INSTRUCTIONS FOR USE

IFU CODE: 40

İB-ER
PROSTHETIC

Single Axis Knee Joint with Friction and Extension Mechanism

(E 84)

CE

Fig. 1

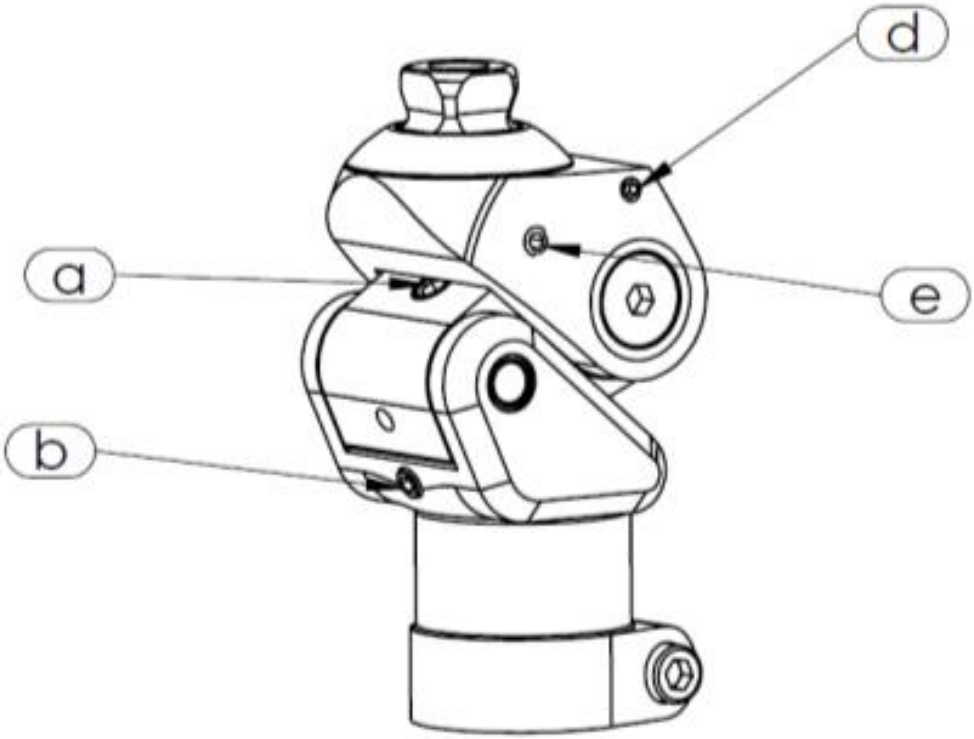


Fig. 2

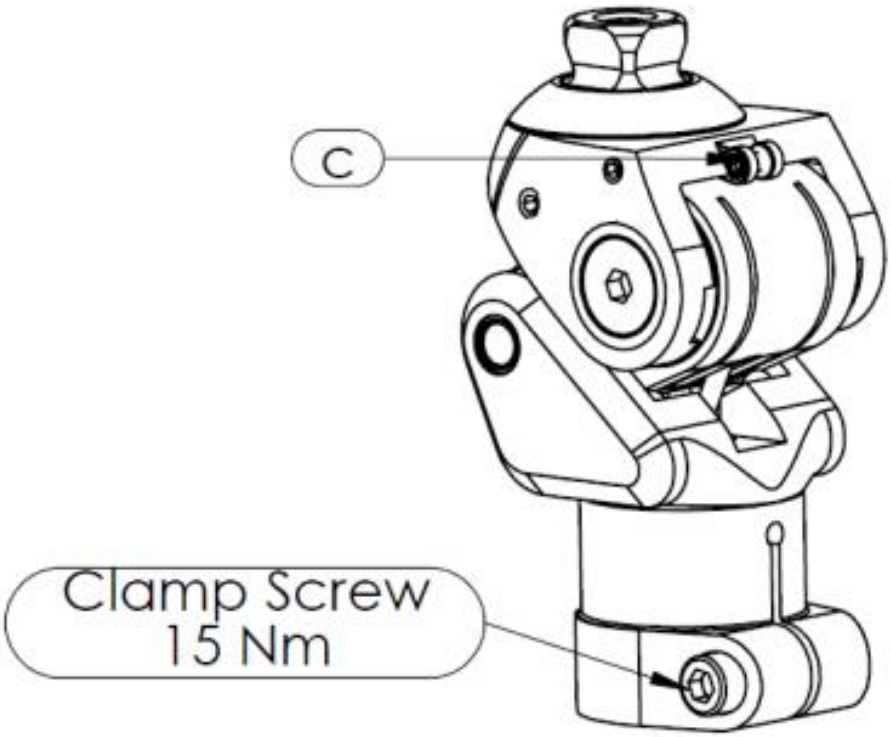
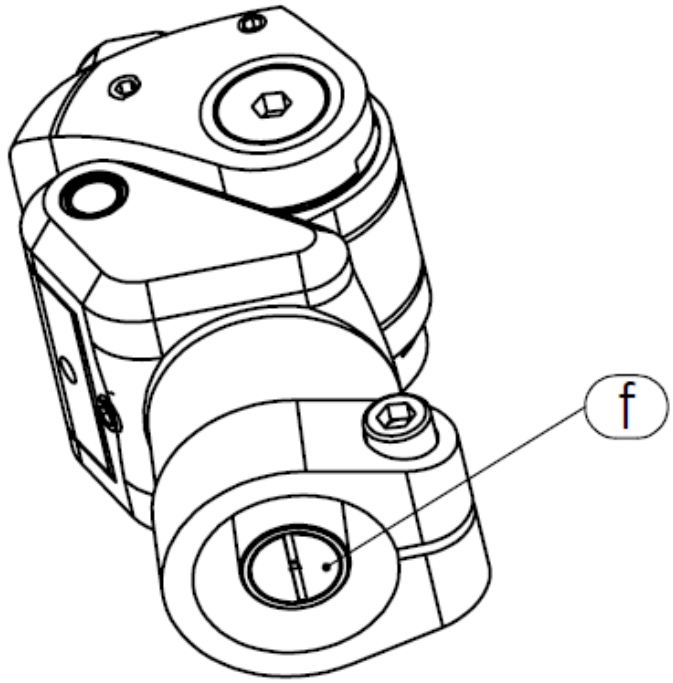


Fig. 3



INFORMATION

Last Update: 11.06.2024

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- Please read this document carefully before using the product.
- Instruct the user in the appropriate and safe use of the product.
- Follow the safety instructions to abstain injuries and damage to the product.
- Please keep this document in a safe place.

Contents

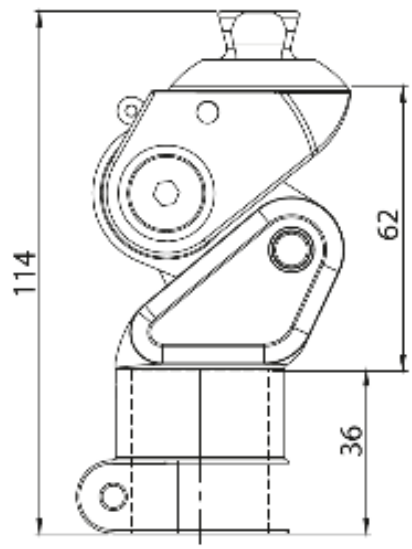
1. E 84

Single Axis Knee Joint with Friction and Extension Mechanism

Monocentric and lightweight knee joint, which can be used with weight activated friction mechanism and also comes with a lock feature
The knee automatically locks when extended
Lock feature is cancel-able anytime desired, depending on the patient's progress
Integrated extension assist spring is adjustable to suit individual requirements

1.1. Features

Product Name	E 84
Advised Activity Level	K1-K2
Material	Aluminum
Max. User Weight	125 Kg
Flexion Angle	145°
Product Weight	490 gr
Overall Length / Build Height	115 mm / 62 mm

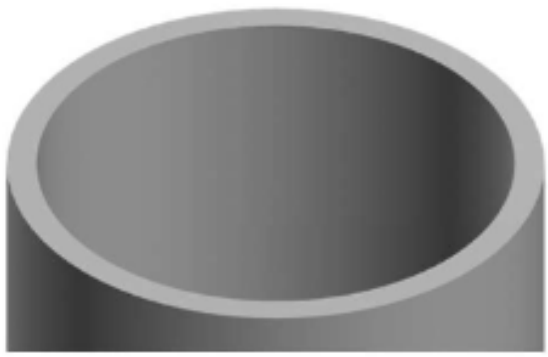


2. Assembly & Setting Instructions

Tube Assembly

The lower side connection of this knee joint is made with an aluminum tube. There are some points to consider for the aluminum tube to be used in assembly.

In order to provide safe construction, the cutting edge of the aluminum tube must be carefully deburred inside and outside after cutting.

	
Incorrect Tube Cutting	Correct Tube Cutting with Chamfers

TIP!

Don’t clamp the tube in order to cut it at desired length, prefer to use cutting edge. Make sure that cut surface is flat and not cut slanting. Clean the burrs on edges after cutting the tube. Avoid any line formation that causes it to be broken.

Tube Clamp Screw Assembly

Tighten Clamp Screw (Fig. 2) using torque wrench.

Torque value: **15 Nm**

ATTENTION!

Secure screw thread with medium strength threadlocker adhesive.

Transformation of the knee joint

I) From lock function to mechanical function

Pull the Lock Part (c) upwards. While holding the lock part up, tighten the Lock Fixing Bolt (d) with a torque meter to **5 Nm**.

At the end of the process, make sure that the bolts are fixed with medium strength threadlocker adhesive.

After tightening the bolt completely, make sure that the Lock Part (c) is fixed at the top.

Thus, the knee joint will not perform its locking function.

ATTENTION!

Secure screw thread with medium strength threadlocker adhesive.

CAUTION!

Failure to perform this conversion correctly may cause the device to fail. Or it may make it impossible to release the connection. Please be careful when performing this process.

II) From mechanical function to lock function

Turn the lock screw (d) to the left until the Lock Part (c) is released. After ensuring that the Lock Part (c) is released, re-secure the lock screw (d) with a medium-strength threadlocker. Check that Lock Part (c) can move freely.

ATTENTION!

Perform functional checks after each function conversion before dynamic alignment.

Removing gaps in the knee joint

TIP!

If the device is used with the locking function, a certain amount of space may occur. You can eliminate this gap by turning the Gap Adjustment Screw (e) to the right. The Stopper located inside can be moved with the help of the Gap Adjustment Screw (e).

Gaps may occur with long-term use of the knee joint. These gaps can be eliminated with the help of the Adjusting Screw (b). Turn the Adjusting Screw (b) to the left in small steps.

Check carefully whether the brake function of the device now suits the individual needs of the patient. If not, readjust the Adjustment Screw (b) until the correct setting is found.

ATTENTION!

Flexion and extension must be possible in all settings.

Adjusting the Stance Phase Control

The responsiveness of the brake effect may be regulated by the stance control adjustment screw (a).
Clockwise rotation= braking is less responsive

Counter-clockwise rotation= braking is more responsive

Adjusting the Swing Phase

Swing phase regulation can be done with the extension assist adjustment.

Turning the adjustment screw ((f) in fig. 3) changes the tension of the spring of the extension support. Thus, the swing phase speed can be changed as desired.

3. Environmental Conditions

Acceptable Environmental Conditions
Temperature use range: -10 °C to +45°C
Humidity: Allowable relative humidity 0% to 90%, non-condensing

Unsuitable Environmental Conditions
Fresh water, salt water, sweat, urine, acids e.g.
Sand, dust, highly hygroscopic particles (e.g., talcum)
Mechanical vibrations, impacts
Cleaning agents containing solvents

4. Service Life

The service life of the product is about 3 years. This duration depends on the daily activity of the user.

5. General Safety Instructions

CAUTION!

To avoid the risk of injury and product damage, do not use for longer than the service life of the product.

The suitability of the device to the patient and the prosthesis should be evaluated by a healthcare professional.

The device must be fitted and adjusted by a healthcare professional.

There is a danger of pinching and injuring your finger or skin.

Do not insert your hand into the joint mechanism!

Avoid using this product in unsuitable environmental conditions. If the product has been exposed to unsuitable environmental conditions, check for damage.
Do not use the product that is damaged, has limited functionality or is in doubtful condition. Ensuring that appropriate measures are taken (e.g. control, cleaning, repair, replacement by the authorized workshop or manufacturer).
To prevent mechanical damage, be careful and caution when working the product.
Use the product for a single patient to avoid injuries and product damage.
Products should be used in appropriate combinations. Using the product with unsuitable combinations may result in possible injury.
In case of feeling any space or sound, apply the rehabilitation center who installed the foot.

6. Maintenance

1. After the first 30 days of use, the prosthesis parts should be visually inspected and function checked.
2. Inspect the entire prosthesis for wear during normal consultations.
3. This prosthesis and its components should be checked for function by a prosthetist at regular intervals every six months. If the recommendations are followed properly, there is no risk.

7. Warranty

IB-ER company provides the warranty for the products in case of material and production flaws. Warranty duration for the above-mentioned products are individually mentioned at below.

Product	Duration After The IB-ER Invoice Date
E 84	24 Months

This warranty covers on only replacement and repair of failed products after assemblies performed by qualified individuals and competent institutions. This warranty is not applicable in case of following points:

- Improper use of the product, using with unsuitable conditions and fault assembly.
- Issues arising from replacement of our products with other products.

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PROSTHETIC

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