

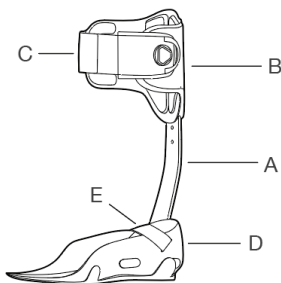


Swift

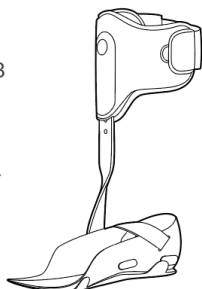
Instructions for Use (IFU)

Let's get started

Swift | Posterior



Swift | Anterior



Components

- A. Carbon Fiber Strut and Footplate
- B. Calf Cuff with CoolFlow Liner
- C. Calf Strap with Boa® Fit System
- D. Inner Boot
- E. Dorsum Strap
- F. HelixBand (Midfoot and Calcaneous bands)

What you'll need (not included)



Casting Tape*



Heat gun



Shears



Hand grinder (optional)

1 Cast user's leg

Using the carbon fiber frame as a casting board, cast the leg. Ensure cast covers the calf area and that the foot is in a natural position. Let cast harden and remove with shears.

Note

The 3/8" heel shim block should be removed after casting.

2 Trim and form inner boot

- a. Place inner boot on the cast.
- b. Mark trim lines where the boot will be trimmed to accommodate patient anatomy and treatment needs. Trim boot.
- c. Place inner boot back on cast. Hold in place with included rubber bands.
- d. Using a heat gun, apply even heat to the boot. Press with fingers and included silicone sheet to mold the boot to the geometry of the cast. Hold shape until material cools.

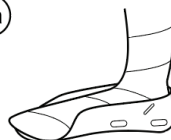
Note

It is important to keep the plugs attached to the inner boot during forming. Removing the plugs may cause distortion of the strap slots.

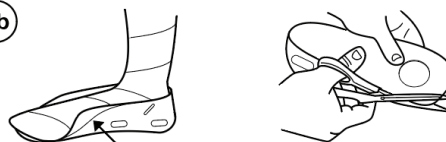
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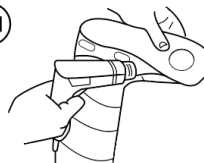
2a



2b



2d



③ Trim and form footplate

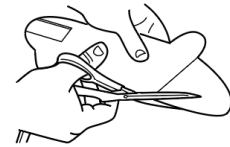
- Place inner boot and carbon fiber strut on the cast.
- On the footplate, mark the 1st and 5th metatarsal heads, calcaneus support and desired shape in heel area. Trim footplate along markings.
- Place inner boot and strut back onto the cast and hold in place with included rubber bands.
- Using a heat gun, apply even heat to the footplate. Press with fingers to mold wings up and in contact with the inner boot.

Note

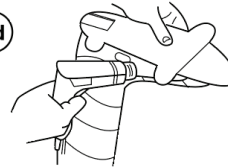
For the anterior model, it is important to note the following:

- Do not over trim the medial edge. This will cause the strut to make contact with the user's lateral arch.
- The strut can be positioned forwards and backwards by trimming the front and back of the footplate accordingly.

3b



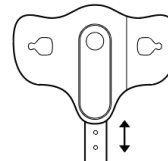
3d



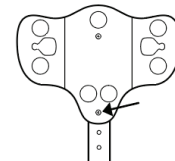
④ Attach and form calf cuff

- Trim calf cuff according to patient needs, if required. It can accommodate calf circumferences of 11-24" (28-61cm).
- Slide calf cuff onto the strut. Position should be 1" (2.5cm) below the fibular head.
- Insert screw and tighten with hex wrench. These can be found in the accessory box.
- Using a heat gun, apply even heat to the boot. Press with fingers to mold the boot to the geometry of the cast.

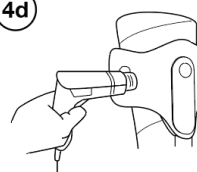
4b



4c



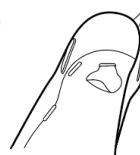
4d



⑤ Attach inner boot

- Remove the product from the cast.
- Feed pointed end of included strap through the heel slot. Remove adhesive on circular end and apply to heel of inner boot.
- Remove adhesive on other side of strap and apply to bottom of footplate.

5b

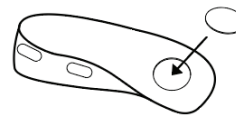


d. Use included hook and loop pieces to secure underside of inner boot to footplate in the forefoot area. Remove adhesive and press firmly.

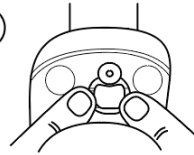
⑥ Attach and adjust calf strap

- Attach hook end of strap into keyhole on the calf cuff.
- Based on patient indications, choose which side to install the Boa dial. Lock in the opposite side with included plastic piece. Make sure to press until piece snaps into place.
- Lock button hook under the Boa dial into the keyhole on the calf cuff. Push the Boa dial in and rotate it clockwise until the strap has been pulled all the way into the tunnel.
- Remove the strap from the hook on the other side and pull the strap as tight as the patient will wear it in use.
- Trim strap with scissors, attach strap back onto hook and be sure to cover the trimmed edge.

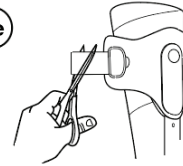
5d



6b



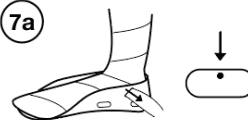
6e



⑦ Attach dorsum strap

- Attach dorsum strap through slot in inner boot. The TPU edge should be on the inside surface of the inner boot, flush against the user's skin.
- Tighten and trim dorsum strap. Apply tab cover over trimmed edge to aide in patient donning and doffing.

7a



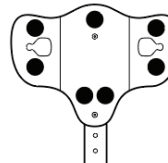
7b



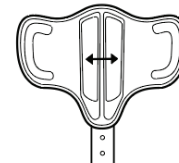
⑧ Attach liner

- Attach adhesive hook dots into corresponding recesses on inside of calf cuff.
- Place liner into inside of calf cuff and reposition as needed to achieve the proper alignment
- (Anterior model only) For tibial pressure relief, add the included tibia shims onto the loop area in the center of the liner. This leaves an open channel for tibial relief.

8a



8c



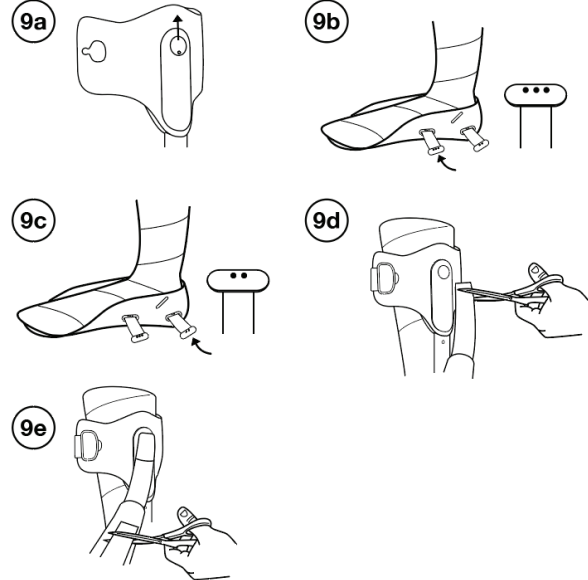
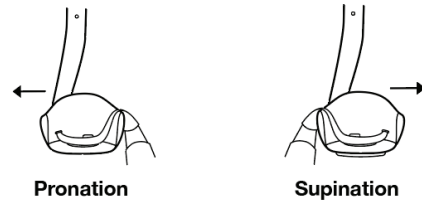
9 Attach and adjust HelixBand

Note

HelixBand consists of two bands, the Midfoot and Calcaneus bands. The direction in which they wrap around the leg is determined by whether the user needs pronation or supination correction. Refer to the image on the right to determine the direction of the finished product.

- Remove the cap on the calf cuff to expose the anchor point. This can be removed by inserting the included wrench in the hole and sliding up.
- Remove all plugs from inner boot. Insert the plug end of the Midfoot band into the inner boot through the slot. To ensure correct installation, match the 3 dots on the plug with the corresponding dots on the inner boot.
- Install the Calcaneus Band by inserting the plug end through through the slot with 2 dots.
- Trim the Midfoot Band as needed by the user and attach the finger loop to the end.
- Trim the Calcaneus Band and attach the hook piece to the end. This will be attached to the loop on the outside of the Midfoot Band. Wrap the bands around the calf and attach the button hook into the anchor point. If desired by the patient, the dorsum strap may be removed.

Orientation of HelixBand



Product Details

Intended Use

This product is to be used exclusively for orthotic fittings of the foot and ankle and is exclusively suitable for contact with healthy and intact skin.

Indications and Effects

This product supports the foot in case of drop foot with no more than mild spasticity, for example, after stroke, traumatic brain injury, multiple sclerosis, neural muscle atrophy, peroneal palsy, etc.

This product is best suited for patients with:

- A stable ankle
- No or mild impairment of motor knee control
- Active patients, walking indoors as well as outdoors
- In case of foot deformity, the product is indicated when the foot deformity can be corrected through the use of an additional insole and a varus/valgus support strap in combination with a sturdy shoe.

The product provides the user with a more natural gait pattern and a faster and more stable walk. The toes and foot are lifted up during the swing phase and the foot slap at heel strike is prevented. Support and correction for pronation or supination is provided. The energy restoring properties of the carbon strut provide a propulsion effect at initial swing phase.

Absolute Contraindications

- Prevention of contractures
- Moderate to severe spasticity in the lower leg
- Leg ulcers
- Severe edema
- Moderate to severe foot deformities

Relative Contraindications

In case of the following indications, consultation with a physician is required: Skin diseases/injuries, inflammatory symptoms, prominent scars, lymphatic flow disorders, sensory and circulatory disorders of the lower extremities.

Prescription Notice

This product must be prescribed and fitted by a certified healthcare professional.

Washing Instructions

Carbon Fiber and Plastic Parts: Wipe clean with a damp cloth.

Liner and Strap: Hand wash with mild detergent. Pat surface dry with towel and leave to air dry completely.

Do not use bleach, fabric softener, chlorinated water, or tumble dry in a dryer.

Safety Instructions

- The patient must be instructed in the proper use/care of the product.
- The initial fitting of the product must only be carried out by a qualified professional.
- The daily duration of use and period of application are dependent on medical indication by the physician.
- The product is designed for single patient use.
- Parts to be fitted and those parts that come directly into contact with the skin can cause functional and hygienic risk if the orthosis is used by another person.
- If the orthosis is applied too tight, it can cause local pressure and, in some cases, even restrict blood flow or nerves. Do not apply it too tight.
- Improper alterations to the product are not permitted.
- Consult a physician immediately if you experience unusual changes, such as an increase in pain.
- The ability to drive a vehicle while wearing the product should be determined on a case-to-case basis.
- The user must be informed of the risks that exceptional situations might present. For example jumping down from a great height (>1meter/39 inches) may cause the carbon fiber to break.
- The product is not flame resistant. Keep the product away from flames and other heat sources.
- The product should not come into contact with grease or acidic agents, unguents and lotions. This may reduce the products period of use.
- Extreme squatting or toe loading may cause the carbon fiber to break and should not be done.
- This product is not made with natural rubber latex.
- Use of this product is not a guarantee against injury.

Product Construction

The strut of the orthosis is made from pre-impregnated carbon fiber and glass fiber material and cannot be thermoformed.

The footplate is made of thermoplastic and can be trimmed and formed. Other parts of the carbon component should not be trimmed or modified.

The inner boot is made of thermoplastic and can be trimmed and formed.

The calf cuff is made from thermoplastic and can be trimmed and formed.

The liner is made from lycra and foam.

The straps are made of synthetic fibers can be adjusted in length by trimming the loose ends and re-attaching the hook ends.

Limited Warranty

This product and its components are guaranteed under Elevate's warranty for 2 years.

Elevate warrants to the original purchaser that this product is free from defects in materials and workmanship. Elevate shall have no obligation under this warranty in the event that:

1. Product was not purchased from Elevate or its authorized dealer.
2. Product has been altered in any way.
3. Parts not supplied by Elevate are inserted into the product.
4. Product has not been used in accordance with this Instruction for Use (IFU).

This Limited Warranty does not cover damage due to accidents, neglect, misuse, or operation beyond capacity, parts damage by improper installation, substitution or parts not approved by Elevate, or any other alteration or repair by others that, in Elevate's judgment, materially or adversely affects the product or part. The duration of this Limited Warranty is effective from the date of delivery to the purchaser. Elevate's sole obligation under this Limited Warranty is to either repair or replace the product at no charge, or to credit the purchaser's account for the value of the defective product at Elevate's sole discretion. Proof of purchase may be required for eligibility. Elevate disclaims and excludes any other express or implied warranties not set forth in this Limited Warranty, including but not limited to warranties of merchantability or fitness for any personal injury, property damage, or special, incidental, or consequential damages arising out of, related, or incident to use the product, even if Elevate has been advised of the possibility of such potential loss or damage, unless state law otherwise precludes this exclusion.

To obtain warranty service, visit:
www.elevatemovement.com/warranty