

INSTRUCTIONS FOR USE:

One-Step Trendelenburg Arm Protectors

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.

CONTRADICTIONS

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

KNOWLEDGE AND USE

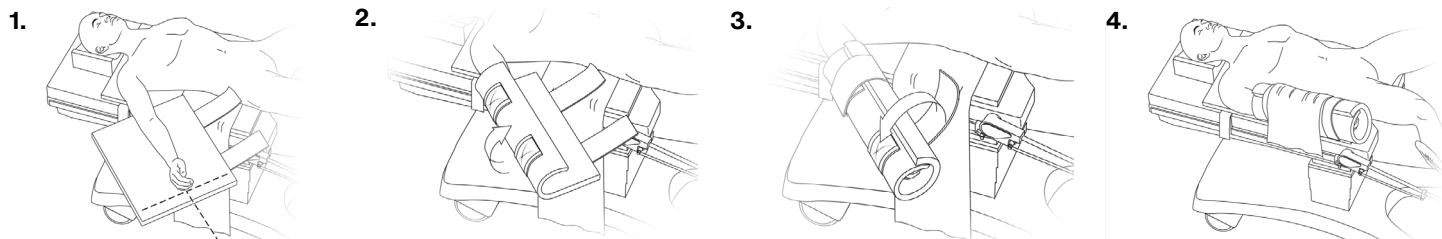
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

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.
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, 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
- 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.



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