

SBI

INSTRUCTIONS FOR USE

**SBI MOTUS
SBI FRAME
SBI W-HEEL**

WARNINGS AND PRECAUTIONS

1. THE PRODUCT

Optima Molliter S.r.l. declares that SBI Motus, SBI Frame and SBI W-Heel walkers are medical devices conceived and designed following the current state of the art, and have been tested to be in compliance with Directive 93/42 CEE in its applicable sections. Nevertheless, bear in mind that inappropriate use of product or underestimation of resulting dangers can cause injuries or harm. Read the following instructions carefully and thoroughly before using any SBI products. They must be correctly used to be effective. Frequently check that no hot spots and irritation appear on the skin. If changes are seen on the skin or pain is felt, reposition the Velcro fixing systems. Do not use these devices if there is a decreased sensitivity resulting from anaesthetic administration. Always protect leg and foot with the specific sock (Protective Sock) supplied together with the SBI walker. Pay utmost care when walking on slippery or wet surfaces. Never walk without the walker sole.

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 with **SBI Motus** and **SBI W-Heel**), single-piece insoles (standard in **SBI Frame**) or **PLTM** insoles must be handled only by specialized staff (a doctor or a licensed healthcare professional);

- Strictly follow cleaning and storage instructions;
- In a NOT contralateral injured foot, it is advisable to wear protective footwear with a sole 3 cm high or more (YDA footwear - www.yda.it or MAC footwear - www.optimamolliter.com);
- Pay utmost care when walking when there are liquids or slippery substances on the floor;
- This device is not a toy or a tool;
- Driving is advised against if you are wearing a SBI Motus, SBI Frame or SBI W-Heel;
- Do not expose the product to open flames or sources of excess heat;
- Make sure that all fasteners are firmly secured before using the device to walk;
- Make sure that the sole is firmly fastened before using the device to walk.



SBI Frame



SBI Motus



SBI W-Heel

2. INTENDED USE

2.1 THERAPEUTIC INDICATIONS

SBI Frame:

Foot stabilization, ankle fractures, serious ankle sprains, metatarsal fractures, postoperative use.

SBI Motus:

Foot stabilization with ulcer/diabetes-related plantar wound offloading, ulcer/forefoot and midfoot plantar wound offloading, post surgery or other wound.

SBI W-Heel:

Heel wound/ulcer management.

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. The product is only suitable for use by individuals **weighing up to 130 kg**.

3. LIMITS OF LIABILITY

3.1 OVERVIEW

The manufacturing process complies with the state of the art, following currently known and disclosed information at a technical scientific level. Optima Molliter S.r.l. shall not be held liable if the product is used under the conditions listed below as improper use.

3.2 IMPROPER 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 SBI products;
- device components are assembled/disassembled by non-qualified personnel;
- failure to comply with assembly or disassembly instructions;
- walking without the SBI sole.

4. INSTRUCTIONS FOR USE

4.1 OVERVIEW

SBI Motus, SBI Frame and SBI W-Heel keep their characteristics unchanged if used and maintained adequately throughout their useful life (6 months on average) depending on environmental characteristics and how they are used. The products can be used directly or with the relevant changes in insoles, as expressly indicated above. It is important not to change the structure and the expected support points so as not to alter the product performance. There are no known contraindications.

4.2 PRODUCT CLEANING AND STORAGE

- Rigid support (1): in the dishwasher (maximum temperature: 45°) or by hand with mild soap and cold-water rinsing;
- Soft coating (2-2a), Sole (5-5a), Tibial reinforcement (3): use cold water and clean with mild soap; rinse once the operation is completed;
- Straps (4), Buckles (8), Socks (11): washing machine, cold water;
- Screws button (7) and Nut elements (7.1): 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 dryers.



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|--------------|--------------------------------------------------------------------|--------------|------------------------------------------------|
| 1 | AFO (SBI Motus, SBI Frame) or AFO open (SBI W-Heel) main unit (PP) | 5a | Rocker Sole (SBI Frame) |
| 1a/1b | Extraction buttons | 5b/5c | Front sole locking points |
| 2 | Soft E.V.A. upper | 6 | NRS- Non removable System (SBI Motus) |
| 2a | Soft E.V.A. protection | 7 | Screws-in button |
| 3 | Semi-rigid tibial reinforcement (TPU) | 7.1 | Nut elements |
| 4 | Strap belts | 8 | Buckles |
| 5 | Fully Rocking sole (SBI Motus/ SBI W-Heel) | 9 | KIT 3*3 |
| | | 10 | PLTM |
| | | 11 | Protective Sock |

5. DISPOSAL OF PRODUCT

The materials used in SBI products are partially environmentally friendly, and therefore, require some specific measures for product disposal. Dispose of product responsibly. Refer to the Italian and local regulations on the disposal of inert products and plastics. PP and ABS parts are 100% recyclable and can be disposed of with plastic waste.

6. PRODUCT IDENTIFICATION DATA

TECHNICAL DATA and PARAMETERS

Year and place of manufacture	2020 Made in Italy
Manufacturer and person in charge of marketing	Optima Molliter srl - Via Breda 19/21 Civitanova Marche (Mc) Italy

DIMENSIONS

SBI MOTUS	S	260x120x335	M	285x128x350
SBI W-HEEL	L	300x135x345	XL	320x143x360
	XXL	340x158x375		

SBI FRAME	S	260x120x330	M	285x128x340
	L	300x135x350	XL	320x143x360
	XXL	340x158x375		

SBI MOTUS		0.77	M	0.87	L	1.05
Net Weight	XL	1.15	XXL	1.26		

SBI FRAME		0.76	M	0.86	L	1.03
Net Weight	XL	1.16	XXL	1.25		

SBI W-HEEL	S	0.74	M	0.85	L	1.03
Net Weight	XL	1.13	XXL	1.27		

Product classification	class I Directive 93/42 CEE					
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EITHER-FOOT SIZE	SIZES: S (small) M (medium), L (large) XL (extra large) XXL (extra extra large) EUR: S 34-36, M 37-39, L 40-42, XL 43-45, XXL 46-48					
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Manufacture lot	As described on the label inside each AFO or AFO OPEN main unit					
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SBI materials used	Semi-rigid Tibial Protection and Buckles (TPU), Upper, Soft Tibial Protection and Insoles (EVA), AFO and AFO OPEN (PP), Zinc plated steel screw buttons, Zinc plated iron nuts, Sole (EVA+Nylon), Velcro Polyamide+Polyester), Protective Sock (90% Cotton, 7% Polyamide, 3% Spandex)					
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Packaging	Weight gr 106	Material: Cardboard + Nylon				
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SBI products are Latex-Free

7. WARRANTY

The warranty, covering only defects in the materials used and only manufacturing defects, protects products as required by law. Optima Molliter S.r.l. will totally or partially replace the product or its accessories within six (6) months after the purchase date in case of manufacturing defects. 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 due to improper use of the product, incorrect maintenance or negligence during storage.

7.1 PRODUCT RETURN SYSTEM

The item considered defective can be returned by the retailer or the customer, only if authorized by Optima Molliter S.r.l.. Such item must be sent to Optima Molliter S.r.l. together with its original package and the proof of purchase, and only carriage free. Should the Company be held liable, the product shall be replaced and sent by the Company to the retailer or the customer.

8. HOW TO PREPARE AN SBI DEVICE

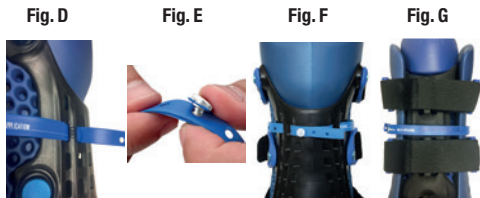
8.1 HOW TO APPLY AN SBI DEVICE

- Open the straps and remove the front tongue (fig. A);
- put on the protective sock included with the walker (**11 Protective Sock**);
- once seated, put your foot into the walker by positioning the heel in the rear section of the SBI device (fig. A). Position the tongue (tibial protection 2a+3) over the top of the foot and leg. Pay attention that the word SBI is positioned as illustrated in the drawing, near the toes (fig. B). Close the straps in the order indicated from No. I to No. IV and carefully insert them into their slits, Ia-Ila-Illa-IVa (fig. C).



8.2 HOW TO APPLY THE NON-REMOVABLE SYSTEM (NRS)

- The indication for the Non Removability of the **SBI Motus** Walker must be given only by the specialist prescribing the device after assessing the patient's clinical conditions;
- the Non-Removable System (NRS) must be applied only by a specialist or a licensed healthcare professional; it is advisable to detach the AFO main unit (1) from the walker before inserting the NRS strap (Non-Removable System);
- each package of the **SBI Motus** Walker contains 1 single-use NRS (6);
- insert the first strap into the corresponding lateral slit of the walker bearing the acronym NRS (Fig. D) on it. Insert the second strap into the opposite slit of the walker bearing the acronym NRS on it and close the first button at the back (Fig. E-F) and then the second one in the front (Fig. G);
- use a permanent marker to write the date the device was applied in the specific space on the NRS strap;
- the NRS system must be removed and replaced in 7 days.



8.3 FITTING AND REPLACES THE SBI FRAME, SBI MOTUS AND W-HEEL SOLE

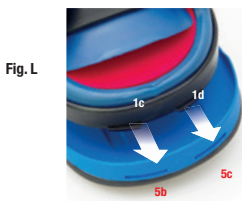
WARNING: Soles can be easily and quickly fitted, removed and replaced from the main unit. However, it is important not to underestimate the risks deriving from an improper use of the system. Before removing the SBI sole, read the following instructions carefully.

WARNING: Never walk without SBI Frame, SBI Motus and SBI W-Heel sole. Walking without SBI Frame, SBI Motus and SBI W-Heel sole is extremely dangerous and might cause falls and adverse events.

REMOVING THE SOLE: Simultaneously press the two release push-buttons 1a and 1b (Fig. H) with the same hand; then pull the sole downwards with the other hand. Now, both front locking points (5b/5c) can be easily released.



FITTING THE SOLE: Place the sole on a flat surface, insert the connectors of the tip of the AFO or AFO OPEN main body in the two front locking points (1c/1d) into the specific slits of the sole (Fig. L). Now, press SBI Frame, SBI Motus or SBI W-Heel towards the sole until two “clicks” can be heard (Fig. M). Make sure that the sole is firmly fastened to the SBI device. Risk of slipping on wet surfaces!



9. INSTRUCTIONS FOR THE ORTHOPAEDIC TECHNICIAN OR LICENSED HEALTHCARE PROFESSIONAL

9.1 REMOVING AND FITTING SCREWS-IN BUTTON AND BUCKLES OF FRAME, SBI MOTUS AND SBI W-HEEL

WARNING: Screws (7-7.1) and Buckles (8) can be released from the main unit (1) and repositioned in the specific seats (Fig. S) easily and quickly. However, it is important not to underestimate the risks deriving from incorrectly fitting and removing them. SBI Buckles and Buttons should be fitted and removed by qualified personnel such as an orthopaedic technician or licensed healthcare personnel. Before releasing the Screws and Buckles, read the following instructions carefully.

REMOVING AND FITTING SCREWS-IN BUTTON OF SBI FRAME, SBI MOTUS AND SBI W-HEEL

Each walker is supplied with 8 SBI screws-in buttons and 8 nut elements.

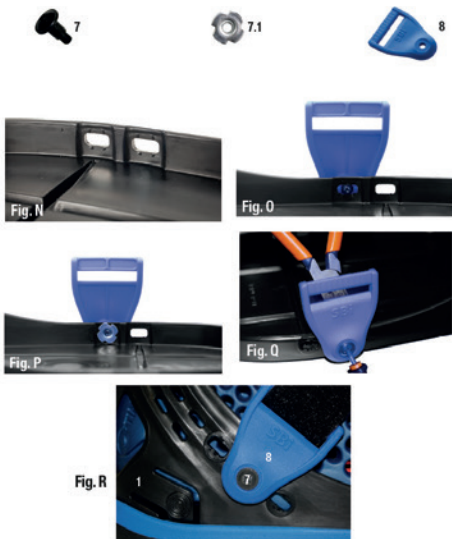
REMOVE THE SCREW-IN BUTTON OF SBI FRAME, SBI MOTUS AND W-HEEL: Remove the entire upper soft part and the sole of SBI Frame, SBI Motus and SBI W-Heel. Use a screwdriver (to unscrew or tighten screw 7) and pliers (to lock the female internal nut element 7.1). Turn the screw counterclockwise until the outer part of screw-in button is dislodged from the internal portion (fig. Q).

INSERT THE SCREW-IN BUTTON OF SBI FRAME, SBI MOTUS AND W-HEEL: Remove the entire upper soft part and the sole of SBI Frame, SBI Motus and W-Heel. Insert the male portion 7 in the dedicated buckle 8 and place it on the outside part of rigid support 1 (Fig. O). Then, insert the female nut element (7.1) on the inside of rigid support 1 (Fig. P). Clamp the nut element with pliers and turn the external male screw button (7) with the screwdriver until the two elements lock (Fig. Q).

WARNING: The screw-in button is made of metal material; screw the two parts taking care not to damage the button thread or head.

REMOVING AND FITTING SBI BUCKLES:

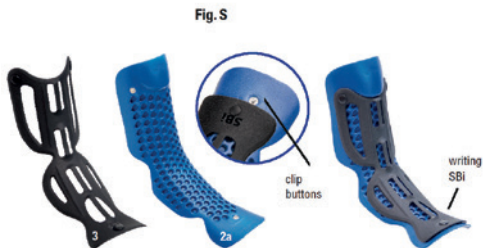
Each SBI Frame, SBI Motus and SBI W-Heel is supplied with 8 "SBI Buckles" (8). To make the process easier, it is advisable to remove the sole of SBI Frame, SBI Motus and W-Heel.



FITTING THE BUCKLE OF SBI FRAME, SBI MOTUS AND SBI W-HEEL: Refer to the procedure “Removing and fitting the screws-in button of SBI Frame, SBI Motus and SBI W-Heel”.

9.2 REMOVING AND REFITTING THE TIBIAL REINFORCEMENT FROM THE TIBIAL PROTECTION

The SBI Frame, SBI Motus and SBI W-Heel Semi-rigid Tibial Reinforcement clip (3) can be easily removed from and refitted into the soft Blue Tibial Protection (2a) thanks to a button system. To remove, unhook the 3 buttons on the reinforcement. To refit it, just reposition it, paying attention to the direction, ensuring that the section bearing the writing “SBI” is near the toes, then hook the 3 buttons (fig. S).



9.3 CUSTOMISING THE KIT 3*3

The modular system **KIT 3*3** included in SBI Motus and SBI W-Heel and optional in SBI Frame is designed to redistribute plantar pressures and manage ulcers/injuries from pressure in the forefoot, midfoot and heel.

WARNING: Only physicians, carers, orthopaedic technicians or qualified healthcare personnel can customise the **KIT 3*3**.

WARNING: The **KIT 3*3** must be used only if inside **SBI Motus** (1 kit comes as standard), **SBI W-Heel** (1 kit comes already as standard), and **SBI Frame** (optional) devices. Never use **KIT 3*3** in regular footwear or other walkers. Optima Molliter S.r.l. shall not be held liable if the **KIT 3*3** is used in devices other than the SBI Frame, SBI Motus or SBI W-Heel ones.

WARNING: The **KIT 3*3** must be used always together with all its components mutually well connected inside the SBI device.

1. **KIT 3*3** (9) consists of 9 interconnected parts in a Puzzle system forming 3 different small plantar soles;
2. the three plantar small soles have 3 different densities (red = soft, beige = medium, blue=rigid) and they can be combined vertically and horizontally. Plantar pressure can be easily redistributed by combining these soles. The procedure consists in simple steps;
3. to reduce pressure on an ulcerated/injured area, the **KIT 3*3** can be customised by marking and cutting part of the plantar small soles:

A. PATIENTS WEIGHING LESS THAN 90 KG (Mark the ulcerated/injured plantar point on the BEIGE small sole).

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, position the tibial tongue and close the 4 straps. 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 **KIT 3*3**;
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 **KIT 3*3** into the device;
8. make sure that the small sole 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**;
10. once the **Protective Sock** (11) (supplied with each product) has been put on, the device can now be used by the patient.

WARNING: NEVER USE THE SBI DEVICE WITHOUT THE **PROTECTIVE SOCK** (11).

B. PATIENTS WEIGHING MORE THAN 90 KG (Mark the ulcerated/injured plantar point on the BLUE small sole).

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, position the tibial tongue and close the 4 straps. 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 **KIT 3*3**;
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 entire **KIT 3*3** into the Device;
9. make sure that the BLUE sole with the hole is in the intermediate segment and the BEIGE small sole 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**;
11. once the **Protective Sock** (11) (supplied with each product) has been put on, the device can now be used by the patient.

WARNING: NEVER USE SBI FRAME, SBI MOTUS AND SBI W-HEEL WITHOUT THE INSOLE INCLUDED AND THE **PROTECTIVE SOCK** (11).

WARNING: REPLACE THE ENTIRE **KIT 3*3** 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**

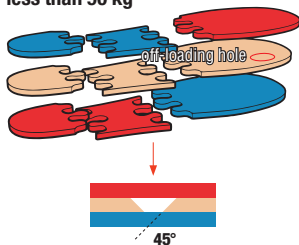
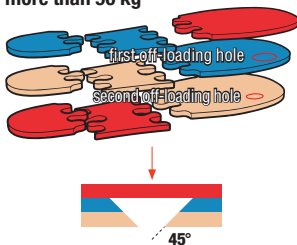


Diagram B

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



9.4 PREPARING THE PLTM INSOLE

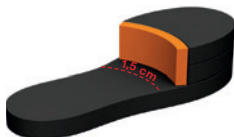
WARNING: **PLTM** must be prescribed only by a specialist physician and customised only by physicians, carers, orthopaedic technicians or qualified healthcare personnel.

WARNING: The **PLTM** must be used only if inside the **SBI Motus** (optional), **SBI W-Heel** (optional), **SBI Frame** (optional) walkers. Never use the **PLTM** in regular footwear or other devices. Optima Molliter S.r.l. shall not be held liable if the **PLTM** is used in devices other than products.

PLTM is designed for postoperative following toe amputation or transmetatarsal amputation.

1. Remove the adhesive film of the black Velcro band and attach it on the insole internal surface;
2. attach the orange material with the Velcro section on the Velcro band;
3. position the foot with minor amputation on the insole being careful that there is at least 1,5 cm between the foot and the orange material (fig. U);
4. always protect foot and leg with adequate dressing. Put on the protective sock supplied with each device over the dressing.

Fig. U



The background features a large, abstract composition of overlapping shapes. On the left, a solid blue shape curves upwards. In the center, a vertical grey bar is partially obscured by a large, semi-transparent blue shape that resembles a stylized letter 'A'. To the right, an orange shape is visible, with several white, teardrop-shaped cutouts. The text 'INSOLES CUSTOMIZATION' is centered in the middle-right area, overlaid on the grey bar and the blue 'A' shape.

**INSOLES
CUSTOMIZATION**

INSOLES CUSTOMIZATION OF THE OFF-LOADING SYSTEM OPTIMA MOLLITER

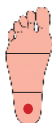
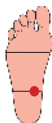
FOOT/WOUND

INSOLE 1

INSOLE 2

INSOLE 3

Patient < 90 Kg



INSOLES CUSTOMIZATION OF THE OFF-LOADING SYSTEM OPTIMA MOLLITER

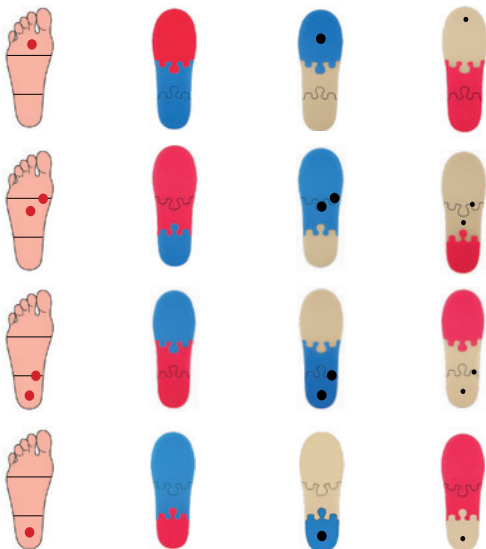
FOOT/WOUND

INSOLE 1

INSOLE 2

INSOLE 3

Patient \geq 90 Kg



KEY POINTS

The wound is always located above the red insole

Patient weighing $<$ 90 Kg 1 insole perforation

Patient weighing \geq 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

All the articles are medical devices Class I
non sterile according to Directive 93/42/EEC
and successive modifications and integrations.



Optima Molliter
Company Certified under:
UNI EN ISO 9001:2008 Certificate N° IT249551
and UNI EN ISO 13485:2012 Certificate N° IT249550

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