

## Symbol-Legende Icon Legend

	Achtung Attention		Europäischer Bevollmächtigter European Authorized Representative
	Artikelnummer Article number		CE-Kennzeichnung CE marking
	einzelner Patient- mehrfach anwendbar single patient- multiple use		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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Rev.4-2023-04\_A6,A8,A9,A15,A17,A18,A19,A20,A21,A86\_101727

Qualität und Funktion

## Gebrauchsanweisung Instruction Manual

### Schaftadapter A6, A8, A9, A15, A17, A18, A19, A20, A21 Knieexartikulations- adapter A86 *Socket adapter A6, A8, A9, A15, A17, A18, A19, A20, A21 Knee disarticulation adapter A86*



unique prosthetic solutions  
A company of the Bauerfeind Group

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

## 1. Intended Use

The lamination anchors are for usage in a modular prosthetic limb prosthesis and laminated into the prosthetic socket.

## 2. Technical data

### 2.1 A6 Socket Adapter

- lamination anchor, incl. dummy
- water resistant: A6-St, A6-Ti



Order No.	Material	Weight Limit	Weight	Article No.
A6-Al	Aluminum	< 75 kg	62 g	4 114 010 00 11 000
A6-St	Steel	< 100 kg	87 g	4 114 010 00 22 000
A6-Ti	Titanium	< 100 kg	53 g	4 114 010 00 33 000

### 2.2 A8, A9 Socket Adapter

- lamination anchor for direct fixation to locking systems
- incl. screws and dummy



Order No.	Material	Weight Limit	Weight	Article No.
A8-Ti	Titanium	< 100 kg	66 g	4 147 019 19 00 000
A9-Ti	Titanium	< 100 kg	69 g	4 147 009 20 00 000

### 2.3 A15, A17, A18 Socket Adapter

- A15: lamination anchor with pyramid fixed
- A17, A18: lamination anchor with inner thread (M36 x 1,5) incl. rotatable pyramid and lamination dummy
- water resistant (with specially waterproof coated screws; not included in the delivery!)



Order No.	Material	Weight Limit	Weight	Article No.
A15-St	Steel, 3-arm long	< 125 kg	110 g	4 114 100 01 22 000
A17-St	Steel, 3-arm long	< 125 kg	167 g	4 114 070 99 22 000
A18-St	Steel, 3-arm long	< 125 kg	135 g	4 114 070 77 22 000

### 2.4 A19, A20, A21 Socket Adapter

- 3-arm lamination anchor w/thread M36x1,5
- incl. Dummy
- water resistant (with specially waterproof coated screws; not included in the delivery!)



Order No.	Material	Weight Limit	Weight	Article No.
A19-St	Steel, 3-Arm long	< 125 kg	110 g	4 114 080 01 22 000
A20-St	Steel, 4-arm long	< 150 kg	120 g	4 114 080 02 22 000
A21-St	Steel, 4-arm short	< 125 kg	91 g	4 114 080 03 22 000

### 2.5 A86 Knee Disarticulation Anchor

- lamination anchor w / thread M36 x 1,5
- incl. dummy
- water resistant (with specially waterproof coated screws; not included in the delivery!)



Order No.	Material	Weight Limit	Weight	Article No.
A86	Steel	< 125 kg	170 g	4 114 080 06 22 000

## 2.6 Spare parts for Socket Adapter

Order No.	Description	Article No.
E-A02	Lamination Dummy made of special rubber	4 114 019 01 00 000

Outside thread M36 x 1,5

Order No.	Material	Article No.
E-A04	Steel	4 114 110 00 00 000

Hex socket head screw (for A17):

Order No.	Model	Lenght	Packaging Unit	Article No.
M28-12	Steel	M8 x 12	10	4 226 050 00 00 012
M28-16	Steel	M8 x 16	10	4 226 050 00 00 016
E-A11-12	Steel with waterproof coating	M8 x 12	4	4 113 018 11 20 612

Cylinder screw with hexagon socket

Order No.	Model	Lenght	Packaging Unit	Article No.
M33	Steel	M5 x 18	10	4 226 030 05 00 018
E-A12-20	Steel with waterproof coating	M5 x 20	1	4 113 018 12 20 520

## 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 non-observance, the function of the product may be impaired, so that product liability is excluded.
- Only approved screws may be used.
- The maximum weight loads are listed under "2. Technical Data". Additional loads must be taken into account when calculating the weight.
- In case of insufficient laminate reinforcement, the Socket Adaptor A6, A8, A9, A15 could break out from the prosthetic socket.
- Pay attention to sufficient form-fit (A8).

## 6. Installation

### 6.1 A6, A8, A9, A15 Socket Adapter

- Bending of the Socket Adapter A6 an A9 could result in crackings in the titanium.
- Seal the male pyramid and the distal holes with plastilina.
- Before placing the socket adaptor put some layers of reinforcement material over the plaster model.
- Then position socket adaptor on the model and tie off the following layers of reinforcement in the groove of the adapter with carbon fibre roving.
- Fix the enclosed Lamination Dummy E-A02 on the socket adaptor.
- The Lamination Dummy E-A02 covers and protects the pyramid during lamination procedure and provides a precisely fitting brim of the laminate.
- During hardening process of A8 and A9 the laminate in the area of the adapter must be cooled.
- After lamination expose the attachment side and holes of the adaptor. Do not damage the socket adaptor.

## 6.2 A17-A21 Socket Adapter

### A17, A19-A21



Screw the E-A04 bending protection in the thread M36x1,5 before bending. For bending the adapter only use bending iron with rounded tines. The bore-hole area should not be round off too strongly as failure and/or Rupture of the material could occur.

### A17-A21

Before lamination remove pyramid receptacle from the socket adapter. Protect the thread and the clamping of the socket adapter from resin with e.g. plastilina. Before placing the socket adapter put some layers of reinforcement material over the plaster model. Then position socket adapter on the model and tie off the following layers of reinforcement before the thread. Expose thread after lamination, insert pyramid receptacle and tighten clamp screw with Torque Wrench.



Torque: 10 Nm

### A17

#### Handling of the Headless Screws

By using the adjusting screws M28-12 or M28-16, static corrections are possible at any time. If a module has to be replaced or removed the previously adjusted position is maintained if only two adjacent adjusting screws (not opposite), the ones screwed in at the deepest, are removed.

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 torque wrench to tighten the adjusting screws. Tightening torque: 12 Nm.



Secure the various screws, used for assembly, with Loctite 222.

## 6.3 A86 Knee Disarticulation Anchor



Screw the E-A04 bending protection in the thread M36x1,5 before bending. For bending the adapter only use bending iron with rounded tines. The bore-hole area should not be round off too strongly as failure and/or Rupture of the material could occur.

Use the dummy included in the scope of delivery to protect the thread from penetrating resin with plasticine. The adapter A86 can also be secured with screws for assembly. These screws are to be held in the definitive socket. When laminating, glass or carbon fiber threads are pulled through the holes in the adapter. These serve as a firm anchorage in the laminate.

The technician must ensure that the processing and reinforcement in the socket are adapted to the weight and mobility of the patient.



Attention: When the knee joint is fully flexed, there must be no contact between the socket and the knee joint. Defect of the prosthesis components possible.



Secure the clamp screw with Loctite 222 and tighten with 8 Nm.

## 7. Maintenance

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 and Guarantee

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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## 1. Zweckbestimmung

Die Eingussanker sind für den Einsatz in Beinprothesen konzipiert und werden als Schaftadapter im Laminat des Prothesenschaftes integriert.

## 2. Technische Daten

### 2.1 A6 Schaftadapter

- Eingussanker, inkl. Laminierschutz
- wasserfest: A6-St, A6-Ti

**REF**

Bestell-Nr.	Ausführung	Gewichtslimit	Gewicht	Artikelnummer
A6-Al	Aluminium	< 75 kg	62 g	4 114 010 00 11 000
A6-St	Stahl	< 100 kg	87 g	4 114 010 00 22 000
A6-Ti	Titan	< 100 kg	53 g	4 114 010 00 33 000

### 2.2 A8, A9 Schaftadapter

- Eingussanker zur direkten Anbindung an Verschlussstücke
- inkl. Schrauben und Dummy

**REF**

Bestell-Nr.	Ausführung	Gewichtslimit	Gewicht	Artikelnummer
A8-Ti	Titan	< 100 kg	66 g	4 147 019 19 00 000
A9-Ti	Titan	< 100 kg	69 g	4 147 009 20 00 000

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

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