Trulife SSK625
Single Axis Knee With Brake, Stance Flexion, And Manual Lock
Instructions and User Guide

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INTRODUCTION

The Trulife SSK625 is a mechanical prosthetic knee joint with dual function:

- Weight activated adjustable brake
- Adjustable stance flexion
- Adjustable extension assist
- Cable actuated locking (optional function)

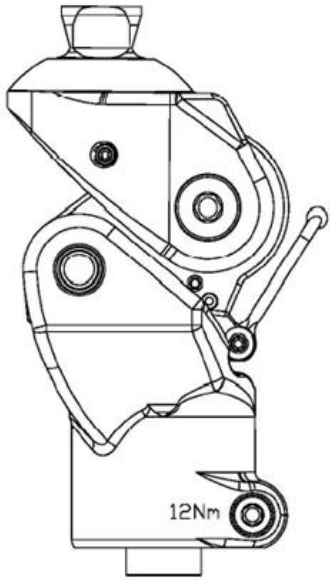
Indications:

Low activity K1-K2 transfemoral amputees (including knee disarticulation and higher)
The device is ideal for rehabilitation

Product Code	Description	Weight Limit
SSK625	SINGLE AXIS KNEE WITH BRAKE, STANCE FLEXION, AND MANUAL LOCK	136 kg / 300 lb

Specifications:

Weight Limit	136 kg / 300 lb
Amputation Level	Transfemoral (knee disartic and higher)
Overall Height	121mm / 4.76"
Effective Fit Height	99mm / 3.9"
Knee Center to Proximal Mounting Surface	26mm / 1.0"
Product Weight	580g
Proximal Connection	Male Pyramid
Distal Connection	30mm Pylon
Swing Phase adjustment	Internal extension assist spring with adjustable pre-load
Stance Phase adjustments	Weight activated brake with sensitivity adjustment
	Stance flexion with adjustable spring resistance
	Optional cable actuated manual lock
Stance Flexion Range	0-5°
Knee Flexion Range	0-145°



INSTALLATION AND USE

⚠ **Never modify the Trulife SSK625. Do not use fasteners other than those supplied or approved by Trulife for use with the Trulife SSK625. Any modifications void the warranty and could contribute to an unexpected failure.**

Socket Attachment

The SSK625 is incorporated with a proximal male pyramid and mates with an appropriate modular adapter with a female receiver.

Rotational Adjustment

The rotational orientation of the Trulife SSK625 can be manipulated only through the use of a rotatable adapter (such as the AAA214-01) when used with either a lamination adapter (such as the AAASS237) or a rotatable flange (AAA212) and Socket Mounting Plate (AAASMP450).

Trulife

Distal 30mm Pylon Attachment

1. Cut the pylon to the appropriate length. The cut must be smooth and level.
2. Remove any burrs from the cut end of the pylon.
3. Insert the pylon into the distal end of the prosthetic knee until it is fully seated.
4. Use a 4mm hex bit with torque wrench to tighten the clamp bolt to 12 Nm (9 ft-lbs //106 in-lbs).

⚠ **Never permit a patient to walk on a partially inserted or shimmed pylon. This will void the warranty and could contribute to component failure.**

Knee Alignment

- Align the socket so that the load line falls approximately 13mm anterior to the knee axis, as indicated in *Figure 1*
- Position the load line further anterior to increase stability

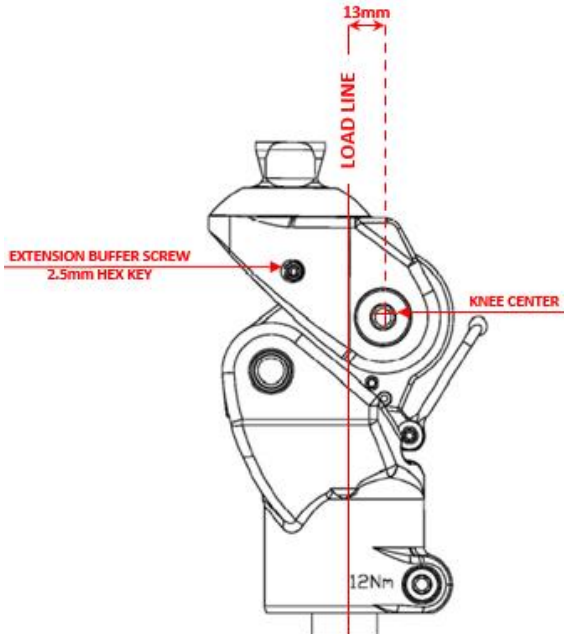


Figure 1

Knee Adjustments

Manual Lock

- Once the knee is assembled, locate an appropriate location on the socket for the locking mechanism handle and attaching it to the socket
- Adjust the cable at the handle by loosening the two set screws with a 2mm hex key and pulling the cable taut leaving minimal slack.
- Retighten the set screws and trim excess cable, if necessary
- Fine tune the adjustment by loosening the attachment screw and sliding the handle along the slot as needed
- Use the cable to pull the lock lever upward to unlock the knee
- If there is joint play when the knee is locked, Use a 2.5mm hex key to tighten the extension buffer adjustment screw until joint play is eliminated. It is located on the upper, left side of the knee (see figure 1)

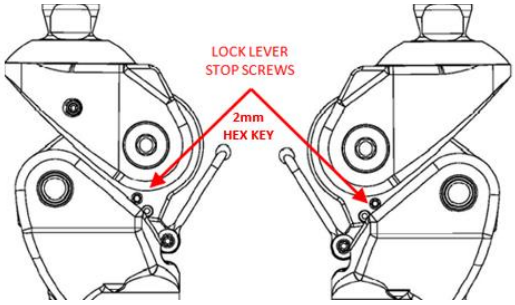


Figure 2

To disengage the manual lock:

- Fully extend the knee
- Pull the lock lever upward and hold it in the unlocked position
- Use a 2mm hex key to tighten the lock lever stop screws on <u>both sides</u>. The stop screws prevent the lock lever from moving down to the lock position (see figure 2)

Brake adjustment (figure 3)

Adjust the load required to activate brake, use a 4mm hex key:

- Screw in the <u>load adjust screw</u> to increase the load required to activate the brake
- Screw-out the <u>load adjust screw</u> to decrease the load required to activate the brake

<u>NOTE:</u> After adjustments are made, make certain that the load adjust screw is not protruding from the surface of the brake component so as not to impede knee function.

- The default setting of the brake adjustment screw is 3 full-turns in from flush
- After setting the load-adjust screw, fine tune the brake using the <u>brake adjust screw</u>. Use a 2.5mm hex key

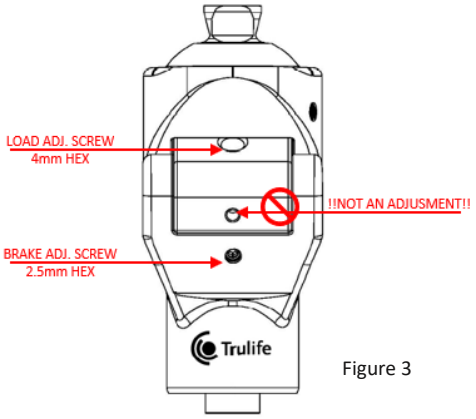


Figure 3

- Note: The brake adjust screw also affects the stance flexion resistance. Tightening the screw will increase resistance to stance flexion

Extension Bias Adjustment (figure 4)
The extension assist adjustment screw is inside the distal tube clamp.
Use a flat-blade screw driver to adjust:

- Screw in to increase extension bias
- Screw out to decrease extension bias
- Re-insert the pylon and tighten the clamp screw 12 Nm (9 ft-lbs).

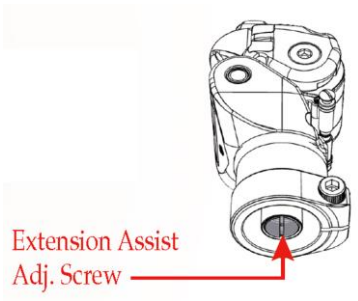


Figure 4

⚠ **Failure to follow the installation and use procedures could contribute to an unexpected failure that would subject the patient to an unnecessary risk of serious personal injury.**

MAINTENANCE

- Service the product at regular intervals.
- Inspect the knee for excessive wear or visual damage during normal consultations.
- Instruct patient to discontinue use and contact their physician or prosthetist if the prosthesis starts to make noise or if they experience any change in function.
- Instruct the patient to notify their physician or prosthetist if they gain a significant amount of weight.

STORAGE AND USE
There are no identified restrictions on the temperature of storage and use.

DISPOSAL
There are no hazardous materials in the device. Comply with local and national laws and regulations.

LEGAL INFORMATION
MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.

Trulife
3225 Woburn St. Suite 160
Bellingham, WA 98226
USA
Phone (+1) 360 697 5656
Email supportop@trulife.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

LIMITED WARRANTY
Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.