

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed RF Arthroscopy Probes
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 devices are reprocessed electrosurgical cutting and coagulation devices (RF Arthroscopy Probes) from various original equipment manufacturers (OEM). These devices are designed for general surgical use, including orthopedic and arthroscopic applications of resection, ablation, excision of soft tissue, hemostasis of blood vessels, and coagulation of soft tissue. Arthroscopic surgery may include the following:

1. Elbow
2. Knee
3. Shoulder
4. Wrist
5. Ankle

Each 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

Arthroscopic probes are used with an electrosurgical system to deliver radio frequency energy for patient treatment. They use either monopolar or bipolar current. The probe tip configuration ranges from single to multiple electrodes incorporating straight, screen, loop, or sheet shaped electrodes and can be straight or angled up to 90 degrees.

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 arthroscopic probes have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and

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returned 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

1. Non-arthroscopic surgical procedure and in procedures not using a conductive solution as an irrigant such as saline or Ringer's Lactate.
2. Patients for whom an arthroscopic procedure is contraindicated for any reason.
3. Do not use on patients with heart pacemakers or other electronic device implants.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of arthroscopic probes. *Safe and effective electrosurgery is dependant on equipment design as well as factors under control of the user.*
2. Inspect the packaging and the arthroscopic probe prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Place probe in a clean, dry, nonconductive and highly visible area away from the patient when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes or other flammable materials may cause fire.
4. Equipment may vary with each manufacturer. Verify appropriate compatibility of all equipment and accessories prior to use.
5. Inadvertent activation or movement of the electrode outside the field of vision may result in patient injury.
6. As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury could occur.
7. Do not touch the electrode tip when power is being applied.
8. Do not insert or withdraw the electrode while power is being applied.
9. Use only conductive irrigant solution (e.g., saline or Ringer's lactate). Do not use non-conductive irrigants (e.g., sterile water, air, gas, glycine, etc.)
10. Ensure that the probe (which houses the electrodes) is fully seated in the handpiece prior to use.
11. Maintain the lowest power setting necessary to achieve the desired end effect.
12. Ensure the probe tip is completely surrounded by irrigant solution during use.
13. The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
14. Carefully insert and withdraw electrodes to avoid possible damage to the devices and/or injury to the patient or surgical personnel.
15. Avoid bubble accumulation in the joint space during use. The accumulation of bubbles around the working tip of the electrode will diminish performance and may produce overheating sufficient to damage adjacent structures.

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16. Use arthroscopic guidance to ensure that the electrode tip is completely surrounded by conductive irrigant solution during use.
17. Do not exceed a 30° angle with the plane of the shaft when bending the flexible electrode.
18. Do not change the flexible electrode shape more than three times at the same point on the shaft. More than three angle modifications can result in electrode fracture.
19. Use of instruments to bend the flexible electrodes can cause damage to the electrode. Bend electrode with fingers only.
20. Avoid touching the ceramic and coil tip of the electrode with your fingers or instruments.
21. Attempts to bend non-flexible electrodes can result in electrode fracture.
22. Do not allow fluid to come into contact where the cable connects to the probe.
23. Avoid unnecessary and prolonged activation between tissue applications as unintended injury may result.

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with use of RF arthroscopic probes. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Swelling
2. Burns

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 upon 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.

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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 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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