


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

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



Qualität und Funktion

Gebrauchsanweisung Instruction Manual

**Uniprox Karbon-Fuß
F63**

**Uniprox Karbon-Fuß
ZUMO F64**

**Uniprox Carbon fiber
foot F63**

**Uniprox Carbon Foot
ZUMO F64**





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

1. Intended Use

The F63 and F64 carbon foot is intended for individuals with lower limb amputations, transtibial amputations or higher, with a mobility grade of 1-3 and a maximum patient weight of 136 kg (F63) and 205 kg (F64).

2. Technical Data

The F63 and F64 carbon feet are foot prostheses with dynamic spring plate and cushioned heel. The composite spring plate provides rollover and stability support.

- Heel height 10 mm.
- Split dynamic forefoot spring for high stance stability
- Cushioned heel due to integrated foamed heel buffer
- Separate big toe
- Integrated pyramid adapter
- Removable spacer block

REF

Order No.	Sizes	Category	Weight	Article No.
F63-Size/ Side/ Category	22 - 30	1 - 4	620 g (Size 25)	4 603 030 0X 0Y 0ZZ
F64-Size/ Side	25 - 30	-	750 g (Size 25)	4 603 090 0X 00 0ZZ

2.1 Service parts

Foot shell

Order No.	Foot	Category	Sizes	Article No.
E-F63-Size/ Side- 12	F63	1-2	22 - 28	4 603 039 0X 0Y 0ZZ
E-F63-Size/ Side- 34	F63/ F64	3-4	23 - 30	4 603 039 0X 34 0ZZ

X = Side: 1 = left 2 = right

Y = Category

ZZ = Size

Spectra-Sock

Order No.	Article No.
E-F60-SS	4 603 019 00 39 000

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.
- 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 have to change the shape of the foot, make sure not to grind the spring plate.
- Never make any changes to the spacer plate. This will void the warranty and may result in a defect.
- Only use the bolts supplied. Using non-approved bolts will void the warranty and may cause the bolts to break.

5. Selection and assembly Uniprox carbon foot F63

5.1 Selection

To optimize selection and ensure the safety of the amputee, follow the subsequent two steps of the procedure to determine the appropriate category and use the table below.

- Consider the column with the applicable mobility level of the amputee.
- Within the selected column, look for the weight of the amputee.
- If the amputee has a long transtibial stump, carries heavy loads, or will reach a "higher" mobility level 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 expose your patient to risk.
- If your patient's weight exceeds the maximum values in the table, please contact Uniprox Customer Service.

Category	Foot size	Impact level 1	Impact level 2	Impact level 3
1	22 - 27 cm	< 60 kg	< 60 kg	< 60 kg
2	22 - 28 cm	61 - 80 kg	61 - 80 kg	61 - 80 kg
3	23 - 29 cm	81 - 100 kg	81 - 100 kg	81 - 100 kg
4	24 - 30 cm	101 - 136 kg	101 - 136 kg	101 - 136 kg

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 bolt 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.

5.2 Assembly and alignment of the F63 carbon foot

The Uniprox Carbon Foot F63 is delivered pre-assembled with a spacer, a foot pyramid and a foot bolt.

5.2.1 Alignment

The recommendations contained in this manual provide reliable starting points for static alignment of the carbon foot. Since each patient is unique, final alignment may require additional adjustment.

5.2.2 Alignment of the drill hole

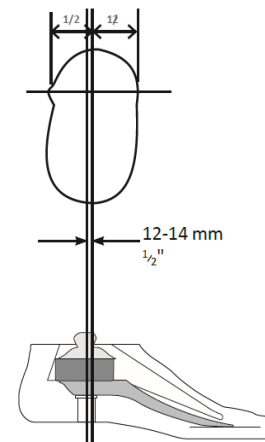
To establish the anterior/ posterior placement of the foot, position the ankle bolt hole 13-25 mm posterior to the midline of the socket. To define the medial/ lateral alignment of the foot, position the ankle bolt hole 6 mm medial to the midline of the socket.

5.2.3 Alignment of the socket

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°.

5.2.4 Above knee alignment

When installing the Carbon Foot, use the standard Multiaxial Foot alignment procedures, but place the tube adapter with a 2° to 3° of posterior tilt. 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 center of the knee behind the TKA line.



If the foot is plantarflexed, the patient can feel the increase during push-off. With an increase in push-off, the hyperextension moment of the knee in the mid-stance phase also increases. For this reason, 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. Assembly and alignment of the Uniprox carbon foot ZUM0 F64

6.1 Assembly

The Uniprox carbon foot Zumo is delivered pre-assembled with a spacer, a foot pyramid and a foot bolt.

6.2 Alignment

The recommendations contained in these instructions provide reliable starting points for the static alignment of the foot. Since each patient is unique, additional adjustments may be required during optimization.

6.3 Alignment of the bolt hole

For anterior/ posterior placement of the foot, place the ankle bolt hole 12-14 mm posterior to the centerline of the socket. For medial/ lateral placement of the foot, position the ankle bolt hole in line with the midline of the socket.

6.4 Above knee alignment

Use standard foot setup procedures when installing the Uniprox Carbon Foot Zumo.

7. Maintenance and cleaning



- The Uniprox carbon feet can be cleaned with soap and a damp cloth.
- Do not use aggressive cleaning agents.
- The foot assembly should be inspected after 30 days of use.
- Inspect the entire prosthesis for wear at the scheduled regular follow-up appointments.
- Check the bolt regularly to make sure it is tight. If it has loosened, retighten it to 59 Nm.



A loose foot bolt can cause the bolt to break!

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/or *Trulife* as well as to the competence European Authority.

9. 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.

10. 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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