EN

Instructions for Use

Cortex
Surface Extender

EN – Original instructions

CE

FERNO®

SE-EN-MU-240726

It is compulsory to consult the Instructions for Use.

Device identification

Commercial name of device	CORTEX SURFACE EXTENDER
Model and catalogue number	REF 21-00066
Risk class	Class I according to Regulation (EU) 2017/745
Device description	Accessory consisting of multiple components: • TSL clamps • Side supports for side edges • Inflatable mattress • Electric inflation pump with connector • Repair kit • Adjustable extensions for restraints
Intended use	The kit increases the lateral surface area of the stretcher. It is intended to facilitate the transport of bariatric Patients. The device must only be used with the ScoopEXL stretcher on the Cortex stretcher. Use is restricted to qualified personnel.

Manufacturer details

FERNO

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

Regulatory compliance

CE

All products sold by Ferno comply with the general safety and performance requirements of Regulation (EU) 2017/745 (MDR) concerning medical devices.

For information, please visit: **www.ferno.it**

Revision index

Document code	Date of issue	Description of changes	Language
SE-EN-MU-240726	24/07/2026	First issue	English (UK)

1. Summary

1. INTRODUCTION AND GENERAL INFORMATION

1.1 Information about this document (purpose, storage and ownership)

Purpose and content of the Instructions for Use

It is compulsory to consult the Instructions for Use.

IMPORTANT

This document provides only technical and operational information regarding the correct operation, safe use, and maintenance of the device. It does not constitute a medical protocol manual.

These Instructions for Use form an integral part of the "**Cortex Surface Extender**" device manufactured by **Ferno S.r.l.**

- The contents are intended for Technical operators and service personnel trained by the Manufacturer.
- The document describes the characteristics and intended use of the device.
- The document provides information regarding the safety of the Operator, Patient, and Service Personnel.
- The instructions cover the entire life cycle of the device.

Storage of the Instructions for Use

- Keep the Instructions for Use close to the device for immediate reference.
- Store the document in a dry place protected from direct sunlight.
- In the event of loss or damage, download a copy of the Instructions for Use from **www.ferno.it** or contact Ferno Technical Support Service.
- The Instructions for Use must accompany the device in the event of a change of ownership.

IMPORTANT

The configuration of some parts illustrated or described in this document may differ from the actual product configuration, as the product may be manufactured according to specific requirements or operational protocols. In such cases, some descriptions, references, or procedures may be generic in nature while remaining valid and applicable to the device.

Safety information update

- The Manufacturer continuously monitors the safety of the device after it has been sold.
- The Manufacturer informs the relevant Authority of any updates concerning health protection.
- The Manufacturer updates the Instructions for Use in the event of technical or regulatory changes.
- In case of doubt, the user must consult the Manufacturer's website to verify that they have the latest version of the Instructions for Use applicable to their model.

Ownership of the information

FORBIDDEN

Reproduction of this document, in whole or in part, is prohibited without the written authorisation of the Manufacturer.

1.2 Definitions

Term	Definition
Expected clinical benefit	Positive effect of the device on the Patient's health.
Max. load capacity	Maximum load that the device can safely withstand without breaking.
Intended use	The medical and clinical purpose for which the device was designed, manufactured, and placed on the market by the Manufacturer.
Disinfection	Treatment intended to eliminate pathogenic micro-organisms on the device through the use of specific chemical or physical agents, in order to ensure an appropriate level of hygienic safety.
Personal protective equipment (PPE)	Equipment worn or used by the Operator to protect against health or safety risks during use of the device.
Incident	Malfunction or alteration of the characteristics of the device.
Serious accident	An event resulting in the death or serious deterioration of the health condition of a Patient or another person.
Responsible Organisation	Entity responsible for the use and maintenance of the medical device.

Term	Definition
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.
Patient	Person receiving the clinical benefit provided by the device.
Service personnel	Person appointed by the Responsible Organisation who carries out preventive maintenance of the device. This role requires the technical training necessary to perform the operations described by the Manufacturer.
Risk	The combination of the probability of the occurrence of damage and the severity of the damage.
Operator	Person who uses the device according to the skills and responsibilities defined by the Manufacturer.
Service life	Period during which the device maintains the specified safety performance.

1.3 Graphic conventions and safety messages

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

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the Patient or Operator, or damage to the device.

IMPORTANT

Provides essential information to ensure the correct use of the device and to prevent damage, malfunctions, or maintenance errors.

Prohibition messages

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

- Patient and Operator safety.
- The performance of the device.
- Regulatory compliance.

⃠ PROHIBITION

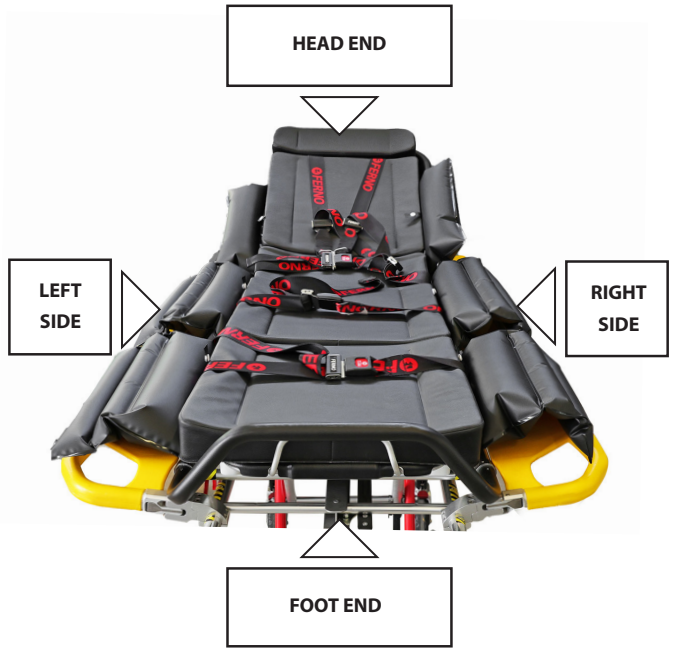
Indicates an action that must not be performed, as it may compromise the safety of the Patient and the Operator and may also damage the device.

1.4 Orientation

These Instructions for Use use spatial references to describe the device.

Refer to the illustration below to correctly identify:

- Foot end.
- Head end.
- Left side.
- Right side.



1.5 Limitation of Liability and Warranty 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 following are excluded from the warranty:

- All consumable materials or components subject to wear resulting from normal use of the product.
- All parts typically subject to sliding or rolling friction (bearings, brushes, sliding pads, tracks, etc.)
- Parts potentially subject to oxidation or corrosion (copper contacts 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 damage 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.

Warranty terms and limitations

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, including 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 and/or treatment not authorised by Ferno.
- If the product is not used in compliance with the Instructions for Use, and/or used for purposes other than those for which it was designed.

Under no circumstances shall Ferno S.r.l. be liable for any direct or indirect damage resulting from use that does not comply with these Instructions for Use or with the intended use of the device.

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

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.

1.6 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.

1.7 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.

1.8 Ferno Technical Support Service and reporting of serious incidents

For information or assistance regarding use, maintenance, or spare parts requests, contact **Ferno S.r.l**. To facilitate support activities, always quote the product serial number in all written communications.

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

In the event of a serious incident involving the device, immediately notify **Ferno S.r.l.** and the **Competent Authority** of the Member State in which the user is established:

E-mail:	eu-regulatory.it@ferno.com
Website dedicated to support Ferno SOS	www.fernosos.it
Telephone	+39 051 6860028

1.9 Labels and symbol legend

The labels (identification, warning, and instruction labels) affixed to the device contain essential information for safety and traceability.
The symbol legend is provided on the following pages.

⚠ WARNING

Keep the labels intact and perfectly legible. Missing, damaged, or illegible labels may lead to incorrect use of the device, resulting in a risk of serious injury to the Patient or Operators.

PROHIBITION

It is strictly forbidden to remove, cover, alter, or modify any labels affixed to the device.

⚠ WARNING

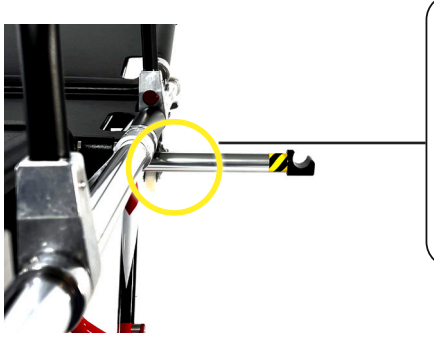
Periodically check that all labels are present and fully legible. If any labels are missing, damaged, or illegible, it is mandatory to contact Ferno Technical Support Service to obtain replacement with original labels.

Identification labels

The identification label identifies the device and the Manufacturer.

It provides the information required for safe use together with the applicable conformity markings.

Label located adjacent to the device side support



Label on the device primary packaging

Warning and instruction labels

Graphic symbols are affixed to the device to prevent potential risks to the user and to provide the information necessary for the correct, safe, and effective use of the product.

Label	Description
	Mechanical hazards

Symbol legend

Symbol	Description
CE	CE marking
	The Instructions for Use must be read
	Manufacturer
ITA	Date and place of manufacture
	Keep away from moisture
	Keep out of sunlight
	Consult the Instructions for Use
EU REP	Authorised Representative in the European Community
	Importer
GTIN	Global Trade Item Number (GTIN)
MD	Medical device indication
S N	Serial number
UDI	Unique device identification
REF	Catalogue number
	GS1 - Data Matrix
	Crush hazard
	Extension limit / End-of-travel indicator
	Lateral clearance indicator
2	Must be used by at least two qualified Operators
--lb --kg --st	Load capacity in pounds (lb), kilograms (kg), and stones (st)

1.10 General safety warnings

- This document provides only Instructions for the Use and maintenance of the device. It does not constitute a medical protocol manual.
- Read this document in full before any use, adjustment, or maintenance operation.
- Keep this document in a location accessible to all trained personnel.
- Use and maintenance are restricted exclusively to personnel who have received appropriate training and are qualified in accordance with the Manufacturer's requirements and as specified in *"5. Operator requirements and training"*. Personnel training must be documented.
- Use the device only if you have received specific training on the *CORTEX SURFACE EXTENDER*. Do not use the device solely on the basis of experience with similar products.
- Use the device exclusively for its intended purpose specified by the Manufacturer, in accordance with the operating specifications prescribed in *"2. Intended use and operating specifications"*.
- The device must be used by a minimum of two qualified and trained Operators.
- Use is permitted only by adults who are physically and mentally fit for the task.
- The device must be used in accordance with local emergency response protocols. In the event of operational uncertainty, the technical specifications and safety limits specified by the Manufacturer shall prevail.
- Do not exceed the maximum load capacity of 250 kg. Distribute the Patient's weight evenly.
- The Patient must always be secured to the device using the appropriate restraints throughout transport.
- If any malfunction, damaged part, worn component, or doubt regarding correct operation is identified, immediately remove the device from service. Contact the Manufacturer to restore the device to service.
- Clean and disinfect the device after each use, before storage, and in accordance with the procedures specified by the Manufacturer in Chapter *"8. Cleaning and Disinfection"*.
- The Manufacturer guarantees stability, performance, and safety only when the device is used in combination with the Cortex self-loading stretcher and the ScoopEXL model stretcher. Refer to Section *"2.7 Combinations and compatibility"*.
- Before loading the Patient, ensure that all mechanical locking systems are fully engaged and correctly secured.

2. INTENDED USE AND OPERATING SPECIFICATIONS

2.1 Purpose

The device is designed to increase the usable surface area of the stretcher to enable the safe and comfortable transport of a Patient, particularly during emergency and rescue operations.

2.2 Medical indication

The device is intended for Patients with impaired mobility, inability to walk independently, or unconsciousness, following the Operator's clinical assessment.

2.3 Expected clinical benefit

Increasing the support surface stabilises the ScoopEXL stretcher on the Cortex stretcher. This eliminates oscillating movement of the bariatric Patient. The device reduces the risk of lateral falls and helps prevent pressure-related tissue injuries.

2.4 Patient Population

The device is intended for use with bariatric Patients (adults or children) with reduced or absent mobility who require increased lateral support.

2.5 Contraindications and adverse effects

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.

2.6 Operational Profile

The device is intended for use in both hospital and pre-hospital environments (EMS - Emergency Medical Services).

2.7 Combinations and compatibility

⚠ WARNING

The Manufacturer guarantees stability, performance, and safety only for officially validated combinations. Use with unapproved combinations voids the warranty and may compromise the safety requirements of the device.

The product is designed to operate exclusively in combination with the following devices (not supplied):

- Self-loading stretcher, model **Cortex,** fitted with side supports for side edges and TSL locking clamps (installed by the Manufacturer). If the stretcher is not fitted with the required components, contact Ferno Technical Support Service.

- **ScoopEXL** model stretcher

2.8 Requirements for Normal Use

Normal use of the device is not limited to clinical application but also includes all operations required to ensure its safety and functionality before, during, and after use. The table below summarises the essential requirements and refers to the relevant chapters describing the procedures that the Operator and the Responsible Organisation are required to follow.

Normal use element	Associated requirement	Chapter reference
Operator profile	Compliance with the specified training and competency requirements	*"5. Operator requirements and training"*
Preparation	Correct configuration of the device before use	*"6. Preparation for use and removal"*
Visual check	Structural integrity and absence of damage or wear before use	*"7.1 Pre-use checks"*
Clinical use	Patient positioning	*"7.2 Patient positioning"*
Removal	Correct removal of the device	*"6. Preparation for use and removal"*
Reconditioning	Cleaning and disinfection of the device after each use	*"8. Cleaning and Disinfection"*
Maintenance	Performance of scheduled inspections and maintenance	*"9. Maintenance"*
Preservation and storage	Conditions for the preservation and storage of the device	*"11. Preservation and storage"*
Disposal	End-of-life disposal procedures	*"12. Service Life and Disposal"*
Records	Traceability of activities performed and verification of compliance with safety requirements	*"15. Records"*

2.9 Incorrect use and prohibited behaviours

The following sections identify improper uses, unauthorised modifications, and behaviours that may compromise the safety of the device, the safety of the Patient and Operator, or the effectiveness of the intended performance.

⚠ WARNING

Compliance with the specifications and prohibitions provided in these Instructions for Use is mandatory. Improper use releases the Manufacturer from any civil and criminal liability for damage to persons or property.

PROHIBITION

- Do not use the device for purposes other than the intended use specified by the Manufacturer.
- Do not use the device without having read, understood, and fully assimilated these Instructions for Use.
- Do not allow the device to be used by unauthorised or inadequately trained personnel.
- Do not use the device based solely on experience with similar products.
- Do not allow the device to be used by minors.
- Do not allow the device to be used by personnel with reduced physical, sensory, or mental capabilities.
- Do not allow the device to be used by personnel under the influence of substances that may impair attention or reaction speed.
- Do not use the device if pre-use checks have not been performed or successfully completed.
- Do not use the device for transporting objects, animals, or loads other than the designated Patients.
- Do not use the device as an independent lifting system.
- Do not use the device if the side supports are not installed, fully extended, and locked.
- Do not use the device if the frame of each side edge is not correctly secured in the recess of the corresponding support.

PROHIBITION

- Do not use the device if the two longitudinal stretcher halves of the ScoopEXL stretcher are not correctly secured to the clamps.
- Do not use the device if the inflatable mattress shows pressure loss or tears.
- Do not use the device in combination with devices not authorised by the Manufacturer.
- Do not install the mattress upside down or with the head-to-foot orientation reversed.
- Do not position the air injection tubes facing upwards.
- Do not use the device if the central holes of the mattress are not perfectly aligned with the Velcro fastener.
- Do not use the device if the inflatable mattress does not completely compensate for the height gap between the ScoopEXL stretcher and the mattress of the Cortex stretcher.
- Do not load the device beyond the maximum permitted capacity of 250 kg.
- Do not leave the Patient unattended, even if correctly secured with the restraints.
- Do not use the device with a Patient unless the restraints and extensions have been correctly installed and adjusted.
- Do not use the device if visible damage or abnormalities are present.
- Do not use the device without cleaning and disinfecting it between one Patient and the next.
- Do not use the device for prolonged or improper purposes outside the operational phases of rescue activities.
- Do not use accessories or spare parts not authorised by the Manufacturer.
- Do not perform maintenance operations while the Patient is on board.
- Do not modify the device or carry out repairs independently.
- Do not use the device without carrying out the scheduled maintenance according to the intervals specified by the Manufacturer.

3. DESCRIPTION

3.1 Operating principle

The device mechanically extends the support surface of the main stretcher.

The extension of the load-bearing area is achieved by manually extracting two side supports, onto which the side edges of the Cortex stretcher are positioned and locked.

Once opened, the side edges act as a structural support base for the two longitudinal stretcher halves of the ScoopEXL stretcher. Each longitudinal stretcher half is securely fastened to the device clamps by means of the TSL locking system. The configuration is completed by a two-chamber inflatable mattress positioned on the ScoopEXL stretcher. The integrated air injection tubes connect the chambers to each other to equalise pressure. The mattress and its cushions are inflated by connecting the rechargeable USB pump connection to the inflation valve.

IMPORTANT

The device does not include any additional accessories sold separately.

3.2 Supplied components

The device is supplied with the following standard components.

Component	Quantity (no.)
Clamps with TSL locking system (pre-installed on the Cortex stretcher).	4 (2 per side)
Side supports (pre-installed on the Cortex stretcher)	2 (one per side)
Inflatable mattress with two independent chambers	1
Rechargeable USB inflation pump	1
Connection	1
Plug connection	1
Repair kit	1
Adjustable extensions for restraints	4

3.3 Components not supplied

The following components are not included in the standard scope of supply for the device:

- ScoopEXL model stretcher.
- Cortex model stretcher.

3.4 Main parts

Reference	Part
1	TSL clamps
2	Side supports for side edges

Reference	Part
3	Air injection valve
4	Air injection tubes
5	Electric inflation and deflation pump
6	Connection
7	Plug connection
8	Inflation connection
9	Deflation connection
10	LEDs
11	Activation button
12	USB charging port

Reference	Part
14	Three-chamber cushions (Two-chamber inflatable mattress:)
15	Single-chamber cushions (Two-chamber inflatable mattress:)
16	Adjustable extensions for stretcher restraints

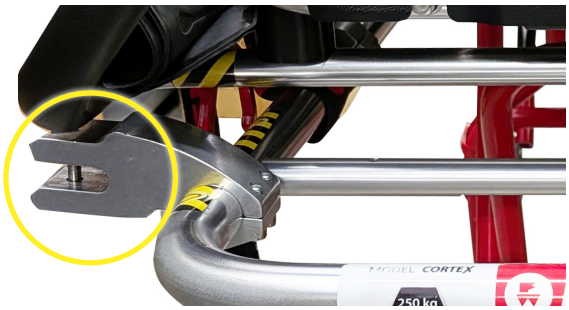
TSL clamps (Twin Slot Lock)

PROHIBITION

Do not install the TSL clamps independently or through the equipment installer. The clamps must only be installed by a technician authorised by the Manufacturer. If installation or reconfiguration is required, promptly contact Ferno Technical Support Service.

The TSL clamps, installed on the frame of the Cortex model stretcher, constitute the integrated mechanical fastening system. This system ensures a rigid and stable connection between the devices during rescue operations.

- **Main function**: secure the surface of the Cortex extender to the tubular structure of the ScoopEXL stretcher.
- **Twin Slot Lock mechanism**: uses a double-slot geometric profile for rapid engagement.
- **Self-centring**: automatically aligns the components during the mechanical coupling phase.
- **Safety locking**: prevents accidental release of the stretcher, even under high loads or significant stress.



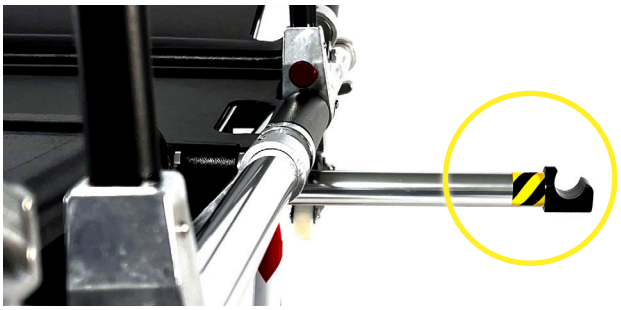
Side supports for side edges

PROHIBITION

Do not install the side edge supports independently or through the equipment installer. The supports must only be installed by a technician authorised by the Manufacturer. If installation or reconfiguration is required, promptly contact Ferno Technical Support Service.

The side edge supports are structural components installed by the Manufacturer directly onto the frame of the Cortex model stretcher. They allow the side edges to be safely housed during Patient transport.

- **Main function**: allow safe positioning of the ScoopEXL stretcher on the Cortex stretcher and support the stretcher side edges.
- **Interlocking geometry**: features reinforced seats for rapid and rigid locking of the side edges.
- **Retractable mechanism**: can be manually folded away when the device is not in use.



Electric inflation and deflation pump

IMPORTANT

For information regarding the technical specifications and operating procedures of the electric pump, refer to the Instructions for Use supplied with the accessory.

- **Rechargeable**: the pump can be recharged via USB.
- **Dual function**: the pump allows rapid inflation and deflation of the mattress.

Inflatable mattress

The mattress, made of cut-resistant material, is fitted with two independent inflatable side cushions for Patient support.

- **Cushions**: each side features two inflatable cushions configured with three air chambers and one single-chamber cushion.
- **Injection valves**: the inflation valves are positioned, one on each side, on the single-chamber cushion.
- **Air distribution**: the injection tubes connect the cushions to each other to distribute air internally.
- **Deflation function**: the same inflation valve allows complete air extraction for folding and closing the mattress.
- **Rapid storage system**: integrated press studs allow deflated cushions to be folded directly onto the frame.
- **Centring system**: holes in the central section facilitate positioning of the device and alignment with the Velcro fastener on the mattress of the Cortex model stretcher.

Adjustable extensions for restraints

The extensions are designed to increase the length of the standard restraints supplied with the Cortex model stretcher, allowing the correct and safe restraint of bariatric Patients

They consist of a strap (bearing the FERNO logo) featuring:

- On one side, a metal tongue to be inserted into the buckle of the restraint supplied with the Cortex model stretcher.
- On the other side, a buckle to which the metal tongue of the restraint strap supplied with the Cortex model stretcher is connected.

Repair kit

The device includes a kit for the rapid repair of small cuts or punctures on the surface of the inflatable mattress.

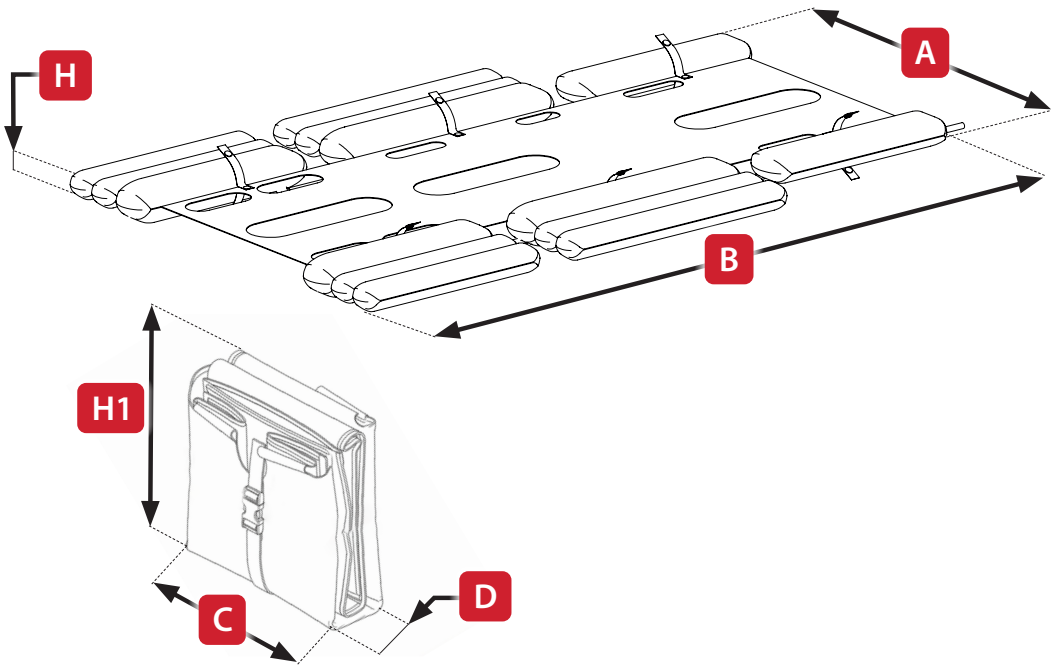
4. TECHNICAL SPECIFICATIONS

Environmental operating conditions	
Temperature	-20°C - +60°C
Maximum relative humidity	≤ 85%, no condensation

Mechanical and dimensional characteristics	
Weight The value includes: mattress, TSL clamps, side edge supports, 4 restraint extensions, and inflation pump	4.15 kg (*6.94 lb*)
Maximum load capacity	250 kg (*551 lb*)

Dimensions in operating configuration	
Maximum height (H)	90 mm (*3.54 in*)
Maximum width (A)	990 mm (*39 in*)
Maximum depth (B)	1570 mm (*61.8 in*)

Dimensions in storage configuration	
Minimum height (H1)	300 mm (*11.8 in*)
Minimum width (C)	500 mm (*19.7 in*)
Minimum depth (D)	100 mm (*3.9 in*)



5. OPERATOR REQUIREMENTS AND TRAINING

5.1 Operator profile

The Operator must meet the following mandatory requirements in order to use the device:

- Be part of a Responsible Organisation or qualified healthcare personnel.
- Be of legal age.
- Be physically and mentally fit while using the device.
- Be able to read and understand the language of these Instructions for Use.
- Correctly interpret the graphical symbols present on the device and in the Instructions for Use.

⚠ WARNING

Use of the device is restricted to trained personnel. Use by untrained personnel may result in malfunctions, Patient falls, and injuries to Operators.

- These Instructions for Use must be read before using the device in real-life scenarios.
- Practical training exercises must be carried out to learn handling and movement procedures.
- All residual risks identified by the Manufacturer must be known before use.

5.2 Training and instruction

The Responsible Organisation must provide appropriate training to the Operator before use, focusing on the following aspects:

- Correct application and operational use of the device.
- Maintenance procedures, intervals, and required inspections.
- Safety protocols and risk management.
- First aid procedures related to the use of the device.

IMPORTANT

Document each training session in the dedicated training record by completing the relevant form in section *"15.1 Training record"*.

6. PREPARATION FOR USE AND REMOVAL

⚠ WARNING

- All the operations described are restricted exclusively to trained Operators or service staff.
- If the side supports for side edges and TSL clamps are not present, contact Ferno Technical Support Service to request installation. Independent installation or installation by the equipment installer is strictly prohibited.

IMPORTANT

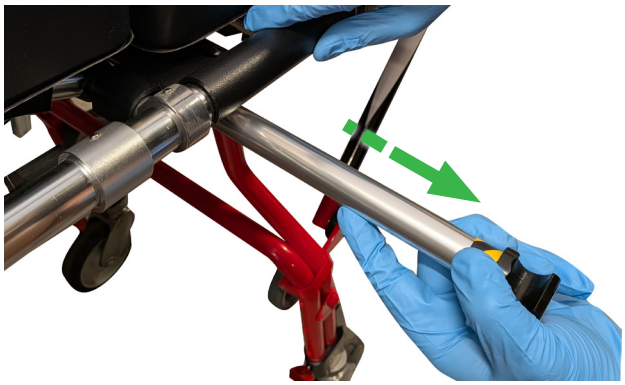
For specific adjustment procedures relating to the Cortex model stretcher and ScoopEXL model stretcher, refer to the relevant Instructions for Use.

6.1 Cortex Stretcher Configuration

1. Raise the backrest by at least one position.
2. Place the side edges in the fully vertical position.
3. Remove both side supports (A) from the frame.
4. Lower the side edges (B).
5. Fit the frame of each side edge into the recess of the corresponding support (C) until the mechanical click confirming correct locking is heard.

⚠ WARNING

Ensure that the frame of each side edge is fully inserted and correctly seated in the recess of the side support. Apply a slight upward pulling force to ensure that the locking mechanism is effective and secure.



6.2 Preparation and securing of the ScoopEXL stretcher

1. Adjust the length of the ScoopEXL to the shortest position.
2. Separate the longitudinal stretcher halves.
3. Rotate both longitudinal stretcher halves so that the Ferno logos face downwards.
4. Place the longitudinal stretcher halves on the side edges of the Cortex stretcher so that the head end of the ScoopEXL is at the foot end of the Cortex stretcher.
5. Open the locking levers of both longitudinal stretcher halves.
6. Secure both longitudinal stretcher halves to the clamps using the TSL locking system (D) until the mechanical click confirming correct locking is heard.

⚠ WARNING

Check the stability of the structure and the correct fastening of each longitudinal stretcher half to the clamps:

- Ensure that the mechanical locking click is clearly audible.
- Apply a test force to the extended support surface to confirm that it is securely fastened before positioning the Patient.

D

6.3 Mattress positioning

1. Release the central storage strap and unfold the mattress.
2. Position the mattress on the ScoopEXL stretcher according to configuration (E):
   - Air injection tubes facing downwards (in contact with the stretcher).
   - Single-chamber side cushions positioned at the top (head end).
   - Central holes in the mattress aligned with the Velcro on the Cortex stretcher.

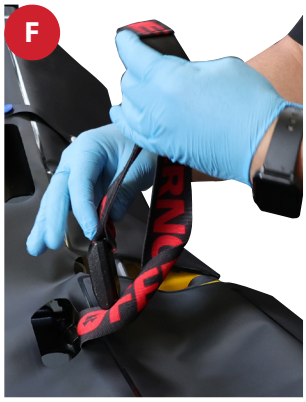
E

3. Pass all restraints through the dedicated slots located laterally on both sides of the inflatable mattress (F).

⚠ WARNING

Ensure that all restraints are correctly inserted through the designated mattress openings.

F



4. Position the Cortex stretcher mattress on top of the inflatable mattress, aligning the centring holes for Velcro fastening.

6.4 Inflating the mattress

1. Connect the connector to the air injection valve (G) located on the head end of the inflatable mattress.
2. Insert the pump connector into the inflation connection.
3. Connect the pump connector to the mattress connection (H).

4. Press the pump activation button.

IMPORTANT

For specific information regarding use of the electric pump, refer to the relevant Instructions for Use.

5. Check that the LEDs illuminate to confirm activation of the inflation phase.
6. Inflate the cushions until the vertical gap between the ScoopEXL stretcher and the Cortex stretcher mattress is completely filled.

⚠ WARNING

- With the Patient on board, ensure that the inflatable mattress completely compensates for the height gap between the ScoopEXL stretcher and the Cortex stretcher mattress.
- Always inflate both sides of the mattress completely before use, avoiding partial or uneven inflation.

7. Disconnect the pump connector from the inflation connection.
8. Press the grey button to disconnect the connector from the mattress valve (I).
9. Repeat the procedure to inflate the other side of the mattress.

6.5 Restraint extension connection

PROHIBITION

- Do not use damaged or worn extensions and restraints.
- Do not use extensions and restraints that are not original or authorised by the Manufacturer.

Install the extensions on the stretcher according to the following arrangement:

- Lower section of the four-point restraint (1): no. 2 extensions.
- Femoral restraint (2): no. 1 extension.
- Tibial restraint (3): no. 1 extension.

Installation:

1. Insert the metal tongue of the extension into the buckle of the supplied restraint until the locking click is heard.
2. Connect the opposite end of the extension (fitted with a buckle) to the metal tongue of the second section of the restraint until the locking "click" is heard.

WARNING

When securing the extensions:

- Always ensure that each metal tongue is fully inserted into the corresponding buckle until the locking click is heard.
- Always perform a manual pull test on each anchorage point to verify that the connection is stable and secure.

7. USE

At least two Operators must be present when using the device.

⚠ WARNING

- Carry out all pre-use checks before each use. In case of any abnormality, do not use the device and contact the Manufacturer.
- Before use, ensure that all parts and accessories removed for cleaning and disinfection have been correctly reinstalled and are completely dry.
- All operations described in this section must only be performed by trained and suitable Operators as specified in chapter *"5. Operator requirements and training"*.
- The Patient weight must be below 250 kg to prevent overloading and structural failure.
- Secure the Patient using the dedicated restraints and extensions provided.
- Distribute the Patient's weight evenly to prevent overloading and structural failure.
- For use of the Cortex and ScoopEXL stretchers, refer to the respective Instructions for Use.

7.1 Pre-use checks

Visual check

- Check that all required parts and accessories are present.
- Inspect the overall condition of the device to exclude the presence of:
  - Cuts or abrasions
  - Cracks
  - Air leaks (if detectable visually or audibly without performing any operations)
  - Deformations
  - Signs of abnormal wear
  - Discoloured parts
  - Rust or corrosion
  - Fraying
  - Worn edges
  - Wet parts and detergent or disinfectant residues
  - Dirt and body fluids (ensure that the required cleaning and disinfection procedure has been carried out).

Mechanical and assembly checks

- Check the assembly and correct fastening of the components:
  - The frame of each side edge must be fully inserted and correctly seated in the recess of the corresponding side support.
  - The ScoopEXL stretcher longitudinal stretcher halves must be secured to the clamps using the TSL locking system.
  - The ScoopEXL stretcher longitudinal stretcher halves must be positioned with the FERNO logo facing downwards.
  - The head end of the ScoopEXL stretcher must face the foot end of the Cortex stretcher.
  - The inflatable mattress air injection tubes must face downwards (in contact with the stretcher).
  - The single-chamber side cushions must be positioned at the upper end (head end) of the Cortex stretcher.
  - All restraints must be connected to the Cortex stretcher and pass through the dedicated openings in the inflatable mattress.
  - The extensions must be correctly connected to the Cortex stretcher restraints.
  - The mattress must be evenly inflated on both sides and must completely compensate for the height gap between the ScoopEXL stretcher and the Cortex stretcher.
- Carry out the following functional checks:
  - Apply a slight upward pull to the side edges to ensure that they are locked in their respective side support housings.
  - Apply a test force to the extended support surface to confirm that the two ScoopEXL stretcher longitudinal halves are securely fastened to the TSL clamps.
  - Perform a manual pull test on each restraint and extension anchorage point; each metal tongue must be fully inserted into the buckle and remain locked.
  - Check that no abnormal noises occur during simulated movements.
  - Check that the locking mechanisms of the clamps and supports operate correctly.

7.2 Patient positioning

1. Place the Patient on the device, distributing the weight evenly.
2. Secure the Patient using the dedicated restraints by connecting the extension buckles to the corresponding metal tongues.
3. Ensure that the locking "click" is heard.

⚠ WARNING

When securing the restraints to the Patient:

- Always ensure that each metal tongue is fully inserted into the corresponding buckle until the locking click is heard.
- Always perform a manual pull test on each anchorage point to verify that the connection is stable and secure before starting Patient movement.

7.3 Deflating the mattress

⚠ WARNING

Deflate the mattress only when the Patient is no longer positioned on the structure.

IMPORTANT

For specific information regarding use of the electric pump, refer to the relevant Instructions for Use.

1. Connect the connector to the air injection valve (L) located on the upper side of the mattress (head end).
2. Insert the pump connector into the deflation connection.
3. Connect the pump connector to the mattress connection (M).
4. Press the pump activation button.
5. Check that the LEDs illuminate to confirm activation of the deflation phase (N).

6. Wait for all the air inside the mattress to flow out.
7. Press the grey button (O) to disconnect the connector from the mattress valve.

8. Repeat the procedure for the other side of the mattress.

7.4 On-board standby

The device may remain on the stretcher when temporarily not required. This avoids repeated installation and removal procedures. The system will be immediately ready for subsequent use.

1. Completely deflate the mattress *"7.3 Deflating the mattress"*.
2. Fold the side cushions (P).
3. Secure the cushions at the sides using the press stud fasteners (Q).

7.5 Removing the device

1. Completely deflate the mattress *"7.3 Deflating the mattress"*.
2. Remove the Patient restraints from the side loops of the mattress.
3. Remove the 5-section cushion from the Cortex stretcher.
4. Remove the mattress.
5. Fold the mattress onto itself.
6. Close the mattress using the dedicated storage strap.
7. Tighten the strap to securely lock the folded mattress in the storage position

⚠ WARNING

After each use and before storage, clean and disinfect the device according to the procedures specified in chapter *"8. Cleaning and Disinfection"*.

8. CLEANING AND DISINFECTION

⚠ WARNING

- Cleaning and disinfection operations must only be performed by trained Operators or qualified Service Personnel.
- During all cleaning and disinfection phases, wear the Personal Protective Equipment (PPE) required by local healthcare protocols.
- The device must be cleaned and disinfected after each use (between Patients) and in any case before storage.
- Use only suitable cleaning and disinfecting products that do not alter the chemical and physical characteristics of the materials (refer to the list of prohibited products).
- Carefully read and strictly follow the instructions, contact times, and dilution ratios indicated on the labels of the chemical products used.
- Used consumable materials (cloths, gloves, cleaning solutions) must be disposed of in accordance with local protocols and regulations applicable to special waste.

⊘ PROHIBITION

- To avoid compromising the structure and safety of the device:
  - Do not use detergents or disinfectants containing phenols, chlorine-based solutions (such as bleach), or iodine-based products.
  - Do not use high-pressure water jets or saturated steam (e.g. pressure washers or autoclaves) on any part of the device.
  - Do not place the cushion, restraints, or buckles of the device in domestic or industrial tumble dryers.

⊘ PROHIBITION

- Do not release cleaning and disinfecting chemicals into the environment or into unauthorised drainage systems. Dispose of chemicals and their containers in accordance with current local regulations and the instructions provided in the Safety Data Sheets (SDS) issued by the respective manufacturers.
- The device must never be used on a new Patient without first completing the entire required cleaning, disinfection, and decontamination cycle. Failure to comply with this requirement may result in cross-contamination and transmission of pathogenic agents.

Cleaning

1. Clean the surfaces using a cloth or sponge soaked in cleaning solution. Rinse the sponge frequently in clean water. For stubborn dirt, use a stiff-bristle brush (non-metallic) or a mild solvent.
2. Remove coarse residues using a damp disposable cloth.
3. Apply a non-abrasive neutral detergent to the surfaces.
4. Gently rub using a soft, non-abrasive sponge.
5. Rinse with a cloth moistened with clean running water.
6. Dry all parts completely using disposable paper, a clean cloth, or allow them to air dry.

Disinfection and decontamination

1. Apply a proven-effective disinfectant to all parts using a non-abrasive cloth or sponge. Apply the product evenly over all surfaces.
2. Allow the disinfectant to act for the time specified by the chemical product manufacturer.
3. Dry thoroughly using a clean cloth or allow to air dry.

If the extensions are visibly contaminated with organic substances:

1. Remove the material using a disposable cloth and/or paper and dispose of it in the specific container for special waste.
2. Disconnect the extensions from the device and restraints and extend them fully.
3. Immerse the extensions in a container filled with water and sanitising solution, leaving the metal and plastic parts outside the container.
4. Leave to soak for approx. 5-20 minutes then dry with paper. If the buckle requires more thorough cleaning, wash it with water and mild soap and rinse thoroughly. Ensure that it does not remain wet for more than 5 minutes.
5. Connect the hooks together and hang the extensions from a support. If the buckles have also been mistakenly soaked, make sure the extension dries as quickly as possible to ensure its longevity
6. Refit the extensions only once they are completely dry.

⚠ WARNING

- Use the device only when all parts are completely dry to prevent the growth of mould or bacteria.
- Check that all safety and identification labels are present and fully legible. If labels are damaged, removed, or illegible, contact Ferno Technical Support Service for replacement.

PROHIBITION

Do not return the device to service if cleaning and disinfection activities reveal structural damage, corrosion, advanced wear, or mechanical abnormalities. If any of these conditions are identified, isolate the device and immediately contact Ferno Technical Support Service.

9. MAINTENANCE

⚠ WARNING

- Ferno directly carries out repair and maintenance operations, without the need of dealers, mechanics or external service centres. Do not trust anyone claiming to be an authorised Ferno technician without direct confirmation from the Manufacturer.
- Strictly comply with the intervals and procedures specified by the Manufacturer for all maintenance operations.
- Use only original spare parts supplied by the Manufacturer and contact Ferno exclusively for any repair or modification.
- Before performing maintenance operations, ensure that the device is completely free of loads.
- After any technical intervention and before the next operational use in the field, verify that all device components are intact, correctly installed, and fully operational.
- If there is any doubt regarding correct operation, the device must be immediately removed from service and identified as unsuitable for use. Contact only Ferno Technical Support Service for repair operations.

IMPORTANT

For maintenance specifications relating to the Cortex stretcher and ScoopEXL stretcher, refer to the respective Instructions for Use.

PROHIBITION

- Do not perform any maintenance, inspection, or cleaning operation while the device is in use.
- Do not use non-original spare parts.
- Do not make modifications, repairs, or carry out any type of intervention not authorised by the Manufacturer.
- Do not use the device if defects or abnormalities are identified. Immediately contact Ferno Technical Support Service.

9.1 Preventive maintenance

The table lists the preventive maintenance operations that must be carried out to ensure the safety and performance of the device.

Methods and criteria for verification are given on the following pages.

Operation	Frequency		
Action	**After each use**	**Every month**	**Whenever necessary**
Inspections		✓	✓
Cleaning	✓	✓	✓
Disinfection	✓	-	✓

9.2 Inspections

⚠ WARNING

- Device inspections must only be performed by specifically trained Operators or authorised Service Personnel.
- Carry out device inspections monthly, even if the device is not used or has remained in storage for an extended period.
- Perform inspections more frequently in the event of intensive use or whenever deemed necessary (for example: following particularly demanding use, operation in extreme environmental conditions, suspected malfunction, or after a long storage period).

Inspections are intended to ensure the safety, integrity, and correct operation of the device.

1. Buckles and metal tongues

- Visual integrity: check for the absence of deformations, cracks, excessive wear, metal burrs, or signs of corrosion/rust.
- Mechanical functionality: ensure that inserting the tongue into the buckle produces a clear locking "click". Check that the release button operates correctly without sticking and that the locking mechanism remains secure when subjected to manual pulling force.
- Cleaning: check that the internal buckle housing is clean and free from foreign bodies or disinfectant residues.
- Anchorage points: inspect the integrity of the stitching or fastening systems securing the buckle to the restraint strap.

2. TSL clamps

- Visual integrity and cleaning: visually check that the clamps show no signs of wear, cracks, or geometric deformation. Carefully remove any dirt, foreign bodies, or disinfectant deposits that could interfere with the correct positioning of the ScoopEXL stretcher.
- Mechanism and return springs: test the smooth operation of moving components. Check that the locking levers and associated secondary safety systems automatically engage into position, without stiffness, and with adequate spring return force.
- Clearance and anchorage check: ensure there is no abnormal mechanical play or millimetric movement caused by wear of the internal pins. Check that the clamp body is securely anchored to the support structure and that the fastening elements are not loose.
- Functional coupling: Insert the ScoopEXL stretcher longitudinal halves into the clamps: the operation must be smooth and free from obstruction. The longitudinal stretcher halves must engage completely, producing a clear mechanical click and activating the TSL safety locking system. Verify final retention by applying a manual pulling force with the clamp closed.

3. Supports for side edges

- Structural integrity and wear: visually inspect the support anchorage points on the frame to exclude cracks (micro-cracks), geometric deformation, signs of metal fatigue, or component wear.
- Tightening and mechanical anchorage: check the stability of the supports on the load-bearing structure. Ensure that the fastening elements are securely tightened and show no loosening or millimetric play.
- Sliding mechanism: remove any accumulation of dust, dirt, or disinfectant residues from the guides and check that opening and closing movements are smooth, without sticking or abnormal friction.
- Side edge recesses: check that there are no debris (stones, soil, or residues from external operations) preventing correct seating of the frame. Ensure that the frame of each side edge is fully inserted and correctly seated in the recess of each side support. Apply a slight upward pulling force to ensure that the locking mechanism is effective and secure.

4. Inflatable mattress

- Check that the mattress has no cuts, abrasions, deformation, compression marks, or discoloured areas.
- Slow leak test: inflate the mattress and leave it inflated in the warehouse/workshop for at least 4-6 hours (or overnight) with the device unloaded. At the end of this period, check that the mattress does not show significant pressure loss or deflation (to identify micro air leaks that may not be audible during daily operations). If small cuts are identified, they can be repaired independently *"9.3 Repairing the mattress"*.
- Valve, connectors, and air injection tubes: check that the valve, connector, and inflation/deflation tubes are intact, clean, and free from cracks in the rubber components.
- Check that there is no layered dirt or encrustation in less accessible areas.

9.3 Repairing the mattress

Small cuts in the mattress may be repaired independently using the supplied repair kit. To carry out the repair, follow these steps:

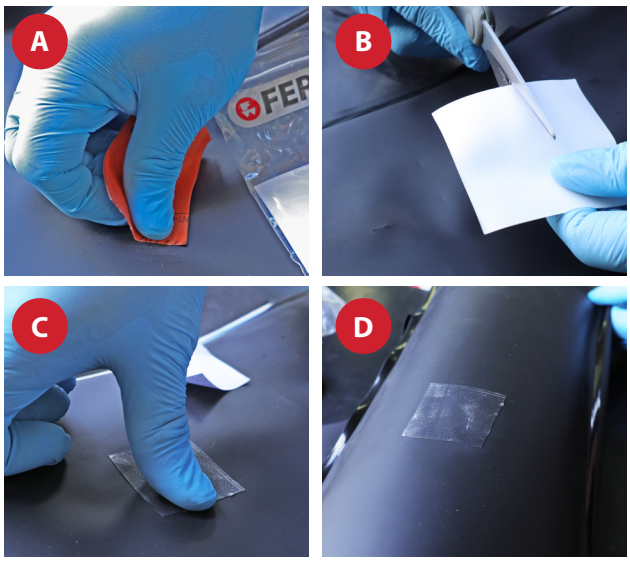
1. Use the abrasive paper included in the kit to gently smooth the area around the cut (A), ensuring better adhesion.
2. Cut the adhesive patch to a suitable size to completely cover the damaged area (B), leaving a small additional margin around the edges.
3. Position the patch over the cut and apply light pressure with the fingers from the centre outwards (C,D) to prevent the formation of air bubbles.
4. Wait several hours before using the mattress to allow the adhesive to fully set and stabilise.

⚠ WARNING

Perform an inflation test to ensure that the repair has been successful and that there are no air leaks.

PROHIBITION

Do not place the Patient on the device if the mattress has cuts, holes, or damage.



9.4 Annual maintenance and repairs

⚠ WARNING

- Any inspection, extraordinary maintenance, or repair work must only be carried out by the Manufacturer by contacting Technical Support Service.
- Strictly comply with the scheduled annual preventive maintenance interval.
- Immediately stop using the device if a malfunction is suspected or if the required maintenance interval has expired.

IMPORTANT

Keep the maintenance completion certificate as proof that the inspection has been performed and to keep the medical device history record up to date.

PROHIBITION

Do not independently perform annual routine maintenance or any repair work.

Annual maintenance is an essential requirement to ensure continuous safety, optimal device performance, and protection of Patients and Operators.

It is also mandatory to maintain product compliance with current applicable regulations.

At the end of the procedures, authorised Ferno technicians issue a maintenance completion certificate confirming the operational suitability of the device.

Repairs are considered extraordinary maintenance operations and must only be performed by the Manufacturer.

10. SPARE PARTS REQUESTS

⚠ WARNING

- Use only original spare parts supplied by the Manufacturer.
- For requests relating to spare parts, components, or accessories, contact Ferno Technical Support Service directly, providing the device identification code.

⃠ PROHIBITION

Do not use non-original spare parts that have not been authorised by the Manufacturer.

Spare part		Part no.
Inflatable mattress		25-00259-M01
Inflation pump		10-00703
Inflation connector		10-00694
no.4 adjustable extensions for restraints		0313659-IT

11. PRESERVATION AND STORAGE

⚠ WARNING

- Whenever possible, store the device in its original packaging or in an environment suitable for protecting it from impacts, contamination, and environmental conditions outside the specified storage limits.
- Before each use, carefully check that the device is intact and shows no visible signs of damage, wear, or tampering. Do not use the device if defects are found that could compromise safety or performance.

Preservation

To maintain the performance and safety of the device over time, comply with the following instructions:

- Store the device at a temperature between -20 °C and +60 °C.
- Maintain relative humidity below 85%.
- Prevent the formation of condensation.
- Store the device away from aggressive chemicals.
- Keep the device away from heat sources and naked flames.
- Protect the device from direct sunlight.
- Protect the device from adverse weather conditions.

The device has no predefined expiry date, provided that the storage conditions specified by the Manufacturer are respected.

Storage

⚠ WARNING

The device must always be cleaned and disinfected before storage.

If the device is not used for a period of time, follow the procedure below to preserve its integrity, safety, and performance:

1. Perform cleaning and disinfection as specified by the Manufacturer *"8. Cleaning and Disinfection"*.
2. Deflate and fold the inflatable mattress as described in *"7.5 Removing the device"*.
3. Store the device, complete with all components, inside the original packaging (if available), or within a protective covering capable of protecting it from dust, dirt, and water.
4. Store indoors.
5. Ensure that the storage environment is dry and well ventilated.
6. Protect the device from impacts, vibrations, and mechanical loads.
7. Prevent potential external contamination.
8. Comply with the storage instructions specified by the Manufacturer.
9. Restrict access to the storage area to authorised personnel only.

12. SERVICE LIFE AND DISPOSAL

Service life

IMPORTANT

Plan the timely replacement of worn components to maintain the device in optimal condition. Regular inspections help extend the service life of the device and maintain its efficiency over time.

The service life of the device and its components is affected by normal wear and depends on frequency and duration of use.

To preserve the service life of the device, comply with the conditions specified by the Manufacturer:

- Correct and compliant use.
- Performance of preventive and periodic maintenance and cleaning operations.
- Periodic replacement of restraints and extensions: as these are components with a limited service life, they must be replaced **10 years** after the date of manufacture (the date is indicated on the labels of the restraints and extensions), even if no visible signs of wear or damage are present. Use only original Ferno spare parts, available separately.

Disposal

IMPORTANT

Traceability and reporting obligation. For medical device vigilance purposes, disposal of the device must be officially reported to the Manufacturer.

- Complete in full the declaration provided in this document in section *"16.1 Disposal declaration"*.
- Send the completed form to: assistenza.it@ferno.com.

⚠ WARNING

Dispose of all discarded device components in accordance with applicable environmental regulations. Carefully check the specific provisions and protocols of the Local Authority or Healthcare Organisation.

IMPORTANT

An authorised collection and disposal service may be requested directly from the Manufacturer. This service includes collection of the device from the user's premises and subsequent disposal in accordance with applicable regulations.

⃠ PROHIBITION

Do not dispose of the device or its components in the environment at the end of their service life.

To dispose of the device:

1. Clean and disinfect all components.
2. Proceed with disposal by one of the following methods:

- **Collection centre (WEEE):** deliver the device to an authorised collection centre for waste electrical and electronic equipment.
- **Specialised company:** entrust disposal to a certified company authorised to manage professional waste. In this case, always attach the Waste Identification Form (FIR).
- **Manufacturer:** entrust collection and disposal directly to the Manufacturer. To request the service and obtain information on management costs, contact Ferno Technical Support Service.
- If disposal is carried out independently, send the disposal declaration *"16.1 Disposal declaration"*, completed in all its parts, to **assistenza.it@ferno.com**.

13. RESIDUAL RISKS

⚠ Residual risk	Cause	Effect / Consequence	Control Measure
Incomplete engagement of mechanical locking systems	Damage, accumulation of dirt, or critical operating conditions	Loss of stability and Patient fall during use, resulting in injury to the Operator and Patient	Verify the condition and correct engagement of all mechanical locking systems
Development of bacterial infections or cross-contamination	Presence of pathogens or microbial growth caused by residual moisture retained in cavities or joints after sanitisation cycles	Infections or inflammatory responses affecting Patients or Operators	Thoroughly clean and disinfect the device after each use in accordance with the specified procedures. Completely dry all components and joints before reuse or storage

14. PROBLEMS, CAUSES AND SOLUTIONS

Problem	Cause	Solution
The device does not engage correctly with the Cortex stretcher	Dirt, debris or blood present in the side supports	Clean and disinfect the surfaces. Remove all debris and foreign matter
	Side supports not fully opened	Adjust the supports so that the stretcher side edges can be inserted into their respective recesses
	Damaged side supports	Stop using the device. Contact Ferno Technical Support Service immediately
The ScoopEXL stretcher does not seat securely on the device	Incorrect positioning or misalignment of the ScoopEXL stretcher with the TSL clamps	Reposition the ScoopEXL stretcher. Check that both longitudinal stretcher halves are correctly engaged in the clamps, ensuring that the locking mechanism clicks into place to confirm correct engagement
	Debris accumulated inside the TSL clamps	Clean the clamp housings before attempting again
	Damaged TSL clamps	Stop using the device. Contact Ferno Technical Support Service immediately
The Patient is unstable or rocks laterally during transport	Restraint systems not fitted or adjusted correctly	Check that all restraints and extensions are correctly positioned and adjusted
	Maximum permissible load for the combined devices exceeded	Strictly observe the maximum load specified by the Manufacturer
	Cushions insufficiently inflated	Ensure that the mattress completely fills the height gap between the two stretchers
	Cushions inflated unevenly	Ensure that both sides of the mattress are inflated evenly
The mattress does not inflate/deflate.	Holes, cuts or abrasions	Use the repair kit. If the problem persists, contact Ferno Technical Support Service
	Damaged air valve and/or injection tubes	Contact Ferno Technical Support Service
	Faulty inflation pump	Refer to the pump Instructions for Use

IMPORTANT

If the fault cannot be identified or resolved using the procedures described in this table, withdraw the device from service and contact Ferno Technical Support Service.

15. RECORDS

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

15.1 Training record

Date	Instructor name	Trained persons	Training type	Instructor signature

15.2 Inspection record (1 of 2)

IMPORTANT

The inspection and verification activities listed in the table below must be carried out monthly and whenever considered necessary.

Device model_____ Serial number _____

Date of Commissioning: ____ / ____ / _____

Operator's name_____ Inspection date: ____ / ____ / _____

Macro-Area Component	Activities relating to Inspection and Verification	Outcome		Notes Corrective Actions
		Compliant	*Non compliant*	
Buckles and metal tongues, restraints and extensions	No deformation, cracks, excessive wear, burrs, corrosion/rust.	☐	☐	
	Smooth engagement with a distinct locking "click". Release button operates freely and the buckle remains secure under manual pull.	☐	☐	
	Buckle interior is clean and free from foreign matter or disinfectant residue.	☐	☐	
	Stitching or buckle fastening systems securely fixed to the restraint strap.	☐	☐	
TSL clamps	No wear, cracks or geometric deformation. Removal of dirt, foreign matter or disinfectant residue from the ScoopEXL stretcher seating area.	☐	☐	
	Moving components operate smoothly. Locking levers and secondary safety systems engage automatically with adequate spring return force.	☐	☐	
	No abnormal or millimetric mechanical play (due to wear of the internal pins). Clamp body securely fastened and all fixing elements tight.	☐	☐	
	ScoopEXL longitudinal stretcher halves engage smoothly, lock fully with a positive click (TSL lock engaged), and remain secure during manual pull testing.	☐	☐	

Inspection record (2 of 2)

Macro-Area Component	**Activities relating to Inspection and Verification**	**Outcome**		**Notes Corrective Actions**
		Compliant	*Non compliant*	
Supports for side edges	No cracks (micro-cracks), geometric deformations, signs of metal fatigue or wear or wear at the frame attachment points.	☐	☐	
	Supports securely fixed to the frame; all fixing elements tight with no looseness or play.	☐	☐	
	Guides clean and free from dust or disinfectant residue. Opening and closing movement smooth, without binding or abnormal friction.	☐	☐	
	No debris (stones, soil or other residues) inside the support recesses. Each side edge frame seats fully in the support recess and withstands a light upward pull.	☐	☐	
Inflatable mattress	No cuts, abrasions, deformation, crushing or discolouration.	☐	☐	
	Slow leak test (4-6h / overnight): No significant pressure loss or collapse after static testing with the device unloaded (micro-leak detection).	☐	☐	
	Air valve, connector and injection tubes intact, clean and free from cracks.	☐	☐	
	No built-up dirt, contamination or deposits in hard-to-reach areas or crevices.	☐	☐	

Operator's signature_____

16. ATTACHMENTS

16.1 Disposal declaration

DECLARATION IN LIEU OF NOTORIETY

(Art. 47 Presidential Decree 28 December 2000, n. 445)

The undersigned _____

Born in _____ () on ____

Residing at _____ Street address:_____ City / State / ZIP: ____

Tax ID code _____

In the capacity of (e.g. Owner/Legal Representative/Private citizen) _____

of the company/studio (if applicable)

_____

DECLARES UNDER HIS OWN RESPONSIBILITY

that the following medical device has been put out of use and destined for disposal:

- Device type: _____
- Make and Model: _____
- Serial Number: _____
- CND Code (if known): _____

FURTHER CERTIFICATES THAT:

The device has become unusable for (check as appropriate):

- o Technical fault that cannot be repaired / is uneconomical.
- o Technological obsolescence.
- o Expiration of the validity/safety period.

The device has been rendered inoperative and free of potentially dangerous or infectious parts (following decontamination, if necessary).

Disposal has taken place (or will take place) in accordance with current legislation (Legislative Decree 152/2006 and subsequent amendments):

- o By delivery to an authorized recycling center (WEEE).
- o Through a specialized company (attach the FIR form if applicable).

The undersigned is aware of the criminal penalties provided for by Article 76 of Presidential Decree 445/2000 in the event of false declarations.

Place and Date: _____ Signature: _____

(Attach a photocopy of your identity document)

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