INSTRUCTIONS FOR USE: JACKSON TABLE POSITIONING KIT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
The Xodus Medical Jackson Table Positioning Kit is a system of foam based components for use on the Jackson Table for spinal surgical procedures.

INDICATIONS
The Jackson Table Positioning Kit is a single use, non-sterile device to be used in surgical procedures.

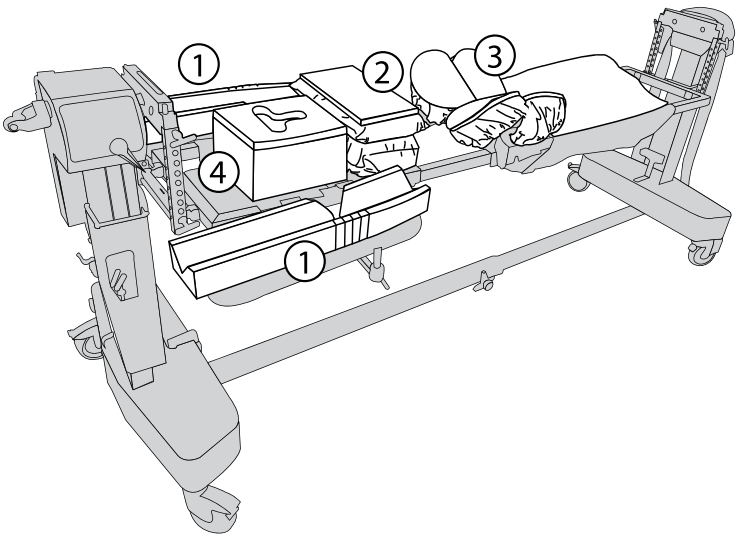
INTENDED PURPOSE AND USER
This device is intended for use by trained healthcare professionals on a Jackson Table to prevent patient skin injury during surgical procedures.

CONTRAINDICATIONS
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
Jackson Table Positioning Kit provides patient skin protection during the Jackson Table Positioning Kit surgical procedure.

PREPARATION AND USE
1. Note: Kit may not contain all products listed below.
2. Place each arm cradle on corresponding arm board pad (left & right), making sure cut outs are facing outward for support of the entire arm.
3. Place Torso Lift Cover securely over chest pad. Have DermaProx layer facing upwards for direct skin contact.
4. Place hip/thigh covers securely over the four hip and thigh pads. If using DermaProx covers, make sure DermaProx is facing upward for direct skin contact.
5. Center head rest on head support board and make sure head rest oval opening is oriented correctly at the top of the table with the DermaProx layer facing upward.



DISPOSAL

- After use, the Jackson Table Positioning 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 Jackson Table Positioning Kit should be disposed of in accordance with hospital policy.
- The Jackson Table Positioning 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 Jackson Table Positioning 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
- Shelf Life – Indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- The Jackson Table Positioning Kit should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

CE



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