



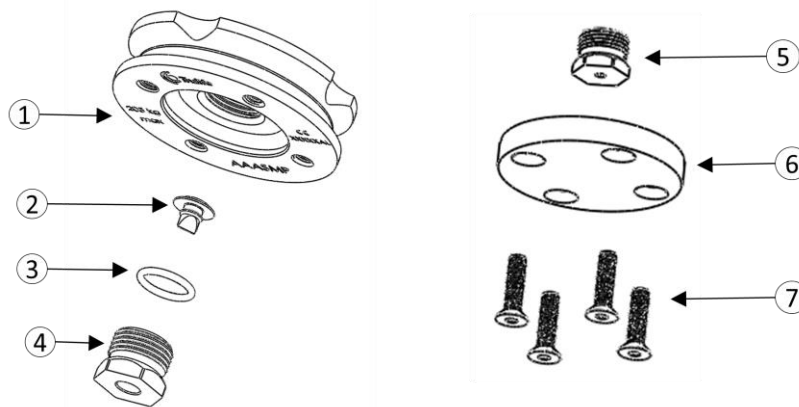
INTRODUCTION

Trulife’s Socket Mounting Plate is intended to be used in the construction of laminated lower limb sockets. The expulsion valve assembly is intended for use with passive or vacuum assisted socket suspension systems.

Product Code	Description	Weight Limit
AAASMP450	SOCKET MOUNTING PLATE 450	205 kg / (450 lb) (Medium Impact)

INDICATIONS

Lower-limb amputees to build a limb system.



AAASMP450 CONTENTS:			
ITEM	QUANTITY	PART NUMBER	DESCRIPTION
1	1	31776-004	AAASMP PLATE 450
2	1	31945-001	DUCKBILL VALVE
3	1	31946-001	O-RING SIZE -015
4	1	31944-001	AAASMP VALVE INSERT
FABRICATION COMPONENTS:			
5	1	31949-001	LAMINATION PLUG
6	1	31948-001	LAMINATION DAM
7	4	9301-025	FLAT HEAD SCREW M6 X 25MM

INSTALLATION AND USE

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

Recommended Tools:

- Drill and Ø3mm (or 1/8”) drill bit
- 4mm Hex driver
- 19mm (or ¾”) hex socket

Additional Recommended Supplies:

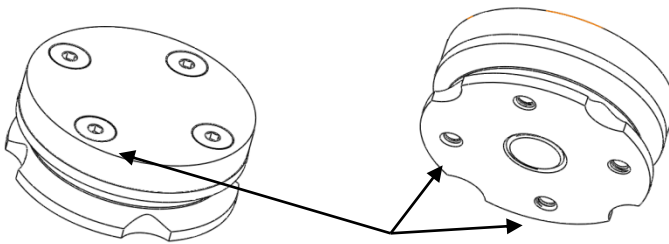
- Synthetic Grease
- Plumber’s Putty
- Fast curing adhesive
- High strength cord (Kevlar or similar)
- Braided Fiberglass Sleeve (or any other non-carbon sleeve material)



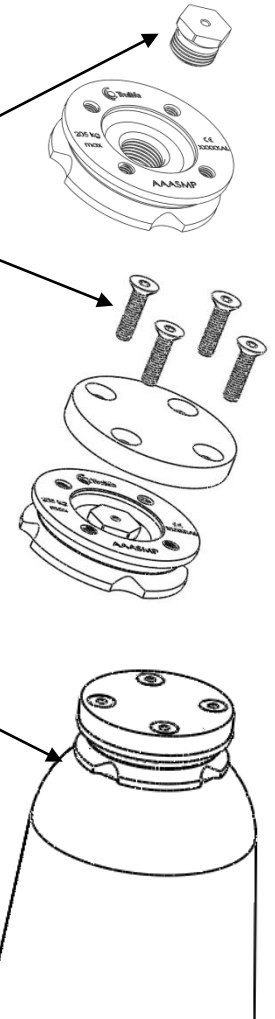


Initial Preparation

1. Prepare and seal the positive model as necessary
2. Apply synthetic grease to the threads of the Lamination Plug and insert it fully into the distal side of the Socket Mounting Plate
3. Apply synthetic grease to the four flat head screws, then fasten the Lamination Dam to the distal side of the Socket Mounting Plate



4. Apply plumber's putty to the top of the four flat head screws and to the proximal side of the Socket Mounting Plate at the center hole and to the four M6 holes to prevent penetration of resin
5. Use the fast curing adhesive to attach the Socket Mounting Plate at the appropriate location on the positive model

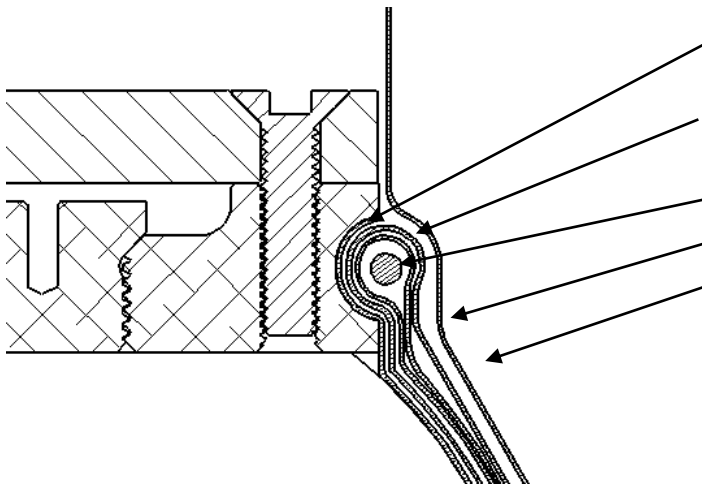


LAMINATION

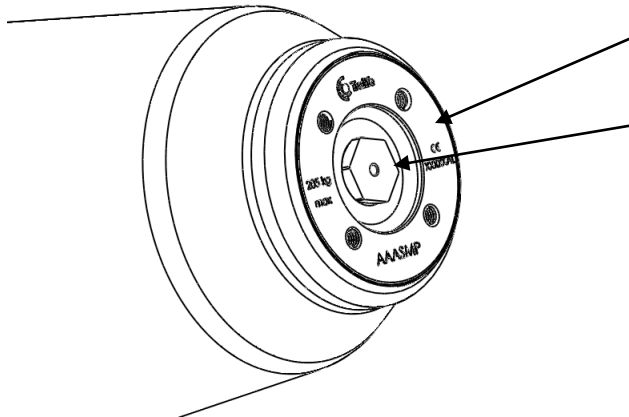
- Select materials to fabricate the socket appropriate to the weight/ activity of the patient

 **Warning: Aluminum + Carbon + Moisture = Galvanic Corrosion!**

- Do not use carbon or materials containing carbon at the first layer which makes contact with the aluminum lamination plate
- Use at least one shield layer of fiberglass or other non-carbon containing material



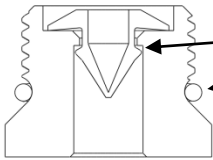
1. Apply first layer: fiberglass or other non-carbon material
2. Add subsequent layers (Carbon OK to use)
3. Tie-off with Kevlar cord
4. Reflect layers
5. Apply PVA bag
6. Apply vacuum and pour in resin to fully saturate layers
7. Tape off at the lamination dam to remove excess resin
8. When resin has set, remove PVA bag
9. Remove Lamination Dam and discard the four screws



10. Remove any excess resin from the mounting surface of the plate
11. Drill a $\varnothing 3\text{mm}$ (or $\varnothing 1/8''$) hole through the valve plug to the positive model, use the partially drilled hole as a guide
12. Remove the valve plug (use a 19mm or $3/4''$ hex socket)



Expulsion valve



1. Ensure the one-way duckbill valve is fully seated in the valve insert
2. Ensure the o-ring is in the proper position
3. Apply synthetic grease to the threads of the insert and the o-ring
4. Assemble the expulsion valve (use a 19mm or 3/4" hex socket), tighten to 11 kg-cm (10 in-lbs)

NOTE: The duckbill valve is made of VMQ silicone elastomer. Some chemicals will attack or degrade the function of the valve.



DO NOT USE WITH THIS VALVE:

- Silicone based lubricants-this will attack the valve
- Petroleum based lubricants such as Vaseline®
- Solvents
- Bleach
- Concentrated acids

OK TO USE:

- Synthetic grease such as Super Lube® Synthetic Multi-Purpose Grease
- Water based lubricants



WARNING:

- 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.
- 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.
- 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.
- 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.
- 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.
- 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 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.



Trulife

3225 Woburn St. Suite 160
Bellingham, WA 98226
USA

Phone (+1) 360 697 5656

Email supportop@trulife.com



MDSS GmbH

Schiffgraben 41
30175 Hannover
Germany



MDSS CH GmbH

Laurenzenvorstadt 61
5000 Aarau
Switzerland

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.