

INSTRUCTIONS FOR USE

IFU CODE: 16

IB-ER
PROSTHETIC



E53s-D



**E53s
E53T**



E53s-L

Modular 4-Bar Linkage Knee Joints

Fig. 1 (3.1)

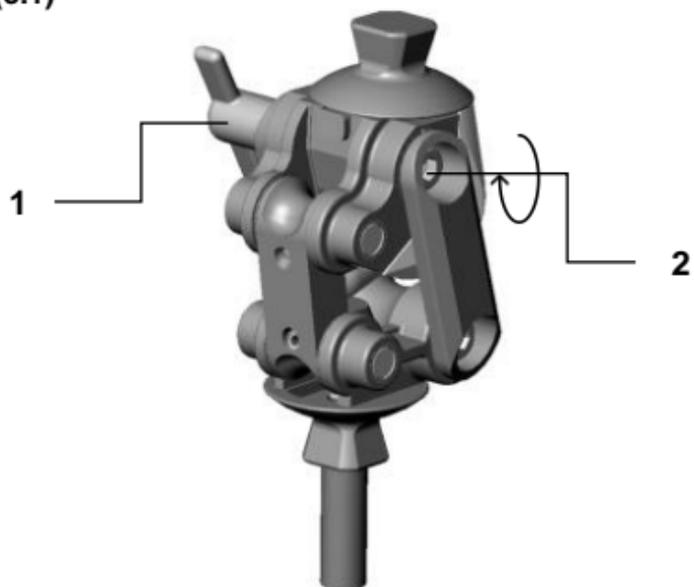
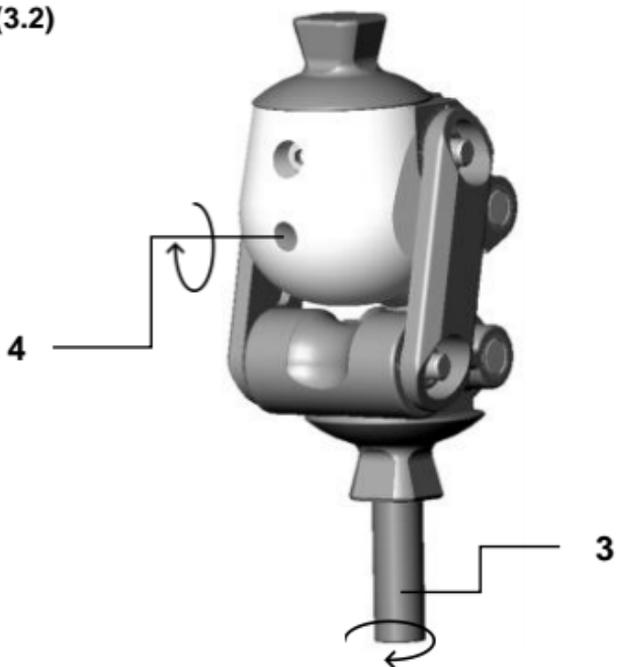


Fig. 2 (3.2)



INFORMATION

Last Update: 17.05.2024



- 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. Polycentric Knee Joints (E 53s – E 53T)..... | 1 |
| 2. Polycentric Knee for Disarticulation (E 53s-D) | 2 |
| 3. Polycentric Knee for Disarticulation with One-Prong Adapter (E53s-L) | 3 |
| 4. Settings | 3 |
| 5. Environmental Conditions..... | 5 |
| 6. Service Life | 5 |
| 7. General Safety Instructions | 5 |
| 8. Maintenance | 6 |
| 9. Warranty | 6 |

1. Polycentric Knee Joints (E 53s – E 53T)

E53 series of the knee joints provides medium functional level and medium stance phase stability.

For trans-femoral amputees

These knee joints are able to provide swing phase speed control ability. They can also be used as hip disarticulation joints.

Not recommended for patients with a higher activity level



E 53

1.1. Features

| Code | Material | Weight | Weight Limit |
|-------|-----------------|--------|--------------|
| E 53s | Stainless Steel | 700 gr | 100 Kg |
| E 53T | Titanium | 475 gr | |

2. Polycentric Knee for Disarticulation (E 53s-D)

These knee joints have been designed as disarticulation knee joints with direct lamination to the socket, without need of extra socket adapters. This reduces total length of prosthesis and allows to make compact disarticulation system. Body mechanism is similar with basic E53 series, which provides medium stance phase ability and swing phase speed control.



E 53s-D

2.1 Features

| Code | Material | Weight | Weight Limit |
|--------|-----------------|--------|--------------|
| E53s-D | Stainless Steel | 750 gr | 100 Kg |

2.2 Assembly

Mount the Prong adapter to the knee joint. Tighten cap screw using torque wrench.

Torque value: **10 Nm**



ATTENTION!

Secure screw thread with medium strength adhesive.

3. Polycentric Knee for Disarticulation with One-Prong Adapter (E53s-L)

Swing phase adjustable

Medium functional level

Medium stance phase stability

With self-socket One-Prong type adapter, easy to apply on socket



E 53s-L

2.1 Features

| Code | Material | Weight | Weight Limit |
|--------|-----------------|--------|--------------|
| E53s-L | Stainless Steel | 790 gr | 100 Kg |

4. Settings

CAUTION!



Polycentric Knee Joints (E 53s, E 53T, E 53s-D, E53s-L) are factory adjusted!

The prosthesis is ready to be installed and immediate use! However, some changes can be made individually if desired.

4.1 Setting Swing Phase Speed

Swing phase speed can be done with the axis friction adjustment in this knee joint.

Bearing in this knee joint allows adjustment of axis friction (resistance to motion) and readjustment of tolerance variation.

Please fix the lock nut by using the attached wrench (1). Turn the cap screw (2) with a hex head wrench.

- Turning clockwise = decreases friction
- Turning counter-clockwise = increase friction

Even very small adjustments 5° to 10° will make a noticeable difference.

4.2 Regulating the Swing Phase

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

Turning the adjustment screw (number 3 in fig. 2) with a hex head wrench changes the tension of the spring of the extension support.

4.3 Adjusting Stance Stability

In this knee joint, the stance stability can be adjusted according to the patient with the extension stop setting. Turn the adjustment screw (number 4 in fig. 2) by using a hex head wrench.

- Turning screw clockwise = Decrease stability of the joint
- Turning screw counter-clockwise = Increases stability of the joint

5. 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 |

6. Service Life

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

7. 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.

8. 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.

9. 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 53s | 24 Months |
| E 53T | |
| E 53s-D | |
| E 53s-L | |

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)