FIOR & GENTZ

Instructions for Use for Patients
System Knee Joint NEURO MATIC

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Instructions for Use for Patients
System Knee Joint NEURO MATIC

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ automatic mechanical 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. Avoid contact with moisture and water. 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 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. In particular, do not loosen any screws on the system joint.

⚠ 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 Incorrect Walking with the Orthosis
Consult a qualified specialist in orthopaedic technology about the correct use of your orthosis and the particularities of the system joint. If necessary, we recommend a physiotherapeutic gait re-education.

⚠ 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.

⚠ WARNING

Risk of Injury Due to Improper Handling of the System Joint
When using the system joint, an opening is formed between the joint's upper and lower part, in which clothing or skin could get caught.

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 automatic mechanical system knee joints must be used exclusively for the orthotic treatment of the lower extremity. The system joint provides stance phase 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.

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.

3. Joint Functions

The **NEURO MATIC** is an automatic system knee joint and provides three joint functions:

- basic function in delivery status in Auto mode
- alternative function in Lock mode
- alternative function in Free mode

It only works in combination with a system ankle joint. The wire (mechanical connection to the system ankle joint) controls the automatically locking system knee joint during the different gait phases (fig. 2).

3.1 Basic Function in Auto Mode

In Auto mode, the system knee joint locks and unlocks automatically in specific gait phases.

Stance

When you are standing with the orthosis (fig. 1), the system knee joint is free moving. It is secured through the integrated posterior offset and the remaining function of your knee and hip extension muscles.

fig. 1

Gait

When walking, the system joint locks/unlocks as follows: the system joint is locked in the direction of flexion from loading response to mid stance. In the gait phases from terminal stance to initial contact, the system joint is unlocked and therefore free moving (fig. 2).

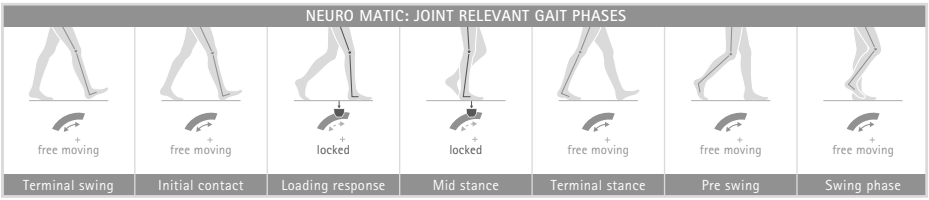

fig. 2

If, contrary to expectations, you put weight on the leg with orthosis during the free moving phases, the system joint will not lock.

3.2 Alternative Function in Lock Mode

In Lock mode, the system knee joint is permanently mechanically locked, i.e. bending the leg is prevented. Stretching remains possible. This mode is beneficial if you do not feel secure in using your orthosis in Auto mode yet.

3.3 Alternative Function in Free Mode

In Free mode, the system knee joint is unlocked, i.e. it is free moving up to a determined position.

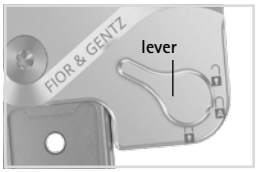

fig. 3

3.4 Lever

On the system joint, there is a lever and three lasered symbols (fig. 3). You can select the available modes Auto ( ), Free ( ) and Lock ( ) with the lever.

Switching the Mode	Explanation	Figure
from Auto mode into Lock mode	You have to extend your knee. The system knee joint must be in contact with the extension stop so that the toothing meshes properly.	4 and 5
from Lock mode into Auto mode	There is nothing special to consider.	w/o fig.
from Auto mode into Free mode	You have to apply an extension moment to unlock the orthosis. The locking pawl must be detached from the toothing and there must be no plantar flexion. You can sit down and manually press the knee backwards.	6
from Free mode into Auto mode	There is nothing special to consider.	w/o fig.
from Lock mode into Free mode	First, set the lever to Auto mode. Then, follow the explanations for changing the mode from Auto mode into Free mode.	w/o fig.

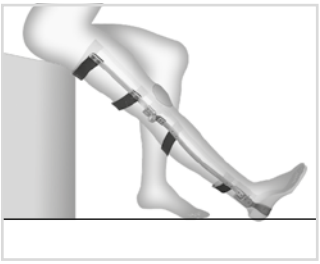
fig. 4

fig. 5

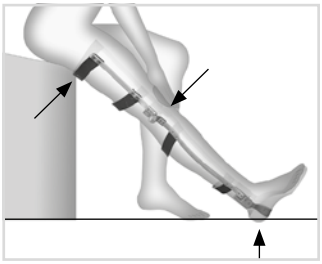
fig. 6

4. Advice on Using Your Orthosis

4.1 The Proper Shoe

A qualified specialist in orthopaedic technology adjusts your orthosis when you try it on and make your first steps. Since you have to get used to your new orthosis, the settings should be regularly checked in the first weeks and, if necessary, newly adapted to your need for safety. The orthosis is adjusted to the pair of shoes (shoe pitch) with which you start walking with your orthosis. If you want to wear other shoes, a qualified specialist in orthopaedic technology must ensure that the orthosis is also adjusted to these shoes.

4.2 Gait Re-Education

In order to be able to use your orthosis optimally, you should make use of a physiotherapeutic gait re-education.

In gait re-education, the following should be specially trained:

- a sufficient step length, as this is decisive for the system knee joint to work properly;
- walking upright, with the upper body slightly bent forward;
- applying as little body weight as possible on orthopaedic devices such as canes, parallel bars or walkers, since otherwise the lock function is not triggered.

With gait re-education, you become more secure in using your orthosis, your gait pattern improves and you get used to your orthosis sooner. This is particularly important when a locked orthosis has been used before for many years. Be extremely careful when managing stairs, going on uneven surfaces or uphill/downhill. If you do not feel secure in using your orthosis in Auto mode yet, we recommend selecting Lock mode (see paragraph 3.2). Regularly report to a qualified specialist in orthopaedic technology your experiences with the orthosis during the first weeks. This is the only way you can get specific advice or help.

The more physiological the gait becomes, the better the orthosis can support you.

5. 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.

5.1 Dirt Removal

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.

6. Storage

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

7. 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. 7).

fig. 7

8. Signs and Symbols

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

MD — medical device

REF — article number

manufacturer

LOT — batch code

SN — serial number

follow the instructions for use

single patient – multiple uses

UDI — Unique Device Identifier – product identification number

9. 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.

10. 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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11. 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.

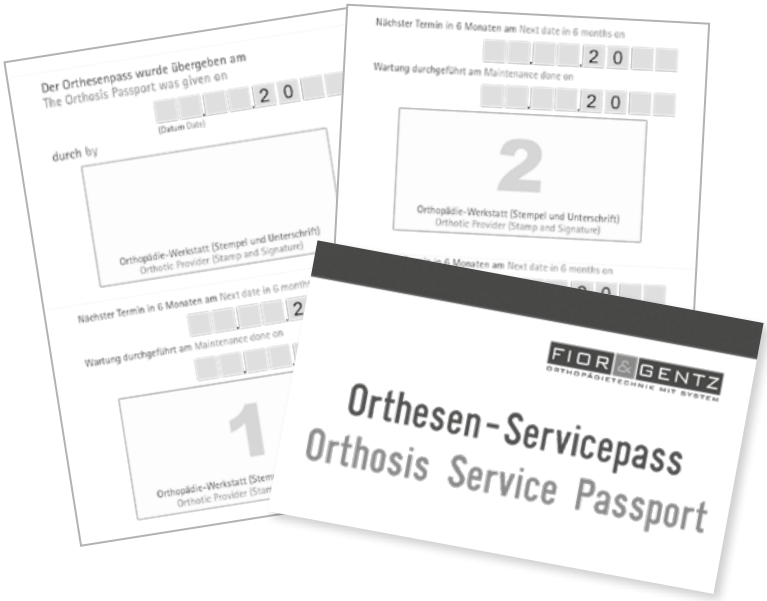
Place, Date

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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FIOR & GENTZ
Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH
Dorette-von-Stern-Straße 5 21337 Lüneburg (Germany)
+49 4131 24445-0 +49 921 95659554
info@fior-gentz.de www.fior-gentz.com