



## Aziyo Announces Publication of RECON Study of Pericardial Reconstruction Using ProxiCor

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### Prospective Study of 1,420 Patients Showed Statistically Significant Reduction in Post-Operative Complications and 30-Day Hospital Readmission Rates

**SILVER SPRING, MD. – April 9, 2019** – [Aziyo®Biologics, Inc.](#), a fully integrated regenerative medicine company, today announced the publication of results from its landmark [RECON](#) study in the *Journal of Cardiothoracic Surgery*<sup>1</sup>. The prospective, single arm study included 1,420 patients in 42 hospitals across the United States and represents the largest pericardial-closure study conducted to date. The goal of the study was to evaluate clinical outcomes with pericardial reconstruction using ProxiCor™, the company's proprietary decellularized extracellular matrix (ECM) scaffold designed for the repair of the pericardium following cardiac surgery.

The study showed that the use of ProxiCor was safe and effective in various pericardial-closure procedures. Additionally, it showed that when compared to the Nationwide Readmissions Database (NRD)<sup>2</sup>, ProxiCor patients had statistically significant ( $p < 0.05$ ) reductions in 30 day all-cause hospital readmission rates of 58-66% as well as statistically significant reductions in bleeding, and post-operative pericardial and pleural effusion rates ( $p < 0.05$ ).

"I think conceptually surgeons believe in the substantial benefits of re-establishing normal anatomy and physiology whenever possible. Using an ECM scaffold such as ProxiCor provides a suitable alternative to rebuild and regenerate the pericardium after open-heart surgery procedures", said the study's author and primary investigator Alfredo Rego, M.D., Ph.D, (Medical Director, South Florida Heart and Lung Institute). "We now have a prospective study in a very large number of patients that supports the clinical and potential financial benefit of rebuilding the pericardium using ProxiCor."

Every year in the United States there are more than 200,000 coronary artery bypass (CABG) procedures and approximately 120,000 valve repair/replacement surgeries. According to the Nationwide Readmission Database, 1 in 9 CABG patients will be readmitted within 30 days of surgery due to a complication from the procedure while 1 in 7 valve repair/replacement patients are readmitted for similar reasons. These readmissions alone each cost \$15,000-\$16,500 on average. Additionally, events such as bleeding and pleural effusion can cost an incremental \$19,000 – \$22,000 on average<sup>2</sup>. The clinical, and corresponding financial implications, of these readmissions and complications create a considerable impact not only on the patient, but also their caregivers and the overall healthcare system.

#### About the RECON Study

- **Published:** *Journal of Cardiothoracic Surgery* March 2019
- **Purpose:** Study the clinical outcomes of pericardial reconstruction using ProxiCor
- **Design:** Prospective, single arm with comparison to National Readmissions Database
- **Enrollment:** 1,420 patients, 42 centers in the United States
- **Included:** 923 CABG, 436 valve repair/replacement, 61 other reconstruction procedures
- **Conclusion:** Pericardial closure with ProxiCor following cardiac surgery is associated with a reduction in the proportion of patients with pleural effusion, pericardial effusion, and 30-day readmission compared to a nationwide database

#### About [Aziyo Biologics, Inc.](#)

Aziyo Biologics is a fully integrated, commercially oriented regenerative medicine company. Since its founding in 2015 the Company has expanded through acquisitions and strategic partnerships, creating a high growth commercial entity. Its proprietary products are used in orthopedic, cardiovascular and other medical specialties. For more information, visit [www.Aziyo.com](http://www.Aziyo.com).

#### For additional information, please contact:

Courtney Guyer  
Aziyo Biologics, Inc.  
Phone: (201) 668-0814  
[PR@aziyo.com](mailto:PR@aziyo.com)

1. Rego et al. *Pericardial Closure with Extracellular Matrix Scaffold following Cardiac Surgery Associated with a Reduction of Postoperative complications and 30-day Hospital Readmissions. Journal of Cardiothoracic Surgery. 2019, 14:61.*

2. The NRD database is developed by the Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) as part of the Healthcare Cost and Utilization Project (HCUP).