Instructions for Use
Reprocessed SoundStar Crystal 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 Crystal Ultrasound Catheter (hereinafter "catheter") is a 9F, sterile, reprocessed 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 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 Plus Catheter connector to connect the SoundStar Crystal catheter to the ultrasound system. Use the multipin SoundStar *eco* cable to connect the SoundStar Crystal catheter to the CARTO 3 System.

For use of the SoundStar Crystal catheter in mapping procedures, additional location reference patches are required for location reference position purposes. Refer to the documentation provided with the CARTO 3 system.

For ultrasound purposes, the SoundStar Crystal Catheter is identical to the Siemens Healthineers AcuNav Crystal Ultrasound Catheter. Refer to the AcuNav Ultrasound Catheter User Manual supplied by the Original Manufacturer.

INDICATIONS FOR USE

The Reprocessed SoundStar Crystal 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 Crystal 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.The catheter is not for use in coronary vessels or fetal tissue. Using this catheter in coronary vessels or fetal tissue can cause patient injury.

Additionally, it is recommended to follow the relevant procedural guidelines when using the catheter for imaging guidance.

WARNINGS

- Use of the catheter is only by or under the supervision of physicians well trained in cardiac catheterization. Preferably, physicians using the catheter have been trained in the placement and use of intracardiac imaging devices and in 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 SwiftLink connector if the connector appears damaged.
- Do not immerse the connector in fluid of any kind. Do not allow fluid or moisture into the junction between the SwiftLink connector and the catheter. Moisture trapped between the SwiftLink 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.

MRI SAFETY INFORMATION

The catheter is MR Unsafe. Keep the catheter 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 the image on the display may become distorted.

PRECAUTIONS

- Excessive bending or kinking of the catheter can damage internal wires and/or distal tip articulating capabilities.
- Completely read and understand the AcuNav Crystal Ultrasound Catheter User Manual, ultrasound system user documentation, and CARTO 3 System documentation before you attempt to connect the catheter to any ultrasound system and operate the catheter. Failure to completely read and understand these 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.
- When verifying the catheter is imaging prior to use with a patient, ensure the junction between the catheter and the connector is clean and dry. Do not allow saline solution to drip into the junction as image degradation or failure to initialize can occur.
- Do not operate the catheter in air. Operating the catheter in air can cause the catheter to overheat and lead to potential performance degradation.
- Ensure the catheter tip is straight and the catheter is aligned with the introducer sheath in a straight position before inserting the catheter into the introducer sheath. Inserting at an angle may damage the imaging capabilities of the catheter.

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

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related infection, embolization of components, device entrapment, surgical intervention (additional), skin burns, localized skin reaction, vascular injury, toxic reaction and endocarditis.

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.

DIRECTIONS

The package label is detachable and may be affixed to the medical record of the patient.
These Directions 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 Crystal catheter, or when used with the ultrasound system only. For this information refer to the OM AcuNav Crystal Ultrasound Catheter User Manual.

Note: The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Refer to your ultrasound system user documentation for information about catheter and connector compatibility with your ultrasound system.

Before you begin the preparation procedures, power on the ultrasound system and the CARTO 3 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. Inspect the extension cable and location reference patches for damage. Do not use the catheter if damage is observed. Return the catheter to Innovative Health. Using a damaged catheter can result in patient injury or death.
- Rotate the steering controls. 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 controls, 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 controls in the neutral position by aligning the ridge on the steering controls to the ridge on the catheter handle.
- Connect the SwiftLink connector to the ultrasound system. Freeze the display on the ultrasound system while preparing the connections.
- If using two narrow sterile sleeves for the SwiftLink connector and the Carto 3 System connector, sterile person: slide the sterile cover onto the catheter handle (plug). Non-sterile person: Fasten the unrolled end of the sleeve to the catheter extender. Place the rolled end of the sterile cover on the catheter base, keeping the catheter plug uncovered.
- Using sterile technique, attach the catheter to the connector. Sterile person: Hold the catheter by the catheter extender. Non-sterile person: Align the diamond on the connector with the triangles on the catheter as you hold the catheter handle, touching only the inside of the sterile cover. Without using force, insert the catheter plug into the connector socket. Rotate the locking ring until the diamond aligns with the lock symbol.

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- Carefully pull the sterile cover over the SwiftLink connector handle and cable.
- Connect the other end of the SwiftLink connector to the ultrasound system.
- Using a second narrow sterile sleeve for the CARTO 3 System connector, pull the sterile sleeve over the catheter interconnect tab until the sleeve is appropriately seated.
- Slowly connect the SoundStar *eco* cable to the catheter interconnect tab until the connector is securely mated with the catheter handle.
- Carefully pull the sterile sleeve over the SoundStar *eco* cable, keeping the uncovered portion outside the sterile field.
- If using one wide sterile sleeve for both the SwiftLink connector and the CARTO 3 System connector, slide the sterile sleeve onto the catheter handle and over the CARTO 3 System connector (sterile person). Non-sterile person: Fasten the unrolled end of the sleeve to the catheter extender. Place the rolled end of the sterile sleeve on the catheter handle keeping both the SwiftLink plug and the CARTO 3 System connector uncovered.
- Using sterile technique, attach the catheter to the connector. Sterile person: Hold the catheter by the catheter extender. Non-sterile person: Align the diamond on the connector with the triangles on the catheter as you hold the catheter handle, touching only the inside of the sterile cover. Without force, insert the catheter plug into the connector socket. Rotate the locking ring until the diamond aligns with the lock symbol.
- Slowly connect the SoundStar eco cable to the catheter interconnect tab until the connector is securely mated with the catheter handle.
- Carefully pull the sterile cover over both cables. Sufficiently cover the cables, keeping the uncovered portions outside the sterile field. The catheter is sterile.
- Verify an image displays on the ultrasound system screen. Using sterile technique, place the catheter tip in a container of sterile saline. Unfreeze the image and then select an exam package. Refer to your ultrasound system user documentation. Move the catheter in the container of saline. Confirm the on-screen image is moving.
- Freeze the display on the ultrasound system while preparing the patient.
- Connect the other end of the SoundStar eco Cable to the CARTO 3 System PIU.
- Connect the location reference patches and ablation catheter, if required, following the CARTO 3 system documentation.

To conduct an ultrasound exam using the catheter:

- Create a vascular access with a catheter introducer sheath large enough to accommodate the catheter.
- Before advancing or withdrawing the catheter, ensure that the steering controls are in the neutral position and that the tension control knob is released.
- Advance the catheter into the vasculature through the catheter introducer sheath. Fluoroscopy can aid in advancing the catheter into the heart.
- When the catheter is inside the heart, rotate the steering controls to reposition the catheter and direct the ultrasound transducer for visualization of the target cardiac anatomy. Note: You can also rotate the catheter tip by changing the position of the catheter handle.
- 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 controls 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.
    - Identify and address the cause of the resistance before resuming the procedure.
    - Withdraw and reinsert the catheter as needed.
    - Manipulate the catheter carefully in order to avoid cardiac damage, entanglement, perforation or tamponade.

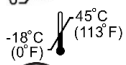
To end a procedure using the catheter:

- Before withdrawing the catheter, ensure that the steering controls are in the neutral position and that the tension control knob is released.
- Slowly and gently withdraw the catheter from the patient.
- Rotate the diamond on the locking ring on the connector toward the connector cable to the cable unlock symbol and then gently pull the catheter base away from the connector handle.
- 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 or implantable cardioverter defribillator (ICD) needs of the patient. If use of the catheter interferes with the function of the patient's implantable device, immediately discontinue use of the catheter.

Explanation of Symbols

	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
IPX8	Liquid-tight (catheter shaft only)
	Relative Humidity up to 90%, noncondensing
	Temperature Limits
	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.

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