

INSTRUCTIONS FOR USE: PINK ARC POSITIONER—XS

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Pink Arc Positioner—XS is a single use device used in surgical procedures. The intended use of the Pink Arc Positioner—XS is to provide protection, proper surgical positioning, and cushioning when positioning patients for surgical positioning and pressure related injury prevention.

INDICATIONS

The Pink Arc Positioner—XS is a single use, non-sterile device to be used during surgery to provide protection, proper surgical positioning, and cushioning in the prevention of patient 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

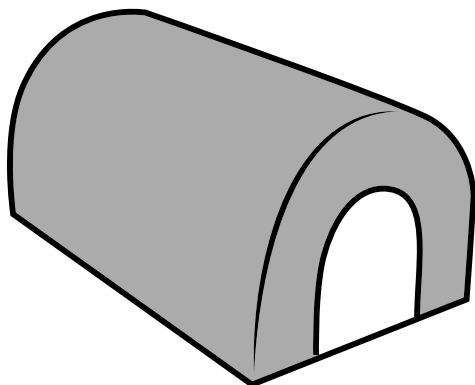
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

Provides provide protection, proper surgical positioning, and cushioning in the prevention of patient injury during surgical procedures.

PREPARATION AND USE

- Pink Arc Positioner—XS can be used for a variety of positioning needs rendered by surgical need.
- Place Pink Arc Positioner—XS in direct contact with skin to utilize the unique softness, immersion, and envelopment characteristics to help protect against positional injuries.
- Make sure to continuously check patient skin integrity and proper circulation.



DISPOSAL

- After use, the Pink Arc Positioner—XS 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 Arc Positioner—XS should be disposed of in accordance with hospital policy.
- Check skin for integrity and proper circulation.
- The PinkProtect Child Prone Head Positioner—XS should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

PRECAUTIONS

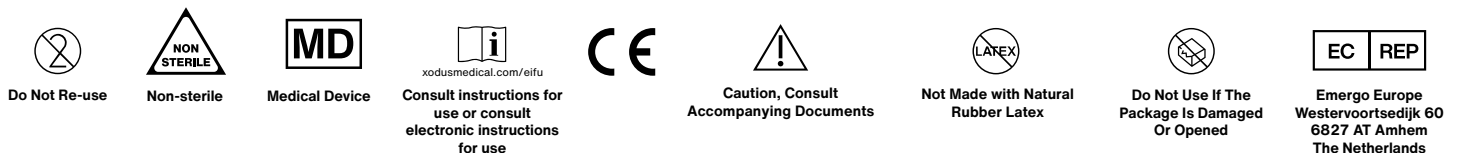
- The Pink Arc Positioner – XS is for use in perioperative settings only.
- The Pink Arc Positioner – XS should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Frequently monitor the patient’s neck, head, eyes, nose and mouth to ensure that a safe position is maintained and that the ET tube has not been kinked or displaced. Failure to do so can lead to serious adverse consequences including blindness and failure to ventilate.
- Be sure to follow your facility’s policies and guidelines for frequency of patient monitoring.
- 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

- Pink Arc Positioner – XS should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



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FDA REGISTERED
ISO 13485 CERTIFIED

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