FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology System Knee Joint and Articulated System Side Bar

EN

NEURO ACTIVE
System Knee Joint

NEURO ACTIVE
Articulated System Side Bar

Content **Page**

1. Information 3
2. Safety Instructions 3
   - 2.1 Classification of the Safety Instructions 3
   - 2.2 All Instructions for a Safe Handling of the System Knee Joint 3
3. Use 6
   - 3.1 Intended Use 6
   - 3.2 Indication 6
   - 3.3 Contraindication 6
   - 3.4 Qualification 6
   - 3.5 Application 6
   - 3.6 Product Range 6
   - 3.7 Combination Possibilities with Other System Joints 7
4. Joint Function 7
5. Scope of Delivery 7
6. Load 7
7. Tools for Assembling the System Joint 8
8. Mounting the System Joint 8
   - 8.1 Mounting the Stops 8
   - 8.2 Mounting the Cover Plate 8
   - 8.3 Checking the Free Movement 10
   - 8.4 Greasing the Joint's Upper and Lower Part/Femoral and Tibial Side Bar Wing 10
   - 8.5 Securing the Screws 10
9. Adjustment Options on the Orthosis 10
   - 9.1 Limitation of the Maximum Extension 10
   - 9.2 Limitation of the Maximum Flexion 11
10. Connecting to the System Side Bar/System Anchor 12
11. Processing the Side Bar Wings of the NEURO ACTIVE Articulated System Side Bar 12
    - 11.1 Bending 12
12. Maintenance 13
    - 12.1 Documentation of Maintenance in the Orthosis Service Passport 14
    - 12.2 Replacing the Bronze Bushings 14
    - 12.3 Dirt Removal 14
13. Period of Use 14
14. Storage 14
15. Spare Parts 15
    - 15.1 Exploded View Drawing NEURO ACTIVE System Knee Joint 15
    - 15.2 Spare Parts for the NEURO ACTIVE System Knee Joint 16
    - 15.3 Spare Parts for the NEURO ACTIVE Articulated System Side Bar 16
16. Disposal 17
17. Signs and Symbols 18
18. CE Conformity 18
19. Legal Information 18
20. Information for the Treatment Documentation 19
21. Handing Over the Orthosis 20

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.

For a simplified illustration, all basic work steps are shown with the **NEURO ACTIVE** system knee joint (fig. 1) as example.
They can be transferred to all mentioned system joints.

fig. 1

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

Risk of Falling Due to Improper Handling
Inform the patient about the correct use of the system joint and potential 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 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 Improper Processing
Errors in processing can lead to a breakage of the **NEURO ACTIVE** articulated system side bar. Bend the side bar wings as described in these instructions for use. Pay particular attention to:
- not to heat the side bar wings for bending;
- using the drilling jig;
- respecting the specified bending radius and
- removing notches or residues by fine smoothing and finishing.

⚠ 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 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 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 Improper Shoe/Wrong Shoe Pitch
Advise the patient to wear a shoe to which the orthosis is adjusted in order to avoid joint dysfunction.

⚠ 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

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 bronze bushings according to the information in these instructions for use.

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 FIOR & GENTZ system knee joints must be used exclusively for the orthotic treatment of the lower extremity. The system joint is only allowed to be used for producing a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg. 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 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. 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, parachuting and football, is excluded.

3.6 Product Range

These instructions for use provide information on the following system knee joints:

NEURO ACTIVE **NEURO ACTIVE** system knee joint

NEURO ACTIVE **NEURO ACTIVE** articulated system side bar

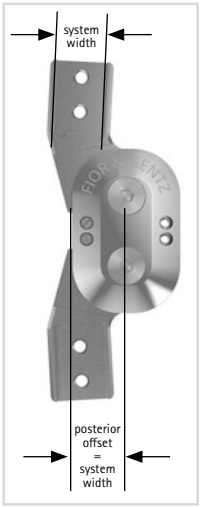

fig. 2

3.7 Combination Possibilities with Other System Joints

The system knee joints can be combined with system ankle joints from the FIOR & GENTZ product range.

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 Function

The free moving, polycentric system knee joints are preassembled at an angle of 5°, corresponding to a physiological knee joint angle. They also have an integrated posterior offset (fig. 2).

System Width	10mm	14mm	16mm	20mm
Posterior Offset of the Joint Axis	10mm	14mm	16mm	20mm

Depending on the used system components, they may have the additional functions listed below:

System Component	Function
extension stop	limitation of the maximum extension in different degrees (0°, 5°, 10°, 20°, 30°)
flexion stop	limitation of the maximum flexion in different degrees - **NEURO ACTIVE** system knee joint: 0°, 10°, 20°, 30°, 50°, 60°, 70°, 80° - **NEURO ACTIVE** articulated system side bar: 0°, 10°, 20°, 30°, 70°, 80° (all system widths), 50° and 60° (16mm and 20mm system widths), 90° and 100° (10mm and 14mm system widths)

5. Scope of Delivery

Description	Quantity
system knee joint or articulated system side bar (without figure)	1
orthosis joint grease, 3g (fig. 3)	1
orthosis joint grease for joints with gear segments, 5g (fig. 4)	1
assembly/lamination dummy (fig. 5)	1

fig. 3

fig. 4

fig. 5

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 for System Joint Screws	System Width			
	10mm	14mm	16mm	20mm
3mm hexagon screwdriver/bit	x	x	-	-
4mm hexagon screwdriver/bit	-	-	x	x
torque screwdriver, 1–6Nm	x	x	x	x
slotted screwdriver, 3.5 x 0.6mm	x	x	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 8.5. In the following, the assembly is illustrated with the **NEURO ACTIVE** system knee joint as an example.

Only use the FIOR & GENTZ orthosis joint greases to grease the system components.

8.1 Mounting the Stops

If you would like to mount another extension stop than the premounted 5° stop, proceed as follows:

1 Unscrew the extension stop (1; fig. 6) from the base plate.
2 Screw a new extension stop onto the base plate.
3 If necessary, screw a flexion stop (2) onto the base plate.
4 Tighten all the slotted pan head screws.

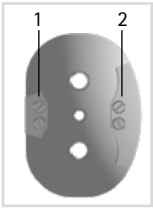

fig. 6

When mounting the extension stop, mind the correct alignment of the entire orthosis. In order for an exchanged extension stop not to affect the orthosis alignment negatively, also correct the system ankle joint, if necessary. You can find more information on this in the online tutorial **KAFO Alignment Guidelines** (see QR code, fig. 7) on the FIOR & GENTZ website.

fig. 7

8.2 Mounting the Cover Plate

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

1 Clean the threads of the base plate with LOCTITE® 7063 Super Clean. Allow the threads to air-dry for 10 minutes.

fig. 8

fig. 9

2 Grease the axle bore of the joint's upper and lower part/femoral and tibial side bar wing as well as the sliding surfaces of the bronze bushings with orthosis joint grease (orange marking on the tube; fig. 3).
3 Screw in both countersunk flat head screws on the back of the base plate.
4 Place the bronze bushings onto the countersunk flat head screws (fig. 8).
5 Apply spray adhesive on one side of the two first sliding washers and adhere them over the bronze bushings to the base plate. The bronze bushings serve as guidance (fig. 9).
6 Remove the bronze bushings and the countersunk flat head screws.
7 Grease the other side of the sliding washers **slightly** with orthosis joint grease (orange marking on the tube; fig. 3).
8 Insert both countersunk flat head screws into the bores of the cover plate.
9 Place the bronze bushings onto the countersunk flat head screws.
10 Apply spray adhesive on one side of the two second sliding washers and adhere them over the bronze bushings to the cover plate.
11 Remove the bronze bushings and the countersunk flat head screws (fig. 10).
12 Grease the other side of the sliding washers **slightly** with orthosis joint grease (orange marking on the tube; fig. 3).
13 Mount the joint's upper part/femoral side bar wing. Make sure that it is positioned on the threaded hole. The surface that strikes against the extension stop must touch the extension stop (fig. 11).
14 Place the first bronze bushing (fig. 12).
15 Mount the joint's lower part/tibial side bar wing. Make sure that it is positioned on the threaded hole. The surface that strikes against the extension stop must touch the extension stop. The gear segments must mesh (fig. 13).

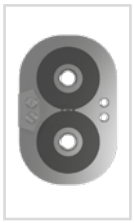
fig. 10

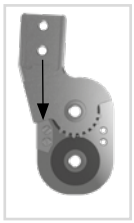
fig. 11

fig. 12

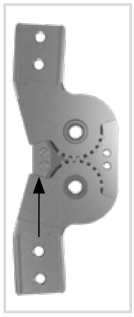
fig. 13

fig. 14

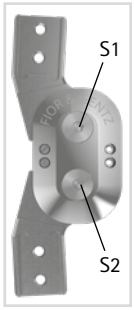

fig. 15

When assembling the system joint, make sure that the gear segments of the joint's upper and lower part/femoral and tibial side bar wing mesh correctly into each other. Make sure that the extension stop face of the the joint's upper and lower part/femoral and tibial side bar wing touches the extension stop.

16 Place the second bronze bushing (fig. 14).
17 Place the cover plate on the system joint.
18 Screw in both countersunk flat head screws (S1 and S2; fig. 15). Clamp the bronze bushings between base and cover plate so that they cannot move. The joint's upper and lower part/femoral and tibial side bar wing should move around the bushings.

8.3 Checking the Free Movement

Tighten the screws for the cover plate with the appropriate torque (see paragraph 8.5). Check if the system joint moves freely. If the articulated side bar runs with lateral play, mount the next smaller bronze bushing. If it does not move freely (it is jammed), mount the next larger bronze bushing.

8.4 Greasing the Joint's Upper and Lower Part/Femoral and Tibial Side Bar Wing

1 Demount the cover plate.
2 Grease the gear segments of the joint's upper and lower part/femoral and tibial side bar wing with orthosis joint grease for joints with gear segments (green marking on the tube; fig. 4).
3 Place the cover plate onto the joint again and screw in the countersunk flat head screws (S1 and S2).

8.5 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. 15) after checking the 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. 15) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

Screws for Cover Plate	System Width			
	10mm	14mm	16mm	20mm
S1 (screw 1)	4Nm	4Nm	4Nm	4Nm
S2 (screw 2)	4Nm	4Nm	4Nm	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.

9. Adjustment Options on the Orthosis

9.1 Limitation of the Maximum Extension

The extension stop (1; fig. 16) is exchangeable. It can be mounted into the system joint depending on the desired extension.

Desired Extension	Required Extension Stop	Work Steps
0°	0° extension stop	inserting the 0° extension stop
5°	5° extension stop	delivery status (fig. 16)
10°	10° extension stop	inserting the 10° extension stop
20°	20° extension stop	inserting the 20° extension stop
30°	30° extension stop	inserting the 30° extension stop

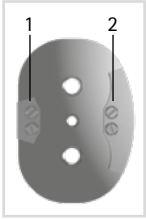

fig. 16

9.2 Limitation of the Maximum Flexion

The flexion stop (2; fig. 16) is exchangeable. It can be mounted into the system knee joint depending on the desired flexion.

NEURO ACTIVE System Knee Joint

Desired Flexion	Required Stop	Work Steps
0°	0° flexion stop	inserting the 0° flexion stop
10°	10° flexion stop	inserting the 10° flexion stop
20°	20° flexion stop	inserting the 20° flexion stop
30°	30° flexion stop	inserting the 30° flexion stop
50°	30° extension stop	inserting the 30° extension stop
60°	20° extension stop	inserting the 20° extension stop
70°	10° extension stop	inserting the 10° extension stop
80°	0° extension stop	inserting the 0° extension stop

NEURO ACTIVE Articulated System Side Bar

Desired Flexion	Required Stop	System Width	Work Steps
0°	0° flexion stop	10mm, 14mm, 16mm, 20mm	inserting the 0° flexion stop
10°	10° flexion stop	10mm, 14mm, 16mm, 20mm	inserting the 10° flexion stop
20°	20° flexion stop	10mm, 14mm, 16mm, 20mm	inserting the 20° flexion stop
30°	30° flexion stop	10mm, 14mm, 16mm, 20mm	inserting the 30° flexion stop
50°	30° extension stop	16mm, 20mm	inserting the 30° extension stop corresponding to the system width
60°	20° extension stop	16mm, 20mm	inserting the 20° extension stop corresponding to the system width
70°	30° extension stop	10mm, 14mm	inserting the 30° extension stop corresponding to the system width
70°	10° extension stop	16mm, 20mm	inserting the 10° extension stop corresponding to the system width
80°	20° extension stop	10mm, 14mm	inserting the 20° extension stop corresponding to the system width
80°	0° extension stop	16mm, 20mm	inserting the 0° extension stop corresponding to the system width
90°	10° flexion stop	10mm, 14mm	inserting the 10° flexion stop corresponding to the system width
100°	0° extension stop	10mm, 14mm	inserting the 0° extension stop corresponding to the system width

10. 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. 17–19). 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. 20). You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

fig. 17

fig. 18

fig. 19

fig. 20

11. Processing the Side Bar Wings of the NEURO ACTIVE Articulated System Side Bar

To ensure an optimal functioning of the **NEURO ACTIVE** articulated system side bar, please note the following processing steps and explanations when bending the side bar wings.

11.1 Bending

- Screw the side bar wings on the corresponding joint retainers.
- Do not use a hammer to bend the side bar wings.
- In order to avoid notches, use a bending iron with round edges for bending the side bar wings (fig. 21). Both bending irons with straight and with curved edges can easily cause breakage of the side bar wings.
- Bending is a cold working technique. Do not heat the material since the material's characteristics can change permanently.
- Do not alternate the bending direction repeatedly as this compacts the material and makes it brittle, which can lead to breakage.
- To avoid fractures when bending the side bar wings, make sure not to fall below the radii given in the table (fig. 22). The bending radius depends on the thickness of the material (see table).

fig. 21

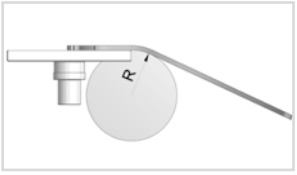

fig. 22

Material	Calculating the Minimum Bending Radius [R*]
aluminium	R = 11 x material thickness

* Calculation example: a side bar wing made of aluminium is 5mm thick. Multiplied by 11, the bending radius is 55mm. This value is the minimum radius.

When bending the side bar wings, wear working clothes with long sleeves as well as work gloves and goggles to avoid injuries in case the side bar wings break.

12. 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
sliding washer	wear	replacing sliding washers	every 6 months	every 18 months
cover plate	wear	replacing cover plate	every 6 months	every 36 months
base plate	wear	replacing base plate	every 6 months	every 36 months
countersunk flat head screw with hexalobular socket	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bronze bushing	wear	replacing bronze bushing, see paragraph 12.2	every 6 months	every 36 months
joint's upper and/or lower part	wear of gear segment	replacing joint's upper and/or lower part	every 6 months	every 36 months
femoral and/or tibial side bar wing	wear of gear segment	replacing femoral and/or tibial side bar wing	every 6 months	every 36 months
extension stop	wear	replacing extension stop	every 6 months	if required
flexion stop	wear	replacing flexion stop	every 6 months	not necessary

* depending on the assessment of the distributor of the custom-made product regarding the patient's usage behaviour

Clean the threads of the base plate 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 8.5). Remove all adhesive residues first.

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 23) on the FIOR & GENTZ website.

fig. 23

12.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport (fig. 24) 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. 24

12.2 Replacing the Bronze Bushings

Bronze bushings are available in different heights (e.g. BB9664**-92** is 4.92mm high). The height (h) is engraved on the outside of the bronze bushing (fig. 25). If it is illegible, measure the height of the bronze bushing (fig. 26). You will find the article numbers of the premounted bronze bushings on the back page of these instructions for use.

fig. 25

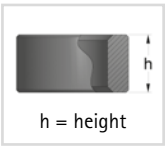

fig. 26

12.3 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.

13. 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 12).
- Adhere to the determined maintenance conditions (see paragraph 12).
- Check the wear parts, as required, and exchange them at the defined intervals (see paragraph 12).
- Check the adjustment of the system joint during maintenance and correct it if necessary (see paragraph 12).
- Check the functionality of the system joint during maintenance (see paragraph 12).
- 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 19).

14. Storage

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

15. Spare Parts

15.1 Exploded View Drawing **NEURO ACTIVE** System Knee Joint

The exploded view drawing of the **NEURO ACTIVE** system knee joint also serves as an exemplary illustration for the **NEURO ACTIVE** articulated system side bar.

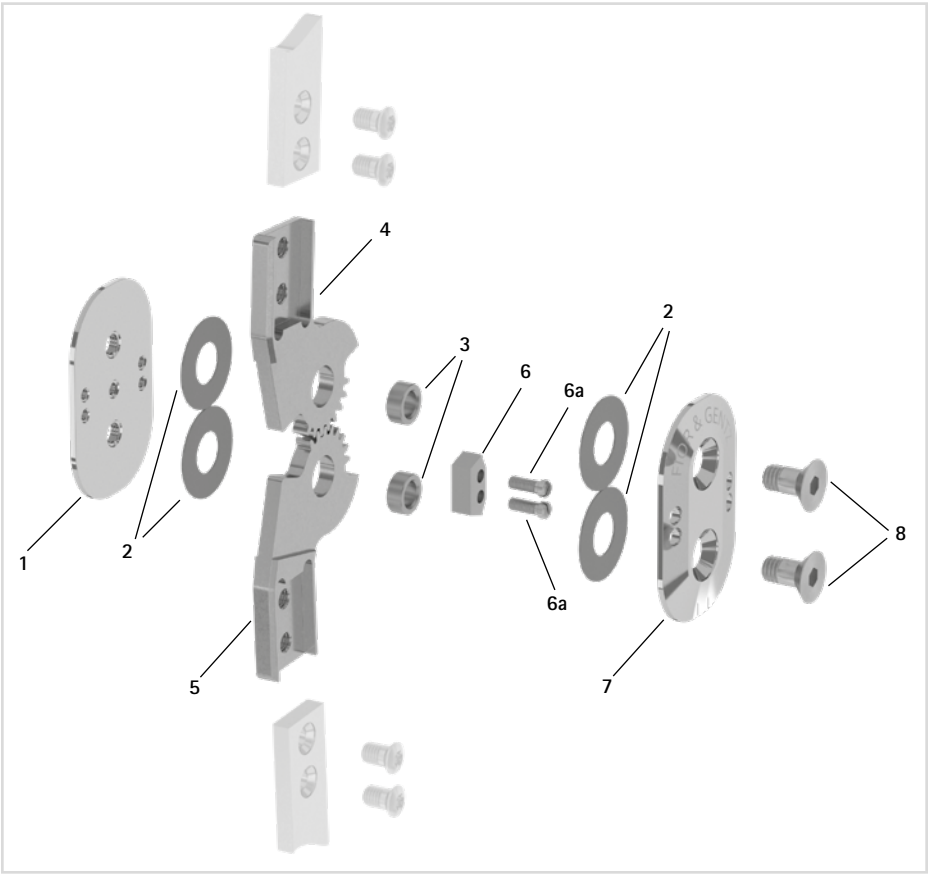

fig. 27

15.2 Spare Parts for the **NEURO ACTIVE** System Knee Joint

Item	Article Number for System Width 16mm	Description
1	SK0250-ST	base plate
2	GS2210-050	sliding washer
3	BB9664-*	bronze bushing*
4	SK0203-L/ST	upper part, left lateral or right medial, straight, steel
4	SK0203-R/ST	upper part, left medial or right lateral, straight, steel
4	SK0223-L/ST	upper part, left lateral or right medial, bent inwards, steel
4	SK0223-R/ST	upper part, left medial or right lateral, bent inwards, steel
5	SK0213-L/ST	lower part, left lateral or right medial, straight, steel
5	SK0213-R/ST	lower part, left medial or right lateral, straight, steel
5	SK0233-L/ST	lower part, left lateral or right medial, bent inwards, steel
5	SK0233-R/ST	lower part, left medial or right lateral, bent inwards, steel
6	BK9051-E005	5° extension stop with 2 slotted pan head screws
6a	SC2103-L08	slotted pan head screw
7	SK0251-ST	cover plate
8	SC1016-L12	countersunk flat head screw with hexagon socket and shank

* Bronze Bushings NEURO ACTIVE System Knee Joint	
Article Number and Height for System Width 16mm	
Ø = 9.6mm	Height (h)
BB9664-92	4.92mm
BB9664-95	4.95mm
BB9664-98	4.98mm

15.3 Spare Parts for the **NEURO ACTIVE** Articulated System Side Bar

The assignment of the items as shown in the exploded view drawing of the **NEURO ACTIVE** system knee joint serves as guidance. The spare parts of the **NEURO ACTIVE** articulated system side bar are not identical to the picture.

Item	Article Number for System Width 10mm	14mm	16mm	20mm	Description
1	KS0150-AL	KS0150-AL	SK0250-ST	SK0250-ST	base plate
2	GS1609-050	GS1609-050	GS2210-050	GS2210-050	sliding washer
3	BB8553-**	BB8554-**	BB9665-**	BB9666-**	bronze bushing**
4	BK0200-AL	BK0202-AL	BK0203-AL	BK0205-AL	femoral side bar wing, aluminium
5	BK0210-AL	BK0212-AL	BK0213-AL	BK0215-AL	tibial side bar wing, aluminium
6	KS9502-E005	KS9502-E005	BK9051-E005	BK9061-E005	5° extension stop with 2 slotted pan head screws

Item	Article Number for System Width				Description
	10mm	14mm	16mm	20mm	
6a	SC2103-L06	SC2103-L06	SC2103-L08	SC2103-L08	slotted pan head screw
7	KS0151-AL/FG	KS0151-AL/FG	SK0251-ST	SK0251-ST	cover plate
8	SC1015-L11	SC1015-L12	SC1016-L13	SC1016-L14	countersunk flat head screw with hexagon socket and shank

**** Bronze Bushings NEURO ACTIVE Articulated System Side Bar**

Article Number and Height for System Width							
10mm		14mm		16mm		20mm	
Ø = 8.5mm	Height (h)	Ø = 8.5mm	Height (h)	Ø = 9.6mm	Height (h)	Ø = 9.6mm	Height (h)
BB8553-89	3.89mm	BB8554-89	4.89mm	BB9665-89	5.89mm	BB9666-89	6.89mm
BB8553-92	3.92mm	BB8554-92	4.92mm	BB9665-92	5.92mm	BB9666-92	6.92mm
BB8553-95	3.95mm	BB8554-95	4.95mm	BB9665-95	5.95mm	BB9666-95	6.95mm
BB8553-98	3.98mm	BB8554-98	4.98mm	BB9665-98	5.98mm	BB9666-98	6.98mm

16. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 28). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

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

fig. 28

17. Signs and Symbols

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

medical device

article number

manufacturer

batch code

serial number

follow the instructions for use

single patient – multiple uses

Unique Device Identifier – product identification number

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 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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20. 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	

21. 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

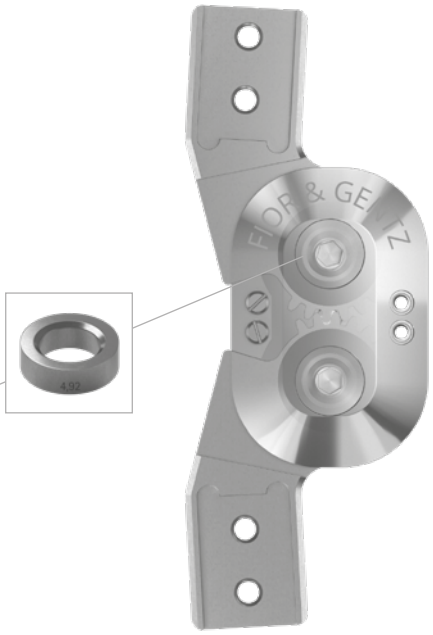
Leg Side

☐ **left** ☐ **right**

Mounted Bronze Bushings

1. BB _____ - _____

2. BB _____ - _____



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