

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Electrophysiology Diagnostic Catheters
Manufactured by SterilMed, Inc.
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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 Reprocessed 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.

DEVICE DESCRIPTION

These closed lumen 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 8F, a length ranging from 60 cm to 160 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 allows the delivery of RF energy. Cables connect to the handle and interface between the catheter and an external stimulator and/or an electrophysiologic recorder.

Devices are reprocessed under contract with the health institution that previously used the device. Reprocessed Electrophysiology Diagnostic Catheters have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times devices have been 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. Caution should be exercised in patients with prosthetic valves.
2. Patients with recurrent sepsis or with hypercoagulable state should not be considered candidates for transvascular catheters.

Note: diagnostic catheters are not indicated for cardiac ablation.

WARNINGS AND PRECAUTIONS

1. Only use this device with equipment that complies with international safety standards.
2. This catheter is not compatible with Magnetic Resonance Imaging (MRI).
3. Do not autoclave the catheter.
4. Excessive x-ray and fluoroscopy exposure may result in radiation injury as well as increased risk for somatic and genetic effects; steps should be taken during cardiac catheterization to minimize this exposure. Caution should be exercised for use of this catheter in pregnant women.
5. Store in a cool, dry place; the sterile packaging and catheter should be inspected for compromised integrity prior to use.
6. Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
7. 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.
8. Catheter advancement and placement should be done under fluoroscopic guidance.
9. Diagnostic catheters should be used only by physicians thoroughly trained in the techniques of angiography, electrophysiology studies, and intracardiac recording and stimulation.
10. The risk of vascular perforation exists with any intracardiac catheter. Do not advance the catheter if resistance is encountered.
11. Diagnostic catheters are not indicated for cardiac ablation.
12. EP Technologies - Steerocath Catheter™ - The transbrachial approach is not recommended.
13. Cordis Webster Electrophysiology Catheter-Deflectable Tip - Always pull the thumb knob of the catheter back before insertion or withdrawal to assure that the catheter tip assumes its original shape.
14. Cordis Webster Electrophysiology Catheter-Deflectable Tip - Before use, make sure the small vent hole at the connector end of the handpiece is patent. Careful catheter manipulation must be performed in order to avoid vessel or cardiac damage.
15. Biosense Webster® Lasso® models – These devices should not be used in the ventricles. The retrograde approach may result in entrapment of the device in the left ventricle or valvular apparatus.

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

SUGGESTED AVAILABLE EQUIPMENT FOR EP LABORATORY

1. Resuscitation equipment
2. Introducer kits
3. Fluoroscopy equipment
4. Multichannel physiologic recorder (50 mm/sec to 200 mm/sec paper speeds) and connecting cables
5. Intracardiac electrode catheters

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6. Programmable stimulator

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. If appropriate, adjust the radius of curvature by manipulating the thumb knob.
6. Connect the interface connectors to the 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.
3. Remove catheter from package using appropriate sterile technique.
4. Use of this reprocessed device should be limited to physicians trained in the use of this catheter 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.
8. Device is sterilized using EtO.

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.

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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 back 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. 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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