BOSCAROL IMMOBILISATION DEVICES

OB SPINAL BOARD

OPERATING INSTRUCTIONS

CE

Class I medical device in accordance with the European Medical Device Regulation 2017/745

PRODUCED BY:

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Manufacturer and medical device information:

- Oscar Boscarol applies a quality management system according to international standards ISO 13485 and ISO 9001
- Medical devices in the "Immobilisation" category (in all their configurations) comply with European Regulation MDR 2017/745 and bear the CE marking in accordance with risk class I (see Annex VIII of the Regulation)
- The medical device meets the safety and performance requirements (GSPR) described in Annex I of the European Regulation 2017/745

About these operating instructions:

- This document contains important information for a safe, effective and compliant use of the medical device
- Use the information reported to train users and confirm their training
- This manual may not be modified (even partially). Only the manufacturer of the device may make changes
- These instructions must always accompany the device. We recommend using the electronic version and making it available on operators' PDAs, tablets and mobile phones

These operating instructions apply to the following devices:

IMM121074A	IMM121077	IMM121078

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0. MEANING OF SYMBOLS AND PICTOGRAMS

0.1. Symbols used in these operating instructions to draw the reader's attention

	Danger: Important safety information on the correct use of the spinal board to prevent injury to the operator or patient and/or damage to the device itself
	Warnings: information requiring special attention
	Notes or information for proper use and to prevent damage to the device or others. Activate the correct preventive measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	Required maintenance service (please contact the manufacturer and/or its authorised service centres)

0.2. Symbols used on the device and accessories of the device

	Use the spinal board only within the specified temperature range. Using the spinal board outside these limits may decrease its functional performance and damage it
	Limits of use with regard to humidity
	Read these operating instructions carefully and completely
	Indicates the need for the user to consult these operating instructions for information such as warnings and precautions that cannot be displayed on the medical device in question
CE	CE marking in accordance with European MDR 2017/745 for class I medical devices
	Manufacturer
REF	Device reference code
	Please read the operating instructions in other languages available on the indicated website
MD	Indicates that the spinal board is a medical device
	Example of UDI-DI and UDI-PI code of medical device: (01) Identification of manufacturer and associated device (11) Production date (20) Product variant (10) Lot number

1. INTENDED USE

Device name	OB spinal board
Primary use	Professional-type medical device intended for the immobilisation and transport, in a horizontal position, of patients with spinal or limb injuries
Other Uses	No uses other than the primary use are envisaged
Medical purpose	Ensures correct, total and safe immobilisation of the spinal column and the patient during transfer

Part of application in the human body	Entire human body
Type of patients	Adults of both sexes and weighing over 40 kg
Application time on the same patient	Temporary' use (maximum 60 minutes of consecutive use)
Information on use	• Follow the procedures approved by the relevant Emergency Medical Service for the immobilisation, positioning and transport of the patient. • The device can be used simultaneously with other medical devices applied to the patient (e.g. a cervical collar) • The transport of a patient must always be carried out by professional rescuers who are trained and familiar with lifting and transport techniques
Misuse	The manufacturer accepts no liability in the event of use of the product under the conditions considered below as improper use: • Handling by unqualified personnel • Transport of patients with pathologies defined as not compatible by medical personnel • Failure of operators to comply with existing safety regulations/procedures • Transport of patients weighing more than 150 kg • Modifications or tampering not authorised by the manufacturer • Failure to comply with what is specified in this user manual.

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

These operating instructions have been prepared using simple, easy-to-understand language. In case of difficulty in interpreting what is written, please contact the manufacturer for further clarification.

Phone +39 0471 93 28 93 **info@boscarol.it**

LATTICE	The OB spinal board is constructed and manufactured without the use of latex. The materials used are latex-free, however, it cannot be ruled out that latex or traces of it may have come into contact throughout the production chain
DEVICE CONTAMINATED	Warning in case of device contamination: Transporting a patient with the spinal board can be a source of contamination. For this reason the device must be cleaned and disinfected after each use to eliminate any residual risk. Follow the instructions in this user manual. In case of doubt, please contact Boscarol's technical service department by sending an e-mail to info@boscarol.it or calling +39 0471 932893

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

The spinal board has been designed and tested to comply with the requirements of the Medical Device Regulation 2017/745. The spinal board is a medical device of risk class I according to Annex VIII of the Regulation.

Should the user or patient become aware of a danger in use, a side effect, an accident caused by the device, or a critical issue (operational and constructional) not addressed in these instructions for use, he or she must immediately report it to the manufacturer at: raq@boscarol.it

PERIODIC SAFETY INSPECTION	**Preventive maintenance and periodic safety inspection:** The spinal board must be checked periodically (a full functional check at least once a week is recommended) There is no periodic safety inspection on the device In case of failure, the device must be removed and replaced
LIFETIME	The OB spinal board has a lifespan of **3 years** from the date of manufacture if stored and used in accordance with these operating instructions
Responsibility of operators/users	• **Take precautions in case of direct contact of the device with the patient's body and always interpose sterile drapes (biocompatibility)** • The OB spinal board is designed for emergency medical service and must therefore be ready for use at any time and in any situation • Follow the procedures approved by the Emergency Medical Service for positioning, immobilising and transporting the patient • Replace the device immediately if it is found to be partially damaged or deformed on inspection. The spinal board must be stored in a place inaccessible to children • The device must be stored without placing material and/or other heavy objects on it that could deform or damage it • Dispose of packaging in accordance with current regulations and ensure that it is out of the reach of children • Tampering with, alterations and modifications of the device are not permitted without the manufacturer's consent • Operators must be trained and knowledgeable in occupational safety rules and regulations (use of PPE)

4. CONTRAINDICATIONS AND SIDE EFFECTS (POSSIBLE DURING USE)

The use of this device, if carried out as described in this user manual and by appropriately trained personnel familiar with emergency medical doctrine, has no particular other contraindications or side effects

CONTRAINDICATIONS	• Direct contact of the patient's skin (injured or intact) with the device. A sterile drape must always be interposed to prevent allergies, irritation or other phenomena related to the type of material used in manufacture
SIDE EFFECTS	• Phenomena of skin irritation and reactivity due to direct patient contact with the surface of the device • Uncontrolled patient reactions related to nervous stress

5. SPINAL BOARD OB

The spinal board arrives ready for use and does not need to be assembled. After receiving it, ensure its structural integrity. In particular, carefully check the efficiency of the safety belts.

TYPE OF CONSTRUCTION

The picture below shows the table and its structure.

Made entirely of plastic material (PE) with radiotranslucent and impermeable characteristics, it has 21 comfortable handles (10 on each long side and 1 on the short side of the stretcher at the patient's foot position) for easy grip of the board and 2 safety belts for safe immobilisation of the patient. In addition, the OB spinal board is designed to accommodate the head restraint, an accessory that is often necessary for correct immobilisation of the patient, quickly and safely.

A label bearing all manufacturer and product identification data, the CE marking and the UDI number, which complies with the requirements of European Regulation MDR 2017/745, is attached to the device. This must never be removed or covered.

7. USE OF THE DEVICE

Attention	**Follow the procedures approved by the relevant Emergency Medical Service for the immobilisation, positioning and transport of the patient.** **The procedures below are drawn up on the basis of generic usage information.**

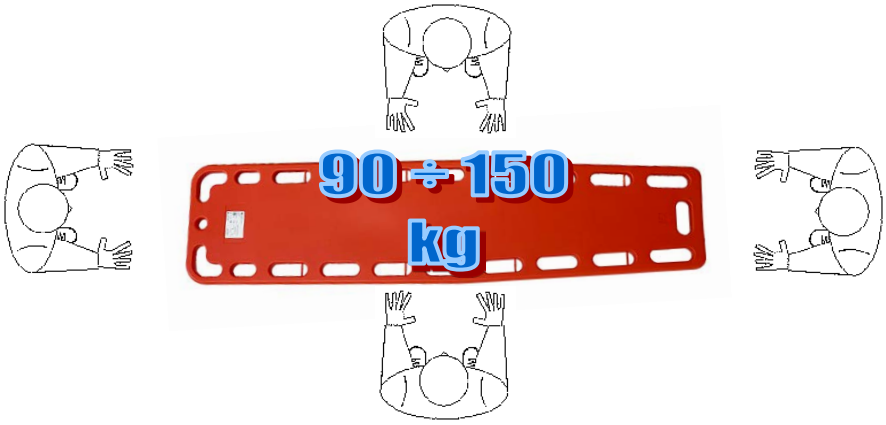
The user manual must be read and made available to the rescuer at all times. For this reason, it should be kept (also in digital format on one's smartphone) near or with the device.

The product is intended for professional use; it is recommended that operators have specific experience in the care sector, particularly in the use of spinal boards, and are in a suitable physical condition, i.e. have the muscular strength and coordination to guarantee the highest level of safety for the patient.

In order to use them correctly, it is good to practice several times using weights and sizes that simulate different patients. Weighted dummies can be used for this purpose, but never exceed the maximum permissible weight (150 kg max.).

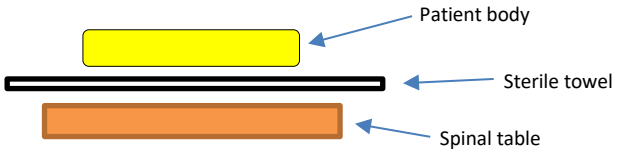
To operate safely and efficiently, the table requires at least two qualified and trained operators (figure below).

In special cases, e.g. when moving along stairs, climbs, uneven surfaces or for overweight patients, two additional attendants/helpers are required (figure below).



In all cases, the control and co-ordination of table movements is the responsibility of a qualified operator, while other operators/additional helpers must contribute to the movements following the instructions of the responsible operator.

1. Before picking up the patient with the spinal board, stabilise the damaged parts and apply appropriate cervical or rescue collars as additional support for the head and neck.
2. While one operator holds the patient's neck and head in a neutral position, the other operators can proceed to apply the spinal board.
3. Before laying the patient down (if possible), interpose a sterile drape.



4. When operators have access to both sides of the patient, use the spinal board by applying the TRONK ROTATION METHOD:
    a. Turn the patient on his side.
    b. Slide the spinal board closer to the patient.
    c. Rotate the patient over the spinal board.
    d. Secure the patient on the spinal board using the safety belts before starting to move it.
5. If it is inadvisable to use the trunk rotation method, the four operators should proceed according to the VERTICAL LIFTING METHOD:
    a. Bring the spinal board closer to the patient.
    b. While one operator supports the patient's head and neck, the others lift the patient just enough to let the spinal board slide under the patient's back.
    c. Secure the patient on the spinal board using the safety belts before starting to move it.
6. Take all measures to avoid worsening the patient's condition
7. After lifting the spinal board with the patient properly secured to it, it is possible to proceed with the transfer of the patient, following orders given by the operations manager. Rescuers should be coordinated and have good physical endurance as well as general control of their strength.
   Lifting and carrying the patient requires care and attention. Never overestimate your own strength and, if necessary, always request the help of other rescuers

Attention	- Always use seat belts, checking their tightness each time they are used; - All operators must face the patient during transport; - At least one operator must never leave the patient for as long as he or she remains on the table.

7. DEVICE CLEANING AND MAINTENANCE

7.1. Cleaning

After each use, the medical device must be cleaned and disinfected. These operations assume greater importance if the patient's pathological condition is unknown and there may be a risk of direct contamination. The user must always take protective measures and means to avoid contact with contaminated devices.

Attention	Failure to carry out cleaning operations may lead to the risk of cross-infection due to the presence of secretions and/or residues. During all control and sanitising operations, the operator must wear appropriate personal protective equipment, such as gloves, goggles, etc.

After removing all substances from the device with lukewarm water and neutral detergent, use a non-abrasive sponge to remove any encrustations and/or any traces of blood and/or secretions left by the patient.

Disinfect the surface of the spinal board with products that are suitable for this purpose and that do not have a solvent or corrosive action on the materials making up the device. Do not use metal brushes, steel wool or blades of any kind to remove fouling as they may damage the surface of the device.

Rinse thoroughly with lukewarm water, making sure to remove all traces of detergent, which could deteriorate it or compromise its integrity and durability.

The use of high-pressure water must be avoided.

Before storing the device make sure it is completely dry.

7.2. Maintenance

Establish a maintenance and periodic inspection schedule, identifying a contact person. The person entrusted with the maintenance of the device must guarantee the basic requirements laid down by the manufacturer.

Attention	During all control, maintenance and sanitisation operations, the operator must wear appropriate personal protective equipment, such as gloves, goggles, etc.

Routine maintenance

The checks to be carried out before and after each commissioning are as follows:
- General functionality of the device
- State of cleanliness of the device (please note that failure to clean can lead to the risk of cross-infection)
- Absence of cuts, holes, tears or abrasions on the entire structure
- State of wear and tear
- Integrity of handles (are they torn or show signs of tearing)

The frequency of checks is determined by factors such as legal requirements, type of use, frequency of use, environmental conditions during use and storage. Please note that it is necessary to carry out the cleaning described under "Cleaning" and the functionality check before and after each use.

Periodic revision

There are no scheduled periodic overhauls at the manufacturer's premises or at a centre authorised by the manufacturer, but the cleaning and checks indicated in the respective sections "Cleaning" and "Routine maintenance" are prescribed.

8. STORAGE OF THE DEVICE

Attention	Periodically check the integrity of the components of the device and the hygienic conditions of the storage place, in order to enjoy maximum efficiency and safety when in use.

The device, before being stored, must be thoroughly checked and replaced if tears or loss of mechanical integrity are detected.

The Boscarol spinal board can be used and stored in the temperature range of -10 to +50 °C. At very low or too high values, the material in contact with the patient may become extremely cold or hot causing complications for the patient (hypothermia and hyperthermia). Take all necessary measures to contain these effects and limit them as far as possible.

The spinal board must be stored clean and dry in a closed environment, taking care to protect it from exposure to the sun, dust and dirt in order to guarantee its hygienic conditions. The device must also not be exposed to or come into contact with sources of combustion and flammable agents and/or substances, chemical agents, which could alter its safety characteristics.

It is also recommended that the board be stored in a place where it can be easily and safely reached by first-aid personnel.

9. DEMOLITION OF THE DEVICE

The device can be disposed of in accordance with national and local regulations for the disposal of plastic-based substances. All materials are REACH-compliant and contain no hazardous substances.

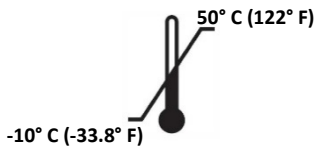
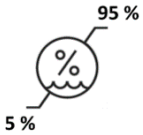
10. TECHNICAL SERVICE AND SPARE PARTS

The device cannot be repaired. In case of breakage or even partial damage it must be replaced with a new one. Should you require additional information to that provided in these operating instructions, please contact the manufacturer by telephone on +39 0471 932893 or by sending an email to info@boscarol.it.

11. TECHNICAL DATA AND CONFORMITY FOR THE BOSCAROL SPINAL BOARD

Classification of the medical device (in accordance with MDR 2017/745)	I
Basic UDI number (in conformity with MDR 2017/745)	805240088IMMGK
Technical Specifications	Device made of plastic material (PE) and equipped with 21 carrying and lifting handles and 2 safety belts for correct patient restraint
Risk assessment (technical documentation)	ISO 14971:2019
Lifespan	3 years from date of manufacture

Spinal board dimensions		
OB spinal board	Dimensions: 182x45x6cm	Weight: 8.15kg

Conditions of storage and use		
	Temperature range for transport, use and storage of the device	-10 to 50° C (14 to 122 °F)
	Humidity range accepted by the device for transport, use and storage	5 ÷ 95 % R.H. n.c.
	For further technical information or information on the use and storage of the device, please contact the manufacturer (info@boscarol.it).	
	On all measurements the tolerance is ±5 cm	
Declaration of conformity		
MD	The declaration of conformity is kept by the manufacturer together with all traceability data applicable to materials and production processes. You can request a copy from the manufacturer by sending an email to: info@boscarol.it	
	The device contains no metal parts or ferrous alloys	

12. ACCESSORIES

Boscarol supplies the complete range of medical equipment and accessories for emergency rescue. In particular, the customer can request the following accessories for the use of the spinal board:

- Universal head retainer OB
- WIND universal head retainer
- Fastening belt system

For the specific codes of the items listed above, please consult www.boscarol.it or send an e-mail to: info@boscarol.it

13. GUARANTEE

Oscar Boscarol warrants the spinal board for a period of 1 year from the date of purchase from the original distributor or manufacturer. The company guarantees that the device is free of defective materials and/or defects due to manufacturing processes.

The guarantee does not cover: normal wear and tear of the device, discolouration and any other cosmetic irregularities that do not affect the operation of the unit.

If, during the entire 1-year warranty period, the product is found to be defective, it must be sent to Oscar Boscarol S.r.l. (Ltd) with a note describing the defect. Oscar Boscarol S.r.l. (Ltd) will repair or replace the defective parts and/or the entire unit at its discretion. All shipping costs shall be borne by the customer.

Warranty Conditions:

To benefit from the guarantee, the registration form in the product documentation must be completed and returned by post, fax or e-mail to the following address:

OSCAR BOSCAROL SRL V. E. Ferrari, 29 - 39100 BOLZANO, ITALY

Fax: +39 0257760142 - E-mail: info@boscarol.it

To validate the guarantee process, the customer must provide evidence of the following documentation:

1. copy of the invoice and/or purchase receipt containing the batch number of the device and the date of purchase
2. confirmation by the manufacturer or a person representing the manufacturer that it is indeed a fault due to the production process or defective components since their procurement
3. absence of tampering, modifications and/or anything not conforming to the original product

In terms of the safety, reliability and functionality of the spinal board, Oscar Boscarol S.r.l. can only be held liable if:

1. all planned technical operations, repairs, modifications and inspections were carried out by Oscar Boscarol S.r.l. or an authorised service centre
2. the device has been and is being used correctly, strictly following the instructions given in these operating instructions

With reference to what is described in these warranty conditions, Oscar Boscarol S.r.l. cannot be held responsible for direct or indirect accidental damage, if modifications, repairs, unauthorised technical interventions have been carried out on the device or any of its parts have been damaged by accident or improper use. There are no other express or limited warranties of merchantability, fitness or otherwise on the spinal board other than those described in this user manual.

BOSCAROL®
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