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INTRODUCTION
Trulife's Natural Stance Flexion Knee with Lock provides the transfemoral amputee with effortless, natural movement and control. Designed for the typical community ambulators, this polycentric knee offers friction swing control, knee extension assist, and adjustable stance flexion. Trulife's design simplifies the fitting process with a built in proximal pyramid and a distal tube adapter.

The Natural Stance Flexion Knee with Lock is appropriate for K1-K2 amputees with low to moderate impact levels and body weights up to 136 kg (300 lbs.)

INDICATIONS
The Natural Stance Flexion Knee with Lock is designed for above knee amputees with low to moderate impact levels, K1-K2, and weigh less than 136 kg (300 lbs).

LIMITATIONS
The Natural Stance Flexion Knee with Lock requires a clearance of 40 mm (1.57") from the center of the knee to the mounting surface.

INSTALLATION AND USE
Recommended installation and use procedures must be followed for maximum safety and service life.

⚠ **Never modify the Natural Stance Flexion Knee with Lock. It will void the warranty and can cause failure. Use only bolts and screws supplied by Trulife. Use of unapproved fasteners will void the warranty and can cause failure.**

⚠ **Do not expose knee to water, functionality will be compromised and can cause failure.**

Socket Attachment for the SSK617:
The SSK617 comes with an attached proximal end male pyramid.

Pylon Attachment
- Cut the pylon to the appropriate length. The cut must be smooth and level.
- Remove any burrs from the end of the pylon with sandpaper.
- Insert the pylon into the distal end of the prosthetic knee.
- Apply Loctite® 242 removable thread-locking compound to the clamp bolt. Loctite requires several hours to cure completely.
- Tighten the 6 mm clamp bolt assembly with a torque wrench to 12 Nm (8.9 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:
When assembling the prosthesis using the SSK617 Natural Stance Flexion Knee with Lock, the bench alignment can be set using the following procedure.

Step 1 – Perform a Medial/Lateral (coronal plane) alignment. Set the alignment so the load line of body weight passes through the center of the knee and reaches the center of the heel.

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Step 2 – Perform an Anterior/Posterior (sagittal plane) alignment. Set the alignment so the load line of body weight passes 5mm (0.20") forward from the anterior superior axis and the midpoint between heel and toe-break. This will be the basic alignment setting.

Note: For a highly active person, it is recommended that the alignment setting be 0 to 5 mm (0 - 0.2") forward from the anterior superior axis. For a less active person, adjustment the alignment setting 5 to 10 mm (0.2 - 0.4") forward.

⚠ **Improper alignment of the knee or excessive forces applied to the knee unit can result in damage and or malfunction.**

Extension Assist Adjustment:

- Remove pylon.
- Locate the Extension Assist Adjustment screw, #1 in *Figure 1*, on the anterior side of the knee.
- Rotate the Extension Assist Adjustment screw counterclockwise to reduce the velocity of the joint's extension.
- Rotate the Extension Assist Adjustment screw clockwise to increase the velocity of the joint's extension.
- After finishing the adjustment, mark the screw's position.
- Remove screw and insert Loctite 242 Thread Locker into the hole.
- Insert screw and tighten to marked position.

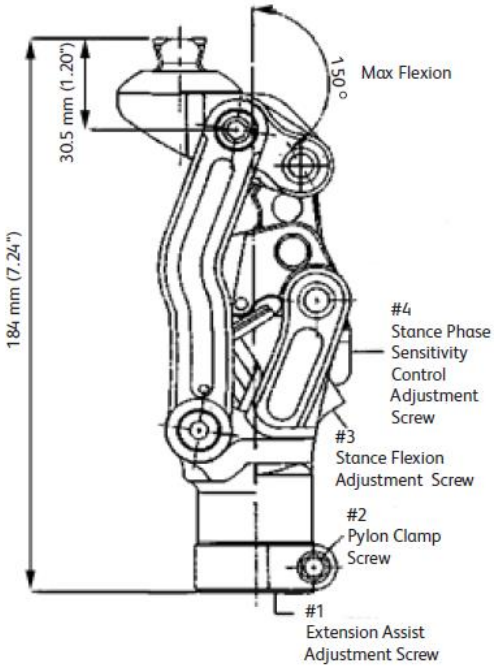

Figure 1

Stance Flexion Adjustment:

- Locate the Stance Flexion Adjustment screw, #3 in *Figure 1*, on the posterior of the knee.
- Rotate the Stance Flexion Adjustment screw clockwise to decrease stance flexion.
- Rotate the Stance Flexion Adjustment screw counterclockwise to increase stance flexion.
- After finishing the adjustment, mark the screw's position.
- Remove screw and insert Loctite 242 Thread Locker into the hole.
- Insert screw and tighten to marked position.

Stance Phase Sensitivity Control Adjustment:

- Locate the Stance Phase Sensitivity Control Adjustment screw, #4 in *Figure 1,* on the posterior of the knee.
- Rotate the Stance Phase Sensitivity Control Adjustment screw clockwise to decrease knee stability.
- Rotate the Stance Phase Sensitivity Control Adjustment screw counterclockwise to increase knee stability.
- After finishing the adjustment, mark the screw's position.
- Remove screw and insert Loctite 242 Thread Locker into the hole.
- Insert screw and tighten to marked position.

⚠ **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.**

Locking Mechanism

The SSK617 Natural Stance Flexion Knee with Lock has a lock that can be manually released when knee flexion is desired by using the lock cable. This lock can also be set open to allow free motion by lifting the lock lever and tightening the Anti-lock screw located on the side of the knee using a 2mm Allen wrench. Use Loctite® 242 on this screw to keep it from backing out.

1. Once the knee is assembled, locate an appropriate location on the socket for the locking mechanism handle and attaching it to the socket with the screw provided.
2. Adjust the cable at the handle by loosening the set screw with a 2mm Allen wrench and pulling the cable taut leaving minimal slack.
3. Retighten the set screw and trim excess cable, if necessary.
4. Fine tune the adjustment by loosening the attachment screw and sliding the handle along the slot as needed.

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.

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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.