

WORKER²
PRODUCTION INSTRUCTIONS



PRODUCTION INSTRUCTIONS

For the incorporation of foot orthoses into safety footwear in accordance with European standards DIN EN ISO 20344 / 20345 and 61340.

These production instructions apply for the WORKER² prefabricated foot orthotic blanks for occupational safety footwear manufactured by Perpedes. The individual work steps are defined and the materials and components to be used for the foot orthoses are specified here. The instructions are required in order to ensure conformity with the EC type examination certificate for occupational safety footwear even after insertion of the foot orthoses.

Deviation from these production instructions shall render the EC type examination certificate null and void!

TYPE-APPROVED TREATMENT SYSTEM AND ITS INTENDED PURPOSE

The WORKER² foot orthoses were tested and certified in combination with occupational safety footwear from a variety of manufacturers in accordance with DIN EN ISO 20344 / 20345 and 61340 by recognised test institutes. The combination of the foot orthoses and ESD occupational safety footwear is therefore type-approved and can be used in static and, depending on the shoe model, even in ESD areas.

The testing applies only for the relevant shoe models from the cooperating shoe manufacturers. The currently approved models of occupational safety footwear can be found at: www.perpedes.de

For orthopedic technicians / orthopedic shoe technicians and other qualified specialists, this results in the advantage of being able to supply in compliance with the requirements of the EU guidelines without any further application for testing procedures (subject to possible variations owing to the legal requirements in the specific country of usage).

INDICATIONS / VARIANTS

The WORKER² foot orthoses are suitable for the conservative treatment of foot, knee, hip and lower back problems. Alongside the treatment of foot problems, they can also be used for the prevention of overloading of the entire postural and musculoskeletal system (knee, hip and back area). The treating physician is responsible for the exact diagnosis.

CONTRAINDICATION

Diabetic foot syndrome

WORKER² VARIANTS

Foot orthosis / Item No: WORKER² PRO/**WPL1**

Foot orthosis / Item No: WORKER² CALCA/**WCL1**

Foot orthosis / Item No: WORKER² CPX/**WXL1**

Foot orthosis / Item No: WORKER² RIGIDUS/**WRL1**

APPLICATION NOTES AND RISKS

- The WORKER² prefabricated foot orthoses must be properly customized for the foot and adjusted in the shoe by a qualified specialist.
- Foot orthoses should be worn with (crease-free) socks and should always be used as a pair! Exceptions must be stated by the treating physician.
- The shoes must ensure a sufficient interior volume (shoe length / width, toe space) for the foot as well as for the chosen WORKER² prefabricated foot orthoses. The inlays included in the scope of delivery for the occupational safety footwear must be removed before the Worker² is inserted.
- The chosen prefabricated foot orthoses need to be cut to match the width and length. The forefoot, mid foot and rear foot must have sufficient flat support from the foot orthosis and should not be on the edge as this can lead to the formation of blisters or calluses on the soles of the feet.
- Clear identification of the left and right foot orthosis must be ensured for the patient / user.
- The foot orthoses should not be exposed to temperatures above 60 °C (e.g. heating, driers, direct sunlight).
- The foot orthoses are not suitable for direct contact with acids and bases. The manufacturer provides no warranty in this case.
- Materials which are used for the foot orthoses are subject to ageing and their properties may change. If the coverings, cushioning material or orthotic shells have become damaged, holey or wrinkled as a result of mechanical stress or are broken then the foot orthosis should no longer be worn!
- Foot orthoses are affected by body weight, pressure, torsion and rubbing and therefore have a load-dependent lifespan. Temperatures, sock materials, orthotic materials, footwear and environmental factors can also limit the functional life.

- Checking of the function and condition of the foot orthoses by an orthopedic technician / orthopedic shoe technician or other qualified specialist after a maximum of 6 months is recommended.

CLEANING AND STORAGE

- Foot orthoses must be removed from the shoes daily in order for moisture to evaporate.
- The surface materials can be cleaned as required with mild washing lotion and a damp sponge or cloth. Soap residues should be removed. Do not use any external heat sources to dry, simply leave to air-dry. Note that the foot orthoses are not machine-washable!
- Mild disinfectant (suitable for human skin) can be sprayed on / used in small amounts. Discolouration of the covering material as a result cannot be excluded and is not grounds for a warranty claim.

STORAGE

- Store in the sealed original packaging between 10 °C and 25 °C without mechanical influences and avoiding direct UV radiation.
- Regular checking of the storage and conditions is recommended.

REUSE / WARRANTY

- The product is used for an individually fitted treatment for an individual foot orthosis wearer and should not be reused or subsequently used by other third persons.
- The manufacturer accepts no liability in the event of improper use.

WARRANTY

- The warranty exists to the extent required by law. The use and fitting of the prefabricated foot orthoses may only be carried out by orthopedic technicians / orthopedic shoe technicians or other qualified specialists, otherwise the manufacturer's liability shall be excluded.
- Slight discolouration and fading of the top cover is possible during the useful life of the foot orthoses. This does not constitute grounds for a warranty claim.

DISPOSAL

Patients can dispose of foot orthoses, which are no longer required, in the household waste.

PROCESSING INSTRUCTIONS

WORKER² PREFABRICATED FOOT ORTHOSES

The production instructions apply for the use of prefabricated foot orthoses with the following item numbers:

Art.name / Item no: WORKER² PRO/**WPL1**

Art.name / Item no: WORKER² CALCA/**WCL1**

Art.name / Item no: WORKER² CPX/**WXL1**

Art.name / Item no: WORKER² RIGIDUS/**WRL1**

The following modifications and alterations are possible with the defined EVA materials in accordance with DIN EN ISO 20345 and 61340:

	WORKER ² PRO	WORKER ² CALCA	WORKER ² CPX	WORKER ² RIGIDUS
Compensation for leg length discrepancies up to 6 mm	X	X	X	X
Compensation for leg length discrepancies up to 10 mm	X			X
Pronation/Eversion wedge	X	X	X	X
Supination/Inversion wedge with / without longitudinal arch filling	X	X	X	X

PROCESSING INSTRUCTIONS

Materials and adhesives for alterations to WORKER² prefabricated foot orthoses.

The foot orthoses must only be modified using the adhesives and covering materials specified by the Perpedes GmbH in order to guarantee the height and continuing ESD conductivity.

	6 mm EVA wedge (conductive)	10 mm EVA wedge (conductive)
Size 1 (35 to 39)	WOK61	WOK101
Size 2 (40 to 44)	WOK62	WOK102
Size 3 (45 to 48)	WOK63	WOK103
Antistat adhesive Ultraflex, 1 kg	79AK1	79AK1
Thinner for Antistat adhesive, 1 litre	79IS1	79IS1

ORDERING ADDRESS:

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www.perpedes.de

ALTERNATIVE ADHESIVE

- Renol AL, Renia GmbH

ASSEMBLY AND ADAPTATION REGULATIONS

The foot orthoses may only be modified or adapted in accordance with the procedures set out below and as defined.

The largest and flattest possible contact surface with the inner shoe sole / template of the shoe must be ensured through proper grinding and modification of the foot orthotic's width and length in order to fulfil the contact resistance requirements in anti-static and ESD areas.

Thanks to the special material combination of the WORKER² foot orthoses, it is possible to individually modify the construction. Functional zones can be built up.

CHANGES TO THE ORTHOTIC SHELL

Fully glued foot orthoses:

- by means of a hot air gun from the underside
- at approx. 130 °C
- approx. 3 mins
- for surface heating at a distance of 30 cm
- core can be moulded by hand or positively moulded

Heat-based material shrinkage of the EVA bottom cover cannot be excluded. We recommend careful heating with a hot air gun.

Foot orthoses with non-bonded top layers:

- by means of a hot air gun from the upper side
- at approx. 130 °C
- approx. 3 mins
- for surface heating at a distance of 20 cm
- core can be moulded by hand or positively moulded

Heat-based material shrinkage of the EVA bottom cover cannot be excluded. We recommend careful heating with a hot air gun.

COMPENSATION FOR LEG LENGTH DISCREPANCIES

For compensating of leg length differences of a max. 10 mm or for bilateral heel elevation of up to 10 mm (Fig. 1). The compensation lift must be carried out proximally to the MTP-joints and may not exceed the original height of the WORKER² prefabricated foot orthoses in the steel toecap area of the occupational safety footwear (Fig. 2)!



Fig. 1



Fig. 2

PROCESSING

1. Cut the conductive EVA wedge (optionally available) to the required size and roughen it on a grinding belt (granulation of 24-40). Thorough de-dusting of the surface to be bonded is then required.
2. Apply an even layer of 79AK1 antistatic adhesive or Renol AL to both of the materials to be bonded. Allow the adhesive to dry off for at least 5 minutes.
3. Activate the adhesive film on the build-up material using a hot air gun at a temperature of 120 °C for a max. of 20 seconds and on the EVA Worker bottom covering for max. 5 seconds. Then press the build-up material onto the prefabricated foot orthosis by hand or with a suitable positive using the vacuum method until it has cooled.

SUPINATION OR PRONATION WEDGE

To modify the WORKER² prefabricated foot orthosis, you can apply and alter the appropriate conductive EVA wedge (optionally available), respecting a maximum height of 4 mm in the heel area, beginning from the lateral or medial heel edge to a maximum of the MTP-joints in a wedge shape to the center line of the foot orthosis at 0 mm (Fig. 3-5). The original height of the WORKER² prefabricated foot orthosis may not be exceeded in the steel toecap area of the occupational safety footwear!



Fig. 3



Fig. 4

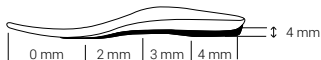


Fig. 5

PROCESSING

1. Cut the conductive EVA wedge (optionally available) to the required size and roughen it on a grinding belt (granulation of 24-40). Thorough de-dusting of the surface to be bonded is then required.
2. Apply an even layer of 79AK1 antistatic adhesive or Renol AL to both of the materials to be bonded. Allow the adhesive to dry off for at least 5 minutes.
3. Activate the adhesive film on the build-up material using a hot air gun at a temperature of 120 °C for a max. of 20 seconds and on the EVA Worker bottom covering for max. 5 seconds. Then press the build-up material onto the prefabricated foot orthosis by hand or with a suitable positive using the vacuum method until it has cooled.

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