FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology System Knee Joint

EN

NEURO MATIC

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1. Information

These instructions for use are addressed to qualified specialists in orthopaedic technology and do not contain any notes about dangers which are obvious to them. To achieve maximum safety, please instruct the patient and/or care team in the use and maintenance of the product.

2. Safety Instructions

2.1 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.

2.2 All Instructions for a Safe Handling of the System Knee Joint

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Advise the patient to gather information about all safety and security issues before driving a motor vehicle with orthosis. The patient should be able to drive a motor vehicle safely.

⚠ 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. Use suitable sliding washers according to the information in these instructions for use.

⚠ WARNING

Risk of Falling Due to Improper Processing
Process the system joint according to the information in these instructions for use. Deviating processing and modifications of the system joint require the written consent of the manufacturer.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
If patient data has changed (e.g. due to weight gain, growth or increased activity), recalculate the expected load on the system joint, plan the treatment again and, if necessary, produce a new orthosis.

⚠ WARNING

Risk of Falling Due to Incorrectly Selected System Components
Make sure that the system joint and the system components are not overloaded and are functionally adapted to the requirements and needs of the patient in order to avoid joint dysfunction.

⚠ WARNING

Risk of Falling Due to Loosened Screws
Mount the cover plate to the system joint according to the assembly instructions in these instructions for use. Secure the screws with the specified torque and the corresponding adhesive and make sure that no sliding washers are damaged in the process.

⚠ WARNING

Risk of Falling Due to Improper Greasing of the System Joint
Only use the orthosis joint grease from the FIOR & GENTZ product range to grease the system joint. Grease the axle bore of the toothed ring and the sliding surfaces of the bearing nut of the joint axis **with just one drop** of orthosis joint grease.

⚠ WARNING

Risk of Falling Due to Improper Handling
Inform the patient about the correct use of the system joint and possible dangers, especially with regards to moisture and water as well as excessive mechanical stress (e.g. due to sports, increased activity or weight gain). Also inform the patient that the system joint may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the system joint and the orthosis by the patient that goes beyond the tasks described in the instructions for use for patients is not permitted.

⚠ WARNING

Risk of Falling Due to Improper Shoe/Wrong Shoe Pitch
Advise the patient to wear a shoe to which the orthosis is adjusted in order to avoid joint dysfunction in Auto mode.

⚠ WARNING

Risk of Falling Due to Improper Handling of the Orthosis
Make sure that the patient is able to handle their orthosis. Recommend a physiotherapeutic gait re-education, if necessary, and explain to them the system joint's particularities.

⚠ WARNING

Damage to the Anatomical Joint Due to Incorrect Position of the Joint's Mechanical Pivot Point
Determine the joint's mechanical pivot points correctly in order to avoid a permanent incorrect load on the anatomical joint. Please refer to the online tutorials on the FIOR & GENTZ website or contact Technical Support.

⚠ WARNING

Breakage of the System Joint Due to Lack of System Anchor
Use a system anchor when producing the orthosis in order to ensure a secure integration of the system joint into the laminate. The system joint can break if it is integrated without a system anchor.

⚠ 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. Please inform the patient of this risk.

NOTICE

Limitation of the Joint Function Due to Improper Processing
Errors in processing can impair the joint function. Pay particular attention to:
- correctly connecting the system side bar/system anchor with the system case in accordance with the production technique;
- greasing the joint components only **slightly** and
- adhering to the maintenance intervals.

NOTICE

Limitation of the Joint Function Due to Improper Dirt Removal
Inform the patient on how to properly remove dirt from the orthosis and the system joint.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Respect the specified maintenance intervals in order to avoid joint dysfunction. Also inform the patient about the maintenance appointments to be respected. Enter the next maintenance appointment in the orthosis service passport of the patient.

3. Use

3.1 Intended Use

The **NEURO MATIC** system knee joint 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. The system joint may only be used for one fitting and must not be reused.

3.2 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. An evaluation regarding the safe handling of the orthosis by the patient must be carried out.

3.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 3.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis, for example after amputations of leg segments.

3.4 Qualification

The system joint must only be handled by a qualified specialist in orthopaedic technology.

3.5 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.

3.6 Combination Possibilities with Other System Joints

The **NEURO MATIC** system knee joint can be combined with system ankle joints from the FIOR & GENTZ product range (see paragraph 10). The **NEURO VARIO** system knee joint can be used as a supporting joint.

We recommend that you use the Orthosis Configurator when selecting all system components for your orthosis and follow the recommendations of the configuration result.

4. 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

The system knee joint is preassembled at an angle of 5°, corresponding to a physiological knee joint angle. By exchanging the 5° joint's upper part for a 0° or a 10° joint's upper part, the joint angle can be changed by 5° in the direction of flexion or extension.

4.1 Basic Function in Auto Mode

fig. 1

In Auto mode, the **NEURO MATIC** is a system knee joint that locks and unlocks automatically.

Stance

When the patient is standing with the orthosis (fig. 1), the system knee joint is free moving. The stance phase control is achieved by means of the integrated posterior offset and the patient's remaining function of the knee and hip extension muscles.

Gait

When walking, the system joint locks/unlocks as follows: Plantar flexion in loading response (fig. 4) pushes the wire (mechanical connection from the system ankle joint to the **NEURO MATIC** system knee joint) upwards, causing the locking pawl to engage in the toothing of the toothed ring (fig. 2). The system joint is thus locked until mid stance in the direction of flexion (fig. 4). Further extension of the system knee joint is possible.

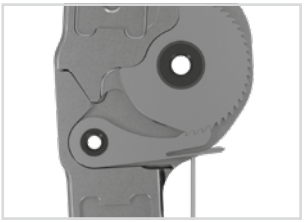
fig. 2

In the gait phases from terminal stance to initial contact, the system joint is unlocked and therefore free moving (fig. 4). When plantar flexion ends, the wire is pulled downwards, which means that the locking pawl no longer engages in the toothing of the toothed ring. However, the system knee joint remains locked due to the flexion-causing load. Only immediately after applying a slight extension moment from mid stance does the locking pawl fall downwards out of the toothing of the toothed ring due to gravity (fig. 3) and the system joint is free in the direction of flexion.

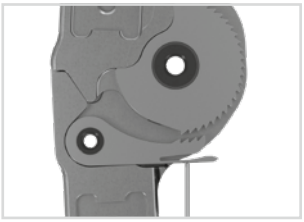
fig. 3

If, contrary to expectations, weight is put on the leg with orthosis in the free moving phases, the system joint does not lock.

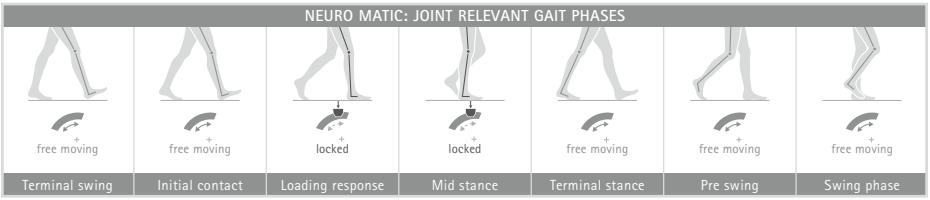

fig. 4

4.2 Alternative Function in Lock Mode

In Lock mode, the **NEURO MATIC** is a locked system knee joint that is permanently mechanically locked in a determined extension position.

4.3 Alternative Function in Free Mode

In Free mode, the **NEURO MATIC** system knee joint is unlocked and free moving up to a defined extension position. When the patient is standing with the orthosis, the stance phase control is achieved by means of the integrated posterior offset (fig. 6) and the patient's remaining function of the knee and hip extension muscles.

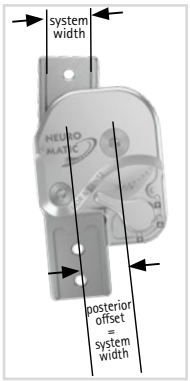

fig. 6

5. Scope of Delivery

Description	Quantity
assembly/lamination dummy (fig. 5)	1
orthosis joint grease, 3g (without figure)	1
NEURO MATIC system knee joint (fig. 6)	1

fig. 5

For producing a KAFO with a **NEURO MATIC** system knee joint, you need the corresponding component set for the orthosis type. The scope of delivery of a set includes the following system components (fig. 7):

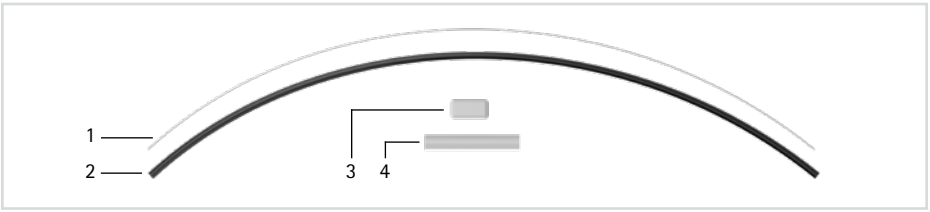

fig. 7

Item	Description	Unit	Quantity	
			Component Set Unilateral	Component Set Bilateral
1	wire, steel, 500mm	piece	2	4
2	cable cover with inner tube, 500mm	piece	1	2
3	lamination dummy for cable cover guidance	piece	1	2
4	cable cover conduit made of plastic	piece	1	2
w/o fig.	cloth bag for orthoses with logo	piece	1	1

You can find more information on special work steps that must be observed when building an orthosis with the **NEURO MATIC** system knee joint, such as the placement of dummies as well as the handling of the cable cover conduit, in the corresponding online tutorial (see QR code, fig. 8) on the FIOR & GENTZ website.

fig. 8

6. Load

The actual load on the system joints is based on the relevant patient data. The load and the appropriate system components can be determined by using the Orthosis Configurator. We recommend that you use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique. You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

7. Tools for Assembling the System Joint

Tools	System Width	
	16mm	20mm
T8 hexalobular screwdriver/bit	x	x
T15 hexalobular screwdriver/bit	x	-
T20 hexalobular screwdriver/bit	x	x
torque screwdriver, 1–6Nm	x	x
combination pliers	x	x
side cutter	x	x

8. Mounting the System Joint

The system joint is delivered fully assembled. All functions are checked beforehand. You have to disassemble the system joint for mounting it to the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure all screws with the torque specified in paragraph 8.4.

You can find more information on the assembly in the online tutorial **Joint Assembly NEURO MATIC** (see QR code, fig. 9) on the FIOR & GENTZ website.

fig. 9

When mounting the system joint, mind the correct basic alignment of the orthosis as it is essential for the later function of the orthosis. You can find more information on this in the online tutorial KAFO **Alignment Guidelines** (see QR code, fig. 10) on the FIOR & GENTZ website.

fig. 10

8.1 Assembling the Locking Parts

Make sure not to damage the sliding washers during the assembly. Jammed sliding washer particles can cause lateral play in the system joint.

1 Before the assembly, clean the threads of the bearing nuts with LOCTITE® 7063 Super Clean. Allow the threads to air-dry for 10 minutes.
2 Apply spray adhesive on one side of the first sliding washer and adhere it to the cover plate (fig. 11).

fig. 11

3 Place the toothed ring on the front side of the joint's upper part so that it is flush with the joint's upper part. The wavy cut-out has to point in direction of the joint's upper part (fig. 12–13).
4 Grease the axle bore of the toothed ring and the sliding surfaces of the bearing nut of the joint axis **with a drop** of orthosis joint grease (fig. 14). Make sure that no grease enters the toothing of the locking pawl and the toothed ring.
5 Put the bearing nut for the locking pawl into the opening of the joint's lower part (fig. 15).
6 Mount the locking pawl (fig. 16).
7 Grease the second sliding washer slightly on both sides with orthosis joint grease.
8 Put the bearing nut of the joint axis into the opening of the joint's lower part. Make sure that the bearing nut is in the correct position (fig. 17). Place the previously greased sliding washer on the joint's lower part (fig. 18).
9 Mount the joint's upper part (fig. 19). Make sure that the joint's upper part is placed without play.

fig. 12

fig. 13

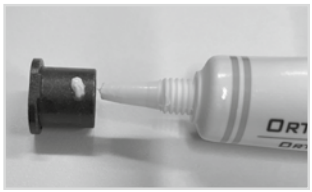
fig. 14

fig. 15

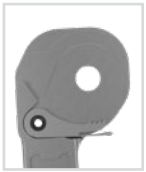
fig. 16

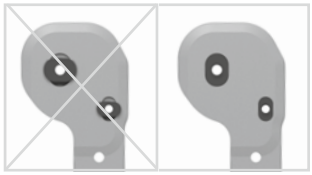
fig. 17

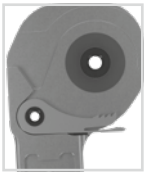
fig. 18

fig. 19

8.2 Mounting the Cover Plate

The lever of the cover plate is already premounted. For the following steps, the lever has to be set on .

1 Place the cover plate on the system joint.
2 Screw in the first countersunk flat head screw (axle screw, S1; fig. 20).
3 Screw in the second countersunk flat head screw (S2; fig. 20).

8.3 Checking the System Joint's Free Movement

Tighten the screws for the cover plate with the appropriate torque (see paragraph 8.4). Check if the system joint moves freely. If the system joint runs with lateral play, mount the next thicker sliding washer. If it does not move freely (it is jammed), mount the next thinner sliding washer.

8.4 Securing the Screws

The screws are secured after the orthosis has been produced and tried on and before it is handed over to the patient.

1 Loosen the screws for the cover plate (fig. 20) after checking the system joint's free movement and remove them from the cover plate.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screws.
3 Secure the screws for the cover plate (fig. 20) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

fig. 20

Screws for Cover Plate	System Width	
	16mm	20mm
countersunk flat head screw with hexalobular socket (axle screw, S1)	4Nm	4Nm
countersunk flat head screw with hexalobular socket (S2)	3Nm	4Nm

The screws for the cover plate are not secured with the necessary torque at delivery. You can also find information on the torque in the openings of the cover plate.

fig. 21

8.5 Mounting the O-Ring Dampers

1 Bend the system joint, turn it upside down and place the O-ring dampers into the bores (fig. 21).
2 Bring the system joint in extension.

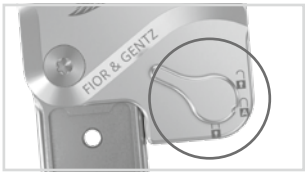

fig. 22

9. Selecting a Mode

On the system joint, there is a lever and the three lasered symbols (fig. 22). You can select the available modes Auto ( ), Free ( ) and Lock ( ) with the lever.

Switching the Mode	Explanation
from Auto mode into Lock mode	The patient must extend the knee. The system joint must be in contact with the extension stop so that the toothing meshes properly.
from Lock mode into Auto mode	There is nothing special to consider.
from Auto mode into Free mode	The patient must apply an extension moment to unlock the orthosis. The locking pawl must be detached from the toothing and there must be no plantar flexion.
from Free mode into Auto mode	There is nothing special to consider.
from Lock mode into Free mode	The patient does not have to pay attention to anything during the intermediate step from Lock to Auto mode. When switching from Auto to Free mode, the corresponding explanation in this table applies.

You can find more information on the individual mode settings in the **NEURO MATIC** function video (see QR code, fig. 23) in the "Products" section on the FIOR & GENTZ website.

fig. 23

10. Connecting the System Ankle Joint

The **NEURO MATIC** system knee joint only works properly when it is connected to a system ankle joint. The mechanical connection to the system ankle joint controls the automatically locking system knee joint during the different gait phases (also see paragraph 11).

10.1 NEURO VARIO-SPRING, NEURO VARIO-SPRING 2 and NEURO CLASSIC-SPRING System Ankle Joint

The **NEURO MATIC** system knee joint is controlled via a wire attached to the system ankle joint, which is guided through a cable cover conduit. This is connected to the **NEURO VARIO-SPRING**, **NEURO VARIO-SPRING 2** or **NEURO CLASSIC-SPRING** system ankle joint using a suitable adaptor screw (fig. 24).

fig. 24

You can find more information on this in the online tutorial **Joint Assembly NEURO MATIC Using a KAFO with NEURO VARIO-SPRING as an Example** (see QR code, fig. 25) on the FIOR & GENTZ website.

fig. 25

10.2 NEURO VARIO-SWING, NEURO CLASSIC-SWING, NEURO SWING and NEURO SWING 2 System Ankle Joint

The **NEURO MATIC** system knee joint is controlled via a wire attached to the system ankle joint, which is guided through a cable cover conduit. This is connected to the NEURO VARIO-SWING, **NEURO CLASSIC-SWING**, **NEURO SWING or NEURO SWING 2** system ankle joint using a suitable adaptor unit (fig. 26).

fig. 26

You can find more information on this in the online tutorial **Joint Assembly NEURO MATIC Using a KAFO with NEURO SWING as an Example** (see QR code, fig. 27) on the FIOR & GENTZ website.

11. Checking the Orthosis' Basic Alignment

Before handing over the orthosis, make sure that the orthosis' alignment is correct. You can find more information on the correct orthosis' alignment in the online tutorial **Checking the Orthosis' Alignment – Dynamically** (see QR code, fig. 28) and **Checking the Orthosis' Alignment – Statically** (see QR code, fig. 29) on the FIOR & GENTZ website, or on our YouTube channel.

fig. 27

On the Workbench

Regardless of the plantar flexion, automatic system knee joints require a systematic adjustment of the dorsiflexion stop for an optimal function of the orthosis. The dorsiflexion stop determines the moment the system knee joint unlocks during mid stance. Furthermore, it leads to an extension moment which is applied to the orthosis and the system knee joint, which is necessary to unlock the system knee joint.

fig. 28

Fix the foot piece of the orthosis firmly in the patient's shoe and put the orthosis on the workbench. The dorsiflexion stop of the system ankle joint must be adjusted in such a way that the line of gravity passes through the middle of the thigh shell and runs vertically downwards in front of the system ankle joint and between the ankle's pivot point and the rolling-off line.

fig. 29

Statically on the Patient

For checking the correct static alignment of the orthosis, the patient must wear the orthosis and stand upright with parallel feet. When viewed from the side, the line of gravity must run from the body's centre of gravity vertically downwards in front of the system ankle joint and between the ankle's pivot point and the rolling-off line. The course of the line of gravity at knee height results from the individual normal posture. Wearing the orthosis leads to deformation of soft tissue. This deformation causes the line of gravity to shift forward. Please consider this by readjusting the dorsiflexion stop, if necessary.

If the dorsiflexion stop is adjusted correctly, a lever is formed between the forefoot and lower leg (activation of the forefoot lever) which brings the patient into a stable balance (they are able to balance themselves) and applies the necessary knee extension moment.

Dynamically on the Patient

For checking the correct dynamic alignment of the orthosis, the patient must wear the orthosis and walk a few steps with it. The dorsiflexion stop must be adjusted in such a way that a heel lift can clearly be seen in terminal stance. The consequence is a lever between forefoot and lower leg which brings the patient into a stable balance and applies the necessary knee extension moment. If the heel does not lift, you must reduce the system ankle joint's range of motion in dorsiflexion.

12. Connecting to the System Side Bar/System Anchor

The system side bar/system anchor must be connected to the system joint by adhering and screwing or screwing and wrapping in accordance with the production technique provided in the planning (fig. 30–32).

fig. 30

fig. 31

fig. 32

You can find more information in the **Instructions for Use for Qualified Specialists in Orthopaedic Technology System Side Bars and System Anchors** (see QR code, fig. 33). You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

fig. 33

13. Conversion Options for the NEURO MATIC System Knee Joint

The **NEURO MATIC** system knee joint can be converted into a **NEURO TRONIC** system knee joint by exchanging a few system components. You can find more information on this in the online tutorial **Joint Conversion NEURO MATIC into NEURO TRONIC** (see QR code, fig. 34) on the FIOR & GENTZ website.

fig. 34

14. Advice on Optimal Orthosis Functionality

Problem	Cause	Measure
In Auto mode, the system joint does not lock in loading response and mid stance.	The wire is too short. As a result, it is not pushed up sufficiently, which means that the locking pawl does not engage in the toothing of the toothed ring.	Mount a longer wire. Follow the instructions in the online tutorial.
	The range of motion in plantar flexion is too small (less than 10°). As a result, the wire is not pushed up sufficiently, which means that the locking pawl does not engage in the toothing of the toothed ring.	Depending on the cause of the insufficient range of motion, carry out the following measure: - Replace the spring unit in the system ankle joint to achieve an increased range of motion. - Produce a functional height compensation for movement limitations. Pay attention to the contralateral leg. - Recommend gait re-education if the step length is very short or the leg cannot/can barely be set back. - Check the basic alignment of the orthosis and, if necessary, the effectiveness of the dorsiflexion stop.
	The cable cover is no longer in the cable cover conduit.	Reinsert the cable cover into the cable cover conduit.
In Auto mode, the system joint locks in a slight flexion position in loading response.	Due to too weak or excessively strong forward swing of the lower leg, the system knee joint is not brought into full extension. The latter leads to bouncing off the stop into a slight flexion position. Ventrally, an instant before heel strike, you can see an obvious opening between the upper and lower part of the system knee joint.	Recommend gait re-education to achieve a harmonious and natural swing phase.
In Auto mode, the system joint does not unlock in terminal stance.	The dorsiflexion stop is not reached in terminal stance. Thus, there is no forefoot lever to apply the necessary extension moment in the knee. Mechanical release of the locking pawl from the toothing is not possible.	Check the basic alignment of the orthosis and adjust the dorsiflexion stop.

Problem	Cause	Measure
In Auto mode, the system joint does not unlock in terminal stance.	In a system ankle joint with dynamic dorsiflexion stop, the anterior spring unit is too soft. The dorsiflexion stop is reached, but there is no forefoot lever to apply the necessary extension moment in the knee. Mechanical release of the locking pawl from the toothing is not possible.	Replace the anterior spring unit with a stronger one.
	The foot piece is too soft and/or too short in the ap and/or ml direction. Thus, there is no forefoot lever to apply the necessary extension moment in the knee. Mechanical release of the locking pawl from the toothing is not possible.	Build a new foot piece. Follow the instructions in the online tutorial.
	The basic alignment of the orthosis is too straight in the knee for this patient. The necessary extension to mechanically release the locking pawl from the toothing is not possible. This can be recognised by a visible gap between the upper and lower parts of the system knee joint when viewed ventrally.	Mount a joint's upper part for flexion increase in the **NEURO MATIC** system knee joint as well as the matching extension stop in the supporting knee joint and check the basic alignment.
	The proximal, posterior thigh shell transmits flexion load when the leg is set back and thus counteracts the extension moment necessary to mechanically release the locking pawl from the toothing.	Shorten the upper edge of the thigh shell parallel to the gluteal fold, so that the gluteal muscles are unobstructed.
In Auto mode, the system joint ratchets during swing phase.	During swing phase, unintentional plantar flexion takes place, pushing the locking pawl into the toothing and causing the teeth to touch.	Depending on the cause of the unintentional plantar flexion, carry out the following measure: - Insert a stronger posterior spring unit in the system ankle joint so that the foot can be adequately held during swing phase. If necessary, convert to a different system ankle joint. - Recommend gait re-education. If active plantar flexion persists, convert to the **NEURO TRONIC** system knee joint.
	The locking pawl does not completely disengage from the toothing due to a wire that is too long.	Shorten the wire.
The system joint cannot be switched into Lock mode.	The locking pawl sits too low, so that the toothing does not mesh properly. The lever cannot therefore be turned to switch into Lock mode.	The system knee joint must be extended to switch into Lock mode.

Problem	Cause	Measure
The system joint cannot be switched into Free mode.	The system knee joint is locked in Auto mode. This prevents the lever from being turned and it pushes the locking pawl further into the toothing instead of releasing it.	The system knee joint must be extended to switch into Free mode. There must be no plantar flexion at this time.

15. Maintenance

Check the system joint regularly for wear and functionality. In particular, check the joint components listed in the following table for the possible problems described and, if necessary, take the appropriate measures. Also check the functionality after every maintenance carried out. It must be possible to move the system joint without problems or unusual noises. Make sure that there is no lateral play.

Joint Component	Potential Problem	Measure	Recommended Inspection, Potential Replacement*	Latest Replacement
toothed ring	wear of the teeth	replacing toothed ring	every 3 months	see table below
locking pawl	wear of the teeth	replacing locking pawl	every 3 months	see table below
O-ring damper	wear	replacing O-ring damper	every 6 months	every 18 months
sliding washer	wear	replacing sliding washer (see paragraph 15.2)	every 6 months	every 18 months
sliding bushing	wear	replacing sliding bushing	every 6 months	every 18 months
countersunk flat head screw with hexalobular socket**	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bearing nut	wear	replacing bearing nut	every 6 months	every 36 months
functional unit***	wear or loss of function	replacing functional unit	every 6 months	every 36 months

* depending on the assessment of the distributor of the custom-made product regarding the patient's usage behaviour
** is part of the functional unit
*** included system components can be exchanged separately

Especially the **toothed ring** and the **locking pawl** are subject to greater stress than other system components, which is why you should replace them on a regular basis, regardless of visible signs of wear (see table below).

Activity Level	Point in Time
1 and 2	every 12 months
3	every 9 months
4	every 6 months

For detailed information on the activity level, refer to the orthotic treatment sheet, the Orthosis Configurator or the online tutorials on the FIOR & GENTZ website.

Clean the threads of the bearing nuts with LOCTITE® 7063 Super Clean at every maintenance. Allow the threads to air-dry for 10 minutes.

Secure the screws for the cover plate with the appropriate torque and LOCTITE® 243 medium strength, during every maintenance (see paragraph 8.4). Remove all adhesive residues first.

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 35) on the FIOR & GENTZ website.

fig. 35

15.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport (fig. 36) from a qualified specialist in orthopaedic technology when the orthosis is handed over. The orthosis must be checked regularly according to the specifications in the maintenance plan in order to maintain its function and to ensure the safety of the patient. The maintenance appointments are noted and confirmed in the orthosis service passport.

fig. 36

15.2 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS1910-040 is 0.40mm thick). Each thickness has a different marking (fig. 37). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

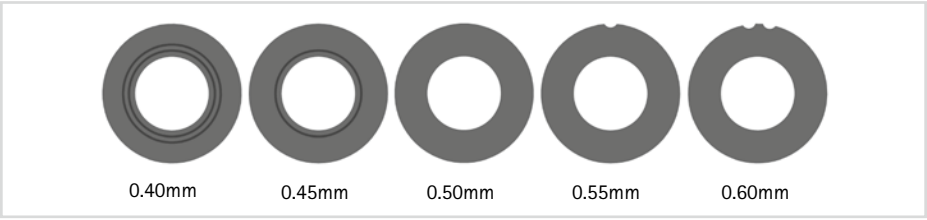

fig. 37

15.3 Dirt Removal

Dirt must be removed from the system joint when necessary and during regular maintenance. For this purpose, disassemble the system joint and clean the soiled system components with a dry cloth.

16. Period of Use

To guarantee a safe use and complete functionality as well as an unlimited period of use of the system joints, you must adhere to the following conditions:

- Adhere to the specified maintenance intervals without interruption and document each maintenance (see paragraph 15).
- Adhere to the determined maintenance conditions (see paragraph 15).
- Check the wear parts, as required, and exchange them in the defined intervals (see paragraph 15).
- Check the adjustment of the system joint during maintenance and correct it, if necessary (see paragraph 15).
- Check the functionality of the system joint during maintenance (see paragraph 15).

- The maximum load determined during the planning of the custom-made product shall not be exceeded by changes in the patient data (e.g. due to weight gain, growth or increased activity). If the determined maximum load on the system joints is exceeded, the system joint must no longer be used. When planning the custom-made product, expected changes in patient data need to be taken into account.
- The period of use of the system joints ends with the period of use of the custom-made product (orthosis).
- The multiple use of the system joint in another custom-made product is not allowed (see paragraph 22).

17. Storage

It is recommended to store the system joint in its original packaging until the custom-made product is produced.

18. Spare Parts

18.1 Exploded View Drawing **NEURO MATIC**

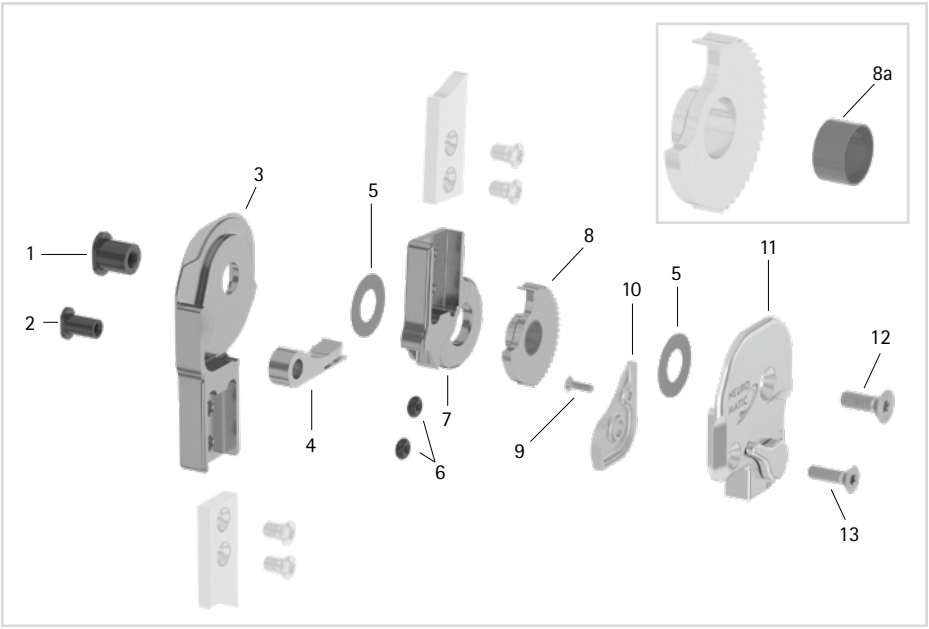

fig. 38

18.2 Spare Parts for the **NEURO MATIC** System Knee Joint

Item	Article Number for System Width		Description
	16mm	20mm	
1	SB9669-L0990	SB1069-L1000	bearing nut (joint axis)
2	SB6049-L0990	SB8559-L1000	bearing nut (locking pawl)
3	SK0313-L/TI	SK0315-L/TI	lower part, left lateral or right medial, straight, titanium
3	SK0313-R/TI	SK0315-R/TI	lower part, left medial or right lateral, straight, titanium
3	SK0333-L/TI	SK0335-L/TI	lower part, left lateral or right medial, bent inwards, titanium
3	SK0333-R/TI	SK0335-R/TI	lower part, left medial or right lateral, bent inwards, titanium
3	SK0333-8L/TI	SK0335-8L/TI	lower part, left lateral or right medial, bent outwards, titanium
3	SK0333-8R/TI	SK0335-8R/TI	lower part, left medial or right lateral, bent outwards, titanium
4	SK0373	SK0375-2	locking pawl
5	GS1910-*	GS2411-*	sliding washer*
6	VE3771-D/012/26	VE3771-D/012/26	O-ring damper set
7	SK0303-2L/TI	SK0305-2L/TI	5° upper part, left lateral or right medial, straight, titanium
7	SK0303-2R/TI	SK0305-2R/TI	5° upper part, left medial or right lateral, straight, titanium
8	SK0363-2L	SK0365-2L	toothed ring with sliding bushing, left lateral or right medial, titanium
8	SK0363-2R	SK0365-2R	toothed ring with sliding bushing, left medial or right lateral, titanium
8a	BP1110-L059	BP1211-L059	sliding bushing
9	SC1403-L08/1	SC1403-L08/1	countersunk flat head screw with hexalobular socket
10	SK0353-4L/AL	SK0355-4L/AL	small cover plate, left lateral or right medial, aluminium
10	SK0353-4R/AL	SK0355-4R/AL	small cover plate, left medial or right lateral, aluminium
11	SK3393-L	SK3395-L	cover plate with lever, left lateral or right medial
11	SK3393-R	SK3395-R	cover plate with lever, left medial or right lateral
12	SC1405-L14	SC1406-L14	countersunk flat head screw with hexalobular socket (axle screw)
13	SC1404-L14	SC1405-L14	countersunk flat head screw with hexalobular socket
9-13	SK3383-L	SK3385-L	functional unit, left lateral or right medial
9-13	SK3383-R	SK3385-R	functional unit, left medial or right lateral

18.3 Sliding Washers

* Sliding Washers	
Article Number for System Width	
16mm	20mm
Ø = 19mm	Ø = 24mm
GS1910-040	GS2411-040
GS1910-045	GS2411-045
GS1910-050	GS2411-050
GS1910-055	GS2411-055
GS1910-060	GS2411-060

19. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 39). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 39

For proper disposal, it is necessary to demount the system joint from the orthosis.

20. 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

21. 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.

22. 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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23. Information for the Treatment Documentation

Add these instructions for use to your treatment documentation!

Patient Data

Name	
Address	
Postcode, City	
Home Telephone	
Telephone at Work	
Insurance	
Insurance No.	
Attending Physician	
Diagnosis	

24. Handing Over the Orthosis

The qualified specialist in orthopaedic technology has also handed over the instructions for use for patients as well as the orthosis service passport to you as a patient, parent or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to you in detail. You will find the next maintenance appointment in the orthosis service passport. Bring the orthosis service passport with you to every maintenance appointment.

Place, Date

Signature Patient

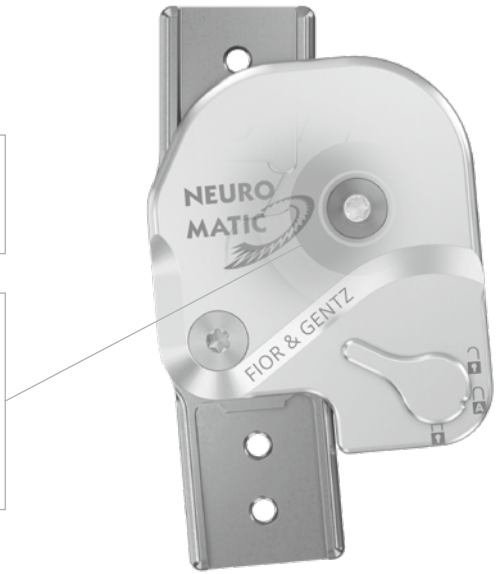
Leg Side

☐ left ☐ right

Mounted Sliding Washers

1. GS _____ - _____

2. GS _____ - _____



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