

# Instructions for Use for Patients Free Moving System Knee Joints

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# Instructions for Use for Patients Free Moving System Knee Joints

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ free moving 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 Loosened Screws**

Do not secure the screws for the system joint yourself, but contact your orthotist or a qualified/trained expert instead. For your own safety, let your orthotist or a qualified/trained expert inform you about maintenance intervals to be respected. You will find the next maintenance appointment in your orthosis service passport.

## 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 in order 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, play in the system joint, change in performance or changed spring forces), immediately contact your orthotist or a qualified/trained expert. 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.

## 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 dysfunction. You will find the next maintenance appointment in your orthosis service passport.



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

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## 2. Use

### 2.1 Intended Use

The FIOR & GENTZ free moving system knee joints are exclusively for use for orthotic treatment of the lower extremity. The system knee joint provides motion control and is only allowed to be used for producing a knee-ankle-foot orthosis (KAFO). Every system joint influences the orthosis' function and thus also the function of the leg. The orthotist or 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 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 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.

### 2.5 Product Range

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

	NEURO CLASSIC zero		NEURO VARIO 2
	NEURO VARIO zero		NEURO VARIO-SWING
	NEURO CLASSIC		NEURO ACTIVE system knee joint
	NEURO VARIO		NEURO ACTIVE articulated system side bar

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### 3. Maintenance of the Orthosis

Ask your orthotist or a qualified/trained expert to check the system joint of your orthosis regularly. When the orthosis is handed over, you receive an orthosis service passport. Bring this orthosis service passport to each follow-up and let 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 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.

### 4. Storage of the System Joint

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

### 5. 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. 1).



fig. 1

### 6. Signs and Symbols

Symbols on the Packaging



medical device

### 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.

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## 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, 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 by 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 copy rights, particularly the distribution, copy and translation of these instructions for use or any part of it, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädiotechnischen Systemen mbH. Reprints, copies and any other electronic reproductions, even partial, are not permitted to be distributed without being authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädiotechnischen Systemen mbH.

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## 9. Übergabe der Orthese

Handing Over the Orthosis/Remise de l'orthèse/Consegna dell'ortesi/Entrega de la ortesis/  
Overhandiging van de orthese/Overlevering av ortosen/装具の引き渡し

Dem Patienten wurde bei der Übergabe der Orthese durch den Orthopädietechniker auch die Gebrauchsanweisung für Patienten ausgehändigt. Die Funktionen und die Handhabung der Orthese wurden mittels dieser Gebrauchsanweisung ausführlich erklärt.

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.

Lorsque l'orthèse a été remise au patient par l'orthopédiste ou par un expert qualifié/formé, le patient a également reçu la notice d'utilisation pour les patients. Les fonction et la manipulation de l'orthèse ont été expliquées en détail au moyen de la présente notice d'utilisation.

Alla consegna dell'ortesi il tecnico ortopedico o un professionista qualificato/abilitato ha consegnato al paziente anche le istruzioni per l'uso per pazienti. Le funzioni e l'utilizzo dell'ortesi sono stati illustrati dettagliatamente tramite le presenti istruzioni per l'uso.

El técnico ortopédico o un experto cualificado/capacitado ha entregado al paciente las Instrucciones de uso para pacientes junto con la ortesis. Las funciones y el manejo de la ortesis se explicaron en detalle en base a estas instrucciones de uso.

Aan de patiënt werd bij de overhandiging van de orthese door de orthopedisch technicus of een gekwalificeerde/opgeleide expert ook de gebruiksaanwijzing voor patiënten overhandigd. De functies en het hanteren van de orthese werden door middel van deze gebruiksaanwijzing uitvoerig toegelicht.

Da pasienten fikk ortosen av ortopediteknikerens eller en kvalifisert/utdannet ekspert, fikk vedkommende også bruksanvisningen for pasienter. Funksjonene til og håndteringen av ortosen er blitt nøye forklart ved hjelp av denne bruksanvisningen.

装具士または有資格/訓練済みの専門職者がこの装具を患者に引き渡す際は、患者向け使用説明書も共に提供されます。この使用説明書を使用して、装具の機能と取り扱い方法が詳しく説明されます。

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Ort, Datum

Place, Date  
Lieu, date  
Luogo, data  
Lugar, fecha  
Plaats, datum  
Sted, dato  
場所と日付

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Unterschrift Orthopädietechniker

Signature Orthotist or Qualified/Trained Expert  
Signature orthopédiste ou expert qualifié/formé  
Firma del tecnico ortopedico o di un professionista qualificato/abilitato  
Firma del técnico ortopédico o experto cualificado/capacitado  
Handtekening orthopedisch technicus of gekwalificeerde/opgeleide expert  
Ortopediteknikerens eller den kvalifiserte/utdannede ekspertens underskrift  
装具士または有資格/訓練済みの専門職者の署名





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## ORTHESEN-SERVICEPASS

**ORTHOSIS SERVICE PASSPORT/PASSEPORT DE SERVICE D'ORTHÈSE/  
PASS DI SERVIZIO ORTESICO/TARJETA DE SERVICIO DE ORTESIS/  
ORTHESE-SERVICEPASPOORT/SERVICEPASS FOR ORTOSE/装具サービスパス**

Sie haben keinen Orthesen-Servicepass erhalten? Fragen Sie Ihren Orthopädietechniker!

Have you not yet received an orthosis service passport? Ask your orthotist or a qualified/trained expert!  
Vous n'avez pas reçu votre passeport de service d'orthèse ? Demandez-le à votre orthopédiste ou à un expert qualifié/formé.

Non ha ricevuto il pass di servizio ortesico? Chieda al Suo tecnico ortopedico o ad un professionista qualificato/abilitato.

¿No ha obtenido ningún carné de mantenimiento de ortesis? Consulte a su técnico ortopédico o a un experto cualificado/capacitado.

Hebt u geen orthese-servicepaspoort ontvangen? Vraag ernaar bij uw orthopedisch technicus of een gekwalificeerde/opgeleide expert!

Fikk du ikke noe servicepass for ortosen? Spør ortopediteknikeren eller en kvalifisert/utdannet ekspert om dette!

装具サービスパスをまだお受け取りになっていない場合は、装具士または有資格/訓練済みの専門職者にお問い合わせください。

