

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Sealed Electrophysiology Diagnostic Catheters**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**Maple Grove, MN 55369**  
**Toll Free 1-888-541-0078/Fax 763-488-3350**  
**www.SterilMed.com**

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

## INDICATIONS FOR USE

These Reprocessed Sealed Electrophysiology Diagnostic Catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and pacing for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.

Each Original Equipment Manufacturer (OEM) provided 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

These closed lumen, sealed electrophysiology catheters generally have a high-torque shaft with a handle at the proximal end and may or may not be steerable. These catheters have an outer diameter ranging from 4F to 7F, a length ranging from 65cm to 120 cm, with 2-20 platinum, radiopaque tip electrodes and a variety of inter-electrode spacings and curve styles at the distal tip. The distal tip generally is deflectable, and the distal tip electrode allows the delivery of RF energy. Cables connect to the handle and interface between the catheter and an external stimulator and/or an electrophysiological recorder.

Devices are reprocessed under contract with the health institution that previously used the device. Reprocessed sealed electrophysiology diagnostic catheters have been cleaned, evaluated for continued electrical and mechanical integrity, and resterilized prior to use. These devices were used once and shipped from the 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.**

## CONTRAINDICATIONS

**STERILMED®**

*Reprocessing, Repair and Refurbishment  
of Medical Devices, Equipment & Instruments*

1. Caution should be exercised in patients with prosthetic valves.
2. Caution should be exercised in patients with recurrent sepsis or with hypercoagulable state should not be considered candidates for transvascular catheters.
3. Diagnostic catheters are not to be used as ablation catheters.

## **WARNINGS AND PRECAUTIONS**

1. Only physicians thoroughly trained in the techniques of angiography, electrophysiology studies and intracardiac recording and stimulation should use diagnostic catheters.
2. This catheter is not compatible with Magnetic Resonance Imaging (MRI).
3. Excessive x-ray and fluoroscopy exposure may result in radiation injury as well as increased risk for somatic and genetic effects, so steps should be taken during cardiac catheterization to minimize this exposure. Caution should therefore also be exercised for use of this catheter in pregnant women.
4. Store in a cool, dry place; the sterile packaging and catheter should be inspected for compromised integrity prior to use.
5. Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
6. Do not autoclave the catheter.
7. This catheter is not compatible with Magnetic Resonance Imaging (MRI).
8. Inappropriate electrical connections, e.g. into a wall socket, or use with unprotected male connectors may pose a serious risk of adverse health consequences or death.
9. Only use this device with equipment that complies with international safety standards.
10. Catheter advancement and placement should be done under fluoroscopic guidance.
11. Only physicians thoroughly trained in the techniques of angiography, electrophysiology studies and intracardiac recording and stimulation should use diagnostic catheters.
12. The risk of vascular perforation exists with any intracardiac catheter. Do not advance the catheter if resistance is encountered.

## **POTENTIAL ADVERSE EVENTS**

The following potential risks may be associated with diagnostic EP procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Death
2. Chest pain
3. Myocardial infarction
4. Hemorrhage

**STERILMED®**

*Reprocessing, Repair and Refurbishment  
of Medical Devices, Equipment & Instruments*

5. Vessel perforation
6. Hypotension
7. Cardiac irritability due to catheter placement
8. Arrhythmias
9. Cardiac or respiratory arrest
10. Catheter entrapment/entanglement
11. Damage to vessel intima or cardiac valvular structures
12. Embolus
13. Endocardial perforation causing cardiac tamponade
14. Hematoma/ecchymosis
15. Local and/or systemic infection
16. Pericardial effusion
17. Pericarditis/pleuritis
18. Pneumothorax
19. Allergic reaction
20. Thrombosis
21. Pseudoaneurysm
22. Stroke or cerebral vascular accident
23. Tamponade
24. Vasovagal reaction
25. X-ray exposure
26. Air embolism
27. Pulmonary edema
28. Sinus or AV node injury
29. Pulmonary embolism

## **SUGGESTED DIRECTIONS FOR USE**

1. Remove catheter from package and place in a sterile work area
2. Create a vascular access in a large central vessel (most catheters are placed via the femoral vein) using aseptic technique
3. Confirm that the catheter tip is in its neutral position before insertion
4. Insert the catheter and advance under fluoroscopic guidance until the tip is in the desired intracardiac position.
5. Adjust the radius of curvature by manipulating the thumb knob if appropriate.
6. Connect the interface connectors to the appropriate recording equipment; observe polarity of connector pins and cables
7. Record electrograms and perform other necessary diagnostic procedures.
8. Prior to removal of the catheter, confirm that the tip is in the neutral position.

## **GENERAL INSTRUCTIONS AND INFORMATION**

1. Verify product receipt and ensure that owner's name is appropriate on the label.
2. Inspect package and product and do not use the device if damage is noted or sterility appears to be compromised.

**STERILMED®**

*Reprocessing, Repair and Refurbishment  
of Medical Devices, Equipment & Instruments*

4. Use of this reprocessed device should be limited to physicians trained in the use of this catheter use as well as appropriate associated equipment. For specific details in the use of electrophysiology catheters and the techniques employed in an electrophysiology procedure the physician should be referred to the medical literature and rely on training and practical experience.
5. Individual physician technique and patient anatomy may require variations in the procedure.
6. The handling characteristics of this reprocessed device may be different from those of the original manufacturer's device.
7. SterilMed relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the cardiac diagnostic procedure.

If additional reprocessing of the product is desired, wipe the device with moist gauze to remove any visible blood or tissue, package, label as "biohazard" and ship product back to SterilMed per written procedure provided by 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, routine sterilization, and functional testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release.

*\*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.*

**STERILMED®**

Reprocessing, Repair and Refurbishment  
of Medical Devices, Equipment & Instruments