Seprafilm
ADHESION BARRIER

PROTECT YOUR PATIENT'S FUTURE

Protect Against Adhesions and Their Complications with **SEPRAFILM Adhesion Barrier**

Please see Indication and Important Risk Information on last page.

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Seprafilm
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UP TO
93%
OF PATIENTS
DEVELOP ADHESIONS
FOLLOWING INITIAL LAPAROTOMY[1,2]

Adhesions are not preventable by surgical technique alone

Adhesions develop routinely following both open and laparoscopic abdominal surgery, and have been reported at second-look surgery to occur in up to **93% of patients** (n=210) following initial laparotomy.[2]

The clinical and economic burden of adhesions is extensive

Adhesions are a **major cause** of small bowel obstruction, infertility, chronic pelvic pain, and complicate future surgery.[3]

No adhesion barrier has been more extensively evaluated

Seprafilm significantly reduces the incidence, extent, and severity of adhesions following abdominopelvic surgery[1,4]

Clinical features and benefits

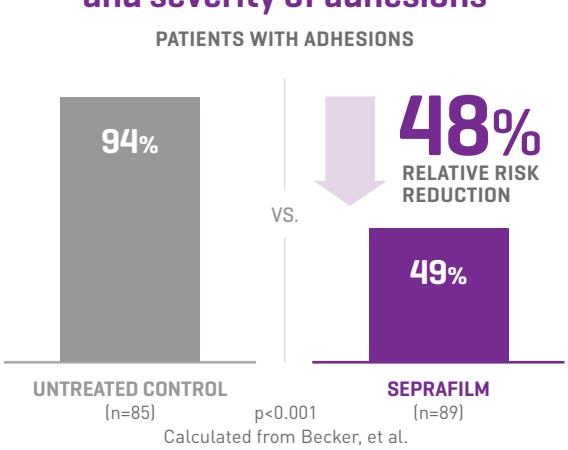
1. Demonstrated efficacy in 5 prospective, randomised, controlled, clinical studies[1,4-7]
2. Separates tissues for up to 7 days – the critical tissue healing period[1,8]
3. Composed of Sodium Hyaluronate/Carboxymethylcellulose (HA/CMC) – bioresorbable, inert, synthetic materials[8]

PROVEN CLINICAL HISTORY

SEPRAFILM efficacy in abdominal surgery[1]

In a randomised, prospective, double-blinded, multicenter clinical study involving 183 patients [175 evaluable] with ulcerative colitis and familial polyposis undergoing 2-stage intestinal resection, **more than half of the patients treated with SEPRAFILM were adhesion-free at 12 weeks** compared to 6% of untreated patients.

Reduces incidence, extent and severity of adhesions

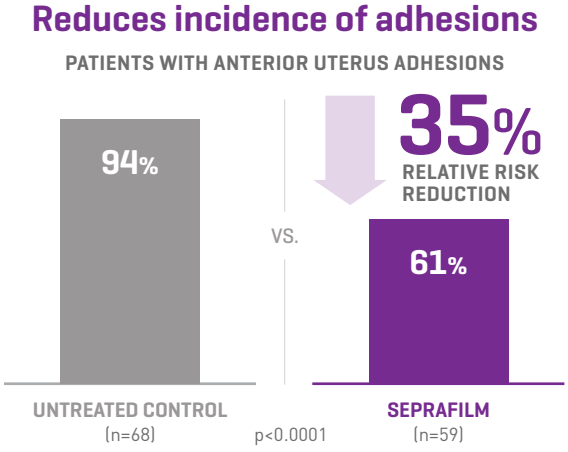


Calculated from Becker, et al.

SEPRAFILM efficacy in pelvic surgery[4]

In a prospective, randomised, blinded, multicenter clinical study involving 127 patients undergoing gynecologic surgery, SEPRAFILM **reduced the mean number of sites adherent to the uterine surface** following myomectomy compared with untreated patients. SEPRAFILM also **significantly reduced the extent and severity of adhesions** in patients undergoing uterine myomectomy compared with untreated patients.

Reduces incidence of adhesions



The safety and efficacy of SEPRAFILM Adhesion Barrier has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity. In patients undergoing surgery for ovarian, primary peritoneal or fallopian tube malignancies, SEPRAFILM use has been reported as having an increased risk of intra-abdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required.

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Ordering Information

Product Code / Catalog #	430103
Rebate Code	BX342
Configuration	Seprafilm Adhesion Barrier
Pouch Contents	 1 full sheet
Individual Sheet Size	1 (13cm x 15cm) sheet/pouch
Packaging	10 pouches/box

Description and intended use

Seprafilm Adhesion Barrier is a sterile, bioresorbable, translucent membrane composed of two chemically modified anionic polysaccharides, sodium hyaluronate and carboxymethylcellulose. Seprafilm Adhesion Barrier is intended as an adjunct in abdominal and pelvic surgery for reducing the incidence, extent and severity of postoperative adhesions at the site to placement and to reduce adhesive small bowel obstruction when placed in the abdomen.

Warnings and Precautions

- Read instruction for use prior to using Seprafilm.
- For single use only. Do not resterilise.
- Seprafilm should not 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.
- Seprafilm is not recommended for use in women undergoing surgery for ovarian, fallopian tube or peritoneal malignancies. Some clinical literature has associated this use of Seprafilm with an increased incidence of fluid collection and/or abscess requiring intervention.
- No controlled clinical studies have been conducted in patients with active infections or abdominopelvic malignancy.
- Foreign body reaction may occur as with 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.
- Adverse events relating to Seprafilm can be reported to Baxter on 1800 BAXTER or 0800 BAXTER.

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

Advancing the art of healing

1. Becker JM, Dayton MT, Fazio VW, et al. Prevention of postoperative abdominal adhesions by a sodium hyaluronate-based bioresorbable membrane: a prospective, randomized, double-blind multicenter study. J Am Coll Surg. 1996;183(4):297-306.
2. Menzies D, Ellis H. Intestinal obstruction from adhesions—how big is the problem? Ann R Coll Surg Engl. 1990;72(1):60-63.
3. Bruggmann 0, Tchartchian G, Wallwiener M, Munstedt K, Tinneberg HR, Hackethal A. Intra-abdominal adhesions. Dtsch Arztebl Int. 2010;107(44):769-775.
4. Diamond MP. Seprafilm Adhesion Study Group. Reduction of adhesions after uterine myomectomy by Seprafilm membrane (HAL-F): a blinded, prospective, randomized, multicenter clinical study. Fertil Steril. 1996;66(6):904-910.
5. Beck DE, Cohen Z, Fleshman JW, Kaufman HS, van Goor H, Wolff BG. Adhesion Study Group Steering Committee; A prospective, randomized, multicenter, controlled study of the safety of Seprafilm adhesion barrier in abdominopelvic surgery of the intestine. Dis Colon Rectum. 2003 Oct;46(10):1310-9.
6. Fazio VW, Cohen Z, Fleshman JW, et al. Reduction in adhesive small-bowel obstruction by Seprafilm adhesion barrier after intestinal resection. Dis Colon Rectum. 2006 Jan;49(1):1-11.
7. Tang C-L, Seow-Choen F, Fook-Chong S, Eu K-W. Bioresorbable adhesion barrier facilitates early closure of the defunctioning ileostomy after rectal excision: a prospective, randomized trial. Dis Colon Rectum 2003;46:1200–1207.
8. Seprafilm Instructions For Use, EU 10/2018

ANZ/SEP/20-0001 06/2020

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