HALF ROLLY

890.02

CE
Directive 93/42/EEC

EN

WWW.KONG.IT

CONTENTS

CHAPTER 1

SYMBOLS AND ASSISTANCE

1.1 SYMBOLS

To make reading this manual comfortable and clear, the following are the symbols used to manage important warnings, for correct and safe use of the device.

REQUISITE FOR CORRECT USE
Identifies the presence of information required to use the device correctly.

INFORMATIVE REQUISITE
Identifies the presence of useful and general information, to guide the user to consciously use the device and/or carry out the actions.

CE

Identifies that the product is manufactured, designed and produced in compliance with what is required by safety requirements in the Medical Devices Directive 93/42/EEC (Class I medical device, in compliance with classification rule 1, as indicated in annex IX).

1.2 ASSISTANCE

For information, contact Kong Customer Service by:
- telephone 0039 0341 630506,
- fax 0039 0341 641550,
- email: safetycare@kong.it,

or write to KONG S.p.A. – Via XXV Aprile, 4 – 23804 Monte Marenzo LC - ITALY.
To facilitate assistance operations, always communicate or indicate the serial number (SN) indicated on the label applied to the Medical Device.

CHAPTER 2

2 GENERAL INFORMATION

Users must read and perfectly understand the information provided by the manufacturer (hereinafter information) before using the device. This information relates to the characteristics, services, assembly, disassembly, maintenance, conservation, disinfection, etc of the device; even though it does include some suggestions on how to use the products, it must not be considered as a true to life instruction manual.

WARNINGS AND LIMITATIONS OF USE:

- This device must be used only by physically suitable people, trained (informed and educated) to use it and with specific experience with handling patients or, in training activities, by people under the direct control of instructors/ supervisors capable of guaranteeing their safety.
- Do not use the device until you have read this entire operating manual.
- Before and after operation, all the checks described in chapter 7 must be carried out. If the user has any doubt about the efficiency of the device, it must be replaced immediately.
- To reduce the risk of exposure/ transmission of infective diseases, clean and disinfect the device as defined in chapter 5.
- Strictly follow the information provided by the manufacturer, improper use of the device is dangerous.
- Incorrect use of the patient restraint systems may cause damage to the patient.
- Use in combination with devices and/or accessories other than those indicated in paragraph 3.4 may be dangerous. Always make sure that the devices are compatible by consulting the information provided by the manufacturer.
- Improper use, deformation, falls, wear, chemical contamination, exposure to temperatures below -30°C or higher than +50°C for the textile/plastic components/ devices, and +100°C for metal devices, are some examples of causes that may reduce, limit or end the life of the device.
- Before any recovery operation, make sure that the weight does not exceed the capacity defined in paragraph 3.3.
- Avoid exposing the device to heat sources or to contact with chemical substances. Reduce direct exposure to sunlight to the minimum necessary. At low temperatures and in the presence of humidity, ice may form. This, on textile devices, may reduce flexibility and increase the risk of cuts and abrasions.
- It is strictly forbidden to modify and/or repair the device.

All our devices are tested/inspected piece by piece in accordance with the procedures of the Quality System certified according to the UNI EN ISO 9001 standard. Laboratory tests, inspections, information and norms do not always manage to reproduce what actually happens in practice, and so performance under real usage conditions in a natural environment can differ, sometimes even considerably. The best information can be gained by continual practice under the supervision of skilled, expert, qualified individuals.

Warning: not suitable for use in ATEX environments (Directive 94/9/EC)

CHAPTER 3

TECHNICAL FEATURES

3.1 NOMENCLATURE AND MATERIALS FOR THE PARTS

A - Support surface in high-density polyethylene,
B - Slings in polyester,
C - Webbing loops in polyester,
D - Handles in polyester,
E - Sling in polyester,
F - Buckles with hook in aluminium alloy,
G - Automatic buckles,
H - Head immobilizer HRP,
I - Head immobilizer chin strap,
L - Thigh straps,
M - Static rope,
N - Sling with ratchet,
O - Transport bag.

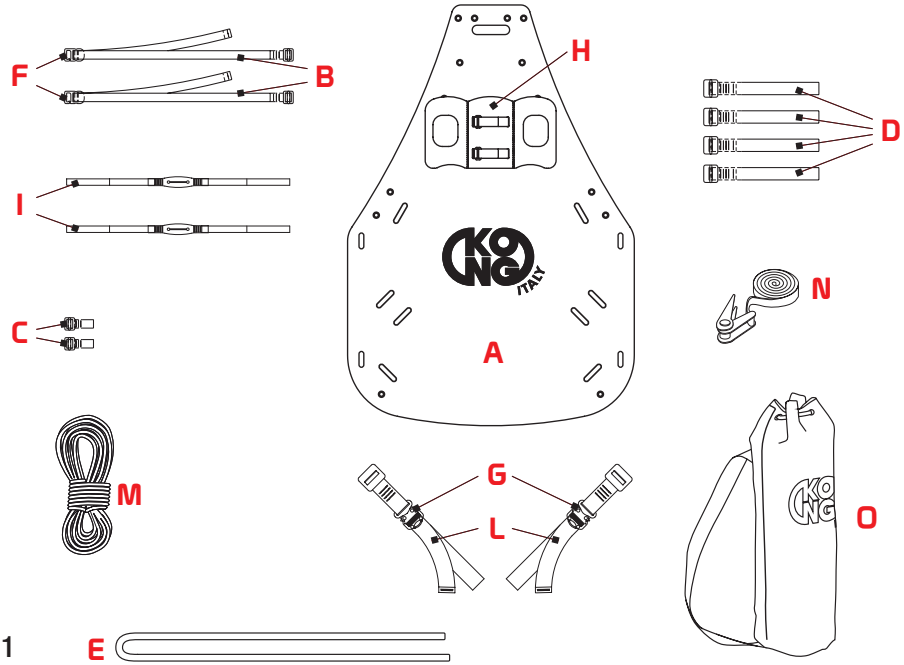
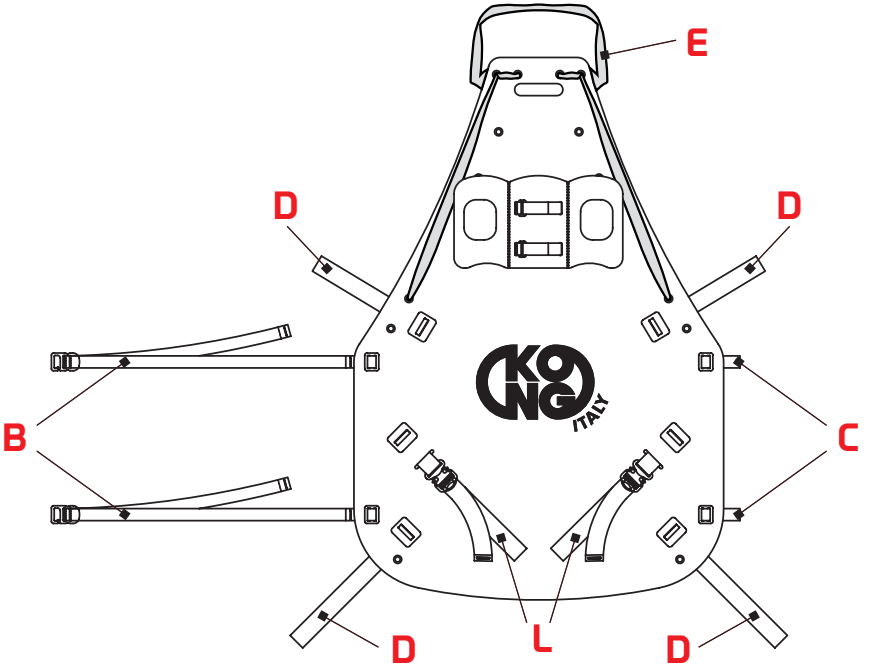


Fig.1


E
D
D
B
C
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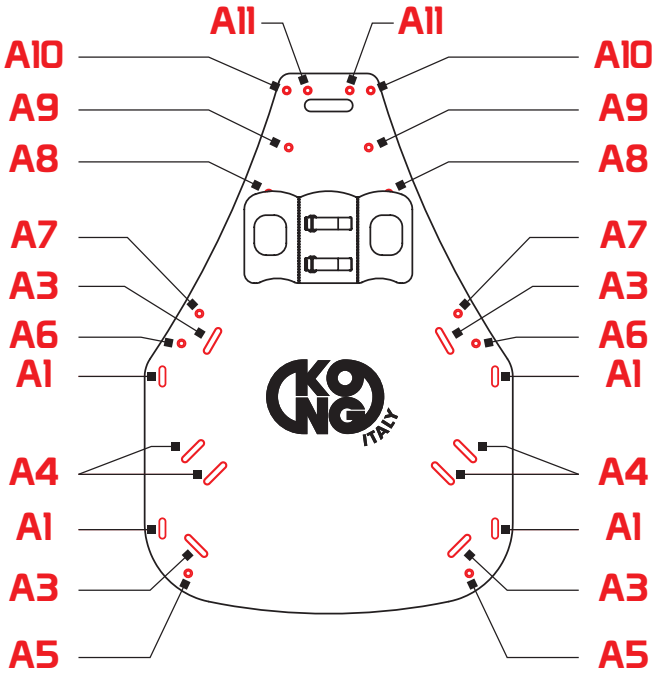
L
D


A11
A11
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A4
A4
A1
A1
A3
A3
A5
A5

Fig.2

3.2 DIMENSIONS

Length:	135 cm
Width:	90 cm
Rolled in the bag:	ø 30 x 110 cm
Overall weight of the parts (fig. 1):	6.6 kg

3.3 CAPACITY

The **"HALF ROLLY"** rescue sheet is tested to support the following loads, evenly distributed:
- 450 Kg lifting from the handles (D),
- 450 Kg dragging using the sling (E),
- 1500 Kg lifting/lowering using the rope (M).

In relation to the lifting and transport procedures that the rescue worker considers suitable, we suggest applying at least the following safety coefficients:
- 1:3 = operating load: 150 Kg for manual lifting using the handles (D) - (fig. 3)
- 1:3 = operating load: 150 Kg for dragging by hand using the sling (E) - (fig. 4)
- 1:10 = operating load: 150 Kg for lifting/lowering with rescue devices using the rope (M) (fig. 5).

Before any recovery operation, make sure that the weight does not exceed the capacity indicated above!

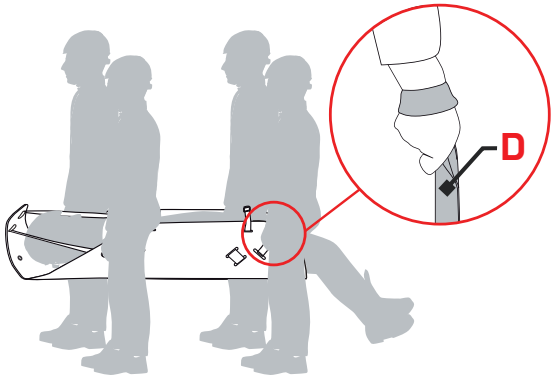


Fig. 3

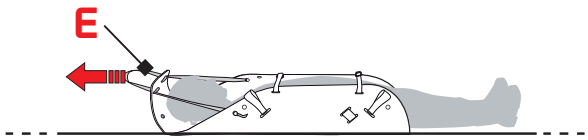


Fig. 4

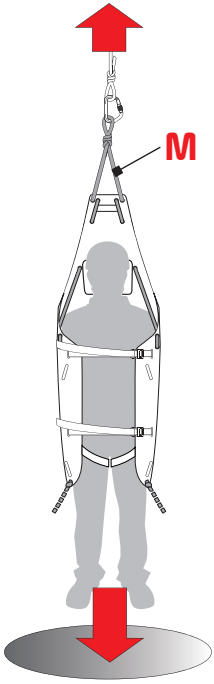


Fig. 5

3.4 ACCESSORIES AND SPARE PARTS

3.4.1 Accessories

The **“HALF ROLLY”** rescue sheet is complete with all accessories for the intended purposes indicated in this manual.

3.4.2 Spare Parts

B - Slings in polyester,
C - Webbing loops in polyester,
D - Handles in polyester,
E - Sling in polyester,
I - Head immobilizer chin strap,
L - Thigh straps,
M - Static rope,
N - Sling with ratchet,
O - Transport bag.

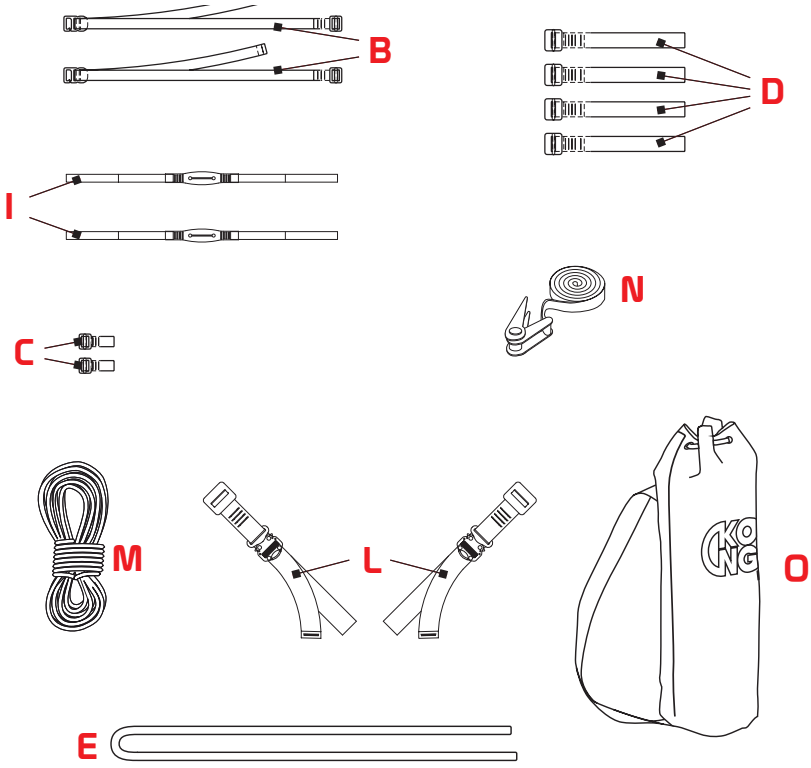


Fig.6

CHAPTER 4

SPECIFIC INFORMATION

4.1 INTENDED USE

The **“HALF ROLLY”** rescue sheet is a medical device suitable for extracting the patient from particularly narrow and tight spaces.
Decisions concerning moving and immobilising the patient, as well as the duration, the procedures to be applied, and any possible combination with other devices must be taken only by expert and trained personnel.

4.2 PREPARATION

a) Remove **“HALF ROLLY”** rescue sheet from the transport bag (O) and remove the ratchet sling (N),
b) Distend the support surface (A) and flatten it, rolling the ends over in the opposite direction and folding the central section (fig. 7)

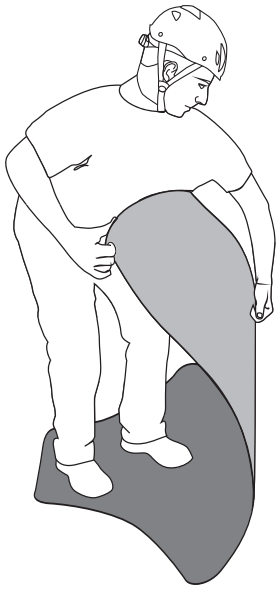


Fig.7

4.3.1 Setting up for immobilising the patient

Prepare the following setup to immobilise the patient:

a) Insert the sling (E) in the A7 holes in the support surface (fig. 8).
b) Insert the slings (B) in the A1 eyelets in the support surface (fig. 9).
c) Insert the webbing loops (C) in the A2 eyelets in the support surface (fig. 10).
d) Insert the thigh straps (L) in the A4 eyelets in the support surface and release the automatic buckles (G) (fig. 12).

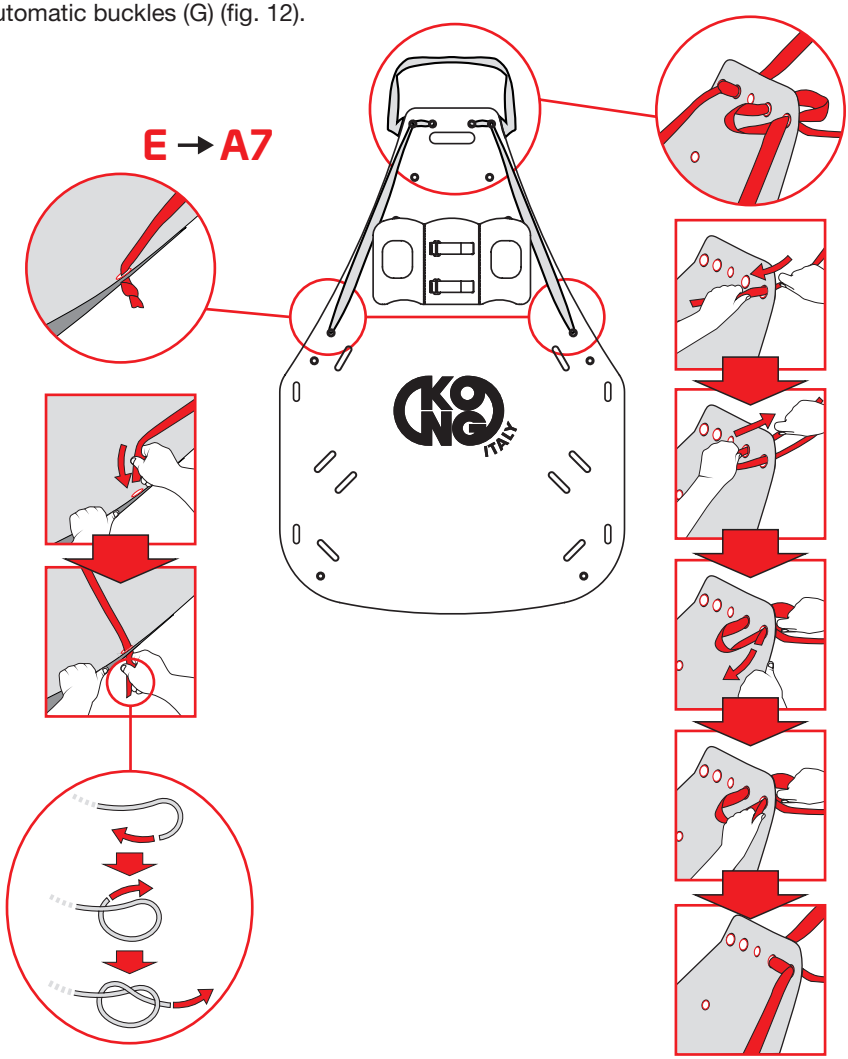


Fig.8

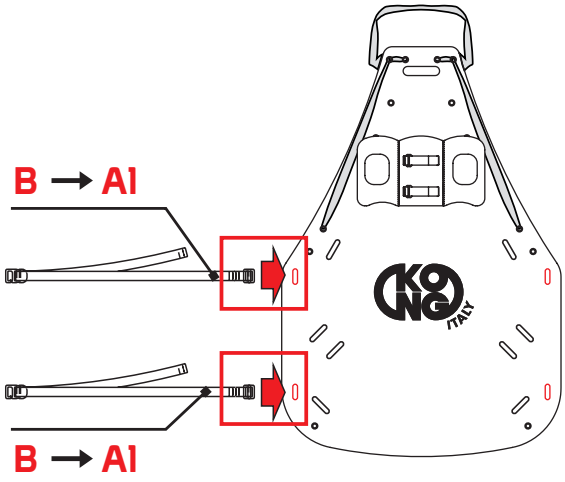
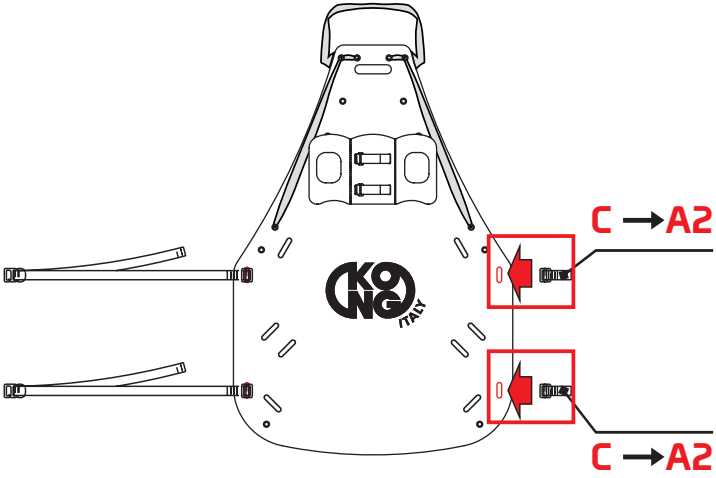


Fig.9



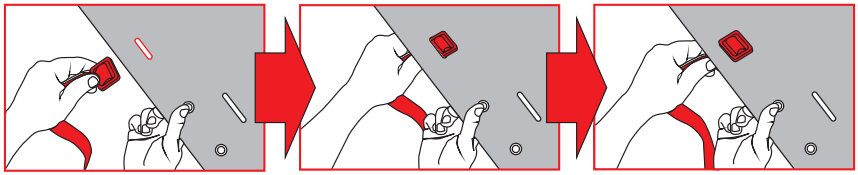
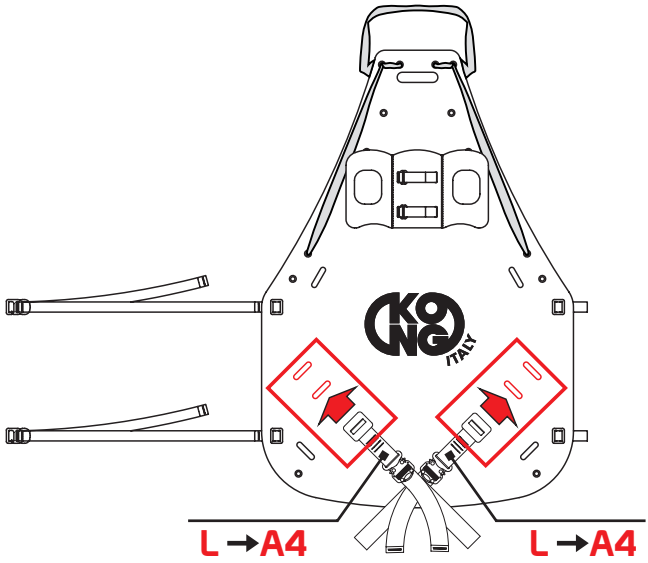
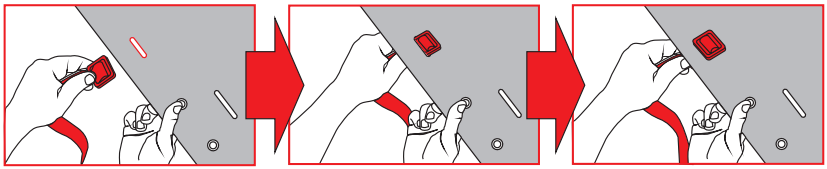


Fig.10





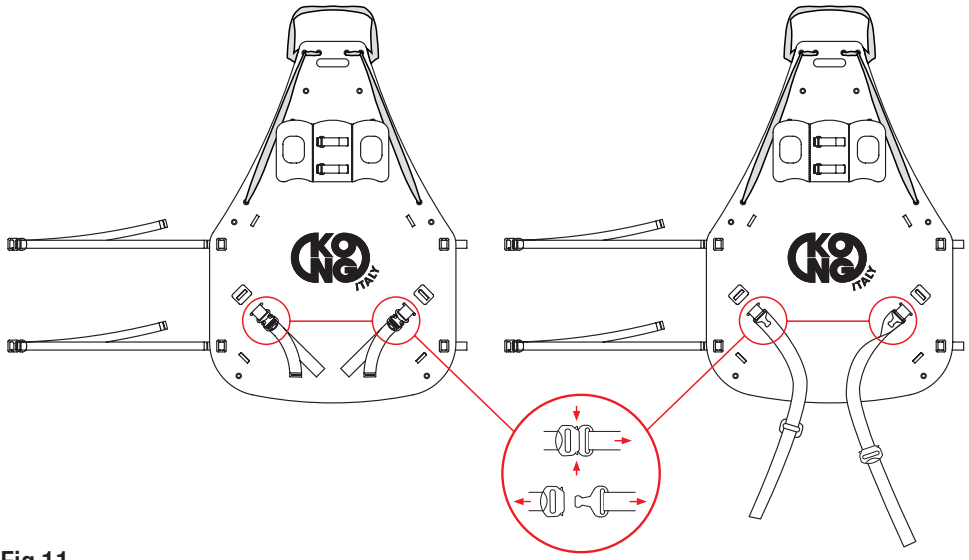


Fig.11

4.3.2 Setting up for moving the patient

In relation to the dragging, transport and lifting/dropping procedures that the rescue worker considers suitable, set the stretcher up with at least one of the following parts:

a) Dragging: tension the sling (E) to lift the end part of the support surface (A) enough to contain the head of the patient and immobilise it (fig. 12).

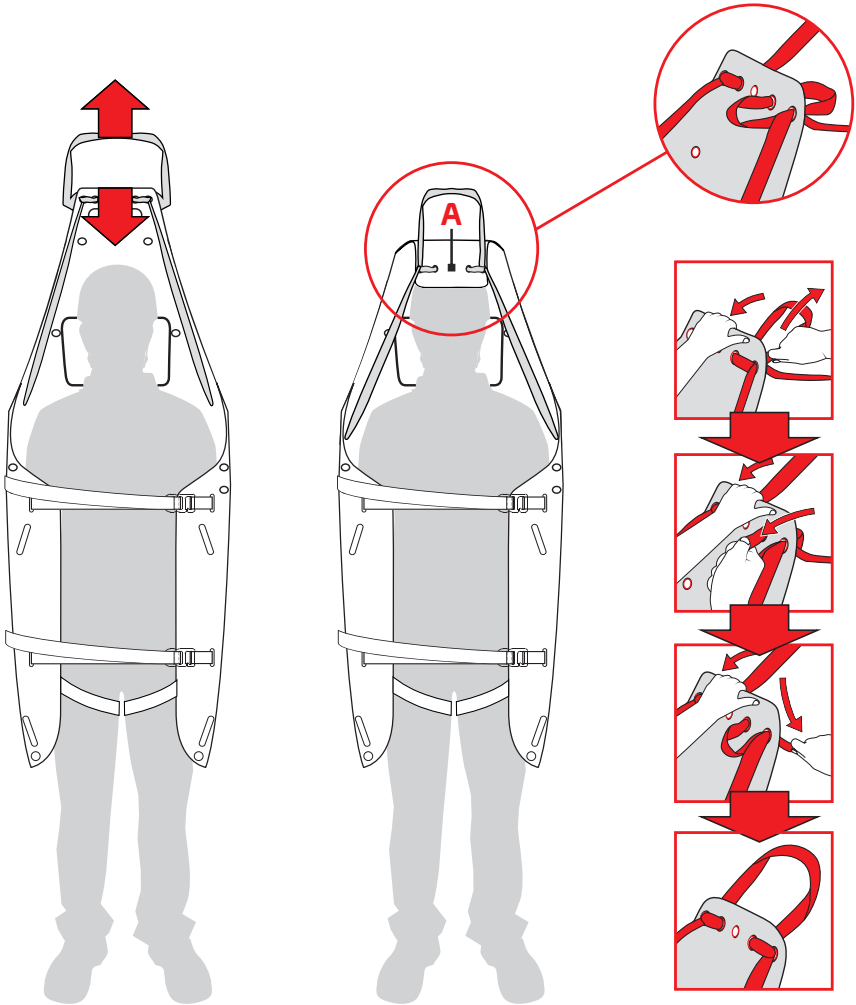


Fig.12

b) Manual transport: insert the side handles (D) in the A3 eyelets in the support surface (fig. 13).

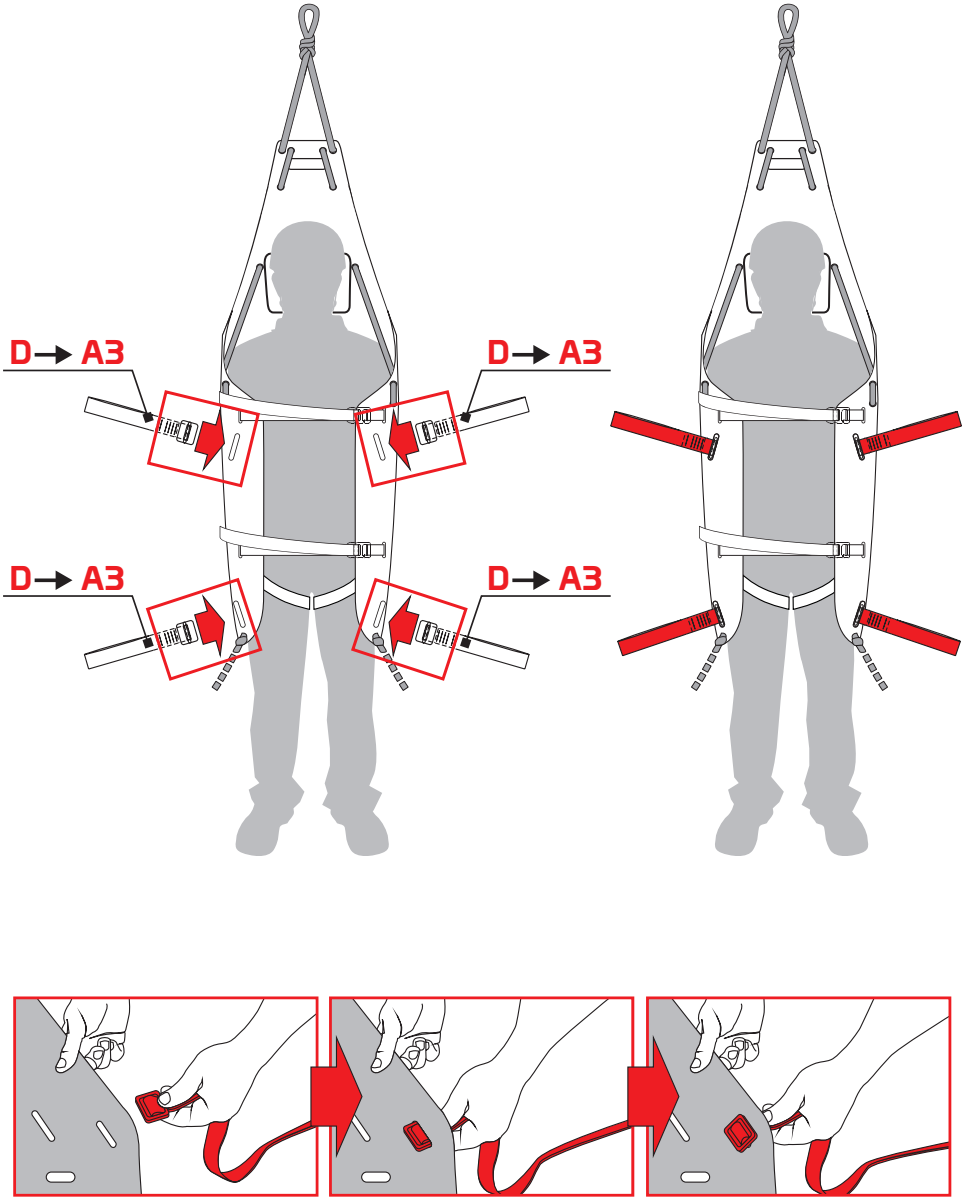


Fig.13

c) Vertical lifting/lowering: insert the rope (M) in the holes from A5 to A11 in the support surface (fig. 14).

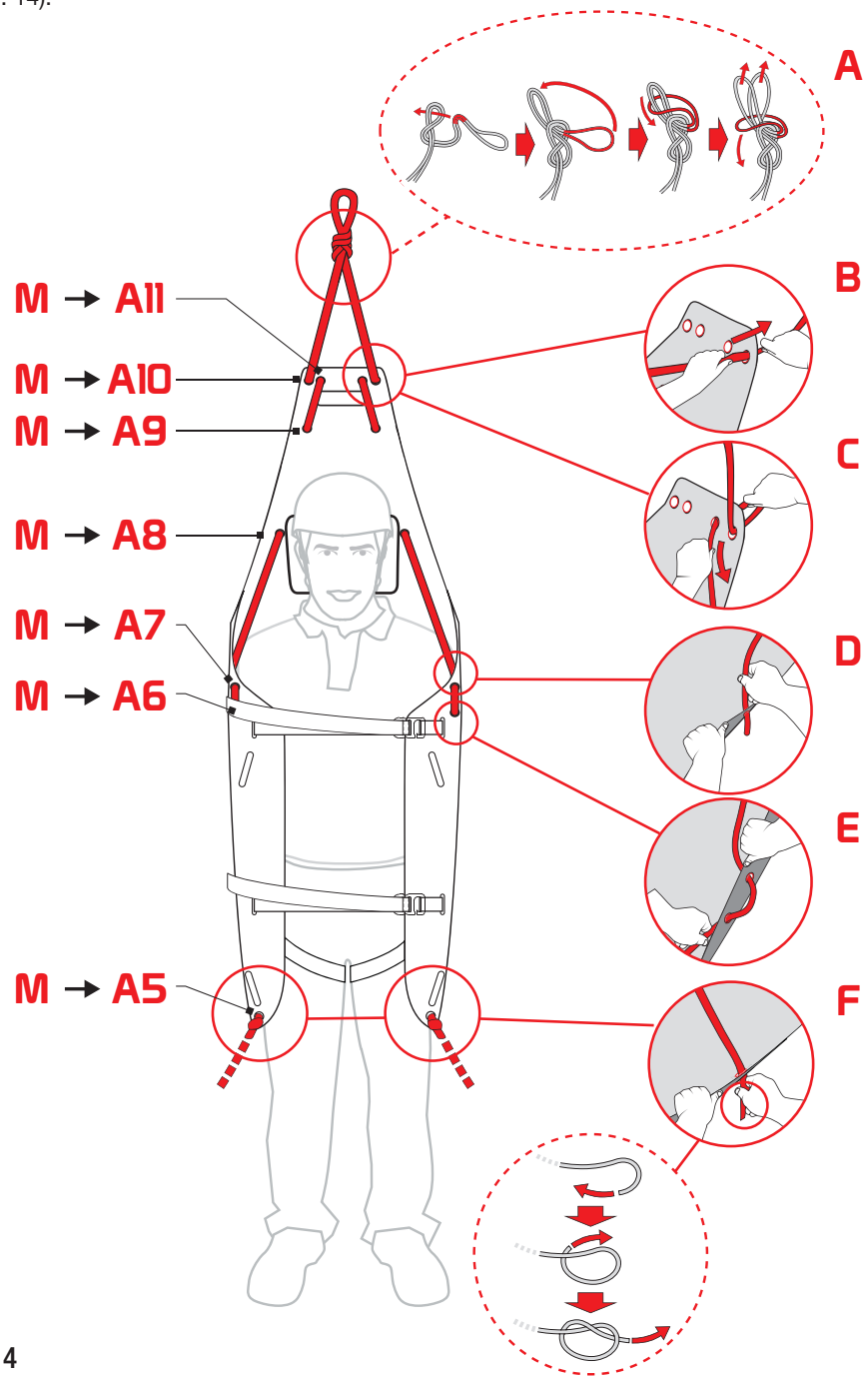


Fig.14

4.4 IMMOBILISING THE PATIENT

After having positioned the patient on the support surface (A):
a) Release the automatic buckles (G) and tension the thigh straps (L) - (fig. 15),
b) Insert the buckles with hook (F) in the corresponding webbing loops (C) and tension the slings (B) to lift the side parts of the support surface (A) enough to contain the patient (fig. 16).

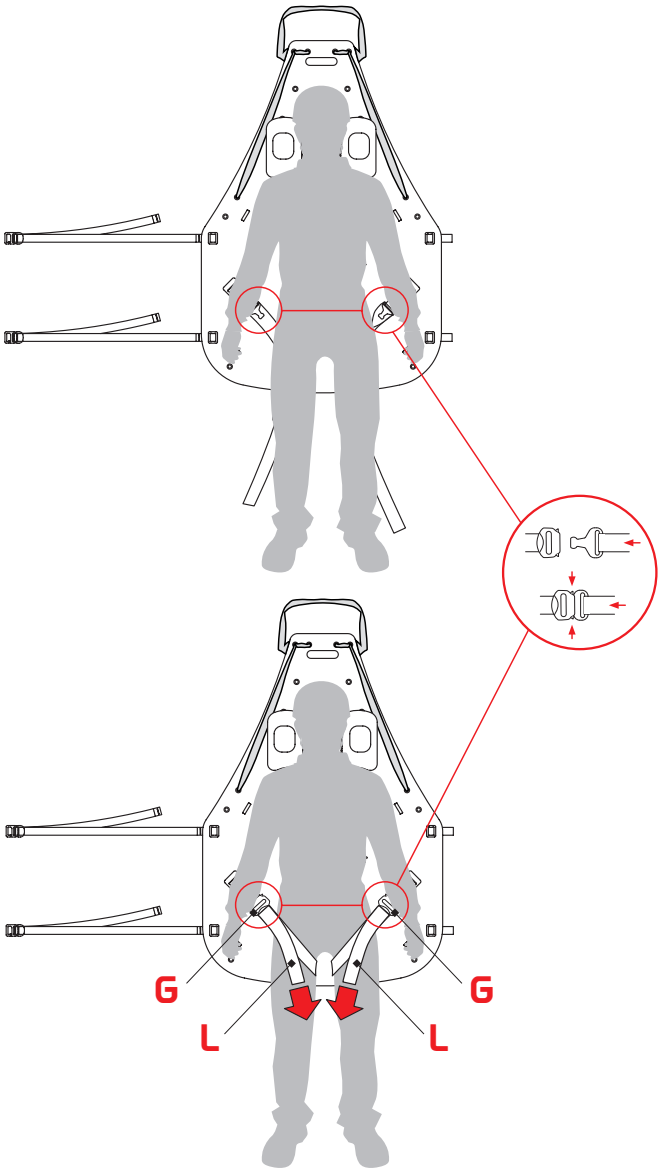


Fig.15

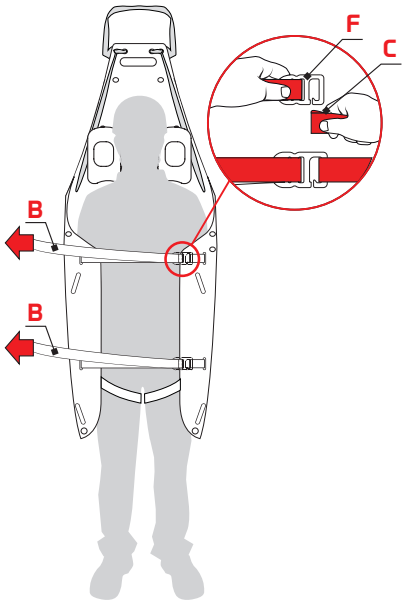


Fig.16

If the rescue worker thinks it is necessary, it is possible to use the head immobilizer HRP (H) to immobilise the patient's head, with the following procedures:
a) Fasten the chin strap (I) to the head immobilizer HRP (H), using the velcro (fig. 17),
b) Wind the chin strap velcro (I) around the rope (M) or the sling (E) and make it adhere to itself (fig. 17).

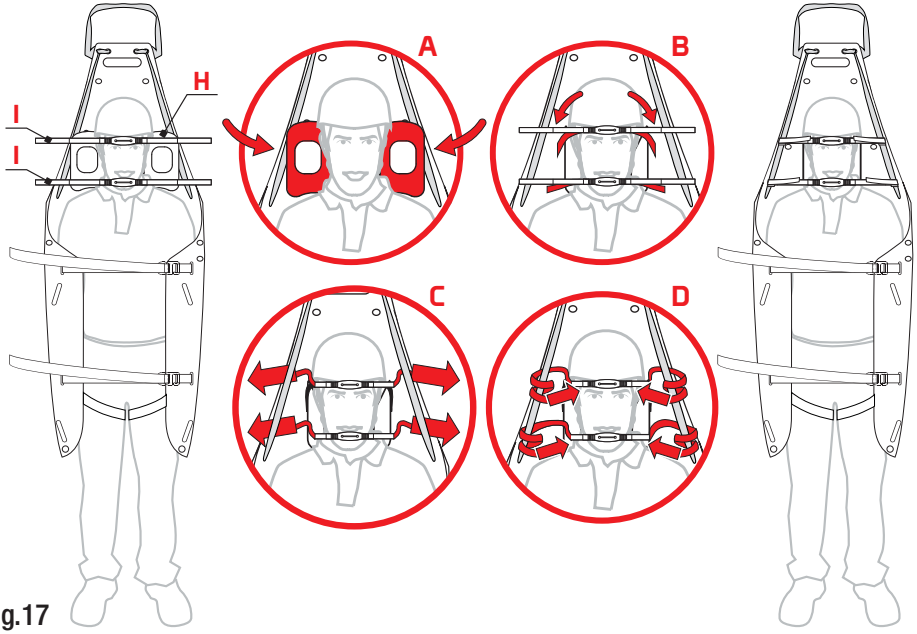


Fig.17

4.5 TRANSPORTING THE PATIENT

The **“HALF ROLLY”** rescue sheet is suitable for lifting and transporting the patient using the side handles (fig. 3), dragging them using the sling (fig. 4), and lifting/lowering them vertically using the static rope (fig. 5).
Using it combined with the **“ROLLY”** sheet increases the level of protection of the lower limbs, and makes the device usable with a winch. Mode of use:
a) Distend the **“ROLLY”** sheet, set up in relation to the planned operating mode,
b) Position the **“HALF ROLLY”** rescue sheet on top, with the immobilised patient, and make sure that the holes are aligned (fig. 18), and insert the rope (M) - fig. 19.

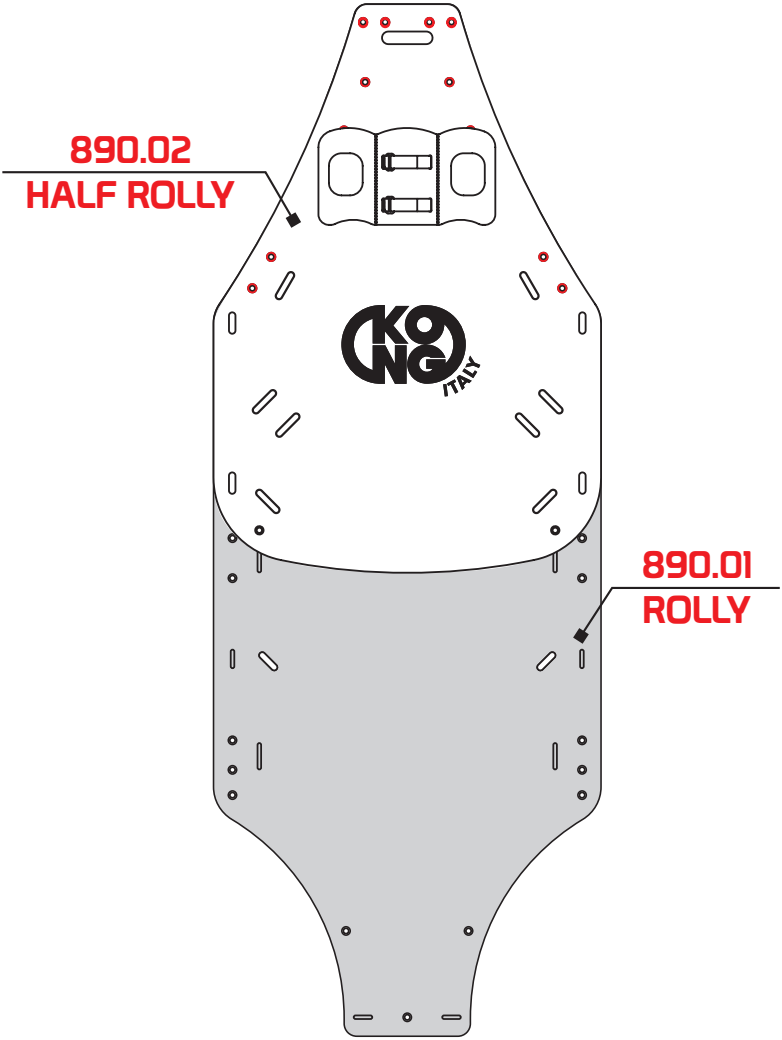


Fig.18

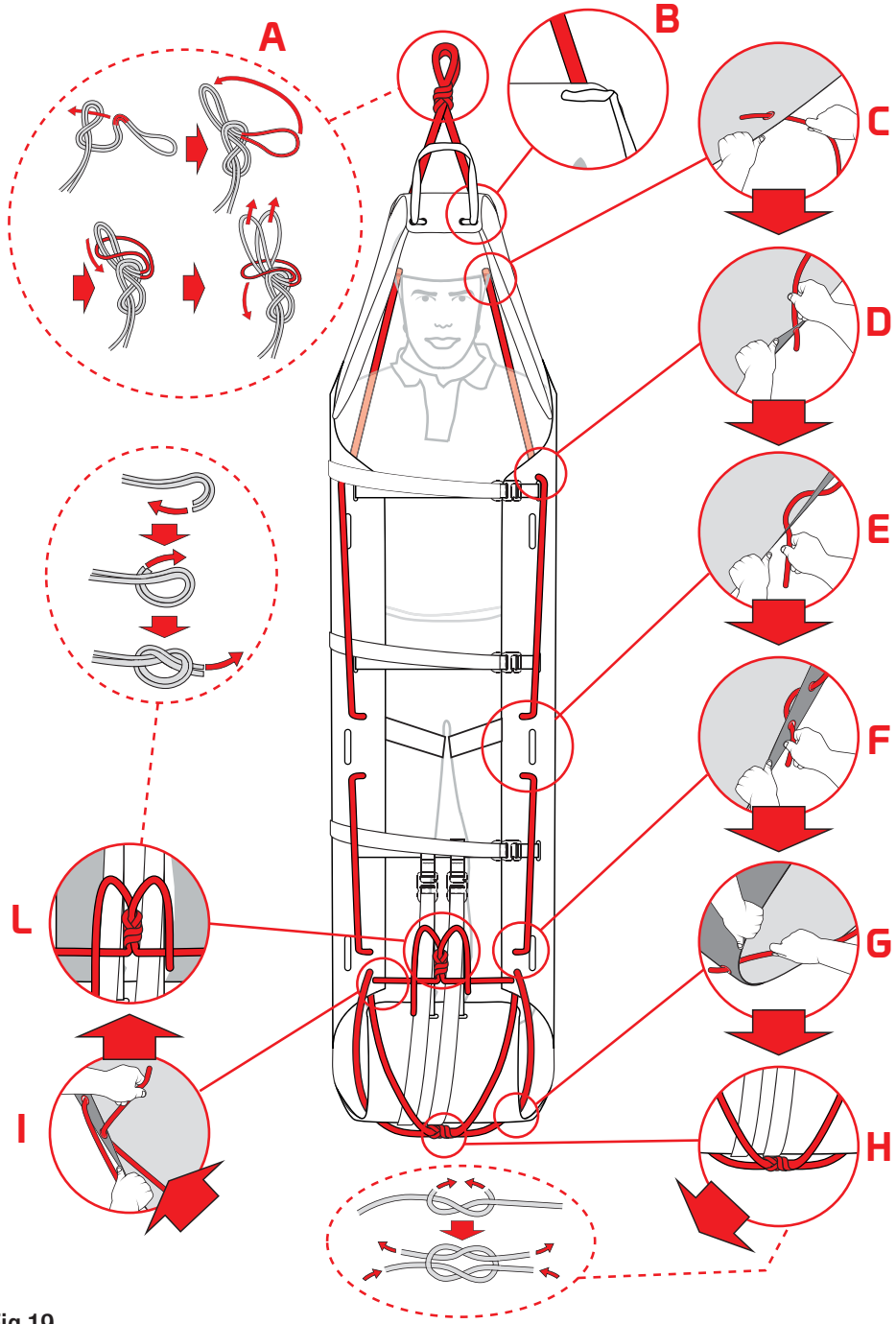


Fig.19

CHAPTER 5

MAINTENANCE AND REPAIRS

5.1 GENERAL

The **"HALF ROLLY"** rescue sheet is made of materials that are highly resistant to wear and to external agents. Despite this, the conditions of use make it necessary to perform maintenance and, in particular cases, even repairs.

Maintenance and repairs must be recorded on a designated register, an example of which is shown in chapter 10.

5.2 MAINTENANCE

Maintenance operations that must be performed by the user are:

a) cleaning: wash after each use with lukewarm drinkable water (max. 40°C), possibly with the addition of a neutral detergent (e.g. Marseille soap). Rinse and allow to dry in the shade, away from direct heat sources,

b) Disinfection, when deemed necessary: dip the product for an hour in lukewarm water in which 1% bleach (sodium hypochlorite) was diluted, then rinse abundantly with drinkable water and allow to dry in the shade, away from direct heat sources.

5.3 REPAIRS

Repairs must be carried out by the manufacturer only.
Users are allowed only to replace the parts mentioned in paragraph 3.4.2 with new and original parts.

CHAPTER 6

6 STORAGE

After cleaning, disinfection and drying, store the device and its accessories in a dry (40-90% relative humidity), fresh (temperature 5-40°C) and dark (avoid U.V. radiation) place, which is also chemically neutral (absolutely avoid salty and/or acid environments), away from sharp edges, sources of heat, dampness, corrosive substances or other possible detrimental conditions.

Do not store this device when wet!

CHAPTER 7

INSPECTIONS AND SERVICING

7.1 CHECKS BEFORE AND AFTER USE

To guarantee the efficiency of the device and the safety of the patient and rescue workers, the **"HALF ROLLY"** rescue sheet and its accessories must be inspected before and after every use.

Before and after each use, it is necessary to check the device and make sure that:

a) fabric parts are not cut or lacerated, particularly in the areas in contact with the holes, eyelets and buckles.
b) the stitching has no loose or cut threads.
c) the support surface does not contain deformations, splits, or wear
d) the eyes inserted in the holes in the support surface have not become deformed and have not developed cutting burrs.

7.2 INSPECTIONS

The "**HALF ROLLY**" rescue sheet does not require inspections.

7.3 SERVICING

The "**HALF ROLLY**" rescue sheet does not require servicing.

CHAPTER 8

PRODUCT LIFE AND GUARANTEE

8.1 PRODUCT LIFESPAN

The product's lifespan is 10 years from the year of manufacture (e.g. year of production 2017 = expiry date 31/12/2027), as long as:

a) maintenance and storage are carried out respectively as described in chapters 5 and 6.
b) inspections and servicing do not encounter defects in operation, deformation, wear, etc.
c) the product is used correctly.

Important: Discard and make unusable any devices that do not pass the pre-use, post-use and periodic inspections.

8.2 DISPOSAL

For correct disposal, it is necessary to follow the rules on disposal of metal or plastic products in force in the country of use, or according to the waste disposal procedures in the hospital facilities where the product is used.

8.3 GUARANTEE

The manufacturer guarantees that the device complies with regulations in force at the time of production. The guarantee covering faults is limited to production defects and raw materials. It does not include wear and tear, oxidation, damages caused by improper use and/or during competition, incorrect maintenance, transport, conservation, storage, etc. The guarantee becomes void as soon as the device is modified or tampered with. The validity corresponds to the legal guarantee of the country where the device was sold by the manufacturer, with effect from the date of sale. After this period no claim can be made against the manufacturer. Any request for repair or replacement under this warranty must be accompanied by a proof of purchase. If the defect is accepted, the manufacturer, at its sole discretion, will repair, replace or refund the device. Under no circumstances does the manufacturer's liability extend beyond the invoice price of the device.

8.4 LEGAL OBLIGATIONS

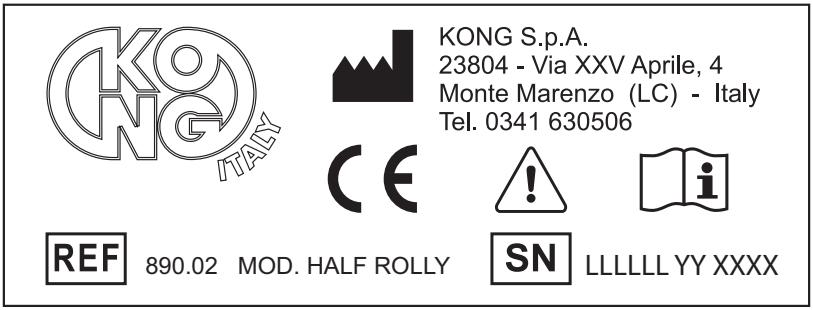
Professional and recreational activities are often regulated by specific national laws that may impose specific limits and/or requirements for the use of these devices. The user is obliged to know and apply these laws, which may in some cases impose obligations different from those contained in this information.

CHAPTER 9

MARKINGS AND SYMBOLS

9.1 MARKING OF THE DEVICE

Example of labels.



Any changes in the distribution of the symbols does not change their contents.

9.2 SYMBOLS

	Identification of the manufacturer	
REF	Product identification code	
SN	Unique serial number	LLLLLL : production lot YY : year of manufacture XXXX : progressive number
	Consult the operating manual	
	Warning: safety-related information, please refer to the operating manual.	
CE	Complies with Council Directive 93/42/EEC and subsequent amendments, Medical Device Class I	

CHAPTER 10

REGISTRATION DOCUMENTS

10.1 MAINTENANCE AND REPAIRS REGISTER

RESCUE SHEET - Medical Device class I			
REF.	890.02	**MOD.**	HALF ROLLY
SN		**Medical Device registration n°**	1519717
Date of first use			

MAINTENANCE AND REPAIRS				
DATE	**M/R**	**Description**	**Outcome**	**Supervisor**

10.2 DECLARATION OF CONFORMITY (FAC-SIMILE)

This device is sold with the corresponding CE Declaration of Conformity, written and signed in the original copy. If it is lost or missing from the packaging, it can be requested from: safetycare@kong.it, communicating the serial number [SN] indicated on the device's label.

KONG S.p.A.
Via XXV Aprile, 4 - (zona industriale)
I - 23804 MONTE MARENZO (Lecco) - ITALY
Tel +39 0341.630506 - Fax +39 0341.641550

www.kong.it

certified UNI EN ISO 9001

DECLARATION OF CONFORMITY

CE

The manufacturer:

Company name:	**KONG S.p.A.**
Legal headquarters:	**Via XXV Aprile, 4 - 23804 Monte Marenzo (LC)**
Operative facilities:	**Via XXV Aprile, 4 - 23804 Monte Marenzo (LC)**
VAT code:	**IT 00703180166**

declares that the:

Medical Device:	**HALF ROLLY**
Class:	**I according to annex IX rule 1**
REF:	**890.02**
SN (serial number):	_____
Production date:	_____

Registered in the data bank of the Ministry of Health with number **1519717**,

complies with the essential requisites indicated by Italian Legislative Decree 46/97 and subsequent amendments, which enforces the Medical Devices Directive 93/42/EEC and subsequent amendments.

Manufacture of the Medical Device took place in accordance with the manufacturer's quality management system, which complies with requisites in annex VII of Directive 93/42/EEC and subsequent amendments.

Monte Marenzo, _____

KONG S.p.A.
The Legal Representative
Dr Marco Bonaiti

Form in revision 0 dated 01/08/2016

Share capital Soc. € 2,000,000.00 Chamber of Commerce Lecco REA 165758
Business Register of Lecco 00703180166 VAT code: IT 00703180166

CHAPTER 11

LIST OF APPLIED AND REFERENCE STANDARDS

11.1 APPLIED STANDARDS

- CEI UNI EN ISO 14971 - Class. CEI 62-121 - CT 62 - Dossier 12929 - Year 2013
  Medical devices - Application of risk management to medical devices.
- CEI EN 62366 - Class. CEI 62-147 - CT 62 - Dossier 9510 E - Year 2008 - First Edition
  Medical devices - Application of usability engineering to medical devices
- CEI UNI EN ISO 15223-1 - Class. CEI 62-234 - CT 62 - Dossier 12811 - Year 2013
  Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.

11.2 STANDARDS USED FOR REFERENCE

- CEI UNI EN ISO 13485 - Year 2012 Medical devices - Quality management systems - Requisites for regulatory purposes
- UNI EN 1865-1 - ICS 11.160 - Year 2015

  Patient Handling Equipment Used In Road Ambulances - Part 1: General Stretcher Systems And Patient Handling Equipment
- UNI EN 13718-1 - Year 2014
  Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances

NOTES

ZZV003EN Rev. 0

Laden Sie die Übersetzung in Ihrer Sprache herunter - Download the translation in your language - Bájate la traducción en tu idioma - Télécharger la traduction dans vostre langue - Scarica la traduzione nella tua lingua

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