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## INTRODUCTION

The PC Friction Control Locking Knee is a 4-bar polycentric knee that utilizes a mechanical locking system with a manually operated release lever. The PC Friction Control Locking Knee is lightweight and durable. The design incorporates constant friction braking mechanisms and spring-loaded extension assists for a natural gait. The PC Friction Control Locking Knee is appropriate for K1-K2 amputees with low to moderate impact levels.

| Product Code | Description | Weight Limit |
|---|---|---|
| SSK602L | PC Friction Control Locking Knee | 136 kg / 300 lb |

## INDICATIONS

The PC Friction Control Locking Knee is designed for above knee amputees with low to moderate impact levels, K1-K2, and weigh less than 136 kg (300 lbs).

## LIMITATIONS

The PC Friction Control Locking Knee requires a clearance of 31.8 mm (1.25") from the center of the knee to the mounting surface. This knee reaches full flexion at 145°.

## INSTALLATION AND USE

⚠ **Never modify the PC Friction Control Locking Knee. Do not use bolts other than those supplied or approved by Trulife for use with the PC Friction Control Locking Knee. Any modifications void the warranty and could contribute to an unexpected failure.**

⚠ **Do not expose knee to water. If the knee comes in contact with water, the extension assist control should be thoroughly evaluated for functionality.**

### Socket Attachment

The SSK602L incorporates a proximal male pyramid and cannot be modified to accept a disarticulation bracket.

### Rotational Adjustment

The rotational orientation of the SSK602L PC Friction Control Locking Knee can be manipulated only using a rotatable adapter (such as the AAA214-01) when used with either a lamination adapter (SCA237-01) or a rotatable flange (AAA212).

### 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 with sandpaper.
3. Insert the pylon into the distal end of the prosthetic knee.
4. Apply Loctite® 242 removable thread-locking compound to the clamp bolt. Loctite® requires several hours to cure completely.
5. Tighten the 5 mm clamp bolt assembly with a torque wrench to 12.2 Nm (9 ft-lbs, 108 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.**



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**Knee Alignment**
Use standard bench alignment techniques to obtain the best performance from the PC Friction Control Knee with. Alignment reference (knee center) should be taken from the distal anterior axis of the knee, as indicated in *Figure 1*.

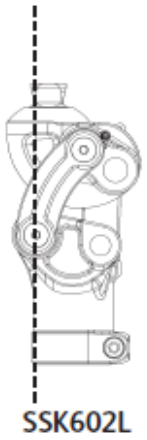

*Figure 1: Knee alignment*

**Knee Adjustment**
The PC Friction Control Locking Knee is packaged with the Friction Adjustment and Extension Assist Adjustment Screws adjusted to nominal (factory) settings.

Friction Resistance determines the overall resistance to movement for both extension and flexion. The Extension Assist applies additional force during the extension portion of swing.

**Extension Assist Adjustment** (requires a 5 mm Allen wrench)
1. Remove the pylon from the distal end of the prosthetic knee.
2. Locate the Extension Assist Screw in the distal end of the prosthetic knee (*Figure 2*).
3. Rotate the Extension Assist Screw clockwise to increase the force of the extension assist.
4. Rotate the Extension Assist Screw counterclockwise to decrease the force of the extension assist.
5. Install the pylon after adjustment.
6. Tighten the 5 mm clamp bolt assembly with a torque wrench to 12.2 Nm (9 ft-lbs, 108 in-lbs).

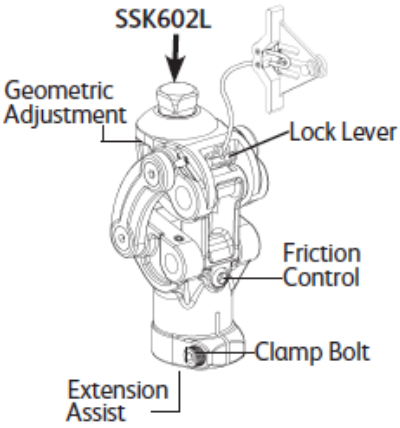

*Figure 2: Friction and extension controls*

**Friction Resistance Adjustment** (requires a 4 mm Allen wrench)
1. Locate the Friction Bar on the posterior side of the knee (*Figure 2*).
2. Locate the Friction Adjustment Screw on the Friction Bar (*Figure 2*).
3. Rotate the Friction Adjustment Screw clockwise to increase the overall resistance to movement.
4. Rotate the Friction Adjustment Screw counterclockwise to decrease the overall resistance to movement.

⚠ **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.**

**Hyperextension impact** is prevented by an extension stop bumper which is located under the knee cap. If the bumper wears over time, it may be replaced by prying off the bumper. Replacement bumpers are available by contacting Trulife technical support.

**Extension spring adjustment** for more active patients may be accomplished by replacing the extension spring from within the extension spring housing. If the spring wears over time, it may be replaced as follows:
1. Loosen the clamping bolt securing the pylon.
2. Remove the pylon.
3. Remove the spring by unscrewing the cap at the distal end of the spring tube with a flathead screwdriver.
4. Remove or adjust the spring as necessary.
5. Replace the cap on the spring tube and tighten until flush with the spring tube.
6. Insert the pylon and tighten the 5 mm clamping assembly to 12.2 Nm (9 ft-lbs, 108 in-lbs).



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**Geometric Adjustment**

According to patient's mobility, modify the adjustment screw shown in figure 3 to increase/reduce the sensitivity of the joint. The adjustment lock screw must be disengage before adjustment and reengaged after adjustment.

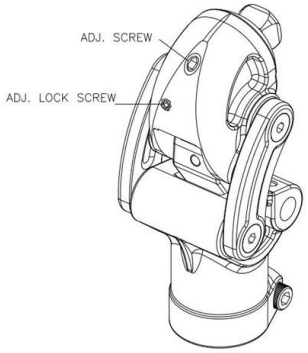


*Figure 3: Geometric Adjustment*

**Locking Mechanism**

The SSK602L PC Friction Control Locking Knee 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.

⚠ **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.

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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