traxi®

Panniculus Retractor

INSTRUCTIONS FOR USE

PRS-1030 - Panniculus Retractor

DEVICE DESCRIPTION

traxi Panniculus Retractor is a sterile, single use retraction device used for retraction of the panniculus during surgical procedures. traxi retracts and holds the panniculus for the duration of the operation, freeing the surgeon's hands and those of the staff to better care for the patient. It can be worn for up to 24 hours and continues to provide care in post-op after surgery.

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.

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.

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. If necessary, manually retract panniculus to expose the surgical site. Remove tab "A" and position the retractor 5cm above the incision line. Apply to patient.
2. Remove "B" panels. Hold in tension while smoothing onto patient's skin from midline out.
3. Fold back the device and relax the panniculus back to normal position. Remove "C" panel by simultaneously pulling "C" tabs.
4. Using the "HOLD HERE" and "PULL HERE" tabs, together, in tension, lift toward the ceiling and pull the retractor cephalad. When the desired retraction is obtained, apply to patient's xiphoid or sternum.

NOTE: Retraction should now be optimal. If the panniculus is not retracted prior to applying panel "C", retractionwill not be optimal. Therefore apply "C" after retraction, not before, as it will not be as effective.

DISPOSAL

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

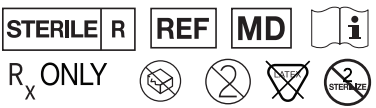
Symbols Glossary

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

ENGLISH

Symbol	Symbol Description
	Do not use if the product is damaged
	Medical Device
	Latex free
	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



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