BOSCAROL IMMOBILISATION DEVICES

CTS

CHILDREN TRANSPORT SYSTEM

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:

IMM120050		

EC INDEX

Note: From now on the word CTS 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 CTS 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 CTS only within the specified temperature range. Using the CTS 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 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 CTS is a medical device
 (01)08052400880753 (11)210408 (20)00 (10)12100	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	CTS - Children Transport System Boscarol
Primary use	A medical device intended to immobilise 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	• CTS 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. • It is recommended to use the CTS 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. 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	Boscarol CTSs 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: Immobilization of a child/infant on the CTS 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

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

Responsibility operators/users	• **Take precautions if the device comes into direct contact with the body of the child/adult by placing sterile drapes over it (biocompatibility).** • The Boscarol CTS 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 any obvious cracks or failures in the frame, fixing straps and hinges. The CTS should be stored in a place inaccessible to children to avoid suffocation. • Never leave the patient alone after immobilisation. 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 considered to be 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 who are not properly trained in the use of CTS 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 placed in between to ensure isolation from device materials. • Do not apply CTS if the infant or child has a suspected fracture of the spinal column or skull base. • 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.

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

6. CTS BOSCAROL

The Boscarol CTS is sold "ready to use" and is complete with all functional parts. Upon receipt, it is necessary to check and, if necessary, to complain to the manufacturer if there are problems with the use or if some of the parts are missing. The CTS do not include accessories or spare parts.

IMM120050 CTS Boscarol (Children Transport System)

7. COMPOSITION OF THE DEVICE

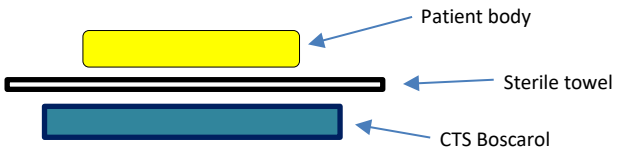
The CTS Boscarol medical device is made of stitched nylon fabrics and arranged in such a way as to prevent damage to the patient. The body of the device (1 in the picture above) is accessible via a hinge on the side which opens like a book.
The straps (detail 2 in the picture above) are designed to allow the device to be attached to a vacuum mattress or stretcher (see side picture 4).
A storage bag allows the device to be stored and kept in the ambulance (see picture 3).

How to use CTS Boscarol

Lay the CTS on a stable and possibly clean surface. The device does not have a rigid bottom support and the fabric can be damaged by objects or debris (e.g. from the road surface).
Stretch the straps on the stretcher or other transportation device.
Open the device by its hinges and disconnect the two central straps. Lift them completely and place a sterile cloth on the bottom of the device which has two specific functions: to isolate the baby/infant from the synthetic fabric of which the device is made and to retain any organic liquid leaks from the patient, thus avoiding contaminating the device and making it difficult to reuse.
In the case of small or very small people, immobilisation of the head or limbs can be carried out before or after laying the patient on the CTS (see cervical collar or splints).
After placing the child/infant on the CTS attach the straps and transfer him/her to the transportation device.
Never improvise as a rescuer unless you have experience, skills and expertise. Normally the number of rescuers for these operations is two.

ATTENTION	The straps that secure the CTS to the stretcher or transportation device are relatively long and can pose a danger to the rescuer and the patient. Always keep an eye on them to prevent them from posing a danger to the rescuer's movements!

The sheet to be placed between the child/infant should be specifically designed to also retain bodily fluids released during rescue and transport operations. The photo on the next page shows how to prepare the sheet.



BIOCOMPATIBILITY	The sterile drape placed between the CTS and the patient's body is necessary to prevent irritation and skin reactivity due to direct patient contact with synthetic fabrics. In addition, it establishes a thermal barrier and limits the release of organic substances.

Always check the condition of the patient during all restraint operations and during transport to the hospital or nearby rescue centre. The photo opposite illustrates the correct use of the device when mounted on a transport stretcher equipped with a vacuum mattress.

8. REUSE OF CTS BOSCAROL

The medical device must be cleaned and disinfected after each use. This is particularly 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 CTS can be washed with water which must not exceed a temperature of 40° C. Never use abrasive metal brushes or very hard brushes, which could damage the fabric. If using a washing machine, avoid spinning.

Pressure washers	Do not use high-pressure cleaning machines as they may damage the surface layers of the CTS and damage the Velcro and polyethylene webbing.
Attention	Do not cut or modify the structure and shape of Boscarol CTS to avoid irreparable damage.
Washing machines	Do not spin the device if machine washed. Do not exceed 40° C water temperature. Aggressive detergents may alter the colours of the device and damage it.

Safely remove the drape between the CTS and the patient's body.
Check the condition of the straps, clean the buckles thoroughly. Soak the device in lukewarm 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 CTS (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.

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

9. STORAGE OF THE DEVICE

Boscarol CTS can be used and stored in the temperature range -10 to +50 °C. At very low or high temperatures, the material in contact with the patient may become extremely cold or hot, resulting in 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 much as possible.
The CTS must be stored clean and dry. It should be checked periodically for mould, seam damage and the functionality of the 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 regulations for the disposal of plastic and polyethylene based substances. All materials are REACH compliant and contain no hazardous substances.

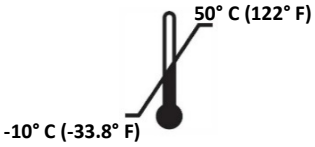
11. TECHNICAL SERVICE AND SPARE PARTS

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 CTS

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):	IP65 without abrasion or breakage
Risk assessment (technical documentation)	ISO 14971:2019
Service life	5 years from date of manufacture

Dimensions CTS Boscarol		
CTS Boscarol	134x57x5 (h) cm	Device weight: 1,5 Kg ±5 %

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 CTS sizes, the tolerance is ±5 cm (due to fitment). 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 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 CTS (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 safety, reliability and functionality of the CTS, 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 made 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 any other kind on the CTS other than those described in this user manual.

NOTES BY THE USER

TRAINING ON USE AND REUSE (by the user)

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