

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Electrophysiology Catheter Cables
Manufactured by SterilMed, Inc.
11400 73rd 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

Reprocessed electrophysiology catheter cables are indicated for use during electrophysiology studies with an appropriate electrode catheter.

The 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

Electrophysiology catheter cables are designed as electrode cables with a multi-pin connector on the distal end and the appropriate number of tails on the proximal end. The cables serve two different purposes. They either serve as an extension between an EP catheter and equipment out of reach or they interface an EP catheter with the appropriate external stimulation of recording equipment.

Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

Reprocessed EP Cables 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 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.

STERILMED®

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

CONTRAINDICATIONS

There are no known contraindications at this time.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of EP Cables.
2. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. The electrophysiology catheter cable should only be connected to the appropriate electrode catheter and equipment. Failure to do this may result in patient, operator or equipment injury.
4. Extreme caution should be used when employing components with unprotected male connectors during device set-up.
5. All amplifiers, pacing equipment and ECG equipment must be isolated or patient injury or death may occur. The maximum leakage current from any connected device to the patient must not exceed 10 microamps.

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.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely on training and practical experience.

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.



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

** 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.

STERILMED®

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