



INSTRUCTIONS FOR USE

PRS-1050 - Panniculus Retractor Extender

DEVICE DESCRIPTION

The traxi EXTENDER is intended for use with the traxi (PRS-1030) on patients with BMIs generally greater than 50.

INTENDED USE

The retractor is intended for use on patients with redundant panniculus tissue. The application of the traxi retractor allows the surgeon to retract redundant panniculus tissue away from the operative field to prevent panniculus tissue interference during surgical procedure.

INDICATIONS FOR USE

Indications for the traxi retractor include a high BMI greater than 30 (extender is for BMI greater than 50) and redundant panniculus tissue that could interfere with the surgical site.

CONTRAINDICATIONS

The device is not to be used in the following conditions:

- On open wounds
- On skin tears, cuts, abrasions, rashes or open breaks in the dermis

CAUTIONS

- Assess skin condition for integrity before affixing retractor to the dermis
- Before applying to the surface of the skin, the skin must be clean, dry, free of all gels, liquids, grease, creams, etc.
- Remove slowly while supporting the skin
- Do not re-apply to the patient-single use only
- Discard and dispose of properly after use

WARNINGS

- Do not use device if expiration date on packaging has been exceeded.
- Do not use device if sterile packaging is damaged or compromised.
- Do not place over the patient's airways.
- Do not leave on patient longer than 24 hours
- Do not cut or modify this device
- Monitor respirations carefully to prevent Hypoventilation

POTENTIAL ADVERSE EVENTS

- Discomfort
- Skin irritation
- Inflammation
- Infection
- Skin dermis layer damage
- Anaphylaxis due to allergic reaction
- Hypoventilation






Applying the Retractor:






1. Apply the PRS-1030 to the panniculus (see PRS-1030 instructions for use).
2. Use tab "A" of the PRS-1050 to remove the release liner and apply panel "A" to the sternum between the breasts near the sternal notch midline.
3. Use "B" tabs to remove the "B" panel, exposing the adhesive.
4. Push the panniculus cephalad toward the sternum, creating optimal retraction of the panniculus.
5. While holding the panniculus in optimal retraction, apply panel B of the PRS-1050 to the PRS-1030, thus creating a new anchor point in support of the optimal panniculus retraction, and then drape as usual.

DISPOSAL

Used device should be disposed according to standard facility biohazard procedure.

Symbols Glossary

Symbol	Symbol Description
	Indicates Device Manufacturer Includes name and address of the manufacturer
	Manufacturer Build Date
 YYYY-MM-DD	Use By Date YYYY-MM-DD is generic placeholder for specified Use By Date
LOT	Batch Code
EC REP	Authorized EC Representative
REF	Catalog Number
	Do Not Reuse
STERILE R	Sterilized by irradiation. Sterility guaranteed unless package opened or damaged. Do not resterilize.
	Consult Instructions For Use

Symbol	Symbol Description
	Do not use if the product is damaged
	Medical Device
	Latex free
R _X ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Caution
	Do not resterilize

To Report Product Complaints:Email: Complaints@Clinicalinnovations.com

Phone: 1.888.268.6222; Ext 3

R_X ONLY

PRS-1050

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