Sepra® Technology

• An extensively studied barrier with more than 10 publications and used clinically since 2007.
• Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.
• Biodegradable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.
• The hydrogel barrier resorbs within 30 days providing visceral protection during the critical healing period.

Proven Sepra® Technology in a Low Profile, Lightweight Mesh

Efficient:
• Low profile design facilitates trocar deployment and mechanical fixation
• Easily cut to customize shape and size

Effective:
• Uncoated lightweight monofilament polypropylene allows for complete tissue ingrowth with a low percentage of contraction* for a strong repair
• Hydrogel barrier minimizes tissue attachment to the visceral side of the mesh
• Lightweight polypropylene mesh may lead to decreased patient discomfort*

Proven Technology:
• Hydrogel barrier is based on Sepra® Technology
• Lightweight monofilament polypropylene
• Both materials have been used in general surgery for years with demonstrated clinical success

* Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.
EFFECTIVE:

Minimal contraction shown in preclinical testing compared to a leading macroporous absorbable barrier mesh

At 4 weeks, VentraLight™ ST Mesh demonstrated 42% less area mesh contracture than a competitive macroporous absorbable barrier mesh. Results are statistically significant.*

VENTRALIGHT™ ST Mesh Preclinical Data with SORBAFix™ Absorbable Fixation System

Laparoscopic Incisional Hernia Repair with VentraLight™ ST Mesh:

At implant  
4 weeks post-op

Strong Tissue Incorporation

The open pore design of the uncoated monofilament polypropylene in VentraLight™ ST Mesh allows for:

- Fast tissue ingrowth
- Strong tissue incorporation into the abdominal wall
- A strong repair long-term repair

Uncoated polypropylene allows for the majority of tissue ingrowth and strength to occur in the first two weeks after placement of a composite hernia prosthesis.**

* Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.
** Based on a preclinical study of a composite polypropylene/ePTFE hernia repair mesh.
EFFICIENT:

Designed to Fit

- Multiple shapes (circle, oval, ellipse, rectangle)
- Sizes ranging from a 4.5” circle to 12” x 14” rectangle
- Customizable; the unique hydrogel barrier covers the edge of the mesh even after trimming

Easy Trocar Deployment

Low profile, lightweight design facilitates trocar deployment.

Secure Fixation

The SorbaFix™ Absorbable Fixation System provides secure fixation with Ventralight™ ST Mesh. Threaded hollow core allows for tissue ingrowth through interior of fastener.

* Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.
Sepramesh™ IP Composite – A Preclinical Study†

“120-Day Comparative Analysis of Adhesion Grade and Quantity, Mesh Contraction, and Tissue Response to a Novel Omega-3 Fatty Acid Biodegradable Barrier Macroporous Mesh After Intraperitoneal Placement”


Key Findings:
Sepramesh™ IP Composite resulted in 0% adhesion coverage, the lowest of all mesh products studied. (Table 1)

Table 1 - Adhesion Properties and Mesh Contraction

<table>
<thead>
<tr>
<th>Mesh Type</th>
<th>N</th>
<th>Adhesion Grade (1–4)</th>
<th>Adhesion Coverage (%)</th>
<th>Mesh Contraction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ProLite Ultra</td>
<td>12</td>
<td>1.7 ± 1.1</td>
<td>10.7 ± 19.8</td>
<td>9.1 ± 8.3</td>
</tr>
<tr>
<td>C-Qur</td>
<td>6</td>
<td>1.2 ± 0.4</td>
<td>3.0 ± 7.3</td>
<td>3.3 ± 2.1</td>
</tr>
<tr>
<td>Composix</td>
<td>10</td>
<td>1.9 ± 1.2</td>
<td>24.8 ± 37.0</td>
<td>7.2 ± 7.1</td>
</tr>
<tr>
<td>Dualmesh</td>
<td>10</td>
<td>1.3 ± 0.9</td>
<td>1.4 ± 4.4</td>
<td>39.0 ± 6.0</td>
</tr>
<tr>
<td>Parietex</td>
<td>6</td>
<td>1.2 ± 0.4</td>
<td>0.8 ± 2.0</td>
<td>14.7 ± 5.0</td>
</tr>
<tr>
<td>Proceed</td>
<td>6</td>
<td>2.8 ± 1.0</td>
<td>28.8 ± 16.1</td>
<td>29.7 ± 12.5</td>
</tr>
<tr>
<td>Sepramesh™ IP</td>
<td>6</td>
<td>1.0 ± 0.0</td>
<td>0.0 ± 0.0</td>
<td>6.4 ± 8.4</td>
</tr>
</tbody>
</table>

* Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

Ventralight™ Absorbable Barrier based on Sepra® Technology

- An extensively studied barrier with more than 10 publications and used clinically since 2007.
- Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.
- Biodegradable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.
- The hydrogel barrier resorbs within 30 days providing visceral protection during the critical healing period.

Sepramesh™ ST Mesh has the same absorbable barrier as Sepramesh™ IP Composite, but with a lightweight polypropylene mesh.

† Results may not correlate to performance in humans.
Monofilament Polypropylene Mesh

- Over 40 years of proven results in hernia repair
- “It is completely inert, resists infection and sinus tract formation, has rapid fibrinous fixation, becomes completely incorporated into the host tissue.”

PGA Fibers

- Biodegradable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh

Sepramesh™ IP Composite – A Clinical Study

A Single-Arm, Single-Center, Retrospective Study with Prospective Follow-Up of Laparoscopic Ventral Hernia Repair Utilizing the Bard Sepramesh™ IP Composite.

Andrew Archer, DO, Stephen Fleischer, DO, Rhett Lohman, DO, Edward Caldwell, DO. Grandview Medical Center, Dept. of Surgery, Dayton, OH.

Results - 90 patients, 3 year follow up

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernia Recurrence</td>
<td>1</td>
<td>1.1%</td>
</tr>
<tr>
<td>Postoperative Subxiphoid Hernia</td>
<td>1</td>
<td>1.1%</td>
</tr>
<tr>
<td>Mean Procedure Time (min)</td>
<td>41.4 ± 20.6</td>
<td></td>
</tr>
</tbody>
</table>

Two additional adverse events (seroma and abdominal pain) were also reported.

†Study was sponsored by C. R. Bard. Dr. Archer is a paid consultant for C. R. Bard.
Ventralight™ ST Mesh

Indications
Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

Contraindications
Do not use the Ventralight™ ST in infants or children whereby future growth will be compromised by use of such material. Do not use Ventralight™ ST Mesh for the reconstruction of cardiovascular defects. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

Warnings
Ensure proper orientation; the coated side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera. If an infection develops, treat the infection aggressively.

Adverse Reactions
Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

Please consult product package insert for more detailed safety information and instructions for use.

SorbaFix™ Absorbable Fixation System

Indications
The SorbaFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Contraindications
Contraindications associated with laparoscopic and open surgical procedures relative to mesh fixation apply including but not limited to:

• Fixation of vascular or neural structures
• Fixation of bone and cartilage
• Situations with insufficient in-growth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is resorbed.

Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera or bone. Use of the SorbaFix™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener is 6.0 mm, the fastener head is another 0.7 mm (total 6.7 mm).

Warnings
The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetic should be evaluated for compatibility prior to use. To prevent patient injury from the piloting tip, stay clear of vessels, nerves, bowel and viscera when entering the surgical site, manipulating tissue and fixing mesh. After use, the SorbaFix™ Absorbable Fixation System may be a potential biohazard. This device has a piloting tip, which should be considered a sharp even when the device is not actuated. Handle and dispose of in accordance with any local and federal laws regarding medical waste and sharps disposal requirements to prevent sharps injuries.

Adverse Reactions
Adverse reactions and potential complications associated with fixation devices such as the SorbaFix™ Absorbable Fixation System may include, but are not limited to the following: hemorrhage; pain, edema and erythema at wound site; allergic reaction to Poly (D, L)-lactide; sepsis/Septicemia/infection; hernia recurrence/wound dehiscence.