BOSCAROL IMMOBILISATION DEVICES

PAEDIATRIC OB HEAD IMMOBILISER

OPERATING INSTRUCTIONS

PAEDIATRIC OB HEAD IMMOBILISER

CE

Medical devices compliant with the European Medical Device Regulation 2017/745

PRODUCED BY:

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Information on the manufacturer and the medical device:

- 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:

IMM121631P

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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 head immobiliser 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

	Use the head immobiliser only within the specified temperature range. Using the head immobiliser outside these limits may reduce 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	Internal reference number (device code)
	Please read the operating instructions in other languages available on the indicated website
MD	Indicates that the head immobiliser 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	Boscarol paediatric OB head immobiliser
Primary use	Medical device intended for head immobilisation in lifting and carrying devices
Other Uses	No known use other than that for which it was designed
Medical purpose	Immobilisation and stabilisation of the patient's head before transport. Can be used with the aid of a cervical collar

Part of application in the human body	Patient's head
Type of patients	Paediatric patients of both sexes
Application time on the same patient	Short-term' use (maximum 30 days of consecutive use)
Information on use	• Due to the size of the device, the paediatric Boscarol OB head immobiliser can only be used on paediatric patients. • Can be used in conjunction with the cervical collar and other immobilisation and transport systems such as the scoop stretcher or spinal stretcher • The immobilisation of the head of a patient with injuries of various kinds or supposed injuries must always be carried out by professional rescuers who are trained and familiar with the specific technologies for immobilising and transporting patients • We recommend using the head immobiliser with at least two trained rescuers

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 paediatric OB head immobiliser is manufactured without the use of latex. The materials used are latex-free, however, it cannot be excluded that during the entire production chain latex may have come into contact with
DEVICE CONTAMINATED	Warning in case of device contamination: Immobilisation of the patient's head on the head immobiliser 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. If in doubt before sending a device in for repair, please contact Boscarol's technical service department by sending an e-mail to info@boscarol.it or by calling +39 0471 932893

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

The paediatric Boscarol OB head immobiliser has been designed and tested to comply with the requirements of the European Medical Device Regulation 2017/745. The Boscarol OB paediatric head immobiliser is a medical device of risk class I

	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 report it immediately to the manufacturer at: raq@boscarol.it
PERIODIC SAFETY INSPECTION	**Preventive maintenance and periodic safety inspection:** The Boscarol head immobiliser should be checked periodically (a full functional check at least once a week is recommended), especially on the removable parts and the Velcro fasteners that allow the attachment of the side wedges, chin straps and fixing straps. In the event of failure, contact the manufacturer or replace them

LIFETIME	The paediatric Boscarol OB head immobiliser has a lifespan of **5 years** from the date of purchase if stored and used according to these instructions for use
Responsibility of operators/users	• **Take appropriate precautions if the device comes into contact with the child's body and place sterile drapes between it (biocompatibility)** • The Boscarol head immobiliser is designed for emergency medical service and must therefore always be ready for use, at any time and in any situation • Replace it immediately if there are obvious faults or failures in the frame and fastening straps. The head immobiliser must be stored in a place inaccessible to children. • Never leave the patient alone after immobilising him/her. He must always be assisted properly • Dispose of packaging in accordance with current regulations and ensure that it is out of the reach of children. Belts are to be regarded as a possible dangerous toy for children and for this reason should never be left within their reach. • 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) • Rescuers not properly trained in the use of the head immobiliser can create injury and damage to the patient as well as themselves. The application of the device always requires 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. A sterile drape must always be interposed to ensure isolation from device materials • Do not apply the head immobiliser if the patient's head is too small and immobilisation operations are complicated due to the size of the medical device

5. SIDE EFFECTS (POSSIBLE DURING USE)

SIDE EFFECTS	• Skin irritation and reactivity due to direct patient contact with vinyl paint applied to the surface of the device • Nervous stress on a conscious person that could cause sudden movements by the patient during and after immobilisation

6. DEVICE COMPOSITION

The paediatric OB head immobiliser is marketed 'ready-to-use' and is complete with all its functional parts. Upon receipt, problems with the use or lack of certain parts must be checked and, if necessary, disputed.

The Boscarol OB paediatric head immobiliser is 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 head immobiliser, the two side wedges with the holes for access to the ears (detail 2 in the photo) and the chin rests (detail 3 in the photo on the right). The base is made in the same way (detail 1 in the photo on the right).

In addition, the Boscarol OB paediatric head immobiliser has on the rigid base of the head immobiliser (detail 1 in the photo on the right), seven slots for the insertion of respectively

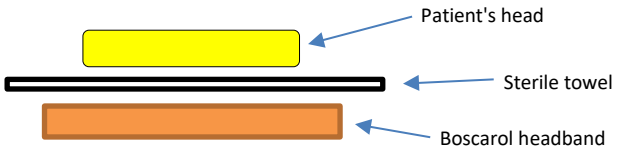
- three Velcro straps for attaching the head restraint to the stretcher

- four belts with eyelets (detail 4 in the photo on the right) for fastening the chin straps, which allow the patient's head to be immobilised on the head immobiliser.

How to use the Boscarol head immobiliser

Before applying the head immobiliser, it is a good idea to immobilise the patient's neck with an appropriately sized cervical collar. This allows the head to be safely raised enough to rest on the head immobiliser. Never improvise as a rescuer unless you have experience, skills and competence. Normally the number of rescuers for these operations is two. The following are the operations required to immobilise the head:

1. Always warn a conscious patient about what you are doing and reassure them as much as possible
2. A rescuer manually stabilises the patient's head and neck (to which the cervical collar had previously been correctly applied). These instructions do not deal with the application of the collar which refers to other manufacturers and user manuals
3. The second rescuer applies a sterile drape to the head immobiliser (both models), which will serve to insulate the head from the device itself and avoid any allergies or irritation. He then applies the device by slightly raising the patient's head and inserts the head immobiliser.
4. Ensure that the base is centred in relation to the patient's head
5. Now simply apply the two wedges to the Velcro on the base, taking care not to over-tighten the head (the wedges must be tight)



BIOCOMPATIBILITY	The sterile drape interposed between the head immobiliser and the patient's head is necessary to prevent possible irritation and skin reactivity due to direct contact of the patient with the vinyl paint applied to the surface of the device. It also establishes a thermal barrier in case the temperature of the device is very high or very low.

6. Always make sure of the patient's condition during all immobilisation operations and during transport to the hospital or nearby rescue centre. The adjacent photo illustrates the correct use of the immobiliser applied to a patient already wearing a cervical collar

7. REUSE OF THE BOSCAROL HEAD IMMOBILISER

After each use, the medical device must be cleaned and disinfected. These operations become more important if the patient's pathological condition is unknown and direct contamination may be present. The user must always take protective measures and means to protect his or her own safety.
The head fastener 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 the PVC coating.

Pressure washers	Do not use high-pressure cleaners, which could damage the surface layers of the head immobiliser and damage the Velcro and polyethylene webbing
Attention	Do not cut or modify the structure and shape of the Boscarol head immobiliser so as not to damage it irreparably

Safely remove the cloth between the headscarf and the patient's head. After separating the parts making up the head immobiliser, clean and remove all substances present with water. If necessary, use a non-abrasive sponge to remove any encrustations. Before disinfecting, remove any blood and/or organic traces left by the patient. Disinfect the head immobiliser (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 fouling. Coloured

disinfectants could irreparably 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.

Disinfection	Always comply with local and regional regulations regarding proper disinfection operations
Sterilisation	The paediatric Boscarol OB head immobiliser CANNOT be sterilised

8. STORAGE OF THE DEVICE

The Boscarol head immobiliser 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, leading to patient complications (hypothermia and hyperthermia). Always insert a sterile drape of appropriate thickness and take all necessary measures to contain these effects and limit them as far as possible.

The head immobiliser must be stored clean and dry. It must be checked periodically to prevent mould or damage due to bending. If it is stored in a very humid place, it must be checked every month by airing it in order to prevent the formation of mould or other substances that could degrade the device.

9. DEMOLITION OF THE DEVICE

The device can be scrapped in accordance with national and local regulations for the disposal of PVC, foam rubber and polyethylene substances. The internal cardboard can be disposed of in the appropriate containers for recycling. All materials are REACH-compliant and contain no hazardous substances.

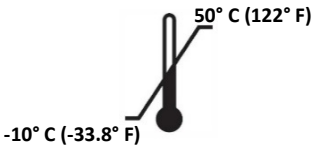
10. TECHNICAL SERVICE AND SPARE PARTS

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

11. TECHNICAL DATA AND COMPLIANCE

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 manufactured to drawing with REACH-compliant technical materials
Degree of protection against the ingress of liquids and solids (IEC 529):	IP65 without abrasion or breakage
Risk assessment (technical documentation)	ISO 14971:2019
Lifespan	5 years from date of manufacture

Boscarol head immobiliser dimensions		
Paediatric Boscarol OB head immobiliser	34x26x14 (h) cm	Device weight: 0.5 kg

Conditions of storage and use		
	Temperature range for transport, use and storage	-10 to 50° C (-33.8 to 122° F)
	Humidity range for transport, use and storage	5÷95 % R.H. n.c.

	Keep out of direct sunlight
	For further technical information or information on the use and storage of the device, please contact the manufacturer (info@boscarol.it).
	On all head immobiliser sizes, the tolerance is ±5 cm (due to coupling). On the remaining sizes it is 5%.
Declaration of conformity	
	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

12. GUARANTEE

Oscar Boscarol warrants the head immobiliser 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 head immobiliser, 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 liable for any direct or indirect accidental damage, if any modifications, repairs, unauthorised technical interventions have been carried out on the device or any of its parts have been damaged by accident or misuse. There are no other express or limited warranties of merchantability, fitness or otherwise on the headphone other than those described in this user guide.

BOSCAROL®
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