

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

E-F60 Knöchelansatz E-F60 Ankle Block





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

1. Intended Use

The Ankle Block is for persons with lower limb amputations and was developed for the construction of a prosthesis with the F31 Uniprox Light Foot.

Made of high-strength polyurethane foam enclosing a nylon core, the ankle attachment incl. screw is lightweight and durable to withstand even the forces occurring in feet with dynamic response.

2. Technical Data

REF

Order No.	Weight limit	Material	Article No.
E-F60	< 136 kg	PU/ Polyamid	4 601 019 00 00 001

3. Indications/ Contraindications

Indications:

- Patients with lower limb amputations to build a prosthesis.

Contraindications:

- None.

4. General Instructions



- The medical device is intended for multiple use on one patient.
- The medical device may only be dispensed/ adapted by orthopaedic technical personnel.
- For the highest possible safety and the longest possible service life, the recommended manufacturing, assembly and use procedures must be observed.

- Never modify the exposed portion of the nylon core except to grind off the rotation control rib when necessary. Other modifications will void the warranty and can cause failure. Sanding or grinding of the foam surrounding the core is permitted only on the tops and sides, and only to a depth of 2 mm.
- The embedded part of the core must never be reduced.
- Testing an unreinforced knuckle attachment after moulding may result in a defect.
- The circular depression on the underside of the knuckle attachment must be placed as close as possible posterior to the centre line of the spring plate.
- Remove any dust from the moulded knuckle boss before laminating.
- Cover the exposed nylon core with a small polyethylene bag and seal it with tape.
- At least two layers of nylon tricot tubing are required for lamination. For ankles with a circumference of less than 23 cm, an additional layer is required. For heavy or very active patients, additional posterior reinforcement is recommended.
- When cutting off the protruding lamination on the ankle former, the nylon core must not be cut off or in as well.

Rotation control can be accomplished by either of two methods:

- If the rotational alignment is sufficient, ensure that the central control rib on the top of the spring plate engages while the foot mounting screw is tightened.
- If further adjustment is required, grind down the rib. Form a rib on the knuckle former by adding a small amount of epoxy resin to the recess. You can also add fillers to the resin to make a paste.



Note: Do not contaminate the mounting threads. You can fill the groove on the top of the spring plate with a small amount of wax or plasticine.

Carefully insert the foot and adjust the position. If the position still needs adjusting after a trial period, simply sand the epoxy out of the recess and repeat the procedure to shape the ribs.

5. Installation

Use only metric screws provided or approved. Use of unapproved screws will void the warranty and may result in a defect.

- Apply some Loctite® 243 to the screw before assembly. If Loctite® 243 is not applied, the screw may seize when screwed in.
- The mounting screw must be screwed at least 22 mm into the knuckle moulding. If the screw is shortened, deburr the sawn-off end to avoid damage to the thread. Make sure that the threads run easily and that the screw does not press against the socket adapter at the bottom.
- Avoid contamination of the screw or thread insert by varnish, glue, adhesive or cement.
- To maintain a tight fit of the screws, apply three drops of the removable threadlocker Loctite® 243 to the part of the screw that is screwed into the thread of the knuckle adapter. Loctite needs a few hours to cure completely.

Loctite: When adjusting alignment of bolts or screws that have been assembled with Loctite, the threads of the screw should be cleaned free of any Loctite residue with a mild solvent such as alcohol. Then reapply new Loctite; this will ensure the proper torque values of the fasteners are set when retightening the fastener to the specified torque values.

- Tighten the foot mounting bolt to 27 Nm. A calibrated torque wrench and hex driver should be used.
- Do not install a wedge to adjust alignment.



Failure to follow the installation and use procedure set forth above may lead to structural failure of the components subjecting the user to risk of serious personal injury.

6. Cleaning



- As part of regular prosthesis checks, we recommend a visual inspection for damage.
- The ankle socket can be cleaned with 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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