Complications

Potential complications associated with use of the device, some of which could be fatal or cause serious injury, include:

Complications associated with surgery in general

- Complications related to anesthesia
- Compromised cardiovascular system
- Myocardial infarction
- Thrombophlebitis
- Gastrointestinal complications
- Pneumonia
- Respiratory difficulties
- Allergies

Complications related to the PerQdisc Nucleus Replacement System

- Anatomical or technical difficulties at time of implantation
- Allergic or foreign body reaction to the materials
- 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 devices
- No pain relief or worsening of pre-operative symptoms
- Partial or complete expulsion of the PerQdisc from the spinal disc
- Abnormal movement in the nuclear space

Other possible procedure-related complications

- 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

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.
- 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.