Characteristics

PRECLUDE® Pericardial Membrane consists of expanded polytetrafluoroethylene (ePTFE), one of the most thoroughly investigated and biocompatible materials known. The membrane thickness is 0.1 mm with a pore size of <1 μm. This pore size now excludes tissue (e.g., blood) 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.

Catalogue Sizes

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PRECLUDE® Pericardial Membrane

The safety and efficacy of PRECLUDE® Pericardial Membrane in preventing adhesion formation between organs, between organs and the pericardium, and between the pericardium and mechanical assist devices has been proven. Clinical trial data are currently unavailable.

WARNING: The safety and efficacy of PRECLUDE® Pericardial Membrane in preventing adhesion formation has not been established when the membrane is used to seal the pericardium after open heart surgery to create a complete neo-pericardium and to wrap around LVAD or TAH. Limited adhesions between tissues and device surfaces without increasing the risk of device complications.

Clinical experience reported in the literature has demonstrated that the application of PRECLUDE® Pericardial Membrane with mechanical assist devices results in fewer adhesions and pericardial fibrosis and thrombosis formation.

REFERENCES

14. For an additional explanation of the use of mechanical assist devices in preparing for heart transplantation, see “The bridge to heart transplantation” in this book.
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. 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. Tuning the membrane at least 2 cm on the edge of the pericardium can prevent attachment of the pericardial incision to the epicardium. Wrinkling can be minimized by partially closing the sternal retractor prior to completion of the implantation of PRECLUDE® Pericardial Membrane.

Reconstruction of the pericardium with PRECLUDE® Pericardial Membrane is recommended to minimize the risk of subsequent occlusion or the need for reoperation. Sutures used to attach PRECLUDE® Pericardial Membrane should be selected to suit the intended application. Suture material, such as GORE-TEX® Suture, has been used to anchor PRECLUDE® Pericardial Membrane to the pericardium with interrupted suture. Similar sutures or clips have been used to secure the membrane into a skin or fascial pedicle, as seen at time of reoperation.

SUTURING TECHNIQUE

Placing sutures adjacent to the anterior cardiac surface should be minimized to reduce epipalvic fibrosis. Sutures should be placed as lateral as possible and the use of continuous suture technique 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 suture.

USE OF DRAINS

When closure of the pericardial sac is performed, it is common practice to place two drains, one intercostal and one retroperitoneal to remove any accumulating fluids and be able to trace the origin of blood, if bleeding occurs."

POSTOPERATIVE

Considerations

CLINICAL EXPERIENCE

Since 1975, clinical experience has established that PRECLUDE® Pericardial Membrane provides an effective plane of dissection as a pericardial substitute. No other pericardial substitute has more clinical experience. 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. PRECLUDE® Pericardial Membrane is loosely attached to the pericardium and can be removed easily.

PERICARDIAL MEMBRANE IDENTIFICATION

At initial implant, PRECLUDE® Pericardial Membrane is a white, opaque material. However, implantation becomes wet with proteinaceous, aqueous fluids and turns translucent. 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. At early postoperative follow-up, difficulty in evaluation of the patient by two-dimensional echocardiography may be encountered only in the paraesophageal view. The resolution improves in ultrasonic scans obtained late postoperatively (one to two months).

PRECLUDE® Pericardial Membrane as seen at time of scheduled reoperation in a pediatric patient. The coronary vasculature is visible at time of reoperation, as seen at time of reoperation, in a pediatric patient. The coronary vasculature is visible at time of reoperation.
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. 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. Tuning the membrane at least 2 cm on the edge of the pericardium can prevent attachment of the pericardial incision to the epicardium. Wrinkling can be minimized by partially closing the sternal retractor prior to completion of the implantation of PRECLUDE® Pericardial Membrane.

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 reoperation and dissection. Anchoring of the membrane to the pedicle or epicardium should be considered.

SUTURING TECHNIQUE

Placing sutures adjacent to the anterior cardiac surface will be minimized, to reduce epicardial fibrosis. Sutures should be placed as lateral as possible and the use of continuous sutures should be avoided. Nonabsorbable, permanent 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 bore the membrane into a sleeve around the IMA pedicle.

POSTOPERATIVE CONSIDERATIONS

CLINICAL EXPERIENCE

Since 1975, clinical experience has established that PRECLUDE® Pericardial Membrane provides an effective plane of dissection as a pericardial substitute. No other pericardial substitute has more clinical experience. 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. PRECLUDE® Pericardial Membrane is loosely attached to the epicardium and can be removed easily.

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. 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. 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 ultrasonic scans obtained late postoperatively (one to two months).

INDICATIONS

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

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 inspect the pericardial space. Removal of mechanical circulatory assist devices has been facilitated when PRECLUDE® Pericardial Membrane is employed in this manner. In addition, sutures or clips have been used to anchor PRECLUDE® Pericardial Membrane to the pericardium with interrupted stitches. Similar sutures or clips have been used to bore the membrane into a sleeve around the IMA pedicle.

For use in patients with a risk of reoperation or repair of the pericardium.

Attention. See Instructions for Use
Characteristics
PRECLUDE® Pericardial Membrane consists of expanded polytetrafluoroethylene (ePTFE), one of the most thermally inert and biocompatible materials known. The membrane thickness is 0.1 mm with a pore size of <0.1 μm. This small pore size limits 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

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Membrane consists of expanded polytetrafluoroethylene (ePTFE), one of the most thermally inert and biocompatible materials known. The membrane thickness is 0.1 mm with a pore size of <0.1 μm. This small pore size limits tissue ingrowth, thereby limiting attachment between the membrane and adjacent structures.

References

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 compromise easy removal and significantly increase the risk of cardiac complications. Clinical experience reported in the literature has demonstrated the value of using PRECLUDE® Pericardial Membrane with mechanical assist devices prior to device removal. This use avoids the need for re-entry and may result in a shorter time to heart transplantation.

For use with mechanical circulatory assist devices and for use with percutaneous left ventricular assist devices, use sterile technique.

Manufactured by W. L. Gore & Associates, Inc.

This device is intended for use with a mechanical assist device. Contact your Gore sales representative for details.

www.goremedical.com

- California: 800 / 437-8181
- United Kingdom: +886 / 2-8771-7799
- Sverige: +39 / 045-6209-333
- Singapore: +46 / 31-706-78-00
- Russia: +7095 / 937-59-46
- United States: +81 / 3-3327-0011
- Italy: +33 / 1-60-79-60-79
- New Zealand: +86 / 21-6485-4990
- France: +43 / 662-629-551
- China: +852 / 2622-9622
- Spain: +64 / 9-415-8334
- France: +33 / 1-60-79-60-79
- Japan: +91 / 22-8217166
- Germany: +7095 / 937-59-46
- Benelux: +44 / 1506-460123
- Australia: +44 / 1506-460123

For use in operations. Clinical experience reported in the literature has demonstrated the value of using PRECLUDE® Pericardial Membrane with mechanical assist devices prior to device removal. This use avoids the need for re-entry and may result in a shorter time to heart transplantation.

For use with mechanical circulatory assist devices and for use with percutaneous left ventricular assist devices, use sterile technique.

PRECLUDE® Pericardial Membrane is a surgical membrane indicated for: (1) closure of pericardial defects created by mechanical circulatory assist devices; and (2) anastomosis of the assist device to the heart. PRECLUDE® Pericardial Membrane is used to span defects created by mechanical circulatory assist devices.

The safety and efficacy of PRECLUDE® Pericardial Membrane in preventing adhesion formation has been established in mechanical circulatory assist devices. No studies of the clinical use of PRECLUDE® Pericardial Membrane have been conducted in the heart transplantation setting.

PRECLUDE® Pericardial Membrane is a monofilament ePTFE membrane comprised of ultra-thin, ultra-porous, ultra-low porosity material that is sterilized with ethylene oxide. It is indicated for use as a surgical membrane. It should be handled with care to avoid damage to the membrane.

PRECLUDE® Pericardial Membrane is a surgical membrane indicated for: (1) closure of pericardial defects created by mechanical circulatory assist devices; and (2) anastomosis of the assist device to the heart. PRECLUDE® Pericardial Membrane is used to span defects created by mechanical circulatory assist devices.

For use with mechanical circulatory assist devices and for use with percutaneous left ventricular assist devices, use sterile technique.

PRECLUDE® Pericardial Membrane is a monofilament ePTFE membrane comprised of ultra-thin, ultra-porous, ultra-low porosity material that is sterilized with ethylene oxide. It is indicated for use as a surgical membrane. It should be handled with care to avoid damage to the membrane.

PRECLUDE® Pericardial Membrane is a surgical membrane indicated for: (1) closure of pericardial defects created by mechanical circulatory assist devices; and (2) anastomosis of the assist device to the heart. PRECLUDE® Pericardial Membrane is used to span defects created by mechanical circulatory assist devices.