

TECHNICAL INFORMATION

SBI FRAME

HIGH LEG-FOOT BRACE

Treatment for stabilising the foot and ankle.

PRODUCT COMPONENTS

- 1- Soft upper / Soft tibial protection
- 2- AFO Main Unit
- 3- Extraction buttons
- 4- NRS Non Removable System
- 5- Strap belt
- 6- Semi-rigid tibial reinforcement
- 7- Buckle
- 8- Front sole locking points



The SBI 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

- Foot stabilisation
- Ankle fracture
- Severe ankle sprains
- Metatarsal fracture, post-operative use.
- In the acute phase, if made non-removable with the NRS system, as a second option for Charcot foot management.
- In the acute phase, removable, as a third option for Charcot foot management.
- Management of Charcot foot in the transition from acute to chronic phase.

TECHNICAL FEATURES

Customizable fixing system.

Removable and heat-mouldable liner with internal anatomical design.

Rigid protection for tibia (2 parts, one soft and one semi-rigid) removable and heat-mouldable.

Removable rocker sole

TECHNICAL CHARACTERISTICS

MATERIALIALS:

SEMI-RIGID TIBIAL REINFORCEMENT AND BUCKLES: TPU UPPER

SOFT TIBIAL PROTECTION AND PLANTAR INSOLES: E.V.A.

AFO ED AFO OPEN: MAIN UNIT PP

SCREWS: GALVANIZED STEEL

NUTS: GALVANIZED IRON

OUTSOLE: E.V.A. + NYLON

VELCRO: POLYAMIDE + POLYESTER

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

SBI PRODUCTS ARE LATEX FREE

CLOSURE: 4 VELCROS.

PACKAGING: WEIGHT: GR 106 / MATERIAL: CARTON + NYLON

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

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

BASE COMPONENTS: MONOLAYER / PROTECTIVE SOCK

ADDITIVES: INSOLE PLTM / SBI KIT 3X3 PLANTAR INSOLE

PRODUCT CLEANING

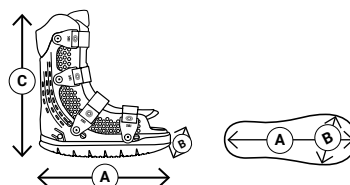
The cleaning of the product must be carried out as follows: Rigid support (2): in the dishwasher (maximum temperature: 45°) or by hand with mild soap and cold-water rinsing. Soft coating (1), Sole (9-10), tibial reinforcement (6): use cold water and clean with mild soap; rinse once the operation is completed. Straps (5), Buckles(7), Sock (13): washing machine, cold water. Screw buttons (11), and Nut elements (12): once removed, they must be cleaned with a soft cloth and dedicated galvanized steel cleaning product (screw buttons) and a dedicated product for galvanized iron (nut elements). Avoid any corrosive liquids such as alcohol, bleach, ammonia, solvents, peroxides or optical bleaching agents. Avoid using abrasive rubbers 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 that attack the materials and by direct exposure to heat sources. Dry by hand with a soft cloth or air dry away from heat sources; avoid direct sunlight. Do not use driers or drying machines/tumble driers.

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

In accordance with the conversion from acute to chronic for Charcot Foot in 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.	265	285	308	330	350
B MM.	118	125	138	143	148
C MM.	325	342	356	365	372
PESO GR. without insole	810	899	1086	1213	1333



Optima Molliter Srl

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

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