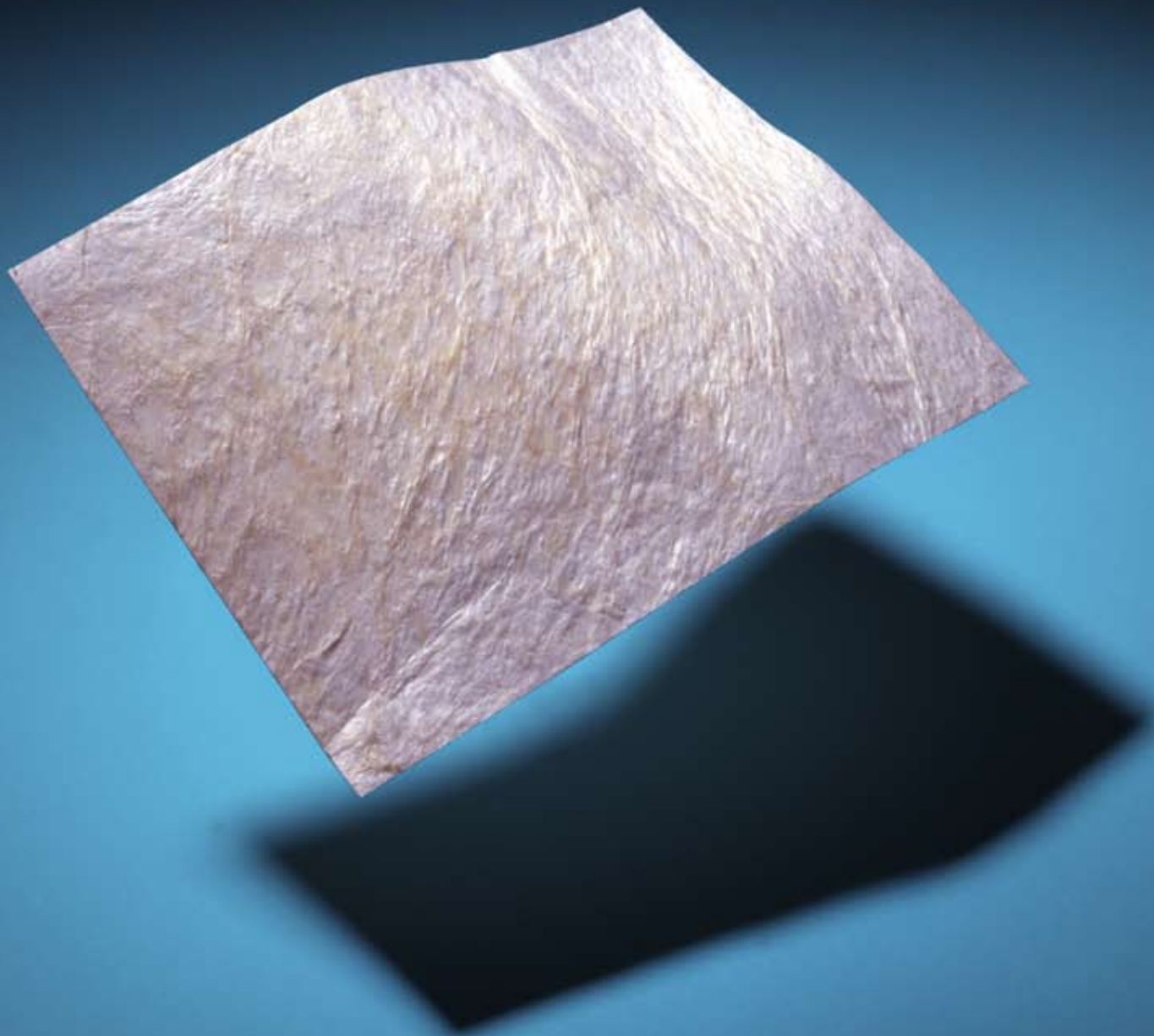


> CorMatrix[®] ECM[™] Technology

Rethink the treatment of a damaged heart



REMODEL. REGROW. RESTORE.

CorMatrix ECM Technology provides a natural bioscaffold matrix that enables the body's own cells to repair and remodel damaged cardiovascular tissue.

Harnessing Science

A NATURALLY OCCURRING BIOSCAFFOLD

CorMatrix ECM Technology is a unique extracellular matrix that combines the innate attributes of nature with the precision of science to help the heart heal itself. It is an acellular biomaterial that does not encapsulate when surgically implanted, but is gradually remodeled, leaving behind organized and healthy tissue.



WHAT IS AN EXTRACELLULAR MATRIX?

Found in all animals, extracellular matrix, or ECM, is the naturally-occurring bioscaffold that surrounds cells in almost all tissues. Historically, the ECM has been viewed as a passive support structure upon which cells orient and move themselves in response to other cells. However, research in the last decade has demonstrated that the matrix is not a passive structure.

Functionally, the extracellular matrix can also regulate:

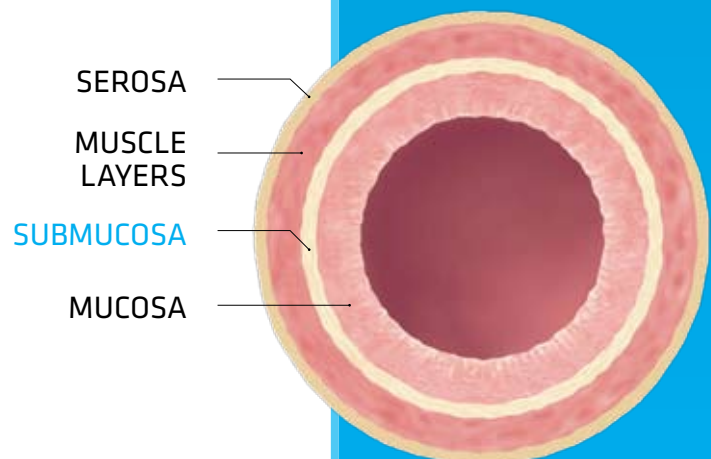
- **cell adhesion**
- **cell division**
- **cell differentiation**
- **cell migration**

All of these processes occur through interaction of the various components of the extracellular matrix with the cell surface. The matrix is necessary to coordinate the activities of the cells that reside within it and is also necessary for tissue maintenance and plays a major role in tissue repair. Without a functional matrix, tissue repair is stalled and is no longer able to support normal cellular processes necessary for tissue repair.

CORMATRIX ECM ORIGIN AND COMPOSITION

CorMatrix ECM products are made from porcine small intestinal submucosa or SIS. SIS has been used as an acellular biologic scaffold in many different surgical applications. It has both structural and functional roles and while the composition of the ECM varies by tissue, it is generally composed of 4 major types of molecules:

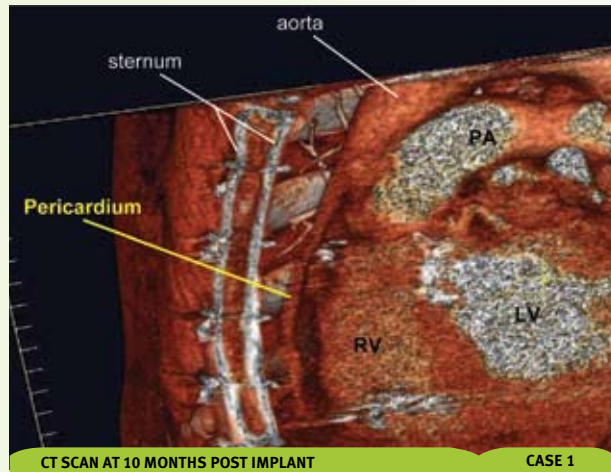
- **Structural proteins**, such as collagen and elastin
- **Adhesion glycoproteins**, such as fibronectin and laminin
- **Glycosaminoglycans (GAGs) and proteoglycans**, such as hyaluronan, heparin sulfate, heparin and dermatan sulfate
- **Matricellular proteins**, such as thrombospondins, osteopontin, and tenascins.



CROSS-SECTION DIAGRAM OF PORCINE SMALL INTESTINE

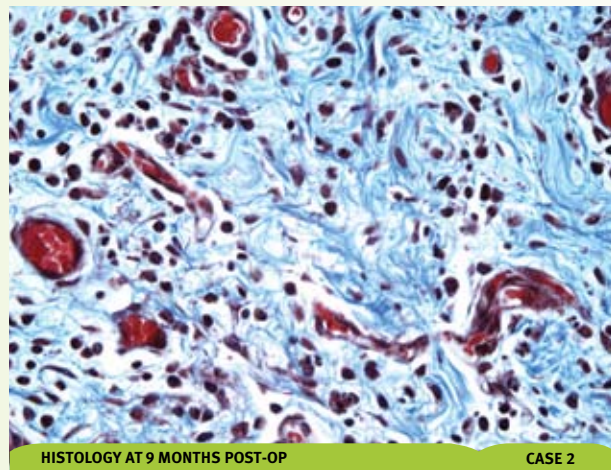
Case Reports

EXPERIENCE UTILIZING CORMATRIX ECM

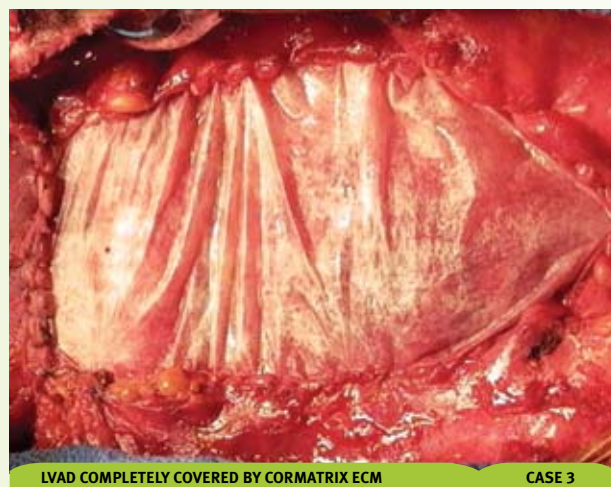


PERICARDIAL CLOSURE

CASE 1 A 50-year old patient following AV surgery had the pericardium repaired using CorMatrix ECM. Image shows a 3-D reconstruction of a 64-slice CT scan performed 10 months post implant. Image is looking through the patient's left chest. Sternum, heart and neo-pericardium with normal anatomical planes anterior and posterior to the remodeled pericardium are clearly visible.



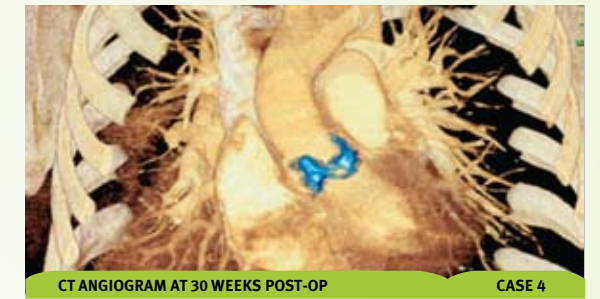
CASE 2 A 5-day-old pediatric patient received a CorMatrix ECM to close the native pericardium following primary surgery. Patient returned 9 months post implant for staged re-op procedure. Re-exposure through the sternum took 10-15 minutes which was much less than expected. A tissue sample was taken at 9 months from across the suture line demarcating native and neo-pericardium. Histology using Massons Trichrome showed extensive collagen deposition (blue), cellular infiltration represented by dark nuclei (black dots), as well as robust angiogenesis (red) throughout the tissue sample.



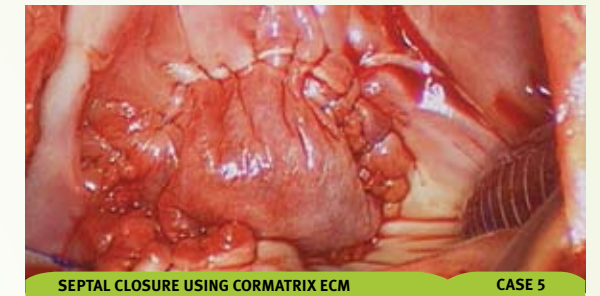
CASE 3 A series of 21 Class IV heart failure patients were evaluated and treated using CorMatrix ECM for Pericardial Closure during left ventricular assist device (LVAD) implantation. Following the LVAD implantation and after obtaining adequate hemostasis to allow closure, CorMatrix ECM was used to replace or augment the native pericardium. 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 redo-sternotomy was required, the native pericardium was fully mobilized prior to LVAD implantation. In one case CorMatrix ECM was histologically identified as native pericardium. There have been no complications related to use of CorMatrix ECM in these 21 patients.

CARDIAC TISSUE REPAIR

CASE 4 A 66-year-old patient with aortic root size not sufficient to avoid patient prosthesis mismatch underwent annular root enlargement utilizing CorMatrix ECM. A CT angiogram of the aorta performed 30 weeks post-op demonstrates no evidence of the implanted CorMatrix ECM. The aortic contour appears completely normal.



CASE 5 A 79-year-old patient with a 3.5 x 1.5 cm broad-based left atrial mass extending up to the mitral valve and septal hypertrophy with SAM and moderate MR underwent a myxoma resection and septal repair using CorMatrix ECM. Image shows CorMatrix ECM implanted for septal repair. Post-operative echocardiography showed an intact septal patch, mild residual MR with no SAM and no residual LV outflow obstruction.

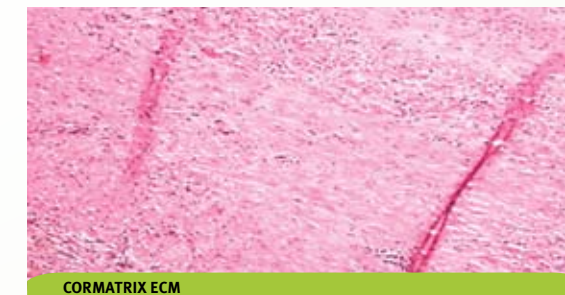


COMPARATIVE DATA

In this sheep study, portions of descending aortic tissue were removed and replaced with either CorMatrix ECM or typical commercial glutaraldehyde-treated pericardium.

CorMatrix ECM:

At seven weeks, cross-sectional histology shows CorMatrix ECM demonstrates rapid recellularization. Some of the implanted ECM is still apparent but new collagen and proteoglycan are being produced by infiltrating cells. H&E stained picture at 10X shows an abundance of new nuclei.



Glutaraldehyde patch:

At seven weeks, cross-sectional histology shows no cells infiltrating the crosslinked material. Scar tissue has formed on the surface of the glutaraldehyde patch seen on H&E stained picture at 10X.



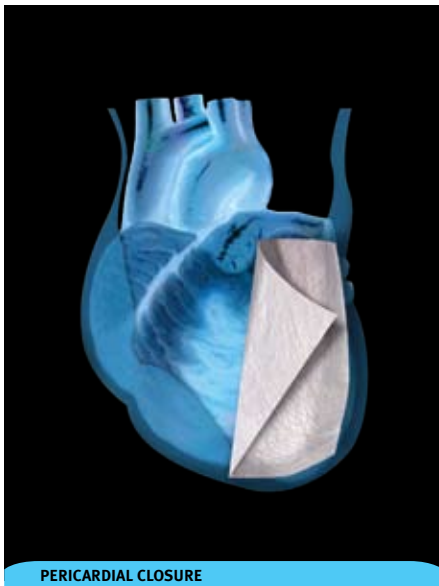
NON-CARDIOVASCULAR EXPERIENCE UTILIZING EXTRACELLULAR MATRIX DEVICES

Studies utilizing extracellular matrix implants in other clinical applications have shown that the biomaterial supports early and abundant new vessel growth and is remodeled and replaced by new functional tissue over time. More than 500,000 extracellular matrix implants have been utilized in clinical applications across all areas of the body.

CorMatrix ECM

PRODUCTS TO ADVANCE CARDIOVASCULAR TREATMENT

CorMatrix currently has U.S. FDA clearance and a European CE Mark to sell its CorMatrix ECM Technology as an implant for pericardial closure, has U.S. FDA clearance for cardiac tissue repair, and is actively researching additional indications that would be beneficial for surgeons and their patients with cardiovascular disease.



CORMATRIX ECM FOR PERICARDIAL CLOSURE

CorMatrix ECM can be used for pericardial closure and reconstruction as cells infiltrate the bioscaffold to form a new pericardial layer. Preclinical and clinical data suggest complete reformation of the pericardial space, including an intact mesothelial lining, which provides a solution for surgeons to now reconstitute the pericardium and restore the normal anatomic structure.

Pericardial Function

The pericardium has an important role in maintaining proper cardiac physiology by maintaining proper wall and septal motion and filling pressures. In addition to its fibrous composition for protection, the pericardium is lined with a single layer of mesothelium. As with many organs, this layer keeps tissues from adhering to each other. The intact mesothelium also secretes proteins that dissolve fibrous adhesions within the pericardial space.

Assisting Pericardial Reapproximation

Once divided during surgery, the pericardium retracts significantly and an inflammatory response starts in the body signaling a change has occurred. Following surgery, the pericardium is difficult to re-approximate and is typically left open to avoid causing undue pressure on underlying grafts and structures. However, the absence of the pericardial barrier often leads to scarring and the formation of adhesions between the heart and sternum. Moreover, the normal function of the heart is compromised. Available synthetic or cross-linked materials have been largely abandoned as viable options for pericardial reconstruction because they have been shown to cause more adhesions, calcifications and infections.

CORMATRIX ECM FOR CARDIAC TISSUE REPAIR

Repair of intracardiac tissue can be very difficult and is needed to repair damaged cardiac structures or during procedures such as valve repair when the prosthetic valve available does not fit properly. CorMatrix ECM is ideal for intracardiac surgery based on its ability to structurally support repairs and ultimately remodel tissue. In cases such as atrial septal defect repair, CorMatrix ECM can effectively close a hole and generate new, healthy tissue in lieu of using objects such as nitinol plugs or synthetic patches. Because CorMatrix ECM is gradually replaced as it is remodeled, there is no foreign material left behind as is the case with historically available repair materials.

CorMatrix ECM for Cardiac Tissue Repair is routinely used for:

- Suture line reinforcing
- Cardioplegia cannulation site
- Buttressing for soft tissue reapproximation
- Right atrium cannulation site
- Pledgets
- Aortotomy reinforcement
- Aortic cannulation sites
- Ventricular reinforcement
- Septal defect repair



www.cormatrix.com



CORMATRIX[®]

A BOLD ADVANCE FOR CARDIAC TISSUE REPAIR.

About CorMatrix[®] Cardiovascular, Inc.

CorMatrix is a medical device company dedicated to developing and delivering innovative biomaterial devices that harness the body's own innate ability to repair damaged heart tissue. The company is currently researching, developing, and commercializing a novel platform technology, known as CorMatrix ECM, for a variety of cardiovascular indications. CorMatrix is a private company headquartered in Atlanta, Georgia with additional facilities in Sunnyvale, California.

Customer Service

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