BOSCAROL IMMOBILISATION DEVICES

CARRYING SHEET

OPERATING INSTRUCTIONS

CE

Class I medical device compliant with European Medical Device Regulation 745/2017

PRODUCED BY:

OSCAR BOSCAROL SRL
Via Enzo Ferrari 29
39100 Bolzano
ITALY

Tel. +39 0471 932893
Fax: +39 02 57760140

info@boscarol.it
www.boscarol.it

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:

IMM120321			

INDEX

INDEX 3

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 the carrying sheet 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 carrying sheet only within the specified temperature range. Using the carrying sheet outside of 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 carrying sheet 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 CARRYING SHEET
Primary use	A medical device intended for lifting and transporting a patient who requires immediate evacuation or transfer and where other medical devices cannot be used
Other uses	Covering and protecting a patient in a safe position, transporting other medical devices and/or materials in specific areas
Medical purpose	Safe transfer, evacuation of a patient for the purpose of applying appropriate treatment

Part of application in the human body	Entire human body
Type of patients	Children and adults of both sexes from 10 Kg
Time of application on the same patient	Temporary use (maximum 60 minutes of consecutive use)
Information on use	• The carrying sheet can be used by placing the patient's body on it. The patient can then be translated, moved or transferred to other suitable restraint systems. • Can be used in conjunction with other medical devices fitted to the patient (e.g. a cervical collar) • The transport of a patient should always be carried out by professional rescuers who are trained and knowledgeable about lifting and carrying techniques. • The use of the carrying sheet can also be extended to the veterinary sector
Compliance with EN 1865-1	The Boscarol carrying sheet complies with the European reference standard EN 1865-1.

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	The Boscarol carrying sheet is 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 of device contamination: Transporting a patient with the carrying sheet 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 by sending an e-mail to info@boscarol.it or calling +39 0471 932893.

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

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

	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 curtain should 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, the device must be removed and replaced

LIFETIME	The Boscarol carrying sheet has a service life of **5 years** from the date of manufacture if stored and used in accordance with these instructions.
Responsibility of operators/users	• **Take precautions if the device comes into direct contact with the patient's body and always place a sterile sheet over it (biocompatibility).** • The Boscarol carrying sheet is designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Replace it immediately if it proves to be torn, partially damaged or if the handles show structural failure. The load carrier must be stored in a place inaccessible to children. • Dispose of packaging in accordance with current regulations and make sure 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).

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 used to prevent allergies, irritation or other phenomena related to the type of material used in manufacture. • Do not use with a winch or mechanical lifting system. • Avoid use if there is any suspicion of injury to the spine or skull base

5. SIDE EFFECTS (POSSIBLE DURING USE)

SIDE EFFECTS	• Phenomena of skin irritation and reactivity due to direct patient contact with PVC • Uncontrolled reactions by the patient related to nervous stress • Breathing difficulties due to head tilt in an unconscious patient

6. BOSCAROL CARRYING SHEET

The carrying sheet arrives ready to use and does not need to be assembled. After receiving it, ensure its structural integrity and lay it on the floor to check how to use it.

CONSTRUCTION TYPE

The picture on the next page shows the sheet and its structure.

There are 8 looped handles (four on each long side), which allow the rescuer to insert the hand, thus avoiding an easy and dangerous release that could cause the patient to fall.

The black tape is made of polyethylene and has a high tensile strength. Being woven allows easy seams that do not break the fibers. These seams are made several times crossing each other.

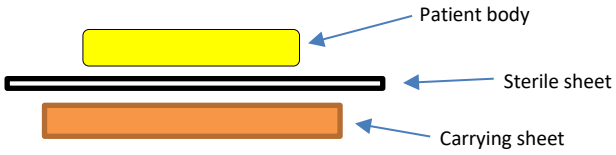
On the device there is a screen printing showing all the identification data, the UDI number and two eloquent images that suggest the correct use and the wrong one. The UDI code complies with the requirements of the European Regulation MDR 745/2017.

How to use the device

Follow the instructions below carefully. In order to properly use, it is good to practice several times using weights and sizes that simulate different patients. For this purpose, it is possible to use heavy mannequins without ever exceeding the maximum permissible weight (150 kg max.).

The user manual should be always read and made available to the rescuer. For this reason, it should be kept (also in digital format on your smartphone) near or with the device.
The device must be thoroughly checked before storage and replaced if tears or loss of mechanical integrity are detected.

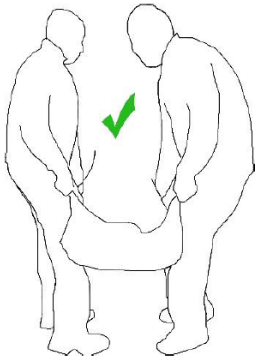
1. Place the carrying sheet on a flat, stable surface and make sure there is no debris or anything else that could tear the carrying sheet and hurt the patient.
2. Before placing the patient (if possible), place a sterile sheet. Place the patient on the carrying sheet after placing a sterile sheet

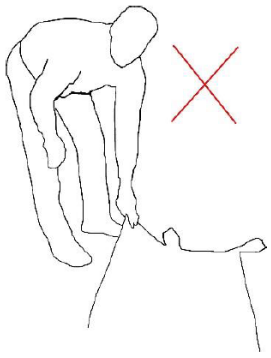


3. Take all measures to avoid worsening the patient's condition
4. Once the patient has been lifted, the patient can be transferred or moved following orders given by the person in charge. Rescuers should be coordinated and have good physical endurance as well as general control of their strength.
5. Lifting and carrying a patient requires care and attention. Never overestimate your own strength and, if necessary, always ask for help from other rescuers.

Attention	The carrying sheet cannot be dragged with a patient lying on it. The weight exerted on a single handle and the friction generated by dragging would cause the carrying sheet to tear and break.

In the two figures on the side it is possible to notice how the patient's movement is possible only by raising the towel. With a patient of 80-100 kg, a possible dragging would only cause the cloth to break.





7. RE-USE OF THE BOSCAROL CARRYING SHEET

The medical device must be cleaned and disinfected after each use. These operations are more important if the patient's pathological condition is unknown and there may be a risk of direct contamination. The user must always adopt protective measures and protective devices to avoid contact with contaminated devices.
The carrying sheet can be washed with water, which must not exceed a temperature of 40° C. Never use metal or very hard abrasive brushes, as these can damage the fabric and the PVC coating.

Pressure washers	Do not use high-pressure washing machines as they may damage the surface layers of the PVC fabric.
Attention	Do not use thinners or substances that could alter PVC and polyethylene tape.

After removing all substances from the device with water, use a non-abrasive sponge to remove any deposits and/or traces of blood and/or secretions left by the patient. Disinfect the surface of the carrying sheet with products suitable for this purpose (test on one side of the device to ensure no damage). Do not use bleach and wire brushes, steel wool or blades of any kind to remove fouling. Stained disinfectants could irreparably stain the surfaces of the device itself.

Before storing the device make sure it is completely dry to prevent mold from forming on the PVC. The drying times of the device are different depending on whether it is the PVC cloth or the polyethylene textile tape.

8. STORAGE OF THE DEVICE

The Boscarol carrying sheet can be used and stored in the temperature range of -10 to +50 °C. If the temperature is too low or too high, the material in contact with the patient may become extremely cold or hot, resulting in complications for the patient (hypothermia and hyperthermia). Take all necessary measures to contain these effects and limit them as much as possible.
The carrying sheet must be kept clean and dry. It should be checked periodically to prevent mould and/or crease damage. If stored in a very humid location, it should be checked every month by stretching and airing it in order to avoid damage or deterioration.

9. DEMOLITION OF THE DEVICE

The device can be dismantled in accordance with national and local regulations for the disposal of PVC and polyethylene substances. All materials are REACH compliant and contain no hazardous substances. The device is fully manufactured and tested in Italy.

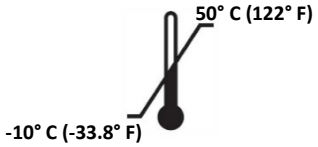
10. TECHNICAL SERVICE AND SPARE PARTS

The device cannot be repaired. In the event of a breakage, or even a partial tear, it must be replaced with a new one. If 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 LOAD-BEARING SHEET

Classification of the medical device (in accordance with MDR 2017/745)	I
Basic UDI number (in conformity with MDR 2017/745)	805240088IMMGK
Technical specifications	Sheet made of PVC and equipped with 8 carrying and lifting handles
Risk assessment (technical documentation)	ISO 14971:2019
Service life	5 years from date of manufacture

Load sheet dimensions		
Boscarol carrying sheet	190x70x1 (h) cm	Device weight: 1.4 kg

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).	
	Tolerance on all sizes is ±5 cm	
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.	
	The device does not contain any metal parts or ferrous alloys	

12. WARRANTY

Oscar Boscarol warrants the device 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 warranty 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 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 supplying
3. absence of tampering, modifications and/or anything not conforming to the original product

In terms of safety, reliability and functionality of the tarpaulin, 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 by 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.

Emergency Medical Systems
Via Enzo Ferrari 29, 39100 Bolzano IT
Tel. +39 0471932893 - Fax: +39 0257760140
info@boscarol.it
www.boscarol.it

Printed in Italy by Oscar Boscarol Srl (Ltd)
ED01_REV02-2021 IFU CARRYING SHEET - ENG
Language of editing: English

https://www.boscarol.it/ita/eifu.php