FIOR & GENTZ
ORTHOPÄDIETECHNIK MIT SYSTEM

Instructions for Use for Orthotists or Qualified/ Trained Experts System Ankle Joint

EN

NEURO SWING H_2O

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Content **Page**

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

⚠ 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 orthotist or qualified/trained expert and/or the patient is established.

2.2 All Instructions for a Safe Handling of the 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 possible dangers, 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 joint according to the information in these instructions for use. Deviating processing and modifications of the system joint require the written consent of the manufacturer.

⚠ WARNING

Risk of Falling Due to Loosening of the Bearing Nut
Secure the screw of the joint case 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 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, plan the treatment again and, if necessary, produce a new orthosis.

⚠ WARNING

Risk of Falling Due to Improper Shoe/Wrong Shoe Pitch
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 Excessive Readjustment of the Spring Unit
Adjust the spring unit according to the information in these instructions for use. Do not make readjustments of more than 10°. Use the laser markings on the system stirrup and the joint case to check the readjustment.

⚠ WARNING

Damage to the Anatomical Joint Due to Incorrect Position of the Joint's Mechanical Pivot Point
Determine the joint's 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 by Not Providing the Necessary 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 these instructions for use.

⚠ WARNING

Jeopardising the Therapy Goal Due to Incorrectly Adjusted Spring Units
Screw in the spring unit up to the system stirrup and do not preload the spring unit. If the stops are reached too early or too late, either the range of motion is restricted or the patient is not sufficiently stabilised by the orthosis, which worsens the gait. In order to make full use of the functional potential of the orthosis, the spring units must be appropriately selected and correctly adjusted.

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

NOTICE

Limitation of the Joint Function Due to Improper Dirt Removal
Inform the patient on how to properly remove dirt from the orthosis and the system joint.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Respect the specified maintenance intervals in order to avoid joint dysfunction. Inform the patient about the maintenance appointments to be respected. Enter the next maintenance appointment in the orthosis service passport of the patient.

3. Use

3.1 Intended Use

The **NEURO SWING H_2O** system ankle joint is exclusively for use for orthotic fittings of the lower extremity. The system joint provides motion control and is only allowed to be used for producing an AFO or a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg. The system joint may only be used for one fitting and must not be reused.

3.2 Indication

The indication for the treatment with an orthosis for the lower extremity is 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 joint must only be handled by an orthotist or qualified/trained expert.

3.4 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme loads connected to activities like running, climbing and parachuting are excluded. The **NEURO SWING H_2O** is waterproof and, therefore, it is suitable for use in wet areas. It is equipped with a waterproof carbon fibre reinforced joint case, a seawater-resistant stainless steel screwing and spring units which are inside water- and dirt-resistant spring unit sleeves. The spring units of the system joint are waterproof in depths of up to 3 metres. The system joint can be used at a maximum temperature of +60° C.

3.5 Combination Possibilities with Other System Joints

The **NEURO SWING H_2O** system ankle joint can be mounted in combination with waterproof system knee joints from our product range in a waterproof orthosis.

We recommend that you use the Orthosis Configurator when selecting all system components for your orthosis and follow the recommendations of the configuration result.

All system ankle joints can also be used for the prosthetic treatment of patients with partial foot amputations. For this purpose, the orthosis produced for the patient by the orthotist or qualified/trained expert as a custom-made product is combined with a foot prosthesis. Further information can be found in the **Guide to Partial Foot Amputations**.

4. Joint Function

The basic function of all system ankle joints is to provide motion control. Due to the used spring units, it has the additional functions listed below:

Function	System Component
dorsal (posterior spring unit): determination of the maximum range of motion in plantar flexion; integrated dorsiflexion assist; ensures a controlled lowering of the foot during loading response	spring units
ventral (anterior spring unit): determination of the maximum range of motion in dorsiflexion; increased energy return during heel lift supports push off	
dorsal and ventral: dynamically bringing the patient into an upright position as well as stabilising the patient when walking and standing by balancing the body	

5. Scope of Delivery

Description	Quantity
system ankle joint (fig. 1)	1
set 2-component adhesive with primer (fig. 2)	1
orthosis joint grease, 3g (without figure)	1
assembly/lamination dummy (fig. 3)	1

The corresponding spring units and system stirrups have to be ordered separately.

fig. 1

fig. 2

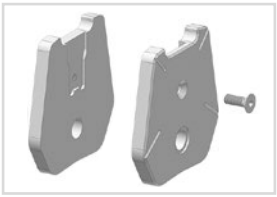


fig. 3

6. 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.

7. Tools for Assembling the System Joint

Tools	System Width			
	12mm	14mm	16mm	20mm
T15 hexalobular screwdriver/bit	x	-	-	-
T20 hexalobular screwdriver/bit	-	x	x	x
torque screwdriver 1-6Nm	x	x	x	x
hexagonal screwdriver with spherical head, 4 x 100mm	x	-	-	-
hexagonal screwdriver with spherical head, 5 x 100mm	-	x	x	x
sliding washer centring pin	x	x	x	x

8. Assembly Instructions

The system joint is delivered fully assembled. All functions are checked beforehand. You have to disassemble the system joint for mounting it in the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure the screw with the torque specified in paragraph 8.4.

fig. 4

8.1 Mounting the System Stirrup

fig. 5

1 Clean the thread of the bearing nut after laminating with LOCTITE® 7063 Super Clean. Allow the thread to air-dry for 10 minutes.
2 Grease the friction surfaces of the bearing nut as well as the contact surfaces of the system stirrup between system stirrup and spring units with orthosis joint grease.
3 Grease the two sliding washers **slightly** on both sides with orthosis joint grease.
4 Place the sliding washers onto both sides of the system stirrup (fig. 4).
5 Slide the system stirrup from below into the joint case (fig. 5). Make sure that the sliding washers remain in the right position. To do so, use the sliding washer centring pin.

fig. 6

Make sure not to damage the sliding washers during the assembly. Jammed sliding washer particles can cause lateral play in the system joint.

fig. 7

6 Put the bearing nut into the joint case. The bearing nut must be fully inserted in the opening (fig. 6).
7 Place the cover disc onto the joint case's front.
8 Screw in the countersunk flat head screw (S1; fig. 7).

8.2 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.

8.3 Mounting the Spring Units

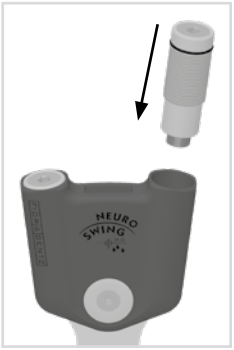


fig. 8

1 Screw the spring unit for dorsiflexion into the anterior spring duct until the required alignment of the orthosis is achieved (fig. 8).
2 Screw the spring unit for plantar flexion into the posterior spring duct until it touches the system stirrup. Do not preload the spring unit.

Do not disassemble the spring unit as it is under pressure. There is a risk of injury when opening the spring unit sleeve. The spring unit and the O-ring for the **NEURO SWING H_2O** system ankle joint must not be greased.

8.4 Securing the Screws

The screws are secured after the orthosis has been produced and tried on and before it is handed over to the patient.

1 Secure the screw for the joint case (fig. 7) with the torque corresponding to the system width and LOCTITE® 243 medium strength.
2 Let the adhesive harden (final strength after approx. 24 hours).

Screw for Joint Case	System Width			
	12mm	14mm	16mm	20mm
S1 (screw 1, axle screw)	3Nm	4Nm	4Nm	4Nm

The screw of the joint case is not secured with the necessary torque at delivery. You can also find information on the torque on the cover disc of the system joint.

9. Adjustment Options on the Orthosis

An orthosis with adjustable system ankle joints (fig. 9) can be individually adapted to the pathological gait. The adjustments described in paragraph 9.1 do not influence each other and can be changed separately.

Mind the correct adjustment of the dorsiflexion stop when mounting the system ankle joint. It is decisive for the entire alignment of the orthosis.

fig. 9

9.1 Adjustments on the Spring Unit

There are spring units with disc springs (2) and pressure springs (3). The alignment of the orthosis can be adjusted by screwing and unscrewing the spring units (1; fig. 9). The spring force can be changed with spring units in different strengths.

9.1.1 Adjustable Alignment

Always unscrew only one spring unit at a time to adjust the angle between lower leg and foot (fig. 10). Only then, screw in the other spring unit until it touches the system stirrup. Do not preload the spring unit as this will restrict the maximum possible range of motion. An O-ring is attached to the external thread of the spring unit to ensure that the position of the spring unit does not change.

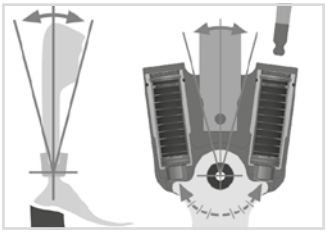


fig. 10

9.1.2 Variable Spring Force

Insert a spring unit into the spring duct that corresponds with the required spring force. There are five spring units with spring forces ranging from normal to extra strong (fig. 11). Note that the spring unit determines the maximum possible range of motion.

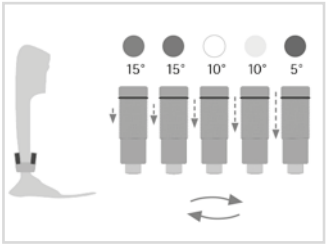


fig. 11

9.2 Reading the Joint Angles

There are markings (fig. 12) on the joint case and the system stirrup which indicate the angle of the system components to each other. This allows you to check the individual normal posture (the orthosis' basic alignment), record the joint angle and compare later deviations.

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

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

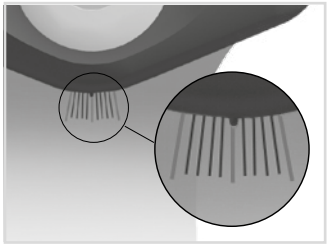


fig. 12

10. Mounting to the System Anchor

The system anchor of the **NEURO SWING H_2O** system ankle joint has to be adhered to the system joint according to our recommended production technique (fig. 13). It is adhered after the orthosis parts have been tempered. Before using the adhesive set, make sure that the expiry date has not yet passed. The adhesive set should be stored in a cool place.

fig. 13

Note that the orthosis should not be tempered after connecting the system anchor to the system joint. The properties of the adhesive connection change at temperatures that are too high.

You will find more detailed information in the **Instructions for Use for Orthotists or Qualified/Trained Experts System Anchors for Waterproof System Joints**. You will find information on the production techniques in the section "Online Tutorials" on our website www.fior-gentz.com.

11. Maintenance

Check the system joint for wear and functionality every 6 months. In particular, check the joint components listed in the following table for the possible problems described and, if necessary, take the appropriate measures. Also check the functionality after every maintenance carried out. It must be possible to move the system joint without problems or unusual noises. Make sure that there is no lateral play and no play around the axis.

Joint Component	Potential Problem	Measure	Inspection/ Replacement, If Necessary	Latest Replacement
spring unit	wear or reduced spring force/range of motion	replacing spring unit	every 6 months	every 18 months
	noises of the spring unit	replacing spring unit	every 6 months	every 18 months
O-ring	wear	replacing O-ring	every 6 months	every 18 months
sliding washer	wear	replacing sliding washer, see paragraph 11.2	every 6 months	every 18 months
sliding bushing	wear	replacing sliding bushing	every 6 months	every 18 months
countersunk flat head screw	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bearing nut	wear	replacing bearing nut	every 6 months	every 36 months
system stirrup	wear or breakage	replacing system stirrup	every 6 months	every 48 months

Clean the thread of the bearing nut with LOCTITE® 7063 Super Clean at every maintenance. Allow the thread to air-dry for 10 minutes.

Secure the screw for the joint case with the torque corresponding to the system width and LOCTITE® 243 medium strength at every maintenance (see paragraph 8.4). Remove all adhesive residues first.

When disassembling the system joint, make sure to fix the bearing nut on the backside with one finger while unscrewing the screw. This prevents the bearing nut from slipping out of the opening and damaging the material of the joint case.

11.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport from their orthotist or a qualified/trained expert when the orthosis is handed over. The orthosis must be checked every 6 months in order to maintain its function and to ensure the safety of the patient. The maintenance appointments are noted and confirmed in the orthosis service passport.

fig. 14

11.2 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS1911-**040** is 0.40mm thick). Each thickness has a different marking (fig. 15). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use. Please use the sliding washer centring pin to position the sliding washers.

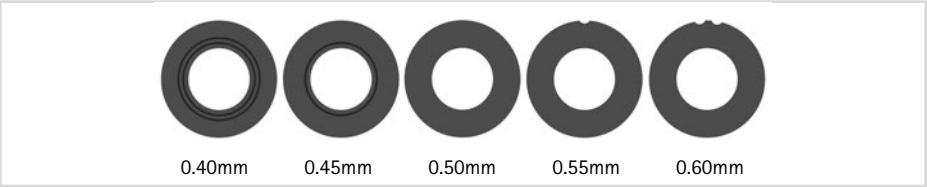


fig. 15

11.3 Dirt Removal

The **NEURO SWING H_2O** system ankle joint is suited for a usage in wet areas. Nevertheless, dirt must be removed when necessary and during regular maintenance. For this purpose, disassemble the system joint - but not the spring units - and clean the soiled parts as well as the spring unit sleeves with a dry cloth.

In order to optimise the lifespan, we recommend rinsing the orthosis with clear tap water, especially after using it in salt water, chlorine water and sand.

12. Period of Use

To guarantee a safe use and complete functionality as well as an unlimited period of use of the system joints, you must adhere to the following conditions:

- Adhere to the specified maintenance intervals without interruption and document each maintenance (see paragraph 11).
- Adhere to the determined maintenance conditions (see paragraph 11).
- Check the wear parts, as required, and exchange them in the defined intervals (see paragraph 11).
- Check the adjustment of the system joint during maintenance and correct it, if necessary (see paragraph 11).
- Check the functionality of the system joint during maintenance (see paragraph 11).
- The maximum load determined during the planning of the custom-made product shall not be exceeded by changes in the patient data (e.g. due to weight gain, growth or an increased activity). If the determined maximum load on the system joints is exceeded, the system joint must no longer be used. When planning the custom-made product, expected changes in patient data need to be taken into account.
- The period of use of the waterproof system joints can be affected by use in salt water, clorine water or sand. After use in salt water, chlorine water or sand, rinse the system joint with clear tap water. Instruct the patient accordingly.The period of use of the system joints ends with the period of use of the custom-made product (orthosis).
- The multiple use of the system joint in another custom-made product is not allowed (see paragraph 18).

13. Storage

It is recommended to store the system joint in its original packaging until the custom-made product is produced.

14. Spare Parts

14.1 Exploded View Drawing NEURO SWING H_2O

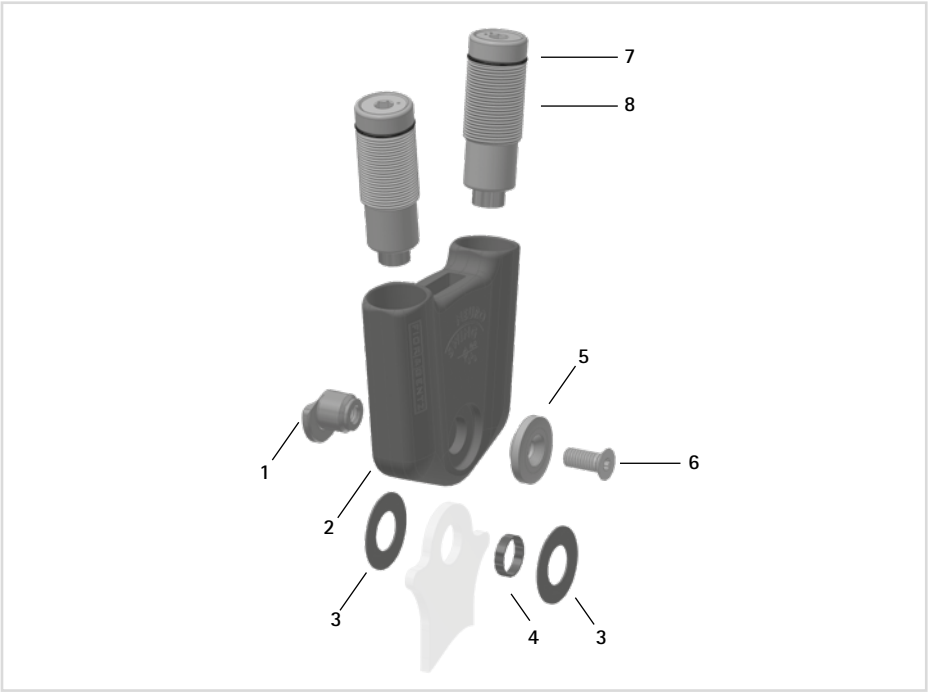


fig. 16

14.2 Spare Parts for the NEURO SWING H_2O System Ankle Joint

Item	Article Number for System Width				Description
	12mm	14mm	16mm	20mm	
1	SF0591-C/1	SF0592-C/1	SF0593-C/1	SF0595-C/1	bearing nut
2	SF0501-C	SF0502-C	SF0503-C	SF0505-C	joint case
3	GS1409-*	GS1911-*	GS2413-*	GS2815-*	sliding washer*
4	BR1009-L020	BR1211-L025	BR1312-L030	BR1514-L030	sliding bushing
5	SF0591-C/2	SF0592-C/2	SF0593-C/2	SF0595-C/2	cover disc
6	SC1404-L10	SC1405-L11	SC1406-L14	SC1406-L14	countersunk flat head screw with hexalobular socket

14.3 Sliding Washers

* Sliding Washers			
Article Number for System Width			
12mm	14mm	16mm	20mm
Ø = 14mm	Ø = 19mm	Ø = 24mm	Ø = 28mm
GS1409-040	GS1911-040	GS2413-040	GS2815-040
GS1409-045	GS1911-045	GS2413-045	GS2815-045
GS1409-050	GS1911-050	GS2413-050	GS2815-050
GS1409-055	GS1911-055	GS2413-055	GS2815-055
GS1409-060	GS1911-060	GS2413-060	GS2815-060

14.4 Spring Units

Item	Article Number for System Width				Description
	12mm	14mm	16mm	20mm	
7	VE3771-085/13	VE3771-100/12	VE3771-12/12	VE3771-15/13	O-ring for securing the spring unit
8	SF5801-C/15/03	SF5802-C/15/05	SF5803-C/15/07	SF5805-C/15/18	spring unit, blue, normal, max. 15° range of motion
8	SF5801-C/15/06	SF5802-C/15/11	SF5803-C/15/15	SF5805-C/15/25	spring unit, green, medium, max. 15° range of motion
8	SF5801-C/10/12	SF5802-C/09/16	SF5803-C/10/21	SF5805-C/10/40	spring unit, white, strong, max. 10° range of motion
8	SF5801-C/10/19	SF5802-C/10/29	SF5803-C/10/31	SF5805-C/10/60	spring unit, yellow, very strong, max. 10° range of motion
8	SF5801-C/05/33	SF5802-C/05/53	SF5803-C/05/63	SF5805-C/05/99	spring unit, red, extra strong, max. 5° range of motion

15. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 17). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 17

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

16. Signs and Symbols

Symbols on the Packaging

MD medical device

17. 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.

18. 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.

19. Informationen für die Versorgungsdokumentation/

Bitte heften Sie diese Gebrauchsanweisung zu Ihrer Versorgungsdokumentation!

Patientendaten

Name	
Straße	
PLZ, Wohnort	
Telefon privat	
Telefon geschäftlich	
Kostenträger	
Mitgliedsnummer	
Behandelnder Arzt	
Diagnose	

20. Handing Over the Orthosis

The orthotist or qualified/trained expert has also handed over the instructions for use for patients as well as the orthosis service passport to you as a patient, parent or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to you in detail. You will find the next maintenance appointment in the orthosis service passport. Bring the orthosis service passport with you to every maintenance appointment.

Place, Date

Signature Patient

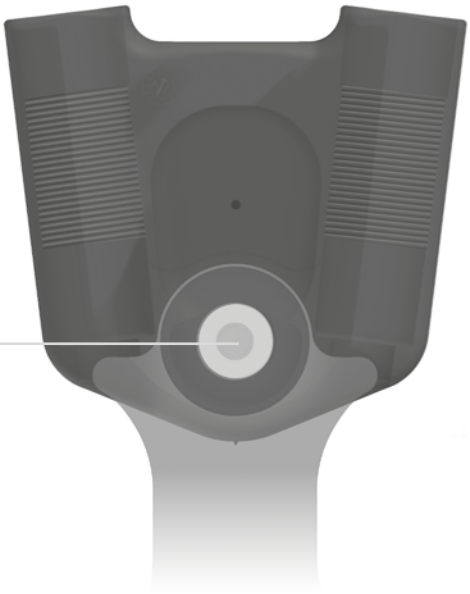
Leg Side

☐ left
☐ right

Mounted Sliding Washer

1. GS _____ - _____

2. GS _____ - _____



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