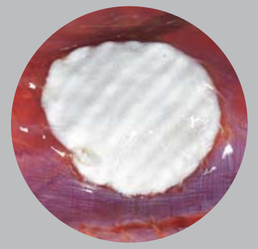

GORE DUALMESH® Biomaterial implanted along the peritoneal wall of the New Zealand White rabbit at seven days postoperative. The translucent nature of the material is the result of an influx of serous (body) fluid and host tissue cells into the interstices of the material. There is no evidence of inflammation in the surrounding soft tissue.

Histological analysis of GORE DUALMESH® Biomaterial reveals numerous blood vessels and tissue attachment along the tissue interface surface.

GORE DUALMESH® BIOMATERIAL

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

800.437.8181 (US)
928.779.2771 (US)

Contraindications

Not for reconstruction of cardiovascular defects. Use of this product in applications other than those indicated has the **potential for serious complications,** such as aneurysm formation or undesired healing to surrounding tissues.

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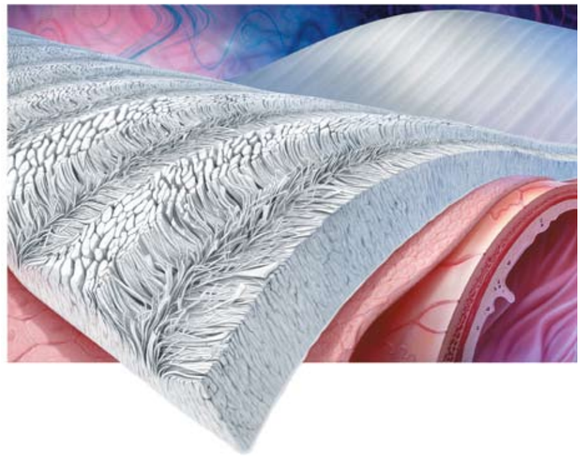
GORE DUALMESH® BIOMATERIAL



- Permanent surface for bowel protection
- Versatile material - easily trimmable to fit defect
- CORDUROY® surface for tissue ingrowth
- Available with PLUS antimicrobial technology

Indications

For use in the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects.

Also available with PLUS antimicrobial technology - designed to inhibit bacterial colonization of, and resist initial biofilm formation on, the device for up to 14 days post implantation.

GORE DUALMESH® PLUS BIOMATERIAL

Gore developed and introduced the first ePTFE hernia repair biomaterial in 1983. Since then, Gore has continued to lead in ePTFE innovation by offering an additional six 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 expanded polytetrafluoroethylene (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 abdominal wall prosthesis.

Composed entirely of ePTFE, GORE DUALMESH® Biomaterial configuration 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.

The GORE DUALMESH® Biomaterial has been successfully used in a wide range of applications. These materials are well known for their successful use in the repair and reconstruction of ventral hernias. In addition, our family of expanded ePTFE patches is commonly used for soft tissue deficiencies, chest wall reconstruction, congenital defects, temporary bridging, and TRAM flap procedures. Gore ePTFE is used on a regular basis for incisional/ventral hernias and occasionally for inguinal hernias. Other less common types of hernias, such as epigastric, lumbar, parastomal, and hiatal/paraesophageal, can also be repaired utilizing the GORE DUALMESH® Biomaterials.

As shown by extensive literature support and long clinical history, GORE DUALMESH® Biomaterial and GORE DUALMESH® PLUS Biomaterial are compelling choices for ventral and incisional hernia repairs.

Surface Orientation

Proper surface orientation is essential for the 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 microstructure 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.[2]
- 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.[3,4] 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.[5,6,7,8]

Use in a Contaminated Field Postoperative Infection

- GORE DUALMESH® Biomaterial is not recommended for use in grossly infected tissue.
- Appropriate preoperative and postoperative use of local and systemic antibiotics is highly recommended. In the event of a postoperative infection, an aggressive regimen of antibiotic treatment, possibly including antibiotic irrigation, aspiration and debridement of the affected area may resolve the infection. Persistent infection may necessitate removal of the device.

Open Healing

- When using this device as a temporary external bridging device where primary closure is not possible, use measures to avoid contamination. The entire device should be removed as early as clinically feasible, not to exceed 45 days after placement.
- When using this device as a permanent implant and unintentional exposure occurs, treat to avoid contamination, or device removal may be necessary.

References

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4. Hamer-Hodges DW, Scott NB. Replacement of an abdominal wall defect using expanded PTFE sheet (GORE-TEX). J R Coll Surg Edinb 1985;30:65-7.
5. Ponka JL. Hernias of the abdominal wall. Philadelphia: Saunders, 1980:339, 352, 392.
6. Durden JG, Pemberton LB. Dacron mesh in ventral and inguinal hernias. Am Surg 1974;40:662-5.
7. Reisfeld D, Schechner R, Wetzel W. Traumatic lumbar hernia. Surg Rounds 1989 Mar;12:69-72.
8. Nichter LS, Morgan RF, Dufresne CR, Lambruschi P, Edgerton MT. Rapid management of persistent seromas by sclerotherapy. Ann Plast Surg 1983;11:233-6.

Contact Information

To receive further information on available sizes and custom configurations for GORE DUALMESH® Biomaterial, contact your Technical Sales Associate or a Product Specialist at **800.437.8181**. *For orders and overnight delivery, call* **800.528.8763**.

Sizes Available

CATALOGUE NUMBER 1 mm Nominal Thickness	CATALOGUE NUMBER 2 mm Nominal Thickness	NOMINAL WIDTH x LENGTH
1DLMC02	–	8 cm x 12 cm
1DLMC03	1DLMC200	10 cm x 15 cm*
1DLMC04	1DLMC201	15 cm x 19 cm*
1DLMC05	–	7.5 cm x 10 cm*
1DLMC06	1DLMC202	18 cm x 24 cm
1DLMC07	1DLMC203	20 cm x 30 cm
1DLMC08	1DLMC204	26 cm x 34 cm*
–	1DLMC208	2 cm x 24 cm

*oval shaped

Packaged Sterile

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 TH-50	ONO7 OUO1
CV-2	TH-26 THX-26	2NO2 2NO5, 2NO6, 2UO5