

About Postsurgical Adhesions

What are Adhesions?

Adhesions are scar tissues that often cause internal organs and/or tissues to stick together after surgery. Adhesions can twist and pull organs out of their normal place and are a primary cause of bowel obstruction, infertility (following gynecologic surgery), and chronic pelvic pain.¹ Adhesions can also complicate subsequent abdominal or pelvic operations.^{2,3}

Adhesions can cause complications, such as:

- Small bowel obstruction, the disruption of normal bowel flow, which can result when adhesions twist or pull the small bowel.
- Infertility, which may result when adhesions twist the tissues of the ovaries and tubes, blocking the normal passage of the egg (ovum) from the ovary to the uterus.
- Chronic pelvic pain, which may result when adhesions are present in the pelvis.

Minimizing Adhesions

There are techniques and principles that surgeons use to minimize postoperative complications, such as the formation of adhesions. Such techniques and principles include:

- Handling all tissue with absolute care
- Using powder-free surgical gloves
- Controlling bleeding
- Choosing sutures and implants carefully
- Keeping tissues moist
- Preventing infection

Even the best surgical techniques cannot always prevent the formation of adhesions.^{1,4} So in addition to these methods, many surgeons have come to rely on adhesion barriers for the prevention of adhesions following abdominal and pelvic surgery.

Seprafilm® Adhesion Barrier

Seprafilm is a physical adhesion barrier. It is composed of chemically modified sugars (sodium hyaluronate and carboxymethylcellulose). Seprafilm physically separates injured tissues from other tissues and organs to prevent the formation of adhesions. Seprafilm remains in place during the critical healing period while the body's natural healing process occurs. Seprafilm is resorbed by the body from the site of application over a period of 7 days.

Seprafilm Adhesion Barrier is indicated for the reduction of post-surgical adhesions in patients undergoing abdominal or pelvic laparotomy. The most common adverse events in clinical trials, which were not different from untreated controls, were: ileus, anastomotic leak, and abdominal abscess. Seprafilm should not be wrapped around an anastomosis as such usage may result in increased anastomotic leak related events. Seprafilm has not been studied prospectively in pregnancies, in the presence of frank infections, or in malignancies. Please see the Seprafilm package insert for full product information.

**For more information about Seprafilm Adhesion Barrier,
visit www.seprafilm.com or call 1-800-261-1570.
Patients: Talk to your doctor to determine whether Seprafilm
is appropriate for your procedure.**

REFERENCES

- 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; 297 - 306.
- 2 Monk BJ, Berman ML, Montz FJ. Adhesions after extensive gynecologic surgery: clinical significance, etiology, and prevention. *Am J Obstet Gynecol.* 1994; 170(5); 1396 - 1403.
- 3 Van der Krabben AA, Dijkstra FR, Nieuwenhuijzen M, Reijnen MMPJ, Schaapveld M, Van Goor H. Morbidity and mortality of inadvertent enterotomy during adhesiotomy. *Br J Surg.* 2000 ; 87 ;467- 471.
- 4 Diamond MP. Reduction of adhesions after uterine myomectomy by Seprafilm® membrane (HAL-F): a blinded, prospective, randomized, multicenter clinical study. *Fert Steril.* 1996; 66(6); 904 - 910.

seprafilm®
ADHESION BARRIER

(Chemically modified sodium hyaluronate
carboxymethylcellulose absorbable adhesion barrier)

YOU'VE GOT IT COVERED™

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).¹ Seprafilm should be stored between 36-86°F (2-30°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 bioresorbable barrier separating apposing tissue surfaces. The physical presence of the membrane separates adhesiogenic 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.

Contraindications: There are no known contraindications for the use of Seprafilm Adhesion Barrier.

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

Seprafilm Adhesion Barrier should not be wrapped directly around a fresh anastomotic suture or staple line. 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.

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 has 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 has 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, infertility, and small bowel obstruction have not been determined in clinical studies.

Adverse Events: Seprafilm Adhesion Barrier has been studied in five clinical trials involving 2133 patients. The most common adverse events in clinical trials, which were not different than controls, were: ileus, anastomotic leak, and abdominal abscess. 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 has completed enrollment of 1791 patients who underwent colorectal resections or adhesiolysis for treatment of bowel obstruction. The follow up is ongoing for this study.

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.

Seprafilm Adhesion Barrier should be stored between 36°F-86°F (2°F-30°C).

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

References: 1. Burns, J.W., S. Cox, and A.E. Walts. Water Insoluble Derivatives of Hyaluronic Acid: United States Patent Number 5,017,229. 1991.

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

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

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12/2003

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