



Personalized Tourniquet Systems

DELFI TOURNIQUET CUFFS SINGLE USE & REUSABLE

IMPORTANT! READ THIS INFORMATION BEFORE USING DELFI TOURNIQUET CUFFS
AND SAVE FOR FUTURE REFERENCE



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PRODUCT DESCRIPTION

Delfi tourniquet cuffs are available in various models for pediatric to bariatric patients. Available in a selection of lengths and widths to facilitate a proper fit, and color coded for size identification.

Delfi tourniquet cuffs include Matching Limb Protection Sleeves, and are available in sterile single use and reusable models. Sterile single use cuffs are equipped with an integral fill line. Dispose of sterile single use cuffs properly 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.

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	Bone grafts
Kirschner wire removal	Amputations
Tumor and cyst excision	Subcutaneous fasciotomy
Knee joint replacements	Nerve injuries
Arthroscopy of certain joints	Tendon repair
Replacement of finger joints	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 distinguished.
- 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

- **Single Use Tourniquet cuffs** are sterile only if package is unopened and undamaged.
- **Single Use Tourniquet Cuffs** are 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.
- **Reusable Tourniquet Cuffs** must be inspected before use. This product is subject to wear and deteriorates with use. It is essential to inspect the cuff before each use. (See Reusable Cuff Care).
- Do not exceed maximum cuff pressure for selected Delfi cuff model. (See Pressure Settings under cuff model).
- 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/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.

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 PO₂ 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 edemic limb may cause cardiac arrest and death. Rhabdomyolysis 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 infiltration 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 on 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.

Pathophysiological 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 Delfi Tourniquet Cuff is designed to accommodate a range of limb circumferences. Refer to the Recommended Limb Circumference Range chart, for the selected Delfi Tourniquet Cuff model.

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

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 Delfi Tourniquet Cuff to the limb. Refer to Matching Limb Protection Sleeve for instructions on proper selection and use.

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. 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 hook straps. 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 selected 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. After application of the cuff, tie the ribbon (for cuffs with tie ribbons) or secure the Application Handle (for Easi-Fit cuffs) to prevent strap or cuff movement during the procedure. See Easi-Fit cuff application below.



1 Grasp the application handle and position the ports on the limb at the desired location

2 Slide the securing strap under the handle

3 Tension the cuff for a snug application and secure the strap

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 Delfi tourniquet cuffs, do not inflate these cuffs to a pressure greater than indicated. (See Pressure Settings for selected cuff model).

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.

For pediatric patients, there is no general agreement concerning what time period should not be exceed without releasing the tourniquet to allow blood circulation to the limb.

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 Delfi cuff from the limb. 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. Store the cuffs laying flat. Protect the internal plastic stiffener from bending, folding or buckling during storage.

Reusable tourniquet cuffs should be stored in a clean, dry area. Do not store the cuffs wet. Store the cuffs laying flat. Protect the internal plastic stiffener from bending, folding or buckling during storage.

REUSABLE CUFF CARE

Inspection Before Use

This product is subject to wear and deteriorates with use. It is essential to inspect the cuff before each use.

1. Has the cuff been cleaned thoroughly after the previous use?
2. After cleaning, is there any obvious discoloration remaining due to blood or residue remaining from previous use that could be a potential source of contamination?
3. Is there any physical damage to the cuff (for example, rips, tears, holes, unevenness or rippling along the length of the cuff when laid flat)?
4. Is (are) the positive-locking hose connector(s) on the valve stem(s) bent, broken or worn, or does the black o-ring on each connector appear to be cracked, damaged or missing?
5. Is the colored ribbon torn or the ribbon stitching broken?
6. Are the hook and loop (Velcro) fasteners of the Application Handle worn or damaged?
7. Is the hook and loop (Velcro) material torn or is any of the stitching around the material broken or fraying?
8. After cleaning, is more than 25% of the (Velcro) contact closure material embedded with fibers that cannot be removed?
9. Connect the cuff to a tourniquet instrument, wrap the cuff onto itself, and inflate the cuff. Are there any leaks in the cuff or connectors?
10. Is there any other physical change or damage to the cuff that would compromise the cuff's ability to maintain pressure and stop blood flow during a surgical procedure?

If any of the above conditions are present the cuff is no longer usable and must be discarded. See WARNINGS for a description of the possible consequences of using a damaged cuff. These consequences include the possibility of catastrophic injury, including death, to the patient due to the release of blood into the surgical site or anesthetic into other parts of the body.

Cleaning

The tourniquet cuff may be cleaned in lukewarm water and an alkaline detergent (formulated to possess good blood dissolving characteristics) and rinsed thoroughly. A soft hand brush may be used to remove encrusted materials. The cuff should not be immersed. Presence of fluid in the bladder may damage the tourniquet instrument.

The cleaned cuff should be allowed to drip dry at room temperature. If loose fibers are present in the contact closure strap, the fibers may be removed using a non-metallic brush or comb using a side-to-side manner.

The cuff must not be sterilized by gas or steam methods. Any increased temperature during cleaning may cause unevenness or rippling in the cuff material, rendering it unsuitable for further use and requiring it to be discarded. (Refer to Inspection Before Use).

Reusable tourniquet cuffs should be stored in a clean, dry area. Do not store the cuffs wet. Store the cuffs laying flat. Protect the internal plastic stiffener from bending, folding or buckling during storage.

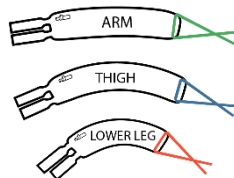
VARI-FIT CUFFS

Single Bladder

Cuff Style

Arm Vari-Fit Contour Cuff	9 to 21 in (23 to 53 cm)
Thigh Vari-Fit Contour Cuff	12 to 30 in (30 to 77 cm)
Lower Leg Vari-Fit Contour Cuff	9 to 17 in (23 to 43 cm)

Recommended Limb Circumference Range



Pressure Settings:

The increased width of the bladder in the Vari-Fit Cuffs, the enhanced fit of the cuff to the limb and the thinner flexible design all contribute to lowering the Minimum Effective Pressure required for limb occlusion. For normotensive patients, it is suggested that an initial cuff inflation pressure of 200 mmHg be considered for use with all Delfi Single Bladder Vari-Fit Tourniquet Cuffs.

To prevent damage to the Vari-Fit Arm, Thigh and Lower Leg tourniquet cuffs, do not inflate these cuffs to a pressure greater than 350 mmHg.

Dual Bladder

Cuff Style

Arm Vari-Fit Contour IVRA Cuff	9 to 21 in (23 to 53 cm)
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Recommended Limb Circumference Range



The dual bladder cuff is connected to the tourniquet instrument via two hose assemblies. Consult the operator's manual for your tourniquet instrument for more information on this connection and any adaptors that may be required. The general procedure for the use of a dual bladder cuff is to fully exsanguinate the limb, inflate the proximal cuff, and after it reaches the pressure setpoint to inject the regional anesthetic.

IMPORTANT! Before the anesthetic agent is injected, full occlusion should be verified by palpation of the radial artery and/or auscultation. This ensures the pressure setting and cuff application for that patient is correct and successful.

When the patient becomes uncomfortable from tourniquet pain, the distal cuff (which is over an anesthetized area) is inflated. When the distal cuff is fully inflated, the proximal cuff is then deflated. This procedure is only a general guideline and may differ in your institution.

Whenever Intravenous Regional Anesthesia is used, it has been suggested in the medical literature that the tourniquet remain inflated for a minimum of 15 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 cuff several times or by decreasing cuff pressure.

Pressure Settings:

Because the bladders on dual bladder cuffs are narrower, a higher pressure is required to achieve and maintain occlusion. For normotensive patients, it is suggested that an initial cuff inflation pressure of 250 mmHg be considered for use with all Delfi Dual Bladder Vari-Fit Tourniquet Cuffs.

To prevent damage to the Vari-Fit Arm IVRA tourniquet cuffs, do not inflate these cuffs to a pressure greater than 350 mmHg.

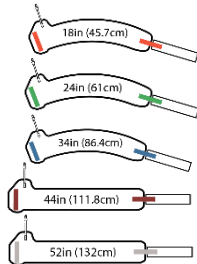
EASI-FIT CUFFS

Cuff Style

18 in. Easi-Fit Contour Cuff
24 in. Easi-Fit Contour Cuff
34 in. Easi-Fit Contour Cuff
44 in. Easi-Fit Cylindrical Cuff
52 in. Easi-Fit Cylindrical Cuff

Recommended Limb Circumference Range

11 to 16 in (27.9 to 40.6 cm)
15 to 22 in (38.1 to 55.9 cm)
21 to 30 in (53.3 to 76.2 cm)
29 to 40 in (73.7 to 101.6 cm)
38 to 46 in (96.5 to 116.8 cm)



Pressure Settings:

To prevent damage to the Easi-Fit 18, 24 and 34 inch tourniquet cuffs, do not inflate these cuffs to a pressure greater than 500 mmHg.

To prevent damage to the Easi-Fit 44 and 52 inch tourniquet cuffs, do not inflate these cuffs to a pressure greater than 600 mmHg.

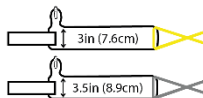
PETITE-FIT CUFFS

Cuff Style

3.0 in. Petite-Fit Cylindrical Cuff
3.5 in. Petite-Fit Cylindrical Cuff

Recommended Limb Circumference Range

6.9 to 12.5 in (17.6 to 31.8 cm)
8.3 to 15.3 in (21.2 to 38.8 cm)



Pressure Settings:

To prevent damage to the Petite-Fit Small Adult 3 and 3.5 inch tourniquet cuffs, do not inflate these cuffs to a pressure greater than 350 mmHg.

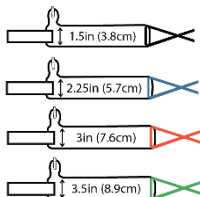
PEDI-FIT CUFFS

Cuff Style

P-1.50 Pedi-Fit Cylindrical Cuff
P-2.25 Pedi-Fit Cylindrical Cuff
P-3.00 Pedi-Fit Cylindrical Cuff
P-3.50 Pedi-Fit Cylindrical Cuff

Recommended Limb Circumference Range

3.5 to 5.6 in (8.8 to 14.2 cm)
4.9 to 8.3 in (12.3 to 21.2 cm)
6.9 to 12.5 in (17.6 to 31.8 cm)
8.3 to 15.3 in (21.2 to 38.8 cm)



Pressure Settings:

To prevent damage to the Pedi-Fit Pediatric 1.5, 2.25, 3 and 3.5 inch tourniquet cuffs, do not inflate these cuffs to a pressure greater than 350 mmHg.

MATCHING LIMB PROTECTION SLEEVES

Intended Use

Delfi Matching Limb Protection Sleeves (MLPS) help protect the patient's limb from possible wrinkling, pinching and shearing of skin and soft tissues of the limb.

Each Delfi Matching Limb Protection Sleeve is intended for use with a specific Delfi tourniquet cuff model and size. Within the range of limb sizes recommended for the matching cuff, the MLPS help to protect the limb's soft tissues beneath the cuff while applying a low pressure that is less than a snugly wrapped cuff.

Utilization

1. Confirm that the selected Delfi tourniquet cuff can encircle the limb with all hook cuff fasteners fully secured and leaves a safe distance between the cuff edges and the joints proximal and distal to the cuff.

Note: the operating surgeon is responsible for determining this safe distance for each patient, to prevent injury to exposed nerves, vessels and soft tissue near the joint.

2. Select the correct Matching Limb Protection Sleeve that matches the selected cuff, by matching the color on the MLPS to the color of the tie ribbon or trim color on the cuff. (For example, the MLPS with green trim/stripes matches the cuff with green tie ribbons/trim).



3. Slide the selected MLPS onto the limb, ensure that the MLPS is applied smoothly and wrinkle-free.



4. Snugly apply cuff on the limb over the MLPS. Ensure that the proximal edge of the MLPS extends approximately 1 inch (2.5 cm) proximally beyond the cuff edge. Connect tubing.



5. Fold the distal portion of the MLPS back over the cuff. Assure that the safe distance distance exists between the cuff and the joints. (see step 1 above).



6. **Upon deflation of the cuff**, immediately remove the cuff from the limb;



7. Next remove the MLPS from the limb.

SYMBOLOLOGY



Catalog
Number*
(Reg 2493)



Batch Code*
(Reg 2492)



Quantity



Use-By Date*
(Reg 2607)



Sterilized Using
Irradiation*
(Reg 2502)



Do Not
Re- Sterilize*
(Reg 2608)



Consult
Instructions
for Use*
(Reg 1641)



Do Not
Re-Use*
(Reg 1051)



Caution*
(Reg 0434A)



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)

*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 physician.



DEHP

Contains or presence of phthalates **

** EN 15986 Symbol for use in the labeling of medical devices – Requirements for labeling of medical devices containing phthalates.



Personalized Tourniquet Systems



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