



INTRODUCTION

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

The Seattle Natural Stance Flexion Knee is appropriate for K1 and K2 amputees with medium-low to low activity levels and body weights up to 100 kg (220 lbs.)

LIMITATIONS

The Seattle Natural Stance Flexion Knee 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.

Warning: Never modify the Seattle Natural 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.

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 (106 in-lbs or 8.9 ft-lbs).

Warning: 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 Seattle Stance Knee, 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.

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.





Caution: 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 Locktite 242 Thread Locker into the hole.
- Insert screw and tighten to marked position.

Stance Flexion Adjustment:

- Locate the Stance Flexion Adjustment screws, #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 Locktite 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 Locktite 242 Thread Locker into the hole.
- Insert screw and tighten to marked position.

Warning: 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.

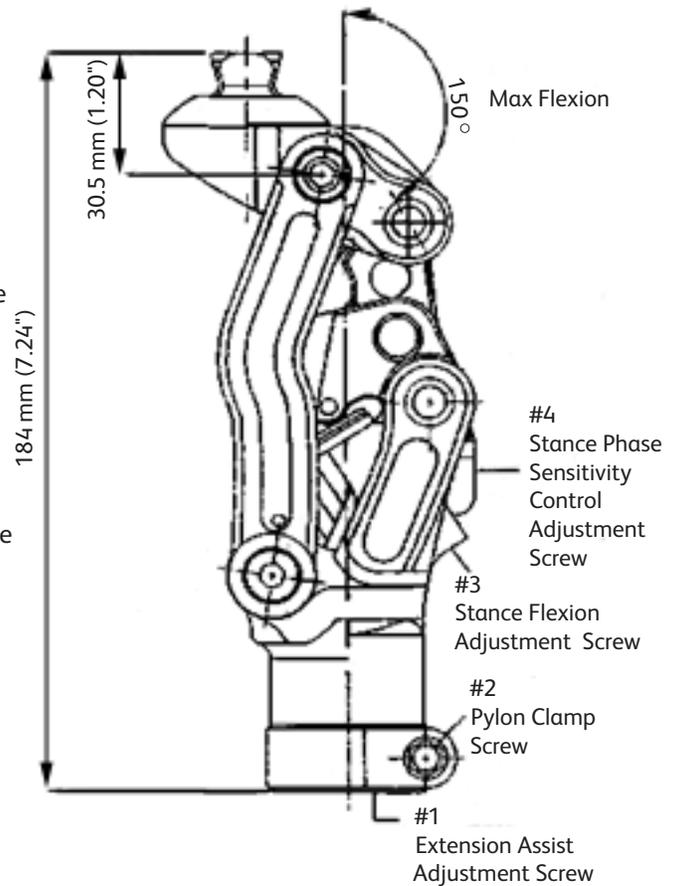


Figure 1





QUESTIONS

Contact Customer Service in the U.S. at 888-878-1238, or fax 888-878-1237

Contact Customer Service in Canada at 800-267-2812, fax 613-392-4139

If calling from outside the U.S. or Canada, contact Customer Service at 360-697-5656, or fax 360-697-6843

Visit Trulife online at www.trulife.com

LIMITED WARRANTY

Trulife warrants that the Seattle Natural Stance Flexion Knee will be free from defects in material and workmanship for two (2) years from the date of installation.

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 Seattle Natural Stance Flexion Knee 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 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 prosthetic 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 prosthesis 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.

