Instructions for Use
Reprocessed AcuNav 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 AcuNav Crystal Ultrasound Catheter is a sterile, single-use device.

Catheter	AcuNav Crystal Ultrasound Catheter
Connector	SwiftLink Plus Catheter Connector

INDICATIONS FOR USE

The Reprocessed AcuNav Crystal Ultrasound Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients.

The reprocessed device is not indicated for use with pediatric patients.

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

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 or abnormalities.

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

- Diagnostic Ultrasound Catheters should be used 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 the interpretation of the resulting ultrasound images.
- Do not use the connector if the connector appears damaged in any way. Using a damaged connector can result in patient or user injury or death.
- Do not allow any fluid or moisture into the junction between the nonsterile connector and the sterile catheter. Moisture trapped between the connector and the catheter can damage the connector and/or the catheter, causing possible patient or user injury. Do not use the catheter if the junction between the catheter and 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 or death.
- Do not use the catheter if the catheter appears damaged in any way, Using a damaged catheter can result in patient or user injury or death.
- Do not use excessive force to advance or withdraw the catheter. Using excessive force can result in patient injury or death. Ensure that the two steering knobs are in the neutral position and the tension control knob is released before advancing or withdrawing the catheter. If you encounter strong resistance during catheter articulation, discontinue the procedure. Identify and address the cause of the resistance before resuming the procedure. Withdraw and redirect the catheter as needed.
- 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 or the catheter can damage internal wires and/or distal tip articulating capabilities.
- Completely read and understand the AcuNav Crystal Ultrasound Catheter 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.
- 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 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 in a straight position before inserting the catheter into the sheath. Inserting at an angle may damage the imaging capabilities of the catheter.

ADVERSE REACTIONS

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

- Femoral Artery or Vein Injury
- Thrombosis
- Pseudoaneurysm
- Cardiac Perforation
- Air Embolism
- Pulmonary Embolism
- Myocardial Infarction
- Valve or Structural Cardiac Damage
- Cardiac Tamponade
- Pericardial effusion
- Pneumothorax
- Hemothorax
- Arteriovenous (AV) Fistula
- Stroke
- Death

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

DIRECTIONS

The Directions for Use are intended as a review of catheter procedures. The Directions for Use do not include essential background and instructional information that is necessary for successful use of the catheter. Refer to the AcuNav Crystal Ultrasound Catheter User Manual and your ultrasound system user documentation for complete catheter use directions.

Note: Before you begin the preparation procedures, power on the ultrasound system.

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the package is opened or damaged, or if the package was opened and the catheter unused, do not use the catheter. Return the catheter to Innovative Health for reprocessing. **Do not attempt to resterilize.**
- If the on-screen image is unfrozen, freeze the image according to instructions provided in your ultrasound system user documentation.
- 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 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 is completely released. Release the tension by rotating the tension control completely in a counter-clockwise direction until the unlock symbol on the control aligns to the ridge on the handle.
- Position the steering controls in the neutral position by aligning the ridges on the steering controls to the ridge on the handle.
- Connect the system connector to the ultrasound system.
- Sterile person: Slide the sterile cover onto the catheter base. Non-sterile person: Fasten the cover to the catheter extender. The rolled end of the sterile cover should rest on the base of the catheter. Leave the catheter plug exposed (not covered).
- 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 base, touching only the inside of the sterile cover. Without using force, insert the catheter plug into connector socket. Rotate the locking ring until the diamond aligns with the lock symbol.
- Carefully pull the sterile cover over the connector handle and cable. The catheter is sterile; the connector is not sterile.
- Verify the ultrasound system displays the image screen. Using sterile technique, place the catheter tip in a container of sterile saline. Unfreeze the image and then select an exam preset. 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.

To conduct an ultrasound exam using the catheter:

- Create a vascular access with an 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 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 to visualize the target cardiac anatomy.
- Note: You can also rotate the catheter tip by changing the position of the catheter handle.

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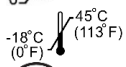
To end an ultrasound exam using the catheter:

- Before you withdraw the catheter, ensure that the steering controls are in the neutral position and that the tension control is released.
- Slowly and gently withdraw the catheter from the patient.
- Rotate the diamond on the locking ring to the 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-defibrillator (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 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.

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