



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

## **FERMATESTA HEAD IMMOBILIZER IMMOBILISATEUR DE TÊTE KOPFHALTEBEFESTIGUNG INMOVILIZADOR DE CABEZA IMOBILIZADOR DE CABEÇA ΣΥΣΚΕΥΗ ΣΤΑΘΕΡΟΠΟΙΗΣΗΣ ΚΕΦΑΛΗΣ مثبت للرأس**

È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.

Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεται.

يجب الإبلاغ فوراً عن أي حادث خطير وقع فيما يتعلق بالجهاز الطبي الذي زدونا به إلى الجهة الصانعة والسلطة المختصة في الدولة العضو التي يقع فيها.

**REF 34020 - 34021**



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## FEATURES

The foreseen use is to block the head of the patient during transport on specific stretchers, in case of suspected injuries at the head or neck.

The product includes:

- a base that is fixed to the stretcher using side straps and a front one and sometimes there are underlying surfaces coated in Velcro;
- two side blocks, padded to hold body in place;
- two padded belts with Velcro closure to block forehead and chin.

For transportation in critical conditions or along rough routes, this piece can be used along with a rigid neck piece. The head piece is made of soft material covered with washable film that causes minimum interference with X-rays.

The product or parts of it, cannot be used in ways not specified in this manual.

## WARNINGS



*The device must be used by trained personnel and must be positioned by at least two operators. For the safety of the patient it is necessary to correctly fix the head immobilizer with the straps, verifying that they do not hinder transportation operations. Non-compliance with this instructions could cause injuries to people.*



*Do not use the product if damaged and contact our distributor. Avoid temporary repairs.*

Since the product is made of corrosion-proof materials suitable for the environmental conditions foreseen for its normal use, does not require special care, however it is necessary to store it in a closed place making sure that is protected from dust and dirt to assure its hygienic conditions. Moreover, it is recommended to store the product in a place which can be reached easily by the personnel in case of necessity.

## UNPACKING



*Always remember that packing elements (paper, cellophane, stitches, adhesive tape, etc.) can cut and/or hurt if they are not carefully handled. They shall be removed with adequate means and shall not be left at the mercy of irresponsible persons; the same is valid for tools used to remove packages (scissors, knives, etc.).*

After opening the packages, first of all it is necessary to check all pieces and parts composing the product. Check that they are all present and in perfect conditions.

## OPERATION

Always secure the patient to the stretcher so the patient does not fall due to jerks or accidental inclinations.

Fix the base to the stretcher using the specific belts and if present use the surfaces covered with Velcro.

If there are suspected injuries to the neck, before transferring the patient, apply a neck collar.

Transfer the patient to the stretcher and place the blocks on the head of the patient exercising a light pressure downwards to fix them to the Velcro-covered base.

The blocks must adhere to the sides of the head without generating excessive pressure and apply symmetrically. The inclined part of the blocks must face outwards.

Apply the padded belts on the chin and forehead according to the trauma and the morphology of

the patient: fixing them to the base using the nearest buckles or buttonholes.



*All emergency operations must be carried out by qualified personnel.*

**MAINTENANCE**

Clean the head immobilizer without using abrasive products or solvents (we recommend using water and soap). After cleaning the immobilizer dry all parts thoroughly.

To disinfect the immobilizer, use a combination of cleaning products/disinfecting products. Dilute the disinfecting product following the manufacturer’s instructions.

Periodically verify the wear of the product and if necessary replace the damaged parts with original spare parts.

	Caution: read instructions (warnings) carefully		Manufacturer
	Keep away from sunlight		Date of manufacture
	Keep in a cool, dry place	<b>REF</b>	Product code
<b>CE</b>	Medical Device compliant with Regulation (EU) 2017/745	<b>LOT</b>	Lot number
<b>MD</b>	Medical Device		Consult instructions for use

**GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies.