elevate

AFO 1 Glide

Professional Instructions

Contents

Product Overview

Intended Use

The AFO1 products are 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, e.g. after stroke, traumatic brain injury, multiple sclerosis, neural muscle atrophy, peroneal palsy etc.

AFO1 FreeFlow is best suited for patients with:
- No or mild impairment of motor knee control
- No or mild impairment of plantar flexors

AFO1 Glide is best suited for patients with:
- Mild to moderate impairment of motor knee control
- Mild to moderate impairment of plantar flexors

HelixBand is best suited for patients with:
- Patients with mild to moderate flexible varus or valgus instability.

These products are best suited for patients with:
- Ambulatory patients, walking indoors as well as outdoors.

In case of foot deformity, the product is indicated when the foot deformity can be corrected through use of an additional insole and/or a varus/valgus support strap in combination with a sturdy shoe.The product provides the user with a more natural gait pattern, a faster and more stable walk. The toes and foot are lifted up during the swing phase and foot slap at heel strike is prevented. The energy restoring properties of the carbon strut provide a propulsion effect at terminal stance.

For HelixBand, the calcaneus band helps to improve heel alignment while the midfoot band improves midfoot and forefoot stability.

Absolute Contraindications

- Contractures
- Moderate to severe spasticity in the lower leg
- Any ulcers of the lower limb
- 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.

Selecting the Correct AFO

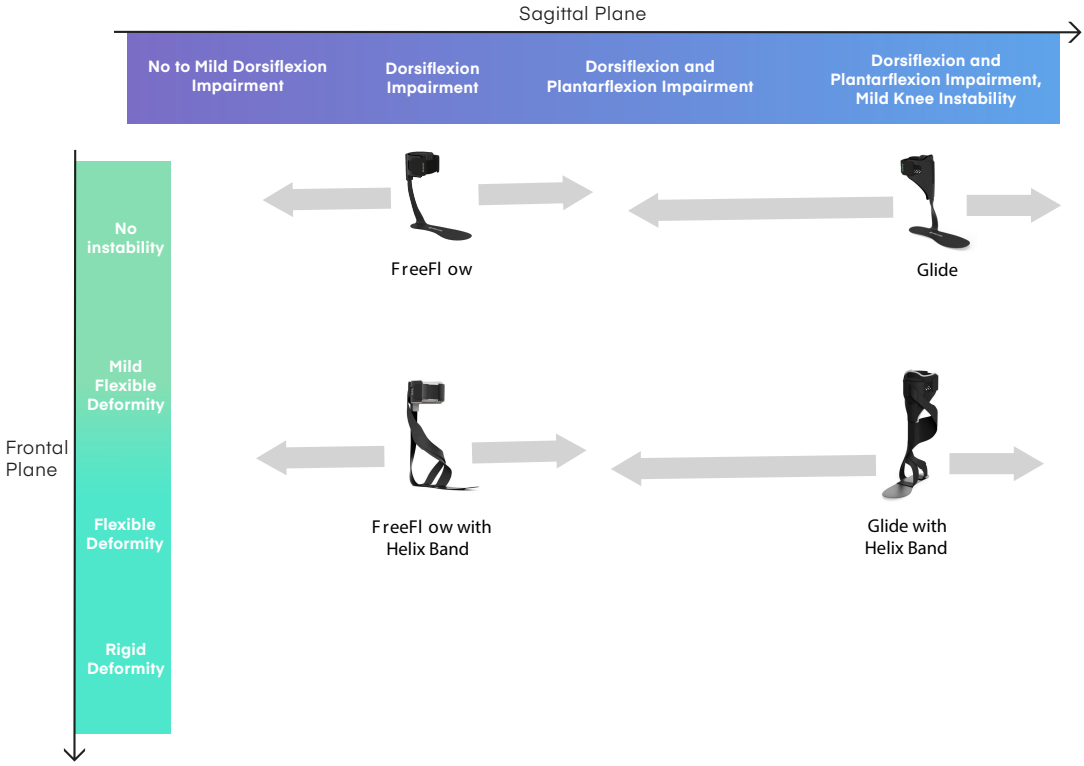
Every patient is different. Observe your patient walk for a while to determine what functions are impaired. After assessing your patient, choose the correct AFO based on their indications.

If your patient only shows dorsiflexion impairment, consider the AFO1 FreeFlow. If your patient exhibits additional plantar flexion impairment or mild knee instability, consider the AFO1 Glide, providing anterior shell support.

If your patient shows mild to moderate flexible varus or valgus instability, consider the HelixBand, providing dynamic varus or valgus support.

In case of severe problems, significant ankle or knee instability, or severe spasticity, please consider a different type of AFO.

Product Selection Matrix



Shoe Selection

The correct shoes are critical for the AFO to function correctly. The most successful shoes have a firm heel counter and allow for a smooth roll of the MTP joints.

In addition to having the correct shoes, it is equally important that the shoes fit the patient correctly.

The back of the shoe is rigid

Laces or Velcro closures

The insole is removable

Low heel, but not too flat

Flat shoes

High heels

Tight shoes

Loafer style shoe

Fitting Glide

First, Trim the Footplate.

Trimming the footplate is critical for strut and tibial alignment, and preventing pressure points.

Step 1) Put Foot on Footplate

Have your patient place their foot on the footplate and ensure correct alignment and patient comfort (See Page 15 for details).

Mark this footplate position. Mark around their entire foot to ensure correct alignment everywhere on the footplate.

Step 2) Place Insole on Footplate

Place their shoe's insole onto the footplate, aligning the insole to the marked locations from Step 1.

Draw a line around insole.

Step 3) Start Cutting

Be careful not to overtrim as this can cause various pressure points and misalignment.

Using professional scissors, cut the footplate. Using included polishing block, sand the edges.

Second, Set the Calf Height.

Step 4) Measure

Measure distance from the floor to the mid-belly of the calf.

As a general guideline, the top of the calf cuff should be 2" below the fibular head.

However, every patient is different and if they require more or less control, you can lower and raise the calf cuff accordingly.

Step 5) Check Sizing Chart

Use the Sizing Chart at the back of the IFU to determine the location of the calf cuff on carbon strut.

Step 6) Secure Calf Cuff

Slide the calf cuff to the desired hole on strut, as determined from Sizing Chart.

Insert screw into the inside of calf cuff and tighten with wrench.

Third, Set the Strap.

Step 7) Determine Side for BOA Dial

Have your patient put their foot back on the footplate. Check which side (medial or lateral) the BOA dial is most comfortable for the patient to adjust the AFO.

Step 8) Lock in Strap

On the opposite side of the BOA Dial, lock in the plastic piece. Push firmly until the plastic locks into place.

Step 9) Attach Strap

Have patient slide into brace and secure the BOA Dial side. Tighten the strap and mark the cut location.

Detach the strap and cut excess. Attach strap back into Velcro alligator clip.

For patient's safety, it is recommended to remove from their leg before cutting.

Finally, Assess your Patient.

Step 10) Watch your patient walk

Ask your patient to walk around. If possible, have them walk up and down stairs, sit down and stand up. Ensure a good fit and function.

Step 11) Teach your patient

Show your patient how to put their new brace on and off. To take the AFO off, pull the BOA Dial out and unhook the strap.

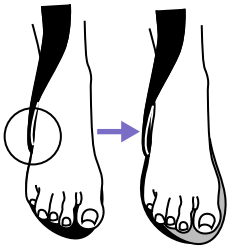
Correct Alignment and Patient Comfort

Correct alignment of the AFO on the patient is critical for successful patient outcomes. Correct alignment will optimize gait pattern and patient comfort.

Strut Alignment

The strut should be just posterior of the 5th metatarsal head and extend upward without contacting the tibia. Move patient's foot forward/backward and medially/laterally to achieve correct alignment.

Distal Strut Pressure



To prevent distal strut pressure, move the foot medially away from the strut.

If patient is experiencing distal strut pressure and footplate has been trimmed, you can move the foot orthotic medially and glue it to the footplate.

Ensure coverage under first metatarsal.

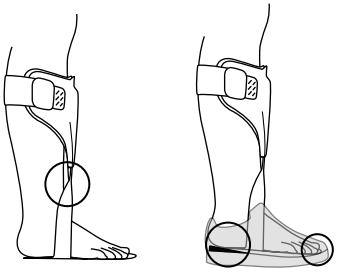
Tibia Alignment

Ensure anterior shell is parallel to tibia to ensure even pressure distribution along tibial crest.

even pressure distribution

If there's a gap at proximal anterior shell, slide foot forward (shorten toe end of footplate).

If there's a gap at distal anterior shell, slide foot forward and correct heel height.



Heel Height

Heel wedges can be used to ensure even pressure distribution along tibia, and encourage more knee extension or flexion.

For more knee extension, decrease heel height.

This encourages knee extension earlier in the gait cycle by shifting the proximal section of the anterior shell backwards.

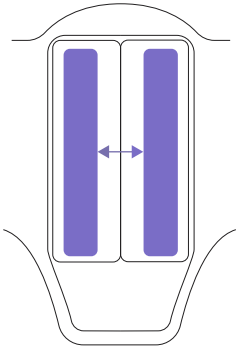
For more knee flexion, increase heel height.

This encourages knee flexion by shifting the proximal section of the anterior shell forwards.

Additionally, you may want to include an adjustment in the other foot's shoe to prevent hip disturbances due to leg length discrepancies.

Optional Tibia Shims

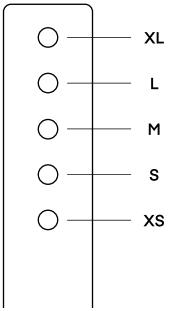
For tibial pressure relief, you can add the included tibia shims onto the loop area in the center of the liner. This leaves an open channel for tibial relief.



Sizing Charts

Strut Size Chart

Vertical Adjustment



(From Floor to Mid Belly of Calf)

	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

Footplate Size Chart

United States (US)

(Foot Length)

IN	8 1/2 - 9 5/8	9 1/8 - 10 1/2	9 5/8 - 10 7/8	10 1/4 - 11 3/8	11 1/8 - 12
	XS	S	M	L	XL
Men	3-7	5-9	7-10	8.5-12	11-13.5
Women	4.5-8.5	6.5-10.5	8.5-11.5	10-13.5	12.5-15

(Shoe Size)

Europe (EU)

(Foot Length)

CM	21.5-24.5	23-26.5	24.5-27.5	26-29	28-30
	XS	S	M	L	XL
	34.5-39.5	37-41.5	39.5-43.5	40-46	44.5-47.5

(Shoe Size)

Safety

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 use on one patient only.

Parts to be fitted and those parts that come directly into contact with the skin can cause functional and hygienic risks 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 product are not permitted.

Consult a physician immediately if you experience unusual changes, such as increase in pain.

The ability to drive a vehicle when 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 great height (>1 meter/39 inches) may cause the carbon fiber to break.

This product is not flame-resistant. Keep the product away from flames or other heat sources.

The product should not come into contact with grease or acidic agents, unguents and lotions. This may reduce the product's 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.

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 limited 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 damaged 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 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 a particular purpose. This Limited Warranty excludes liability 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

Fitting HelixBand

Step 1) Fit the Patient Seated

Fit the patient in seated position. Calf girth is bigger than standing in seated position. Fitting in a seated position prevents over trimming of the straps.

Step 2) Attach Cuff Cover

Wipe the cuff outside surface with alcohol or paint thinner. Wait until dry. Attach calf cuff cover.

NOTES: Must clean the surface before attaching cover.

Apply pressure over the pressure sensitive adhesives to ensure strong bond.

Ensure the cover is tight.

Step 3) Attach Anchors

Clean the top and bottom of footplate. Attach anchors as shown. Ensure to attach midfoot anchor at the arch of the foot, just slightly past the strut.

Step 4) Trim Insole

Trim insole to fit to footplate or use patient's existing insole if required.

Attach insole attachment loop to patient's insole to ensure secure attachment of insole to footplate.

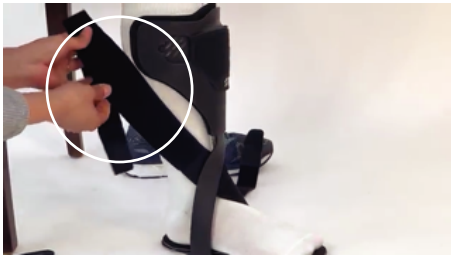
Step 5) Attach Midfoot Band

Attach midfoot band to anchor. Orient the band perpendicular to the foot plate/line of progression toward varus or valgus orientation.

Step 6) Trim Midfoot Band

Trim the bottom of midfoot band to allow for the wide part of the band to sit higher up around the calf.

Having wide part of the band to cover the gastrocnemius part of the calf allows for a more even distribution of pressure than narrow band.



Step 7) Attach Calcaneus Band

Attach calcaneus band to anchor. Orient the band perpendicular or angle slightly to the foot plate/line of progression.

NOTE: Calcaneus band is for valgus or varus rearfoot correction and helix band is for excessive supination or excessive forefoot pronation - both only for flexible deformities. Use under clinician's discretion.

Step 8) Varus / Valgus

Valgus

Varus

Check if product is correctly assembled to varus or valgus configuration.

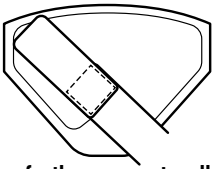
Fold midfoot band to cover the top of footplate and place insole over the straps on top of the footplate.

Place insole.

Step 9) Place Midfoot Band

Place midfoot band tab on cuff cover. At an angle, centered as shown.

Place the tab just towards the far end of the cuff. This ensures the band is at it's longest length to allow for adjustment.



Place further away to allow for extra strap length.

Wrap band around the front of the ankle, around gastrocnemius and pull towards the cuff cover until the band is tight and snug.

Use midfoot band tab to hold the band to check the fit. Test for fit with patient standing and sitting. Tighten the band until patient feels a corrective force to their foot position. This may gradually increased as patient walks if necessary.

Step 10) Trim Midfoot Band

Trim midfoot band along fold line of midfoot band tab.

Press tab into the calf cuff cover to ensure hook and loop are engaged.

Note: Have the patient to stand and walk to ensure there is enough tension before trimming.

Step 11) Attach Calcaneus Band

Place calcaneus band tab at the wide part of the helix band.

Pull calcaneus band up and place onto calcaneus band tab to hold band in place. Check for fit and trim along where the tab folds.

Secure band in place.

Step 12) Check Final Setup

Check to see if the setups are correct for varus and valgus configurations as shown. Ensure the bands are tight enough. Have the patient to stand and walk to check for fit. Trim and adjust to ensure snug fit as needed.

Varus

Valgus

elevate

Manufactured by Elevate Dynamics
2040 Imperial Ave #3
San Diego, California 92102 USA

www.elevatemovement.com

077-1021-A