



PRS-09 Intraoperative Tissue Retractor and Patient Positioner

Instructions for Use

The **PRS-09** is an intraoperative tissue retractor and patient positioning tool designed to retract surplus tissue from the operative field or to act as an aid in the positioning of patients for procedures or surgeries.

Note: Read complete set of instructions prior to use.

Applying the PRS-09 intraoperative retractor and patient positioner

The **PRS-09** device should be applied intraoperatively to clean, dry skin that is free of: lotions, powders or additional adhesives. It is recommended to remove excess hair prior to application. Assess the patient to ensure there are no skin integrity issues prior to product use. Application of the product for Lateral Spinal Procedures, as an example, consists of the following steps and with respect to torso positioning only. All extremity positioning and patient padding should be provided according to institutional policy and current accepted industry standards.

- 1.) Place the patient in the lateral position with operative area exposed.
- 2.) Remove product from package. (It is non-sterile). Items in package consist of nine pads and three straps four feet in length each.
- 3.) Peel backing from pad #1, discard appropriately and adhere pad to intended retraction tissue point. (Lateral chest wall near axilla).
- 4.) Repeat step three with pad #2 and place below intended operative site. Pad #2. (Lateral hip area near iliac wing).
- 5.) Place final patient pad #3 on upside leg approximately mid-femoral area.
- 6.) When applying the pads it is recommended to use a rolling motion (i.e. right-side to left- side) apply the exposed adhesive to the intended retraction tissue point. Use mild hand pressure to ensure the adhesive is adequately adhered to skin and that pad lies flat without wrinkles. **DO NOT COVER PROPOSED INCISIONAL AREA.**
- 7.) Remove backing and discard appropriately from pad pairs #4 and #5, #6 and #7, and finally #8 and #9. Apply these pads to the underside of the operative bed at the corresponding areas of the patient pads. Ensure smooth and wrinkle free application for best retention.
- 8.) Attach strap #1 to corresponding axilla pad, strap #2 to hip pad and strap #3 to upside leg.
- 9.) Gently pull on strap ends and attach to pads placed on bed (underside) with appropriate tension as to secure patient to the table. Once attached, straps may then be adjusted for clinician preference.

Warnings and Precautions:

- Product is intended for intraoperative use only.
- Product should be removed from patient prior to transfer from the Operating Suite.
- Product should not be placed upon compromised skin.
- Product should not attach to or cover the proposed incisional site.
- The product should be removed immediately in the presence of adverse signs and symptoms including pain and discomfort.
- Do not modify the **PRS-09** device, for example: by cutting or folding the device.
- When removing the device, do so slowly while supporting the skin to ensure optimal removal and to limit risk for skin integrity issues.
- Skin integrity is a function of many factors. Because every patient is unique, caregivers should carefully determine and monitor what is best for their patients.
- Product is single-use only. Reuse of product could result in cross-contamination.



Caution



Non-sterile in package



Single-use Only



Product not made with natural latex rubber



Consult Instructions for use



Do not use if packaging is damaged

RX ONLY

Caution: Federal Law (US) restricts device sale by or on the order of a physician

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PRS-09 Intraoperative Retractor and Patient Positioner
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