

















Symbol-Legende Icon Legend


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

QR-Code Download GA



QR-Code Download IFU



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Ein Unternehmen der Bauerfeind Gruppe – www.uniprox.de

Qualität und Funktion


Gebrauchsanweisung Instruction Manual

Modular SACH Prothesenfuß-Adapter E-F01, E-F02, E-F04 Modular SACH foot adapter E-F01, E-F02, E-F04



unique prosthetic solutions
A company of the Bauerfeind Group

 uniprox®

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

1. Intended Use



Adapters are load-bearing components within a prosthesis.

2. Technical data

- connector: pyramid with a \varnothing 50 mm spherical segment
- incl. bolt assemblies (M10)
- incl. 2-component glue
- water resistant (E-F02, E-F04 only)

REF

Order No.	Weight limit	Material	Article No.
E-F01	< 75 kg	Aluminum 10M	4 101 019 99 11 010
E-F02	< 125 kg	Steel M10	4 101 019 99 22 010
E-F04	< 100 kg	Titanium M10	4 101 019 99 33 010

2.1 Individual and spare parts

Order No.	Description	Material	Article No.
E-F19	Connection Plate	Plastic	4 101 079 00 00 000

3. Indications/ Contraindications

Indications:

- Leg amputation
- Dysmelia

Contraindications:

- None

4. Side effects

There are no known side effects.

5. 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.
- The patient must be instructed by the technician on correct use and informed about possible side effects/ residual risks.
- 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.

6. Residual risks

Despite proper installation and use of the fitting parts in a prosthesis, adverse circumstances can lead to insecurity (e.g. stumbling, loss of balance, falling).

7. Installation

Tighten the included M10 screw with a torque wrench to 30 Nm.



Secure the screw with Loctite 243 when finishing the prosthesis.



Connect the SACH-Foot adapter to the SACH-Foot by using the included 2-component glue.



8. Maintenance and Cleaning

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



Cleaning:

- Soap and hand warm water
- Do not use aggressive solvents for cleaning.

9. 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.

10. Warranty and service life

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.

11. Storage and Disposal

This product has no special storage regulations.

Please note the country-specific disposal.

Please direct any questions to:

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