GORE DUALMESH® and GORE DUALMESH® PLUS BIOMATERIALS

Comparison to a Polypropylene/ePTFE Composite
Not all ePTFE is GORE ePTFE

• “The methods of manufacturing the ePTFE differ between the [GORE DUALMESH® Biomaterial] and Composix...”¹

GORE DUALMESH® BIOMATERIAL

5100x 3 μm

Ingrowth-resistant side of GORE DUALMESH® Biomaterial with porosity of <3 μm.

BARD® COMPOSIX® Mesh

5100x 3 μm

The ePTFE structure of BARD® COMPOSIX® Mesh is more open.

BARD® COMPOSIX® E/X Mesh

- Holes created in the ePTFE portion of BARD® Composix® E/X Mesh, by a tack, exposing the polypropylene mesh.

“Although exposed PP formed the most adhesions, up to 40% of the other PP-based meshes formed adhesions despite protective barriers.”

Clinical Evaluation

- **GORE DUALMESH® Biomaterial and GORE DUALMESH® PLUS Biomaterial** – studied extensively for over 12 years

### Laparoscopic Ventral Hernia Repair: Clinical Performance Reported in Literature

<table>
<thead>
<tr>
<th>Pooled Data from all Studies</th>
<th>Recurrence Rate</th>
<th>Infection</th>
<th>Fistula</th>
<th>Erosion</th>
<th>Seroma</th>
<th>Ileus</th>
<th>Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>GORE DUALMESH® Biomaterials and GORE DUALMESH® PLUS Biomaterials (n = 3151)*</td>
<td>4.3%</td>
<td>1.1%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>3.9%</td>
<td>2.5%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>


* Data based on an analysis of current literature: several Medline searches were performed to identify publications pertaining to ePTFE synthetic patches. Search criteria included (1) articles published from January 1998 through June 2007, (2) key words used were GORE-TEX®, DUALMESH®, hernia, ventral, laparoscopic, human, ePTFE, (3) articles in English language, (4) N equal to or greater than 10 hernia repairs, (5) clinical publications, (6) case reports were excluded, (7) studies which included multiple ePTFE patches were identified and percent use with GORE DUALMESH® Biomaterial were reported in study details. Articles that did not meet the above criteria were not included in this analysis.
Clinical Evaluation

Vascularity – GORE DUALMESH® Biomaterial

A laparoscopic photograph of the GORE DUALMESH® Biomaterial implanted for 16 months
Clinical Evaluation

Vascularity – GORE DUALMESH® Biomaterial

Follow-up picture of GORE DUALMESH® Biomaterial, with new vascularized mesothelium layer.

Courtesy of Dr. Karl LeBlanc
Clinical Evaluation

BARD® Composix® Kugel Hernia Mesh – Potential Complications

“The ePTFE/PP group (Composix) had statistically significant higher rates of adhesions formation than did the [GORE DUALMESH® Biomaterial]. ... Between the Composix and [GORE DUALMESH® Biomaterial], a difference in the manufacturing of the ePTFE must play a role.”1

Potential Complications

BARD® Composix® Kugel Hernia Mesh – Potential Complications

• “The proposed benefit of reduced adhesions to ePTFE is obviously lost when the PP becomes exposed.”¹

• “In each episode of infected Composix mesh, there was no incorporation of the ePTFE component, but there was dense adherence of the polypropylene mesh to the abdominal wall as well as adhesions to bowel.”¹

• “. . .appeared to be a heavyweight polypropylene/polytetrafluoroethylene (PTFE) composite mesh. The adhesions seemed denser at point fixation sites and at the edges, where some rolling of the mesh allowed the polypropylene side to be exposed.”²

• “Contraction of the polypropylene portion of the mesh is usually greater than the ePTFE side. This can lead to fluting or rolling of the mesh edge, exposing polypropylene to viscera.”²

• “It was discovered that the entire prosthesis was covered with dense adhesions of the small bowel and the omentum.”³

Thank You