FIOR & GENTZ

Instructions for Use for Patients
Orthosis Shoes

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Instructions for Use for Patients
Orthosis Shoes

Dear Patient,

You have received from your supplier a FIOR & GENTZ orthosis 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
Gather information about all issues concerning safety and security and potential dangers, concerning the orthosis shoe, your indication and your orthosis, before driving a motor vehicle.

⚠ 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 Orthosis Shoe
Have a qualified specialist in orthopaedic (shoe) technology select an orthosis 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 Impairment of the Orthosis' Function
Immediately stop the usage and contact a qualified specialist in orthopaedic (shoe) technology if you notice any impairments of the orthosis' function. This includes, for example, an incorrect fit of the orthosis in the shoe or damages to the material at the spot where it is in direct contact with the orthosis shoe.

⚠ WARNING

Manifestation of Pressure Points Due to Insufficient Shoe Space
Make sure that the orthosis shoe provides enough space for wearing an orthosis in order to prevent pressure points on the feet. The qualified specialist in orthopaedic (shoe) technology must consider and check this when selecting, adapting and handing over the orthosis shoe.

⚠ CAUTION

Risk of Falling Due to Damages and Wear of the Orthosis Shoe
Check the orthosis shoe regularly for damages and severe signs of wear and dispose of it, if it shows any of the interruption criteria defined in paragraph 5.

⚠ CAUTION

Postural Damages Due to Lack of Height Compensation
Have a qualified specialist in orthopaedic (shoe) technology check whether there is a correct height compensation, in order to avoid loss of orthosis function and postural damages. Remove the insoles to balance the height difference between the foot with and the foot without orthosis. If the height still differs, ask a qualified specialist in orthopaedic (shoe) technology to produce a height compensation for you.

NOTICE

Use of the Orthosis Shoe
Always wear socks when using the orthosis shoe.

NOTICE

Multiple Persons Wearing the Shoe
The orthosis shoe may only be worn by one patient. Only wear the orthosis shoe yourself. For hygienic reasons, do not pass it on to third parties.

NOTICE

Combination of the Orthosis Shoe with Joints from Other Manufacturers
Have a qualified specialist in orthopaedic (shoe) technology confirm the suitability of a combination before you combine your FIOR & GENTZ orthosis shoe with joints from other manufacturers.

2. Use

2.1 Intended Use

The FIOR & GENTZ orthosis shoes were designed for people wearing an orthosis for the lower extremity (AFO or KAFO) with a joint in the ankle area. Due to the elastic material on the outer side, the orthosis shoes can accommodate mechanical ankle joints.

Although the orthosis shoes have been primarily developed to be used with FIOR & GENTZ system ankle joints, they can also be combined with joints from other manufacturers. The orthosis shoes support you when walking with an orthosis.

2.2 Indication

The FIOR & GENTZ orthosis shoes stabilise the foot while walking and are easy to put on and take off. Due to the indication-based selection, the individual adaptation and for hygienic reasons, the orthosis shoes may only be used by yourself.

2.3 Contraindication

The orthosis shoes are not suitable for severe foot deformities such as clubfeet, hollow feet or similar indications where there are fit problems with a preproduced orthosis shoe.

2.4 Qualification

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

2.5 Application

Orthosis shoes are used outdoors and indoors and are meant to be used by one patient only. Furthermore, they should only be worn with socks.

2.6 Product Range

The following **orthosis shoes** are part of the FIOR & GENTZ product range:

CROSSROADS

PARKSTREET

URBANSTREET

CITYDRIVE

3. Scope of Delivery

The scope of delivery includes the following articles:

Description	Quantity	Unit
orthosis shoe (fig. 1)	1	pair
insole (fig. 2)	2	piece
shoelaces (for normal use; without fig.)	1	piece
shoelaces (for one-handed lacing; without fig.)	1	piece
Guide for One-Handed Lacing (without fig.)	1	piece

fig. 1

fig. 2

You will find the lengths of the shoelaces in the following table:

Shoelaces	Shoe	Length of the Shoelace	Shoe Size (EU)
shoelace for normal use	CROSSROADS	80cm	36–48
	PARKSTREET URBANSTREET	95cm	32–36
		120cm	37–42
		150cm	43–48
	CITYDRIVE	85cm	36–48
shoelace for one-handed lacing	CROSSROADS	110cm	36–48
	PARKSTREET URBANSTREET	125cm	32–36
		150cm	37–42
		180cm	43–48
	CITYDRIVE	120cm	36–48

You will find a comparison of the three most common shoe size systems in the following table:

Shoe Size			
EU	**UK**	**US (Male)**	**US (Female)**
32	0	1	2
33	1	2	3
34	2	3	4
35	2.5	3.5	4.5
36	3.5	4.5	5.5
37	4	5	6
38	5	6	7
39	5.5	6.5	7.5
40	6	7	8
41	7	8	9
42	8	9	10
43	9	10	11
44	9.5	10.5	11.5
45	10	11	12
46	11	12	13
47	12	13	14
48	13	14	15

You will find the technical data of the orthosis shoes in the following table:

Shoe Measurements		Shoe	Use
Pitch*	Heel Height**	CROSSROADS	h-Cast Orthosis Configurator
15mm	25mm		
Pitch*	Heel Height**	PARKSTREET URBANSTREET	
0mm	14mm		
Pitch*	Heel Height**	CITYDRIVE	
10mm	25mm		

* The height of the pitch corresponds to the height of the h-cast plate to be used in the physical examination.
** The heel height is used in the Orthosis Configurator as part of the calculation basis.

You will find the material of the orthosis shoes in the following table:

Upper Material	Inner Lining	Outsole	Shoe
cow leather	calf leather	EVA material	CROSSROADS brown
		vibram® flat sole (made of rubber mixture)	CROSSROADS black
fabric	-	EVA material with rubber coating	PARKSTREET URBANSTREET
nubuck leather	calf leather	polyurethane (PU)	CITYDRIVE

4. Use

Orthosis shoes must always be used in pairs.

4.1 Insoles

To compensate for a height difference between a foot without orthosis and a foot with orthosis, you need to remove both insoles from the shoe in which you are wearing your orthosis. If the height still differs, ask a qualified specialist in orthopaedic (shoe) technology to produce a height compensation for you.

Only use labelled FIOR & GENTZ insoles.

4.2 Putting On the Orthosis Shoe

Always put on and take off the orthosis shoe while you are seated. Remember to wear socks in your orthosis shoe.

1 Open the hook and loop fastener and/or the lacing of the orthosis shoe.
2 Place the orthosis' foot piece in the shoe (fig. 3).
3 Partially lace the orthosis shoe.
4 Step into the foot piece in the orthosis shoe by using the heel strap (fig. 4).
5 Completely lace the orthosis shoe, then tighten the shoelaces.
6 Close the hook and loop fastener, if applicable (fig. 5).

The foot should fit steady in the shoe. However, excessive pressure should be avoided.

fig. 3

fig. 4

4.3 One-Handed Lacing

If you can only use one hand to lace your orthosis shoe due to a physical impairment, follow the Guide for One-Handed Lacing. You can find the leaflet enclosed with the orthosis shoe. If you are physically not capable to put on the orthosis shoe on your own, ask another person for assistance.

fig. 5

5. Period of Use

Note that the period of use of the orthosis shoes depends on the intensity of use. Check the orthosis shoes for external damages regularly.

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

Interruption Criterion	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

6. Care

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

6.1 General Information on Dirt Removal

Clean your orthosis shoe regularly. Every time you remove dirt from the orthosis shoe, check it for signs of wear and have it repaired or dispose of it, according to the interruption criteria (see paragraph 5), if necessary. The orthosis shoe must not be dried in the dryer or at the radiator (fig. 6). Instead, let it dry slowly at room temperature. After taking off the orthosis shoe, leave it open so that moisture can escape and no unpleasant odours develop.

fig. 6

6.2 Dirt Removal on Orthosis Shoes Made of Fabric

Remove minor soiling with a soft brush. In case of heavy dirt or soiling, you can use a damp cloth.

6.3 Dirt Removal on Orthosis Shoes Made of Nubuck Leather

Remove minor soiling with a special velours-nubuck leather brush or carefully with a damp cloth. Furthermore, the orthosis shoe should be regularly covered with an impregnation spray that protects the shoe against moisture. In order to preserve the colour freshness, we recommend using an impregnation spray that matches the colour of the leather. Please refer to the manual of the respective product for the frequency of application. Shoes made of nubuck leather should not be greased, since the grease cannot be absorbed by the material.

Avoid exposing your orthosis shoe to heavy moisture. You should also keep it away from intense sunlight.

7. Disposal

Orthosis shoes can be disposed of as residual waste (fig. 7). If treated properly, they do not pose a greater risk than properly disposed municipal waste.

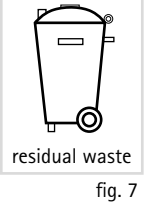

fig. 7

8. Signs and Symbols

CE	CE labelling according to Regulation (EU) 2017/745 for medical devices
MD	medical device
REF	article number
	manufacturer
LOT	batch code
SN	serial number
	follow the instructions for use
	single patient – multiple uses
UDI	Unique Device Identifier – product identification number

9. 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.

10. Legal Information

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

Please note that the product is, under ideal circumstances, supposed to be worn with FIOR & GENTZ insoles or custom-made soles in combination with the orthosis.

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.

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