FIOR & GENTZ

Instructions for Use for Patients
System Ankle Joint NEURO HiSWING

EN

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Instructions for Use for Patients
System Ankle Joint NEURO HiSWING

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ system ankle joint from a qualified specialist in orthopaedic technology.

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 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 before driving a motor vehicle with orthosis.

⚠ WARNING

Jeopardising the Therapy Goal by Not Providing the Necessary Free Movement
Check if the system joint moves freely in order to avoid restrictions of the joint function.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
Do not engage in sport activities with the orthosis that expose it to excessive load. If your patient data has changed (e.g. due to weight gain, growth or increased activity), consult a qualified specialist in orthopaedic technology and have them check the suitability of your orthosis with regard to the changed load. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Improper Heel Height
The maximum heel height is specified in consultation with a qualified specialist in orthopaedic technology and must not be exceeded.

⚠ WARNING

Risk of Falling Due to Improper Handling
Have a qualified specialist in orthopaedic technology inform you about the correct use of the system joint and potential dangers. Do not use the orthosis if you notice any damage on the system joint. Avoid contact with moisture and water.

⚠ WARNING

Risk of Falling Due to Improper Handling
System joint components and orthosis components may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the system joint and the orthosis from your side that goes beyond the activities described in these instructions for use is not permitted. Do not make any modifications to the system joint other than those specified as permissible in these instructions for use. In particular, do not loosen any screws on the system joint.

⚠ WARNING

Risk of Falling Due to Improper Handling of the Lever
Use the lever as described in these instructions for use. Pay particular attention to:
- pushing the lever all the way up before adjusting the ankle joint angle,
- changing the ankle joint angle with low effort,
- not putting weight on the orthosis when the lever is pushed up (e.g. while walking, running or cycling) and
- securing the system joint before putting weight on the orthosis by pushing the lever completely down so it does not protrude.

⚠ WARNING

Risk of Falling Due to Use of the Orthosis without a Shoe
If you want to wear the orthosis without a shoe, your orthosis must fulfil the necessary requirements. The qualified specialist in orthopaedic technology must attach a fixation for your foot to the foot piece of the orthosis and a slip-resistant sole. Only wear the orthosis without a shoe in consultation with a qualified specialist in orthopaedic technology.

⚠ WARNING

Risk of Falling Due to Changes in the Orthosis
If you notice any changes in the orthosis (e.g. loosely attached joint components, loosened screws, play in the system joint, change in performance or changed spring forces), immediately contact a qualified specialist in orthopaedic technology. Do not secure screws for the system joint on your own. All settings must be checked by a qualified specialist in orthopaedic technology before handing over the orthosis and during the maintenance appointments. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Modified Heel Height
If your heel height has changed (e.g. by wearing a different shoe), adjust the ankle joint angle to the new heel height using the lever. Use the spirit level attached to the lower leg shell of the orthosis as a guide.

NOTICE

Damage to the System Joint Due to Improper Handling of the Lever
Use the lever as described in these instructions for use. Otherwise, the hydraulics of the system joint will be damaged. Pay particular attention to:
- not putting weight on the orthosis when the lever is pushed up (e.g. while walking, running or cycling) as well as
- adjusting the ankle joint angle only when the lever is pushed all the way up.

NOTICE

Limitation of the Joint Function Due to Improper Handling
Change the ankle joint angle only as specified in these instructions for use. Any changes for which the use of tools is required is not permitted from your side.

NOTICE

Limitation of the Joint Function Due to Improper Dirt Removal
Remove dirt from the orthosis and the system joint as described in these instructions for use. Do not grease the system joint on your own. If necessary, consult a qualified specialist in orthopaedic technology.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Have a qualified specialist in orthopaedic technology inform you about the maintenance intervals to be observed in order to avoid joint dysfunctions. You will find the next maintenance appointment in your orthosis service passport.

2. Use

2.1 Intended Use

The FIOR & GENTZ system ankle joints must be used exclusively for the orthotic treatment of the lower extremity. The system joint is only allowed to be used for producing an AFO or a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg.

2.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/ malfunctions or as a result of physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. A safe handling of the orthosis must be ensured. A qualified specialist in orthopaedic technology selects the appropriate system joints for the orthosis.

All system ankle joints can also be used for the prosthetic treatment of patients with partial foot amputations. For this purpose, the orthosis produced for the patient by a qualified specialist in orthopaedic technology (custom-made product) is combined with a foot prosthesis. Further information can be found in the **Guide to Partial Foot Amputations** (see QR code, fig. 1).

fig. 1

2.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 2.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis that affects more than just part of the foot, for example after amputations of leg segments.

2.4 Qualification

The system joint must only be handled by a qualified specialist in orthopaedic technology.

2.5 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing and parachuting, is excluded.

3. Using the Orthosis

For safety reasons, it is not possible to change the ankle joint angle of the orthosis when one of the spring units of the system joint is loaded. If you push the lever upwards while one of the spring units is loaded, a safety mechanism engages. To deactivate it, take the load off the spring units by making minimal alternating forward and backward movements with the lower leg.

3.1 Adjusting the Ankle Joint Angle when Walking Uphill and Downhill

Via the lever, you can change the ankle joint angle to facilitate walking uphill and downhill with the orthosis. An adjusted ankle joint angle increases the safety, especially when walking downhill. Proceed as follows:

1 Place your foot in the desired position by placing it flat on the slope.
2 Push the lever upwards (fig. 2).
3 Make minimal alternating forward and backward movements with your lower leg to deactivate the safety mechanism (fig. 3).
4 Adjust the ankle joint angle by tilting your lower leg forwards or backwards until the lower leg inclination specified by a qualified specialist in orthopaedic technology is reached. Use the spirit level on the lower leg shell as a guide. After the adjustment, the air bubble must be aligned centrally (fig. 4).
5 Push the lever downwards.

fig. 2

Make sure that the lever is fully pushed down. If it protrudes slightly, the orthosis does not provide you with the necessary safety. Furthermore, this can cause damage to the hydraulics of the system joint.

fig. 3

If you stand or walk on level ground again, the ankle joint angle set by a qualified specialist in orthopaedic technology must be restored. Proceed as follows:

6 Push the lever upwards.
7 Make minimal alternating forward and backward movements with your lower leg to deactivate the safety mechanism (fig. 3).
8 Place your lower leg in the desired position using the spirit level on the lower leg shell as a guide. The air bubble must be aligned centrally (fig. 4).
9 Push the lever downwards.

fig. 4

3.2 Increase the Range of Motion When Sitting

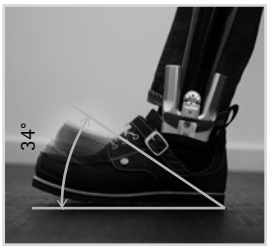

fig. 5

Via the lever, you can increase the range of motion of the system joint by 34° in order to relax your foot muscles when sitting or to put on or take off the orthosis. Proceed as follows:

1 Push the lever upwards when sitting.
2 Make minimal alternating forward and backward movements with your lower leg to deactivate the safety mechanism (fig. 3).
3 Lower the forefoot until the sole fully touches the ground (fig. 5).
4 Push the lever down before standing up. To do so, move your foot forwards or backwards to readjust the ankle joint angle with the orthosis' alignment specified by a qualified specialist in orthopaedic technology. Pay particular attention that the air bubble of the spirit level is aligned centrally (fig. 4).

Use this setting only for adjusting the ankle joint angle, sitting as well as putting on and taking off the orthosis. This setting is not suitable for walking, running or cycling as the function of the orthosis is disabled for this setting and it does not provide you with the necessary safety. Furthermore, this can cause damage to the hydraulics of the system joint.

3.3 Adjusting the Ankle Joint Angle when Climbing Stairs

fig. 6

Via the lever, you can change the ankle joint angle to facilitate climbing stairs with the orthosis. Proceed as follows:

1 Put the leg with the orthosis on the first step (fig. 6).
2 Place the leg without the orthosis on the floor close to the first step.
3 Push the lever upwards.
4 Make minimal alternating forward and backward movements with your lower leg to deactivate the safety mechanism (fig. 3).
5 Bend your lower leg forward until the centre of your knee is above the toes (fig. 6).
6 Push the lever downwards.

Proceed as described in 1–6 for walking down stairs while alternating feet. Move into the correct position for adjusting the lever by walking down the first step, then turn around and place the leg with the orthosis on the step above.

3.4 Adjusting the Ankle Joint Angle for Wearing Shoes with Different Heel Heights

fig. 7

Via the lever, you can change the ankle joint angle to prepare the orthosis for wearing shoes with a different heel height. Proceed as follows:

1 Place the orthosis in the shoe (fig. 7). You can also make this adjustment while wearing the orthosis and the shoe.
2 Push the lever upwards.
3 Make minimal alternating forward and backward movements with your lower leg to deactivate the safety mechanism (fig. 3).
4 Adjust the ankle joint angle by tilting your lower leg forwards or backwards until the lower leg inclination specified by a qualified specialist in orthopaedic technology is reached. Use the spirit level on the lower leg shell as a guide. After the adjustment, the air bubble must be aligned centrally (fig. 4).
5 Push the lever downwards.

The maximum heel height is specified in consultation with a qualified specialist in orthopaedic technology and must not be exceeded. The qualified specialist in orthopaedic technology has indicated the maximum heel height taken into account in the planning of the orthosis in paragraph 10. If it is exceeded, it may cause damage to your orthosis.

3.5 Adjusting the Ankle Joint Angle for Wearing the Orthosis without a Shoe

fig. 8

Via the lever, you can adjust the ankle joint angle in order to wear the orthosis without a shoe. The requirement for this is that the orthosis has been appropriately prepared by a qualified specialist in orthopaedic technology, particularly regarding a fixation for your foot on the foot piece of the orthosis and a slip-resistant sole. If these requirements are met, you can adjust the ankle joint angle for wearing the orthosis without a shoe. Proceed as described in paragraph 3.4.

4. Maintenance

Ask a qualified specialist in orthopaedic technology to maintain the system joint of your orthosis regularly. When the orthosis is handed over to you, you receive an orthosis service passport. Bring this orthosis service passport to each follow-up and let a qualified specialist in orthopaedic technology enter the next maintenance appointment. For your own safety, respect the maintenance appointments. Never carry out maintenance work or other adjustments and repairs yourself. In the case of children and people with cognitive impairments, we would like to point out to you as parents or care team that you must regularly check the orthosis and the system joint for signs of wear. If you notice any changes, immediately contact a qualified specialist in orthopaedic technology.

4.1 Dirt Removal

Remove dirt from the system joint on a regular basis. Use a dry cloth and clean the system joint only superficially. Then, remove visible dust and lint from the mechanics by using tweezers. Check the orthosis in straight and flexed position.

5. Storage

We recommend not storing the system joint in a damp environment.

6. Disposal

If you no longer need the orthosis, please return it to a qualified specialist in orthopaedic technology. The product must not be disposed of with the residual waste (fig. 9).

fig. 9

7. 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
1	single patient – multiple uses
UDI	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 warranty expires, for example, if the product is mounted several times. Please note that the product is not supposed to be combined with other components or materials than with those recommended in the configuration result of the FIOR & GENTZ Orthosis Configurator. The combination of the product with products from other manufacturers is not permitted.

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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10. Handing Over the Orthosis

When handing over the orthosis to the patient, parents or care team by the qualified specialist in orthopaedic technology, they also received the instructions for use for patients as well as the orthosis service passport. The functions and handling of the orthosis were explained in detail by means of these instructions for use. Enter the next maintenance appointment in the orthosis service passport.

Place, Date

Signature Qualified Specialist in Orthopaedic Technology

Heel Height Considered when Selecting the System Joint:

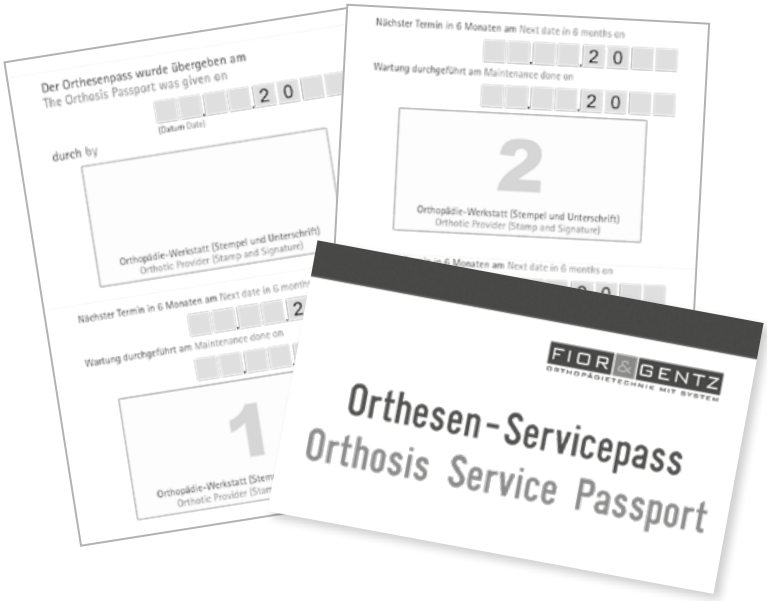
_____ **mm**

The patient was informed about the maximum heel height to be used.

FIOR & GENTZ

ORTHOSIS SERVICE PASSPORT

Have you not yet received an orthosis service passport?
Ask the qualified specialist in orthopaedic technology!



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CE

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