Ethicon provides comprehensive solutions to advance hernia repair

PROCEED® Surgical Mesh with macroporous, partially absorbable monofilament construction has been trusted by surgeons for more than 10 years

• Designed for strength and performance
  - Physically designed for strong and comfortable healing
  - Less foreign materials as well as bactericidal properties against bacteria commonly associated with SSI (MRSA, MRSE, VRE, and E. coli)
  - Can promote potentially improved abdominal wall mobility with less inflammation, tissue attachment, and potential pain when compared to polypropylene mesh
• Proven patient outcomes
  - In a study from the International Hernia Mesh Registry (IHMR), patients receiving laparoscopic hernia repair with PROCEED® Mesh reported significant improvement in pain and movement limitations from baseline at 12 months postsurgery
  - Results also showed low rates of complications (seromas/hematomas 10.5%, chronic discomfort 1.8%, urinary infection 1.1%) and hernia recurrence (3.5%) at 12-month follow-up

For more product information, go to www.ethicon.com

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

References:
7. PROCEED® Surgical Mesh. Instructions for Use. Ethicon, Inc.

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Introduction

What are key considerations in selecting a mesh for ventral hernia repair?

This guide discusses PROCEED® Surgical Mesh versus competitive tissue-separating meshes (TSMs) from Medtronic and Bard Davol Inc. TSMs (also called composite meshes) are composed of more than 1 material and are designed to:

• Promote tissue ingrowth/tissue integration
• Separate the mesh from internal viscera to reduce tissue attachment to the mesh

The TSMs mentioned in this guide all have a permanent component and an absorbable component.

Key considerations

• Mesh construction (eg, type of polymer, filament, absorbable barrier, pore size)
• Ease of use
• Biomechanical properties (eg, flexibility, tensile strength)
• Size of hernia defect
• Patient characteristics (eg, obesity, comorbidities)
• Proven patient outcomes and quality of life (QoL)

Impact of mesh fixation technique

In addition, adequate fixation and mesh overlap are critical to help prevent hernia recurrence.

Follow the product’s Instructions for Use. Permanent transfascial sutures may supplement absorbable straps, screws, or tacks, based on surgeon’s judgment.

PROCEED MESH

Preimplantation

Postabsorption

Absorbable resorbable oxidized cellulose (ORC) physically separates the mesh from underlying tissue and organs during the wound-healing process, while the nonabsorbable component remains for strong extended support.

PROCEED® Surgical Mesh

The first macroporous mesh with an absorbable tissue-separating barrier

• In an in vitro study, PROCEED Mesh demonstrated bacteriostatic properties against bacteria commonly found in surgical site infections (MRSA, MRSE, VRE, and E. coli)
• Blue stripes aid placement orientation
• Trusted by surgeons for more than 10 years

*Shown in an animal model.

An in vitro study (24 hour study with inoculum challenge in the range of 10^5-10^6 CFUs) demonstrated bacteriostatic properties of PROCEED Mesh against MRSA, MRSE, VRE, and E. coli.

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Medtronic

Symbotex™ Composite Mesh

3D monofilament polyester textile with absorbable, continuous, hydrophilic film

Parietex™ Optimized Composite Mesh

3D multifilament polyester mesh with absorbable collagen barrier

Bard Davol

Ventralight™ ST Mesh

Monofilament polypropylene with absorbable hydrogel barrier
Larger pore size is a key characteristic of macroporous, partially absorbable meshes

Pore size is the distance between mesh fibers. In meshes with a smaller pore size—less than 1 mm—the gaps between mesh fibers are not sufficient to prevent bridging of scar tissue.²

In meshes with a pore size greater than 1 mm, bridging of scar tissue is more likely to be avoided.

• Although a scar plate forms with all meshes, it will be less dense when there is less bridging
• After tissue integration, the scar is more flexible and causes less mesh sensation

Pore sizes and mesh densities are calculated following absorption of absorbable film or PGA acid (post implantation)

PROCEED® Surgical Mesh: medium-density (44 g/m²) PROLENE® Soft Polypropylene Mesh; Symbotex™ Composite Mesh: medium-density (66 g/m²) monofilament polyester; Parietex™ Optimized Composite Mesh: medium-density (90 g/m²) multifilament polyester; Ventralight™ ST Mesh: medium-density (64 g/m²) monofilament polypropylene.⁷,¹²

• Pore size is important in calculating porosity.
• Initial porosity is defined by the ratio of free surface to polymer surface.
• Porosity represents only the area of good pores after ingrowth.

Pore size is the distance between mesh fibers. In meshes with a smaller pore size—less than 1 mm—the gaps between mesh fibers are not sufficient to prevent bridging of scar tissue.²

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**Mesh construction**

**Materials**

**PROCEED® Surgical Mesh is a macroporous, partially absorbable, tissue-separating mesh**

**PROCEED Mesh** is distinctive:

- It combines large-pore mesh knitted with monofilament fibers with natural, absorbable tissue-separating technology.
- It may enable patients to heal more naturally with a strong, comfortable repair.

**Material composition of PROCEED Mesh**

1. PDS® (polydioxanone) Suture polymer film
2. PROLENE® Soft Polypropylene Mesh
3. PDS Suture polymer film
4. Oxidized regenerated cellulose (ORC) knitted fabric

The nonabsorbable polypropylene mesh side (parietal—indicated by the blue stripes) allows for tissue ingrowth, while the ORC* side (visceral) minimizes tissue attachment to the mesh by providing a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during wound healing.

**PROCEED Mesh post-op experience (rabbit model)**

- After implantation, although PROCEED Mesh came in contact with blood, it maintained its functional characteristics.
- At day 14, PROCEED Mesh was completely covered by a neoperitoneum.
- PROCEED Mesh adhesion and adhesion severity scores were:
  - Superior to polypropylene mesh and numerically better than Sepramesh™.
  - Similar to Bard Composix™ and GORE® DUALMESH®.

**PROCEED Mesh inhibits the growth of bacteria commonly associated with surgical site infections**

ORC is known to produce acidic pH, and a lower pH is a physiological detriment to the survival of microorganisms.

In an in vitro study, PROCEED Mesh demonstrated bacteriostatic properties against bacteria commonly found in surgical site infections (MRSA, MRSE, VRE, and E. coli). *An in vitro study (24 hour study with inoculum challenge in the range of 10⁵-10⁶ CFU’s) demonstrated bacteriostatic properties of PROCEED Mesh against MRSA, MRSE, VRE, and E. coli.*
TSMs vary in their strength profile
Adequate strength is necessary in a mesh to provide a durable repair with potentially improved patient comfort and reduced complications. Commonly used meshes vary in their tensile strength due to differences in density, pore size, and textile structure.2,3

PROCEED® Surgical Mesh is physiologically designed for strong and comfortable healing1,6,13,14

Biomechanical properties

• In a study of patients from the International Hernia Mesh Registry (IHMR), on average those receiving hernia repair with PROCEED Mesh reported significant improvement in pain and movement limitations from baseline at 12 months postsurgery.3†

Comparison of maximum intra-abdominal pressure in healthy adults with mesh burst strength6,13*

<table>
<thead>
<tr>
<th>Activity</th>
<th>Pressure (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing</td>
<td>27</td>
</tr>
<tr>
<td>Bench press</td>
<td>34</td>
</tr>
<tr>
<td>Valsalva</td>
<td>64</td>
</tr>
<tr>
<td>Coughing</td>
<td>127</td>
</tr>
<tr>
<td>Jumping</td>
<td>252</td>
</tr>
</tbody>
</table>

PROCEED Mesh gives patients the reassurance of a strong repair

Patient outcomes and quality of life

Ethicon—a vision to advance hernia repair
The Ethicon-sponsored IHMR is a large international data registry with a vision to advance hernia repair. The IHMR provides prospective, longitudinal, patient-reported data on ventral (primary, incisional) and inguinal hernia repairs for more than 4300 patients and reflects patient outcomes as seen in clinical practice. The registry includes Ethicon and non-Ethicon products.5

• The IHMR uses the Carolinas Comfort Scale®, a validated, hernia-specific QoL tool for assessing early and long-term symptoms following hernia repair6
• IHMR data are independently collected and managed by a third party6

Low rate of recurrence in an IHMR laparoscopy study3
PROCEED Mesh delivered a strong and durable repair for up to 1 year postsurgery and had a low rate of recurrence (1.3%) in 157 patients undergoing hernia repair.7

In the same study, PROCEED Mesh significantly improved patient comfort at 1 year postsurgery versus presurgery4

Advanced pain management

Patient-reported symptomatic pain at baseline and 12 months postoperatively

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Preoperative</th>
<th>12 months postoperatively</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change from baseline</td>
<td>-0.66 (1.16SD) P&lt;0.001</td>
<td>-0.64 (1.27) P&lt;0.001</td>
</tr>
</tbody>
</table>

Mean pain score and 95% confidence interval

<table>
<thead>
<tr>
<th>Change from baseline</th>
<th>Preoperative</th>
<th>1 month postoperative</th>
<th>6 months postoperative</th>
<th>12 months postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative</td>
<td>12 months postoperative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Strength requirements may not be the same in certain patient populations, such as those who are obese.
†Data from a prospective, longitudinal study of 157 patients receiving laparoscopic hernia repair using PROCEED® Mesh from the IHMR. Hernia types repaired included incisional ventral (75.1%), epigastric (5.1%), umbilical (18.5%) and trocar (1.3%). 77.7% (n=122) were primary repairs.
Observational results in obese and nonobese patients

A 2011 retrospective analysis of data from 86 obese and nonobese patients who underwent hernia repair using PROCEED® Surgical Mesh demonstrated equivalent rates of recurrence.\(^*\)

In a multicenter observational study from 2004 to 2006, PROCEED® Surgical Mesh was evaluated in 114 patients (mean age 45 years) who underwent a laparoscopic ventral hernia repair. The mean follow-up period was 27 months.\(^1\)

- There were no major complications related to the mesh.\(^2\)
- Surgeons identified these advantages with PROCEED Mesh in performing laparoscopic hernia repair:\(^1\)
  - Good compliance
  - Excellent laparoscopic handling characteristics
  - Good local tolerance

• According to the investigators, the equivalent recurrence rates between the obese and nonobese populations in this study indicated that PROCEED Mesh possesses adequate strength for use in obese patients.\(^1\)

### Laparoscopic ventral hernia repair

In a multicenter observational study from 2004 to 2006, PROCEED® Surgical Mesh was evaluated in 114 patients (mean age 45 years) who underwent a laparoscopic ventral hernia repair. The mean follow-up period was 27 months.\(^1\)

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#### Surgery results

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean hernia defect size</td>
<td>24 cm(^2) (range 2.25–256 cm(^2))</td>
</tr>
<tr>
<td>Mean mesh size used</td>
<td>306 cm(^2) (range 100–875 cm(^2))</td>
</tr>
<tr>
<td>Major intraoperative complications or organ damage</td>
<td>None</td>
</tr>
<tr>
<td>Severe bleeding</td>
<td>None</td>
</tr>
<tr>
<td>Conversions to open repair or death</td>
<td>None</td>
</tr>
</tbody>
</table>

#### Postoperative complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seroma/hematoma</td>
<td>12 (14.0%)</td>
</tr>
<tr>
<td>Chronic pain (&gt;6 months)</td>
<td>2 (1.8%)</td>
</tr>
<tr>
<td>Recurrence</td>
<td>4 (3.5%)</td>
</tr>
<tr>
<td>Urinary Retention</td>
<td>1 (0.9%)</td>
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\(^*\)A retrospective analysis to compare the recurrence rate in obese (n=31) and nonobese (n=47) patients who underwent laparoscopic repair of hernias using PROCEED Mesh. Two obese patients and 6 nonobese patients underwent open technique hernia repair. Transfascial sutures and staples were used in tandem with the double crown technique.

\(^{†}\)There were no recurrences in the 23 patients with BMI \(\geq\) 32.

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\(^{‡}\)Three of the patients who had recurrences had a second laparoscopic procedure with an extra sheet using PROCEED Mesh without further complications.

Procedures covered in this study include primary hernia repairs (umbilical, epigastric, and Spigel) and incisional hernia repairs. Both tacks and transfascial sutures were used according to the surgeon’s preference.