Elutia's Portfolio of Natural, Regenerative Biomatrices for Cardiovascular Surgical Repairs

> **ProxiCor**[®] For Cardiovascular Repairs



Tyke[®] For Neonatal and Infant Repair

Trusted by surgeons. Validated by data. Naturally.



Elutia's Biomatrices for Cardiovascular Tissue

The Natural Choice for Repair and Regeneration

Elutia's biomatrix portfolio is built on engineered extracellular matrix (ECM) biology—designed to facilitate surgical repair, support healing, and address key causes of complications.

Trusted in over one million patients and supported by hundreds of peer-reviewed publications, Elutia's ECM biomatrices offer confidence in every repair.



Clinical Experience in Infected and High-Risk Surgical Fields*

Elutia's biomatrices (ProxiCor, VasCure) have been used for valve and annular repair in patients with endocarditis, as well as in high-risk conditions such as prior infection or radiation. Though based on limited number of patients, these cases showed no infection-related failures and good tissue integration—supporting potential use in contaminated or compromised fields.^{7,9,10}

*ProxiCor, VasCure and Tyke are not specifically cleared or indicated by regulatory authorities for the prevention or treatment of infection. Clinical judgment should guide their use in infected or high-risk surgical fields.

- 1. Allen K, et al. Front Cardiovasc Med. 2021;8:631750.
- 2. Bibevski S, et al. Front Cardiovasc Med. 2020;7:562136.
- **3.** Ferng A, et al. Ann Thorac Surg. 2017;104(3):e239-e241.
- 4. Grimes M, et al. Biomed Mater Eng. 2005;15(1-2):65-71.
- 5. Haney L, et al. Ann Thorac Surg. 2021;S0003-4975(21)01384-9.
- **6.** Piterina A, et al. Int J Mol Sci. 2009;10(10):4375-4417.

- 7. Sundermann S, et al. Interact Cardiovasc Thorac Surg. 2015;20(1):10–14.
- 8. Elutia Data on File.
- 9. Myers P, et al. Circulation. 2012;126:A16130.
- 10. Gerdisch M, et al. J Thorac Cardiovasc Surg. 2014;148(4):1370–1378.
- 11. Badylak S, et al. J Biomed Mater Res B Appl Biomater. 2003;67(1):648-654.
- 12. Jernigan T, et al. Ann Surg. 2004;239(5):733-738.



Restore and Protect. Naturally.

Pericardial Integrity Matters

Rebuild the Natural Barrier^{1,2}

- Reduce adhesions to surrounding tissue
- Preserve retrosternal distance for easier reentry
- Protect the heart from mechanical injury

Engineered for a Tension-Free, Hemostatic Closure^{2,3}

- Suture-friendly for fast, secure fixation
- Conforms to minimize tension and bleeding at suture lines
- No stretching or forced approximation required. Enables full pericardial coverageeven after large resections

Support Better Surgical Outcomes^{1,2,4}

- May reduce post-op complications and hospital readmissions
- Aids in identification of post-op bleeding
- Contributes to a cleaner operative field during reentry

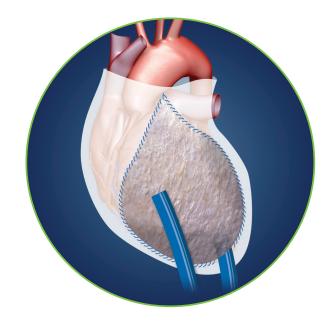
Learn more on next page – RECON study

ProxiCor is carefully trimmed to fit the defect precisely and sutured circumferentially to ensure secure placement and optimal tissue integration

Courtesy of Dr. Alfredo Rego

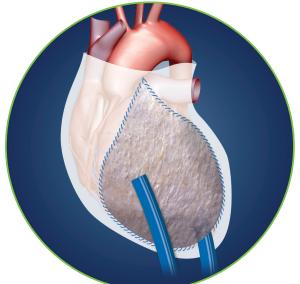


- 1. Rego A, et al. J Cardiothorac Surg. 2019;14(1):61.
- 2. Rego A, et al. Heart Surg Forum. 2022;25(1):E008–E019.
- 3. Sundermann S, et al. Interact Cardiovasc Thorac Surg. 2015;20(1):10–14.
- 4. Rao V, et al. Ann Thorac Surg. 1999;67(2):484-488.





Fewer Post-Op Complications. Naturally.

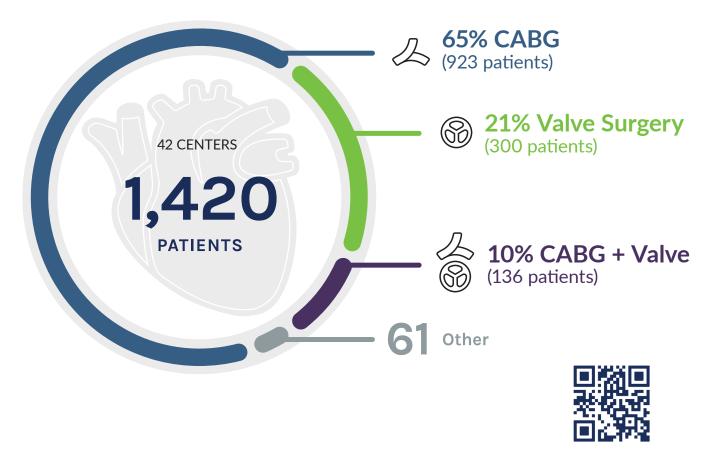


Pericardial closure with ProxiCor was shown to reduce post-operative complications in the RECON Study.

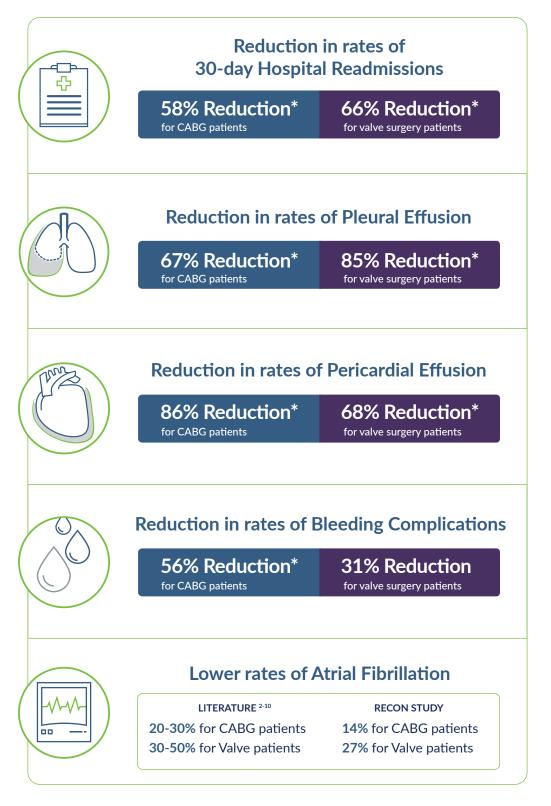
This prospective, multicenter study evaluated 1,420 patients undergoing cardiac surgery (CABG or valve repair/replacement). ProxiCor was used for pericardial closure following the index procedure, with outcomes compared to a matched national cohort.¹

The **RECON** Study

Included the most common cardiac surgeries



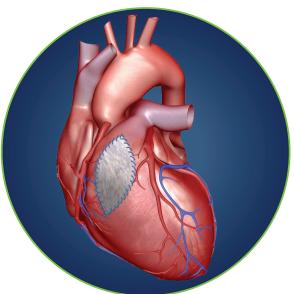
The benefits of closing



- 1. Rego A, et al. J Cardiothorac Surg. 2019 Mar 15;14(1):61.
- 2. Kaleda VI et al. Interact Cardiovasc Thorac Surg. 2012;14:384-9;
- **3.** Saxena A et al. Am J Cardiol. 2012;109:219–25;
- 4. Rostagno C et al. J Cardiothorac Vasc Anesth. 2010;24:952-8;
- 5. Filardo G et al. Circ Cardiovasc Qual Outcomes. 2009;2:164-9;
- 6. Aranki SF et al. Circulation. 1996;94:390-7;
- 7. Mathew JP et al. JAMA. 2004;291:1720;
- 8. El-Chami MF et al. J Am Coll Cardiol. 2010;55:1370-6;
- 9. Helgadottir S et al. J Cardiothorac Surg. 2012;7:87;
- **10.** Shen J et al. J Thorac Cardiovasc Surg. 2011;141:559–70.



Strength and Regeneration for Intracardiac Repair. Naturally.



ProxiCor CTR provides a biologic alternative for intracardiac repair, offering immediate structural support while promoting healthy tissue remodeling. Its natural scaffold encourages regeneration through cellular infiltration and angiogenesis, with less foreign body response than synthetic materials.¹

Engineered for Reliable Intracardiac Defect Repair^{1,2}

- Conforms to complex intracardiac defect geometries for precise repair
- Pliable and easy to trim for tailored fit and full contact with viable tissue
- Facilitates remodeling into vascularized, functional native tissue

Promote Long-Term Healing and Patient Outcomes^{1,3}

- Minimizes chronic inflammation and fibrotic response
- Encourages vascularized tissue ingrowth and constructive remodeling
- Enhances durability of repair through natural tissue regeneration

Supports a range of intracardiac repairs, including:

PROCEDURE	USAGE		
PROCEDORE	USAGE		
Ventricular Septal Defect (VSD)	Critical in congenital repairs; supports closure and regeneration		
Atrial Septal Defect (ASD)	Supports closure and tissue regeneration		
Endocarditis	Aids reconstruction of affected tissue		
Aortic Root Enlargement	Enables secure placement of larger prosthetic valves		
Left Ventricular Aneurysm Repair	Stabilizes infarcted tissue; supports ventricular geometry		
Sinus of Valsalva Aneurysm Repair	Reinforces weakened aortic wall		
Suture Line Buttressing	Enhances strength at high-pressure suture sites		
Use as a Pledget	Adds reinforcement for suture retention		

Supports constructive tissue remodeling

ProxiCor has shown effective tissue remodeling in challenging cases.

Case Report: Aortic Root Repair⁴

A 90-year-old woman with critical aortic valve stenosis and a severely calcified, hypoplastic aortic root underwent surgical valve replacement. ProxiCor was used to augment the aortic root, serving as a biologic scaffold in this anatomically restricted, high-risk setting.

The patient recovered well and resumed normal activity. She passed away at age 93, and with the family's consent, a unique opportunity arose to perform histological evaluation of the explanted ascending aorta and aortic valve.

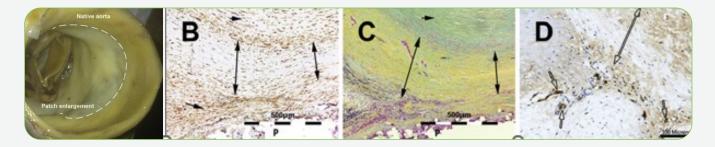
Findings 3 Years Post-Implant

- Histology showed the **ProxiCor graft was indistinguishable from native aortic tissue**, confirming full incorporation.
- Microscopy revealed organized neotissue with endothelialized microvasculature and host cell repopulation, indicating **regenerative healing** rather than fibrosis.
- Minimal inflammatory response demonstrated excellent biocompatibility, even in an elderly patient.
- No calcium deposition was observed in the patch.

Clinical Relevance

This case illustrates the regenerative capacity of ProxiCor in a comorbid, elderly patient—a population with diminished cellular turnover and healing potential. The decellularized ECM structure of ProxiCor supports endogenous cell infiltration, vascularization, and remodeling into functional tissue.

ProxiCor provides both structural reinforcement and biologic activity, enabling durable outcomes in complex aortic reconstructions. Its use in this challenging scenario reinforces its role as a preferred biologic patch in cardiac repair—especially where healing potential is limited and surgical precision is critical.



Tissue integration and healing with ProxiCor.(A) The explanted aortic root shows the interface between native tissue and the ProxiCor patch (dashed line), used to enlarge the aortic root in a high-risk surgical repair.(B) Staining for smooth muscle actin (SMA) reveals active cellular integration within the patch (double arrows), along with organized neointimal development (short arrow) and well-formed adventitial tissue (long arrow). P: Polyester suture.(C) Movat pentachrome stain further demonstrates the presence of mature, fibromuscular neointima (arrow) and highlights the patch (double arrows) as structurally incorporated.(D) von Willebrand factor (vWF) staining shows clear evidence of neovascularization (arrows) along the outer surface of the patch, indicating healthy tissue remodeling and blood vessel formation.

- 1. Piterina A, et al. Int J Mol Sci. 2009 Nov 20;10(10):4375-4417.
- 2. Ferng A, et al. Ann Thorac Surg. 2017 Sep;104(3):e239-e241.
- **3.** Grimes M, et al. Biomed Mater Eng. 2005;15(1-2):65-71.
- 4. Slachman FN. Ann Thorac Surg. 2014;97(5):e129.



Engineered for Durable Repair. Naturally.

VasCure combines the strength to withstand arterial pressures with the flexibility to conform to complex anatomies—supporting durable repair and healing where it matters most.

Designed for Complex Vascular Repairs¹⁻³

- Supports vascular integrity while maintaining compliance
- Conforms to challenging anatomies for precise repairs
- Provides mechanical strength to reinforce suture lines and withstand vessel pressures

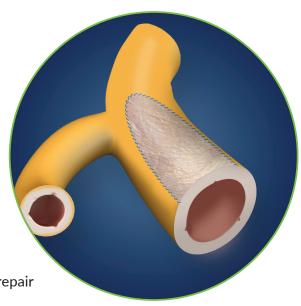
Clinically Backed Performance¹

- Enhances healing and recovery at the repair site
- Reduces the risk of restenosis, thrombosis, and other complications
- Promotes site-specific tissue remodeling and natural integration
- Promotes sustained vessel performance over time
- Helps minimize the need for reintervention

A versatile solution for vascular repair procedures, including:

PROCEDURE	USAGE	
Carotid/iliofemoral endarterectomy	Support vessel integrity and protect suture lines after plaque removal	
AV fistula repair	Reinforces anastomoses in high-flow hemodialysis access sites	
Repair of peripheral vasculature	Structural reinforcement in vessel reconstruction	

Whether repairing the carotid or femoral artery, reinforcement must withstand arterial pressure and movement without compromising healing. VasCure provides the strength for repair and the flexibility to conform to complex anatomies—ideal for endarterectomy closure and beyond.



Clinical Evidence at a Glance:

Proven Safety and Performance¹

VasCure delivers durable, healthy healing across a range of vascular repairs

- ~100% procedural success in iliofemoral and carotid artery cases
- Excellent vessel patency up to 24 months post-op
- <3% restenosis rate
- <0.8% graft-related adverse events

Real-World Integration

A 55-year-old male underwent femoral endarterectomy with VasCure patch angioplasty. Over three procedures spanning 19 months, two separate patches were observed to be fully integrated and visually indistinguishable from native artery.

Histology confirmed site-specific remodeling with no inflammation or degeneration. Post-operative testing showed normal function and complete pain symptom resolution. (See Figures, right)

"Synthetic materials, such as polyethylene terephthalate (Dacron[®]) or polytetrafluoroethylene (PTFE), are ready to use and have a long shelf-life, have high biomechanical strength, but do not mimic the native vasculature, and stimulate a foreign body response on implantation which can lead to post-operative complications due to chronic inflammation, lack of remodeling, limited compliance, and poor resistance to infection."

-Allen K, et al. Front Cardiovasc Med. 2021

1. Allen K, et al. Front Cardiovasc Med. 2021;8:631750.

2. Piterina A, et al. Int J Mol Sci. 2009;10(10):4375-4417.

3. Data on file.



Article: Extracellular Matrix Patches forEndarterectomy Repair **PERFORM Study:** 221 patients with iliofemoral artery repair

Carotid Registry: 45 cases of carotid artery reconstruction (38 patients)

Complete Integration in Femoral Artery Repair¹

Figure 1:



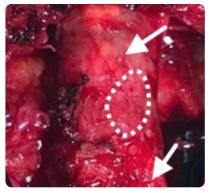
Initial patch angioplasty of the right common femoral artery (CFA) using VasCure (arrow) following endarterectomy.

Figure 2:



At 16 months, the VasCure patch (arrow) in the right CFA was fully incorporated into native vascular tissue, indistinguishable from the surrounding artery. Due to disease at an adjacent site, a second VasCure patch was used to extend the repair.

Figure 3:



Twenty months post-index procedure, a third surgery was performed for bypass. Both previously placed VasCure patches (arrows) appeared fully incorporated into the native femoral artery. The dashed line indicates the patch-to-artery anastomosis for histology.



Designed for the smallest patients

Tyke features a thin, pliable design ideal for intracardiac and arterioplasty procedures. Easy to suture—even in fragile anatomy—and designed for confident handling in small, high-risk patients.

- Promotes tissue regeneration for native tissue-like vessel and cardiac repair
- Shown to reduce reintervention compared to synthetic alternatives.

Usage:

- For use in neonates and infants for arterioplasty procedures, particularly pulmonary artery repair, as well as venoplasty and general vascular reconstruction (for delicate vessels <12 mm diameter and pressures <50 mmHg)
- Additional Applications: Intracardiac repairs (e.g., septal or annulus repair), valve reconstruction, pericardial repair, and epicardial covering

Demonstrated Success in a Large Pediatric Study: Over 400 Uses in a Congenital Heart Program¹

400 77% 58% 8.5 In a study involving over 400 grafts (309 patients),

of the patches were used in arterioplasties, of which

were for pulmonary artery repair

the median patient age

success rate free fromreoperation was observed at3 years, with sustained outcomes

96%

10

98%

success rate at 5-years



Article: Congenital Heart Program

Haney L, et al. Ann Thorac Surg. 2021;S0003-4975(21)01384-9.
Bibevski S, et al. Front Cardiovasc Med. 2020;7:562136.

Proven Regenerative Healing

Histological evaluation confirms Tyke's capacity for integration with native host tissue. In a 12-year-old patient following pulmonary artery reconstruction, the graft underwent complete remodeling. At the graft-native vessel interface, seamless integration and minimal inflammatory infiltrate were observed findings indicative of true structural incorporation (figures below).

Tyke not only delivers structural support, but also facilitates true tissue regeneration, preserving vessel integrity and functionality.

Histology of Remodeled Tyke in Pulmonary Artery at 12 Months²

Twelve-year-old patient who underwent pulmonary artery reconstruction.



Masson's trichrome stain shows organized collagen and spindle-shaped cells aligned with the vessel wall, along with a continuous endothelial lining and preserved vascular structure.



The graft-native vessel junction demonstrates seamless integration, aligned tissue architecture, and minimal inflammation.

ProxiCor[®] VasCure[®]

Tyke

Surgical Technique Guide

Hydrates quickly and handles intuitively, like native tissue.



1. Prepare

- Handle using strict aseptic technique.
- Hydrate biomatrix in sterile saline for 1–2 minutes (up to 1 minute for Tyke).



2. Trim

 Trim to fit repair size anatomy—use only what is needed. Do not oversize.

(Tyke can be trimmed before or after hydration)

Avoid the use of glutaraldehyde-based glues, platelet gels, and hemostatic agents, which may interfere with remodeling.



3. Position & Secure

- Position to allow full contact with viable, vascularized tissue.
- Avoid free edges for effective tissue integration. Do not sew to synthetic material.
- Use non-absorbable, monofilament polypropylene sutures to achieve full circumferential closure.

Elutia's customizable biomatrix tissue adapts to your needs, with robust options for structural support and ultra-conforming profiles for delicate repairs.

Refer to the product Instructions for Use for detailed indications, contraindications, warnings, and usage information. Use by or on the order of a physician only.

Ordering Information

Product	Ply	Order Code	Size
ProxiCor ®	4	CMCV-003-401	7x10 cm (5-pack)
For Pericardial Closure		CMCV-003-402	7x15cm (5-pack)
ProxiCor [®]	4	CMCV-004-401	7x10 cm (5-pack)
For Cardiac Tissue Repair		CMCV-004-404	4x7 cm (5-pack)
VasCure [®]	6	CMCV-014-609	1x10 cm (5-pack)
For Vascular Repair		CMCV-012-606	2x10 cm (5-pack)
Tyke [®]	2	CMCV-098-204	4x7 cm (single)
For Neonatal and Infant Repair		CMCV-099-204	4x7cm (5-pack)



©2025 Elutia Inc. All rights reserved. | Elutia.com



Contact Us Customer Service: 877-651-2628 customerservice@Elutia.com

1100 Old Ellis Road, Suite 1200, Roswell, GA 30076 Phone: 470-514-4085 | Customer Service: 877-651-2628