

Instructions for Use for Patients System Knee Joint NEURO LOCK Carbon

EN



Content	Page
1. Safety Instructions	3
1.1 Classification of the Safety Instructions	3
1.2 All Instructions for Your Safety	3
2. Use	5
2.1 Intended Use	5
2.2 Indication	5
2.3 Contraindication	5
2.4 Qualification	5
2.5 Application	6
3. Using the Orthosis	6
3.1 Locking the System Joint	6
3.2 Unlocking the System Joint	6
3.3 Adjusting the Permanent Unlock Function	7
3.4 Releasing the Permanent Unlock Function	7
4. Maintenance	7
4.1 Dirt Removal from the System Joint	7
5. Storage	7
6. Disposal	7
7. Signs and Symbols	8
8. CE Conformity	9
9. Legal Information	9
10. Handing Over the Orthosis	10

Instructions for Use for Patients




System Knee Joint NEURO LOCK Carbon

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ system knee 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.
<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.

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 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 dysfunctions.

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. Do not use the orthosis if you notice any damage on the system joint.

WARNING

Risk of Falling Due to Improper Handling

System joint components and orthosis components may only be opened and repaired by orthotists or qualified/trained experts. 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. Do not loosen any screws on the system joint in particular.

WARNING

Risk of Falling Due to Changes in 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), immediately contact your orthotist or a qualified/trained expert. Do not secure screws for the system joint on your own. All settings must be checked by your orthotist or a qualified/trained expert before handing over the orthosis and at every maintenance. 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 (e.g. a fall) 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.

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 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.

2. Use

2.1 Intended Use

The locked FIOR & GENTZ system knee joints are exclusively for use for orthotic fittings 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 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 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. The orthotist or a qualified/trained expert 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 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 **NEURO LOCK Carbon** system knee joint is water-resistant and, therefore, it is suited for use in wet areas. The system joint can be used at a maximum temperature of +60°C.

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 locked 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

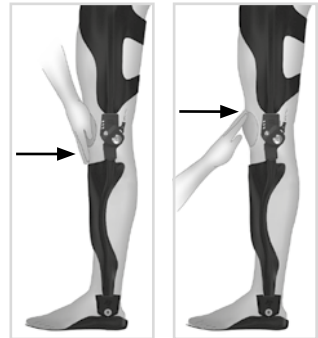


fig. 2

fig. 3

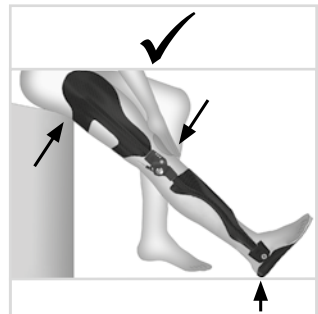


fig. 4



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).

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.
- 2 Hold it in this position.
- 3 Press the fixing pawl against the joint's upper part until it snaps into the joint's upper part (fig. 5).



fig. 5

3.4 Releasing the Permanent Unlock Function

- 1 Press the locking pawl against the joint's upper part again. The unloaded fixing pawl is released from the joint's upper part.

As soon as the system joint is in maximum extension, the locking pawl locks in its normal position. You can use the system joint with the lock function again.

4. 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.

4.1 Dirt Removal from the System Joint

Remove dirt from the system joint 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, we recommend rinsing the orthosis with clear tap water, especially after using it in salt water, chlorine water and sand.

5. Storage

No special storage conditions are prescribed for the NEURO LOCK Carbon system knee joint.

6. 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. 6).

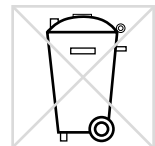


fig. 6

7. Signs and Symbols



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



medical device



article number



manufacturer



batch code



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.

All copy rights, particularly the distribution, copy and translation of these instructions for use or any part of them, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädie-technischen 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 orthopädiotechnischen Systemen mbH.

.....

10. 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

ORTHOISIS SERVICE PASSPORT

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

