FIOR & GENTZ

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

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.

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 potential dangers (e.g. breakage of the system side bar/system anchor), 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 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:
- fitting the system side bar/system anchor correctly into the system case;
- connecting the system side bar/system anchor with the system case in accordance with the production technique and
- correctly connecting the system anchor with the laminate of the 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 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;
- ensuring that the bending iron does not come into contact with the vice;
- using the drilling jig;
- respecting the specified bending radius and
- removing notches or residues by fine smoothing and finishing.

⚠ WARNING

Breakage of the System Joint Due to Lack of System Anchor
Use a system anchor when producing the orthosis in order to ensure a secure integration of the system joint into the laminate. The system joint can break if it is integrated without a system anchor.

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. A system side bar connects a system knee joint with a system ankle joint directly. The bands of a side bar shell orthosis are attached to the system side bars. A system anchor connects a system knee joint or a system ankle joint with the shell of a laminated orthosis. It is embedded into the laminate. A system side bar or a system anchor may only be used for one treatment 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.

4. Scope of Delivery

Description	Quantity
system side bar/system anchor (fig. 1)	1
raised countersunk head screw with hexalobular socket (fig. 1)	2

The AGOMET® adhesive required to secure the system side bar/system anchor to the system case must be ordered separately (see paragraph 12).

fig. 1

5. 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.

6. Tools for Mounting the System Side Bars/System Anchors

Tools	System Width					
	10mm	12mm	14mm	16mm	20mm	24mm
T10 hexalobular screwdriver	x	-	-	-	-	-
T15 hexalobular screwdriver	-	x	-	-	-	-
T20 hexalobular screwdriver	-	-	x	x	x	-
T30 hexalobular screwdriver	-	-	-	-	-	x

7. 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.

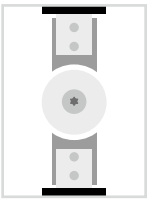

fig. 2

Side Bar Shell Technique

System side bars can be processed using a production technique of your choice.

Anchor Lamination/Prepreg Technique

In this production technique, only the system anchors are embedded into the laminate. The joints' system cases remain free (fig. 2).

You can find more information on the Anchor Lamination Technique in the online tutorial **KAFO in Anchor Lamination Technique** (see QR code, fig. 3) on the FIOR & GENTZ website.

fig. 3

Joint Lamination/Prepreg Technique

In this production technique, the system anchors and the joints' system cases are embedded into the laminate (fig. 4).

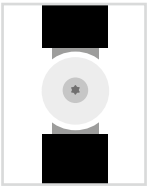

fig. 4

You can find more information on the Joint Lamination Technique in the online tutorial **KAFO in Joint Lamination Technique** (see QR code, fig. 5) on the FIOR & GENTZ website.

fig. 5

7.1 Fitting

The system side bars/system anchors are produced with oversize so that they can only be connected with the system case via press fit. For a better alignment in the system case, the system side bars/system anchors are produced with a slight chamfer.

1 Press the system side bar/system anchor to the joint's upper part by using a washer and a screw. To do so, use a torque screwdriver and the torque corresponding to the system width.
2 Remove washer and screw (fig. 6).

Screw	System Width					
	10mm	12mm	14mm	16mm	20mm	24mm
pressing screw	2.5Nm	4Nm	6Nm	6Nm	6Nm	6Nm

fig. 6

7.2 Bending

fig. 7

- 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. 7). 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. 8). The bending radius depends on the thickness of the material (see table).

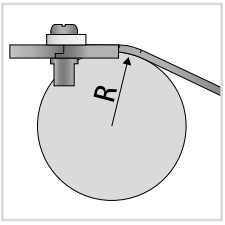

fig. 8

Material	Calculating the Minimum Bending Radius [R*]
aluminium	R = 11 x material thickness
titanium grade 2	R = 5 x material thickness
titanium grade 5	R = 10 x material thickness

* Calculation example: a system side bar made of titanium grade 5 is 5mm thick. Multiplied by 10, the bending radius is 50mm. 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.

7.3 Drilling

System anchors as well as system side bars used in the ankle joint area are pre-drilled. In order to drill precise holes for screwing system side bars used in the knee joint area as well as for system side bars available by the metre, it is absolutely necessary to use the drilling jig (fig. 9). When the bores are set, fit the system side bar as described in paragraph 7.1.

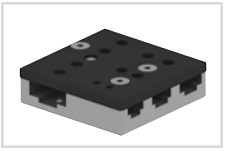

fig. 9

7.4 Processing the Surface

Remove notches and other residues from the surface before connecting the system side bar/system anchor to the system case. Smooth and finish the surface in direction of rolling (fig. 10–11). Make sure that you do not remove too much material.

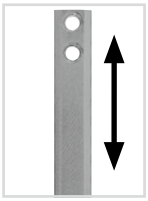

fig. 10

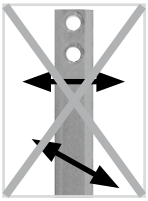

fig. 11

7.5 Connecting to System Case

fig. 12

fig. 13

Side Bar Shell Technique

The system side bar must always be screwed to the system joint or other system components and additionally adhered using AGOMET® adhesive after the try-on. Secure the screws of the system side bar with a hexalobular screwdriver and with AGOMET® adhesive or LOCTITE® 243 medium strength (fig. 12–13).

Anchor Lamination/Prepreg Technique

The system anchor must always be screwed to the system joint or other system components and additionally adhered using AGOMET® adhesive after the try-on. Secure the screws of the system anchor with a hexalobular screwdriver and with AGOMET® adhesive or LOCTITE® 243 medium strength (fig. 12–13).

fig. 14

Joint Lamination/Prepreg Technique

The system anchor must be connected to the system joint or other system components by screwing and wrapping (fig. 14).

8. Maintenance

All system side bars and system anchors should be checked regularly for wear and damage during maintenance of the system joint and 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

9. 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 8).
- 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).

10. Storage

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

11. Spare Parts

Screws that are damaged during assembly or disassembly or that are worn have to be replaced with new screws of the same size.

Fastening Screw for System Side Bars and System Anchors			
Article Number	**System Width**	**Description**	**Unit**
SC5303-L05	10mm	raised countersunk head screw with hexalobular socket, M3 x 8	piece
SC5404-L06	12mm	raised countersunk head screw with hexalobular socket, M4 x 6	piece
SC5405-L08	14mm	raised countersunk head screw with hexalobular socket, M5 x 8	piece
SC5405-L08	16mm	raised countersunk head screw with hexalobular socket, M5 x 8	piece
SC5405-L09	20mm	raised countersunk head screw with hexalobular socket, M5 x 9	piece
SC5406-L10	24mm	raised countersunk head screw with hexalobular socket, M6 x 10	piece

12. Accessory Parts

You need AGOMET® adhesive for adhering the system side bar/system anchor to the system case.

Adhesive AGOMET® F330			
Article Number	**Content**	**Description**	**Unit**
KL1101	5g	set of adhesive and hardener powder, AGOMET® F330	tin
KL1100-H	30g	hardener, AGOMET® F330	tube
KL1100	800g	adhesive, AGOMET® F330	tin

13. Disposal

Dispose of the system side bars and system anchors 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.

14. 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.

15. 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, made available online, reflects the current status at the time of their most recent publication. Changes and updates are published exclusively online. The contained product information serves as guidelines. Subject to technical modifications.

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