

TECHNICAL INFORMATION

OPTIMA DIAB

HIGH LEG-FOOT BRACE

Treatment of diabetic foot ulcers, post-operative/traumatic phases and foot fractures.

PRODUCT COMPONENTS

- | | |
|-----------|---------------------------------------|
| 1- Leg | 4- Bottom |
| 2- Lining | 5- NRS SYSTEM Non-removability system |
| 3- Insole | 6- Velcro |

The Optima line is indicated for the treatment of alterations in the morphology of the foot. Optima Molliter S.r.l. declares that the Optima tutors are medical devices conceived and designed according to the state of the art, have been checked and made compliant with EU Regulation 2017/745 for the applicable parts. The braces comply with IWGDF's international guidelines for the management of diabetic foot ulcers. <https://iwgdfguidelines.org/guidelines/guidelines>.

THERAPEUTIC INDICATIONS

- Plantar diabetic ulcer.
- Plantar ulcer.
- Minor post-amputation rehabilitation (except Lisfranc and Chopart amputations).
- Post-tarsal surgery rehabilitation.
- Plantar diabetic ulcer with vascular complications in the leg, neuroischaemic ulcer before and/or after revascularisation (using the Kit 3x3 insole in addition).
- Management of the foot contralateral to the injured foot or management of the foot at risk of ulceration.
- Compound fracture of the metatarsals.
- Preoperative stabilisation.
- Postoperative management of the toes and Morton's neuroma.
- Osteoarthritis.
- Metatarsal and malleolar fracture

TECHNICAL FEATURES

High leg-foot walker with components that can be adapted to the patient, high heat-mouldable stiffener, breathable and washable upper. Rigid anti-flexion and anti-torsion midsole, Fully Rocking outsole, with movement control and redistribution of the pressure load.

TECHNICAL CHARACTERISTICS

MATERIALIALS:

UPPER: PU 70% + PES 20% + COT 10%

LINING POLYESTER: 100%

INSOLE INSERT: POLYAMIDE PA6 70% +GLASS FIBER 30%

BOTTOM SOLE: POLYURETHANE

PROTECTIVE SOCK: 90% COTTON, 7% POLYAMIDE, 3% ELASTANE

OPTIMA PRODUCTS ARE LATEX FREE.

CLOSURE: 4 VELCROS

PACKAGING: WEIGHT: GR 205 / MATERIAL: CARTON

OPERATIVE TEMPERATURE AND STORAGE: - 5° | + 45°

PRODUCTION LOT: AS DESCRIBED ON THE LABEL ON THE FRONT OF THE BOX

BASE COMPONENTS: OPTIMA KIT 3X3 PLANTAR INSOLE / NRS SYSTEM

ADDITIVES: OPTIMA PLTM / MONOLAYER PLANTAR INSOLE / PROTECTIVE SOCK

PRODUCT CLEANING

To clean the product, use warm or cold water and neutral soap; rinse once the operation is completed. Avoid any corrosive liquids such as alcohol, laundry detergents, bleach, ammonia, and solvents. Avoid using abrasive materials such as brushes, steel wool, and sand paper, or a knife blade to remove stains. Optima Molliter S.r.l. shall NOT be held liable for damages caused by abrasive products, by products which attack the materials, by direct exposure to heat sources.

"An Off-the-Shelf Instant Contact Casting Device for the Management of Diabetic Foot Ulcers. A randomized prospective trial versus traditional fiberglass cast" Alberto Piaggese, MD, Silvia Macchiarini, DPM, Loredana Rizzo, MD, Francesca Palumbo, MD, Anna Tedeschi, MD, Laura Ambrosini Nobili, DPM, Elisa Leporati, DPM, Vincenzo Scire, DPM, Ilaria Teobaldi, DPM, Stefano del Prato, MD, PHD. **DIABETES CARE, VOLUME 30, NUMBER 3, MARCH 2007 PAGG. 586- 590**

"Comparison of Removable and Irremovable Walking Boot to Total Contact Casting in Offloading the Neuropathic Diabetic Foot Ulceration".

Alberto Piaggese, MD, Chiara Goretti, MD, Elisabetta Iacopi, MD, Giacomo Clerici, MD, Fabio Romagnoli, MD, Fabrizia Toscanella, MD, and Cristiana Vermigli, MD.

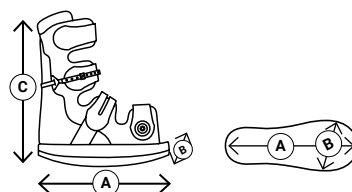
FOOT & ANKLE INTERNATIONAL 1- 7 THE AUTHOR(S) 2016

Class I medical device according to Regulation (EU) 2017/745

In accordance with Recommendations 1a-1b-2-5-6-7a-7b-7c-9; and conversion from acute to chronic phase of the IWGDF International Guidelines on the Management of Diabetic Foot Ulcers. <https://iwgdfguidelines.org/guidelines/guidelines>

SIZES

	S 34-36	M 37-39	L 40-42	XL 43-45	XXL 46-48
A MM.	247	267	288	316	336
B MM.	101	108	115	119	131
C MM.	315	320	330	350	360
PESO GR. without insole	480	574	626	730	917



Optima Molliter Srl

Company Certified under: ISO 9001:2015 IT346378 - ISO 13485:2016 IT346377

Via Breda 19/21 62012 Civitanova Marche (MC) Italy T +39 0733 801060

info@optimamolliter.com / www.yda.it / www.optimamolliter.com

