SSK610A
Child's Play Knee with Manual Lock
Installation and User Guide

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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 appropriate for pediatric amputees utilizing a 22 mm endoskeletal prosthesis, with low to high activity levels.

Model No.	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
SSK610A-PYR	Pyramid Adapter for SSK610A	55 kg/121 lb
SSK610A-KIT	Refurbishment Kit for SSK610A	n/a

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

Warning: 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.

Warning: 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 SSK610A comes preassembled with a pyramid (SSK610A-PYR). The attachment screw should be tightened to 12.2 Nm (8.9 ft-lbs 108 in-lbs) using a 8mm allen wrench. 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 the adherence 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 a 6mm allen wrench. Remove the attachment screw and set it aside until the knee is to be assembled.
5. Prepare the mounting bracket for lamination. Use clay to protect the attachment surface and screw holes from filling with laminate. Glue Kemblo or Pelite over the attachment surface and screw holes to further prevent resin intrusion.
6. Temporarily secure the mounting bracket into place with methylmethacrylate or epoxy. If necessary, the mounting bracket can be riveted into place through the four mounting holes for additional strength.

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

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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 set screw. 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. To maintain mounting bolt tightness, apply Loctite® 242 removable thread locking compound to the bolt threads. Tighten the attachment screw to 12 Nm (9 ft-lbs 108 in-lbs). A 6 mm hex head driver and torque wrench should be used. Note that the thread locking compound will require several hours to cure completely.

Loctite®: When adjusting alignment of bolts or screws that have been assembled with Loctite®, the threads of the screw and screw hole should be cleaned free of any Loctite® residue with a mild solvent such as alcohol. After cleaning reapply new Loctite®; this will ensure the proper torque value of the fasteners are set when retightening the fastener to the specified torque values.

Rotational Adjustment of the SSK610A
The rotational orientation of the SSK610A Child's Play Knee with Manual Lock can be manipulated only through the use of the Child's Play 4-Hole Pyramid Receiver Adapter (P13003) when used with the Child's Play Laminating Block (SLB240).

Rotational adjustment of the SSK610A-DIS Knee Disarticulate Mounting Bracket may be obtained by loosening the distal attachment screw with a 6mm allen wrench and setting the bracket at the desired direction of rotation. Re-tighten the attachment screw to 12 Nm (9 ft-lbs 108 in-lbs) using a 6mm allen wrench.

Pylon Attachment
1. Cut the pylon to the appropriate length. The cut must be smooth and level.

Note: If using Trulife's Child's Play Pylon, Flex 3 (SSL260-P3), do not cut the end noted by the decal. Use this end to attach the Child's Play Knee.

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 clamp bolt assembly with a 5mm hex head driver and torque wrench to 7.3 Nm (5.4 ft-lbs or 65 in-lbs).

Caution: Never permit a patient to walk on a partially inserted or shimmed pylon. This will void the warranty and could contribute to component failure.

FIGURE 1: Knee alignment

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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.

Knee Adjustment
Extension spring-assist adjustment of the knee is accomplished by loosening or tightening the allen head screw on the distal surface of the knee using a 6 mm allen wrench.

- Turning the screw clockwise increases the knee extension bias.
- Turning the screw counter-clockwise decreases the knee extension bias.

Friction swing control is accomplished by loosening or tightening the allen head screw on the friction bar located within the anterior side of the rear linkage using a 4 mm allen wrench.

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

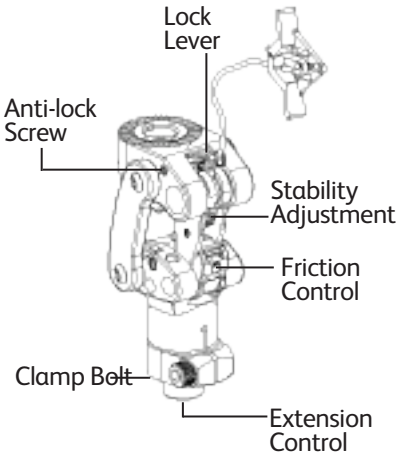

FIGURE 2: Child's Play Knee with Manual Lock adjustments

Stability adjustment of the knee is accomplished by loosening or tightening the allen head screw located on the posterior side of the rear linkage using a 4 mm allen wrench.

- Turning the screw clockwise decreases stability.
  Note: If you decrease the stability, the manual locking mechanism will not function.
- Turning the screw counter-clockwise increases stability.

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 side of the knee using a 2mm allen wrench. Use Loctite® 242 on this screw to keep it from backing out. (See Loctite® precautions above.)

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
A Refurbishment Kit is available for the SSK610A Child's Play Knee with Manual Lock (SSK610A-KIT). It includes an axis pin, two sets of washers adjacent to the axis pin, a pylon clamp screw, a locking screw, and an extension stop bumper.

- 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 physicial or prosthestist 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.

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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 Child's Play Knee with Manual Lock 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 Child's Play Knee with Manual Lock 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.

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