Docket #: S20-192

Intraoperative Aortic Valve Visualization Test Device

Stanford researchers in the Woo Lab have developed a novel device that allows for direct visual assessment of the aortic valve apparatus under physiologic pressure in aortic valve procedures. The funnel shaped device with a cantilevered edge on the proximal end fits a wide range of graft or aorta sizes without distortion and is secured to the distal end of a graft or the aorta without slippage or fluid leakage. Two standard luer lock ports provide clear fluid injection (pressurization) and de-airing for a clear view. With continued clear fluid injection, the surgeon can clearly assess the aortic valve under physiologic pressure via the transparent top. Given the reversible attachment mechanism, this device enables surgeons to assess aortic morphology, cusp symmetry, and coaptation before and after aortic valve repair in an iterative process without the need to come off bypass (See video.)

Intraoperative Aortic Valve Visualization Test Prototype

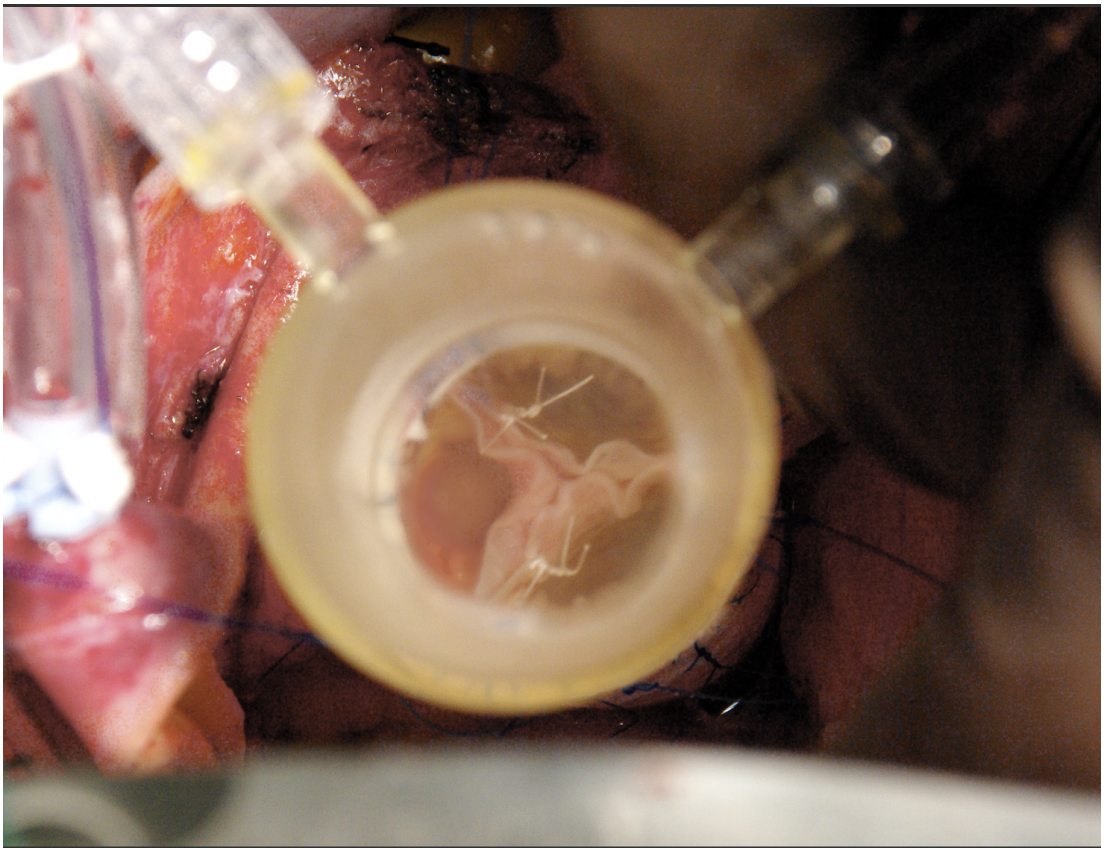
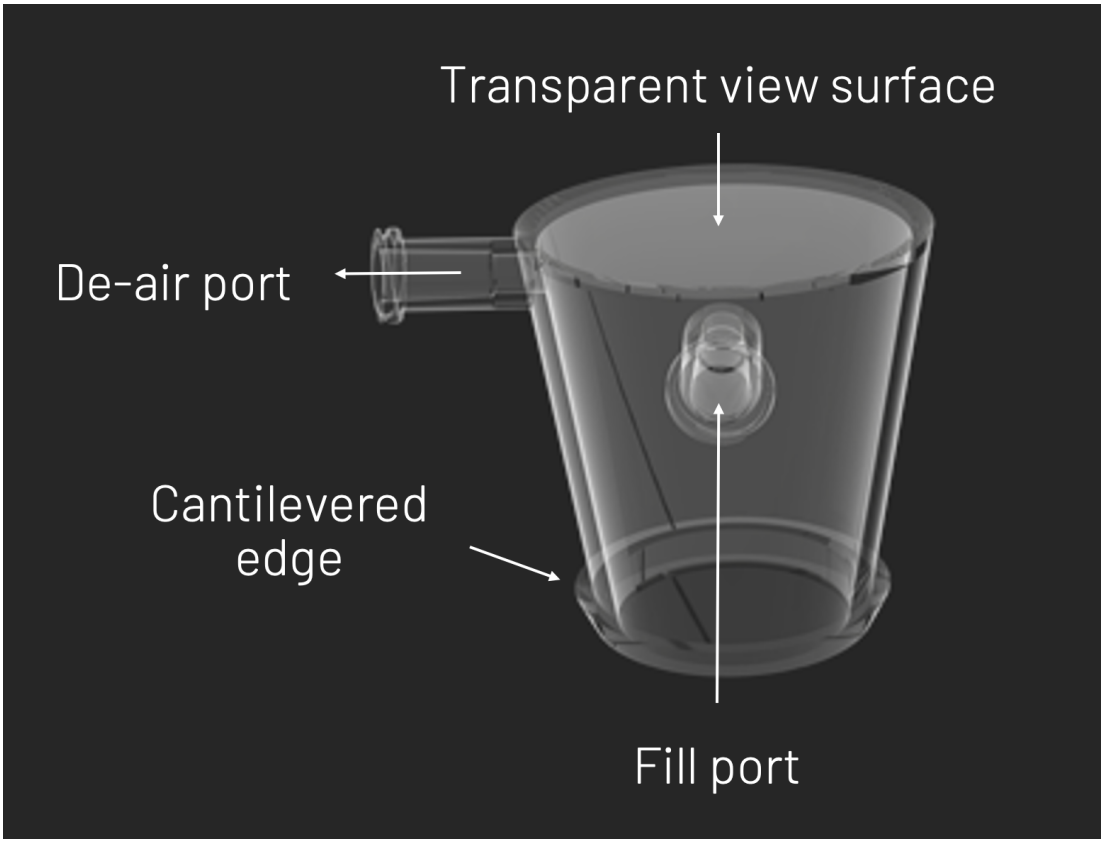


Fig. 1



CAD rendering of the device

Post aortic valve repair, surgeons often test valve competency via saline injection test, which provides inadequate pressurization. Graft clamping test only provides subjective information and does not allow a direct view of the valve. Transesophageal echocardiogram evaluation remains the primary mode of intraoperative assessment of the aortic valve, but the results are highly operator dependent and also do not provide direct visualization of the aortic valve. If the repair is unsuccessful deemed by echocardiogram, the surgeon would have to re-cross clamp, re-arrest the heart, and re-repair the aortic valve, all of which can significantly increase intraoperative and postoperative risk, such as stroke and heart attack.

The Woo Lab device mimics the physiologic pressure that the aortic valve experiences in diastole, allows surgeons to visually inspect the valve before aortic closure and complete any additional repairs without re-arresting the heart, and thereby provides a safer and more effective outcome than current techniques.

Stage of Development

Researchers in the Woo Lab at Stanford Medicine has completed a preliminary first

in man testing, demonstrating safety and efficacy of the device.

Applications

- **Cardiothoracic surgery** - aortic valve testing

Advantages

- **Safer and more effective** than current techniques
  - **Surgeon can directly inspect valve competency and repair success** without an echocardiogram, potentially reducing surgery time and reducing the need to re-cross clamp and re-repair aortic valves.
  - **Provides physiologic pressure for aortic valve competency test** without clamps, which block the surgeon's view to the aortic valves
  - **Decreases intraoperative risk and risk of postoperative complications,** such as stroke and heart attack.

Publications

- Zhu, Y., Imbrie-Moore, A. M., Paulsen, M. J., Park, M. H., Tran, N. A., & Woo, Y. J. (2022). A Novel Device for Intraoperative Direct Visualization of a Pressurized Root in Aortic Valve Repair. *The Annals of Thoracic Surgery*.
- Zhu, Y., Imbrie-Moore, A. M., Paulsen, & Woo, Y. J. (2021). *U.S. Patent Application No. WO2021252405A1*.

Patents

- Published Application: WO2021252405
- Published Application: 20230109069

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