INSTRUCTIONS FOR USE: FOAM ARM CRADLES

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The arm cradles are a single use high density arm positioning device used in a various surgical procedures. The intended use is to provide extra skin-friendly support and cushioning when positioning patients for surgical positioning and pressure related injury prevention.

INDICATIONS

The arm cradles are a single use, non-sterile device to be used during surgery to provide protection, proper surgical positioning, and skin-friendly cushioning in aiding 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.

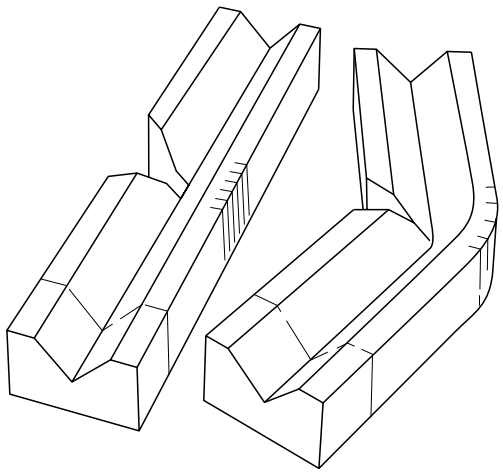
CLINICAL BENEFITS

The arm cradles were developed with a high density, supportive material that aids alignment and positioning of the upper extremities during surgical procedures. The skin-friendly material is a quality addition in supporting the prevention of patient positional injuries during indicated surgical procedures.

PREPARATION AND USE

1. Remove both arm cradles from packaging. To ensure full expansion of the arm cradles, wait at least five minutes prior to use.
2. Place the both arm cradles on the OR table relative to the anticipated position of the patient's arms.
3. Place each of the patient's arms into the center cut out of the cradle. Place the shorter side of the Arm Cradle on the upper arm and longer portion below the elbow.

   Additionally, there are convenient cut outs to allow easy positioning adjustments at the elbow area for positioning support if indicated. When there is a need to bend at the elbow for positioning, place the single "V" cut out of the Arm Cradle at the medial area of the patient. This will allow cradle coverage around the elbow area when flexed.
4. Upon completion of the surgical procedure, carefully remove the arm cradles prior to transferring patient from operating room.



DISPOSAL

- After use, the arm cradles 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 and improper storage of this device may create the risk of contamination and patient infection.
- Do not reuse or reprocess this device.
- After use, the arm cradles should be disposed of in accordance with hospital policy.
- The arm cradles should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

PRECAUTIONS

- The arm cradles should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturers of any associated instruments or equipment used.
- Monitoring of the patient's arms is suggested if any adjusts to the patients arms occur during surgery.
- Keep the arm cradles dry and protected from fluids while in use. Excess moisture can contribute to additional skin injury risk.
- 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 arm cradles should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.


Do Not Re-use

Non-sterile

Medical Device

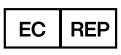
Consult instructions for use or consult electronic instructions for use


CE


Caution, Consult Accompanying Documents

Not Made with Natural Rubber Latex


Do Not Use If The Package Is Damaged Or Opened



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