



PRS-06 Intraoperative Tissue Retractor and Patient Positioner

Instructions for Use

The **PRS-06** 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.

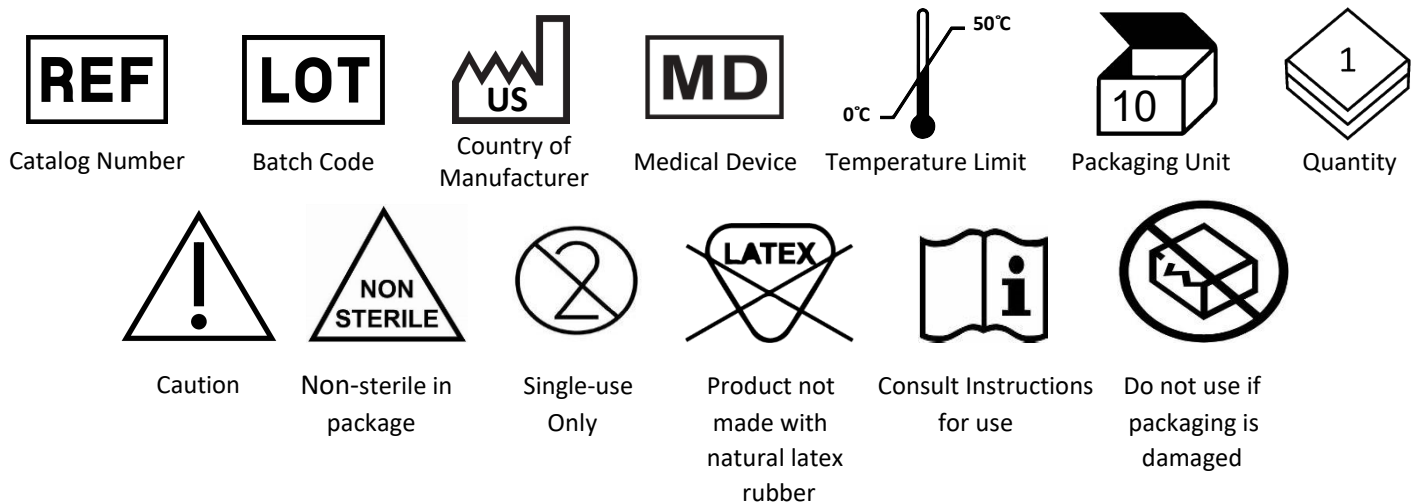
Applying the PRS-06 intraoperative retractor and patient positioner

The **PRS-06** 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 four pads and two straps eight feet in length each.
- 3.) Peel backing from pad #1, discard appropriately and adhere pad to intended retraction tissue point. (ACDF would be superior shoulder).
- 4.) Repeat step three to opposite side of intended retraction site. Pad #2. (ACDF would be opposite superior shoulder).
- 5.) 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. 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.**
- 6.) Remove backing and discard appropriately from pad #3. Apply this pad to the underside of the operative bed at foot of bed ensuring smooth and wrinkle free application.
- 7.) Repeat above step with pad #4 being applied to opposite side of operative bed in manner described above.
- 8.) Attach strap #1 to corresponding pad (superior shoulder) and repeat with strap #2 (opposite superior shoulder).
- 9.) Gently pull on straps and attach to pads placed on bed (inferior), exposing the proposed incisional area, as desired. 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-06** 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.



RX ONLY

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



Unique Device Identifier

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PRS-06 Intraoperative Retractor and Patient Positioner Manufactured by Stetrix, Inc.