

Post-Market Clinical Study of Functional Motion Outcomes in Subjects Treated With the Minuteman Device

NCT06355791

Status	RECRUITING
Phase	Not Applicable
Sponsor	Spinal Simplicity LLC
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (9)

- Be a candidate for Spinal Simplicity Minuteman G5 Fusion Plate device per labeled indication
 - Be willing and capable of giving written consent to participate in this clinical study based on voluntary agreement after a thorough explanation of the subject's participation has been provided
 - Be willing and capable of subjective evaluation, read and understand written questionnaires, and read, understand the written informed consent
 - Be 18 years of age or older at the time of enrollment
 - Have been diagnosed with degenerative conditions of the lumbar spine resulting in chronic low back pain with lower extremity symptoms and concurrent neurogenic claudication
- ... and 4 more (see full listing online)

Exclusion (13)

- Had previous spinal surgery at the level of intervention (e.g. lumbar fusion, discectomy, Laminectomy) MILD procedure is not considered an exclusion.
 - Patient physically unable to perform the Gait and/or Balance tests.
 - Current systemic infection or local infection increasing the risk of surgery
 - History of medications decreasing bone quality or soft tissue healing in the opinion of the Investigator
 - Grade II-V spondylolisthesis
- ... and 8 more (see full listing online)

Locations (6 total)

Vista Clinical Research, Newnan, Georgia, United States
Comprehensive Pain & Spine Specialists, Indianapolis, Indiana, United States
University of Kansas Medical Center, Kansas City, Kansas, United States
... and 3 more locations