Independent Study Explores Genesee BioMedical's Cutting-Edge TransForm™ Mitral Valve Repair Ring for Cardiac Surgery

Peer-reviewed independent bench testing examines the TransForm™ mitral valve repair ring and highlights lifetime management considerations in cardiac surgery.

DENVER, CO, UNITED STATES, February 13, 2026 /EINPresswire.com/ -- Genesee BioMedical, Inc. acknowledges the recent publication of a new peer-reviewed, open-access article in Structural Heart authored by Keith B. Allen, MD, et al, 2026, reporting independent bench testing of the Genesee TransForm™ McCarthy Mitral Annuloplasty Ring under transcatheter conditions. As mitral valve repair continues to evolve, long-term treatment planning has become an increasingly important consideration for multidisciplinary heart teams. While surgical mitral valve repair remains the preferred treatment for many patients, durability can vary depending on underlying disease and surgical technique.

> Our findings demonstrate that the TransForm™ ring does indeed circularize and can anchor a balloon-expandable THV to facilitate TMViR."
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> *(Allen et. al, 2026)*

In this context, independent researchers explored how annuloplasty ring design may influence future treatment pathways. The recently published article contributes to ongoing scientific discussion around annuloplasty ring geometry, flexibility, and lifetime management considerations.

Origins of the TransForm™ McCarthy Mitral Annuloplasty Ring:
The TransForm™ McCarthy Mitral Annuloplasty Ring was developed by Patrick M. McCarthy, MD, Executive Director of the Bluhm Cardiovascular Institute at Northwestern University Feinberg School of Medicine and Northwestern University, to address evolving needs in modern mitral valve repair. Drawing on decades of surgical experience, Dr. McCarthy sought to design a ring that supports durable surgical repair while encouraging long-term treatment planning. The ring

was engineered with a focus on preserving native mitral valve geometry, supporting minimally invasive and robotic approaches, and maintaining flexibility to accommodate future therapeutic considerations as patient care continues to evolve. Its design reflects a growing emphasis on lifetime management in mitral valve disease rather than a single-procedure mindset.

Overview of the Independent Bench Testing:
The independent bench testing reported in Structural Heart was led by Keith B. Allen, MD, Director of Surgical Research for the Mid America Heart & Lung Surgeons at Saint Luke's Hospital of Kansas City, together with a multidisciplinary team of cardiac surgeons and interventional cardiologists. The study was investigator-initiated and conducted independently of Genesee BioMedical, Inc. The authors examined the mechanical behavior of the TransForm™ ring in a bench-top setting. The ring is described as semirigid and saddle-shaped at baseline, with anterior and posterior stiffeners and a silicone core at the commissures that allows controlled stretch. Bench testing was performed using TransForm ring sizes ranging from 24 mm to 32 mm in combination with balloon-expandable transcatheter heart valves. Valve deployment was assessed visually and subjectively by both a cardiac surgeon and an interventional cardiologist to evaluate ring circularization and valve anchoring under controlled conditions.

Key Findings Reported by the Authors:
According to the authors, bench testing demonstrated that the ring transformed from its resting D-shaped, saddle geometry toward a circular configuration corresponding to the transcatheter valve diameter in multiple tested configurations. The study also reports that balloon filling volumes varied depending on valve and ring size pairings and notes that larger ring sizes may require larger or dedicated transcatheter mitral devices to achieve optimal conformity.
The authors emphasize that these findings are based on bench testing and serve as proof of concept rather than clinical evidence.

Implications for Lifetime Management:
Beyond the mechanical observations, the publication highlights broader implications for the lifetime management of valvular heart disease. As the use of bioprosthetic surgical and transcatheter valves expands, particularly in younger patients, the likelihood of future interventions increases. Drawing parallels to aortic valve replacement, the authors suggest that lifetime management considerations are increasingly relevant in mitral valve repair and emphasize the importance of heart-team collaboration when evaluating long-term treatment strategies.

Looking Ahead:
While limited to bench-top testing with a small number of devices, the study contributes to ongoing scientific discussion around annuloplasty ring design and future treatment planning. The authors note that further evaluation in physiologic environments and with dedicated transcatheter mitral technologies is warranted.

The full article is available open access in Structural Heart:

https://doi.org/10.1016/j.shj.2025.100791

About Genesee BioMedical, Inc.:
Genesee BioMedical, Inc. is a medical device company focused on developing innovative solutions for cardiac surgery. The company's portfolio includes technologies designed to support modern surgical workflows and evolving treatment strategies, with a focus on thoughtful design and long-term planning. Learn more: https://geneseebiomedical.com/

Reference:
Allen, K.B., Romary, D.J., Grier, E.A., Huded, C.P., Pham, D.T., Johnston, D.R., et al. 2026. Bench Testing of a New, Semirigid, Saddle-Shaped, Complete Mitral Annuloplasty Ring Designed to Circularize During Transcatheter Mitral Valve-in-Ring Procedures. Structural Heart, Volume 0, Issue 0, 100791.
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Note: Bench testing is non-clinical and does not represent an approved indication for use.

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