INSTRUCTIONS FOR USE

IFU CODE: 15

İB-ER
PROSTHETIC



Single Axis Locking Type Knee Joints

(E 43, E 49AI)

CE

Fig. 1 (E 49Al)

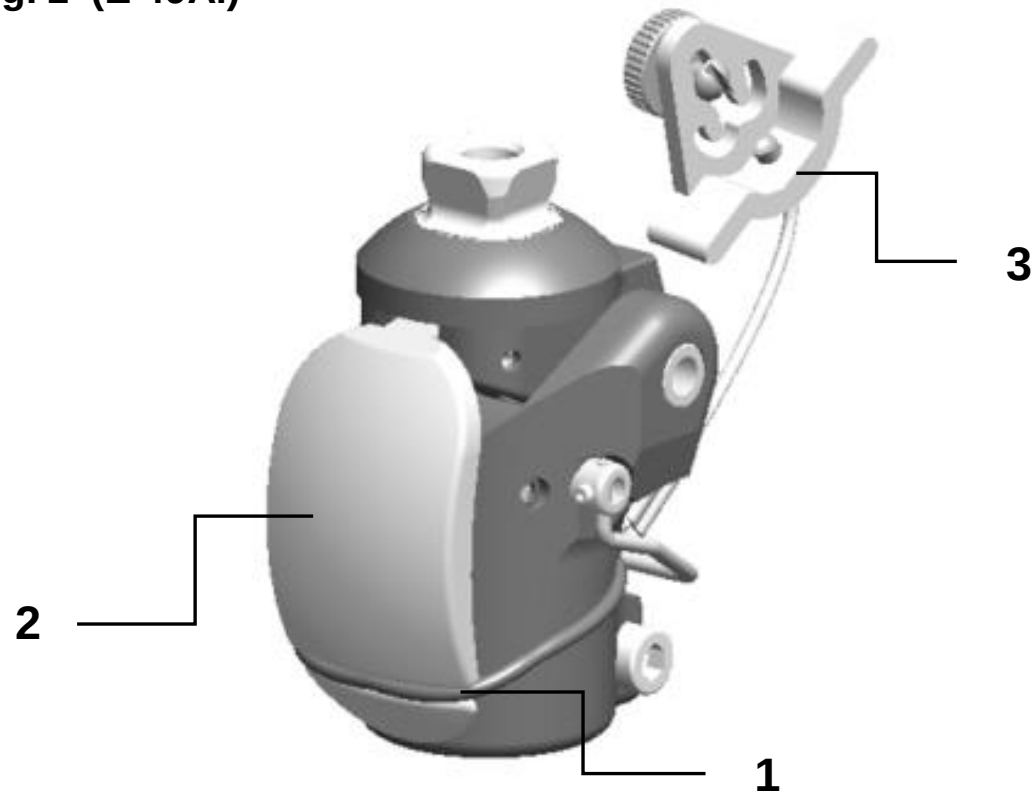


Fig. 2 (E 49Al)

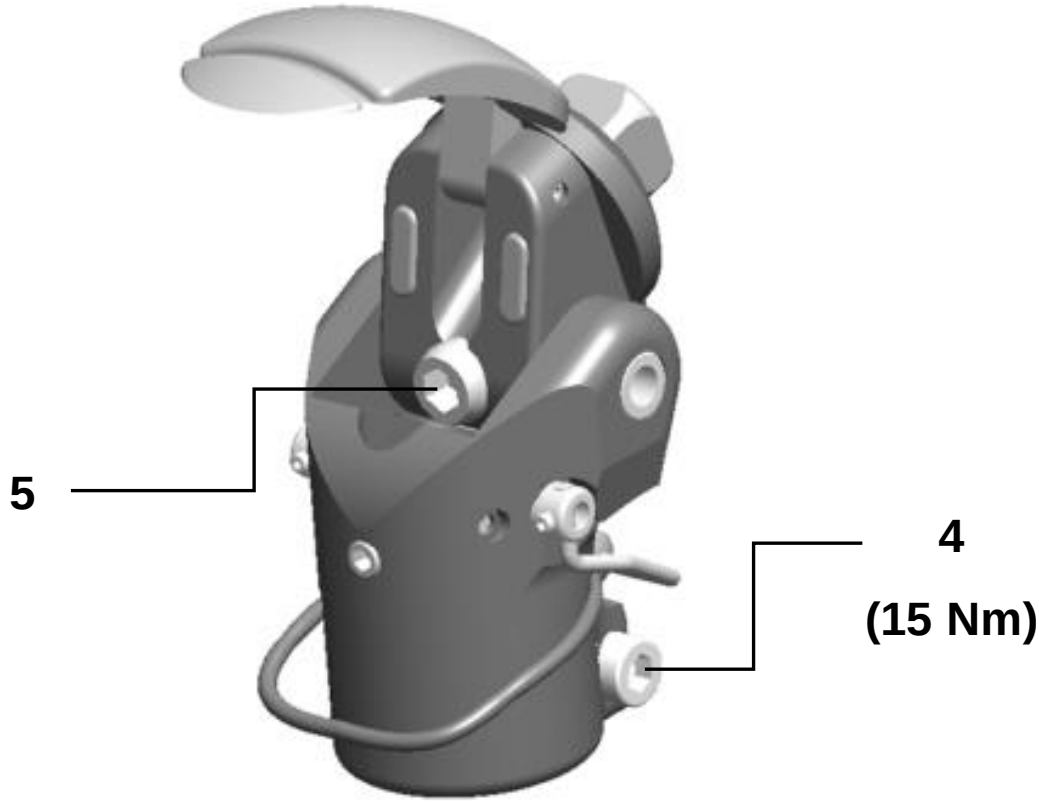


Fig. 3 (E 43)

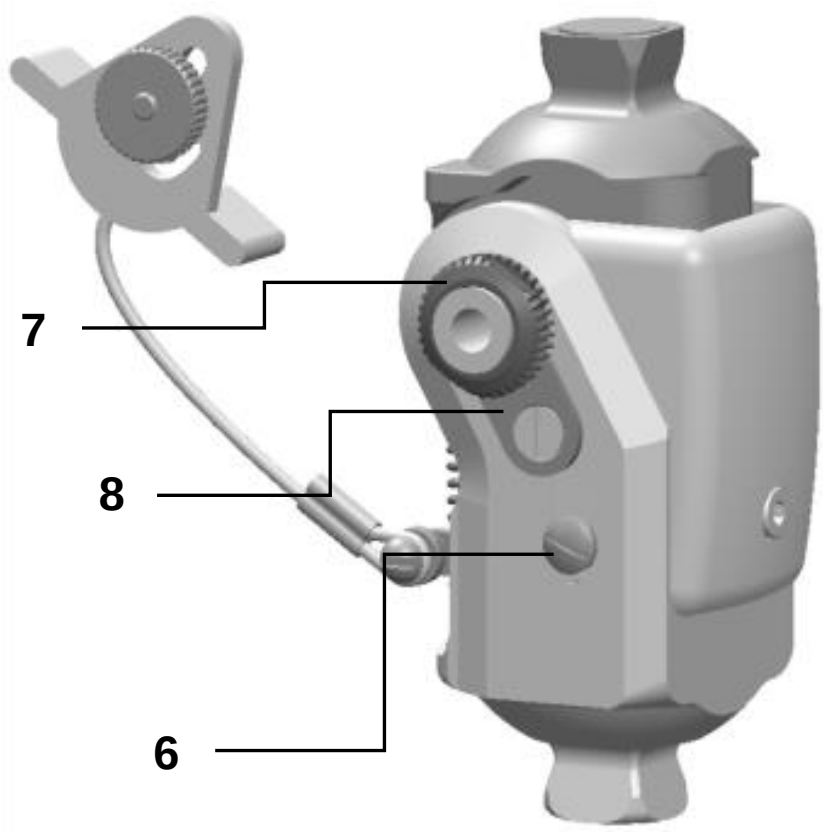
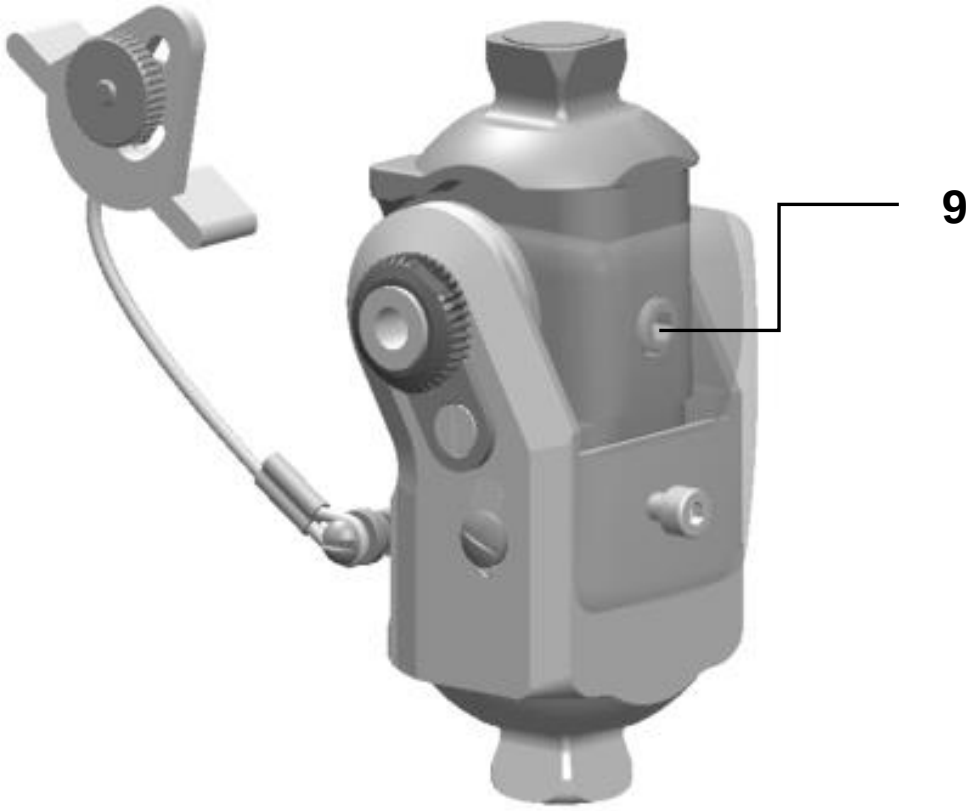


Fig. 4 (E 43)



INFORMATION

Last Update: 01-02-2023

İB-ER PROSTHETIC

- 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.

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1. E 43

Single Axis Knee



E43 knee joint provides high stance phase stability. It's a very secure and solid joint with in-built extension assist springs. This knee joint doesn't provide the swing phase control ability. Locking mechanism automatically triggers with the support of the extension assist springs. The lock can be opened with the wire which can be placed on lateral and medial sides of the knee joint.

1.1. Features

Code	Material	Weight	Weight Limit
E 43s	Stainless Steel	540 gr	125 Kg
E 43T	Titanium	420 gr	125 Kg

1.2 Adjusting the Extension Stop

The extension stop is adjustable at the E43 knee joint. When the lock is engaged, the amount of hyperextension movement in the knee can be controlled. This adjustment is made with the set screw (9) shown in figure 4.

Flex the Knee Joint until the set screw becomes accessible (4 mm Allen wrench).

Turning clockwise = reduces hyperextension movement

Turning counter-clockwise = increases hyperextension movement

IMPORTANT!

Reducing the hyperextension movement makes it more difficult for the lock to engage.

1.3 Adjusting the Axle Location

If mediolateral side play develops, it may be reduced by tightening the Axis Nut (7). In this case the following steps should be followed:

1) Remove the Safety Plate (8).

2) After that the Axis Nut (7) must be finely adjusted (wrench width 17 mm).

3) Then it must be secured by screwing the Safety Plate (8) again.

ATTENTION!

Overtightening the Axis Nut (7) may restrict normal movement of the E 43 Knee Joint.

Make sure to properly install the Safety Plate (8) after the adjustment has been made.

2. E 49Al

Single Axis Knee W/Manuel Lock Aluminum

E49 knee joint provides high stance phase stability. Even though it doesn't have an extension assist ability, its weight is considerably low and this makes the knee joint is very compact and easy to carry on.



2.1 Features

Code	Material	Weight	Weight Limit
E 49Al	Stainless Steel	350 gr	100 Kg

2.2 Assembly

Tighten cap screw (4) using torque wrench.

Torque value: **15 Nm**

ATTENTION!

Secure screw thread with medium strength adhesive.

The cord guide can be slid over the lock clamp.

2.3 Lock Mechanism Adjustment

CAUTION!

E 49Al Single Axis Knee Joint is factory adjusted!

The prosthesis is ready to be installed and immediate use!

The stop screw is secured with Loctite screw retention. Slight clearance does not result in functional disadvantages. In order to adjust the extention stop screw, please stick to following steps:

1) Remove the plastic ring (1) by means of screwdriver or by hand from the plastic knee cap (2).

2) Disengage the lock mechanism and flex the knee.

3) Use a 6 mm allen key to adjust the “play” of the stop (5).

- Turn stop screw clockwise = more play
- Turn stop screw counter-clockwise = less play

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 components should be checked for its functions at least once a year with regular intervals by a prosthesis specialist. There is no risk if suggestions are followed by properly.

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 43	24 Months
E 49 Al	

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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