CorMatrix ECM® Bioscaffold

REMODEL. REGROW. RESTORE.

CorMatrix ECM Bioscaffold provides a natural bioscaffold matrix that enables the body’s own cells to repair and remodel damaged cardio-vascular tissue.
Harnessing Science

A Naturally Occurring Bioscaffold

CorMatrix ECM 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 differentiation
- cell division
- 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

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

**CorMatrix ECM for Pericardial Repair and Reconstruction**

CorMatrix ECM can be used for pericardial repair 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 Repair and Reconstruction**

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

The data contained in this brochure is on file at CorMatrix Cardiovascular, Inc.
Case Report

Experience Using CorMatrix ECM

PERICARDIAL REPAIR AND RECONSTRUCTION

CASE 1  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 is 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 2  A 56 year-old patient with Multi Vessel Coronary Artery Disease received CorMatrix ECM to reconstruct the native pericardium. A vicryl suture was used.

CORMATRIX SUTURING TECHNIQUE: The CorMatrix for Pericardial Repair and Reconstruction is placed with a running continuous suture to the native transected pericardium. One side, typically the left, is sutured starting in the inferior aspect and continuing toward the top of the incision. Once this side is done, the retractor is allowed to close slightly in order to estimate how much of the CorMatrix will be required to reach the opposite side without tension yet without redundancy or excess material. The CorMatrix can be cut to meet the required width. The remaining circumference can now be sutured with the same or different suture in a continuous manner leaving only a small opening at the inferior edge for an angled chest tube to be placed inside the pericardial space.

Healthy Patient
- Normal Anatomy
- Normal Pericardial Space
- Native pericardium plays an important role of provide a barrier and allows freedom of movement of the heart under the sternum

Pericardial Reconstruction with CorMatrix
- Retrosternal Space is Maintained
- Compartmentalizes Bleeding Post-Op
- Allows Free Movement of the Heart under the Sternum

Pericardial Reconstruction without CorMatrix
- No Pericardial Space
- Heart and Vascular Structures are Adhered to the Sternum
- Potential for Increased Patient Risk during Re-Op Procedure
**Cardiac Tissue Repair**

**CASE 3**  Use of CorMatrix ECM to repair a mitral valve anterior leaflet perforation caused by endocarditis. The CorMatrix ECM is visible as a small patch sutured to the anterior leaflet (upper right).

**CASE 4**  A 79-year-old patient with a 3.5 x 1.5 cm broadbased 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.

**CorMatrix ECM Benefits**

- Porcine small intestine submucosa is a naturally occurring non-crosslinked biomaterial that once processed, yields a unique acellular Extracellular Matrix (ECM) that supports tissue repair and remodeling.

- CorMatrix ECM is processed in a manner that removes cells, leaving the complex extracellular matrix intact.

- Extracellular matrix materials have been used in over a million patients for general soft tissue reconstruction, pericardial and cardiac tissue repair, urogynecological procedures, wound treatment, and the repair of body wall defects.

- CorMatrix ECM material retains the natural composition of extracellular matrix molecules including collagen, growth factors, proteins, and cytokines which are known to have important roles in host tissue repair and remodeling.

**Non-cardiovascular Experience Utilizing Extracellular Matrix Devices**

Studies utilizing 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 1,000,000 extracellular matrix implants have been utilized in clinical applications across all areas of the body.

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CorMatrix ECM® Carotid Repair

The CorMatrix ECM for Carotid Repair acts as an acellular scaffold for use as a vascular patch to repair the carotid artery. The extracellular matrix (ECM) scaffold is a biomaterial derived from porcine small intestinal submucosa (SIS). The SIS is developed from a select layer of tissue that is recovered from porcine small intestine. The acellular ECM scaffold allows the patient’s own cells to migrate and attach within the ECM to naturally repair the tissue defect.

CorMatrix ECM Benefits for Carotid Repair

• Hemostatic: Minimal bleeding at suture line
• Thickness similar to normal carotid artery
• Remodels into native tissue
• Easily conforms to repair defect
• Good handling facilitates suturing
• Leaves no materials behind to induce a foreign body response
• Good suture retention strength

Customer Service
Telephone: 877-651-2628  |  Email: customerservice@cormatrix.com

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