

"Lumbar Operatively Inserted PerQdisc Artificial Implant Following Nucleotomy" (LOPAIN2)

NCT05508360

Status	RECRUITING
Phase	Not Applicable
Sponsor	Spinal Stabilization Technologies
Enrollment	72 participants

Key Eligibility Criteria

Inclusion (8)

- Patient is skeletally mature aged 22-70.
- Patient has Degenerative Disc Disease (DDD) at one or more levels between L1 and S1 but the discogenic pain must be limited to a single level.
- Patient has adequate disc height (6mm) at the level to be treated
- Patient has exhausted a minimum of 6 months of conservative treatment for their back (e.g. physical therapy, medications, injections, life style changes, etc).
- Patient has a preoperative Oswestry Disability questionnaire score \leq 40 out of 100 points (40/100)
- ... and 3 more (see full listing online)

Exclusion (23)

- Patient has less than 6 mm of disc height.
- Patient has had prior lumbar spine surgery (nucleoplasty at non-index level is considered acceptable).
- Patient has had spinal fusion in the lumbar or thoracic intervertebral spaces. Cervical fusion is allowed as long as there are no neurologic deficits in the lower extremities.
- Patient has spondyloarthropathy or other spondylolisthesis greater than 2 mm.
- Patient has congenital moderate or severe spinal stenosis or epidural lipomatosis.
- ... and 18 more (see full listing online)

Locations (10 total)

CIGE: Centro de Inmunología y Genética, Medellín, Antioquia, Colombia
Fundacion Hospitalaria San Vicente de Paul, Medellín, Antioquia, Colombia
Cediul S.A., Barranquilla, Atlántico, Colombia
... and 7 more locations