

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



NEURO CLASSIC



NEURO VARIO-CLASSIC



NEURO VARIO

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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.



For a simplified illustration, all basic work steps are shown with the **NEURO VARIO-CLASSIC** 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.

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 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 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.

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 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 these instructions for use. 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 by Not Providing the Necessary Free Movement

Check if the system joint moves freely in order to avoid restrictions of the joint function. Use suitable sliding washers according to the information in these instructions for use.

WARNING

Jeopardising the Therapy Goal by Incorrectly Filing the System Stirrup

If you need to file the system stirrup, note all information provided in these instructions for use. Do not file the system stirrup too far, especially for the dorsiflexion stop, otherwise the forefoot lever is not activated.

As a result, the patient's gait worsens due to a lack of stability. Therefore:

- file the system stirrup always gradually up to the required stop angles and
- do not file it more than 10° later on.

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;
- 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. 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 ankle joints are exclusively for use for orthotic fittings of the lower extremity. The system joints are only allowed to be used for producing an AFO or KAFO. Every system joint influences the orthosis' function and thus also the function of the leg. The system joint may only be used for one fitting and must not be reused.

3.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities that lead to a pathological gait. This can be caused, for example, by central, peripheral, spinal or neuromuscular paralyses, structurally conditioned deformities/malfunctions 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.

All system ankle joints can also be used for the prosthetic treatment of patients with partial foot amputations. For this purpose, the orthosis produced for the patient by the orthotist or qualified/trained expert (custom-made product) is combined with a foot prosthesis. Further information can be found in the **Guide to Partial Foot Amputations**.

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 that affects more than just part of the foot, for example after amputations of leg segments.

3.4 Qualification

The system joint must only be handled by an orthotist or a qualified/trained expert.

3.5 Application

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.

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3.6 Product Range

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



NEURO CLASSIC

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NEURO VARIO-CLASSIC

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NEURO VARIO

3.7 Combination Possibilities with Other System Joints

The system ankle joints can be combined with other system joints from our product range. The NEURO CLASSIC system ankle joint can be used as supporting joint for NEURO SPRING, NEURO CLASSIC-SPRING, NEURO CLASSIC-SWING, NEURO SWING-CLASSIC and for system ankle joints with plug + go modularity. The NEURO VARIO and NEURO VARIO-CLASSIC system ankle joints can be used as supporting joints for NEURO VARIO-SPRING.

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 system ankle joints have the following functions depending on the used system components:

System Component	Functions	System Joint
adjusting screw	dorsal (posterior adjusting screw): readjustment of the range of motion in plantar flexion	NEURO VARIO-CLASSIC NEURO VARIO
	ventral (anterior adjusting screw): readjustment of the range of motion in dorsiflexion	

System Component	Functions	System Joint
system stirrup which can be adjusted by filing	dorsal: adjustment of the range of motion in plantar flexion by filing the system stirrup along the laser lines	NEURO CLASSIC NEURO VARIO-CLASSIC NEURO VARIO
	ventral: adjustment of the range of motion in dorsiflexion by filing the system stirrup along the laser lines	

4.1 Borggreve Rotationplasty

With the Borggreve rotationplasty, the lower leg and foot are fixed to the thigh rotated by 180°. The ankle joint then assumes the function of the no longer existing knee (fig. 2).

The **NEURO CLASSIC** system ankle joint can be used for this special ortho-prosthesis technique. For this purpose, a special system stirrup, the Borggreve stirrup, is used (fig. 3). It was designed in cooperation with the Department of Orthopaedics of the Heidelberg University.



fig. 2



fig. 3

5. Scope of Delivery

Description	Quantity
system ankle joint (without figure)	1
securing pin (fig. 4) for NEURO VARIO-CLASSIC	1
for NEURO VARIO	2
AGOMET® F330, 5g (fig. 5)	1
orthosis joint grease, 3g (without figure)	1
assembly/lamination dummy (fig. 6)	1

The corresponding system stirrups have to be ordered separately.



fig. 4



fig. 5



fig. 6

6. Load Capacity

The load capacity results from the relevant patient data and 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.

7. Tools for Assembling the System Joint

Tools for all System Joints	System Width				
	10mm	12mm	14mm	16mm	20mm
torque screwdriver 1-6Nm	x	x	x	x	x

Tools for NEURO CLASSIC	System Width				
	10mm	12mm	14mm	16mm	20mm
T8 hexalobular screwdriver/bit	x	-	-	-	-
T15 hexalobular screwdriver/bit	-	x	-	-	-
T20 hexalobular screwdriver/bit	-	x	x	x	x

Tools for NEURO VARIO-CLASSIC	System Width		
	14mm	16mm	20mm
T20 hexalobular screwdriver/bit	x	x	x
slotted screwdriver 3.5 x 0.6 x 100mm	x	-	-
pin punch 3.5 x 0.6mm	x	x	x

Tools for NEURO VARIO	System Width				
	10mm	12mm	14mm	16mm	20mm
T10 hexalobular screwdriver/bit	x	-	-	-	-
T15 hexalobular screwdriver/bit	-	x	-	-	-
T20 hexalobular screwdriver/bit	-	-	x	x	x
pin punch 3.5 x 0.6mm	x	x	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 8.4. The assembly is illustrated with the NEURO VARIO-CLASSIC system ankle joint as an example.



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

8.1 Mounting the System Stirrup

- 1 Before the assembly, clean the thread of the bearing nut and of the joint's upper part as well as the bores of the cover plate with LOCTITE® 7063 Super Clean. Allow the threads to air-dry for 10 minutes.
- 2 Grease the sliding surfaces of the bearing nut with orthosis joint grease.
- 3 Put the bearing nut into the joint's upper part. The bearing nut must be fully inserted in the opening (fig. 7).
- 4 Grease the first sliding washer slightly on both sides with orthosis joint grease.
- 5 Place the sliding washer onto the joint's upper part (fig. 9).
- 6 Mount the system stirrup (fig. 10).

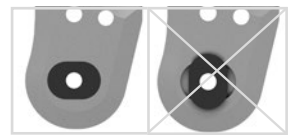


fig. 7

fig. 8

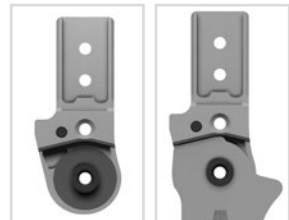


fig. 9

fig. 10

8.2 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 Apply spray adhesive on one side of the second sliding washer and adhere it to the cover plate (fig. 11).
- 2 Grease the other side slightly with orthosis joint grease.
- 3 Place the cover plate onto the system stirrup.
- 4 Screw in the first countersunk flat head screw (axle screw, S1; fig. 13).
- 5 Screw in the second countersunk flat head screw (S2; fig. 14).



fig. 11



fig. 12

8.3 Checking the System Joint's Free Movement

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



fig. 13



fig. 14

8.4 Securing the Screws

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

- 1 Loosen the screws for the cover plate (fig. 14) after checking the system joint's free movement and remove them from the cover plate.
- 2 Apply a small drop of LOCTITE® 243 medium strength to the threads of the screws.
- 3 Secure the screws for the cover plate (fig. 14) 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	12mm	14mm	16mm	20mm
S1 (screw 1, axle screw)	1.5Nm	3Nm	4Nm	4Nm	4Nm
S2 (screw 2)	1.5Nm	3Nm	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

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



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 or plantar flexion can be adjusted by filing the system stirrup (maximum 10°) provided that the system joint has a system stirrup that can be filed (fig. 15). If you file the system stirrup up to the round auxiliary line, the system ankle joint becomes free moving in dorsiflexion or plantar flexion.

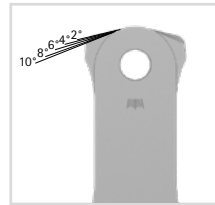


fig. 15



fig. 16

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. 16). To do so, screw 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.

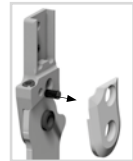


fig. 17

9.2.1 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.

- 1 Unscrew the adjusting screw from the thread (fig. 16).
- 2 Demount the cover plate.
- 3 Drive out the premounted securing pin with a pin punch (fig. 17).
- 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. 18).
- 7 Turn the worn position of the securing pin by about 90° (fig. 19).
- 8 Drive the securing pin from the back into the bore (fig. 20).
- 9 Let the adhesive harden (final strength after approx. 24 hours).



fig. 18



fig. 19



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. Depending on the system joint, one or two additional securing pins are included in the scope of delivery.



fig. 20

9.3 Reading the Joint Angles

There are markings (fig. 21) 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	10mm	12mm	14mm	16mm	20mm
Degree	5°	5°	2°	2°	2°

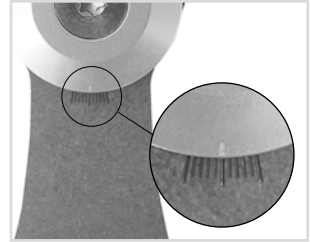


fig. 21

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-CLASSIC	NEURO VARIO-SPRING
NEURO CLASSIC (as supporting joint with corresponding system stirrup)	NEURO CLASSIC-SPRING NEURO SPRING NEURO CLASSIC-SWING NEURO SWING-CLASSIC NEURO VARIO-CLASSIC 2 NEURO VARIO 2 NEURO VARIO-SPRING 2 NEURO VARIO-SWING NEURO SWING NEURO SWING 2 NEURO HiSWING

10.2 Conversion of NEURO VARIO-CLASSIC to NEURO VARIO-SPRING

- 1 Demount the cover plate of the NEURO VARIO-CLASSIC system joint.
- 2 Mount the functional unit of the NEURO VARIO-SPRING system joint in the correct system width (fig. 22).

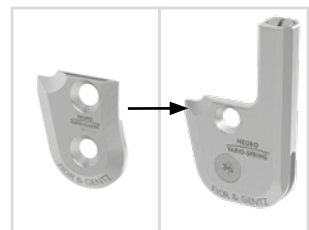


fig. 22

10.3 Conversion of NEURO CLASSIC

As supporting joint, the NEURO CLASSIC system ankle joint can be converted into the main joint if the system stirrup from the main joint has been used.

- 1 Demount the cover plate of the NEURO CLASSIC system joint.
- 2 To convert to system ankle joints with plug + go modularity, you need a longer bearing nut. Use the bearing nut for the conversion to plug + go modularity.
- 3 Mount the functional unit or the cover plate of the main joint in the correct system width (fig. 23).



fig. 23

11. 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 and no play around the axis.

Joint Component	Potential Problem	Measure	Inspection/ Replacement, If Necessary	Latest Replacement
sliding bushing	wear	replacing sliding bushing	every 6 months	every 18 months
sliding washer	wear	replacing sliding washer, see paragraph 11.2	every 6 months	every 18 months
cover plate	wear	replacing cover plate	every 6 months	every 36 months
countersunk flat head screw	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bearing nut	wear	replacing bearing nut	every 6 months	every 36 months
system stirrup	wear or breakage	replacing system stirrup	every 6 months	every 48 months
securing pin	wear	replacing securing pin, see paragraph 9.2.1	every 6 months	not applicable
adjusting screw	wear	replacing adjusting screw	every 6 months	not applicable

Clean the thread of the bearing nut and of the joint's upper part as well as the bores of the cover 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 torque corresponding to the system width and LOCTITE® 243 medium strength during every maintenance (see paragraph 8.4). Remove all adhesive residues first.

11.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport from their orthotist or a qualified/trained expert when the orthosis is handed over. The orthosis must be checked every 6 months 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

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

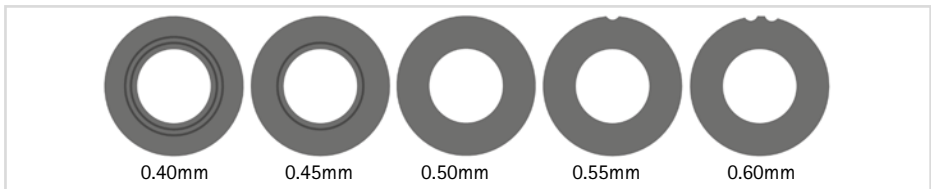


fig. 25

11.3 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.

12. 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 section 11).
- Adhere to the determined maintenance conditions (see paragraph 11).
- Check the wear parts, as required, and exchange them in the defined intervals (see paragraph 11).
- Check the adjustment of the system joint during maintenance and correct it, if necessary (see paragraph 11).
- Check the functionality of the system joint during maintenance (see paragraph 11).
- 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 18).

13. Storage

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

14. Spare Parts

14.1 Exploded View Drawing NEURO VARIO-CLASSIC

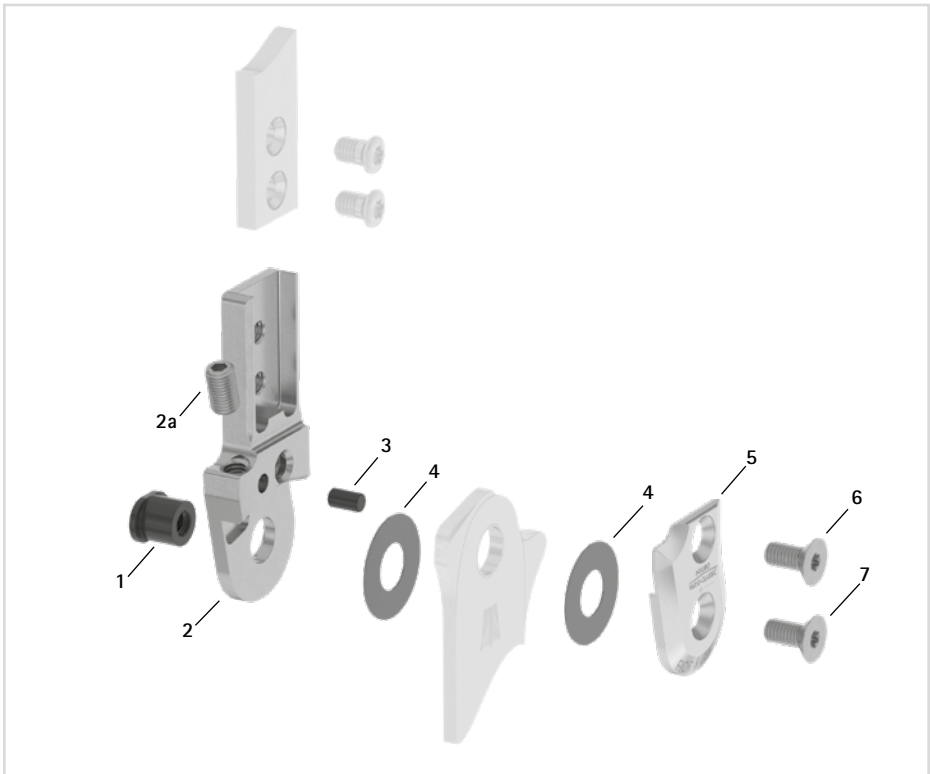


fig. 26

All system stirrups of the system ankle joints are delivered with an integrated sliding bushing.

14.2 Spare Parts for the NEURO CLASSIC System Ankle Joint

The assignment of the items as shown in the exploded view drawing of the NEURO VARIO-CLASSIC system ankle joint serves as guidance. The spare parts of the NEURO CLASSIC system ankle joint are not identical to the picture.

Item	Article Number for System Width					Description
	10mm	12mm	14mm	16mm	20mm	
1	SB6039-L0480	SB7049-L0540	SB8559-L0580	SB9669-L0710	SB1069-L0760	bearing nut
2	SF0310-P/ST	SF0311-P/ST	SF0312-P/ST	SF0313-P/ST	SF0315-P/ST	upper part with feather keys, straight, steel
2	-	SF0311-P/TI	SF0312-P/TI	SF0313-P/TI	SF0315-P/TI	upper part with feather keys, straight, titanium
2	SF0330-P/ST	SF0331-P/ST	SF0332-P/ST	SF0333-P/ST	SF0335-P/ST	upper part with feather keys, bent inwards, steel
2	-	SF0331-P/TI	SF0332-P/TI	SF0333-P/TI	SF0335-P/TI	upper part with feather keys, bent inwards, titanium
2	SF0330-8P/ST	SF0331-8P/ST	SF0332-8P/ST	SF0333-8P/ST	SF0335-8P/ST	upper part with feather keys, bent outwards, steel
2	-	SF0331-8P/TI	SF0332-8P/TI	SF0333-8P/TI	SF0335-8P/TI	upper part with feather keys, bent outwards, titanium
w/o fig.	SF0390-01	SF0391-01	SF0392-02	SF0393-02	SF0395-02	feather key with pin
4	GS1206-*	GS1407-*	GS2009-*	GS2210-*	GS2611-*	sliding washer*
5	SF0160-AL	SF0161-AL	SF0162-AL	SF0163-AL	SF0165-AL	cover plate
6	SC1403-L08	SC1404-L08	SC1405-L10	SC1405-L11	SC1405-L12	countersunk flat head screw with hexalobular socket
7	SC1403-L08	SC1404-L08	SC1405-L10	SC1405-L11	SC1406-L12	countersunk flat head screw with hexalobular socket (axle screw)

* Sliding Washers NEURO CLASSIC

Article Number for System Width				
10mm	12mm	14mm	16mm	20mm
Ø = 12mm	Ø = 14mm	Ø = 20mm	Ø = 22mm	Ø = 26mm
GS1206-040	GS1407-040	GS2009-040	GS2210-040	GS2611-040
GS1206-045	GS1407-045	GS2009-045	GS2210-045	GS2611-045
GS1206-050	GS1407-050	GS2009-050	GS2210-050	GS2611-050
GS1206-055	GS1407-055	GS2009-055	GS2210-055	GS2611-055
GS1206-060	GS1407-060	GS2009-060	GS2210-060	GS2611-060

Bearing Nut for the Conversion to plug + go Modularity

Article Number for System Width				
10mm	12mm	14mm	16mm	20mm
SB6039-L0580	SB7049-L0590	SB8559-L0630	SB9669-L0760	SB1069-L0960

14.3 Spare Parts for the NEURO VARIO-CLASSIC 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)

Item	Article Number for System Width			Description
	14mm	16mm	20mm	
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	SH0262-L/AL	SH0263-L/AL	SH0265-L/AL	cover plate, left lateral or right medial
5	SH0262-R/AL	SH0263-R/AL	SH0265-R/AL	cover plate, left medial or right lateral
6	SC1405-L10	SC1405-L11	SC1405-L12	countersunk flat head screw with hexalobular socket
7	SC1405-L10	SC1405-L11	SC1406-L12	countersunk flat head screw with hexalobular socket (axle screw)

** Sliding Washers NEURO VARIO-CLASSIC			
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	

14.4 Spare Parts for the NEURO VARIO System Ankle Joint

The assignment of the items as shown in the exploded view drawing of the NEURO VARIO-CLASSIC system ankle joint serves as guidance. The spare parts of the NEURO VARIO system ankle joint are not identical to the picture.

Item	Article Number for System Width					Description
	10mm	12mm	14mm	16mm	20mm	
1	SB6034-L0490	SB7049-L0590	SB8559-L0670	SB9669-L0760	SB1069-L0810	bearing nut
2	SF0200-ST	SF0241-ST	SF0242-ST	SF0243-ST	SF0245-ST	upper part, straight, steel (with adjusting screws)
2	-	SF0241-TI	SF0242-TI	SF0243-TI	SF0245-TI	upper part, straight, titanium (with adjusting screws)

Item	Article Number for System Width					Description
	10mm	12mm	14mm	16mm	20mm	
2	SF0220-ST	SF0281-ST	SF0282-ST	SF0283-ST	SF0285-ST	upper part, bent, steel (with adjusting screws)
2	-	SF0281-TI	SF0282-TI	SF0283-TI	SF0285-TI	upper part, bent, titanium (with adjusting screws)
2a	SC9604-L06ST	SC9604-L06ST	SC9605-L08ST	SC9606-L10ST	SC9606-L10ST	adjusting screw
3	GS4007	GS4007	GS4007	GS4007	GS4007	securing pin
4	GS1206-***	GS1407-***	GS1609-***	GS2210-***	GS2611-***	sliding washer***
5	SF0260-AL	SF0261-AL	SF0262-AL	SF0263-AL	SF0265-AL	cover plate
6	SC1403-L08	SC1404-L08	SC1405-L11	SC1405-L11	SC1405-L12	countersunk flat head screw with hexalobular socket
7	SC1403-L08	SC1404-L08	SC1405-L11	SC1405-L11	SC1406-L12	countersunk flat head screw with hexalobular socket (axle screw)

*** Sliding Washers NEURO VARIO

Article Number for System Width				
10mm	12mm	14mm	16mm	20mm
Ø = 12mm	Ø = 14mm	Ø = 16mm	Ø = 22mm	Ø = 26mm
GS1206-040	GS1407-040	GS1609-040	GS2210-040	GS2611-040
GS1206-045	GS1407-045	GS1609-045	GS2210-045	GS2611-045
GS1206-050	GS1407-050	GS1609-050	GS2210-050	GS2611-050
GS1206-055	GS1407-055	GS1609-055	GS2210-055	GS2611-055
GS1206-060	GS1407-060	GS1609-060	GS2210-060	GS2611-060

15. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 27). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.



fig. 27



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

16. Signs and Symbols



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



medical device



article number



manufacturer



batch code



follow the instructions for use



single patient – multiple uses



Unique Device Identifier – product identification number

17. 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.

18. 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 according to the configuration result from 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.

All rights, particularly the distribution, copy and translation of these instructions for use or any part of it, must be authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädie-technischen Systemen mbH. Reprints, copies and any other electronic reproduction, even partial, must be authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädiotechnischen Systemen mbH.

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19. 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	

20. 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 _____ - _____

