

Spinal Fusion Device Trial With Fusion Review

28 sites

CT, flexion-extension radiographs

24-month fusion endpoint

Challenge

Establishing the effectiveness of a spinal fusion medical device requires objective, repeatable evidence that fusion has occurred and that the implant has remained stable. Fusion status and subsidence had to be assessed consistently across 24 months of post-surgical follow-up, with measurements sufficiently reproducible to support the trial's fusion endpoint. Given the well-documented subjectivity of radiographic fusion assessment, the sponsor needed a central methodology that could withstand scrutiny in an IDE final report.

Our Solution

Intrinsic Imaging's musculoskeletal radiologists employed calibrated measurement tools to quantify angular and translational motion on flexion-extension radiographs, providing an objective biomechanical complement to morphological assessment. CT examinations were reviewed for bridging bone formation under standardized criteria, and the two lines of evidence were integrated into a single documented fusion determination for each timepoint. Uniform methods applied across the full follow-up period ensured that longitudinal comparisons rested on a stable measurement foundation.

Results

- Reader agreement above 0.90 on fusion status
- Complete 24-month imaging dataset
- Core lab findings included in the IDE final report

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

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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