

**NEURO  
VARIO**

# Systemknöchelgelenk

System Ankle Joint



DE

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Der Inhalt dieser Produktbeilage wird regelmäßig aktualisiert und ist beim Einsatz des Produktes unbedingt zu beachten.  
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Seite 2

GB

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## 1. Declaration of Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of the Medical Devices Directive 93/42/EEC. Therefore, the FIOR & GENTZ products bear the CE marking.

## 2. Warranty

The warranty only applies if the product is used under the described conditions and for the intended purpose. The warranty expires if the product is used differently, if it is combined with other system components or materials or if it is mounted according to a different production technique than the one recommended by the FIOR & GENTZ Orthosis Configurator. A combination with products from other manufacturers requires a written consent by the seller. The warranty and guarantee expire if the product is mounted several times. For further information, we refer to our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment.

## 3. Safety Information

This manual is addressed to orthotists. That is why the content basically confines to features of the product. It does not contain any notes about dangers which are obvious to orthotists. 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. To achieve maximum safety, please show the patient and/or the care team how to use and maintain the product correctly. Enclosed to this manual you will find a patient information which has to be given to the patient and/or the care team. For information reasons and for the safety of your patient, please note all information provided in this manual including notes, tables and illustrations. In particular, note the safety instructions indicated by DANGER, WARNING, CAUTION and NOTICE that are listed and explained in the following paragraph. Ignoring this information may lead to patient injuries and property damage.



All serious incidents connected to the product shall be reported to the manufacturer or the responsible authorities.

## 4. Safety Instructions

### 4.1 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.

## 4.2 All Instructions for a Safe Handling of the NEURO VARIO 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 potential dangers 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 Loosely Attached Cover Plate**

Mount the cover plate to the system joint according to the assembly instructions in this manual. Secure the screws 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 Permanent Higher Load**

If patient data has changed (e.g. due to weight gain, growth or increased activity), recalculate the load capacity of the system joint. For this purpose, use the Orthosis Configurator or contact Technical Support.

### WARNING

#### **Risk of Falling Due to Improper Shoe**

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 Incorrectly Adjusted Adjusting Screw**

Adjust the adjusting screw according to the information in this manual. Do not make a fine adjustment of more than 10° and secure the adjusting screw with the securing pin and the corresponding adhesive.

### WARNING

#### **Damage to the Anatomical Joint Due to Incorrect Position of the Joint's Mechanical Pivot Point**

Determine the mechanical pivot points correctly in order to avoid a permanent incorrect load on the anatomical joint. Please refer to the online tutorials on our website or contact Technical Support.

## WARNING

### **Jeopardising the Therapy Goal Due to Lack of 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 this manual.

## WARNING

### **Jeopardising the Therapy Goal Due to Incorrectly Filed System Stirrup**

Do not file the system stirrup too far. This applies especially to the dorsiflexion stop, otherwise the forefoot lever is not activated. As a result, the patient is only stabilised insufficiently by the orthosis and the gait worsens. In order to avoid this, always file the system stirrup:

- gradually up to the required stop angles and
- only so far that no more than a 10° fine adjustment is possible.

## *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 case in accordance with the production technique;
- greasing the joint components only slightly and
- adhering to the maintenance intervals.

## 5. Application

The **NEURO VARIO** system ankle joint is exclusively for use for orthotic fittings of the lower extremity. It must be handled by a professionally trained user. You will find more information about this product under paragraph 6 Joint Function.

Every mechanical joint influences the orthosis' function and thus also the function of the leg. All FIOR & GENTZ system joints were developed for everyday life activities such as standing, walking and running but not for extreme loads due to sports such as climbing and parachuting.

Depending on the type of orthotic fittings and the patient's individual physical abilities, driving a motor vehicle safely should be guaranteed. This is subject to national laws and checked by authorised medical bodies. It is recommended to modify the motor vehicle to the patient's special needs (e.g. automatic transmission) so that the driving ability is given even without a functioning orthosis.

## 6. Joint Function

The basic function of the **NEURO VARIO** system ankle joint is to provide motion control. The range of motion in plantar flexion and dorsiflexion can be adjusted by filing the system stirrups and additionally by using the adjusting screws.

## 7. Scope of Delivery

The scope of delivery includes the following articles:

Description	Quantity
NEURO VARIO system ankle joint (fig. 1)	1
securing pin (fig. 2)	2
AGOMET F330, 5g (fig. 3)	1
orthosis joint grease, 3g (fig. 4)	1
assembly/lamination dummy (fig. 5)	1



fig. 1



fig. 2



fig. 3



fig. 4

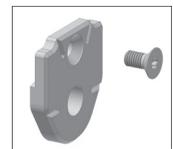


fig. 5

Corresponding system stirrups in different designs and for different production techniques have to be ordered separately.

## 8. Load Capacity

You can find all relevant patient data for your selected system joint in the configuration you performed with the Orthosis Configurator and/or on your completed orthotic treatment sheet.

## 9. Tools for Assembling the System Joint

Tools	System Width				
	10mm	12mm	14mm	16mm	20mm
T10 hexalobular screwdriver as well as T10 hexalobular bit	x	-	-	-	-
T15 hexalobular screwdriver as well as T15 hexalobular bit	-	x	-	-	-
T20 hexalobular screwdriver as well as T20 hexalobular bit	-	-	x	x	x
torque screwdriver 1-6Nm	x	x	x	x	x
pin punch	x	x	x	x	x

## 10. Assembly/Lamination Dummies

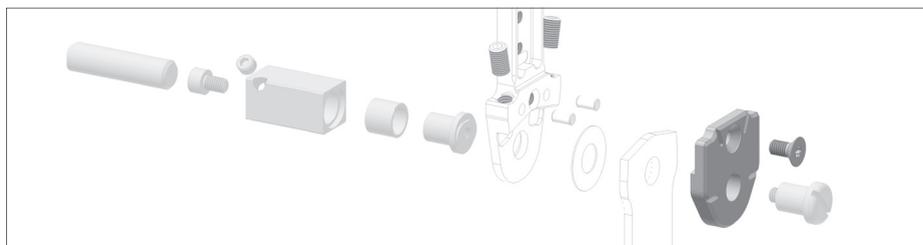


fig. 6

Assembly/lamination dummies are included in the scope of delivery of the system joint. You can find the article numbers as well as the corresponding tools for the parallel alignment in our product catalogue **System Joints and Articulated System Side Bars**.

## 11. Assembly Instructions

The system joint is delivered fully assembled (fig. 7). All functions are checked beforehand. You have to disassemble the system joint for mounting it in the orthosis and for maintenance. When disassembling the system joint, make sure not to interchange the different parts with each other or with parts of other system joints. Clean all system components. To clean the threads in the cover plate, use Super Clean LOCTITE® 7063 (article no.: WZ7063) in order to remove any insulating wax residues. To ensure optimum functionality, please follow the assembly instructions below.

### 11.1 Mounting the System Stirrup

Start the assembly of the **NEURO VARIO** system ankle joint by mounting the system stirrup which corresponds to the system width and production technique. Proceed as follows:

1. Grease the axle bore of the system stirrup as well as the friction surfaces of the bearing nut and the first sliding washer with the delivered orthosis joint grease.



fig. 7

- Put the bearing nut into the intended opening of the joint's upper part. The bearing nut has to be placed completely into the opening:
  - **correct** position of the bearing nut (fig. 8);
  - **incorrect** position of the bearing nut (fig. 9).
- Place the first sliding washer **slightly** greased on both sides onto the joint's upper part (fig. 10).
- Mount the system stirrup (fig. 11).



fig. 8

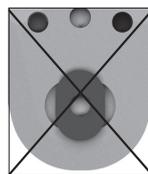


fig. 9

## 11.2 Mounting the Cover Plate

Mount the cover plate of the **NEURO VARIO** system ankle joint. Proceed as follows:

- Apply spray adhesive on one side of the second sliding washer and adhere it to the cover plate (fig. 12). Grease the other side of the sliding washer **slightly** with the delivered orthosis joint grease.

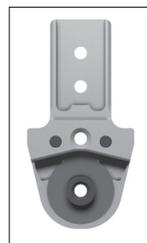


fig. 10

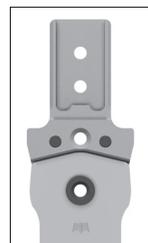


fig. 11

Place the sliding washer in a way that prevents it from being damaged when mounting the cover plate. If you have nevertheless placed the sliding washer **incorrectly** (fig. 13-14), remove the particles and place a new sliding washer.



fig. 12



Jammed sliding washer particles cause lateral play in the system joint and a damaged sliding washer could lead to restrictions of the joint function.

- Mount the cover plate. Screw in the first countersunk flat head screw (axle screw, S1; fig. 15) according to the torque given in the table (see paragraph 11.5).
- Now, screw in the second countersunk flat head screw (S2; fig. 16) according to the torque given in the table (see paragraph 11.5).



fig. 13



fig. 14

## 11.3 Checking the System Joint's Free Movement

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. For more information about the sliding washers see paragraph 14.2.



fig. 15

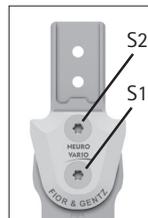


fig. 16

## 11.4 Basic Alignment

When mounting the system ankle joint, mind the correct adjustment of the dorsiflexion stop as it is decisive for the entire alignment of the orthosis. Correct the dorsiflexion stop, if necessary.

## 11.5 Securing the Screws

After the orthosis has been produced and tried on and before it is given to the patient, secure the screws for the cover plate with a torque which corresponds to the system width (see table and cover plate of the system joint) and **LOCTITE® 243** medium strength (article no.: KL2000). Let the adhesive harden (final strength after approx. 24 hours).

Position of the Screw (Fig. 16)	System Width				
	10mm	12mm	14mm	16mm	20mm
S1 (screw 1, axle screw)	1.5Nm	3Nm	4Nm	4Nm	4Nm
S2 (screw 2)	1.5Nm	3Nm	4Nm	4Nm	4Nm



The screws of the cover plate are not secured with the necessary torque at delivery.

## 12. Adjustment Options on the Orthosis

### 12.1 Adjustable Alignment

When producing a static orthosis with the NEURO VARIO system ankle joint, the alignment of the orthosis can or has to be adjusted to the patient's pathological gait using the adjusting screw (fig. 17). Furthermore, changes in the pathological gait can be treated flexibly. The position of the adjusting screw cannot change due to a securing pin installed in the system joint (see paragraph 12.2.3).



fig. 17

### 12.2 Adjustable Range of Motion

The range of motion is the joint's angle of rotation between two defined limitations of movement.

#### 12.2.1 Filing the Range of Motion

The range of motion in plantar flexion and dorsiflexion can be adjusted by filing the system stirrup. For this purpose, the system stirrup is marked with lines which serve as orientation (fig. 18). If the system stirrup is filed to 50°, the system joint becomes free moving.

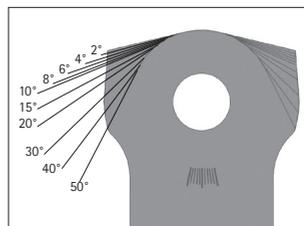


fig. 18



For more detailed information about the adjustment of the range of motion please refer to the publications in the download section on our website at [www.fior-gentz.com/downloads](http://www.fior-gentz.com/downloads).

#### 12.2.2 Fine Adjusting the Range of Motion

The range of motion is roughly adjusted by filing the system stirrup. Use the adjusting screw of the system joint to fine adjust the range of motion at a maximum of 10 more degrees (fig. 19).

When screwing in the adjusting screw too much (more than 10° fine adjusting), the surface pressure between adjusting screw and system stirrup can become so high that the screw is compressed and loses its function.



fig. 19

### 12.2.3 Securing the Adjusting Screw

When the adjusting screw turns or loosens, it must be secured again with the securing pin. Please follow the assembly instructions below:

1. Unscrew the adjusting screw out of the thread (fig. 19).
2. Demount the cover plate and drive out the premounted securing pin with a pin punch (fig. 20).
3. Turn the worn position of the securing pin by about 90° (fig. 21) and put it in again (fig. 22).
4. Mount the cover plate (fig. 23).
5. Now, screw the adjusting screw into the desired position (fig. 19).
6. Additionally, secure the adjusting screw with LOCTITE® 243 (article no.: KL2000). Let the adhesive harden (final strength after approx. 24 hours).

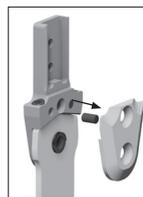


fig. 20



fig. 21



fig. 22



fig. 23



If the securing pin is deformed after the driving, put in a new one (article no.: GS4007). If necessary, cut the new pin with a sharp knife so that it does not protrude. The scope of delivery includes two additional securing pins.

### 12.3 Reading Joint Angles

The lasered degree markings on the system stirrup and the lasered line on the cover plate (fig. 24) show the angle of the system joint towards the system stirrup. When handing over the orthosis, you can check the individual normal posture (the orthosis' basic alignment) by the markings. You can read as well as record the joint angle indicated at this time. By doing so, you can easily compare later adaptations or deviations of the individual normal posture with your documentation.

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

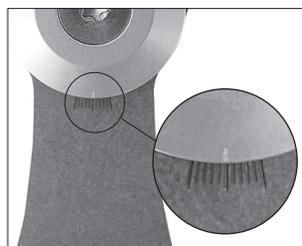


fig. 24

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



You will find more information about the individual normal posture on the internet at [www.fior-gentz.com](http://www.fior-gentz.com).

## 13. Advice on Production Techniques

Use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique.



You will find detailed information about our production techniques in the section "Orthosis Production" under "Online Tutorials" and "Producing the Orthosis" on our website [www.fior-gentz.com](http://www.fior-gentz.com).

### 13.1 Parallel Alignment of System Joints

You will find the necessary tools for the parallel alignment of the system joints on the positive cast in our latest product catalogue **System Joints and Articulated System Side Bars**.

### 13.2 Mounting to the System Side Bar/System Anchor

Depending on the production technique, the system side bar/system anchor must be adhered and screwed or sewed together with the system joint (fig. 25-27). You will find further information concerning the different production techniques on the internet or in the manual **System Side Bars and System Anchors** (article no.: PB1000-SA).



fig. 25



fig. 26



fig. 27

## 14. Maintenance

We recommend checking the system joint's functionality and wear every **6 months**.

Check the following parts in particular:

Joint Part	Problem	Measure
adjusting screw	wear	replacing
securing pin	wear	replacing, see paragraph 12.2.3
bore for bearing nut of system stirrup	oversize	inserting repair bushing, see paragraph 14.1
sliding washers	wear	replacing, see paragraph 14.2
bearing nut	wear	replacing

### 14.1 Repairing the Bearing Nut Bore

If the bore for the bearing nut is worn out at the system stirrup, bore (fig. 28) and ream (fig. 29) it with a reamer (see product catalogue **System Joints and Articulated System Side Bars**) in order to insert a repair bushing (boring and reaming measurements see table). For a centred boring and reaming, clamp the system stirrup firmly. After inserting the repair bushing made of bronze (fig. 30), the bore has the specified size again. The joint system is now free of play (fig. 31).



fig. 28



fig. 29



fig. 30



fig. 31

## Boring and Reaming Measurements [mm]

System Width	Bearing Nut Outer Ø	Repair Bushing Inner Ø	Repair Bushing Outer Ø	Ø Measurement for Boring	Ø Measurement for Reaming	Art. No. Repair Bushing
10mm	6.0	6.0	7.0	5.7	6.0 H7	BP0706-L020
12mm	7.0	7.0	8.0	7.7	8.0 H7	BR0807-L020
14mm	8.5	8.5	9.6	9.3	9.6 H7	BR1009-L025
16mm	9.6	9.6	10.5	10.2	10.5 H7	BR1110-L030
20mm	10.5	10.5	11.5	11.2	11.5 H7	BR1211-L030

### 14.2 Replacing the Sliding Washers

If the premounted sliding washers wear out, they have to be replaced by new ones with the same thickness. The article numbers of the premounted sliding washers are on the back page of this manual. The last three digits of the article number stand for the thickness of the sliding washer, e.g. GS1407-**040**. The thickness of this sliding washer is 0.40mm. In total, the sliding washers are available in five different thicknesses. The thickness of a sliding washer is indicated by the markings. For example, a sliding washer with two grooves is 0.40mm thick, whereas a sliding washer with one notch is 0.55mm thick (fig. 32). Note and respect that when reordering.

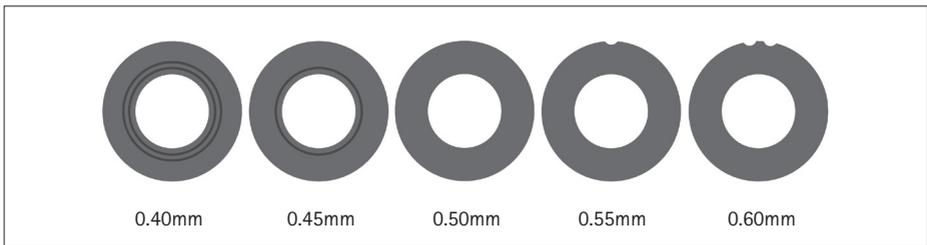


fig. 32

### 14.3 Cleaning

While using the orthosis, the system joint has to be cleaned if needed and during regularly carried out maintenance. For this purpose, disassemble the system joint and clean the soiled system components with a dry cloth.

## 15. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 33). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.



For proper disposal, it is necessary to demount the system joint from the orthosis.

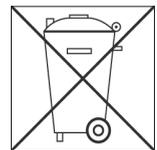


fig. 33

## 16. Spare Parts

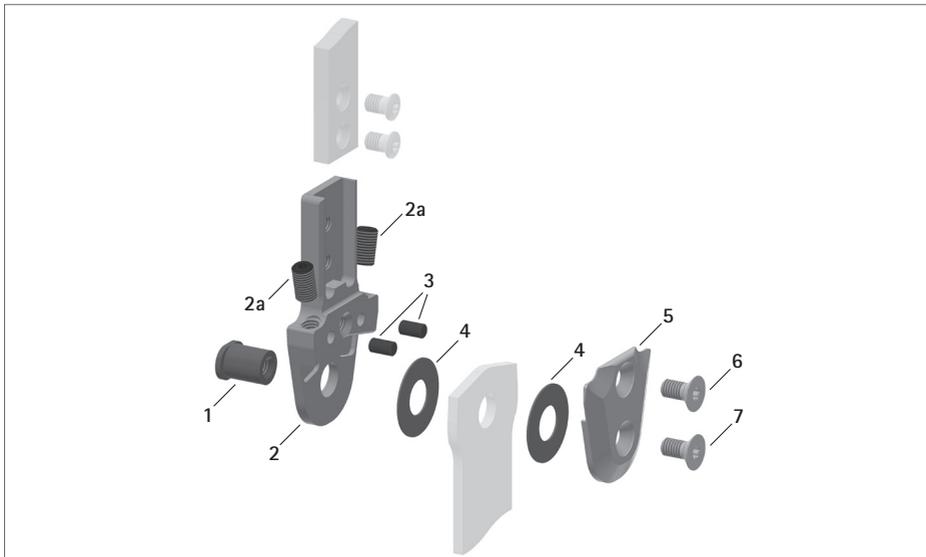


fig. 34

Item	Article Number for System Width					Description
	10mm	12mm	14mm	16mm	20mm	
1	SB6034-L0490	SB7049-L0590	SB8559-L0670	SB9669-L0760	SB1069-L0810	bearing nut
2	SF0200-ST	SF0241-ST	SF0242-ST	SF0243-ST	SF0245-ST	upper part, straight, steel (with adjusting screws)
2	-	SF0241-TI	SF0242-TI	SF0243-TI	SF0245-TI	upper part, straight, titanium (with adjusting screws)
2	SF0220-ST	SF0281-ST	SF0282-ST	SF0283-ST	SF0285-ST	upper part, bent, steel (with adjusting screws)
2	-	SF0281-TI	SF0282-TI	SF0283-TI	SF0285-TI	upper part, bent, titanium (with adjusting screws)
2a	SC9604-L06ST	SC9604-L06ST	SC9605-L08ST	SC9606-L10ST	SC9606-L10ST	adjusting screw
3	GS4007	GS4007	GS4007	GS4007	GS4007	securing pin
4	GS1206-*	GS1407-*	GS1609-*	GS2210-*	GS2611-*	sliding washer*
5	SF0260-AL	SF0261-AL	SF0262-AL	SF0263-AL	SF0265-AL	cover plate
6	SC1403-L08	SC1404-L08	SC1405-L11	SC1405-L11	SC1405-L12	countersunk flat head screw, hexalobular socket
7	SC1403-L08	SC1404-L08	SC1405-L11	SC1405-L11	SC1406-L12	countersunk flat head screw, hexalobular socket (axle screw)

### \* Sliding Washers

Article Number for System Width				
10mm	12mm	14mm	16mm	20mm
Ø = 12mm	Ø = 14mm	Ø = 16mm	Ø = 22mm	Ø = 26mm
GS1206-040	GS1407-040	GS1609-040	GS2210-040	GS2611-040
GS1206-045	GS1407-045	GS1609-045	GS2210-045	GS2611-045
GS1206-050	GS1407-050	GS1609-050	GS2210-050	GS2611-050
GS1206-055	GS1407-055	GS1609-055	GS2210-055	GS2611-055
GS1206-060	GS1407-060	GS1609-060	GS2210-060	GS2611-060



When reordering, note and respect the thickness of the sliding washers (explanation see paragraph 14.2).

## 17. Accessory Parts

You will find a big variety of accessory parts in our latest product catalogue System Joints and Articulated System Side Bars.

## 18. Informationen für die Versorgungsdokumentation/Information for the Treatment Documentation

Bitte heften Sie diese Produktbeilage zu Ihrer Versorgungsdokumentation!  
Add this manual to your treatment documentation!

Patientendaten/Patient's Data

<b>Name</b> Name	
<b>Straße</b> Address	
<b>PLZ, Wohnort</b> Postcode, City	
<b>Telefon privat</b> Home Telephone	
<b>Telefon geschäftlich</b> Telephone at Work	
<b>Kostenträger</b> Insurance	
<b>Mitgliedsnummer</b> Insurance No.	
<b>Behandelnder Arzt</b> Attending Physician	
<b>Diagnose</b> Diagnosis	

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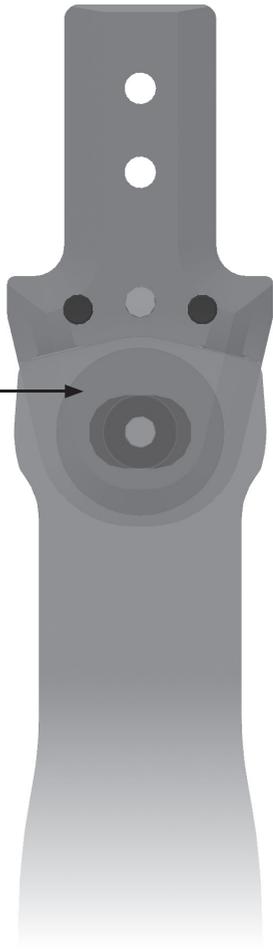
Beinseite  
Leg Side

■ links/left    ■ rechts/right

Montierte Gleitscheiben-Version  
Mounted Sliding Washer Version

1. GS \_\_\_\_\_ - \_\_\_\_\_

2. GS \_\_\_\_\_ - \_\_\_\_\_



Der Qualitätsstandard der Firma FIOR & GENTZ ist durch eine unabhängige Zertifizierungsgesellschaft nach den internationalen Normen ISO 9001 und ISO 13485 geprüft und bescheinigt worden.  
The quality standard of the FIOR & GENTZ company has been controlled and certified by an independent certification organisation according to the international standards ISO 9001 and ISO 13485.

PB2000-SF-11/2018