

Systemkniegelenk

System Knee Joint



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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 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 patients, please note all information provided in this manual including notes, tables and illustrations. Please note especially the safety instructions indicated by ATTENTION! CAUTION! WARNING! and DANGER! which are listed and explained in the following paragraph. Ignoring this information may lead to patient injuries and property damage.

4. Safety Instructions

4.1 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.*



ATTENTION!

➔ *Important information about a possible situation which, if not avoided, leads to damage of the product.*

4.2 Structure of the Safety Instructions

The following example demonstrates the structure of the safety instructions:

Attention Symbol	Signal Word	ATTENTION!
	Type of Danger	<i>Mechanical load is too high!</i>
	Possible Consequences for Components	➔ <i>Wear of the joint parts.</i>
	Possible Consequences for the Patient	➔ <i>Maintenance intervals shorten.</i>
	Measures	Explain to the patient the correct use of the system joint and possible dangers.

4.3 All Instructions for a Safe Handling of the NEURO CLASSIC zero System Knee Joint

There is detailed information on some of the safety instructions in the course of this manual. Respect the following safety instructions to avoid patient injuries and property damage.



DANGER!

The patient is not able to drive a motor vehicle safely!

➔ *Reduced driving ability and danger of traffic collision.*

Make sure that the patient gathers information about all safety and security issues before driving a motor vehicle with orthosis.



WARNING!

Mechanical load is too high!

➔ *Breakage of the joint parts.*

➔ *Fall.*

Explain to the patient the correct use of the system joint and possible dangers.



WARNING!

Mechanical load is too high due to changing patient data!

➔ *Breakage of the joint parts.*

➔ *Fall.*

Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.



WARNING!

Cover plate is not fixed correctly!

➔ *Breakage of the joint parts.*

➔ *Fall.*

Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washer is not damaged.



WARNING!

System side bar/system anchor is not connected to the system case of the system joint according to our recommended production technique!

➔ *Breakage of system components.*

➔ *Fall.*

Always connect the system side bar/system anchor with the system case of the system joint according to our recommended production technique.

**WARNING!**

Maintenance intervals are not respected!

- ➔ *Increased wear of the joint parts.*
- ➔ *Fall.*

Respect maintenance intervals.

**WARNING!**

Moisture and water!

- ➔ *Failure of the joint function.*
- ➔ *Fall.*

Explain to the patient the correct use of the system joint and possible dangers.

**WARNING!**

Soiling caused by sand and other particles!

- ➔ *Failure of the joint function.*
- ➔ *Fall.*

Explain to the patient the correct use of the system joint and possible dangers.

**WARNING!**

False pivot point regarding statics!

- ➔ *Failure of the joint function.*
- ➔ *Fall.*

Determine the system joint's pivot point correctly.

**WARNING!**

The patient is wearing a shoe to which the orthosis is not adjusted!

- ➔ *Failure of the joint function.*
- ➔ *Fall.*

Point out to the patient to only wear a shoe to which the orthosis is adjusted.

**WARNING!**

False pivot point regarding anatomy!

- ➔ *Damage of the anatomical joint.*

Determine the system joint's pivot point correctly.

**WARNING!**

System joint is over-greased!

- ➔ *Quick soiling and probable failure of the joint function.*
- ➔ *Fall.*

Grease the system joint only slightly.

**WARNING!**

System joint does not move freely!

- ➔ *Restrictions of the joint function.*
- ➔ *Treatment goal might not be achieved.*

Check if the system joint moves freely and use the right sliding washers.

**ATTENTION!**

Mechanical load is too high!

- ➔ *Wear of the joint parts.*
- ➔ *Maintenance intervals shorten.*

Explain to the patient the correct use of the system joint and possible dangers.

**ATTENTION!**

Mechanical load is too high due to changing patient data!

- ➔ *Wear of the joint parts.*
- ➔ *Maintenance intervals shorten.*

Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.

**ATTENTION!**

Cover plate is not fixed correctly!

- ➔ *Wear of the joint parts.*
- ➔ *Maintenance intervals shorten.*

Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washer is not damaged.

5. Application

The NEURO CLASSIC zero system knee joint is exclusively for use for orthotic fittings of the lower extremity. It must be handled by a professionally trained user. At this point, the production of ortho-prostheses is expressly excluded. You will find more information about this product under paragraph 6 Joint Function.



DANGER!

The patient is not able to drive a motor vehicle safely!

➔ *Reduced driving ability and danger of traffic collision.*

Make sure that the patient gathers information about all safety and security issues before driving a motor vehicle with orthosis.

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 NEURO CLASSIC zero system knee joint is a free moving, monocentric joint to control and support the motion. The zero stands for the small posterior offset (fig. 1). You can find the measures of the posterior offset in the table below.

System Width	12mm	14mm	16mm	20mm
Posterior Offset of the Joint Axis	3mm	4mm	5mm	7mm

The system joint is preassembled in a physiological joint angle of 5°. The mounted extension stop dampers minimise the bumping noises.

The posterior offset of the joint axis of the NEURO CLASSIC zero system knee joint is very small so that only patients with normal muscle power get stability in stance. Therefore, it is not suitable for patients who require secured standing through integrated posterior offset but only for patients with knee joint instabilities in one or more directions. The system joint can be mounted, for example, into a KAFO to avoid a genu recurvatum. Due to the small posterior offset, the mechanical pivot point approximates the anatomical pivot point of the human knee. The bottom-up shifting of the femoral shell on the patient's leg is, therefore, reduced.

Furthermore, it is possible to bring the system joint into a knee flexion position of 0° by exchanging components. To do so, exchange the 5° upper part for a 0° upper part. You will find the article numbers of the 0° upper parts in our latest product catalogue System Joints and Articulated System Side Bars.



Fig. 1

7. Scope of Delivery

The scope of delivery includes the following articles:

Description	Quantity
NEURO CLASSIC zero system knee joint (fig. 5)	1
AGOMET F330, 5g (fig. 2)	1
orthosis joint grease, 3g (fig. 3)	1
assembly/lamination dummy (fig. 4)	1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

8. Load Capacity



WARNING!

Mechanical load is too high!
 ➔ *Breakage of the joint parts.*
 ➔ *Fall.*

Explain to the patient the correct use of the system joint and possible dangers.



WARNING!

Mechanical load is too high due to changing patient data!
 ➔ *Breakage of the joint parts.*
 ➔ *Fall.*

Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.



ATTENTION!

Mechanical load is too high!
 ➔ *Wear of the joint parts.*
 ➔ *Maintenance intervals shorten.*

Explain to the patient the correct use of the system joint and possible dangers.



ATTENTION!

Mechanical load is too high due to changing patient data!
 ➔ *Wear of the joint parts.*
 ➔ *Maintenance intervals shorten.*

Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.

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			
	12mm	14mm	16mm	20mm
T15 hexalobular screwdriver as well as T15 hexalobular bit	x	-	-	-
T20 hexalobular screwdriver as well as T20 hexalobular bit	x	x	x	x
torque screwdriver 1-6Nm	x	x	x	x

10. Assembly/Lamination Dummies

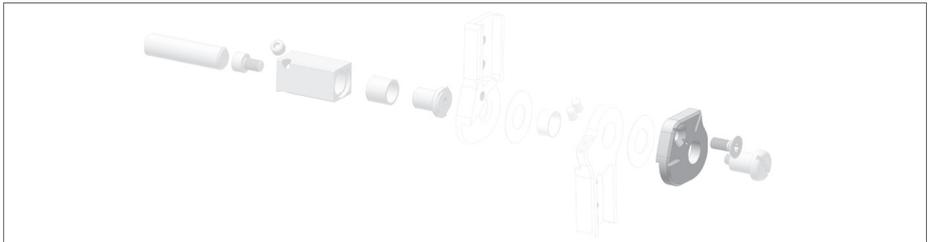


Fig. 6

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.

To ensure optimum functionality, please follow the assembly instructions below:

11.1 Mounting the Cover Plate

Start the assembly of the **NEURO CLASSIC** zero system knee joint by connecting the joint's upper part with the lower part and mounting the cover plate.

- Before starting the assembly, grease the axle bore of the joint's lower part as well as the friction surfaces of the bearing nut with the delivered orthosis joint grease.
- Put the bearing nut into the intended opening of the joint's upper part:
 - **correct** position of the bearing nut (fig. 8);
 - **incorrect** position of the bearing nut (fig. 9).



Fig. 7



Fig. 8

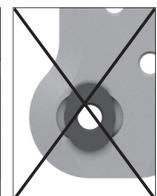


Fig. 9

- Grease the first sliding washer slightly on both sides and place it (fig. 10).
- Mount the joint's lower part with integrated sliding bushing (fig. 11).
- 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



Fig. 12

Note:

Place the sliding washer in a way that prevents it from being damaged when mounting the cover plate. Jammed sliding washer particles cause lateral play in the system joint which could lead to breakage of the system joint and to a possible fall. If you have nevertheless placed the sliding washer incorrectly (fig. 13–14), remove the particles and place a new sliding washer.



Fig. 13



Fig. 14

- Mount the cover plate. Turn 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, turn in the second countersunk flat head screw (S2; fig. 16) according to the torque given in the table (see paragraph 11.5).



Fig. 15



Fig. 16

11.2 Checking the System Joint's Free Movement

WARNING!
System joint does not move freely!
 ➔ *Restrictions of the joint function.*
 ➔ *Treatment goal might not be achieved.*
Check if the system joint moves freely and use the right sliding washers.

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 13.1.

11.3 Mounting the Extension Stop Dampers

Mount the delivered extension stop dampers to the system joint by putting them into the intended bores and pressing them in with your finger. By extending the system joint, the extension stop dampers are tightened in the bores.

11.4 Basic Alignment

When mounting the system knee joint, please note that the joint angles of the system knee joint and the system ankle joint influence each other. This is essential for the entire alignment of the orthosis. In order for an exchanged extension stop not to affect the orthosis alignment negatively, also correct the system ankle joint, if necessary.

11.5 Securing the Screws



WARNING!

Cover plate is not fixed correctly!

- ➔ *Breakage of the joint parts.*
- ➔ *Fall.*

Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washer is not damaged.



ATTENTION!

Cover plate is not fixed correctly!

- ➔ *Wear of the joint parts.*
- ➔ *Maintenance intervals shorten.*

Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washer is not damaged.

After the orthosis has been produced and tried on and before it will be given to the patient, secure the screws for the cover plate with a torque which corresponds to the system width (see table) 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			
	12mm	14mm	16mm	20mm
S1 (screw 1, axle screw)	4Nm	4Nm	4Nm	4Nm
S2 (screw 2)	3Nm	4Nm	4Nm	4Nm

Note:

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

12. Advice on Production Techniques

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

12.1 Production Techniques Online

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.

12.2 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**.

12.3 Mounting to the System Side Bar/System Anchor



WARNING!

System side bar/system anchor is not connected to the system case of the system joint according to our recommended production technique!

- ➔ *Breakage of system components.*
- ➔ *Fall.*

Always connect the system side bar/system anchor with the system case of the system joint according to our recommended production technique.

Depending on the production technique, the system side bar/system anchor must be adhered and screwed or sewed together with the system joint (fig. 17-19). 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. 17



Fig. 18



Fig. 19

13. Maintenance



WARNING!

Maintenance intervals are not respected!

➔ *Increased wear of the joint parts.*

➔ *Fall.*

Respect maintenance intervals.

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

Check the following parts in particular:

Joint Part	Problem	Measure
extension stop damper	wear	replacing, see paragraph 11.3
sliding bushing	wear	replacing
bearing nut	wear	replacing
sliding washers	wear	replacing, see paragraph 13.1

13.1 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. 20). Note and respect that when reordering.

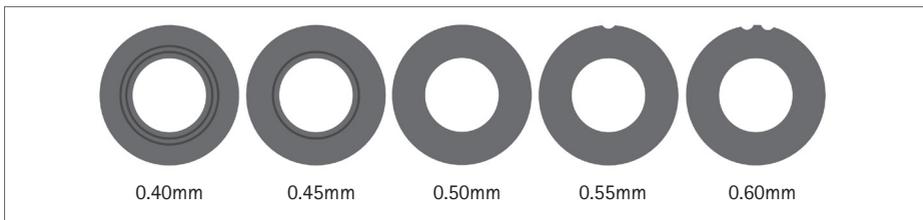


Fig. 20

13.2 Cleaning



WARNING!

Moisture and water!

➔ *Failure of the joint function.*

➔ *Fall.*

Explain to the patient the correct use of the system joint and possible dangers.



WARNING!

Soiling caused by sand and other particles!

➔ *Failure of the joint function.*

➔ *Fall.*

Explain to the patient the correct use of the system joint and possible dangers.

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.

14. Spare Parts (see table and fig. 21)

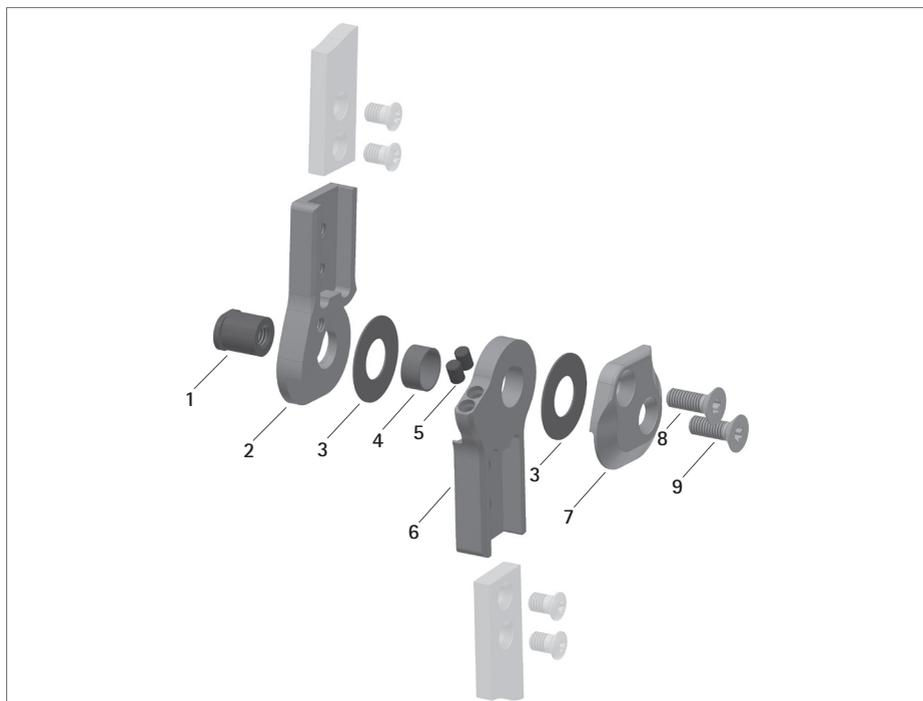


Fig. 21

Item	Article Number for System Width				Description
	12mm	14mm	16mm	20mm	
1	SB8559-L0840	SB9669-L0840	SB1069-L0960	SB1069-L1020	bearing nut
2	SJ0101-2L/ST	SJ0102-2L/ST	SJ0103-2L/ST	SJ0105-2L/ST	5° upper part, left lateral or right medial, straight, steel

Item	Article Number for System Width				Description
	12mm	14mm	16mm	20mm	
2	SJ0101-2R/ST	SJ0102-2R/ST	SJ0103-2R/ST	SJ0105-2R/ST	5° upper part, left medial or right lateral, straight, steel
2	SJ0101-2L/TI	SJ0102-2L/TI	SJ0103-2L/TI	SJ0105-2L/TI	5° upper part, left lateral or right medial, straight, titanium
2	SJ0101-2R/TI	SJ0102-2R/TI	SJ0103-2R/TI	SJ0105-2R/TI	5° upper part, left medial or right lateral, straight, titanium
2	SJ0121-2L/ST	SJ0122-2L/ST	SJ0123-2L/ST	SJ0125-2L/ST	5° upper part, left lateral or right medial, bent inwards, steel
2	SJ0121-2R/ST	SJ0122-2R/ST	SJ0123-2R/ST	SJ0125-2R/ST	5° upper part, left medial or right lateral, bent inwards, steel
2	SJ0121-2L/TI	SJ0122-2L/TI	SJ0123-2L/TI	SJ0125-2L/TI	5° upper part, left lateral or right medial, bent inwards, titanium
2	SJ0121-2R/TI	SJ0122-2R/TI	SJ0123-2R/TI	SJ0125-2R/TI	5° upper part, left medial or right lateral, bent inwards, titanium
2	SJ0121-9L/ST	SJ0122-9L/ST	SJ0123-9L/ST	SJ0125-9L/ST	5° upper part, left lateral or right medial, bent outwards, steel
2	SJ0121-9R/ST	SJ0122-9R/ST	SJ0123-9R/ST	SJ0125-9R/ST	5° upper part, left medial or right lateral, bent outwards, steel
2	SJ0121-9L/TI	SJ0122-9L/TI	SJ0123-9L/TI	SJ0125-9L/TI	5° upper part, left lateral or right medial, bent outwards, titanium
2	SJ0121-9R/TI	SJ0122-9R/TI	SJ0123-9R/TI	SJ0125-9R/TI	5° upper part, left medial or right lateral, bent outwards, titanium
3	GS1609-*	GS1910-*	GS2311-*	GS2611-*	sliding washer*
4	BP1009-L050	BP1110-L050	BP1211-L055	BP1211-L060	sliding bushing
5	PN1000-L06	PN1000-L06	PN1000-L06	PN1000-L06	extension stop damper
6	SJ0111-L/ST	SJ0112-L/ST	SJ0113-L/ST	SJ0115-L/ST	lower part, left lateral or right medial, straight, steel
6	SJ0111-R/ST	SJ0112-R/ST	SJ0113-R/ST	SJ0115-R/ST	lower part, left medial or right lateral, straight, steel
6	SJ0111-L/TI	SJ0112-L/TI	SJ0113-L/TI	SJ0115-L/TI	lower part, left lateral or right medial, straight, titanium
6	SJ0111-R/TI	SJ0112-R/TI	SJ0113-R/TI	SJ0115-R/TI	lower part, left medial or right lateral, straight, titanium
6	SJ0131-L/ST	SJ0132-L/ST	SJ0133-L/ST	SJ0135-L/ST	lower part, left lateral or right medial, bent inwards, steel

Item	Article Number for System Width				Description
	12mm	14mm	16mm	20mm	
6	SJ0131-R/ST	SJ0132-R/ST	SJ0133-R/ST	SJ0135-R/ST	lower part, left medial or right lateral, bent inwards, steel
6	SJ0131-L/TI	SJ0132-L/TI	SJ0133-L/TI	SJ0135-L/TI	lower part, left lateral or right medial, bent inwards, titanium
6	SJ0131-R/TI	SJ0132-R/TI	SJ0133-R/TI	SJ0135-R/TI	lower part, left medial or right lateral, bent inwards, titanium
6	SJ0131-8L/ST	SJ0132-8L/ST	SJ0133-8L/ST	SJ0135-8L/ST	lower part, left lateral or right medial, bent outwards, steel
6	SJ0131-8R/ST	SJ0132-8R/ST	SJ0133-8R/ST	SJ0135-8R/ST	lower part, left medial or right lateral, bent outwards, steel
6	SJ0131-8L/TI	SJ0132-8L/TI	SJ0133-8L/TI	SJ0135-8L/TI	lower part, left lateral or right medial, bent outwards, titanium
6	SJ0131-8R/TI	SJ0132-8R/TI	SJ0133-8R/TI	SJ0135-8R/TI	lower part, left medial or right lateral, bent outwards, titanium
7	SJ0151-L/AL	SJ0152-L/AL	SJ0153-L/AL	SJ0155-L/AL	cover plate, left lateral or right medial, aluminium
7	SJ0151-R/AL	SJ0152-R/AL	SJ0153-R/AL	SJ0155-R/AL	cover plate, left medial or right lateral, aluminium
8	SC1404-L12	SC1405-L12	SC1405-L12	SC1405-L14	countersunk flat head screw, hexalobular socket
9	SC1405-L12	SC1405-L12	SC1406-L12	SC1406-L14	countersunk flat head screw, hexalobular socket (axle screw)

* Sliding Washers

	Article Number for System Width			
	12mm	14mm	16mm	20mm
	Ø = 16mm	Ø = 19mm	Ø = 23mm	Ø = 26mm
	GS1609-040	GS1910-040	GS2311-040	GS2611-040
	GS1609-045	GS1910-045	GS2311-045	GS2611-045
	GS1609-050	GS1910-050	GS2311-050	GS2611-050
	GS1609-055	GS1910-055	GS2311-055	GS2611-055
	GS1609-060	GS1910-060	GS2311-060	GS2611-060

Note:

When reordering, note and respect the thickness of the sliding washers (explanation see paragraph 13.1).

15. Accessory Parts

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

16. Informationen für die Versorgungsdokumentation/Information for the Treatment Documentation

Hinweis/Note:

Bitte heften Sie diese Produktbeilage zu Ihrer Versorgungsdokumentation!

Add this manual to your treatment documentation!

Patientendaten/Patient's Data

Name Name	
Straße Street	
PLZ, Wohnort Zip Code, City	
Telefon privat Home Telephone	
Telefon geschäftlich Telephone at Work	
Kostenträger Insurance	
Mitgliedsnummer Insurance No.	
Behandelnder Arzt Attending Physician	
Diagnose Diagnosis	

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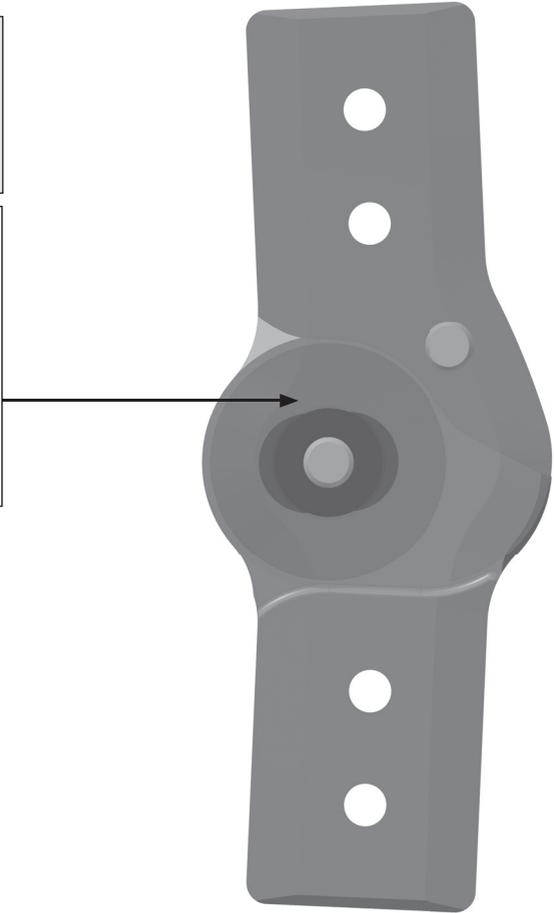
Beinseite
Leg Side

■ links/left ■ rechts/right

Montierte Gleitscheiben-Version
Mounted Sliding Washer Version

1. GS/SW _____ - _____

2. GS/SW _____ - _____



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.

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FIOR & GENTZ

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