

INSTRUCTIONS FOR USE:

PinkProtect™ Armboard Pads

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The PinkProtect™ Armboard Pads are a single use device for use in surgical procedures. The device provides a secure and skin-friendly solution for supporting the patient's arm during medical procedures

INDICATIONS

The PinkProtect™ Armboard Pads 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

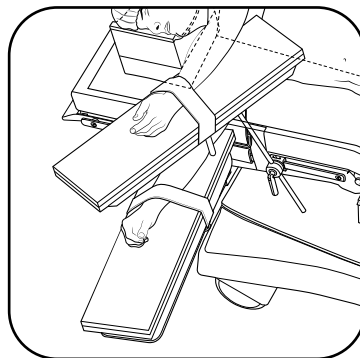
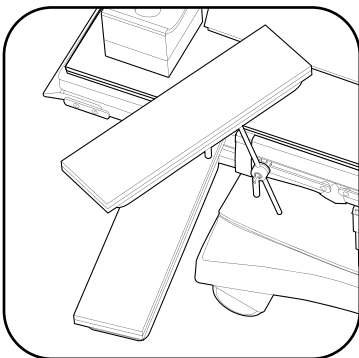
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

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. Apply PinkProtect™ Armboard Pads to the corresponding OR table surface, with the pink side facing up/ towards the patient.
2. Position the patient's arm in an anatomically appropriate fashion.
3. Secure the patient's arm as well as the PinkProtect™ Armboard Pad to the OR table section with supplied Skin-Friendly Arm Straps.



DISPOSAL

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

PRECAUTIONS

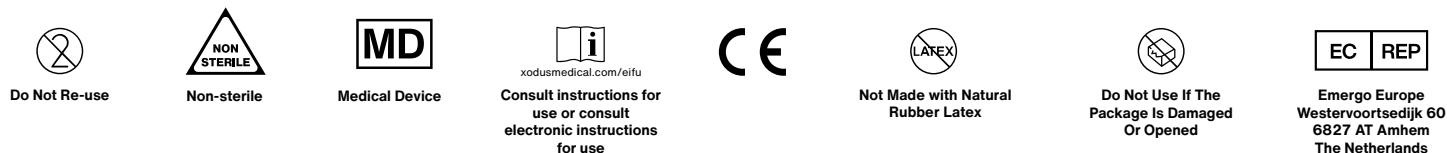
- The PinkProtect™ Armboard Pads should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Be sure to follow your facility's policies and guidelines for frequency of patient monitoring. Check 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

- The PinkProtect™ Armboard Pads should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



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