The Pink Pad EXT™

INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Pink Pad® EXT™ Kit is a single use system for use in surgical procedures. The system consists of a proprietary formulation for the pink foam pad, non-woven lift sheet, body straps, and One-step™ arm protectors.

INDICATIONS

The Pink Pad® EXT™ Kit is a single-use, non-sterile device intended for use during surgical procedures to support patients in the Trendelenburg, reverse Trendelenburg, and supine positions.

INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals to position patients and to help prevent patient skin injury and hospital-acquired pressure injuries during surgical procedures.

CONTRADICTIONS

This device is not designed, sold, or intended for use except as indicated.

KNOWLEDGE AND USE

Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

The Pink Pad® EXT™ Kit provides patient skin protection during the surgical procedure.

PREPARATION AND USE

1. Place the Pink Pad EXT on the table so the white Hook & Loop straps read “This Side Up”. The Pink Pad EXT should be used while patient is in supine position, and warming devices can be placed under the Pink Pad EXT.

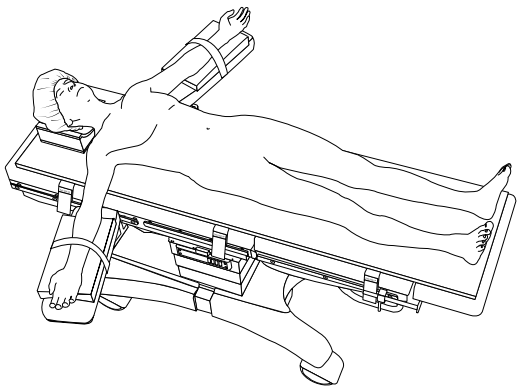
2. Attach the white hook & loop straps to the surgical bed rails by looping under the rail, and affixing the ends of the Hook & Loop to each other.

3. Lay the lift sheet over the pad, centered between the Hook & Loop straps. The lift sheet should cover only the portion of the pad that will be addressing the small of the patient’s back- below the Scapula Region and above the Sacrum.

4. Follow hospital protocol for intubation. Then properly position patient on the pad.
   IMPORTANT: THE PATIENT’S SKIN MUST MAKE DIRECT CONTACT WITH THE PAD.
   Utilize the included lift sheet to carefully lift the patient up and off the pad to reposition as needed. Do not drag patient on pad. Make sure pad remains completely flat at all times.

5. Lay each arm board pad with DermaProx™ over each arm board. Position patient’s arm so that the elbow and wrist rests comfortably on top of arm board pad.

6. Attach the arm board strap by wrapping it around the arm board, arm board pad and patient’s arm and then over lapping the end of the strap onto the Hook & Loop part of the strap, securing the patient’s arm to the arm board pad.



7. Attach the body strap as follows:

    A. Place the strap component with the small Hook & Loop, Hook square around the table's accessory rail and through strap buckle.

    B. Repeat the above step on the other side of the table with the remaining strap component with the Hook & Loops, Hook side facing downward. Join the straps together.

8. Please see instructions on how to properly use the One-Step™ Arm Protectors.
   IMPORTANT: NOT ALL KITS COME WITH ARM PROTECTORS.

DISPOSAL

- After use, the Pink Pad EXT Kit™ should be disposed of in accordance with hospital policy.

WARNINGS

- This device was designed, test and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure or subsequent injury.
- Reprocessing of this device may create the risk of contamination and patient infection.
- Do not reuse or reprocess this device.
- After use, the Pink Pad EXT Kit™ should be disposed of in accordance with hospital policy.
- The Pink Pad EXT Kit™ should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.
- Please visually inspect for breaches of packaging integrity prior to use. Do not use if damaged, opened or breached.

PRECAUTIONS

- Before using The Pink Pad EXT, ensure that the O.R table pad is securely affixed to the O.R table and is clean and free of residue
- Be sure to follow your facility's policies and guidelines for frequency of patient monitoring. Check skin for integrity and proper circulation. Product is to be used by licensed medical professional only
- The Pink Pad EXT Kit™ should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Care should be taken to safeguard The Pink Pad EXT from exposure to prep solutions.
- Handling & Storage: During ALL handling and storage, assure that the pad is flat.
- Notice to the User and/or patient that any serious incident that has occurred in relation to the device should be reported and the competent authority of the Member State in which the user and/or patient is established, as well as, Xodus Medical and its Authorized Representative.

TECHNICAL SPECIFICATIONS

- Materials of manufacture include:
  - Polyurethane Foam
- Shelf Life – Indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

The Pink Pad EXT Kit™ should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

One-Step Trendelenburg Arm Protectors

INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The One-Step™ Trendelenburg Arm Protectors are a single use device for use in surgical procedures. The device wraps around the patient's arms and secures onto itself to prevent and protect the patient's arm, ulnar nerve, and fingers from injury.

INDICATIONS

The One-Step™ Trendelenburg Arm Protector are a single use, non-sterile device to be used during surgery to prevent and protect the patient's arm, ulnar nerve, and fingers from injury.

INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals only.

CONTRAINDICATIONS

This device is not designed, sold, or intended for use except as indicated.

KNOWLEDGE AND USE

Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

To aid hospital facilities in providing a safe and effective method of management of the patient for injury for patients in a surgical procedure.

PREPARATION AND USE

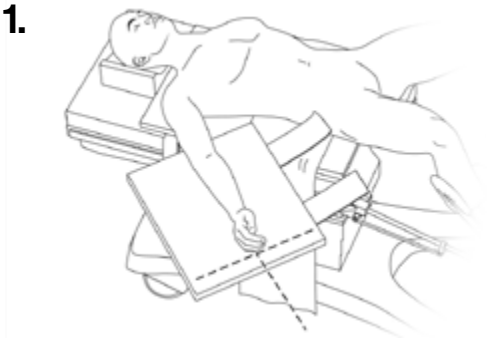
1. Place the One-Step™ Trendelenburg Arm Protector beneath the patient's arm, centering the arm protector laterally with straps facing down and inward toward the patient's torso. The pad should extend above the elbow and just below the fingertips. The hand should be positioned in a natural anatomical position with the palms facing inward so as not to impinge upon the ulnar nerve. The One-Step™ will protect the arm, ulnar nerve and fingers when adjusting the stirrups, while permitting easy access to the fingers and IV site. It will also safeguard against tissue breakdown.

2. Wrap the outer portion of the protector over the arm.

3. Next, wrap the remaining portion of the arm protector over the arm and secure the straps to the corresponding hook & loop patches as shown. Ensure that the One-Step™ Trendelenburg Arm Protector is firmly wrapped around the patient's arm. At this stage, check for proper alignment of the wrist and fingers. Also, inspect pulse oximeters, IV lines, etc. to ensure proper placement. Accessing these patient monitors is simple and repeatable.

4. Repeat steps 1-3 for the remaining arm. Once the One-Step™ protectors are in place, wrap the lift sheet per hospital protocol, tucking it between the patient and The Pink Pad.®Tucking methods vary according to hospital protocol. The lift sheet can be tucked either beneath the patient or beneath the O.R. table mattress. Lift sheets should not be tucked between The Pink Pad® and the O.R. table mattress.

1.



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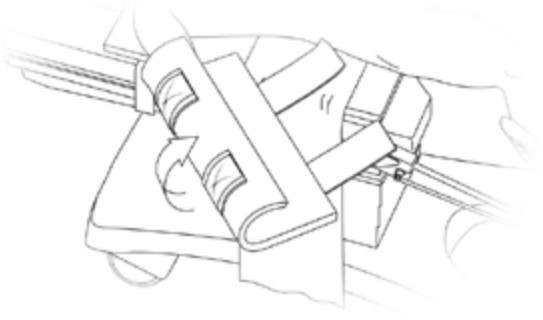

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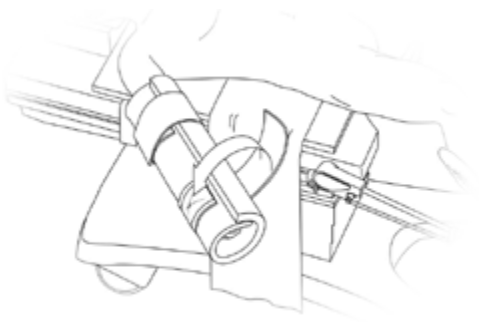

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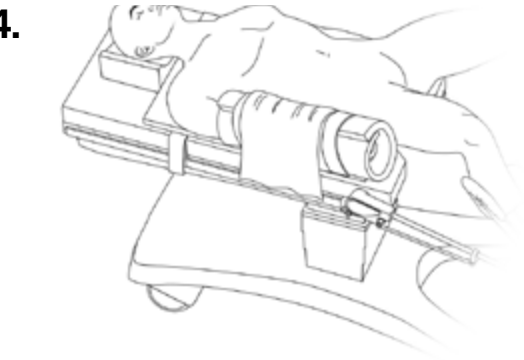

DISPOSAL

- After use, the One-Step™ Trendelenburg Arm Protectors should be disposed of in accordance with hospital policy.

WARNINGS

- This device was designed, test and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure or subsequent injury.
- Reprocessing of this device may create the risk of contamination and patient infection.
- Do not reuse or reprocess this device.
- After use, the One-Step™ Trendelenburg Arm Protectors should be disposed of in accordance with hospital policy.
- The One-Step™ Trendelenburg Arm Protectors should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

PRECAUTIONS

- The One-Step™ Trendelenburg Arm Protectors should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Be sure to follow your facility's policies and guidelines for frequency of patient monitoring. Check skin for integrity and proper circulation. Product is to be used by licensed medical professional only.
- Notice to the User and/or patient that any serious incident that has occurred in relation to the device should be reported and the competent authority of the Member State in which the user and/or patient is established, as well as, Xodus Medical and its Authorized Representative.

TECHNICAL SPECIFICATIONS

- Materials of manufacture include:
  - » Polyurethane foam; Nylon
- Shelf Life – indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- One-Step™ Trendelenburg Arm Protectors should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

Non-Sterile

Medical Device

Consult Electronic Instructions for Use

Do Not Re-use

Not Made with Natural Rubber Latex

Do Not Use If The Package Is Damaged Or Opened

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzlerland

702 Prominence Drive
New Kensington, PA 15068,
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FDA REGISTERED
ISO 13485 CERTIFIED

MADE IN THE USA

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