

# INSTRUCTIONS FOR USE: STANDARD PINK LAT PACK™

## BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

### DESCRIPTION

The Pink Lat Pack™ is a single use system for use in lateral surgical procedures. The system consists of a proprietary formulation for the pink foam pad, non-woven lift sheet, body straps, head positioner, body wedge, armboard pads, and an intra-leg positioner.

### INDICATIONS

The Pink Lat Pack™ 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 to provide patient protection from injury during lateral 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

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 lateral position.

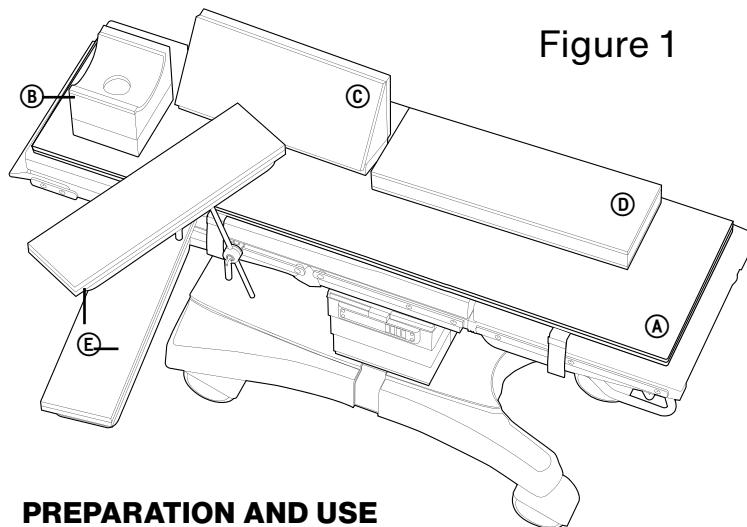


Figure 1

- A. Pink Pad EXT™
- B. Adjustable Lateral Head Positioner
- C. Multi-Angle Body Wedge
- D. Intra-Leg Positioner
- E. Armboard Pads with DermaProx™

### PREPARATION AND USE

1. Make sure the O.R. table is level and in position. Lay down Pink Pad® EXT on the entire O.R. table and attach the Pink Pad® EXT to the O.R. table according to the Pink Pad® EXT Instructions For Use. (figure 1)
2. Lay Adjustable Lateral Head Positioner on O.R. table relative to where the patient's head will lay. The hole in the head positioner is where the patient's ear should end up. The taller part of the head positioner should encompass the back of the patient's head. (figure 1)
3. Begin positioning the patient on their side. Tear away perforated part of the head positioner as needed.
4. Put Multi-Angle Body Wedge behind the patient so that the wedge supports the patient's back while in lateral position. Use the 35° 55° or 90° angle depending upon the surgeon's preference. (figure 2)
5. Place the patient's down arm on the Armboard Pad with DermaProx™ on top of the armboard with their palms facing up. Attach each arm board strap to the armboard and patient's arm between patient's wrist and elbow. Depending on the table set up, place the patient's up arm on the Armboard Pad with DermaProx™ on top of the limb holder. (figure 2)
6. Lay Intra-Leg Positioner on top of the patient's bent leg so that it lays in between the patient's legs; ensuring the knees and thighs do not rub against one another. (figure 2)
7. Use remaining body straps to secure the patient at locations the surgeon prefers or per hospital protocol. Attached body straps by following the steps below:
  - A. Secure both portions of the two-part body strap to the accessory rails.

- B. Identify each portion of the strap – Part A has a small Velcro square and Part B has a long Velcro tab. (Figure 3)
  - C. Beginning with Part A, orient the strap so that the small Velcro square is facing outward, away from the table. Draw the end of the belt up between the table and the accessory rail and lay the free end over the table.
  - D. Repeat the procedure with Part B of the strap on the other side of the table, ensuring that the hook side of the long Velcro tab is facing inward toward the pad
  - E. Join straps together with the long Velcro tab of Part B on top of Part A.
8. If applicable, jackknife/tilt table to desired position and begin procedure.

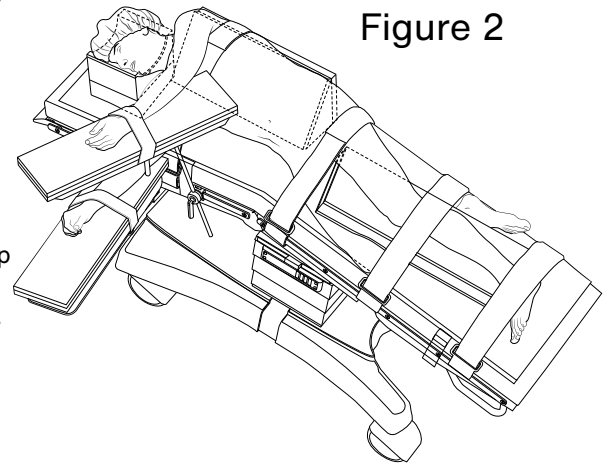


Figure 2

## DISPOSAL

- After use, The Pink Lat Pack 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 Lat Pack should be disposed of in accordance with hospital policy.
- The Pink Lat Pack 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.
- USA Federal law restricts this device to sale by or on the order of a physician.

## PRECAUTIONS

- The Pink Lat Pack 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 Pink Lat Pack, 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 Pink Lat Pack 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 Pink Lat Pack 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.

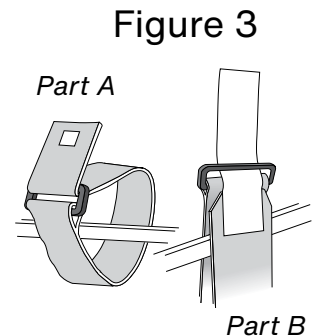


Figure 3



702 Prominence Drive Ph. 1- 724.337.5500  
Pittsburgh, PA 15068 U.S.A.

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xodusmedical.com | info@xodusmedical.com

LITIFULP001 R3 8/8/2023