FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology
Pulling Cables

EN

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1. Information

These instructions for use are addressed to qualified specialists in orthopaedic technology 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

You can find the safety instructions for handling system joints containing pulling cables in the instructions for use of the locked system knee joints**.**

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 qualified specialist in orthopaedic technology and/or the patient is established.

3. Use

3.1 Intended Use

The FIOR & GENTZ pulling cables are available as accessory parts for locked system knee joints. They facilitate unlocking the system knee joint as well as putting the orthosis on or taking it off. Pulling cables are well suited for patients with adequate motor and cognitive skills.

3.2 Indication

The indications for the treatment with an orthosis for the lower extremity 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.

3.3 Qualification

Pulling cables must only be handled by a qualified specialist in orthopaedic technology.

3.4 Application

All FIOR & GENTZ pulling cables were developed for orthoses for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing, parachuting and football, is excluded.

4. Scope of Delivery

Depending on the construction of the orthosis, you can choose between two pulling cables.

Description	Quantity
pulling cable, unilateral (fig. 1)	1
pulling cable, separable (fig. 2)	1

5. Load

The actual load on the system joints is based on the relevant patient data. The load and the appropriate system components can be determined by using the Orthosis Configurator. We recommend that you use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique. You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

6. Pulling Cables

6.1 Unilateral Pulling Cable

The unilateral pulling cable (fig. 1) can be used for an orthosis with a locked system knee joint and a unilateral construction at knee height. The following system knee joints are suitable for this:

fig. 1

- **NEURO LOCK MAX**
- **NEURO FLEX MAX** lock function
- **NEURO FLEX MAX** step lock function
- **NEURO LOCK Carbon**

This pulling cable makes it easier for the patient to unlock the system knee joint.

In order to mount the pulling cable to the locking pawl of the system knee joint, you need a pulling cable adaptor (see paragraph 8.1).

6.2 Separable Pulling Cable

The separable pulling cable with coupler (fig. 2) can be used for an orthosis with locked system knee joints and a bilateral construction at knee height. The following system knee joints are suitable for this:

fig. 2

- **NEURO LOCK**
- **NEURO LOCK MAX**
- **NEURO FLEX MAX** lock function
- **NEURO FLEX MAX** step lock function
- **NEURO LOCK Carbon**

This pulling cable contains a coupler which can be used to open and close the pulling cable. This makes it easier for the patient to put the orthosis on and take it off. The coupler is already premounted to the pulling cable.

In order to mount the pulling cable to the locking pawl of the system knee joint, you need a pulling cable adaptor (see paragraph 8.1).

7. Tools for Assembling the Pulling Cable

Description
diagonal cutters
thread cutter
punch and hammer
LOCTITE® 243 medium strength
1.5mm hexagon screwdriver (for headless pin in the connecting screw for coupler)

8. Assembling the Pulling Cables

To ensure an optimal functioning of the pulling cables on the locked system knee joint, follow the assembly instructions below.

You can find more information on preparing and mounting the pulling cables in the online tutorial **Preparing and Mounting the Pulling Cable** (see QR code, fig. 3) on the FIOR & GENTZ website.

fig. 3

8.1 Mounting to the Locking Pawl

Use the pulling cable adaptor (fig. 4 and 6) to attach the pulling cable to the locking pawl.

NEURO LOCK, NEURO LOCK MAX, NEURO FLEX MAX

1 Secure the threaded sleeve (3) on the pulling cable.
2 Push the pulling cable from below through the pulling cable holder (2). The threaded sleeve (3) should be flush with the holder and no longer visible.
3 Place the pulling cable holder (2) into the bore of the locking pawl (fig. 5).
4 Secure the pulling cable holder (2) with the pan head screw (1). Secure the pan head screw with LOCTITE® 243 medium strength.

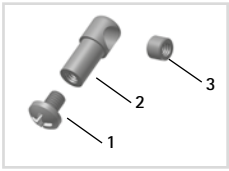

fig. 4

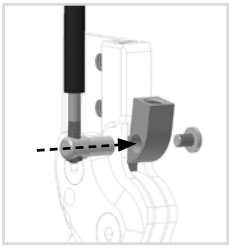

fig. 5

NEURO LOCK Carbon

1 Adhere the retainer for pulling cable holder (2; fig. 6) with the 2-component adhesive into the bore of the locking pawl. The bore of the retainer for pulling cable holder must run parallel to the joint axis.
2 Place the pulling cable holder (4) into the bore of the retainer for pulling cable holder (fig. 7).
3 Secure the pulling cable holder with the pan head screw (1). Secure the pan head screw with LOCTITE® 243 medium strength.
4 Secure the threaded sleeve (5) on the pulling cable (3).
5 Push the pulling cable from below through the pulling cable holder. The threaded sleeve should be flush with the holder and no longer visible.

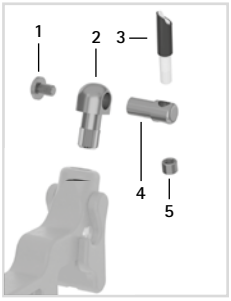

fig. 6

The 2-component adhesive is a disposable product. Adhere the retainer for pulling cable holder and the system anchor at the same time.

8.2 Mounting the Unilateral Pulling Cable

1 Pull the ferrule over the upper, free end of the pulling cable.
2 Insert this end into the ferrule's second opening to form a loop.
3 Adjust the pulling cable length and the loop size to your patient's needs.
4 Flush-cut the exceeding end of the pulling cable.
5 Secure the ferrule with centre-punch marks on the pulling cable (fig. 8).

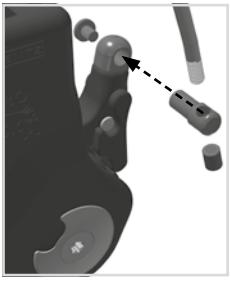
fig. 7

If the pulling cable is too long, you can shorten it subsequently:

1 Sever the pulling cable above the pulling cable holder.
2 Cut a new thread onto the pulling cable's end (fig. 9).
3 Mount the pulling cable to the locking pawl again. Only secure the threaded sleeve after you have inserted the pulling cable into the pulling cable holder.

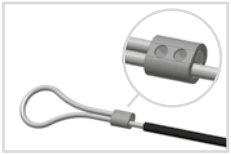
fig. 8

fig. 9

8.3 Mounting the Separable Pulling Cable for a Bilateral Construction

The separable pulling cable is delivered preassembled. If you want to adapt the pulling cable, place the coupler (fig. 10) in a position that is well suited for the patient.

fig. 10

Do not mount the coupler in the middle of the thigh as otherwise the nylon cable in the coupler can be damaged.

1 Reduce the length of the long and/or short pulling cable, if necessary. The coupler should be positioned in such a way that it is easy to handle by the patient (fig. 10).
2 Cut an M3 thread with a maximum length of 6mm on the shortened end of the separated nylon cable (fig. 9).
3 **If you reduce the length of the long pulling cable:**
- Screw the connecting screw for the coupler completely onto the thread end of the nylon cable (fig. 11).
- Tighten the headless pin in the connecting screw with a hexagon screwdriver.
- Turn the spring (1) into the connecting screw and screw the coupler case (2) onto it (fig. 12).

If you reduce the length of the short pulling cable:
- Screw the threaded sleeve onto the nylon cable (fig. 13).
- Cut the exceeding nylon cable so that it is flush with the threaded sleeve.

4 Check if the coupler works in the best way.

fig. 11

fig. 12

fig. 13

In order to open the coupler, proceed as follows:

1 Hold the coupler between thumb and index finger.
2 Use your thumb to press the spring down.
3 Take the free end of the pulling cable with threaded sleeve out of the holder (fig. 14).

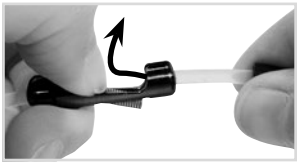

fig. 14

In order to close the coupler, press the free end of the pulling cable with threaded sleeve into the holder against the resistance of the spring (fig. 15). Thus, the pulling cable cannot be opened unintentionally.

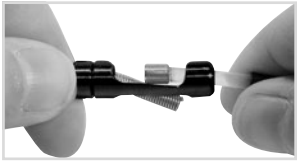

fig. 15

Make sure that both system joints unlock at the same time to ensure an optimal functioning of the orthosis with bilateral construction at knee height.

9. Maintenance

All pulling cables should be checked regularly for wear and damage during maintenance of the locked system knee joint and replaced if necessary.

Joint Component	Potential Problem	Measure	Recommended Inspection, Potential Replacement*	Latest Replacement
pulling cable	wear	replacing pulling cable	every 6 months	every 36 months

* depending on the assessment of the distributor of the custom-made product regarding the patient's usage behaviour

Also check the pulling cable's individual parts listed below:

Joint Component	Potential Problem	Measure
nylon cable	damage (e.g. notch, kink)	replacing nylon cable
coupler case	structural changes in the material (e.g. incipient crack)	replacing coupler case, see paragraph 8.3
spring of the coupler	fatigue of spring	replacing coupler, see paragraph 8.3

9.1 Dirt Removal

Dirt must be removed from the pulling cable when necessary. Clean the soiled system components with a dry cloth.

10. Spare Parts

10.1 Separable Pulling Cable

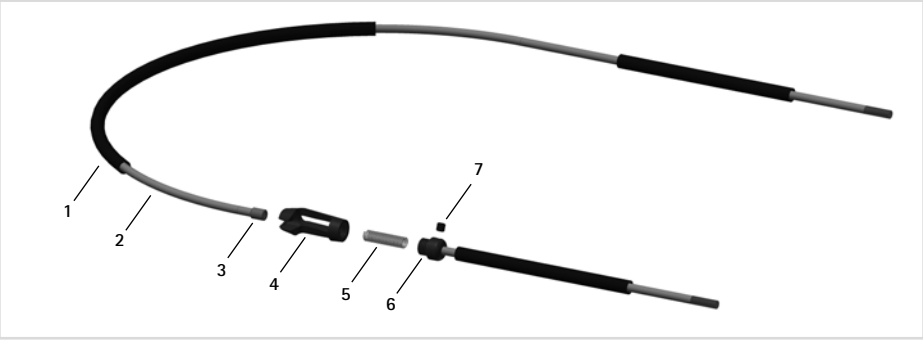

fig. 16

Item	Article Number	Description
1	ZS0102	cable cover, 1000mm long
2	ZS0002	nylon cable, 1000mm long
3	ZS0235	threaded sleeve, 5mm long
4	VE0101-AL	coupler case, aluminium
5	FE1420-01	coil spring
6	VE0102-AL	connecting screw for coupler
7	SC9603-L03	headless pin with hexagon socket
3-7	VE1000-AL	coupler, aluminium

Use the coupler (fig. 17) in order to convert a pulling cable into a separable pulling cable, if necessary.

fig. 17

10.2 Unilateral Pulling Cable

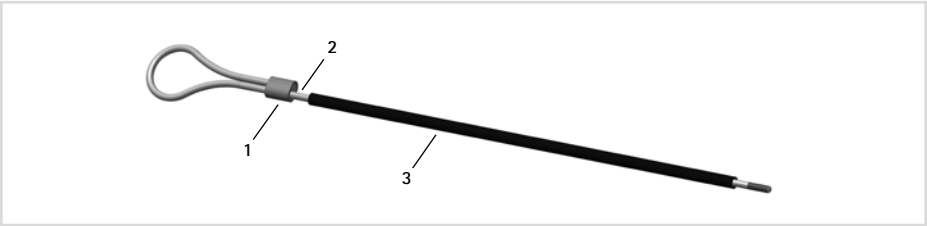

fig. 18

Item	Article Number	Description
1	ZS0403-AL	ferrule for 3mm nylon cable, aluminium
2	ZS0001-L600	nylon cable with thread
3	ZS0102-L500	cable cover, 500mm long

You always need a pulling cable adaptor in order to mount a unilateral pulling cable.

10.3 Pulling Cable Adaptor

To unlock a locked system knee joint with a pulling cable, you need to mount the pulling cable adaptor corresponding to the system knee joint (see table). You need one pulling cable adaptor (fig. 19 and 20) per locking pawl.

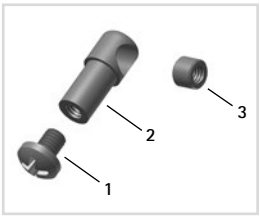

fig. 19

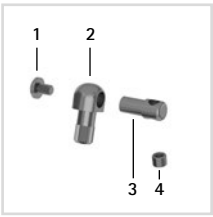

fig. 20

Article Number	Description
ZS3502	pulling cable adaptor for NEURO LOCK, 14mm
ZS3503	pulling cable adaptor for NEURO LOCK, 16/20mm
ZS3701	pulling cable adaptor for NEURO LOCK MAX/NEURO FLEX MAX, 12mm
ZS3702	pulling cable adaptor for NEURO LOCK MAX/NEURO FLEX MAX, 14mm
ZS3703	pulling cable adaptor for NEURO LOCK MAX/NEURO FLEX MAX, 16mm
ZS3705	pulling cable adaptor for NEURO LOCK MAX/NEURO FLEX MAX, 20mm
SK0872-50/C	pulling cable adaptor for NEURO LOCK Carbon, 14mm
SK0875-50/C	pulling cable adaptor for NEURO LOCK Carbon, 16/20mm

10.4 Accessory Parts Pulling Cable Adaptor

You can also order the pulling cable adaptor's individual parts, if necessary. Mind the corresponding system width of the system knee joint.

Pulling Cable Adaptor **NEURO LOCK** (fig. 19):

	Article Number for System Width			
Item	14mm	16mm	20mm	Description
1	SC4303-L04	SC4303-L04	SC4304-L04	pan head screw with cross recess H
2	ZS0324-06	ZS0324-07	ZS0324-07	pulling cable holder
3	ZS0233	ZS0233	ZS0233	threaded sleeve

Pulling Cable Adaptor **NEURO LOCK MAX** and **NEURO FLEX MAX** (fig. 19):

	Article Number for System Width				
Item	12mm	14mm	16mm	20mm	Description
1	SC4303-L04	SC4303-L04	SC4303-L04	SC4304-L08	pan head screw with cross recess H
2	ZS0324-06	ZS0324-07	ZS0324-08	ZS0326-10	pulling cable holder
3	ZS0233	ZS0233	ZS0233	ZS0235	threaded sleeve

Pulling Cable Adaptor **NEURO LOCK Carbon** (fig. 20):

	Article Number for System Width			
Item	14mm	16mm	20mm	Description
1	SC4303-L04	SC4303-L04	SC4303-L04	pan head screw with cross recess H
2	SK0872-50/C/0	SK0875-50/C/0	SK0875-50/C/0	retainer for pulling cable holder
3	ZS0324-07	ZS0324-07	ZS0324-07	pulling cable holder
4	ZS0233	ZS0233	ZS0233	threaded sleeve

11. Disposal

Dispose of the pulling cable and its individual parts properly. The product must not be disposed of with the residual waste (fig. 21). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 21

For proper disposal, it is necessary to remove the pulling cable from the system joint.

12. 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.

13. 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 in the configuration result of 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, made available online, reflects the current status at the time of their most recent publication. Changes and updates are published exclusively online. The contained product information serves as guidelines. Subject to technical modifications.

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