Risks and Benefits of the PerQdisc™ Device

Anticipated clinical benefits:

- Improvement in the patient's back and leg pain (if present)
- Improvement in the patient's degree of disability
- Preservation of disc height at the affected level
- Maintain Range or Motion (ROM) at the affected level
- Reduction in analgesic scores
- Reduction in opioid use

Anticipated adverse device effects:

The anticipated adverse device effects for the PerQdisc device implantation include the following:

- Allergic or foreign body reaction to the implant materials
- Anatomical or technical difficulties at time of implantation
- Back pain due to altered spinal biomechanics
- Technical problems with bending or breakage of surgical instruments or device delivery system
- Development of new radiculopathy
- Fracture, wear or breakdown of the PerQdisc device
- Fusion of the spinal disc
- Implant subsidence into the vertebral endplate(s)
- Implant migration outside of the vertebral space but not subsiding into the vertebral endplate(s)
- Intra-operative findings that preclude implantation of the PerQdisc device
- Loss of neurological function or interference with neural structures
- Improper placement of the PerQdisc device
- No pain relief or worsening of pre-operative symptoms
- Expulsion of the PerQdisc from the spinal disc
- Abnormal movement in the nucleus space

Additional risks related to participation in the PerQdisc clinical study include the following:

- Radiation from the X-Ray investigations
- Progression of the disease and pain at an adjacent level
- Pulmonary emboli
- Reoperation to relieve pain
- Revise, remove or replace the implant
- Seizures
- Sepsis
- Septicemia
- Spasms
- Spinal instability
- Stroke
- Subsidence
- Thromboembolism
- Wound drainage, dehiscence or delayed wound healing

Serious adverse events directly related to the PerQdisc device or procedure:

- Serious allergic reaction or a foreign body reaction to any materials of the PerQdisc Nucleus Replacement System that requires hospitalization or surgery to remove the device.
- PerQdisc device fracture into two or more pieces.
- Vertebral osteomyelitis at the index level that requires hospitalization or surgery.
- Post-operative hemorrhage requiring transfusion or hospitalization.
- Intra-operative hemorrhage requiring transfusion or hospitalization.
- Radiculopathy at the index level including numbness that lasts more than 6 weeks
- Dural lesion, with leakage of cerebrospinal fluid
- Vascular lesion requiring intervention or surgical management
- Systemic infection
- Abscess at the surgical site (if it requires hospitalization or surgery)
- Autofusion of the spinal disc at the affected level
- Implant subsidence > 2 mm into the vertebral endplates
- Loss of neurological function (motor)
- Loss of neurological function (sensory)
- Expulsion (complete) of the PerQdisc from the spinal disc
- Vertebral bone fracture

Risks associated with participation in the study:

In addition to the anticipated adverse device effects outlined in Section 4.2 the risks associated with any spine surgical procedure include the following:

- Allergic drug reaction
- Anesthesia reactions
- Apnea
- Bleeding- loss of blood from vascular system requiring 1 unit of blood or >5g/dl drop in hemoglobin
- Blindness as a consequence of prone positioning
- Bone damage, facture or degeneration
- Cardiac arrest
- CSF (Cerebrospinal Fluid) Leakage
- Changes to mental status
- Complications of pregnancy, including miscarriage and fetal birth defects
- Damage to surrounding nerves, blood vessels or tissues
- Death
- Dural tear
- Dural lesion
- Dysesthesia
- Incidental durotomy
- Edema
- Facet joint degeneration
- Failure to relieve pain or a worsening of pain
- Fever > 101.5°F
- Formation of scar tissue
- Headache
- Hematoma
- Ileus
- Inability to resume activities of daily living
- Infection
- Insomnia
- Loss of anatomical sagittal plane curvature
- Nerve root injury
- Neurological deficit
- Neuropraxia
- Organ damage
- Pain
- Pneumonia
- Progression of the disease and pain at an adjacent level
- Pulmonary emboli
- Reoperation to relieve pain

- Revise, remove or replace the implant
- Seizures
- Sepsis
- Septicemia
- Spasms
- Spinal instability
- Stroke
- Subsidence
- Thromboembolism
- Wound drainage, dehiscence or delayed wound healing