DISCPAIN1

Per DPQ163.A

Indications for Use

The PerQdisc Nucleus Replacement System is intended for replacement of the nucleus pulposus to an intervertebral disc at one level (L1-L5) following single-level nuclectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD), with or without leg pain, with less than 3mm static spondylolisthesis (anterolisthesis or retrolisthesis) or less than 4mm dynamic spondylolisthesis. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The PerQdisc is implanted using a lateral surgical approach. Prior to receiving the PerQdisc, patients must have exhausted conservative (nonoperative) treatment for at least 6 months.

Inclusion Criteria

- Skeletally mature male or female subjects aged 22-70 (inclusive).
- Subject has a primary diagnosis of single level discogenic back pain caused by degenerative disc disease (L1 to L5) identified via MRI.
- Subject has an intact annulus (as determined by MRI) and endplates (as determined by MRI and X-ray) at the level to be treated.
- Subject must have failed to respond to a minimum of 6 months of conservative treatment for their back pain (e.g., physical therapy, medications, injections, ablations, lifestyle changes, etc.).
- Subject has a low back pain VAS ≥40 mm (4 cm).
- Subject has adequate disc height (≥6mm measured at the center of the disc) at the level to be treated. [As measured by the investigator]
- Subject is psychosocially, mentally and physically able and willing to fully comply with this protocol including adhering to follow-up schedule and requirements and filling out forms.
- Subject has read and understands the IRB approved informed consent document prior to signing and dating the document and before the initiation of any study-related procedures.
- Subject is appropriate candidate for the PerQdisc surgical approach [as defined in the surgical technique guide].

Exclusion Criteria

- Subject has symptomatic degenerative disc disease at more than one lumbar level
- Subject has had a prior spinal fusion in the lumbar or thoracic intervertebral spaces.
- Subject has had a prior SI-joint fusion.
- Subject has a spinal cord stimulator.
- Subject has had any prior lumbar spine surgery (instrumented or non-instrumented)

- Subject 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.
- Subject has congenital moderate or severe spinal stenosis or epidural lipomatosis.
- Subject has spondylolisthesis (antero- or retrolisthesis) in static X-ray ≥3 mm [measured via neutral lateral x-ray]
- Subject has ≥4 mm dynamic spondylolisthesis [measured via flexion/extension x-rays]
- Subject has > 20 degree range of motion at the index level [measured via flexion/extension x-rays]
- Subject has a history of any invasive malignancy (except non-melanoma skin cancer) unless treated with curative intent and there have been no clinical signs or symptoms of malignancy for at least 5 years (in particular, spinal tumors).
- Subject has an active systemic infection or infection at the operative site.
- Subject has evidence of symptomatic facet joint degeneration or disease where the investigator feels the facet is a major contributor to the subject's pain as diagnosed by injection and/or imaging.
- Subject has a known allergy to silicone or barium sulfate.
- Subject has been diagnosed with fibromyalgia, hepatitis, rheumatoid arthritis, lupus erythematosus, AIDs, ARC, HIV, or an autoimmune disease that affects the musculoskeletal system.
- Subject has been diagnosed with Paget's disease, osteomalacia or any other metabolic bone disease.
- Subject has current or recent history (defined ≤ 1 year prior to screening) of substance abuse (alcoholism and/or narcotic addiction) using standard medical definitions of DSM-5
- Subject has morbid obesity defined as a body mass index (BMI) > 40.
- Subject participated in an investigational drug or another medical device study within the last 30 days prior to surgery.
- Subject has Osteoporosis, defined as a T-score ≤ -2.5.
    - An existing DEXA is allowed if completed within 6 months of subject surgery.
    - For all subjects without an existing DEXA, the SCORE/MORES will be utilized to screen if a DEXA scan is indicated. If SCORE/MORES value ≥ 6, then a DEXA scan is required.
- Female subjects who are pregnant or are trying to become pregnant during the course of the trial.
- Subject has diabetes mellitus (Type 1 or 2) requiring daily insulin management.
- Subject 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)

- Subject is currently receiving worker's compensation or is involved in any litigation for medical
  negligence, trauma, or worker's compensation.
- Subject has lumbar scoliosis > 10 degrees at index level.
- Subject has a large, rectangular or irregularly shaped Schmorl's node with an associated active
  inflammatory process (Modic I changes).
- Subject has motion of < 3 degrees on pre-operative lateral flexion/extension radiographs at index level.
- Subject has opioid medication usage > 60 MME (morphine milligram equivalent)/day or change in opioid prescription within 60 days of surgery.
- Subject has a preoperative VAS right or left leg pain score > the preoperative VAS Back score.
- Subject has a history of vertebral fractures in the lumbar spine.
- Subject has evidence of severe compression of cauda equina.
- Subject is on chronic anticoagulation therapy due to a bleeding disorder and is unable to safely
  stop anticoagulants or has taken anticoagulants within 3 days prior to procedure.
- Subject has low back pain (LBP) of non-spinal or unknown etiology.
- Subject is unable to undergo X-ray, MRI, or other radiographic assessments, including discography.
- Subject has a degenerative muscular or neurological condition that would interfere with evaluation of outcomes, including but not limited to spinal disease (not at index level), Parkinson's disease, amyotrophic lateral sclerosis (ALS), or multiple sclerosis.
- Subject has, in the opinion of the investigator, a behavioral, cognitive, social or medical problem
  that may interfere with the assessment of the safety or effectiveness of the device.
- In the opinion of the investigator the subject has a major psychiatric disorder that may interfere
  with the assessment of the safety or effectiveness of the device.
- Subject has myelopathy.
- Subject has primarily leg pain with associated nerve root compression, in the opinion of the investigator.
- Subject has an annular defect greater than 6mm that extends from the interior of the disc to the
  outer margin of the annulus as evaluated on MRI.