FIOR & GENTZ
ORTHOPÄDIETECHNIK MIT SYSTEM

Instructions for Use for Orthotists or Qualified/Trained Experts System Ankle Joints

EN

NEURO SPRING

NEURO SPRING

NEURO VARIO-SPRING

NEURO VARIO-SPRING

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Content **Page**

1. Information

This manual is addressed to orthotists and does not contain any notes about dangers which are obvious to orthotists. 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 work steps are shown with the **NEURO VARIO-SPRING** system ankle joint (fig. 1) as an 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 orthotist or qualified/trained expert and/or the patient is established.

All serious incidents connected to the product shall be reported to the manufacturer or the responsible authorities.

2.2 All Instructions for a Safe Handling of the System Ankle 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).

⚠ WARNING

Risk of Falling Due to Loosely Attached Cover Plate
Mount the cover plate to the system joint according to the assembly instructions in this manual. 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 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.

⚠ WARNING

Risk of Falling Due to Incorrectly Adjusted Adjusting Screw
Adjust the adjusting screw according to the information in this manual. Do not make a fine adjustment of more than 10° and secure the adjusting screw with the securing pin and the corresponding adhesive.

⚠ 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 Due to Lack of 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 this manual.

⚠ WARNING

Jeopardising the Therapy Goal Due to Incorrectly Filed System Stirrup
Do not file the system stirrup too far. This applies especially to the dorsiflexion stop, as otherwise the forefoot lever will not be activated. As a result, the patient is only stabilised insufficiently by the orthosis and the gait worsens. In order to avoid this, always file the system stirrup:
- gradually up to the required stop angles and
- only so far that no more than a 10° fine adjustment is possible.

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

Breakage of System Components Due to Predetermined Breaking Point at the System Stirrup
If you need to file the system stirrup, note all information provided in this manual in order to avoid predetermined breaking points. File the system stirrup along the laser lines.

3. Application

The FIOR & GENTZ system ankle joints are exclusively for use for orthotic fittings of the lower extremity. They must be handled by a professionally trained user. 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.

This manual provides information on the following system ankle joints:

NEURO SPRING

NEURO VARIO-SPRING

4. Joint Function

The basic function of all system ankle joints is to provide motion control. Depending on the used system components, they have the additional functions listed below:

System Component	Function
pressure spring	dorsiflexion assist

System Component	Function
adjusting screw	**ventral (anterior adjusting screw):** readjustment of the maximum range of motion in dorsiflexion

System Component	Function
system stirrup which can be adjusted by filing	**ventral:** adjustment of the range of motion in dorsiflexion by filing the system stirrup along the laser lines

5. Scope of Delivery

Description	Quantity
system ankle joint (without figure)	1
securing pin (only for **NEURO VARIO-SPRING**; fig. 2)	1
AGOMET® F330, 5g (fig. 3)	1
orthosis joint grease, 3g (without figure)	1
assembly/lamination dummy (fig. 4)	1

Appropriate system stirrups have to be ordered separately.

fig. 2

fig. 3

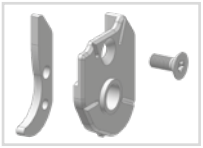


fig. 4

6. 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.

7. Tools for Assembling the System Joint

Tools	System Width		
	14mm	16mm	20mm
T20 hexalobular screwdriver/bit	x	x	x
slotted screwdriver 3.5 x 0.6mm	x	x	x
torque screwdriver 1-6Nm	x	x	x
assembly aid for cover plate	-	x	x
pin punch 3.5 x 0.6mm	x	x	x

8. 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 8.5. The assembly is illustrated with the **NEURO VARIO-SPRING** system ankle joint as an example.

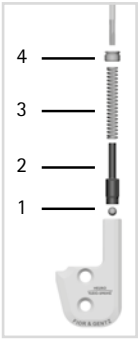


fig. 5

8.1 Mounting the Functional Unit

1 Assemble the functional unit. Mind the correct order: ball (1), pin (2), pressure spring (3) (fig. 5).
2 Screw in the pressure screw (4) tightly. This fixes the functional unit in the spring duct of the cover plate.


fig. 6

8.2 Mounting the System Stirrup

1 Grease the friction surfaces of the bearing nut with orthosis joint grease.
2 Put the bearing nut into the joint's upper part. The whole bearing nut must be placed in the opening (fig. 6).
3 Grease the first sliding washer **slightly** on both sides with orthosis joint grease.
4 Place the sliding washer onto the joint's upper part (fig. 7).
5 Mount the system stirrup (fig. 8).


fig. 7

8.3 Mounting the Cover Plate

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

1 Clamp the assembly aid for cover plate into a vice.
2 Place the cover plate with the ball on the pin of the assembly aid for cover plate.
3 Compress the pressure spring by pulling the cover plate in your direction until the cover plate fits into the assembly aid for cover plate.
4 Remove the assembly aid for cover plate with the cover plate from the vice (fig. 9).


fig. 8

The assembly aid for cover plate can only be used for the system widths 16mm and 20mm. System ankle joints with a system width of 14mm can easily be mounted without the assembly aid.


fig. 9

5 Apply spray adhesive on one side of the second sliding washer and adhere it to the cover plate (fig. 10).
6 Grease the other side **slightly** with orthosis joint grease.
7 Clean the threads of the cover plate with LOCTITE® 7063 Super Clean, if necessary.
8 Place the cover plate from the side on the system stirrup by using the assembly aid for cover plate (fig. 11).
9 Screw in the first countersunk flat head screw (axle screw, S1; fig. 12).
10 Screw in the second countersunk flat head screw (S2; fig. 13).
11 Grasp the assembly aid for cover plate at the top and carefully pull it up first and then sideways from the functional unit.


fig. 10

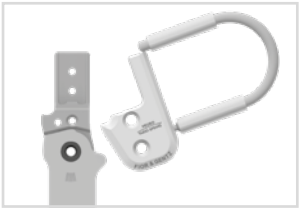


fig. 11

8.4 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.

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

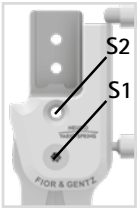


fig. 12

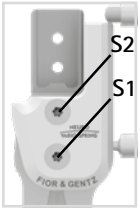


fig. 13

Position of the Screw	System Width		
	14mm	16mm	20mm
S1 (screw 1, axle screw)	4Nm	4Nm	4Nm
S2 (screw 2)	4Nm	4Nm	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.

9. Adjustment Options on the Orthosis

The orthosis with adjustable system ankle joints can be individually adapted to the pathological gait.

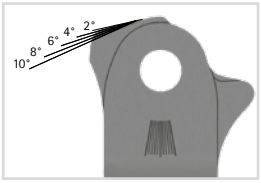


fig. 14

Mind the correct adjustment of the dorsiflexion stop when mounting the system ankle joint. It is decisive for the entire alignment of the orthosis.

9.1 Adjustable Range of Motion

The maximum range of motion in dorsiflexion can be adjusted by filing the system stirrup (maximum 10°) provided that the system joint has a system stirrup that can be filed (fig. 14). If you file the system stirrup up to the round auxiliary line, the system ankle joint becomes free moving in dorsiflexion.

fig. 15

9.2 Fine Adjusting the Range of Motion

Use the adjusting screw of the system joint to fine adjust the range of motion up to 10° (fig. 15). To do so, screw in or unscrew the adjusting screw in the system joint. Note that no more than 10° fine adjustment is allowed. Otherwise, the surface pressure between adjusting screw and system stirrup can become so high that the screw is compressed and loses its function.


fig. 16

Securing the Adjusting Screw

The position of the adjusting screw cannot change due to the securing pin that is installed in the system joint. If the adjusting screw turns or loosens, it must be secured again with the securing pin.


fig. 17

1 Unscrew the adjusting screw from the thread (fig. 15).
2 Demount the cover plate.
3 Drive out the premounted securing pin with a pin punch (fig. 16).
4 Mount the cover plate.
5 Apply some LOCTITE® 243 medium strength to the adjusting screw to secure it.
6 Screw in the adjusting screw up to the desired position (fig. 17).
7 Turn the worn position of the securing pin by about 90° (fig. 18).
8 Drive the securing pin from the back into the bore (fig. 19).
9 Let the adhesive harden (final strength after approx. 24 hours).

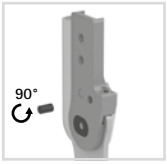


fig. 18

If the securing pin is deformed after the driving, put in a new one. If necessary, cut the new pin with a sharp knife so that it does not protrude. An additional security pin is included in the delivery.


fig. 19

9.3 Reading the Joint Angles

There are markings (fig. 20) on all system joints and system stirrups which indicate the angle of the system components to each other. This allows you to check the individual normal posture (the orthosis' basic alignment), record the joint angle and compare later deviations.

The distances between the degree markings for each system width can be seen in the following table.

Degree Marking			
System Width	14mm	16mm	20mm
Degree	2°	2°	2°

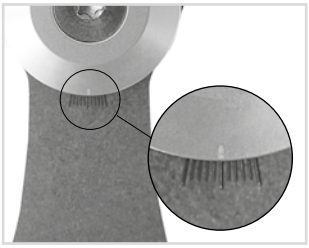


fig. 20

10. Converting the System Ankle Joints

10.1 Converting Options

The following table shows the converting options for the system ankle joints.

System Ankle Joint	Convertible into
NEURO VARIO-SPRING	NEURO VARIO-CLASSIC
NEURO SPRING	NEURO CLASSIC-SWING NEURO CLASSIC

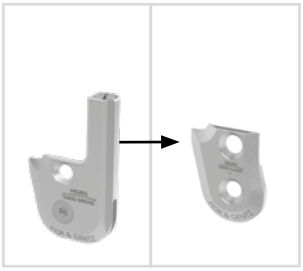


fig. 21

10.2 Converting NEURO VARIO-SPRING into NEURO VARIO-CLASSIC

1 Demount the functional unit of the **NEURO VARIO-SPRING** system joint.
2 Mount the cover plate of the **NEURO VARIO-CLASSIC** system joint in the correct system width (fig. 21).

fig. 22

10.3 Converting NEURO SPRING into NEURO CLASSIC-SWING

1 Grind the system stirrup slightly in the nose area (fig. 22).
2 Demount the functional unit of the **NEURO SPRING** system joint.
3 Mount the functional unit of the **NEURO CLASSIC-SWING** system joint in the correct system width (fig. 23).

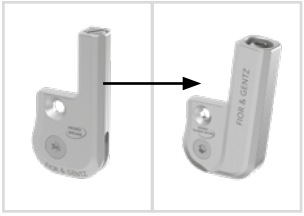


fig. 23

10.4 Converting NEURO SPRING into NEURO CLASSIC

1 Demount the functional unit of the **NEURO SPRING** system joint.
2 Mount the cover plate of the **NEURO CLASSIC** system joint in the correct system width (fig. 24).
3 If necessary, grind the nose for the pressure spring at the system stirrup (fig. 25).

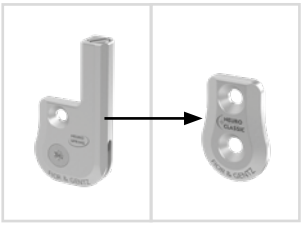


fig. 24

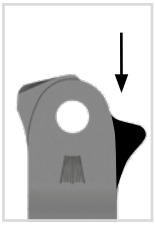


fig. 25

11. Maintenance

Check the system joint for wear and functionality every **6 months**. Also check the functionality after every maintenance carried out.

Joint Component	Problem	Measure
pressure spring	fatigue of spring force	replacing pressure spring
pin	wear	replacing pin
adjusting screw	wear	replacing adjusting screw
securing pin	wear	replacing securing pin, see paragraph 9.2
bore for bearing nut of system stirrup	oversize	inserting repair bushing, see paragraph 11.1
sliding washer	wear	replacing sliding washer, see paragraph 11.2
bearing nut	wear	replacing bearing nut

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 8.5). Remove all adhesive residues first.

11.1 Repairing the Bearing Nut Bore

Insert a repair bushing if the bore for the bearing nut at the system stirrup is worn out.

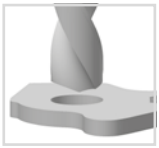


fig. 26

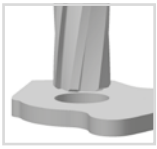


fig. 27

1 Clamp the system stirrup firmly into a vice.
2 Bore and ream the hole until it has reached the desired dimension (fig. 26 and 27).
3 Insert the repair bushing made of bronze completely into the bore.

Boring and Reaming Measurements [mm]						
System Width	Bearing Nut Outer Ø	Repair Bushing Inner Ø	Repair Bushing Outer Ø	Ø Measurement for Boring	Ø Measurement for Reaming	Art. No. Repair Bushing
14mm	8.5	8.5	9.6	9.3	9.6 H7	BR1009-L025
16mm	9.6	9.6	10.5	10.2	10.5 H7	BR1110-L030
20mm	10.5	10.5	11.5	11.2	11.5 H7	BR1211-L030

11.2 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS2210-**040** is 0.40mm thick). Each thickness has a different marking (fig. 28). You will find the article numbers of the premounted sliding washers on the back page of this manual.

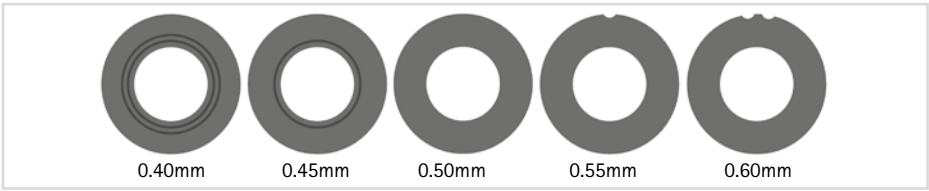


fig. 28

11.3 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.

12. Spare Parts

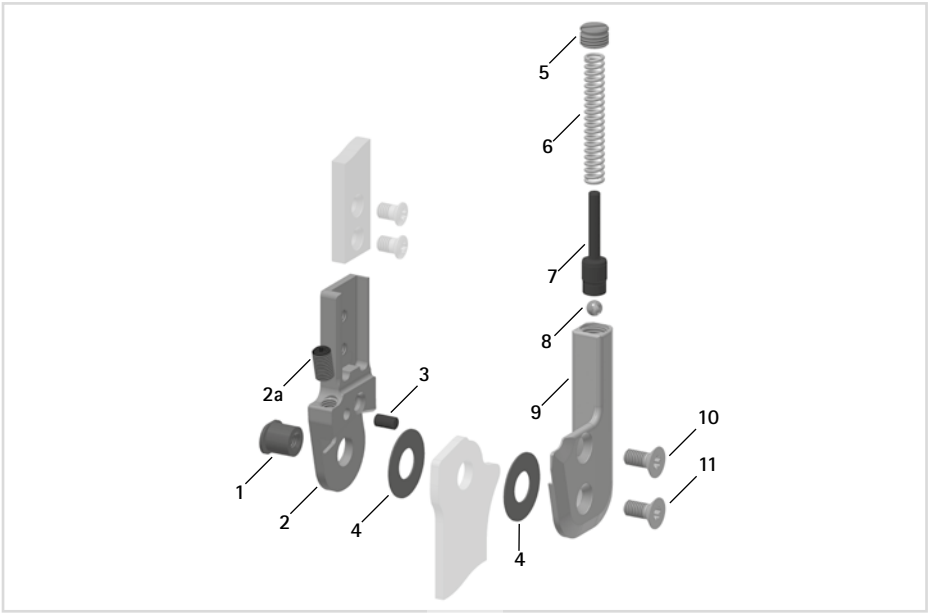


fig. 29

Spare Parts for the NEURO VARIO-SPRING System Ankle Joint

Item	Article Number for System Width			Description
	14mm	16mm	20mm	
1	SB8559-L0620	SB9669-L0760	SB1069-L0810	bearing nut
2	SF0412-L/ST	SF0413-L/ST	SF0415-L/ST	upper part, left lateral or right medial, straight, steel (with adjusting screw)
2	SF0412-R/ST	SF0413-R/ST	SF0415-R/ST	upper part, left medial or right lateral, straight, steel (with adjusting screw)
2	SF0412-L/TI	SF0413-L/TI	SF0415-L/TI	upper part, left lateral or right medial, straight, titanium (with adjusting screw)
2	SF0412-R/TI	SF0413-R/TI	SF0415-R/TI	upper part, left medial or right lateral, straight, titanium (with adjusting screw)
2	SF0432-L/ST	SF0433-L/ST	SF0435-L/ST	upper part, left lateral or right medial, bent inwards, steel (with adjusting screw)
2	SF0432-R/ST	SF0433-R/ST	SF0435-R/ST	upper part, left medial or right lateral, bent inwards, steel (with adjusting screw)
2	SF0432-L/TI	SF0433-L/TI	SF0435-L/TI	upper part, left lateral or right medial, bent inwards, titanium (with adjusting screw)
2	SF0432-R/TI	SF0433-R/TI	SF0435-R/TI	upper part, left medial or right lateral, bent inwards, titanium (with adjusting screw)
2	SF0432-8L/ST	SF0433-8L/ST	SF0435-8L/ST	upper part, left lateral or right medial, bent outwards, steel (with adjusting screw)
2	SF0432-8R/ST	SF0433-8R/ST	SF0435-8R/ST	upper part, left medial or right lateral, bent outwards, steel (with adjusting screw)
2	SF0432-8L/TI	SF0433-8L/TI	SF0435-8L/TI	upper part, left lateral or right medial, bent outwards, titanium (with adjusting screw)
2	SF0432-8R/TI	SF0433-8R/TI	SF0435-8R/TI	upper part, left medial or right lateral, bent outwards, titanium (with adjusting screw)
2a	SC9605-L08ST	SC9606-L10ST	SC9606-L10ST	adjusting screw
3	GS4007	GS4007	GS4007	securing pin
4	GS2009-*	GS2210-*	GS2611-*	sliding washer*
5	SC2108-L04	SC2109-L05	SC2110-L05	pressure screw
6	FE1634-02	FE2836-02	FE2752-02	pressure spring, golden
7	SF0342-75	SF0343-72	SF0345-81	pin
8	KU1005-ST	KU1005-ST	KU1005-ST	ball
9	SF0462-L/AL	SF0463-L/AL	SF0465-L/AL	cover plate, left lateral or right medial
9	SF0462-R/AL	SF0463-R/AL	SF0465-R/AL	cover plate, left medial or right lateral
10	SC1405-L10	SC1405-L11	SC1405-L12	countersunk flat head screw, hexalobular socket

Item	Article Number for System Width			Description
	14mm	16mm	20mm	
11	SC1405-L10	SC1405-L11	SC1406-L12	countersunk flat head screw, hexalobular socket (axle screw)
5-11	SF4972-L/AL	SF4973-L/AL	SF4975-L/AL	functional unit, left lateral or right medial
5-11	SF4972-R/AL	SF4973-R/AL	SF4975-R/AL	functional unit, left medial or right lateral

Spare Parts for the NEURO SPRING System Ankle Joint

Item	Article Number for System Width			Description
	14mm	16mm	20mm	
1	SB8559-L0580	SB9669-L0710	SB1069-L0760	bearing nut
2	SF0312-ST	SF0313-ST	SF0315-ST	upper part, straight, steel
2	SF0312-TI	SF0313-TI	SF0315-TI	upper part, straight, titanium
2	SF0332-ST	SF0333-ST	SF0335-ST	upper part, bent inwards, steel
2	SF0332-TI	SF0333-TI	SF0335-TI	upper part, bent inwards, titanium
2	SF0332-8/ST	SF0333-8/ST	SF0335-8/ST	upper part, bent outwards, steel
2	SF0332-8/TI	SF0333-8/TI	SF0335-8/TI	upper part, bent outwards, titanium
4	GS2009-*	GS2210-*	GS2611-*	sliding washer*
5	SC2108-L04	SC2109-L05	SC2110-L05	pressure screw
6	FE1634-02	FE2836-02	FE2752-02	pressure spring, golden
7	SF0342-75	SF0343-72	SF0345-81	pin
8	KU1005-ST	KU1005-ST	KU1005-ST	ball
9	SF0362-L/AL	SF0363-L/AL	SF0365-L/AL	cover plate, left lateral or right medial
9	SF0362-R/AL	SF0363-R/AL	SF0365-R/AL	cover plate, left medial or right lateral
10	SC1405-L10	SC1405-L11	SC1405-L12	countersunk flat head screw, hexalobular socket
11	SC1405-L10	SC1405-L11	SC1406-L12	countersunk flat head screw, hexalobular socket (axle screw)
5-11	SF3972-L/AL	SF3973-L/AL	SF3975-L/AL	functional unit, left lateral or right medial
5-11	SF3972-R/AL	SF3973-R/AL	SF3975-R/AL	functional unit, left medial or right lateral

* Sliding Washers		
Article Number for System Width		
14mm	16mm	20mm
Ø = 20mm	Ø = 22mm	Ø = 26mm
GS2009-040	GS2210-040	GS2611-040
GS2009-045	GS2210-045	GS2611-045
GS2009-050	GS2210-050	GS2611-050
GS2009-055	GS2210-055	GS2611-055
GS2009-060	GS2210-060	GS2611-060

13. Disposal

fig. 30

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 30). 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.

14. Signs and Symbols

Symbols on the Packaging

MD medical device

15. 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.

16. 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. 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 serve as guidelines. Subject to technical modifications.

17. 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	

18. Handing Over the Orthosis

The orthotist or qualified/trained expert 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

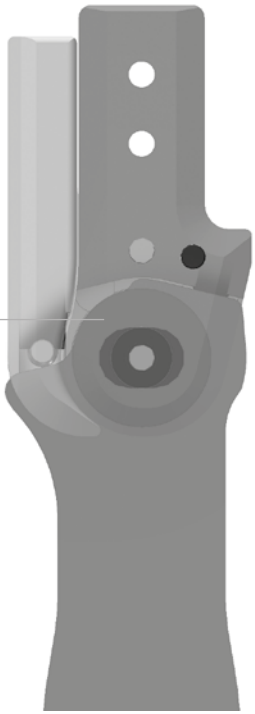
Leg Side

☐ **left** ☐ **right**

Mounted Sliding Washer

1. GS _____ - _____

2. GS _____ - _____



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CE

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