FIOR & GENTZ

Instructions for Use for Patients
Locked System Knee Joints

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Instructions for Use for Patients
Locked System Knee Joints

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ locked 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

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 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 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.

⚠ WARNING

Risk of Falling Due to Improper Handling of the Lock Function
Have a qualified specialist in orthopaedic technology 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 unlock function is used.

⚠ WARNING

Risk of Falling Due to Improper Dirt Removal
In order to avoid a failure of the lock function, 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.

⚠ 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. 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.

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 locked system knee joints must be used exclusively for the orthotic treatment of the lower extremity. The system 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 when standing and walking that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/malfunctions or as a result of neurological disorders (such as stroke or PAD), 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, parachuting and football, is excluded.

2.6 Product Range

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

NEURO LOCK	NEURO LOCK	NEURO FLEX MAX	NEURO FLEX MAX Lock Function
NEURO LOCK MAX	NEURO LOCK MAX	NEURO FLEX 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).

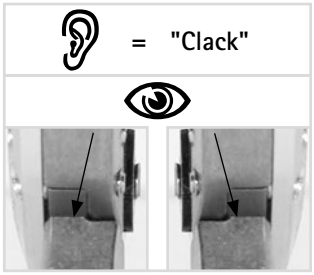

fig. 1

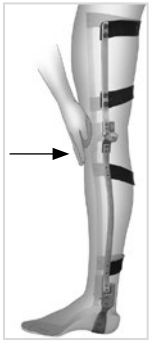

fig. 2

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 must:

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

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

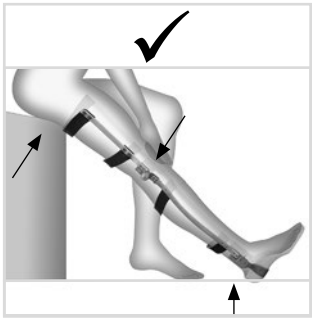

fig. 4

3.3 Adjusting the Permanent Unlock Function

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

1 Press the locking pawl against the joint's upper part and hold it in this position.
2 Push the locating pin into the locking pawl 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

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 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

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. 6).

fig. 6

7. Signs and Symbols

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

medical device

article number

manufacturer

batch code

serial number

follow the instructions for use

single patient – multiple uses

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.

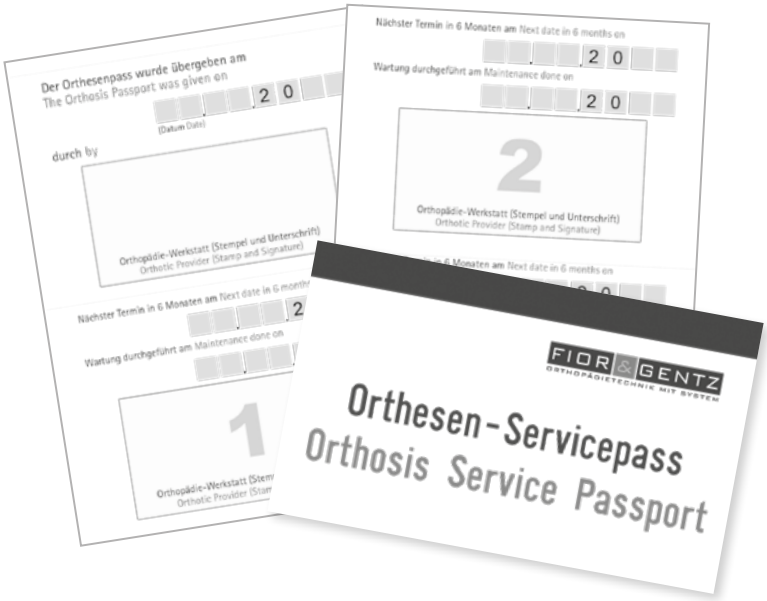
Place, Date

Signature Qualified Specialist in Orthopaedic Technology

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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