

CASE STUDY · MEDICAL DEVICE

International Class III Device Trial for Lower Back Pain

Large international Class III device trial · Lumbar radiographs, CT, MRI · Device position, disc height and adjacent segments

Challenge

A large international clinical trial investigated the efficacy of a Class III medical device for the treatment of lower back pain. Spinal device trials combine quantitative radiographic measurement of disc height, segmental alignment and device position with CT assessment of bony response and MRI assessment of adjacent-segment and soft-tissue change, and metal artifact degrades both CT and MRI around the implant.

Class III devices carry the highest regulatory burden, so the sponsor needed measurement methods and reader conventions documented to a premarket approval standard, applied consistently across readers and years of follow-up at sites with widely differing spine imaging practice.

Intrinsic Imaging's Solution

Intrinsic Imaging's musculoskeletal team developed the imaging charter with standardized lumbar radiographic positioning including flexion-extension views, CT metal artifact reduction parameters and MRI sequences suited to periprosthetic assessment, and qualified sites with test acquisitions. Image transfer and quality control were centralized with acquisition feedback.

Fellowship-trained spine radiologists performed quantitative measurements of disc height, segmental range of motion, device position and migration under fixed landmarks, and qualitative assessment of heterotopic ossification, subsidence, radiolucency and adjacent-segment degeneration under predefined grading. Primary endpoint measurements were double-read with adjudication.

Reader agreement was monitored at planned intervals with recalibration, and project management tracked the multi-year follow-up schedule across all regions.

Intrinsic Imaging's Results

- Standardized spine imaging implemented at 36 sites in 9 countries with flexion-extension radiography, artifact-reduced CT and MRI
- Approximately 3,800 examinations measured and graded with double reads on primary endpoints and reader agreement above 90%
- Metal artifact reduction parameters kept unevaluable periprosthetic CT and MRI under 5%
- Measurement and grading documentation produced to a premarket approval standard under an ISO 13485 certified quality system

Read the full study online: <https://intrinsicimaging.com/case-studies/device-class-iii-lower-back>

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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