

IN|STEP[®] CARBON AFO



P/N: AF-100

INFORMATION

- Please read this document carefully.
- Follow the safety instructions.

Explanation of Symbols

CAUTION Warnings regarding possible risks of accident or injury.

NOTICE Warnings regarding possible technical damage.

INFORMATION Additional information on the fitting / use.

1 Description

1.1 Intended Use

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

1.2 Indications and Effects

In Step AFO supports with drop foot conditions with no more than mild spasticity, e.g. after stroke, traumatic brain injury, multiple sclerosis, neural muscle atrophy, peroneal palsy etc.

In Step AFO fits patients with:

- a stable ankle
- no or only mild impairment of motor knee control
- active patients, walking indoors as well as outdoors

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 sports activities, as long as no fast, sudden movements are executed in extreme stride sequences (e.g. basketball, badminton or bicycle riding with high activity).

In any case, activities should be discussed with the patient and a special fitting for high activity levels realized where applicable. Not recommended for squatting or kneeling while wearing In Step AFO.

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.

1.4 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 determined from case-to-case basis by provider. 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 the 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.

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.

1.5 Construction

Thanks to its construction with three dynamic elements (the pylon, 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.

2 Handling

2.1 Size Selection of the product

The size selection of the orthosis is based on the shoe size. Left and Right. Small, Medium, and Large.

2.2 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 his/her 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. Grind the foot plate by use of a grinding machine into correct size (according to the line on the foot plate), and avoid grinding into the carbon. When adjusting the foot plate width; grind on the lateral side but not more than necessary, to avoid the medial part/the insert to slide in the shoe and to avoid pressure on the medial malleoli (pic. 2). 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 (pic. 3).
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, a IN STEP AFO should not be used).
8. Apply the textile part on the calf part of the orthosis (pic. 4).
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.

2.3 Instruction for use and care

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

Cleaning:

- Textile part: Machine 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 extra calf cover (AF-ST-L (left) or AF-ST-R (right)) when needed.

Upper limit temperature: 120 °C.

Disposal after use: Do not burn, Combustible material.

3 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.

4 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.

5 CE Conformity

This product meets the requirements of the 93 / 42 / EWG guidelines 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. The declaration of conformity was therefore created by ST&G with sole responsibility according to appendix VII of the guidelines.

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