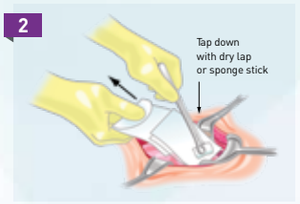
Seprafilm
ADHESION BARRIER

Preparation and Application Techniques

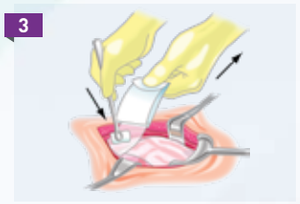
SEPRAFILM Full Sheet Application

The "Taco" Technique

Expose edge of SEPRAFILM (1-2 cm)



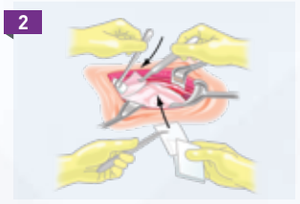
Allow exposed SEPRAFILM to adhere to desired tissue



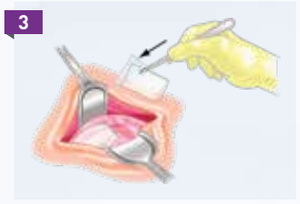
Withdraw holder

The "Quilting" Technique

Cut SEPRAFILM and holder with scissors

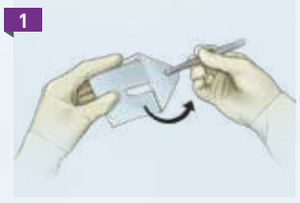


Remove from holder and apply

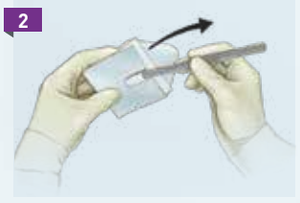


May be curved to facilitate entry

SEPRAFILM 4-Section Application



Open protective envelope



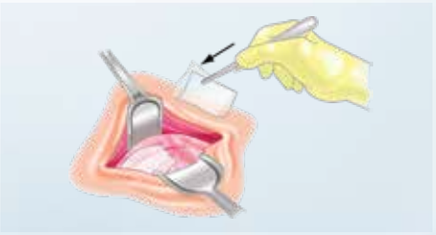
Slide product out

Apply and tap

Handling Tips

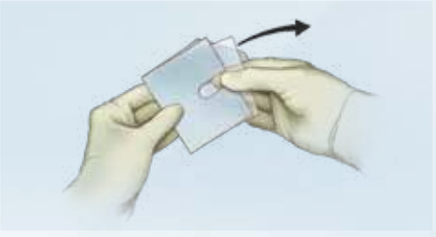
SEPRAFILM can be:

Cut to any shape or size



Curved or rolled

Molded to desired contour



Packaging notch facilitates exchange in the OR **(SEPRAFILM 4-Section ONLY)**

General Considerations & Directions for Use

- Keep SEPRAFILM, gloves, instruments and site of application dry.
- Keep a dry lap on the field to dry off wet gloves and instruments before handling SEPRAFILM.
- Use standard irrigation solution if contact occurs with unintended tissue surface.
- You may choose to place SEPRAFILM with dry instruments, the product covering, dry gloved hand, or any combination of the above.

Please see Indication and Detailed Important Risk Information on the reverse side.

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Indications

Seprafilm Adhesion Barrier is indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the under-lying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder.

Important Safety Information

Seprafilm Adhesion Barrier is contraindicated in patients with a history of hypersensitivity to Seprafilm and/or to any component of Seprafilm. Seprafilm Adhesion Barrier is contraindicated for use wrapped directly around a fresh anastomotic suture or staple line; as such use increases the risk of anastomotic leak and related events (fistula, abscess, leak, sepsis, peritonitis). Seprafilm Adhesion Barrier must be used according to the instructions for use. Seprafilm Adhesion Barrier is for single use only, supplied sterile and must not be re-sterilized. Every opened and unused Seprafilm pouch must be discarded. Do not use product if pouch is damaged or opened. The number of sheets used should be just adequate to cover the under surface of the abdominal wall or uterine incision in a single layer.

In patients who have ovarian, primary peritoneal or fallopian tube malignancies, Seprafilm use has been reported to have an increased risk of intra-abdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required.

The safety and effectiveness of Seprafilm Adhesion Barrier has not been evaluated in clinical studies for the following: Patients with frank infections in the abdominopelvic cavity; patients with abdominopelvic malignancy; device placement in locations other than directly beneath an abdominal wall incision following laparotomy, or directly on the uterus following open myomectomy (not laparoscopic); patients with ongoing local and/or systemic inflammatory cell responses; device use in the presence of other implants, e.g. surgical mesh; patients requiring re-operation within four weeks of Seprafilm placement – during anticipated time of peak adhesion formation. Foreign body reactions have occurred with Seprafilm Adhesion Barrier.

The safety and effectiveness of Seprafilm Adhesion Barrier in combination with other adhesion prevention products and/or in other surgical procedures not within the abdominopelvic cavity have not been established in clinical studies.

The safe and effective use of Seprafilm Adhesion Barrier in pregnancy and Cesarean section has not been evaluated. No clinical studies have been conducted in pregnant women or women who have become pregnant within the first month after exposure to Seprafilm Adhesion Barrier. Therefore, this product is not recommended for use during pregnancy and avoidance of conception should be considered during the first complete menstrual cycle after use of Seprafilm Adhesion Barrier

Long term clinical outcomes such as chronic pain and infertility have not been determined in clinical studies.

Ordering Information

Item Number	430102	638001	664101	664201	508602
Configuration	Seprafilm Adhesion Barrier	Seprafilm 4-Section	Seprafilm Single Site	Seprafilm Small Incision	Seprafilm Procedure Pack
Pouch Contents	 1 full sheet	 4 quarter sheets	 1 half sheet	 2 half sheets	 6 half sheets
Individual Sheet Size	1 (5" x 6") sheet /pouch	4 (3" x 2.5") sheets /pouch	1 (3"x 5") sheet /pouch	2 (3" x 5") sheets /pouch	6 (3" x 5") sheets /pouch
Packaging	10 pouches/box	10 pouches/box	5 pouches/box	10 pouches/box	5 pouches/box

For questions or ordering information, please contact your Baxter representative.

Advancing the art of healing

USA
Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015

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