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

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. 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. The interpretive challenge extends beyond identifying an implant on an image. Motion, alignment, bony response and adjacent tissue findings describe different aspects of the postoperative spine, and their relationship to pain is not necessarily direct. A reproducible imaging endpoint therefore requires both consistent anatomical references and a clear distinction between structural observations and the clinical efficacy question.

## 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. Standardized positioning is central to interpreting flexion-extension images because measured movement depends on how the spine is presented during acquisition. Artifact reduction and periprosthetic sequence selection address visibility near the implant rather than guaranteeing unrestricted assessment. Site test acquisitions provide an opportunity to evaluate whether the required anatomy can be depicted under the specified acquisition conditions.

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. Fixed landmarks give serial quantitative measurements a consistent anatomical reference, while predefined grades organize observations that are not adequately represented by a distance or angle alone. Double reading addresses the reproducibility of primary endpoint interpretation. It does not establish that a structural change explains symptoms, nor does agreement overcome a region that remains obscured by artifact.

Reader agreement was monitored at planned intervals with recalibration, and project management tracked the multi-year follow-up schedule across all regions. Planned agreement monitoring and recalibration address the possibility that reader conventions may diverge during prolonged follow-up. Schedule tracking addresses a separate source of uncertainty: gaps in the longitudinal imaging record. Together, these documented activities support consistency over time, while the reported unevaluable examinations remain a reminder that acquisition optimization cannot make every periprosthetic region fully assessable in every patient.

## 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

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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 50 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.

Contact:
Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com