Reprocessed by

ReNu Medical, Inc.

Instructions for Use
Reprocessed Tourniquets

Reprocessed Device for Single Use

Symbol Legend:

	Date of Reprocessing		Reprocessor/Manufacturer
	Do Not Reuse		Not made with natural rubber Latex
	Consult instructions for use		Fragile, handle with care
	Do not use if package is damaged		Keep dry
	Non-Sterile – High Level Disinfection	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution See Instructions for use	OEM	Original Equipment Manufacturer Catalog#
REF	ReNu Medical Catalog#	LOT	ReNu Medical Sales Order
CID	Customer ID#, if none specified; ReNu Medical Catalog#	QTY	Qty of Devices included in Pkg/Cs

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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.
- DO NOT use the limb protection sleeve more than once. Failure to comply may result in patient injury.
- 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:
    - under pressurizing the cuff
    - insufficient exsanguination
    - excessively slow inflation and deflation
    - poor tourniquet pressure

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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 Reprocessed Tourniquet Cuffs 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.
- Always route the tourniquet cuff and fill line tubing away from traffic areas to avoid tube damage and a tripping hazard. Failure to comply may result in patient and/or healthcare staff injury.
- 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

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- Vascular complications
- Ischemia
- Deep vein thrombosis
- Venous emboli or thromboembolism
- Blood vessel trauma
- Reperfusion problems and arterial occlusion
- Loss of sense of touch, pressure and other stimuli response
- Death, specific to the Bier Block procedure.

Directions for Use

1. Before beginning the procedure, verify compatibility of all devices and accessories.
2. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted.
3. Prior to surgery, select the proper sized tourniquet cuff and limb protection sleeve by measuring the circumference of the patient's limb. This will avoid problems caused by a tourniquet cuff and limb protection sleeve that is too small or too large.
4. Prior to application, wrap the area with a limb protection sleeve, avoiding any wrinkles in the sleeve.
5. Wrap the cuff around the patient's limb, aiming for a snug and secure fit without wrinkles.
6. Position the tubing so that it cannot be kinked, which could cause airflow interruption.
7. Secure the cuff fasteners to ensure that the cuff stays in place during the procedure.
8. Connect the tourniquet cuff to the tourniquet controller. Refer to the tourniquet controller manual for usage instructions.
9. Prepare and drape the limb for surgery.
10. Avoid liquid skin preparations that can flow under the tourniquet cuff.
11. Verify that the limb tissue is viable prior to exsanguinating the limb and inflating the tourniquet.
12. Use an elastic bandage and follow a suitable protocol to exsanguinate the limb.
13. Follow a suitable tourniquet application protocol.
14. Use the minimum effective pressure setting.
15. Follow established surgical guidelines to determine inflation, duration of procedure, pressure setting, timing of inflation and timing of release.
16. Follow accepted surgical guidelines for cuff removal.
17. Follow accepted surgical guidelines for anesthetic agent usage.
18. Device is intended for multiple uses during a single patient procedure.
19. Place used tourniquets in the reprocessing collection container to be returned to ReNu Medical.

The names of the actual Original Equipment Manufacturer and products mentioned within this document and any information listed on the label is provided as identification prior to High-Level Disinfection reprocessing and may contain trademarks of unrelated third parties who may not represent the device after reprocessing.

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