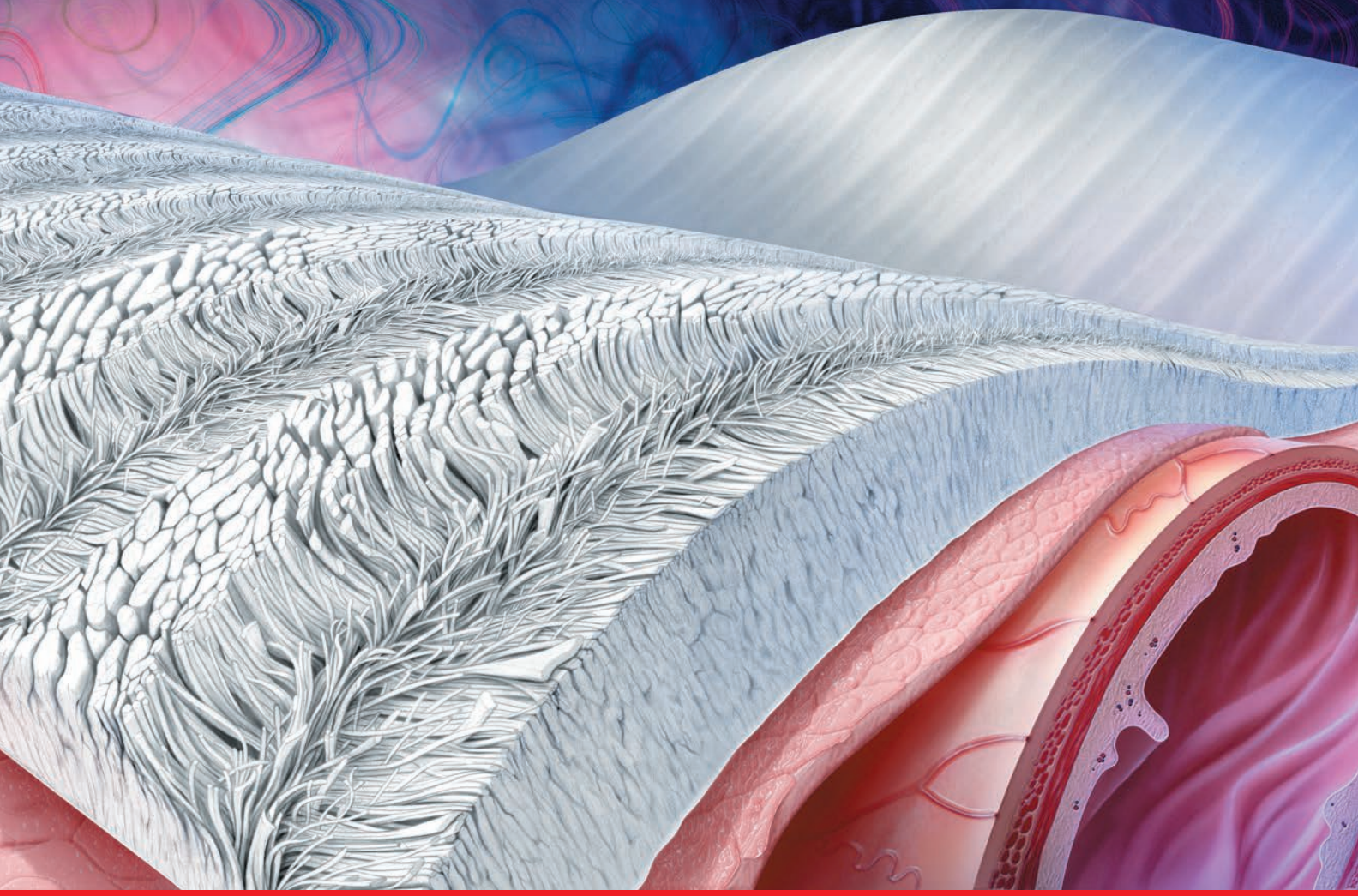


GORE® DUALMESH® Biomaterial

Well known clinical reputation and proven performance

- Proven visceral protection
- Versatile material—easily trimmable to fit defect
- GORE CORDUROY Surface

GORE® DUALMESH® Biomaterial

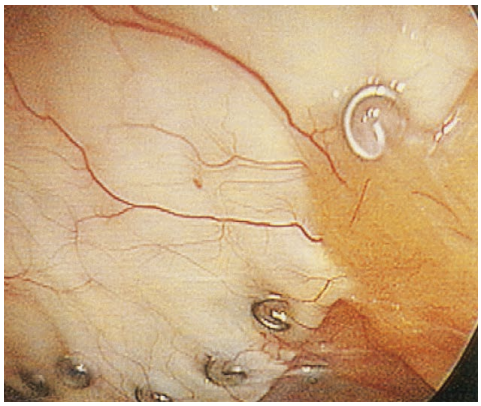
Gore developed and introduced the first expanded polytetrafluoroethylene (ePTFE) hernia repair biomaterial in 1983. Since then, Gore has continued to lead in ePTFE innovation by offering several configurations to meet and anticipate surgical needs.

The visceral interface side has a pore size consistently less than three microns that has been clinically documented to result in minimal tissue attachment[1]. The fascial interface side—the patented* CORDUROY Surface—features ePTFE "ridges" and "valleys." Animal models have shown that the CORDUROY Surface stimulates a heightened tissue fixation process rendering the material translucent in less than one week, due to the rapid influx of cells and proteinaceous fluids.* Long-term, the product is designed to bond firmly to host fascia, yet function as a physically smooth and conformable prosthesis.

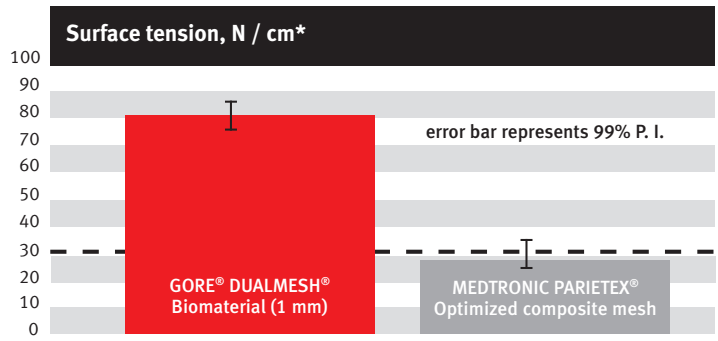
Composed entirely of ePTFE, GORE® DUALMESH® Biomaterial can be cut, folded and sewn without fear of material separation, which has been a reported drawback of hybrid meshes on the market. Moreover, several surgeons evaluating the material report that the "ridges" on the patented CORDUROY Surface significantly aid in the abdominal laparoscopic introduction of the material as well as facilitate the unrolling and placement of the material.[2]

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, GORE® DUALMESH® Biomaterial is commonly used for parastomal hernia repair, diaphragmatic hernia repair and chest wall soft tissue deficiency reconstructions.

As shown by extensive literature support and long clinical history, GORE® DUALMESH® Biomaterial is a compelling choice for ventral and incisional hernia repairs.



At 16 months, GORE® DUALMESH® Biomaterial develops a neomesothelialization or reperitonealization on the visceral side.



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.[3–5] 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.

GORE® DUALMESH® Biomaterial

Surface orientation

Proper surface orientation is essential for GORE® DUALMESH® Biomaterial to function as intended. The smoother surface should be placed adjacent to those tissues or structures where minimal tissue attachment is desired. The patented CORDUROY Surface has an open structure that stimulates host tissue incorporation and should be placed adjacent to those tissues where incorporation is desired.

Suture / Staple recommendations

- Use only nonabsorbable sutures, such as GORE-TEX® Suture, with a noncutting needle (such as taper or piercing point). For best results, use monofilament sutures.
- Suture size should be determined by surgeon preference and the nature of the reconstruction. A bite and spacing ratio of 1:1 is recommended.[6]
- Staples or helical tacks (also known as helical coils) can be used as an alternative to sutures. Staple size and staple or tack spacing should be determined by surgeon preference.

Surgical drains / Seroma

- Use of a drain should reflect surgeon preference.[7,8] Closed-suction drains rather than gravity drains are recommended to prevent handling-related infections.
- In any hernia defect repair, it is possible for seroma to occur up to six weeks postoperatively. Aspiration or placement of a drain, followed by pressure dressing, may resolve the seroma.[9–12]

Material strength

GORE® DUALMESH® Biomaterial has a material strength which is more than two times as strong as the clinically derived strength requirement of 32 N/cm.[3–5]

Visceral protection

The visceral side of GORE® DUALMESH® Biomaterial minimizes tissue attachment while supporting the formation of a neoperitoneal surface. A multiinstitutional reoperative study reported the following regarding GORE® DUALMESH® Biomaterial implanted intraperitoneally:[1]

- No severe adhesions were found.
- 91 percent of patients had either no 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.

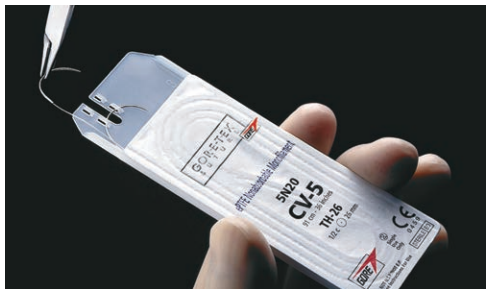
Item references

- 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.

Commonly requested GORE-TEX® Sutures for Ventral Hernia Repair

Catalogue number	Needles	Thread size
0N07	THX-36	CV-0
0U01	TH-50	CV-0
2N02	TH-26	CV-2
2N05	THX-26	CV-2
2N06	THX-26	CV-2
2U05	THX-26	CV-2

For additional product information, visit goremedical.com.



GORE-TEX® Sutures

* US 6,780,497; US D445,188; US D444,878

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.
2. W. L. Gore & Associates, Inc. *Clinical Performance in Laparoscopic Ventral Hernia Repair*. Literature Summary (n=3756 patients). Flagstaff, AZ: W. L. Gore & Associates, Inc; 2011. [Product brochure]. AL2956-EN2.
3. 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.
4. 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.
5. 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.
6. deLemos DM. Closure of minor skin wounds with sutures. UpToDate, Inc. website. Updated Jun 28, 2018. Accessed April 16, 2020. https://www.uptodate.com/contents/closure-of-minor-skin-wounds-with-sutures
7. DeBord R. Special Comment. Expanded polytetrafluoroethylene prosthetic patches in repair of large ventral hernia. In: Nyhus LM, Condon RE, eds. *Hernia*. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 1995;20:328-336.
8. Hamer-Hodges D, Scott NB. Surgeon's workshop. Replacement of an abdominal wall defect using expanded PTFE sheet (GORE-TEX). *Journal of the Royal College of Surgeons of Edinburgh* 1985;30(1):65-67.
9. Ponka JL. *Hernias of the Abdominal Wall*. Philadelphia, PA: W. B. Saunders Company; 1980.
10. Durden JG, Pemberton LB. Dacron mesh in ventral and inguinal hernias. *American Surgeon* 1974;40(11):662-665.
11. Reisfeld D, Schechner R, Wetzel W. Traumatic lumbar hernia. *Surgical Rounds* 1989;12:69-72.
12. Nichter LS, Morgan RF, Dufresne CR, Lambruschi P, Edgerton MT. Rapid management of persistent seromas by sclerotherapy. *Annals of Plastic Surgery* 1983;11(3):233-236.

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.

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