AAASAB450
Trulife Socket Attachment Block
Installation and User Guide
32219-001 REV D 2022-05-23

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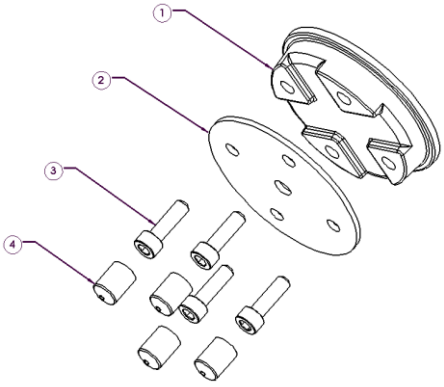
INTRODUCTION

The AAASAB450 Trulife Socket Attachment Block is intended to be used in the construction of laminated lower limb prosthetic sockets. It is constructed of highly durable compression-molded fiberglass composite and provides a structural distal mounting location compatible with most modular adapters that have a four-hole bolt pattern on a 2.00” (50.8 mm) diameter bolt circle. The steel threaded inserts accept screws with thread size M6 x 1.0.

Product Code	**Description**	**Weight Limit**
AAASAB450	TRULIFE SOCKET ATTACHMENT BLOCK	205 kg / (450 lb) (Medium Impact)

AAASAB450 CONTENTS:			
ITEM	**QTY.**	**PART NO.**	**DESCRIPTION**
1	1	32220-001	AAASAB450 ASSEMBLY
LAMINATION SUPPLIES:			
2	1	32217-001	LAMINATION CAP
3	4	18743-006	SOCKET CAP SCREWS, M6 X 20MM LONG
4	4	32216-001	BOLT HEAD CAPS
5	2	32218-001	FIBERGLASS TAPE STRIP 2” W X 12” L (NOT SHOWN)



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.

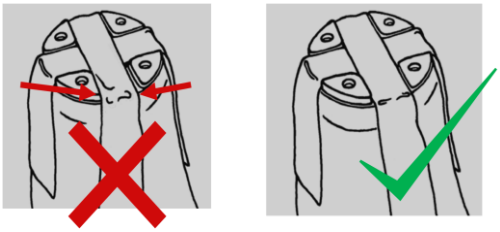
Additional Supplies Required:

- Structural adhesive
- Plumber’s Putty or other non-adhering gap-filler
- Release agent, such as petroleum jelly, synthetic grease, or release wax

Initial Preparation

1. Prepare and seal the positive model as necessary.
2. Apply plumber’s putty to the four cavities of the proximal side of the Socket Attachment Block to prevent adhesive or resin infiltration of the threads.
3. Attach the Socket Attachment Block to the socket with structural adhesive. Orient the two channels Anterior-Posterior and Medial-Lateral.
4. Fold the two fiberglass strips lengthwise into thirds so they will fit completely within the channels. Place one in each channel.

Note: Ensure the fiberglass strips are within the channels of the Socket Attachment Block so the final mounting surface is level.



⚠ **Failure to use the provided fiberglass strips to reinforce the attachment could lead to failure of the prosthesis.**

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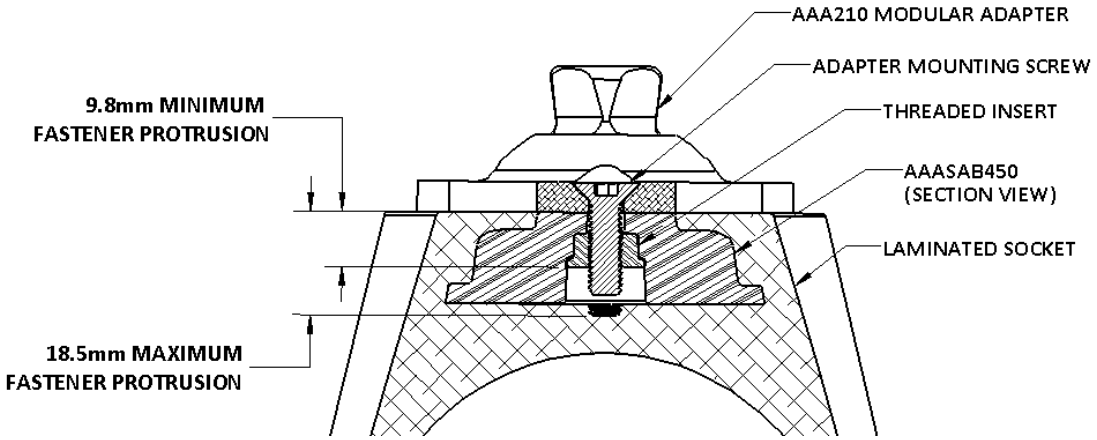
5. Attach the supplied aluminum lamination cap to the Socket Attachment Block with the four socket head cap screws. Lubricate the threads of the screws with release agent to facilitate removal. The cap will hold the fiberglass tape in place and provide a ridge to tie off the lamination.
6. Apply the plastic caps and putty onto the heads of the screws to prevent the resin from filling the gaps and facilitate removal.
7. Fan out the ends of the fiberglass tape onto the socket and pull tight. Secure the fiberglass tape with spray adhesive.
8. Cut a piece of tubular nylon stockinette twice as long as the socket.
9. Pull the stockinette onto the socket and tie it off just proximal to the aluminum lamination cap.
10. Pull the distal end of the stockinette down over the socket so that there is a double layer of stockinette over the fiberglass tape and socket.
11. Proceed with the finish lamination. Use strong vacuum to ensure proper saturation of the fiberglass strips.
12. After the lamination has completely cured, break the excess resin off of the lamination cap, remove and discard the four screws and lamination cap.

Final Assembly:

13. Ensure distal mounting surface is flat and free of any residual resin.
14. Ensure the four threaded inserts are free of any resin and that mounting screws have a free running fit.
15. With the mating modular adapter and adapter mounting screws (typically provided with modular adapter), measure the protruding length of the screws proximal to the mounting surface of the adapter.
    - **MINIMUM mounting screw protrusion = 9.8mm (.386”) for full thread engagement with the inserts.**

    ⚠ **INSUFFICIENT FASTENER LENGTH WILL LEAD TO FAILURE OF THE PROSTHESIS!**
    - **MAXIMUM mounting screw protrusion = 18.5mm (.728”)**

    ⚠ **EXCESSIVE FASTENER LENGTH WILL RESULT IN FALSE ASSEMBLY TORQUE READING AND COMPONENT FAILURE!**



16. Assemble the mating adapter and torque the four M6x1.0 adapter mounting screws as specified by the mating adapter instructions.

⚠ **WARNING:**

- Never modify the Trulife Socket Attachment Block unless directed to in this installation guide. Any modifications will void the warranty and can lead to failure.
- Final application of fastener tightening torque must be done within 2 hours of initial application of blue Loctite 243 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 strip threads.
- Torque settings should be checked periodically. A loose fastener may lead to component failure.
- 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 reuse bolts. If you need to reinstall Trulife components for any reason, please call Trulife for new fasteners.
- Do not contaminate fasteners with any type of paint, glue, or cement, except for the recommended thread retaining compounds. For all fasteners, ensure a free-running thread fit prior to applying final tightening torque.
- 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/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.

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