Qualität und Funktion

Gebrauchsanweisung
Instruction Manual

JT06 Weight activated brake knee manual lock

ST&G USA Corp.
2691 Saturn Street
Brea, CA 92821, USA

EC REP
MDSS GmbH
Schiffsgraben 41
30175 Hannover, Germany

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

Ein Unternehmen der Bauerfeind Gruppe – www.uniprox.de

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

1. Intended Use

The JT06 Weight activated brake knee is designed for prosthetic limb users in the K1 and K2 activity scales with a maximum body weight of 125 kg. The knee joint has a manual knee lock that can be used locked or un-locked depending the rehabilitation and activity development of the user.

2. Technical data

Materials: Aluminum Alloy, Stainless Steel, Steel, Urethane
Tube clamp: Ø 30 mm
Tube clamp torque setting: 16 Nm
Operating /Storage Temperature Range: -10°C to 50°C

REF

Order No.	Installation height above the axix center / complete	Weight	Flexion angle	Article No.
JT06	26 mm / 65 mm	495 g	145°	4 610 130 00 12 000

3. Indication/ Contraindication

Indications:

- Amputation of lower extremities
- Activity for K1 up to K2
- Weightlimit < 125 kg

Contraindications:

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

4. Side effects

Not known.

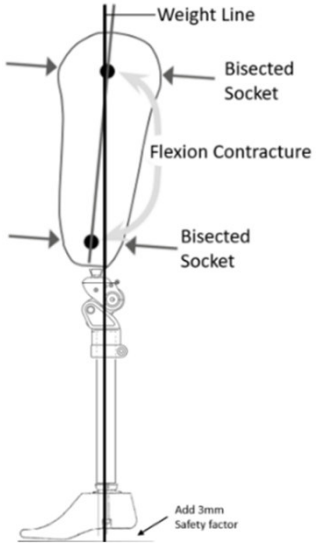
5. General safety instructions

- The medical device is designed for multiple use to a single patient.
- 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. inability to engage manual lock mechanism, 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.

- English -

6. Alignment and Set-Up

Alignment for the L1311A should be adhered to so as to enable a stable and safe functioning prosthesis for the wearer. The recommended alignment is to the Knee Center which will have the weight line on the centerline along the length of the pylon.
Weight line should also be along the centerline of the Pylon in the sagittal plane so as to not promote undue stress on the knee joint axis.



Important: If the weight line is too close to the knee center, there is possibility of inadvertent knee instability. Adhere to allowance for safety factor of at least 3mm for initial fitting, and to reassess knee alignment and function on a regular basis initially (especially for new amputees) so as to gauge their progression and ability with the need for fine tuning knee function!

- English -

⚠ Do not insert any tube spacers into tube clamp section – This can lead to potential failure. Only the intended pylon should be fully inserted to the tube clamp bottom. Be sure that the 5mm Hex Wrench Tube Clamp Pinch Bolt torque is set to 16Nm.

7. Adjustment

The knee joint is supplied by the factory in the basic setting. Carefully assess the brake function with the wearer during the dynamic initial fitting to see if the basic setting is optimal.
If adjustment is necessary, it is best to start with the Stance Phase adjustment and then go to Swing Phase adjustments.

NOTE: There is a fine balance to adjusting this so as to ensure that the wearer will have a smooth transition to swing. Overly adjusting will cause the knee to not release during swing initiation!

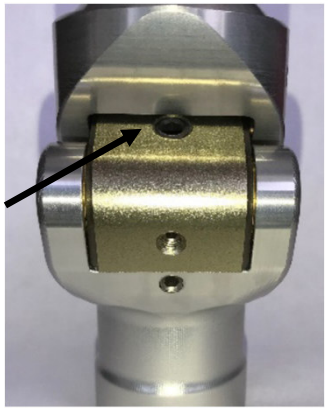
- English -

7.1 STANCE PHASE – Brake Sensitivity Stance Adjustment

The brake sensitivity adjustment is to fine tune the amount of load required during stance phase to activate the brake mechanism.
(See the image for the position of the brake set screw).

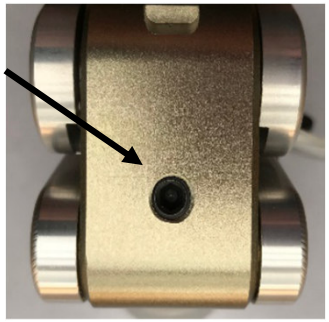
To set the adjustment screw, flex the knee-joint and use a 4mm hex wrench:

- Clockwise adjustment = more weight is needed to trigger the brake function
- Anti-Clockwise adjustment = less weight is needed to trigger the brake function



NOTE: Adjustment as little as 5 degree turn makes a notable difference!

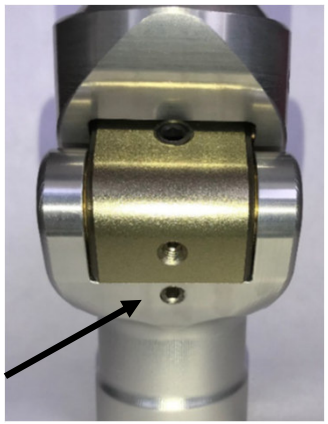
Resetting Brake sensitivity to factory setting: Brake sensitivity adjustment screw head should be flush with the knee brake mechanism surface.



7.2 SWING PHASE – Friction Adjustment

The Knee Friction Adjustment screw is located towards the bottom of the knee joint on the anterior and can be adjusted with a 3mm hex wrench:

- Clockwise adjustment = increased friction (more resistance in the swing phase)
- Anti-Clockwise = decreased friction (smoother to free swingphase)



NOTE: Minor adjustments of as little as 3 degree turn will provide a notable difference!
The knee friction effect may occur anyway during initial swing (prosthesis sticks) depending on the user's weight or walking habits which could impair the safety and the user's walking behavior.

Reassess knee function during walking and adjust accordingly.
Important: flexion and extension must be possible at all settings!
Resetting Friction to factory setting: Friction adjustment screw should be reset to be flush with knee frame surface.

7.3 SWING PHASE – Spring Extension Assist

The Knee Spring Extension Adjustment screw is located Within the tube clamp portion of the knee joint and is adjusted with with a 5 mm hex wrench :

- Clockwise adjustment = increases extension assist
- Anti-Clockwise adjustment = decreases extesion assist

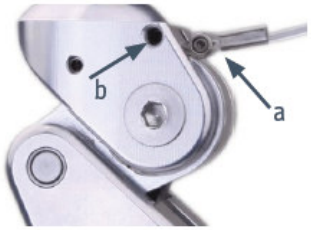
Important: Knee action should be smooth. This knee is a low activity knee, so do not expect for very rapid extension assist to occur. Excessive spring tension could possibly affect knee friction tension.

7.4 Unlocked Knee Mode – Manual Lock Disable Procedure

Note: Lock should only be disabled by the prosthetist when patient has been released to have the ability to control the prosthesis without the need for the manual lock mechanism!

Manual Lock Disable:

- Push the locking lever (a) upwards and secure in this position by turning the set screw (b) with a 2 mm hex wrench clockwise. Apply thread locker!
- Lanyard can be removed by removing the retainer screw with 2.5mm hex wrench.



IMPORTANT: Set screw (b) should be tightened to a torque of 5 Nm and secured with thread locker when finishing the prosthesis. Do not over tighten! Use a torque wrench!

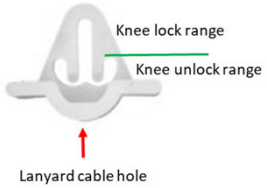
Note: Failure to adequately secure the set screw (b) when disabling the locking lever (a), can result in loss of function of the knee and / or makes it impossible to move the knee freely.

Note: If being used with the locking function, the disable set screw (b) must not impede the function of the locking lever (a) and must be secured with Loctite to rule out inadvertent loosening and inadvertent function.

7.5 The Lanyard Handle

The Lanyard Handle has the ability to keep the knee in either the temporary unlocked or locked position.

Setting the Lanyard Handle on the Cable:
Once the retainer screw is mounted with the star nut on the socket, adjust the cable to the in desired length:



- Set the lanyard length by having knee in locked posit and handle in the locked position.
- Take out unwanted slack in the lanyard cable by push excess length out of the handle, and remove ferrule b unscrewing but do not remove handle.
- Mark cable as indicated.
- Cut cable at a 45 degree angle as indicated.
- Screw ferrule onto cable.
- Confirm lock function by cycling the lanyard handle to assess that the knee locks, and unlocks. Adjust length as needed by screwing ferrule more onto the cable and cut excess.
- If used with the locking function, the locking lever or lanyard cable must not be impeded by the cosmesis. The cable must run freely.

IMPORTANT! Secure the cable so that it cannot catch in grinding tools when modifications are required to socket! Hazard potential!

7.6 Attachment of Star Nut

The Star Nut needs to be laminated into the socket. For attachment an M4 thread should be drilled into the button.

8. Maintenance and Cleaning

The Maintenance must be carried out by qualified personnel. Bi-Annual inspection is recommended. Check for visual defects that may affect proper function.

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.

9. 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 *ST&G USA Corp*. as well as to the competence European Authority.

10. Warranty

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

11. Disposal

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