

OssiMend BA in Posterolateral Instrumented Lumbar Fusion

NCT04775537

Status	RECRUITING
Sponsor	Collagen Matrix
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (6)

- Subject must be 18 years of age or older at the time of consent and must have a documented diagnosis of degenerative disc disease (DDD) that has failed to respond to nonoperative treatment for at least 6 months. DDD is defined by back and/or radicular pain with degeneration of the disc as confirmed by medical history, physical examination, and radiographic studies that may include CT, MRI, plain X-ray film, discography, myelography, etc. with one or more of the following findings:
 - Instability as defined by $\gt 3$ mm translation or $\gt 5$ degrees angulation
 - Osteophyte formation of facet joints or vertebral endplates
 - Decreased disc height, on average by $\gt 2$ mm, but dependent upon the spinal level
 - Herniated nucleus pulposus
- ... and 1 more (see full listing online)

Exclusion (6)

- Subject is under 18 years of age at the time of consent
 - Subject has had prior lumbar spine fusion surgery at any level
 - Subject is currently undergoing treatment for malignancy or has undergone treatment for malignancy
 - Subject is pregnant or nursing or planning to become pregnant during the two years (24 months) following arthrodesis
 - Subject has an active (local or systemic) infection or is undergoing adjunctive treatment for infection
- ... and 1 more (see full listing online)

Locations (4 total)

San Diego Neurosurgery, Encinitas, California, United States
Hartford Hospital, Hartford, Connecticut, United States
University Orthopaedic Associates, Division of OrthoNJ, Somerset, New Jersey, United States
... and 1 more locations