

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Tourniquet Cuffs
Manufactured by SterilMed, Inc.
11400 73rd Avenue North
Maple Grove, MN 55369
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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 tourniquet cuffs from various original equipment manufacturers (OEM). Tourniquet cuffs are designed for use in surgical procedures where temporary occlusion of blood flow is required.

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

Tourniquet cuffs are either single or dual bladder inflatable cuffs. Tourniquet cuffs can supply enough pressure to restrict blood flow and create a bloodless surgical field. Tourniquet cuffs are offered in a wide variety of sizes in order to accommodate a wide range of limbs.

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 tourniquet cuffs have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned to the owner 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. If the device is to be used again, it must undergo reprocessing prior to use.

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CONTRAINDICATIONS

1. Severe crushing injuries
2. Open fractures of the leg
3. Skin grafts
4. Diabetes mellitus
5. Elbow surgery
6. Severe hypertension
7. Compromised vascular circulation
8. Lengthy hand reconstruction
9. Sickle cell of clotting disease

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of tourniquet cuffs.
2. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Minimum pressure and application time should be used in each procedure.
4. The pressure should be watched closely throughout the procedure to ensure the pressure is maintained.
5. Avoid equipment that can puncture the cuff and result in a lack of pressure.
6. The cuff should be deflated rapidly.
7. Personnel should be made aware of the complications and prevention strategies.

POTENTIAL ADVERSE EVENTS

1. Motor Paralysis
2. Stiffness in limb
3. Weakness in limb
4. Pain in the limb
5. Loss of sense of touch and pressure
6. Skin discoloration
7. Reactive hyperemia

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.

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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.

METHODS TO TEST REPROCESSED DEVICES

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 reruse.

** 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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