# **INSTRUCTIONS FOR USE:** BODY WEDGES

# BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

## **DESCRIPTION**

Body Wedges are single-use devices designed for use in surgical procedures. They provide support, stability, and controlled elevation of the patient's body to achieve proper surgical positioning and to help reduce the risk of pressure-related injuries.

These wedges are available in multiple configurations and sizes (including low-profile, lateral, and multi-angle designs) to meet a variety of surgical and anatomical needs.

## **INDICATIONS**

Body Wedges are single-use, non-sterile devices intended for use during surgery to assist in achieving proper patient positioning. They provide support and stability in lateral, supine, and prone positions, while reducing the risk of patient injury related to prolonged pressure or improper positioning.

### INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals only.

### **CONTRADICTIONS**

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

## **KNOWLEDGE AND USE**

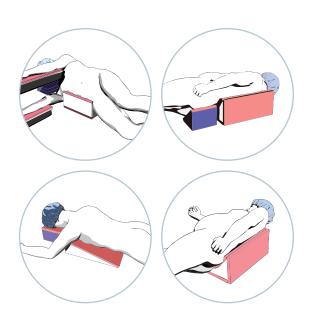
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

## **CLINICAL BENEFITS**

- Provides stable patient positioning in multiple surgical positions and angles.
- · Facilitates optimal access for surgical teams.
- Helps reduce the risk of positioning-related or pressure-related injuries.

#### PREPARATION AND USE

- Body Wedges can be used for a range of positioning requirements based on surgical need and patient anatomy.
- Position the wedge beneath or alongside the patient to achieve the desired orientation (lateral, supine, prone, or angled support)
- Ensure the wedge is placed securely and comfortably to optimize stability and prevent slippage or patient discomfort.
- Continuously monitor the patient's skin integrity and circulation throughout the procedure.
- Follow your facility's policies and protocols for frequency of patient monitoring.
- This product is to be used by licensed medical professionals only.
- Safeguard the device from exposure to prep solutions.



#### **DISPOSAL**

· After use, the Body Wedges should be disposed of in accordance with hospital policy.

#### **WARNINGS**

- Single-use only. Reuse or reprocessing may result in device failure, contamination, or patient injury.
- Reprocessing of this device may create the risk of contamination and patient infection.
- Do not reuse or reprocess this device.
- After use, the Body Wedges should be disposed of in accordance with hospital policy.
- Check skin for integrity and proper circulation.
- Store the wedges in a clean, dry location at room temperature. Avoid prolonged exposure to elevated temperatures.

#### **PRECAUTIONS**

- The Body Wedges are intended for use in perioperative settings only.
- · Use this device in accordance with the instructions for use and with attention to any contraindications, warnings, or precautions provided by the manufacturer of the associated positioning equipment or surgical instrumentation.
- Be sure to follow your facility's policies and guidelines for frequency of patient monitoring.
- · 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

 Store the Body Wedges in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.









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



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