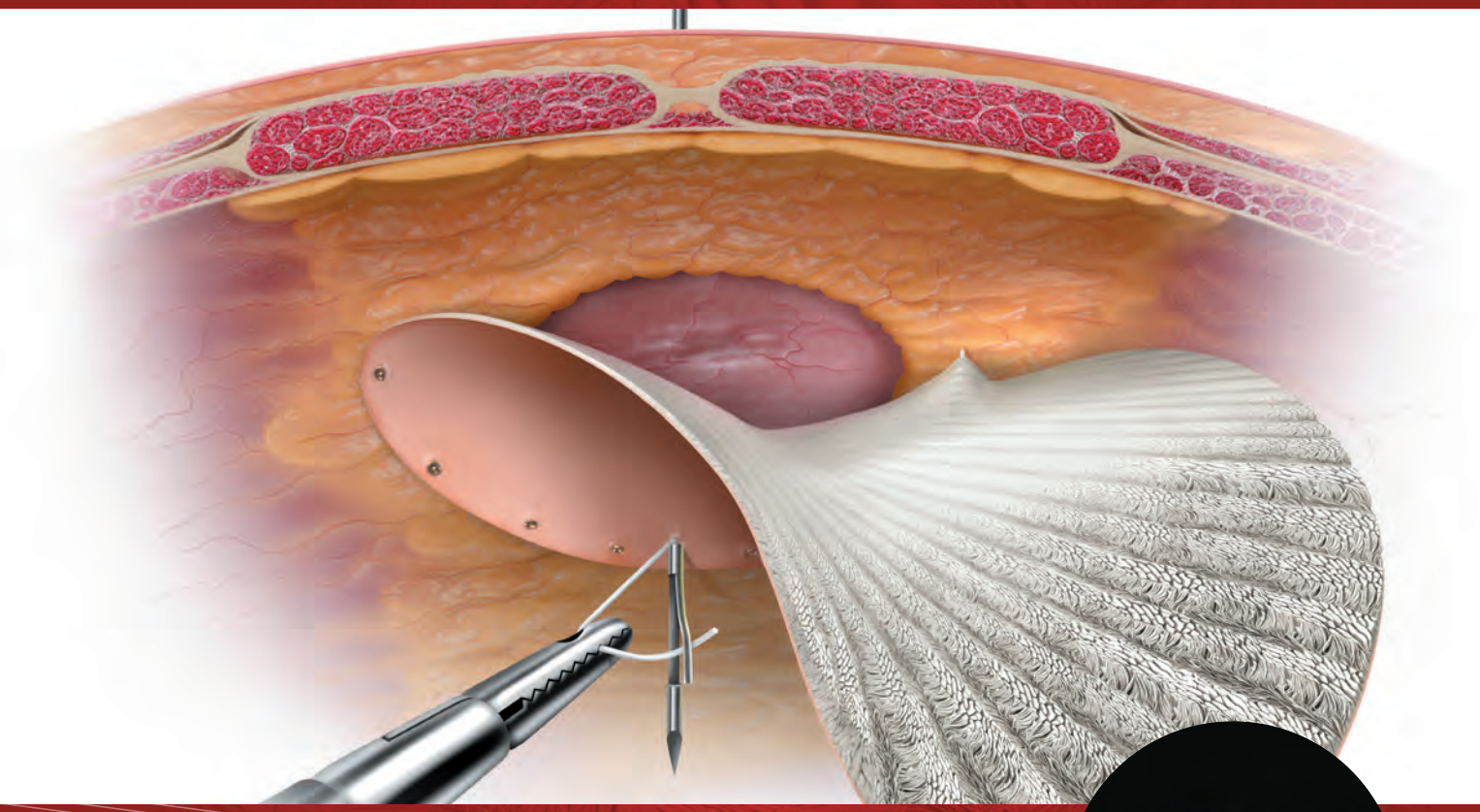
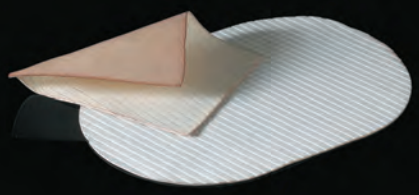
Proven reliability



PERFORMANCE through experience

GORE DUALMESH® PLUS

BIOMATERIAL



GORE DUALMESH® PLUS
Biomaterial

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

The use of prosthetic biomaterials for incisional and ventral hernias larger than four square centimeters greatly reduces 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 have shown that it takes fewer organisms to produce an infection if biomaterials are present.

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.

W. L. Gore & Associates, Inc — the innovator and leader in expanded polytetrafluoro-ethylene (ePTFE) technology — has combined an innovative surgical biomaterial with two antimicrobial preservative agents. GORE DUALMESH® PLUS Biomaterial features not only the anti-microbial agents of chlorhexidine diacetate and silver carbonate, but also an advanced tissue ingrowth surface.

The two antimicrobial preservatives act synergistically to inhibit microbial 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:

- Methicillin-resistant Staphylo-coccus aureus (MRSA)
- Vancomycin-resistant Entero-coccus faecalis (VRE)
- Staphylococcus epidermidis
- Klebsiella pneumoniae
- Pseudomonas aeruginosa
- Candida albicans
- Escherichia coli
- Staphylococcus aureus
- Group A Streptococcus
- Acinetobacter baumannii

Gore's antimicrobial technology is coupled with the CORDUROY Tissue Ingrowth Surface of the GORE DUALMESH® PLUS Biomaterial. In addition to a low-porosity, smooth visceral surface, the fascial interface side features ePTFE "ridges" and "valleys." Experimental models have shown that this surface stimulates a heightened tissue fixation process that results in a firm bond to host tissue[2]. Additionally, the processing of the GORE DUALMESH® PLUS Biomaterial with the anti-microbial agents results in a darkening of the barrier membrane side to provide for side differentiation and to reduce glare from laparoscopic light sources.

Surface Orientation

Proper surface orientation is essential for the GORE DUALMESH® PLUS Biomaterial 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. Absorbable tacks have been shown to work with GORE DUALMESH® Biomaterial (1 mm) provided proper technique is used which includes holding the fixation device as perpendicular to the tissue as possible and providing counter pressure.

Surgical Drains/Seroma

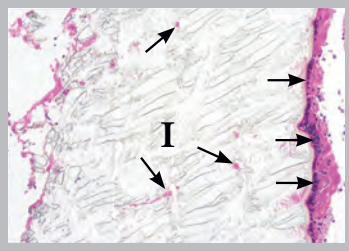
- Use of a drain should reflect surgeon preference.[4,5] Closed-suction drains rather than gravity drains are recommended to prevent handling-related infections.
- In any hernia defect repair it is possible for seroma to occur up to six weeks postoperatively. Aspiration or placement of a drain, followed by pressure dressing, may resolve the seroma.[6,7,8,9]

Use in a Contaminated Field/Postoperative Infection

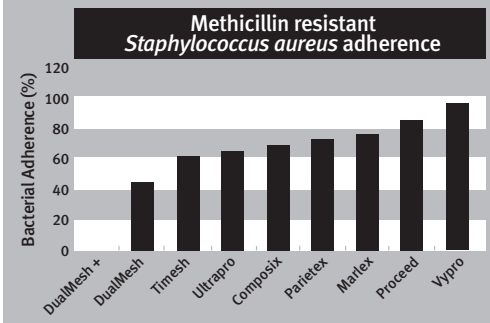
- GORE DUALMESH® PLUS Biomaterial is not recommended for use in grossly infected tissue.
- Appropriate preoperative and postoperative use of local and systemic antibiotics is highly recommended. In the event of a postoperative infection, an aggressive regimen of antibiotic treatment, possibly including 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.



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



The graph shows the percentage of MRSA adherence to various materials. GORE DUALMESH® PLUS Biomaterial is statistically significant in ability to reduce bacterial adherence relative to all other materials.[10]

Sizes Available

Catalogue Number (1 mm)	(2 mm)	Nominal Width x Length
1DLMCP02	–	8 cm x 12 cm
1DLMCP03	1DLMCP200	10 cm x 15 cm*
1DLMCP04	1DLMCP201	15 cm x 19 cm*
1DLMCP05	–	7.5 cm x 10 cm
1DLMCP06	1DLMCP202	18 cm x 24 cm
1DLMCP07	1DLMCP203	20 cm x 30 cm
1DLMCP08	1DLMCP204	26 cm x 34 cm*

*** oval shaped**

Packaged Sterile

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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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