

Symbol-Legende Icon Legend

	Achtung Attention		Europäischer Bevollmächtigter European Authorized Representative
	Artikelnummer Article number		CE-Kennzeichnung CE marking
	einzelner Patient- mehrfach anwendbar <i>single patient- multiple use</i>		Übersetzung Translation
	Reinigung Cleaning		Vertriebspartner Distributor
	Hersteller Manufacturer		Importeur Importeur
	Nicht bleichen Do not bleach		Keine chemische Reinigung No chemical cleaning
	Nicht bügeln Do not iron		Nicht im Trockner trocknen Do not tumble-dry
	Umpacken Repackaging		

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Tätigkeiten nach MDR, Artikel 16: 2a /
Activity according MDR, Article 16: 2a



Rev.0-2023-07_VA10-AL

Qualität und Funktion

Gebrauchsanweisung Instruction Manual

VA10-AL Verschiebeadapter VA10-AL Shifting Adapter





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

1. Intended Use

The Shifting Adapter VA10-AL is intended for use into the modular construction of a lower limb prosthesis and enables axial shifting.

2. Technical Data

- Max. weight: 100 kg
- Scope of delivery: Adapter Plate
4 Cap screws (M6x15)

REF

Order No.	Material	Weight	Article No.
VA10-AL	Aluminum	76 g	4 620 070 00 00 000

3. Indications/ Contraindications

Indications:

- Prosthetic fitting of the lower extremity

Contraindications:

- 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 non-observance, the function of the product may be impaired, so that product liability is excluded.
- Avoid contact with water, sand, dust and dirt.
- If there is visible damage, stop using the product.
- Notice the repair and maintenance periods specified for the product.
- The professional should instruct the correct use of the device to the user.

6. Installation

- Clean all bolts before starting assembly.
- During installation, perform the following operations in order:
 - Position the shifting adapter as desired.
 - Slide the adapter into the desired position.
 - Screw the desired adaptation to the elements of the shifting adapter.
 - Screw on the cylinder screws M6x15 with a tightening torque of 10 Nm.
 - When completing the prosthesis, secure the threads with Loctite® 222.

7. Cleaning



Check the prosthesis after 30 days of use.

Checks should be made at periodic intervals deemed appropriate for the technician.

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/ or ORTOTEK A.Ş.* as well as to the competence European Authority.

9. Warranty an Guarantee

The product is warranted from the date of purchase and the warranty period is 2 years.

The manufacturer is not responsible for problems caused by user and technician errors.

10. Storage and transport conditions

- Storage temperature -20 °C to +60 °C
- Do not store in damp and dusty rooms
- Protect from mechanical shocks

11. Disposal

Please note the country-specific disposal.

Please direct any questions to:

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