



Instructions for use

B-lock 2 head immobiliser



EN – Translation of the original instructions



Commercial name of device	B-LOCK V.2 HEAD IMMOBILIZER
Item code / Catalogue number (REF)	21-00063
Basic UDI-DI	805138087V0880HIMMK
Risk class	I

Revision index

Part no.	Date	Note
BL-EN-MU-160126	16/01/2026	First issue
BL-EN-MU-070426	07/04/2026	Page 36 - Spare part table updates: • Removal Chin strap and Cushion • Update of Cervical wedge code • Inclusion T-shaped band code



Ferno's products meet the general safety and performance requirements of Regulation (EU) 2017/745 (MDR) concerning medical devices.

For information, please visit: www.ferno.it



Consult the Instructions for Use

Additional free copies of the Instructions for Use are available on the website www.ferno.it

1.SUMMARY

1. Introduction.....	4	9.2 Suitability of the User	22
1.1 Instructions for use	4	9.3 Required training.....	22
1.2 Limitation of liability	4	10. Reasonably foreseeable misuse	23
1.3 Ownership of the information	5	11. Use	24
1.4 Manufacturer	5	11.1 Application of device on the Patient in combination with Ferno SCOOPLEX™ atraumatic stretcher.....	24
1.5 Ferno Technical Support	5	11.2 Application of the device to other spine supports.....	27
1.6 Reporting accidents	5	11.3 Checks before patient handling	27
1.7 Definitions	6	11.4 Use with Patient.....	28
1.8 Safety messages	7	12. Storage and preservation.....	29
1.9 Prohibition messages	7	13. Maintenance	30
1.10 Symbols	7	13.1 Maintenance table.....	30
2. Labels	8	13.2 Inspections.....	31
2.1 Device label	8	13.3 Velcro maintenance	31
2.2 Packaging label	8	13.4 Removing/repositioning T-shaped band and connection ties	32
3. Warnings.....	9	14. Cleaning and disinfection	33
3.1 General warnings.....	9	14.1 Cleaning.....	33
3.2 Specific warnings.....	10	14.2 Disinfection	34
4. Residual risks, contraindications and undesirable effects.....	11	15. Accessories	35
5. Intended use	12	15.1 Transport and storage bag	35
5.1 Purpose of the device	12	15.2 Additional cervical wedge.....	35
5.2 Target population	12	16. Spare parts	36
5.3 Expected clinical benefit.....	12	17. Problems, causes and solutions	37
5.4 Environment of use	12	18. Disposal	38
6. Stability conditions.....	13	19. Warranty	39
6.1 Device integrity	13	19.1 Warranty terms and conditions	39
6.2 Environmental parameters	13	19.2 Limitation of liability	39
6.3 Transport	13	19.3 Warranty claims	40
6.4 Storage life.....	13	19.4 Claims.....	40
7. Description.....	14	19.5 Return authorisation	40
7.1 The device	14	20. Records	41
7.2 Supplied components.....	14	20.1 Inspection record	41
7.3 Components not supplied	14	20.2 Training record.....	42
7.4 Main parts	15		
7.5 Technical specifications.....	18		
8. Compatibility with accessories/devices	21		
9. User and training	22		
9.1 Intended user of the device	22		

1. INTRODUCTION

1.1 Instructions for use

IMPORTANT



Consult the Instructions for Use.

IMPORTANT

Store the Instructions for Use in the immediate vicinity of the device, in a place protected from water, dust or other substances that may impair readability.

In the event of loss or damage of the Instructions for Use, contact Ferno S.r.l. to request a replacement copy. Additional free copies are available at www.ferno.it.

IMPORTANT

The configuration of some parts described or depicted in the documentation provided may differ from that of the product in the specific configuration made according to particular requirements or safety regulations; in this case, some descriptions, references or procedures indicated may be of a generic nature while retaining their effectiveness.

Any safety-relevant changes to the device will be communicated by the Manufacturer in accordance with the applicable regulations. The Manufacturer will update these Instructions for Use and make them available to the User.

These Instructions for Use are an integral and essential part of the type I medical device "**B-lock 2 head immobiliser**" (hereinafter "**Device**"), manufactured by Ferno S.r.l. (hereinafter "**Manufacturer**").

The documentation was drawn up in accordance with current safety regulations.

Its contents are intended for technical users trained and qualified in accordance with the Manufacturer's specifications.

The Instructions for Use contain the information necessary to ensure correct understanding of the intended use, how to use the device and the precautions to be taken during the entire life cycle of the product.

They are divided into autonomous chapters, organised according to the temporal sequence of the device's life stages. Each chapter contains warnings, precautions and measures to ensure the safety of the device, the Operator and the Patient.

The abbreviations and symbols used are explained in the following paragraphs.

1.2 Limitation of liability

The Manufacturer is not liable for damage resulting from:

- use of the device not in accordance with these instructions;
- unauthorised modifications to the product;
- combination with accessories or components not approved by the Manufacturer;
- failure to observe warnings, storage conditions or disposal.

The User is responsible for verifying the integrity of the device before use and for using it correctly according to the stated intended use.

1.3 Ownership of the information

The information in these instructions for use is the property of **Ferno s.r.l.** - Via Benedetto Zallone 26, 40066 Pieve di Cento (Bologna) Italy.

All patent rights, design, construction, reproduction, use and sale rights relating to any item covered in these instructions are the confidential and exclusive property of Ferno s.r.l., except for rights expressly transferred to third parties or not attributable to parties owned by the supplier. ANY reproduction of these instructions, in whole or in part, is prohibited unless expressly authorised by Ferno s.r.l..

1.4 Manufacturer



Ferno s.r.l., Via Benedetto Zallone, 26
40066 - Pieve di Cento (BO) - ITALY

Telephone (toll-free for Italy)	800 501 711
Phone	0039 0516860028
E-mail	info.it@ferno.com
Website	www.ferno.it

1.5 Ferno Technical Support

Please contact Ferno s.r.l. for any information, support regarding use, maintenance or to request spare parts.

To facilitate assistance, please provide the product serial number and specify it in all written communications.

Telephone (toll-free for Italy)	800 501 711
Phone	0039 0516860028
E-mail	info.it@ferno.com
Website	www.ferno.it

1.6 Reporting accidents

In the event of a serious accident in relation to the device, immediately contact Ferno S.r.l. and the competent authority of the member State in which the User has its main office.

E-mail:	eu-regulatory.it@ferno.com
Telephone:	+39 051 6860028

1.7 Definitions

Term	Definition
Expected clinical benefit	Positive results for the Patient's health obtained through the use of the device.
Intended purpose	The use for which the device is intended according to the information provided by the Manufacturer on the label, in the Instructions for Use or in promotional material or regulatory statements.
PPE	Personal Protective Equipment; equipment intended to be worn or held by the User or maintenance technician for protection against one or more risks to their health and safety.
Storage life	The period of time during which a medical device, when stored under recommended conditions, maintains its performance, safety and conformity to its intended use.
Label	Any type of written, printed or graphic information on the medical device and/or packaging.
Body in charge	Body that supervises work activities to ensure the correct use of the device and compliance with safety regulations.
Manufacturer	The natural or legal person who manufactures or refurbishes a device or has it designed, manufactured or refurbished and markets it under their name or trademark.
Serious accident	Any accident that, directly or indirectly, has caused, may have caused or may cause any of the following consequences: a) the death of a Patient, User or other person; b) the serious temporary or permanent deterioration of the health condition of the Patient, the User or another person; c) a serious threat to public health.

Term	Definition
CE conformity marking	Marking by which a Manufacturer indicates that a device complies with the applicable requirements set out in Regulation (EU) 2017/745 and in other applicable Union harmonisation legislation providing for its affixing.
Patient	Person in an emergency, illness or accident situation.
Neutral position of the head	Head alignment position in which the head is centred, the gaze is horizontal and the neck is neither flexed nor extended or rotated.
Risk	The combination of the probability of the occurrence of damage and the severity of the damage.
User/Operator	Healthcare professional using the device.
Reasonably foreseeable misuse	Any use of the device that is not intentional according to the Manufacturer's instructions, but which can be foreseen by an Operator (e.g. common mistakes, confusion with other devices, stressful conditions or emergency situations).

1.8 Safety messages

Safety messages within these Instructions for Use warn of potentially dangerous situations or essential information for the correct use of the device. These messages are classified as, WARNING and IMPORTANT, depending on the severity of the risk and the nature of the information.



WARNING

It indicates potentially dangerous situations that, if disregarded, may result in accidents, damage and/or injury.

IMPORTANT

It indicates important information on use and/or maintenance of the device.

1.9 Prohibition messages

The **PROHIBITION** messages contained in these Instructions for Use indicate actions that the user must not take, as they could jeopardise

- the safety of the Patient and/or the Operator;
- the performance of the device;
- regulatory compliance.



FORBIDDEN

It indicates an action that must not be performed, as it may cause injury to the Operator or Patient and/or damage to the device.

1.10 Symbols

The symbols shown in the table are included in the instructions and/or on the labels affixed to the device.

Symbol	Definition
	CE marking
	It is mandatory to read the instructions
	Manufacturer
	Date and place of manufacture
	Keep away from moisture
	Keep out of sunlight
	Consult the Instructions for Use or the electronic Instructions for Use
	Authorised Representative in the European Community
	Importer
	Global Trade Item Number (GTIN)
	Lot code / number
	Medical device indication
	Unique device identification
	Catalogue number
	May be subjected to MRI
	GS1 - Data Matrix

2. LABELS

2.1 Device label

 **WARNING**

In the event of a missing, illegible or damaged label, do not use the device and contact Ferno Technical Support Service.

The device has a label that contains the minimum information necessary to identify the device and the Manufacturer, to guarantee safety and to indicate compliance with regulations.

The label is placed on the outer side of the two cushions



2.2 Packaging label

The label is applied to the device packaging



3. WARNINGS

3.1 General warnings

- Read the contents of these instructions carefully and in full;
- the Manufacturer cannot be held responsible or liable for damage to property and/or persons resulting from incorrect use of the device and from failure to read or misunderstanding these Instructions for Use;
- these Instructions for Use are an integral part of the device; they must always be accessible and easily consulted by the User;
- these Instructions for Use do not provide medical advice but contain general instructions for the Operator regarding the use and maintenance of the device;
- if the Instructions for Use are lost or damaged, contact the Manufacturer or download a copy from www.ferno.it;
- the Instructions for Use must be kept in good condition and protected from conditions that could impair their readability;
- the Instructions for Use must be kept for the entire life cycle of the device. In the event of transfer of ownership to a new User, attach these instructions to the product;
- always follow the local healthcare instructions and protocols, except when they contradict these Instructions for Use;
- always adhere to the protocols and procedures laid down by the Body in charge. Any safety measure implemented must comply with the regulations in force in the country of use;
- take preventive measures and use appropriate PPE as required by health protocols to avoid contact with blood and body fluids;
- for the use of the device, it is mandatory to be a first-aid officer, to attend a training course organised by the Body in charge and to be trained in the correct use and safety of the device;
- record the training carried out in the special register contained within these instructions. The register must be retained by the Body in charge and handed over to the competent authorities if requested;
- to ensure safety, ensure that untrained personnel or casual helpers cannot apply, use or maintain the device;
- the application, use and inspection of the device must be carried out exclusively by personnel trained in the specific product and not other devices, even if they have an equivalent function;
- only personnel designated by the Manufacturer should be permitted to use the device.
- when using the device, the assistance of the patient by at least one operator must always be guaranteed;
- The device must not, under any conditions or for any reason, obstruct rescue operations or the use of other devices;
- to ensure the safety of the device and the Patient, check its integrity and functionality before each use and periodically, as prescribed by the Manufacturer. If signs of faults, breakage, wear or damage are found, take the device out of service and contact Ferno Technical Support Service immediately;
- using the device in a manner not intended by the Manufacturer and not specified in these instructions may impair safety and lead to dangerous situations;
- non-compliance with the stability conditions laid down for the device may impair its performance, safety and integrity. Observe the stability conditions specified by the Manufacturer;
- always perform all manoeuvres carefully and as specified by the Manufacturer to ensure the safety of the patient and yourself;
- unauthorised modifications or the use of parts and/or spare parts not supplied or approved by the Manufacturer may impair safety and lead to dangerous situations;
- carry out the planned inspections, according to the times and methods indicated by the Manufacturer. Inadequate maintenance can impair safety and lead to dangerous situations;
- keep the device clean and sanitised in order to avoid infections and/or contamination;
- if the labels on the device are damaged (even partially), faded, not legible in their parts or entirely, request a copy from the Manufacturer.

3.2 Specific warnings

- use of the device is only permitted in situations where the Operator is able to ensure that the neutral position of the patient's head and neck is correctly maintained; in the absence of such conditions, the device must not be used;
- using the device in combination with other devices that are not compatible and not provided for by the Manufacturer may compromise safety and lead to dangerous situations;
- the simultaneous presence of two operators is required to ensure the correct and safe application of the device;
- the device must not be used as the sole means of immobilising the Patient;
- the device is not a long-term fixation device; use is limited to the rescue and transport phase.

4. RESIDUAL RISKS, CONTRAINDICATIONS AND UNDESIRABLE EFFECTS



WARNING

The application, use or any intervention on the device by unauthorised, unsuitable or untrained personnel may lead to damage to the device, injury or death. Only allow use by suitable and trained personnel, in accordance with the prescribed operating procedures.

Incorrect application of the device can cause serious injury to the Patient. Follow the application procedures given in these instructions.

Inadequate cleaning or disinfection of the device can promote the transmission of infectious diseases. Properly clean and disinfect the device as required.

Damage to the device or loss of tightness of the Velcro straps can cause accidents or injury to the Patient. Carry out the preventive checks and maintenance operations required to ensure the safety and functionality of the product.

Exposure of the device to high temperatures may cause alterations to its structure, compromising its safety and functionality.

On the basis of the risk analysis conducted and the available clinical data, no specific contraindications or known side effects were identified in the context of the intended use of the device.

Use the device in strict adherence to the general warnings and precautions given in these Instructions for Use.

5. INTENDED USE



WARNING

Use by unqualified, untrained or unsuitable operators may result in accidents and/or injury to the Patient, the User and damage to the device.

Only use the device in accordance with its intended use and as specified by the Manufacturer in these Instructions for Use.

Observe the compatibility of the device as stipulated by the Manufacturer to ensure the safety of the device.

Unintended use of the device may result in injury, complications and damage to the health of the Patient, the User and damage to the device.

5.1 Purpose of the device

The device is designed for restricting movement of the head and neck of the patient during emergency procedures, transport or clinical evaluation in combination with a stretcher or spine board.

5.2 Target population

The device is intended for use on patients requiring restriction of head and neck movement, as assessed by the healthcare professional.

5.3 Expected clinical benefit

The device helps prevent lateral movements, flexion-extension and rotation of the head, reducing the risk of aggravation of possible neck injuries.

5.4 Environment of use

The device is to be used in out-of-hospital (EMS) and hospital settings.

6. STABILITY CONDITIONS



WARNING

Failure to comply with stability conditions may compromise the safety and performance of the device.



WARNING

Any visible damage or alterations to the device must be reported to Ferno Technical Support Service.



WARNING

Do not use the device if stability conditions are not met.



FORBIDDEN

It is forbidden to use the device if stability conditions are not met.

To ensure the integrity, safety and performance characteristics of the device during preservation, use, transport and storage, please follow the stability guidelines below.

6.1 Device integrity

- keep the device in its original packaging until use;
- visually check the device before use for any damage or alterations.

6.2 Environmental parameters

Operating temperature range	-20°C - +60°C
Storage temperature range	-20°C - +60°C
Max. relative humidity	≤ 85%, no condensation
Exposure to light	Avoid exposing the device to direct sunlight for prolonged periods
Chemical agents	Avoid contact with corrosive solvents and vapours

6.3 Transport

- pack the device (if possible in the original packaging or in the storage bag provided as an accessory), so as to avoid shocks, vibrations or compression during transport;
- protect the device from extreme temperatures, high humidity, direct sunlight and chemical agents;
- comply with the labelling, orientation and handling instructions provided by the Manufacturer.

6.4 Storage life

The service life of the device and its components depends on several factors.

Factors influencing the storage life of the device and components are:

- **conditions of use:** correct use in accordance with the manufacturer's instructions;
- **frequency of use:** number of applications and time of use;
- **maintenance and cleaning:** performance of preventive and periodic operations according to the Manufacturer's instructions;
- **environmental parameters:** compliance with the conditions laid down by the Manufacturer.

7. DESCRIPTION

7.1 The device

The device consists of several components that, when positioned in the manner prescribed by the Manufacturer, ensure proper restriction of movement of the Patient's head and neck during rescue and diagnostic operations.

The device is composed as follows:

- **head immobiliser base** - for positioning the Patient's head on the stretcher/spine board and keeping it in a neutral position;
- **side cushions** - for supporting the Patient's head with a hole for inspecting the auricle;
- **T-shaped band** - to secure the cushions to the Patient's head;
- **K-shaped band** - to complete immobilising operations;
- **cervical wedge** - to compensate and support the head in case of spinal misalignment.

7.2 Supplied components

The device is supplied with the following standard components.

Component	Quantity
Head immobiliser base	1
Cushion	2
Cervical wedge	2
T-shaped band	1
K-shaped band	1
Velcro strap	3
Connection ties	3

7.3 Components not supplied

The device requires the use of additional accessories that are not included:

- atraumatic stretcher or spine board;
- cervical collar;
- products for cleaning the device;
- accessories for device and Velcro maintenance.

7.4 Main parts



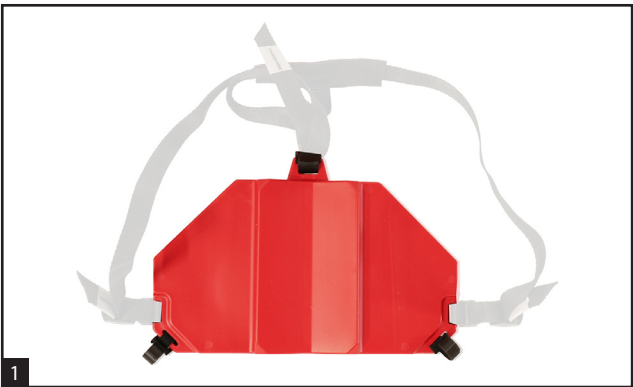
Reference	Part
1	Head immobiliser base
2	Cushions
3	Cervical wedge
4	T-shaped band
5	K-shaped band

Head immobiliser base

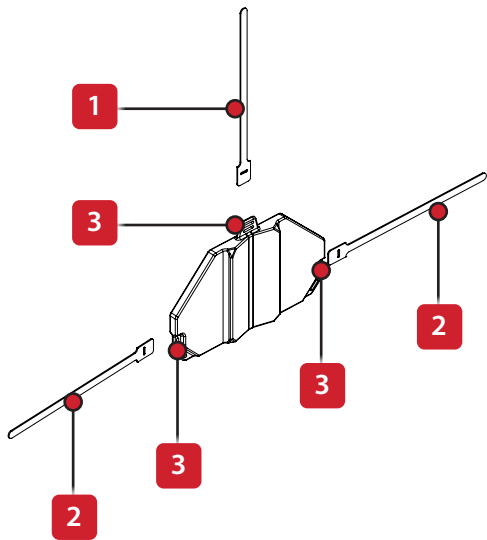
The head immobiliser base has a recess designed to accommodate the Patient's head.

The upper Velcro strap, inserted into the relevant loop holder, allows the device to be attached to the stretcher in the case of semi-vertical Patient positioning.

By also inserting the two side Velcro straps into the respective slots, the device can be firmly attached to the spine boards "11.2 Application of the device to other spine supports".



Head immobiliser base



Reference	Part
1	Upper Velcro strap
2	Side Velcro strap
3	Slot

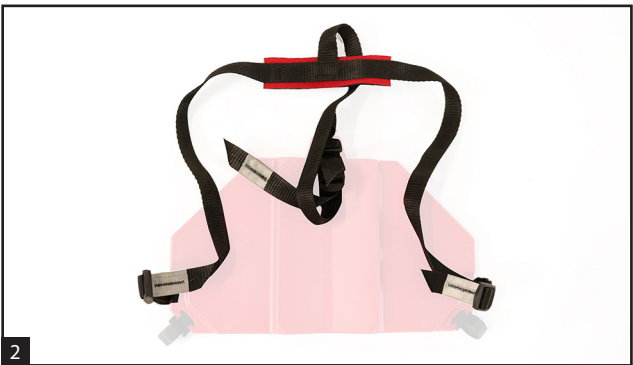
T-shaped band

The T-shaped band is supplied already attached to the head immobiliser base by means of the connection ties.

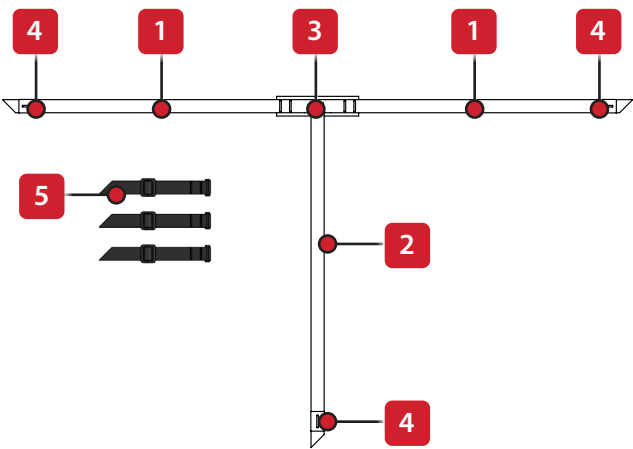
It consists of two straps: one horizontal and one vertical.

The neoprene insert, placed in the centre of the horizontal strap, must be positioned on the Patient's forehead.

At the ends of the straps are reflective fabric inserts, which increase visibility.



T-shaped band



Reference	Part
1	Horizontal strap
2	Vertical strap
3	Neoprene insert
4	Reflective fabric insert
5	Connection ties

Cushions

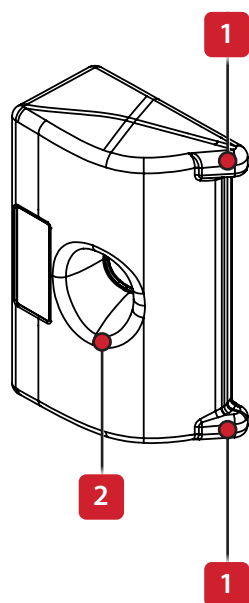
The two cushions are placed on the side of the Patient's head and held in position by means of the T-shaped band and the K-shaped band.

Teeth on the top of both cushions prevent the straps from slipping or sliding out, ensuring that the tension of the bands is maintained and that the device remains stable.

Thanks to the side opening of each cushion, it is possible to monitor the Patient's auricles.



Cushions



Reference	Part
1	Tooth
2	Opening

K-shaped band

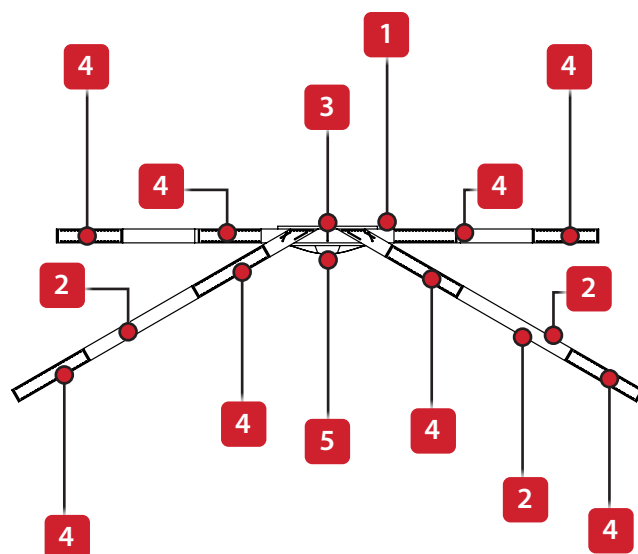
The K-shaped band consists of a horizontal strap and two oblique straps.

The neoprene insert, placed in the centre of the horizontal strap, must be positioned on the Patient's chin. The centring mark on the insert facilitates correct alignment. The four ends of the K-shaped band are tensioned by the Operator and inserted into the eyelets provided on the stretcher/spine board.

Next, the ends are folded over to allow the Velcro strips (male and female) to adhere, ensuring that the band is closed and firmly fixed in place. Only in the justified absence of the cervical collar, the elastic webbing should be placed under the Patient's chin to restrict head and neck movements.



K-shaped band



Reference	Part
1	Horizontal strap
2	Oblique straps
3	Centring mark
4	Velcro closures
5	Elastic webbing

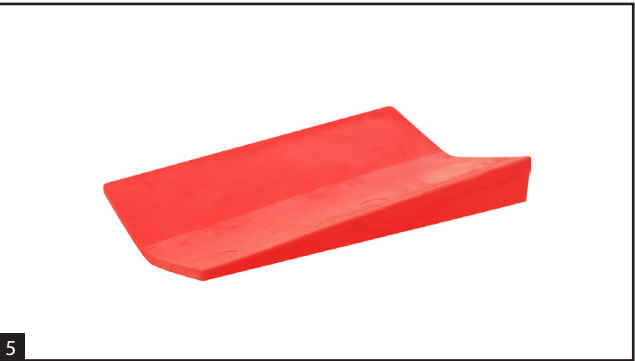
Cervical wedge

The cervical wedge provides additional support and can be inserted under the Patient's head to help maintain a neutral position.

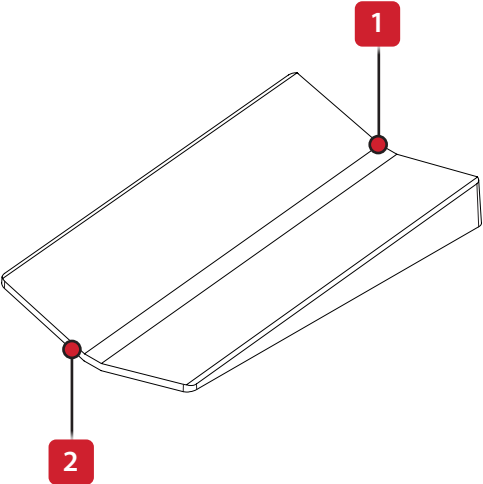
The cervical wedge is inserted pointwise under the Patient's head to compensate for the position of the cervical spine.

The lower side of the wedge supports the neck, the higher side acts as a support for the head.

If required, the Manufacturer can supply a second cervical wedge as an accessory.

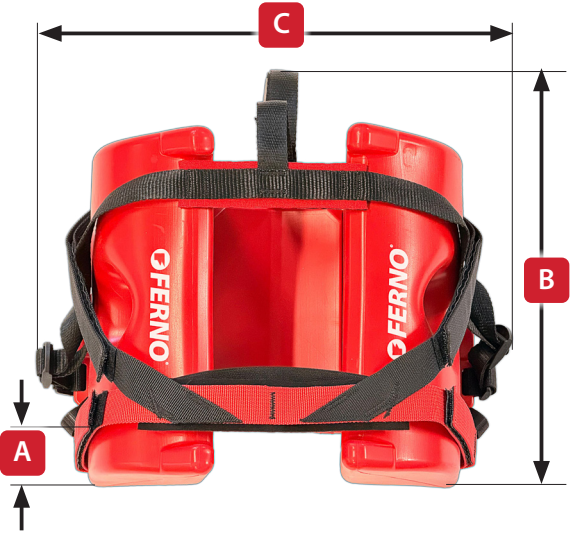


Cervical wedge



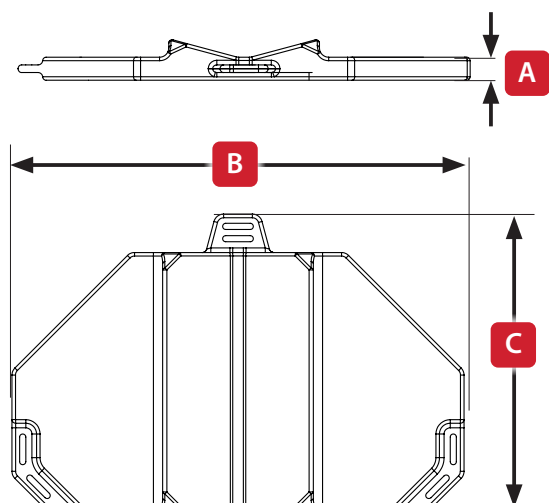
Reference	Part
1	Head support end
2	Neck support end

7.5 Technical specifications



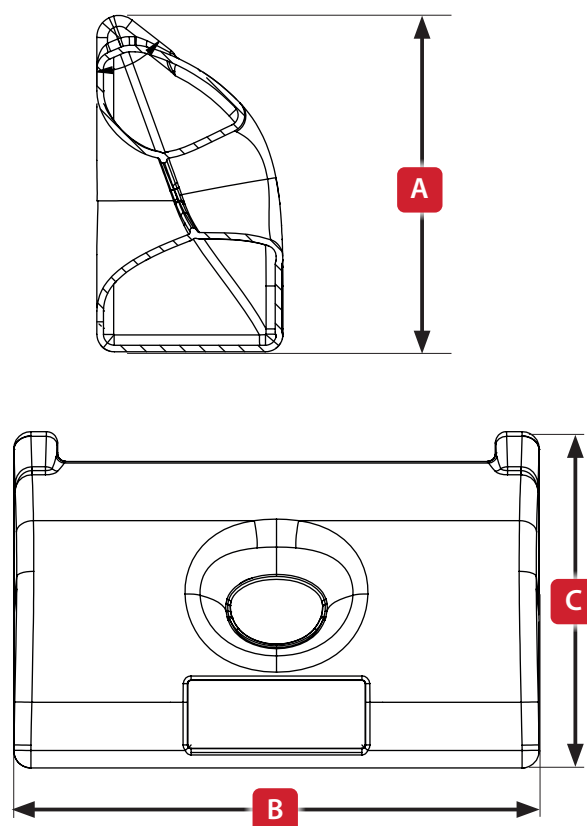
Feature	Value
Weight	1.6 kg (3.52 lbs)
Height (A)	165 mm (6.5 in)
Width (B)	300 mm (11.8 in)
Depth (C)	190 mm (7.5 in)

Head immobiliser base



Feature	Value
Thickness (A)	26.3 mm (1.03 in)
Width (B)	294 mm (11.57 in)
Depth (C)	192 mm (7.55 in)

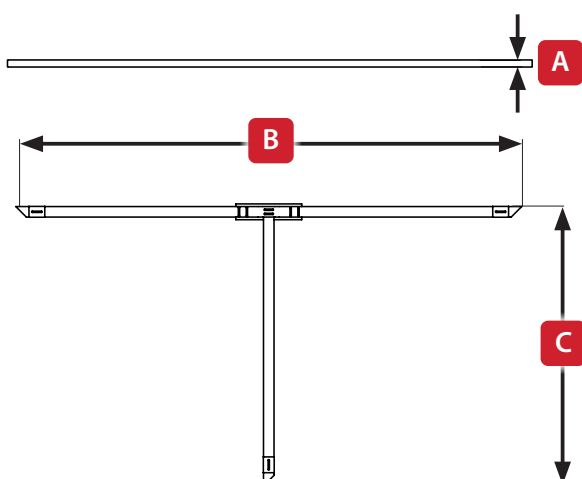
Cushion



Feature	Value
Height (A)	150 mm (5.9 in)
Width (B)	230 mm (9.1 in)
Depth (C)	85 mm (3.3 in)

T-shaped band

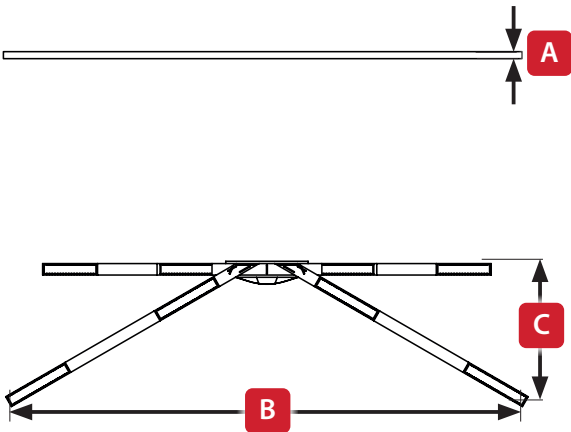
Feature	Value
Thickness (A)	1.5 mm (0.05 in)
Width (B)	960 mm (37.80 in)
Depth (C)	530 mm (20.90 in)



Description

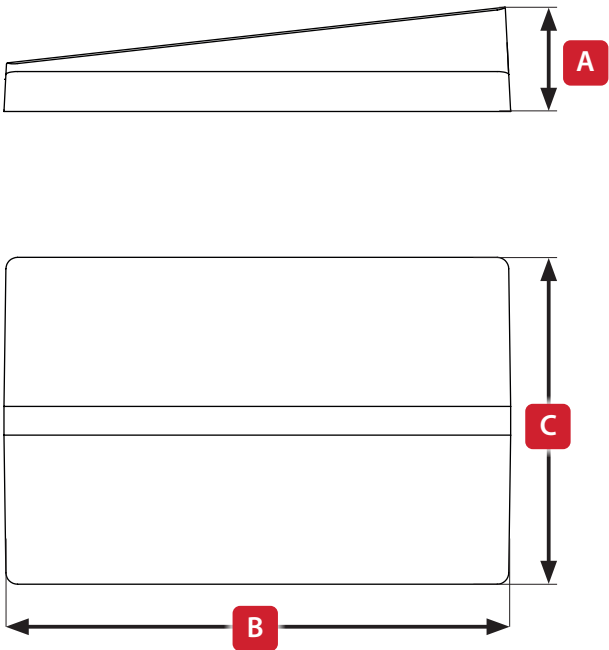
K-shaped band

Feature	Value
Thickness (A)	2 mm (0.08 in)
Width (B)	1141.5 mm (44.94 in)
Depth (C)	312.5 mm (12.30 in)



Cervical wedge

Feature	Value
Height (A)	30.8 mm (1.21 in)
Width (B)	147.6 mm (5.81 in)
Depth (C)	96.8 mm (3.81 in)



8. COMPATIBILITY WITH ACCESSORIES/DEVICES



WARNING

The use of the device with devices other than those indicated does not guarantee its safe use; in the event of any damage to persons and/or property, the Manufacturer cannot be held liable.

The safety and functionality of the device is only guaranteed when used in combination with a **Ferno SCOOPExL™ atraumatic stretcher** and the **Ferno Millennia and Najo series spine boards**.

The cervical collar for use in combination with the device must comply with applicable regulations and must be used according to the instructions of the respective Manufacturer.

9. USER AND TRAINING

9.1 Intended user of the device

The device is intended for use by trained healthcare personnel, including rescuers, rescue technicians, nurses and doctors.

9.2 Suitability of the User

For the application, use and maintenance inspections of the device, users must:

- be informed and trained in the safety and use of the device as prescribed by the Manufacturer and the Body in charge;
- know and respect the health protocols and safety measures required by the regulations in force in the country of use;
- be physically and cognitively capable of using the medical device safely and in accordance with the instructions for use;
- be of legal age.

9.3 Required training



WARNING

Training and instruction in the use of the device are mandatory and provided by the Body in charge. The Manufacturer is not liable for damage and/or injury caused by inadequate or insufficient information and training.

Record the training sessions in the register contained in the paragraph "20.2 Training record".

For safe and correct use of the device, it is strongly recommended that you undergo specific training, which includes:

- careful and complete reading and understanding of these Instructions for Use;
- attending a specific training course organised by the relevant Body on the application, use, safety, usability and risk management of the device;
- practical exercises, organised by the Body in charge, with the device and its accessories before using it in real situations.

Record all training sessions in the appropriate register contained within these instructions in the paragraph "20.2 Training record".

10. REASONABLY FORESEEABLE MISUSE

The device is designed for a specific use but there are some unintended modes of use that, based on clinical experience or the literature, can be reasonably expected. This list helps prevent accidents or malfunctions.

- Failure to follow the instructions may pose a risk to the Patient, reduce effectiveness or damage the device. Make sure you read and understand all instructions and warnings before use;
- use by unsuitable, qualified or untrained personnel may compromise Patient safety, the effectiveness of the device and may cause damage to the device itself. Ensure that the Operator is trained, familiar with the correct procedures and fit for use before using the device;
- improper use or use not in accordance with the intended use may cause risks to the Patient and malfunctions. Always follow the Manufacturer's intended use;
- use of the device in violation of the instructions of the Body in charge or local protocols may cause risk to the Patient, reduce effectiveness or damage the device. Respect local operating procedures and health protocols
- use while impaired by alcohol or drugs can damage the device and cause accidents or injuries. Use the device only under suitable physical, decision-making and cognitive conditions;
- use without adequate familiarity with the device's functions may pose risks to the Patient and cause malfunctions. Carry out exercises or mock trials before clinical use;
- use with devices not intended by the Manufacturer may pose risks to the Patient and reduce effectiveness. Use only in combination with the accessories and equipment provided for by the Manufacturer;
- use when the Patient does not maintain a neutral head position may lead to clinical risks and device malfunction. Always check that the neutral position of the head is respected;
- inadequate surveillance of the Patient during use of the device may pose a risk to Patient safety and compromise the effectiveness of the device. Continuously monitor the Patient and follow the operating procedures outlined in these instructions and local health protocols;
- the application of the device by a single Operator may compromise the safety of the Patient. Apply the device with the help of two operators working simultaneously;
- use of the device if not properly applied may increase the risk of falls, injuries or malfunctions. Always apply the device as intended and carry out the necessary checks before use;
- the use of a damaged or deteriorated device may compromise Patient safety and reduce the effectiveness of the device. Always ensure the integrity of the device before use in accordance with these instructions;
- the use of the device beyond the intended time for rescue, transport and diagnostics may lead to increased risks to the Patient from inappropriate use. Use the device only as long as strictly necessary;
- improper handling of the device (disassembly, unauthorised modifications) may lead to damage or malfunction of the device. Only carry out interventions as planned or authorised by the Manufacturer;
- the addition of accessories or the application of non-compliant spare parts can lead to malfunction and/or damage to the device. Use only the intended components;
- incorrect or improper cleaning, disinfection and maintenance can lead to contamination, risk of infection and malfunction. Observe cleaning, disinfection and maintenance instructions;
- use of the device after storage or transport in non-compliant conditions may reduce effectiveness and compromise Patient safety. Observe the prescribed storage and transport conditions.

11. USE

WARNING

Upon receipt of the product, visually check the integrity of the packaging, the presence of all expected components and the general condition of the device. In the event of non-conformities, contact Ferno Technical Support Service.

Read all safety warnings before using the device.

The application and use of the device is only permitted to suitable operators who are adequately trained and instructed according to the Manufacturer's instructions.

FORBIDDEN

Application and use of the device by casual helpers and uninstructed/untrained personnel is prohibited.

11.1 Application of device on the Patient in combination with Ferno SCOOPExL™ atraumatic stretcher

WARNING

Coordinated action by two operators is required for correct application.

When positioning the head immobiliser base and cushions, keep the Patient's head in a neutral position by placing the hands at the sides of the head.

1. Positioning the head immobiliser base

1. place the head immobiliser base under the Patient's head;
2. aim the device with the shorter side facing upwards;
3. check that the upper loop holder is uncovered;
4. place the Patient's head in a neutral position, without lateral tilt or excessive extension.



Positioning the head immobiliser base

2. Positioning the cushions:

1. place the cushions, one at a time, on the sides of the Patient's head;
2. ensure that the cushions are resting on the Patient's shoulders;
3. aim the cushion opening so that the Patient's auricles can be monitored;
4. If necessary, insert the cervical wedge with the tip under the head for additional support.



Positioning the cushions

3. Positioning the T-shaped band

1. place the T-shaped band on the Patient's forehead;
2. tension the vertical and horizontal straps.



Positioning the T-shaped band on the Patient's forehead



Tensioning the T-shaped band straps

4. Positioning the Ferno SCOPEXL™ atraumatic stretcher



WARNING

Please refer to the Ferno SCOPEXL™ atraumatic stretcher instructions for the correct positioning and use of the product.

In the case of partial verticalisation procedures, the clamp must be attached to the stretcher's carrying handle.

Insert the two longitudinal stretcher halves under the Patient and under the device.



Positioning the SCOPEXL™ atraumatic stretcher



Securing the device to the SCOPEXL™ atraumatic stretcher

5. Positioning the K-shaped band

1. place the K-shaped band on the Patient's chin;
2. align the centring mark with the centre of the Patient's chin;
3. insert the ends of the horizontal strap into the eyelets provided on the stretcher;
4. tension the straps;
5. fold back the ends of the straps to allow the Velcro strips (male and female) to adhere;
6. repeat the same procedure to apply, tension and tighten the oblique straps.



Positioning the K-shaped band



Securing the horizontal strap



Securing the oblique straps

6. Positioning the elastic webbing

The elastic webbing of the K-shaped band can be used for head stabilisation both in the presence and absence of a cervical collar, when the medical rescuers assess that the collar is not suitable, does not fit properly or does not provide adequate support.

The elastic webbing of the K-shaped band is a safe and effective alternative in cases where the collar cannot be used or is inadequate.



WARNING

The use of elastic webbing is limited to extreme situations and does not replace the cervical collar in routine use.

Place the elastic webbing between the Patient's lip and chin.



Positioning the elastic webbing

11.2 Application of the device to other spine supports

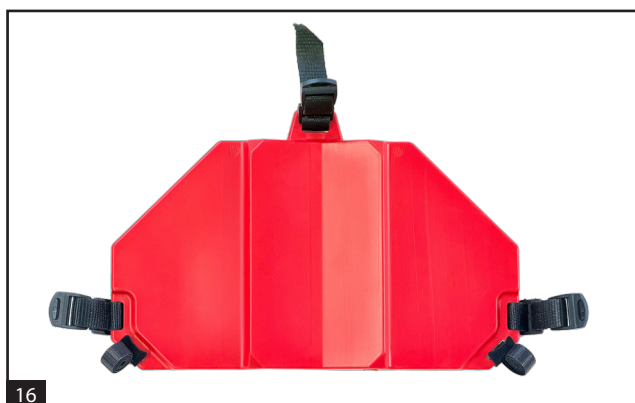


WARNING

The safety and functionality of the device are only guaranteed when used in combination with a Ferno SCOOPLEX™ atraumatic stretcher and the Ferno Millennia and Najo series spine boards. The use of the device with devices other than those indicated does not guarantee safe use; therefore, the Manufacturer cannot be held liable for any damage to persons and/or property.

To apply the device to other spine supports:

1. place the head immobiliser base on the spine board;
2. attach the three Velcro straps to the spine board, following the instructions for the attachment points in the Instructions for Use of the product;
3. Position the patient on the head immobiliser base and apply the device as described in the previous paragraphs.



Head immobiliser base

11.3 Checks before patient handling

Once the device has been applied to the patient, check before each use that:

- the Patient's head is in a neutral position;
- the head immobiliser base is secured with Velcro straps (if the device is installed on spine supports or in the case of partial verticalisation procedures);
- both cushions are resting on the Patient's shoulders and that their position is maintained throughout the operations;
- the side openings of the cushions allow easy monitoring of the patient's auricles;
- the centring mark of the K-shaped band is positioned in the centre of the Patient's chin;
- the ends of the K-shaped band are positioned and tightened in the eyelets provided on the stretcher/spine board;
- all straps are correctly tensioned to ensure restriction of movement of the Patient's head during transport and diagnostic procedures;
- all Velcro closures are securely closed and ensure a proper seal, preventing accidental opening;

11.4 Use with Patient



WARNING

Familiarise yourself with the device by preliminary testing it before first use on a Patient.

Clean and disinfect the device before use to reduce the risk of infection transmission.

Before each use, make sure you have carried out all the preventive checks required to reduce the risk of accidents or injuries.

Follow applicable local health protocols when using the device.

Ensure continuous Patient care during device use

Use the device only for the time strictly necessary to carry out rescue, transport and diagnostic operations.



FORBIDDEN

Do not use the device if it is faulty, damaged or malfunctioning.

Do not use the device at temperatures below -20 °C or above 60 °C.

Do not use in the event of faults or damage to the device or its components.

Do not leave the Patient unattended while using the device.

12. STORAGE AND PRESERVATION



WARNING

The storage location must guarantee a temperature of -20 °C to +60 °C and a maximum relative humidity of 85%, with no condensation.



FORBIDDEN

Do not store the device in direct sunlight or in the weather.

Do not store the device near heat sources or open flames.

Do not store the device near aggressive chemicals.

Do not store the device in places subject to shock, vibration or mechanical pressure.

Do not store the device in places with uncontrolled and unsafe access.

When not in use, take the following precautions to preserve the integrity, safety and performance of the device:

- before storage, clean and disinfect it as prescribed by the Manufacturer;
- store it, complete with all its parts, inside the special storage bag (accessory) or keep it inside a protective box or wrapping that provides protection from dust, dirt and water;
- Keep it in a safe storage place, with access forbidden to non-experts.
- Store it indoors, in an environment that can ensure the following conditions:
 - Dry and well ventilated;
 - Temperature between -20 °C and +60 °C;
 - Maximum relative humidity of 85%, no condensation;
 - Protected from shock, vibration and mechanical pressure;
 - Free of aggressive chemicals;
 - Free of heat or open flames;
 - Protected from shock, vibration and contamination;
 - Not exposed to the weather or direct sunlight.

13. MAINTENANCE

IMPORTANT

Ferno directly carries out repair maintenance operations, without the need of dealers, mechanics or external service centres. You are thus invited to be wary of those who present themselves as Ferno's authorised technician.

WARNING

Inadequate maintenance may result in accidents and/or damage, even permanent, to the Patient or the Operator. Improperly performed maintenance, not at the time and in the manner specified by the Manufacturer, will invalidate the warranty and release the Manufacturer from any liability for damage or injury.

Any maintenance, modification or repair not authorised by the Manufacturer invalidates the warranty and releases the Manufacturer from any liability for damage or injury.

The use of non-original spare parts invalidates the warranty and releases the Manufacturer from any liability for damage or injury. To request original spare parts, contact Ferno Technical Support Service.

After any maintenance work and before use, check that all parts of the device are intact and correctly installed. In the event of faults, contact Ferno Technical Support Service and do not use the device.



WARNING

All repairs are considered extraordinary maintenance and may only be carried out by the Manufacturer. Contact the Ferno Technical Support Service.

13.1 Maintenance table

The following table summarises the preventive and periodic checks of the device, with the frequency of execution. Methods and criteria for verification are given on the following pages.

Check	Frequency		
	After each use	Every month	Whenever necessary
Inspection	✓	✓	✓
Velcro maintenance	-	-	✓
Cleaning	✓	✓	✓
Disinfection	✓	✓	✓



FORBIDDEN

It is forbidden to perform any maintenance work while the device is in use with the Patient.

13.2 Inspections

WARNING

In the event of any anomalies, signs of wear or damage found during inspections, do not use the device and contact Ferno Technical Support Service immediately.

Document all inspections carried out in the special register in the paragraph “20.1 Inspection record”.

Preventive checks serve to ensure the safety, integrity and proper functioning of the device. They must be performed before each use and periodically, as instructed by the Manufacturer, and when deemed necessary.

Checks to be carried out:

- ensure that the device includes all components specified by the Manufacturer;
- ensure that the device labels are intact and fully legible;
- visually check all parts of the device, ensuring the absence of:
 - signs of wear and tear;
 - cuts or abrasions;
 - discoloured parts;
 - crushing and/or deformation;
 - unstitched parts;
 - worn edges;
 - dust and/or dirt;
 - body fluids.
- apply light pressure to the cushions with your hands to check for air leaks;
- make sure that there are no elements that could diminish the Velcro attachment surface such as lint, hair, dirt, frayed or protruding fibres, etc.;
- maintain Velcro as described in the paragraph **11.3 Velcro maintenance**;
- test the tightness of the Velcro closures:
 - connect the two parts of the Velcro closure;
 - manually tighten the two ends of the straps;
 - ensure that the two parts remain connected.

13.3 Velcro maintenance

WARNING

Ensure that all Velcro closures are intact, snug and secure; wear and tear can compromise the safety of the device.

If the Velcro does not adhere properly or is damaged, stop using the device and contact Ferno Technical Support Service.

FORBIDDEN

Do not use scissors to straighten Velcro hooks.

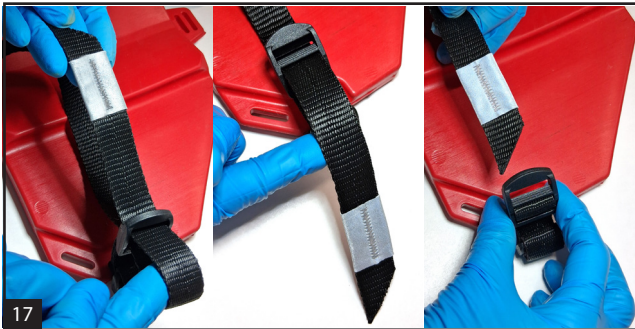
Check the Velcro periodically and, if it loses its grip, carry out the maintenance described below to ensure proper attachment:

- remove any items trapped in the Velcro; use a brush to clean the Velcro (not supplied), a stiff comb or needle to remove lint, hair, dirt or other material accumulated on the Velcro;
- remove any fibres obstructing closure;
- cut any frayed or protruding fibres with scissors, taking care not to damage the Velcro.

13.4 Removing/repositioning T-shaped band and connection ties

To release the connecting ties from the T-shaped band and head immobiliser base, follow the procedure below:

- remove the T-shaped band from the plastic loop of the connection tie as shown in the sequence in image 17;



Releasing the T-shaped band strap

- remove the end of the connection tie from the plastic loop as shown in the sequence in image 18;



Releasing the connection tie

- pull the connection tie out of the loop on the head immobiliser base as shown in the sequence in image 19;



Removing the connection tie from the head immobiliser base

- repeat the procedure for all three straps and ties present;

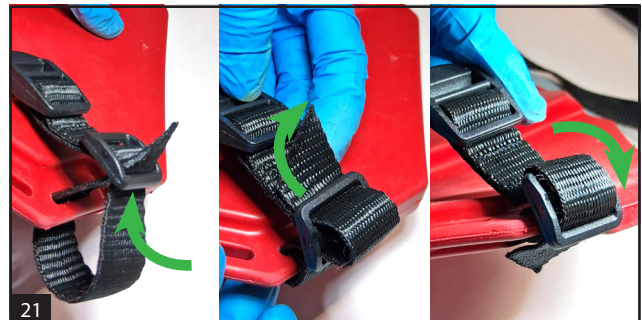
To restore the original configuration, follow the procedure below:

- Insert the plastic loop into the connection tie (A, image 20);
- Insert the connection tie into the slot of the head immobiliser base (B, image 20);



Connecting the tie to the head immobiliser base

- Insert the end of the tie inside the plastic loop, passing it through both openings and finally folding it back on itself to ensure that it does not slip out, as shown in the sequence in image 21;



Securing the tie to the head immobiliser base

- Pass the strap of the T-shaped band through the plastic loop as shown in the sequence in image 22;



Securing the T-shaped band strap

14. CLEANING AND DISINFECTION



WARNING

Inadequate cleaning and disinfection can lead to the risk of transmission of infectious diseases.

Contact with cleaning and disinfection products may pose risks to human health and the environment. Use according to the Manufacturer's instructions and current regulations.

Only use disinfectants and compatible, non-aggressive products on the materials of the device, as indicated by the Manufacturer.

Carefully read the indications on the labels and instructions of the products used before cleaning or disinfecting the device.

Dispose of cleaning and disinfection products, including containers, in accordance with the regulations in force in the country of use.

Use or store the device only after completion of cleaning and disinfection and when all surfaces are completely dry.

If the labels are damaged during cleaning, discontinue use and contact Ferno Technical Support Service.

If damage/abnormalities are found during cleaning and disinfection, contact Ferno Technical Support Service.

14.1 Cleaning



FORBIDDEN

Do not use high-pressure water to wash the device, in order to avoid damage to components and compromising safety.

After each use and when necessary, clean the device as follows:

1. wash the components with water and soap or a mild detergent, wiping it with a non-abrasive sponge. If necessary, use a non-metallic bristle brush to remove any stains;
2. rinse with clean water;
3. dry all components with a clean cloth or allow to air dry;
4. check that the locking system is secure;
5. carry out disinfection.

14.2 Disinfection

After cleaning the device after each use, it is necessary to disinfect it as follows:

6. disinfect the entire surface of the device with a proven effective disinfectant using a non-abrasive cloth or sponge;
7. ensure that the disinfectant used is not aggressive on the materials to be treated, and does not corrode, stain or alter their properties;
8. dry with a clean, dry cloth or leave to air dry.

Disinfection of head immobiliser base, cushions and cervical wedge:

- apply the disinfectant solution to all surfaces of the device using a non-abrasive cloth or sponge;
- alternatively, soak the device parts in disinfectant, following the instructions on the label for soaking time and dosage;
- ensure that there is no air leakage from the cushions;
- dry with a clean, dry cloth or leave to air dry.

Disinfection of chin strap, Velcro straps and K-shaped band:

- soak in the disinfectant, following the instructions on the label for soaking time and dosage;
- leave to air dry;
- check the integrity and tightness of the Velcro closures before use;

15. ACCESSORIES

IMPORTANT

Accessories are not included with the device and must be ordered separately. For the request, contact Ferno Technical Support Service and provide the accessory code shown in the table.

Accessory	Part no.
Transport and storage bag	10-9900-005
Additional cervical wedge	18-00077

15.1 Transport and storage bag

The transport and storage bag protects the device from dust, dirt and moisture, facilitating its safe transport and storage.

The bag, which opens like a book, is equipped with a carrying handle and a zip fastener.



15.2 Additional cervical wedge

To increase cervical support, an additional cervical wedge can be placed under the Patient's head in addition to the one supplied with the device.



16. SPARE PARTS



WARNING

Use only original spare parts.

To request spare parts, contact Ferno Technical Support Service.

The use of non-original spare parts invalidates the warranty and releases the Manufacturer from any liability in the event of damage and/or injury.



FORBIDDEN

It is forbidden to use non-original spare parts. The use of unauthorised spare parts may compromise the safety of the device.

Contact Ferno Technical Support Service to request a spare part.

Spare part	Part no.
Head immobiliser base (standard)	10-00521
K-shaped band (standard)	10-00522
T-shaped band (standard)	25-00278
Cervical wedge (standard/accessory)	18-00077
Transport and storage bag (accessory)	10-9900-005

17. PROBLEMS, CAUSES AND SOLUTIONS

Problem	Cause	Solution
Excessive head mobility	Loose straps	Tension the straps until they are securely fastened. <i>"11.1 Application of device on the Patient in combination with Ferno SCOOPLEX™ atraumatic stretcher"</i>
	Poorly positioned cushions	Position the cushions as prescribed by the Manufacturer <i>"11.1 Application of device on the Patient in combination with Ferno SCOOPLEX™ atraumatic stretcher"</i>
	Straps incorrectly positioned and/or attached to the stretcher/spine board	Check that the straps are positioned and secured as prescribed by the Manufacturer <i>"11.1 Application of device on the Patient in combination with Ferno SCOOPLEX™ atraumatic stretcher"</i>
	Wear or malfunctioning of components	Do not use the device and contact Ferno Technical Support Service immediately
Unintentional opening of Velcro closures	Lack of or insufficient Velcro maintenance	Perform Velcro maintenance as prescribed by the Manufacturer <i>"13.3 Velcro maintenance"</i>
	Damage or wear to Velcro parts	Do not use the device and contact Ferno Technical Support Service immediately to request a spare part

18. DISPOSAL



WARNING

Dispose of the device parts in accordance with local regulations for separate waste collection. Check the provisions of the Municipality.

IMPORTANT

You can contact Ferno Technical Support Service to arrange for the device to be collected and the plastic material to be completely recycled.



FORBIDDEN

Do not dispose of the device and its parts in the environment. Ensure disposal in accordance with local environmental protection regulations.

To properly dispose of the device:

9. clean and disinfect all components;

10. sort device components by material and place them in the containers specified in the table below.

Part	Plastic collection	Mixed waste collection
Head immobiliser base	✓	-
Cushion	✓	-
Cervical wedge	✓	-
K-shaped band	-	✓
Chin strap	-	✓
Transport and storage bag	-	✓

19. WARRANTY

19.1 Warranty terms and conditions

Ferno's products are guaranteed against manufacturing defects for a period of 24 months from the date on the Ferno s.r.l. shipping document.

During the warranty period, Ferno will repair and/or replace any parts found to have manufacturing defects free of charge, excluding the costs of labour, travel, transport, and packaging.

The warranty does not cover consumables or parts subject to wear and tear due to normal use of the product, all parts typically subjected to sliding or rolling friction (bearings, brushes, shoes, tracks, etc.), parts potentially exposed to oxidation or corrosion (copper or metal alloy contacts, mechanical equipment).

On new devices, the surface finishes (gelcoat/resin, paint, powder paint, decals, tape, inscriptions, etc.) are guaranteed for 90 days.

Repairs are performed by trained technical staff at the Ferno s.r.l. site in Via Zallone 26 - 40066 Pieve di Cento (BO), Italy or at the Customer's premises if suitable arrangements with Ferno s.r.l.'s Customer Service have been made.

Technical support at the Customer's premises must be arranged beforehand and involves a refund of costs incurred and documented on request.

For information on the costs of technical support, please contact the relevant department at Ferno s.r.l..

Repairs are guaranteed for 6 months from the date of repair. This warranty applies only when the product is used according to the Instructions for Use provided with the product. Misuse and negligence invalidate this warranty.

The warranty is valid from the day the product is shipped from Ferno s.r.l., and the shipping costs are not covered by this warranty. Ferno s.r.l. is not liable for damages incurred during shipment or due to misuse of the product.

Products sold by Ferno s.r.l. that do not bear the Ferno trademark are covered by the warranty of the original manufacturer. Ferno s.r.l. does not extend the warranty periods of other manufacturers; Ferno s.r.l. assumes no responsibility for products manufactured by others.

The warranty is rendered null and void in the case of:

- Failure to observe the Instruction for Use;
- Failure to carry out checks or incorrect checks before use;
- Misuse;
- Inappropriate use or handling;
- Any modification or replacement of device parts by personnel not authorised by Ferno;
- Damage during transport due to improper packaging of items returned by the user;
- Failure to perform periodic maintenance and preventive checks as described in the chapter "13. Maintenance".

In cases not covered by the warranty, Ferno will not cover the transport costs for sending or returning the product.

19.2 Limitation of liability

If a product is found to be defective, Ferno s.r.l. will repair, replace it, or refund the purchase price. Under no circumstances can Ferno s.r.l. be held liable for more than the selling price of the product. The buyer accepts these conditions for all types of damage. Ferno s.r.l. does not offer other warranties, either express or implied, or any implied warranties of saleability or fitness for a particular purpose for its own products, or those manufactured by others.

In case of infringement of the limited warranty, any legal actions must be filed within one year from the date on which the infringement was, or should have been, discovered. Ferno s.r.l. reserves the right to terminate the warranty of the products sold:

- If the labels or plates bearing the Manufacturer's logo and/or the serial or registration number are rendered illegible or removed;
- If the product has undergone modifications, repairs or treatment not authorised by Ferno;
- If the product is not used in compliance with the instructions, and/or used for purposes other than those for which it was designed;
- According to what is reported in the paragraph "19.1 Warranty terms and conditions".

Ferno s.r.l. cannot, in any event, be held liable for direct or indirect damage due to usage that is non-compliant with the instructions for use and the intended purpose of the product.

19.3 Warranty claims

Contact Ferno's Customer Service immediately if you receive a product that is suspected to be defective. An Operator will assist the Customer through the complaints procedure. Before returning a product to Ferno s.r.l., contact Ferno's Customer Service to request authorisation.

19.4 Claims

Any complaints must be communicated to the reseller, or to Ferno s.r.l.'s Customer Service, within 5 days of receipt of the product or of discovery of the alleged defect.

Claims or disputes regarding a single product shall not release the buyer from the obligation to collect and pay for other products in the order, unless otherwise agreed with the seller.

19.5 Return authorisation

No return will be accepted without the prior approval of Ferno s.r.l..

Products returned for business reasons, or for reasons not relating to nonconformity, will be accepted only after verification of their condition by Ferno s.r.l.'s qualified personnel.

20. RECORDS

IMPORTANT

Make several copies of the pages of the records and keep them for future reference.

20.1 Inspection record

Operator name _____ Serial number _____

Type of inspection	Outcome		Notes
	YES	NO	
Are all the components of the device present? Make sure that all the components specified by the Manufacturer are present.	☐	☐	
Are all labels intact and entirely legible? Make sure that all labels applied to the device are always intact and legible.	☐	☐	
Is the device intact in all its parts? Make sure that the device is not damaged, broken or abnormal, which could compromise its safety or proper functioning. In particular, ensure that there are no discoloured parts, signs of wear, cuts or abrasions, crushing or deformation.	☐	☐	
Are cushions undamaged? Check the integrity of the cushions by applying light pressure with both hands and checking for air leakage.	☐	☐	
Do the Velcro closures ensure an adequate grip? Perform a tightness test by connecting the two parts of the Velcro and tighten the ends of the straps.	☐	☐	
Has the Velcro been properly maintained? Check that there are no unstitched parts, frayed edges or elements that could diminish the attachment surface such as lint, hair, dirt, frayed or protruding fibres, etc.	☐	☐	
Has the device been properly cleaned? Check that no dust, dirt or body fluids are present and that the Manufacturer's prescribed cleaning has been carried out.	☐	☐	
Has the device been properly disinfected? Make sure that the device has been disinfected as specified by the Manufacturer.	☐	☐	

Date _____ Operator's signature _____

20.2 Training record

[illegible]

Date	Instructor name	Trained persons	Training Type	Instructor name



Ferno s.r.l.

Via Benedetto Zallone 26
40066 - Pieve di Cento (BO) - ITALY

Telephone (toll-free for Italy)	800 501 711
Phone	0039 0516860028
E-mail	info.it@ferno.com
Website	www.ferno.it

Ferno s.r.l.

Subsidiary in Savosa
Via Tesserete, 67

6942 - Savosa - SWITZERLAND

Telephone	+41 (0) 412596000
E-mail	info.ch@ferno.com
Internet	www.ferno-schweiz.ch