

INSTRUCTIONS FOR USE FOR:



PRECLUDE®

P E R I T O N E A L M E M B R A N E

en

English

hu

Magyar

bg

Български

it

Italiano

cz

Čeština

lt

Lietuvių

dk

Dansk

no

Norsk

nl

Nederlands

pl

Polska

ee

Eesti

pt

Português

fi

Suomi

ro

Română

fr

Français

sk

Slovenčina

de

Deutsch

es

Español

gr

Ελληνικά

se

Svenska

INSTRUCTIONS FOR USE

GORE PRECLUDE® Peritoneal Membrane

INDICATIONS

FOR THE RECONSTRUCTION OF THE PERITONEUM WHERE MINIMAL ADHESIONS TO A PROSTHETIC ARE DESIRED

CONTRAINDICATIONS

Not for reconstruction of:

- Cardiovascular defects
- Dura mater
- Hernias

Use of this product in applications other than those indicated has the potential for serious complications, such as suture pullout or failure of the repair (aneurysm formation).

FOR OTHER PATCHING APPLICATIONS

The GORE-TEX® Cardiovascular Patch is available for cardiovascular patching reconstructions.

The GORE MYCROMESH® Biomaterial and GORE DUALMESH® Biomaterial are available for reconstruction of hernias and soft tissue deficiencies.

STERILITY

The GORE PRECLUDE® Peritoneal Membrane is supplied **STERILE**. Provided that the package is not compromised in any way, the package will serve as an effective sterile barrier until the "use by" (expiration) date printed on the box. There is no expiration date for product function or characteristics.

RECOMMENDED TECHNIQUES

HANDLING

The GORE PRECLUDE® Peritoneal Membrane should be handled only with sterile, preferably powderless, gloves or atraumatic instruments. It need not be rinsed before implantation. The product is best trimmed, if necessary, using sharp surgical instruments and will not fray or deteriorate from trimming.

SIZING

A correctly sized GORE PRECLUDE® Peritoneal Membrane should be larger than the defect by **at least 1 cm** on all sides. Greater amounts of overlap are encouraged, especially at sites of possible copious oozing (e.g., myomectomy sites). Undersized pieces may develop unwanted adhesions adjacent to the edge.

FIXATION

To ensure adequate anchoring, the GORE PRECLUDE® Peritoneal Membrane should be secured with at least one nonabsorbable fixation device. This may be a suture or staple.

- Sutures should be nonabsorbable monofilament on a taper or piercing point needle.
- Staples should equally overlap the intact peritoneum and GORE PRECLUDE® Peritoneal Membrane upon closure.
- A sufficient number of additional absorbable or nonabsorbable fixation devices should be placed to ensure the GORE PRECLUDE® Peritoneal Membrane is smooth and completely overlaps the defect.

WARNINGS

As with all prosthetics, an appropriate regimen of antibiotics should be considered. Strict aseptic techniques should be followed. The GORE PRECLUDE® Peritoneal Membrane should be removed if involved in an infection. The GORE PRECLUDE® Peritoneal Membrane should not be implanted into obviously contaminated or inflamed sites.

PRECAUTIONS

A correctly sized GORE PRECLUDE® Peritoneal Membrane should be larger than the defect by **at least 1 cm** on all sides. Greater amounts of overlap are encouraged, especially at sites of possible copious oozing (e.g., myomectomy sites). Undersized pieces may develop unwanted adhesions adjacent to the edge.

ADVERSE REACTIONS

Possible adverse reactions with the use of any membrane prosthesis may include but are not limited to infection, inflammation, adhesions, fixation line adhesions, fibrous reaction and tissue encapsulation.

RESTERILIZATION

The GORE PRECLUDE® Peritoneal Membrane may be resterilized up to three times using steam or gas techniques without compromising its mechanical or structural quality. Do not resterilize the GORE PRECLUDE® Peritoneal Membrane in the original packaging materials. The GORE PRECLUDE® Peritoneal Membrane must be repackaged in materials appropriate for sterilization. Sterility of repackaged product is the responsibility of the health care institution.

Clean, unused, and undamaged portions of the GORE PRECLUDE® Peritoneal Membrane may be resterilized if handled with clean gloves or atraumatic instruments such as dry transfer forceps. Protect the GORE PRECLUDE® Peritoneal Membrane from heavy or sharp objects during sterilization.

- Do not expose the GORE PRECLUDE® Peritoneal Membrane to temperatures greater than 482 °F (250 °C).
- Do not sterilize the GORE PRECLUDE® Peritoneal Membrane using radiation.

STEAM

Using a validated gravity displacement steam sterilizer, autoclave at or above these minimum requirements: 250 °F (121 °C) for 30 minutes or 270 °F (132 °C) for 15 minutes.

Using a validated pre-vacuum (also known as high vacuum) steam sterilizer, autoclave at or above these minimum requirements: 270°F (132°C) for 4 minutes.

ETHYLENE OXIDE

Due to the tremendous variation in gas sterilization equipment, the choice and validation of specific cycles and aeration parameters are the responsibility of the health care institution.

DEFINITIONS



Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.



Contents sterile unless enclosed package has been opened or damaged. Sterilized by steam.



AC0913-ML2



W. L. GORE & ASSOCIATES, INC.

Flagstaff, Arizona 86004 • USA

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

Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**



GORE, GORE-TEX®, DUALMESH®, MYCROMESH®, PRECLUDE®, and designs are trademarks of W. L. Gore & Associates.

© 1999, 2008 W. L. Gore & Associates, Inc.

Printed on recyclable paper.

NOVEMBER 2008