

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Harmonic Scalpels
Manufactured by SterilMed, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed harmonic scalpels from various original equipment manufacturers (OEM.) These harmonic scalpels are intended to be used for cutting soft tissue and providing hemostasis when control of bleeding and minimal thermal injury is desired.

The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecologic, exposure to orthopedic structures (such as spine and joint space) and other endoscopic procedures.

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. The OEM supplied IFU, associated documents, and training materials supercede all other IFU's that may have been produced with respect to this product.

DEVICE DESCRIPTION

Harmonic scalpels are part of an ultrasonic system and are intended to be used in soft tissue surgery for simultaneous cutting and hemostasis. The system consists of a generator, handle, scalpel blade, and may include a torque wrench as an accessory piece (the torque wrench is designed to ensure that the device is properly secured to the handpiece).

The scalpel blade is vibrated longitudinally. The ultrasonic activation of the scalpel blade by the generator reduces friction of the cutting action and generates heat as the mechanical energy of the moving blade is converted to thermal energy in the tissue. The highly localized heat creates a narrow zone of thermal coagulation that reduces or eliminates bleeding.

Harmonic scalpels can be manufactured using aluminum with a nickel chrome alloy edge or a titanium alloy (with or without a coating). These scalpels are available in a variety of lengths, outer circumferences, angles, and sharpness.

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Note: Because the wrench may be missed during the collection process, SterilMed has designed and manufactured a replacement wrench that performs to the same specifications as the original manufacturer's wrench for the ACE36E and ACE23E models. The slight change in appearance does not reflect any change in functionality as compared to a wrench supplied by the OEM. This wrench is not to be used with other harmonic scalpel models.

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 harmonic scalpels have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices are shipped from a health care facility, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times the 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.

CONTRAINDICATIONS

1. The harmonic scalpel is not indicated for contraceptive tubal occlusion/ligation
2. The harmonic scalpel is not indicated for incising bone.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of harmonic scalpels.
2. Inspect the device packaging prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Equipment may vary with each manufacturer. Verify compatibility of all equipment and accessories prior to use.
4. During prolonged use the instrument blades may become hot.
5. Use of these products may require surgical setting adjustments. Ensure appropriate system settings are used with each brand of scalpel.
6. Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips or other instruments while the instrument is activated may result in cracked or broken blades which may be identified by generator solid tone or instrument error.
7. Do not introduce or withdraw the instrument with the jaws open through a trocar sleeve as this may damage the instrument.
8. Care should be taken not to apply pressure between the instrument blade and tissue pad without having tissue between them. This can result in possible damage to the instrument. Both conditions may cause a system failure signaled by a continuous beep when the hand control buttons or foot pedals are depressed.

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9. The SterilMed torque wrench is to be used with the ACE36E and the ACE 23E device models only.
10. Keep the clamp arm open when backcutting or while the blade is active without tissue between the blade and tissue pad to avoid damage to the tissue pad.
11. The entire exposed blade tip is active and will cut/coagulate tissue when the instrument blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissues.
12. Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure.
13. Take care to avoid injury from the blade tip while attaching or removing the blade.
14. Use of harmonic scalpels can create mist, smoke, spray, or splatter of blood and tissue as do electrosurgical, laser, and other powered instruments. Use appropriate precautions.
15. Avoid contact with the patient, tissue, drapes, surgical gowns, or flammable materials in case of accidental activation when blade is not in use.
16. Consult literature relative to techniques, complications, and hazards prior to performing any procedure.
17. Minimally invasive surgery should be performed only by persons having adequate training and familiarity with minimally invasive techniques.
18. Audible high-pitch noise from the blade or handpiece indicates the blade or handpiece is not operating correctly. This may be an indication the handpiece is beyond its useful life or the blade may not be attached correctly. This may result in high shaft temperatures and user or patient injury.
19. Blood and tissue buildup between blade and shaft may result in higher temperatures at the distal end of the shaft. Remove visible tissue build at the distal end of the shaft.
20. Prolonged activation against solid surfaces, including bone, may result in blade heating and malfunction.
21. Adjust MIN power level to 2 or lower for optimal hemostasis on vessels greater than 3mm.
22. Examine tissue for hemostasis after instrument removal. Use appropriate techniques should hemostasis not be achieved.
23. Use caution when applying these instruments on solid organs. These devices have limited ability to grasp large portions of solid organs and achieve hemostasis. Hemostasis with large solid organs is unpredictable and may require further means of coagulation.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that the owner's name is appropriate on the label. 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, refer to the medical literature and appropriate training and 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 for patient contact materials following reprocessing. 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 (EO). Even though the product is processed in compliance with all applicable laws and regulations relating to EO 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 at 1-888-541-0078.

