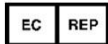


Symbol-Legende Icon Legend

	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

 Orthoservice AG, Via Milano 7
CH-6830 Chiasso (TI)



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07937 Zeulenroda-Triebes

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



Gebrauchsanweisung Instruction Manual

OF01/OF02 Peroneus-Orthese OF01/ OF02 Peroneal Orthosis





Please read the IFU carefully before fitting. Only correct usage will warrant the function.

1. Intended Use

The peroneus orthosis is exclusively used for the orthotic fitting of the lower leg / foot.

2. Technical Data

2.1 Material

- Body OF01: polypropylene structure with rounded-off edges
- Body OF02: hygroscopic, non-malleable, robust and elastic polyoxymethylene (acetal resin)
- Soft padding for protection of the tibia and the calf (MTP padding, with light velour covering on both sides)
- Velcro®* closure at the calf
- Thermo-formable (OF01)
- Velcro®* closure across the arch of the foot

2.2 Order-/ Size selection OF01

- available in white

REF

Order No.	Shoe size	Size	Side	Height	Lenght	Article No.
OF01-1L	35-39	S	left	28 cm	24 cm	4 533 010 01 00 260
OF01-2L	40-43	M	left	29 cm	26 cm	4 533 010 01 00 290
OF01-3L	41-44	L	left	34 cm	28 cm	4 533 010 01 00 340
OF01-4L	> 44	XL	left	39 cm	30 cm	4 533 010 01 00 400
OF01-1R	35-39	S	right	28 cm	24 cm	4 533 010 02 00 260
OF01-2R	40-43	M	right	29 cm	26 cm	4 533 010 02 00 290
OF01-3R	41-44	L	right	34 cm	28 cm	4 533 010 02 00 340
OF01-4R	> 44	XL	right	39 cm	30 cm	4 533 010 02 00 400

2.3 Order-/ Size selection OF02

- available in light blue

REF

Order No.	Shoe size	Size	Side	Height	Lenght	Article No.
OF02-1L	35-39	S	left	28 cm	24 cm	4 533 020 01 00 260
OF02-2L	40-43	M	left	29 cm	26 cm	4 533 020 01 00 290
OF02-3L	41-44	L	left	34 cm	28 cm	4 533 020 01 00 340
OF02-4L	> 44	XL	left	39 cm	30 cm	4 533 020 01 00 400
OF02-1R	35-39	S	right	28 cm	24 cm	4 533 020 02 00 260
OF02-2R	40-43	M	right	29 cm	26 cm	4 533 020 02 00 290
OF02-3R	41-44	L	right	34 cm	28 cm	4 533 020 02 00 340
OF02-4R	> 44	XL	right	39 cm	30 cm	4 533 020 02 00 400

2.4 Spare parts for OF01 and OF02

Pad for calf cushioning

Order No.	Article No.
E-OF03	4 533 021 02 00 000

3. Indications/ Contraindications

Indications:

- Weakness of dorsiflexion of the foot (drop foot)
- Light to moderate spastic equinus foot (OF02)

Contraindications:

- Not known

* Velcro® is a registered trademark of Velcro Industries B.V.

4. General safety information



- The product has been designed for the specific indications stated below and must be prescribed by a doctor and fitted by an orthopaedic technician. The orthopaedic technician is responsible for fitting the product and providing information about how to use it safely in accordance with individual requirements.
- The product must be fitted with the utmost care to ensure its efficacy, tolerability and correct function.
- Any changes to the structure or adjustment of the device must be prescribed by a physician and performed by an orthopaedic technician.
- Under no circumstances should the adjustment made by the physician/orthopaedic technician be altered.
- The manufacturer is no longer liable if the product is used or adapted inappropriately.
- The orthosis is intended to be used only by a single patient; if it is used for more than one patient, the manufacturer accepts no responsibility or liability in accordance with medical device legislation.
- Direct contact with the skin may cause reddening or irritation in hypersensitive individuals.
- In the case of onset of pain, swelling, lumps or any unusual reaction, immediately contact your physician.
- The orthopaedic efficacy of the product may only be guaranteed when all of its components are used.
- It is advised that the pressure exerted by the product does not act on parts of the body suffering from wounds, swelling or lumps.
- The product should not be tightened too firmly so as to avoid the development of pressure points or compression of the nerves or blood vessels underneath.
- It is advisable to wear the product over a garment, avoiding direct contact with the skin.
- If in doubt about how to apply, contact an orthopaedic technician.
- Please read the composition of the product on the inside label carefully.
- The device should not be worn in the vicinity of open flames or strong electromagnetic fields.

5. Adating/ Putting on the appliance

5.1. Adapting for the doctor/ technician

- Where necessary, trim the end of the foot section (fig. A) with scissors, so as to adapt the appliance to the shoe and foot of the patient. Roll over the edges.
- If necessary, thermoform the appliance, in order to ensure that it fits the patient's leg better (OF01 only).
- Insert the appliance into the shoe.
- Put the shoe on with the appliance already inserted.
- Fasten the padding on the calf (fig. B).
- Pull the Velcro®* strap around the calf (fig. C).
- Where necessary, use the foot strap to secure the appliance (fig. D).

5.2. Putting on the appliance for the patient

- Insert the appliance into the shoe.
- Put the shoe on with the appliance already inserted.
- Fasten the padding on the calf (fig. B).
- Pull the Velcro®* strap around the calf (fig. C).
- Where used, fasten the foot strap (fig. D).



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6. Maintenance and cleaning



Do not bleach



No chemical cleaning



Do not iron



Do not tumble-dry



Washing instructions:

hand wash at max. 30° C with neutral soap (a sponge is recommended);
not dry in the vicinity of heat sources (or, better, dry with a cloth)

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 *Orthoservice AG* as well as to the competence European Authority.

10. Warranty

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

11. Disposal

Do not dispose of the product or any of its components into the environment.

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