



INTRODUCTION

Trulife's Aluminum Adapters are designed for use in endoskeletal construction of Trulife limb systems. It provides $\pm 8^\circ$ angular adjustment. For maximum allowable patient weights, please refer to the chart below.

Product Code	Description	Weight Limit
AAA285	Foot Pyramid AL	136 kg / (300 lb) (Medium Impact)
AAAK285	Child's Play Foot Pyramid AL	65 kg / (144 lb) (High Impact)

INDICATIONS

Lower-limb amputees to build a limb system.

INSTALLATION AND USE

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



Never modify any Trulife Aluminum Adapter unless directed to in this installation guide. Any modifications to an adapter will void the warranty and can lead to failure.

Foot adapter mounting instructions - initial fit check:

1. Position the foot adapter onto the keel, matching its central rib to the groove on the keel top, and insert the foot bolt up through the distal hole of the foot and thread it into the foot adapter. Hand-tighten the foot bolt until it is fully seated.
2. Check bolt length for full thread engagement. If the bolt length is appropriate, remove the foot bolt and skip to step 3. If the bolt extends more than 2.5 mm (0.1") above the foot adapter pyramid:
 - Measure and mark the bolt so it will be flush with the pyramid when fully assembled
 - Remove the foot bolt
 - Using a fine-tooth saw, evenly cut the bolt at the marked location
 - Bevel and deburr the cut end of the foot bolt to avoid thread damage
 - Do not cut the bolt too short. The foot bolt should fully thread the foot adapter
3. Apply Loctite 242 thread retaining compound (or similar) to foot bolt prior to assembly. Loctite 242 is a thread retaining compound, but it also serves as a thread lubricant during the assembly process. This ensures proper bolt torque is achieved, and it prevents seizing or galling of the threads.



Failure to apply Loctite 242 prior to final assembly torque may cause the foot bolt to seize to the adapter.

4. Torque foot mounting bolt (included with foot) to the value specified in foot installation guide. Use a calibrated torque wrench.

For all Trulife's Aluminum Adapters

- Use only bolts, set screws and other fasteners supplied by Trulife. Use of unapproved fasteners will void the warranty and may lead to component failure.
- When adjusting alignment or re-assembling components that had been assembled with thread retaining compounds, the threads of the fasteners and threaded holes should be cleaned and free of any retaining compound residue.
- Use a mild solvent such as alcohol.
- Re-apply new thread retaining compound. This will ensure that proper fastener torque values are achieved.



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.




Torque settings should be checked periodically. A loose fastener may lead to component failure.



Never reuse bolts. If you need to reinstall Trulife components for any reason, please call Trulife for new fasteners.





 Do not contaminate the fasteners with any type of paint, glue, or cement, except for the recommended thread retaining compounds. For all fasteners, make sure to have a free-running thread fit prior to applying final tightening torque.


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

 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/repared 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.

