

CASE STUDY · MEDICAL DEVICE

Four-Year Venous Stent Trial for Symptomatic Venous Outflow Obstruction

4,000+ venogram, x-ray and ultrasound exams · Venography, duplex ultrasound, radiographs · Primary patency and stent integrity

Challenge

A four-year clinical trial of an interventional device for symptomatic venous outflow obstruction required radiological review of more than 4,000 venograms, radiographs and ultrasound examinations. Venous patency assessment combines duplex ultrasound flow and diameter measurements with venographic stenosis grading, and the two modalities can disagree; stent integrity and migration must be assessed on radiographs against a post-deployment baseline.

Across a long follow-up, the sponsor needed consistent patency definitions, consistent measurement across readers and years, and a process that kept the longitudinal record intact as patients moved through annual follow-up visits.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with definitions for primary, assisted primary and secondary patency, stenosis thresholds on venography, duplex flow and diameter criteria, and radiographic stent integrity assessment. Sites were qualified and trained on acquisition across all three modalities, including standardized duplex protocols for the iliofemoral segments.

Full-time interventional radiologists performed blinded reads of each examination against the patient's baseline, with the charter governing how discordant duplex and venographic findings would be reconciled. A second reader reviewed every examination with a patency failure or integrity finding, and adjudication resolved discordance.

Centralized image transfer, quality control and processing linked each patient's serial examinations, and project managers tracked the four-year follow-up schedule against protocol windows.

Intrinsic Imaging's Results

- More than 4,000 venographic, radiographic and ultrasound examinations reviewed over four years by a dedicated interventional radiology team
- Patency definitions and stenosis thresholds applied uniformly across 28 sites with reader agreement on patency status above 90%
- Every patency failure and stent integrity finding double-read and adjudicated with documented rationale
- Follow-up imaging compliance maintained above 88% through the 36-month visit via active schedule tracking

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

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and 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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