

# Instructions for Use for Orthotists or Qualified/ Trained Experts System Side Bars and System Anchors



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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.

## 2. Safety Instructions

### 2.1 Classification of the Safety Instructions

 <b>DANGER</b>	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
 <b>WARNING</b>	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
 <b>CAUTION</b>	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
<b>NOTICE</b>	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 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 a breakage of the system side bar/system anchor or other system components. Pay particular attention to:

- fit the system side bar/system anchor correctly into the system case;
- correctly connect the system side bar/system anchor with the system case in accordance with the production technique and
- correctly connect the system anchor with the laminate of the orthosis.

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## 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 a 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 heat the system side bar/system anchor for bending;
- use the drilling jig;
- respect the specified bending radius and
- remove notches or residues by fine smoothing and finishing.

## NOTICE

### **Limitation of the Joint Function Due to Improper Processing**

Errors in processing can impair the joint function. Pay particular attention to:

- grease the joint components only slightly and
- adhere to the maintenance intervals.

## NOTICE

### **Limitation of the Joint Function Due to Lack of Maintenance**

Respect the specified maintenance intervals in order to avoid joint and system component dysfunction. 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 exclusively for use for orthotic fittings of the lower extremity. A system side bar directly connects a system knee joint with a system ankle joint. The bands of a Strong Light 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 fitting and must not be reused.

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## 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.

## 3.3 Qualification

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

## 3.4 Application

All FIOR & GENTZ system side bars and system anchors were developed for everyday life activities such as standing and walking. Extreme loads connected to activities like running, climbing and parachuting are 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



fig. 1

To secure the system side bar/system anchor to the system case, use the corresponding AGOMET® adhesive that is enclosed to the system joint's scope of delivery. It can also be ordered separately (see paragraph 10).

## 5. 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. You will find information on the production techniques in the section "Online Tutorials" on our website [www.fior-gentz.com](http://www.fior-gentz.com).

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

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

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## 7. Processing

The system side bar/system anchor has to be customised to the patient's leg. To ensure an optimal functioning of the system side bar/system anchor, please note the following explanations on the production techniques and the processing steps.

### Strong Light Technique

This production technique is characterised by its high load capacity, even though it has a lightweight construction. The system side bars can be used in orthoses with shells made of PE/PP plastics as well as in orthoses with bands made of carbon or aluminium (fig. 2).

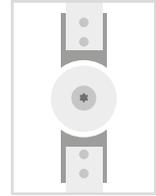


fig. 2

### Anchor Lamination/Prepreg Technique

In this production technique, only the system anchors are embedded into the laminate. The joints' system cases remain free (fig. 3).

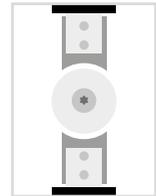


fig. 3

### Joint Lamination/Prepreg Technique

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

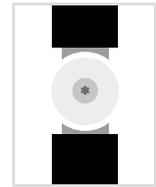


fig. 4

### 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.
- 2 To do so, use a torque screwdriver and a torque of 6 Nm.
- 3 Remove washer and screw again (fig. 5).



fig. 5

## 7.2 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. 6). 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 as the material's characteristics can change permanently.
- Do not alternate the bending direction repeatedly because this would stress the material and could cause it to break.
- To avoid fractures when bending the system side bar/system anchor, make sure not to fall below the radii given in the table (fig. 7). The bending radius depends on the thickness of the material (see table).



fig. 6

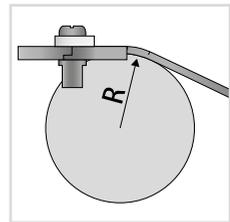


fig. 7

Material	Calculation of the Minimum Bending Radius [R*]
aluminium	$R = 11 \times \text{material thickness}$
titanium grade 2	$R = 5 \times \text{material thickness}$
titanium grade 5	$R = 10 \times \text{material thickness}$

\* 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/ the system anchor, wear working clothes with long sleeves as well as gloves and goggles to avoid injuries resulting from a possible breakage of the system side bar/ system anchor.

## 7.3 Drilling

System anchors as well as system side bars used in the ankle joint area are predrilled. For precise drilling of holes into system side bars used for knee joints as well as for system side bars available by the metre, it is absolutely necessary to use the drilling jig (fig. 8). When the bores are set, fit the system side bar as described in paragraph 7.1.

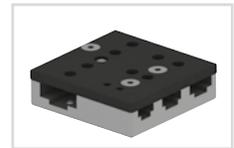


fig. 8

## 7.4 Processing the Surface

Before connecting the system side bar/system anchor to the system case, remove notches and other residues from the surface. Smooth and finish the surface in the direction of rolling (fig. 9–10). Make sure that you do not remove too much material.

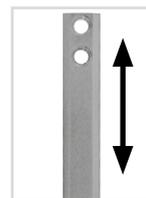


fig. 9

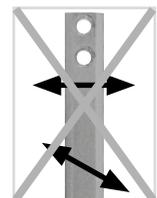


fig. 10

## 7.5 Connecting to System Case

### Strong Light Technique

The system side bar must always be screwed together with the system joint or other system components. After fitting, it must be adhered using the enclosed AGOMET® adhesive. Secure the screws of the system side bar with a hexalobular screwdriver and with AGOMET® adhesive or LOCTITE® 243 medium strength (fig. 11–12).



fig. 11



fig. 12

### Anchor Lamination/Prepreg Technique

The system anchor must always be screwed together with the system joint or other system components. After fitting, it must be adhered using the enclosed AGOMET® adhesive. Secure the screws of the system anchor with a hexalobular screwdriver and with AGOMET® adhesive or LOCTITE® 243 medium strength (fig. 11–12).

### Joint Lamination/Prepreg Technique

The system anchor must be connected to the system joint or other system components by screwing and wrapping (fig. 13).



fig. 13

## 8. Maintenance

All exposed components of the system side bars and system anchors should be checked for wear and damage during maintenance (every 6 months) and replaced if necessary.

Joint Component	Potential Problem	Measure	Inspection/ Replacement, If Necessary	Latest Replacement
system side bar	wear or breakage	replacing system side bar	every 6 months	not applicable
system anchor	wear or breakage	replacing system anchor	every 6 months	not applicable

## 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.

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## 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

## 12. Accessory Parts

The system joints are delivered with a small unit of AGOMET® adhesive that is sufficient for adhering the system side bar/system anchor to the system case of the system joint. If there is a need for more adhesive, you can order more.

AGOMET® Adhesive 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. 14). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.



fig. 14



For proper disposal, it is necessary to demount 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 by 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.

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