Facts Not Fiction

Learn the facts about GORE® DUALMESH® Biomaterial
GORE® DUALMESH® Biomaterial

GORE® DUALMESH® Biomaterial is a soft, conformable, expanded Polytetrafluoroethylene (ePTFE), material that offers a unique, two-surface design intended for such applications as certain hernia and soft tissue reconstructions, and in temporary bridging of fascial defects. The biomaterial features two functionally distinct surfaces: the textured CORDUROY Surface encourages host tissue incorporation while the smooth surface minimizes tissue attachment to the material.

Gore Medical Products Division provides creative solutions to complex medical products, general surgery solutions and surgical meshes. The GORE® DUALMESH® PLUS Biomaterial is the only two-surface hernia repair material with antimicrobial technology for controlling potential operative contamination of the material.

GORE® DUALMESH® Biomaterial demonstrates dependable clinical performance that is RELIABLE.

For additional product information, please visit goremedical.com, telephone, 800.528.8763 or send an e-mail to generalmedicalproducts@wlgore.com.
**Fact #1  Strength (STRONG)**

Strength is an obvious concern when performing a structural repair such as bridging a fascial defect in ventral hernia repair. Based upon the samples tested, GORE® DUALMESH® Biomaterial has a statistically higher abdominal wall surface tension than either Parietex™ composite or PHYSIOMESH™ mesh, which is above the clinically derived strength requirement.

![Surface Tension, N/cm](image)

Based upon the samples tested, GORE® DUALMESH® Biomaterial has a statistically higher abdominal wall surface tension than either Parietex™ composite or PHYSIOMESH™ composite mesh, which is above the clinically derived strength requirement of 32 N / cm.¹ ² ³

Any absorbable barriers were removed prior to testing simply by soaking the devices in water in order to assess long-term strength.

---


Fact #2  Proven Visceral Protection (PROVEN)

The visceral side of GORE® DUALMESH® Biomaterial minimizes tissue attachment while supporting the formation of a neoperitoneal surface. A multi-institutional reoperative study reported the following regarding GORE® DUALMESH® Biomaterial implanted intraperitoneally:

1. No severe adhesions were found
2. 91% of patients had either no or filmy avascular adhesions
3. Even in patients with a possible tendency to form adhesions, GORE® DUALMESH® Biomaterial serves to minimize such formation to the material.

Fact #3 Unique Antimicrobial Technology (RESILIENT)

GORE® DUALMESH® PLUS Biomaterial is the only two-sided, prosthetic material with antimicrobial agents (chlorhexidine and silver) that act synergistically to inhibit microbial colonization of, and resist initial biofilm formation on, the biomaterial for up to 14 days post implantation.

The graph shows the percentage of MRSA adherence to various materials. GORE® DUALMESH® PLUS Biomaterial is statistically significant in ability to reduce bacterial adherence relative to all other tested devices.¹

---

**Fact #4 Proven Ingrowth (INGROWTH)**

All of GORE® DUALMESH® Biomaterial products have the patented CORDUROY Surface to encourage rapid fixation and tissue ingrowth. Animal testing has demonstrated the ingrowth through tensiometer testing which found that GORE® DUALMESH® Biomaterial had significantly greater attachment strength than polypropylene ($p=0.02$). In addition, histologic studies indicated that this was due to cellular ingrowth.¹

Furthermore, in a separate long-term animal study, the authors demonstrated no difference in ingrowth among various meshes including GORE® DUALMESH® Biomaterial.²

---


Fact #5 Low Infection (DEPENDABLE)

The treatment of ventral hernias with prosthetic devices has reduced recurrence rates but has led to questions concerning infection. Open hernia repair has been associated with infection rates from 3% to 18%.\(^1\)

Laparoscopic ventral hernia repair has been associated with lower incidence of infection. In the largest series with GORE® DUALMESH® Biomaterial of patients to date, the infection rate was shown to be 0.7%.\(^2\)

Furthermore, in clean-contaminated procedures such as stomal hernias, ePTFE has been extensively used with acceptable clinical outcomes.\(^3,4,5,6\) In a study of 25 patients with stomal hernias, only 1 patient developed a mesh infection necessitating removal.\(^4\)

In addition, a recent case report has shown excellent results for continuous ambulatory peritoneal dialysis (CAPD) in a patient with a prior ventral hernia repair with ePTFE.\(^7\)

Finally, recent studies have shown successful treatment of infected GORE® DUALMESH® Biomaterial with a percutaneous lavage method.\(^8,9\)

**Fact #6 Minimal Contraction (DURABLE)**

All biomaterials, including polypropylene, polyester, and ePTFE, will contract to some degree after implantation due to the activity of myofibroblasts during wound healing. Gore’s ePTFE patches are soft and supple and mimic normal wound shrinkage and collagen alignment.

In the only human clinical studies to date, GORE® DUALMESH® Biomaterial has been shown to have a mean shrinkage of 7-8%.$^{1,2}$

---


---

*Colored line on CT represents measurement using AquariusNET™ Software program. Figures 1 and 2 from P.R. Carter *et al.*: *Hernia* (2012) 16: 321-325*
Fact #7 Industry Leader (LEADER)

GORE® DUALMESH® Biomaterial is indicated for use in the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. Both GORE® DUALMESH® Biomaterial and GORE® DUALMESH® PLUS Biomaterial have been successfully used in a wide range of applications. The clinical reputation of GORE® DUALMESH® Biomaterial products for the repair and reconstruction of ventral hernias is well known, exceeding 150 peer-reviewed scientific articles published since 1996 and more than 19 years of clinical history. When a strong, durable repair is needed, GORE® DUALMESH® Biomaterial has the proven performance.

Laparoscopic Ventral Hernia Repair: Clinical Performance Reported in Literature

<table>
<thead>
<tr>
<th></th>
<th>GORE® DUALMESH® Biomaterials and GORE® DUALMESH® PLUS Biomaterials (n=3756)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence</td>
<td>4.0%</td>
</tr>
<tr>
<td>Infection</td>
<td>1.1%</td>
</tr>
<tr>
<td>Fistula</td>
<td>0.0%</td>
</tr>
<tr>
<td>Erosion</td>
<td>0.0%</td>
</tr>
<tr>
<td>Seroma</td>
<td>4.7%</td>
</tr>
<tr>
<td>Ileus</td>
<td>2.3%</td>
</tr>
<tr>
<td>Pain</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

As Compared to:

<table>
<thead>
<tr>
<th></th>
<th>Open Primary (no mesh)</th>
<th>Open with Mesh</th>
<th>Polyester Mesh</th>
<th>Polypropylene Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence</td>
<td>Up to 51%*</td>
<td>10-24%*</td>
<td>34%</td>
<td>15%</td>
</tr>
<tr>
<td>Infection</td>
<td>N/R</td>
<td>5-10%*</td>
<td>16%</td>
<td>5%</td>
</tr>
<tr>
<td>Fistula</td>
<td>N/R</td>
<td>N/R</td>
<td>16%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

N/R – Not reported in literature


* Data on file
Size Chart (SIZE CHART)

Sizes Available

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>1 mm Nominal Thickness</th>
<th>2 mm Nominal Thickness</th>
<th>Nominal Width x Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>1DLMC02</td>
<td>–</td>
<td>–</td>
<td>8 cm x 12 cm</td>
</tr>
<tr>
<td>1DLMC03</td>
<td>1DLMC200</td>
<td>–</td>
<td>10 cm x 12 cm</td>
</tr>
<tr>
<td>1DLMC04</td>
<td>1DLMC201</td>
<td>–</td>
<td>15 cm x 19 cm*</td>
</tr>
<tr>
<td>1DLMC05</td>
<td>–</td>
<td>1DLMC201</td>
<td>7.5 cm x 10 cm*</td>
</tr>
<tr>
<td>1DLMC06</td>
<td>1DLMC202</td>
<td>–</td>
<td>18 cm x 24 cm</td>
</tr>
<tr>
<td>1DLMC07</td>
<td>1DLMC203</td>
<td>–</td>
<td>20 cm x 30 cm</td>
</tr>
<tr>
<td>1DLMC08</td>
<td>1DLMC204</td>
<td>–</td>
<td>26 cm x 34 cm*</td>
</tr>
<tr>
<td>1DLMC09</td>
<td>–</td>
<td>–</td>
<td>12 cm**</td>
</tr>
</tbody>
</table>

* Oval Shaped ** Round

Remember GORE-TEX® Suture: The Perfect Close to Your Soft Tissue Repairs

Commonly Requested GORE-TEX® Sutures for Ventral Hernia Repairs

<table>
<thead>
<tr>
<th>Thread Size</th>
<th>Needles</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV-0</td>
<td>THX-36</td>
<td>OU07</td>
</tr>
<tr>
<td>CV-2</td>
<td>TH-50</td>
<td>OU01</td>
</tr>
<tr>
<td>CV-2</td>
<td>TH-26</td>
<td>2NO2</td>
</tr>
<tr>
<td></td>
<td>THX-26</td>
<td>2NO5, 2NO6, 2UO5</td>
</tr>
</tbody>
</table>

Suture Passer Instrument

<table>
<thead>
<tr>
<th>Catalogue Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1GSP01</td>
<td>One Complete Unit</td>
</tr>
<tr>
<td>1GSP01</td>
<td>Three Replacement Needle/Sleeves</td>
</tr>
</tbody>
</table>
For additional product information, visit: goremedical.com,
Telephone: 800.528.8763, or
E-mail: generalmedicalproducts@wlgore.com

W. L. GORE & ASSOCIATES, INC.
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

Refer to Instructions For Use for a complete description of all warnings, precautions, and contraindications.

Products listed may not be available in all markets.

MARLEX and COMPOSIX are trademarks of C.R. Bard, Inc.
PHYSIOMESH, ULTRAPRO, and VYPRO are trademarks of Ethicon, Inc.
PARIETEX is a trademark of Covidien AG or its affiliates.
TiMesh is a trademark of GFE Medical LLC.

AquariusNET™ is a trademark of TeraRecon, Inc.

GORE®, GORE-TEX®, CORDUROY, DUALMESH®, DUALMESH® PLUS,
PERFORMANCE THROUGH EXPERIENCE and designs are trademarks of W. L. Gore & Associates.

©2012 W. L. Gore & Associates, Inc. AP6261-EN1 JUNE 2012