INSTRUCTIONS FOR USE: ALLEN BOW FRAME KIT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical Allen Bow Frame Kit is a system of foam based components for use on the Allen Bow Table for spinal surgical procedures.

INDICATIONS

The Allen Bow Frame Kit is a single use, non-sterile device to be used in spinal surgical procedures.

INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals on the Allen Bow Table to prevent patient skin injury during surgical procedures.

CONTRADICTIONS

This device is not designed, sold, or intended for use except as indicated.

KNOWLEDGE AND USE

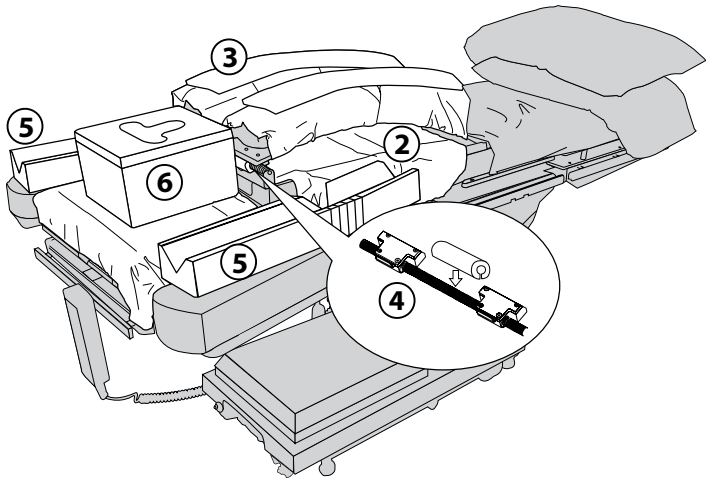
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

Allen Bow Table Frame Kit provides patient skin protection during spinal surgical procedure.

PREPARATION AND USE

1. Raise the torso pads.
2. Place drape cover under the torso pads. Make sure drape is flat and even on both sides of the table. Use the adhesive tabs to secure the drape to the frame.
3. Slide torso pad sleeve covers over each pad, covering the entire pad. Then return torso pads to their normal position. Have DermaProx™ layer is facing updward for direct skin contact.
4. Slide traverse bar cover over transverse bar. Observe the slit opening in the cover and place it over the bar.
5. Place each arm cradle on corresponding arm board (left and right) making sure cut outs are facing outward for support of the arm.
6. Center head rest on head support board and make sure head rest oval eye opening is oriented correct at the top of the table with DermaProx layer facing upward.



DISPOSAL

After use, the Allen Bow Frame Kit 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 Allen Bow Frame Kit should be disposed of in accordance with hospital policy.
- The Allen Bow Frame Kit 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 Allen Bow Frame Kit 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
  - Polypropylene
- Shelf Life – Indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- Allen Bow Frame Kit should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.





Medical Device



Non-Sterile



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

EU REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzlerland

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FDA REGISTERED
ISO 13485 CERTIFIED

MADE IN THE USA