



INSTRUCTIONS FOR USE

MAC 123



Via Breda, 19/21 - 62012 CIVITANOVA MARCHE (MC) I

WARNINGS

THE PRODUCT

Optima Molliter S.r.l. declares that MAC 1-2-3 shoes are conceived and designed to treat alterations of foot morphology, in accordance with the current state of the art. They are Class I medical devices, pursuant to Directive 93/42 CEE, as amended, if used for personalized or customized insoles made and controlled applying standard tests by licensed healthcare professionals to treat changes to foot morphology. MAC 1-2-3 footwear comply with international guidelines for management of diabetic foot. Nevertheless, it should be considered that inappropriate use of the product or underestimation of resulting hazards can cause injuries or harm.

FOR A CORRECT USE

2.1 INTENDED USE

THERAPEUTIC INDICATIONS MAC1: semi-rigid footwear with rocker design (boat-shaped), with space for a removable insole. It is a medical device if used for personalized or customized insoles made and controlled applying standard tests by licensed healthcare professionals to treat changes to foot morphology.

It is recommended for:

- primary prevention of diabetic foot with Level 0 risk (no neuropathy-no vasculopathy);
- primary prevention of diabetic foot with Level 1 risk (neuropathy-vasculopathy), only if used with an insole made on the patient's foot template by a licensed healthcare professional;
- metatarsalgia, only if used with insole made from the patient's foot template by a licensed healthcare professional;
- polyarthritis, only if used with insole made from the patient's foot template by a licensed healthcare professional;
- Morton's neuroma, only if used with insole made from the patient's foot template by a licensed healthcare professional;
- arthrosis, only if used with insole made from the patient's foot template by a licensed healthcare professional;

THERAPEUTIC INDICATIONS MAC2: rigid-sole footwear with rocker design (boat-shaped), pre-fitted for removable insole. It is a medical device if used for secondary prevention purposes of diabetic patients with Level 2 or Level 3 risk. It must be provided with medical prescription and always accompanied by an insole made from the patient's foot template by a licensed healthcare professional.

It is recommended for:

- patients with previous ulcers at risk of relapse (Level 2 risk);
- patients with previous ulcers at risk of relapse (Level 2 risk);
- arthrodesis of toes;
- arthrodesis of the tarsus;
- Charcot foot;
- biomechanical movement problems;

All MAC2 footwear must be worn only with an insole made from the patient's foot template by a licensed healthcare professional. Any other use is expressly prohibited and considered improper.

THERAPEUTIC INDICATIONS MAC3: footwear with semi-rigid sole and rocker design (boat-shaped), pre-fitted for removable insole. It is a medical device for secondary prevention in high-risk diabetic patients.

It is recommended for:

- metatarsalgia, only if used with insole made from the patient's foot template by a licensed healthcare professional;
- biomechanical movement problems;
- metatarsalgia, only if used with insole made from the patient's foot template by a licensed healthcare professional.

2.2 LIMITATIONS

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

3. LIMITS OF LIABILITY

3.1 IMPROPER USE

Improper use means using the product in the following conditions:

- failure to comply with the rules and instructions of the manufacturer;
- non-compliance with or use contrary to current safety standards;

- for healing purposes without a personalized insole made by a licensed healthcare professional;
- for healing purposes, without medical indications;
- for MAC2 footwear, without a personalized insole made by a licensed healthcare professional;
- alteration of dimensions;
- alteration of the structure by changing/adding items;
- adaptation of footwear by altering the form;
- use product to practice sports, even if not extensive;
- use of unsuitable cleaning products;
- unsuitable storage;
- patients with plantar lesions;
- patients with allergies to components and/or processing of components and/or materials used to manufacture the footwear;
- wearing the product when there are osteo-structural alterations of the foot and/or concomitant metabolic and/or neurological and/or vascular disorders without medical written prescription/indication;
- use in presence of liquids and/or substances and/or slippery/oily surfaces.

3.2 PRECAUTIONS

- Strictly follow cleaning instructions;
- do not expose product to open flames or heat sources in general;
- do not use tools, blades and tools that can pierce, scratch and/or permanently damage the product;
- do not soak the product in water, solvents and liquids in general;
- pay utmost care when walking if there are liquid substances on the floor; do not walk on slippery/oily floors or substances;
- do not store product in a damp place;
- do not let product come in contact with water;
- it is expressly prohibited to use the product for any purpose other than as footwear and, in particular, to use the product as a weapon, tool or toy.

4. INSTRUCTIONS FOR USE

The product keeps its characteristics unchanged if used and adequately maintained throughout its useful life (one season/6 months on average), depending on environmental characteristics and its use.

MAC1 and MAC3 products can be used directly, or can accommodate a suitable orthopaedic insole made by a licensed healthcare professional replacing the one supplied as standard with the footwear.

The MAC2 product can only be used only if prescribed by a doctor (rigid-sole footwear with rocker sole or boat-shaped sole) and only with an insole made from the patient's foot template by a licensed healthcare professional.

It is important not to change the structure and the expected support points so as not to alter product performance. We point out that the lining is made exclusively with materials that have not been chemically treated and not with prohibited products, and, that in any case, discoloration and/or stains caused by normal foot transpiration must be regarded as natural. We recommend wearing socks with both winter and summer footwear.

4.1 PRODUCT CLEANING

The product must be cleaned using:

- for leather: creams (moisturising-polishing) specific for the type of leather to be treated and compliant with and approved by the CEE, applied and polished with a clean, dry, soft and non-abrasive cloth;
- for suede or similar products: only brushes or soft cloths; remove any stains (mud and the like) only when leather is dry.

Make sure you regularly hydrate the leather by applying special creams, especially in the case of particularly soft leather, such as nappa and suede.

Do not use alcoholic and corrosive liquids, detergents, alcohol, laundry detergents, bleach, ammonia, and solvents.

Do not use abrasive materials and/or products, brushes, steel wool, glass paper, blades or similar, to remove stains or residues.

Do not wash the product.

Do not let the product come in contact with water.

If the product gets accidentally wet, let it dry away from heat sources and in a dry environment.

4.2 WASHING INSTRUCTIONS

Footwear **MUST NOT** be machine-washed or washed by being immersed in or put under water. To clean the lower lateral surface of the sole, use soft sponges dampened in warm water not exceeding 30°C, and neutral soap.

Do not use abrasive or aggressive degreasers; preferably use detergents with a high degree of biodegradability.

Do not dry the wet or soaked product in front of heat sources. This may irreparably damage the footwear and the warranty will be void.

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 and by improper use/maintenance.

5. DISPOSAL OF THE PRODUCT

The materials used in MAC 1-2-3 footwear are partially environmentally friendly, and, therefore, must be disposed of in accordance with specific recommendations. Dispose of product responsibly.

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

6. PRODUCT IDENTIFICATION DATA

DATA	SPECIFICATION
Year of manufacture	2018
Dimensions	according to sizes, footwear numbers, fitting and models
Weight	according to sizes, models and types of sole applied
Product class	class I Directive 93/42 CEE, as amended, when used as medical device
Manufacture lot	according to the code number on the front piece of each box under the photo of the item

7. WARRANTY

The warranty which refers only to defects of materials used and manufacturing defects, protects the footwear pursuant to the law, only if recognized as defective by the Company, after application of the proof of purchase of the product on the back of the booklet.



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