

## 6.1 Haftung

Der Hersteller haftet, wenn das Produkt gemäß den Beschreibungen und Anweisungen in diesem Dokument verwendet wird. Für Schäden, die durch Nichtbeachtung dieses Dokuments, insbesondere durch unsachgemäße Verwendung oder unerlaubte Veränderung des Produkts verursacht werden, haftet der Hersteller nicht.

## 6.2 CE-Konformität

Das Produkt erfüllt die Anforderungen der europäischen Richtlinie 93/42/EWG für Medizinprodukte. Aufgrund der Klassifizierungskriterien nach Anhang IX dieser Richtlinie wurde das Produkt in die Klasse I eingestuft. Die Konformitätserklärung wurde deshalb vom Hersteller in alleiniger Verantwortung gemäß Anhang VII der Richtlinie erstellt.

## 6.3 Lokale Rechtliche Hinweise

Rechtliche Hinweise, die **ausschließlich** in einzelnen Ländern zur Anwendung kommen, befinden sich unter diesem Kapitel in der Amtssprache des jeweiligen Verwenderlandes.

# 1 Foreword

English

### INFORMATION

Last update: 2016-12-05

- ▶ Please read this document carefully before using the product.
- ▶ Follow the safety instructions to avoid injuries and damage to the product.
- ▶ Instruct the user in the proper and safe use of the product.
- ▶ Please keep this document in a safe place.

These instructions for use provide important information on the fitting and application of the 28U24 WalkOn Reaction, WalkOn Reaction Junior and WalkOn Reaction Plus 28U25 ankle foot orthoses.

## 2 Intended use

### 2.1 Indications for use

The orthosis is intended **exclusively** for orthotic fittings of the lower limbs and **exclusively** for contact with intact skin.

The orthosis must be used in accordance with the indications.

- **28U25 WalkOn Reaction Junior:** The orthosis may be combined with other dynamic foot/ankle foot orthoses if the biomechanical requirements can be met more effectively as a result.

### 2.2 Indications

- Dorsiflexor weakness, with or without mild spasticity (e.g. post CVA, traumatic brain injury, multiple sclerosis, neuromuscular atrophy, peroneal paralysis or infantile cerebral palsy (ICP))
- Minor impairment of plantarflexors
- Impairment of plantarflexors (only 28U25)
- Minor impairment of knee extensors
- Impairment of knee extensors (only 28U25)

Indications must be determined by the physician.

### 2.3 Contraindications

#### 2.3.1 Absolute Contraindications

- Moderate to severe spasticity in the lower leg
- Moderate to severe oedema

- Leg ulcers
- Moderate to severe foot deformities

### 2.3.2 Relative Contraindications

The following indications require consultation with a physician: skin diseases/injuries, inflammation, prominent scars that are swollen, reddening and hyperthermia of the fitted limb/body area; lymphatic flow disorders, including unclear soft tissue swelling distal to the body area to which the medical device will be applied; sensory and circulatory disorders in the lower leg and the foot area.

### 2.4 Further Usage Restrictions

The orthosis must not be used for the prevention of contractures (shortening) etc.

The orthosis must not be used for sports activities that involve jumping, sudden movements or rapid step sequences (e.g. basketball, badminton, riding sports). Sports activities should generally be discussed with the patient.

### 2.5 Effects




The orthosis enables a more natural gait pattern for the user. In the swing phase, the foot remains in the neutral position which permits a natural swing-through for the patient without executing compensating movements for ground clearance.

At heel strike, the carbon spring allows the foot to plantarflex in a controlled and harmonious manner preventing foot slap. The force exhibited is used to support the mid-stance phase.


Prior to toe-off, stored energy is released to preserve momentum into swing phase.


## 3 Safety


### 3.1 Explanation of warning symbols

 <b>WARNING</b>	Warning regarding possible serious risks of accident or injury.
 <b>CAUTION</b>	Warning regarding possible risks of accident or injury.
 <b>NOTICE</b>	Warning regarding possible technical damage.

### 3.2 General safety instructions

 <b>CAUTION</b> <b>Reuse on other persons and improper cleaning</b> Skin irritation, formation of eczema or infections due to contamination with germs <ul style="list-style-type: none"> <li>▶ The product may be used by one person only.</li> <li>▶ Clean the product regularly.</li> </ul>
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 <b>CAUTION</b> <b>Contact with heat, embers or fire</b> Risk of injury (such as burns) and risk of product damage. <ul style="list-style-type: none"> <li>▶ Keep the product away from open flames, embers and other sources of heat.</li> </ul>
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 <b>CAUTION</b> <b>Mechanical damage to the product</b> Injuries due to changes in or loss of functionality <ul style="list-style-type: none"> <li>▶ Use caution when working with the product.</li> <li>▶ Check the product for proper function and readiness for use.</li> </ul>
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- ▶ In case of changes in or loss of functionality, discontinue use of the product and have it checked by authorised, qualified personnel.

#### NOTICE

##### **Contact with salves, lotions or other products that contain oils or acids**

Insufficient stabilization due to loss of material functionality

- ▶ Do not expose the product to salves, lotions or other products that contain oils or acids.

## 4 Handling

#### ⚠ WARNING

##### **Operation of motor vehicles**

Risk of accidents due to restricted body function

- ▶ Observe the applicable legal and insurance regulations for the operation of motor vehicles and have your driving ability examined and certified by an authorised agency.

#### INFORMATION

- ▶ The daily duration of use and period of application are generally determined by the physician.
- ▶ The initial fitting and application of the product must be carried out by qualified personnel.
- ▶ Instruct the patient in the handling and care of the product.
- ▶ Instruct the patient to see a physician immediately if any exceptional changes are noted (e.g. worsening of the complaint).

### 4.1 Size Selection

- ▶ Select the orthosis size based on the shoe size (see sizing table).

### 4.2 Adaptation

#### ⚠ CAUTION

##### **Improper moulding or application**

Injuries or damage to the orthosis due to overloading of the material and improper fit of the orthosis due to breakage of load-bearing components

- ▶ Do not make any improper changes to the orthosis.
- ▶ Always apply the orthosis according to the information in the instructions.

#### ⚠ CAUTION

##### **Incorrect or excessively tight application**

Risk of local pressure and constriction of blood vessels and nerves due to improper or excessively tight application

- ▶ Ensure that the orthosis is applied properly and fits correctly.

#### NOTICE

##### **Use without suitable footwear**

Restriction of functionality due to insufficient stabilisation

- ▶ Only use the orthosis with closed footwear, taking the allowable effective heel height into account.

### Footwear selection:

- ▶ Choose a sturdy lace-up shoe with solid heel cup to ensure the optimum effectiveness of the orthosis. The effective heel height should be between 0.5 cm and 1.5 cm.

### Adapting the orthosis size:

- 1) **As needed:** If the patient uses footwear with removable insoles, take the insole out of the shoe on the fitting side.

**INFORMATION: Keep the insole in order to use the shoe without the orthosis.**

- 2) Have the patient sit on a chair with the shoe and without the orthosis, and position the foot at a 90° angle to the lower leg (see fig. 1).
- 3) Mark the position of the malleoli in the shoe with a small piece of adhesive tape (see fig. 1).
- 4) Have the patient sit on a chair without the shoe and with the orthosis, and position the foot at a 90° angle to the lower leg.

**INFORMATION: Apply the orthosis to the patient so that the ankle joint has sufficient freedom of movement and does not impact the hard medial spring.**

- 5) Determine the position of the ankle according to the "WalkOn® Reaction" lettering (see fig. 2).
- 6) Trim the orthosis sole (see fig. 3) so that the mark on the shoe corresponds to the position on the orthosis (see fig. 4).
- 7) Adapt the sole shape according to the removable insole. Note that the required exterior rotation of the foot must be maintained (see fig. 3).

### Adapting the orthosis:

- 1) Insert the orthosis in the shoe and cover it with an insole if required (see fig. 5).
- 2) Put on the orthosis together with the shoe (see fig. 6).
- 3) Measure the correct AP position of the knee joint (e.g. on the L.A.S.A.R Posture).

**INFORMATION: The load line of the knee joint in the AP position lies approx. 15 mm in front of the knee compromise pivot point according to Nietert.**

- 4) **As needed:** Wedges can be used to provide a comfortable base of support. For example, an extrinsic forefoot wedge can be used to increase knee extension force (see fig. 10). An extrinsic heel wedge can be used to reduce knee extension force (see fig. 11).

**INFORMATION: Materials other than those supplied may also be used to build up the bottom sole if needed.**

- 5) **As needed:** Sand the top edge and wings of the front support and modify the padding accordingly.

**NOTICE! The functionality of the orthosis must not be impaired. Do not sand in the area of the medial spring or the surfaces!**

- 6) **As needed:** If the patient has a foot deformity, correct it with an insole or a custom moulded medical device.

**INFORMATION: The manufacturer offers lateral pronation traction (28Z10) which attaches to the lateral sole with hook-and-loop fasteners. Frontal and dorsal traction stabilise the foot with the help of hook-and-loop fasteners in the area of the spring.**

- 7) Close the textile component at calf height (see fig. 6).

- 8) **CAUTION! The child size closures may be swallowed by young children.**

Sew the closures of the hook-and-loop straps to the hook-and-loop straps after fitting.

### Final inspection:

- ▶ Conduct trial walking with the patient. Testing on inclines, ramps and stairs is mandatory. Fine tune as required.

## 4.3 Application

### NOTICE

#### Use of a worn or damaged product

Limited effectiveness

- ▶ Before each use, check the product for functional reliability and for possible wear or damage.
- ▶ Do not continue using a product that is no longer functional, or that is worn or damaged.

- 1) Take the insole out of the shoe on the fitting side.
- 2) Open the calf band.
- 3) Slide the orthosis into the shoe.
- 4) Put on the orthosis together with the shoe.
- 5) Close the calf band.

## 4.4 Removal

- 1) Open the calf band.
- 2) Remove the shoe with the orthosis.
- 3) **As needed:** Remove the orthosis from the shoe and put the original insole back in.

## 4.5 Cleaning

### NOTICE

#### Use of improper cleaning agents

Damage to the product due to use of improper cleaning agents

- ▶ Only clean the product with the approved cleaning agents.

Clean the orthosis regularly:

#### Textile component

- Remove the textile component from the orthosis.
- Fasten all hook-and-loop closures.
- Hand or machine wash the textile component in warm water at 30 °C with a standard mild detergent. Rinse thoroughly.
- Allow to air dry. Do not expose to direct heat (e.g. sunshine, stove or radiator).

#### Orthosis frame

- 1) Wipe with a damp cloth as needed.
- 2) Allow to air dry. Do not expose to direct heat sources (e.g. sunlight, stove or radiator).

## 5 Disposal

Return the product to the specialist dealer for disposal.

All components of the product must be disposed of properly in accordance with the respective national environmental regulations.

## 6 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

### 6.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregard of this document, particularly due to improper use or unauthorised modification of the product.

## 6.2 CE Conformity

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

## 6.3 Local Legal Information

Legal information that applies **exclusively** to specific countries is written in the official language of the respective country of use after this chapter.

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## 1 Avant-propos

Français

### INFORMATION

Date de la dernière mise à jour : 2016-12-05

- ▶ Veuillez lire attentivement l'intégralité de ce document avant d'utiliser le produit.
- ▶ Respectez les consignes de sécurité afin d'éviter toute blessure et endommagement du produit.
- ▶ Apprenez à l'utilisateur à bien utiliser son produit et informez-le des consignes de sécurité.
- ▶ Conservez ce document.

Les présentes instructions d'utilisation vous apportent des informations importantes pour adapter et poser les releveurs de pied WalkOn Reaction 28U24, WalkOn Reaction Junior et WalkOn Reaction Plus 28U25.

## 2 Utilisation conforme

### 2.1 Usage prévu

L'orthèse est **exclusivement** destinée à un appareillage orthétique de l'extrémité inférieure et elle est conçue **uniquement** pour entrer en contact avec une peau intacte.

Il est impératif d'utiliser l'orthèse conformément aux indications.

- **WalkOn Reaction Junior 28U25** : la combinaison de l'orthèse avec un autre pied dynamique/d'autres releveurs de pied est autorisée si elle permet de mieux répondre aux exigences biomécaniques.

### 2.2 Indications

- Faiblesse des muscles releveurs du pied ne présentant aucune ou une légère spasticité (par exemple à la suite d'un accident vasculaire cérébral, d'une lésion cérébrale traumatique, en cas de sclérose en plaques, d'atrophie neuromusculaire, de paralysie des péroniers ou de parésie cérébrale infantile (PCI))
- Trouble léger des muscles abaisseurs du pied
- Trouble des muscles abaisseurs du pied (seulement 28U25)
- Trouble léger de l'extension du genou
- Trouble de l'extension du genou (seulement 28U25)

L'indication est déterminée par le médecin.

### 2.3 Contre-indications

#### 2.3.1 Contre-indications absolues

- Spasticité de la jambe modérée à sévère
- Œdème modéré à sévère
- Ulcères de jambe
- Déformations du pied modérées à sévères