INSTRUCTIONS FOR USE: ANDREWS TABLE KIT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

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

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

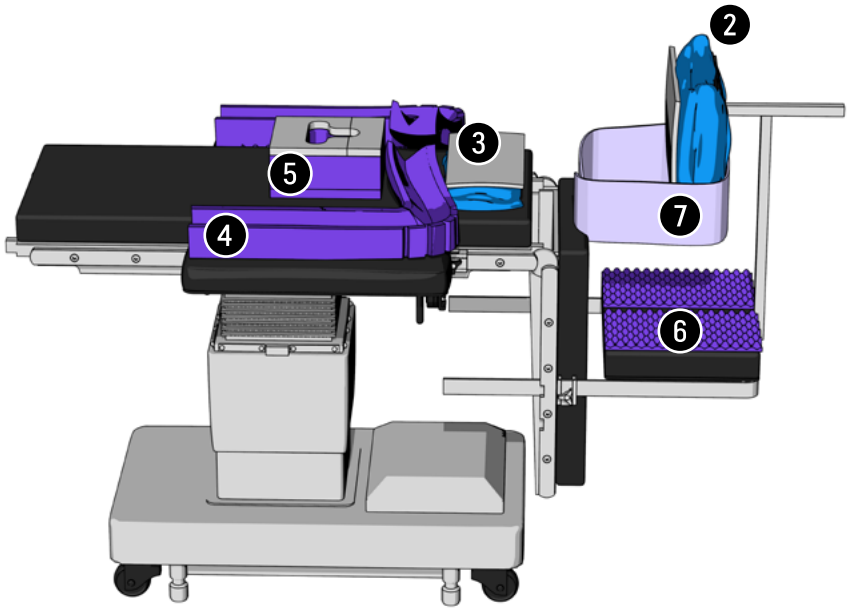
INTENDED PURPOSE AND USER
This device is intended for use by trained healthcare professionals on a Andrews Table to prevent patient skin injury during surgical procedures.

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
Andrews Table Kit provides patient skin protection during the Andrew Table spinal surgical procedure.

PREPARATION AND USE
1. Open the Andrews Table Kit.
2. Apply the seat cover.
3. Slide torso pad sleeve covers over each pad, covering the entire pad. Then return torso pads to their normal position. DermaProx™ layer is facing updward for direct skin contact.
4. Place each arm cradle on corresponding arm board (left and right) making sure cut outs are facing outward for support of the arm.
5. Center the Single-Use Head Positioner on the 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.
6. Place the Craddle Armboard pads on the knee platform to alleviate pressure.
7. Use the Single-Use Andrews Frame Strap to secure patient to the seat; one slit above and one below the seat post.
8. Apply the Single-Use Heel Protectors to the patient's feet. Secure in place using the strap.





DISPOSAL

After use, the Andrews Table 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 Andrews Table Kit should be disposed of in accordance with hospital policy.
- The Andrews Table 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 Andrews Table 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

- Andrews Table 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

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