LOPAIN2

Per DPQ099_Panama.F

Intended purpose and populations of the medical device:

The SST PerQdisc Nucleus Replacement System (REF 9011) is intended to replace the nucleus pulposus of the intervertebral disc in the L1-S1 spinal region in patients with single level discogenic pain. The patient may have single or multi-level degenerative disc disease (DDD) but the discogenic pain must be limited to a single level. The patient must be skeletally mature, aged 22-70, presenting with moderate to severe low back pain (with or without leg pain) that is unresponsive to at least 6 months of non-surgical conservative treatments. The patient should not have a history of prior lumbar spine surgery. The patient should have a minimum disc height of 6 mm. The patient should have a preoperative Oswestry Disability Questionnaire score of ≥40 out of 100 points (40/100) and a low back pain Visual Analog Scale (VAS) of ≥40 mm (4 cm).

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 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 pain (e.g., physical therapy, medications, injections, lifestyle changes, etc.).
- Patient has a preoperative Oswestry Disability Questionnaire score ≥40 out of 100 points (40/100)
- Patient has a low back pain Visual Analog Scale (VAS) ≥40 mm (4 cm).
- Patient has signed the approved Informed Consent Form.
- All surgeries must be approved by the Medical Advisory Board (MAB).

Exclusion Criteria:

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

- 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.
- Patient has significant facet disease. Significant is defined as pain improvement of 80% or more following image-guided medial branch blocks of the target level according to SIS guidelines (diagnostic, contrast controlled).
- 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 or local systemic infection.
- Patient has been diagnosed with hepatitis, rheumatoid arthritis, lupus erythematosus, or other autoimmune disease including AIDS, 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). A DEXA scan should be performed to rule out patients considered at risk for osteopenia.
- Patient has morbid obesity defined as a body mass index (BMI) more than 40 or a weight of more than 45 kg (100 lbs.) over ideal body weight.
- Patient has a known allergy to silicone or barium sulfate.
- Patient has a significant disc herniation at the level to be treated. Significant is defined as a large, extruded herniation that creates a risk for expulsion.
- Patient has a significant Schmorl's node in the level to be treated. Significant is defined as a large, rectangular or irregular shaped node that has an associated active inflammatory process (Modic I changes).
- Patient has motion of less than 3 degrees on pre-operative lateral flexion/extension radiographs.
- 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 urine or serum HCG.

Intraoperative Exclusion Criteria:

- Protrusion of the 20A 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.
- Patient has a disc space that is too narrow for implantation.

MIPL Specific:

- Poor radiological visualization of Kambin's triangle

  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.