrhythmias, myocardial infarction, cardiac perforation, pericardial effusion, cardiac tamponade, thrombosis, embolism, pulmonary embolism, air embolism, valvular damage, phrenic nerve injury, vagal nerve injury, pericarditis, coronary artery stenosis, vessel perforation (peripheral and/or central), soft tissue injury, persistent atrial communication, device related infection, embolization of components, device entrapment, surgical intervention (additional), skin burns, and localized skin reaction.

The following complications associated with cardiac catheterization have also been reported in the literature:

Major bleed, hematoma, reaction to medications, allergic reaction, vascular access complication, damage to vasculature, implanted device interactions, renal artery stenosis, pneumothorax, ST segment changes, fluid overload, urinary catheter complications, hypotension, sepsis, wound infection, respiratory failure, heart injury, renal injury, heart failure, cardiac arrest and death.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

MRI SAFETY INFORMATION
The catheter is MR Unsafe. Keep it outside the MRI scanner room. The MRI safety of the catheter has not been assessed. Do not use the catheter near MRI equipment because movement or heating of the catheter may occur and an image on the display may become distorted.

DIRECTIONS
The package label is detachable and may be affixed to the medical record of the patient.
These Direction for Use relate only to the safe and effective use of the catheter in conjunction with CARTO 3 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. 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 entire catheter for physical integrity and overall condition. Do not use the catheter if damage is observed. Return the catheter to Innovative Health. Using a damaged catheter can result in patient injury.
- Rotate the steering knobs. The steering function should be smooth. The catheter tip should flex in a corresponding direction.
  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.
- Inspect the SwiftLink connector for damage.
- If using two narrow sterile sleeves, lift the lever on the SwiftLink connector. Slip the SwiftLink 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 SwiftLink connector.
- Carefully slip the sterile sleeve over the SwiftLink connector. Cover enough of the connector cable such that the connector is outside the sterile field.
- Connect the other end of the SwiftLink connector to the ultrasound system. Ensure that the ultrasound image appears in the ultrasound system screen.
- Using a second narrow sterile sleeve for the CARTO systems connector, slip the sterile sleeve over the catheter interconnect tab until the sleeve is appropriately seated.
- Slowly slip the SoundStar *eco* catheter extension cable onto the catheter interconnect tab until the connector is securely mated with the catheter handle.
- Carefully slip the sterile sleeve over the cable. Cover enough of the SoundStar cable such that it is outside of the sterile field.
- Connect the other end of the SoundStar cable to the CARTO system PIU.
- If using one wide sterile sleeve for both the SwiftLink connector and the CARTO System connector, slip the sterile sleeve over the SoundStar catheter interconnect tab until the sleeve is appropriately seated, leaving both the SwiftLink and the CARTO System connectors uncovered.
- Lift the lever on the SwiftLink connector. Slip the SwiftLink 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 SwiftLink connector.
- Slowly connect the SoundStar eco extension cable to the SoundStar catheter.
- Carefully slip the sterile sleeve over both cables. Cover enough of the cables such that the uncovered portions are outside of the sterile field.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Connect the other end of the cables to their respective systems.
- For connection to CARTO systems, follow the operating instructions for the CARTO system.
- Connect the location reference patches and ablation catheter, if required, following the CARTO system documentation.
- 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

Rx 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
REF	Catalog Number
SN	Serial Number
LOT	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
IPX8	Liquid-tight (catheter shaft only)
90 0 %	Relative Humidity up to 90%, noncondensing
-18°C (0°F) 45°C (113°F)	Temperature Limits
MR	MR Unsafe

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.

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