



INTRODUCTION

Trulife's Child's Play Socket Mounting Plate is intended to be used in the construction of laminated lower limb sockets. The four-hole bolt pattern is on a 42mm diameter bolt circle and is tapped to accept M5 screws.

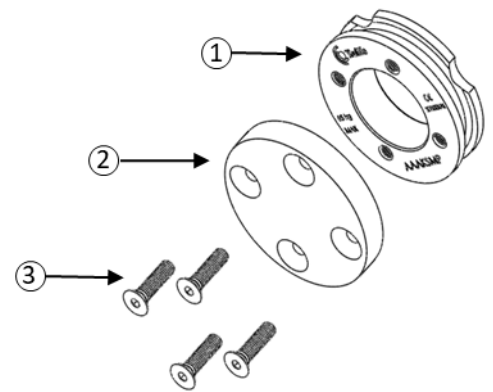
Product Code	Description	Weight Limit
AAAKSMP	CHILD'S PLAY SOCKET MOUNTING PLATE AL	65 kg / (144 lb) (High Impact)

INDICATIONS

Lower-limb amputees to build a limb system.

CONTENTS

ITEM	QTY.	PART NO.	DESCRIPTION
1	1	31964-004	PEDIATRIC LAMINATION PLATE
FABRICATION COMPONENTS:			
2	1	31789-001	LAMINATION DAM
3	4	9302-020	FLAT HEAD SCREW M5 X 20MM



INSTALLATION AND USE

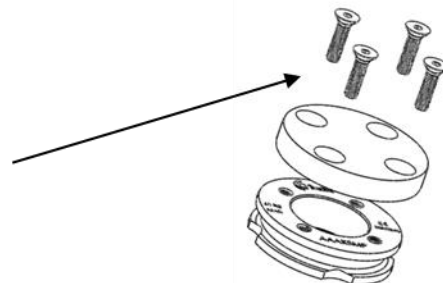
Recommended installation and use procedures must be followed for maximum safety and service life.

Recommended Supplies:

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

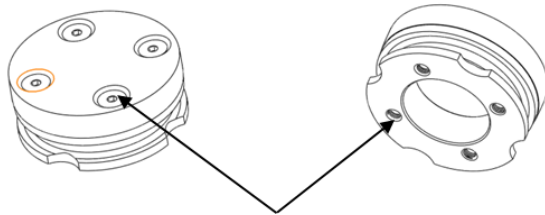
Initial Preparation

1. Prepare and seal the positive model as necessary
2. Apply synthetic grease to the four flat head screws then fasten the Lamination Dam to the distal side of the Socket Mounting Plate

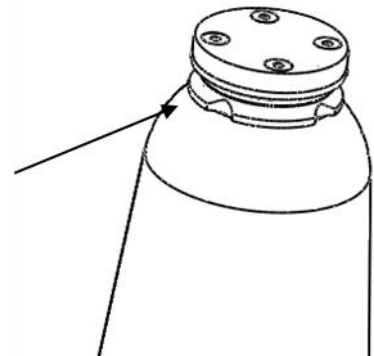




3. Apply plumber's putty to the top of the four flat head screws and to the proximal side of the Socket Mounting Plate at the four M5 holes to prevent penetration of resin



4. Use the fast curing adhesive to attach the Socket Mounting Plate at the appropriate location on the positive model



LAMINATION:

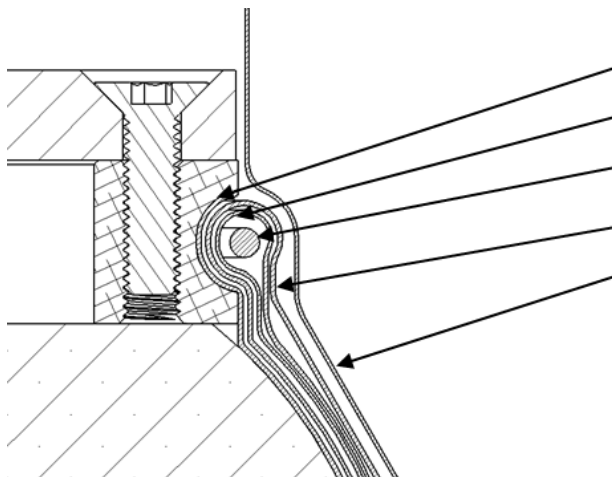
- Select materials to fabricate the socket appropriate to the weight and activity of the patient



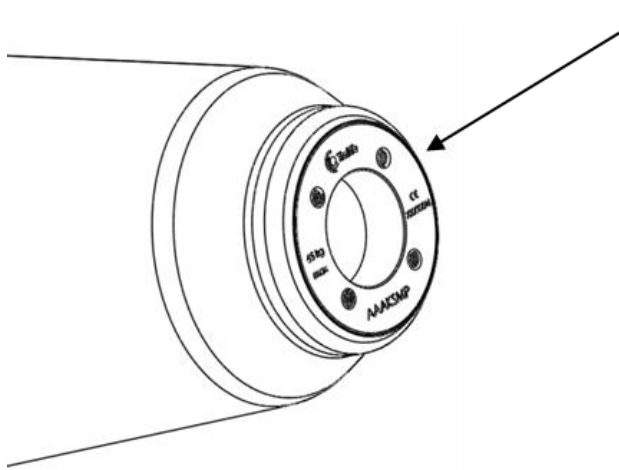
NOTE:

!!! Aluminum + Carbon + Moisture = Galvanic Corrosion!!!

- Do not use carbon or materials containing carbon at the first layer which makes contact with the AAAKSMP
- 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. Mount the mating distal four-hole modular component
12. Assemble and tighten fasteners per the instructions of the mating component.

 **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.
- 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.



Trulife

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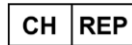
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LIMITED WARRANTY

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.