Docket #: S22-035

An Adjustable Mitral Ring for Asymmetric and Continuous Off-Bypass Annulus Reduction

Researchers at Stanford University have created a novel mitral valve annuloplasty ring that can be adjusted in size off-bypass in response to regurgitation.

Mitral annuloplasty ring implantation is one of the most common mitral valve surgeries to reduce mitral regurgitation by establishing proper leaflet coaptation. Mitral ring sizing is a difficult process whereby a surgeon decides how much to reduce the size of the annulus while the heart is arrested. Methods currently do not exist to adjust the ring size once the heart has been restarted, and small sizing errors often result in persistent regurgitation, which requires the surgeon to re-arrest the heart and re-perform the annuloplasty procedure.

To avoid exposing patients to this additional risk, Stanford researchers have developed an annuloplasty ring with a mechanism to adjust its size after the heart has been closed and re-animated. They used custom folding and semiflexible material technologies to enable asymmetric annulus constriction via sutures routed through the ring. The suture-based tightening mechanism exits the left atrium and allows for post-implantation adjustments based on real-time heart function. This invention enables surgeons to address minor sizing errors without extensive reoperation.

Figure

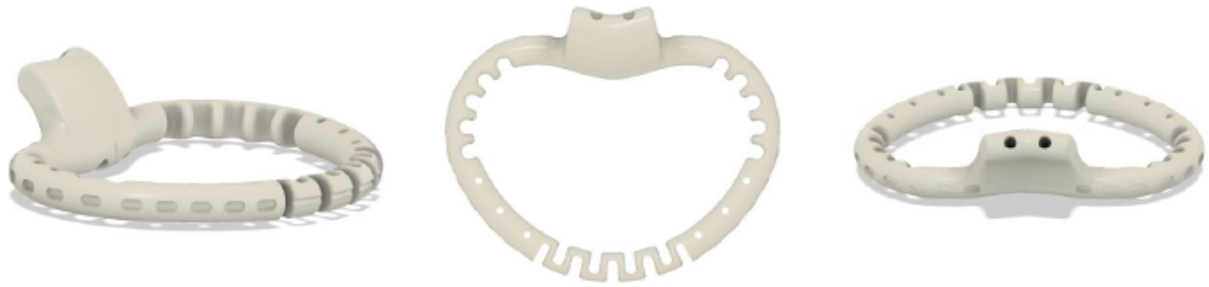

Figure Description: Adjustable mitral ring design (image credit: the inventors)

Stage of Development
Prototype, *ex vivo* proof of concept

Applications

- Mitral valve annuloplasty

Advantages

- Off-bypass adjustability
- Reduced surgery time
- Improved surgical outcome

Publications

- Zhu, Y., Imbrie-Moore, A. M., Wilkerson, R. J., Paulsen, M. J., Park, M. H., & Woo, Y. J. (2022). Ex vivo biomechanical analysis of flexible versus rigid annuloplasty rings in mitral valves using a novel annular dilation system. *BMC cardiovascular disorders, 22*(1), 73.

- Pandya, P. K., Park, M. H., Zhu, Y., & Woo, Y. J. (2023). Biomechanical analysis of novel leaflet geometries for bioprosthetic valves. *JTCVS open, 14*, 77–86.
- Park, M. H., Marin-Cuartas, M., Sellke, M., Pandya, P. K., Zhu, Y., Wilkerson, R. J., Holzhey, D. M., Borger, M. A., & Woo, Y. J. (2023). An analytical, mathematical annuloplasty ring curvature model for planning of valve-in-ring transcatheter mitral valve replacement. *JTCVS techniques, 20*, 45–54.
- Zhu, Y., Park, M. H., Wilkerson, R. J., Joo, H. C., Pandya, P. K., & Woo, Y. J. (2024). A 3D-Printed Externally Adjustable Symmetrically Extensible (EASE) Aortic Annuloplasty Ring for Root Repair and Aortic Valve Regurgitation. *Cardiovascular engineering and technology, 15*(2), 224–231.

Patents

- Published Application: WO2024026049
- Published Application: 20250169951

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