

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Ablation 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

Ablation cables are indicated for use with the appropriate ablation catheter during cardiac ablation procedures.

The OEM packaged an Instruction for Use (IFU) document with the original device. The Health care facility that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

Reprocessed ablation cables have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from a health care facility, reprocessed, and returned to a health care facility for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor 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

There are no known contraindications.

WARNINGS AND PRECAUTIONS

SterilMed ablation cables are reprocessed for single use only and must be returned for reprocessing prior to another use.

1. It is necessary to have adequate training and a thorough understanding associated

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- with the use and applications of ablation cables.
2. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
 3. Use caution when using components with unprotected male pin connectors during device set-up in order to avoid injury to operator or patient.
 4. Ensure the ablation cable is connected to the proper power source and device to avoid serious injury to operator and patient. Refer to the specific radiofrequency (RF) generator manual for operating instructions.
 5. The leakage and end-to-end resistance must be tested prior to use. Refer to original manufacturer's instructions-for-use for specific testing requirements.
 6. All ECG equipment, pacing equipment, and amplifiers must be isolated or patient injury or death could occur. Noise induction into the cable can be caused by the use of other electrical equipment.
 7. All hospital protocols and electromechanical device guidelines must be followed where line powered equipment is powered near the patient. Electrical currents could lead to fatal arrhythmias.
 8. The ablation cables should not be changed or altered in any way.
 9. The ablation cables should not be immersed or exposed to strong solvents.
 10. The ablation cable should be checked for compatibility with the ablation catheter prior to use.
 11. The ablation cable should be stored in a dark, cool, and dry place.

GENERAL INSTRUCTIONS AND INFORMATION

Inspect package and product for signs of damage or sterility compromise.

Open product using appropriate sterile technique when needed for use.

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, consult instructions for use included with the original product. If the original instructions are not available, contact the original device manufacturer for instructions or training on proper procedural technique for this device.

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 are comprised of materials known to be biocompatible. 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.

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** 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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