Augmented Discectomy Patient Qualifications

- The SST PerQdisc Nucleus Replacement System is intended to replace the nucleus pulposus of the spinal disc in the L1-S1 spinal region in patients with single level discogenic pain.
- Patient may have single or multi-level degenerative disc disease (DDD) but the discogenic pain must be limited to a single level.
- Patient must be skeletally mature, at least 21 years of age, presenting with moderate to severe low back pain (with or without leg pain) that is unresponsive to non-surgical conservative treatments.
- Patient should not have a history of prior lumbar spine surgery.
- Patient should have a minimum disc height of 6 mm.

Contraindications

- 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 immuno-suppressive therapy. Steroids used to treat inflammation are acceptable.
- 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 disc herniation 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).

Intraoperative Contraindications

- Protrusion of the 20A Imaging Balloon up to or beyond the outer vertebral margin of the vertebra during the imaging steps.
- Patient has a violated endplate as determined by imaging balloons during fluoroscopy.

Minimally Invasive Posterolateral (MIPL) Approach Specific

- Poor radiological visualization or 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.