

INSTRUCTIONS FOR USE: PRONESAFE HEAD POSITIONER

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical ProneSafe head positioner is a foam based device for use on the prone position for surgical procedures.

INDICATIONS

The ProneSafe head positioner is a single use, non-sterile device to be used in surgical procedures.

INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals to prevent patient facial skin injury during 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.

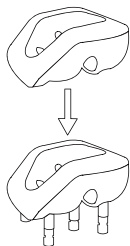
CLINICAL BENEFITS

ProneSafe head positioner provides patient facial skin protection during surgical procedures.

PREPARATION AND USE

1. Open ProneSafe head positioner packaging 5 minutes prior to use to assure proper expansion.
2. Fit ProneSafe head positioner inside the ProneView Helmet and align openings (Figure 1).
4. After turning prone onto ProneView Mirror Platform, recheck face and Prone Safe head positioner for fit. Ensure face and eyes are within ProneSafe head positioner opening and adequate clearance between nose and mirror. ET Tube or other devices should not be kinked or obstruct view of eyes (Fig. 3).

Figure 1



3. While supine, place ProneView Helmet with ProneSafe head positioner over patient's face, making sure the eyebrows are visible. Hold the ProneView Helmet securely on face during turn to prone position (Fig. 2).

Figure 2

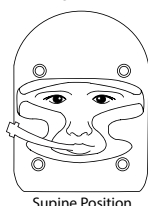
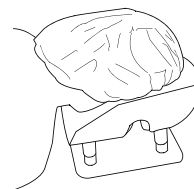
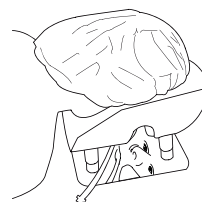


Figure 3



5. Engage ProneView Helmet legs with mirror posts. Adjust patient's body as necessary to maintain neutral neck position. Frequently recheck eyes, nose and neck to ensure they are in a safe position and that nothing is in contact with the eyes or eyelids (Fig. 4).

Figure 4



DISPOSAL

- After use, the ProneSafe head positioner should be disposed of in accordance with hospital policy.

WARNINGS

- 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.
- Failure to maintain neutral neck position can result in neck damage and/or chin abrasions.
- Do not use ProneSafe head positioner that has not been expanded to the top of the helmet.
- 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 ProneSafe head positioner should be disposed of in accordance with hospital policy.
- The ProneSafe head positioner 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 ProneSafe head positioner is to be used with the ProneView system and should never be used by itself.
- The ProneSafe head positioner is SINGLE USE ONLY, do not reuse.
- Clean helmet and mirror as needed per hospital protocol.
- The ProneSafe 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.
- 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

- ProneSafe head positioner should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



Do Not Re-use



Not Made with Natural
Rubber Latex



Do Not Use If The
Package Is Damaged
Or Opened



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ISO 13485 CERTIFIED

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