Symbol-Legende
Icon Legend

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

Trulife
3225 Woburn St Ste 160
Bellingham, WA 98226
USA

MDSS GmbH
Schiffgraben 41
30175 Hannover
Deutschland

Uniprox GmbH & Co.KG,
H.-Heine-Str.4,
07937 Zeulenroda-Triebes

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

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Ein Unternehmen der Bauerfeind Gruppe – www.uniprox.de

Qualität und Funktion

Gebrauchsanweisung
Instruction Manual

Uniprox Leicht-Fuß F31
Uniprox light Foot F31

unique prosthetic solutions
A company of the Bauerfeind Group

uniprox®

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

1. Intended Use

The F31 Light Foot is intended for individuals with lower limb amputation, transtibial or higher, with a mobility grade of 1-3 and a maximum patient weight of 136 kg.

2. Technical Data

- Flexible base molding with plastic core
- Incl. spacer block and pyramid adapter
- Separate big toe
- Suitable for bathing prostheses

REF

Order No.	Sizes	Category	Weight	Article No.
F31-Size/ Side/ Category	24-29	6 - 9	480 g (Size 25)	4 601 040 0X 0Y 0ZZ

X = Side: 1 = left 2 = right
Y = Category
ZZ = Size

3. Indications/ Contraindications

Indications:
Lower extremity amputations; 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.
- To optimize selection and ensure the safety of the amputee(s), follow the following two steps of the procedure to determine the appropriate category.
    1. consider the column with the applicable mobility level of the amputee(s).
    2. within the selected column, search for the weight of the amputee(s).
- If the amputee has a long transtibial stump, carries heavy loads, or will reach a "higher" mobility grade within a year, select the next higher category.
- Selecting a category with a lower strength than that determined based on the above procedure will void the warranty and put your patient at risk.
- If your patient's weight exceeds the maximum values in the table, please contact Uniprox Customer Service.

	Foot size	Impact level 1	Impact level 2	Impact level 3
Spring 6	24-28 cm	46-68 kg	46-68 kg	46-68 kg
Spring 7	24-29 cm	69-90 kg	69-90 kg	69-90 kg
Spring 8	24-29 cm	91-113 kg	91-113 kg	91-113 kg
Spring 9	24-29 cm	114 - 136 kg	114 - 136 kg	114 - 136 kg

- For the highest possible safety and the longest possible service life, the recommended assembly and usage procedures must be followed.
- The light foot is supplied pre-assembled with a spacer washer, a foot pyramid and a foot bolt. Before assembly, check the bolt for tightness and a tightening torque of 59 Nm.
- Never make any modifications to the spring plate. This will void the warranty and may cause the screws or spring plate to break. If you have to change the shape of the foot, make sure not to grind the spring plate.
- Never re-drill the mounting hole.
- Never make any modifications to the spacer washer. This will void the warranty and may result in a defect.
- Only use the bolts provided by Uniprox. The use of non-approved bolts will void the warranty and may cause the bolts to break.

Note: The spacer can be removed to increase the distance; add a Symes adapter (E-F49) or use a Ankle Block (E-F60). Simply shorten the enclosed screw to the appropriate length. Ensure a free running thread fit and adequate screw-in depth on the part to be installed. Apply Loctite® 243 to the threads and tighten them to 59 Nm for the foot adapter and 27 Nm for the Symes adapter and the Ankle Block.

5. Assembly

5.1 Alignment

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

5.2 Alignment of the drill hole

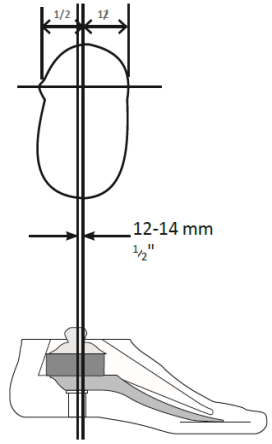
To establish the anterior/posterior alignment of the foot, position the ankle bolt hole 13-25 mm posterior to the midline of the socket. To define the medial/ lateral placement of the foot, position the pyramid center 6 mm medial to the midline of the socket.

5.3 Socket flexion

Due to the flexibility of the forefoot and the required preload of the foot, +3° of socket flexion for walking and -3° for running are recommended as starting points. The socket should also be adducted by 5°.

5.4 Alignment for above knee

When installing the Light Foot, use the standard Multiaxial Foot alignment procedures, place the tube adapter with a 2° to 3° tilt 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 centre behind the TKA line.



If the foot is plantarflexed at the ankle joint, the patient can feel the increase in push-off. With an increase in push-off, the hyperextension moment of the knee in the mid-stance phase also increases. Therefore, you need to find a balance between the hyperextension moment in the mid-stance phase and the required push-off behavior. Overextension of the knee must be avoided in every gait phase.

6. Maintenance and cleaning

- The F31 Light Foot 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 foot 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:
Customer Service: + 49 (0) 36628-66-33 70
Fax: + 49 (0) 36628-66-33 77
E-mail: export@uniprox.de