

Reprocessed by



Instructions for Use Reprocessed Tourniquet Cuffs


Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**

Explanation of Icons


 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

REF Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Tourniquet Cuffs

Tourniquet Cuff Description

Tourniquet cuffs are single- or dual-bladder inflatable cuffs connected to a tourniquet system via a hose assembly. When wrapped around a limb and inflated, tourniquet cuffs apply an adequate amount of pressure on the arterial blood flow in a limb to create a bloodless surgical field. Tourniquet cuffs are available in a variety of sizes to accommodate a wide range of limb circumferences.

Indications for Use

Reprocessed tourniquet cuffs are indicated for use in patients who require surgery of the extremities with an expected duration of less than 90 minutes when temporary exsanguination of a limb is desired.

Contraindications for Use

Reprocessed tourniquets are contraindicated for the following:

- Open fracture of the leg
- Prolonged hand reconstruction surgery
- Severe crushing injuries
- Elbow surgery with concomitant swelling
- Severe hypertension
- Skin grafts
- Compromised vascular circulation
- Diabetes mellitus

Note: Sickle cell disease is a relative contra-indication. Patients with hemoglobin S should be closely monitored using blood pO₂ and pH testing when a tourniquet is in use.

Warnings

- These devices are only intended for use by individuals with adequate training and familiarity with tourniquet use. For further information about techniques, complications and hazards, consult the medical literature.
- It is important that the tourniquet cuff be applied at the proper location with adequate pressure for the appropriate amount of time.
- Follow established tourniquet use procedures.
- Placing the tourniquet over the peroneal or ulnar nerve can cause nerve damage or paralysis.
- To avoid damage to the underlying tissue from shearing forces, do not rotate the tourniquet cuff when adjusting its placement.
- Avoid needles, towel clips, leg holders and other equipment that can puncture or otherwise damage the cuff.
- Never use the tourniquet cuff to control distention medium gases.
- To prevent intraoperative bleeding avoid the following:
 - underpressurizing the cuff
 - insufficient exsanguination
 - excessively slow inflation and deflation
 - poor tourniquet pressure

Precautions

- When a tourniquet cuff is used, patients with sickle-cell disease or trait may experience severe postoperative pain and worsening of their overall condition.
- When using an elastic bandage for exsanguination, leave approximately 1 inch (2.5 cm) of uncovered skin between bandage and tourniquet cuff.
- Avoid using an elastic bandage:
 - In the presence of infections or painful fractures.
 - Post cast removal.
 - When this could result in the distribution of bacteria, exotoxins, malignant cells and thrombi to the general circulation.
 - Instead, elevate the limb for 3 to 5 minutes.
- Preoperative skin preparations should not be applied to the area under the tourniquet cuff.
- Inflate the tourniquet cuffs quickly for the simultaneous occlusion of arteries and veins as well as the prevention of blood return into the limb.
- Deflate rapidly to prevent enlarged or swollen areas.
- Avoid heat from light and other sources.
- Avoid prolonged ischemia and prolonged tourniquet time to prevent serious conditions like tourniquet paralysis and

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pooling of blood in the edemic limb.

- Do not reapply a tourniquet cuff to a limb with no or insufficient exsanguination.
- If a tourniquet cuff must be reapplied, ensure that it is fully deflated first.
- Remove tourniquet cuff from limb immediately after final deflation.
- When applying the cuff, ensure that it is smooth and unwrinkled to prevent possible blistering or tissue damage.
- Apply pressure dressings and elevate the limb as necessary to protect the operative site from blood resurgence when cuff pressure is released.
- Immediately following final tourniquet deflation, remove the cuff and all underlying padding to avoid slowing of venous return and resulting blood pooling at the operative site.
- Users should be familiar with the inflation/deflation sequence and use care when using a dual-bladdered cuff or two single-bladdered cuffs together. Release of the incorrect bladder or cuff could cause severe injury or death.
- When using infiltration anesthesia, published literature suggests keeping the cuff inflated for at least 15 minutes after injection of the anesthetic agent to ensure that the agent has been adequately absorbed by limb tissues. If the procedure itself is less than 15 minutes long, rapid deflation and re-inflation of the cuff may keep the agent from being prematurely released and allow its absorption into surrounding tissue.

Adverse Reactions

- Tourniquet pain throughout the limb
- Limb stiffness
- Limb weakness
- Reactive hyperemia
- Skin discoloration
- Motor paralysis
- Loss of sense of touch, pressure and other stimuli response.

Directions for Use

1. Before beginning the procedure, verify compatibility of all devices and accessories.
2. Inspect the device and package before opening. The contents of the package are sterile if the packaging has not been compromised.
3. Do not attempt to resterilize.
4. If the package is damaged or if it was opened and the device was not used, return the device and packaging to Ascent Healthcare Solutions.
5. Remove the device from the package and place it in a sterile work area using aseptic technique.
6. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for surgery.
7. Prior to surgery, select the proper sized tourniquet cuff by measuring the circumference of the patient's limb. This will avoid problems caused by a tourniquet cuff that is too small or too large.
8. Wrap the cuff around the patient's limb, aiming for a snug and secure fit without wrinkles.
9. Position the tubing so that it cannot be kinked, which could cause airflow interruption.
10. Secure the cuff fasteners to ensure that the cuff stays in place during the procedure.
11. Connect the tourniquet cuff to the tourniquet controller. Refer to the tourniquet controller manual for usage instructions.
12. Prepare and drape the limb for surgery.
13. Avoid liquid skin preparations that can flow under the tourniquet cuff.
14. Verify that the limb tissue is viable prior to exsanguinating the limb and inflating the tourniquet.
15. Use an elastic bandage and follow a suitable protocol to exsanguinate the limb.
16. Follow a suitable tourniquet application protocol.
17. Use the minimum effective pressure setting.
18. Follow established surgical guidelines to determine inflation, duration of procedure, pressure setting, timing of inflation and timing of release.
19. Follow accepted surgical guidelines for cuff removal.
20. Follow accepted surgical guidelines for anesthetic agent usage.
21. Device is intended for multiple uses during a single patient procedure. Return to Ascent Healthcare Solutions for reprocessing or discard after use.

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Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then 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.