Symbol-Legende *Icon Legend*

 \triangle

Achtung Attention



Artikelnummer Article number



einzelner Patientmehrfach anwendbar single patientmultiple use



Reinigung Cleaning



Hersteller Manufacturer



Nicht bleichen Do not bleach



Nicht bügeln Do not iron



Europäischer Bevollmächtigter European Authorized Representative



CE-Kennzeichnung CE marking



Übersetzung Translation



Vertriebspartner Distributor



Importeur Importeur



Keine chemische Reinigung No chemical cleaning



Nichtim Trockner trocknen
Do not tumble-dry

Qualität und Funktion

Gebrauchsanweisung
Instruction Manual

A89-HD Anschlussplatte A89-HD Mounting Plate





Trulife 3225 Woburn St Ste 160 Bellingham, WA 98226 USA



MDSS GmbH Schiffgraben 41 30175 Hannover Deutschland





Uniprox GmbH & Co.KG, H.-Heine-Str.4, 07937 Zeulenroda-Triebes Tätigkeiten nach MDR, Artikel 16: 2a+b / Activity according MDR, Article 16: 2a+b









Please read the IFU carefully before fitting. Only correct usage will provide maximum safety and service life.

1. Intended Use

The A89-HD mounting plate is intended for use when constructing a lower limb socket. The expulsion valve is intended for use with socket adapters with passive or vacuum-assisted suspension systems.

2. Technical Data

- HEAVY DUTY version
- Incl. expulsion valve and dummy
- Max. Body weight: 205 kg



Order No.	Material	Weight	Article No.
A89-HD	Aluminum	135 g	4 620 060 00 11 200

3. Indications/ Contraindications

Indications:

Patients with lower limb amputations for the construction of a prosthetic system.

Contraindications:

None.

4. General Instructions





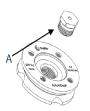
- This medical product is designed for: single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- For the highest possible safety and the longest possible service life, the recommended assembly and use procedures must be observed.
- Avoid exposing the Uniprox aluminum adapter to corrosive substances such as salt water, chlorinated water, ammonia, strongly acidic or basic substances. In case of exposure, rinse with fresh water and allow to dry thoroughly.

- The ingress of moisture into the adapter must be avoided.
- Uniprox aluminum adapters must not be modified under any circumstances unless instructed to do so in these installation instructions. Any modification of an adapter will void the warranty and may result in a defect.
- Bolts must be tightened to the specified torque within 2 hours of the initial application of Loctite® 243 blue threadlocker.
- DO NOT use high-strength threadlocker.
- Insufficient tightening of the screws will cause fatigue failure in modular adapters.
- Over-tightening the screws can damage the threads.
- Use only screws or fasteners recommended by Uniprox. Use of unapproved fasteners will void the warranty and may result in component breakage.
- When aligning or reassembling components that have been previously assembled
 with Loctite screw locking compound, the threads of the screw holes should be
 cleaned until no residue of the screw locking compound is visible and the threads
 run smoothly.
- The tightening torque settings should be checked regularly. A loose fastener can cause the components to break.
- Screws must never be reused. If Uniprox components need to be reassembled for any reason, please contact Uniprox for new fasteners.

5. Structure

5.1 First preparation

- Prepare the plaster positive and seal the connection plate as required.
- Apply synthetic grease to the thread of the lamination plug and insert it fully into the distal side of the connection plate. (A)
- Apply synthetic grease to the four flathead screws, then attach the lamination dummy to the distal side of the socket mounting plate. (B)

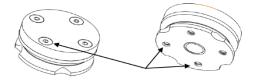




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Put some plasticine on the top of the four flathead screws and on the proximal side
of the socket mounting plate at the center hole, as well as on the four M6 holes to
prevent resin penetration.



 Using the fast-curing adhesive, attach the connection plate to the corresponding position of the plaster model.



5.2 Laminating

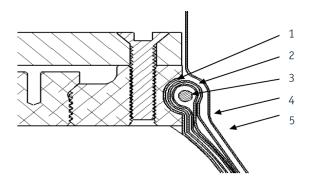
 Select the materials used to make the socket according to the patient's weight/ activity.



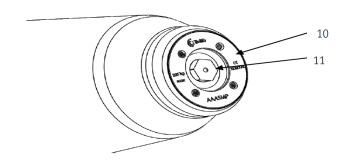
Warning: aluminum + carbon + moisture = galvanic corrosion!

- Don't use carbon or carbon-containing materials as the first contact layer to the aluminum lamination plate.
- Use at least one layer of fiberglass or other carbon-free material.

- 1. Apply the first layer: fiberglass or other carbon-free material.
- 2. Add more layers (carbon can be used).
- 3. Tie off with a Kevlar cord.
- 4. Reflect layers.
- 5. Apply the PVA bag.
- 6. Apply vacuum and pour resin until the layers are fully impregnated.
- 7. Tape the lamination dummy to remove excess resin.
- 8. Remove the PVA film after the resin has cured.



- $9. \quad \text{Remove the lamination dummy and discard the four screws.} \\$
- 10. Remove excess resin from the mounting surface of the plate.
- 11. Drill a hole, \emptyset 3 mm through the valve plug to the plaster model. Use the partially predrilled hole as a guide.
- 12. Remove the valve plug (use a 19 mm hex socket).

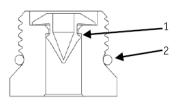


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5.3 Use with Expulsion valve

- 1. Make sure that the check valve is completely in the valve insert.
- 2. Make sure that the 0-rings are in the correct position.
- 3. Apply synthetic grease to the threads of the insert and the 0-ring.
- 4. Assemble the expulsion valve (with 19 mm Allen key) and tighten it to 11 Nm.







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



DO NOT USE WITH THIS VALVE:

- Silicone-based lubricants
- Petroleum-based lubricants, such as Vaseline®.
- Solvents
- Bleach
- Concentrated acids

CAN BE USED:

- Synthetic grease, such as lithium grease (MM202), synthetic multi-purpose grease
- Water-based lubricant

6. Maintenance and cleaning



- The adapters do not require any special maintenance. As part of regular prosthesis checks, we recommend a visual inspection for damage.
- The adapters can be cleaned with soap and a damp cloth with <30°C.
- No aggressive cleaning agents may be used.

7. CE-Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to *Uniprox* and/or *Trulife* as well as to the competence European Authority.

8. Guarantee and Warranty

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

A 2-year Guarantee is provided for defects in materials and workmanship.

9. Storage and disposal

There are no special storage regulations.

The product does not contain any substances hazardous to health. Local and national laws and regulations must be observed.

Please direct any questions to:

Customer Service: +49 (0) 36628-66-33 70
Fax: +49 (0) 36628-66-33 77
E-mail: export@uniprox.de

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