FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology System Ankle Joints

EN

NEURO SWING Carbon

NEURO CLASSIC Carbon

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1. Information

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

For a simplified illustration, all basic work steps are shown with the **NEURO SWING Carbon** 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 qualified specialist in orthopaedic technology 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 possible dangers, especially with regards to 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 Loosening of the Bearing Nut
Secure the screw of the joint case 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

Risk of Falling Due to Excessive Readjustment of the Spring Unit
Adjust the spring unit according to the information in these instructions for use. Do not make readjustments of more than 10°. Use the laser markings on the system stirrup and the joint case to check the readjustment.

⚠ 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

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 Due to Incorrectly Adjusted Spring Units
Screw in the spring unit up to the system stirrup and do not preload the spring unit. If the stops are reached too early or too late, either the range of motion is restricted or the patient is not sufficiently stabilised by the orthosis, which worsens the gait. In order to utilise the full functional potential of the orthosis, the spring units must be suitably selected and correctly adjusted.

⚠ WARNING

Jeopardising the Therapy Goal Due to Loosening of the Spring Unit
Do not grease the spring unit and the O-ring, neither intentionally nor accidentally.

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 joint 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 ankle joints must be used exclusively for the orthotic treatment of the lower extremity. The system joints are only allowed to be used for producing an AFO or 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.

All system ankle joints can also be used in complement to a prosthetic treatment of patients with partial foot amputations. For this purpose, the orthosis produced for the patient by a qualified specialist in orthopaedic technology (custom-made product) is combined with a foot prosthesis. Further information can be found in the **Guide to Partial Foot Amputations** (see QR code, fig. 2).

fig. 2

Furthermore, all system ankle joints can be used for the treatment of patients with peripheral arterial disease (PAD). For this purpose, the orthosis produced for the patient by a qualified specialist in orthopaedic technology (custom-made product) is combined with a foot orthotic. Further information can be found in the **PAD Guide** (see QR code, fig. 3).

fig. 3

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 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.

The carbon system ankle joints are water-resistant and therefore suitable for use in wet areas. They are equipped with a water-resistant carbon fibre reinforced joint case and a seawater-resistant stainless steel screwing. The **NEURO SWING Carbon** also has spring units which are inside water- and dirt-resistant spring unit sleeves. The spring units of the system joint are waterproof in depths of up to 3 metres. The system joints can be used at a maximum temperature of +60°C.

3.6 Product Range

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

NEURO SWING Carbon

NEURO CLASSIC Carbon

3.7 Combination Possibilities with Other System Joints

The carbon system ankle joints can be mounted in combination with carbon system knee joints from the FIOR & GENTZ product range in a water-resistant orthosis. The combination with other system knee joints from the FIOR & GENTZ product range is also possible. The **NEURO CLASSIC Carbon** can be used as a supporting joint for the **NEURO SWING Carbon**.

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

Due to the spring units used, the **NEURO SWING Carbon** system ankle joint has the following functions:

System Component	Function
spring units	**dorsal (posterior spring unit):** - determination of the maximum range of motion in plantar flexion - integrated dorsiflexion assist - controlled lowering of the foot during loading response
	ventral (anterior spring unit): - determination of the maximum range of motion in dorsiflexion - increased energy return during heel lift to support push off
	ventral (static dorsiflexion stop): - limitation of the maximum range of motion in dorsiflexion
	dorsal and ventral: - dynamically bringing the patient from a bent into an upright position as well as improving the patient's stability while walking and standing by balancing the body

5. Scope of Delivery

Description	Quantity
system ankle joint (without figure)	1
set 2-component adhesive with primer (fig. 4)	1
orthosis joint grease, 3g (without figure)	1
assembly/lamination dummy (fig. 5)	1

The corresponding spring units and system stirrups have to be ordered separately.

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	System Width					
	10mm	12mm	14mm	16mm	20mm	24mm
T10 hexalobular screwdriver/bit	x	-	-	-	-	-
T15 hexalobular screwdriver/bit	-	x	-	-	-	-
T20 hexalobular screwdriver/bit	-	-	x	x	x	-
T30 hexalobular screwdriver/bit	-	-	-	-	-	x
torque screwdriver, 1–6Nm	x	x	x	x	x	x
hexagonal screwdriver with spherical head, 3 x 100mm	x	-	-	-	-	-
hexagonal screwdriver with spherical head, 4 x 100mm	-	x	-	-	-	-
hexagonal screwdriver with spherical head, 5 x 100mm	-	-	x	x	x	x
sliding washer centring pin, two parts	x	x	x	x	x	x
diagonal cutters	-	-	-	-	-	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 the screw with the torque specified in paragraph 8.4.

You can find more information on the assembly in the online tutorial **Joint Assembly NEURO CLASSIC Carbon, NEURO SWING Carbon** (see QR code, fig. 6) on the FIOR & GENTZ website.

In the following, the assembly is illustrated with the **NEURO SWING Carbon** system ankle joint as an example.

fig. 6

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 with LOCTITE® 7063 Super Clean. Allow the thread to air-dry for 10 minutes.
2 Grease the sliding surfaces of the bearing nut and, if existing, the contact surfaces of the system stirrup between system stirrup and spring units with orthosis joint grease.

fig. 7

Greasing the contact surfaces of the system stirrup is important in order to prevent wear of the system stirrup.

fig. 8

3 Grease the two sliding washers **slightly** on both sides with orthosis joint grease.
4 Place the sliding washers onto both sides of the system stirrup (fig. 7).
5 Slide the system stirrup from below into the joint case (fig. 8). Make sure that the sliding washers remain in the correct position. To do so, use the sliding washer centring pin.

fig. 9

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

6 Put the bearing nut into the joint case. The bearing nut must be fully inserted in the opening (fig. 9).
7 Place the cover disc onto the joint case's front.
8 Screw in the countersunk flat head screw (S1; fig. 10).

fig. 10

8.2 Checking the Free Movement

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

8.3 Mounting the Spring Units **NEURO SWING Carbon**

For the **NEURO CLASSIC Carbon** system ankle joint, skip these steps and continue the assembly at paragraph 8.4.

The spring unit and the O-ring (if existing) for the **NEURO SWING Carbon** system ankle joint must not be greased, neither intentionally nor accidentally.

Before mounting the spring unit, make sure that the workspace and your fingers as well as the spring unit, O-ring (if existing) and spring duct are grease-free. If necessary, degrease everything.

1 Screw the spring unit for dorsiflexion or the static dorsiflexion stop into the anterior spring duct until the required alignment of the orthosis is achieved (fig. 11).
2 Screw the spring unit for plantar flexion into the posterior spring duct until it touches the system stirrup. Do not preload the spring unit.
3 Position the spring unit covers as described in paragraph 9.

fig. 11

Do not disassemble the spring unit as it is under pressure. There is a risk of injury when opening the spring unit sleeve.

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 screw for the joint case (fig. 10) after checking the free movement and remove it from the joint case.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screw.
3 Secure the screw for the joint case (fig. 10) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

Screw for Joint Case	System Width					
	10mm	12mm	14mm	16mm	20mm	24mm
S1 (screw 1, axle screw)	2.5Nm	3Nm	4Nm	4Nm	4Nm	6Nm

The screw of the joint case is not secured with the necessary torque at delivery. You can also find information on the torque on the cover disc of the system joint.

9. Adjustment Options on the Orthosis

The orthosis can be individually adapted to the patient's needs with adjustable system ankle joints (fig. 12). The adjustments described do not influence each other and can be made independently of each other.

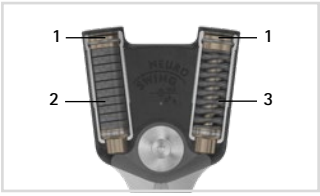

fig. 12

Mind the correct adjustment of the dorsiflexion stop when mounting the system ankle joint. It is decisive for the entire alignment of the orthosis. You can find more information on this in the online tutorial **AFO Alignment Guidelines** (see QR code, fig. 13) on the FIOR & GENTZ website.

fig. 13

NEURO SWING Carbon 24mm:
Once all adjustments to the **NEURO SWING Carbon** system ankle joint in the 24mm system width have been completed, and before handing the orthosis over to the patient, use a hexagon screwdriver with spherical head to adjust the spring units so that the position of the hexagon socket drive on the spring units aligns with the recess in the spring unit cover. Insert the hexagonal pins into the spring units. Place the spring unit covers with the marking facing the system anchor over the hexagonal pins and fully onto the spring units. Now, you can cut off the protruding end of the hexagonal pins with diagonal cutters (fig. 14). For visual purposes, you can then insert the hexagonal pins into the spring units with the cut end facing downwards. To remove the spring unit covers later, insert a small slotted screwdriver on the side of the system joint between the joint case and the spring unit cover.

fig. 14

9.1 Adjustments on the Spring Unit NEURO SWING Carbon

There are spring units with disc springs (2) and coil springs (3). The alignment of the orthosis can be adjusted by screwing and unscrewing the spring units (1) (fig. 12). The spring force can be changed with spring units in different strengths.

9.1.1 Adjustable Alignment **NEURO SWING Carbon**

Always unscrew only one spring unit at a time to adjust the angle between lower leg and foot (fig. 15). Only then, screw in the other spring unit until it touches the system stirrup. Do not preload the spring unit as this will restrict the maximum possible range of motion. For the system widths of 10, 12, 14, 16 and 20mm, an O-ring is placed on the external thread of the spring unit to ensure that the position of the spring unit does not change. For the 24mm system width, this is ensured by a hexagonal pin and a spring unit cover.

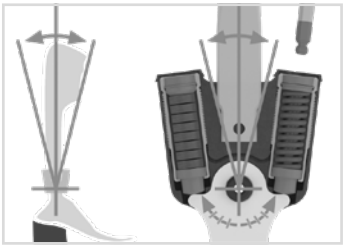

fig. 15

9.1.2 Variable Spring Force **NEURO SWING Carbon**

The spring force can be changed by exchanging the spring units. Insert a spring unit into the spring duct that corresponds with the required spring force. There are five spring units with spring forces ranging from normal to extra strong (fig. 16). The static dorsiflexion stop (fig. 16) does not have any dynamic properties (0° range of motion). Note that the spring unit as well as the static dorsiflexion stop determine the maximum possible range of motion.

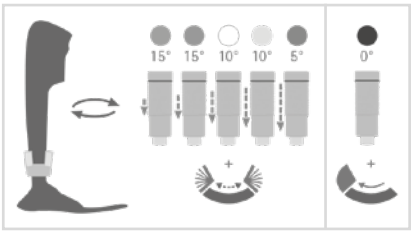

fig. 16

9.2 Reading the Joint Angles

There are markings (fig. 17) on the joint case and the system stirrup 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 joint angle in the individual normal posture must not be outside the degree markings.

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

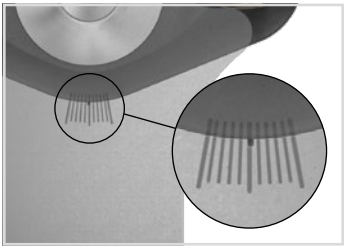

fig. 17

Degree Marking						
System Width	10mm	12mm	14mm	16mm	20mm	24mm
Degree	5°	5°	2°	2°	2°	2°

10. Connecting to the System Side Bar/System Anchor

The system side bar/system anchor must be adhered to the system joint according to the recommended production technique (fig. 18). It is adhered after the orthosis parts have been tempered. Before using the adhesive set, make sure that the expiry date has not yet passed. The adhesive set should be stored in a cool place.

fig. 18

Note that the orthosis should not be tempered after connecting the system side bar/system anchor to the system joint. The properties of the adhesive connection change at temperatures that are too high.

You can find more information in the **Instructions for Use for Qualified Specialists in Orthopaedic Technology System Side Bars and System Anchors for Carbon System Joints** (see QR code, fig. 19). You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

fig. 19

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	Recommended Inspection, Potential Replacement*	Latest Replacement
O-ring for securing the spring unit and the static dorsiflexion stop	wear	replacing O-ring	every 6 months	every 18 months
spring unit	wear	replacing spring unit	every 6 months	every 18 months
	noise of spring unit	replacing spring unit	every 6 months	every 18 months
sliding washer	wear	replacing sliding washer, see paragraph 11.2	every 6 months	every 18 months
sliding bushing	wear	replacing sliding bushing	every 6 months	every 18 months
countersunk flat head screw with hexalobular socket	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bearing nut	wear or breakage	replacing bearing nut	every 6 months	every 48 months
system stirrup	wear or breakage	replacing system stirrup	every 6 months	every 48 months
joint case	wear or breakage	replacing joint case	every 6 months	every 48 months
spring unit cover	wear	replacing spring unit cover	every 6 months	if required
hexagonal pin	wear	replacing hexagonal pin	every 6 months	if required
adhesive bond (system side bar/ system anchor and system joint)	breakage of adhesive bond	adhering new carbon joint component	every 6 months	if required

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

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

Secure the screw for the joint case with the appropriate torque and LOCTITE® 243 medium strength at every maintenance (see paragraph 8.4). Remove all adhesive residues first.

When disassembling the system joint, make sure to fix the bearing nut on the backside with one finger while unscrewing the screw. This prevents the bearing nut from slipping out of the opening and damaging the material of the joint case.

fig. 20

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 20) on the FIOR & GENTZ website.

11.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport (fig. 21) 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. 21

11.2 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS1911-**040** is 0.40mm thick). Each thickness has a different marking (fig. 22). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use. Please use the sliding washer centring pin to position the sliding washers.

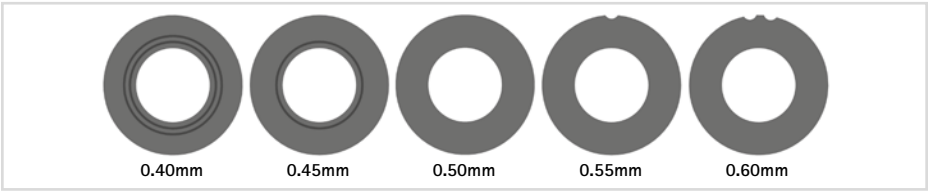

fig. 22

11.3 Dirt Removal

The system ankle joint is suited for use in wet areas. Nevertheless, dirt must be removed when necessary and during regular maintenance. For this purpose, disassemble the system joint - but not the spring units (if existing) - and clean the soiled parts as well as, if existing, the spring unit sleeves with a dry cloth.

In order to optimise the lifespan, we recommend rinsing the orthosis with clear tap water, especially after using it in salt water, chlorine water and sand.

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 paragraph 11).
- Adhere to the determined maintenance conditions (see paragraph 11).
- Check the wear parts, as required, and exchange them at 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 water-resistant system joints can be affected by use in salt water, chlorine water or sand. After use in salt water, chlorine water or sand, rinse the system joint with clear tap water. Instruct the patient accordingly.

- 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 SWING Carbon**

The exploded view drawing of the **NEURO SWING Carbon** system ankle joint also serves as an exemplary illustration for the **NEURO CLASSIC Carbon** system ankle joint.

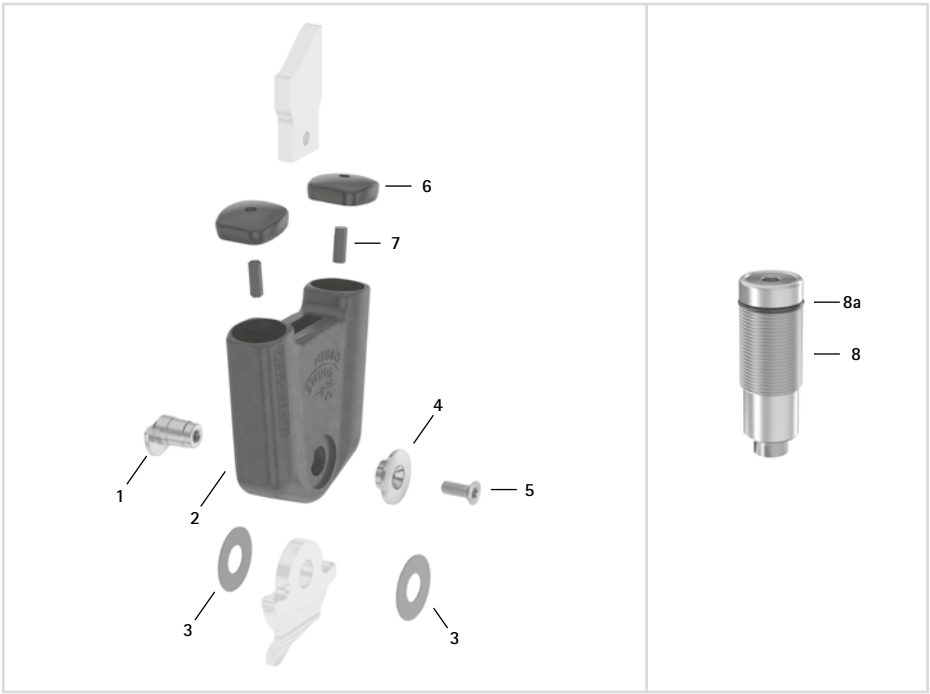

fig. 23

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

14.2 Spare Parts for All System Ankle Joints

Item	Article Number for System Width						Description
	10mm	12mm	14mm	16mm	20mm	24mm	
1	SF0590-C/1	SF0591-C/1	SF0592-C/1	SF0593-C/1	SF0595-C/1	SF0597-C/1	bearing nut
3	GS1207-*	GS1409-*	GS1911-*	GS2413-*	GS2815-*	GS3013-*	sliding washer*
4	SF0590-C/2	SF0591-C/2	SF0592-C/2	SF0593-C/2	SF0595-C/2	SF0597-C/2	cover disc
5	SC1403-L08	SC1404-L10	SC1405-L11	SC1406-L14	SC1406-L14	SC1416-L16	countersunk flat head screw with hexalobular socket

* Sliding Washers					
Article Number for System Width					
10mm	12mm	14mm	16mm	20mm	24mm
Ø = 12mm	Ø = 14mm	Ø = 19mm	Ø = 24mm	Ø = 28mm	Ø = 30mm
GS1207-040	GS1409-040	GS1911-040	GS2413-040	GS2815-040	GS3013-040
GS1207-045	GS1409-045	GS1911-045	GS2413-045	GS2815-045	GS3013-045
GS1207-050	GS1409-050	GS1911-050	GS2413-050	GS2815-050	GS3013-050
GS1207-055	GS1409-055	GS1911-055	GS2413-055	GS2815-055	GS3013-055
GS1207-060	GS1409-060	GS1911-060	GS2413-060	GS2815-060	GS3013-060

14.3 Spare Parts for the **NEURO SWING Carbon** System Ankle Joint

Item	Article Number for System Width						Description
	10mm	12mm	14mm	16mm	20mm	24mm	
2	SF0500-C	SF0501-C	SF0502-C	SF0503-C	SF0505-C	SF0507-C	joint case
6	-	-	-	-	-	SF0597-C/4/1	spring unit cover
7	-	-	-	-	-	SF0597-C/4/0	hexagonal pin

14.4 Spring Units and Static Dorsiflexion Stop **NEURO SWING Carbon**

Item	Article Number for System Width						Description
	10mm	12mm	14mm	16mm	20mm	24mm	
8	SF5800-C/15/02	SF5801-C/15/03	SF5802-C/15/05	SF5803-C/15/07	SF5805-C/15/18	SF5807-C/15/12	spring unit, blue, normal, max. 15° range of motion
8	SF5800-C/15/04	SF5801-C/15/06	SF5802-C/15/11	SF5803-C/15/15	SF5805-C/15/25	SF5807-C/15/25	spring unit, green, medium, max. 15° range of motion
8	SF5800-C/10/06	SF5801-C/10/12	SF5802-C/09/16	SF5803-C/10/21	SF5805-C/10/40	SF5807-C/10/53	spring unit, white, strong, max. 10° range of motion
8	SF5800-C/10/09	SF5801-C/10/19	SF5802-C/10/29	SF5803-C/10/31	SF5805-C/10/60	SF5807-C/10/80	spring unit, yellow, very strong, max. 10° range of motion
8	SF5800-C/05/17	SF5801-C/05/33	SF5802-C/05/53	SF5803-C/05/63	SF5805-C/05/99	SF5807-C/05/99	spring unit, red, extra strong, max. 5° range of motion
8	-	-	-	SF5803-C/0	SF5805-C/0	SF5807-C/0	static dorsiflexion stop, black, 0° range of motion
8a	VE3771-070/12	VE3771-085/13	VE3771-100/12	VE3771-12/12	VE3771-140/15	-	O-ring for securing the spring unit and the static dorsiflexion stop

14.5 Spare Parts for the **NEURO CLASSIC Carbon** System Ankle Joint

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

Item	Article Number for System Width	Description
	16mm	
2	SF0103-C	joint case

15. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 24). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 24

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

MD — medical device

REF — article number

manufacturer

LOT — batch code

SN — serial number

follow the instructions for use

single patient – multiple uses

UDI — Unique Device Identifier – product identification number

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 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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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 qualified specialist in orthopaedic technology made sure that the instructions for use for patients as well as the orthosis service passport were also handed over with the orthosis to the patient, parents or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to the patient in detail. The next maintenance appointment was entered in the orthosis service passport. The patient was asked to bring the orthosis service passport along to every maintenance appointment.

Leg Side

☐ left ☐ right

Mounted Sliding Washers

1. GS _____ - _____

2. GS _____ - _____

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