



SafeLimb

Post-Operative BKA Protector

Medical Professional Instruction Guide

Indications

These indications are pathological conditions that the post-operative BKA (below knee amputation) protector was intended to address, but the assessment of a healthcare professional is always recommended.

- Limb protection after transtibial amputation
- Prevention of knee flexion contracture following transtibial amputation

Contraindications

- Size of limb or deformity that would require a custom design.
- Patients with severe arterial insufficiency.
- Allergy to one of the components.
- Severe cognitive and/or psychiatric disability.

Cautions

- Do not place the product directly in contact with the skin. SafeLimb must be used over a dressing and/or a sock.
- Follow the recommendations of the healthcare professional who prescribed or supplied the product. In case of discomfort or hindrance, or any unusual reaction during the use of the product, remove the device and consult this healthcare professional.
- Restrict yourself to physical activities authorized by the doctor who is responsible for evaluation your physical condition prior to defining the activities that are safe and appropriate for you to do while wearing the brace.
- Store the brace at normal room temperature, and don't expose the brace to extreme temperatures, especially very hot temperature.
- For reasons of hygiene, performance and safety, this brace should only be used by the original users and should not be worn by any other person.
- Straps should never cross over the top of the patella to avoid risk of ischemia, unwanted patella pressure or skin breakdown.
- The side slide bars may contain sharp edges. Leather or equivalent gloves are recommended during the fitting.

Adverse effects

- There are no known adverse effects when the product is used correctly.

Warranty

- 90 days

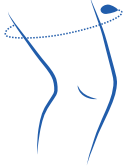
Fitting and adjustment

CAUTION: The side slide bars may contain sharp edges. Leather or equivalent gloves are recommended during the fitting.

1. Size selection

- Measure thigh circumference 6" above mid-patella
- Pick the appropriate size based on the size chart below.

Size	Thigh circumference 6" Above Mid Patella
SM	14 – 16 ¾ inch
MD	16 ¾ – 20 ¾ inch
LG	20 ¾ – 24 ¾ inch
XL	24 ¾ – 29 ½ inch
XXL	29 – 34 inch



2. Brace adjustment in case of contracture

- Use goniometer or observe to see if patient is presenting with a fixed flexion contracture. If no flexion contracture accommodation is necessary, then skip this step.
- If patient has a contracture, that requires accommodation for, then use the edge of a hard surface to add a flexion bend to the bars at knee center.
- **CAUTION:** The side slide bars must be fully collapsed prior to flexion bend to prevent an unwanted bend in the proximal and distal slide mounts (*see figure 1 and 2*).

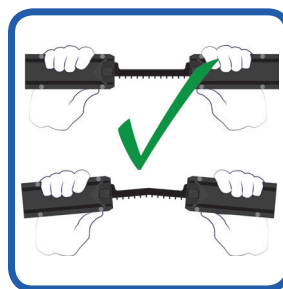


Figure 1

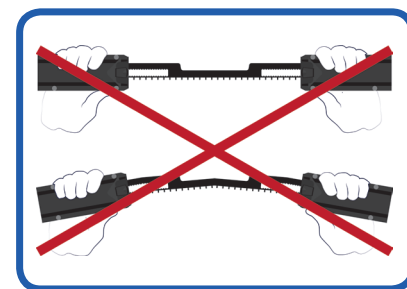


Figure 2



SafeLimb

Post-Operative BKA Protector

3. SafeLimb fitting

- a. Prior to applying the brace on the patient:
 - Open all the straps.
 - Make sure all 4 SnapLocks are open to be able to lengthen the brace (*see figure 3*).
- b. Place the brace on the patient limb and adjust the brace to desired length. Once the length is set, lock all 4 slide mechanisms into place by gently pushing down on the SnapLocks (*see figure 4*).
- c. Fold distal foam tibial pad down, trim if necessary to avoid patella.
- d. Make sure that the medial and lateral fabric Velcro tabs are positioned at knee center.
- e. Position the thigh strap and chafe (proximal to the patella) and the pre-tibial strap and chafe (distal to the patella) by sliding them up or down (*see figure 5*).
- f. Lock straps into place by pulling up and locking into the side bars strap keeper teeth (*see figure 6*).
- g. First attach the upper and lower foam wraps with the small blue Velcro tab. Then, close all the straps to secure the SafeLimb on the patient's leg.
- h. (optional) If the residual limb is very short and lacks room below the knee, you can remove the distal strap and chafe with scissors (*see figure 7*).

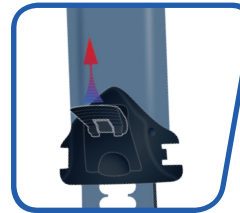


Figure 3

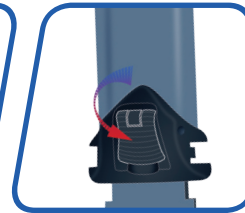


Figure 4

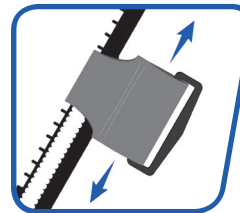


Figure 5

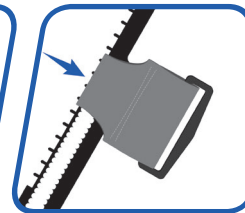


Figure 6

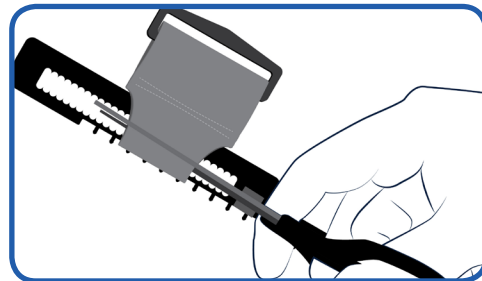


Figure 7

Disclaimer

Because the manufacturer has no role in patient selection, fitting and adjusting the brace, instructing the patient, and/or monitoring patient use and compliance, there can be no guarantee that every patient will experience the same results and benefits



Video instructions





Patient Instruction Guide

Fitting instructions

1. Place the brace on the limb and make sure that the central Velcro tabs are positioned at knee center (*see figure 1*).
2. First attach the upper and lower foam wraps with the small blue Velcro tab (*see figure 2*). Make sure you fold the black foam pad at the bottom of the brace (*see figure 3*) prior to this step.
3. Then, close the straps in this order: A, B, C and D (*see figure 4*), to secure the brace on the limb.

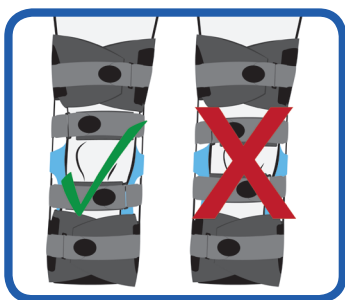


Figure 1

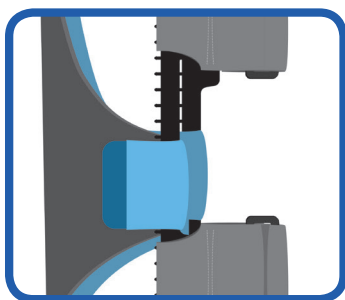


Figure 2

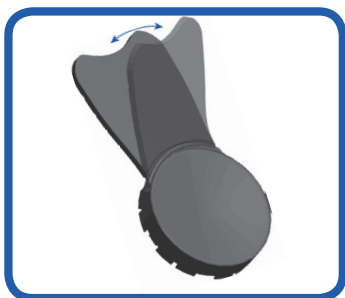


Figure 3

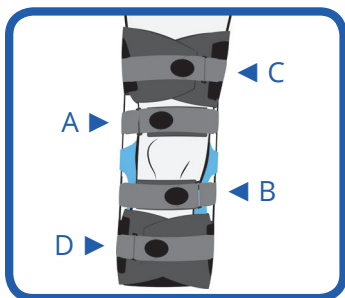


Figure 4

Cautions

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Adverse effects

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Warranty

- 3 months