

# Instructions for Use for Orthotists or Qualified/ Trained Experts System Knee Joints

EN



NEURO TRONIC

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## 1. Information

These instructions for use are addressed to orthotists or qualified/trained experts 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

 <b>DANGER</b>	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
 <b>WARNING</b>	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
 <b>CAUTION</b>	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.

### 2.2 All Instructions for a Safe Handling of the NEURO TRONIC 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 not lock the system joint unintentionally and should generally be able to drive a motor vehicle safely.

#### **WARNING**

##### **Risk of Falling Due to Improper Handling**

Inform the patient about the correct use of the system joint and the integrated electronics especially with regards to:

- moisture and water as well as
- excessive mechanical stress (e.g. due to sports, increased activity or weight gain).

#### **WARNING**

##### **Risk of Falling Due to Loosely Attached Cover Plate**

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.

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## 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 load capacity of the system joint. For this purpose, use the Orthosis Configurator or contact Technical Support.

## 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 Failure of Electronics**

Carry out a cable connection test before handing over the orthosis to the patient. The cables must **not** be extended, bent or processed with unsuitable tools. In case of persistent failure, contact Technical Support.

## WARNING

### **Risk of Falling Due to Improper Maintenance**

Follow the instructions in these instructions for use and gather information about joint-specific particularities before maintenance of the system joint. To do so, attend one of our production technique workshops, refer to the online tutorials on our website or contact Technical Support.

## WARNING

### **Risk of Falling Due to Improper Handling of the Orthosis**

Make sure that the patient is able to handle their orthosis. The first step with orthosis in **Auto mode** should be made with the leg with orthosis. Recommend them a physiotherapeutic gait re-education, if necessary, and explain them the system joint's particularities.

## WARNING

### **Risk of Injury Due to Improper Handling of the Batteries**

Use the batteries as described in these instructions for use. When handling the batteries, avoid:

- strong heat,
- knocks and shocks as well as
- contact with high humidity and water.

## 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 our website or contact Technical Support.

## 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.

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## NOTICE

### Limitation of the Joint Function Due to Improper Processing

Errors in processing can impair the joint function. Pay particular attention to:

- correctly connect the system side bar/system anchor with the system case in accordance with the production technique;
- grease the joint components only slightly and
- adhere to the maintenance intervals.

## NOTICE

### Damages to Batteries Due to Improper Handling

Use the batteries as described in these instructions for use. Pay particular attention to:

- using the batteries with the delivered charger;
- only using the batteries at temperatures of  $-20^{\circ}\text{C}$  to  $+45^{\circ}\text{C}$ ;
- only using undamaged batteries (without leakage of substances/liquids) and
- properly disposing of the batteries.

## 3. Application

The NEURO TRONIC knee joint system with component set, including the system knee joint and the controller, is exclusively for use for orthotic fittings of the lower extremity. It must be handled by an orthotist or qualified/trained expert. All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme loads connected to activities like running, climbing and parachuting are excluded.

## 4. Joint Functions

The NEURO TRONIC system knee joint is an automatic joint and provides four joint functions:

- basic function at delivery status in Auto mode
- alternative function in Lock mode
- alternative function in Free mode
- alternative function in permanent unlocking

The system knee joint is preassembled in a physiological joint angle of 5°. It can be brought into a knee flexion position of 0° or 10° by exchanging system components. To do so, exchange the 5° upper part for a 0° or 10° upper part.

### 4.1 Basic Function in Auto Mode

The controller of the orthosis has motion sensors which detect the movement and position of the lower leg. Thus, the controller can lock/unlock the system joint in the corresponding gait phases.

#### Locking

When the patient is standing with the orthosis (fig. 1) or when they do not finish their step in stance phase, the NEURO TRONIC system knee joint locks, as no movement is registered. When walking, the system joint is locked from terminal swing to mid stance in direction of flexion (fig. 2). The solenoid shuts off and the pressure spring pushes the plunger upwards, which causes the locking pawl to mesh into the tothing of the toothed ring (fig. 3).

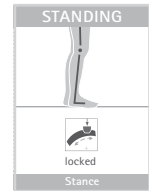


fig. 1

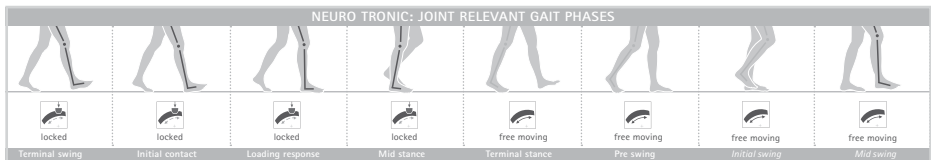


fig. 2



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

#### Unlocking

The motion sensors register when the patient is walking with the orthosis. In the gait phases from terminal stance to swing phase, the system knee joint is unlocked and is therefore free moving (fig. 2). The solenoid turns on and generates an electromagnetic field, which causes the plunger to retract magnetically against the spring force, while gravity causes the locking pawl to fall downwards out of the tothing of the toothed ring (fig. 4).

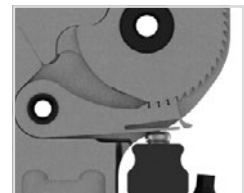


fig. 3

The locking/unlocking moment can be fine adjusted with the multi-purpose device or the Expert app.

#### 4.2 Alternative Function in Lock Mode

In Lock mode, the **NEURO TRONIC** system knee joint is a locked joint to provide motion control. It is permanently mechanically locked in a determined extension position.

#### 4.3 Alternative Function in Free Mode

In Free mode, the **NEURO TRONIC** system knee joint is an unlocked joint to provide motion control. It is free moving up to a determined extension position. When the patient is standing with the orthosis, the stance phase control is not achieved mechanically but by means of the integrated posterior offset (fig. 5) and the patient's remaining function of the knee and hip extension muscles.

#### 4.4 Alternative Function in Permanent Unlocking

The **NEURO TRONIC** system knee joint can be permanently unlocked mechanically with a lever, for example for activities such as driving a car or bicycle. In this mode it is guaranteed that the system knee joint does not lock unintentionally. To do so, unlock the system joint manually by setting the lever to F.

In order to save energy, you can then press the Lock button with the remote control/User app. The system knee joint also remains unlocked if you select another mode (e.g. Auto) with the remote control/app since the lever blocks the locking pawl, which therefore, cannot mesh into the tootthing (fig. 6). In order to change the system joint's mode as usual with the remote control/app, the lever must be set to the dot (fig. 5).

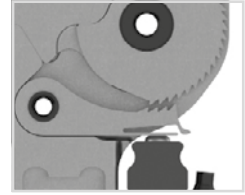


fig. 4



fig. 5

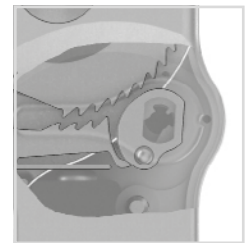


fig. 6



## 5. NEURO TRONIC Knee Joint System

The knee joint system is also available with Bluetooth® technology\* and consists of the following articles (fig. 7):

- 1 system knee joint
- 2 component set including controller
- 3 remote control for the patient including microprocessor-controlled quick charger or USB charging cable and User app
- 4 multi-purpose device for the orthotist or qualified/trained expert and Expert app

The system knee joint and the controller are mounted to the patient's orthosis. In order to put the orthosis into operation and adjust it, you need the multi-purpose device or the Expert app. The app has to be unlocked with a multi-purpose device with Bluetooth once. The patient needs the remote control to use the orthosis. As a complement, the User app can be used.

**i** In order to operate or adjust the orthosis via an app, the orthosis has to be equipped with a controller with Bluetooth.

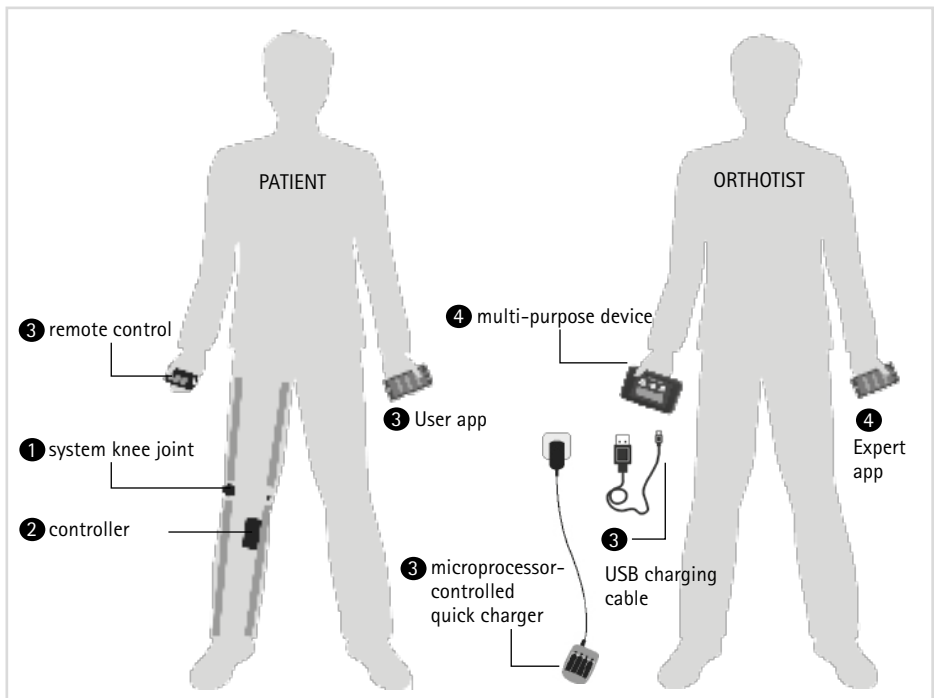


fig. 7

\* The Bluetooth® word mark and logos are registered trademarks of Bluetooth SIG, Inc. and any use of such marks by FIOR & GENTZ is under license.

For producing a KAFO with a **NEURO TRONIC** system knee joint, you need the corresponding component set for the orthosis type. You also need to select the appropriate controller (see table). A set includes in the scope of delivery the following system components (fig. 8):

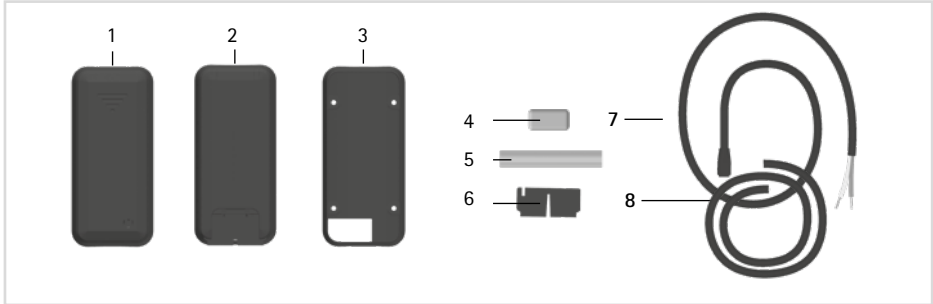


fig. 8

Item	Description	Unit	Quantity for Construction	
			Unilateral	Bilateral
1	controller without Bluetooth with exchangeable batteries*	pce.	1	1
1	controller with Bluetooth with exchangeable batteries*	pce.	1	1
2	controller with Bluetooth with lithium-polymer battery*	pce.	1	1
3	retainer for controller**	pce.	1	1
w/o fig.	countersunk flat head screw, cross recessed H***	pce.	4	4
4	lamination dummy for cable cover guidance	pce.	1	2
5	cable cover conduit made of plastic	pce.	1	2
6	cable connecting aid****	pce.	1	1
7	connection cable for solenoid, tinned ends, 360mm	pce.	1	2
8	lamination dummy for solenoid connection cable	pce.	1	2
w/o fig.	cloth bag for orthoses with logo	pce.	1	1

\*Only one controller is included in each component set. You have received the controller based on your selected component set.

\*\* is part of the controller

\*\*\* are required for mounting the controller retainer and are supplied with the controller

\*\*\*\* is part of the controller with integrated lithium-polymer battery

## 6. Scope of Delivery of the System Knee Joint

Description	Quantity
NEURO TRONIC system knee joint (without figure)	1
AGOMET® F330, 5g (fig. 9)	1
assembly/lamination dummy (fig. 10)	1



fig. 9



fig. 10

## 7. Load Capacity

The load capacity results from the relevant patient data and can be determined by using the Orthosis Configurator. 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 our website [www.fior-gentz.com](http://www.fior-gentz.com).

## 8. 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
stripping tool	x	x
combination pliers	x	x

## 9. Assembly Instructions

The system joint is delivered fully assembled. All functions are checked beforehand. You have to disassemble the system joint for mounting it in the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure all screws with the torque specified in paragraph 9.6.



When mounting the system joint, mind the correct basic alignment as it is essential for the later function of the orthosis. Note the information on this in the **Instructions for Use for Orthotists or Qualified/Trained Experts Multi-Purpose Device**.

## 9.1 Mounting the Locking Parts



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

- 1 Grease the axle bore of the locking pawl and of the toothed ring as well as the friction surfaces of the bearing nuts **slightly** with orthosis joint grease. Make sure that no grease enters the tothing of the locking pawl and the toothed ring.
- 2 Put the bearing nut for the locking pawl into the opening of the joint's lower part (fig. 11).
- 3 Mount the locking pawl (fig. 12).
- 4 Put the bearing nut for the joint axis into the opening of the joint's lower part (fig. 13).
- 5 Grease the first sliding washer **slightly** on both sides with orthosis joint grease and place it onto the joint's lower part (fig. 14).
- 6 Put 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. 15–16).
- 7 Mount the joint's upper part (fig. 17). Make sure that the joint's upper part is placed without play.
- 8 Apply spray adhesive on one side of the second sliding washer and adhere it to the cover plate (fig. 18).
- 9 Grease the other side **slightly** with orthosis joint grease.



fig. 11



fig. 12

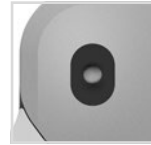


fig. 13

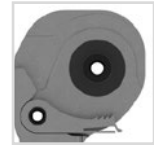


fig. 14



fig. 15



fig. 16



fig. 17

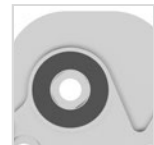


fig. 18

## 9.2 Mounting the Solenoid

- 1 Place the pressure spring (2; fig. 19) onto the plunger (1).
- 2 Place the washer (4) onto the solenoid (5).
- 3 Slide the plunger through the solenoid fixation (3) into the solenoid.
- 4 Screw the solenoid into the solenoid fixation as far as possible.
- 5 Secure the solenoid by pressing it into the cover plate (fig. 20).

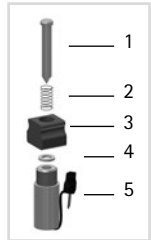


fig. 19



fig. 20

## 9.3 Mounting the Cover Plate

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

- 1 Clean the threads of the cover plate with LOCTITE® 7063 Super Clean, if necessary.
- 2 Place the cover plate onto the system joint.
- 3 Screw in the first countersunk flat head screw (axle screw, S1; fig. 21).
- 4 Screw in the second countersunk flat head screw (S2; fig. 22).



fig. 21



fig. 22

## 9.4 Checking the System Joint's Free Movement

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.

## 9.5 Mounting the Extension Stop Damper and the Small Cover Plate

- 1 Turn the system joint upside down and place the extension stop damper into the bore (fig. 23).
- 2 Bring the system joint in extension.
- 3 Lay the cable for the solenoid (fig. 24).
- 4 Mount the small cover plate to the back of the system joint (fig. 25).

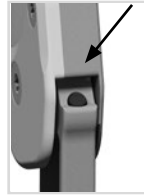


fig. 23



fig. 24



fig. 25

## 9.6 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 Secure the screws for the cover plate (fig. 22) with the torque corresponding to the system width and LOCTITE® 243 medium strength.
- 2 Let the adhesive harden (final strength after approx. 24 hours).

Screws for Cover Plate	System Width	
	16mm	20mm
S1 (screw 1, axle screw)	4Nm	4Nm
S2 (screw 2)	3Nm	4Nm



The screws of 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.

## 10. Controller

The controller is delivered with the component set and has to be mounted to the orthosis. It receives adjustments from the multi-purpose device/Expert app and commands from the remote control/User app, registers the patient's movements and controls the NEURO TRONIC system knee joint.

The controller can be used for a unilateral as well as a bilateral treatment. It automatically recognises whether one or two system knee joints are connected to the controller.

Controller with Exchangeable Batteries	Item	Description
	1	battery compartment cover
	2	acoustic signal generator
	3	LED battery indicator
	4	LED function indicator
	5	LED mode indicator
	6	MODE button
	7	positive pole
	8	negative pole
	9	cable joints
	10	battery compartment for 2 AA batteries

Controller with Integrated Lithium-Polymer Battery	Item	Description
	1	cover for Micro-USB port
	2	LED battery level indicator and LED mode indicator
	3	LED pairing indicator Bluetooth
	4	Micro-USB port
	5	MODE button

**i** For more information on mounting the controller to the orthosis, refer to our online tutorials on our website [www.fior-gentz.com](http://www.fior-gentz.com).

### 10.1 Cable Connection of the Controller

Before you mount the controller to the orthosis, you have to connect it with the solenoid of the system knee joint by using the cable joints.

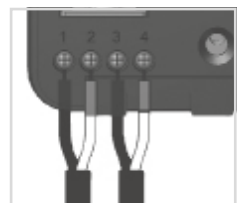


fig. 26

On a controller with exchangeable batteries are four cable joints, which are marked with numbers from 1 to 4 (fig. 26). On a controller with integrated lithium-polymer battery, the numbers can be found on the cable connecting aid (fig. 27). Connect the cables as follows:

Cable Joint	Cable
3 and 4	solenoid connection cable
1 and 2	pressure sensor connection cable (if existing)

In order to connect the cables to the controller, proceed as follows. If you use the connection cable with tinned ends (360mm long) included in the component set, start at step 4. If you use the longer replacement cable (550mm long), start at step 1.

- 1 Strip the cables of the solenoid about 50mm (fig. 28–29).
- 2 Strip the exposed wires about 5mm (fig. 30).
- 3 Twist and tin the exposed conductors.
- 4 Insert the wires into the corresponding cable joints. For a bilateral treatment, connect the second solenoid to the same cable joints.



fig. 27



fig. 28



fig. 29



fig. 30



When making the cable connection, the polarity of the connection cables is irrelevant.

- 5 On a controller with exchangeable batteries, secure the wires by tightening the respective screws. On a controller with integrated lithium-polymer battery, use the cable connecting aid to open the cable conduits for the flexible wires to be inserted. The wires are automatically clamped by removing the cable connecting aid.
- 6 Carry out the cable connection test (see *Instructions for Use for Orthotists or Qualified/Trained Experts Multi-Purpose Device*).

## 11. Putting Into Operation Controller and Remote Control

With the multi-purpose device, you put the controller and the remote control without Bluetooth into operation and establish a connection between the remote control and the controller (see *Instructions for Use for Orthotists or Qualified/Trained Experts Multi-Purpose Device*).

A remote control with Bluetooth can be directly connected to a controller with Bluetooth:

- 1 Press the MODE button at the controller. First, a short beep is emitted. Keep the button pressed until a second, longer beep is emitted after about 6–10 seconds.
- 2 Press the Auto and Lock button of the remote control at the same time for about four seconds. The LED blinks yellow.

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If the connection to the controller has been successfully established, the LED at the remote control blinks green. If establishing the connection has failed, it blinks red.

A remote control with Bluetooth can also be connected to two controllers with Bluetooth:

- 1 Press the MODE button at both controllers. First, a short beep is emitted. Keep the buttons pressed until a second, longer beep is emitted after about 6–10 seconds.
- 2 Press the Auto and Lock button of the remote control at the same time for about four seconds. The LEDs light up.

If the connection to both controllers has been successfully established, the LED at the remote control blinks green twice. If the LED at the remote control blinks green only once, the remote control is only connected to one controller. In this case, repeat steps 1–2. If establishing the connection has failed, the LED blinks red.



The orthosis can only be controlled by the one remote control or app to which it is currently connected. Other remote controls/apps have no influence on the orthosis.

By acquiring our Bluetooth products, you have the possibility to use the apps. If there is an active connection to an app, the blue LED on the controller blinks permanently and the controller cannot be operated with the remote control.

You need a multi-purpose device with Bluetooth to adjust a controller with Bluetooth and to unlock the Expert app once (see *Instructions for Use for Orthotists or Qualified/Trained Experts Multi-Purpose Device*). You can switch from a controller without Bluetooth to one with Bluetooth at any time, as it also fits into the retainer for the controller of the controller without Bluetooth.

## 12. Converting Options of the NEURO TRONIC System Knee Joint

The NEURO TRONIC system knee joint can be converted into a NEURO MATIC system knee joint by exchanging certain system components. To do so, please contact our Technical Support.

## 13. Maintenance

Check the system joint for wear and functionality every 3 months. Also check the functionality after every maintenance carried out.

Joint Component	Problem	Measure
toothed ring and locking pawl	wear of the teeth	replacing toothed ring and locking pawl
extension stop damper	wear	replacing extension stop damper
sliding bushing	wear	replacing sliding bushing
sliding washer	wear	replacing sliding washer, see paragraph 13.2
bearing nut	wear	replacing bearing nut

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:



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



For detailed information on the activity level, refer to the orthotic treatment sheet, our Orthosis Configurator at [www.orthosis-configurator.com](http://www.orthosis-configurator.com) or our online tutorials at [www.fior-gentz.com](http://www.fior-gentz.com).

Secure the screws for the cover plate with the torque corresponding to the system width and LOCTITE® 243 medium strength at every maintenance (see paragraph 9.6). Remove all adhesive residues first.

### 13.1 Checking the Battery Health

If the orthosis is equipped with a controller with integrated lithium-polymer battery, check the battery health regularly (see Instructions for Use for Orthotists or Qualified/Trained Experts Multi-Purpose Device). To do so, connect the controller with the multi-purpose device/Expert app. If the battery health is no longer good, replace the controller on the orthosis.

### 13.2 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. 31). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

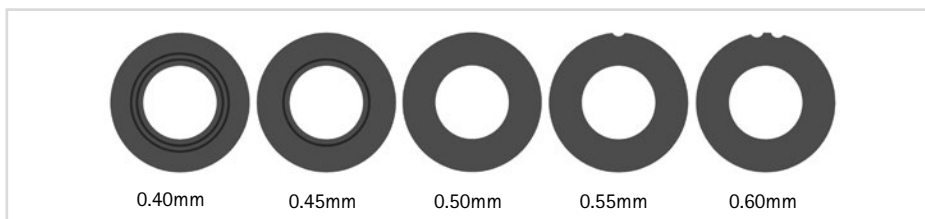


fig. 31

### 13.3 Exchanging Components of the Cover Plate

If one component of the cover plate wears out, it has to be exchanged for a new one.

To assemble the cover plate again, proceed as follows (fig. 32):

- 1 Place the sliding washer (1) onto the lever (2).
- 2 Slide the lever into the hole in the cover plate (3).
- 3 Slide the ball (4) and the pressure spring (5) into the lever.
- 4 Press the switching pawl (6) onto the lever from behind.
- 5 Secure the sub-assembly with the retaining washer for shafts (7) on the cover plate.

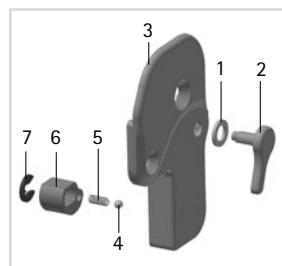


fig. 32

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## 13.4 Cleaning

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

## 14. Advice on Optimal Orthosis Functionality

### 14.1 Bluetooth Connection

In a knee joint system with Bluetooth, the quality of connection depends on how interference-free your environment is.

### 14.2 Walking with the Orthosis in Auto Mode

For safety reasons, the system knee joint remains locked during the first step. When the patient starts to walk from a standing position, they should make the first step with the leg with orthosis. The electronics require a stride to switch from standing mode to walking mode in order to avoid disturbed gait or stumbling when starting to walk.

### 14.3 System Knee Joint

Problem	Cause	Action
The system joint locks unintentionally in a slightly flexed position.	The extension stop damper is too long. Ventrally, an instant before heel strike, you can see an obvious opening between upper and lower part of the system knee joint.	Cut the extension stop damper.
	The patient's leg is extended by a high momentum. If the leg comes into full extension before the heel touches the floor, the lower leg bounces off the extension stop into a slightly flexed position. Ventrally, an instant before heel strike, you can see an obvious opening between upper and lower part of the system knee joint.	Gait re-education! Teach the patient a harmonious and natural swing phase. In terminal swing, the heel should be about to touch the ground. Alternatively, the locking of the system joint can be set earlier via the fine adjustment using the multi-purpose device/the app, so that the system joint locks when full extension is reached.

Problem	Cause	Action
The system joint does not unlock.	The proximal, dorsal thigh band transfers flexion load when a leg is set back.	Remove material from the upper thigh band area.
	The extension stop damper is too long. Thus, the extension stop damper is compressed to such an extent that the necessary extension moment to unlock the system joint is more than the patient can apply.	Cut the extension stop damper.
	The patient does not reach the dorsiflexion stop due to short steps during heel lift. Thus, the knee extension moment to unlock the system joint cannot be applied.	KAFO with system ankle joint: Adjust the dorsiflexion stop on the system ankle joint in such a way that the forefoot lever causes a knee extension moment.
		KAFO without system ankle joint: The necessary forefoot lever can be applied through the foot piece and/or shoe modifications or adjustments. Produce the foot piece stiffly enough and shift the rolling-off line further forward, if necessary.
	The forefoot lever of the foot piece does not achieve its effect on the knee extension.	Check the orthosis' basic alignment. If the system ankle joint has a dynamic dorsiflexion stop, you might need to insert a stronger spring unit.
The system joint unlocks too late.	The patient does not reach the dorsiflexion stop due to short steps during heel lift. Thus, the knee extension moment to unlock the system joint cannot be applied.	KAFO with system ankle joint: Adjust the dorsiflexion stop on the system ankle joint in such a way that the forefoot lever causes a knee extension moment.
		KAFO without system ankle joint: The necessary forefoot lever can be applied through the foot piece and/or shoe modifications or adjustments. Produce the anterior part of the foot piece stiffly enough and shift the rolling-off line further forward, if necessary.

Problem	Cause	Action
The system joint switches unintentionally into Lock mode.	Only applies to a controller with exchangeable batteries: The battery/batteries is/are empty.	Insert a new battery set and/or charge empty batteries.
	Only applies to a controller with exchangeable batteries: The battery/batteries is/are defect.	Insert a new battery set and properly dispose of defect batteries.
	There is a short circuit in a cable.	Carry out the cable connection test and change cables if necessary.
	The orthosis undergoes strong shocks when it is set to Free or Auto mode.	Due to shocks, the magnetic field is interrupted and the orthosis locks automatically. Switch to other mode and then back to the desired.
The system joint creates a ratcheting noise in swing phase.	The washer for the plunger of the solenoid has not been mounted.	Mount the washer. If the problem remains, contact Technical Support.

## 15. Spare Parts

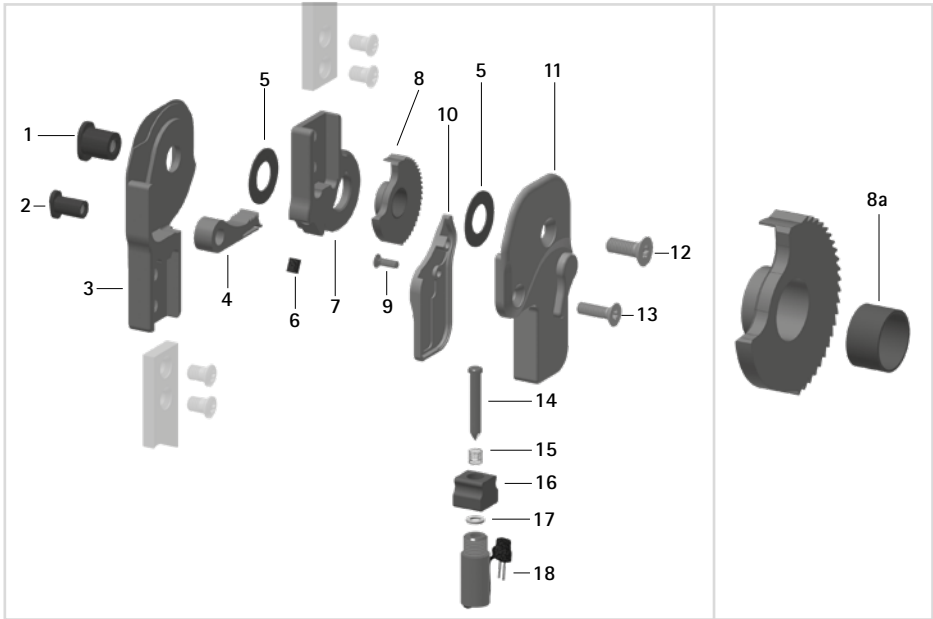


fig. 33

The cover plate is delivered preassembled. If individual components of the cover plate (fig. 34) have to be exchanged, you can order them as well.

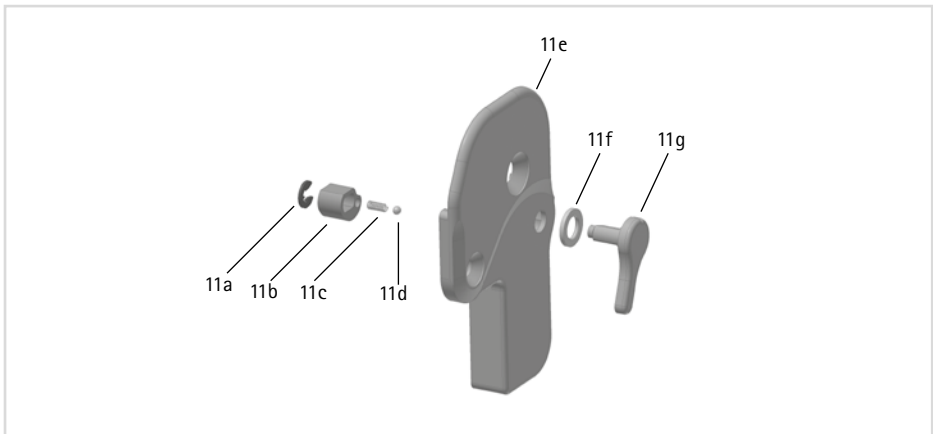


fig. 34

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	PN1000-L06	PN1000-L06	extension stop damper
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	SK0343-2L/AL	SK0345-2L/AL	small cover plate, left lateral or right medial, aluminium
10	SK0343-2R/AL	SK0345-2R/AL	small cover plate, left medial or right lateral, aluminium
11	SK3893-L	SK3895-L	cover plate with lever, left lateral or right medial
11	SK3893-R	SK3895-R	cover plate with lever, left medial or right lateral
11a	VE6799-23/0	VE6799-23/0	retaining washer for shafts
11b	SK0373-24/L	SK0375-24	switching pawl, left lateral or right medial
11b	SK0373-24/R	SK0375-24	switching pawl, left medial or right lateral
11c	FE1207-01	FE1207-01	pressure spring
11d	KU1002-ST	KU1002-ST	ball
11e	SK0343-1L/AL	SK0345-1L/AL	big cover plate, left lateral or right medial, aluminium
11e	SK0343-1R/AL	SK0345-1R/AL	big cover plate, left medial or right lateral, aluminium
11f	GS0905-100	GS0905-100	sliding washer for lever
11g	SK0375-23	SK0375-23	lever for switching pawl
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
14	SK0385-01	SK0385-01	plunger for solenoid

Item	Article Number for System Width		Description
	16mm	20mm	
15	FE1508-02	FE1508-01	pressure spring
16	SK0383-5	SK0383-5	solenoid fixation
17	SK0385-03	SK0385-03	washer for plunger
18	SK0385-00	SK0385-00	solenoid without plunger, with connector

* Sliding Washers		
Article Number for System Width		
16mm	20mm	
$\varnothing = 19\text{mm}$	$\varnothing = 24\text{mm}$	
GS1910-040	GS2411-040	
GS1910-045	GS2411-045	
GS1910-050	GS2411-050	
GS1910-055	GS2411-055	
GS1910-060	GS2411-060	

## 16. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 35). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

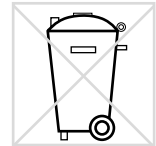


fig. 35



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

## 17. Signs and Symbols

Symbols on the Packaging



medical device

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## 18. 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.

## 19. 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 by the FIOR & GENTZ Orthosis Configurator. Should the product be combined with products from other manufacturers, a written consent by the seller is required.

The information in these instructions for use is valid at the date of printing. The contained product information serves as a guideline. Subject to technical modifications.



**Beinseite**  
Leg Side

■ links/left

■ rechts/right

**Montierte Gleitscheibe**  
Mounted Sliding Washer

1. GS \_\_\_\_\_ - \_\_\_\_\_

2. GS \_\_\_\_\_ - \_\_\_\_\_

