BOSCAROL IMMOBILIZATION DEVICES

RIGID SPLINTS

OPERATING INSTRUCTIONS

CE

Medical devices compliant with the European Regulation on Medical Devices 745/2017

PRODUCT BY:

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Manufacturer and medical device information:

- Oscar Boscarol applies a quality management system (QMS) according to international ISO 13485 and ISO 9001 standards
- Medical devices of the "Immobilization" category (in all their configurations) comply with the European MDR Regulation 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 to the European Regulation 2017/745

About these operating *instructions:*

- This document contains information that is important for safe, effective and compliant use of your medical device
- Use the information below to train users and confirm their training
- It is not allowed to modify (even partially) this manual. Only the device manufacturer can make changes to it
- These instructions must always accompany the device. It is recommended to use the electronic version and make it available on PDAs, tablets and mobile phones of operators

These operating instructions apply to the following devices:

IMM123120	IMM123100	IMM123110

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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 rigid splints to prevent injury to the operator or patient and/or damage to the device itself
	Warnings: Information that requires special attention
	Notes or information for proper use and to prevent damage to your device or others. Activate the correct prevention measures
1.	List of actions to perform: follow them step by step
	These operating instructions
	Required maintenance service (contact the manufacturer and/or his authorized service centers)

0.2. Symbols used on the device

	Use the rigid splint only within the indicated temperature range. The use of the rigid splint outside these limits may decrease its functional performance and damage the
	Moisture-related usage limits
	Read these operating instructions carefully and completely
	Indicates the user's need to consult these operating instructions for the presence of information, such as warnings and precautions that cannot be displayed on the medical device in question
CE	CE mark in accordance with the European MDR Regulation 2017/745 for medical devices in class I
	producer
REF	Order number (device code)
	Please read the operating instructions in other languages available on the website indicated
MD	Indicates that the rigid splint is a medical device
 (01)08052400880753 (11)210408 (20)00 (10)12100	Example of a UDI-DI and UDI-PI code of the medical device: (01) Manufacturer and associated device identifier (11) Date of production (20) Product variant (10) Lot number

1. INTENDED USE

Device name	Rigid splint BOSCAROL
Primary use	Medical device intended for immobilization of upper or lower limbs with suspected fractures or injuries of various kinds that need to be immobilized before transport to the hospital
Other uses	It is possible to use the splints in the veterinary field
Medical purpose	Immobilization of the patient's limb or limbs before transport

Application part in the human body	Upper and lower limbs
Type of patients	Children and adults of both sexes from 10 kg
Application time on the same patient	"Short-term" use (maximum 30 days of consecutive use)
Usage information	• Rigid splint can be used on the limbs of all types of patients (excluding those under 10 kg in weight) • Can be used at the same time as other immobilization and transport systems such as scoop stretcher or spinal stretcher The immobilization of the limbs of a patient with injuries of various kinds or supposed to be carried out always by professional rescuers, trained and aware of the specific technologies of immobilization and transport of patients

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully!

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

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

Latex	Boscarol rigid splints are manufactured without the use of latex. The materials used are latex-free, but it is not excluded that throughout the production chain they maybe come into contact with latex.
device contaminated	Warning in case of contamination of the device: the immobilization of the patient's limb with the rigid splint can be a source of contamination. For this reason, after each use the device must be cleaned and disinfected to eliminate any residual risk. Follow the instructions in this user manual. If you have any concerns before sending a device for repair, contact Boscarol Technical Service by sending an e-mail to the address info@boscarol.it or calling +39 0471 932893

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

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

	If the user or patient becomes aware of a user hazard, a side effect, an accident caused by the device or a criticality (operational and constructive) not dealt with in these instructions for use, he must immediately report it to the manufacturer at the email address: raq@boscarol.it
PERIODIC SAFETY INSPECTION	**Preventive maintenance and periodic safety inspection:** The rigid splint should be checked periodically (a complete functional check is recommended at least once a week) especially on heat-sealed joints. In the event of a failure, you must contact the manufacturer or replace them
LIFE SPAN	Boscarol rigid splints have a lifespan of **5** years from the date of manufacture if stored and used in accordance with the provisions of these operating instructions

responsibility operators/users	• **Take due precautions in case of contact of the device with the child/adult body and interpose special sterile sheets (biocompatibility)** • The Boscarol rigid splint is designed for the emergency health service and must therefore be used at any time and in any situation • Replace immediately if there are obvious structural and weld failures. The rigid splint must be stored in a place inaccessible to children • Dispose of packaging in accordance with applicable regulations and make sure it is out of reach of children. • Tampering, alterations and modifications of the device are not allowed without the consent of the manufacturer • Operators must be trained and aware of the legal rules and provisions on safety at work (use of PPE)

4. CONTRAINDICATIONS (DO NOT USE FOR)

Contraindications	• Direct contact of the patient's skin (injured or intact) with the device. It is mandatory to always interpose a sterile cloth • Limb crush syndrome

5. SIDE EFFECTS (POSSIBLE DURING USE)

Effects	• Skin irritation and reactivity due to the patient's direct contact with PVC • Worsening of fracture or fracture exposed due to incorrect immobilization of the limb • Excessive compression of the limb resulting in reduced circulatory flow

6. RIGID SPLINTS BOSCAROL

The Boscarol rigid splints can be marketed in kits or individually. The rigid splint come ready to use. Upon receipt, problems relating to use must be verified and possibly contested.

Types of Boscarol Rigid Splints available

IMM123110 Rigid "upper splint"
IMM123100 Rigid "lower splint"
IMM123120 Set rigid splints (2 pieces plus carrying bag)

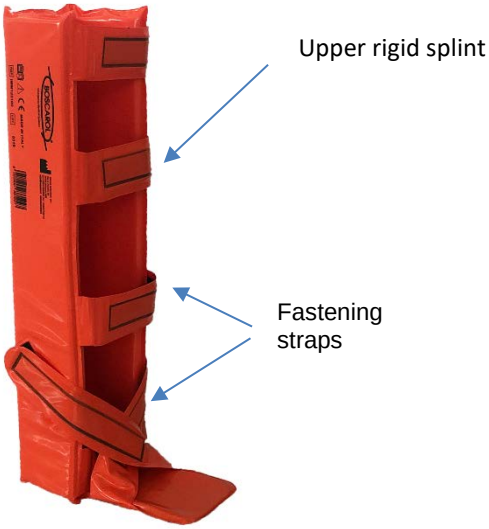
7. COMPOSITION OF DEVICES

The Boscarol rigid splints are manufactured by welding two sheets of synthetic PVC-based material (polyvinylchloride) of appropriate and determined resistance to traction and abrasion. High frequency welding ensures stability and durability even in case of prolonged use.
Boscarol splints are radio-transparent and translucent ensuring radiological investigations without having to remove them from the limb.
Inside the device is inserted a special sponge material of appropriate thickness that guarantees structural rigidity.

TYPE OF CONSTRUCTION

In the figure on the next page, you can see the splint for immobilization. Rigid splints, thanks to its constructive flexibility can be used for the leg in a small patient or child.

IMM123100 Upper Rigid Splint

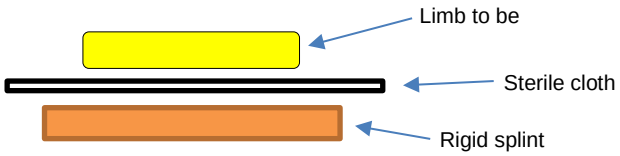


IMM123110 Lower Rigid Splint

How to use the device

Carefully follow the next instructions. Continuous training and exercise on use allows you to achieve maximum benefits on the patient and reduce the risk of complications. Patient immobilization techniques are very important to obtain the small as much damage as possible during transport to the hospital. Never improvise rescuers if you have no experience, skill and expertise.

1. Lay the splint on a flat and stable surface and open the straps equipped with Velcro
2. The splint is rigid and has a shape such as to contain the injured limb. Do not use it if the limb is broken down and the fracture includes a non-axle stump
3. Lay the limb on the splint after interposing a sterile cloth between the splint and the patient's limb



4. Lay the limb in the splint without straining or crushing the limb itself in the intended space
5. Take all measures to avoid worsening patient status
6. Close the fastening straps and make sure that the splint wraps around the limb and is fully immobilized
7. Always check the patient's condition during all immobilization operations and during transport to the hospital or nearby rescue center

Attention	If the splint is used to immobilize a small patient or child, make sure of vital conditions during all operations and during transport to a rescue center. Prevent straps from acting by preventing their regular circulatory flow

8. REUSE OF RIGID SPLINTS

After each use it is necessary to proceed with the cleaning and disinfection of the medical device. These operations are of greater importance if the patient's pathological condition is not known and direct contamination maybe present. The user must always take protective measures and means to protect himself.
The rigid splint can be washed with water that must not exceed 40 °C of temperature. Never use metal or very hard abrasive brushes that could ruin the fabric and coating of PVC.

Cleaners	Do not use high pressure machines that may damage the surface layers of PVC fabric
attention	Do not cut or change the structure and shape of the rigid splint so as not to damage it irreparably

After removing all substances on the splint with water, use a non-abrasive sponge to remove any fouling. Before proceeding with disinfection remove any traces of blood and/or organic substances left by the patient. Disinfect the splint (the entire surface) with products suitable for this purpose (do a test on one side of the device to check does not damage). Do not use bleach and iron brushes, steel wool and blades of any kind to eliminate fouling. Colored disinfectants could irreparably stain the surfaces of the device itself.
Before storing the device, make sure it is completely dry to avoid mold forming on the PVC.

9. DEVICE STORAGE

Boscarol rigid splints can be used and stored in the temperatura range from -10 to +50 °C. With very low or too high values the material in contact with the patient could become extremely cold or hot causing complications to the patient (hypothermia and hyperthermia). Take all necessary measures to contain these effects and limit them as much as possible.
The splint should be stored dry and clean. It must be periodically checked to prevent mold, damage due to bending and leakage on welds. If stored in very humid places it should be checked every month and ventilated in such a way as to avoid the formation of mold or other substances that could damage the device.

10. DEMOLITION OF THE DEVICE

The device may be scrapped in accordance with national and local guidelines for the disposal of PVC-based substances. The inner sponge material can be disposed of in the appropriate containers for recycling purposes. All materials comply with REACH and do not contain dangerous substances. The device is fully manufactured and tested in Italy.

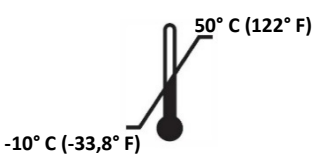
11. TECHNICAL SERVICE AND SPARE PARTS

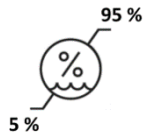
In the event of a functional failure or if auxiliary information is required regarding reuse and/or storage and transport operations, please contact the manufacturer at +39 0471 932893 or by sending an email to info@boscarol.it.

12. TECHNICAL DATA AND COMPLIANCE FOR BOSCAROL RIGID SPLINTS

Classification of medical devices (in accordance with MDR2017/745)	**I**
Basic UDI number (in conformity at MDR 2017/745)	805240088IMMGK
Technical specifications	Welded and hermetically sealed PVC container with a special sponge material inside
Degree of protection against the ingress of liquids and solids (IEC 529):	IP65 in the absence of abrasion or breakage
Risk assessment (technical documentation)	ISO 14971:2019
Lifespan	5 years from the date of manufacture

Size rigid splints		
Upper rigid splint	51x27.5x3.5 (h) cm	Weight of the device: 0.6 kg
Lower rigid splint	74x40x3.5 (h) cm	Weight of the device: 1.1 kg
Set 2 rigid splints	76x19x19 (h) cm	Device weight: 2.1 kg

Conditions ofpreservation and use		
	Temperature range for transport, use and storage	-10 a 50° C (da -33,8 a 122° F)

	Humidity range for transport, use and storage	5÷95 % U.R. (not condensed)
	For further technical or storage information, please contact the manufacturer (info@boscarol.it).	
	On all sizes of the rigid splints the tolerance is ±5 cm (due to the couplings). Of the remaining measures, it is 5%.	
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 it in copy from the manufacturer by sending an email to: info@boscarol.it	

13. GUARANTEE

Oscar Boscarol guarantees rigid 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 production processes.

The warranty does not cover normal wear of the device, discoloration and any other cosmetic irregularities that do not affect the operation of the unit.

If, throughout the 1-year warranty period, the product is found defective, it must be sent to Oscar Boscarol S.r.l. (Ltd) complete of a describing of the defect. Oscar Boscarol S.r.l. (Ltd) repairs or replaces at its discretion defective parts and/or the entire unit. All shipping costs are borne by the customer.

Warranty conditions:
To qualify for the warranty, the registration form in the product documentation must be completed and returned by post, fax or e-mail at the following address:

OSCAR BOSCAROL SRL V. E. Ferrari, 29–39100 BOLZANO, ITALY
Fax: +39 0257760142 – E-mail: info@boscarol.it

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

1. copy of the invoice and/or purchase receipt containing the lot number of the device and the date of purchase
2. confirmation by the manufacturer or a person representing him that it is indeed a failure due to the production process or defective components from the time of their supply
3. absence of tampering, modifications and/or something that does not conform to the original product

In terms of safety, reliability and functioning of the rigid splint, Oscar Boscarol S.r.l. can be held responsible only if:

1. all planned technical operations, repairs, modifications and checks were carried out by Oscar Boscarol S.r.l. or an authorized service center
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, unauthorized technical interventions or any of its parts have been damaged by accident and improper use. There are no other express or limited guarantees of marketability, suitability or other guarantees outside those described in this user manual.

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