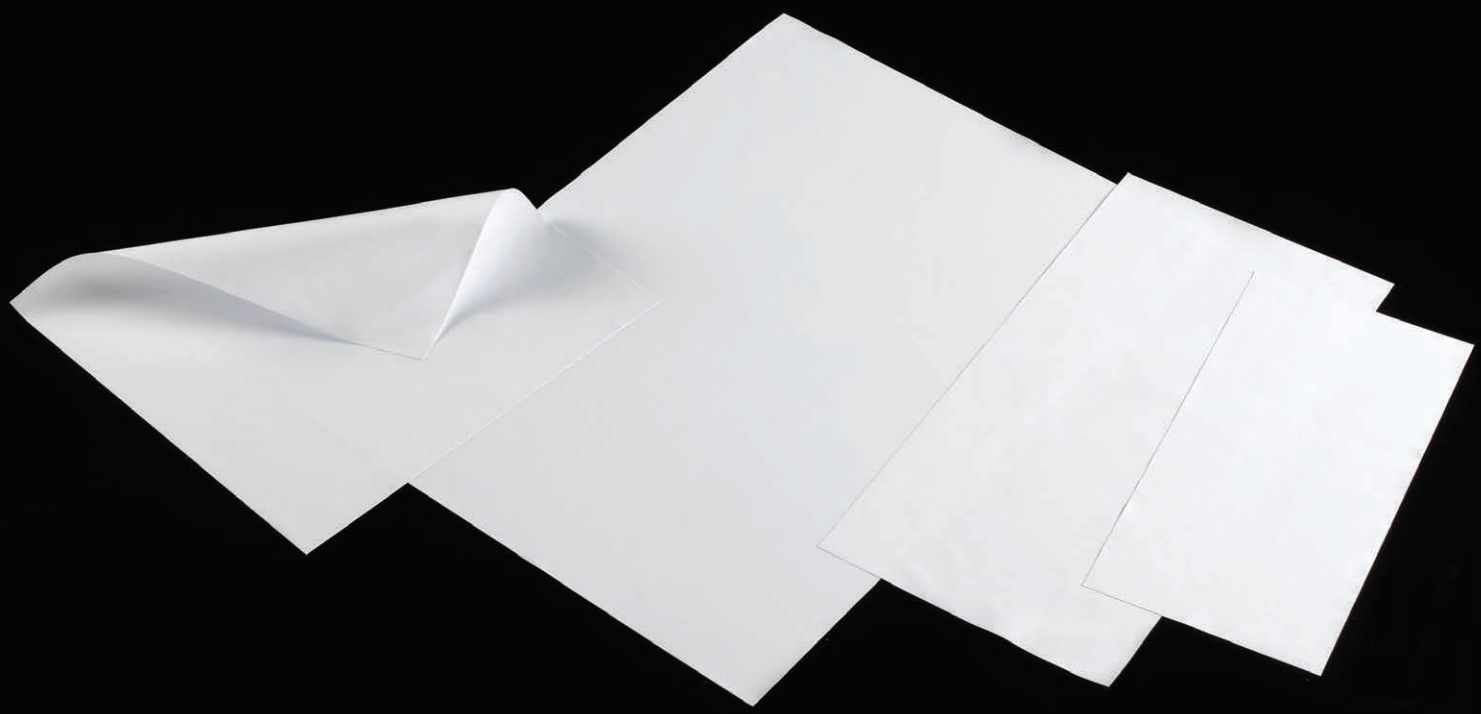


GORE® PRECLUDE® Pericardial Membrane

More than 40 years of experience with ePTFE in medical implants

GORE
Creative Technologies
Worldwide

Features and benefits

Bioinert

Biocompatible

Minimal tissue attachment

Clear plane of dissection

Long-term flexibility

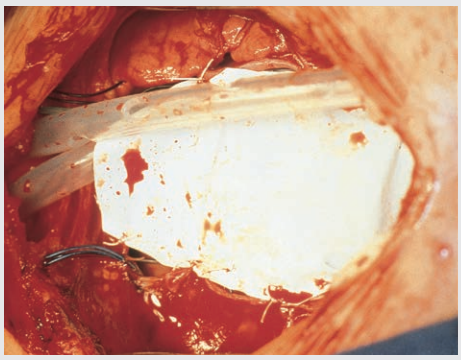


Photo courtesy of Professor Roland Hetzer, M.D.

GORE® PRECLUDE® Pericardial Membrane as seen at time of implantation.

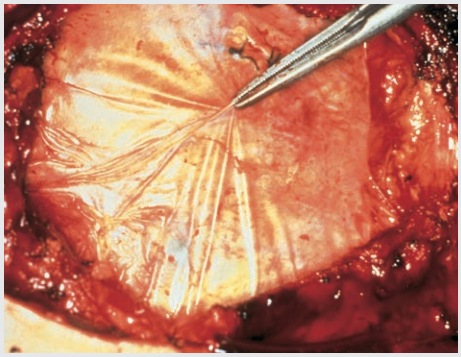


Photo courtesy of Yumi Imai, M.D.

GORE® PRECLUDE® Pericardial Membrane as seen at seven years implantation. After implantation the material becomes wet with proteinaceous, aqueous fluids and turns translucent.[1,2,3] *Minimal adhesion formation was noted and the material was non-adherent to the epicardial surface of the heart.*

Ideal for use with left ventricular assist device (LVAD) or total artificial heart (TAH)

Sizing / Implant techniques

Reoperative experience and current implantation techniques support placement of the GORE® PRECLUDE® Pericardial Membrane between the epicardial surface of the heart and the pericardium.[1,2] **It is essential that the membrane be tailored to the size of the repair site.** If the GORE® PRECLUDE® Pericardial Membrane is too small, impairment of cardiac function may occur and sutures may pull out.

If the GORE® PRECLUDE® Pericardial Membrane is too large when implanted, excessive wrinkling may occur, possibly resulting in undesired tissue attachment caused by accumulation of blood next to the heart. Tucking the membrane at least 2 cm under the edge of the pericardium can prevent attachment of the pericardial incision to the epicardium. **Wrinkling can be minimized by partially closing the sternal retractors prior to completion of the implantation of the GORE® PRECLUDE® Pericardial Membrane.**[2]

Use with LVAD or TAH

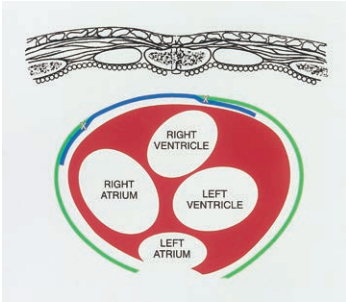
Reconstruction of the pericardium with GORE® PRECLUDE® Pericardial Membrane concurrent with implantation of mechanical circulatory assist devices should be completed utilizing the recommended techniques of handling, sizing and suturing in the *Instructions for Use*. If multiple pieces of the GORE® PRECLUDE® Pericardial Membrane are required for the repair, they should be sutured together with non-absorbable monofilament suture. Removal of mechanical circulatory assist devices has been facilitated when the GORE® PRECLUDE® Pericardial Membrane is employed in this manner.

Internal mammary artery (IMA) wrapping

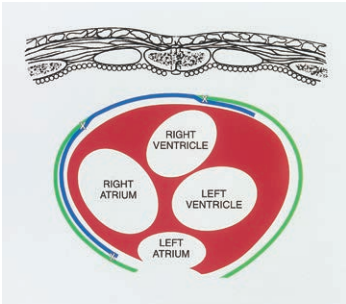
When placing the GORE® PRECLUDE® Pericardial Membrane around the IMA pedicle, it is essential that the membrane be tailored to the size of the pedicle. If the width of the membrane is inadequate, the resulting sleeve may compress the pedicle, causing graft occlusion. In addition, sutures or clips may pull out, resulting in incomplete protection. The membrane should be of sufficient length to ensure adequate coverage of the portion of the IMA pedicle at risk during resternotomy and dissection. Anchoring of the membrane to the pedicle or epicardium should be considered.

Suturing technique

Placing sutures adjacent to the anterior cardiac surface should be minimized, to reduce epicardial fibrosis.[4] **Sutures should be placed as lateral as possible and the use of continuous suture lines should be avoided.** Non-absorbable, monofilament sutures, such as the GORE-TEX® Suture, have been used to anchor GORE® PRECLUDE® Pericardial Membrane to the pericardium with interrupted stitches. Similar sutures or clips have been used to form the membrane into a sleeve around the IMA pedicle.



Protection of the anterior surface of the heart.



Protection of the anterior surface of the heart and atrial cannulation site.

Use of drains

When closure of the pericardial sac is performed, it is common practice to place two drains (in the intrapericardial and extrapericardial cavity) to remove any accumulating fluids and to be able to trace the origin of blood if bleeding occurs. [5,6]

Sizes available

Catalogue number	Width × length
1PCM001	7 cm x 10 cm
1PCM100	6 cm x 12 cm
1PCM101	8 cm x 16 cm
1PCM102	12 cm x 12 cm
1PCM103	15 cm x 20 cm

All configurations have a membrane thickness of 0.1 mm.

Sizing, availability and pricing varies by country. Please check with your Gore representative for availability.

GORE
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928 779 2771 (United States)

goremedical.com

Consult Instructions for Use

INDICATIONS FOR USE: 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). Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. ℞ Only

Products listed may not be available in all markets.

AE0710-EN7 OCTOBER 2019

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3. Harada Y, Imai Y, Kurosawa H, Hoshino S, Nakano K. Long-term results of the clinical use of an expanded polytetrafluoroethylene surgical membrane as a pericardial substitute. *Journal of Thoracic & Cardiovascular Surgery* 1988; 96(5):811-815.

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6. Cunningham JN Jr, Spencer FC, Zeff R, Williams CD, Cukingnan R, Mullin M. Influence of primary closure of the pericardium after open-heart surgery on the frequency of tamponade, postcardiotoy syndrome, and pulmonary complications. *Journal of Thoracic & Cardiovascular Surgery* 1975;70(1):119-125.

Suggested reading

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