


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 Importer
	Nicht bleichen Do not bleach		Keine chemische Reinigung No chemical cleaning
	Nicht bügeln Do not iron		Nicht im Trockner trocknen Do not tumble-dry

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



Rev.1-2023-02_F1_F20

Qualität und Funktion

Gebrauchsanweisung Instruction Manual



Uniprox Herren- SACH-Fuß F1, F20 Uniprox SACH-Foot for men F1, F20



Please read the IFU carefully before fitting. Only correct usage will provide maximum safety and service life.

1. Intended Use

The F1 and F20 foot is intended for individuals with lower limb amputation, transtibial or higher, a max patient weight of 102 kg and a mobility grade of 1 for the F1 foot and mobility grade 1-2 for the F20 foot.

2. Technical Data

- F1: Flexible foot molding with plastic core
Separate big toe
Suitable for bathing prostheses
- F20: Lightweight and dynamic prosthetic foot
Flexible foot molded part with synthetic core
Suitable for bathing prostheses



Order No.	Sizes	Weight	Article No.
F1-Size/ Side	22-29	360-585 g	4 101 010 0X 00 0ZZ
F20-Size/ Side	22-29	425-605 g	4 101 200 0X 00 0ZZ

X = Side: 1 = Left 2 = Right

ZZ = Size

2.1 Service parts

Modular SACH foot adapter for men's feet F1 and F20, includes bolt assemblies



Order No.	Weight limit	Connector	Material	Article no.
E-F01	< 75 kg	Pyramid	Alu M10	4 101 019 99 11 010
E-F02*	< 125 kg	Pyramid	Steel M10	4 101 019 99 22 010
E-F04*	< 100 kg	Pyramid	Titanium M10	4 101 019 99 33 010

* waterproof

Connection Plate



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

Bolt assembly for Ankle Block



Order No.	Material	Article No.
E-F08	Screw: Steel, galvanized M10 × 90	4 101 049 00 00 010

Wooden Ankle Block incl. bolt assembly



Order No.	Material	Article No.
E-F10	Wood/ M10	4 101 059 00 77 000

3. Indications/ Contraindications

Indications:

Lower extremity amputation; transtibial or higher.

Contraindications:

None.

4. 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.
- For the highest possible safety and the longest possible service life, the recommended assembly and usage procedures must be followed.

- Never make any modifications to the spring plate. This will void the warranty and may cause the bolts or spring plate to break. If you need to change the shape of the base, be careful not to grind the spring plate.
- Never re-drill the mounting hole.
- Use only the screws provided. The use of non-approved screws will void the warranty and may cause the screws to break.
- When installing the foot screw, ensure a free running thread fit and adequate screw depth. Apply Loctite® 243 to it and tighten it to 27 Nm.

5. Assembly

5.1 Alignment

The recommendations contained in this manual provide a reliable starting point for the static alignment of the Uniprox SACH feet with pyramid connection. Since each patient is unique, additional adjustments may be required for fine alignment.

5.2 Alignment of the drill hole

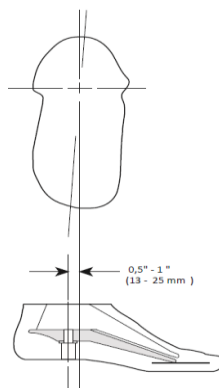
To establish the anterior/ posterior placement of the foot, position the ankle bolt hole 13-25 mm posterior to the midline of the socket. To define the medial/lateral placement of the foot, position the ankle bolt hole 6 mm medial to the midline of the socket.

5.3 Socket flexion

Due to the flexibility of the forefoot and the preload of the foot, a starting point of +3° of socket flexion during walking is recommended. The socket should also be adducted by 5°. Foot motion should be smooth during the gait cycle and provide adequate toe resistance without active push-off. Hyperextension of the knee should be avoided during each gait phase.

5.4 Alignment for above knee

When installing the Uniprox SACH base with pyramid connection, use the standard procedures for aligning a multiaxis foot, but place the tube adapter with an inclination of 2° to 3° to the posterior. This will preload the spring plate and keep the tube adapter vertical during the mid-stance phase. If the knee becomes unstable, increase the toe lever by plantarflexing the foot or by moving the knee center behind the TKA line.



6. Maintenance and cleaning



- The SACH feet can be cleaned with soap and a damp cloth.
- Do not use aggressive cleaning agents.
- The foot assembly should be checked after the first 30 days of use.
- Check the entire prosthesis for wear during regular consultations.
- Check the bolt regularly to make sure it is tight. If it has loosened, retighten it to 27 Nm.



A loose foot bolt can cause the bolt to break!

7. 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 *Trulife* as well as to the competence European Authority.

8. Guarantee and Warranty

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

A 2-year Guarantee is provided for defects in materials and workmanship.

9. Storage and disposal

There are no special storage regulations.

The product does not contain any substances hazardous to health. Local and national laws and regulations must be observed.

Please direct any questions to:

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