LOPAIN3

Per DPQ114_Uzbekistan.D

Intended purpose and populations of the medical device:

The SST PerQdisc™ Nucleus Replacement System (REF 9012) is intended to replace the nucleus pulposus and support the annulus fibrosis of the intervertebral disc in the L1-S1 spinal region in patients with symptomatic radiculopathy from a focal lumbar disc herniation that undergo partial discectomy and/or sequestrectomy. The patient must be skeletally mature, at least 21 years of age, presenting with symptomatic radiculopathy from focal disc herniation. The patient should not have a history of prior lumbar spine surgery at the index level. The patient should have a minimum disc height of 6 mm.

Inclusion Criteria:

Prospective subjects must meet all of the inclusion criteria as listed below to participate in this clinical study.

- Patient is skeletally mature and at least 21 years of age.
- Patient has a lumbar disc herniation, between L1-S1, with compressive radiculopathy of the traversing nerve root requiring partial discectomy or sequestrectomy. Only one lumbar disc may be treated with the PerQdisc™ device.
- Patient must have an overall disc herniation (extrusion or protrusion) such that half or less of the width of the dorsal annulus of the spinal canal, is affected by the herniation. The width of the canal is defined by the lateral recesses and the central canal (i.e. pedicle to pedicle).
- Patient must have a minimum of 6 mm of disc height as measured in the center of the affected disc.
- Patient is willing and able to give informed consent.
- All surgeries must be approved by at least 2 members of the Medical Advisory Board (MAB) – potential anatomical limitations of safely accessing Kambin's, extent of annular disruption, as well as overall patient criteria will be evaluated.

Exclusion Criteria:

Patient must not meet any of the exclusion criteria included in the list that follows:

- Patient has had prior lumbar spine surgery at the index level (nucleoplasy is acceptable).
- Patient has had spinal fusion in the lumbar spine. Cervical or thoracic fusion is allowed as long as there are no neurologic deficits in the lower extremities.
- Patient has spondyloarthropathy or other spondylolisthesis greater than 4 mm or spondylolysis at the index level (on standing X-ray).

- Patient has underlying moderate or severe spinal stenosis (congenital, degenerative, or due to epidural lipomatosis) at any level. If the index level shows stenosis due to the disc herniation, it is acceptable if the index level is going to be treated concurrently with the PerQdisc procedure.
- Patient has compressive radiculopathy of the exiting nerve root at the index level.
- Patient has significant facet disease. Significant is defined as clinically confirmed by diagnostic block or radiologically grade 2 or higher (mild joint narrowing and irregularity are acceptable, but not sclerosis or osteophyte formation).
- Patient has any known active malignancy.
- Patient has previously undergone or currently on immunosuppressive therapy. Steroids used to treat inflammation are allowed.
- Patient has active local or systemic infection.
- Patient has been diagnosed with hepatitis, rheumatoid arthritis, lupus erythematosus, or other autoimmune disease including AIDS, AIDS related complex (ARC) and HIV.
- Patient has diabetes mellitus (Type 1 or 2) requiring daily insulin management.
- Patient has osteopenia of the spine (T-score of -1.0 or lower). All patients 50 years of age or older, and any post-menopausal women with a history of fractures should have a dual x-ray absorptiometry (DEXA) scan to confirm exclusion.
- Patient has morbid obesity defined as a body mass index (BMI) more than 35 (>35).
- Patient has a known allergy to silicone or barium sulfate.
- Patient has a broad disc herniation that is wider than ½ of the dorsal annulus forming the wall of the spinal canal.
- Patient requires decompression involving disruption of the midline bony-ligamentous elements (i.e. laminectomy).
- Patient has a significant Schmorl's node at the level to be treated, or any Schmorl's nodes affecting 3 or more lumbar levels. Significant is defined as a large, rectangular or irregular shaped node that has an associated active inflammatory process (Modic I changes).
- Patient has more than 20 degrees of mobility on flexion/extension radiographs at the index level.
- Patient has more than 10 degrees of lumbar scoliosis.
- Patient belongs to a vulnerable population or has a condition such that his/her ability to provide informed consent, comply with follow-up requirements, or provide self-assessments is compromised (e.g. developmentally disabled, prisoner, chronic alcohol/ substance abuser).
- Patient is pregnant or plans to become pregnant during the course of the study. Pregnancy ruled out by serum HCG. If patient becomes pregnant during the course of the study and wishes to continue study participation, a new Pregnancy Informed Consent must be completed.

Intraoperative Exclusion Criteria:

- Poor radiological visualization of Kambin's triangle
- Patient has annular defect following surgical treatment of the disc herniation/protrusion that is greater than 6 mm
- Sustained irritation of the exiting nerve root during any aspect of the annular dilation technique (leg movement or if performing with electrical monitoring) in spite of repositioning instruments.
- Protrusion of the 50A Imaging Balloon up to or beyond the outer margin of the vertebra during the imaging steps.
- Patient has a violated endplate as determined by imaging balloons during fluoroscopy.