IN STEP CARBON AFO – ANTERIOR

AF-300

P/N	Description * SIZING IS BASED ON US MEASUREMENT	SIZING (Can be trimmed down to)
AF-300S/L	Left – Small (Men's 5-6 / Women's 6-8.5)	(25.5 cm)
AF-300S/R	Right – Small (Men's 5-6 / Women's 6-8.5)	(25.5 cm)
AF-300M/L	Left – Medium (Men's 6-9 / Women's 8.5-10)	(27 cm)
AF-300M/R	Right – Medium (Men's 6-9 / Women's 8.5-10)	(27 cm)
AF-300L/L	Left – Large (Men's 9-12 / Women's 10-13)	(29 cm)
AF-300L/R	Right – Large (Men's 9-12 / Women's 10-13)	(29 cm)

P/N	Replacement Pad	Left or Right
300-ST-S/L	Small	Left
300-ST-S/R	Small	Right
300-ST-M/L	Medium	Left
300-ST-M/R	Medium	Right
300-ST-L/L	Large	Left
300-ST-L/R	Large	Right

INTENDED USE

The In Step Anterior AFO is to be used exclusively for lower leg stabilization and positioning of the lower limb, and a sock should always be used when there is contact with healthy and intact skin. Weight Limit 125kg / 275lbs.

Indications and Effects

Foot drop secondary to neurologic conditions such as stroke, multiple sclerosis, trauma, injury or other conditions that result in weak ankle dorsiflexion function with the need for mild knee stability.

CONTRAINDICATIONS

Hypersensitivity or allergies to any of the materials from which the brace is made.
Neurologic conditions or injury resulting in diminished sensation.
Not intended for contracture management.
Not to be used with any open wounds within the AFO structure.
Excessive swelling / edema.
Not indicated for severe spasticity or absent muscle strength of the ankle and or knee complex.
Moderate to high tone, deformity of foot/ankle or other condition where a brace is not allowed according to medical instructions.
Do not fit to a patient with severely atrophied, or excessively large calf muscle compartment, as this can unduly stress the anterior calf cuff which could lead to a failure. This would not be considered a manufacturing defect, so be sure to fit only appropriately sized patients.
Not intended for running or high impact activities.

In Step Anterior AFO fits patients with:

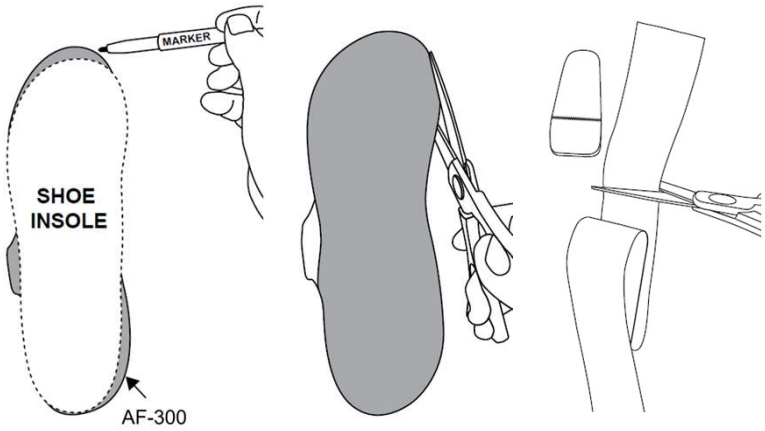
- a stable ankle – severe pes cavus is not indicated for usage.
- mild impairment of motor knee control
- patients walking indoors as well as outdoors, but not for hiking or for extreme terrain or squatting exercises.

For foot deformities: In Step Anterior AFO is indicated when a passive foot deformity can be corrected through the use of an additional insole in combination with a sturdy shoe. Not intended to be fitted with any high force corrective strapping system.
The In Step Anterior AFO is generally suitable for drop foot conditions requiring mild to moderate knee stability.
Not recommended for squatting or kneeling, as this will cause undue stresses.

FITTING THE BRACE

To identify appropriate AFO size, measure the length of the foot, choose the orthosis based on the measurements.

ANTERIOR AFO SIZING	S	M	L
LENGTH	255mm / 10.04 in	270mm / 10.63 in	290mm / 11.42 in
HEIGHT	380mm / 14.96 in	405mm / 15.95 in	430mm / 16.9 in
HEEL HEIGHT	12mm / 0.5in	15mm / 0.59in	16mm / 0.63in

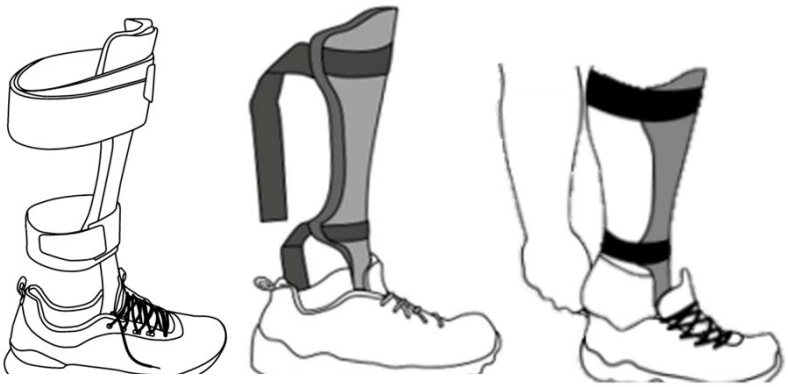


ADJUSTMENT

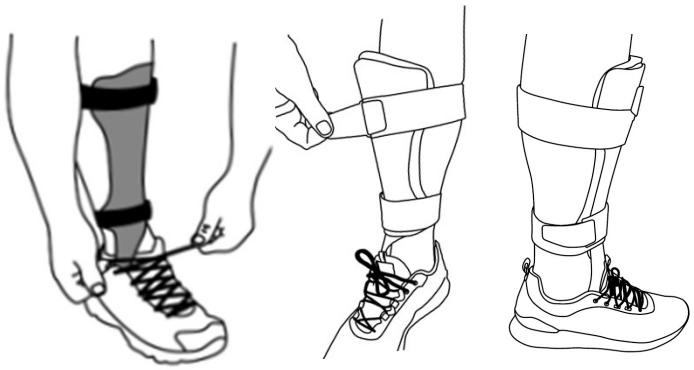
A. Mark the footplate to the appropriate size. If removable, use the insole from the shoe to be fitted and trace.
B. Use scissors to trim away excess material. Use sandpaper to smooth edges.
C. To trim the straps, remove the tab from the strap. Trim to the desired length and reapply the tab.

APPLICATION

A. Remove the insole and from the shoe of the side to be fitted. Insert the orthosis and replace the insole B. Open the straps and apply the orthosis with the shoe. Close the straps.
NOTE: Ensure the orthosis is not in contact with any boney prominences and is comfortable to the patient. If needed, adjust orthosis appropriately by reducing the length of the strap closures.
To remove, loosen the straps and remove the foot from the shoe. Ensure the orthosis remains in the shoe for easy application.



Insert Foot Plate completely into the shoe. Be sure that the insole is removed prior to inserting AFO, and loosen shoe laces.



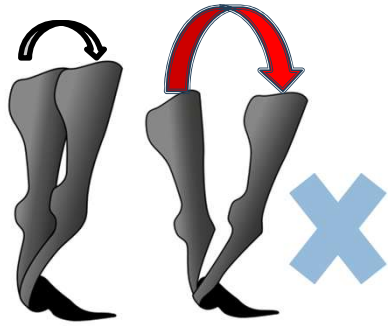
Slide your foot into the shoe, using a shoe horn if needed. If the shoe has shoestrings – tie snugly. Secure the straps snugly around your leg.

Shoe / AFO Removal

Undo straps pulling front to back.
If shoe has shoelaces, undo laces.
Slide heel up and out of the shoe. It is most beneficial to retain the AFO inside the shoe after removal.

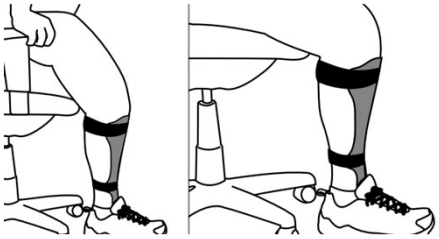
Removing AFO from Shoe

Slide hand under heel portion of foot plate and guide up and out to remove from shoe.



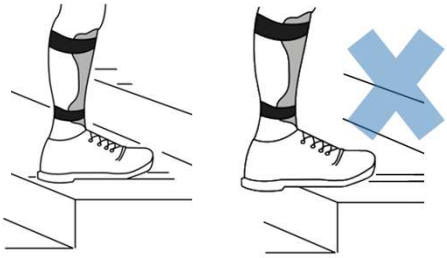
This AFO is designed with normal range of motion through the foot plate shape while walking.
Excessive forward, backward, or lateral bending forces may lead to accelerated wear and tear stresses. AFO is not for controlling severe Cerebral Palsy walking anomalies, excessive spasticity, or high tone incidents.

ONLY pull from front to back to release the straps.
The wings are flexible for comfort. Do not flex the wings back and forth excessively, as it could lead to accelerated damaging stress. The flexibility is not for accommodating excessively atrophied or large calf anatomy.



STANDING FROM SEATED POSITION
Feet should be placed flat on floor prior to transitioning to an upright position. Use arms of chair to help push yourself up or use stationary item for assistance to pull upward. Similar transitioning should take place from any seated location including car, chair or toilet. Avoid placing feet too far back, as this can lead to unwanted excessive bending force to the AFO similar to squatting.

STAIRS
Place ENTIRE foot on step, not just the forefoot
SQUATTING
Squatting will significantly increase unwanted stress on the AFO increasing the risk of causing damage.



⚠ **CAUTION** In Step Anterior 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.** 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 Anterior AFO is 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 Anterior 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.

PRECAUTIONS

READ INSTRUCTIONS BEFORE USE.
These directions are guidelines only and are not offered as medical recommendations. If you suffer from a serious medical condition, we strongly suggest that you consult with a licensed health care professional before using this product. Proper fitting is required for this product to be effective, and should only be used when prescribed by a physician. Please see the limited warranty for further information.

LIMITED WARRANTY

ST&G warrants to the user who originally purchases this product that it is free from defects in material and workmanship. The sole obligation of ST&G in the event of breach of warranty shall be to repair or replace the defective product or part(s).
ST&G shall have no obligation under this limited warranty in the event:
(a) The product was not purchased from ST&G or through its authorized channels of distribution;
(b) The product is altered;
(c) Any parts not supplied by ST&G are inserted into the product; or
(d) The product is not used in accordance with the ST&G Instructions for Use.
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. Shell Cover is warranted for 6 months, but is considered a consumable item.

⚠ **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

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.

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 necessary.

Your Orthotist can supply you with extra calf cover when needed. Refer to Replacement Pad sizing chart.

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

CE Conformity

This product meets the requirements Council EU 2017/1745 (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