

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Imaging Catheters**  
**Manufactured by SterilMed, Inc.**  
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**Maple Grove, MN 55369**  
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**www.SterilMed.com**

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

## INDICATIONS FOR USE

These devices are reprocessed imaging catheters from various original equipment manufacturers (OEM). Imaging catheters are intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, and other devices in the heart. *These catheters are intended for use in the right heart only.*

Each OEM packaged an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

## DEVICE DESCRIPTION

The SterilMed reprocessed imaging catheter is intended to be used with a compatible ultrasound imaging system. These imaging catheters are an ultrasound tipped catheter device which is used directly in the vasculature and/or right heart for intravascular or intracardiac imaging. These devices consist of an ultrasonic phased-array imaging transducer which is used with an ultrasound imaging platform to generate the acoustic waves and process the information to display a two dimensional (90 degree vector) image to the physician.

Devices are reprocessed under contract with the health institution that previously used the device. Reprocessed imaging catheters have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were used once and shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed.

**This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.**

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## CONTRAINDICATIONS

1. This device is contraindicated in cases where vascular access is inadequate, or in the presence of conditions which create an unacceptable risk during cardiac catheterization, such as:
  - A. Sepsis
  - B. Major coagulation abnormalities
  - C. Presence of any right sided intracardiac thrombus
  - D. Presence of class IV angina or heart failure
  - E. Deep vein thrombosis
  - F. Significant peripheral vascular disease.
  
2. **Warning: This device is not intended for:**
  - A. Use in the coronary vessels
  - B. Insertion into the arterial system
  - C. Fetal uses.

## WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of these devices as well as cardiac imaging procedures.
2. Inspect the packaging, and the imaging catheter prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. The catheter is to be used with the Aspen™ or Sequoia™ ultrasound system.
4. The catheter is connected to the ultrasound system with the SwiftLink™ catheter connector.
5. The device should only be used by physicians trained in cardiac catheterization and, preferably, in the placement and use of intracardiac imaging devices and the interpretation of the resulting ultrasound images.
6. Do not attempt to connect and operate the device before completely reading and understanding the instructions for use and system manual.
7. Carefully manipulate the catheter in order to avoid cardiac damage, perforation or tamponade.
8. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
9. Discontinue the procedure and determine the cause of resistance before proceeding if strong resistance is encountered during articulation of the catheter.
10. Perforation of the vasculature or cardiac structures is an inherent risk of any catheter placement.
11. Do not immerse or allow any fluid or moisture between the catheter connector and ultrasound catheter; the device may not function properly.
12. Regular visual inspection of the catheter connector is recommended. Replace a damaged catheter connector immediately.

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13. Excessive bending or kinking of the catheter may damage internal wires and/or distal tip articulating capabilities.

## **POTENTIAL ADVERSE EVENTS**

Several major adverse events have been documented for cardiac catheterization procedures including the following:

1. Death
2. Stroke
3. Cardiac tamponade
4. Myocardial infarction
5. Pulmonary embolism
6. Stroke

In addition, the following complications have been reported in the literature:

1. Air embolism
2. AV fistula
3. Femoral artery or vein injury
4. Hemothorax
5. Perforation/Dissection
6. Pneumothorax
7. Pseudoaneurysm
8. Thrombosis
9. Valve or structural cardiac damage

## **DIRECTIONS FOR USE**

1. Remove the catheter from the sterile packaging using proper sterile technique.
2. Check the device for any signs of damage and do not use catheter if damaged in any way.
3. Manipulate the steering control knobs to verify proper flexion of the catheter tip and place them in the neutral position.
4. Place the sterile sheath over the interconnect tab so that it is fully seated onto the handle.
5. Mate the catheter connector with the steering handle making certain that the connector is locked in place.
6. Place the sterile sheath over the catheter connector in a manner that will allow the distal portion to be outside the sterile field.
7. Connect the end of the catheter connector to the ultrasound system and verify that the imaging screen appears.
8. Create a vascular access with an appropriate introducer sheath.
9. Advance the catheter into the vasculature through the introducer sheath under fluoroscopic guidance.

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10. Manipulate steering knobs to direct the transducer inside the cardiac anatomy.
11. Release the tension control knob and return the steering knobs to the neutral position prior to withdrawal of the catheter.

## **GENERAL INSTRUCTIONS AND INFORMATION**

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

## **METHODS TO TEST REPROCESSED DEVICES**

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

*\*Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO 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.*

*Instructions for Use can be found at [www.SterilMed.com](http://www.SterilMed.com). Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.*

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