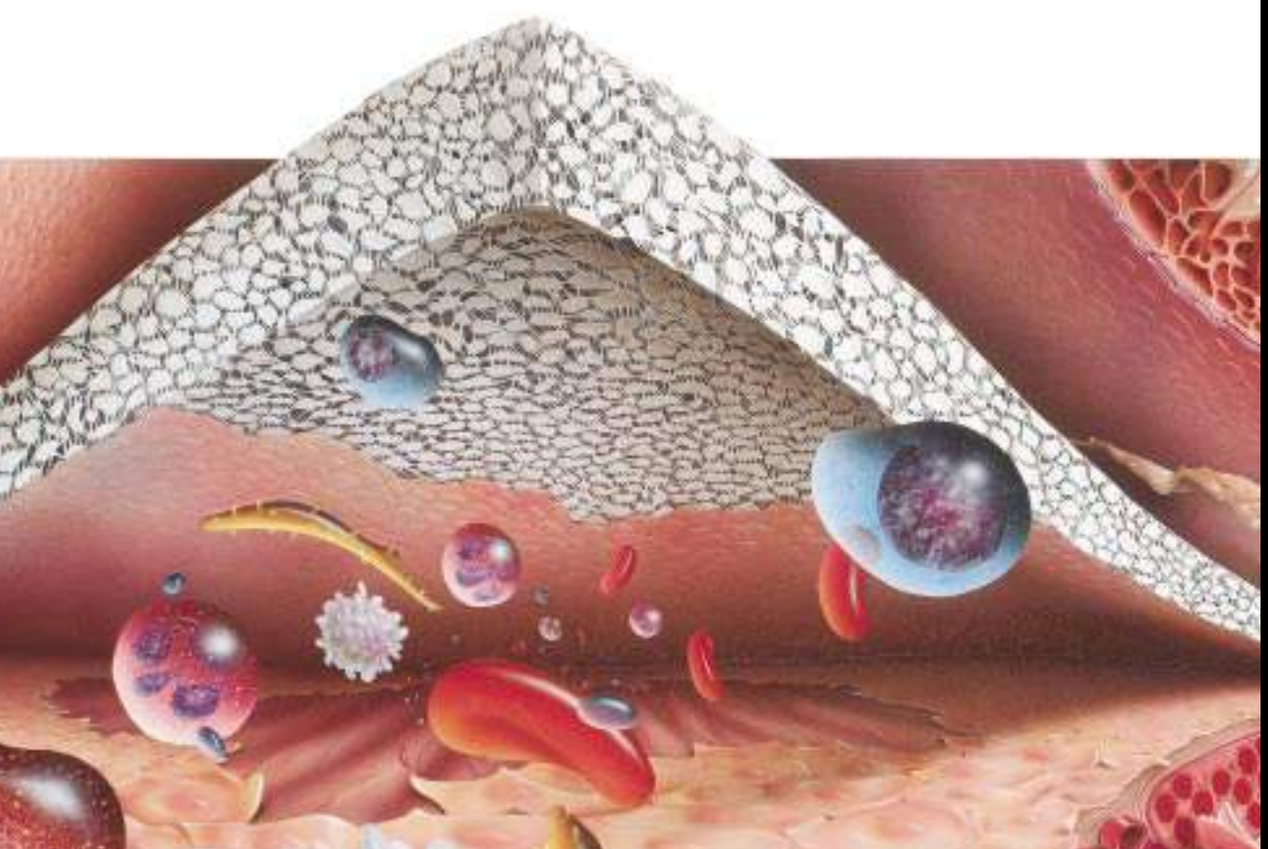
PRECLUDE®

PERICARDIAL MEMBRANE

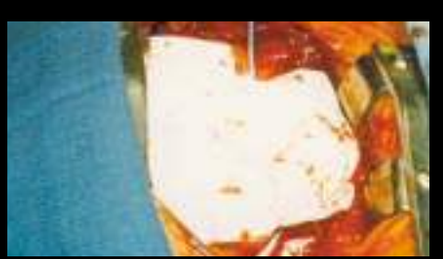
GORE



FOR USE WITH MECHANICAL CIRCULATORY ASSIST DEVICES

Surgeons preparing for heart transplantation often encounter dense adhesions during removal of mechanical circulatory assist devices. These adhesions complicate reoperation by obscuring the heart, drive-lines, and great vessels which are vulnerable during re-entry. Additionally, these adhesions often extend operative times and increase the risk of iatrogenic complications.

Clinical experience reported in the literature has demonstrated that implantation of PRECLUDE® Pericardial Membrane with mechanical circulatory assist devices aids in device removal during reoperation, and reduces the removal time from 2 hours to 1 hour or less[3,4]. As stated by Copeland et al, “Using ePTFE membrane to fashion a complete neo-pericardium and to wrap the ascending aorta at the time of Cardio West implantation dramatically reduces adhesions and pericardial thickening and facilitates explantation.”[3] Additionally, Leprince and colleagues stated, “At resternotomy for transplantation, the plane of dissection between tissues, ePTFE membranes, and surfaces of the mechanical support device were easily discerned. No adhesions were observed between tissues and membranes. There were no injuries during resternotomy, and no patient had to undergo re-operation because of bleeding [sic]. Use of ePTFE membranes in patients undergoing bridge to transplantation with either an LVAD or TAH limited adhesions between tissues and device surfaces without increasing the risk of infection.”[4]



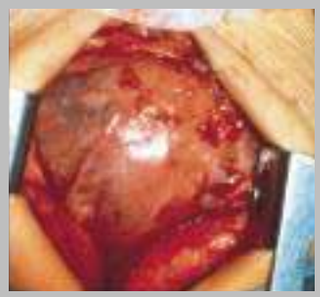
PRECLUDE® Pericardial Membrane as seen at time of scheduled reoperation in a pediatric patient, seven years after implantation for correction of a stenotic right ventricular outflow tract. Minimal adhesion formation was noted and the material was nonadherent to the epicardial surface of the heart.

Photo courtesy of Y. Imai, M.D.

PRECLUDE® Pericardial Membrane as seen at time of scheduled reoperation in a pediatric patient, two months after implantation of an aorto-pulmonary shunt.

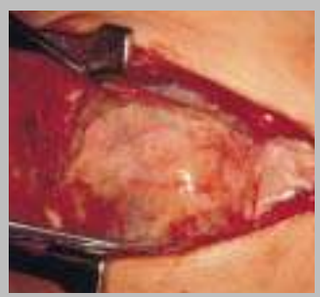
The coronary vasculature is visible and there is a lack of adherent tissue.

Photo courtesy of H. Lindberg, M.D.



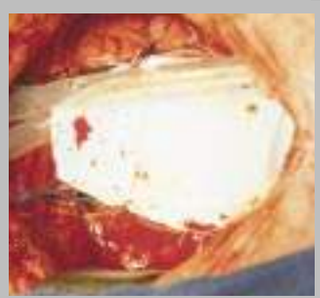
PRECLUDE® Pericardial Membrane as seen at time of reoperation, three years after implantation.

Photo courtesy of Professor Ruochewski Universitätsklinik Göttingen, Germany



PRECLUDE® Pericardial Membrane as seen at time of implantation.

Photo courtesy of Professor R. Hetzer, Deutsches Herzzentrum Berlin, Germany



INDICATIONS

PRECLUDE® Pericardial Membrane is indicated for use in the reconstruction or repair of the pericardium.

For use in patients with a risk of reoperation when the autologous pericardium cannot be closed.

⚠ Attention, See Instructions for Use

OPERATIVE *Considerations*

SIZING/IMPLANTATION TECHNIQUE

Reoperative experience and current implantation techniques support placement of the PRECLUDE® Pericardial Membrane between the epicardial surface of the heart and the pericardium.[5,8] It is essential that the membrane be tailored to the size of the repair site. If PRECLUDE® Pericardial Membrane is too small, impairment of cardiac function may occur, and sutures may pull out.

If 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 PRECLUDE® Pericardial Membrane.[8]

Reconstruction of the pericardium with 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 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 PRECLUDE® Pericardial Membrane is employed in this manner.

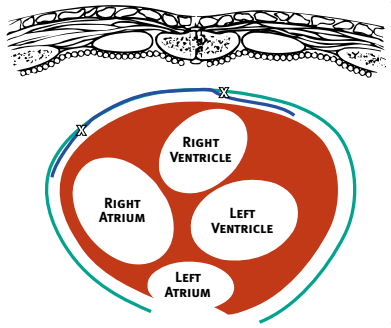
When placing PRECLUDE® Pericardial Membrane around the IMA pedicle, it is essential that the membrane be tailored to the size of the pedicle. If the width of the membrane is inadequate, the resulting sleeve may compress the pedicle, causing graft occlusion. In addition, sutures or clips may pull out, 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.

Postoperative *Considerations*

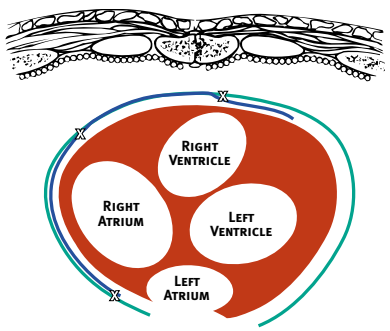
SUTURING TECHNIQUE

Placing sutures adjacent to the anterior cardiac surface should be minimized, to reduce epicardial fibrosis.[7] Sutures should be placed as lateral as possible and the use of continuous suture lines should be avoided. Nonabsorbable, monofilament sutures, such as the GORE-TEX® Suture, have been used to anchor 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.

XXX **SUTURES**

Pericardium
PRECLUDE® Pericardial Membrane
Heart

USE OF DRAINS

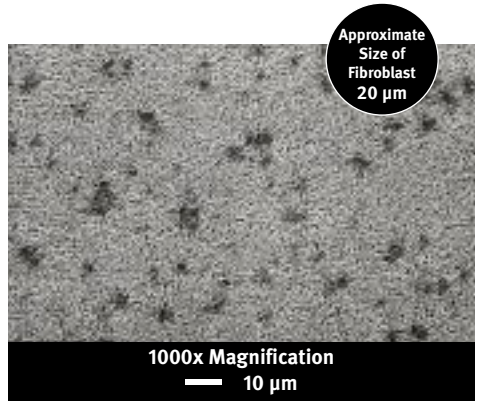
When closure of the pericardial sac is performed, it is common practice to place two drains (in the intrapericardial and extrapericardial cavity) to remove any accumulating fluids and to be able to trace the origin of blood, if bleeding occurs.[6,9]

CLINICAL EXPERIENCE

Since 1975, clinical experience[10,11] has established that PRECLUDE® Pericardial Membrane provides an effective plane of dissection as a pericardial substitute. No other pericardial substitute has more clinical experience. Re-entry into the pericardial space is facilitated and associated complications are minimized. Adhesions between the chest wall and PRECLUDE® Pericardial Membrane are significantly reduced due to the special microstructure of PRECLUDE® Pericardial Membrane.[5,10] PRECLUDE® Pericardial Membrane is loosely attached to the epicardium and can be removed easily.[6]

PERICARDIAL MEMBRANE IDENTIFICATION

At initial implant, PRECLUDE® Pericardial Membrane is a white, opaque material. After implantation the material becomes wet with proteinaceous, aqueous fluids and turns translucent.[5,8,10] This is due to the microporous nature and the thinness of the material and usually occurs within two to six weeks. Consequently, at reoperation it may be possible to view the epicardial anatomy of the heart surface through PRECLUDE® Pericardial Membrane.[10] At early postoperative follow-up, difficulty in evaluation of the patient by two-dimensional echocardiography may be encountered only in the para-sternal view. The resolution improves in ultrasound scans obtained late postoperatively (one to two months).[6]



A Scanning Electron Micrograph of PRECLUDE® Pericardial Membrane

Over Twenty-Five Years *of Clinical Success*

Four Years
Clinical retrieval of a PRECLUDE® Pericardial Membrane four years post-op in a four-year-old female. A loosely adherent, well-vascularized, fibrocollagenous tissue is observed along one surface of the membrane. The fibrous matrix is unremarkable and non-inflammatory. There is no tissue attachment along the opposite surface. H&E stain; 25X magnification

Six Years
Clinical retrieval of a PRECLUDE® Pericardial Membrane implanted for six years in a 13-year-old male. There is no tissue attachment to either surface of the PRECLUDE® Pericardial Membrane. Degenerate cells and fibrinous material are scattered along one surface. Proteinaceous material is observed at periphery and within the interstices of the implant. Milligan's trichrome stain; 25X magnification

Ten Years
Clinical retrieval of a PRECLUDE® Pericardial Membrane implanted for ten years in a 78-year-old male. There is no tissue attachment to either surface of the PRECLUDE® Pericardial Membrane. Occasional clusters of red blood cells, fibrinous strands and collagen fibers are observed at the interface. Proteinaceous material is observed within the interstices of the implant. There is no evidence of a foreign-body tissue response or inflammation. Milligan's trichrome stain; 25X magnification

Four and One Half Years
Scanning Electron Micrograph (SEM), of a clinically retrieved PRECLUDE® Pericardial Membrane 4.5 years post-op. The surface of the PRECLUDE® Pericardial Membrane is covered with fibrinous strands and proteinaceous deposition. Red blood cells are predominantly scattered along the fibrinous matrix. There is no evidence of tissue attachment. There is no evidence of fibroblasts or collagen fibers. 1000X magnification

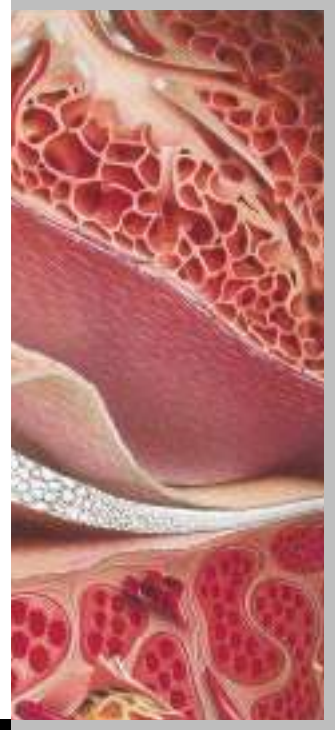
Characteristics

PRECLUDE® Pericardial Membrane consists of expanded polytetrafluoroethylene (ePTFE), one of the most chemically inert and biocompatible materials known. The membrane thickness is 0.1 mm with a pore size of <1 µm. This small pore size excludes tissue ingrowth, thereby limiting attachment between the membrane and adjacent structures. PRECLUDE® Pericardial Membrane provides a smooth plane of dissection during reoperation and maintains its flexibility long-term.

PRECLUDE® PERICARDIAL MEMBRANE GORE

Catalogue Number	Sizes Available
1PCM100	6 cm x 12 cm
1PCM101	8 cm x 16 cm
1PCM102	12 cm x 12 cm
1PCM103	15 cm x 20 cm

Special sizes are available upon request.
Minimum order required. Packaged sterile.



W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004
www.goremedical.com

Australia: +61 / 2-9453-0300
Benelux: +31 / 73-687-24-46
中国: +86 / 21-6485-4990
Deutschland: +49 / 89-46-12-0
España: +34 / 93-480-6900
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25 YEARS GORE Medical Products
INNOVATION. INGENUITY. INTEGRITY.

PRECLUDE® PERICARDIAL MEMBRANE GORE

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WARNING: The safety and efficacy of 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.

PRECAUTION: If 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 of the Instructions for Use. If multiple pieces of the membrane are required, they should be sutured together with non-absorbable monofilament suture.