HELP PROTECT YOUR PATIENT'S FUTURE WITH SEPRAFILM®

SEPRAFILM IS INTENDED AS AN ADJUNCT IN ABDOMINAL, PELVIC AND THORACIC SURGERY TO REDUCE THE INCIDENCE, EXTENT AND SEVERITY OF POSTOPERATIVE ADHESIONS, AND TO REDUCE ADHESIVE SMALL BOWEL OBSTRUCTION WHEN PLACED IN THE ABDOMEN[1]

- Well-established efficacy in clinical practice
- Established safety profile
- Site specific and stays on intended sites for up to 7 days during the critical healing period
- Cost-effective—may lower healthcare costs by reducing incidence of hospital readmissions, shortening operating theatre time, and lowering the risk of adhesive small bowel obstruction[2-4]

SEPRAFILM ORDERING INFORMATION

CONFIGURATIONS	CATALOG NUMBERS	FILM DIMENSIONS	POUCH CONTENTS	PACKAGING
Seprafilm	4301-03	12.7 cm x 15.2 cm	1 film	10 pouches per carton
Seprafilm Procedure Pack	5086-03	12.7 cm x 7.5 cm	6 films	5 pouches per carton
Seprafilm Single Site	6641-03	12.7 cm x 7.5 cm	1 film	5 pouches per carton
Seprafilm Mini Site	6379-03	6.5 cm x 7.5 cm	1 film	10 pouches per carton
Seprafilm 4-Section	6380-03	6.5 cm x 7.5 cm	4 films	10 pouches per carton

MANUFACTURED BY
Genzyme Corporation, a Sanofi company
76 New York Avenue
Framingham, MA 01701 USA

References:
1. Seprafilm [CE Instructions for Use]. Cambridge, MA: Genzyme Corporation; 2007.
2. Bristow RE, Santillan A, Diaz-Montes TP, et al. Prevention of adhesion formation after radical hysterectomy using a sodium hyaluronate-carboxymethylcellulose (HA-CMC) barrier: a cost-effectiveness analysis. *Gynecol Oncol* 2007;104(3):739-46.
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SANOFI

seprafilm® ADHESION BARRIER

WHAT IF YOU COULD PREVENT ADHESIONS?

seprafilm® ADHESION BARRIER

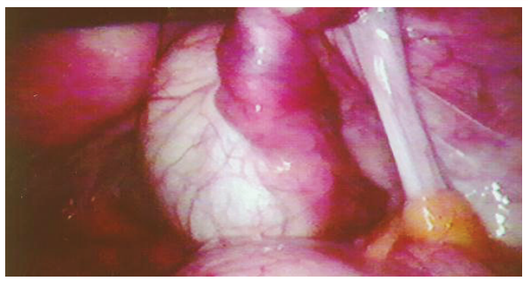
ADHESIONS: A FREQUENT COMPLICATION WITH UNDER-RECOGNIZED DANGERS

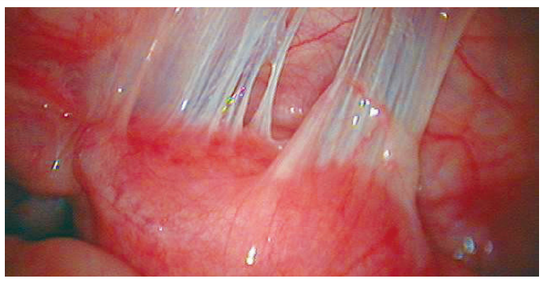
SEPRAFILM® ADHESION BARRIER

ADHESIONS ARE NOT PREVENTABLE BY SURGICAL TECHNIQUE ALONE[1,2]

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 following initial laparotomy.[2]

ADHESION-RELATED CONSEQUENCES	
Secondary infertility	Adhesions are the leading cause of secondary female infertility (20% to 40% of all cases)[3]
Chronic pelvic pain	Adhesions are implicated as the primary cause in up to 48% of chronic pelvic pain cases[4-5]
Small bowel obstruction (SBO)	Up to 80% of SBO cases are caused by adhesions[6] Adhesive SBO has a high risk of recurrence with mortality rates ranging from 3% to 10%[6-10] Abdominal hysterectomy is the leading contributor to SBO; in one retrospective study of female patients diagnosed with adhesion-related SBO, abdominal hysterectomy accounted for 38% of the surgical procedures.[11]
Inadvertant enterotomy	Adhesions increase the risk of iatrogenic bowel injury by 10% to 25%[12-13]
Reoperative complexity	Adhesions prolong operative time and may limit access to surgical sites[14-16] Adhesions may complicate repeat cesarean deliveries and lengthen operating time, which may negatively impact fetal well-being[17] Adhesions are the primary reason for conversion from laparoscopy to laparotomy[18]





Pelvic adhesions are the cause of postoperative complications.

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1. DeWilde RL, Trew G. Postoperative abdominal adhesions and their prevention in gynaecological surgery. Expert consensus position. Part 2—steps to reduce adhesions. *Gynecol Surg.* 1. 2007;4:243-253.
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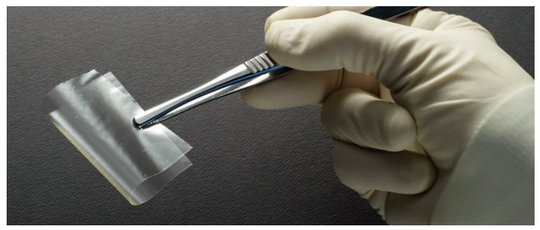
REDUCE ADHESIONS AND THEIR COMPLICATIONS WITH SEPRAFILM

No adhesion barrier has been more extensively evaluated than Seprafilm (HA/CMC).

CLINICAL FEATURES AND BENEFITS
Demonstrated in five prospective, randomized, controlled, clinical studies to significantly reduce adhesions and related complications[19-23]
Separates tissues for up to 7 days – the critical tissue healing period
Composed of Sodium Hyaluronate/Carboxymethylcellulose (HA/CMC)—two bioresorbable, inert, non-animal-derived polysaccharides

Important Safety Information—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. Foreign body reaction may occur as with most surgical adjuncts but have been rarely reported during clinical use. Please see full Seprafilm Instructions for Use (IFU).



Seprafilm is intended to reduce the incidence, severity an extent of post-operative adhesions.

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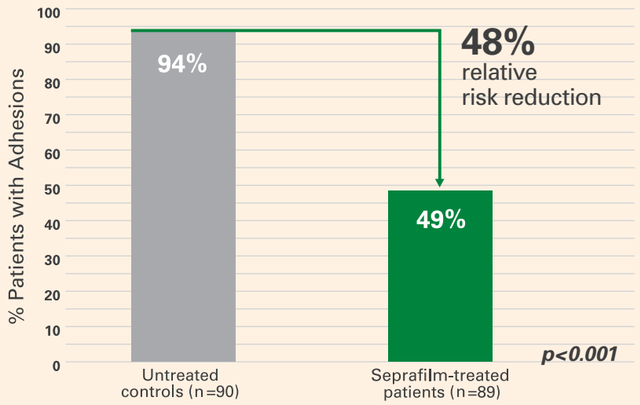
As demonstrated in prospective, randomized clinical trials,

SEPRAFILM® REDUCES ADHESIONS AND SIMPLIFIES REOPERATION

PREVENTION OF POSTOPERATIVE ABDOMINAL ADHESIONS BY A HA-BASED BIORESORBABLE MEMBRANE[1]

STUDY DESIGN: Randomized, prospective, double-blind, multicenter study evaluating the safety and effectiveness of Seprafilm in preventing post-operative adhesions in patients undergoing 2-stage intestinal resection (N=183).

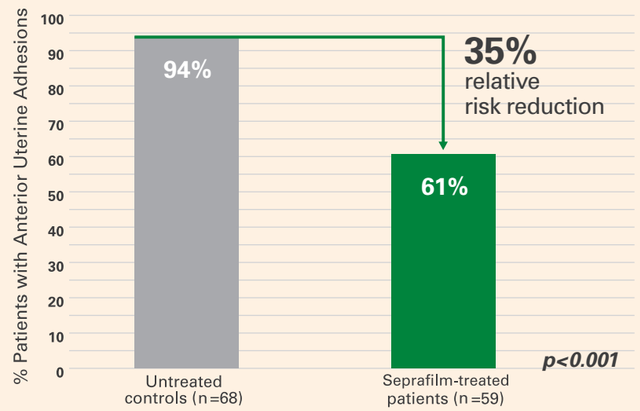
RESULTS: Seprafilm significantly reduced the incidence of adhesions and there was no statistical difference in adverse events between the Seprafilm and control groups.



REDUCTION OF ADHESIONS AFTER UTERINE MYOMECTOMY WITH SEPRAFILM[2]

STUDY DESIGN: Randomized, prospective, blinded, multicenter study evaluating efficacy of Seprafilm in reducing incidence of adhesions after uterine myomectomy (N=127).

RESULTS: Seprafilm significantly reduced the incidence, severity, extent, and area of adhesions following myomectomy. No adverse events were observed to be related to Seprafilm use.



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Note: Data charts have been adapted from the respective clinical studies.

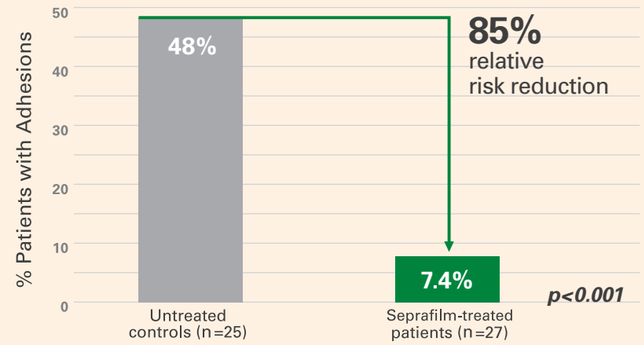
As demonstrated in prospective, randomized clinical trials,

SEPRAFILM® SIGNIFICANTLY REDUCES ADHESION-RELATED MORBIDITY

EFFICACY OF SEPRAFILM AS AN ADHESION PREVENTION BARRIER IN C-SECTIONS[3]

STUDY DESIGN: Prospective, controlled, cohort study evaluating Seprafilm for the prevention of adhesions following cesarean section, as evaluated at repeat cesarean delivery (N=52).

RESULTS: Seprafilm significantly reduced the incidence and severity of adhesions following C-section. Seprafilm also decreased both delivery and overall procedure times. No significant difference in blood loss (including amniotic fluid) was observed between the two groups.



IMPROVED OUTCOMES REPORTED IN SEPRAFILM CLINICAL TRIALS

	RESULTS	STUDY DESIGN
Reoperative complexity	15% relative reduction in operative time at repeat cesarean delivery (45.3 minutes in untreated controls vs. 38.7 minutes in Seprafilm-treated patients, P=0.009). No significant difference in blood loss (including amniotic fluid) was observed between the two groups.[3]	Prospective, cohort controlled study examining use of Seprafilm at first cesarean delivery to prevent pelvic adhesions, as evaluated at repeat cesarean delivery (N=52)
Adhesive small bowel obstruction (ASBO)	47% relative reduction in reoperative ASBO (3.4% of untreated controls vs. 1.8% of Seprafilm-treated patients, P=0.043). No significant difference between Seprafilm and control groups was reported for abdominal abscess, pelvic abscess, and pulmonary embolism. Foreign body reaction was not reported for any patient. However, in a subpopulation of patients in whom Seprafilm was wrapped around a fresh bowel anastomosis, leak-related events occurred more frequently.[4]	Randomized, prospective, multicenter, international, single-blind trial evaluating the efficacy of Seprafilm in preventing ASBO in patients undergoing intestinal resection (N=1701; mean follow-up 3.5 years)
Early postoperative small bowel obstruction (EPSBO)	61% relative reduction in EPSBO (7.0% of untreated controls vs. 2.7% of Seprafilm-treated patients, P=0.045). There were no significant differences between Seprafilm and control in the incidence of complications.[5]	Randomized, prospective, multicenter, multinational, single-blind trial evaluating the efficacy of Seprafilm in reducing the incidence of adhesive intestinal obstruction within 30 days after colorectal resection (N=427)

Important Safety Information—Seprafilm should not be wrapped directly around a fresh bowel anastomotic suture or staple line of the intestine, as this may result in an increased risk of bowel anastomotic leak-related events. However, the incidence of these events was not affected when Seprafilm was placed elsewhere in the abdomen. Please see full Seprafilm Instructions for Use (IFU).

As demonstrated by prospective, randomized trials and extensive clinical use,

SEPRAFILM® HAS A WELL-ESTABLISHED SAFETY PROFILE

USING SEPRAFILM® ADHESION BARRIER

SEPRAFILM SAFETY PROFILE IS COMPARABLE TO UNTREATED CONTROLS

In a prospective, randomized, multicenter, international trial evaluating the safety and efficacy of Seprafilm in patients undergoing elective colorectal surgery (N=1791),[1]

- No statistical difference in adverse event rates between Seprafilm and untreated control groups

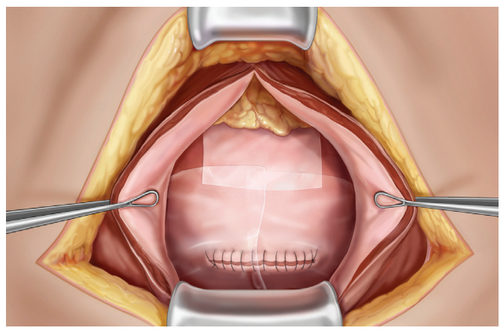
In a randomized, prospective, blinded, multicenter study evaluating Seprafilm to reduce adhesions after uterine myomectomy (N=127)[2]

- No adverse events and no increased risk of complication were observed to be related to Seprafilm use.

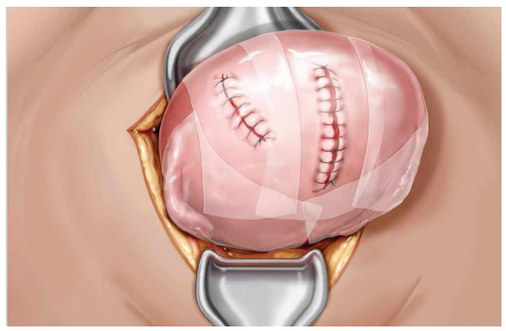
THE CONFIDENCE OF EVIDENCE-BASED SURGERY

- Seprafilm has been studied in over 20 published abdominopelvic surgical trials involving more than 4,000 patients
- More than 3.3 million patients worldwide have received Seprafilm since 1996[3]

Important Safety Information—No controlled clinical studies have been conducted in patients with active infections. Foreign body reaction may occur as with most surgical adjuncts but have been rarely reported during clinical use. Please see full Seprafilm Instructions for Use (IFU).



Seprafilm placement in a C-section

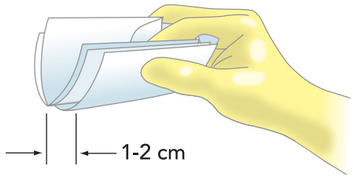


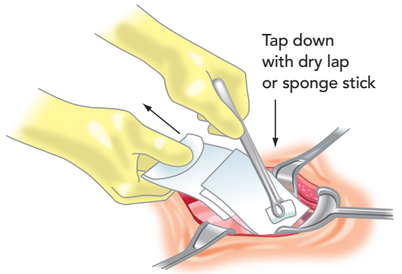
Seprafilm placement in a myomectomy

PREPARATION AND HANDLING

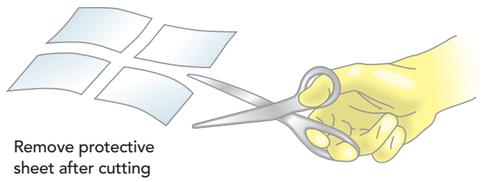
- Dry off gloves and instruments before handling (Seprafilm is hydrophilic and will stick to moist surfaces)
- Seprafilm may be applied to any raw or denuded surface in the abdominopelvic cavity
- If incision or application site is small, Seprafilm may be cut to shape or size to aid in placement (Note: Remove protective sheets after cutting)
- Large pieces can be curved or rolled to facilitate application

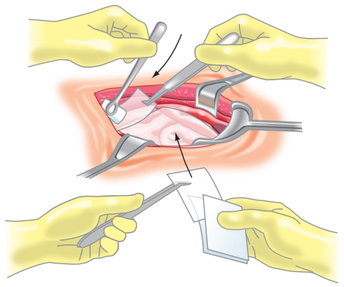
"TACO" APPLICATION TECHNIQUE





"QUILTING" APPLICATION TECHNIQUE





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