

Coflex PS3 Actual Conditions for Use Study

NCT02555280

Status	RECRUITING
Phase	Not Applicable
Sponsor	Xtant Medical
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (8)

- Radiographic confirmation of at least moderate lumbar stenosis at one or two contiguous levels from L1-L5 that require surgical decompression.
- Visual Analog Scale back pain score of at least 50 mm on a 100 mm scale.
- Neurogenic claudication as defined by leg/buttocks or groin pain that can be relieved by flexion such as sitting in a chair.
- Subject has undergone at least one lumbar injection at any prior time point, AND/OR at least 6 months of prior conservative care without adequate and sustained symptom relief.
- Skeletally mature

... and 3 more (see full listing online)

Exclusion (12)

- Prior fusion or decompressive laminectomy at index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 25°).

... and 7 more (see full listing online)

Locations (19 total)

Desert Institute for Spine Care (DISC), Phoenix, Arizona, United States

Hoag Orthopedics, Irvine, California, United States

Sutter Health, Sacramento, California, United States

... and 16 more locations