

# Instructions for Use for Patients Locked System Knee Joints

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Dear Patient,

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

## 1. Safety Instructions

### 1.1 Classification of the Safety Instructions

 <b>DANGER</b>	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
 <b>WARNING</b>	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
 <b>CAUTION</b>	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
<i>NOTICE</i>	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.

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## 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.

## WARNING

### **Risk of Falling Due to Modified Orthosis Adjustments**

If you notice any changes on the orthosis (e.g. loosely attached joint components, loosened screws, play in the system joint, change in performance), immediately contact your orthotist or a qualified/trained expert. Do not secure the screws for the system joint on your own. The 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.

## WARNING

### **Risk of Falling Due to Improper Handling of the Lock Function**

Have your orthotist or a qualified/trained expert inform you about the correct use of the lock function and potential dangers.

- Avoid an unintentional unlocking of the system joint through external influences and a (forceful) unlocking under flexion load.
- Disable the permanent unlock function if you no longer wish to use it.
- Avoid unintentional locking of the system joint by activating the lock lever when the permanent lock function is used.

## NOTICE

### **Limitation of the Joint Function Due to Improper Dirt Removal**

In order to avoid a failure of the lock function, clean 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 knee joints are exclusively for use for orthotic fittings of the lower extremity. The system joint provides motion control and is only allowed to be used for producing a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg. The orthotist or a qualified/trained expert must determine whether the type of orthotic treatment and the patient's individual physical abilities guarantee the safe driving of a motor vehicle.

### 2.2 Indication

The indication for the treatment with an orthosis for the lower extremity is 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 a qualified/trained expert selects the appropriate system joints for the orthosis.

### 2.3 Qualification

The system joint must only be handled by an orthotist or a qualified/trained expert.

### 2.4 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme loads connected to activities like running, climbing and parachuting are excluded. The system joint can be used at a maximum temperature of +60° C.

### 2.5 Product Range

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



NEURO LOCK



NEURO FLEX MAX lock function



NEURO LOCK MAX



NEURO FLEX MAX step lock function

### 3. Using the Orthosis

#### 3.1 Locking the System Joint

You can lock the system knee joint by stretching the knee completely. The permanent unlock function must not be set. Check the correct locking of the system knee joint. If your orthosis has two system joints in the knee area, you have to make sure that both system joints always lock at the same time.

##### Acoustic Check

You must hear a "clack" when the system joint locks.

##### Visual Check

No opening must be seen at the front side of the system joint (fig. 1).

If the system joint cannot be locked actively and reliably, it must be locked passively. To do this, push the knee back with the hand (fig. 2). Alternatively, another person can assist in locking the system joint when you are seated or lying down (fig. 3).

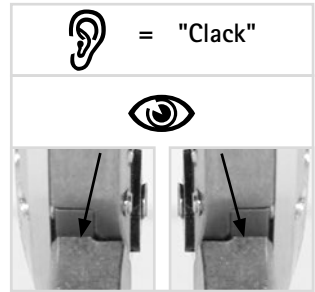


fig. 1

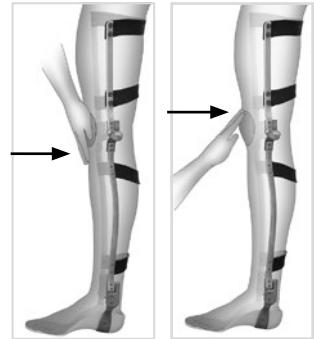


fig. 2

fig. 3



Your first walking and standing attempts with the orthosis should only be carried out under the supervision of an instructed person.

#### 3.2 Unlocking the System Joint

To unlock the system knee joint, press the locking pawl against the joint's upper part by using the lever extension (lock lever) or a pulling cable. For low effort and minimal wear of the system components you have to:

- take the body weight off the orthosis and
- apply a slight extension moment (fig. 2- 4).

Sit on the edge of the chair. The heel should touch the ground (fig. 4).

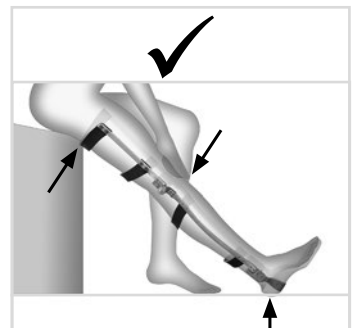


fig. 4

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### 3.3 Adjusting the Permanent Unlock Function

With the permanent unlock function you can disable the system joint's lock function permanently.

- 1 Press the locking pawl against the joint's upper part and hold it in this position.
- 2 Push the locating pin against the spring force until it snaps into the joint's upper part (fig. 5).



fig. 5

### 3.4 Releasing the Permanent Unlock Function

- 1 Stretch your knee.
- 2 Press the locking pawl against the joint's upper part again. By doing so, the locating pin is automatically pushed out.

You can use the system joint with the lock function again.

## 4. Maintenance of the Orthosis

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.

### 4.1 Dirt Removal from the System Joint

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.

## 5. Storage of the System Joint

We recommend that you do not store the system joint in a damp environment.

## 6. Disposal of the Orthosis

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. 6).

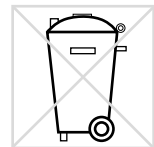


fig. 6

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## 7. Signs and Symbols

### Symbols on the Packaging



medical device

## 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 according to the configuration result from 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 serve as guidelines. Subject to technical modifications.

All rights, particularly the distribution, copy and translation of these instructions for use or any part of them, in paper or as electronic document, must be authorised in writing 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.





## 10. Handing Over the Orthosis

When handing over the orthosis to the patient by the orthotist or qualified/trained expert, they also received the instructions for use for patients. The functions and handling of the orthosis were explained in detail by means of these instructions for use.

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Place, Date

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Signature Orthotist or Qualified/Trained Expert

# ORTHOISIS SERVICE PASSPORT

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

