Dynamic Walk

Product Manual

Fillauer.

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Intended Use/Purpose

The Dynamic Walk is a revolutionary orthosis recommended for patients with foot drop. Its unique design provides stable free movement and constant lifting of the foot. The open heel construction allows for natural and comfortable foot movement.

With Dynamic Walk, users can enjoy everyday activities like walking on flat surfaces, uphill or downhill, going up or down stairs, running and even driving. It is easy to put on, offers maximum performance and fits into normal shoes. The unique, lightweight design combines strength with simple and secure application. Featuring a heat-moldable, trimmable calf band and foot plate, the Dynamic Walk ensures a comfortable fit every time.

Indications

- · Peroneal pares or paralysis
- Unload the anterior tibialis tendon

Contraindications

- Neuropathy
- Severe spasticity
- DW Standard: if the user has a weak quadriceps muscle
- DW Anterior: if the user has hyperextension in the knee

Performance Characteristics

- · Reshapeable thermoplastic carbon fiber
- Flexible
- Lightweight
- · Easy donning and doffing
- · Fits easily into normal shoes
- · Primary Materials: Thermoplastic carbon fiber,
- LCP reinforcement

Storage and Handling

Do not place this product in direct sunlight for long periods of time. When not in use, store in a cool, clean, dry and dark place.

Warnings and Precautions



WARNING: This device has been designed and tested for activities of daily living and not for abnormal activities such as extreme sports. To avoid risk of injury, handle your orthosis and its components with care. If your orthotic components are subjected to abnormal stress (such as a fall) contact your prosthetist /orthotist. to have the components inspected for any damage.



NOTICE: Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist/orthotist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.



NOTICE: Contact your local governing authorities regarding any driving restrictions or limitations.



NOTICE: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the Dynamic Walk and is not covered under the warranty of the device. This prosthetic/orthotic component must not be subjected to dust/debris, harsh chemicals, abrasives, vibration, activities which would damage the biological limb, or extreme temperatures (<-15C or >50C).



NOTICE: If you experience swelling, blisters or skin irritation, stop wearing the product and contact your health care provider



NOTICE: Excessive pressure on the rods may cause the Kevlar protective sheath to tear prematurely and damage the rods.

Specifications and Preparations Before Use

Shoe Selection

Please choose shoes either with shoelaces or Velcro straps together with a firm heel cap. For best result, choose a shoe with removable insoles.

Fitting

Test the chosen orthosis on the user without the shoe, see that the load line falls in the right position. Otherwise see where adjustment is needed. Trim the foot section to the correct size needed to fit the orthosis properly into the shoe (use the innersole from the shoe as a guideline).

Take the chosen shoe and see that the orthosis fits, then take out the innersole. If needed: reshape the foot section to follow the shape of the shoe (see the adjustment guide). If the calf band is either too large or too small, change it (see the adjustment guide) and install the orthosis in the shoe. Ask the user to put on the shoe and orthosis (it is normally easier to put on if the orthosis is in the shoe when the user puts it on).

Adjustment Guide

Even off the shelf products may need adjustments. It is possible to reshape the carbon part of the Dynamic Walk either with hot water (100 degrees Celsius) or using a heat gun with the temperature between 100-120 degrees Celsius. But it is NOT possible to reshape the PEEK rods or the carbon where the PEEK rods are inserted.

Recommendation: if you need to adjust for pressure or on the edge use a heat gun. If you need to reshape a whole section like the foot section, submerge in to warm water.

Frequently asked Questions

- Q: What should be done if the calf band doesn't fit?
- A: Heat and open/close the band.
- **Q:** What should be done if an edge or point rubs the skin?
- A: Heat and flare out.
- **Q:** What is the heel doesn't stay in the orthosis/shoe?
- **A:** First reheat and reshape footplate and second add an instep strap.

Casting Guide for Custom Dynamic Walk

To make the right heel height and toe lift, use the following materials: plaster, stocking, pen, knife and footplate.

- 1. Take all the measurements on the measurement form
- **2.** Put on the stocking and mark the malleolus, the MTP joint and other prominent bones
- 3. Make a 4-layer thick plastercast and it should have the height of the tuberositia tibia
- **4.** * Put the foot on the plate, 90 degrees in the foot and knee. Remember to have a neutral position in the mediolateral plane to. Get the patient to put some weight on the leg still seated
- 5. Take off the cast
- **6.** Reinforce the cast with 2 layers of plaster

Consumable Components

Padding and straps can be ordered separately.

Disposal/Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

If possible, recycle the device per material as follows:

Plastic material as plastic and the carbon fiber as metallic waste.

User Instructions

The providing health care professional must review the following information directly with the user.

Attachment, alignment, and delivery of this orthotic device must be performed by or under the direct supervision of a qualified prosthetist/ orthotist. Any adjustment or modifications should be done by the clinician and not by the user.

Dynamic Walk is an ankle foot orthosis for drop foot. It provides high strength and flexibility to dynamically lift your foot. Whether your goal is to walk, hike, jog, or play, the Dynamic Walk's flexible dorsi-assist joints permit you to move your foot freely. The open heel construction allows for a natural foot movement and together with the slim design easily fits into normal shoes.

Care and Maintenance

The orthosis should be cleaned with warm water and soap or alcohol. The padding should be handwashed at 30 degrees Celsius and then airdried on a flat surface.

Consumable Components

Padding and staps can be changed. Contact your CPO/clinic for ordering.

Warnings and Precautions



WARNING: This device has been designed and tested for activities of daily living and not for abnormal activities such as extreme sports. To avoid risk of injury, handle your orthoses and its components with care. If your orthotic components are subjected to abnormal stress (such as a fall) contact your prosthetist/orthotist to have the components inspected for any damage.



NOTICE: Contact your local governing authorities regarding any driving restrictions or limitations.



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NOTICE: If you experience swelling, blisters or skin irritation, stop wearing the product and contact your health care provider.



NOTICE: Excessive pressure on the rods may cause the Kevlar protective sheath to tear prematurely and damage the rods.



NOTICE: Always use Padding in between the calf band and the leg. User's skin should never come in direct contact with the TFC material.

Consultation of Health Care Professional

The user should monitor their orthotic component daily and contact their health care professional if they experience changes in performance of the device or noise.

The user should monitor skin condition daily and contact their health care professional immediately if the device causes skin damage or irritation.

Specifications and Preparations Before Use

Fitting the Dynamic Walk

Single Side

- 1. Remove the insole from the shoe.
- 2. Place the orthosis with the insole on top of it into the shoe.
- 3. Open the shoe and put your foot into it.
- **4.** Grab the calf band and pull it behind your calf. Tighten the shoelaces, (it's important that the shoe is tight enough to hold the orthosis in position while you are walking).
- **5**. Now you are done and can start using the orthosis.

Standard Wide Ankle

- 1. Remove the insole from the shoe.
- **2.** Place the orthosis with the insole on top of it into the shoe.
- **3.** Place the toe of the opposite foot on the shoe for stabilization. Open the shoe widely and grab the calfband with your hand.
- **4.** Put your foot into the shoe and leave the calfband on your calf.
- **5.** Tighten the shoe laces, (it is important that the shoe is tight enough to hold the orthosis in position while you are walking.)
- 6. Now you are done and can start using the orthosis

Warranty

- · 12 month warranty for the off the shelf versions
- 6 month warranty for the custom versions

Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the Instructions for Use. The device must only be operated with tested modular components. The manufacturer is not liable for dam- age caused by component combinations that were not authorised by the manufacturer.

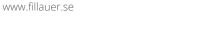


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