

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}

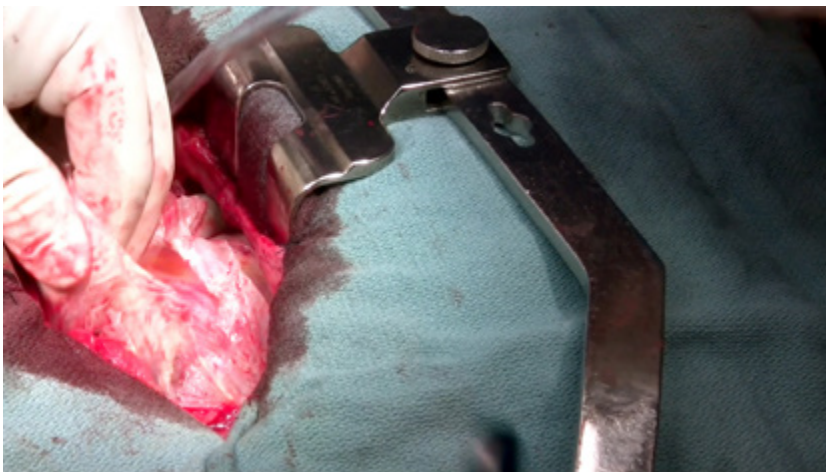


>50%

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

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