

CorMatrix® ECM® for Pericardial Closure

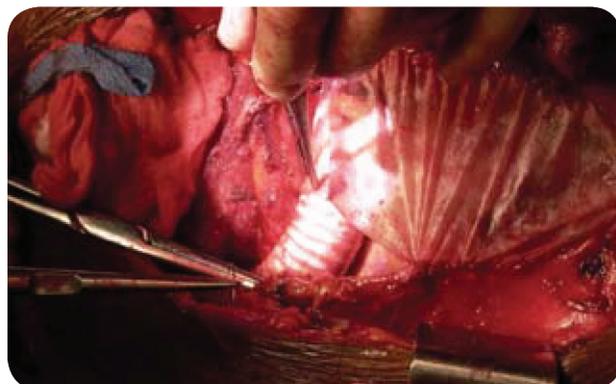
Left Ventricular Assist Device (LVAD)

The St. Vincent Heart Center of Indiana Indianapolis, Indiana

A series of 21 Class IV heart failure patients were evaluated and treated using CorMatrix ECM for Pericardial Closure during left ventricular assist device (LVAD) implantation. In all cases the LVAD was offered as either a bridge to transplant, bridge to decision, or destination therapy. In each case the ventricular assist device was placed via a median sternotomy and efforts were made to preserve the native pericardium. In cases where a redosternotomy was required, the native pericardium was fully mobilized prior to LVAD implantation. All devices were placed using left ventricular apical cannulation (for the LVAD inflow) and the ascending aorta for the anastomosis of the LVAD outflow conduit.

Following the LVAD implantation and after obtaining adequate hemostasis to allow closure, CorMatrix ECM was used to replace or augment the native pericardium. After two chest tubes were placed inside the pericardium, the CorMatrix ECM was sewn to the native pericardium using a running 4-0 Prolene suture. Care was taken to ensure the CorMatrix ECM was in direct contact with native tissue on all four sides. When possible the LVAD outflow graft was placed completely inside the pericardial space; when this was not possible the outflow graft was wrapped in a separate sheet of CorMatrix ECM. Prior to sternal closure another drain was placed anterior to the reconstructed pericardium.

To date, several patients have gone back to surgery for transplant and in all cases sternal re-entry was easily performed without incident. On redo cases we routinely perform a sub-sternal dissection prior to dividing the sternum. In all cases no more than minimal retro-sternal adhesions were encountered. This facilitated a rapid and safe redosternotomy. In our experience the intra-pericardial adhesions varied significantly from patient to patient. In one case CorMatrix ECM was histologically identified as native pericardium. There have been no CorMatrix ECM related complications. Overall we have experienced clinical improvement through the use of CorMatrix ECM, which has decreased the time and complexity of redo operations.



The inferior and diaphragmatic pericardium being restored with the CorMatrix ECM over the outflow graft of the LVAD.



The LVAD is completely covered by the ECM utilizing the required circumferential closure technique with a running 4-0 Prolene.



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What is CorMatrix?

CorMatrix develops and delivers innovative biomaterial devices that harness the body's innate ability to repair damaged cardiac and vascular tissues.

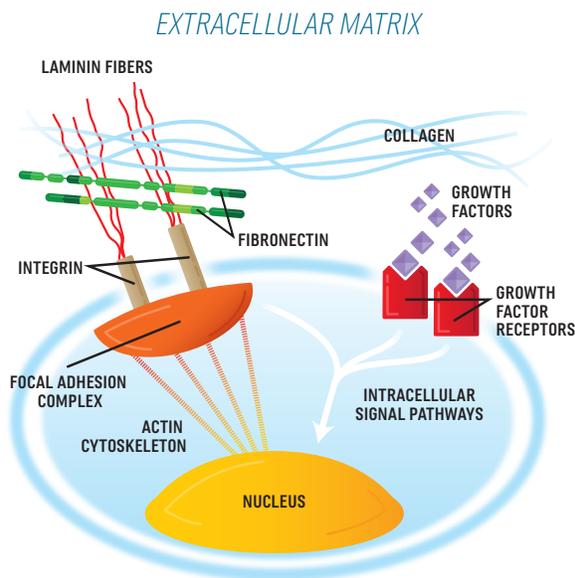
Extracellular matrix (ECM®) is the naturally occurring bioscaffold that surrounds cells in almost all tissues. ECM functions to regulate cell adhesion, differentiation, division, and migration.

CorMatrix acts as a scaffold into which the patient's own cells migrate and integrate — stimulating natural wound healing mechanisms which mature to form a strong, permanent tissue repair.

CorMatrix products are de-cellularized biologic scaffolds primarily composed of:

- » Structural proteins
- » Adhesion glycoproteins
- » Glycosaminoglycans (GAGs)
- » Proteoglycans
- » Matricellular proteins

CorMatrix is produced in a manner that retains these natural ECM molecules including growth factors, proteins, and cytokines which are known to play important roles in host tissue repair and remodeling. CorMatrix devices enable surgeons to restore the native anatomy of cardiac and vascular tissues in need of repair, serving as a superior alternative to synthetic or cross-linked materials.



Proliferation, Differentiation, Attachment, Migration

The cell is in constant communication with ECM through transmembrane receptors contained within the cell membrane. Through the specific cell attachments, ECM guides the gene expression and enables cell migration, proliferation, and differentiation.