FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology System Knee Joint

EN

NEURO CLASSIC H_2O

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.

2. Safety Instructions

2.1 Classification of the Safety Instructions

⚠ **DANGER**	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ **WARNING**	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ **CAUTION**	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

All serious incidents according to Regulation (EU) 2017/745 which are related to the product have to be reported to the manufacturer and to the competent authority of the Member State in which the qualified specialist in orthopaedic technology and/or the patient is established.

2.2 All Instructions for a Safe Handling of the System Knee Joint

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Advise the patient to gather information about all safety and security issues before driving a motor vehicle with orthosis. The patient should be able to drive a motor vehicle safely.

⚠ WARNING

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

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 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 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 Loosened Bearing Nuts
Secure the screw of the bearing nut 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 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 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

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.

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 joint 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 **NEURO CLASSIC Carbon** system knee joint must be used exclusively for the orthotic treatment of the lower extremity. The system joint is only allowed to be used for producing a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg. The system joint may only be used for one fitting and must not be reused.

3.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities when standing and walking that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/malfunctions or as a result of neurological disorders (such as stroke or PAD), physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. An evaluation regarding the safe handling of the orthosis by the patient must be carried out.

3.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 3.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis, for example after amputations of leg segments.

3.4 Qualification

The system joint must only be handled by a qualified specialist in orthopaedic technology.

3.5 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing, parachuting and football, is excluded. The **NEURO CLASSIC Carbon** system knee joint is water-resistant and therefore suitable for use in wet areas. It is equipped with a water-resistant carbon fibre reinforced joint case and a seawater-resistant stainless steel screwing. The system joint can be used at a maximum temperature of +60°C.

3.6 Combination Possibilities with Other System Joints

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

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 **NEURO CLASSIC Carbon** is a free moving, monocentric system knee joint. The system knee joint is preassembled at an angle of 5°, corresponding to a physiological knee joint angle.

The system joint has an integrated posterior offset (fig. 1).

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

fig. 1

5. Scope of Delivery

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

fig. 2

fig. 3

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		
	14mm	16mm	20mm
T8 hexalobular screwdriver/bit	x	x	x
T15 hexalobular screwdriver/bit	x	-	-
T20 hexalobular screwdriver/bit	-	x	x
torque screwdriver, 1–6Nm	x	x	x
sliding washer centring pin	x	x	x

8. Mounting the System Joint

The system joint is delivered fully assembled. All functions are checked beforehand. You have to disassemble the system joint for mounting it to the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure 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 LOCK Carbon** (see QR code, fig. 4) on the FIOR & GENTZ website.

fig. 4

When mounting the system joint, mind the correct basic alignment of the orthosis as it is essential for the later function of the orthosis. You can find more information on this in the online tutorial **KAFO Alignment Guidelines** (see QR code, fig. 5) on the FIOR & GENTZ website.

fig. 5

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

8.1 Mounting the Extension Stop

1 Stick the cheese head screw (1; fig. 6) into the extension stop (2).
2 Place the coil spring (3) onto the cheese head screw (1).
3 Screw the sub-assembly into the joint's lower part.

fig. 6

8.2 Mounting the Joint's Lower Part

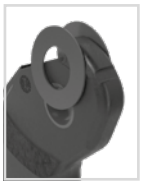
fig. 7

fig. 8

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 two sliding washers **slightly** on both sides with orthosis joint grease.
3 Place the sliding washers on both sides of the joint's lower part. Do not place the sliding washers centrally, but slightly above the bore (fig. 7).
4 Slide the joint's lower part from below into the joint's upper part (fig. 8). Make sure that the sliding washers are centred correctly (fig. 9). To do so, use the sliding washer centring pin.
5 Grease the axle bore of the joint axis and the sliding surfaces of the bearing nut **with a drop** of orthosis joint grease.
6 Put the bearing nut into the opening of the joint's upper part. Make sure that the cut-outs of the bearing nut and the joint's upper part match (fig. 10). The bearing nut must be fully inserted in the opening.

fig. 9

fig. 10

7 Place the cover disc onto the front of the joint's upper part. The cover disc must be fully inserted in the opening. Make sure that the cut-outs of the cover disc and the joint's upper part match.
8 Screw in the countersunk flat head screw (S1; fig. 11).

fig. 11

8.3 Checking the Free Movement

Tighten the screw for the joint's upper part 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.

8.4 Securing the Screws

The screw is 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's upper part (fig. 11) after checking the free movement and remove it from the joint's upper part.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screw.
3 Secure the screw for the joint's upper part (fig. 11) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

Screw for Joint's Upper Part	System Width		
	14mm	16mm	20mm
S1 (screw 1)	3Nm	4Nm	4Nm

The screw for the joint's upper part 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. Notes on the Production of the Orthosis

9.1 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. 12). 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. 12

Note that the orthosis must 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. 13). You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

fig. 13

10. Conversion of the Orthosis with NEURO CLASSIC Carbon System Knee Joint

An orthosis with a **NEURO CLASSIC Carbon** system knee joint can be converted into an orthosis with a **NEURO LOCK Carbon** system knee joint by exchanging the system joint.

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.

Joint Component	Potential Problem	Measure	Recommended Inspection, Potential Replacement*	Latest Replacement
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
extension stop	wear or breakage	replacing extension stop	every 6 months	every 48 months
joint's upper part	wear or breakage	replacing joint's upper part	every 6 months	every 48 months
joint's lower part	wear or breakage	replacing joint's lower part	every 6 months	every 48 months
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's upper part 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.

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 14) on the FIOR & GENTZ website.

fig. 14

11.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport (fig. 15) 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. 15

11.2 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS2413-**040** is 0.40mm thick). Each thickness has a different marking (fig. 16). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

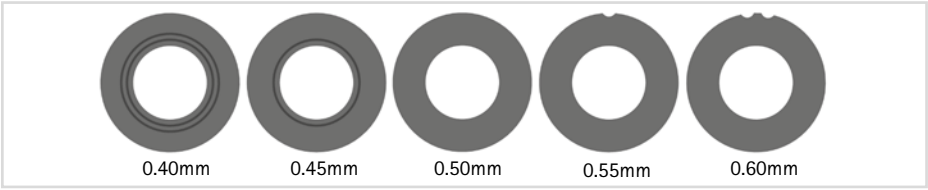

fig. 16

11.3 Dirt Removal

The **NEURO CLASSIC Carbon** system knee 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 and clean the soiled system components 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 CLASSIC Carbon**

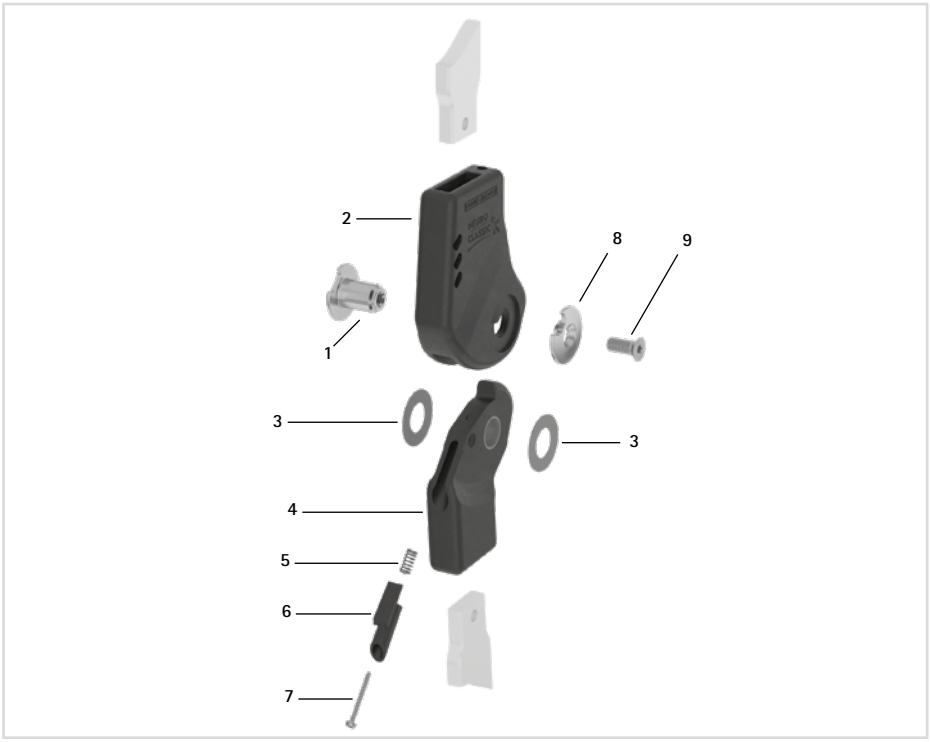

fig. 17

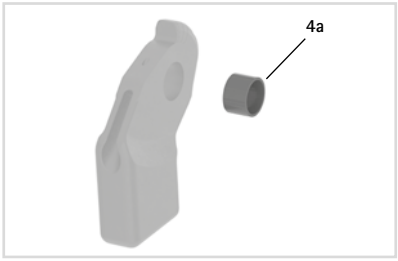

fig. 18

14.2 Spare Parts for the **NEURO CLASSIC Carbon** System Knee Joint

Item	Article Number for System Width			Description
	14mm	16mm	20mm	
1	SK0892-1/C	SK0893-1/C	SK0895-1/C	bearing nut
2	SL0102-C	SL0103-C	SL0105-C	upper part, straight, carbon
3	GS2009-*	GS2311-*	GS2413-*	sliding washer*
4	SK0812-2/C	SK0813-2/C	SK0815-2/C	5° lower part with sliding bushing, straight, carbon-titanium hybrid
4a	BP1009-L059	BP1211-L077	BP1412-L090	sliding bushing
5	FE1510-02	FE1510-02	FE1510-02	coil spring
6	SK9802-E005/C	SK9803-E005/C	SK9805-E005/C	5° extension stop
7	SC4402-L22	SC4402-L22	SC4402-L22	cheese head screw
8	SK0892-2/C	SK0893-2/C	SK0895-2/C	cover disc
9	SC1404-L10	SC1405-L14	SC1406-L14	countersunk flat head screw with hexalobular socket

* Sliding Washers		
Article Number for System Width		
14mm	16mm	20mm
Ø = 20mm	Ø = 23mm	Ø = 24mm
GS2009-040	GS2311-040	GS2413-040
GS2009-045	GS2311-045	GS2413-045
GS2009-050	GS2311-050	GS2413-050
GS2009-055	GS2311-055	GS2413-055
GS2009-060	GS2311-060	GS2413-060

15. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 19). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 19

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

serial number

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 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 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 Washers

1. GS _____ - _____

2. GS _____ - _____

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CE

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