

Instructions for Use: Knee & Body Strap

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical Knee and Body Strap is a foam based patient body restraint with a buckle and hook material for use restraining a patient on an OR table during surgical procedures.

INDICATIONS

The Knee and Body Strap 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 patient on an OR table during a surgical procedure.

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.

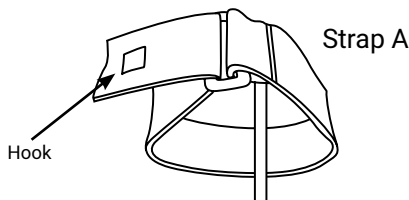
CLINICAL BENEFITS

Provides body restraint and stability on an OR table to prevent the patient from falling during t surgical procedures.

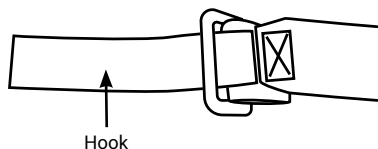
PREPARATION AND USE

1. Attaching Straps to bed/table rail:

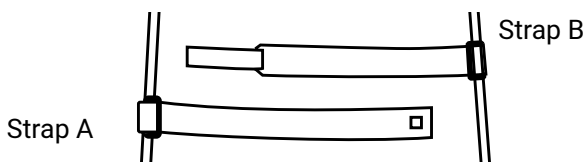
- A. Slide end of strap A around bed/ table frame and through end clasp. Make sure Hook square is face up, smooth side should always face patient.



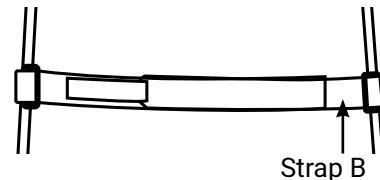
- B. Repeat above step with strap B hook side face down around the other side of the bed/table frame and through the end clasp.



- C. Belts will look like below when properly attached to the bed/ table frame.

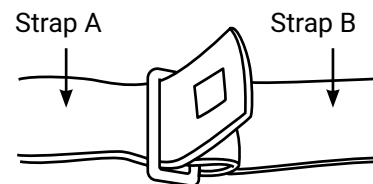


- D. Place the end of strap B with the hook across strap A.

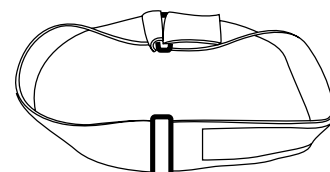


2. Attaching straps to each other:

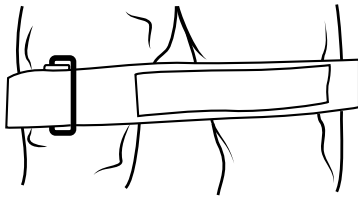
- A. Place end of strap A through the clasp at the end of strap B and fasten. Smooth side should face patient.



- B. Place end of strap A through the clasp at the end of strap B and fasten. Smooth side should face patient.



- C. This is how the straps should look when fastened across the patient's body.



DISPOSAL

- After use, the Knee and Body Strap should be disposed of in accordance with hospital policy.

WARNINGS

- Do not over-tighten the Knee and Body Strap.
- 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 Knee and Body Strap should be disposed of in accordance with hospital policy.
- The Knee and Body Strap 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 Knee and Body Strap 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
 - » Polycarbonate Buckle
 - » Nylon
- Shelf Life – Indefinite

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- Knee and Body Strap 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



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



702 Prominence Drive Ph. 1-724.337.5500
Pittsburgh, PA 15068 U.S.A.

FDA REGISTERED
ISO 13485 CERTIFIED

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