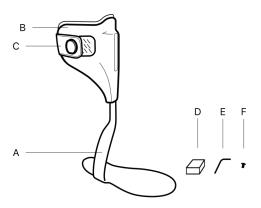


GlideInstructions for Use (IFU)

Let's get started



Components

- A. Carbon Fiber Strut and Footplate
- B. Calf Cuff with CoolFlow Liner
- C. Strap with Boa® Fit System
- D. Polishing Tool
- E. 3mm Hex Wrench
- F. Screws

1 Trim Footplate

With scissors, trim the footplate using the trimlines or use the insole from the patient's footwear as a guide.

Trimming the footplate is critical for strut and tibial alignment, and preventing pressure points. Please see Professional IFU for details.

Note: The only section of the footplate that is trimmable is the thin gray area where lines are shown.

(2) Polish Footplate

Polish the trimmed edges with the polishing tool provided. Ensure no sharp edges

3 Measure calf height

Measure the distance from the floor to the mid belly of the calf. Use the sizing chart in this IFU to determine the location of calf cuff on carbon strut. The final position of the top of the calf cuff should be 3/4" (2cm) below the fibular neck, however can be adjusted as needed.





(2)



(3)



(4) Tighten Screw

Insert screw on inside of calf cuff in the hole shown. Using included wrench, tighten screw fully. Screw should tighten 1/4 turn past engagement point.

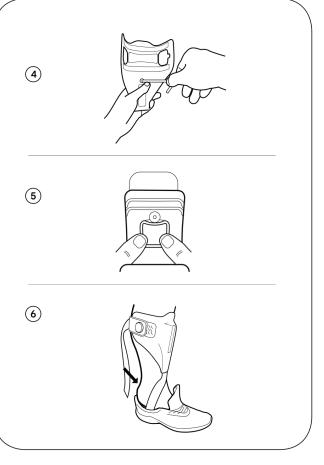
(5) Lock in Strap

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.

6 Insert into shoe

Place the carbon fiber into shoe and place patient's insole on top of the footplate. With the shoe laces loosened, use the product as a shoe horn to place the foot into the shoe.

Note: Ensure that the heel sites flat on the insole and the shoe is not distorted.



(7) Tighten Strap

Lock button hook under the Boa dial into the keyhole on the calf shell. Push the Boa dial in and rotate it clockwise until the strap has been pulled all the way into the tunnel.

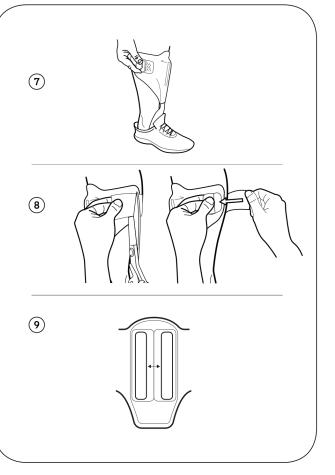
(8) Determine strap length and trim strap

Remove the strap from the alligator on the other side and pull the strap as tight as the patient will wear it in use. Check fit and comfort with patient.

Trim strap with scissors, attach strap back into hook and close alligator.

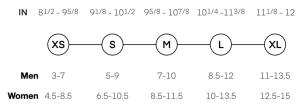
(9) Optional: Attach Tibia Shims

For tibial pressure relief, you can add the included tibia shims onto the loop area in the center of the liner. This leaves an open channel for tibial relief.



Footplate Size Chart

United States (US)



(Shoe Size)

Europe (EU)

Strut Size Chart

Vertical Adjustment

IN CM XL 15 38.1 L 14 1/8 35.8 M 13 3/8 34 S 12 5/8 32 XS 11 1/4 28.5

(From Floor to Mid Belly of Calf)

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, waling 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. 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, unquents 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 orthosis is made from pre-impregnated carbon fiber and glass fiber material and cannot be thermoformed. The footplate can be trimmed only in the areas with a solid gray color. Other parts of the carbon component should not be trimmed or modified.

The calf cuff is made from nylon plastic and can be trimmed in predefined areas. It can accommodate calf circumferences between 11-24"(28-61cm), measured from the mid belly of the calf.

The liner is made from lycra and foam and can also be trimmed in the predefined areas.

The strapping system can be adjusted in length by trimming the soft loop strap and re-inserting back into the alligator piece.

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.
- 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 Warrantv 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