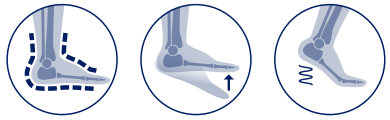
SpryStep® Custom - SpryStep® Vector

Instructions for use
CUSTOM MADE DYNAMIC ANKLE-FOOT ORTHOSIS (AFO)

Custom-made device.
Custom fabricated orthosis, made from a positive model of the patient's limb.



Stabilisation | Biomechanical correction | Energy return

MD

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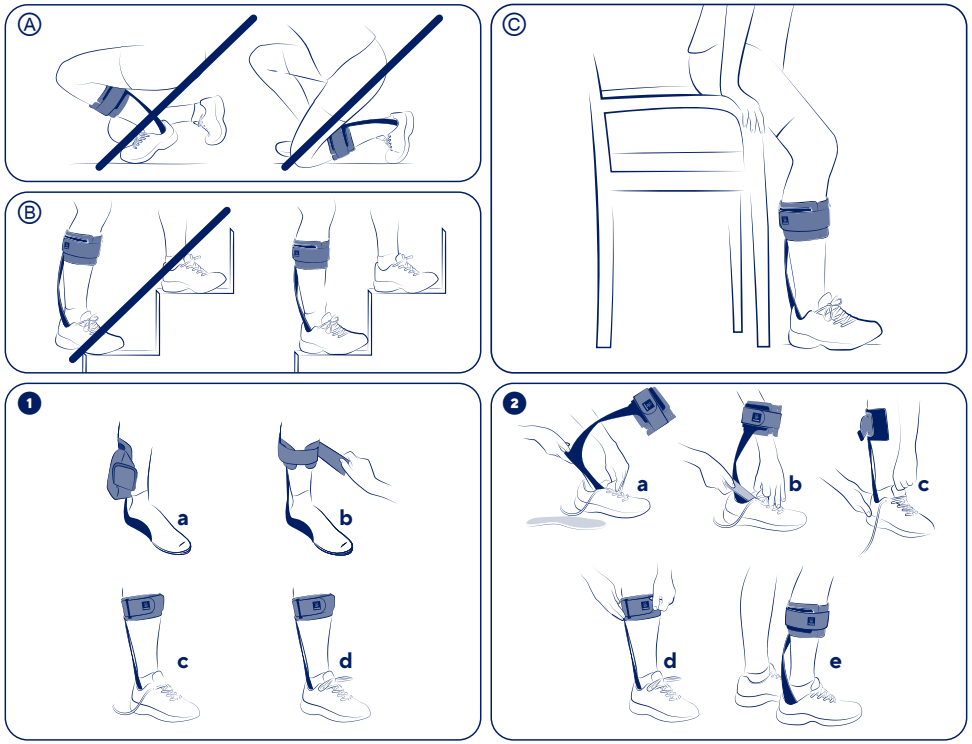

Description/Destination
The device is intended only for the treatment of the indications listed and for patients whose measurements correspond to the sizing table.
This device is a dynamic ankle-foot orthosis (AFO) that supports and/or stabilizes the foot and ankle while walking.

Composition
Rigid components: carbon fibre - glass fibre - high density polyethylene - polypropylene copolymer - stainless steel.
Textile components: polyamide - elastane - polyurethane - ethylene vinyl acetate.

Properties/Mode of action
The AFO is composed of two parts (rigid and soft part) already assembled.
The rigid part, made of composite materials and polyamide, is positioned under the foot and along the leg to provide stabilisation, biomechanical correction and energy return.

Indications
These indications are biomechanical deficits of neurological, traumatic or muscular origin.
Excessive plantarflexion during swing phase (secondary to weak dorsiflexors).
Weakness of the pretibial muscles ≤ 3.
Plantar flexor strength 0 to 4.
Knee instability during stance phase.
Quadriceps weakness.
Knee hyperextension.
Excessive knee flexion during stance phase (secondary to weak plantarflexors).
Partial foot amputation (Chopart or more distal).
Fatigueable footdrop.
Footdrop.
Footslap.
Circumduction.
Vaulting (plantarflexion of the contralateral ankle joint in median stance phase).
High knee gait.
Hip hiking/contralateral trunk bending. Trendelenburg gait/limp.
The custom application allows to accommodate for the following after full assessment:
Plantarflexion contracture.
Knee hyperextension caused by calf muscle spasticity.
High tone.
Non-correctable triplanar instability.
High pitched footwear.
Running/high impact activities on lower limb.

Contraindications
Do not use the product if the diagnosis has not been confirmed.
Do not apply the product in direct contact with broken skin.
Do not use in the event of known allergy to any of the components.
Do not use for patients weighing > 160 kg.
Open ulcers of the foot, ankle or lower leg.
Severe loss of sensation in the lower limb.

Precautions
Verify the product's integrity before every use.
Do not use the product if it is damaged.
The initial fitting and adjustment must be done by a healthcare professional.
Strictly comply with your healthcare professional's prescription and recommendations for use.
Check the condition of the affected limb and the state of the skin daily (with particular attention for patients with sensory deficit).
In the event of discomfort, significant hindrance, pain, variation in limb volume, abnormal sensations or change in colour of the extremities, remove the device and consult a healthcare professional.
For hygiene, security and performance reasons, do not re-use the product for another patient.
Do not use the device in case of application of certain products on the skin (creams, ointments, oils, gels, patches...).
Do not wear the product in a medical imaging machine.
The ability to drive a vehicle with the device must be assessed by a healthcare professional and according to local regulations.
The systematic use of a sock is recommended when wearing the device.
It is recommended to adequately tighten the device to achieve a good fit on the limb without restricting blood circulation.
Do not expose the product to extreme temperatures.
In the event of any modification in the product's performance, remove it and consult a healthcare professional.
Do not kneel or squat with the device (to the exception of a SpryStep® Flex Custom configuration). Ⓐ
Avoid excessive pressure on the forefoot area:
- Always place the entire foot on any step or uneven surface. Ⓑ
- Transition sitting/standing position (chair, toilet, car, ...): put the foot flat on the ground before moving to standing. Use any fixed support (armrests, support bar...) to limit the overload of the foot lifter. Ⓒ

In pediatric applications:
It is recommended that an adult supervises the application and use of the product by a child.
Regularly check the patient's growth (change in shoe size, floor-to-calf height...).
It is recommended to renew the device (bigger size) if the child's shoe size (foot length) evolves by more than 2 sizes.

Undesirable side-effects
This device can cause skin reactions (redness, itching, burns, blisters,etc.) or wounds of various degrees of severity.
Possible risk of venous thrombosis.
Any serious incidents related to the product should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is resident.

Instructions for use/Application
The device must be worn in shoes with the following features:
- Stiff posterior heel cup sufficiently high to fully encapsulate the foot and the orthosis.
- Shoe closure system: self-fastening tabs or laces.

Trainers or athletic shoes are the best type of shoes to use with the device.
Preparation of the AFO performed by the healthcare professional:
Make sure that the patient's footwear complies with the recommendations.
The healthcare professional must supervise the fitting of the product and the specific walking conditions of the patient when using the device for the first time.
Fitting the AFO:
Take the inlay out of the shoe, if removable.
If the device provided has a moulded inner boot: place the foot inside the moulded inner boot. **1a**
Secure the strap(s) **1b**:
Feed the strap(s) through the corresponding buckle(s).
If a strap is too long, remove the self-fastening tab, trim the strap with scissors and reposition the self-fastening tab.
Tighten the strap(s).
Loosen the shoe laces and slide the foot inside the shoe **1c**.
You may use a shoe horn if required.
Ensure laces or other tightening mechanisms are firmly fastened **1d**.
Ensure comfort of foot and leg, with no impingements, prior to use.
If the device provided has no moulded inner boot:
Place the device into the shoe **2a**.
Ensure the device's foot plate sits flat on the sole of the shoe and that the posterior heel cup of the shoe is not distorted.
Replace the removable inner sole on top of the device's footplate, unless it makes the shoe too tight **2b**.
If there is no removable inner sole then disregard this step.
Loosen the shoe laces and slide the foot inside the shoe **2c**.
You may use a shoe horn if required.
Check the fit:
Secure the strap(s) **2d**:
Feed the strap(s) through the corresponding buckle(s).
If a strap is too long, remove the self-fastening tab, trim the strap with scissors and reposition the self-fastening tab.
Tighten the strap(s).
Ensure laces or other tightening mechanisms are firmly fastened **2e**.
Ensure comfort of foot and leg, with no impingements, prior to use.
It may take several weeks to feel comfortable with the brace on your leg.
Depending on country of sale, additional accessories/spare parts could be available.

Fitting the spare parts (by a healthcare professional or by the patient):
The spare parts kit contains the following components: foam pad(s), strap(s), self-fastening tab(s).
Remove the textile parts and the self-fastening tab(s) (if damaged) sticked on the rigid part.
Clean the area where the self-fastening tabs were applied.
Replace the self-fastening tab by new one(s) and then position the new foam pad.
If needed, shorten the replacement strap(s): remove the self-fastening tab, trim the strap(s) and replace the tab.
Position the buckle of the strap on the rigid part and follow the fitting instructions.
Alterations that can be done to the brace during fitting:
- Shell: some minimal trimming of the shell can be done (max. 2 cm).
  Do not remove material within 2 cm of the strut insertion.
- Footplate:
  - Trimming of the footplate to facilitate shoe fitting.
  - Heat molding the inner boot (if ordered).
  - Adding posting intrinsically or extrinsically to fine tune the alignment or accommodate for plantarflexion contracture.

The following actions would waive the warranty:
- Trimming in or near (< 2 cm) the strut.
- Over trimming of the shell.
- Trimming the footplate below the patient foot length.
- Any attempt to heat-mold the composites materials.

Care
Product can be washed in accordance with the instructions shown on this leaflet and on the label. If the device comes into contact with water, dry the textile part and wipe the rigid part well with a dry cloth. If the device is exposed to seawater or chlorinated water, make sure to rinse it in clear water and dry it. Rigid components: wash the rigid part with a moist cloth. Textile components: the soft part can be fully removed for washing. Replace in the original location before next use. Machine washable at 30 °C (delicate programme). Remove the self-fastening tabs before washing. Do not use detergents, fabric softeners or aggressive products (products containing chlorine). Do not dry clean. Do not tumble-dry. Do not iron. Squeeze out excess water. Dry flat. Dry away from any direct heat source (radiator, sun, etc.). After prolonged use, if the fibers on your strap do not adhere as well to the self-fastening tab, cut the strap shorter so the self-fastening tab adheres to a section of the strap that has fresher fibers. If this is not possible, you should contact the medical provider who fit your brace.

Storage
Store at room temperature, preferably in the original packaging.

Disposal
Dispose of in accordance with local regulations.

Keep these instructions for use.

COMMERCIAL WARRANTY AGREEMENT AND WARRANTY LIMITATIONS
Thuasne offers a free, limited commercial warranty to the user, in the territory where the device was purchased, against defects in manufacturing and workmanship for a period of:
- six months for the textile components;
- one year for the rigid components.

The limited warranty is effective from the date of purchase of the product by the end-user.
The limited commercial warranty does not apply to any defects in manufacturing and workmanship in case of:
- misuse of the product or any damage occurred by a usage outside the normal and intended use of the product as mentioned in the instructions for use,
- damages occurred while user is squatting or kneeling,
- heavy loads on the toe plate,
- damage that occurs due to attempts to modify the product.

Any deterioration or improper trimming of the product during its modification or adjustment process by the healthcare professional when fitting device is expressly excluded from this warranty.
Any claim for this commercial warranty must be sent by the user or its legal representative (parents, guardian...) to the entity where the product was purchased, which will forward this claim to the corresponding Thuasne entity.
Any warranty claim will first be reviewed by Thuasne to determine if the conditions of the limited warranty are fulfilled and do not fall into one of the cases of exclusion of the commercial warranty.
To benefit from the warranty, the buyer must mandatorily provide an original and dated proof of purchase of the product.
If the conditions of the limited warranty are fulfilled and the claim is made by the user or its legal representative (parents, guardian...) within the warranty delays indicated above, the buyer will get a new substitution product.
It is expressly agreed that this commercial warranty is in addition to the legal warranties binding the entity which sold the product to the user, in accordance with the applicable local legislation in the country of purchase of the product.