

Imaging Endpoints for a Coronary Stent IDE

30 sites

Angiography, IVUS, OCT

Late lumen loss endpoint

Challenge

An investigational device exemption trial for a novel coronary stent required quantitative angiographic endpoints—late lumen loss, percent diameter stenosis, and binary restenosis—measured with enough precision to detect clinically meaningful differences between study arms. Intravascular imaging substudies using IVUS and OCT added further complexity, demanding consistent pullback technique and frame selection. The sponsor needed a core lab whose measurements would withstand FDA's scrutiny of pivotal device data.

Our Solution

Intrinsic Imaging performed quantitative coronary angiography using validated edge-detection software with cardiologist oversight of every measurement, applying standardized frame selection and calibration procedures across all sites. IVUS and OCT pullbacks underwent central quality review for acquisition adequacy before analysis, and volumetric measurements followed a pre-specified analysis plan with blinded replicate reads to quantify measurement variability. All endpoint data were documented in an audit-ready format aligned with the trial's statistical analysis plan.

Results

- Late lumen loss measured with 0.12 mm precision
- Pivotal endpoint data accepted without FDA measurement queries
- IDE approval supported by core lab dataset

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

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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