

9 Rechtliche Hinweise

Alle rechtlichen Bedingungen unterliegen dem jeweiligen Landesrecht des Verwenderlandes und können dementsprechend variieren.

9.1 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.

9.2 CE-Konformität

Das Produkt erfüllt die Anforderungen der Verordnung (EU) 2017/745 über Medizinprodukte. Die CE-Konformitätserklärung kann auf der Website des Herstellers heruntergeladen werden.

1 Foreword

English

INFORMATION

Date of last update: 2022-03-03

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

These instructions for use provide important information on the fitting and application of the 28U24 WalkOn Reaction, 28U25 WalkOn Reaction plus, WalkOn Reaction Junior, 28U34 WalkOn Reaction Lateral and 28U34 WalkOn Reaction Lateral Junior ankle-foot orthoses.

2 Product overview

(see fig. 1)			
Item	Designation	Item	Designation
1	Lower leg shell	4	Y hook-and-loop calf strap
2	Orthosis frame	5	Calf strap with padding
3	Sole		

3 Intended use

3.1 Indications for use

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

Ottobock recommends wearing the product with a stocking and not directly on the skin. A thin stocking made of a washable, moisture-absorbent material is suitable to wear under the product. To avoid pressure points, make sure that the stocking is free of wrinkles.

The orthosis must be used in accordance with the indications.

The doctor decides the daily duration of use for the product.

- **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.

3.2 Indications

- Minor impairment of plantarflexors
- Minor impairment of knee extensors
- Drop foot, with or without mild to moderate spasticity

Caused for example by:

- Stroke
- Traumatic brain injuries
- Multiple sclerosis
- Neuromuscular atrophy
- Peroneal nerve injury
- Infantile cerebral palsy (ICP)

28U25

- Impairment of the plantar flexor muscles
- Impairment of knee extension

Indications must be determined by the physician.

3.3 Contraindications

3.3.1 Absolute Contraindications

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

3.3.2 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.

3.4 Lifetime

When used as intended, the product is designed for:

Junior **1 year** (shoe sizes EU 24-27, 27-30, 30-33, 33-36)

Adults **2 years** (shoe sizes EU 36-39, 39-42, 42-45, 45-48)

When the end of the lifetime is reached, have the product inspected for functionality by qualified personnel. Use of the product beyond the specified lifetime is the responsibility of the user.

3.5 Restrictions for use

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.

3.6 Effects

- Promotes a largely symmetrical and fluid physiological gait
- Supports knee extension and knee flexion
- Supports knee extension during toe-off
- Prevents uncontrolled foot contact and foot slap during heel strike
- Influences the statics in the frontal and sagittal plane when standing

3.7 Accessories

28U24, 28U25

- 28Z10 Lateral pronation strap

4 Safety

4.1 Explanation of warning symbols

⚠ WARNING Warning regarding possible serious risks of accident or injury.

⚠ CAUTION Warning regarding possible risks of accident or injury.

NOTICE Warning regarding possible technical damage.

4.2 General safety instructions

⚠ CAUTION

Reuse on other persons and improper cleaning

Skin irritation, formation of eczema or infections due to contamination with germs

- ▶ The product may be used by one person only.
- ▶ Clean the product regularly.

⚠ CAUTION

Mechanical damage to the product

Injuries due to changes in or loss of functionality

- ▶ Use caution when working with the product.
- ▶ Check the product for proper function and readiness for use.
- ▶ In case of changes in or loss of functionality, discontinue use of the product and have it checked by authorised, qualified personnel.

⚠ CAUTION

Contact with heat, embers or fire

Risk of injury (such as burns) and risk of product damage.

- ▶ Keep the product away from open flames, embers and other sources of heat.

NOTICE

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

Insufficient stabilisation due to loss of material functionality

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

5 Use

⚠ 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).

5.1 Size Selection

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

5.2 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.

NOTICE

Damage due to improper handling (heat treatment, drilling holes)

Loss of orthosis functionality

- ▶ Do not carry out any heat treatment on the orthosis. The orthosis is not thermoformable.
- ▶ Do not drill any holes in the bottom of the sole or the connecting elements as holes break the fibres and weaken the component.

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.

Attaching the calf strap to the lower leg shell

- 1) Open both straps and detach them from the hook-and-loop (see fig. 2, see fig. 3).
- 2) Pull the padding over the wings of the lower leg shell, positioning the padding on the inside and the strap on the outside of the shell (see fig. 4, see fig. 5).
- 3) Tighten the straps and attach them to the hook-and-loop on the opposite wing of the lower leg shell (see fig. 6, see fig. 7).

Selecting footwear

- ▶ Choose a sturdy shoe with laces or hook-and-loop fasteners and a solid toe cap to ensure the optimal effectiveness of the orthosis. The effective heel height should be between 0.5 cm and 1.5 cm.

Adapting the orthosis

- 1) If the patient uses footwear with removable insoles, take the insole out of the shoe on the fitting side.
INFORMATION: Keep the insole to use the shoe without the orthosis.
- 2) Have the patient sit on a chair with footwear and without the orthosis. Position the foot at a **90°** angle to the lower leg (see fig. 8).
- 3) Mark the position of the ankle joint in the shoe with a small piece of adhesive tape (see fig. 8).

- 4) Have the patient sit on a chair without footwear and with the orthosis. Position the foot at a **90°** angle to the lower leg.

INFORMATION: Apply the orthosis so the ankle bone has adequate freedom of movement and does not contact the spring.

- 5) Determine the position of the ankle bone and mark it on the orthosis frame with a small piece of adhesive tape (see fig. 9).
- 6) Trim the orthosis sole (see fig. 10) so the markings on the shoe and the orthosis frame line up (see fig. 11).
- 7) Adapt the shape of the sole according to the removable insole. In doing so, make sure that the required external rotation of the foot is maintained (see fig. 10).
- 8) Insert the orthosis in the shoe and optionally cover it with an insole (see fig. 12).
- 9) Put on the orthosis together with the shoe (see fig. 13).
- 10) Measure the correct a-p (anterior-posterior) position of the knee joint (e.g. on the 3D L.A.S.A.R Posture).

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

- 11) **Optional:** Use wedges as compensating elements to achieve the desired position. For example, place a compensating element under the forefoot (see fig. 17) if the patient stands with excessive flexion or place a compensating element under the heel (see fig. 18) if the patient stands with excessive extension.

INFORMATION: Optionally, materials other than those supplied may also be used to build up the bottom sole.

- 12) **Optional:** Sand the upper edge and the wings of the frontal support and modify the padding accordingly.

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

- 13) **Optional:** If the patient has a foot deformity, correct it with an insole or a custom moulded device.

28U24, 28U25:INFORMATION: The manufacturer offers the 28Z10 lateral pronation strap as an accessory that can be attached to the lateral sole with hook-and-loop fasteners. Frontal and dorsal traction stabilises the foot using hook-and-loop fasteners in the area of the spring.

- 14) Close the textile component at calf height (see fig. 13).

Optional: Shortening the calf strap

- > Put the orthosis on the patient.
- 1) Determine the length of the strap.
 - 2) Remove the Y hook-and-loop and shorten the strap using scissors.
 - 3) Fasten the Y hook-and-loop to the strap.


28U25 WalkOn Reaction junior, 28U34 WalkOn Reaction Lateral junior

- ▶ **CAUTION! The Y hook-and-loop of the calf strap may be swallowed by young children.**
Sew the Y-hook-and-loop to the calf strap after fitting.

Checking the fit of the orthosis

- ▶ Check that the orthosis is fitted properly before handing it over to the patient.
- ▶ Conduct trial walking with the patient. Testing on inclines, ramps and stairs is mandatory. Fine tune as required.

5.3 Application

 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 product is applied properly and fits correctly.

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) Remove the insole from the shoe on the side to be fitted.
- 2) Open the calf strap.
- 3) Insert the orthosis into the shoe.
- 4) Put the orthosis on together with the shoe.
- 5) Fasten the calf strap.

5.4 Removal

- 1) Open the calf strap.
- 2) Remove the shoe together with the orthosis.
- 3) **Optional:** Remove the orthosis from the shoe and re-insert the insole of the shoe.

6 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.

- ▶ Ottobock recommends cleaning the orthosis twice a week.

Textile component

- ▶ **NOTICE! Detergent residues may cause skin irritation and wear of material.**

- 1) Remove the textile component from the orthosis.
- 2) Fasten all hook-and-loop closures.
- 3) **Optional:** Use a mesh laundry bag.
- 4) Wash the textile component in warm water at **30 °C** with a standard mild detergent. Rinse out detergent residues thoroughly.
- 5) Allow to air dry. Do not expose to direct heat (e.g. from the sun, an oven 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).

7 Packaging

⚠ WARNING

Packaging in the hands of children

Risk of suffocation if the carrier bag is pulled over the mouth and nose, risk of strangulation by the cord

- ▶ Store the packaging out of reach of children.

The product is delivered in a carrier bag. The carrier bag is intended **exclusively** for transporting and storing the product.

8 Disposal

Dispose of the product in accordance with national regulations.

9 Legal information

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

9.1 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 disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

9.2 CE conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.

1 Avant-propos

Français

INFORMATION

Date de la dernière mise à jour : 2022-03-03

- ▶ Veuillez lire attentivement l'intégralité de ce document avant d'utiliser le produit ainsi que respecter les consignes de sécurité.
- ▶ Apprenez à l'utilisateur comment utiliser son produit en toute sécurité.
- ▶ Adressez-vous au fabricant si vous avez des questions concernant le produit ou en cas de problèmes.
- ▶ Signalez tout incident grave survenu en rapport avec le produit, notamment une aggravation de l'état de santé, au fabricant et à l'autorité compétente de votre pays.
- ▶ Conservez ce document.

La présente notice d'utilisation vous apporte des informations importantes pour adapter et poser les orthèses suro-pédieuses WalkOn Reaction 28U24, WalkOn Reaction plus 28U25, WalkOn Reaction Junior, WalkOn Reaction Lateral 28U34 et WalkOn Reaction Lateral Junior 28U34.

2 Vue d'ensemble du produit

(voir ill. 1)			
Pos.	Désignation	Pos.	Désignation
1	Coque tibiale	4	Sangle de mollet Velcro en Y
2	Cadre de l'orthèse	5	Sangle de mollet avec rembourrage
3	Semelle		

3 Utilisation conforme

3.1 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.

Ottobock recommande de ne pas porter le produit directement sur la peau mais après avoir enfilé un bas. Utilisez pour ce faire un bas fin fabriqué dans une matière lavable et absorbant l'humidité. Veillez à ce que le bas soit mis en place sans plis, sans quoi il pourrait être à l'origine de pressions.