

INSTRUCTIONS FOR USE FOR:



MYCROMESH® PLUS

B I O M A T E R I A L

en

English

pt

Português

fr

Français

es

Español

INSTRUCTIONS FOR USE FOR

Expanded Polytetrafluoroethylene GORE® MYCROMESH® PLUS Biomaterial with Antimicrobial Preservatives

INDICATIONS

Reconstruction of Hernias and Soft Tissue Deficiencies and for the Temporary Bridging of Fascial Defects

CONTRAINDICATIONS

- **GORE® MYCROMESH® PLUS BIOMATERIAL SHOULD NOT BE USED IN PATIENTS WITH HYPERSENSITIVITY TO CHLORHEXIDINE OR SILVER.**
- **NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.**
- **NOT FOR RECONSTRUCTION OF CENTRAL NERVOUS SYSTEM OR PERIPHERAL NERVOUS SYSTEM DEFECTS.**
- **NOT FOR PRE-TERM AND NEONATAL POPULATIONS.**

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.

STERILITY

GORE® MYCROMESH® PLUS Biomaterial is supplied **STERILE**. 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. **This is a single use device and should not be resterilized.**

The GORE® Medical Device is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.

RECOMMENDED TECHNIQUES

HANDLING

Use clean, sterile gloves and / or atraumatic instruments when handling GORE® MYCROMESH® PLUS Biomaterial.

MAINTAINING ASEPSIS

GORE® MYCROMESH® PLUS Biomaterial contains two antimicrobial agents , silver carbonate and chlorhexidine diacetate, which act as preservatives to inhibit microbial colonization of, and resist initial biofilm formation on, the device for up to 14 days post implantation. To help maintain strict asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary. When operative infection is suspected, dissection of involved tissues should be considered. Any postoperative infection should be aggressively treated at the earliest possible time. An unresolved infection may require removal of the device. Staged repairs should be considered when GORE® MYCROMESH® PLUS Biomaterial will be subjected to gross contamination or infection.

SIZING

Cutting GORE® MYCROMESH® PLUS Biomaterial to the proper size is essential. Use sharp surgical instruments to trim the device.

If GORE® MYCROMESH® PLUS Biomaterial is cut too small, excessive tension may be placed on the suture line, which may result in recurrence of the original, or development of an adjacent, tissue defect.

SUTURING

Use only **nonabsorbable sutures**, such as GORE-TEX® Suture, with a noncutting needle (such as taper or piercing point) of appropriate size to anchor the device. The use of absorbable sutures may lead to inadequate anchoring of GORE® MYCROMESH® PLUS Biomaterial to the host tissue and necessitate reoperation.

For best results, use monofilament sutures. Suture size should be determined by surgeon preference and the nature of the reconstruction.

When suturing GORE® MYCROMESH® PLUS Biomaterial to the host tissue, a bite and spacing ratio of 1:1 in both GORE® MYCROMESH® PLUS Biomaterial **and** the host tissue is recommended. The same ratio applies when suturing two pieces of GORE® MYCROMESH® PLUS Biomaterial together. Follow the curve of the needle when piercing the device and pierce through the full thickness of the device to ensure adequate mechanical strength of the device. Interrupted sutures can provide additional security against recurrence due to suture failure. Mattress suturing can provide additional strength to the suture line.

OTHER FIXATION DEVICES

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 to provide for adequate tissue fixation and to prevent reherniation.

WARNINGS

- GORE® MYCROMESH® PLUS Biomaterial should be used with caution in patients with methemoglobinopathy or related disorders.
- 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.
- As with any implantable surgical device, strict aseptic techniques should be followed. If an infection develops, it should be treated aggressively. An unresolved infection may require removal of the device.
- When using this device as a permanent implant and exposure occurs, treat to avoid contamination, or device removal may be necessary.
- Transvaginal insertion techniques, which expose the biomaterial to the vaginal flora, can increase the risk of contamination leading to colonization of the biomaterial. Prolonged exposure to bacteria may necessitate material removal.

PRECAUTIONS

- Do not alter usual practice of pre-, peri-, or post-operative administration of local or systemic antibiotics.
- Do **not** use absorbable sutures or cutting needles to secure the device in place.
- Ensure the size of the device is adequate for the intended repair.

ADVERSE REACTIONS

Possible adverse reactions with the use of any tissue deficiency prosthesis may include, but are not limited to, contamination, infection, inflammation, adhesion, fistula formation, seroma formation, hematoma, and recurrence.

ANTIMICROBIAL PRESERVATIVES

GORE® MYCROMESH® PLUS Biomaterial consists of GORE® MYCROMESH® Biomaterial with antimicrobial preservatives (silver carbonate and chlorhexidine diacetate) intended to inhibit microbial colonization of, and resist initial biofilm formation on, the device for up to 14 days post implantation. Clinical and patient factors such as disease processes, health status of the patient, or exposure of the device to the external environment may potentially affect the number of days the device is protected. Significant operative lavage may also reduce the number of days the device is protected.

Using zone of inhibition bioassays, substantial preservative activity associated with the device has been demonstrated against laboratory strains and clinical isolates of the following organisms:




- Escherichia coli
- Staphylococcus aureus

- Pseudomonas aeruginosa
- Klebsiella pneumoniae
- Staphylococcus epidermidis
- Candida albicans
- Staphylococcus aureus including methicillin resistant Staphylococcus aureus (MRSA)
- Vancomycin-resistant Enterococcus faecalis (VRE)
- Group A Streptococcus
- Acinetobacter baumannii

STORAGE

Exposure to light may cause the device to darken. This does not alter the effectiveness of the preservative or the device.

DEFINITIONS


-  Use By
-  Caution
-  Consult Instructions for Use

 Do Not Resterilize

 Do Not Reuse

 Catalogue Number

 Batch Code

 **CAUTION:** USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.


 Sterile

 Sterilized using Ethylene Oxide

 Do Not Use if Package is Damaged

 Configured For Inguinal Hernia Repair

 Manufacturer

 Outer Pouch is the Only Sterile Barrier



AP3366-ML2



Manufacturer

W. L. GORE & ASSOCIATES, INC.

Flagstaff, Arizona 86004 • USA


Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763

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For international contact and additional product information,
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