



Instructions for Use Reprocessed AcuNav™ 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 AcuNav Diagnostic Ultrasound Catheter distal end has an ultrasound transducer providing 2-D imaging. A steering mechanism controls the image plane orientation through four-way articulation of the tip.

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| Catheter | <ul style="list-style-type: none">• AcuNav 8F Diagnostic Ultrasound Catheter, 90cm insertion length• AcuNav 10F Diagnostic Ultrasound Catheter, 90cm insertion length |
| Connector | SwiftLink Catheter Connector |

INDICATIONS FOR USE

The Reprocessed AcuNav Diagnostic Ultrasound Catheter is intended for intracardiac and intraluminal 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.

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.
- Do not use the connector if the connector appears damaged in any way. Using a damaged connector can result in patient or user injury.

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- Do not immerse the connector. 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.
- 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.

PRECAUTIONS

- Excessive bending or kinking of the catheter can damage internal wires and/or distal tip articulating capabilities.
- Completely read and understand the AcuNav Diagnostic 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 tip is straight and the catheter is aligned with the introducer in a straight position before inserting the catheter into the introducer. Inserting at an angle may damage the imaging capabilities.

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
- Pneumothorax
- Hemothorax
- Arteriovenous (AV) Fistula
- Stroke
- Death

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 ACUSON AcuNav Ultrasound Catheter User Manual and your ultrasound system user documentation for complete catheter use directions.

- 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.**
- Using proper sterile technique, remove the catheter from its package and place it in a sterile work area.

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














- 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 up to 160°.
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.
- Connect the system connector to the ultrasound system.
- Slip the sterile sheath over the catheter interconnect tab until the sheath is fully seated on to the catheter handle.
- Lift the lever on the connector. Slip the connector on to the catheter interconnect tab until the connector is fully 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 so the connector is out of the sterile field.
- Verify that the imaging screen appears.
- 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.
- When the catheter is inside the heart, use the steering knobs to direct the ultrasound transducer to visualize the target cardiac anatomy.
- Before you withdraw 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 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.

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Explanation of Symbols

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|  | 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 |
|  | Non-pyrogenic |
|  | Fragile |
|  | Air freight only in pressurized cargo |
|  | 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 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.

ACUSON, AcuNav, and SwiftLink are registered trademarks of Siemens Medical Solutions USA, Inc.

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