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

- 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

SEPFRAFILM ORDERING INFORMATION

<table>
<thead>
<tr>
<th>CONFIGURATIONS</th>
<th>CATALOG NUMBERS</th>
<th>FILM DIMENSIONS</th>
<th>POUCH CONTENTS</th>
<th>PACKAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seprafilm</td>
<td>4301-03</td>
<td>12.7 cm x 15.2 cm</td>
<td>1 film</td>
<td>10 pouches per carton</td>
</tr>
<tr>
<td>Seprafilm Procedure Pack</td>
<td>5086-03</td>
<td>12.7 cm x 7.5 cm</td>
<td>6 films</td>
<td>5 pouches per carton</td>
</tr>
<tr>
<td>Seprafilm Single Site</td>
<td>6641-03</td>
<td>12.7 cm x 7.5 cm</td>
<td>1 film</td>
<td>5 pouches per carton</td>
</tr>
<tr>
<td>Seprafilm Mini Site</td>
<td>6379-03</td>
<td>6.5 cm x 7.5 cm</td>
<td>1 film</td>
<td>10 pouches per carton</td>
</tr>
<tr>
<td>Seprafilm 4-Section</td>
<td>6380-03</td>
<td>6.5 cm x 7.5 cm</td>
<td>4 films</td>
<td>10 pouches per carton</td>
</tr>
</tbody>
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MANUFACTURED BY
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76 New York Avenue
Framingham, MA 01701 USA

References:

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ADHESIONS: A FREQUENT COMPLICATION WITH UNDER-RECOGNIZED DANGERS

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.

ADHESION-RELATED CONSEQUENCES

- **Secondary infertility**: Adhesions are the leading cause of secondary female infertility (20% to 40% of all cases).
- **Chronic pelvic pain**: Up to 80% of SBO cases are caused by adhesions.
- **Small bowel obstruction (SBO)**: Adhesive SBO has a high risk of recurrence with mortality rates ranging from 3% to 10%.
- **Abdominal hysterecstomy**: The leading contributor to SBO: in one retrospective study of female patients diagnosed with adhesions, 38% of the surgical procedures.
- **Inadvertent enteroctomy**: Adhesions increase the risk of iatrogenic bowel injury by 10% to 25%.
- **Reoperative complexity**: Adhesions prolong operative time and may limit access to surgical sites.

Adhesions may complicate repeat cesarean deliveries and lengthen operating time, which may negatively impact fetal well-being.

Adhesions are the primary reason for conversion from laparoscopy to laparotomy.

References
REOPERATION ADHESIONS AND SIMPLIFIES

As demonstrated in prospective, randomized clinical trials,

**SEPFRAFLM® REDUCES ADHESIONS AND SIMPLIFIES REOPERATION**

**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.

<table>
<thead>
<tr>
<th>% Patients with Adhesions</th>
<th>Untreated controls (n=90)</th>
<th>Seprafilm-treated patients (n=93)</th>
</tr>
</thead>
<tbody>
<tr>
<td>94%</td>
<td>49%</td>
<td>p&lt;0.001</td>
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</table>

**PREVENTION OF POSTOPERATIVE ABDOMINAL ADHESIONS BY A HA-BASED BIORESORBABLE MEMBRANE**


**REDUCTION OF ADHESIONS AFTER UTERINE MYOMECTOMY WITH SEPFRAFLM®**

**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.

<table>
<thead>
<tr>
<th>% Patients with Adhesions</th>
<th>Untreated controls (n=68)</th>
<th>Seprafilm-treated patients (n=59)</th>
</tr>
</thead>
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<tr>
<td>94%</td>
<td>61%</td>
<td>p&lt;0.001</td>
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**EFFICACY OF SEPFRAFLM AS AN ADHESION PREVENTION BARRIER IN C-SECTIONS**

**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.

<table>
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<th>% Patients with Adhesions</th>
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<td>48%</td>
<td>7.4%</td>
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**IMPROVED OUTCOMES REPORTED IN SEPFRAFLM CLINICAL TRIALS**

**RESULTS**

- **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.

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- **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 abscesses, pelvic abscesses, 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.

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- **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.

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**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).
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),

- 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)

- 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

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).

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