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INTRODUCTION

Trulife's Select Stance Flexion Knee offers transfemoral amputees dynamic features in a lightweight package. Designed for the moderate to active amputee (K3 or K4 activity levels), Trulife's polycentric pneumatic 5-bar offers significant advantages for the amputee including: pneumatic swing phase control, adjustable stance flexion, spring knee extension assist, and adjustable flexion control and extension control. The fitting process is simplified with a built in distal tube adapter.

Product Code	Description	Weight Limit	Proximal Attachment
SSK615	Select Stance Flexion Knee	136 kg (300 lb)	Pyramid
SSK615-THR	Select Stance Flexion Knee with Threaded Adapter	136 kg (300 lb)	Threaded

INDICATIONS

Above knee amputations with a medium to high impact level, K3-K4.

LIMITATIONS

- The SSK615 Select Flexion Knee requires a clearance of 30mm • 1.18" from knee center to mounting surface of the knee unit. The knee reaches full flexion at 145°.
- The SSK615-THR Threaded Select Flexion Knee requires a clearance of 23mm • 0.91" from knee center to mounting surface of the knee unit. The knee reaches full flexion at 145°.

INSTALLATION AND USE

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

⚠ **Never modify the Select Stance Flexion Knee. 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.**

Proximal Socket Attachment

- The SSK615 comes with an attached proximal standard male pyramid.
- The SSK615-THR has a threaded proximal attachment point which is designed to be used either with the AAA212 4-Hole Rotatable Base, or the AAASS237 3-Prong Threaded Lamination Anchor.

Pylon Attachment

1. Cut the pylon to the appropriate length. The cut must be smooth and level.
2. Remove any burrs from the end of the pylon using sand paper.
3. Fully insert the pylon into the distal knee unit.
4. Apply Loctite® 242 removable thread locking compound to the clamp bolt. Loctite® requires several hours to cure completely.
5. Using a torque wrench, tighten the Clamp Bolt (*Figure 1*) to 12 Nm (9 ft-lbs or 108 in-lbs) using a 5mm hex wrench.

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

Knee Alignment

When assembling the prosthesis using the Select Stance Flexion Knee, the bench alignment can be set using the following procedure.

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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.
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.

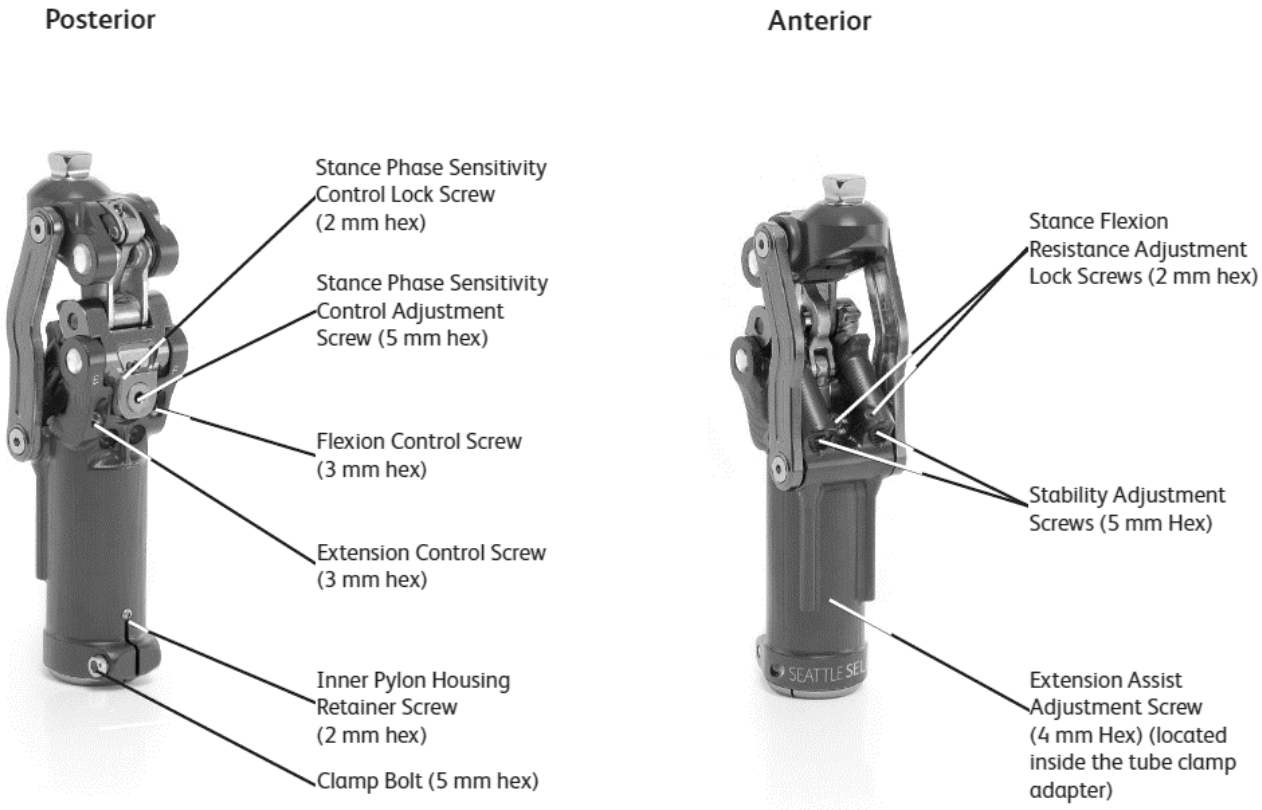

Figure 1: SSK615 and SSK615-THR knee adjustment locations (SSK615 Select Stance Flexion Knee show)

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

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

Knee Adjustment

The Seattle Select Stance Flexion Knee is packaged with the extension and flexion adjustment screws at nominal (factory) setting.

Stance Phase Sensitivity Control Adjustment

1. Locate the Stance Phase Sensitivity Lock Screw on the posterior of the knee (*Figure 1*). Using a 2mm hex wrench, loosen the lock screw. **NOTE: This screw is located vertically along the knee body**
2. Locate the Stance Phase Sensitivity Control Adjustment Screw, (*Figure 1*) on the posterior of the knee.
   Using a 5mm hex wrench:
   - Rotate the adjustment screw counterclockwise to increase the overall sensitivity of the joint (decreasing stability).

- Rotate the adjustment screw clockwise to decrease the overall sensitivity of the joint (increasing stability).

3. Re-tighten the Stance Phase Sensitivity Lock Screw.

Stance Flexion Resistance Adjustment

1. Locate the two Stance Flexion Resistance Adjustment Lock Screws on the anterior of the knee (*Figure 1*). Using a 2mm hex wrench, loosen the two lock screws.
2. Locate the Stability Adjustment screws on the anterior of the knee (*Figure 1*). Using a 5mm hex wrench:
   - Rotate both of the adjustment screws counterclockwise to allow more stance flexion.
   - Rotate both of the adjustment screws clockwise to decrease stance flexion.
3. Re-Tighten the two Stance Flexion Resistance Adjustment Lock Screws.
   - If the knee still does not have the desired level of stability:

   a. Locate the two Stance Flexion Resistance Adjustment Lock Screws on the anterior of the knee (*Figure 1*). Using a 2mm hex wrench, loosen the two lock screws.

   b. Locate the Stability Adjustment screws on the anterior of the knee (*Figure 1*). Using a 5mm hex wrench, remove both of the Stability Adjustment screws.

   c. Remove the Extension Spring (*Figure 2*) and replace it with one of the included Extension Springs that has the proper resistance.
      - Green — most resistance
      - Red — mid resistance
      - Blue — least resistance

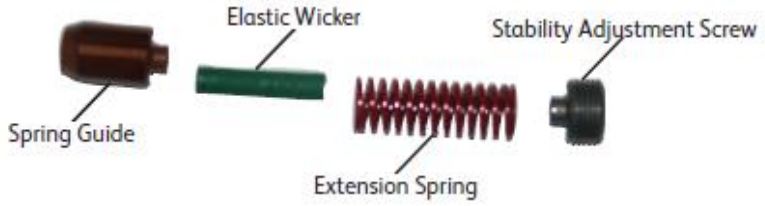

Figure 2: Stability spring kit

   d. Re-insert the Stability Adjustment Screws using a 2mm hex wrench and rotate them clockwise until the desired amount of stance flexion resistance obtained.

   e. Re-tighten the Stance Flexion Resistance Adjustment Lock Screws (*Figure 1*).

Swing Flexion and Extension Control Adjustments

1. Locate the Flexion and Extension Control Adjustment Screws on the posterior of the knee (*Figure 1*). Using a 3mm hex wrench:
   - Rotate the Flexion Control Screws clockwise to decrease the velocity of the joint's flexion.
   - Rotate the Extension Control Screws clockwise to decrease the velocity of the joint's extension.

⚠ **Failure to follow the installation and use procedures set forth above may lead to structural failure of the components subjecting the user to a 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.

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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.

1 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.

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