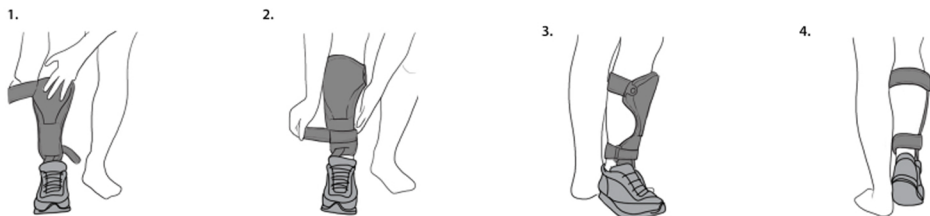


2.2. Adapting and applying the products

1. Shoe selection: for effective function of orthosis, the user should wear stable, laced shoes with a firm heel counter. The height of the heel counter should be 1 cm (+/- 5 mm) / 0,4 inches (+/- 0,2, inches).
2. Selection of proper size may be done only with size chart.
3. For selection the proper size there is necessary to place the foot on paper and draw a line around it. Then, there is necessary to measure the length between extreme positions in drawing.
4. If foot deformation is present, it should be corrected with insole, custom-made orthopaedic device or shoes. In this two last cases, patient should not use AM-ASS-OS orthosis.
5. In case of using insole, remove it from shoes, put the orthosis there and then place the insole on the orthosis.
6. If some part of the carbon piece is larger than insole, there is possible to cut excessive material off with scissors. In this case, the edge of the carbon should be polished with emery paper. First, use the emery paper in high grade and then in lower grade.
7. First, put the orthosis into shoe, insert foot and fasten all straps.
8. If it is present, the additional kit: T-strap for ankle and foot AFO PLUS, made of EVA foam, should be assembled.
9. Excessive material of straps may be cut off.



2.3. Instruction for use and care:

Material:

- 70% - carbon fiber
- 10% - cevlar
- 18% - polyamide
- 2% - elastane

Cleaning and maintaining:

- Textile part: Machine wash at 40o (104 °F) s 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. In case of overusing or damage of textile parts of AFO orthosis, you can purchase them. In this case, contact your distributor or REH4MAT company directly.

- Composite part: wipe off with a moistened rag when necessarily.

Upper limit temperature: 120 °C.

Flammable material.

3. Other information:

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 manufacturer guarantees their products for a period of 12 months from the date of invoice. 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.

It conforms the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Annex VII), as amended by Medical Device Directive 2007/47/EEC regarding medical products belong to the 1 Class Of Medical Devices without measuring function, non-sterile and associated with it norms: PN-EN 1041:2010 - Information Supplied By The Manufacturer Of Medical Devices, PN-EN 12182:2012 - Assistive Products For Persons With Disability - General Requirements And Test Methods, PN-EN ISO 13485:2012 - Medical devices - Quality management systems - Requirements for regulatory purposes, PN-EN ISO 14971:2011 - Medical products - Application of risk management to medical products, PN-EN ISO 15223-1:2012 - Medical devices - Symbols to be used with medical device labels,



AM-ASS-OS

ANKLE FOOT ORTHOSIS FOR FOOT DROP



KOD KATALOGOWY	AM-ASS-OS
NAZWA HANDLOWA	ORTEZY STAWU SKOKOWEGO
MODEL	AM-ASS-OS
CODE	AM-ASS-OS
TRADE NAME	ANKLE ORTHOSIS
MODEL	AM-ASS-OS

PATIENT INFORMATION

Dear AM-ASS-OS User,

You have received our dynamic ankle foot orthosis AM-ASS-OS made of carbon. the aim of the orthosis is providing support and compensation for reduced function. AM-ASS-OS AFO orthosis is made by REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, POLAND.

The orthosis AM-ASS-OS helps you to keep your foot raised during the swinging phase itself walking, it means: when the leg is swinging freely. To meet your expectations, the orthosis should be used together with a stable shoe for it to function well. The orthosis is placed on the leg with self-attached straps. It should be assembled firmly to avoid involuntary moving the orthosis and skin lesions.

When the valgus ankle is observed, we highly recommend to use our T-strap for ankle and foot AFO PLUS, made of EVA foam, that provides ankle stabilization by pulling the talocrural and subtalar joints laterally to position them back underneath the tibia.

If you have any problems using our AFO orthosis, please send us e-mail: export@reh4mat.com or call us: +48 16 621 42 20 i +48 16 621 41 35.



36-060 Głogów Małopolski, ul. Piaski 47, POLAND | Adres korespondencyjny/Mailing address:
ul. Truskawkowa 17, Widna Góra, 37-500 Jarosław, POLAND | tel. +48 (16) 621 42 20, +48 (16) 621 41 35
Adres mailowy/ e-mail address: biuro@reh4mat.com | www.reh4mat.com

INSTRUCTION FOR USE

INFORMATION

Date of the last update: 05/08/2017

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

1 DESCRIPTION

1.1. Intended use

Ankle and foot orthosis AM-ASS-OS should be used only as an orthopaedic device of the lower limbs. The orthosis should have contact only with healthy and intact skin.

1.2 Indications and effects

Aim of AM-ASS-OS orthosis is reducing of drop foot conditions with no more than mild spasticity, e.g. after stroke, traumatic brain injury, in multiple sclerosis, neural muscle atrophy, peroneal palsy etc.

AM-ASS-OS should be used only when conditions below are presented:

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

Foot deformations: AM-ASS-OS can be used in case with foot deformations, but using the insoles is crucial.

Amputation in foot area: AM-ASS-OS can be used in case of fingertip amputations but before that you need to consult that with your doctor. There is possible to use AM-ASS-OS after foot and heel amputations (e.g. Chopart or Lisfranc's amputation) but there is necessary to use special clamshell sockets.

ATTENTION!

In case of using insoles, there is necessary to remove the insole, put the orthosis and place the insole on it. If some part of the carbon piece is larger than insole, there is possible to cut excessive material off with scissors. In this case, the edge of the carbon should be polished with emery paper. First, use the emery paper in high grade and then in lower grade.



In case of putting AFO orthosis directly on the insole, there is risk of improper working of insole and damage the leg and shoes!

Effects: AFO AM-ASS-OS orthosis provides the user with a more natural gait pattern and 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. Because of this, the walking is easier and more effective.

ATTENTION! AM-ASS-OS is a dynamic ankle foot and cannot be using as a protection against the muscles contractures. Indications of using the orthosis should be consulted with doctor.

1.3.1 Absolute contraindications:

- Mild and severe spasticity of lower limb
- Leg lesions and ulcers
- Mild and severe swelling of lower limb
- Mild and severe foot deformations

1.3.2 Relative contraindications:

If some of following symptoms are present, consultations with physician is required:

- skin diseases and injuries
- inflammations
- prominent scars that are swollen
- reddened and warm skin when touched
- lymphatic conditions
- circulatory conditions
- sensory conditions

1.4 Safety instruction:

INFORMATION

The patient should be instructed in the proper use and 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 doctor's recommendations.

ATTENTION!

Risk of injury is a result of improper use of the orthosis. One product may be used only by one patient.

In case of using orthosis by another person, there is high risk of skin infections and allergy. When the orthosis is applied too tightly, there is risk of local pressure which can cause veins and nerves conditions. 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.

ATTENTION!

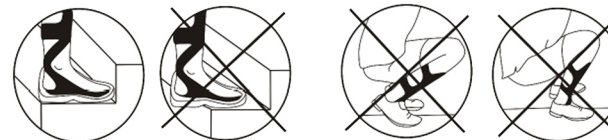
Risk of car accident while using the AFO orthosis:

We do not recommend drive when AM-ASS-OS orthosis is applied.

ATTENTION!

Risk of injury and orthosis damage as a result of adverse weather and environmental conditions:

User should be informed about risk of everyday situations. For instance, jumping down from a height can result in injuries. The products is not flame-resistant. Keep it away from flames and other heat sources. The orthosis cannot interact with liquids, grease, acidic agents and lotions. This contact may reduce the product's warranty period.



1.5 Construction

Thanks to three points dynamic construction (caf, foot and forefoot), the orthosis provides a smooth natural gait pattern on even and uneven surfaces.

⚠ Walking in stairs by taking weight on the forefoot and squatting with applied orthosis are permitted due to risk of orthosis damage.

ATTENTION!

Damage of AFO orthosis as a result of improper using:

The carbon material of the orthosis is impregnated initially in 100°C. If there is need for custom fitting the orthosis, only qualified orthotist can do that in electric heater. This heater can heat particular part of the orthosis and after that it can be fitted to the patient. There is required temperature 120°C for achieving material plasticity. The heating process should be under control because of high risk of burning the orthosis.

DO NOT, UNDER ANY CIRCUMSTANCES, PUT WHOLE ORTHOSIS TO OVER OR HEATER, BECAUSE OF RISK OF DAMAGE THE ORTHOSIS.

After heating the external structure can change and it is normal process.

⚠ ANY ATTEMPTS OF CUSTOM FITTING THE ORTHOSIS MAY BE DONE ONLY AT PATIENT'S OWN RISK, AND PRODUCER DOES NOT TAKE ANY RESPONSIBILITY AND PRODUCT CAN NOT BE COMPLAINED. FURTHERMORE, PRODUCER DOES NOT TAKE ANY RESPONSIBILITY FOR ANY INJURIES OR MEDICAL INCIDENTS.

2. Handling:

2.1 Size selection

The size choosing is based on the foot length. Available sizes: S – XL. The orthosis is anatomic-shaped and is available for right/left leg.