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 and clinical value
- Established safety profile—no contraindications
- Site specific and stays where you place it for up to 7 days, the critical healing period
- Cost-effective—may help to lower healthcare costs by reducing hospital readmissions, reducing operating room time, and preventing complications such as adhesive small bowel obstruction[2-5]

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

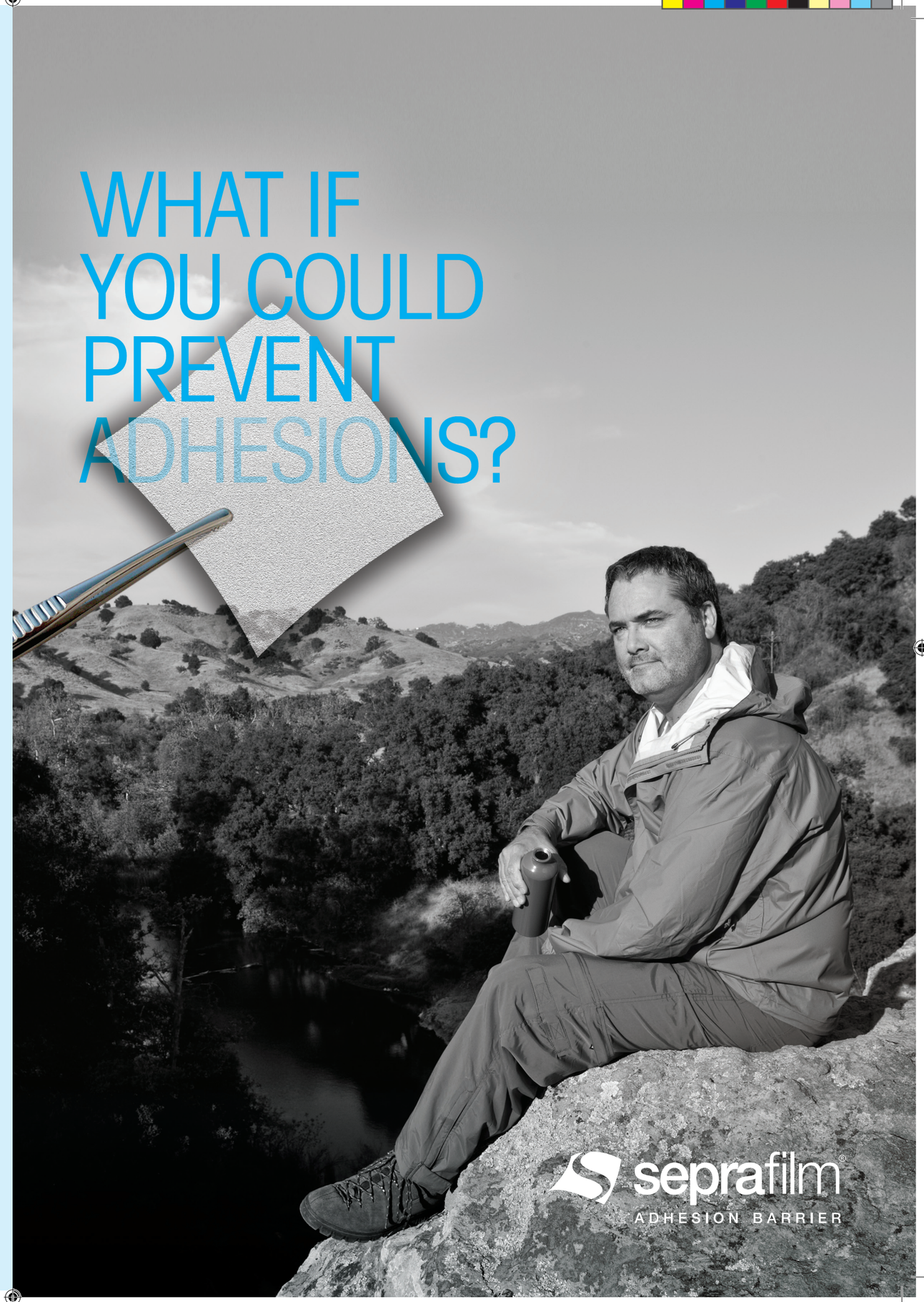
Genzyme Corporation, a Sanofi company
76 New York Avenue
Framingham, MA 01701 USA

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.
3. Kusunoki M, Ikeuchi H, Yanagi H, et al. Bioresorbable hyaluronate-carboxymethylcellulose membrane (Seprafilm) in surgery for rectal carcinoma: a prospective randomized clinical trial. *Surg Today.* 2005;35(11):940-5.
4. Ellis H, Moran B, Thompson J, et al. Adhesion-related hospital readmissions after abdominal and pelvic surgery: a retrospective cohort study. *Lancet.* 1999; 353:1476-1480.
5. Fazio V, Cohen Z, Fleshman J, et al. reduction in adhesive small-bowel pbstrauction by Seprafilm® adhesion barrier after intestinal resection. *Dis Colon Rectum.* 2005;49:1-11.

SANOFI

seprafilm® ADHESION BARRIER



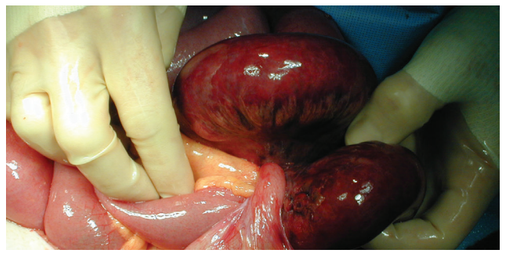
ADHESIONS: A FREQUENT COMPLICATION WITH UNDER-RECOGNIZED DANGERS

SEPRAFILM® ADHESION BARRIER

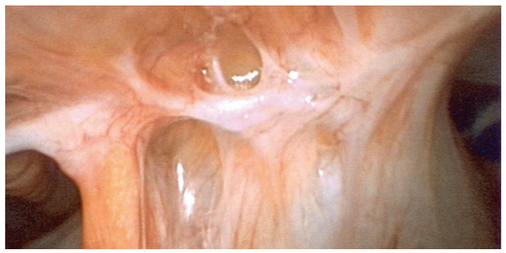
ADHESIONS ARE NOT PREVENTABLE BY SURGICAL TECHNIQUE ALONE[1-2]

Adhesions develop routinely following open and laparoscopic abdominal surgery, and are reported at second-look surgery to occur in 93% of patients following initial laparotomy.[1]

ADHESION-RELATED CONSEQUENCES	
Small bowel obstruction (SBO)	Adhesions are responsible for up to 80% of reported cases[3] Adhesive SBO has a high risk of recurrence with mortality rates ranging from 3% to 10%[3-7]
Reoperative complexity	Adhesions prolong operative time and limit access to surgical sites[8-10] Adhesions are the primary reason for conversion from laparoscopy to laparotomy[9]
Inadvertent enterotomy	Adhesions increase risk of iatrogenic bowel injury by 10% to 25%[11-12]
Secondary infertility	Adhesions are the leading cause of secondary female infertility (reported to cause 20% to 40% of cases)[13]



Adhesive small bowel obstruction



Adhesions to the anterior abdominal wall

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 of prospective, randomized, controlled, clinical studies to significantly reduce adhesions and related complications[14-18]
Separates tissues for up to 7 days – the critical tissue healing period
Offers site-specific protection for adhesiogenic tissues
Composed of Sodium Hyaluronate/Carboxymethylcellulose (HA/CMC)—two bioresorbable, inert, non-animal-derived polysaccharides

Important Safety Information

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. No controlled clinical studies have been conducted in patients with active infections. Please see full Seprafilm Instructions for Use (IFU).

References

1. Menzies D, Ellis H. Intestinal obstruction from adhesionshow big is the problem? *Ann Royal Coll Surg Eng.* 1990;72:60-63.
2. DeWilde RL, Trew G. Postoperative abdominal adhesions and their prevention in gynaecological surgery. Expert consensus position. Part 2–steps to reduce adhesions. *Gynecol Surg.* 2007;4:243-253.
3. Farinella E, Cirocchi R, La Mura F, et al. feasibility of laparoscopy for small bowel obstruction. *World J Emerg Surg.* 2009;4:3.
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5. Roseano M, Dobrinja C, Turoldo A, et al. Adhesive small bowel occlusion: a clinical and therapeutic study of 163 consecutive patients. [Article in Italian]. *Chir Ital.* 2007;59(5):651-9.
6. Wysocki A, Pożniczek M, Kulawik J, et al. Peritoneal adhesions as cause of small bowel obstruction. [Article in Polish]. *Przegl Lek.* 2003;60 *Suppl* 7:32-5.
7. Fevang BT, Fevang J, Lie SA. Long-term prognosis after operation for adhesive small bowel obstruction. *Ann Surg.* 2004;240(2):193-201.
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11. Van Der Krabben AA, Dijkstra FR, Nieuwenhuijzen M, et al. Morbidity and mortality of inadvertent enterotomy during adhesiotomy. *Br J Surg.* 2000;87(4):467-71.
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14. 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.
15. 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.
16. Diamond MP, For the 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;66:904-910.
17. 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.
18. Data on file. Genzyme Corporation.

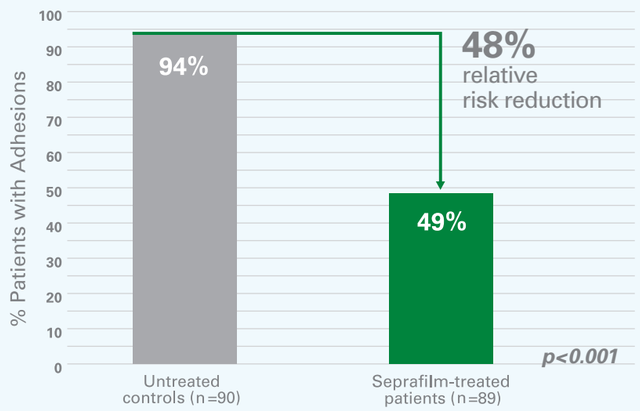
As demonstrated in prospective, randomised clinical trials,

SEPRAFILM® REDUCES ADHESIONS AND SIMPLIFIES REOPERATION

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

STUDY DESIGN: Randomised, prospective, double-blind, multicenter study evaluating Seprafilm to prevent adhesions in patients undergoing 2-stage intestinal resection (N=183).

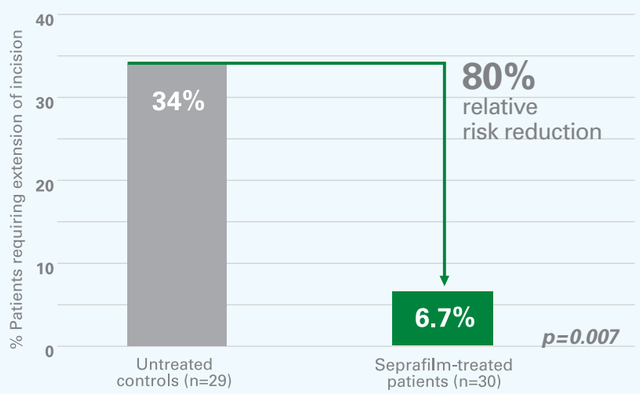
RESULTS: Seprafilm significantly reduced the incidence of adhesions and there was no difference in adverse events between the Seprafilm and control groups.



BIORESORBABLE HA-CMC MEMBRANE (SEPRAFILM) IN SURGERY FOR RECTAL CARCINOMA[2]

STUDY DESIGN: Randomised, prospective, evaluator-blinded trial evaluating the severity and extent of adhesions at ileostomy closure following radical rectal resection (N=59).

RESULTS: Seprafilm significantly reduced adhesions in the midline incision and peristomal areas. This, in turn, reduced operation time, blood loss, and extent of the incision at ileostomy closure. Seprafilm was not associated with any postoperative complications or chemoradiation-related toxicity, nor did it affect recurrence or survival rates.



Important Safety Information

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. Please see full Seprafilm Instructions for Use (IFU).

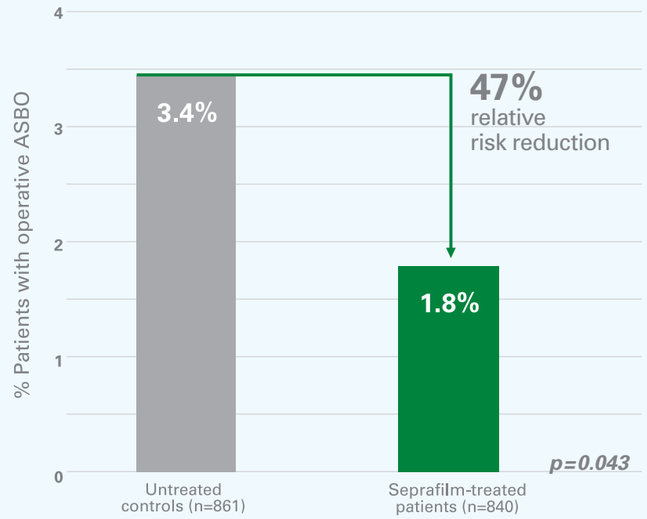
As demonstrated in prospective, randomised clinical trials,

SEPRAFILM® SIGNIFICANTLY REDUCES ADHESION-RELATED MORBIDITY

REDUCTION IN ADHESIVE SMALL-BOWEL OBSTRUCTION BY SEPRAFILM AFTER INTESTINAL RESECTION[3]

STUDY DESIGN: Randomised, prospective, multicenter, international, single-blind trial evaluating Seprafilm to prevent ASBO in patients undergoing intestinal resection (N=1701; mean follow-up 3.5 yr).

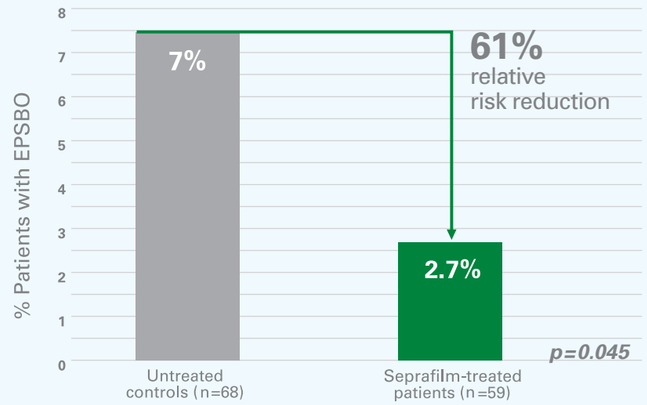
RESULTS: Seprafilm decreased adhesive small bowel obstruction. No significant difference between the Seprafilm and control groups was reported for abdominal abscess, pelvic abscess, and pulmonary embolism. Foreign body reaction was not reported for any patient. However, in a subpopulation of patients in whom Seprafilm was wrapped around a fresh bowel anastomosis, leak-related events (which included anastomotic leak, fistula, peritonitis, abscess, and sepsis) occurred more frequently.



SEPRAFILM REDUCED EARLY POSTOPERATIVE INTESTINAL OBSTRUCTION AFTER LOWER ABDOMINAL SURGERY FOR COLORECTAL CANCER[4]

STUDY DESIGN: Randomised, prospective, multicenter, multinational, single-blind trial evaluating Seprafilm to reduce early post-operative SBO (within 30 days) after colorectal resection (N=427).

RESULTS: Seprafilm reduced the incidence of early postoperative intestinal obstruction. There were no significant differences between Seprafilm and control in the incidence of complications.



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(4):297-306.
2. Kusunoki M, Ikeuchi H, Yanagi H, et al. Bioresorbable hyaluronate-carboxymethylcellulose membrane (Seprafilm) in surgery for rectal carcinoma: a prospective randomized clinical trial. *Surg Today.* 2005;35(11):940-5.
3. Fazio V, Cohen Z, Fleshman J, et al. reduction in adhesive small-bowel pbstrauction by Seprafilm® adhesion barrier after intestinal resection. *Dis Colon Rectum.* 2005;49:1-11.
4. Park CM, Lee WY, Cho YB, et al. Sodium hyaluronate-based bioresorbable membrane (Seprafilm) reduced early postoperative intestinal obstruction after lower abdominal surgery for colorectal cancer: the preliminary report. *Int J Colorectal Dis.* 2009;(3):305-10.

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

SEPRAFILM® HAS A WELL-ESTABLISHED SAFETY PROFILE

SEPRAFILM SAFETY PROFILE IS COMPARABLE TO THAT REPORTED FOR UNTREATED CONTROLS

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

- No difference in adverse event rates between Seprafilm and untreated control groups
- Seprafilm was reported safe for use in the presence of a fresh bowel anastomosis; however, it should not be applied directly to a fresh anastomotic suture line, as this may prevent adhesions to the anastomotic site and thereby increase the risk of anastomotic leak-related events

In a randomized, prospective trial evaluating Seprafilm in cancer patients to prevent adhesions after radical rectal resection (N=59),[2]

- Seprafilm did not increase chemotherapy- or radiation-related toxicity or negatively affect recurrence or survival rates over five years of follow up

THE CONFIDENCE OF EVIDENCE-BASED SURGERY

- Seprafilm has been studied in more than 4,000 patients in over 20 published abdominopelvic surgery trials
- More than 3.3 million patients have received Seprafilm in more than 17 years of worldwide clinical use

Important Safety Information
No controlled clinical studies have been conducted in patients with active infections. Please see full Seprafilm Instructions for Use (IFU).

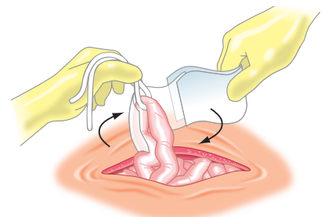
References
1. Beck DE, Cohen Z, Fleshman JW, et al. A prospective, randomized, multicenter, controlled study of the safety of Seprafilm adhesion barrier in abdominopelvic surgery of the intestine. *Dis Colon Rectum*. 2003;46(10):1310-9.
2. Kusunoki M, Ikeuchi H, Yanagi H, et al. Bioresorbable hyaluronate-carboxymethylcellulose membrane (Seprafilm) in surgery for rectal carcinoma: a prospective randomized clinical trial. *Surg Today*. 2005;35(11):940-5.

USING SEPRAFILM® ADHESION BARRIER

PREPARATION AND HANDLING

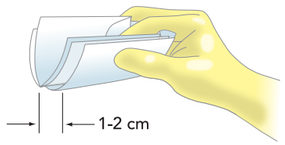
- Dry off gloves and instruments before handling (Seprafilm is hydrophilic and will stick to moist surfaces)
- Seprafilm may be applied to any raw or denuded surface in the abdominopelvic cavity

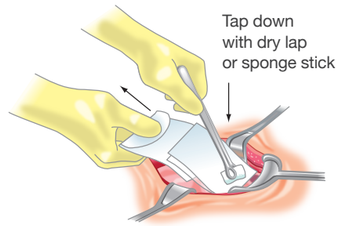
If incision or application site is small, Seprafilm® may be cut to shape or size to aid in placement (Note: Remove protective sheets after cutting)



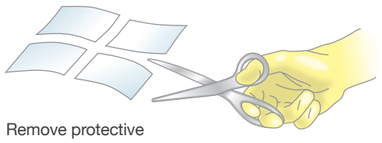
Seprafilm can be wrapped to desired contour

"TACO" APPLICATION TECHNIQUE





"QUILTING" APPLICATION TECHNIQUE



Remove protective sheet after cutting