

BioPro Fasciotome™ Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Description

The BioPro Fasciotome is intended to assist surgeons in percutaneous plantar fasciotomies. The Fasciotome features an extremely sharp, one-sided blade for effortless releases; provided in convenient single-use, sterile packs.

Materials

Stainless Steel

Indications for use:

1. Percutaneous partial release of the plantar fascia.

Contra-indications:

1. A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months.
3. A local or systemic infection.
4. Significant deficiency in the vascular supply to the extremity.

Precautions and Handling

- Inspect the sterile pouches prior to use. Sterilization cannot be assured, and devices should not be used if the pouch or seal is damaged.
- Device is single use only
- Do not autoclave device

Potential Complications and Adverse Effects

- Damage to soft tissue caused by improper surgical technique
- Delayed healing
- Device may bend or break

Sterile:



Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

Instructions for use:

1. After an appropriate local block has been obtained, locate the medial band of the plantar fascia by dorsiflexing the foot and great toe. This allows you to palpate the medial band in the arch area and follow it back to proximal of the heel.
2. The percutaneous portal is located by bisecting the medial malleolus and drawing the bisection line down to the medial plantar area of the foot. This approach brings you to a safe location for percutaneous release of the fascia by being proximal to the medial and lateral plantar nerves.
3. Ultrasound imaging can aid in the accurate placement of the percutaneous Fasciotomy.
4. The foot should be appropriately prepped and draped. Utilizing the Fasciotome the skin is penetrated and the Fasciotome is brought in contact with the medial band of the plantar fascia, cutting the medial band of the plantar fascia and a portion of the central band, if desired.
5. After the Fasciotome releases the medial band, there should be a loss of the prominence of the medial band to the fascia in the arch area.
6. No suturing of the portal is necessary, dry sterile dressing, and a modified Campbell's rest strapping of the foot and ankle is recommended.
7. Patient may immediately weight bear.