INSTRUCTIONS FOR USE: ORTHOPEDIC FRACTURE TABLE KIT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
The Xodus Medical Orthopedic Fracture Table Kit is a system of foam based components designed to be used with the Hana® Table, and protect patients throughout surgical procedures.

INDICATIONS
The Orthopedic Fracture Table 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 an Orthopedic Fracture Table Kit 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
The Orthopedic Fracture Table Kit provides patient skin protection during the surgical procedure.

PREPARATION AND USE
The Orthopedic Fracture Table Kit consists of the following components:

A. Armboard Pads (1pr)
B. Armboard Straps (1pr)
C. Head Positioner (1)
D. Perineal Post Cover
E. Ball Joint Cover (2)

1. Place the Armboard Pads onto the Armboards of the OR table.
2. Place the patient's arms onto the Armboard Pads with the palms up and secure with the Armboard Straps.
3. Place head positioner on the table in a location sufficient for patient head placement.
4. Center and drape Ball Joint Covers over the ball joints. Secure hook & loop closures along the underside of the ball joints. (Figure 3)
5. Slide the Perineal Cover over the post. (Figure 4)

Kit Components

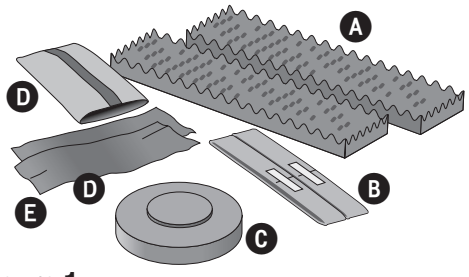

Figure 1

Components in Place

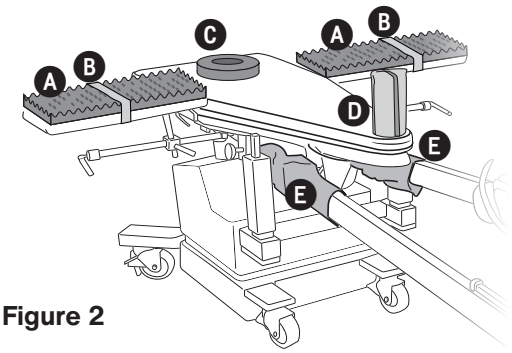

Figure 2

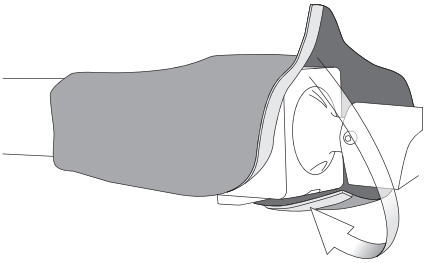

Figure 3

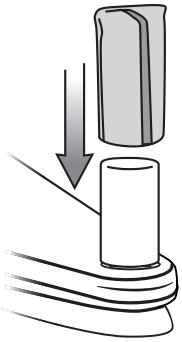

Figure 4

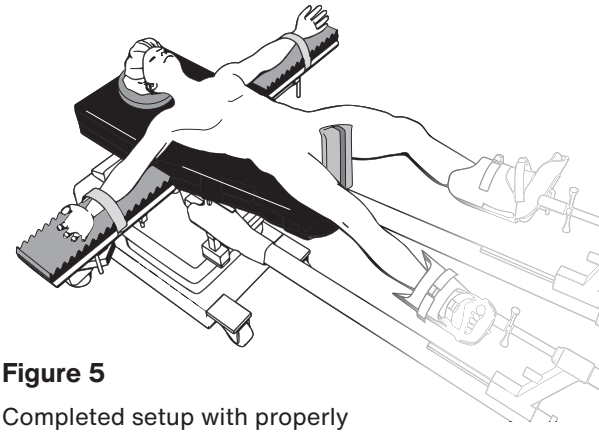

Figure 5

Completed setup with properly positioned patient.

DISPOSAL

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

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

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

Non-Sterile

Medical Device

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

MedEnvoy
Switzerland
Gotthardstrasse
28 6302 Zug

702 Prominence Drive
New Kensington, PA 15068,
United States

xodusmedical.com
info@xodusmedical.com
Tel: 1+724-337-5500

FDA REGISTERED
ISO 13485 CERTIFIED

MADE IN THE
USA

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