

INSTRUCTIONS FOR USE: PRONE HEAD POSITIONER

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

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

INDICATIONS

The Prone Headrest 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

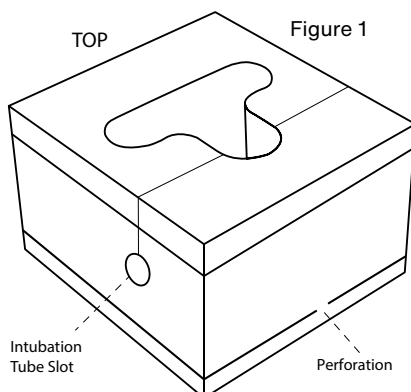
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

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

PREPARATION AND USE

1. Remove prone headrest from packaging. To ensure full expansion of the headrest, wait at least five minutes prior to positioning patients.
2. Place the head positioner on the OR table relative to the anticipated position of the patient's head. The "T" shaped hole should be positioned as shown in Figure 1.
3. Place the intubated patient's face onto the head positioner and feed the intubation tube through the slot on the side of the head positioner. The patient's eyes, eyebrows and nose should be centered within the "T" shaped hole on the head positioner to prevent pressure on the patient's eyes.
4. Upon completion of the surgical procedure, remove the intubation tube from the head positioner slot BEFORE removing the patient's face from the head positioner.



DISPOSAL

- After use, the Prone Head Positioner 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 Prone Headrest should be disposed of in accordance with hospital policy.
- The Prone Head Positioner should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

PRECAUTIONS

- The head positioner 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.
- 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

- Prone Head Positioner should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



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ISO 13485 CERTIFIED

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