Most Common Surgical Procedures

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Description</th>
<th>Potential Areas of Adhesion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Bowel (Colon) Resection: Colostomy/Colectomy</td>
<td>Removal of diseased colon (colectomy) with or without intestinal anastomosis, which can be combined with a definite or reversal of the opening of the colon to the outside of the abdomen (colostomy). Alternative names for colectomy include: ascending, descending, transverse, subtotal, or sigmoid colectomy. May be indicated for several conditions including colon cancer, bowel obstruction, diverticulitis, or Crohn’s disease. Can be performed by laparotomy or laparoscopy.</td>
<td>Between intraperitoneal organs and damaged serosal layer; most commonly between omentum and wound; less commonly to anterior abdominal wall.</td>
</tr>
<tr>
<td>Small Bowel (Small Intestine) Resection: Ileotomy/Ileostomy</td>
<td>Removal of diseased small intestine (ileotomy) with or without intestinal anastomosis, which can be combined with a definite or reversal of the opening of the small intestine to the outside of the abdomen (ileostomy). May be indicated for several conditions including small bowel obstruction, ulcerative colitis, and severe diverticulitis. Can be performed by laparotomy or laparoscopy.</td>
<td></td>
</tr>
<tr>
<td>Adhesiolysis</td>
<td>Removal/dissection of adhesions; may be necessary to progress in surgical dissection or sole purpose of surgery. May create new (de novo) adhesions. Can be performed by laparotomy or by laparoscopy.</td>
<td></td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>Removal of the gallbladder. Indicated for cholelithiasis (gallstones). Gallstones may provoke inflammation or infection of the gallbladder (cholecystitis) or carcinoma. Can be performed by open laparotomy or laparoscopy.</td>
<td></td>
</tr>
<tr>
<td>Appendectomy</td>
<td>Surgery to remove appendix after it becomes inflamed or infected. Most often performed by open laparotomy, but may be performed by laparoscopy at select centers.</td>
<td></td>
</tr>
</tbody>
</table>

COSEAL SURGICAL SEALANT IS INDICATED FOR PATIENTS UNDERGOING LAPARATOMY OR LAPAROSCOPIC ABDOMINOPELVIC SURGERY AS AN ADJUNCT TO GOOD SURGICAL TECHNIQUE INTENDED TO REDUCE THE INCIDENCE, SEVERITY, AND EXTENT OF POST-SURGICAL ADHESION FORMATION.

Application | Benefits of Using COSEAL Surgical Sealant in General Surgery |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominopelvic adhesion prevention.</td>
<td>Postoperative abdominopelvic adhesion formation may lead to chronic pain, small bowel obstruction and, in females, secondary infertility. It also makes reoperation much more challenging with an increased risk for inadvertant enterotomy (puncture of bowel) and prolonged operative time. Adhesion related complications are an important source of morbidity in a substantial number of patients undergoing lower abdominal surgery. COSEAL is a synthetic hydrogel designed to prevent or reduce the incidence, severity and extent of postsurgical adhesion formation.</td>
</tr>
</tbody>
</table>
Challenges in General Surgery

- A lack of awareness of the clinical significance and frequency of adhesions is one of the greatest impediments to reducing their formation. In a prospective analysis, patients undergoing a laparotomy, who had previously had one or more abdominal operations, 93% had intra-abdominal adhesions that were the result of a previous surgery.
- Postoperative adhesions are the largest single cause of small bowel obstruction (SBO). SBO is the most serious adhesion-related complication with a 10% risk of mortality if not diagnosed and treated immediately.
- Up to 1 in 5 patients undergoing reoperation through a laparotomy scar sustains injury from an inadvertent enterotomy (puncture of bowel) following adhesiolysis.
- Inadvertent enterotomy results in conversion from laparoscopy to laparotomy in almost 100% of cases.
- Following surgical removal of adhesions (adhesiolysis), reformation is a frequent problem - even in laparoscopic procedures.
- In 1994, the total direct cost for hospitalizations related to abdominal adhesions in the U.S. was estimated at 1.3 billion.

Probing Questions

Questions before COSEAL introduction:
- What adhesion prevention agents do you use and when?
- Do you consider adhesion prevention agents to be a standard of care for the majority of your surgical patients?
- Have you experienced difficulties with procedures at reoperation due to adhesions?
- Are you concerned with the medicolegal implications of postoperative abdominopelvic adhesions?
- Would you be interested in an adhesion prevention agent clinically proven to offer safe, effective coverage in both laparoscopic and open laparotomy procedures?

Objections

I don’t use adhesion prevention agents because good surgical technique prevents adhesion formation.

Despite advances in abdominopelvic surgical techniques, epidemiological studies of adhesion formation in patients undergoing abdominopelvic surgery concluded that surgical techniques to reduce adhesions had little impact on the burden of adhesion-related complications. Recently published “Call to Action” indicated that the “best possible standard of care” in patients undergoing high-risk general surgery includes the use of anti-adhesion agents.

I only perform laparoscopic procedures, so adhesion prevention agents are unnecessary.

Adhesion formation even after laparoscopic procedures remains one of the most common complications of abdominopelvic surgery. In epidemiological studies examining the readmission rate for complications related to adhesions following abdominopelvic surgery, it has been demonstrated that the overall risk following laparoscopic or open surgery is similar.

I use INTERCEED, SEPARFILM, or ADEPT for adhesion prevention.

Probe as to why they use these products. Counter with the following:
- COSEAL offers sprayable coverage for multiple sites in both laparoscopic and open procedures. Fabric or film barriers are less practical than a sprayable hydrogel, especially in laparoscopic procedures.
- Do you require coverage for multiple focal sites of potential adhesion formation, or is broad coverage needed? An additional consideration is the use of BOTH COSEAL and ADEPT to provide high efficacy site specific protection combined with broad protection for potential unanticipated de novo adhesion formation

I’ve heard COSEAL is expensive.

COSEAL is in line with other adhesion prevention agents for focal and multiple site coverage. When using fabric or film barriers, especially in laparoscopic surgery, coverage of multiple of sites may be difficult and/or impractical and require the use of multiple sheets, thus increasing overall cost.

Tips for Success

- Emphasize importance of adhesion prevention as a standard of care, refer to “Call to Action” paper (see “Reference Overview” section).
- Emphasize ease of use of sprayable hydrogel vs. fabric or film sheets, especially in laparoscopic procedures.
- Prepare and demo product with surgeon and staff prior to use:
  - Determine appropriate applicator for procedures most often performed by the surgeon.
  - Work with surgeon and staff to increase familiarity and comfort level with the device through frequent use.

Marketing Materials

General Surgery Reference Overview

<table>
<thead>
<tr>
<th>Article Title</th>
<th>Reference</th>
<th>Key Finding</th>
</tr>
</thead>
</table>

References