FIOR & GENTZ
ORTHOPÄDIETECHNIK MIT SYSTEM

# 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 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

**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 opened and repaired 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 in particular.

## ⚠ 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 Shoe/Wrong Shoe Pitch**
Wear a shoe to which your orthosis is adjusted to avoid joint dysfunction.

## ⚠ 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 or change in performance), immediately contact a qualified specialist in orthopaedic technology. Do not secure screws for the system joint on your own. The adjustments must be checked by a qualified specialist in orthopaedic technology before handing over the orthosis. You will find the next maintenance appointment in your orthosis service passport.

## ⚠ 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.

## *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 free moving system knee joints are exclusively for use for orthotic treatment of the lower extremity. The system knee joint 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.

## 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.

## 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, 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.

## 2.6 Product Range

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

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

## 3. Maintenance

Ask a qualified specialist in orthopaedic technology to check 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 remind you as parents or care team to 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.

### 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.

## 4. Storage

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

## 5. Disposal

If you no longer need the orthosis, please return it to writing a qualified specialist in orthopaedic technology. The product must not be disposed of with the residual waste (fig. 1).

fig. 1

## 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, 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.

## 9. 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

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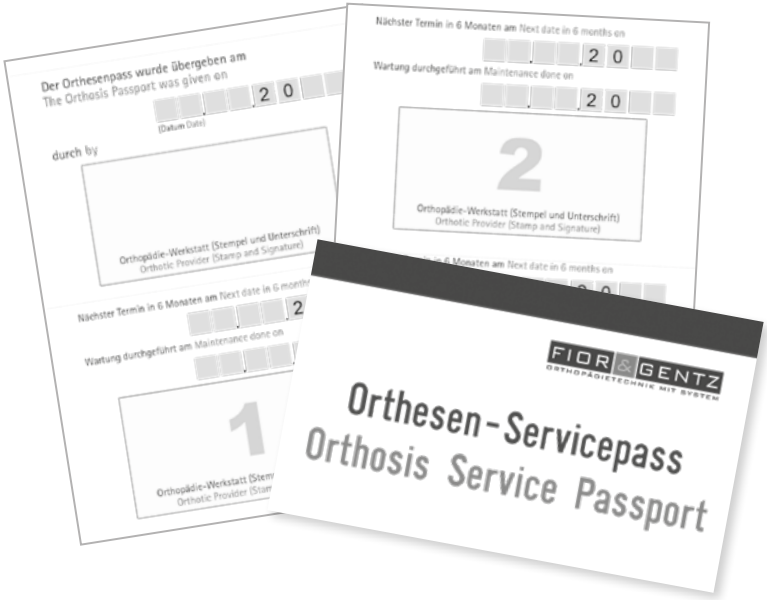
# ORTHOSIS SERVICE PASSPORT

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

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