FIOR & GENTZ

Instructions for Use for Patients
Therapeutic Shoes

EN

Content **Page**

1. Safety Instructions 3
   - 1.1 Classification of the Safety Instructions 3
   - 1.2 All Instructions for Your Safety 4
2. Use 6
   - 2.1 Intended Use 6
   - 2.2 Indication 6
     - 2.2.1 Indication for Therapeutic Shoes POST-OP 6
     - 2.2.2 Indication for Therapeutic Shoes DIABETES 7
     - 2.2.3 Indication for Therapeutic Shoes HOMECARE 7
   - 2.3 Qualification 7
   - 2.4 Application 8
   - 2.5 Product Range 8
     - 2.5.1 Therapeutic Shoes POST-OP 8
     - 2.5.2 Therapeutic Shoes DIABETES 9
     - 2.5.3 Therapeutic Shoes HOMECARE 10
3. Use 10
   - 3.1 Putting on the Therapeutic Shoe 10
   - 3.2 Attaching the Protective Forefoot Cap 11
   - 3.3 Attaching the Protective Heel Cap 12
4. Period of Use 13
5. Care 14
   - 5.1 General Information on Dirt Removal 14
   - 5.2 Dirt Removal 14
6. Disposal 14
7. Signs and Symbols 15
8. CE Conformity 16
9. Legal Information 16

Instructions for Use for Patients
Therapeutic Shoes

Dear Patient,

You have received from your supplier a FIOR & GENTZ therapeutic shoe.

1. Safety Instructions

1.1 Classification of the Safety Instructions

⚠ DANGER	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ WARNING	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ CAUTION	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

All serious incidents according to Regulation (EU) 2017/745 which are related to the product have to be reported to the manufacturer and to the competent authority of the Member State in which the qualified specialist in orthopaedic (shoe) technology and/or the patient is established.

1.2 All Instructions for Your Safety

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
You must not cycle or drive a vehicle when wearing a therapeutic shoe.

⚠ WARNING

Risk of Falling Due to Improper Handling
Have a qualified specialist in orthopaedic (shoe) technology inform you about the correct use of the shoe and potential dangers (e.g. slippery and wet ground) as well as dangers with regard to your indication and possible associated physical disabilities.

⚠ WARNING

Risk of Falling Due to Incorrectly Selected Therapeutic Shoe
Have a qualified specialist in orthopaedic (shoe) technology select a therapeutic shoe suitable for your indication and your shoe size. The qualified specialist in orthopaedic (shoe) technology checks the shoe label in order to hand over the correct product.

⚠ WARNING

Risk of Falling Due to Damages and Wear of the Therapeutic Shoe
Check the therapeutic shoe regularly for damages and severe signs of wear and dispose of it if it shows any of the interruption criteria defined in paragraph 4.

⚠ WARNING

Risk of Infection of Existing Wounds Due to Multiple Persons Wearing the Shoe
The shoe may only be worn by one patient. Only wear the therapeutic shoe yourself. For hygienic reasons, do not pass it on to third parties.

⚠ WARNING

Risk of Infections and Wounds for Patients with Diabetic Foot Syndrome
Have a qualified specialist in orthopaedic (shoe) technology select a therapeutic shoe suitable for your risk group. Also note the following:
- Wear your therapeutic shoe with a custom-made diabetic foot orthotic to avoid chafing due to an incorrect load/relief.
- Wear closed therapeutic shoes or therapeutic shoes with protective caps to avoid the risk of infection from dirt entering.

⚠ WARNING

Jeopardising the Therapy Goal Due to the Use of a Relief Shoe Without Crutches
Use crutches when wearing a relief shoe in order to reduce the wear of the sole and thus prevent a loss of function of the shoe and the resulting insecurities in gait.

⚠ WARNING

Jeopardising the Therapy Goal Due to Incorrect Foot Orthotic
When handing over the therapeutic shoe, have a qualified specialist in orthopaedic (shoe) technology check whether the foot is properly bedded according to your indication. Particular attention has to be paid to correct pressure relief of the wounds.

⚠ CAUTION

Postural Damage Due to Different Heel Heights
Wear a height compensation shoe on the healthy foot, e.g. a matching FIOR & GENTZ TWINSHOE.

NOTICE

Use of the Therapeutic Shoe
Always wear socks when using the therapeutic shoe.

2. Use

2.1 Intended Use

The FIOR & GENTZ therapeutic shoes must be used for the treatment of the foot in the case of damage to the skin and subcutaneous tissue as part of the conventional or post-operative treatment of wounds with padded bandages.

A therapeutic shoe's function is to protect, relieve and guide the foot in the best possible way. Thus, it supports the healing process while still ensuring mobility.

Due to the indication-based selection, individual adaptation and for hygienic reasons, the therapeutic shoe may only be used by yourself. Therapeutic shoes are used in home health care settings, outdoor settings and professional health care facilities.

2.2 Indication

The FIOR & GENTZ therapeutic shoes are used for various indications. You can find the model-specific indications in the therapeutic shoe catalogue and in the section "Products" and "Therapeutic Shoes" on the FIOR & GENTZ website.

2.2.1 Indication for Therapeutic Shoes POST-OP

The POST-OP therapeutic shoes protect the foot after surgery. They prevent chafing and pressure on the wound. Moreover, they help to stabilise and immobilise the foot. There are two sub-categories, each with specific features:

Bandage Shoes

The bandage shoes offer ample space for bandages and can be opened wide so that they can be put on and taken off easily.

Relief Shoes

The relief shoes reduce the pressure on the injured area of the foot and are divided into forefoot and heel relief shoes. Forefoot relief shoes relieve wounds or the entire forefoot and prevent pain in this area. Heel relief shoes relieve wounds or the entire heel area and prevent pain in this area.

2.2.2 Indication for Therapeutic Shoes DIABETES

The DIABETES therapeutic shoes are used for a diabetic foot syndrome depending on the state of the wound and the associated wound healing disorder. The causes of a diabetic foot syndrome can be either a neuropathic or an ischaemic foot, or a combination of both.

The shoes protect the foot by preventing pressure points and the smallest injuries. They are used for the treatment of diabetes mellitus with sensory neuropathy caused by PNP/relevant PAD (risk group II), for the treatment of a condition after a plantar ulcer (risk group III) as well as for the treatment of acute lesions (risk group VII).

2.2.3 Indication for Therapeutic Shoes HOMECARE

The HOMECARE therapeutic shoes offer a high wearing comfort for wounds (e.g. due to traumatic injuries) or swellings in the foot area.

2.3 Qualification

The selection of a shoe model should only be carried out by a qualified specialist in orthopaedic (shoe) technology.

2.4 Application

Therapeutic shoes must only be worn with socks and in combination with bandages to avoid skin contact. If there is a considerable difference in height between the sole of the therapeutic shoe and that of the normal shoe, you need a slip-resistant height compensation shoe or a height compensation for a normal shoe.

In the FIOR & GENTZ therapeutic shoe catalogue, you will find the matching height compensation shoe for your shoe model under the name TWINSHOE.

We recommend the use of crutches to improve gait stability. Additionally, you should practice a safe heel-to-toe movement with the therapeutic shoe. You must not cycle or drive a vehicle when wearing a therapeutic shoe.

2.5 Product Range

2.5.1 Therapeutic Shoes POST-OP

The following POST-OP therapeutic shoes are part of the FIOR & GENTZ product range:

AMSTERDAM
AUGSBURG
BERLIN
BREMEN
ERFURT
FLENSBURG
FRANKFURT
FREIBURG
HAMBURG
HANNOVER
KÖLN
KOPENHAGEN
LONDON
MADRID
MAILAND
MÜNCHEN
REGENSBURG
STENDAL
STOCKHOLM
STUTTGART
WUPPERTAL

Bandage Shoes

The bandage shoes have an adaptable inner volume. Due to big, handy hook and loop or instep fasteners, the inner volume can be adapted to the individual need for space of the foot at any time.

Relief Shoes

Some models of the relief shoes can be combined with a protective cap that protects the foot from cold and wet conditions. The forefoot relief shoes (example FRANKFURT, fig. 1) provide an open toe area and a wedge sole with a forefoot support or a forefoot rocker. The latter assists the foot's heel-to-toe movement. Forefoot relief shoes without forefoot support can be supplied with a protective stirrup if required.

fig. 1

fig. 2

The heel relief shoes (example WUPPERTAL, fig. 2) provide an open heel area. Some shoe models also have a shortened sole without heel support which completely relieves the heel area.

2.5.2 Therapeutic Shoes DIABETES

The following DIABETES therapeutic shoes are part of the FIOR & GENTZ product range:

AUGSBURG	KASSEL
DRESDEN	KONSTANZ
ERFURT	LEIPZIG
FLENSBURG	NÜRNBERG
HEIDELBERG	WETZLAR

The DIABETES therapeutic shoes (example KASSEL, fig. 3) have removable insoles. This allows you to easily place an individual diabetic foot orthotic into the shoe. Do not select a shoe that

fig. 3

is too tight to avoid pressure points and chafing. If more space is required due to bandages, foot deformities, etc., the inner volume can be adapted or a wider shoe version can be selected.

2.5.3 Therapeutic Shoes HOMECARE

The following HOMECARE therapeutic shoes are part of the FIOR & GENTZ product range:

HEIDELBERG
KONSTANZ
LEIPZIG

The HOMECARE therapeutic shoes (example HEIDELBERG, fig. 4) have a flexible sole and can be worn both inside and outside. They are particularly useful for a stay in a (rehabilitation) clinic or a retirement home.

fig. 4

3. Use

3.1 Putting on the Therapeutic Shoe

Always put on and take off the therapeutic shoe while seated. Always wear socks when wearing therapeutic shoes.

1 Open the therapeutic shoe (fig. 5).
2 Place your foot on the sole (fig. 5).
3 Close the hook and loop fasteners (fig. 6). If your therapeutic shoe has a hook and loop fastener in the heel area, close that one at the end (fig. 7-8).

fig. 5

fig. 6

fig. 7

fig. 8

3.2 Attaching the Protective Forefoot Cap

1 Depending on the model, attach the protective forefoot cap on the inside or the outside of the therapeutic shoe (fig. 9-10).
2 Place your foot in the shoe.
3 Place the tongue of the protective cap over the foot (fig. 11).
4 Then, put the wings of the upper on top of the tongue and close the hook and loop fasteners (fig. 12).

fig. 9

fig. 10

fig. 11

fig. 12

The hook and loop fasteners should fit tightly. However, excessive pressure should be avoided.

3.3 Attaching the Protective Heel Cap

1 Attach the protective heel cap (fig. 13). With the exception of the WETZLAR model (fig. 14), this should be done before putting on the shoe.
2 Place your foot in the shoe.
3 Close the hook and loop fasteners in the heel area (fig. 15).

fig. 13

fig. 14

fig. 15

The hook and loop fasteners should fit tightly. However, excessive pressure should be avoided.

4. Period of Use

Note that the period of use depends on the intensity of use as well as your indication which determines the medically adequate period of time the shoe should be used. The end of the indication also ends the period of use and the shoe must no longer be used. Check the therapeutic shoe regularly for external damages during the period of use.

If you notice the damage or signs of wear listed in the following table, the shoe must be disposed of.

Interruption Criteria	Measure
The fastener system is no longer functional.	dispose of the shoe
The stability is no longer guaranteed (e.g. with a deformed shoe or torn seams).	dispose of the shoe
The sole detaches from the shaft.	dispose of the shoe
The sole profile is worn out.	dispose of the shoe

In the following table you will also find our general recommendation for the period of use of all FIOR & GENTZ therapeutic shoes.

Recommended Period of Use	Therapeutic Shoe
6 months	DRESDEN, HEIDELBERG, KASSEL, KONSTANZ, LEIPZIG, NÜRNBERG, WETZLAR
4 months	AMSTERDAM, AUGSBURG, BREMEN, ERFURT, FLENSBURG, FRANKFURT, FREIBURG, HAMBURG, KOPENHAGEN, MADRID, REGENSBURG, STUTTGART
2 months*	BERLIN, HANNOVER, KÖLN, LONDON, MAILAND, MÜNCHEN, STENDAL, STOCKHOLM, WUPPERTAL

* Please note that the indicated periods for the use of therapeutic shoes with wedge soles only apply if crutches are used.

5. Care

To avoid pressure points, chafing and unnecessary material wear, always check inside your therapeutic shoe for foreign objects like small stones or coarse dirt before wearing it.

5.1 General Information on Dirt Removal

Clean your therapeutic shoe regularly. Every time you remove dirt from the therapeutic shoe, check for signs of wear and have it repaired or dispose of it according to the interruption criteria (see paragraph 4), if necessary. The therapeutic shoe must not be dried in the dryer or at the radiator (fig. 16). Instead, let it dry slowly at room temperature. After taking off the therapeutic shoe, leave it open so that moisture can escape and no unpleasant odours develop.

fig. 16

5.2 Dirt Removal

Remove minor soiling with a soft brush or a damp cloth. In case of severe soiling, you can wash the therapeutic shoe in the washing machine at 40°C without spin cycle (fig. 17). Use a laundry net as well as neutral detergent. Close the hook and loop fasteners before washing so that they will not become matted. Afterwards, stuff the therapeutic shoe with newspaper and let it dry.

fig. 17

6. Disposal

Therapeutic shoes can be disposed of as residual waste (fig. 18). If treated properly, they do not pose a greater risk than properly disposed municipal waste.

fig. 18

7. Signs and Symbols

CE labelling according to Regulation (EU) 2017/745 for medical devices

medical device

article number

manufacturer

batch code

serial number

follow the instructions for use

single patient – multiple uses

Unique Device Identifier – product identification number

8. CE Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of Regulation (EU) 2017/745. Therefore, the FIOR & GENTZ products bear the CE marking.

9. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply.

The information in these instructions for use is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

All copy rights, particularly the distribution, copy and translation of these instructions for use or any part of them, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH. Reprints, copies and any other electronic reproduction, even partial, must be authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH.

FIOR & GENTZ

PB1000-TS-PI-GB-2024-10

CE

FIOR & GENTZ
Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH

Dorette-von-Stern-Straße 5
21337 Lüneburg (Germany)

+49 4131 24445-0
+49 921 95659554

info@fior-gentz.de
www.fior-gentz.com