SLB240
Child's Play Laminating Block
Instructions and User Guide
14104-001 REV K 2022-05-23

CE

INTRODUCTION

The Child's Play® Laminating Block adapts laminated sockets to endoskeletal limb systems. Created using high strength rigid polyurethane foam, the Child's Play® Laminating Block is durable, lightweight, and easily shaped during fabrication.

Product Code	Patient Weight Limit
SLB240	65kg / 144lb

INDICATIONS

Lower-limb amputees to build a limb system.

FABRICATION

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

The Child's Play® Laminating Block can be cut to a minimum height of 7/8". Following bench or dynamic alignment, roughen the distal socket surface and tack the socket in place using epoxy resin. Shape the laminating block to the socket, stopping when you reach the minimum circumference.

Secure the laminating block to the socket using several layers of fiberglass casting tape for temporary reinforcement. After achieving satisfactory alignment, remove the temporary fiberglass casting tape before applying definitive lamination.

Before laminating, remove all dust from the shaped laminating block.

Cover the exposed distal mounting surface with layers of PVA tape, Kemblo padding or similar.

Lamination must extend to the base of the laminating block.

⚠ **Warning:**

- Never modify the core of the Child's Play® Laminating Block. Modifications to the core will void the warranty and can lead to failure.
- Never carve the Child's Play® Laminating Block down to a diameter smaller than 2.5" (indicated on the distal surface by a groove). Other modifications can cause failure and will void the warranty. Sanding or grinding the foam is permitted only on the top and sides.
- Test walking on an unreinforced laminating block after shaping can cause failure.
- Avoid contamination of the mounting threads with resin during the lamination process.
- Do not nick or cut the exposed mounting surface of the laminating block when trimming the laminate flush with the mounting surface.

INSTALLATION AND USE

For installation of the Child's Play Laminating Block, use the bolts supplied with the AAAK210 Childs Play Four Hole Adapter.

To maintain bolt tightness, apply Loctite® 242 removable thread locking compound to the threads of the mounting bolt. Loctite® requires several hours to cure completely.

Attach the AAAK210 Childs Play Four Hole Adapter, tightening the 5mm mounting bolts to 4.7 Nm (3.5 ft-lbs or 42 in-lbs) using a calibrated torque wrench. Trim and deburr bolts if necessary. Thread fit should be free-running and bolts must engage the laminating block a minimum of four full turns.

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. Then reapply new Loctite; this will ensure the proper torque value of the fasteners are set when retightening the fastener to the specified torque values.

⚠ **Warning:**

- Use only bolts and washers supplied by Trulife. Use of unapproved fasteners will void the warranty and can lead to failure.
- Torque settings should be checked periodically. A loosely fastened bolt could lead to failure.

Trulife

- Never reuse bolts. If you need to reinstall the laminating block for any reason, please call Trulife for new bolts.
- 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.

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.

Trulife
3225 Woburn St. Suite 160
Bellingham, WA 98226
USA
Phone (+1) 360 697 5656
Email supportop@trulife.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

CH REP
MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau
Switzerland

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.