

AAAHDTI217, AAAHDTI218
Titanium Heavy Duty Splined Rotatable Adapter
Installation and User Guide

31996-001 REV B



INTRODUCTION

Trulife's Heavy Duty Titanium Splined Rotatable Adapters provide discrete rotational adjustment in 3° increments and ±8° A-P and M-L angular adjustment. The Adapter Base component has a standard 2" (50.8mm) diameter, four hole pattern and is typically attached to a distal four hole socket lamination anchor. Four M6 x 20mm socket head cap screws are provided.

Product Code	Description	Weight Limit
AAAHDTI217	Male Splined Four Hole Rotatable Adapter HD Ti	205 kg / (450 lb) (Medium Impact)
AAAHDTI218	Female Splined Four Hole Rotatable Adapter HD Ti	205 kg / (450 lb) (Medium Impact)

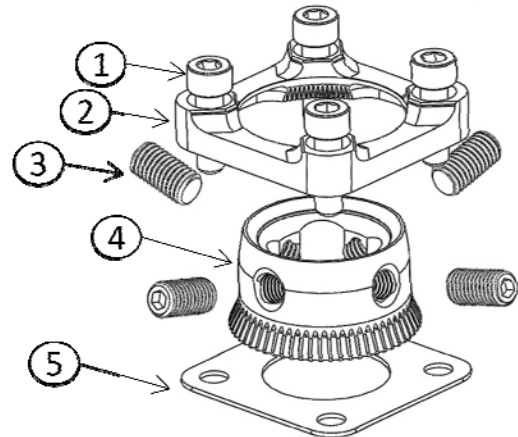
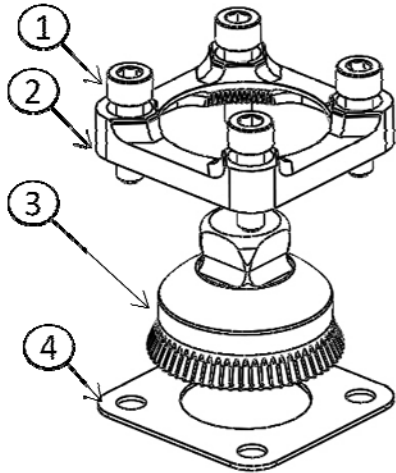
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AAAHDTI217

ITEM	QTY.	PART NO.	DESCRIPTION
1	4	18743-006	MOUNTING SCREWS M6 X 20MM
2	1	32009-003	SPLINED ROTATABLE BASE
3	1	32008-003	MALE SPLINED INSERT
4	1	31766-003	PRESSURE PLATE BLACK OXIDE

AAAHDTI218

ITEM	QTY.	PART NO.	DESCRIPTION
1	4	18743-006	MOUNTING SCREWS M6 X 20MM
2	1	32009-003	SPLINED ROTATABLE BASE
3	4	9300-016	SET SCREW M8 X 16MM
4	1	32011-003	FEMALE SPLINED INSERT
5	1	31766-003	PRESSURE PLATE BLACK OXIDE





INSTALLATION AND USE

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

Rotational Alignment

1. Ensure the mounting surface is flat and free of any lamination residue or foreign debris.
2. Position the black pressure plate on the mounting surface followed by either the male insert (AAAHDTI217) or female insert (AAAHDTI218); then position the base to retain the insert.

Note: The insert will slightly protrude below the mounting surface of the base. This is normal as to ensure compressive pressure between the interlocking components when the final assembly torque is applied to the mounting screws.

3. Apply [BLUE] Loctite 242, removable thread retaining compound, to the threads of all socket cap mounting screws and loosely assemble the screws so that the rotatable insert can be turned to achieve the desired rotational alignment.

Important: Do not tighten at this time.

4. With the insert positioned at the desired alignment, slightly push down on the base so the splines are engaged, then tighten all four screws **EVENLY** until they are in contact with the base, but not tight.
5. Using a calibrated torque wrench with 5mm hex driver, steadily apply increasing torque in a cross pattern to the four mounting screws until 12-15 Nm (9-11 ft-lbs/107-133 in-lbs) is achieved.

Important: Do not completely tighten one screw at a time. This could case the base to seat unevenly.

If further rotational alignment changes are needed then follow these instructions in the sequence specified:

6. Remove the component connected to either the male (AAAHDTI217) or female (AAAHDTI218) insert.
7. Note or mark the current insert position.
8. In a cross-pattern, loosen each of the four mounting screws a little a time until the insert can rotate.
9. Rotate the insert to the new location and follow steps 4-5 above.

Angular Alignment

10. Apply [BLUE] Loctite 242, removable thread retaining compound, to the threads of all set screws.
11. Place the mating male pyramid into the female receiver end and use a 4mm hex driver to tighten the set screws.
12. Alternately loosen and tighten opposing set screws to achieve desired alignment. Make sure all set screws are tight before allowing the patient to bear weight on the limb.
13. Tighten ALL set screws to 15-18 Nm (11-13 ft-lbs/132-159 in-lbs) using a calibrated torque wrench.

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

Final Assembly

14. Allow patient to load and/or walk on the prosthesis.
15. Re-apply tightening torque to all screws.

Important: Follow steps 14 and 15 above to account for any settling or compression set of the assembled components.





WARNING:

- **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.**

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 for the PRODUCT 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 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 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.

