

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

Qualität und Funktion

Gebrauchsanweisung Instruction Manual

F51 Uniprox Multiaxial-Fuß F51 Uniprox multiaxial foot



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



Rev.3-2023-02_F51



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

1. Intended Use

The Multiaxial Foot is intended for individuals with lower limb amputation, transtibial or higher, with a mobility grade 1-2 and a max patient weight of 160 kg.

2. Technical Data

The foot is designed to incorporate variable ankle stiffness, excellent ML compliance adjustment and plantar flexion in an aesthetically pleasing cosmesis.

- Integrated multiaxial ankle joint
- Carbon spring
- Seperate big toe
- Features full length flexible spring plate, integrated multiaxial ankle and proximal adapter
- Proximal adapter with male pyramid

REF

Order No.	Sizes	Category	Weight	Article No.
F51-Size/ Side/ Category	24-29	1-5	531 g	4 602 040 0X 0Y 0ZZ

X = Side: 1 = left 2 = right

Y = Category

ZZ = Size

2.1 Service and Spare parts

REF

Order No.	Material	Article No.
E-F50-M	Tool-Set (contains: Hex-kex, axis-extension and leading bushing)	4 602 019 00 30 000
E-F51-T	Maintenance kit for F51 (contains: Bushing, washer, axis with screw, dorsal bumper, distance plate, plastic washer)	4 602 049 00 43 000
MM202	Lithium grease	4 690 240 00 89 100

2.2 Bumpers

REF

Order No.	Description	Article No.
E-F50-P2	Bumper, Medium	4 602 019 00 02 000
E-F50-P3	Bumper, Firm	4 602 019 00 03 000
E-F50-P4	Bumper, X-Firm	4 602 019 00 04 000
E-F50-P5	Bumper, XX-Firm	4 602 019 00 05 000

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 the selection and ensure the safety of the amputee(s), follow the following two steps of the procedure to determine the appropriate category.
 1. find the row corresponding to the weight of the amputee(s).
 2. locate the column corresponding to the foot length of the amputee(s).
- The area where the column and row overlap contains the appropriate category.
- If the amputee has a long transtibial stump or carries heavy loads, select the next higher category.
- Selecting a category with a lower strength than as determined based on the above procedure will void the warranty and expose your patient to risk.

Patient weight	Foot length (cm)					
	24	25	26	27	28	29
137–160 kg	–	–	5	5	5	5
101–136 kg	4	4	4	4	4	4
81–100 kg	3	3	3	3	3	3
<80 kg	2	2	2	2	2	–

- For the highest possible safety and longest possible service life, follow the recommended installation and use procedures.
- Failure to follow the installation and use instructions may result in structural failure of the components, exposing the user to the risk of serious injury.
- Never make any modifications to the spring plate or structural ankle components.

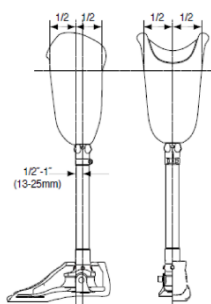
5. Assembly

5.1 Assembly of the base

- Following typical procedures for modular components, connect the proximal connectors (tube adapters, clamp adapters, etc.) to the pyramid of the foot.
- Refer to the instruction manuals of the included components for correct tightening torques and assembly instructions (typical tightening torque for 3 mm titanium and stainless steel adapters with internal threads is 15 Nm).

5.2 Alignment

The recommendations contained in this manual provide reliable starting points for static alignment.



To determine the anterior/ posterior placement of the foot, ensure that the pyramid receiver is 13 mm to 25 mm posterior to the midline of the socket.

To establish the medial/ lateral placement of the foot, position the pyramid center 6 mm medial to the midline of the socket.

5.3 Replacing and reconditioning the bumper

5.3.1 Required tools and aids

- Assembly tool kit: Order no.: E-F50-M
- Maintenance kit: Order no.: E-F51-T



5.3.2 Disassembly

- Remove the two cosmetic plugs on each side of the foot.
- Using two 4 mm Allen wrenches, remove the button head screw and the step washer from one side of the foot.

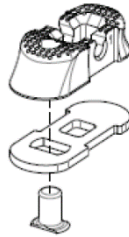


- Lightly tap the head of the Allen wrench with the rubber mallet to dislodge the shaft.
- Remove the internal components from the foot.



5.3.3 Assembly

- Coat the cylindrical part of the dorsal stop with white lithium grease (MM202) and then guide it upwards through the distal pad and the bumper.



- Insert the bumper assembly into the foot cavity, then coat the spherical Delrin washers with white lithium grease (MM202) and place them on the sides of the bumper. Align the spherical surfaces of the washers so that they face inward toward the bumper.



- Use an Allen key to roughly align the buffer and the components.

Lubricate the proximal surfaces of the bumper with white lithium grease (MM202).



- Insert the Allen key into the head of the shaft and put the bullet on the axis



Note: If the foot is being refurbished, the bushing must be pressed into distal end of the upper bracket before the upper bracket is inserted into the foot cavity.

- Place the upper bracket through the cavity in the foot down onto the assembly



- Using the 4 mm Allen wrench, roughly align the holes in the assembly.
- Using an arbor press or screw clamp, press the assembly together until the holes are aligned. Place a piece of wood or plastic underneath to avoid scratching the surface of the upper bracket



- Lubricate the bullet and axis with some white lithium grease (MM202). Push the axis assembly through the ankle until the bullet protrudes slightly on the other side. A light tap with the rubber mallet may be necessary while continuing to compress the assembly.



- Insert the protruding bullet into the shaft guide and use the arbor press or screw clamp to drive the shaft until it protrudes through the far side of the internal bracket.



- Remove the bullet from the axis.



The bullet should be easy to remove. If this is not the case, the stem has not been pushed completely through the assembly. Repeat the previous step if necessary.

- Install the M6 button head screw and the washer in the axis. Apply Loctite® 243 to the threads



Make sure that the indentation of the disc is facing inward, toward the foot.



- Use a 4 mm Allen wrench to hold the shaft in place and use a torque wrench to tighten the button head screw to 8 Nm.
- Put the cosmetic plugs back into the base.

6. Maintenance and cleaning



- To maintain the optimal performance of the Uniprox Multiaxial Foot, it is recommended to replace the bumper once a year (less frequently for low activity amputees). Refer to the table in section 2.2 Bumper for the recommended replacement bumper.
- The F51 Multiaxial Foot can be cleaned with soap and a damp cloth.
- Do not use aggressive cleaning agents.



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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