Don’t let adhesions block the way.
Adhesion-related complications are clear.

Adhesions are a common result of surgery, with potentially serious consequences for your patients. Adhesions can account for up to

- 75% of small bowel obstructions
- 40% of infertility cases
- 48% of chronic pelvic pain cases

Adhesions can also complicate future surgery:

- Increased procedure and re-entry time
- Difficulty differentiating and accessing tissues planes
- Increased risk of inadvertent enterotomy

Adhesions may limit future treatment options as well:

- Added complexity in future laparoscopy
- Limited distribution and effectiveness of intraperitoneal therapeutics
- Increased risk of postoperative radiation-induced small bowel perforation

Sepraﬁlm® reduces postoperative adhesions and related complications.

Reduction in postoperative adhesions
In a study of patients receiving Sepraﬁlm during 2-stage intestinal resection, Sepraﬁlm patients were 8.5 times more likely than untreated control to be adhesion-free.¹

Reduction in reoperative complexity
In a series of prospective clinical studies in which Sepraﬁlm was placed at the initial procedure, Sepraﬁlm reduced adhesions observed at subsequent surgery, resulting in:
- Fewer inadvertent injuries²
- Less operative time³
- Reduced blood loss¹
- Easier ileostomy reversal³
- Reduced extension of peristomal incision³

“Cement Belly” – Cohesive adhesions between loops of small bowel

Reduction in reoperative adhesive SBO
In a study of patients receiving Sepraﬁlm at intestinal resection, Sepraﬁlm reduced reoperation required for adhesive SBO.⁴

Sepraﬁlm use led to a 47% relative reduction in reoperative ASBO.

Please see important safety information in the back of this brochure.

No adhesion barrier has been more extensively evaluated than Seprafilm.¹

**Evidence-based adhesion prevention**

Seprafilm has been studied in more than 4,000 patients, in 20 published trials.¹ It has been proven in a wide range of open abdominal and pelvic surgical procedures, including:

- Colectomy
- Radical pelvic surgery
- Omentum creation and closure

Seprafilm has been in clinical use for over ten years, and used in more than a million patients.

**Proven safety**

A prospective, randomized, controlled, multicenter trial in elective colorectal resection reported that the rates of adverse events in Seprafilm-treated patients were not significantly different from those in untreated controls.¹

![Adverse Event rates in subpopulations of patients in which Seprafilm was not wrapped around a fresh anastomotic suture line](image)

**Safe in the presence of an anastomosis**

In a trial of patients receiving a mean of 4.4 (up to 10) sheets of Seprafilm following bowel anastomosis (n=1791) Seprafilm did not increase the complication rate when used as directed.²

Seprafilm should not be wrapped around a fresh bowel anastomosis, as such usage may result in increased anastomotic leak-related events. However, Seprafilm may be applied safely elsewhere in the abdomen regardless of the presence of an anastomosis.³

Please see important safety information in the back of this brochure.

A cost-effective choice

Treatment of adhesions poses a considerable financial burden on the healthcare system. A widely publicized study by Fox Ray et al (1994) demonstrated that adhesiolysis accounted for 1.3 billion in hospital and surgical expenditures.¹

A 2006 decision analysis study by Bristow et al evaluated the cost-effectiveness of using Seprafilm® to manage the risk of adhesive small bowel obstruction (ASBO) in patients undergoing radical hysterectomy for the treatment of cervical cancer. The model demonstrated that using Seprafilm as an adhesion prevention strategy is cost-effective from both third-party payer and societal perspectives.²

The estimate of third-party payer costs included direct costs of hospitalization and professional reimbursement for each episode of ASBO. The estimate of societal costs included the cost of the adhesion barrier, direct and indirect cost of hospitalization with professional reimbursement for each episode of ASBO, estimates of lost wages and caregiver support, and lost Quality of Life Years (QALYs) due to hospitalization, recovery time and death as a result of ASBO.

Results of the Bristow Cost-effectiveness Analysis²

10 years of clinical use

Seprafilm Adhesion Barrier is a temporary, biodegradable adhesion barrier composed of two chemically modified polysaccharides: hyaluronic acid and carboxymethylcellulose (HA and CMC).

Upon hydration, Seprafilm becomes a gel within 24-48 hours. This gel remains in place during the critical seven-day healing period – the time during which new adhesions typically form.³ It is slowly resorbed and is excreted from the body in less than 28 days.

Seprafilm features:

- Proven effective in fields with incomplete hemostasis
- Can be cut to desired size and shape
- Stays in place without sutures
- Stays at application site for seven days
- Can be layered and overlapped for complete coverage

Seprafilm can be applied to any raw or denuded surface during abdominopelvic laparotomy, including:

- Pelvic floor
- Abdominal wall
- Ostomy site
- Small bowel
- Large bowel
- Peritoneal surface
- Loops of bowel
- Paracolic gutters
- Omentum
- Stomach
- Liver bed
- Lymph node beds
- Uterus and adnexa
- Bladder
- Vaginal cuff

**Don't let adhesions block the way.**

To get Seprafilm® for your operating room, or to arrange for a product demonstration, please call 800-261-1570 or visit www.Seprafilm.com.

<table>
<thead>
<tr>
<th>Seprafilm Adhesion Barrier</th>
<th>Seprafilm Adhesion Barrier Procedure Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reorder No.: 4301-02</td>
<td>Reorder No.: 5086-02</td>
</tr>
<tr>
<td>Size: 5”x6” (12 cm x 15.2 cm)</td>
<td>Size: 6 each 3” x 5” (7 cm x 13 cm) membranes/pouch</td>
</tr>
<tr>
<td>Quantity: 10 membranes/box</td>
<td>Quantity: 5 pouches / box</td>
</tr>
</tbody>
</table>

**Description:** Seprafilm Adhesion Barrier (membrane) is a sterile, bioresorbable translucent adhesion barrier composed of two anionic polysaccharides, sodium hyaluronate (HA) and carboxymethylcellulose (CMC). Together, these biopolymers have been chemically modified with the activating agent 1-(3-dimethylaminopropyl)-3-ethylcarbodiimide hydrochloride (EDC). Seprafilm should be stored between 36°F-86°F (2°C-30°C) until the package expiration date.

**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 underlying 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.

**Actions:** Seprafilm Adhesion Barrier serves as a temporary bioreabsorbable barrier separating apposing tissue surfaces. The physical presence of the membrane separates adhesogenic tissue while the normal tissue repair process takes place. When applied as directed, Seprafilm Adhesion Barrier can be expected to reduce adhesions within the abdominopelvic cavity. Approximately 24 to 48 hours after placement, the membrane becomes a hydrated gel that is slowly resorbed within one week. Components are excreted in less than 28 days.

**Warnings:** Seprafilm Adhesion Barrier should not be wrapped directly around a fresh anastomotic suture or staple line, whether or not the anastomosis was diverted. An increased potential for abdominal events related to anastomotic leak was identified in a post-approval study when Seprafilm Adhesion Barrier was wrapped directly around a fresh anastomotic suture or staple line.

Seprafilm Adhesion Barrier is supplied sterile and must not be re-sterilized.

**Precautions:** 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 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. Foreign body reactions may occur with Seprafilm Adhesion Barrier, as with any implanted material.

The safety and effectiveness of Seprafilm Adhesion Barrier have not been evaluated in clinical studies in the presence of frank infections in the abdominopelvic cavity. Seprafilm Adhesion Barrier did not promote the growth of test microorganisms within the abdominopelvic cavity in animal studies.

The safety and effectiveness of Seprafilm Adhesion Barrier have not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.

A mean of two of the 5” x 6” Seprafilm membranes were applied to patients in the two pre-market studies. In the post-market study a mean of 4.4 of the 5” x 6” membranes were applied to patients.

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

**Adverse Events:** Seprafilm Adhesion Barrier has been studied in five clinical trials involving 2133 patients. Two safety pilot studies enrolled a total of 32 patients, two pivotal studies enrolled a total of 310 patients. One of the pivotal studies enrolled ulcerative colitis and familial polyposis patients undergoing colectomy followed by ileal pouch anal anastomosis with temporary ileostomy. The second pivotal study enrolled uterine myomectomy patients. No statistically significant differences were observed in the incidence of adverse events, serious or non-serious, comparing 172 Seprafilm-treated patients and 170 control patients for a period of up to 53 weeks after the initial surgeries of the 342 patients in the pre-market studies.

A post-market study enrolled 1791 patients (882 Seprafilm, 909 Control) with similar baseline characteristics from the United States, Canada, and Europe, who underwent intestinal resections or adhesiolysis for treatment of bowel obstruction. Although there was no difference in the overall number of patients in this post-market study with serious adverse events, a higher incidence of anastomotic leak related events was observed in patients who had Seprafilm wrapped around a fresh anastomotic site. These complications were not observed when Seprafilm was used throughout the abdomen, without deliberately covering the anastomosis. However the placement of Seprafilm under the abdominal wall incision did not affect wound healing or surgical site infection rates. In addition, there was no statistical difference between groups in the incidence of either abdominopelvic abscess or pulmonary embolism. No foreign body reaction was detected in the 882 Seprafilm patients.

**How Supplied:** Seprafilm Adhesion Barrier is packed in a Tyvek®† holder within a plastic sleeve and packed in an outer sealed foil pouch. The contents of the foil pouch are sterilized by gamma radiation.

Refer to package label for film size and quantity.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

**References:**

**Manufactured By:** Genzyme Biosurgery, A division of Genzyme Corporation, 500 Kendall Street, Cambridge, MA 02142 USA

For more information call: 1-800-261-1570

†Tyvek is a registered trademark of the DuPont Company, Wilmington, DE, USA.

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Seprafilm® Adhesion Barrier is indicated for the reduction of post-surgical adhesions in patients undergoing abdominal or pelvic laparotomy. The type and frequency of adverse events reported are consistent with events typically seen following surgery when used as directed. Seprafilm should not be wrapped around an intestinal anastomosis as such usage may result in increased anastomotic leak related events. For important safety information, please see package insert.
How to use Seprafilm®

Please refer to the Package Insert for detailed information.

Seprafilm is designed to be hydrophilic, such that it adheres to moist surfaces in the abdominopelvic cavity without requiring sutures. Following a few easy guidelines will aid in successful placement.

Preparation and Handling

- Dry off all gloves and instruments. Seprafilm will not stick to dry surfaces.
- If the incision or application site is small, Seprafilm may be cut to any shape or size to aid in placement. (Figure A)
- Larger pieces can be curved or rolled to ease application. (Figure B)
- Seprafilm can also be wrapped to desired contour. (Figure C)

Standard “Taco” Technique

1-2 cm

Alternative “Quilting” Technique

Call 800-261-1570 to arrange for a product demonstration, or visit www.Seprafilm.com to view helpful instructional videos and animations.