



INTRODUCTION

Trulife's Aluminum Rotatable 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
AAA212	4-Hole Rotatable Flange AL	160 kg / (350 lb) (Med. Activity)
AAA214-01	4-Hole Rotatable Female Insert AL	160 kg / (350 lb) (Med. Activity)
AAA216-01	4-Hole Rotatable Male Pyramid Insert AL	160 kg / (350 lb) (Med. Activity)

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.

Angular Alignment Instructions for all Trulife's Aluminum Adapters:

1. Place the mating male pyramid into the female receiver end and tighten the set screws while maintaining appropriate alignment.
2. Alternately loosen and tighten opposing set screws until the desired alignment is achieved. Make sure all set screws are tight before allowing the patient to bear weight on the limb.

To maintain integrity of the assembled prosthesis, perform these final assembly steps:

3. Apply a generous amount of [BLUE] Loctite 242 (or equivalent) removable thread retaining compound to the threads of all set screws.
4. Refasten the set screws and tighten to 15 Nm (11 ft-lbs/132 in-lbs) using a torque wrench with 4 mm hex driver.
5. Allow patient to load and/or walk the prosthesis.
6. Re-apply 15 Nm torque to all set screws.

Important: Follow steps 5 and 6 above to account for any settling or compression set of the assembled components.

- Final application of fastener tightening torque must be done within 2 hours of initial application of thread retaining compound.
- **DO NOT** use high-strength forms of thread retaining compound (example: Red or Green Loctite formulations).
- Insufficient fastener torque will lead to fatigue failure of any modular adapter.
- Excessive fastener torque can cause component failure; stripped threads and/ or stress fractures.

Rotatable Socket Adapters (AAA214-01, AAA216-01)


Trulife's Modular Aluminum Rotatable Adapters provide continuous (non-discrete) rotational adjustment and $\pm 8^\circ$ A-P and M-L angular adjustment. The Flange has a standard 4-hole pattern and is typically attached to a distal four-hole socket lamination anchor. Four flat head screws, size M6-1.0 x 30mm long are provided. To prevent inadvertent rotation or movement of the rotatable components, follow these instructions in the sequence specified:

1. Disassemble the rotatable component (female insert, or male insert) from the flange.
2. Using isopropyl alcohol, wipe the internal and external M36 threads of the disassembled components to ensure they are free of any grease or lubricants. Allow the components to dry.
3. Apply a generous amount of [BLUE] Loctite 242 (or equivalent) removable thread retaining compound to the threads of the four M6 flat head screws and the socket cap clamp screw on the flange.
4. Assemble the flange component to the mating 4-hole adapter using the four provided flathead screws until the components are seated flush. **DO NOT APPLY TIGHTENING TORQUE TO THE SCREWS YET.**





5. Assemble the mating rotatable insert (female insert, or male insert) by screwing the component all the way until it is flush with the flange, then back it out as little as necessary to achieve the desired rotational alignment.

 **DO NOT back out the Rotatable insert more than 180° from where it makes contact with the flange. Component failure may occur. These components are NOT to be used as adjustable vertical height adapters.**

6. Tighten the socket head clamp screw on the flange to 8.5 Nm (6.3 ft-lb or 75 in-lb) using a torque wrench with 4 mm hex driver.

7. In a cross-pattern tighten the four M6 flathead mounting screws to 9.5 Nm (7 ft-lbs/ 84 in-lbs) using a torque wrench with 4 mm hex driver.

 **The flange clamp screw MUST be tightened PRIOR to tightening the 4 mounting screws.**

8. For the AAA214-01, insert the pyramid of the mating modular component and then make alignment adjustments per the section at the beginning of this guide labeled “Angular Alignment Instructions for all Trulife’s Aluminum Adapters.

For all Trulife’s Aluminum Adapters

1. Apply a generous amount of [BLUE] Loctite 242 (or equivalent) removable thread retaining compound to the threads of all fasteners.
2. Apply the specified torque to the fastener while the thread retaining compound is still wet.
3. Allow patient to load and/or walk the prosthesis.
4. Re-apply torque to all fasteners within 2 hrs of initial application of thread retaining compound.

WARNING:

- Do not connect flange to carbon fabric lamination. Galvanic corrosion of the aluminum component will occur.
- Avoid exposing any Trulife Aluminum Adapter to corrosives such as salt water, chlorinated water, ammonia, highly acidic, or highly alkaline agents. In case of exposure, rinse with fresh water and allow to thoroughly dry.
- Do not allow moisture to accumulate or dwell inside the adapter.
- Insufficient fastener torque will lead to fatigue failure of any modular adapter.
- Excessive fastener torque can strip threads.
- Torque settings should be checked periodically. A loose set screw may lead to component failure.
- Stop use immediately if a set screw needs to be re-tightened more than once. Loosening of set screws may be an early indication of component failure.
- Use only bolts, set screws and other fasteners supplied or recommended by Trulife. Use of unapproved fasteners will void the warranty and may lead to component failure.
- Final application of fastener tightening torque must be done within 2 hours of initial application of blue Loctite 242 thread retaining compound.
- Do not contaminate fasteners with any type of paint or adhesive, except for the recommended thread retaining compounds. For all fasteners, ensure a free-running thread fit prior to applying final tightening torque.
- When adjusting alignment or re-assembling components that had been previously assembled with thread retaining compounds, the threads of the fasteners and threaded holes should be cleaned and free of any retaining compound residue to ensure a free-running thread fit.
- 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.
- 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.



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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.