BOSCAROL IMMOBILISATION DEVICES

VACUUM SPLINTS

OPERATING INSTRUCTIONS

CE

Medical devices compliant with European Medical Device Regulation 745/2017

PRODUCED BY:

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Information on the manufacturer and the medical device:

- Oscar Boscarol applies a quality management system in accordance with international standards ISO 13485 and ISO 9001.
- Medical devices in the "Immobilization" 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 European Regulation 2017/745

Information on these operating instructions:

- This document contains important information for the 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 should 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:

IMM120180	IMM120184	IMM120172	IMM120174	IMM120176	IMM120178	IMM120190	IMM120194	IMM120200

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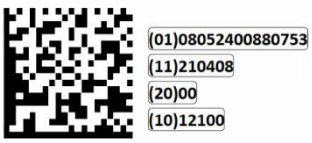
0. MEANING OF SYMBOLS AND PICTOGRAMS

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

	Danger: important safety information on the correct use of vacuum splints 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 prevention measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	Required maintenance service (contact the manufacturer and/or its authorised service centres)

0.2. Symbols used on the device and its accessories

	Use the vacuum splint only within the specified temperature range. Using the vacuum splint outside this range may reduce its functional performance and damage it.
	Limits of use in relation 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 mark in accordance with European Regulation MDR 2017/745 for medical devices in class I
	Manufacturer
REF	Order number (device code)
	Please read the operating instructions in other languages available on the indicated website
MD	Indicates that the vacuum splint is a medical device
	Example of medical device UDI-DI and UDI-PI code: (01) Identification of manufacturer and associated device (11) Date of production (20) Product variant (10) Lot number

1. INTENDED USE

Device name	BOSCAROL VACUUM SPLINT (mattress)
Primary use	A medical device intended for the immobilisation of limbs with suspected fractures or injuries of various kinds that need to be immobilised before transport to hospital.
Other uses	Whole patient immobilisation for very small weights and sizes
Medical purpose	Immobilisation and stabilisation of the patient's limb(s) prior to transport

Part of application in the human body	Upper and lower limbs
Type of patients	Children and adults of both sexes from 10 Kg
Time of application on the same patient	Short-term use (maximum 30 days of consecutive use)

Information on use	• The vacuum splint can be used on the limbs of all types of patients (except those weighing less than 5 kg). Lower limb splints can be used to immobilise infants or small patients following the appropriate medical immobilisation technique. • It can be used in conjunction with other immobilisation and transport systems such as the scoop stretcher. • The immobilisation and transport of the limbs of a patient with injuries of various kinds or suspected injuries must always be carried out by professional rescuers who are trained and familiar with specific patient immobilisation and transport technologies. • The vacuum splints can be suctioned through suitable suction units (see BSU - Boscarol Suction Units).	

Compliance with EN 1865-1	Boscarol vacuum splints are not covered by any specific reference standard. They do, however, refer to the European standard EN 1865-1 with regard to vacuum tightness and maximum deflection.

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

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

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

LATEX	Boscarol vacuum splints are designed and manufactured without the use of latex. The materials used are latex-free, however, it cannot be excluded that latex or traces of it may have come into contact during the entire production chain.
DEVICE CONTAMINATE	Warning about device contamination: Immobilization of the patient's limb on the vacuum splint may 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. If you have any doubts before sending a device in for repair, please contact Boscarol's technical service department by sending an email to info@boscarol.it or by calling +39 0471 932893

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

The vacuum splint has been designed and tested to comply with the requirements imposed by the Medical Device Regulation 745/2017. The vacuum splint is a medical device of risk class I

If the user or patient becomes aware of a danger in use, a side effect, an accident caused by the device or a critical issue (operational and design) not covered in these instructions for use, he must immediately report this to the manufacturer at the following e-mail address: raq@boscarol.it

PERIODIC SAFETY INSPECTION	**Preventive maintenance and periodic safety inspection:** The vacuum splint 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 the event of a fault, please contact the manufacturer
LIFETIME	Boscarol vacuum devices all have a lifetime of **8 years** from the date of manufacture if stored and used according to these instructions for use
Responsibility of operators/users	• **Take appropriate precautions if the device comes into direct contact with the patient's body and always place a sterile sheet over it (biocompatibility).** • The Boscarol vacuum splint is designed for emergency medical service and must therefore be ready for use at any time and in any situation • Replace immediately any components/parts that are damaged, altered or missing and/or suspected of malfunctioning. Always replace such parts with original spare parts. The vacuum splint should be stored in a place inaccessible to children. • Dispose of packaging in accordance with local regulations and ensure that it is out of the reach of children. • Tampering with, altering or modifying the device is not permitted without the manufacturer's consent. • Operators must be trained and aware of the legal regulations and provisions regarding safety at work (use of PPE).
Attention	• The device cannot be considered as buoyant and although it can be used in water, auxiliary measures must be taken to avoid sinking. • Every 30 minutes, check the vacuum in the splint and reset it if necessary.

4. CONTRAINDICATIONS (DO NOT USE FOR)

CONTRAINDICATIONS	• Direct contact of the patient's skin (injured or intact) with the device. A sterile sheet must always be placed in between. • Amputated or partially amputated limbs • Limb crushing syndrome

5. SIDE EFFECTS (POSSIBLE DURING USE)

SIDE EFFECTS	• Phenomena of skin irritation and reactivity due to direct patient contact with PVC • Phenomena related to excessive haemostatic compression • Worsening of the fracture or exposed fracture due to incorrect immobilisation of the limb

6. BOSCAROL VACUUM SPLINTS

Boscarol vacuum splints can be sold in sets, individually or with the suction pump. After receiving the device(s), ensure that all parts are present (in the case of a set). The vacuum splint arrives assembled and ready to use and can be fitted with a manual suction pump. The pump is not to be considered a "medical device".

Available types of Boscarol vacuum splints

IMM120172	108 cm long vacuum splint for leg
IMM120174	vacuum splint for hand
IMM120176	Vacuum splint for arm
IMM120178	Vacuum splint for leg with standard length

Depending on the chosen configuration, the device can be equipped with the following accessories:

- Manual suction pump
- Storage and transport bag

7. COMPOSITION OF DEVICES

Boscarol vacuum splints are manufactured by permanently welding together two sheets of PVC-based synthetic material (polyvinyl chloride) coated on the outside to make it waterproof. The high-frequency welding guarantees stability and durability even with prolonged use.
Boscarol splints are radiotranslucent and translucent, ensuring radiological investigations without having to remove them from the limb.
The splint consists of an internal chamber containing polystyrene microspheres of a specific density, which, thanks to the action of the vacuum, make it possible to conform the device to the patient's limb.
A plastic (ABS) valve with no metal elements (which would compromise the radiolucency and translucency of the device) allows the air in the splint to be sucked in and closes the inlet when the required vacuum level is reached.

CONSTRUCTION TYPE

The picture below shows the splint for leg immobilization. In the picture you can see the suction valve and the three straps that allow the splint to be fixed to the limb.

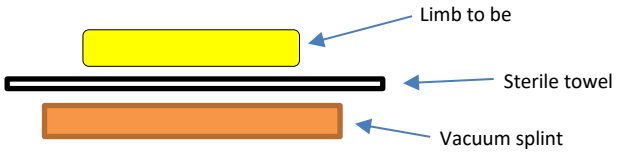
Given the size of the splint, it can also be used to immobilise small patients, infants or in the veterinary sector for small animals.

Aspirated and shaped splint

How to use the device

Carefully follow the instructions below. Continuous training and practice in its use will ensure maximum benefit for the patient and reduce the risk of complications.
The user manual must be read and attached to the device at all times. For this reason it should be kept (also in digital format on your smartphone) near or with the device. The device should be checked for functional integrity before use.

1. Place the splint on a flat, stable surface and distribute the beads inside. If this is not possible, take the splint in both hands and shake it in all directions to distribute the beads.
2. Open the suction valve by turning it counterclockwise by 90°.
3. Connect the pump suction pipe to the valve connection.
4. Place the limb on the splint after placing a sterile sheet in between.



5. Take all measures to avoid worsening the patient's condition
6. Thanks to the pump, air is sucked into the splint
7. Conform the splint to the limb during aspiration.
8. When the correct suction level has been reached before disconnecting the pump, close the valve by turning it anticlockwise.
9. Close the fastening straps and ensure that the splint wraps around the limb and that it is fully immobilised
10. Always check the patient's condition during all immobilisation operations and during transport to the hospital or nearby rescue centre
11. Proper immobilisation of the limb prevents it from flexing during patient transport. The splint must remain rigid

Attention	If the splint is used to immobilise a small patient or an infant, ensure that the patient's vital condition is maintained throughout the operation and during transport to a rescue centre. Do not allow the straps to act to prevent regular breathing.

8. REUSE OF BOSCAROL VACUUM SPLINTS

The medical device must be cleaned and disinfected after each use. This is even more important if the patient's pathological condition is unknown and direct contamination may be present. The user must always adopt protective measures and means to protect his or her own safety.
The vacuum splint can be washed with water, which must not exceed a temperature of 40° C. Never use metal or very hard abrasive brushes, which could ruin the fabric and PVC coating.

Attention	Always close the suction valve before cleaning and disinfecting
Pressure washers	Do not use high-pressure washing machines as they may damage the surface layers of the PVC fabric.
Attention	Never inflate the vacuum splint! It may be irreparably damaged

After removing all substances from the splint with water, use a non-abrasive sponge to remove any encrustations. Remove any blood and/or organic traces left by the patient before disinfecting. Disinfect the splint (the entire surface) with products suitable for this purpose (test one side of the device to make sure it is not damaged). Do not use bleach and iron brushes, steel wool or blades of any kind to remove scale. Coloured disinfectants may permanently stain the surfaces of the device itself.
Before storing the device, make sure it is completely dry to prevent mould from forming on the PVC.

9. STORAGE OF THE DEVICE

Boscarol vacuum splints can be used and stored in the temperature range of -30 to +70 °C. Very low or too high temperatures may cause the material in contact with the patient to become extremely cold or hot, resulting in complications for the patient (hypothermia and hyperthermia). If the temperature range is too low or too high, the

material in contact with the patient may become extremely cold or hot, leading to complications for the patient (hypothermia and hyperthermia). Take all necessary measures to contain these effects and limit them as much as possible.

The splint must be stored clean and dry. It should be checked periodically to avoid mould, damage due to bending and leakage at the welds. If stored in a very humid place, it should be checked every month by stretching and airing it in order to avoid the formation of mould or other substances that could degrade the device.

10. DEMOLITION OF THE DEVICE

The device can be dismantled according to national and local regulations for the disposal of PVC-based substances, ABS (the intake valve) and polystyrene (internal microspheres). All materials are REACH compliant and contain no hazardous substances. The device is completely manufactured and tested in Italy.

11. TECHNICAL SERVICE AND SPARE PARTS

In the event of a functional failure or if you need additional information regarding reuse and/or storage and transport, please contact the manufacturer by phone at +39 0471 932893 or by sending an email to info@boscarol.it.

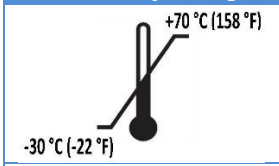
11.1. Solving common problems

Malfunctioning	Possible cause	Solution
The splint does not compress	• ON-OFF valve closed • Pump damaged • Damaged device	• Open the valve by turning 90° anticlockwise (follow the embossed instructions on the valve) • The pump must be able to suck by operating it. If not, replace it. The pump must be a suction pump • Contact the manufacturer
The suction ON-OFF valve is blocked	• Damaged valve • Damaged valve seat	• Contact the manufacturer • Replacing the splint
Boscarol suction pump does not work	• Damage to the plunger • Damaged internal gasket	• Contact the manufacturer • Replacing the splint

12. TECHNICAL DATA AND CONFORMITY FOR BOSCAROL VACUUM SPLINTS

Classification of the medical device (in accordance with MDR 2017/745)	I
Basic UDI number (in conformity with MDR 2017/745)	805240088IMMGK
Technical specifications	1 made-to-measure interior room
Degree of protection against ingress of liquids and solids (IEC 529):	IP67 (with closed valve)
Risk assessment (technical documentation)	ISO 14971:2019
Service life	8 years from date of manufacture

DimensionLe vacuum splints		
Standard leg splint	92x64x52x4 (h) cm	Device weight: 1.7 kg
Leg splint 108 cm	108x62x43x4 (h) cm	Device weight: 1.9 kg
Hand splint	51x33x4 (h) cm	Device weight: 0.4 kg
Arm splint	75x47x36x4 (h) cm	Device weight: 0.9 kg
Manual suction pump	32x45 (diameter) cm	Device weight: 0.5 kg

Conditions of storage and use		
	Temperature range for transport, use and storage of the device	-30 to 70° C (-22 to 158 °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 sizes of splints the tolerance is ±5 cm (due to coupling). On the remaining sizes it is 5%.
Declaration of conformity	
MD	The declaration of conformity is kept by the manufacturer together with all traceability data applicable to the materials and production processes. You can request a copy from the manufacturer by sending an email to info@boscarol.it.

13. WARRANTY

Oscar Boscarol warrants the vacuum splint (all models) 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 from defective materials and/or defects due to manufacturing processes.

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

If, during the entire warranty period of 1 year, 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 at its discretion the defective parts and/or the whole unit. All shipping costs are the responsibility of 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. a 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 safety, reliability and functionality of the vacuum splint, Oscar Boscarol S.r.l. can only be held liable if:

1. all 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 accidental direct or indirect damages, if modifications, repairs, unauthorized technical interventions have been carried out on the device or any of its parts have been damaged due to accident or improper use. There is no express or limited guarantee of merchantability, suitability or any other kind on the carrying sheet other than those described in this user manual.

BOSCAROL®
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