

Instructions for Use: Beach Chair Head Restraint

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical Beach Chair Head Restraint is a foam based head restraint for use in the Beach Chair position for shoulder arthroscopy surgical procedures.

INDICATIONS

The Beach Chair Head Restraint 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 only to retain a patients head positioning during shoulder arthroscopy 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.

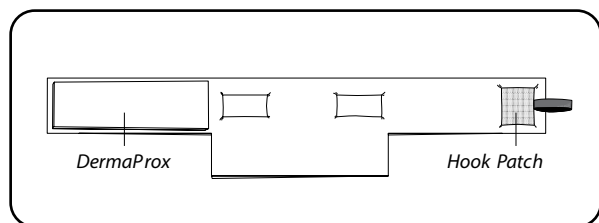
CLINICAL BENEFITS

Provides head restraint and stability during the Beach Chair shoulder arthroscopy surgical procedure.

Head Restraint

Inside View

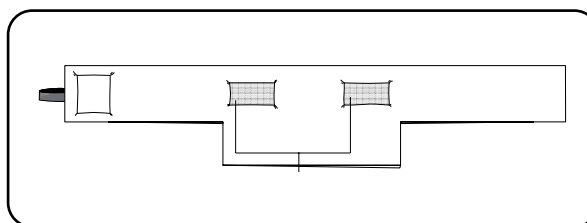
(Patient Makes Contact Here)



Head Restraint

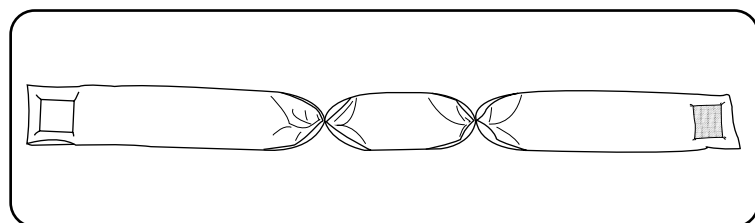
Outside View

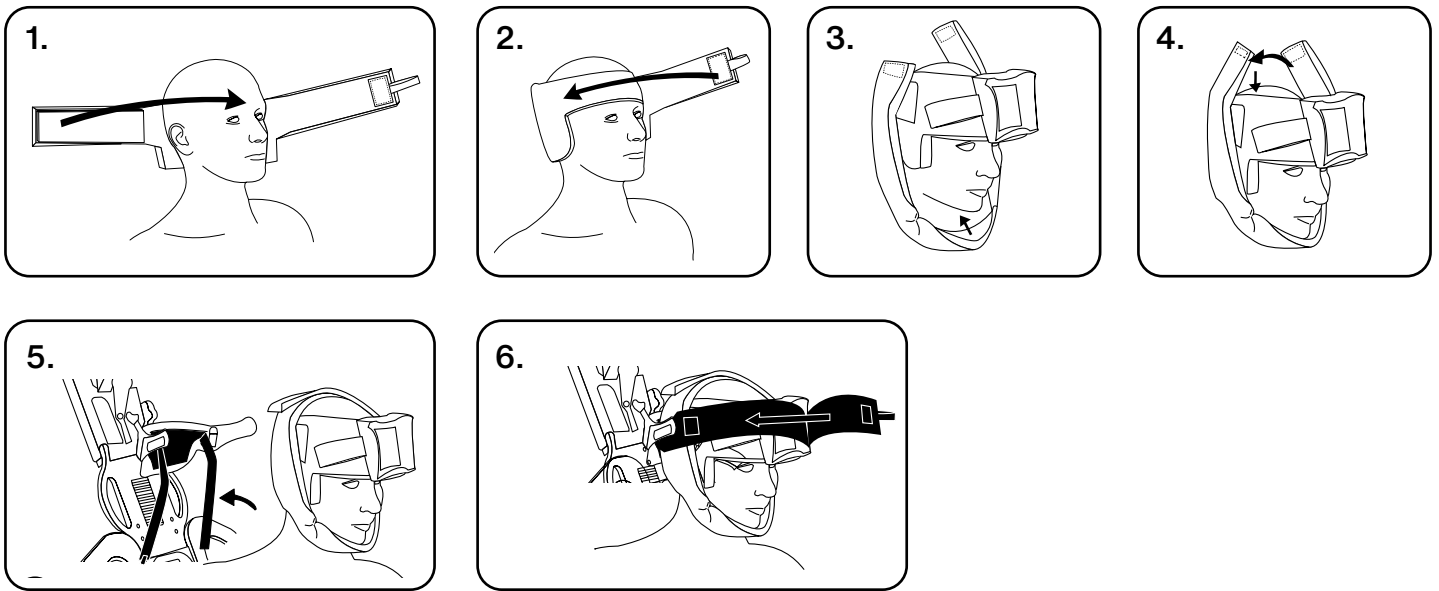
(Faces away from Patient)



Chin Strap

(Cups Patient's Chin)





PREPARATION AND USE

1. Center the inside of the head restraint on the back of the patient's head. Place the strap with the DermaProx pad over the patient's forehead so that the pad rests against the forehead.
2. Place the strap with the hook patch over the strap with the DermaProx pad.
3. Place the chin strap over the chin as shown — centering the portion of the strap between the two gathers.
4. Place side with hook & loop facing away from crown of patient's head then close remaining side of chin strap snugly securing the hook & loop.
5. Place patient's head into head assembly of Beach Chair, attaching the hook & loop squares of the head restraint to that of the head assembly.
6. Close Beach Chair strap over head restraint, securing the hook & loop of the Beach Chair strap to the head restraint.

DISPOSAL

- After use, the Beach Chair Head Restraint should be disposed of in accordance with hospital policy.

WARNINGS

- Do not over-tighten the Beach Chair Head restraint.
- 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 Beach Chair Head Restraint should be disposed of in accordance with hospital policy.
- The Beach Chair Head Restraint 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.

PRECAUTIONS

- The Beach Chair Head Restraint 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
 - » Nylon
- Shelf Life – Indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

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



Caution, Consult
Accompanying
Documents



Medical Device



xodusmedical.com/elfu

Consult instructions
for use or consult
electronic
instructions for use



Do Not Re-use



Not Made with
Natural Rubber
Latex



Do Not Use If
The Package Is
Damaged Or
Opened



Emergo Europe
Westervoortsedijk 60
6827 AT Amhem
The Netherlands



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FDA REGISTERED
ISO 13485 CERTIFIED



MADE IN THE
USA