Qualität und Funktion

Gebrauchsanweisung **Instruction Manual**

Shifting Adapter VA1, VA2, VA9













Please read the IFU carefully before fitting. Only correct usage will warrant the function.

1. Intended use

The shifting adapters are for integration into a modular prosthetic limb prosthesis to enable axial shifting.

2. Technical data

2.1 VA1 Shifting Adapter

- Pyramid and 30 mm tube-receiver
- 10 mm A P and M L shifting
- water resistant*
- weight limit: 100 kg



| VA1-Ti Titanii | ım 130 g | g 4 117 (| 010 99 00 000 |
|----------------|----------|-----------|---------------|

^{*} with specially waterproof coated bolts; not included

2.2 VA2 Shifting Adapter

- Pyramid-receiver and 30 mm tube-receiver
- 10 mm A P and M L shifting
- water resistant*
- weight limit: 100 kg



| Order No. | Material | Weight | Article No. |
|-----------|----------|--------|---------------------|
| VA2-Ti | Titanium | 140 g | 4 117 010 77 00 000 |

^{*} with specially waterproof coated bolts; not included

2.3 VA9 Shifting Adapter - Only for trial fitting in the workshop!

- 25 mm A P and M L shifting
- weight limit: 100 kg



| Order No. | Material | Weight | Article No. |
|-----------|-----------|--------|---------------------|
| VA9-Al | Aluminium | 333 g | 4 117 060 00 00 000 |

2.4 Service Parts for VA1, VA2

Hex socket head screw:

| Order No. | Thread | Lenght | Units p. package | Article No. |
|-----------|--------|--------|------------------|---------------------|
| M28-12 | M8 | 12 mm | 10 | 4 226 050 00 00 012 |
| M28-16 | M8 | 16 mm | 10 | 4 226 050 00 00 016 |

With waterproof coating

| Order No. | Thread | Lenght | Units p. package | Article No. |
|-----------|--------|--------|------------------|---------------------|
| E-A11-12 | M8 | 12 mm | 4 | 4 113 018 11 20 612 |

Hexagon socket head cap screw:

| Order No. | Thread | Lenght | Units p. package | Article No. |
|-----------|--------|--------|------------------|---------------------|
| M33 | M5 | 18 mm | 10 | 4 226 030 05 00 018 |

With waterproof coating

| Order No. | Thread | Lenght | Units p. package | Article No. |
|-----------|--------|--------|------------------|---------------------|
| E-A12-20 | M5 | 20 mm | 1 | 4 113 018 12 20 520 |

2.5 Service parts for VA9

Base VA9-Al

| Order No. Description | | Article No. |
|-----------------------|--|---------------------|
| E-VA01 | Housing for shifting adapter with 6 cap screws M5 x 10 | 4 117 069 00 00 001 |

Sliding unit for VA9-Al

| Order No. | Description | Article No. |
|-----------|---|---------------------|
| E-VA02 | Sliding unit for shifting adapter (with central bore) | 4 117 069 00 00 002 |

Strips for VA9-Al

| Order No. | Description | Article No. |
|-----------|--|---------------------|
| E-VA03 | 2 strips for shifting adapter with 6 countersunk screws M3 x 6 | 4 117 069 00 00 003 |

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2.6 Recommended Fitting for VA9

A87 M36 × 1,5 outside thread and pyramid receiver

| Order No. | Material | Weight Limit | Weight | Article No. |
|-----------|----------|--------------|--------|---------------------|
| A87 | Steel | < 150 kg | 55 g | 4 620 040 00 00 000 |

A22 Threaded Adapter, M36 × 1,5 and pyramid

| Order No. | Material | Weight Limit | Weight | Article No. |
|-----------|----------|--------------|--------|---------------------|
| A22-Ti | Titanium | < 150 kg | 40 g | 4 114 090 99 33 000 |

A23 Threaded Adapter, M36 × 1,5 and pyramid receiver

| Order No. | Material | Weight Limit | Weight | Article No. |
|-----------|----------|--------------|--------|---------------------|
| A23-Ti | Titanium | < 100 kg | 51 g | 4 114 090 77 33 000 |

3. Indication/ Contraindication

Indication:

• Amputation of lower extremities

Contraindication:

not known

4. Side effects

There are no known side effects.

5. General safety 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.
- Improper modification or application to the product is not allowed. In case of nonobservance, the function of the product may be impaired, so that product liability is excluded.
- The maximum weight loads are listed under "2. Technical Data". Additional loads must be taken into account when calculating the weight.
- The sliding adapter VA9-Al is intended solely for use during the trial run in the orthopedic workshop. It is absolutely unsuitable for use in actual prostheses.

6. Installation

6.1 Installation VA1 and VA2

The Shifting Adapters VA1-Ti and VA2-Ti have a shifting possibility of approx. 10 mm in sagittal direction.

6.1.1 Connection to the Ø 30 mm Tube Adapters

Before fitting the tube, first loosen the Hexagon socket head cap screw (M33) with two turns. Be certain that the cut surface is even and the longitudinal axis of the tube is rectangular. Smoothen the area of the tube cut on the in- and outside. Insert the tube into the clamp adapter until the tube reaches the bottom of the clamp. Fix the tube in the clamp adapter by tightening the clamp screw with a torque wrench.

6.1.2 Shifting of the Shifting Adapter

To shift both ends of the Shifting Adapter VA1-Ti against each other, first loosen the headless screw in which direction you want to shift. Reclamp the adapter by tightening the opposite headless screw. Take care to always tighten all headless screws.

6.1.3 Instructions of Use - Headless Screws

By using the adjusting screws M28-12 or M28-16, static corrections are possible at any time. When replacing or removing a module, the previously set position is maintained if only two adjacent adjusting screws (not opposite) are removed, which are screwed in at the deepest.



If the adjusting screws are too long (damage of the foam cover) or too short (reduced stability) these have to be replaced with appropriate ones.

Use a toque wrench to tighten the headless screws.

Tightening torque: 12 Nm.



When the prosthesis is completed secure thread with Loctite $^{\rm B}$ 222.

6.2 Installation VA9

The shifting elements enable/ allow adaptation via 4-hole attachment or adapters with M36 fine thread.

Screw the required adaption to the elements of the shifting adapter.

Fix the shifting adapter in neutral position.

Tighten the six lateral cylinder head screws.

Tightening torque: 5 Nm.

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Set up the prosthesis in accordance with the usual configuration guidelines. During the trial run, adapt the prosthesis configuration to your patient's requirements. Make sure that the slides are always clamped by at least two of the lateral cylinder head screws.



The slides can be shifted max. 2.5 cm to each side.



Attention by using 4-hole attachment:

Make sure that the adaption surface is even. Otherwise the sliding element may get tense and jam in the adapter housing.

7. Maintenance and Cleaning

The adapters must be checked as part of regular prosthetic service/maintenance.

8. 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 the competence European Authority.

9. Warranty an Guarantee

We recommend to change/renew the adapter after 5 years of usage. Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

10. Storage and Disposal

The product is disposable with standard household garbage.

There are no storage recommendations.

Please direct any questions to:

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