AAASS237
AK Laminating Adapter
Installation and User Guide

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INTRODUCTION

The Trulife Laminating Adapter is designed for use exclusively in lower limb prostheses. This adapter can be easily incorporated into a two part socket lamination for AK limbs. The section below indicates the maximum patient weight.

Product Code	Description Patient	Weight Limit
AAASS237	Stainless Steel, Anchor, Rotatable	136 kg / 300 lb (Medium Activity)
SCA237-01	3-Prong Lamination Dummy	N/A

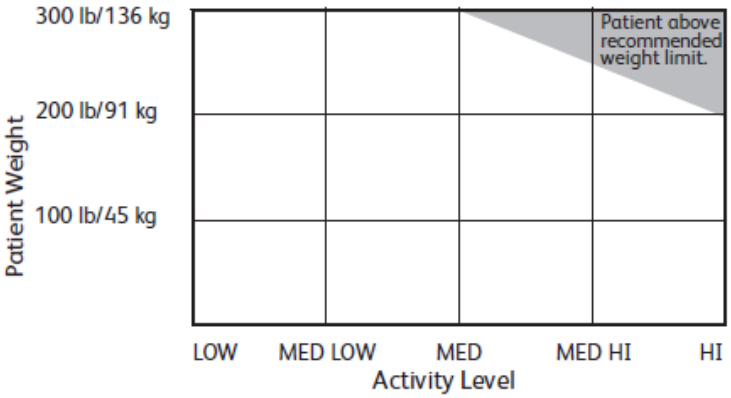

CHART 1: AK lamination adapter weight limit selection chart.

LOW	Walking with aid
MED LOW	Limited walking
MED	Walking
MED HIGH	Jogging, light sports
HIGH	Running, basketball, farming, and other strenuous activities

TABLE 1: Activity Levels

INSTALLATION AND USE

Note: Recommended installation and use procedures must be followed for maximum safety and service life.

1. Begin lamination using 2 layers of Nyglass Stockinette, 1 layer of carbon cloth, and 1 layer of fiberglass matting.
2. Apply 2 strips of carbon cloth — 1 from the medial to lateral areas of the socket and 1 wrapped around the socket just below the patella.
3. Apply 2 layers of Nyglass Stockinette.
4. Continue laminating in the usual manor. After the lamination has cured, roughen out surface and align laminating adapter accordingly to the distal end.
5. Attach the adapter to the lamination using an acrylic bonding paste.

   Note: Be sure not to leave any gaps or air pockets between the lamination and the adapter.
6. If applicable, place the pyramid cap onto the unit.
7. Proceed with final layup over the adapter using 1 layer of carbon cloth and 2 layers of fiberglass Stockinette. The second layer of fiberglass should extend half the length of the socket. Finally, apply 2 layers of Nyglass Stockinette.
8. Continue with lamination of remainder of socket using resin system of choice.
9. Fill the receptacle with putty or Trulife's 3-Prong Laminating Dummy (SCA237-01). Remove the tightening screw and apply Vaseline or other grease before replacing.
10. Proceed with I-Beam layup over the adapter and continue with lamination of remainder of socket as normal.
11. Once lamination is complete, remove the putty. Clear the threads of any putty, grease, and/or resin.
12. Screw in the attachment unit until the attachment piece makes contact with the top of the flange unit, again ensuring that there is no foreign material between assemblies. The attachment piece may now be rotated in the reverse direction in order to obtain proper alignment. However, it is extremely important that the maximum amount of threads be engaged for full component strength.
13. Tighten the clamp ring attachment screw to 9 Nm (6.3 ft lb) and the set screws (if applicable) to 15 Nm (11 ft-lb). To maintain bolt tightness, apply Loctite 242 removable thread locking compound to the threads of the clamp bolt. Loctite requires several hours to cure completely.

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Warning: 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.

QUESTIONS

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Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

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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.