Quality and Function

Instruction Manual

JT30 Swan Polycentric Knee Joint with Hydraulics and flexible Stance-Control



<u>....</u>

Imasen Engineering Corporation 3-1-8 Techno Plaza Kakamigahara, Gifu, 509-0109 Japan

MedNet EC-REP GmbH
Borkstrasse 10,
48163 Münster, Germany



A→文

Uniprox GmbH & Co.KG, H.-Heine-Str.4, 07937 Zeulenroda-Triebes









Please read the IFU carefully before fitting. Comply with all instructions, especially the safety instructions. Only a conscientious fitting guarantees the trouble free function.

1. Intended Use

The knee joint JT30 is only suitable for prosthetic care of the lower extremities. It contains a hydraulic swing phase control. Thanks to its special 5-axis geometry the JT30 allows a primary diffraction up to 5 $^{\circ}$ at heel strike with knee-save moving of the joint pivot point. The JT30 prosthetic knee joint is intended for Mobility level 2 & 3 (according to MDS) and is limited to a body weight of 125 kg.



Additional loads and patient activities must be taken into account when calculating the load.

2. Technical data

Proximal connection: pyramid Distal connection: pyramid



Order No.	Material	Installation height	Weight	Flexion angle	Article No.
JT30	Aluminum	164 mm	840 g	150°	4 610 060 00 00 000

Included in delivery:

1 prosthetic knee joint with preassembled extension assist spring ("hard") on the left side



2.1. Service parts for JT30



Order No.	Model	Article No.	
E-JT30-EFS	Extension spring-set	4 610 069 00 00 000	

The spring-set contains springs in ,hard' and ,soft' for the right side of the joint and ,soft' springs for the left side. So you can choose from six different options for setting the extension. See Table 1:

Strength	Left Side	Right Side		
1 (Soft)	-	-		
2	soft spring	-	The color of the spring cap indicates the strenght of the spring:	
3 (Factory setting)	hard spring	-		
4	soft spring	soft spring	soft spring - white	
5	hard spring	soft spring	hard spring - black	
6 (Hard)	hard spring	hard spring		

3. Indications/ Contraindications

Indications:

- · Transfemoral amputation
- Knee disarticulation
- Hip disarticulation
- Congenital limb deficiency

Contraindications:

- The patient is over 125 kg (275 lbs) and/or has a mobility level of 1 or 4
- The doctor decides the prescription of the product is inappropriate.

4. Side effects

There are no known side effects.

2

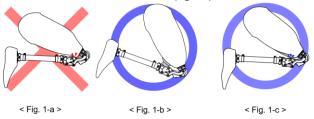


5. General safety instructions





- This medical device is designed for single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the device to the user.
- The joint must be protected against dust, moisture, aggressive media, and mechanical forces so its function is not affected.
- The joint is intended for use at temperatures from -10°C to 50°C.
- Do not longer use the knee joint if its function is impaired. This may be due to stiffness, restricted extension, noise generation, faulty swing phase control or stance phase safety, as well as impact from an external force (for example, if dropped). In such cases, it must be checked by a professional and, if necessary, sent to Uniprox GmbH & Co. KG.
- · There is a risk of jamming when the joint is in use.
- The product must not be changed or applied in any improper way. Non-compliance can impair the function of the product and thus no liability will be accepted.
- The safety of the user is not guaranteed if the product is not used for its intended purpose.
 This will also terminate the warranty of the product.
- Joint components may heat up slightly during walking.
- Silicone spray should be used to prevent noises being generated by contact between the cosmetic foam and knee joint. Do not use Talcum powder as it removes lubricant from the bearings and may lead to impaired function as a result.
- Avoid loading onto the prosthetic knee joint in the maximum flexed position.
- In case of maximum flexion, posterior part of the socket or other components may hit and
 damage the knee device and the socket (Fig. 1-a). If it is inevitable, place a soft pad
 between socket and the knee for shock reduction (Fig. 1-b) and make a new hitting point
 to distal part of the knee to reduce moment force (Fig. 1-c).

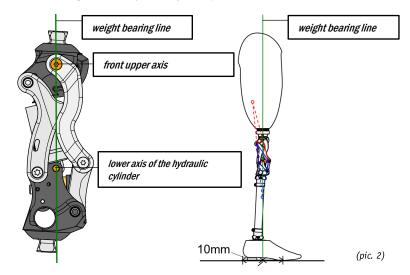


- When the knee joint is bent, never put hands around the device.
- Insertion of fingers between knee components or the knee device and another prosthetic component could cause severe injury such as laceration or fracture.
- This instruction should be given to users as well.

6. Construction and installation instructions

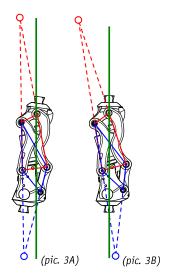
6.1 Static construction

The weight bearing line (load line) should run through the center of the front, top axis and the lower connecting axis of the hydraulic cylinder (pic.2).



6.2 Dynamic adjustment

6.2.1 Adjustment of the axes position
To reduce the knee safety, the JT30
can be tilted forward. So the initial
rotation point moves anteriorly and
the knee can be bent easily.
At the same time the bouncing effect
is reduced. (pic. 3A)
To increase the knee safety the JT30
can be tilted backwards. So the initial
rotation point is located more posteriorly.
Therefore it becomes harder to bend the joint.
The bouncing-effect increases. (pic. 3B)

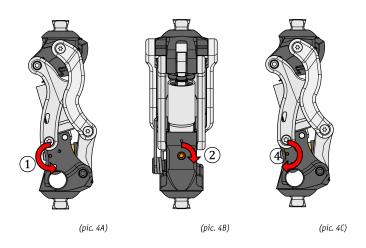


4 5



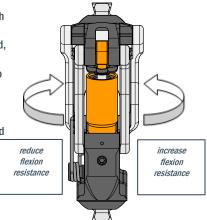
6.2.2 Adjusting the flexible stance control (bouncing)

In addition, the bouncing buffer can be adjusted. First open the locking screw on the right side (pic.4A) with a 2 mm Allen key. By screwing in the rear screw clockwise with a 4 mm Allen key, you increase the bouncing resistance. (pic.4B) Then secure the bouncing buffer setting by tightening the locking screw. (pic. 4C)



6.2.3 Adjustment of the hydraulic swing phase Only the flexion in the hydraulic system can be adjusted. Please rotate the hydraulic housing with the knurled ring. A counter-clockwise rotation Increases the flexion, clockwise on the other hand, reduces the flexion. The maximum adjustment is 1 1/4 turns. Upon delivery the JT30 is adjusted to minimum resistance (pic. 5).

Due to the polycentric structure an additional damping of the extension is not necessary. The pendulum motion of the lower leg can be adjusted via the extension springs. At higher walking speeds, a higher flexion resistance is required. The extension spring can impede the pendulum movement and should be removed during fast running style.



6.2.4 Adjustment of the springs

To remove the springs please turn the screw out in the center of the spring. Prevent a sudden uncontrolled movement of the spring by some pressure on the wound spring area from posterior to anterior. Please note that the color of the plastic sleeve corresponds to the spring strength.

Apply some grease on all contact surfaces of the spring and plastic parts. Now insert the plastic sleeve with the screw from outside in the spring. Push the disc on the inside on the screw and then insert the angled ends into the provided holes of the joint. Press the spring in the wound area towards anterior to make sure that the spring can be screwed using the hole intended. In the final installation, the screw must be secured with Loctite.

7. Maintenance and Cleaning

The function of the JT30 must be checked at regular intervals not exceeding 12 months. The extension spring must be cleaned and all moving and sliding areas must be greased.



- · Compressed air up to 2 bar can be used for cleaning.
- Do not use any aggressive cleansers.

In case of defects please return the knee joint to the Uniprox customer service for inspection or repair.

8. 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 Uniprox and/or Imasen Engineering Corporation as well as to the competence European Authority.

9. Warranty an Guarantee

Depending on the degree of usage, the knee joints can generally be used for 5 years with regular maintenance.

Warranty is provided as stated in the terms of sale and supply (T & C) of Uniprox GmbH & Co. KG provided that the above conditions are met.

10. Storage and Disposal

This product has no special storage regulations.

The product is disposable with standard household garbage.

Please direct any questions to:

Customer Service: + 49 (0) 36628-66-33 70 Fax: + 49 (0) 36628-66-33 77 E-mail: export@uniprox.de

 δ