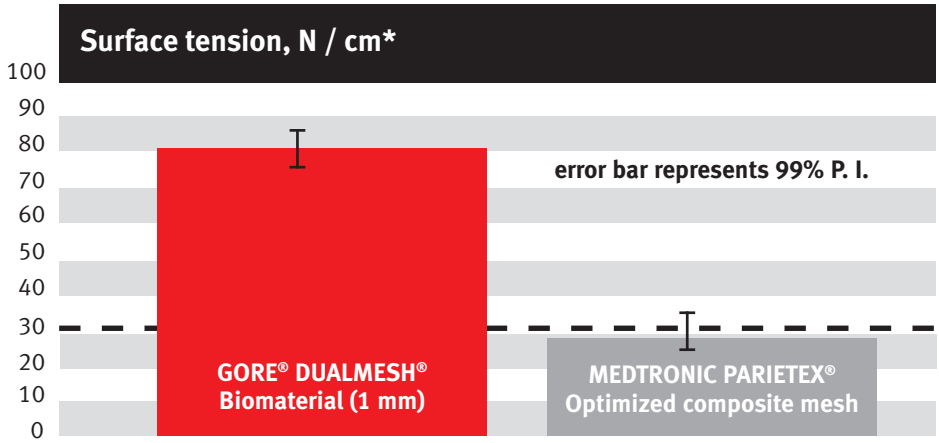
STRENGTH you can rely on

In hernia and soft tissue deficiency repairs

GORE® DUALMESH® Biomaterial has a material **STRENGTH** which is more than two times as strong as the clinically derived strength requirement.



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 MEDTRONIC PARIETEX® Optimized composite mesh, which is above the clinically derived strength requirement of 32 N / cm.[1–3]

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

Strength

Long-term performance

Industry leader

* Data on file 2020; W.L Gore & Associates, Inc; Flagstaff, AZ.

Strength

Strength is an obvious concern when performing a structural repair such as bridging a fascial defect in ventral / incisional hernia repairs or in complex parastomal and diaphragmatic herina repairs or chest wall reconstructions. This has become critical as patient BMIs continue to increase. A biomaterial must be able to serve its intended use over time 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.[1–3] ASTM D3786-8[4] 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.[5] Polypropylene has been shown to oxidize over time resulting in degradation of the polymer in-vivo.[6] 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[7]; these levels exceed normal therapeutic exposures.

Industry leader

The clinical reputation of GORE® DUALMESH® Biomaterial products for the repair and reconstruction of hernias and soft tissue deficiencies is well known, exceeding 450 peer reviewed scientific articles published since 1996 and over 20 years of clinical history.

When a strong, durable repair is needed, GORE® DUALMESH® Biomaterial has the proven performance.[8–10]

Summary

The GORE® DUALMESH® Biomaterial is a dual-surface mesh comprised of a non-absorbable patch constructed entirely of expanded polytetrafluoroethylene (ePTFE) material. The smooth visceral surface is designed to minimize tissue attachment. The textured parietal GORE CORDUROY Surface is designed to encourage host tissue incorporation. The GORE® DUALMESH® Biomaterial is designed for intraperitoneal placement. It is ideal for use in the reconstruction of certain hernias and soft tissue deficiencies.

For complete information regarding indications for use, contraindications, warnings, precautions, adverse reactions and instructions for use see the published *Instructions for Use* (IFU) found on the eifu.goremedical.com website for your region.

1. Klinge U, Klosterhalfen B, Conze J, *et al.* Modified mesh for hernia repair that is adapted to the physiology of the abdominal wall. *European Journal of Surgery* 1998;164(12):951-960.
2. Junge K, Klinge U, Prescher A, Giboni P, Niewiera M, Schumpelick V. Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants. *Hernia* 2001;5(3):113-118.
3. Song C, Alijani A, Frank T, Hanna GB, Cuschieri A. Mechanical properties of the human abdominal wall measured in vivo during insufflation for laparoscopic surgery. *Surgical Endoscopy* 2006;20(6):987-990.
4. ASTM Standard D3786-08. *Standard Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method.* ASTM International, West Conshohocken, PA, 2008, DOI: 10.1520/D3786-08.
5. Riepe G, Loos J, Imig H, *et al.* Long-term in vivo alterations of polyester vascular grafts in humans. *European Journal of Vascular & Endovascular Surgery* 1997;13(6):540-548.
6. Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. *Journal of Biomedical Materials Research. Part B: Applied Biomaterials* 2007;83B(1):44-49.
7. Boyce B. Physical characteristics of expanded polytetrafluoroethylene grafts. In: Stanley JC, ed. *Biologic and Synthetic Vascular Prostheses.* Philadelphia, PA: Grune and Stratton; 1982;33:553-561.
8. LeBlanc KA. Incisional hernia repair: laparoscopic techniques. *World Journal of Surgery* 2005;29(8):1073-1079.
9. Fabian TC, Croce MA, Pritchard FE, *et al.* Planned ventral hernia. Staged management for acute abdominal wall defects. *Annals of Surgery* 1994;219(6):643-650.
10. Leber GE, Garb JL, Alexander AI, Reed WP. Long-term complications associated with prosthetic repair of incisional hernias. *Archives of Surgery* 1998;133(4):378-382.

Consult Instructions for Use
eifu.goremedical.com

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.
MEDTRONIC and PARIETEX are trademarks of Medtronic, Inc.
GORE, DUALMESH and designs are trademarks of W. L. Gore & Associates.
 AP2951-EN3 JUNE 2020

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65 67332882 (Asia Pacific)
1800 680 424 (Australia / New Zealand)
00800 6334 4673 (Europe)
800 437 8181 (United States)
928 779 2771 (United States)

goremedical.com