IN STEP LATERAL CARBON AFO

AF-200

Description

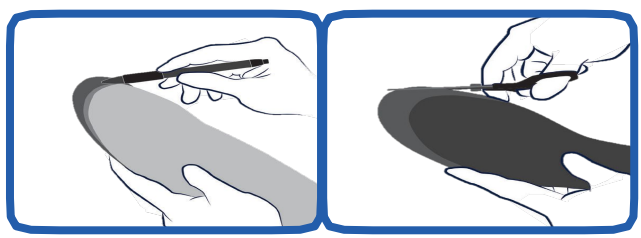
Intended Use

The In Step Lateral AFO is to be used exclusively for single patient orthotic fittings of the lower limbs and a sock should be used when there is contact with healthy and intact skin.

Footplate Preparation

1. Fitting Footplate to shoe

- Use the insole from the footwear to measure the template size
- Trace the template onto the In Step footplate
- Use scissors to trim the footplate to the correct template size
- Note: Do not cut into the Carbon Fiber. If you find that the Footplate is too large, it may be necessary to go to the next size down



Fitting instructions

1. Place In Step into Shoe

- The In Step should fit into the shoe with minimal distortion to the shoe

2. Place insole Over the Footplate

- Place original insole over the top of the In Step foot plate
- It may be necessary in some instances to provide the necessary insole to fit over the footplate.

3. Fitting the In Step

- With the shoelaces loose, slide the foot inside the shoe. You may use a shoe horn if needed

4. Check the Fit

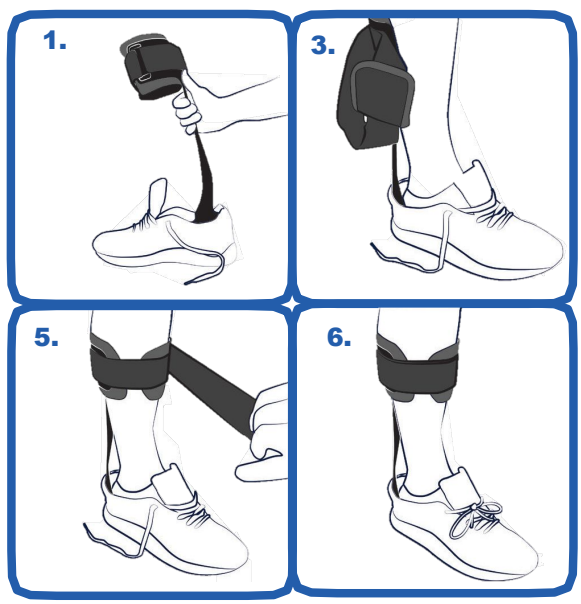
- Ensure the heel sits flat on the sole and that the shoe heel is not distorted

5. Secure the Calf Strap

- Feed the straps through the loop
- If the strap is too long, trim the strap with scissors
- Fasten strap firmly

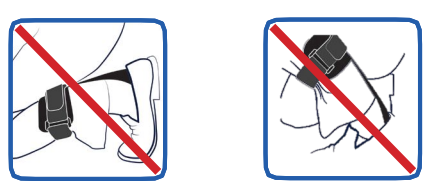
6. Secure the Fit

- Ensure laces or other fastening mechanisms are firmly tightened
- Ensure comfort with no impingements prior to use



Restricted uses:

Kneeling down, squatting down



P/N	DESCRIPTION	**SIZING** (Foot plate can be trimmed)
AF-200S/L	Left – Small (Mens 5-6 / Womens 6-8.5)	(25 cm)
AF-200S/R	Right – Small (Mens 5-6 / Womens 6-8.5)	(25 cm)
AF-200M/L	Left – Medium (Mens 6-9 / Womens 8.5-10)	(27 cm)
AF-200M/R	Right – Medium (Mens 6-9 / Womens 8.5-10)	(27 cm)
AF-200L/L	Left – Large (Mens 9-12 / Womens 10-13)	(29 cm)
AF-200L/R	Right – Large (Mens 9-12 / Womens 10-13)	(29 cm)

In Step Replacement Sleeve	Side
AF-ST-L	Left
AF-ST-R	Right

Indications

These indications are biomechanical deficits that the orthosis is intended to address. Assessment by a healthcare professional is always recommended. May include mild drop foot conditions with no more than mild spasticity, e.g. after stroke, traumatic brain injury, multiple sclerosis, neural muscle atrophy, peroneal palsy etc

- Foot Drop
- Excessive plantarflexion during swing phase (secondary to weak dorsiflexors)
- Weakness of the pretibial muscles <=3

Contraindications

These contraindications are pathological conditions the orthosis was not intended to address. In some scenarios the assessment of a trained CPO can override these suggestions.

- Patients over 250lbs
- Moderate to severe spasticity of the foot and ankle
- Open ulcers of the foot, ankle or lower leg
- Moderate to severe edema
- Moderate to severe foot deformities
- Moderate to severe ankle instabilities
- triplanar instability
- Plantarflexion contracture
- Running/high impact activities

In Step AFO fits patients with:

- a stable ankle
- mild impairment of motor knee control
- active patients, walking indoors as well as outdoors, but not for hiking or for extreme terrain or squatting exercises.

For foot deformities: In Step AFO is indicated when a passive foot deformity can be corrected through the use of an additional insole in combination with a sturdy shoe.
The In Step AFO is generally suitable for drop foot conditions.
Not recommended for squatting or kneeling while wearing In Step AFO, as this can cause undue stresses leading to premature failure and could void warranty.

Effects:

In Step AFO provides the user with a more natural gait pattern; a faster and more stable walk. The toes and foot are lifted up during swing phase (clearance) and “foot slap” is prevented. Energy restoring gives a propel effect at initial swing phase.

⚠ **CAUTION** In Step AFO is a dynamic ankle foot orthosis and not be used for prevention of contractures, etc.

Safety Instructions

INFORMATION The patient is to be instructed in the proper use/care of the product.
The initial fitting and application of the product must only be carried out by trained, qualified personnel. The daily duration of use and period of application are dependent on medical indication by the physician.

⚠**CAUTION** **Risk of injury as a result of improper use.** 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.
An orthosis/support applied too tightly to the body can cause local pressure and, in some cases, even restrict adjacent vessels or nerves. Do not apply the product too tightly. Consult a physician immediately if you experience unusual changes (such as increase in pain).
⚠ **Improper changes to the product are not permitted.**

⚠**CAUTION** Risk of accident when driving a motor vehicle. The ability to drive a vehicle when wearing an In Step AFO is to be determined from case-to-case basis by Clinician. Criteria include the type of fitting (clinical picture, fitting) and the individual abilities of the In Step AFO user. All users are required to observe their applicable national driving laws when operating motor vehicles.
For insurance purposes, drivers should have their driving ability examined and approved by an authorized test center.
The manufacturer warrants this device for 6 months from the date of purchase. The warranty covers defects that can be proven to be a direct result of flaws in the production or construction and that are reported to the manufacturer within the warranty period. Signs of abuse will not be a covered event.

⚠ **CAUTION** Risk of injury due to incorrect environmental conditions. The user must be informed of the risks that exceptional situations might present. For example, jumping down from great height (more than 1 meter / 39 inches) may expose the spring to severe overload and cause it to break.

⚠ ***NOTICE*** Damage due to incorrect environmental conditions. 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 products period of use.

Construction

With three dynamic elements (the upright, the heel and forefoot of the sole) the orthosis provides a smooth natural gait on even and uneven grounds.

⚠ ***NOTICE*** Damage due to inadmissible handling. The orthosis is made of pre-impregnated carbon fiber material and cannot be thermoformed. The foot of the sole and the connection elements must be free from holes as these would interrupt the fibers and weaken the component.

Adapting and Applying the product

1. Shoe selection: to obtain best effect of the In Step AFO, the user needs to wear a stable, laced shoe with a firm heel counter. The heel height should be 1,0 cm (+/-5 mm) / 0,4 inches (+/-0,2 inches).
2. Pick out correct size from the size chart.
3. Adapt the In Step AFO into correct size: If the user has a removable inner sole in the shoe, use that for marking the correct size on the footplate. (pic. 1), or draw a line around the user's foot directly on the foot plate.
4. Cut with scissors, or grind the foot plate with a grinding machine into correct size (outline on the foot plate), and avoid grinding into the carbon. When adjusting the foot plate width; grind on the medial side but not more than necessary, to avoid the lateral part of the insert to slide in the shoe and to avoid pressure on the malleoli. When adjusting the length of the foot plate, focus on grinding the back of the foot plate, then the insert will automatically be positioned behind (posterior) the medial malleoli which prevents pressure on the ankle and malleoli.
5. The shell can be adjusted by grinding, if necessary. Never modify the upright or around footplate attachment.
6. In the event of sharp edges at the orthosis, smooth them out by grinding the edges in water with wet/dry sand paper.
7. If the user has a foot deformity, correct it with a corrective insole or a custom molded device (If the foot cannot be corrected by an insole, the orthosis and a stable shoe, then an IN STEP AFO should not be used).
8. Apply the textile part on the calf part of the orthosis.
9. Cut the soft Velcro part at a proper length. To assure a good attachment, the soft Velcro should not be more than 2 cm longer than the hard Velcro, when the calf band is attached around the user's calf.

Instruction for use and care

Material: Carbon fiber composite. Calf band: Neoprene material, micro hook and loop, soft Velcro tape.

Cleaning:

• Textile part: Hand wash at 40 °C (104 °F) is recommended when necessary but approximately twice a week. Use a standard mild detergent. Wash out thoroughly and air-dry. Note: Residues of cleaning agents may cause skin irritations and wear of material.
• Composite part: wipe off with a moistened rag when necessarily.
Your Orthotist can supply you with a replacement calf cover when needed.
Upper limit temperature: 120 °C.
Disposal after use: Do not burn, Combustible material.

Further Usage Restriction Clause

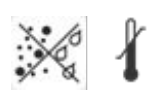
The product has been designed for use on only one patient. The daily duration of use and period of application are dependent on the medical indication.
Latex Safe: To our knowledge this product does not contain any natural rubber.

Liability

The ST&G warranty applies only if the product has been used under the conditions and for the purposes described. The manufacturer recommends that the product be used and maintained in accordance with the instructions for use.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10˚C to 50˚C [14˚F and 122˚F]
Do not store in wet or very hot environment.



Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing
Storage/transportation – relative humidity: 20 % to 90 %, non-condensing
Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics
cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts
Cleaning agents containing solvents

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CE Conformity

This product meets the requirements Council EU 2017/745 (MDR) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

ST&G USA CORPORATION
stngco.com

CORPORATE OFFICE
2691 Saturn Street | Brea, CA 92821
Tel: (714) 524-0663 | Fax: (714) 364-8113

ST&G CORPORATION
Rm. 911 43, Yangsan-ro
Yeongdeungpo-gu, Seoul, Korea

CE EC REP
MDSS GmbH
Schiffgraben 41 | 30175 Hannover, Germany