FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology
System Side Bars and System Anchors for Carbon System Joints

EN

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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 Side Bars/System Anchors

⚠ WARNING

Risk of Falling Due to Improper Handling
Inform the patient about the correct use of the system joint and possible dangers (e.g. breakage of the system side bar/system anchor), especially with regards to excessive mechanical stress (e.g. due to sports, increased activity or weight gain).

⚠ WARNING

Risk of Falling Due to Improper Processing
Process the system side bar/system anchor according to the information in these instructions for use. Deviating processing and modifications of the system joint require the written consent of the manufacturer. Errors in processing can lead to breakage of the system side bar/system anchor or other system components. Pay particular attention to:
- adhering the system side bar/system anchor into the system joint according to the production technique;
- correctly connecting the system anchor with the laminate of the orthosis and
- not grinding the widened area of the system side bar/system anchor.

⚠ 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 and the system components, plan the treatment again and, if necessary, produce a new orthosis.

⚠ WARNING

Risk of Falling Due to Improper Processing
Errors in processing can lead to breakage of the system side bar/system anchor. Bend the system side bar/system anchor as described in these instructions for use. Pay particular attention to:
- **not** heating the system side bar/system anchor for bending;
- respecting the specified bending radius and
- removing notches or residues by fine smoothing and finishing.

⚠ WARNING

Risk of Falling Due to Lack of Corrosion Protection
A system side bar that is not embedded into the laminate requires additional corrosion protection. Apply this to the system side bar after mechanical processing.

NOTICE

Limitation of the Function Due to Lack of Maintenance
Respect the specified maintenance intervals in order to avoid system joint and system component dysfunction. Also inform the patient about the maintenance appointments to be respected.

3. Use

3.1 Intended Use

The FIOR & GENTZ system side bars and system anchors are connecting elements for orthotic treatments of the lower extremity. The system side bar for carbon system joints is used for adhering and riveting/screwing to the orthosis shells. The bands of a side bar shell orthosis are attached to the system side bars. The system anchor for carbon system joints connects the system joint to the shell of a laminated orthosis. The system side bar/system anchor must be attached to a carbon system joint in the corresponding system width and with the corresponding production technique. A system side bar or a system anchor 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 Qualification

The system side bar/system anchor must only be handled by a qualified specialist in orthopaedic technology.

3.4 Application

All FIOR & GENTZ system side bars and system anchors were developed for orthoses 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.

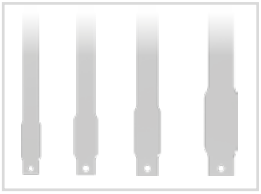

fig. 2

4. Scope of Delivery

Description	Quantity
system side bar (fig. 2)	1
system anchor (fig. 3 and 4)	1

For the **NEURO SWING Carbon** and **NEURO CLASSIC Carbon** system ankle joint as well as for the **NEURO LOCK Carbon** and **NEURO CLASSIC Carbon** system knee joint, system side bars are available in a straight and a bent shape (fig. 2).

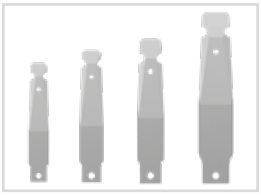

fig. 3

For the **NEURO SWING Carbon** and **NEURO CLASSIC Carbon** system ankle joint, system anchors are available in a straight and a bent shape (fig. 3). For the **NEURO LOCK Carbon** and **NEURO CLASSIC Carbon** system knee joint, system anchors are available in the shapes straight, bent as well as calf curved left/right (fig. 4). The adhesive set (fig. 5) for adhering the system side bar/system anchor into the system joint consists of a 2-component adhesive and a primer. It is included in the scope of delivery of the system joint and can be reordered separately (see paragraph 10).

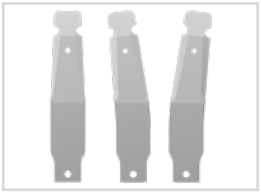

fig. 4

5. Load

fig. 5

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.

6. Processing

The system side bar/system anchor must be adapted to the individual shape of the leg. To ensure an optimal functioning of the system side bar/system anchor, note the following explanations on the production techniques and the processing steps.

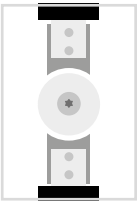

fig. 6

Side Bar Shell Technique

The system side bars for carbon system joints can be processed using a production technique of your choice.

Anchor Lamination Technique

The system anchors for carbon system joints were developed by FIOR & GENTZ for the production of a laminated orthosis using the Anchor Lamination Technique (fig. 6). In this production technique, the system anchor is embedded into the laminate.

You can find more information on the Anchor Lamination Technique in the online tutorial **KAFO with Carbon System Joints in Anchor Lamination Technique** (see QR code, fig. 7) on the FIOR & GENTZ website.

fig. 7

6.1 Bending

- Do not use a hammer to bend the system side bar/system anchor.
- In order to avoid notches, use a bending iron with round edges for bending the system side bar/system anchor (fig. 8). Both bending irons with straight edges and with curved edges can easily cause breakage of the system side bar/system anchor.
- Bending is a cold working technique. Do not heat the material since the material's characteristics can change permanently.
- Do not alternate the bending direction repeatedly as this compacts the material and makes it brittle, which can lead to breakage.
- To avoid fractures when bending the system side bar/system anchor, make sure not to fall below the radii given in the table (fig. 9). The bending radius depends on the thickness of the material (see table).

fig. 8

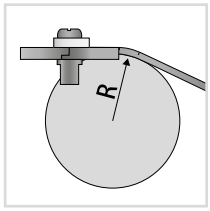

fig. 9

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

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

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

6.2 Processing the Surface

Before connecting the system side bar/system anchor to the system joint, remove notches and other residues from the surface. Smooth and finish the surface in direction of rolling (fig. 10). Make sure that you do not remove too much material.

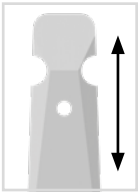

fig. 10

6.3 Adhering

The system side bars/system anchors for carbon system joints are connected to the system joint by adhering them into the system joint.

1 Clean the system side bar/system anchor and the system joint.
2 Apply the primer to the adhesive surfaces for the system side bar/system anchor in the system joint and the system side bar/system anchor by using the cotton swab from the adhesive set (fig. 11–12).
3 Let the primer flash off completely.

fig. 11

fig. 12

Before injecting the 2-component adhesive into the system joint, press about 2cm of adhesive on a piece of paper until the colour is uniform.

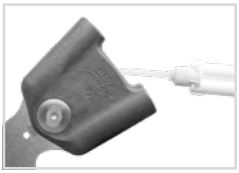

fig. 13

4 Inject a sufficient amount of the 2-component adhesive into the system joint by using the set's dual-chamber syringe (fig. 13).
5 Immediately stick the system side bar/system anchor as far as possible into the system joint (fig. 14).
6 Let the adhesive harden for 24 hours until the final strength is reached.
7 Remove the removable sticker and any adhesive residues from the system joint.

fig. 14

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.

7. Maintenance

All system side bars and system anchors should be checked regularly for wear and damage as part of the maintenance of the system joint and be replaced if necessary.

Joint Component	Potential Problem	Measure	Recommended Inspection, Potential Replacement*	Latest Replacement
system side bar	wear or breakage	replacing system side bar	every 6 months	if required
system anchor	wear or breakage	replacing system anchor	every 6 months	if required

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

8. Period of Use

To guarantee an unlimited period of use of the system side bars and system anchors, you must adhere to the following conditions:

- Adhere to the specified maintenance conditions for system side bars and system anchors (see paragraph 7).
- Note the correct construction of the orthosis and a regular maintenance of the system joint. An incorrect construction as well as an improper maintenance can reduce the period of use of the system side bars and system anchors.
- The period of use of the system side bars and system anchors ends with the period of use of the custom-made product (orthosis).

9. Storage

It is recommended to store the system side bar/system anchor in its original packaging until the custom-made product is produced.

10. Accessory Parts

The amount of the 2-component adhesive and the primer from the adhesive set is sufficient to adhere a system side bar/system anchor into a system joint. If required, you can reorder the adhesive set.

Adhesive Set		
Article Number	Content	Description
KL1110	2.5mg adhesive component A and B each 2.5ml primer cotton swab for applying the primer	set 2-component adhesive and primer

11. Disposal

Dispose of the system side bar/system anchor for carbon system joints properly. The product must not be disposed of with the residual waste (fig. 15). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 15

For proper disposal, it is necessary to remove the system side bars and system anchors from the orthosis.

12. 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.

13. 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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14. 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	

FIOR & GENTZ

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