



Pre-preg Carbon AFO

INSTRUCTION FOR USE



Advance

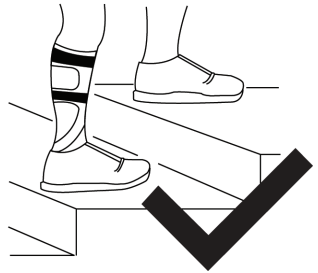
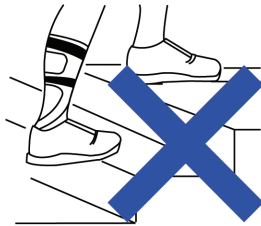
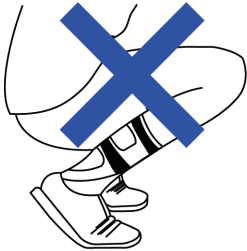


Stability



Fixation

ORTHO BALTIC



DO NOT OVERBEND YOUR AFO WHEN GOING DOWNSTAIRS OR UPSTAIRS AND SQUATTING

READ THIS INSTRUCTION FOR USE CAREFULLY BEFORE USING THE PRODUCT

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1. PURPOSE OF THIS DOCUMENT

The main purpose of this document is to inform the patient about instructions and precautions to follow while using this medical device. Following these guidelines will also ensure the longevity of the product.

2. MAIN PRODUCT INFORMATION

2.1. Product name

Easy Walk® Ankle-Foot Orthosis (AFO)



Product model	Product code	Basic-UDI	EU Patent No
Easy Walk® Fixation AFO	AFO10F	477903210EWAFO10FSZ	LT5887
Easy Walk® Stability AFO	AFO10T	477903210EWAFO10TTV	LT5874
Easy Walk® Advance II AFO	AFO12A	477903210EWAFO12ASV	LT5450
Easy Walk® Advance AFO	AFO10A	477903210EWAFO10ASP	LT5450
Easy Walk® Eco AFO	AFO10E	477903210EWAFO10ESX	LT5450

2.2. Manufacturer



Ortho Baltic UAB
Taikos Ave. 131A, LT-51124 Kaunas, Lithuania
+370 37 473970
info@orthobaltic.lt
www.orthobaltic.eu

2.3. Intended purpose and benefits

Easy Walk® pre-preg carbon fibre ankle-foot orthoses (AFOs) are designed to support a patient with foot drop condition. The Easy Walk® devices optimize the toe lift due to the energy return during the gait cycle, provided by carbon composites.

2.4. Indications

Easy Walk® Advance Easy Walk® Advance II Easy Walk® Eco	Easy Walk® Stability	Easy Walk® Fixation
<ul style="list-style-type: none">• Foot drop secondary to neurological disorders	<ul style="list-style-type: none">• Foot drop secondary to neurological disorders• Ankle instability• Spasticity (mild level)• Proprioceptive deficit	<ul style="list-style-type: none">• Foot drop secondary to neurological disorders• Severe ankle instability• Spasticity (mild-moderate level)• Proprioceptive deficit

2.5. Contraindications

- Severe ankle and foot deformities
- Severe spasticity
- Oedema
- Inflammatory lesions of calf and foot skin

3. WARNINGS AND PRECAUTIONS



Failure to follow this instruction may lead to the damage of the orthosis and unsafe use. It may also void the warranty.

3.1. Fitting

Only certified Orthotist can fit you with this orthosis. You have to be instructed on how to wear your device by a professional. The statements of this Instruction For Use have to be explained to you as well. Visit your Orthotist regularly for monitoring and always follow his/ her instructions.

The user weight limit for this orthosis is 120 kg.

3.2. Restrictions of use

The orthosis is intended for partial compensation of the movement disorder, i.e. the orthosis helps a patient to move. However, it does not fully perform the functions of the healthy leg and does not give the patient other additional physical capabilities. On the contrary, the orthosis may impede to carry out certain motions that can be made with a healthy leg. Therefore, it is necessary to be aware of the potential risk arising in certain situations: the orthosis could prevent you from braking quickly while driving a car or overstepping instantly appeared the unexpected obstacle, etc.

3.3. Daily activity

The orthosis is created for usual daily movements and can be bent to a limited extent. However, excessive and sudden bending in any direction shall be avoided. This shortens the longevity of the orthosis and can lead to a sudden breakage that could even cause an injury. Therefore, be careful not to overbend your AFO when going downstairs or upstairs and squatting.

Do not stand too much on the forefoot only and never on the toes. If you are not confident, put your full foot carefully on the surface to prevent you from slipping accidents.

In general, active life is recommended. This orthosis can be used in some sports activities with limitations. However, every case is individual. Discuss your daily activities and special needs with your Orthotist and follow his/her advice in order to ensure safe use of your AFO.

If you feel any unusual discomfort while wearing the orthosis, discontinue use and contact your Orthotist for advice.

3.4. Shoes and other components

The orthosis shall always be used only together with shoes, insoles, padding, strapping and other components approved by your Orthotist.

An AFO with a wrong shoe can lose its functionality and even cause an accident.

There shall be certain intermediate layers between the orthosis and the leg in order to prevent skin damage (irritations, ulcers and others).

See more information in section 4.

3.5. Skin Monitoring

It is recommended to examine the leg every time after use of the orthosis. If you see any skin irritation, blisters or feel discomfort, stop using the orthosis and contact your Orthotist. Be especially careful if you have diabetes.

3.6. Daily orthosis monitoring

Check your orthosis daily for possible damage, wear or formation of material creases. If you notice anything, do not use the orthosis further and contact your Orthotist.

Be careful with a broken orthosis - cracked carbon parts can be sharp and may cause an injury.

Check whether strapping, padding and insoles are not worn out. If that is the case, contact your Orthotist for new replacement.

3.7. Modification of the orthosis

Do not cut, heat or modify your orthosis in any way because this could lead to damage or impair the functionality of the device. Any modifications shall be carried out by your Orthotist only.

4. HOW TO PUT YOUR ORTHOSIS ON

The orthosis with a shoe, a sock and an insole complement each other. The orthosis cannot be used alone. Only a combination of all elements together, chosen by your Orthotist, provides the intended functionality.

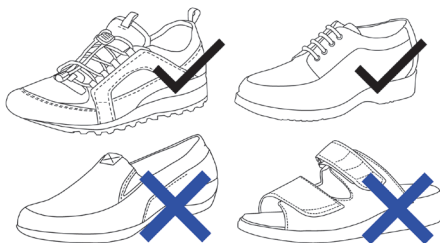
There are three steps to put Easy Walk® AFO on:

1. Put the orthosis in the shoe and slip your foot in;
2. Secure the orthosis with the calf strap;
3. Fasten the shoe firmly.

4.1. Shoes

In order to position the orthosis properly, the shoe shall meet the following requirements:

- shall have correct heel height, matching the prescribed AFO;
- shall be stable and provide proper support from all sides, especially at the heel;
- height shall be up to malleolus, not higher;
- shall fasten firmly, limiting the foot slipping in any direction.



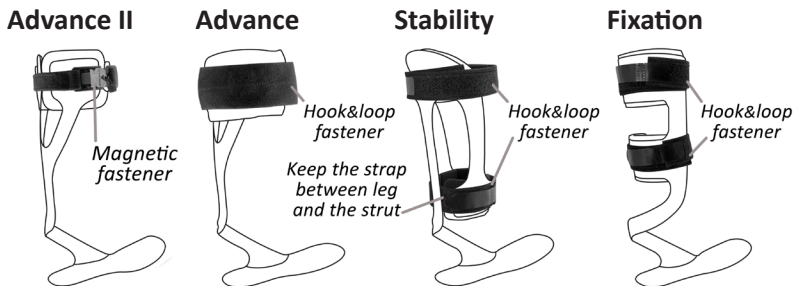
4.2. Intermediate layers

There shall be intermediate layers between the orthosis and the leg:

- The orthosis shall always be worn with padding;
- The insole or cover material shall be fixed to the top of the footplate;
- Socks shall be worn for skin protection and reduction of perspiration.

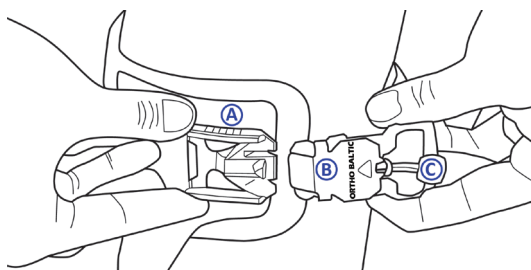
4.3. Fastening of the calf part

The calf straps shall be fastened firmly but not too tight to avoid restriction of blood circulation.



For Advance II: adjust the strap length with hook & loop and use the magnetic buckle for fastening.

To fasten, hold the A part of the buckle with one hand and tighten the strap by pulling the B part over the A part. The magnet will catch both parts together and lock them safely. To open, just pull off the pull-tab (C).



5. CARE

Check your orthosis daily as it is described in section 3.6. Clean AFO with a damp cloth when necessary. Wash paddings at up to 40°C and air dry.

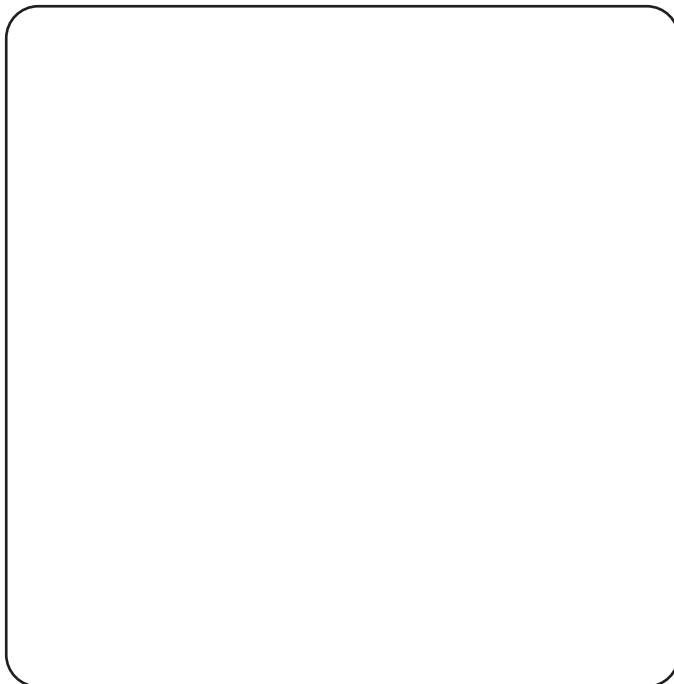
6. DISPOSAL

The orthosis shall be disposed of in accordance with the national law and regulations.

7. REPORTS

Your practical experience when using this AFO is important for further development of Easy Walk® products. If you have any complaints, comments or ideas on how to improve the AFO, please report to your Orthotist or the manufacturer by e-mail info@orthobaltic.it

In case of any serious incident that occurred in relation to the device, please report to your Orthotist, or the manufacturer, or your local competent authority.



ORTHO BALTIC

Ortho Baltic UAB
Taikos Ave. 131A, LT-51124
Kaunas, Lithuania
+370 37 473970
info@orthobaltic.lt
www.orthobaltic.eu



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