

IDE Pivotal Transcatheter Valve Trial

Structural heart

CT, fluoroscopy, echocardiography

Pre- and post-implant assessment

Challenge

A pivotal IDE trial of a transcatheter valve replacement system placed extraordinary demands on imaging. Precise anatomical sizing before the procedure was essential to device selection and patient safety, while consistent core lab review of post-implant imaging over extended follow-up was required to document device performance, positioning, and durability. Measurements taken at different timepoints and by different readers had to remain directly comparable, and every assessment needed to satisfy the evidentiary standard of a PMA submission.

Our Solution

Intrinsic Imaging assembled a dedicated team of cardiovascular radiologists and imaging engineers to evaluate each case. Pre-procedural CT studies were analyzed using three-dimensional multiplanar reconstruction with calibrated measurement methods, yielding reproducible anatomical sizing for every implant candidate. Post-implant assessments followed the same calibrated methodology across all follow-up timepoints, with rigorous quality control applied to every submission so that longitudinal comparisons rested on a consistent measurement foundation.

Results

- 100% technical protocol compliance across implant sites
- Core lab data included in the PMA submission
- Core laboratory assessments accepted by FDA reviewers

Read the full study online: <https://www.intrinsicimaging.com/case-studies/medical-device>

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 750 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System, Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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