ENGLISH

Delfi

Personalized Tourniquet Systems

STERILE DISPOSABLE
CONTOUR TOURNIQUET CUFF

THIS TOURNIQUET CUFF IS A SINGLE USE DEVICE AND MUST NOT BE REUSED

IMPORTANT! **READ THIS INFORMATION BEFORE USING CUFF AND SAVE FOR FUTURE REFERENCE**

delfimedical.com/ifu

Pat.: www.delfimedical.com/patents

REF

Dual Port Contour Tourniquet Cuff	Single Port Contour Tourniquet Cuff
60-7970-103-00	60-7975-103-00
60-7970-104-00	60-7975-104-00
60-7970-105-00	60-7975-105-00
60-7970-106-00	60-7975-106-00
60-7970-107-00	60-7975-107-00

PRODUCT DESCRIPTION

This cuff is a sterile, single use product. The cuff is equipped with an integral fill line. Dispose of sterile single use cuffs in appropriate medical waste disposal after use.

The cuff is inflated by connecting it, via a hose assembly with 1/8" flow Positive Locking Connectors (PLC), to a tourniquet system which has 1/8" flow Positive Locking Connectors. Refer to your tourniquet operator's manual for proper use of your system.

The cuffs are available in a selection of lengths to facilitate proper size selection.

INDICATIONS AND USAGE

Tourniquets are intended to be used by qualified medical professionals to exert enough pressure on the arterial blood flow in a limb to produce a bloodless operating field. Tourniquets are generally used for operations lasting less than 90 minutes.

A sterile tourniquet cuff is indicated when reduction in the risk of infection from tourniquet cuff application is required.

Tourniquets have been found useful in surgical procedures involving the extremities, such as:

Reduction of certain fractures
Kirschner wire removal
Tumor and cyst excision
Knee joint replacements
Arthroscopy of certain joints
Replacement of finger joints
Bone grafts
Amputations
Subcutaneous fasciotomy
Nerve injuries
Tendon repair
Total wrist joint replacement

CONTRAINDICATIONS

Refer to the medical literature for possible contra-indications to tourniquet use. A partial list is provided below; however, in every case the final decision to use a tourniquet rests with the attending physician.

- Open fractures of the limb.
- Post-traumatic lengthy hand reconstruction.
- Severe crushing injuries.
- Elbow surgery (where there is concomitant excess swelling).
- Severe hypertension.
- Skin grafts in which all bleeding points must be readily identified and addressed.

- Compromised vascular circulation, e.g., peripheral artery disease.
- Diabetes mellitus.
- Secondary or delayed procedures after immobilization.

The presence of sickle-cell disease is a relative contraindication. (See PRECAUTIONS)

WARNINGS

- This product is intended for single use only. The hook and loop fasteners and inflatable portions of the device have not been designed to permit reuse or reprocessing. It is essential to dispose of this device after use. Reuse or reprocessing of this product could result in one or more of the following events: loss of cuff pressure; release of the cuff from around the patient's limb; movement of the cuff on the patient's limb; excessive leakage of cuff pressure; or pinching of tissue under the cuff. Some of these events could cause catastrophic injury, including death, to the patient by releasing blood into the surgical site or by releasing anesthetic into other parts of the body.

- Maximum cuff pressure must not exceed 475mmHg.

- The cuff should only be connected to a tourniquet instrument known to be in operable condition. Refer to your tourniquet instrument operator's manual for information on testing and maintenance of your tourniquet instrument.

- The tourniquet cuff must be applied at the proper location on the limb, for an appropriate period of time, and within the appropriate pressure range. (See UTILIZATION) Application of the tourniquet cuff over the area of the peroneal nerve (the knee or ankle), or over the area of the ulnar nerve (the elbow) may produce nerve compression on bone/bone impingement resulting in nerve damage or paralysis.

- Do not readjust an already positioned tourniquet cuff by rotation. Rotation produces shearing forces which may damage the underlying tissues. Never puncture the cuff. Therefore, towel clips used near the cuff must be handled with care. Excessive compression by a leg holder may damage the cuff.

- Select the proper tourniquet cuff size. (See UTILIZATION for cuff size selection) Application of the cuff in a smooth, wrinkle-free manner helps reduce the chances of mechanical injury to the skin, including blistering.

- If the cuff is applied over any material that may shed loose fibers (such as Webril), these fibers may become embedded in the contact closures and reduce the closure effectiveness.

- Do not use tourniquet cuffs to control the distal flow of CO2 or any other gases used as a distention media. Tourniquet cuffs have not been evaluated for safety or effectiveness in controlling gas flow. The effects of using a tourniquet cuff in this manner include serious subcutaneous emphysema proximal to the cuff.

- Sterile only if package is unopened and undamaged.

PRECAUTIONS

When using a tourniquet on patients with sickle-cell disease or trait, severe postoperative pain may result in the operative limb which may be caused by sickling of cells.

Test for hemoglobin type and level before using a tourniquet on patients with sickle-cell disease or trait. When the tourniquet is used for these patients, carefully exsanguinate the limb and closely monitor the patient's PO_2 and pH since sickling is dependent on oxygen tension and pH.

Careful and complete exsanguination reportedly prolongs pain-free tourniquet time and improves the quality of Intravenous Regional Anesthesia (Bier Block anesthesia). However, partial exsanguination may be desirable in certain cases where residual blood flow will aid in visualization and identification of vascular structures.

In the presence of infection and painful fractures, after the patient has been in a cast, or in amputations because of malignant tumors, exsanguination before tourniquet application must be done without the use of an elastic bandage by elevating the limb for 3 to 5 minutes.

Do not use an elastic bandage for exsanguination in cases where bacteria, exotoxin, or malignant cells could be spread to the general circulation, or where it could dislodge thrombi that may have formed in the vessels.

Do not allow preoperative skin preparations to flow and collect under the cuff where they may cause chemical burns.

Inflation must be done as rapidly as possible to occlude arteries and veins simultaneously, and to avoid return of blood into the limb. Quick deflation aids in preventing engorgement.

Heat generated by surgical lights or powered instruments is not dissipated in limbs under tourniquet control and tissue may be subject to drying or trauma. Frequent irrigation, special draping and low power surgical lights are recommended to reduce the risk of thermal damage.

Tourniquet paralysis may result from excessive pressure. Insufficient pressure may result in passive congestion of the limb with possible irreversible functional loss. Always use the minimum effective tourniquet pressure, as

described in the medical literature.

Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves. Prolonged tourniquet time can also produce changes in the coagulability of the blood with an increase in clotting time. In severe cases, pooling of blood in the edematous limb may cause cardiac arrest and death. Rhabdomyolsis may develop in orthopedic cases that use tourniquet cuffs for extended periods of time (over 90 minutes). Always minimize tourniquet time.

Observe the cuff during inflation and periodically while inflated to ensure the cuff is not migrating on the patient's limb.

In case of incomplete or improper inflation, the tourniquet cuff must be fully deflated, and the limb exsanguinated again before cuff reinflation. Reinflation over blood-filled vasculature may lead to intravascular thrombosis.

If the tourniquet cuff migrates on the limb during surgery, apply a pressure dressing to the wound and exsanguinate the limb by elevation. Deflate and reapply the cuff. Reinflate the cuff and observe for migration. If migration persists, replace the cuff.

Whenever the tourniquet cuff pressure is released, the wound must be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level.

Completely remove the deflated cuff, matching Limb Protection Sleeve or any underlying padding immediately following final cuff deflation. Even the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field.

Tourniquet users must be familiar with the inflation-deflation sequence when using a dual bladder cuff or using two single bladder cuffs together (See UTILIZATION) so that the wrong bladder or cuff will not be released accidentally, which could cause severe injury to the patient or death.

Whenever intravenous anesthesia is used, it has been suggested in the medical literature that the tourniquet remain inflated for a minimum of 20 minutes from the time of injection to ensure that most of the anesthetic agent has been absorbed into the limb tissue. For a procedure requiring only a few minutes, too rapid a release of the anesthetic agent can be prevented by quickly deflating and reinflating the tourniquet several times.

The following clinical conditions have been cited in published medical literature as factors that should be carefully considered before use of a tourniquet during surgical procedures

- Severe atherosclerotic disease and presence of calcified vessels
- Severe brain injury
- Proven or suspected deep vein thrombosis
- Tumor in the surgical site
- Abscess or other limb infections
- Rheumatoid arthritis and other immune disease with vasculitis
- Poor cardiac reserve
- Fragile skin and soft tissue
- Compartment syndrome
- Hemoglobinopathy
- Previous revascularization of the extremity
- Extremities with dialysis access (eg, arteriovenous grafts, fistulas)
- Acidosis
- Medications (eg, antihypertensives) and supplements (eg, creatine)
- History of pain or weakness in muscles or bones in extremities
- Increased intracranial pressure.

Delfi recommends that users regularly review published medical literature for other factors that warrant careful consideration before use of a tourniquet during surgical procedures.

ADVERSE EFFECTS

A dull, aching pain (tourniquet pain) may develop throughout the limb following use. Stiffness, weakness, reactive hyperemia, and skin discoloration may also occur to some degree in all patients after tourniquet use.

Pathophysioiogical changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissue occur and become significant after about 1 1 /2 hours of tourniquet use. Symptoms of tourniquet paralysis are: motor paralysis and loss of the sense of touch, pressure, and proprioceptive responses.

Intraoperative bleeding may be caused:

1. By the slight impeding effect exerted by an underpressurized cuff (and padding, if used) which prevents venous return at the beginning of the operation.

2. By blood remaining in the limb because of insufficient exsanguination.

3. By inadequate tourniquet pressure (between systolic and diastolic blood pressure of the patient), or slow inflation and deflation, all of which allow arterial flow to enter while preventing venous return. (See UTILIZATION)

4. By blood entering through the nutrient vessels of the long bones (such as the humerus).

Some other adverse effects of tourniquet use identified in the published medical literature include:

- Cardiovascular, respiratory, cerebral circulatory, and hematological effects related to the metabolic changes that result from ischemia caused by the pneumatic tourniquet applied to the extremity during surgery
- Temperature changes
- Prolonged postoperative swelling of the affected limb
- Arterial injury
- Skin injuries (eg, blistering, bruising, necrosis)
- Compartment syndrome
- Deep Vein Thrombosis
- Rhabdomyolysis
- Skin chemical burns caused by solutions used for operative preparation passed underneath the tourniquet cuff and remaining there during inflation
- Tissue or muscle injury may occur due to ischemia and local pressure
- Reperfusion injury may occur to the limb and produce systemic effects if the tourniquet inflation is prolonged
- Hematoma

Delfi recommends that users regularly review published medical literature for other adverse effects that warrant careful consideration before use of a tourniquet during surgical procedures.

UTILIZATION

Proper Size Selection:

Prior to cuff application, measure the circumference of the patient's limb at the point where the center of the cuff will be. Each style of Contour Tourniquet Cuff is designed to accommodate a range of limb circumferences. The following chart shows the Recommended Limb Circumference Range for each Contour Tourniquet Cuff.

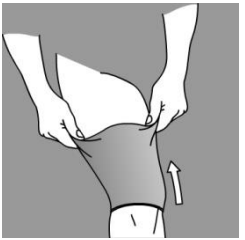
Cuff Style	Recommended Limb Circumference Range	
18 in. Contour Cuff	12.0 to 16.5 in.	(30.5 to 41.9 cm)
24 in. Contour Cuff	16.5 to 21.5 in.	(41.9 to 54.6 cm)
30 in. Contour Cuff	21.5 to 27.0 in.	(54.6 to 68.6 cm)
34 in. Contour Cuff	24.0 to 30.0 in.	(61.0 to 76.2 cm)
44 in. Contour Cuff	30.0 to 39.5 in.	(76.2 to 100.3 cm)

The maximum limb circumference of a cuff is visually indicated when the hook material on the underside of the cuff no longer fully engages the loop material on the top surface of the cuff.

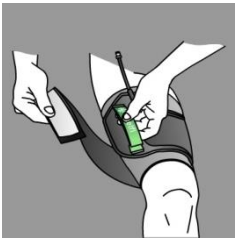
Selection of a cuff that is too small may result in the ends of the bladder not overlapping and the cuff's inability to sustain occlusion, possibly resulting in venous engorgement.

If the patient's limb circumference is not within the Recommended Limb Circumference Range, the selected cuff should not be used.

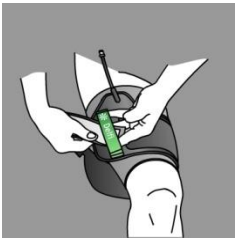
Cuff Application



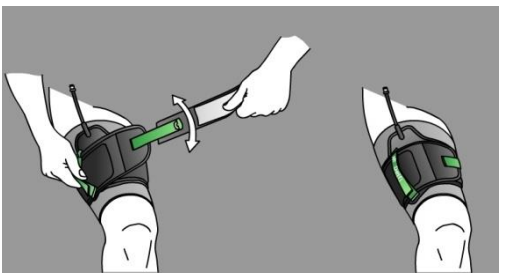
1. Apply Limb Protection Sleeve to limb. (Optional)



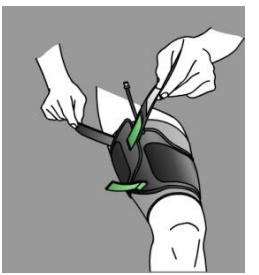
2. Position port proximally on limb at desired location with tubing directed away from surgical site.



3. Slide hook strap under application handle.



4. Snugly apply cuff to limb and secure hook.



5. To remove cuff, disengage hook strap and open application handle.

In most cases, a cuff should be applied at the widest part of the limb to allow as much tissue as possible to lie between the cuff and any nerves or vascular structures susceptible to damage.

The optimum positions are the upper arm and the proximal third of the thigh. Safe cuff positioning at the calf has been reported in the medical literature. The cuff should be applied so as to avoid being compressed by a limb holder**.**

Delfi strongly recommends the application of a matching Limb Protection Sleeve to the limb beneath the cuff prior to the application of a Contour Tourniquet Cuff to the limb.

Apply the cuff smoothly, without wrinkles over the matching Limb Protection Sleeve. Place the tube connections(s) so that tubing will not be kinked when the limb is positioned for surgery.

Apply the cuff snugly by sliding the hook fastener strap under the stabilizer strap / application handle. Once snugly applied to the limb, ensure that the hook strap is fully engaged with the loop material on the Contour Cuff and that the fasteners on the stabilizer strap / application handle are fully secure.

A cuff that is applied too loosely will reduce the effectiveness of the selected pressure. Secure the cuff to the limb using the hook material on the underside of the cuff and the pivoting hook strap. All hook materials must be pressed firmly against the loop material on the cuff surface. Confirm that the patient's limb circumference is within the range of the cuff. (see Proper Size Selection)

Loose fibers in the hook material must be removed prior to cuff application since these fibers will reduce their effectiveness. If more than 25% of the hook is embedded with fibers that cannot be removed, the cuff is no longer usable and must be discarded.

Connect the cuff to the tourniquet instrument using a hose assembly. Note that the hose assembly has positive-locking connectors on one end to match the cuff connector(s) on the other end to match the tourniquet instrument. For procedures that require two single bladder cuffs use two hose assemblies.

The limb is then prepared and draped for surgery. Establish the viability of the skin and deeper tissues prior to exsanguination of the limb and tourniquet inflation. Exsanguinate the limb by elevating it for a minimum of two minutes and wrapping it, starting from the distal and progressing to the proximal part, using an Esmarch, Martin, or other elastic bandage. The bandage should come up approximately to 1 in. (2.5 cm) from the edge of the tourniquet cuff. The elastic bandage is removed following rapid inflation of the cuff.

Refer to your tourniquet instrument operator's manual for information on the proper use of your instrument with cuffs and accessories.

If skin preparations are used preoperatively, do not allow them to flow and collect under the cuff where they may cause chemical burns. In addition, soaking of the contact closure straps by fluids may reduce their effective strength. The cuff may be draped to prevent contact with preoperative solutions.

Pressure Settings

For each patient, the tourniquet pressure should be set to the minimum effective pressure. It is well established in the medical literature that the optimal method for setting the minimum effective pressure of a tourniquet cuff is based on "Limb Occlusion Pressure".

Limb Occlusion Pressure (LOP) is defined in the medical literature as the minimum pressure required to stop the flow of arterial blood into the limb distal to the tourniquet cuff, at a specific time in a specific tourniquet cuff applied to a specific patient's limb at a specific location.

The minimum effective pressure setting is defined in the medical literature to be equal to the LOP plus an offset to account for changes in blood pressure and other variables that commonly occur during surgery.

For more information on determining the minimum effective pressure for the patient, a list of references in the medical literature can be obtained from Delfi Medical Innovations Inc. upon request.

To prevent damage to the Contour tourniquet cuffs, do not inflate these cuffs to a pressure greater than 475 mmHg.

Inflation Time

Tourniquet inflation time depends greatly on the patient's anatomy, age, and absence of vascular disease. A physician needs to determine when: the tourniquet is to be inflated; to what pressure; for what time duration; and at what point in the operation the tourniquet should be released. In many operating rooms it is customary to prominently note the time of inflation and to warn the physician after a certain elapsed time period so that the need for further tourniquet time can be assessed.

There is also general agreement that, for reasonably healthy adults, two hours should not be exceeded without releasing the tourniquet to allow blood circulation to the limb for about 15 to 20 minutes. During this time, the limb should be elevated about 60 degrees with steady pressure applied to the incision with sterile dressing.

Cuff Removal

Whenever the tourniquet pressure is released, the wound must be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. Transient pain upon tourniquet release can be lessened by elevation of the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level.

Remove the contour cuff from the limb by first opening the stabilizer strap / application handle and disengaging the hook fastener strap. To prevent venous congestion, the matching Limb Protection Sleeve and any underlying padding should also be removed from the limb immediately following final deflation of the cuff. The time of tourniquet removal should be noted, and the circulation of the limb should be checked.

Storage

Sterile Single Use tourniquet cuffs should be stored in a clean, dry area.

PRODUCT REPORTING

Notify Customer Service Department, Zimmer Surgical, at 1-800-348-2759 or contact your local Zimmer representative. Please provide details about the nature of the problem and include the product serial number or lot number. Upon receipt of this information, Zimmer will provide assistance for resolution or a return shipping authorization.

European Union customers: The user and/or patient should report any suspected serious incident related to the device by informing Delfi Medical Innovations Inc, Zimmer Surgical, Inc. representative and the competent authority of the member state in which the serious incident has occurred.

WARRANTY INFORMATION: Please contact your Zimmer representative for warranty information.

SYMBOLOGY

REF	Catalog Number* (Reg 2493)	LOT	Batch Code* (Reg 2492)	QTY	Quantity
	Use-By Date* (Reg 2607)	STERILE R	Sterilized Using Irradiation* (Reg 2502)		Do Not Re- Sterilize* (Reg 2608)
CE 0050	European Conformity Mark		Consult Instructions for Use* (Reg 1641)		Do Not Re-Use* (Reg 1051)
	Caution* (Reg 0434A)	EC REP	Authorized Representative in the European Community (Ref 5.1.2)		Manufacturer* (Reg 3082)
	Do Not Use If Package Is Damaged* (Reg 2606)		Does not contain and no presence of natural rubber latex* (Ref 5.4.5)		Non-Sterile* (Reg 2609)
					Single Sterile Barrier System* (Reg 3707)
UDI	Unique Device Identifier* (Ref 5.7.10)	MD	Medical Device* (Ref 5.7.7)		Importer* (Reg 3725)

*ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.

℞ only CAUTION: Federal law (USA) restricts this device to sale by or on the order of a healthcare professional

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