



Model 445

Universal Head Immobilizer



FERNO[®]

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Ferno Customer Relations

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INSTRUCTIONS FOR USE



Read this Manual and Retain for Future Reference. To request additional free manuals, contact Ferno.

MD

Medical Device



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Disclaimer

This manual contains general instructions for the use, operation and care of this product. Instructions are not all-inclusive. Safe and proper use of this product is solely at the discretion of the user. Safety information is included as a service to the user. All other safety measures taken by the user should be within and under consideration of applicable regulations and local protocol. Training on the proper use of this product must be provided before using this product in an actual situation.

Retain this manual for future reference. Include it with the product in the event of transfer to new users. Additional free copies are available upon request from Customer Relations.

Proprietary Notice

The information disclosed in this manual is the property of Ferno. Ferno reserves all intellectual property rights, proprietary design rights, manufacturing rights, reproduction use rights, and sales use rights thereto, and to any article disclosed therein except to the extent those rights are expressly granted to others or where not applicable to vendor proprietary parts.

Limited Warranty Statement

Ferno products are covered by a limited warranty, printed on all Ferno invoices. Complete terms and conditions, and limitations of liability, are available from Ferno.

Adverse Event Notice

In the event of an adverse event or serious incident related to the use of this device, the end user/operator must report the incident to Ferno at 1-877-733-0911, or via email at tscordinator@ferno.com. If the incident occurred outside the U.S., report it to Ferno's Authorized Representative for that area.

Disposal

Prior to disposal, clean and disinfect the product according to the Maintenance section of this manual. Recycle or dispose of the product following local protocols and regulations. Do not dispose of the product in municipal waste.

Unique Device Identification (UDI)

Production information can be found on the reverse side of the base plate.

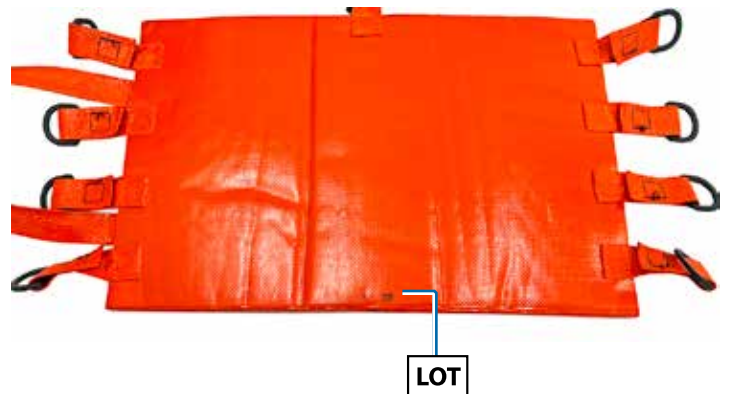



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1 - SAFETY INFORMATION

1.1 Warning

Warning safety alerts indicate a potentially hazardous situation that, if not avoided, could result in injury or death.

 WARNING
Professional use by trained operators only. Maintain control of product at all times.
Use the product only for its intended purpose. Improper use, operation, or maintenance can cause injury. Use, operate and maintain only as instructed.
An unattended patient can be injured. Stay with the patient at all times.
Improper parts, modifications or items not designed for the product can cause injury. Use only Ferno-approved parts and service. Attach only approved items to the product. Do not modify the product.







1.2 Notice

Notices emphasize important, but not hazard-related information. Failure to follow Notices could result in product or property damage.

NOTICE

1.3 Symbol Glossary

Ferno uses, as applicable, the following safety and regulatory symbols.

Symbol	Definition
	General warning of potential injury
	Consider instructions for use (ISO 7000)
	Refer to instructions for use (ANSI Z535/ISO 3864)
	Two trained operators required
	Disinfecting
	Cleaning

2 - OPERATOR TRAINING

2.1 Operator Training

Operators must: read and understand this manual, have the physical ability to assist the patient, be trained on proper product operation, be trained on emergency-medical service and patient-handling procedures, and practice with the product before using it with a patient. Keep training records.

 WARNING
Professional use by trained operators only. Maintain control of product at all times.

3 - ABOUT THE HEAD IMMOBILIZER

3.1 Description

The Ferno® Model 445 Universal Head Immobilizer is an emergency patient-handling device designed to aid in immobilizing a patient's head and neck. It is for professional use only, by a minimum of two trained operators.

The head immobilizer is vinyl coated, and is both waterproof and buoyant. It is designed not to interfere with medical scanners, and may be left in place during X-rays, MRI or CT scans.

The head immobilizer includes a base plate with retention straps, two support pads, and two forehead/chin straps. Each component features hook-and-loop fastening strips.

The head immobilizer can be used with a Ferno Scoop stretcher or on a long (full-length) backboard which has either cervical device slots or a center hole at the head end.

3.2 General Specifications

Product specifications are shown in the table. General specifications are rounded. Metric conversions are calculated before rounding the Imperial measurement.

Ferno reserves the right to change specifications without notice. For more information, contact Ferno (page 2).

3.3 Components

WARNING

Use the product only for its intended purpose. Improper use, operation, or maintenance can cause injury. Use, operate and maintain only as instructed.

Specifications	Imperial	Metric
Length	16 in	410 mm
Width	10 in	255 mm
Height	6 in	160 mm
Weight	2 lb	0.86 kg

Components	
A	Base plate
B	Fastening strip (2)
C	Side retention strap (2)
D	"D" ring (8)
E	Top retention strap
F	Support pad (2)
G	Forehead or chin strap (2)



4 - USING THE HEAD IMMOBILIZER

4.1 General Guidelines for Use

Medical advice is beyond the parameters of this manual. It is the operators' responsibility to ensure safe practices for the patient and themselves.

- A minimum of two trained operators is required.
- Use the head immobilizer only as described in this manual.
- Follow standard emergency patient-handling procedures when operating the head immobilizer.
- Qualified personnel should assess the patient's condition and determine the proper procedures and equipment to use.
- Typical operation is for one operator to support the patient's head and neck while the other operator applies the head immobilizer.
- Typical procedure is to use a cervical extrication collar with the head immobilizer whenever possible.
- Stay with the patient at all times.

4.2 Using the Head Immobilizer With a Backboard

Use a full-length backboard with the head immobilizer. The backboard must have either a center hole or cervical device slots at the head end.

1. Separate head immobilizer components and unfasten the retention straps.
2. Position base plate (A) with the fastening strips (B) facing up and side fastening strips (C) at the head end of the backboard, below the center hole (H, if present) (Figure 1 and Figure 2).
3. Thread side retention straps (C) through cervical device slots (I) (if present, Figure 1) and fasten to a base plate fastening strip (B). If the backboard does not have cervical device slots, wrap side retention straps under the backboard (Figure 2) and fasten to the base plate fastening strips (B).
4. If the backboard has a center hole (H), insert the top retention strap (E) through hole (H), loop it over the end of the backboard, then thread the strap through the plastic buckle before securing it to the hook and loop fastener on the strap itself (Figure 3).
5. Confirm base plate (A) is firmly in place (does not slip) on the backboard. Adjust and tighten retention straps (C and E) as needed. If the straps cannot be adjusted to hold the base plate in place, attach the head immobilizer to a different backboard.
6. Transfer the patient onto the backboard following approved emergency service procedures and following local guidelines for patient movement.

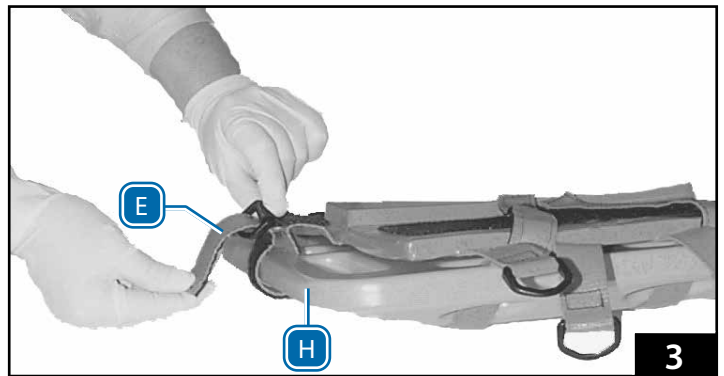
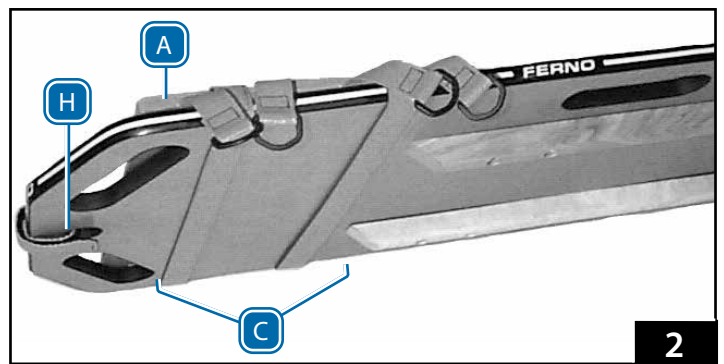
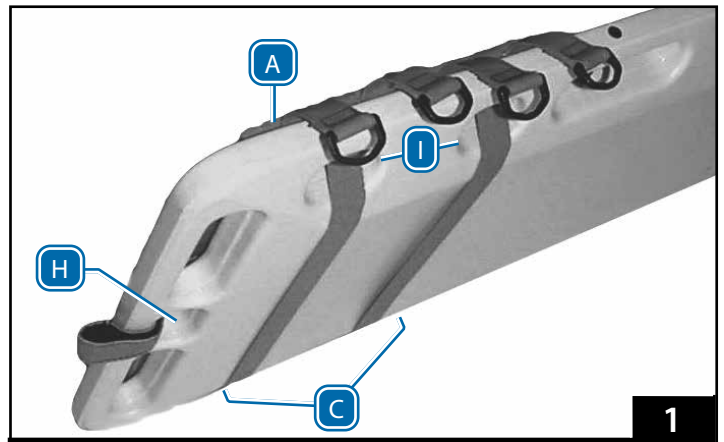
WARNING

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An unattended patient can be injured. Stay with the patient at all times.

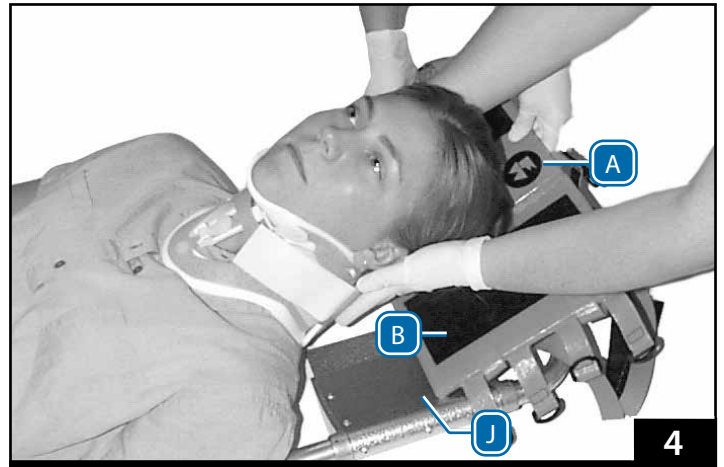
NOTICE

Affix the base plate tight to the backboard for proper function. If the base plate slips, tighten the retention straps. If it continues to slip, use a different backboard.



4.3 Using the Head Immobilizer With a Scoop Stretcher

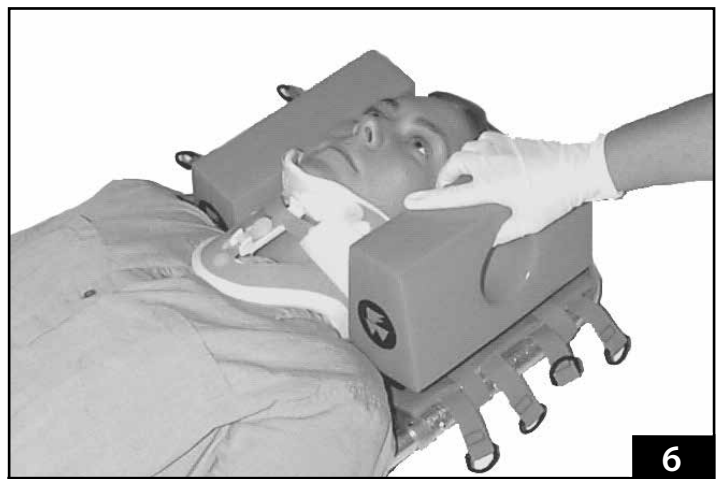
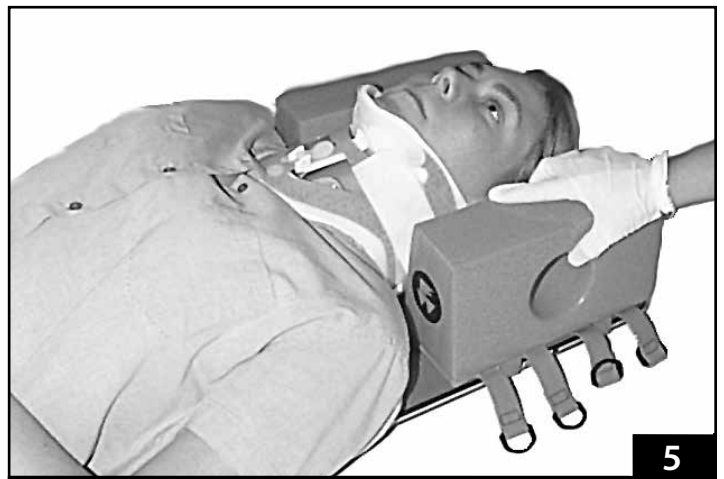
1. Separate head immobilizer components and unfasten the retention straps.
2. Transfer the patient onto the scoop stretcher following approved emergency service procedures and following local guidelines for patient movement.
3. As one operator holds the patient's head and neck, a second operator slides base plate (A) under the patient's head and onto the scoop stretcher head panels (Figure 4).
4. Wrap side retention straps (C) under scoop stretcher head panels (J) and secure them to base plate fastening strips (B).
5. Wrap top retention strap (E) around the scoop stretcher frame, then thread the top retention strap through the plastic buckle and secure it to the fastening strip on the strap itself.



4.4 Securing the Patient in the Head Immobilizer

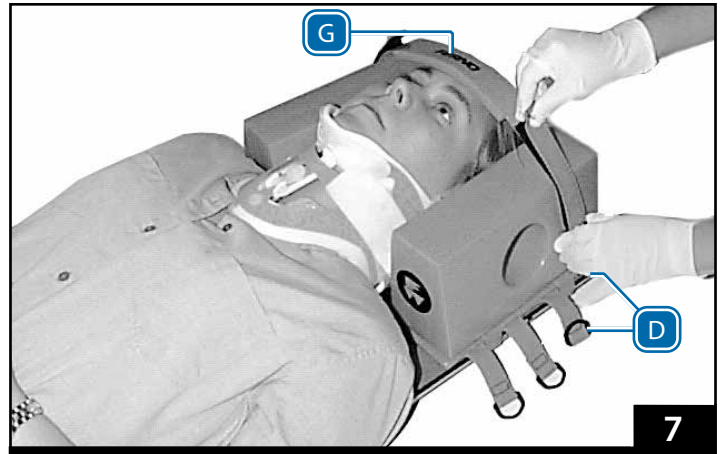
Always follow approved emergency medical procedures and local protocols for providing patient care. To apply support pads (Figure 5):

- Position the patient on the backboard or scoop stretcher with the head centered on the base plate.
- Secure the patient on the backboard or scoop stretcher using approved patient restraints.
- When the patient is on a backboard, typical application is to place the straight side of the support pads against each side of the patient's head (Figure 5).
- When the patient is on a scoop stretcher, place the angled side of the support pads against the patient's head (Figure 6).
- Follow local medical guidelines for support pad positioning if the patient's neck is twisted or angulated.
- When possible, align support pad holes with the patient's ears. This helps the patient hear the operator and allows the operator to check the patient's ears for blood or drainage, and to ease communication with the patient.
- Where possible, position the end of each pad against the patient's shoulders.



4.5 Using the Forehead/Chin Straps

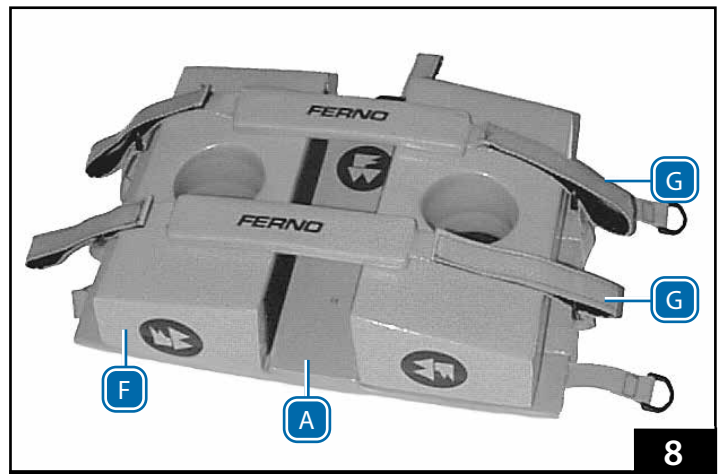
1. Center a forehead/chin strap (G) on the patient's forehead, with the fastening strips up.
2. Thread each end of the forehead/chin strap (G) through a base plate "D" ring (D). Tighten as needed and secure the ends to the fastening strips on the forehead/chin strap (Figure 7).
3. Follow your local protocols to determine the use and placement of the second forehead/chin strap.



4.6 Storing the Head Immobilizer

Clean and disinfect the head immobilizer before storage. See "Maintenance" on page 9. There are two options for storing the head immobilizer:

- Store the head immobilizer base plate attached to a backboard if desired.
- For compact storage, loop side retention straps (C) under base plate (A) and secure them to the fastening strip (not visible in Figure 8). Lay support pads (F) on their sides on base plate (A), and attach the forehead/chin straps (G) over support pads. Secure forehead/chin strap ends in "D" rings (D) (Figure 8).



5 - MAINTENANCE, PARTS AND SERVICE

5.1 Maintenance Schedule

The product requires regular maintenance. Set up and follow a maintenance schedule. Refer to the table for minimum intervals for maintenance. Keep maintenance records. For a sample record sheet, see "Maintenance Record" on page 11. When using maintenance products, follow the manufacturers' directions and read the manufacturers' material safety data sheets.

5.2 Service Life

Factors affecting product service life include frequency of use, local environment (temperature, humidity, etc.); maintenance (adherence to the inspection and maintenance schedule); and other factors. Follow the disinfecting, cleaning, and inspection procedures in this manual to ensure long life for the product.

5.3 Bloodborne Disease Notice

To reduce the risk of exposure to blood or other potentially infectious materials when using the product, follow the disinfecting and cleaning instructions in this manual.

5.4 Disinfecting and Cleaning

Remove the head immobilizer from the backboard or scoop stretcher and inspect it. Replace if it is ripped, punctured or damaged.



Wipe all surfaces with disinfectant. Follow the disinfectant manufacturer's instructions for application method and contact time.



Hand clean with warm water and a mild detergent. Rinse with warm, clear water. Dry with a towel or allow it to air-dry.

5.5 Inspecting

Have your service's equipment maintenance personnel inspect the head immobilizer regularly. Follow the checklist at right. If inspection shows damage or excessive wear, remove the head immobilizer from service until repair is made. See "Parts and Service" below.

5.6 Ferno Parts and Service

For parts or professional repair, contact your Ferno distributor, Ferno Customer Relations, or visit our website for a list of Authorized Service providers.

Ferno-Washington, Inc., 70 Weil Way
Wilmington, Ohio 45177-9371, U.S.A.

Information www.ferno.com
Authorized Service ferno.com/service-and-support

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WARNING

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Minimum Maintenance	Each Use or Daily	As Needed	Monthly
Disinfecting	•		
Cleaning		•	
Inspecting		•	•

NOTICE

Do not use disinfectants or cleaners containing phenolics or iodines. If bleach is used, rinse with plenty of clear water to remove bleach residue.

Inspection Checklist

- Are all components present?
- Is the head immobilizer free of excessive wear?
- Is the head immobilizer in good condition, free of punctures, frayed edges or tears?
- Does the base plate remain firmly in place (does not slip) when secured to the backboard or Scoop stretcher?

PARTS LIST

Description	Part #
Chin or forehead strap (pair)	081-9724
Head support pad (pair)	081-9882
445 Base plate	081-9883



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Aviation

Military

Mortuary

EMS

Rescue

