



# FOOT ORTHOSES INSTRUCTIONS FOR USE

ORTHOPEDIC/PODIATRIC RETAIL



## CONTENTS

Introduction .....	20
Product description .....	21
Purpose/Indications .....	21
Contraindications .....	22
Instructions for use and information on risks.....	22
Requirements for modifications .....	24
Safety instructions and residual risks .....	26
Cleaning and care/General rules .....	27
Technical specifications/Parameters / Disposal .....	28
Guarantee .....	29

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## INTRODUCTION

Dear clients,

Please read the instructions for use carefully before using the product. Follow all instructions, especially the safety instructions.

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## PRODUCT DESCRIPTION

Foot orthotic blanks are semi-finished products that serve as the basis for the production of foot orthoses. They are used on the sole of the feet in shoes that are suitable for use with orthotics. The adjustment to the foot and the correct fit of the orthotic's functional elements must be carried out by trained specialist personnel. The orthotics must also be fitted in the shoes. The outline of an orthosis corresponds to the inlay of the shoes in which the foot orthoses are worn.

The orthotic blanks consist of a thermoplastically deformable shell, a reinforcing layer, a base cover and optional padding elements and/or supporting pads (depending on the variant). In order to make the orthotic blank ready for use by a user/patient, it must be provided with a top cover. Different orthotic variants are offered depending on the indication.

## PURPOSE

Foot orthotic blanks are semi-finished products for foot orthoses. After patient/user-specific fitting and customization, foot orthoses are used to prevent or aid in the treatment of foot diseases or complaints. They are worn in footwear suitable for use with orthotics. They exercise a supporting, guiding or muscle-stimulating effect to preserve the arches of the foot. Foot orthoses also relieve specific areas of the foot and alleviate complaints.

## INDICATIONS

Indications for the use of foot orthoses include diseases and complaints that affect the foot and lower limbs and require support of the foot or leg structure or relief of certain areas of

the foot. Such painful symptoms of overuse or foot discomfort may occur due to:

- Foot misalignments (and their accompanying problems): Pes valgus, arch decreased conditions / Pes planus, Pes transverso-planus (splayfoot), moderate Pes cavus
- Pathological changes: Hallux valgus, Hallux limitus/rigidus, plantar fasciitis / Calcaneal spur, knee joint complaints, achillodynia, metatarsalgie, static foot complaints (fracture restorations, surgeries, etc.), (osteo)arthrosis / arthritis of toe joints and/or MTP-joints, Kohler's disease (osteonecrosis), neuropathologic foot discomfort
- Deformations of the leg axis

## CONTRAINDICATIONS

Contraindications to the use of foot orthoses include:

- Deformities of the feet with strong variations in foot proportion and shape
- Distinct sensory disturbance of the feet

## INSTRUCTIONS FOR USE AND INFORMATION ON RISKS

- Before being used for the first time, the foot orthotics must be fitted to the needs of the user/patient by qualified personnel.
- Foot orthoses are to be worn with (wrinkle-free) socks and always in pairs! The orthotics must not slip or buckle when putting on the shoes.

- The shoe must provide sufficient internal space (length/width, toe space) for both the foot and the orthotic.
- The selected foot orthotics can be fitted according to width and length. The forefoot, midfoot and hindfoot must be supported by the orthotic across the entire surface and must not hang over the edges; otherwise, blistering or callus formation may occur on the soles or sides of the feet.
- Materials used for foot orthoses are subject to natural aging or wear and tear and may change in their characteristics. Foot orthoses must not be worn if the covers, padding material or orthotic shell have become perforated or wrinkled or broken due to overuse!
- Foot orthotics are influenced by body weight, pressure, torsion and friction and therefore have a load-dependent lifespan. Temperatures, hosiery materials, cover materials, footwear and environmental influences also limit their service life.
- It is recommended that foot orthoses be checked after 6 months at the latest for function and condition by an orthopedic technician, podiatrist, or other qualified specialized personnel.
- Feet should be checked regularly for signs of pressure, redness and other changes.

## REQUIREMENTS FOR MODIFICATIONS:

Perpedes' self-supporting orthoses may only be modified in accordance with the following procedures:

### **Shell/orthotic blanks (self-supporting glass or carbon fiber composite shells with and without base covers):**

Heating: in a convection oven or with a heat gun from the top (surface heating, approx. 20 cm distance)

- Temperature: approx. 140°C
- Heating time: approx. 3 min (depending on material, thickness, heat source), material must be thoroughly warmed and flexible
- Direct contact between the orthotic's shell or base layer and the oven's grate should be avoided (Teflon film recommended).
- When heating base cover and padding materials there is a risk of shrinkage and possibly delamination.

Forming: shell/orthotic blank should be formed on a positive (e.g. plaster cast, or shoe last) by vacuum process.

Grinding: Recommended abrasive graining 40 - 100

### **Foot orthotic blanks with base covers (self-supporting glass or carbon fiber composite shells with base covers):**

Heating: in a convection oven or with a heat gun from the top (surface heating, approx. 20 cm distance)

- Temperature: approx. 140°C



- Heating time: approx. 3 min (depending on material, thickness, heat source), material must be thoroughly warmed and flexible
- When heating base cover and padding materials there is a risk of shrinkage and possibly delamination.

Forming: shell/orthotic blank should be formed on a positive (e.g. plaster cast, or shoe last) by vacuum process.

Grinding: Recommended abrasive graining 40 - 100

**Perpedes' foot orthotic blanks/bases made of EVA foam may only be modified in accordance with the following procedures:**

Heating: in a convection oven

- Temperature: approx. 90° - 110°C
- Heating time: approx. 2-3 min (depending on material, thickness, heat source), material must be thoroughly warmed and flexible
- Direct contact between the orthotic's base and the oven's grate should be avoided (Teflon film recommended)
- When EVA foams are heated, there is a risk of shrinkage and possibly delamination.

Forming: EVA blanks/bases should be formed on a positive (e.g. plaster cast, or shoe last) by vacuum process.

Grinding: Recommended abrasive graining 24 - 100

## SAFETY INSTRUCTIONS AND RESIDUAL RISKS



Fitting, trimming and modifications of foot orthoses as instructed in this manual should only be carried out by qualified personnel.



The product is only for use with one patient/user.



It should be ensured that the foot orthoses are worn side-correct and in footwear with sufficient internal space. Foot orthoses may not be worn if they are wrinkled or have slipped out of place in the shoe.



If excessive pain, swelling, numbness or changes in sensitivity, unusual reactions or discomfort occur during use, please contact your physician, orthopedic technician/podiatrist or qualified personnel immediately.



The product must not be used in water and must be protected from heat  $> 50^{\circ}\text{C}/122^{\circ}\text{F}$ .



If the product is damaged, please replace it immediately or have it repaired by qualified personnel.



Depending on the country, foot orthoses may be medically prescribed products that should be worn under medical supervision. They may only be used in accordance with these instructions for use and within their intended purpose.

## CLEANING AND CARE

- Foot orthotics need to be taken out of the shoes daily to allow moisture to evaporate.
- If necessary, the top cover materials can be cleaned with mild washing lotion and a damp sponge or cloth. The soap residue should be removed. Do not use external heat sources to dry; only allow to air-dry. Orthotics are not suitable for washing machines!
- Mild disinfectants (suitable for human skin) can be sprayed on/applied sparingly. Discoloration of cover materials may occur and does not constitute a defect under warranty.



## GENERAL RULES

- Foot orthoses may only be used by one patient/user due to indication-based selection, individual fitting and hygienic reasons. Orthotics are therefore not suitable for multiple use (re-use for different people).
- Check the product regularly, but at least every 4 weeks for wear and tear. The properties of orthotics diminish as a result of repeated use (wearing). It is therefore not possible to define a specific lifespan or wearing period. Foot orthoses should be replaced when worn.
- The combination of foot orthoses with other medical devices is only allowed with selected and adaptable products. Maintenance must be carried out by qualified specialist personnel!

## TECHNICAL SPECIFICATIONS / PARAMETERS

Foot orthotic materials may vary depending on the model. However, a foot orthosis is composed of the following main components:

- Thermoplastic deformable, self-supporting orthotic shell or orthotic base made of EVA or cork
- Padding materials (optional)
- Reinforcement materials (optional)
- Supporting components, e.g. met pad (optional)
- Top cover and base cover
- Posture-affecting “Balancer” heel module (optional)

## DISPOSAL

You may dispose of the product in accordance with the applicable national regulations.

## GUARANTEE

The current statutory provisions apply. Disregard of the instructions for use, improperly performed cleaning as well as independent technical changes and additions to the product will void the warranty and the general product liability.

 The CE marking confirms compliance with the requirements of Regulation (EU) 2017/745 on medical devices (MDR).



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