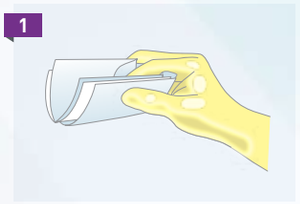
Seprafilm
ADHESION BARRIER

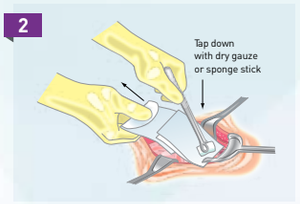
Preparation and Application Techniques

SEPRAFILM Full Sheet Application

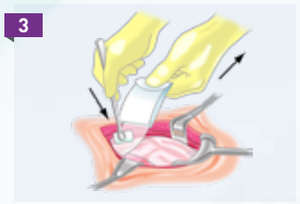
The "Taco" Technique



Expose edge of SEPRAFILM (1-2 cm)



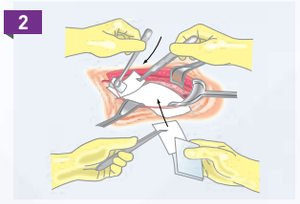
Allow exposed SEPRAFILM to adhere to desired tissue



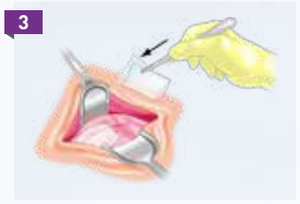
Withdraw holder

The "Quilting" Technique

Cut SEPRAFILM and holder with scissors



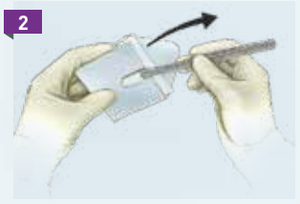
Remove from holder and apply



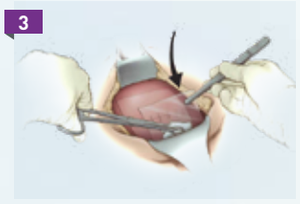
May be curved to facilitate entry

SEPRAFILM 4-Section Sheet Application

Open protective envelope



Slide product out

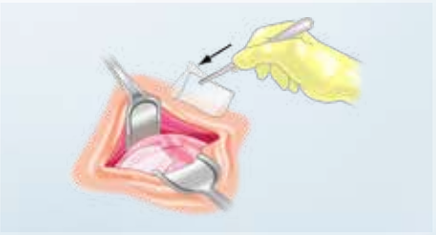


Apply, overlap and tap

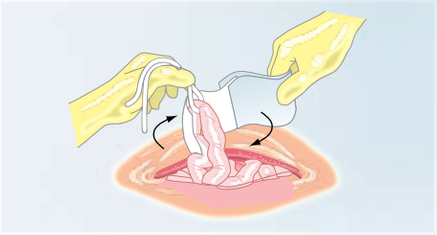
Handling Tips

To facilitate application, SEPRAFILM can be:

Cut to any shape or size



Curved or rolled



Molded to desired contour

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

General Considerations & Directions for Use

- Keep SEPRAFILM, gloves, instruments and site of application dry.
- Keep a dry gauze 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 can place SEPRAFILM with dry instruments, the product covering, dry gloved hand, or any combination of the above.

Please see Indications for Use and Detailed Important Risk Information on the reverse side.

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Indications

Seprafilm is intended as an adjunct in abdominal and pelvic surgery for reducing the incidence, extent and severity of postoperative adhesions at the site of placement, and to reduce adhesive small bowel obstruction when placed in the abdomen.

Important Safety information

Seprafilm is not recommended to be wrapped directly around a fresh anastomotic suture or staple line of the intestine. Clinical trial data on Seprafilm indicate that such use may result in an increased risk of anastomotic leak related events (fistula, abscess, leak, sepsis and peritonitis). The incidence of these events was not affected when Seprafilm was placed elsewhere in the abdomen.

In patients undergoing surgery for ovarian, primary peritoneal or fallopian tube malignancies, Seprafilm use has been reported as having an increased risk of intraabdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required.

No controlled clinical studies have been conducted in patients with active infections. Foreign body reactions may occur, as with any implanted material and most surgical adjuncts, but have been rarely reported during clinical use.

No pre-clinical reproductive studies have been conducted. No clinical studies have been conducted in women who become pregnant in the first month after application of Seprafilm. Therefore, avoiding pregnancy during the first complete menstrual cycle after the use of Seprafilm should be considered.

Ordering Information

*please check with your Baxter account manager on code availability, not all codes currently available in UK & Ireland

Product code	430103	664103	638001	508602
Configuration	Seprafilm Adhesion Barrier	Seprafilm Small Incision	Seprafilm 4-Section	Seprafilm Procedure Pack
Pouch Contents	 1 full sheet	 1 half sheet	 4 quarter sheets	 6 half sheets
Individual Sheet Size	1 (15cm x 13cm) sheet /pouch	1 (13cm x 7.5cm) sheet /pouch	4 (7.5cm x 6.5cm) sheets /pouch	6 (13cm x 7.5cm) sheets /pouch
Packaging	10 pouches/box	5 pouches/box	10 pouches/box	5 pouches/box

Any medical device product quality complaints (including medical device adverse incidents) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team:
In the UK on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com.
In Ireland on +353 (0)1 2065500 or by email to shs_complaints_dublin@baxter.com

Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

Medical device adverse incidents should also be reported:
In the UK to the MHRA. Reporting forms and information can be found at: www.mhra.gov.uk/safetyinformation/reportingsafetyproblems/index.htm .
In Ireland to the HPRA. Reporting forms and information can be found at: http://www.hpra.ie/homepage/about-us/report-an-issue

Advancing the art of healing

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UKI-AS30-230014 Ausgust 2023