



2gaad

[Patienteninformation]

[Patient Information]

DE	Druckdatum: 2014-11 Der Inhalt dieser Patienteninformation wird regelmäßig aktualisiert und ist beim Einsatz des Produktes unbedingt zu beachten. Mehr unter: www.2gaad.de	Seite 2
GB	Date printed: 2014-11 This patient information is regularly updated and should be strictly followed. More information at: www.2gaad.de/gb	Page 11

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Dear Patient,

You have received from your orthopaedic shoemaker a therapeutic shoe.

1. Declaration of Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of the Medical Devices Directive 93/42/EEC. Regarding to these tests, all FIOR & GENTZ products have the CE marking.

2. Warranty

Our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment apply. Please keep in mind that therapeutic shoes wear out. The warranty applies only if the product has been used under the described conditions and for the intended applications. Damage resulting from normal wear is excluded from warranty. Furthermore, we do not accept a multi-use of the product.

3. Application

All therapeutic shoes are exclusively for use for orthotic fittings of the foot.

4. Safety Instructions

In order that you wear the therapeutic shoe correctly, it is able to fulfil its function and you can use it as long as possible, please note all information provided in this patient information, especially the safety instructions indicated by ATTENTION! CAUTION! WARNING! and DANGER! which are listed and explained in the following paragraph. Ignoring this information may lead to injuries and property damage.

4.1 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.



ATTENTION!

Important information about a possible dangerous situation which, if not avoided, leads to damage of the product.

4.2 Structure of the Safety Instructions

The following example demonstrates the structure of the safety instructions:

Attention symbol	Signal word	CAUTION!
	Type of danger	<i>Therapeutic shoe is worn too long!</i>
	Possible consequences for the therapeutic shoe	➔ <i>Sole wears down.</i>
	Possible consequences for you	➔ <i>Goal of treatment is maybe not achieved.</i>
	Measures	Do not wear the therapeutic shoe longer than recommended.

4.3 Overview of all Safety Instructions for Therapeutic Shoes

There is detailed information to some of the safety instructions in the course of this manual. Respect the following safety instructions to avoid injuries and property damage:



WARNING!

Therapeutic shoe is put on incorrectly!

➔ *Pressure points and possible loss of fixing function.*

Put the therapeutic shoe on as described in the manual.



WARNING!

Therapeutic shoe is used incorrectly!

➔ *Delay of healing process and possible fall.*

Let your orthopaedic shoemaker explain you correct use of the therapeutic shoe and possible dangers.



WARNING!

Therapeutic shoe is worn by several persons!

➔ *Improper handling of therapeutic shoe.*

➔ *Infection of existing wounds.*

Therapeutic shoe is only for personal use. Do not pass it on to third persons.



WARNING!

Risk group concerning the diabetic foot syndrome was not respected!

➔ *Lesions and possible delay of healing process.*

Please make sure that your orthopaedic shoemaker selects the correct therapeutic shoe.



WARNING!

Therapeutic shoe is worn without custom-made foot orthotic for diabetic patients!

➔ *No wound relief.*

Always wear a custom-made foot orthotic for diabetic patients in the therapeutic shoe or let your orthopaedic shoemaker adapt it for you.



CAUTION!

Therapeutic shoe is worn too long!

➔ *Sole wears down.*

➔ *Goal of treatment is maybe not achieved.*

Do not wear the therapeutic shoe longer than recommended.

5. Putting the Therapeutic Shoe on



WARNING!

Therapeutic shoe is put on incorrectly!

➔ *Pressure points and possible loss of fixing function.*

Put the therapeutic shoe on as described in the manual.

1. Unless your foot is not protected by a bandage, always wear socks in the therapeutic shoe.
2. Put the therapeutic shoe on and take it off when seated (fig. 1-2).
3. Make sure that the hook and loop fasteners are always attached in such a way that the logo is positioned on the outside.
4. The hook and loop fasteners have to be tight fitted but they must not apply pressure to the muscles and soft parts.



Fig. 1



Fig. 2

6. Using the Therapeutic Shoe



WARNING!

Therapeutic shoe is used incorrectly!

➔ *Delay of healing process and possible fall.*

Let your orthopaedic shoemaker explain you correct use of the therapeutic shoe and possible dangers.

7. Restrictive Use



WARNING!

Therapeutic shoe is worn by several persons!

➔ *Improper handling of therapeutic shoe.*

➔ *Infection of existing wounds.*

Therapeutic shoe is only for personal use. Do not pass it on to third persons.

The therapeutic shoe is specially adapted to your clinical picture and to your foot's anatomy. Because of this and for hygienic reasons, only you should wear the shoe. It is, therefore, **not** suitable for multi-use and is not allowed to be passed on to third persons.

8. Maximum Useful Life



CAUTION!

Therapeutic shoe is worn too long!

➔ *Sole wears down.*

➔ *Goal of treatment is maybe not achieved.*

Do not wear the therapeutic shoe longer than recommended.

The maximum useful life of therapeutic shoes depends on your clinical picture and on the period of use that seems to be medically adequate. It begins with dispensing the shoe to you.

Let your orthopaedic shoemaker inform you about the maximum useful life and respect it.

The maximum useful life of 2gaad therapeutic shoes is **6 months**.

9. Special Indications for Diabetic and Rheumatic Patients



WARNING!

Risk group concerning the diabetic foot syndrome was not respected!

➔ *Lesions and possible delay of healing process.*

Please make sure that your orthopaedic shoemaker selects the correct therapeutic shoe.



WARNING!

Therapeutic shoe is worn without custom-made foot orthotic for diabetic patients!

➔ *No wound relief.*

Always wear a custom-made foot orthotic for diabetic patients in the therapeutic shoe or let your orthopaedic shoemaker adapt it for you.

If you have diabetes mellitus or rheumatism, you are particularly prone to foot injuries and have to wear special shoes. Since small stones or coarse dirt can quickly lead to pressure points and chafing, it is important that you always wear socks or a bandage in the therapeutic shoe.

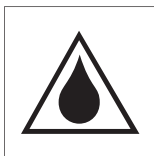
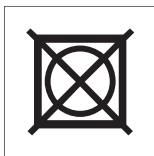
If you suffer from diabetic foot syndrome, you need an adequate wound relief. For this purpose, your orthopaedic shoemaker produces a custom-made foot orthotic for diabetic patients to insert into the therapeutic shoe. Furthermore, your orthopaedic shoemaker can directly grind the insole from inside the shoe to adapt it to your special needs. But it can lose its support and pressure-relieving effect after some time due to high loads.

Thus we recommend you to check the foot orthotic regularly and replace it, if necessary. Despite all measures taken, check your feet every day for pressure points and injuries. If you notice any changes, immediately bring the therapeutic shoe to your orthopaedic shoemaker for checking it.

10. Shoe Care

Remove dirt carefully with a soft brush or wipe it off with a damp cloth. In case of heavy dirt or soiling, wash the shoe in a washing machine at 30 °C and the insoles at 40 °C. Use a washing net as well as neutral soap or diluted vinegar. To avoid hook and loop fasteners getting matted, close them before washing. Afterwards, gently dry the therapeutic shoe, i.e. do not tumble dry and do not dry close to or on the heating. Stuff it with newspaper and put it into a warm room. Each time you clean the therapeutic shoe, pay attention to signs of wear and ensure replacement or repair at an early stage. Since small stones or coarse dirt can quickly lead to pressure points and chafing, always check your therapeutic shoe for foreign objects before wearing it. Clean it regularly to remove hair and scaly skin deposits since these promote the growth of germs and bacteria and encourage inflammations and athlete's foot to develop.

If necessary, widely open the therapeutic shoe and use a shoehorn to put it on and take it off easily. After taking off the therapeutic shoe, leave it open so that moisture can escape and no unpleasant odour can develop.



11. Disposal

For orthopaedic and hygienic reasons, worn therapeutic shoes should be disposed of as residual waste and can no longer be used or recycled.



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