BOSCAROL IMMOBILIZATION DEVICES

WIND AND OB HEAD IMMOBILIZER

OPERATING INSTRUCTIONS

WIND HEAD IMMOBILIZER

OB HEAD IMMOBILIZER

CE

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

PRODUCED BY:

OSCAR BOSCAROL SRL
Enzo Ferrari 29
39100 Bolzano
Italy

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

info@boscarol.it
www.boscarol.it

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:

IMM121640	IMM121628	IMM121631B	IMM121631V	IMM121631R

INDEX

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 head immobilizer 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 head immobilizer only within the indicated temperature range. The use of the head immobilizer outside these limits may decrease its functional performance and damage it too
	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
	CE mark in accordance with the European MDR Regulation 2017/745 for medical devices in class I (of risk)
	Manufacturer of the medical device
	Order number (device code)
	Please read the operating instructions in other languages available on the website indicated near the symbol
	Indicates that the head immobilizer is a medical device
	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	Head Immobilizer Boscarol OB e WIND
Primary use	Medical device intended for head immobilization in lifting and transport devices
Other uses	There are no known uses other than that for which it was designed
Medical purpose	Immobilization and stabilization of the patient's head before transport. It can be used with the aid of a cervical collar

Application part in the human body	Patient's head
Type of patients	Children and adults of both genders starting from 25 Kg
Application time on the same patient	"Short-term" use (maximum 30 days of consecutive use)
Usage information	• Boscarol head immobilizer (OB model and WIND model) can be used on all types of patients, excluding those under 25 kg in weight due to head size which may be too small • It can be used simultaneously with the cervical collar and other immobilization and transport systems such as the scoop stretcher or spinal stretcher • Immobilization of a patient's head with injuries of various kinds must be carried out by professional rescuers, trained and aware of the specific technologies of immobilization and transport of patients • It is recommended to use the head immobilizer with at least two trained rescuers

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 these instructions, please contact the manufacturer for further clarification.

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

LATEX	Boscarol head immobilizers are made without the use of latex. The materials used are latex-free, but it is not excluded that along the entire production chain they may have come into contact with substances or traces of latex.
Contaminated device	Warning in case of contamination of the device: immobilization of the patient's head on the head immobilizer may 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 or before sending a device for repair, contact Boscarol Technical Service by emailing info@boscarol.it or calling +39 0471 932893

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

Boscarol head immobilizer has been designed or tested to comply with the requirements imposed by the European Medical Devices Regulation 2017/745. WIND and OB head immobilizers are medical devices in class of risk 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:** Boscarol head immobilizer must be checked periodically (full functional verification is recommended at least once a week) especially on removable parts and on Velcro attachments that allow the fixing of the side wedges, the chin guards and fastening straps. In the event of a failure, you must contact the manufacturer or replace them asap

LIFE SPAN	Boscarol head immobilizers have a lifespan of **5 years** from the date of manufacture if stored and used in accordance with 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 head immobilizer is designed for the emergency health service and must therefore always ready to use, at any time and in any situation • Replace it immediately if there are obvious failures or failures to the structure, fastening straps and welds (in the case of the WIND head immobilizer). The head immobilizer must be stored in a place inaccessible to children • Do not leave the patient alone after immobilizing him. It must always be properly assisted • Dispose of the packaging in accordance with current regulations and make sure it is out of reach of children. Straps are considered a possible toy that is dangerous for children and for this reason they must never be left within their reach • Tampering, alterations and modifications of the device are not allowed without the authorization of the manufacturer • Operators must be trained and aware of the legal rules and provisions on safety at work (use of PPE) • Rescuers not properly trained to use the head immobilizer can create wounds and damage to the patient as well as to themselves. The application of the device always provides for maximum cooperation within the rescue team

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 place a sterile cloth to ensure insulation from the materials of the device • Do not apply the head immobilizer if the patient's head is too small and the immobilization operations are made complicated due to the size of the medical device

5. SIDE EFFECTS (POSSIBLE DURING USE)

Collateral effects	• Skin irritation and reactivity phenomena due to the patient's direct contact with PVC (WIND) or vinyl paint applied to the surface of the OB device • Nervous stress on conscious person that could cause sudden movements by the patient during immobilization and after

6. FERMACAPO BOSCAROL

Boscarol head immobilizers are marketed "ready to use" and are complete with all their functional parts. Upon receipt, problems relating to the use or lack of certain arts provided must be verified and possibly contested. The head immobilizers do not include accessories or spare parts.

Boscarol head immobilizers type available:

IMM121640 WIND Head Immobilizer

IMM121628 OB Head Immobilizer (yellow color version)
IMM121631B Black OB Head Immobilizer (black color version)
IMM121631V Green OB Head Immobilizer (green color version)
IMM121631R Red OB Head Immobilizer (red color version)

7. COMPOSITION OF DEVICES

WIND HEAD IMMOBILIZER

The WIND head immobilizer type has been designed and built to be as compact as possible when not used and stored in the emergency vehicles. It is made by of a semi-rigid base covered of a layer of PVC (1 in the figure on the side) to ensure functional stability and durability.

The fastening straps are made of polyethylene and Velcro. The two chin guards (2 in the figure on the side) are soft and made in the same way as the base in PVC. Two other Velcro straps are available for fixing (see 3 in the picture on the side).

The sewing of the belts to the chin guards guarantees a high tensile strength. The two side wings are welded at the base but can be raised to hold the head and secure it. High-frequency welding of PVC guarantees stability and durability over time even in case of prolonged use.

The BOSCAROL WIND head immobilizer is radio-transparent and translucent and ensuring radiological investigations without having to be removed from the patient.

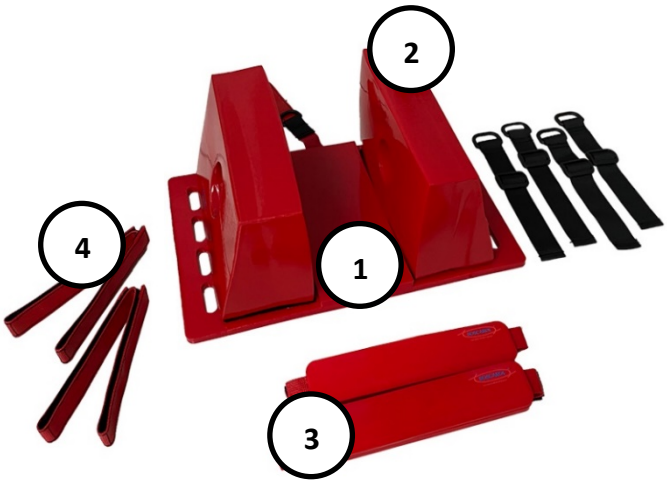
Inside the base of the device is inserted a recycled cardboard of appropriate thickness, coated with a thin layer of foam, that guarantees structural rigidity. The two chin guards are identical and are used to ensure that the forehead and chin are good fastened to the device.

OB HEAD IMMOILIZER

The Boscarol 'OB' type headband is available in three models: yellow, black, green and red.

The models also differ in the way the belts are attached to the rigid base of the headband. In particular:

- The models in the yellow and red colour (see image opposite) have eight straps inserted in the eight slots at the base of the headband (detail 1 in the photo on the right). These straps, thanks to the presence of 'D' rings, allow the anchorage of the four securing belts. In particular, the two fixation belts without chin straps (detail 4 in the photo on the right) allow the head restraint to be fixed to the stretcher, while the two fixation belts with chin straps (detail 3 in the photo on the right) allow the head restraint to be fixed to the patient's head, following the insertion of the chinstraps.



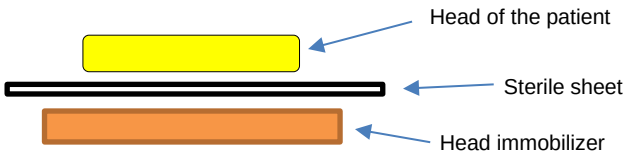
- The models in the black and green colours do not have the eight straps inserted in the eight slots at the base of the head restraint. In this case, the four fastening belts made of Velcro are inserted directly into the slots in the rigid base of the head restraint. In particular, two belts, once inserted into the slots, allow the headcap immobilizer to be attached to the stretcher, while the other two belts, following the insertion of the chin straps and once passed through the slots, allow the headcap immobilizer to be attached to the patient's head.

In general, all 'OB' head-restraint models, while maintaining the functional characteristics of the 'WIND' model, are made of elastic polyurethane foam better known as 'foam rubber'. Thanks to the specific density and the possibility of obtaining geometric pieces with a defined shape, it is possible to make the base of the headband, the two side wedges with the holes for access to the ears (detail 2 in the photo) and the chin straps (detail 3 in the photo on the right). The base is made in the same way (detail 1 in the photo on the right).

How to use Boscarol head immobilizers

Before applying the device, it is good to immobilize the patient's neck through a cervical collar of an appropriate size. This allows to safely raise the patient head enough to place it on the base of the device. Never improvise rescuers if you have no experience, skill and expertise. Normally the number of rescuers for these operations is two. Below are the operations necessary for the immobilization of the head:

1. Always warn a conscious patient about what we are doing and calm them down as much as possible
2. One rescuer manually stabilizes the patient's head and neck (to which the cervical collar had previously been applied correctly). These instructions do not deal with the application of the collar that refers to other manufacturers and user manuals
3. The second rescuer applies a sterile sheet on the head immobilizer (both models) that will serve to isolate the head and the skin from the device itself and avoid any allergies or irritations. Then apply the device by slightly raising the patient's head and insert the head immobilizer (applies to both the WIND and OB version)
4. Make sure the base is centered relative to the patient's head
5. Now if you are using the WIND head immobilizer it is enough to raise the two wings and apply the two chin guards respectively to fix the chin and forehead. In the OB head immobilizer, it is enough instead to apply the two wedges on the Velcro of the base, taking care not to tighten the head excessively (the wedges must be adherent)



BIOCOMPATIBILITY	Sterile sheet placed between the head immobilizer and the patient's head is necessary to prevent skin irritation and reactivity due to the patient's direct contact with PVC (WIND) or vinyl paint applied to the surface of the device (OB). It also establishes a thermal barrier in case the temperature of the device is very high or very low

6. Always check the patient's condition during all immobilization operations and during transport to the hospital or nearby rescue center. The photo on the side illustrates the correct use of the immobilizer WIND applied to a patient already equipped with a cervical collar

8. REUSE OF BOSCAROL HEAD IMMOBILIZER

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 his or her safety.
OB and WIND head immobilizers must be washed with water not exceeding 40°C of temperature. Never use metal or very hard abrasive brushes that could ruin the fabric and coating of PVC.

Pressure washer	Do not use high pressure washers that could damage the surface layers of the head immobilizer and damage Velcro and polyethylene flaps
Attention	Do not cut or change the structure and shape of Boscarol head immobilizer so as not to damage it irreparably

Remove the sheet that was placed between the patient's head and the device and discard it. After separated the wedges (by removing from the Velcro strap), the chin guards and the fasten belts of the OB head immobilizer (the WIND head immobilizer is composed of a single piece) clean and remove with the use of water all the substances present. If necessary, use a non-abrasive sponge to remove any fouling. Before proceeding with disinfection remove any traces of blood and/or organic left from the patient. Disinfect the head immobilizer (the entire surface) with

substances suitable for that 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.

Disinfection	Always comply with the provisions of local and regional provisions about the correct disinfection operations
Sterilization	Boscarol OB and WIND head immobilizers cannot **be** sterilized

9. DEVICE STORAGE

Boscarol head immobilizers can be used and stored in the temperature range between -10 and 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). Always insert a barrier of appropriate thickness and equip all the necessary measures to contain these effects to reduce any consequently risk.

The head immobilizer must be stored clean and dry. It must be periodically checked to avoid mold, damage due to bending and leakage on the welds. If stored or in very humid places it must be checked either every month airing it or to avoid the formation of mold or other substances that could degrade the device.

10. DEMOLITION OF THE DEVICE

The device may be scrapped in accordance with national and local guidelines for the disposal of substances based on PVC, foam and polyethylene. The inner cardboard can be disposed of in the appropriate containers for recycling purposes. All materials comply with REACH and do not contain dangerous substances.

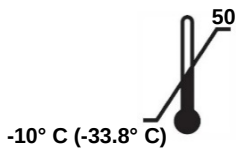
11. TECHNICAL SERVICE AND SPARE PARTS

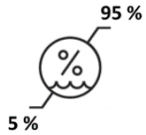
In the event of a functional failure or if auxiliary information is required regarding reuse and/or storage and transport operations, please contact the manufacturer at +39 0471 932893 or by sending an email to info@boscarol.it.

12. TECHNICAL DATA AND COMPLIANCE FOR BOSCAROL HEAD IMMOBILIZERS

Classification of medical devices (in accordance with MDR 2017/745)	I
Basic UDI number (in conformity a MDR 2017/745)	805240088IMMGK
Technical specifications	Device produced on design with technical materials compliant with REACH Regulation
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

Dimension head immobilizer		
Fermacapo Boscarol WIND	40x30.5x16 (h) cm (with wings raised)	Device weight: 1.28 kg
Fermacapo Boscarol OB	42.5x26.5x16 (h)	Device weight: 0.92 kg

Conditions of preservation and use		
	Temperature range for transport, use and storage	-10 to 50° C (from -33.8 to 122° F)

	Humidity range for transport, use and storage	5÷95 % U.R. not condensed
	Keep away from direct sunlight	
	For further technical or storage information, please contact the manufacturer (info@boscarol.it).	
	On all sizes of the head immobilizer 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 the head immobilizer (all models) for a period of 1 year or from the date of purchase from the original distributor or manufacturer. The company guarantees that the device is free of defective materials and/or other 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) with a note describing 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 - Email: 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 function of the WIND and OB head immobilizer, Oscar Boscarol S.r.l. can only be held liable 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 on the WIND and OB head immobilizer outside those described in this user manual.

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