

Instructions for Use for Patients System Ankle Joints

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Instructions for Use for Patients




System Ankle Joints

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ system ankle joint from your orthotist or a qualified/trained expert.

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 orthotist or qualified/trained expert 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 any sports with the orthosis that expose it to excessive strain. If your patient data has changed (e.g. due to weight gain, growth or increased activity), consult your orthotist or a qualified/trained expert 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 Shoe/Wrong Shoe Pitch

Wear a shoe to which your orthosis is adjusted to avoid joint dysfunction.

⚠ WARNING

Risk of Falling Due to Improper Handling

Have your orthotist or a qualified/trained expert inform you about the correct use of the system joint and potential dangers. Avoid contact with moisture and water when using system joints made of metal.

⚠ WARNING

Risk of Falling Due to Changes to the Orthosis

If you notice any changes on the orthosis (e.g. loosely attached joint components, loosened screws, play in the system joint, change in performance or changed spring forces), immediately contact your orthotist or a qualified/trained expert. Do not secure screws for the system joint on your own. All adjustments must be checked by your orthotist or a qualified/trained expert before handing over the orthosis and during the maintenance appointments. You will find the next maintenance appointment in your orthosis service passport.

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 your orthotist or a qualified/trained expert.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance

Have your orthotist or a qualified/trained expert 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.



Any modification of the system joint from your side is not permitted.

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 central, peripheral, spinal or neuromuscular paralyses, structurally conditioned deformities/malfunctions 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. The orthotist or qualified/trained expert 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 the orthotist or qualified/trained expert (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).



Abb. 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 an orthotist or a qualified/trained expert.








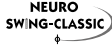







2.5 Application

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.

The carbon system ankle joints are waterproof and therefore suitable for use in wet areas. The spring units of the **NEURO SWING Carbon** system ankle joint are waterproof in depths of up to 3 metres. The carbon system ankle joints can be used at a maximum temperature of +60°C.

2.6 Product Range

The following system ankle joints are part of the FIOR & GENTZ product range:

 NEURO CLASSIC	NEURO CLASSIC	 NEURO VARIO-SPRING	NEURO VARIO-SPRING
 NEURO CLASSIC-SPRING	NEURO CLASSIC-SPRING	 NEURO VARIO-SPRING 2	NEURO VARIO-SPRING 2
 NEURO CLASSIC-SWING	NEURO CLASSIC-SWING	 NEURO VARIO-SWING	NEURO VARIO-SWING
 NEURO VARIO-CLASSIC	NEURO VARIO-CLASSIC	 NEURO SWING-CLASSIC	NEURO SWING-CLASSIC
 NEURO VARIO-CLASSIC 2	NEURO VARIO-CLASSIC 2	 NEURO SWING	NEURO SWING
 NEURO VARIO	NEURO VARIO	 NEURO SWING 2	NEURO SWING 2
 NEURO VARIO 2	NEURO VARIO 2	 NEURO SWING Carbon	NEURO SWING Carbon
 NEURO CLASSIC Carbon	NEURO CLASSIC Carbon		

3. Maintenance

Have your orthotist or a qualified/trained expert check the system joint of your orthosis during regular maintenance. When the orthosis is handed over to you, you receive an orthosis service passport. Bring it to each follow-up and have your orthotist or a qualified/trained expert 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 your orthotist or a qualified/trained expert.

3.1 Dirt Removal

Remove dirt from the system joints 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.

In order to optimise the lifespan of orthoses with waterproof system joints, we recommend rinsing the orthosis with clear tap water, especially after using it in salt water, chlorine water and sand.

4. Storage

We recommend that you do not store the system joint in a damp environment. For the carbon system joints, a damp environment is harmless.

5. Disposal

If you no longer need the orthosis, please return it to your orthotist or a qualified/trained expert. The product must not be disposed of with the residual waste (fig. 2).

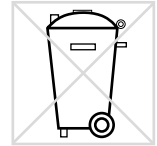


Abb. 2

6. Signs and Symbols



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



medical device



article number



manufacturer



batch code



follow the instructions for use



single patient – multiple uses



Unique Device Identifier – product identification number

7. 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.

8. 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, among others, 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 are valid at the date of printing. Product information serve as guidelines. Subject to technical modifications.

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9. Handing Over the Orthosis

When handing over the orthosis to the patient, parents or care team by the orthotist or qualified/trained expert, 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 Orthotist or Qualified/Trained Expert

ORTHOSES SERVICE PASSPORT

Have you not yet received an orthosis service passport? Ask your orthotist or a qualified/trained expert!

