Reprocessed by

Sustainability Solutions

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

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Product Code
2	Do Not Reuse
	See Instructions For Use

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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 pO_2 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:
  - 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

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 Stryker Sustainability 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 Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
7. 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.
8. Prior to application, wrap the area with a limb protection sleeve, avoiding any wrinkles in the sleeve.
9. Wrap the cuff around the patient’s limb, aiming for a snug and secure fit without wrinkles.
10. Position the tubing so that it cannot be kinked, which could cause airflow interruption.
11. Secure the cuff fasteners to ensure that the cuff stays in place during the procedure.
12. Connect the tourniquet cuff to the tourniquet controller. Refer to the tourniquet controller manual for usage instructions.
13. Prepare and drape the limb for surgery.
14. Avoid liquid skin preparations that can flow under the tourniquet cuff.
15. Verify that the limb tissue is viable prior to exsanguinating the limb and inflating the tourniquet.
16. Use an elastic bandage and follow a suitable protocol to exsanguinate the limb.
17. Follow a suitable tourniquet application protocol.
18. Use the minimum effective pressure setting.
19. Follow established surgical guidelines to determine inflation, duration of procedure, pressure setting, timing of inflation and timing of release.
20. Follow accepted surgical guidelines for cuff removal.
21. Follow accepted surgical guidelines for anesthetic agent usage.
22. Device is intended for multiple uses during a single patient procedure. Return to Stryker Sustainability Solutions for reprocessing or discard after use.

Warranty
Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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.

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