Qualität und Funktion

Gebrauchsanweisung

Instruction Manual

JT25 Polycentric Prosthetic Knee



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Please read the IFU carefully before fitting. Only correct usage will warrant the function.

### 1. Intended Use

The JT25 Polycentric Prosthetic Knee is designed for prosthetic limb users in the K2 and K3 activity scales with a maximum body weight of 125 kg. The knee joint has pneumatic swing phase control.

#### 2. Technical data



Order No.	Installation height above the axis center/complete	Weight	Flexion angle	Article No.
JT25	23 mm / 172 mm	766 g	135°	4 610 110 00 020 00

Materials: Aluminium, Stainless Steel, Steel, Urethane

Tube clamp: Ø 30 mm
Tube clamp torque setting: 12 Nm
Pyramid Center Bolt torque setting: 18 Nm

Operating/Storage Temperature Range: -10°C to 50°C

#### 2.1. Service Parts for JT25

Order No.	Material	Article No.	
E-JT16-01	Pyramid adapter with screw	4 610 099 00 00 001	

## 3. Indication/ Contraindication

#### Indications:

- Amputation of lower extremities
- Activity for K2 up to K3
- Weight limit < 125 kg</li>

#### Contraindications:

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities

#### 4. Side effects

Not known

## 5. General safety instructions





- This medical device is designed for single patient, multiple use.
- Fitting/service of the medical devise is only allowed by a certificated orthopedic professional.
- Be aware of additional weight that the user is carrying often, as this weight needs to be added to the users weight.
- The professional should instruct the correct use of the devise to the user.
- Be aware of finger trap hazard at all times.
- Any changes in performance of the knee e.g. instability or lag in transition from flexion moment to full knee extension moment in the knee, or unusual noise should be immediately reported to the Clinician/ Practitioner.
- Any excessive changes in heel height may adversely affect the stability of the knee.
- The user should be advised to contact their Clinician/ Practitioner if their condition changes.
- Avoid abrasive environments such as those containing dust or sand for example as these may promote premature wear. Avoid contact with talcum powder.
- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Knee is not waterproof do not submerge in water or prolonged exposure to salt or chlorinated water environment! These types of exposure will cause corrosion and can void warranty.

# 6. Alignment

In general, 4-axis knee joints are very safe due to the axis geometry. The intersection of the connecting lines of the two front and two rear axles marks the momentary pivot point. The further back and above the intersection point, the safer the joint. The prosthesis is built up according to the TKA reference. The reference line should run centrally through the main axis and through the tube clamp. In certain cases it may be necessary to move the joint back up to 10 mm.

Ideally, the clamp adapter should stand vertically above the foot. There may be deviations depending on the foot model. In this case, the maximum forward inclination of the pylon should not exceed 3degrees.



If the joint is tilted forward due to the set up of the foot, the joint becomes less secure and must be shifted further backwards!

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Take the heel height of the shoe into account and add a safety factor of 3mm. When the prosthesis is on, the load line in the M-L plane should run through the middle of the knee. Significant deviations lead to excessive stress on the knee joint.

Adjusting the tilt of the proximal section of the knee is not recommended as this will affect the function of the locking mechanism. Adjustment can result in the lock not engaging or material damage can occurring, which will invalidate the guarantee!

### 7. Knee Adjustment

### 7.1 Flexion / Extension Adjustment

Swing Phase Pneumatic setting is pre-set from the factory. It is advisable to adjust flexion before extension for optimum walking symmetry.

Ensure full knee extension occurs before performing extension adjustment.

Use following procedure only if there is a need to adjust extension or flexion:

- 1) Turn extension screw anti-clockwise to lowest resistance then
- 2) Turn the flexion screw clockwise to set to highest resistance (Do not over tighten if screw has resistance, or bottoms out damage may occur and void warranty!)
- 3) Incrementally loosen (anti-clockwise) the flexion screw to adjust heel lift;
- 4) Incrementally tighten (clockwise) the extension screw to smoothly stop extension.

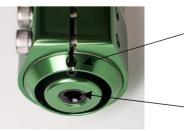
Use a 2.5 mm hex wrench.

Extension



Flexion

## 7.2 Extension Assist Adjustment



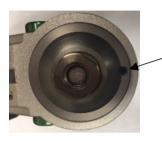
Loosen set screw prior to any adjustment to Assist! Tighten back up after adjustment is

Use 6mm driver and turn clockwise to increase extension assist. Turn screw anti-clockwise to reduce the extension assist.



After inserting pylon, apply Loctite 242 to pinch bolt and torque 12Nm using 5mm driver.

## 7.3 Adjusting the position of the pyramid head



Loosen set screw using 2.5mm driver.



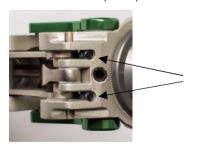
Loosen pyramid bolt Using 8mm driver.

Establish orientation and tighten bolt: Mark new location, remove pyramid bolt, apply Loctite and torque 18Nm. Tighten set screw to help prevent rotation.

#### 8. Maintenance

The Maintenance must be carried out by qualified personnel. A 6 months period check is recommended. Check for visual defects that may affect proper function.

### Service Flexion stop bumper:



Use a small screw driver to pick out the rubber on the back of knee head. Apply glue to new insert back into knee head.



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# Servicing Extension stop Bumper:



Use a small screw driver to flip out the extension stop rubber bumper. Insert new one into slot.

## 9. Cleaning

Use a damp cloth and mild soap to clean the outside surfaces.

DO NOT use aggressive cleaning agents or lubricants.

If the knee comes into contact with salt or chlorinated water, or bodily fluids, it should be rinsed with fresh water and dried.

## 10. CE-Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to the manufacturer or Uniprox and the competence European Authority.

### 11. Warranty

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

# 12. Storage and Disposal

The product is disposable with standard household garbage.

### Please direct any questions to:

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