

INSTRUCTIONS FOR USE FOR:



PRECLUDE®

P E R I C A R D I A L M E M B R A N E

en

English

hu

Magyar

bg

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it

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cz

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lt

Lietuvių

dk

Dansk

no

Norsk

nl

Nederlands

pl

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ee

Eesti

pt

Português

fi

Suomi

ro

Română

fr

Français

sk

Slovenčina

de

Deutsch

es

Español

gr

Ελληνικά

se

Svenska

INSTRUCTIONS FOR USE FOR GORE PRECLUDE® Pericardial Membrane

INDICATIONS

Reconstruction or repair of the pericardium

CONTRAINDICATIONS

Not for reconstruction of:

- **CARDIOVASCULAR DEFECTS** such as cardiac, great vessel, and peripheral vascular
- 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 and GORE ACUSEAL Cardiovascular Patch** are available for cardiovascular patching reconstructions.

The **GORE DUALMESH® Biomaterial** is available for reconstruction of hernias and soft tissue deficiencies.

STERILITY

The GORE PRECLUDE® Pericardial Membrane is supplied **STERILE**. Provided that the integrity of 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

Use clean, sterile gloves and/or atraumatic instruments when handling the GORE PRECLUDE® Pericardial Membrane.

SIZING

Proper sizing of the GORE PRECLUDE® Pericardial Membrane is essential for optimal results. Size the material to completely cover the defect. If the Pericardial Membrane is cut too small, excessive stress may be placed on the tissue or material and sutures could pull out. If the material is cut too large, excessive wrinkling may occur, possibly resulting in undesired tissue attachment.

SUTURING

Use **nonabsorbable** suture with a taper, piercing point, or **reverse** cutting needle of appropriate size to anchor the material. Absorbable sutures can be used once the material is adequately anchored. **If ONLY absorbable sutures are used to anchor the Pericardial Membrane, the repair may fail, possibly resulting in detachment from the implant site.** For best results, use monofilament sutures. Suture size should be determined by surgeon preference and the nature of the reconstruction. Use the minimum number of sutures required to maintain adequate anchoring of the material.

WARNINGS

Strict aseptic techniques should be followed. If an infection develops, it should be treated aggressively. An unresolved infection may require removal of the material.

The safety and efficacy of GORE PRECLUDE® Pericardial Membrane in preventing adhesion formation between tissues or between tissue and a mechanical circulatory assist device has not been proven. Clinical trial data are currently unavailable.

PRECAUTIONS

Use appropriately sized material for the repair. If the GORE PRECLUDE® Pericardial Membrane is cut too small for the repair, excessive tension may be placed at the fixation points, which may lead to pull-out. Inadequate overlap will expose the defect to possible adhesion formation. Inadequate fixation may allow the material to migrate and expose the defect.

If the GORE PRECLUDE® Pericardial Membrane is fabricated into a sleeve to protect the internal mammary artery, the pedicle should fit loosely in the sleeve. A tight fit could result in graft occlusion.

If GORE PRECLUDE® Pericardial Membrane is to be used concurrent with implantation of a mechanical circulatory assist device, it should be completed utilizing the recommended techniques given under the Handling, Sizing, and Suturing sections. If multiple pieces of the membrane are required, they should be sutured together with non-absorbable monofilament suture.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, inflammation, adhesions, suture line adhesions, fibrous reaction, tissue encapsulation, and cardiac tamponade. Additionally, contraindicated uses may result in material failure.

RESTERILIZATION

The GORE PRECLUDE® Pericardial Membrane may be resterilized up to three times using steam or gas techniques without compromising its mechanical or structural quality. **Do not resterilize the Pericardial Membrane in the original packaging materials.**

The Pericardial 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 Pericardial Membrane may be resterilized. Protect the Pericardial Membrane from heavy or sharp objects during sterilization.

- Do not expose the Pericardial Membrane to temperatures greater than 482 °F (250 °C).
- **Do not sterilize the Pericardial 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.



AB0360-ML3



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visit **www.goremedical.com**

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