

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**

**Reprocessed Reflexion™ 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

The Reflexion Spiral™ catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

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

## DEVICE DESCRIPTION

SterilMed reprocessed Reflexion EP diagnostic catheters consist of a shaft with a handle at the proximal end and are considered to be steerable. These catheters have an outer diameter of either 6 or 7F and are either 99 or 105cm in length, with 2 – 20 platinum, radiopaque tip electrodes and a variety of inter-electrode spacing's and curve styles at the distal tip. The distal tip is steerable and cables connect to the handle and interface between the catheter and an external stimulator and /or an electrophysiological recorder.

Reprocessed electrophysiology diagnostic catheters have been cleaned, evaluated for continued integrity, packaged and sterilized 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 only and must be returned for reprocessing prior to another use.**

## CONTRAINDICATIONS

1. This device is contraindicated for use as an ablation catheter.
2. Electrophysiology studies are contraindicated when acute factors make the findings unrepresentative of the patient's usual state (i.e. electrolyte abnormality, acute, ischemia, and drug toxicity).

3. This device is contraindicated when the patient's underlying cardiac disease makes it likely that induced arrhythmias will be extremely difficult to terminate and carry a high risk of death (i.e., acute myocardial infarction, unstable angina, hemodynamic instability).
4. This device is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch.

## **WARNINGS AND PRECAUTIONS**

1. Vascular and/or cardiac perforation may occur during use. If resistance is observed, **DO NOT FORCE CATHETER**. Withdraw catheter, correct difficulty, and reinsert.
2. This device should be used by or under the supervision of physicians thoroughly trained in the techniques of interventional electrophysiology studies.
3. To avoid potential damage to catheter or anatomical structures, always straighten deflectable shaft and open loop to largest diameter before insertion or withdrawal of catheter through a vascular introducer. Verify by using fluoroscopy and/or handle indicators.
4. To maintain integrity of loop, use straightener provided when inserting catheter into introducer.
5. Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
6. Read instructions for use prior to use of this device.
7. Use only St. Jude Medical® vascular introducers.
8. Do not deflect loop or shaft while distal tip portion is in vascular introducer.
9. Adjust the spiral loop to the fully closed position prior to actuating the shaft to the full 180° deflection.
10. Use with electrically isolated equipment.
11. This catheter is not compatible with Magnetic Resonance Imaging (MRI).
12. Do not alter this device.
13. Do not expose the catheter to organic solvents such as alcohol.
14. Inspect all components prior to use.
15. Not recommended for long term pacing.
16. This device should only be used with equipment that complies with international safety standards.
17. Proper electrical functioning of this device requires that the catheter be handled with care. Stretching and/or kinking while removing device from packaging may result in damage.
18. For specific details in the use of electrophysiology catheters and the techniques employed in an electrophysiology study, the physician should be referred to the medical literature and rely on training and practical experience.
19. Store in a cool, dry place; the sterile packaging and catheter should be inspected for compromised integrity prior to use.
20. Catheter advancement and placement should be done under fluoroscopic guidance.

21. 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.
22. 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.
23. Do not autoclave the catheter.

## **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
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. Use a St. Jude Medical introducer with hemostatic valve to insert the Reflexion Spiral catheter into the vascular system.
4. Prior to insertion in patient, become thoroughly familiar with the operation of the handle controls.
  - To manipulate the distal shaft of the catheter, adjust the shaft actuator mechanism on either side of the handle.
  - To adjust the spiral loop, adjust the loop actuator mechanism anywhere between a fully closed loop to a fully open loop.
5. Prior to insertion, deflect the catheter shaft to straight position and fully open the catheter spiral loop.
6. Advance the tip straightener over the distal tip of the catheter prior to insertion into the hemostasis introducer.
7. Insert the tip straightener fully into the hemostasis valve before advancing catheter into introducer.
8. Never manipulate the spiral loop or deflectable section of the shaft while within the introducer.
9. Insert the catheter and advance under fluoroscopic guidance until the tip is in the desired intracardiac position.
10. Connect the interface connectors to the recording equipment; observe polarity of connector pins and cables.
11. Record electrograms and perform other necessary diagnostic procedures.
12. Prior to removal, deflect catheter shaft to straight position and fully open the catheter spiral loop.

## **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 ethylene oxide (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.

## **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.*

*St. Jude Medical® is a registered trademark and Reflexion Spiral™ is a trademark of St. Jude Medical Corporation or an affiliate.*