Adhesion: Need to Know

What are adhesions?

• Adhesions are fibrous bands connecting structures and organs that are normally separated.

What causes adhesions?

• Adhesions can be the result of:
  – Surgical Trauma
  – Endometriosis
  – Inflammation

Source: http://www.webmd.com/a-to-z-guides/adhesion-general-post-surgery
Adhesion: Need to Know

What are the consequences?

*Clinical consequences*

- pelvic pain
- infertility
- bowel obstruction
- repeat surgery (35% of patients within 10 years)\(^1\)

*Economical consequences*

- increased surgery time
  + 24 minutes\(^1\)

Adhesion: Need to Know

How big a problem are adhesions?

• After laparotomy, adhesions develop in 93% of patients

• 3.3% of laparotomies resulted in bowel obstruction, 1% within 12 months following surgery

• 50% of SBO are the result of previous gynecological surgery
Adhesion: Need to Know

How big a problem are adhesions?

• Pelvic adhesions have been implicated in the causation of as many as 15% to 20% of cases of infertility

• Laparoscopic surgical procedures with their minimal access to the abdominal cavity are associated with fewer postoperative adhesions compared to open surgery, although adhesion formation still occurs.
## Adhesion: Need to Know

How big a problem are adhesions?

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adhesiolysis</td>
<td>76%</td>
</tr>
<tr>
<td>Surgical treatment of endometriosis</td>
<td>82%</td>
</tr>
<tr>
<td>Ovarian surgery</td>
<td>75%</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>68%</td>
</tr>
<tr>
<td>Tubal surgery</td>
<td>76%</td>
</tr>
</tbody>
</table>

1. http://www.mitek.com/home.jhtml?loc=USENG&page=viewContent&contentId=09008b988103bf4f&parentId=09008b988103b84a
## SCAR Study
### Readmission Risk Due to Adhesions over 10 yrs

#### GYNECOLOGICAL SURGERY

<table>
<thead>
<tr>
<th>Site of initial open surgery</th>
<th>No. of women w/Initial Open Procedure</th>
<th>No. of women readmitted</th>
<th>Women readmitted (%)</th>
<th>No. of readmissions</th>
<th>Avg per women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovary</td>
<td>624</td>
<td>300</td>
<td>48.1%</td>
<td>664</td>
<td>2.2</td>
</tr>
<tr>
<td>Fallopian Tubes</td>
<td>1171</td>
<td>482</td>
<td>41.2%</td>
<td>943</td>
<td>2.0</td>
</tr>
<tr>
<td>Uterus</td>
<td>6616</td>
<td>2122</td>
<td>32.1%</td>
<td>3759</td>
<td>1.8</td>
</tr>
<tr>
<td>Vagina</td>
<td>78</td>
<td>27</td>
<td>34.6%</td>
<td>67</td>
<td>2.5</td>
</tr>
<tr>
<td>Total</td>
<td>8489</td>
<td>2931</td>
<td>34.5%</td>
<td>5433</td>
<td>1.9</td>
</tr>
</tbody>
</table>

#### GENERAL ABDOMINAL SURGERY

<table>
<thead>
<tr>
<th>Site of initial open surgery</th>
<th>No. of women w/Initial Open Procedure</th>
<th>No. of women readmitted</th>
<th>Women readmitted (%)</th>
<th>No. of readmissions</th>
<th>Avg per women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foregut</td>
<td></td>
<td></td>
<td>37.3%</td>
<td></td>
<td>2.1</td>
</tr>
</tbody>
</table>

Adhesion Need to Know

How do adhesions form?

Parietal Peritoneum
– mesothelial layer on abdominal wall

Visceral Peritoneum
– mesothelial layer on bowel viscera

Source: http://www.laparoscopyhospital.com/laparoscopy_and_postoperative_adhesion.htm
Physiopathological Cascade Reaction

Peritoneal Trauma

Increased vascular permeability and production of fibrinous exudate

Fibrinous deposition

Fibrinolysis

Plasminogen

Plasmine

Normal Tissue Formation

Abnormal Tissue Formation

Adhesion Formation

Normal peritoneal healing

Normal peritoneal healing & Restoration of a natural cleavage plane

Fibrinolysis

Fibrinous deposition on either side of the barrier

Normal Tissue Formation
The healing process (so called physiopathologic cascade) may be summarized as shown here:

**Adhesion Prevention Barrier Method**

- **Abrasion and other trauma during surgery lead to disruption of the mesotheal lining.**
- **Fibrin (yellow) is deposited at damaged surfaces by bleeding and post traumatic inflammation.**
- **The enlarging fibrin mass reaches an adjacent surface, form a bridge between surfaces. Locally generated fibronolytic factors may degrade all or part of the fibrin bridge.**
- **Fibroblasts and other cells migrate across the remnants of the fibrin bridge, and transform the initially reversible fibrinous adhesion to a connective tissue structure.**

The healing process shown here with an adhesion barrier:

- **Adhesion barriers provides physical separation of surfaces that have a disruption of the mesotheal lining.**
- **Fibrin (yellow) is deposited at damaged surfaces by bleeding and post traumatic inflammation.**
- **The enlarged fibrin mass is prevented from reaching the adjacent surface by the barrier, preventing the formation of a fibrin bridge.**
- **A natural cleavage plane is restored with all surface have a complete uninterrupted mesotheal layer.**

**Design Key**

- **Mesothelial lining**
- **Fibrin**
- **Wound**
- **Barrier**
Example of GI Adhesions

Adhesions causing small bowel obstruction
Examples of GYN Adhesions

Adhesions between anterior uterine wall

Adhesions between uterus, adnexa and bowel posteriorly
Adhesion Need to Know

How do adhesions form?

- **Fibrin**
- **Fibrin clot**
- **Macrophages**
- **Fibroblasts**
- **Collagen deposits**

12-24hrs

5 days

12 weeks

T0

Source: [http://www.laparoscopyhospital.com/laparoscopy_and_postoperative_adhesion.htm](http://www.laparoscopyhospital.com/laparoscopy_and_postoperative_adhesion.htm)
Adhesion Barrier Role

Natural Healing Process occurs under the Adhesion Barrier

Fibrin

Fibrin clot

Macrophages

Fibroblasts

Collagen deposits

Source: http://www.laparoscopyhospital.com/laparoscopy_and_postoperative_adhesion.htm
SprayShield™ Adhesion Barrier System

Indication

The SprayShield™ Adhesion Barrier System is indicated for use in patients undergoing laparotomy or laparoscopic abdominopelvic surgery as an adjunct to good surgical technique intended to reduce the incidence, severity, and extent of post surgical adhesion formation.

Contraindication

• Patients who are pregnant or lactating.
• Patients with severely altered renal or hepatic function.
• Patients with a known allergy to FD&C #1 Blue dye.

* The SprayShield™ Adhesion Barrier System has CE Mark, it is not approved for use in the US

Source: IFU
Effective & Ease of Use
Efficacy: Number of Adhesions

Average number of adhesions to injured uterine horns and side walls - Porcine Model -

- 47%

Efficacy: Area of Adhesions\(^1\)

Average adhesion area to injured uterine horns and side walls
- Porcine Model -

\(- 83\%\)

Efficacy: Severity of Adhesions

Average adhesion severity to injured uterine horns and side walls - Porcine Model -

31%*

* Results are not statistically significant

Ease of Use: Sprayable
Ease of Use: Multiple Site Protection
Ease of Use: Laparoscopic
Ease of Use: Complex Surfaces
SprayShield™
Adhesion Barrier

The adhesion barrier spray, for multiple site abdominopelvic protection.
A Complete Portfolio

SprayShield™ Adhesion Barrier

*Multiple site abdominopelvic protection*

- Laparoscopic surgery
- Complex anatomy
- Dry surfaces
Technology
SprayShield™ Adhesion Barrier Components

1) PEG powder with blue dye
2) Phosphate buffer + Trilysine (blue)
3) Borate buffer (clear)
4) Air Assisted Sprayer

Always connect
1) blue vial with
2) blue syringe!

Note: Flow Regulator sold separately
SprayShield™ Adhesion Barrier Technology

Clear Precursor Syringe
Borate Buffer to initiate Polymer Reaction

Blue Precursor Syringe
Amino Acid and PEG with Reactive End Groups

Reaction (~2 sec)
Hydrolyzable Segments

When mixed, the liquids crosslink to form an absorbable hydrogel
(> 90% water)

Amino Acid
Segments Hydrolyze

LIQUID
Amino acid with Reacted End Groups cleared by kidneys

Absorption (within 7 days)

GEL
Water Soluble PEG cleared by kidneys
SprayShield™ Air-Assisted Sprayer

- Plug resistant, start and stop
- For precise and controlled application
- Venting system allows instant polymerization
- Fits into 5mm trocar
- 32cm shaft for reach
- Malleable tip for positioning
## SprayShield™ Adhesion Barrier Technology

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sprayable</td>
<td>Complex surface coverage</td>
</tr>
<tr>
<td>Stop &amp; Go</td>
<td>Multiple site abdominopelvic protection</td>
</tr>
<tr>
<td>32cm Shaft</td>
<td>Designed for laparoscopic surgery</td>
</tr>
<tr>
<td>Instant polymerization &amp; Blue color</td>
<td>Site specific</td>
</tr>
<tr>
<td>Adherent to Tissue</td>
<td>Secure protection</td>
</tr>
<tr>
<td></td>
<td>Allows irrigation</td>
</tr>
<tr>
<td>Synthetic &amp; Absorbable</td>
<td>No risk of viral transmission¹ &amp; reduced risk of</td>
</tr>
<tr>
<td></td>
<td>immune system response</td>
</tr>
<tr>
<td>Resorbable within 7 Days</td>
<td>Allows natural healing</td>
</tr>
</tbody>
</table>

¹ TP/TR 1222
SprayShield™ Adhesion Barrier System

Product Application

Source: IFU
SprayShield™ Application In-Service

- Prior to application, **ensure that adequate hemostasis** has been obtained, and that the **target tissues have been thoroughly rinsed**.

- The Air assisted sprayer is compatible with 5-mm trocars.

- Once inserted through the trocar, bend the sprayer tip as needed to coat surfaces not readily visible or accessible. The tip will self-straighten when removed from the trocar.

Source: IFU
SprayShield™ Application In-Service

1. In preparation for SprayShield™ application, adjust insufflation pressure to 10 to 12 mmHg.

2. Insert sprayer through trocar into abdomino-pelvic cavity and wait 1 minute prior to applying SprayShield™.

3. When applying SprayShield™, position the sprayer tip a minimum of 2 cm from the target tissue surface. Closer application results in excessive dripping or run-off.

4. Move the sprayer tip in a back and forth motion while slowly depressing the syringes to apply a thin uniform coating of adhesion barrier.

Source: IFU
SprayShield™ Application In-Service

5. Apply SprayShield™ to the target tissue and surrounding margins to provide an effective adhesion barrier. Continue applying SprayShield™ until a 1-2 mm uniform coating is formed.

Note:

Using the Sprayer to manipulate tissue during laparoscopic procedures may obstruct the Sprayer ventilation holes. Wipe off any gel that forms on the sprayer tip. Avoid additional manipulation of treated tissue surfaces or gross disruption of the adhesion barrier when suctioning.
Ensure Appropriate Application Thickness

**INCORRECT:** Application that is TOO THIN

**INCORRECT:** Application that is TOO THICK

**CORRECT:** Application of CONTROLLED THICKNESS (1-2mm)

Source: IFU
SprayShield™ Application In-Service

6. After application, thoroughly rinse SprayShield™ coated tissues with irrigation fluid to ensure a lubricious surface that allows adjacent surfaces to slide freely on the adhesion barrier.

Source: IFU