



PRS-02 Intraoperative Tissue Retractor and Patient Positioner

Instructions for Use

The **PRS-02** 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-02 intraoperative retractor and patient positioner

The **PRS-02** 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 Anterior Cervical Discectomy and Fusion, as an example, consists of the following steps:

- 1.) Place the patient in the supine position with operative area exposed.
- 2.) Remove product from package. (It is non-sterile). Items in package consist of two pads and one straps eight feet in length each.
- 3.) Peel backing from pad #1, discard appropriately and apply to underside of patient panniculus (lateral to belly button) on side where femoral access is desired. Ensure pad fully adheres flat against skin and that there are no bubbles or creases in pad. Position pad according to physician preference.
- 4.) Peel backing from second adhesive pad and place pad on the underside/edge at the head of procedure table on opposite side of patient pad (at underside corner of table).
- 5.) Place one end of strap (so side down) on hook and loop surface of pad on patient panniculus, and drape remainder of strap over patient shoulder toward pad on corner head of procedure table.
- 6.) Use one hand to grasp end of strap and pull it up toward pad on table while using the other hand to gently lift panniculus up into position.
- 7.) Once desired positioning of patient panniculus has been achieved, attach remaining end of strap to hook and loop surface of pad on head of procedure table to secure.
- 8.) To remove PRS from patient, remove strap from hook & loop pads and peel pad off of procedure table. To remove hook & loop pad from patient, start at one corner and gently peel edge of pad straight up with one hand, while holding patient skin down with the other hand.

Discard PRS according to hospital protocol.

* PRS pads may be left on patient up to 24 hours, and can be used to retract panniculus at conclusion of procedure to ensure surgical site remains dry and clean.

** If re-positioning the panniculus becomes necessary during the procedure, circulator/anesthesiologist will remove strap from hook & loop pad at head of procedure table. Adjust patient and panniculus positioning as necessary, then re-affix strap to hook & loop pad on underside of procedure table to re-secure.

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-02** 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-02 Intraoperative Retractor and Patient Positioner Manufactured by Stetrix, Inc.