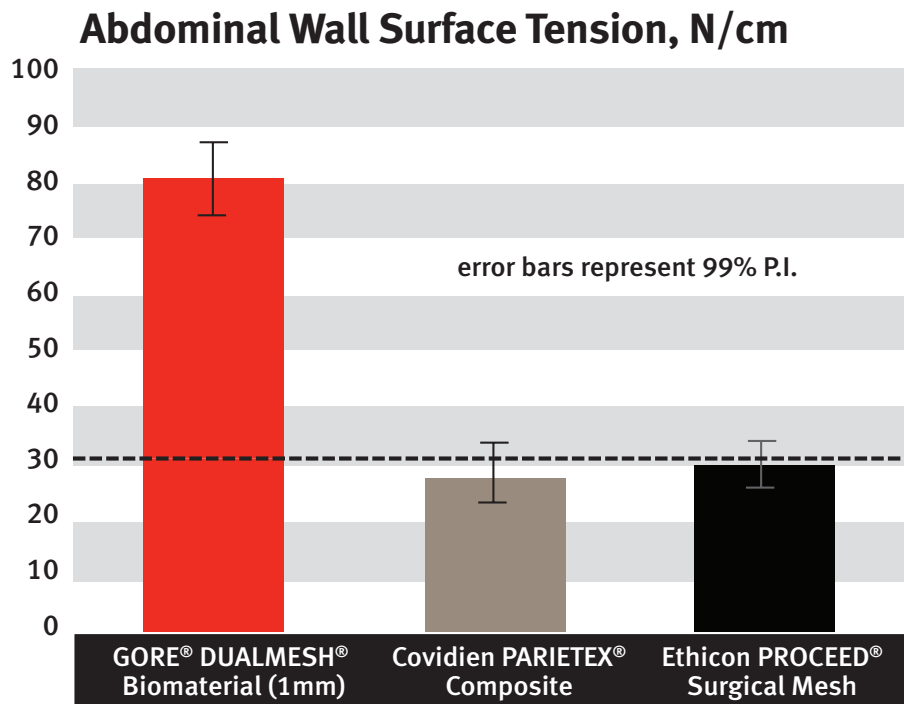


# Strength You Can Rely On

IN VENTRAL HERNIA REPAIR



## GORE® DUALMESH® Biomaterial



Based upon the samples tested, GORE® DUALMESH® Biomaterial has a statistically higher abdominal wall surface tension than either PARIETEX® composite or PROCEED® mesh\*, which is above the clinically calculated strength requirement of 32 N/cm<sup>1,2,3</sup>. The absorbable barriers were removed prior to testing simply by soaking in water in order to assess long term strength.

- **Strength**
- **Long-Term Performance**
- **Unique Antimicrobial Technology**



**PERFORMANCE**  
through experience

\* Data on File

## Strength

Strength is an obvious concern when performing a structural repair such as bridging a fascial defect in ventral hernia repair. This has become critical as patient BMIs continue to increase. A biomaterial must be able to serve its intended use over the life of the patient without degradation or loss in strength.

The strength requirement for intraperitoneal ventral hernia repair has been suggested in the literature as having an abdominal wall surface tension of 32 N/cm<sup>1,2,3</sup>. ASTM D3786-8<sup>4</sup> was used to measure the burst strength and deformation of meshes. This information, in conjunction with non-spherical membrane deformation models, can be used to calculate the surface tension of several hernia materials.

## Long-Term Performance

Long-term mesh performance is critical to a durable repair, but the physiologic environment provides a challenge to materials susceptible to common chemical reactions like hydrolysis and oxidation. Polyester under physiological conditions can hydrolyze over time leading to a change in properties including loss of strength. An in-vivo study on polyester grafts demonstrated a 30% loss of strength within 10 years<sup>5</sup>. Polypropylene has been shown to oxidize over time resulting in degradation of the polymer in-vivo<sup>6</sup>. PTFE, however, is not susceptible to either hydrolysis or oxidation due to the strong chemical bonds that make up the molecular structure. PTFE contains carbon-carbon and carbon-fluorine bonds (C-C, C-F) which require high levels of radiation or thermal energy in order to degrade them<sup>7</sup>; these levels exceed normal therapeutic exposures.

## Unique Antimicrobial Technology

Many surgeons agree that the use of a prosthetic material with antimicrobial preservatives is sound medical practice. Gore has combined an innovative surgical biomaterial with two antimicrobial preservative agents, silver carbonate and chlorhexidine diacetate to create GORE® DUALMESH® PLUS Biomaterial.

The two antimicrobial preservatives act synergistically to inhibit microbial colonization of the device and resist initial biofilm formation on the device for up to 14 days post implantation. Zone-of-inhibition bioassays have found that this device has substantial preservative activity, and is effective against MRSA.

## Summary

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 for the repair and reconstruction of ventral hernias is well known, exceeding 150 peer-reviewed scientific articles published since 1996 and more than 14 years of clinical history. When a strong, durable repair is needed, GORE® DUALMESH® Biomaterial has the proven performance.

## References

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**CONTRAINDICATIONS:** Patients with hypersensitivity to chlorhexidine or silver; reconstruction of cardiovascular defects; reconstruction of central nervous system or peripheral nervous system defects; pre-term and neonatal populations.

**WARNINGS:** Use with caution in patients with methemoglobinopathy or related disorders. When used as a temporary external bridging device, use measures to avoid contamination; the entire device should be removed as early as clinically feasible, not to exceed 45 days after placement. When unintentional exposure occurs, treat to avoid contamination or device removal may be necessary. Improper positioning of the smooth non-textured surface adjacent to fascial or subcutaneous tissue will result in minimal tissue attachment.

**POSSIBLE ADVERSE REACTIONS:** Contamination, infection, inflammation, adhesion, fistula formation, seroma formation, hematoma and recurrence.



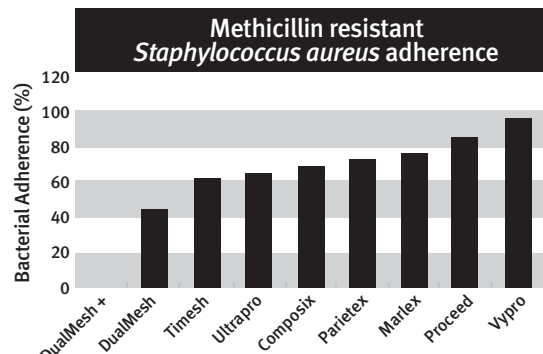
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The graph shows the percentage of MRSA adherence to various materials. GORE® DUALMESH® PLUS Biomaterial is statistically significant in ability to reduce bacterial adherence relative to all other materials.<sup>8</sup>