

The Pink® Reverse-T Kit

INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical Pink Reverse Trendelenburg Kit™ is a single-use, foam-based positioning system designed to support and protect patients during surgical procedures performed in the reverse Trendelenburg position.

INDICATIONS

The Pink Reverse Trendelenburg Kit™ is a single use, non-sterile device to be used in surgical procedures.

INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals to position patients in the reverse Trendelenburg position 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 Reverse Trendelenburg Kit™ provides patient skin protection during the surgical procedure.

PREPARATION AND USE

1. Start with table flat and without incline, then place The Pink® Reverse T Pad at the very edge of the middle table segment, positioning the white Hook & Loop straps on the underside of The Pink® Reverse T Pad.

IMPORTANT: DO NOT use any table covers, linens, other transfer devices or materials between The Pink® Reverse T Pad and surface of the surgical table. The Pink® Reverse T Pad must contact the surface of the table pad. The "This Side Up" tags should be facing upward.

2. Attach the white Hook & Loop straps of The Pink® Reverse T Pad 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 as shown. 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's buttocks on the pad as seen in **Diagram 1**.

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 rest comfortably on top of arm board pad with DermaProx™.
6. Attach the arm board strap by wrapping it around both the arm board, arm board pad and patient's arm and looping the end of the strap through. **OPTIONAL ACCESSORY:** Please see instructions on how to properly use the One-Step Arm Protectors.

IMPORTANT: NOT ALL KITS COME WITH ARM PROTECTORS.

Diagram 1

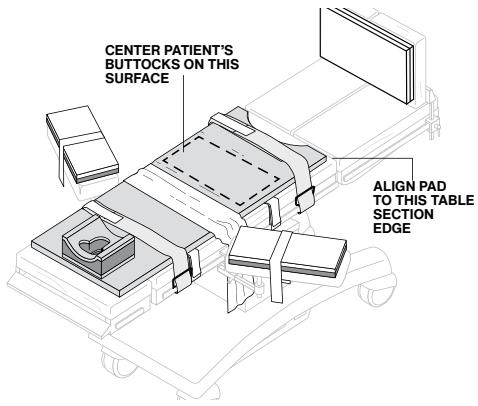
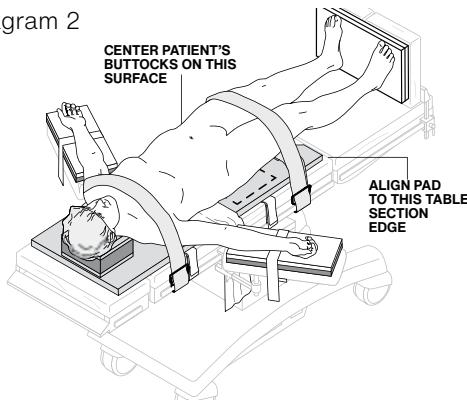


Diagram 2



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. Add incline to table and safely position patient into Reverse Trendelenburg.

DISPOSAL

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

WARNINGS

- This device was designed, tested 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 Reverse Trendelenburg Kit™ should be disposed of in accordance with hospital policy.
- The Pink Reverse Trendelenburg 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® Reverse T Pad, ensure that the O.R. table pad is securely affixed to the O.R. table and is clean and free of residue.
- The Pink Reverse Trendelenburg 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 from exposure to prep solutions.
- Handling & Storage: During ALL handling and storage, assure that the pad is flat. Do not roll or fold the pad.
- Be sure to follow your facility's policies and guidelines for frequency of patient monitoring. Check for skin integrity and proper circulation. Product is to be used by a 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
- Shelf Life – Indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

The Pink Reverse Trendelenburg 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

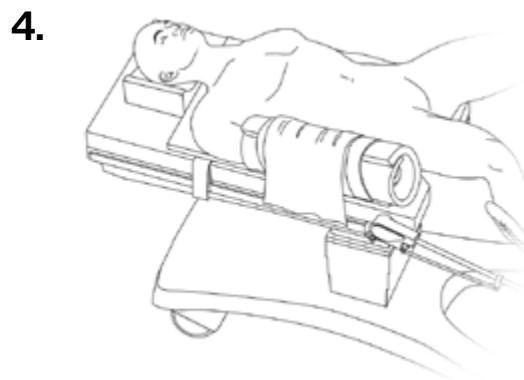
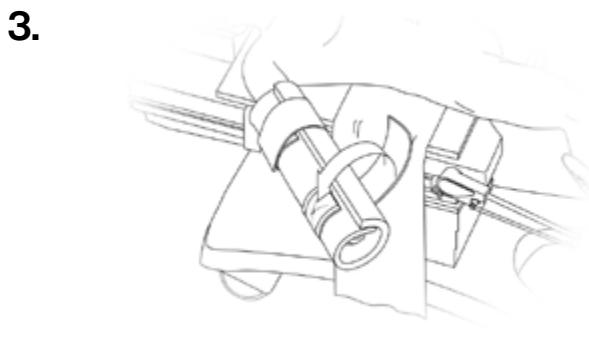
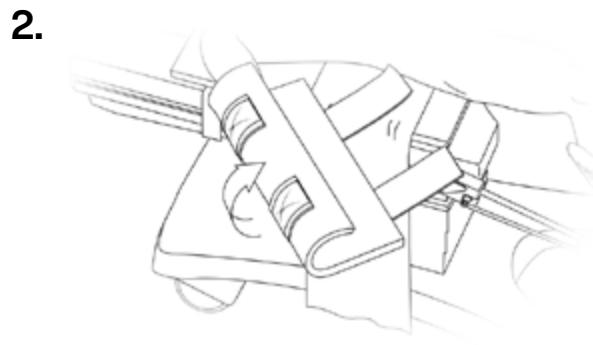
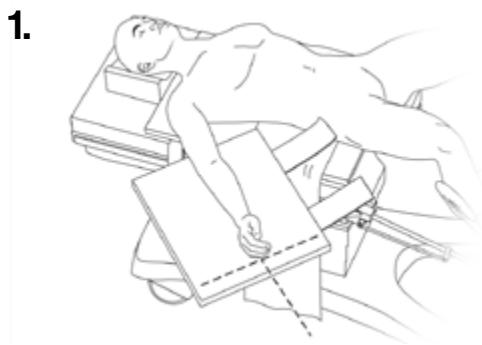
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

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.



DISPOSAL

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

WARNINGS

- This device was designed, tested 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.



 xodusmedical.com/eifu

Consult Electronic
Instructions for Use



Medical Device



Non-Sterile



Do Not Re-use



Do Not Use If The
Package Is Damaged
Or Opened



Not Made with Natural
Rubber Latex



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland



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FDA REGISTERED
ISO 13485 CERTIFIED



MADE IN THE
USA

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