BOSCAROL IMMOBILISATION DEVICES

ITU

INFANT TRANSPORT UNIT

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:

IMM120071		

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Note: From now on the word ITU will be used to indicate and refer to the medical device.

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 ITU 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

	Use the ITU device only within the specified temperature range. Using the device outside these limits 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 mark in accordance with European Regulation MDR 2017/745 for medical devices in class I
	Manufacturer
	Order number (device code)
	Please read the operating instructions in other languages available on the indicated website
	Indicates that the ITU device 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	ITU - Infant Transport Unit Boscarol
Primary use	A medical device intended for the immobilisation and protection of an infant or young child for the purpose of lifting and carrying him or her safely on other transport equipment
Other uses	Can also be used on healthy patients for the sole purpose of protecting them
Medical purpose	Immobilisation and safe transport of the immobilised patient. The device allows the immobilisation of a patient wearing a cervical collar.

Part of application in the human body	Entire body of the patient
Type of patients	Children and infants up to 15 kg
Time of application on the same patient	Short-term use (maximum 30 days of consecutive use)
Information on use	• ITU Boscarol can be used on all types of children and infants (up to a maximum weight of 15 kg) • Can be used in conjunction with cervical collar and other related medical devices • The immobilisation and transport of a patient should always be carried out by professional rescuers who are trained and knowledgeable about specific patient immobilisation and transport technologies. • ITU with at least two trained rescuers is recommended

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	ITU Boscarol devices are manufactured without the use of latex. The materials used are latex-free, however, it cannot be excluded that during the entire production chain they may have come into contact with latex.
DEVICE CONTAMINATE	Warning about device contamination: Immobilisation of a child/infant with the ITU device 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

ITU Boscarol has been designed and tested to comply with the requirements imposed by the European Medical Device Regulation 745/2017. ITU Boscarol 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 ITU Boscarol device must be checked periodically (a full functional check at least once a week is recommended) especially on the removable parts and the fastening straps. In the event of a malfunction, contact the manufacturer or replace the device.
LIFETIME	The ITU Boscarol has a lifetime of **5 years** from the date of manufacture if stored and used in accordance with these operating instructions

Responsibility of operators/users	• **Take precautions in case of direct contact of the device with the child's/adult's body by placing sterile sheet (biocompatibility).** • The ITU Boscarol device 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 cracks or failures in the outer structure, fastening straps and hinges and inspection ports. The ITU device must be stored in a place inaccessible to children to prevent them from using it as a toy and creating dangerous situations. • Never leave the patient alone after immobilisation and insertion into the ITU. He must always be properly attended to • Dispose of packaging in accordance with current regulations and ensure that it is out of the reach of children. Belts are a possible dangerous toy for children and should therefore never be left within 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). • Rescuers not properly trained in the use of the ITU can create injury and damage to the patient as well as themselves. The application of the device always requires maximum co-operation 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 placed in between to ensure isolation from device materials. • Do not apply the ITU device if the infant or child has a suspected fracture of the spinal column or skull base without using proper spinal immobilization systems • Do not place the body of the child/infant upside down or sideways to avoid suffocation • Do not use the device if the fastening straps are not secured to the patient. • Do not use the device to create a temperature and humidity-controlled environment

5. SIDE EFFECTS (POSSIBLE DURING USE)

SIDE EFFECTS	• Phenomena of skin irritation and reactivity due to direct patient contact with the synthetic fabric or fastening straps • Choking syndrome • Colic (typical in babies/infants) • Convulsions • Claustrophobia or phenomena derived from claustrophobia

6. ITU BOSCAROL

The ITU Boscarol device is marketed folded up in a storage and transport bag and is complete with all functional parts. Upon receipt, it must be checked and, if necessary, the manufacturer must be notified if there are any problems with its use or if any parts are missing. ITU devices do not include accessories or spare parts. Photo of the transport bag on the right.

IMM120071 ITU

7. COMPOSITION OF THE DEVICE

Inside the transport and storage bag, the device is folded up to minimise space requirements and to be stowed in rescue ambulances.
The device has been designed and built to be stored in this way for a long time without suffering deformation or structural damage.
The figure below shows the device open and mounted (1). Detail 2 illustrates the side pocket (one on the right and one on the left) equipped with a hinge that can be opened and used to store small medical devices. Also visible in the picture are the portholes (3) for patient access (there are two on both sides) and the rigid structure made by means of profiles inserted in a fabric pocket (two upper and two lower ones).
On the upper side there is an opening made of transparent Crystal with zips and a final Velcro strap to ensure that no substances or gases can enter and to guarantee discreet water resistance.
Detail 5 shows one of the two lifting and carrying handles of the device.

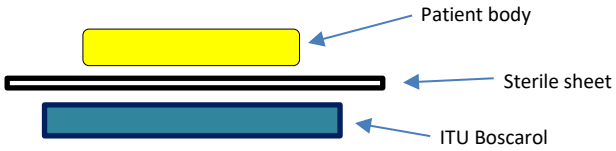
The ITU Boscarol medical device is made of synthetic nylon and PVC fabrics sewn and arranged in such a way as to prevent damage to the patient. The entire device is accessible by means of a system of hinges and windows made of Crystal, which allows the child/infant to be placed in it without difficulty and in complete safety. The device is not completely airtight and allows for the necessary ventilation. Patient attachment straps are available on the lower mattress (see detail on the right).

How to use the ITU Boscarol device

The first thing to do is to assemble the device after removing it from the carrying case and placing it on a clean, solid base. Close the two side hinges to make the device conform to its structure. Then open the transparent top and insert a sterile sheet before laying the patient down.
Then secure it with the appropriate straps and make sure it can breathe without difficulty.
The photo on the right shows the correctly executed immobilisation.
Never improvise as a rescuer unless you have experience, skills and expertise. Normally the number of rescuers for the use of this device is two.

ATTENTION	Straps for attaching the ITU device to the stretcher or transport device are not included with the device and depend on the type of transport system. Pass them through the slots on the underside of the device.

The sheet to be placed between the child/infant should be specifically designed to retain bodily fluids released during rescue and transport operations. The figure below shows how to prepare the sheet.



BIOCOMPATIBILITY	The sterile sheet placed between the ITU device and the patient's body is necessary to prevent irritation and skin reactivity due to direct patient contact with synthetic fabrics. It also establishes a thermal barrier and containment of the release of organic substances.

8. REUSE OF ITU BOSCAROL

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 ITU device can be washed with water which must not exceed a temperature of 40° C. Never use abrasive metal brushes or very hard brushes, as these can damage the fabric. Do not use washing machine. Before soaking, the internal rigid parts and the rigid plastic panels must be removed.

Pressure washers	Do not use high-pressure cleaning machines, which could damage the surface layers of the ITU and damage the Velcro and polyethylene webbing
Attention	Do not cut or modify the structure and shape of the device in order not to damage it irreparably
Washing machines	It is not possible to wash the device in a washing machine due to its size

Before starting to clean the device safely remove the sheet between the ITU device and the patient's body (could be contemned).
Check the condition of the internal straps, clean the buckles thoroughly. Soak the device in water not exceeding 40° C with a mild detergent. Clean and remove all substances. If necessary, use a non-abrasive sponge to remove any deposits. Remove any traces of blood and/or organic matter left by the patient before disinfecting. Disinfect the ITU device (the entire surface) with products suitable for this purpose (test on one side of the device to ensure no damage). 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. Ensure that disinfectants do not make the Crystal opaque by testing in one corner of the device.

Disinfection	Always comply with local and regional regulations regarding validation of disinfection operations
Sterilisation	The ITU Boscarol device **CANNOT** be sterilised!

9. STORAGE OF THE DEVICE

ITU Boscarol dispsoitive can be used and stored in the temperature range of -10 to +50 °C. If the temperature range is too low or too high, the material in contact with the patient may become extremely cold or hot, resulting in patient complications (hypothermia and hyperthermia). Always insert a sterile sheet of appropriate thickness and take all necessary measures to contain these effects and limit them as much as possible.
The dispositive must be stored clean and dry. It should be checked periodically for mould, seam damage and the functionality of straps and hinges. If stored in a very humid location, it should be checked every month by 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 in accordance with national and local disposal guidelines for plastic and polyethylene-based substances and foam rubber for the mattress. All materials are REACH compliant and contain no hazardous substances. Aluminium parts can be fully recycled.

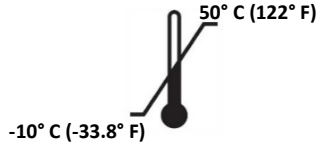
11. TECHNICAL SERVICE AND SPARE PARTS

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.

12. TECHNICAL DATA AND CONFORMITY FOR BOSCAROL DEVICES

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 design with technical materials in compliance with REACH Regulation
Degree of protection against ingress of liquids and solids (IEC 529):	IPX0. The device is not protected.
Risk assessment (technical documentation)	ISO 14971:2019
Service life	5 years from date of manufacture

Boscarol device dimensions		
ITU - Infant Transport Unit	89x40x47 (h) cm assembled and ready to use	Device weight: 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 away from 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 sizes of the ITU device the tolerance is ±5 cm (due to fits). 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 ITU device (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 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 procurement
3. absence of tampering, modifications and/or anything not conforming to the original product

In terms of security, reliability and functionality of the ITU, 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 are no other express or limited warranties of merchantability, fitness or otherwise on the ITU other than those described in this user manual.

NOTES BY THE USER

TRAINING ON USE AND REUSE (by the user)

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