

GORE® PRECLUDE®
Pericardial Membrane

DESIGNED TO MINIMIZE TISSUE ATTACHMENT

Evidence supporting improved reoperation:
GORE® PRECLUDE® Pericardial Membrane for
pericardial reconstruction or repair in conjunction
with left ventricular assist device (LVAD) and
other circulatory device patients



Together, improving life



GORE® PRECLUDE® Pericardial Membrane

Evidence supporting improved reoperation.

EFFECTIVE

Shown to facilitate reentry during reoperation.¹⁻¹⁴

CONSERVES TIME

Reported to reduce reoperation time and ease explantation.^{2,5,6,13}

SAFE

Demonstrated to have low risk of infection.^{1-4, 7-9, 11-17}

15 clinical experiences

demonstrate efficacy and safety of utilizing GORE® PRECLUDE® Pericardial Membrane to support reoperations^{1-5, 6-9, 12-17}

~2,900 patients

were reported to be implanted with GORE® PRECLUDE® Pericardial Membrane, mostly to minimize tissue attachment¹⁻¹⁸

EFFECTIVE

According to results from clinical studies/reports utilizing GORE® PRECLUDE® Pericardial Membrane in total artificial heart (TAH) and LVAD surgeries:



100%

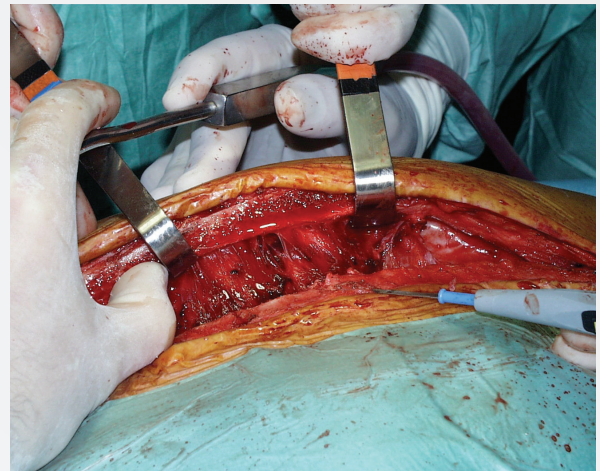
of patients were free of severe adhesion at reoperation^{5, 11-13, 18}

Reoperation patients implanted with an LVAD or TAH and GORE® PRECLUDE® Pericardial Membrane

N = 65

Patients with severe adhesions

0 (0.0%)



Tissue attachment is known to lead to cardiac injury and increase reoperation time.

Image courtesy of Redo Valve Surgery Nowadays: What Have we Learned?, Acta Chirurgica Belgica, 103:5, 475-480, DOI: 0.1080/00015458.2003.11679470 Dr. Pierre Wauthy, Acta Chirurgica Belgica, © The Royal Belgian Society for Surgery, reprinted by permission of Taylor & Francis Ltd, <http://www.tandfonline.com> on behalf of The Royal Belgian Society for Surgery and Prof. Pierre Wauthy. Used with permission.

CONSERVES TIME

Results reported from a clinical study utilizing GORE® PRECLUDE® Pericardial Membrane while implanting a TAH demonstrate:¹³

GORE® PRECLUDE® Pericardial Membrane can reduce reoperation time substantially.^{2,5,6,13}

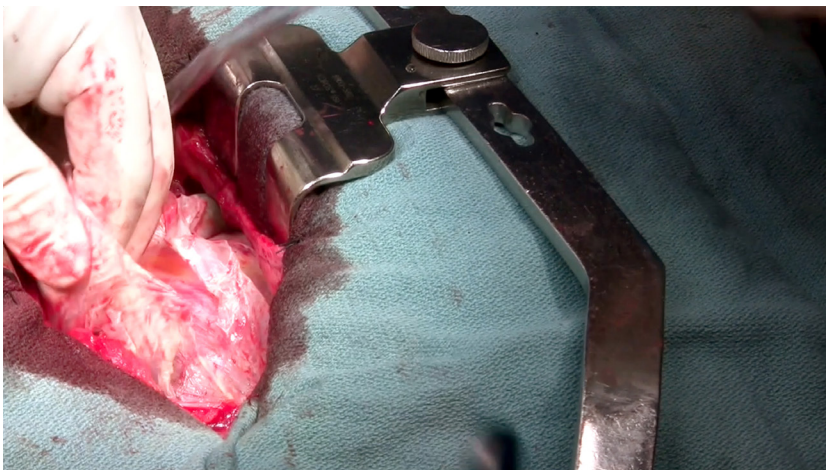


>50%

decrease in time required to remove a TAH¹³

Reoperation steps	Average time without GORE® PRECLUDE® Pericardial Membrane ¹³	Average time with GORE® PRECLUDE® Pericardial Membrane ¹³
Removal of TAH	~2 hours	~0.5–1 hour
From incision to cannulation	84 minutes	57 minutes

“In the few patients who were reoperated, mediastinal and heart dissection was accomplished in a few minutes.”²



Yau TM, Rao V. Facilitating reoperations using GORE® PRECLUDE® Pericardial Membrane to wrap left ventricular assist devices. Presented at Optimizing reoperation in LVAD patients utilizing GORE® PRECLUDE® Pericardial Membrane. A Gore webinar series for healthcare professionals; March 4, 2021; Toronto Ontario, Canada.

SAFE

According to published studies, LVAD and TAH implantations increase the risk of infection regardless of utilizing GORE® PRECLUDE® Pericardial Membrane during surgery.^{19,20}

6.4% – 53.7%²¹

Meta analysis: infection rate range of LVAD and TAH surgeries



7.7%

clinical studies/reports utilizing GORE® PRECLUDE® Pericardial Membrane have shown an infection rate within the range associated with LVAD and TAH surgeries^{5, 11–13, 18}

ORDERING INFORMATION

GORE® PRECLUDE® Pericardial Membrane.

Catalogue number	Nominal thickness (mm)	Nominal width (cm)	Nominal length (cm)
1PCM100	0.1	6	12
1PCM102	0.1	12	12
1PCM103	0.1	15	20

To schedule a meeting with a specialist or to place an order please contact your Gore Field Sales Associate or via:

U.S. toll free: 800 528 8763

Direct: 928 864 2927

PRECLUDEinformation@wlgore.com

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 Consult Instructions
for Use
eifu.goremedical.com

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 eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ^{Rx} Only

Products listed may not be available in all markets.

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