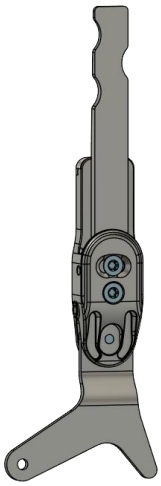
CARBON FLEX



Device: Carbon Flex 16 mm
Item No.: CF16GEL

DE: Gebrauchsanweisung
EN: User Manual

Please carefully read the user manual before device use.
Be sure to follow all instructions, in particular the safety notices.

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DEVICE DESCRIPTION

Carbon Flex is a novel system ankle joint for integration into custom orthotic devices, allowing for separate adjustment of plantar flexion and dorsiflexion, as well as providing a defined point of rotation. Energy recovery is achieved via spring units consisting of a carbon-fibre composite.

Maximum range of motion (ROM) with Carbon Flex is 40°, enabling natural gait. The joint body may be used for the left or the right leg, medially or laterally, as well as bilaterally or unilaterally.

The distinct spring packs, available in different strengths, can be combined in various ways.

The low-weight and large-ROM Carbon Flex system joint ensures high patient compliance. Furthermore, the base angle may be adjusted by up to 20° to adapt to different shoe heel heights.

INTENDED USE

The Carbon Flex system ankle joint is a dynamic double action joint designed to compensate for muscle deficits and to ease movement impairments of the ankle joint, which may result from central / peripheral / spinal or neuromuscular paresis, from structure-related malposition, or from surgically induced changes. The system ankle joint is part of individual orthotic treatment of children, adolescents, and adults alike. The joint body may be used for the left or the right leg, medially or laterally, as well as bilaterally or unilaterally. By applying force and torque, the orthotic ankle joint and its components provide for functional safety, stabilisation, support, guidance, correction, and relieve of the joint and of the ankle muscles in deficit. The Carbon Flex joint can be worn both indoors and outdoors for standing, walking, and sitting down.

INDICATIONS FOR USE

Insecurities leading to gait abnormalities. This may result from central / peripheral / spinal or neuromuscular paresis, from structure-related malposition / malfunction, or from surgery.

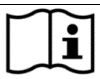
CONTRAINDICATIONS

Not suitable for upper limb treatment, and not to be used in combination with prosthetic and ortho-prosthetic solutions following segmental leg amputation.

ACCESSORY / CONTENT

- Carbon Flex 16 mm joint body
  Including 5x M5 grub screws, 1x M4 screw for the joint cap
- 10° limiting tool
- Mounting / Sprue Dummy - Including screws and bolts

EXPLANATION OF SYMBOLS USED

	**Caution:** This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	**Consult instructions for use:** This symbol indicates the need for the user to consult the instructions for use.
	**Single patient – multiple use:** This symbol indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	**Medical device:** This symbol indicates the item is a medical device.
	**Manufacturer:** This symbol indicates the medical device manufacturer.
	The **CE Marking** indicates conformity with the requirements of Regulation (EU) 2017/745 on Medical Devices.

INFORMATION FOR TECHNICIANS

HANDLING INSTRUCTIONS

Only certified professionals may mount and adjust the Carbon Flex system joint.

The Carbon Flex system joint may only be incorporated into fibre composite orthotic devices.

The specified torques must be complied with and the Mounting Manual must be followed.

Screws must be fastened as specified in the user manual.

It is recommended to wear nitrile gloves or similar when mounting the joint.

Follow warning and safety instructions when mounting and adjusting the joint. Failure to comply may cause damage.

MOUNTING THE FOOT STIRRUP ON THE JOINT USING THE MOUNTING AID

1) Secure the mounting aid within the bench vice.

2) Slip the compensator onto the mounting aid (Position 1). (Figure 1.1)

3) Slip the joint body over the compensator onto the mounting aid (Position 1). (Figure 1.2)

4) Insert the foot stirrup into the joint until the thread for the cheese head screw becomes visible within the compensator. (Figure 1.3)

5) Secure the M3 cheese head using Loctite 243 and screw through the M5 bore of the axle bolt. Torque it manually. (Figure 1.4)

6) Remove the joint body including the foot stirrup from Position 1. Then insert it vertically into mounting aid Position 2. (Figure 1.5)

7) Place the sliding washers onto the foot stirrup. Then slide the foot stirrup into the joint. Ensure correct guidance within the compensator. (Figure 1.6)

8) Grease the clevis pin. Align the foot stirrup and the sliding washers. Then, in a rearward motion, insert the clevis pin into the intended recess of the joint body. There should be no resistance.

9) Secure the M5 axle bolt using Loctite 243. Then fasten the bolt using a torque of 4 Nm.

MOUNTING THE SPRING PACKS

⚠ Before mounting the spring packs, the foot stirrup must be mounted, set to 0° neutral position, and secured onto the joint body using the lower M5 grub screws. (Figure 2.1)

1) Slide the joint body (without the system anchor) into mounting aid Position 3. Unscrew the M4 screw for the joint cap from the joint cap.

   This will pull the joint cap out of the joint. (Figure 2.2)

2) Insert the clipped spring packs into the joint body. (Figure 2.3.)

3) Grease the M4 screw for the joint cap. Set the joint cap onto the joint body. Using the M4 screw for the joint cap, pull the spring packs into the joint body. (Figure 2.4)

   Observe the permissible range of motion of the spring packs!

MOUNTING THE SYSTEM ANCHOR

1) Insert the system anchor into the joint. Align it to 0°. Secure the lower M5 flat head screw by torquing it manually. (Figure 3.1)

2) Secure the system anchor by screwing the upper M5 grub screws in and torquing them manually. (Figure 3.2)

3) Screw the upper M5 flat head screw into the system anchor. (Figure 3.3)

4) After static adjustment has been performed on the patient, secure the M5 flat head screws to the system anchor using Loctite 423. Then fasten them using a torque of 4 Nm.

STATICALLY ADJUSTING THE BASE ANGLE

In principle, the Carbon Flex system joint is to be mounted in a 0° position.

The Carbon Flex system joint allows for statically adjusting the base angle by 20° overall – e.g., to adapt to different shoe heel heights.

1) For this purpose, unscrew the two M5 flat head screws of the system anchor. Then adjust the static angle using the upper M5 grub screws of the joint body. (Figure 4.1)

2) After adjustment has been performed, re-secure the M5 flat head screws using Loctite 423. Then fasten them again using a torque of 4 Nm.

Adjustment of the base angle must be performed by qualified professionals only, not by the user.

ADJUSTING THE RANGE OF MOTION (ROM)

By using the lower M5 grub screws of the joint body, the range of motion can be limited.

Limiting plantarflexion is achieved by screwing the anterior screw.

Limiting dorsiflexion is achieved by screwing the posterior screw.

The foot stirrup features a scale of degrees with 5° graduation.

After adjustment on the patient, the screw lock of the M5 grub screws must be checked and secure them again with Loctite 423 if necessary.

Observe the permissible range of motion of the spring packs!

When using the **medium spring kit**, the joint must be set to a **maximum deflection of 10°**.

Using the enclosed 10° limiting tool, screw the M5 grub screw into the joint body until the tool touches the joint body. (Fig. 5.1 / 5.2)

This ensures that the joint has been set to 10° deflection.

The deflection must be checked using the angle scale on the foot stirrup.

SERVICING

At regular intervals (at least every 6 months), the Carbon Flex ankle joint must be inspected regarding function, deterioration, and damages.

In case of deteriorated or faulty components, affected components must be replaced by a certified professional.

Dismount the entire joint and clean all parts using a special detergent (e.g., Loctite 757 or similar product).

Remove any residuals from the spring chamber by air purging it using compressed air.

Following components must be replaced at least every 6 months:

- Spring packs
- Compensator
- Cheese head screw
- Clevis pin, and axle bolt
- Brass ring of the foot stirrup

The joint must move without difficulty and without producing any unusual sounds.

Service life of the system joint ends with the service life of the custom orthotic device, after 3 years latest.

USE IN COMBINATION WITH OTHER DEVICES

Any use in combination with other devices requires prior approval of the manufacturer: Calluna Tec GmbH. Any use in combination with a knee ankle foot orthosis (KAFO) is prohibited.

INFORMATION FOR USERS

⚠ Only certified professionals may mount and adjust the Carbon Flex joint.

OPERATION

The Carbon Flex system is designed for regular, natural movement.

Attention: The joint must not be used for sports activities.

The joint is not water-resistant.

CLEANING / MAINTENANCE INSTRUCTIONS

- Remove residuals such as lubricant from the joint and from the orthotic device. Degrease the exterior joint surfaces.
- With spring packs dismounted, remove any residuals from the spring chamber by air purging it using compressed air.

OPERATION INSTRUCTIONS, SAFETY NOTICES AND RISKS

⚠ Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and to the competent authority of the member state in which the user is established.

- Prior to first use, training by a qualified professional is required.
- Not suitable for sports activities / sports prostheses and sports orthoses.
- Do not use under wet conditions.
- Only use in combination with a shoe that has been fitted to the orthotic device.
- Do not polish the joint. Only grind, mount or dismount as specified.
- Faulty components must be replaced by a certified professional.
- Moving parts pose the risk of crushing fingers, soft tissue or clothing of users or of their personal assistants.
- Comply with the maximum approved user weight of 100 kg.

STORAGE

Store in a dry place. Keep away from extreme heat. Protect from sunlight.

DISPOSAL

Dispose of the joint and its individual parts as per applicable regulations. Do not dispose of this device as municipal waste. The spring packs of the joint (CFRP) are to be disposed of as special waste.

REUSABILITY

This medical device is intended for single patient multiple use. It must not be reused for other patients. Failure to comply poses the risk of failure of the joint system due to material fatigue.

WARRANTY

Warranty only applies as long as the device is used for its intended purpose and is used and handled by certified professionals as specified. Warranty is void in case applicable regulations are not complied with, in case the device is used repeatedly, or in case the device is used for unintended purposes.

MATERIAL

Titanium | Carbon-fibre reinforced polymer (CFRP) | Glass-fibre reinforced plastic (GRP) | Steel | Brass | Plastic

This is a medical device.

The CE Marking indicates conformity with the requirements of Regulation (EU) 2017/745 on Medical Devices.

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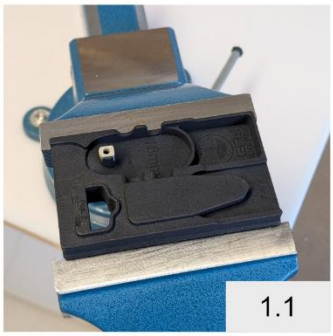
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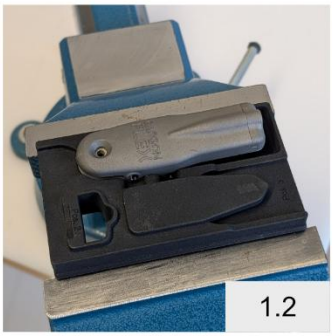
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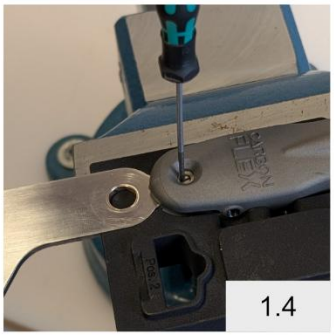
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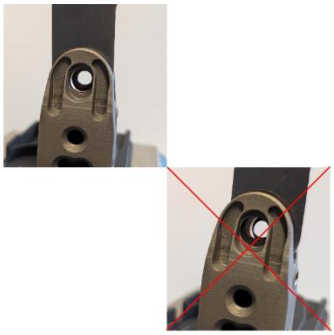

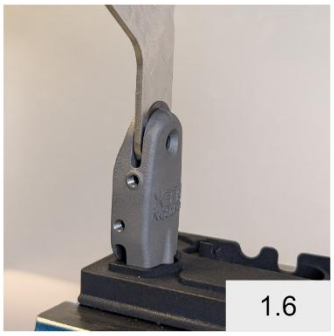
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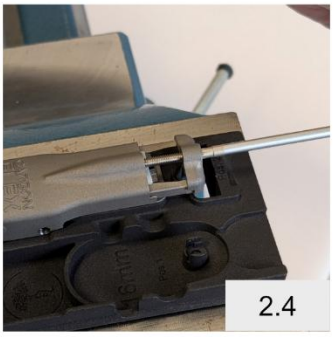
2.1


2.2


2.3

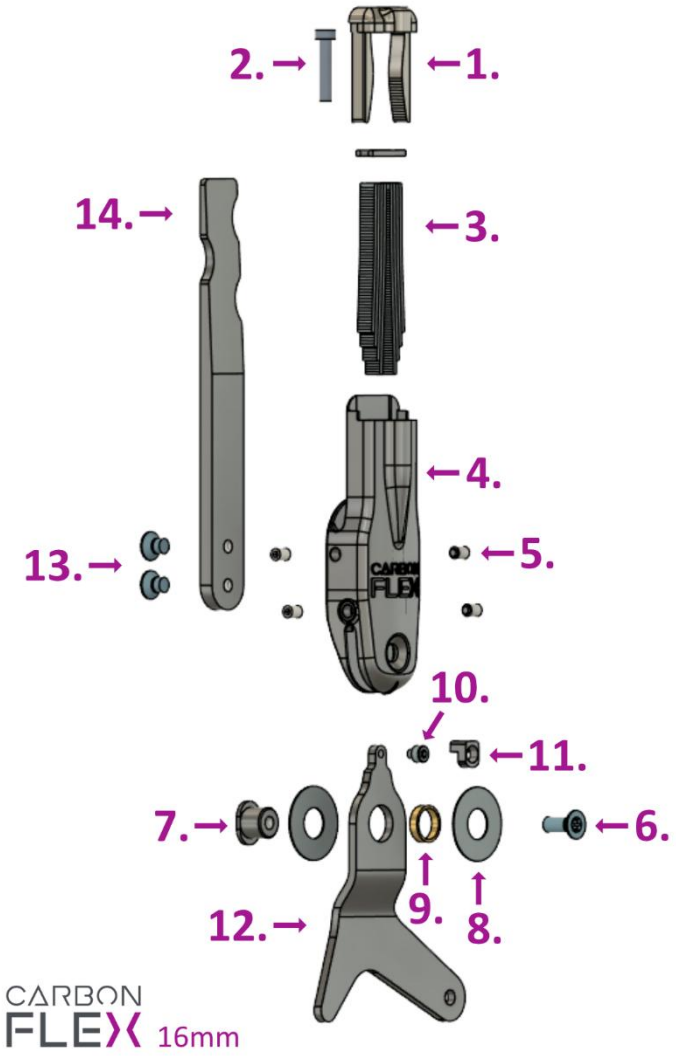

2.4


3.1


3.2


4.1


5.1 / 5.2



1.Joint cap | 2.Joint cap screw | 3. Spring packs | 4. Joint body | 5. Grub screws joint body

6. Axle bolt | 7. Bush | 8. Sliding washers | 9. Brass ring | 10.Cheese head screw | 11. Compensator

12. Foot stirrup | 13. Grub screws | System anchor