Instructions for Use: Trendelenburg Pad

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
The Trendelenburg Pad 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, head rests, and boot liners.

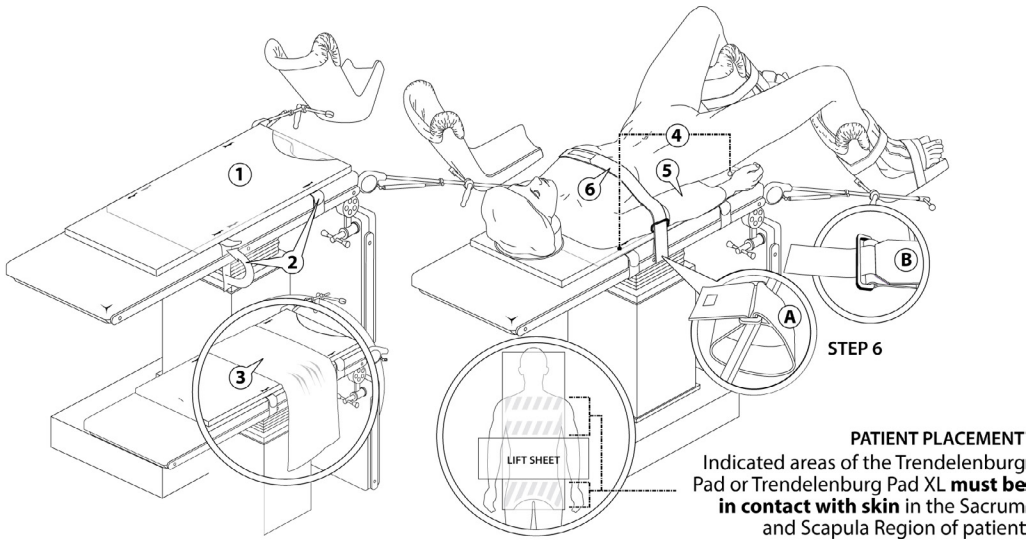
INDICATIONS
The Trendelenburg Pad is a single use, non-sterile device to be used during surgery to provide patient protection from injury.

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 pressure ulcers and non-movement for patients in the Trendelenburg position.



PREPARATION AND USE
1. Place the Trendelenburg Pad at the very edge of the middle table segment nearest the perineal cutout, positioning the white hook & loop straps on the underside of the Trendelenburg Pad in direct contact with the table pad's surface. IMPORTANT: DO NOT use any table covers, linens, other transfer devices or materials between the Trendelenburg Pad and surface of the surgical table. The Trendelenburg 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 Trendelenburg Pad to the surgical bed rails by looping under the rail, as shown, 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 (inset A). 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 pad. IMPORTANT - THE PATIENT'S SKIN MUST MAKE DIRECT CONTACT WITH THE TRENDELENBURG PAD. The skin of the Scapula Region and Sacrum must contact

the pad surface (inset B). Utilize the included lift sheet to carefully lift the patient up and off the pad to reposition as needed for safe and proper application of stirrups. Do not drag patient on pad. Make sure pad remains completely flat at all times.

5. Tuck arms as shown or per hospital protocol.
6. Attach the body strap as follows:
   A. Place the strap component with the small hook & loop 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 & loop's hook side facing downward. Join straps together.

DISPOSAL

- After use, the Trendelenburg Pad 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 Trendelenburg Pad should be disposed of in accordance with hospital policy.
- The Trendelenburg Pad should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

PRECAUTIONS

- The Trendelenburg Pad should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Before using the Trendelenburg Pad, 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.
- Care should be taken to safeguard the Trendelenburg Pad from exposure to prep solutions.
- 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, synthetic adhesive, nylon strap
- Shelf Life – indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- The Trendelenburg Pad should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.
- During ALL handling and storage, assure that the pad is flat. Do not roll or fold the pad.

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

MADE IN THE
USA

LITCOMBO006 R0 7/17/2025