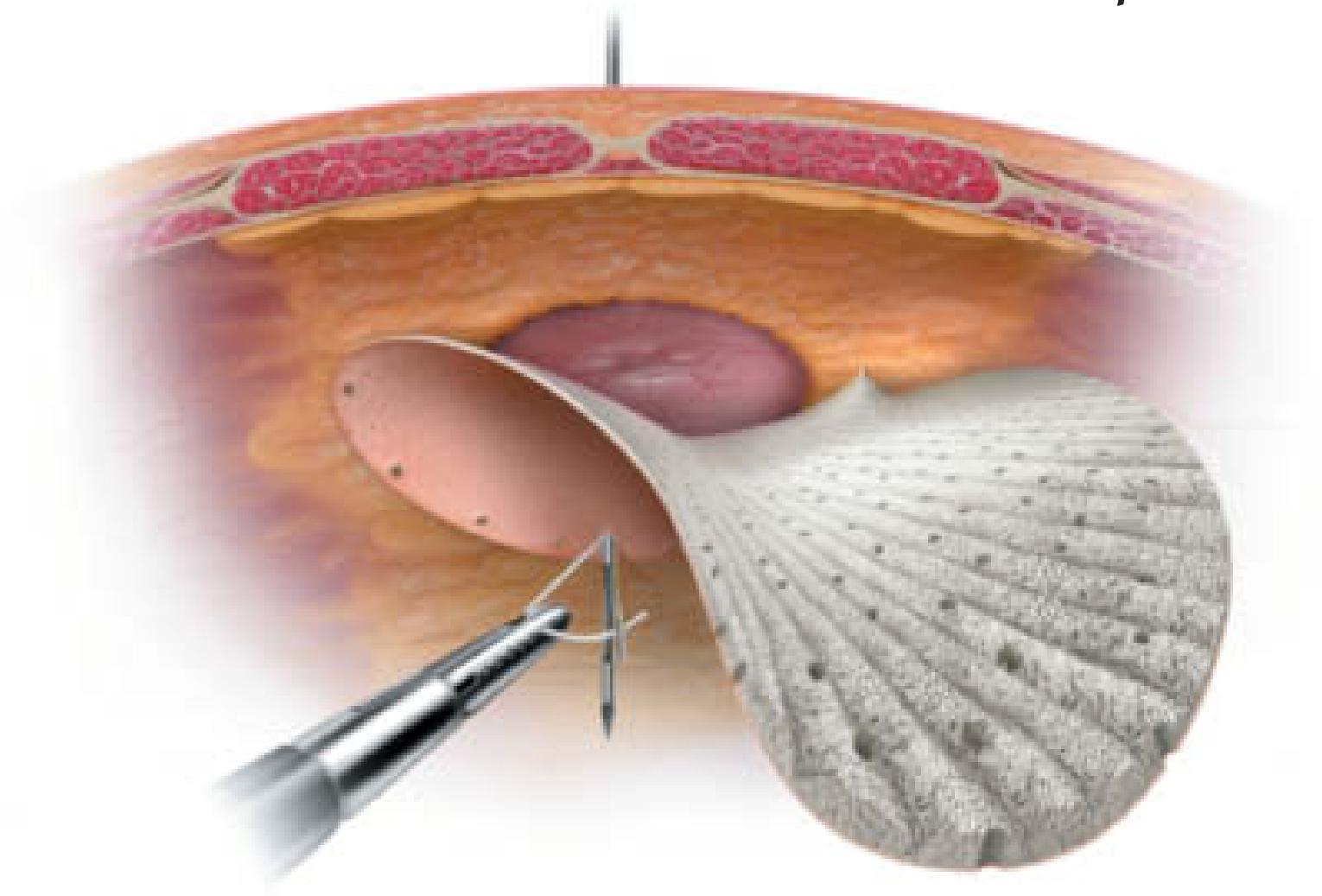
A Legacy of Innovation

In Hernia Repair



PERFORMANCE through experience

CORDUROY Tissue
Ingrowth Surface

GORE DUALMESH® PLUS

BIOMATERIAL WITH HOLES

How Do You Rate a Perfect "10" in Abdominal Wall Reconstruction Biomaterials?

1 **Smooth, low porosity, visceral interface surface**

2 **Holes ('macropores')**

3 **Extra thickness for conformability**

4 **CORDUROY surface for heightened tissue fixation to abdominal wall**

\+ **PLUS Antimicrobial technology**

10

It All Adds Up

Since 1996, when it comes to two-sided biomaterials for intra-abdominal placement, GORE® DUALMESH® PLUS Biomaterial with Holes has had it all. GORE® DUALMESH® PLUS Biomaterial with Holes features a low porosity surface designed for visceral interface. The smooth bowel surface has met the needs of thousands of challenging ventral or incisional hernia repairs. Additionally, the macropores, or holes, and extra thickness inherent in the product have made GORE® DUALMESH® PLUS Biomaterial with Holes attractive to surgeons worldwide for abdominal wall reconstructions. The macropores aid in the rapid infiltration of fibrous tissue which may reduce the incidence of seroma formation. And, now PLUS antimicrobial technology - which inhibits bacterial colonization of, and resists initial biofilm formation on, the device for up to 14 days post implantation — is an added benefit in abdominal wall reconstructions.

The Role of PLUS

Antimicrobial Preservative Agents

The use of prosthetic biomaterials for incisional and ventral hernias larger than four square centimeters have been shown to greatly reduce the recurrence rate.[1] At the same time, the use of a biomaterial can increase the infection rate. Postoperative infection has been shown to be a significant factor in hernia recurrence. Studies indicate it takes fewer organisms to produce an infection if biomaterials are present.[2]

Traditionally, surgeons have used various prophylactic regimens when a prosthetic material is used. These have had limited results in reducing the incidence of infection. This may be especially true in the repair of recurrent hernias where a significant increase in the incidence of infection has been demonstrated. Additional individual patient characteristics (i.e., diabetes, ascites, steroid therapy) may also increase the risk of infection.

GORE® DUALMESH® PLUS Biomaterial with Holes features the antimicrobial agents chlorhexidine diacetate and silver carbonate. The two antimicrobial preservatives act synergistically to inhibit 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 against the following gram-positive and gram-negative organisms:

- Escherichia coli
- Klebsiella pneumoniae
- Candida albicans
- Methicilllin resistant Staphylococcus aureus (MRSA)
- Group A Streptococcus
- Pseudomonoas aeruginosa
- Staphylococcus epidermidis
- Staphylococcus aureus
- Vancomycin-resistant Enterococcus faecalis (VRE)
- Acinetobacter baumannii

Surface Orientation

Proper surface orientation is essential for the GORE® DUALMESH® PLUS Biomaterial with Holes to function as intended. The smooth, non-ingrowth surface is shaded darker in comparison to the textured ingrowth surface to provide side differentiation and to reduce glare from laparoscopic light sources. The darker shaded surface should be placed adjacent to tissues where minimal tissue attachment is desired. The lighter shaded surface has an open microstructure that stimulates tissue ingrowth and should be placed adjacent to 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.[3]
- 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.[4,5] 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.[6,7,8,9]

Use in a Contaminated Field / Postoperative Infection

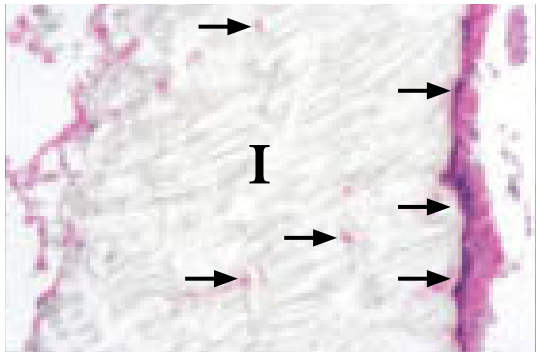
- GORE® DUALMESH® PLUS Biomaterial with Holes is not recommended for use in grossly infected tissue.
- Appropriate preoperative and postoperative use of local and systemic antibiotics is highly recommended. In the event of a postoperative infection, an aggressive regimen of antibiotic treatment, possibly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

Open Healing

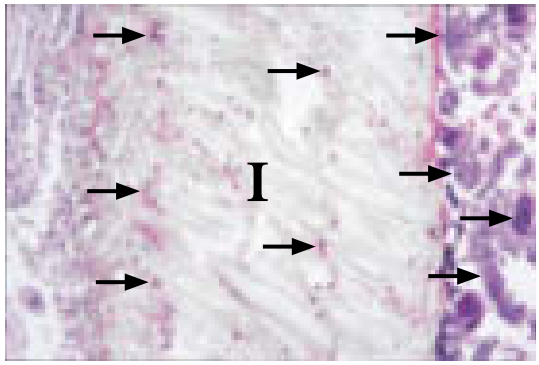
- When using this device as a temporary external bridging device where primary closure is not possible, use measures to avoid contamination. The entire device should be removed as early as clinically feasible, not to exceed 45 days after placement.
- When using this device as a permanent implant and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

Indications

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



GORE® DUALMESH® PLUS Biomaterial inoculated with Staphylococcus aureus in a rabbit model 10 days post-inoculation. H&E stain showing large numbers of acute inflammatory cells and eosinophilic cellular debris (arrows) covering the surface of the implant. The interstices of the implant (I) contain small amounts of eosinophilic cellular debris and very few acute inflammatory cells suggesting protection of the implant interstices from bacterial infection. H&E; 20x magnification.



GORE® DUALMESH® Biomaterial inoculated with Staphylococcus aureus in a rabbit model 10 days post-inoculation. H&E stain showing large numbers of acute inflammatory cells and necrotic cellular debris covering the surface of the implant (arrows). The interstices of the implant (I) also contain large numbers of acute inflammatory cells and eosinophilic cellular debris indicating bacterial infection of the implant surface and interstices. H&E; 20x magnification.

So, What Else Could Be Added To The Equation?

W. L. Gore & Associates – the inventor of the original two-sided prosthetic material with the patented* CORDUROY tissue ingrowth surface. The fascial interface side of GORE® DUALMESH® PLUS Biomaterial with Holes features expanded polytetrafluoroethylene (ePTFE) "ridges" and "furrows." Animal models have shown that this surface stimulates a heightened tissue fixation process 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, the GORE® DUALMESH® PLUS Biomaterial with Holes can be cut, folded, and sewn without fear of material separation, which has been a reported drawback of hybrid meshes on the market. Moreover, surgeons have reported that the "ridges" on the fascial interface surface aid in the handling and placement of the material.

Ordering Information

To receive further information on available sizes and custom configurations for GORE® DUALMESH® PLUS Biomaterial with Holes, 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	Nominal Thickness	Nominal Width x Length
1DLMCPH02	1.5 mm	8 cm x 12 cm
1DLMCPH03	1.5 mm	10 cm x 15 cm*
1DLMCPH04	1.5 mm	15 cm x 19 cm*
1DLMCPH06	1.5 mm	18 cm x 24 cm
1DLMCPH07	1.5 mm	20 cm x 30 cm
1DLMCPH08	1.5 mm	26 cm x 34 cm*

*oval shaped

Packaged Sterile

References

1. Hesselink VJ, Luijendijk RW, de Wilt JHW, Heide R, Jeekel J. An evaluation of risk factors in incisional hernia recurrence. *Surgery, Gynecology & Obstetrics* 1993;176:228-234.
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3. Nealon TF. Fundamental skills in surgery. Philadelphia: Saunders, 1979:47.
4. Nyhus LM, Condon RE, eds. *Hernia*. 4th ed. Philadelphia: Lippincott, 1995:331-6.
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8. Reisfeld D, Schechner R, Wetzel W. Traumatic lumbar hernia. *Surg Rounds* 1989 Mar;12:69-72.
9. Nichter LS, Morgan RF, Dufresne CR, Lambruschi P, Edgerton MT. Rapid management of persistent seromas by sclerotherapy. *Ann Plast Surg* 1983;11:233-6.

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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