

INSTRUCTIONS FOR USE: ComfortFit™ ProneSafe Head Positioner

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical ComfortFit ProneSafe Head Positioner is a foam based device for use on the prone position for surgical procedures.

INDICATIONS

The ComfortFit 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.

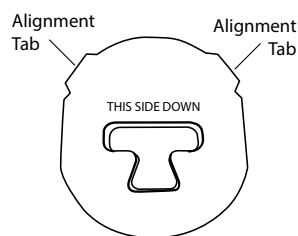
CLINICAL BENEFITS

ComfortFit ProneSafe Head Positioner provides patient facial skin protection during surgical procedures.

PREPARATION AND USE

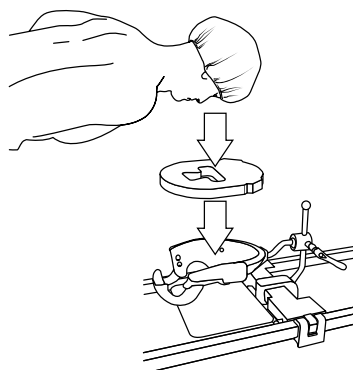
1. Verify the packaging and/or product is not damaged in any way.
2. Remove the ComfortFit ProneSafe Head Positioner from its outer packaging and, to assure proper expansion, let rest for 5 minutes prior to use.
3. Identify the bottom side of the product that contains the printed information “THIS SIDE DOWN.” (Figure 1).

Figure 1



4. Insert the product into the chassis with “THIS SIDE DOWN” facing downward and the white DermaProx layer facing up. Be sure to properly align the ComfortFit alignment tabs with the corresponding holes in the face mask chassis. (Figure 2).

Figure 2



5. Position the patient with their head facing downward into the DermaProx lined side of the ComfortFit ProneSafe Head Positioner.

DISPOSAL

- After use, the ComfortFit ProneSafe Head Positioner should be disposed of in accordance with hospital policy.

WARNINGS

- Be sure to follow proper hospital protocol regarding the positioning of the patient's neck, face, and eyes on the ComfortFit ProneSafe Head Positioner. Frequently monitor the patient's neck, head, eyes, nose and mouth to ensure that a safe position is maintained and they are in a safe position and nothing is in contact with the patient's eyes or eyelids. Failure to do so can lead to serious adverse consequences including blindness and failure to ventilate.
- 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 ComfortFit ProneSafe Head Positioner should be disposed of in accordance with hospital policy.
- The ComfortFit 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 ComfortFit ProneSafe Head Positioner is SINGLE USE ONLY, do not reuse.
- The ComfortFit 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

- ComfortFit ProneSafe 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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FDA REGISTERED
ISO 13485 CERTIFIED

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