INSTRUCTIONS FOR USE

ACUTE PHASE

OPTIMA MOLLITER

WARNINGS

1. THE PRODUCT

Optima Molliter S.r.l. declares that Optima Molliter walkers are medical devices conceived following the current state of the art, have been tested to be in compliance with Directive 93/42 EEC, as amended, in its applicable sections. Nevertheless, bear in mind that inappropriate use of product or underestimation of resulting dangers can cause injuries or harm.

FOR A CORRECT USE

- The product must be sold and used only if prescribed by a doctor or recommended by a licensed healthcare professional.
- Multi-layered insoles Kit 3*3 (standard in Optima Diab and Optima Clheel products), single-piece insoles (standard in Optima Post Op, Optima Europa and Optima Free products) must be handled only by specialised personnel (doctor, nurse, specialised orthopedic technician, or licensed healthcare professional).
- Strictly follow cleaning and storage instructions.
- Do not use or pay utmost care when using tools, blades or tools that can pierce, scratch and/or permanently damage the product.
- Pay utmost care when walking if there are liquids or slippery substances on the floor.
- This device is not a toy or a tool.
- Driving is advised against while wearing OPTIMA DIAB, OPTIMA POST OP, OPTIMA EUROPA, OPTIMA CLHEEL and OPTIMA FREE walkers.
- Do not expose the product to open flames or excess heat sources.
- Make sure that all fasteners are firmly secured before using the device to walk.

2. THERAPEUTIC USE

2.1 THERAPEUTIC INDICATIONS

OPTIMA DIAB: diabetic foot ulcer. Foot ulcer, Rehabilitation after minor amputation (except for Lisfranc and Chopart amputations). Rehabilitation after tarsus surgery. Management of Charcot foot during transition from acute to chronic phase. Malleolar fracture. Metatarsal fracture.

OPTIMA POST OP: diabetic foot ulcer with vascular complications in the leg, neuroischemic ulcer before and after revascularization (with additional use of the 3*3 Kit). Management of non-injured foot or management of patients at risk for foot ulceration. Metatarsal compound fracture. Rehabilitation after toe amputation. Preoperative stabilisation. Fracture of toes. Toe surgery.

OPTIMA EUROPA: management of interdigital ulcer, management after bunion surgery. After hammer toe surgery. Post-operative management of Morton's toes Morton's neuroma. Fracture of toes. Nail excision. Plantar wart excision. Interdigital lesion. Toe lesions.

OPTIMA FREE: management of dorsal foot ulcer. After forefoot surgery. After toe surgery. After bunion surgery. Recommended for containing functional bandages.

OPTIMA CLHEEL: management of heel ulcer (plantar and dorsal) heel ulcer. Ulcer/laceration of Achilles tendon. Heel decubitus ulcer (plantar and dorsal). Postoperative rehabilitation of heel/Achilles tendon.

2.2 LIMITATIONS

The product has limitations that derive from the specific use and the characteristics of the materials used. Stop using the device and contact your doctor should structural changes in the device be noticed or negative walking alterations are caused.

3. LIMITS OF LIABILITY

3.1 OVERVIEW

The manufacturer Optima Molliter S.r.l. shall not be held liable if the product is used under conditions listed below as improper use.

3.2 INCORRECT USE

Improper use means using the product in the following conditions:

- failure to comply with the therapeutic indications;
- failure to comply with the rules and instructions of the manufacturer;
- non-compliance with or use contrary to current safety standards;
- significant alteration of dimensions;
- significant alteration of the structure by changing/adding items;
- adapting the product with significant alteration of its shape;
- use product to practice sports, even if not extensive;
- use of unsuitable cleaning products;

- unsuitable storage;
- product abuse;
- driving automobiles while wearing Optima Molliter products.

4. INSTRUCTIONS FOR USE

4.1 OVERVIEW

The product keeps its characteristics unchanged if used and adequately maintained throughout its useful life (one season/6 months on average), depending on environmental features and product use. It is important not to change structure and expected support points, so as not to alter product performance. It is important not to change the structure and the expected support points so as not to alter the product performance.

4.2 PRODUCT CLEANING AND STORAGE

- 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.

5. DISPOSAL OF THE PRODUCT

Dispose of product responsibly. Refer to the Italian and local regulations on the disposal of inert products.

6. PRODUCT IDENTIFICATION DATA

DATA	DETAILS
Year of manufacture	2018
Dimensions	according to sizes and products
Weight	according to sizes and products
Product class	class I Directive 93/42 CEE, as amended
Manufacture lot	according to the code affixed on the front of each box
Size	S (34-35-36) M (37-38-39) L (40-41-42) XL (43-44-45) XXL (46-47-48)

Optima Molliter walkers and Optima Molliter insole kits are manufactured entirely in Italy.

7. WARRANTY

The warranty which refers only to defects of materials used and manufacturing defects, protects the footwear pursuant to the law and may include product replacement, only if recognized as defective by the Company.

The warranty has no effect in case of:

- damage caused by transport and not notified by the purchaser to the carrier upon delivery;
- repairs carried out by persons other than the manufacturer;
- regular product wear;
- damage attributable to the purchaser resulting from improper use of the product, incorrect maintenance or negligent storage.

7.1 PRODUCT RETURN SYSTEM

The item considered defective can be returned by the retailer or the customer, only if authorised by Optima Molliter S.r.l. It must be sent to Optima Molliter S.r.l. with its original packaging and proof of purchase, at the recipient's expense. Should the Company be held liable, the product shall be replaced and sent by the Company to the retailer or the customer at the recipient's expense.

CUSTOMISING THE KIT 3*3 AND THE KIT CLHEEL

A. PATIENTS WEIGHING LESS THAN 90 KG

(Mark the ulcerated/injured plantar point on the BEIGE insole).

1. cover the plantar injury/ulcer with a transparent sterilised film and using a lipstick or non-permanent marker mark the perimeter of the injury/ulcer directly over the transparent film (Fig. T.1);
2. insert the entire insole KIT 3*3 into the device and make sure that the BEIGE insole is in contact with the foot (BEIGE-RED-BLUE);
3. put the patient's foot into the device and help the patient to walk (10 steps). In this way, the plantar surface will be marked at the injury point;
4. now, open the device and remove the entire insole system;
5. using a pen mark the perimeter of the imprint with a plus margin of about 6/8 mm (fig. T.2a);
6. using a scalpel with a 10 mm-blade perforate the perimeter of the mark with the blade at about 45° (fig. T.2b);
7. assemble the components according to the desired pressure redistribution (see Diagram A) and insert the entire insole system into the device;
8. make sure that the insole with the hole is in the intermediate segment;

WARNING: THE AREAS WITH THE OFF-LOADING HOLE MUST NEVER BE IN CONTACT WITH THE PLANTAR ULCER/INJURY.

9. to avoid infections, always protect the ulcer/injury with suitable dressing before using the KIT 3*3 or the KIT CLHEEL;
10. once the bendage or the sock has been put on, the device can now be used by the patient.


Fig. T.1


Fig. T.2a


Fig. T.2b


Fig. T.3a


Fig. T.3b


Fig. T.3c

B. PATIENTS WEIGHING MORE THAN 90 KG

(Mark the ulcerated/injured plantar point on the BLUE insole).

1. Cover the plantar injury/ulcer with a transparent sterilised film and using a lipstick or non-permanent marker mark the perimeter of the injury/ulcer directly over the transparent film (Fig. T.1);
2. insert the entire insole KIT 3*3 into the device and make sure that the BLUE insole is in contact with the foot (BLUE-BEIGE-RED);
3. put the patient's foot into the device and help the patient to walk (10 steps). In this way, the plantar surface will be marked at the injury point;
4. now, open the device and remove the entire insole system;
5. using a pen mark the perimeter of the imprint with a plus margin of about 6/8 mm (fig. T.3a);
6. using a scalpel with a 10 mm-blade perforate on the BLUE insole the perimeter of the mark with the blade at about 45° (fig. T.3b);
7. place the BLUE drilled part on the corresponding BEIGE part. Mark the base of the conical hole with a pen. Drill a conical hole also on the BEIGE insole (fig. T.3c);
8. assemble the components according to the desired pressure redistribution (see Diagram B) and insert the individually adapted insole system into the device;
9. make sure that the BLUE insole with the hole is in the intermediate segment and the BEIGE insole in the segment below;

WARNING: THE AREAS WITH THE OFF-LOADING HOLE MUST NEVER BE IN CONTACT WITH THE PLANTAR ULCER/INJURY.

10. to avoid infections, always protect the ulcer/injury with suitable dressing before using the KIT 3*3 or the KIT CLHEEL;
11. once the bendage or the sock put on, the device can now be used by the patient.

WARNING: REPLACE THE ENTIRE KIT 3*3 or KIT CLHEEL every 21 days after the specialist so prescribes (in case the ulcer/injury is not cured yet).

For further information, request the video with the instructions for use to the following e-mail address: info@optimamolliter.com

Diagram A

customisation for patients **weighing less than 90 kg**

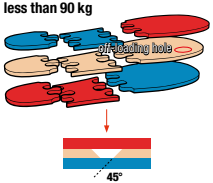
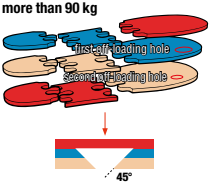


Diagram B

customisation for patients **weighing more than 90 kg**

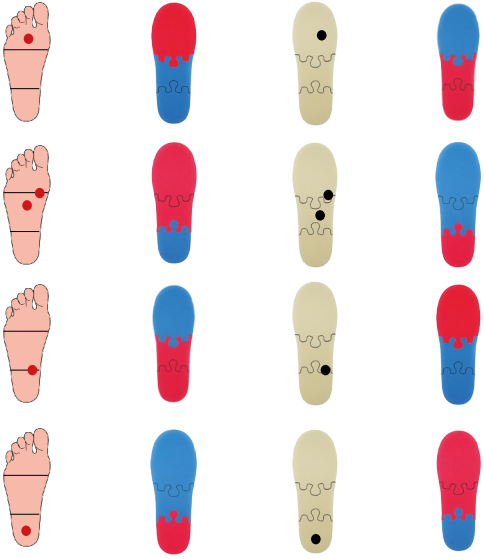


INSOLE CUSTOMISATION

INSOLES CUSTOMIZATION OF THE OFF-LOADING SYSTEM OPTIMA MOLLITER

FOOT/WOUND	INSOLE 1	INSOLE 2	INSOLE 3

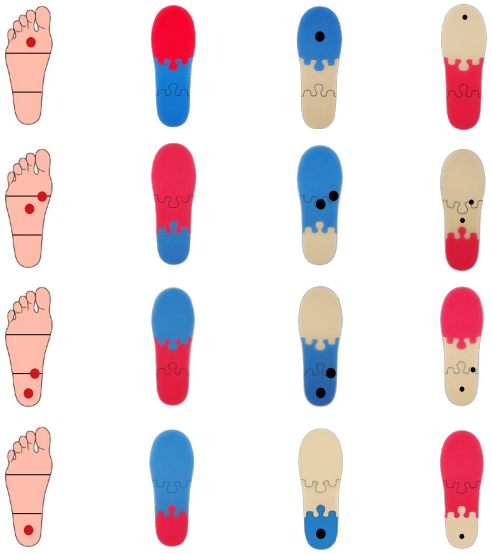
Patient < 90 Kg



INSOLES CUSTOMIZATION OF THE OFF-LOADING SYSTEM OPTIMA MOLLITER

FOOT/WOUND	INSOLE 1	INSOLE 2	INSOLE 3

Patient ≥ 90 Kg



KEY POINTS	
	The wound is always located above the red insole
	Patient weighing < 90 Kg 1 insole perforation
	Patient weighing ≥ 90 Kg 2 insole perforations
	Select always a size up than the patient's usual size
	5 sizes: S (34-35-36), M (37-38-39), L (40-41-42), XL (43-44-45), XXL (46-47-48)
	Insole shore hardness: Red: soft hardness Beige: medium hardness Blu: hard hardness

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