## Symbol-Legende Icon Legend

Achtung Attention



Artikelnummer Article number



einzelner Patientmehrfach anwendbar single patientmultiple use



Cleaning



Manufacturer



Nicht bleichen Do not bleach



Nicht bügeln Do not iron



Europäischer Bevollmächtigter European Authorized Representative



CE-Kennzeichnung CE markina



Übersetzung Translation



Vertriebspartner **Distributor** 



Importeur



Keine chemische Reinigung No chemical cleaning



Nicht im Trockner trocknen Do not tumble-dry



Rev.1-2023-02\_A1-Ti-H20\_A3-Ti400-H20\_A3-Ti400-i

Qualität und Funktion

Gebrauchsanweisung **Instruction Manual** 

A1-Ti-H20 Schraubadapter A3-Ti400-H20 Rohradapter A3-Ti400-i Rohradapter A1-Ti-H20 Clamp Adapter A3-Ti400-H20 Tube Adapter A3-Ti400-i Tube Adapter





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MDSS - Medical Devices Safety Services Schiffgraben 41, 30175 Hanover, Germany





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







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

#### 1. Intended Use

The use of Tube Clamp Adapter A1-Ti-H2O and Tube Adapter A3-Ti400-H2O or A3-Ti400-i is exclusively intended for prostheses of the lower limb and also suitable for use in fresh and salt water. The clamp-screws and adjusting-screws have a water resistant coating.

#### 2. Technical Data



Order No.	Weight limit	Material	Lenght	Weight	Article No.
A1-Ti-H20	< 125 kg	Titanium	47 mm	84 g	4 113 011 30 22 820
A3-Ti400-H2	0 < 125 kg	Titanium	445 mm	348 g	4 113 081 30 33 400
A3-Ti400-i	< 125 kg	Titanium	435 mm	350 g	4 113 060 30 33 400

### 2.1 Service parts

Order No.	Description	Thread	Units per package	Article No.
E-A11-12	Grub screw	M8 x 12	4	4 113 018 11 20 612
E-A12-20	Clamping screw	M5 x 20	1	4 113 018 12 20 520

<sup>\*</sup> With waterproof coating

#### 3. Installation



The tube adapter has to be shortened regarding the patient's measurements. Do not use a bench vise to fix the tube clamp or tube adapter. It is necessary that the cut surface and the longitudinal axis are perpendicular to each other. After shortening you have to deburr the end of the cut tube on the in- and outside. Now insert the tube into the clamp adapter until the tube reaches the bottom of the clamp. Fix the tube in the tube clamp adapter by tightening the clamp-screw with a torque wrench.



Torque setting for the clamp screw: 9 Nm
Torque setting for the adjusting screws: 15 Nm



Always position the tube clamp adapter on the proximal end of the tube adapter. It is not permitted to pull out the tube of the tube clamp adapter to correct the length. Secure the adjusting screws with Loctite 242 when completing the prosthesis.

#### 4. Safety instructions



- Insufficient fastener torque will lead to fatique 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 component screw needs to be re-tightened more than
  once.
- Loosening of component screws may be an early indication of component failure.
- Use only bolts, screws and other fasteners supplied or recommended by Uniprox.
- 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 Loctite 242 thread retaining compound. Loctite takes several hours to cure.
- 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 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.

### 5. Product care and maintenance

There is no product-specific maintenance required for the adapters. Nevertheless regular visual inspection for damage is highly recommended as part of general prosthesis maintenance.



The adapters can be cleaned with soap and a cleaning wipe at a temperature < 30°C. Do not use aggressive detergents.

completing the prosthesis.



# 6. 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 *American Prosthetic Components, LLC* as well as to the competence European Authority.

### 7. Warranty

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

Using the APC Modular Components for amputees that do not meet the criteria noted above or amputees who engage in extremely abusive activities, activities that could result in injury to their natural limb, or activities which could expose the prosthesis to a corrosive environment will void the APC warranty. Never modify the APC Modular Components in any way not typical for constructing a prosthesis, this will void the warranty and could cause failure.

### 8. Disposal

The product is disposable with standard household garbage.

## Please direct any questions to:

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