INFORMATION

Date of the last update: 2013-01-09

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

Explanation of Symbols

⚠ CAUTION	Warnings regarding possible risks of accident or injury.
NOTICE	Warnings regarding possible technical damage.
INFORMATION	Additional information on the fitting / use.

1 Description

1.1 Intended Use

The WalkOn Flex is to be used exclusively for orthotic fittings of the lower limbs and is exclusively suitable for contact with healthy and intact skin.

1.2 Indications and Effects

WalkOn Flex supports the foot at 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. Especially appropriate when the ability to lift the foot decreases during activities (muscle exhaustion).

WalkOn Flex fits patients with:

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

For foot deformities: the WalkOn Flex is indicated when a foot deformity can be corrected through the use of an additional insole and a lateral stop in combination with a sturdy shoe.

The WalkOn Flex is generally suitable for sports activities, as long as no fast, sudden movements are executed in extreme stride sequences (e.g. basketball, badminton or riding with high activity). In any case, activities should be discussed with the patient and a special fitting for high activity levels realised where applicable.

Effects:

WalkOn Flex provides the user with a more natural gait pattern; a 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. At heel contact WalkOn Flex provide the user with a slight outward rotation of the foot.

NOTICE

The WalkOn Flex is a dynamic ankle foot orthosis and must not be used for prevention of contractures etc.

Indication must be determined by the physician.

1.3 Contraindication

1.3.1 Absolute contraindication

- Moderate to severe spasticity in the lower leg
- Leg ulcers
- Moderate to severe oedema
- Moderate to severe foot deformities

1.3.2 Relative contraindication

In case of the following indications, consultation with a physician is required:

Skin diseases/-injuries, inflammatory symptoms, prominent scars that are swollen, reddened and feel excessively warm when touched; Lymphatic flow disorders, including unclear soft tissue swelling distant to the body area to which the appliance will be applied; Sensory and circulatory disorders of the lower extremities.

1.4 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 be carried out by trained, qualified personnel only. 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. The product is designed for use on one patient only. Parts to be fitted and those 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 a WalkOn Flex is determined from case-to-case basis. Criteria include the type of fitting (clinical picture, fitting) and the individual abilities of the WalkOn Flex 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 authorised test centre.

⚠ 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 product‘s period of use.

1.5 Construction

Thanks to its construction with three dynamic elements (the pylon, the heel and forefoot of the sole) the orthosis provides a smooth natural gait even on uneven grounds.

Walking in stairs by taking weight on the fore foot as well as squat is permitted due to its dynamic features.

NOTICE

Damage due to inadmissible handling. The orthosis is made of pre-impregnated compostie 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.

2 Handling

2.1 Size Selection

The size selection of the orthosis is based on the shoe size. Left and right. S – XL.

2.2 Adapting and Applying the product

1. Shoe selection: to obtain best effect of the WalkOn Flex, the user need to wear a stable, laced shoe with a firm heel counter. The heel height should be 1,0 cm (+/-5 mm) / 0,4 inches (+/-0,2 inches).
2. Pick out correct size from the size chart.
3. Adapt the WalkOn Flex into correct size: If the user has a removable inner sole in his/her shoe, use that for marking the correct size on the foot plate. (pic. 1), or draw a line around the user’s foot directly on the foot plate.
4. Cut the foot plate into correct size (according to the line on the foot plate) (pic. 2). When adjusting the foot plate width; cut on the lateral side but not more than necessary, to avoid the medial part/the insert to slide in the shoe and to avoid pressure on the medial malleol. When adjusting the length of the foot plate, focus on cutting the back of the foot plate, then the insert will automatically be positioned behind (posterior) the medial malleol which prevents pressure on the ankle and malleol (pic. 3).
5. The shell can be adjusted by grinding, if necessary.
6. In the event of sharp edges at the orthosis, smooth them out by grinding the edges in water, with a grinding paper.
7. If the user has a foot deformity, correct it with a corrective insole or a custom moulded device. (If the foot cannot be corrected by an insole, the orthosis and a stable shoe, a WalkOn Flex should not be used).
8. Apply the textile part on the calf part of the orthosis (pic. 4).

9. Cut the soft velcro part at a proper length. To assure a good attachment, the soft velcro should not be more than 2 cm longer than the hard Velcro, when the calf band is attached around the user's calf.

2.3 Instruction for use and care

Material: Glass fiber composite. Calf band: PCM (Phase Change Material), a temperature regulative material, micro hook and loop, soft velcro tape.

Cleaning:

- Textile part: Machine 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 necessarily.

Your Orthotist can supply you with extra calf parts (art. no. 29U5*), in cases of lost, poor function of the velcro straps, worn out etc.

Upper limit temperature: 120 °C.

Disposal after use: Combustible material.

3 Further Usage Restrictions

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's warranty applies only if the device has been used under the conditions and for the purposes described. The manufacturer recommends that the device be used and maintained according to the instructions for use.

5 CE Conformity

This device meets the requirements of the 93/42/EEC guidelines for medical devices. This device has been classified as a class I device according to the classification criteria outlined in appendix IX of the guidelines. The declaration of conformity was therefore created by Ottobock with sole responsibility according to appendix VII of the guidelines.

Français

INFORMATION

Date de la dernière mise à jour : 2013-01-09

- Veuillez lire attentivement l'intégralité de ce document.
- Respectez les consignes de sécurité.

Signification des symboles

⚠ ATTENTION	Mises en garde contre les éventuels risques d'accidents et de blessures.
AVIS	Mises en garde contre les éventuels dommages techniques.
INFORMATION	Autres informations relatives à l'appareillage/l'utilisation.