

INSTRUCTIONS FOR USE

IFU CODE: 38

IB-ER
PROSTHETIC



Polycentric Knee Joint
with Extension Mechanism

E 44

CE

Fig. 1 (Clamp Screw)

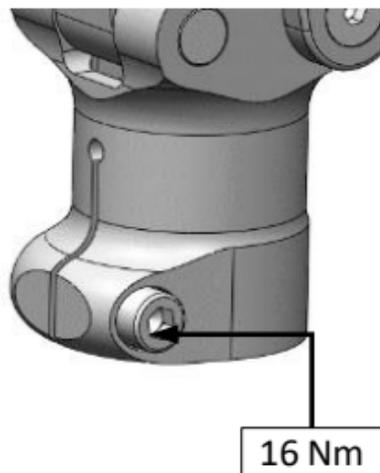


Fig. 2

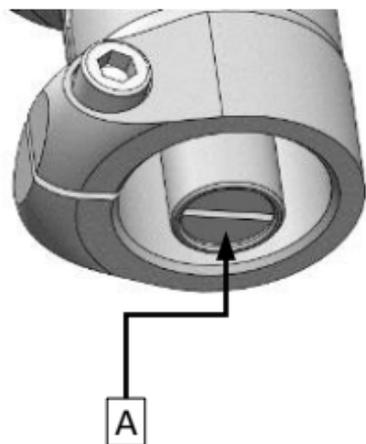


Fig. 3

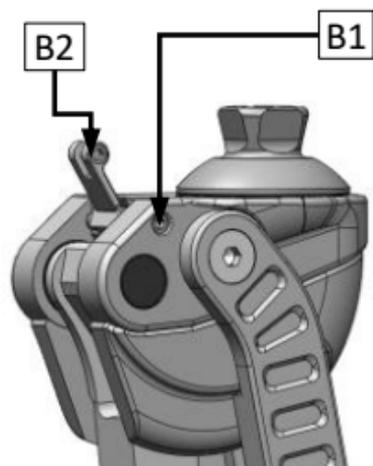


Fig. 4

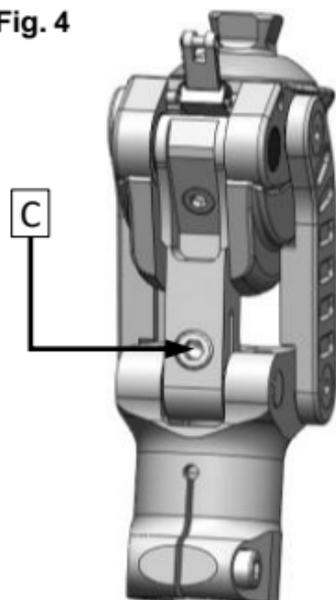


Fig. 5 (Stance Phase Adjustments)

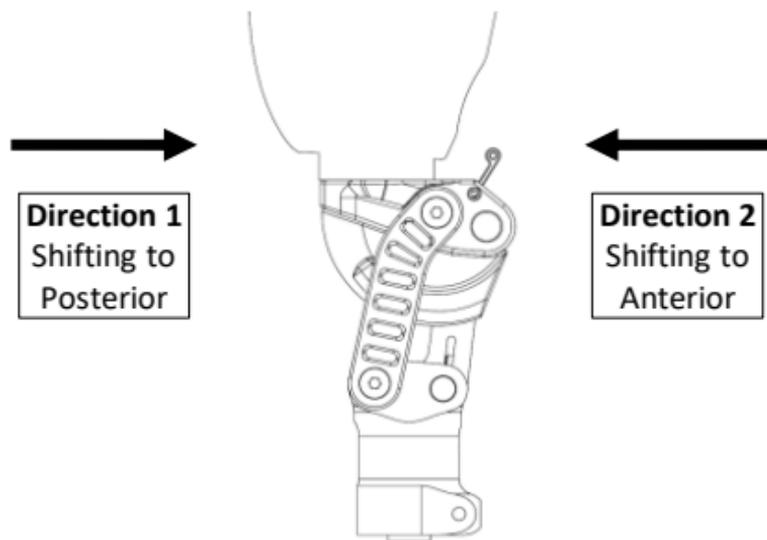
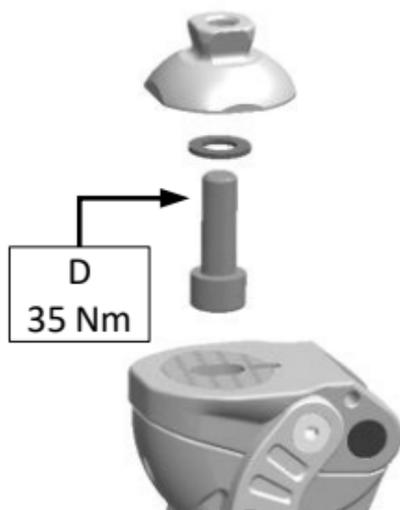


Fig. 6



Fig. 7 (Center Screw)



INFORMATION

Last Update: 01.11.2024



- 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. Description	1
2. Assembly & Setting Instructions	2
3. Environmental Conditions.....	6
4. Service Life	6
5. General Safety Instructions	7
6. Maintenance	8
7. Warranty	8

1. Description

Mechanical 4-Bar polycentric knee joint, can be used as locked or unlocked

Locking function for a high degree of safety; ideal for first standing and walking exercises, afterwards locking function is cancel-able.

More ground clearance for a safer and more confident gait

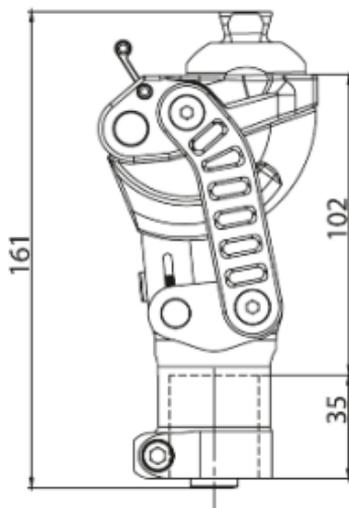
Rates of flexion and extension can be adapted to the user.

Flexion range is up to 150°

Integrated shift adjustment by adapter up to 5 mm.

1.1. Features

Product Name with Pyramid Connection	E 44-A
Product Name with M36 Connection	E 44-B
Product Name with One-Prong Connection	E 44-C
Advised Activity Level	K1-K2
Material	Aluminum
Max. User Weight	125 Kg
Flexion Angle	150°
Product Weight	680 gr
Overall Length / Build Height	161 mm / 102 mm



1.2 Connection Adapter Types

E 44-A

Pyramid
Connection



E 44-B

M36
Connection



E 44-C

One-Prong
Connection



2. Assembly & Setting Instructions

2.1 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.

2.2 Tube Clamp Screw Assembly

Tighten Clamp Screw (**Fig. 1**) using torque wrench.

Torque value: **16 Nm**



ATTENTION!

Secure screw thread with medium strength threadlocker adhesive.

2.3 Swing Phase Adjustments (Fig.2)

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

Turning the adjustment screw (A in fig. 2) changes the tension of the spring of the extension support. Thus, the swing phase speed can be changed as desired.

For a faster Swing Phase:

Turn the screw **(A)** to the right

For a slower Swing Phase:

Turn the screw **(A)** to the left

ATTENTION!

 Swing phase control works when you use the knee joint as a freely movable joint. See Converting Joint from Locking to Mechanical section.

2.4 Converting the Knee Joint

From Locking Function to Mechanical Function

Push the Locking Part (B2) upwards and hold it in this position.

Fix the Locking Part (B2) in this position by tightening it to the right with the two Locking Screws (B1) located opposite each other on the knee joint.

ATTENTION!

 Tighten the Locking Screws (B1) to **5 Nm**. Secure screw thread with medium strength threadlocker adhesive.

If the Locking Screws (B1) fails as mentioned above, it will cause the device to lose operation and / or make it impossible to release the joint.

From Mechanical Function to Locking Function

The Locking Screw (B1) should be turned to the left until the Locking Part (B2) moves freely.

After checking that the Locking Part (B2) can move freely, the Locking Screws (B1) should be fixed with a medium strength threadlocker.

CAUTION

 After each transformation, perform a functional check before dynamic alignment.

2.5 Stance Phase Adjustments (Fig.5)

In the E44 Knee joint, the head adapter can be displaced up to 5 mm. Stance phase stability can be adjusted by shifting the knee according to the following:

To increase stance phase stability; shift the knee backwards relative to the socket (Direction 1: Shifting to Posterior in fig. 5).

To allow a more dynamic gait: shift the knee forwards - relative to the socket (Direction 2: Shifting to Anterior in fig. 5).

2.6 Adjustment of Axle Friction (Fig.4)

Axle Friction Adjustment is adjusted with the C screw in Figure 4.

To increase friction on the axle	Turn the screw (C) to the right
To reduce friction on the axle	Turn the screw (C) to the left

2.7 Head Adapter Positioning

The head adapter of the E44 knee joint can be positioned at the desired location up to 5 mm in the anterior and posterior directions, then fixed with the central bolt.

After the adapter is placed in the correct and desired position, it should be fixed with the center screw (D in Fig 7.), as follows:

1. Put the washers on the center screw. Place the head adapter in the desired position.
2. Mount the head adapter to the knee joint by tightening the center screw and using a medium-strength threadlocker.
3. Tighten the center screw with a torque wrench to **35 Nm**.

3. Environmental Conditions

Acceptable Environmental Conditions
Temperature use range: -10 °C to +40°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. The warranty period of the above mentioned product is stated below.

Product	Duration After The IB-ER Invoice Date
E 44-A	24 Months
E 44-B	
E 44-C	

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.



İB-ER Makina A.Ş
Selvitepe OSB Mah. OSB 2006. Cad. No: 13/1
45400, Turgutlu - Manisa / Turkey

Phone : +90 (236) 312 32 00

Fax : +90 (236) 312 32 06

info@ib-er.com

www.ib-er.com



Ercan Gozuacik
Reinickendorfer Str 45 13347 Berlin GERMANY
(for regulatory affairs only)