Panni®XL Intra-Operative and Post Partum Pannus Retractor

Instructions For Use

Indications for use:

The Panni® XL device is an intra-operative and postpartum pannus management system.

Caution: Read the complete set of instructions prior to use or placement on a patient.

Warnings and Precautions:

- This device is supplied sterile in package. If the package has been opened or damaged in any way, the product is considered non-sterile and is not safe for use.
- The safety and efficacy of this product has been evaluated for its intended and expressed use only.
- The product should be removed immediately in the presence of adverse signs or symptoms.
- 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 prior to and throughout use.
- Do not modify the Panni®XL device, for example: by cutting, tearing or otherwise altering it from it's manufactured and intended construction.
- Contact Stetrix®, Inc. for any questions regarding the intended or expressed use of the product.

Possible Adverse Events/Complications:

Misuse of mishandling of the product may cause injury to the patient. Improper handling can render the product unsuitable for its intended use. Other potential complications may include, but are not limited to:

- Pain, discomfort or abnormal sensation resulting from the presence of the device against the skin.

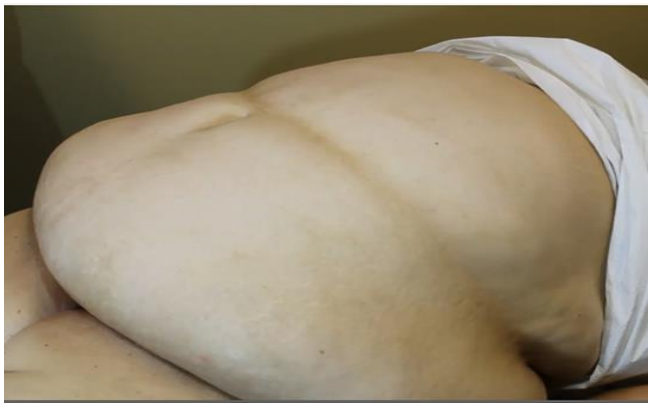
Description

The Panni®XL intra-operative and postpartum pannus management system is a device used in the management of tissue both intra-operatively (during cesarean sections, for example) and in the immediate postpartum period for up to 72hrs. The product is for single patient use, is disposable and latex free.

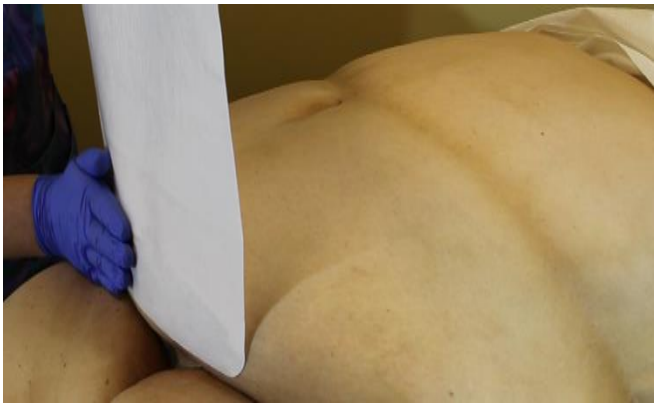
Directions For Use:

Intra-operative Use:

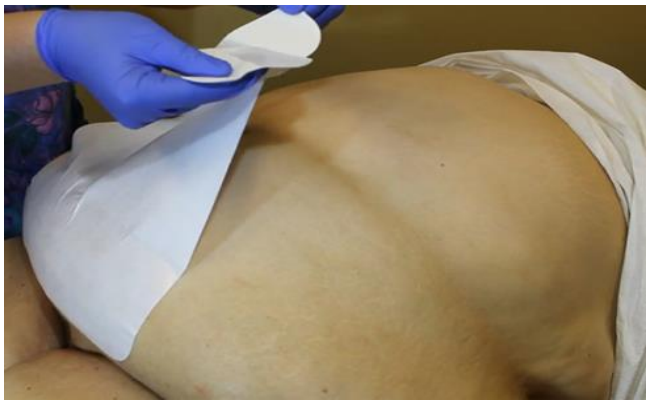
Although not required, the device is best placed while the patient is in the supine position. For best results, ensure the patient's skin is free from powders, lotions or other moisturizers. The device may be placed prior to or after prepping the patient. Prep should be allowed to fully dry prior to device placement. Consideration should be made for prep solution choice, such as betadine-based prep, when device is to be worn into immediate postpartum environment. Once the patient's abdominal and inguinal area's exposed, remove the device from its packaging. Remove the disposable liner from the lower (non-hook and loop) portion of the device exposing the adhesive. In a rolling-on motion and while using mild hand pressure, place adhesive side of the device to the patient's most distal exposed, pannus (DO NOT COVER THE PROPOSED INCISIONAL SITE WITH THE DEVICE). Next, while leaving the anchor pad (loop pad of hook and loop) connected to the upper (hook and loop) end of the device, remove the disposable liner on the back of the anchor pad. Gently pull superiorly, raising the pannus off the intended incision site. Once desired retraction is achieved, affix the upper pad to the skin using a gentle rolling on motion near the anatomical xyphoid or lower breast area of the middle chest. From this point, the Panni®XL pannus management system may be adjusted to suit the comfort of the patient by gently peeling back the main support from the upper pad (hook and loop) and re-affixing to the upper pad (hook and loop) for the desired tension.



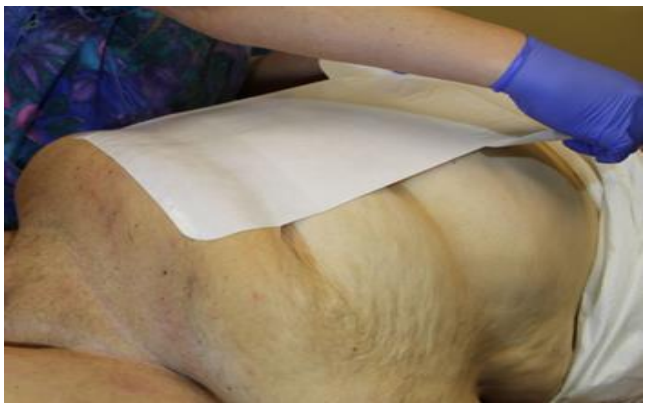
1. Expose the Abdomen



2. Remove the disposable liner from the lower (Non hook and loop) portion, exposing the adhesive and in a rolling motion, place the adhesive side to the most distal exposed pannus tissue. (DO NOT COVER THE INTENDED INCISION SITE)

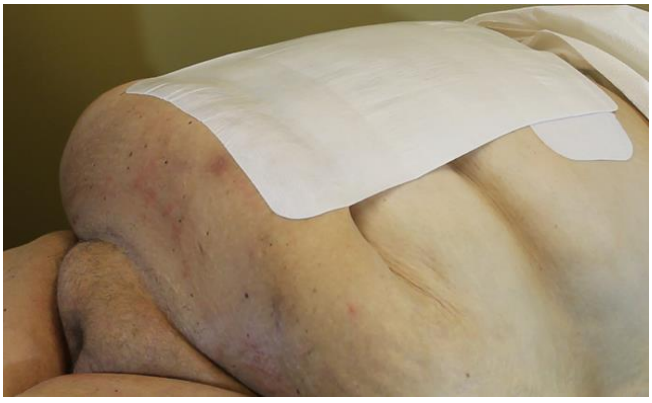


3. Remove the disposable liner from the upper (hook and loop) portion [Anchor Pad], exposing the adhesive.



4. Gently pull superiorly, raising the pannus exposing the proposed incision site. Once adequate visualization. Affix to patient's skin.

(Near Anatomical Xyphoid)



5. The Panni®XL pannus management system is now positioned properly and may be adjusted by loosening the device from the upper (hook and loop) Anchor pad and re-applied for patient comfort and/or clinician need.

Post-operative (Postpartum) Use: **Use of the Panni®XL pannus management system is intended for up to 72 hours of intermittent, non-continuous load.**

Allow the Panni®XL pannus management system to remain in place upon transitioning the patient into the immediate post-operative environment (i.e. PACU, floor, etc.).

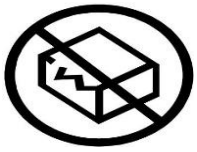
- The Panni®XL pannus management system may remain in the retracted (connected) position during ambulation, showering, resting, during medical examinations or treatments and/or as needed.
- Intermittently while the patient is at rest in either a hospital bed or bedside chair the Panni®XL pannus management system should be relaxed (disconnected) to allow for a non-continuous loading of the device.
- If the device is to be worn in the shower, limit the exposure of the upper pad to surfactants (shampoo, moisturizing soaps, etc.), which may loosen the adhesive on the upper pad from skin.
- Upon exiting the shower, simply towel dry off all exposed surfaces of the device prior to replacement and retraction (connecting device to upper pad).
- Upon removal of device, anchor the upper pad with one hand while gently peeling off hook and loop and disconnecting body of device. Once device is disconnected then utilize same technique to remove upper pad from skin, gentle anchoring and peeling of pad from skin (if desired, a releasing agent such as alcohol pad, saline soaked gauze or other commercially available agent may be used to assist in pad/device removal from skin). Once upper pad is removed, the body (lower portion of device) may be removed in the same manner as the upper pad was removed.
- Take care to not abruptly pull device off skin as this could cause increased risk of irritation and/or skin integrity disruption.
- Once removed, dispose of device in medically appropriate refuse container.

Sterile in package

Single-use only

Product not made with natural latex rubber

Consult Instructions for use



Do not use if packaging is damaged

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Panni™XL Intra-operative and Post Partum Retractor
Manufactured by Stetrix, Inc.