Review the Data. Learn the Facts.

GORE® DUALMESH® Biomaterial
dependable clinical performance
that is RELIABLE

GORE

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

The success of more than 30 million clinical implants is evidence of the quality of Gore Medical Products. Our **innovative, expanded polytetrafluoroethylene (ePTFE) based products** have demonstrated superior biocompatibility and inertness in a wide range of applications, including: Cardiothoracic, vascular and endovascular surgery, neurosurgery, hernia repair and thoracic reconstruction.

GORE® DUALMESH® Biomaterial is a soft, conformable, material that offers a unique, two-surface design intended for such applications as certain hernia and soft tissue reconstructions. The GORE® DUALMESH® Biomaterial is comprised of a non-absorbable patch constructed entirely of ePTFE material. The smooth visceral surface possesses an average pore size of < 3 µm designed to minimize tissue attachment. The textured parietal GORE CORDUROY Surface possesses a node and fibril structure (*Figure 1*) with a 17–22 µm average pore size designed to encourage host tissue incorporation. The GORE® DUALMESH® Biomaterial is designed for intraperitoneal placement.

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

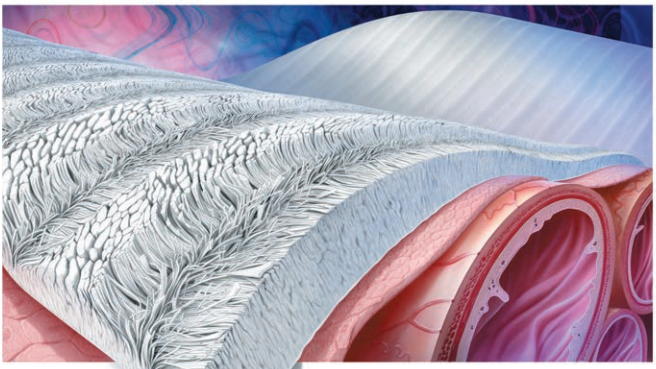
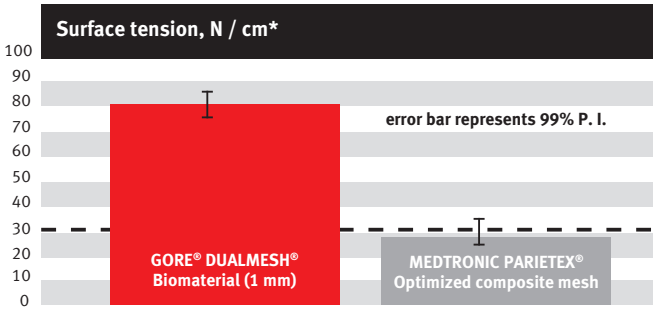


Figure 1: Node and fibril structure of GORE® DUALMESH® Biomaterial

Fact #1 — Strength

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]

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



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

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

MEDTRONIC and PARIETEX are trademarks of Medtronic, Inc.

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.

Fact #2 — Proven visceral protection

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
- 91 percent of patients had either no adhesions or filmy avascular adhesions
- Even in patients who had previously formed adhesions to other mesh, GORE® DUALMESH® Biomaterial served to minimize such formation to the material

Visceral protection is clinically PROVEN

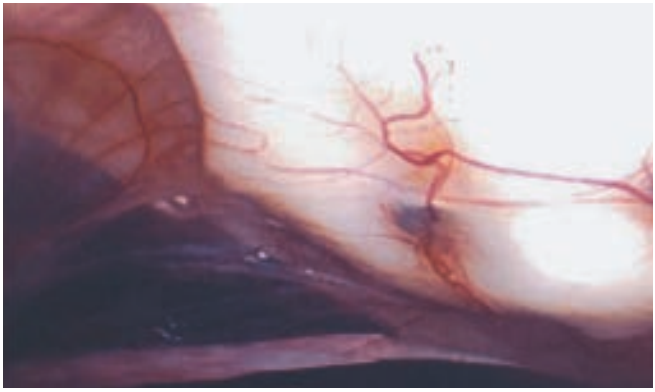


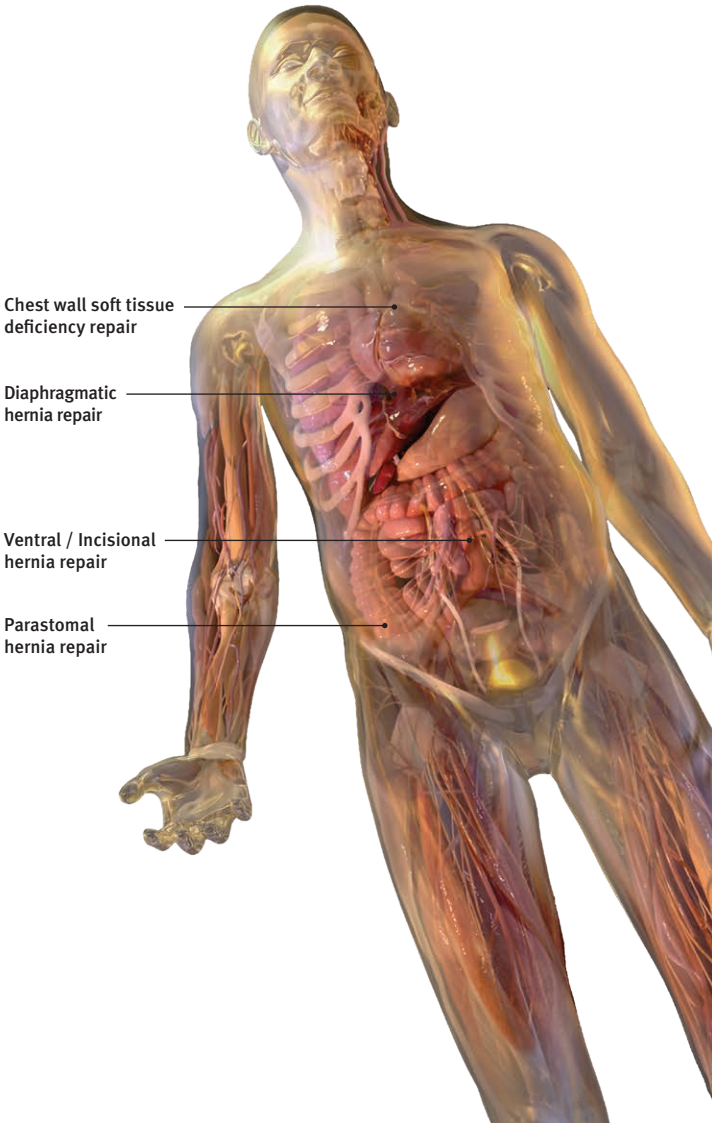
Photo courtesy of Karl A. LeBlanc, M.B.A., M.D., F.A.C.S. © 2005

1. Koehler RH, Begos D, Berger D, *et al.* Minimal adhesions to ePTFE mesh after laparoscopiventral incisional hernia repair: reoperative findings in 65 cases. *Journal of the Society of Laparoendoscopic Surgeons* 2003;7(4):335-340.

Fact #3 — Clinical evidence by application

GORE® DUALMESH® Biomaterial has been successfully used in a range of applications. These materials are well known for their successful use in the repair and reconstruction of ventral hernias. In addition, these devices are commonly used for parastomal hernia repairs, diaphragmatic hernia repairs and chest wall reconstruction of soft tissue deficiencies.

With **EVIDENCE**, including extensive literature support and long clinical history, GORE® DUALMESH® Biomaterial is a compelling choice for hernia and soft tissue deficiency repairs.



Fact #3 — Clinical evidence by application

Ventral / Incisional hernia repair	
Study type	Prospective, multicenter database
Authors / Journal	Sánchez LJ, Piccoli M, Ferrari CG, *et al*. Laparoscopic ventral hernia repair: results of a two thousand patients prospective multicentric database. *International Journal of Surgery* 2018;51:31-38.
Highlighted data	1,979 patients, 24-months follow-up
Facts	• 18.8% of patients had a previous failed open repair • Reoperation needed 1.8% (n = 38) • Recurrence rate 3.8% (n = 62) • Prolonged seroma 4.1% (n = 83) • Mesh infection 0% (n = 1)

Parastomal hernia repair	
Study type	Retrospective study
Authors / Journal	Hansson BM, Morales-Conde S, Mussack T, Valdes J, Muysoms FE, Bleichrodt RP. The laparoscopic modified Sugarbaker technique is safe and has a low recurrence rate: a multicenter cohort study. *Surgical Endoscopy* 2013;27(2):494-500.
Highlighted data	61 patients, 26-months follow-up
Facts	• Laparoscopic parastomal hernia repair with modified Sugarbaker technique • Recurrence rate 6.6% (n = 4) • Re-intervention 3.3% (n = 2) • Wound infection 1.6% (n = 1)

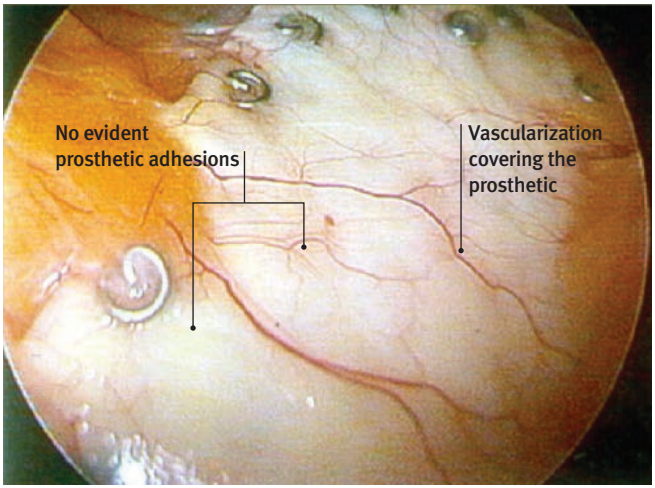
Diaphragmatic hernia repair	
Study type	Retrospective, cohort study
Authors / Journal	Tsai J, Sulkowski J, Adzick NS, Hedrick HL, Flake AW. Patch repair for congenital diaphragmatic hernia: is it really a problem?. *Journal of Pediatric Surgery* 2012;47(4):637-641.
Highlighted data	99 patients, 24 months follow-up
Facts	• Pediatric large diaphragmatic hernia repair • Recurrence rate 5.4% (n = 4) • Recurrence not requiring revision 2.7% (n = 2), • Bowel obstruction 2.7% (n = 2)

Chest wall soft tissue deficiency repair	
Study type	Retrospective, case series
Authors / Journal	Nagayasu T, Yamasaki N, Tagawa T, *et al*. Long-term results of chest wall reconstruction with DualMesh. *Interactive CardioVascular & Thoracic Surgery* 2010;11(5):581-584.
Highlighted data	11 patients, 23-months follow-up
Facts	• Chest wall reconstruction after resection of lung cancer, mesothelioma, thymoma, osteomyelitis or chondro-hamartoma • Routine CT showed no chest wall deformities or shrinking of GORE® DUALMESH® Biomaterial • Infection – None • Dehiscence – None

Fact #4 — Proven ingrowth

All of GORE® DUALMESH® Biomaterial products have the patented GORE 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 ($P = .02$). 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]



Clinical Experience: *Second look picture of GORE® DUALMESH® Biomaterial after 16 months. Photo courtesy of Richard H. Koehler, M.D.*

1. LeBlanc KA, Bellanger D, Rhynes KV, Baker DG, Stout RW. Tissue attachment strength in prosthetic meshes in ventral and incisional hernia repair: a study in the New Zealand white rabbit adhesion model. *Surgical Endoscopy* 2002;16(11):1544-1548.

2. Novitsky YW, Harrell AG, Cristiano JA, *et al*. Comparative evaluation of adhesion formation, strength of ingrowth, and textile properties of prosthetic meshes after long-term intra-abdominal implantation in a rabbit. *Journal of Surgical Research* 2007;140(1):6-11.

Fact #5 — Low infection

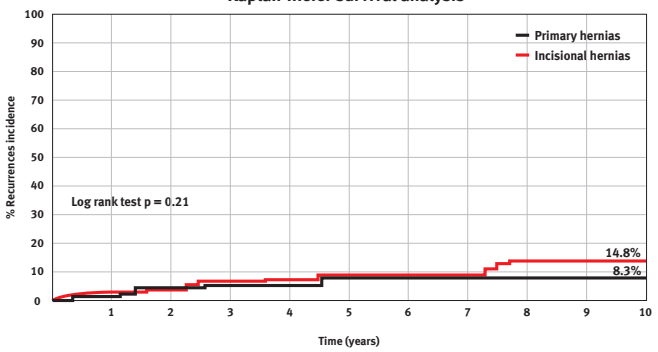
The treatment of ventral hernias with prosthetic devices has reduced recurrence rates but has led to questions concerning infection. Open hernia repair, with and without use of mesh, has been associated with an infection rate of 3 to 18 percent.[1] Laparoscopic ventral hernia repair has been associated with lower incidence of infection. As an example, a systematic review found lower incidences of wound infection (2.8 vs. 16.2 percent) for laparoscopic incisional hernia repairs compared with open hernia repairs.[2]

In the largest series with GORE® DUALMESH® Biomaterial of patients to date (n = 1979), the infection rate was shown to be 0 percent (n = 1) at 24 months of follow-up.[3]

Furthermore, a Kaplan-Meier survival analysis, according to the type of hernia recurrence, showed an incidence of 14.8 and 8.3 percent for incisional and primary hernia, respectively ($P = .21$) at 10 years.

The study authors conclude "The excellent reported outcomes included few recurrences or severe complications, leading us to consider the use of LIVHR (laparoscopic incisional and ventral hernia repair) to be a good alternative, if not superior, to standard open surgery in the routine clinical setting of most hospitals experienced in laparoscopy."[2]

Kaplan-Meier survival analysis[3]



1. LeBlanc, KA, Heniford BT, Voeller GR. Innovations in ventral hernia repair. Materials and techniques to reduce MRSA and other infections. *Contemporary Surgery* 2006;62(4)Supplement:1-8.

2. Zhang Y, Zhou H, Chai Y, Cao C, Jin K, Hu Z. Laparoscopic versus open incisional and ventral hernia repair: a systematic review and meta-analysis. *World Journal of Surgery* 2014;38(9):2233-2240.

3. Sánchez LJ, Piccoli M, Ferrari CG, *et al*. Laparoscopic ventral hernia repair: results of a two thousand patients prospective multicentric database. *International Journal of Surgery* 2018;51:31-38.

Fact #6 — Minimal contraction

All biomaterials, including polypropylene, polyester, and ePTFE, will contract to some degree after implantation due to the activity of myofibroblasts during wound healing. GORE® DUALMESH® Biomaterial is soft and supple and mimics normal wound contraction and collagen alignment.

In the only human clinical studies to date, GORE® DUALMESH® Biomaterial has been shown to have a mean shrinkage [contraction] of 7-8 percent.[1,2]

Carter et al conclude, "Our results are markedly different from animal studies and confirm that ePTFE has **MINIMAL CONTRACTION** in the human clinical situation. Concerns voiced by many that there are problems, such as recurrence of the hernia, related to the mesh contraction of ePTFE are not supported by our data."[2]

1. Schoenmaeckers EJP, van der Valk SBA, van den Hout HW, Raymakers JFTJ, Rakic S. Computed tomographic measurements of mesh shrinkage after laparoscopic ventral incisional hernia repair with an expanded polytetrafluoroethylene mesh. *Surgical Endoscopy* 2009;23(7):1620-1623.
2. Carter PR, Leblanc KA, Hausmann MG, *et al*. Does expanded polytetrafluoroethylene mesh really shrink after laparoscopic ventral hernia repair? *Hernia* 2012;16(3):321-325.

Fact #7 — Industry leader

GORE® DUALMESH® Biomaterial has been successfully used in a wide range of applications including ventral / incisional hernias, parastomal hernias, diaphragmatic hernias and chest wall soft tissue deficiencies. 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 more than 20 years of clinical history.

When a strong, durable repair is needed, GORE® DUALMESH® Biomaterial has the **proven performance**.

Ventral / Incisional hernia repair:
Clinical performance reported in literature*

GORE® DUALMESH® Biomaterials (n = 5,510)†	
Recurrence	0–7.5%
Infection	0–4.3%
Fistula	0.0%
Erosion / protrusion	0.0%
Ileus	0.7–4.3%
Bowel obstruction	0.3–3.6%
Follow-up	1 month –8 years

As compared to synthetic polypropylene and polyester surgical meshes (n = 194):[1–3]	
Recurrence	0–10%
Infection	1.1–3.3%
Fistula	NR
Erosion / protrusion	5.4–12.8%
Ileus	NR
Bowel obstruction	2.2–3.3%
Follow-up	6 months –6 years

NR = Not reported

* In the literature reviewed, data are limited to peer-reviewed studies or patient cohorts within studies that exclusively used GORE® DUALMESH® Biomaterial. The review was objective and is based on a comprehensive analysis of available clinical data pursuant to applicable regulations and standards relevant to the intended purpose of the subject device.

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

1. Lambrecht JR, Vaktskjold A, Trondsen E, Øyen OM, Reiertsen O. Laparoscopic ventral hernia repair: outcomes in primary versus incisional hernias: no effect of defect closure. *Hernia* 2015;19(3):479-486.
2. Pawlak M, Hilgers RD, Bury K, Lehmann A, Owczuk R, Śmietański M. Comparison of two different concepts of mesh and fixation technique in laparoscopic ventral hernia repair: a randomized controlled trial. *Surgical Endoscopy* 2016;30(3):1188-1197.
3. Rogmark P, Ekberg O, Montgomery A. Long-term retromuscular and intraperitoneal mesh size changes within a randomized controlled trial on incisional hernia repair, including a review of the literature. *Hernia* 2017;21(5):687-696.

Product specifications

***Instructions for Use* (IFU)**
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.

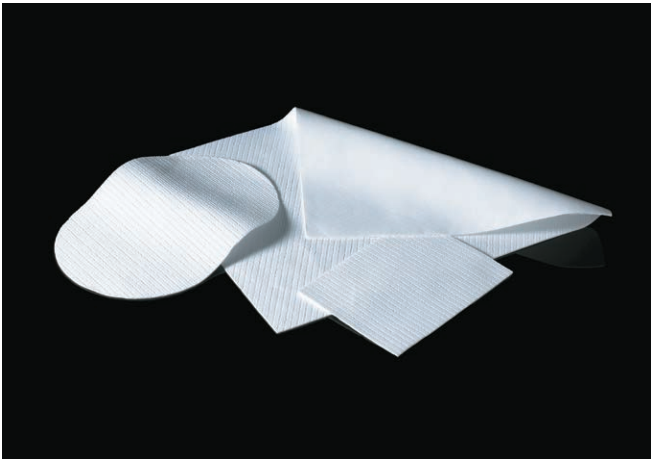
Item references
GORE® DUALMESH® Biomaterial is available in both 1 mm and 2 mm nominal thicknesses and a range of shapes and sizes from 7.5 cm × 10 cm through 26 cm × 34 cm.

GORE® DUALMESH® Biomaterial availability varies by country. Current specifications can be found on the product webpage on goremedical.com.

Storing conditions
The storing conditions must comply with the IFU requirements and it is strongly recommended to store the device in a cool and dry environment.

Product shelf life
Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier until the “use by” (expiration) date printed on the box.

MRI safety
The GORE® DUALMESH® Biomaterial is MR safe.



Remember GORE-TEX® Suture: The perfect close to your soft tissue repairs

Commonly Requested GORE-TEX® Sutures for ventral hernia repairs

Thread size	Needles	Catalogue number
CV-0	THX-36	OU07
	TH-50	OU01
CV-2	TH-26	2NO2
	THX-26	2NO5, 2NO6, 2UO5

For additional product information, visit goremedical.com

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Products listed may not be available in all markets.

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