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INTRODUCTION

The Child's Play Knee with Manual Lock is a four-bar, polycentric knee that utilizes a mechanical locking system with a manually operated release lever. It is a lightweight, low-profile knee that provides constant friction and spring extension-assist for pediatric amputees. The Child's Play Knee with Manual Lock is compatible with 22mm endoskeletal modular prosthetic components.

Product Code	Description	Weight Limit
SSK610A	Child's Play Knee with Manual Lock	55 kg/121 lb
SSK610A-DIS	Lamination Bracket for SSK610A	55 kg/121 lb

INDICATIONS

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

LIMITATIONS

The Child's Play Knee with Manual Lock (SSK610A) requires a clearance of 15 mm (.59") from center of knee to the mounting surface. The knee reaches full flexion at 140°.

INSTALLATION AND USE

⚠ **Recommended installation and use procedures must be followed for maximum safety and service life. Never modify the Child's Play Knee with Manual Lock. Failure to follow the installation and use procedures set forth following may lead to structural failure of the components subjecting the user to a risk of serious personal injury.**

⚠ **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

SSK610A comes preassembled with a pyramid (SSK610A-PYR). The attachment screw should be tightened to 66 Nm (48.7 ft-lbs) using an 8mm hex driver. Use low-strength thread retaining compound such as Loctite 242 or similar (this is to prevent galling or seizing of the threads when the bolt is tightened). A rotatable Knee Disarticulation Mounting Bracket, (SSK610A-DIS Laminating Bracket for SSK610A), is also available and is designed to be laminated into place as follows:

1. Roughen the mounting area of the socket surface with sandpaper to ensure adhesion of the lamination.
2. Mark the position of the bracket in the appropriate alignment on the laminated socket.
3. Bend the metal mounting bracket to closely match the contour of the socket in the desired position while maintaining correct alignment. Remove any bending iron impressions from the surface of the metal bracket.
4. Remove the mounting bracket from the knee by loosening the attachment screw located distally on the bracket with an 8mm hex key. Remove the attachment screw and set it aside until the knee is to be re-assembled.
5. Prepare the mounting bracket for lamination. Use clay to protect the attachment surface and screw holes from filling with laminate. Bond Kemblo or Pelite over the attachment surface and screw hole to further prevent resin intrusion.
6. Temporarily secure the mounting bracket into place with methyl methacrylate or epoxy. If necessary, the mounting bracket can be riveted into place through the four mounting holes for additional strength.

⚠ **Test walking on an unreinforced mounting bracket after temporarily securing it in place may cause failure.**

7. Secure the mounting bracket to the socket using several layers of fiberglass casting tape as a temporary reinforcement. When satisfactory alignment has been achieved, remove the fiberglass casting tape before application of the definitive lamination.
8. Laminate the mounting bracket to the socket surface using an appropriately strong layup for the individual patient.
9. Trim the hardened lamination to expose the distal mounting surface for the screw hole. Do not cut or nick the mounting bracket when trimming the laminate away from the distal surfaces.
10. Reinstall the knee unit into the mounting bracket so that the label is anterior facing.
11. Use the attachment screw, previously set aside, to attach the mounting bracket to the knee unit. Use a torque wrench with an 8mm hex driver to tighten the attachment screw to 66 Nm (48.7 ft-lbs). Use low-strength thread retaining compound such as Loctite 242 or similar.

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Note:

- The application of the thread retaining compound is to prevent galling or seizing of the threads when the bolt is tightened, and to ensure proper torque value is achieved.
- When adjusting alignment bolts or screws that have been previously assembled with thread retaining compound, the threads of the screw and screw hole should be cleaned free of any residue with a mild solvent such as isopropyl alcohol, then reapply new thread retaining compound.

Rotational Adjustment of the SSK610A Relative to Socket.

The rotational orientation of the SSK610A Knee can be manipulated only through the use of the SSK610A-DIS Lamination Bracket.

1. Loosen the bracket attachment screw with an 8mm hex key.
2. Rotate the knee to the desired location. Ensure that the interlocking splines of the knee and the bracket are fully seated.
3. Re-tighten the attachment screw to 66 Nm (48.7 ft-lbs) using an 8mm hex key.

Pylon Attachment

1. Cut the 22mm diameter pylon to the appropriate length. The cut must be level. Remove any burrs or sharp edges from the end of the pylon.
2. Insert the pylon into the distal end of the prosthetic knee until fully seated and rotate to the desired position.
3. Apply Loctite 242 (or similar) low strength thread-locking compound to the clamp bolt.
4. Tighten the clamp bolt to 7.3 Nm (5.4 ft-lbs, 65 in-lbs) with a 5mm hex driver and torque wrench.

⚠ **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

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

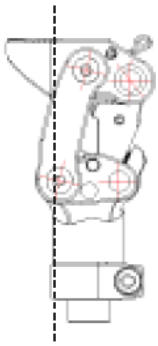

Figure 1: Knee alignment

Knee Adjustment

Extension Bias Adjustment:

1. Remove the attached pylon from the distal clamp.
2. Use a 5mm hex key to loosen or tighten the extension spring pre-load screw located inside the distal clamp of the knee.
   - Turning the screw clockwise increases the knee extension bias.
   - Turning the screw counter-clockwise decreases the knee extension bias.

Friction Swing Control

Loosen or tighten the screw on the lower, anterior side of the rear linkage using a 4mm hex key.

- Turning the screw counter-clockwise decreases the knee friction.
- Turning the screw clockwise increases the knee friction.

Stability Adjustment

1. Loosen the locking set screw on the left side of the rear linkage with a 2mm hex key.
2. Loosening or tightening the screw located on the posterior side of the rear linkage with a 4mm hex key.
   - Turning the screw counter-clockwise increases stability.
   - Turning the screw clockwise decreases stability.

   Note: The manual locking mechanism will not function if stability is decreased too much
3. Re-tighten the locking set screw to prevent migration of the stability adjustment screw.

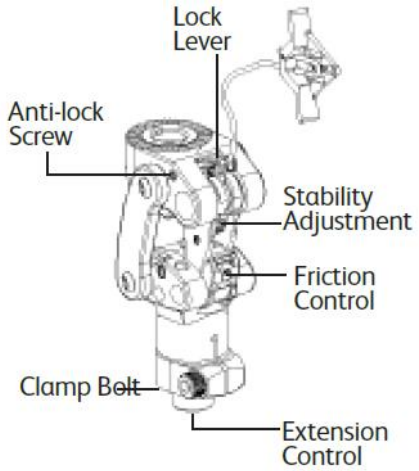

Figure 2: Child's Play Knee with Manual Lock adjustments

Locking Mechanism

The SSK610A Child's Play Knee with Manual 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 upper, left and right sides of the knee using a 2mm hex key. Use Loctite® 242 (or similar) 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 hex key 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.