FIOR & GENTZ

Product Manual for Qualified Specialists in Orthopaedic Technology NEURO SWING FIT TEST-AFO

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NEURO SWING FIT TEST-AFO

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1. Information

This product manual is addressed to qualified specialists in orthopaedic technology and does not contain any notes about dangers which are obvious to them. To achieve optimal test results, please instruct the patient and/or care team in the use of the product.

2. General Safety Instructions

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.

Risk of Falling Due to Improper Use of the Test Orthosis
Only use the test orthosis for a short-term test in a health care facility and under your supervision. The test orthosis may not be handed over to the patient for a longer period of time.

Risk of Falling Due to Breakage of the Orthosis Shell
Errors in processing can lead to a loss of material strength and breakage of the orthosis shells. Regarding the orthosis shells, avoid:
- heating them;
- mechanically deforming them;
- extensively grinding them and
- processing them in the area where the system stirrup or system anchor is integrated.

Non-Optimal Test Results Due to Leg Length Discrepancy
Determine the leg length discrepancy caused by the foot piece of the test orthosis and provide for an appropriate leg length compensation or take the effects into account during the test.

Non-Optimal Test Results 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 this product manual.

Non-Optimal Test Results 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 test orthosis, which worsens the gait. In order to utilise the full functional potential of the test orthosis, the spring units must be suitably selected and correctly adjusted.

Non-Optimal Test Results Due to Loosening of the Spring Unit
Do not grease the spring unit and the O-ring, neither intentionally nor accidentally.

Non-Optimal Test Results Due to Improper Joint Adjustment
For a correct adjustment of the system joint note the instructions for use for the **NEURO SWING Carbon** system ankle joint.

Limitation of the Joint Function Due to Improper Dirt Removal
Check the test orthosis for dirt particles after each test and remove them properly.

Limitation of the Joint Function Due to Lack of Maintenance
Respect the specified maintenance intervals in order to avoid joint dysfunction which could affect the test results negatively.

3. Use and Indication

The **NEURO SWING FIT TEST-AFO** with premounted **NEURO SWING Carbon** system ankle joint is a preproduced orthosis used as test orthosis for a later treatment with a custom-made AFO to which a system ankle joint with dynamic dorsiflexion and plantar flexion stop is mounted, such as the **NEURO SWING**. It is only meant for sale to a qualified specialist in orthopaedic technology and may not be handed over to the patient permanently.

The indications for the treatment with an orthosis for the lower extremity which is equipped with a system ankle joint with dynamic dorsiflexion and plantar flexion stop are insecurities when standing and walking that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/ malfunctions or as a result of neurological disorders (such as stroke or PAD), physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. An evaluation regarding the safe handling of the orthosis by the patient must be carried out.

With the **NEURO SWING FIT TEST-AFO**, the benefit of an AFO for the above-mentioned indications and the individual requirements of the patient can be evaluated.

4. Joint Function

Due to the spring units used, the mounted system ankle joint has the following functions:

System Component	Function
spring units	**dorsal (posterior spring unit):** - determination of the maximum range of motion in plantar flexion - integrated dorsiflexion assist - controlled lowering of the foot during loading response
	ventral (anterior spring unit): - determination of the maximum range of motion in dorsiflexion - increased energy return during heel lift to support push off
	ventral (static dorsiflexion stop): - limitation of the maximum range of motion in dorsiflexion
	dorsal and ventral: - dynamically bringing the patient from a bent into an upright position as well as improving the patient's stability while walking and standing by balancing the body

5. Scope of Delivery

The **NEURO SWING FIT TEST-AFO** is only available as a set consisting of a left and a right test orthosis.

Description	Quantity
preproduced **NEURO SWING FIT TEST-AFO** with premounted **NEURO SWING Carbon** system ankle joint (fig. 1)	2
spring unit	5
cloth bag made of cotton for orthoses (without fig.)	2

fig. 1

6. Selection of the Orthosis Size for the Test

Determine the patient's shoe size and select the corresponding orthosis size. For patients with a heavy body weight or of sturdy build, it may be necessary to select a larger orthosis size.

Shoe Size	Orthosis Size	System Width
29–31	XXS	14mm
32–34	XS	14mm
35–37	S	16mm
38–40	M	16mm
41–43	L	20mm
44–46	XL	20mm

7. Selection of a Suitable Shoe

A closed low shoe with removable foot orthotic in the correct shoe size is required so that the test result is not distorted by an incorrectly selected shoe. A suitable fastener (e.g. lacing) should securely fix the foot and the test orthosis in the shoe. The pitch of the shoe should match the pitch of the foot piece so that the foot piece fits completely into the shoe.

Instruct the patient to wear a knee stocking or a knee high compression stocking.

8. Tools for Assembling the System Joint

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

9. Assembly Instructions

The **NEURO SWING FIT TEST-AFO** is delivered with a premounted **NEURO SWING Carbon** system ankle joint. All functions are checked beforehand. You have to disassemble the system joint for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure the screw with the torque specified in paragraph 9.4.

You can find more information on the assembly in the online tutorial **Joint Assembly NEURO CLASSIC Carbon, NEURO SWING Carbon** (see QR code, fig. 2) on the FIOR & GENTZ website.

fig. 2

Only use the FIOR & GENTZ orthosis joint grease to grease the system components.

9.1 Mounting the Foot Piece with Integrated System Stirrup

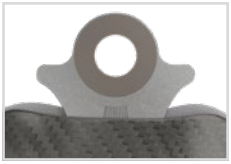

fig. 3

1 Before the assembly, clean the thread of the bearing nut with LOCTITE® 7063 Super Clean. Allow the thread to air-dry for 10 minutes.
2 Grease the sliding 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.

fig. 4

Greasing the contact surfaces of the system stirrup is important in order to prevent wear of the system stirrup.

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. 3).
5 Slide the system stirrup from below into the joint case (fig. 4). Make sure that the sliding washers remain in the correct position. To do so, use the sliding washer centring pin.

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

fig. 5

6 Put the bearing nut into the joint case. The bearing nut must be fully inserted in the opening (fig. 5).
7 Place the cover disc onto the joint case's front.
8 Screw in the countersunk flat head screw (S1; fig. 6).

fig. 6

9.2 Checking the Free Movement

Tighten the screw for the joint case with the appropriate torque (see paragraph 9.4). 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.

9.3 Mounting the Spring Units

The spring unit and the O-ring for the **NEURO SWING Carbon** system ankle joint must not be greased, neither intentionally nor accidentally.

fig. 7

Before mounting the spring unit, make sure that the workspace and your fingers as well as the spring unit, O-ring and spring duct are grease-free. If necessary, degrease everything.

1 Screw the spring unit for dorsiflexion or the static dorsiflexion stop into the anterior spring duct until the required alignment of the test orthosis is achieved (fig. 7).
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.

9.4 Securing the Screw

The screw is secured after the maintenance of the test orthosis.

1 Secure the screw for the joint case (fig. 6) 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		
	14mm	16mm	20mm
S1 (screw 1, axle screw)	4Nm	4Nm	4Nm

The screw of the joint case is secured with the necessary torque at delivery. You can also find information on the torque on the cover disc of the system joint.

10. Adjustment Options on the Test Orthosis

To achieve optimal test results, the test orthosis can be individually adapted to the patient's needs with adjustable system ankle joints (fig. 8). The adjustments described do not influence each other and can be made independently of each other.

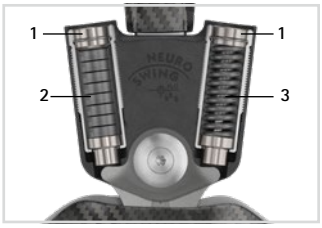

fig. 8

Mind the correct adjustment of the dorsiflexion stop when mounting the system ankle joint. It is decisive for the entire alignment of the test orthosis. You can find more information on this in the online tutorial **AFO Alignment Guidelines** (see QR code, fig. 9) on the FIOR & GENTZ website.

fig. 9

10.1 Adjustments on the Spring Unit

There are spring units with disc springs (2) and coil springs (3) (fig. 8). The alignment of the test orthosis can be adjusted by screwing and unscrewing the spring units (1) (fig. 7). The spring force can be changed with spring units in different strengths.

10.2 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.

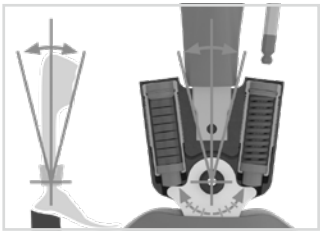

fig. 10

The system joint can be readjusted by up to 10° in both dorsiflexion and plantar flexion. Depending on the height of the heel height or a possible height compensation, this degree decreases. For patients with a heel height or height compensation too high to correctly adjust the test orthosis, the **NEURO SWING FIT TEST-AFO** is not suitable.

10.3 Variable Spring Force

The spring force can be changed by exchanging the spring units. 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). The static dorsiflexion stop (fig. 11) does not have any dynamic properties (0° range of motion). Note that the spring unit as well as the static dorsiflexion stop determine the maximum possible range of motion.

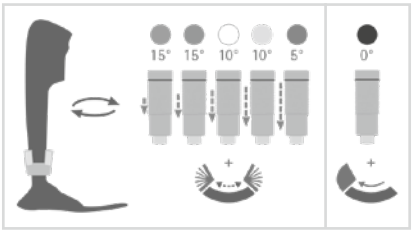

fig. 11

11. Regular Inspection of the Test Orthosis

To ensure a proper functioning of the test orthosis and especially of the mounted **NEURO SWING Carbon** system joint during the test, it is useful to check the test orthosis, but especially the components listed in the following table, regularly for wear and functionality. It should be possible to move the system joint without problems or unusual noises and it should neither present lateral play nor play around the axis.

Joint Component	Potential Problem	Measure
O-ring for securing the spring unit and the static dorsiflexion stop	wear	replacing O-ring
spring unit	wear	replacing spring unit
	noise of spring unit	replacing spring unit
sliding washer	wear	replacing sliding washer, see paragraph 11.1
sliding bushing	wear	replacing sliding bushing
countersunk flat head screw with hexalobular socket	wear	replacing countersunk flat head screw
bearing nut	wear	replacing bearing nut

It is recommended to clean the thread of the bearing nut with LOCTITE® 7063 Super Clean at every inspection. Allow the thread to air-dry for 10 minutes.

It is recommended to secure the screw for the joint case with the appropriate torque and LOCTITE® 243 medium strength at every inspection (see paragraph 9.4). 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.

You can find more information on the maintenance of the mounted **NEURO SWING Carbon** system ankle joint in the instructions for use for the **NEURO SWING Carbon** (see QR code, fig. 12) on the FIOR & GENTZ website.

fig. 12

11.1 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. 13). You will find the article numbers of the premounted sliding washers on the back page of this product manual. Please use the sliding washer centring pin to position the sliding washers (fig. 14).

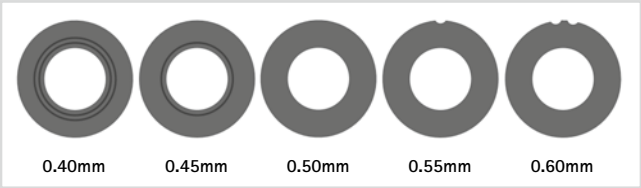

fig. 13

fig. 14

11.2 Dirt Removal

The **NEURO SWING FIT TEST-AFO** can be used by several people. Therefore, it is recommended to clean the **NEURO SWING FIT TEST-AFO** after each use.

If there is no visible soiling, the entire test orthosis should be cleaned/sprayed with a disinfectant suitable for hospitals and completely dried before the next use.

If there is visible soiling, the padding material can be hand washed. If the padding material is too worn or damaged at your discretion, it should be replaced.

You have to disassemble the **NEURO SWING Carbon** system joint to clean it. Do not disassemble the spring units. Clean soiled system components as well the spring unit sleeves with a dry cloth.

12. Spare Parts

The following spare parts are available in case something on your **NEURO SWING FIT TEST-AFO** has to be replaced:

12.1 Exploded View Drawings Padding Set and **NEURO SWING Carbon**

fig. 15

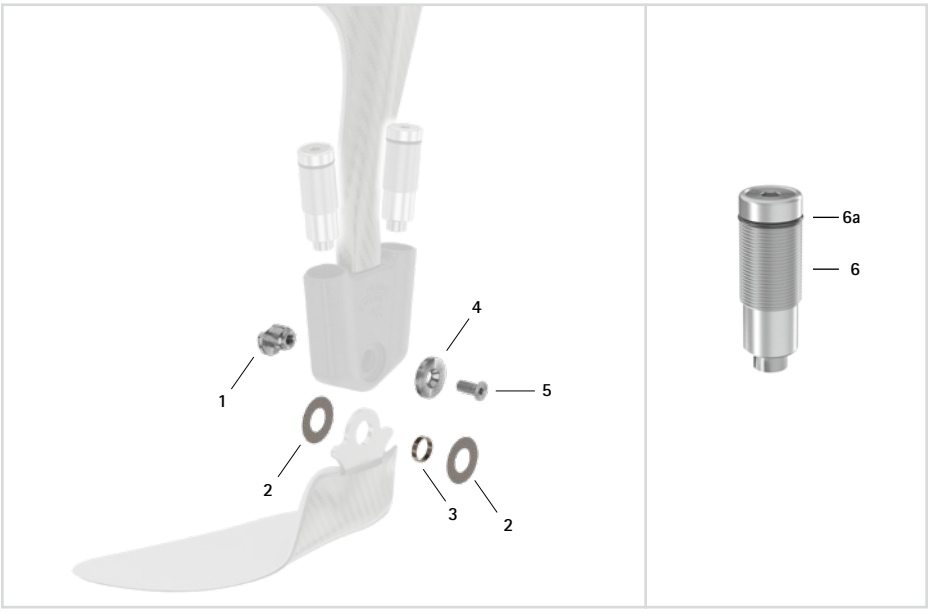

fig. 16

12.2 Spare Parts for the **NEURO SWING FIT TEST-AFO**

12.2.1 Padding Set

Fig.	Article Number for System Width 14mm, left	14mm, right	Orthosis Size	Padding Set Components
15	AC5202-XXS/P/L	AC5202-XXS/P/R	XXS	PL3751-XXS/L pre-cut padding material, black, left PL3751-XXS/R pre-cut padding material, black, right
				KV1004-L400 hook and loop fastener with loop
				GP1000-L090 strap pad
				GP1201-L070 strap pad holder
				KV0020-22/06 6 x hook dots, self-adhesive, transparent
				NI2111-L04 upper part for hollow rivet
				NI2011-L08 lower part for hollow rivet
15	AC5202-XS/P/L	AC5202-XS/P/R	XS	PL3752-XS/L pre-cut padding material, black, left PL3752-XS/R pre-cut padding material, black, right
				KV1004-L450 hook and loop fastener with loop
				GP1000-L090 strap pad
				GP1201-L070 strap pad holder
				KV0020-22/06 6 x hook dots, self-adhesive, transparent
				NI2111-L04 upper part for hollow rivet
				NI2011-L08 lower part for hollow rivet
Fig.	**16mm, left**	**16mm, right**	**Orthosis Size**	**Padding Set Components**
15	AC5203-S/P/L	AC5203-S/P/R	S	PL3753-S/L pre-cut padding material, black, left PL3753-S/R pre-cut padding material, black, right
				KV1004-L500 hook and loop fastener with loop
				GP1000-L130 strap pad
				GP1201-L100 strap pad holder
				KV0020-22/06 6 x hook dots, self-adhesive, transparent
				NI2111-L04 upper part for hollow rivet
				NI2011-L08 lower part for hollow rivet
15	AC5203-M/P/L	AC5203-M/P/R	M	PL3753-M/L pre-cut padding material, black, left PL3753-M/R pre-cut padding material, black, right
				KV1004-L500 hook and loop fastener with loop
				GP1000-L130 strap pad
				GP1201-L100 strap pad holder
				KV0020-22/06 6 x hook dots, self-adhesive, transparent
				NI2111-L04 upper part for hollow rivet
				NI2011-L08 lower part for hollow rivet

Fig.	Article Number for System Width 20mm, left	20mm, right	Orthosis Size	Padding Set Components
15	AC5205-L/P/L	AC5205-L/P/R	L	PL3755-L/L pre-cut padding material, black, left PL3755-L/R pre-cut padding material, black, right
				KV1004-L550 hook and loop fastener with loop
				GP1000-L130 strap pad
				GP1201-L100 strap pad holder
				KV0020-22/06 6 x hook dots, self-adhesive, transparent
				NI2111-L04 upper part for hollow rivet
				NI2011-L08 lower part for hollow rivet
15	AC5205-XL/P/L	AC5205-XL/P/R	XL	PL3755-XL/L pre-cut padding material, black, left PL3755-XL/R pre-cut padding material, black, right
				KV1004-L550 hook and loop fastener with loop
				GP1000-L170 strap pad
				GP1201-L130 strap pad holder
				KV0020-22/06 6 x hook dots, self-adhesive, transparent
				NI2111-L04 upper part for hollow rivet
				NI2011-L08 lower part for hollow rivet

12.3 Spare Parts for the **NEURO SWING Carbon** System Ankle Joint

Fig. 16 Item	Article Number for System Width 14mm	16mm	20mm	Description
1	SF0592-C/1	SF0593-C/1	SF0595-C/1	bearing nut
2	GS1911-*	GS2413-*	GS2815-*	sliding washer*
3	BR1211-L025	BR1312-L030	BR1514-L030	sliding bushing
4	SF0592-C/2	SF0593-C/2	SF0595-C/2	cover disc
5	SC1405-L11	SC1406-L14	SC1406-L14	countersunk flat head screw with hexalobular socket

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

12.3.1 Spring Units and Static Dorsiflexion Stop

Fig. 16 Item	Article Number for System Width			Description
	14mm	16mm	20mm	
6	SF5802-C/15/05	SF5803-C/15/07	SF5805-C/15/18	spring unit, blue, normal, max. 15° range of motion
6	SF5802-C/15/11	SF5803-C/15/15	SF5805-C/15/25	spring unit, green, medium, max. 15° range of motion
6	SF5802-C/09/16	SF5803-C/10/21	SF5805-C/10/40	spring unit, white, strong, max. 10° range of motion
6	SF5802-C/10/29	SF5803-C/10/31	SF5805-C/10/60	spring unit, yellow, very strong, max. 10° range of motion
6	SF5802-C/05/53	SF5803-C/05/63	SF5805-C/05/99	spring unit, red, extra strong, max. 5° range of motion
6	-	SF5803-C/0	SF5805-C/0	static dorsiflexion stop, black, 0° range of motion
6a	VE3771-100/12	VE3771-12/12	VE3771-140/15	O-ring for securing the spring unit and the static dorsiflexion stop

13. Disposal

Dispose of the test orthosis 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 test orthosis.

14. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply.

The information in this product manual is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

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FIOR & GENTZ

Mounted Sliding Washers for Left Test Orthosis

1. GS _____ - _____

2. GS _____ - _____

Mounted Sliding Washers for Right Test Orthosis

1. GS _____ - _____

2. GS _____ - _____

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