Risks

Possible risks associated with any surgery include:

- **Local incision risks:**
  - o Injury to blood vessels - Hematoma (collection of blood outside of a blood vessel)
  - o Soft tissue and muscular damage
  - o Edema (swelling)
  - o Failure of the tissue to heal properly (e.g., hematoma [a pocket of blood caused by bleeding from a broken blood vessel]; seroma [buildup of clear body fluid in the tissue]; wound dehiscence [failure of the incision to completely heal which may allow it to reopen]) which may require drainage, aspiration (removing a substance using suction), debridement (surgery to clean foreign material and dead tissue out of a wound), or other treatment
  - o Pain at the incision
- **Local infection risks:**
  - o Superficial (shallow) infection
  - o Abscess (swollen tissue containing pus)
  - o Deep wound infection
- **Systemic infection risks:**
  - o Pneumonia (lung infection)
  - o Septicemia (blood poisoning)
- **Systemic medical complication risks:**
  - o Atelectasis (collapsed lung)
  - o Phlebitis (inflammation of the blood vessel in your leg)
  - o Thrombosis (blood clot in the vessel)
  - o Pulmonary embolism (blood clot in the lung)
  - o Respiratory distress or depression (slow, shallow, or difficulty breathing)
  - o Pulmonary edema (abnormal collection of fluid in the lungs)
  - o Myocardial infarction (heart attack)
  - o Stroke
  - o Death
- **Unexpected reactions:**
  - o Reactions to the drugs or anesthesia used before, during and after surgery
  - o Reactions to imaging techniques used during and after surgery (e.g., x-ray, fluoroscopy).
  - o Reactions to blood transfusions
- Inability to resume activities of daily living
- Surgery may not reduce the preoperative pain experienced

Possible anticipated, procedure-related risks associated with any lateral approach lumbar surgery include:

- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing
- Spinal instability
- Damage to nerves, blood vessels, and nearby tissues
- Injury to kidney, ureter, or bowel
- Impaired muscle or nerve function
- Degenerative changes to the spine
- Damage to bony structures during or after surgery
- Loss of proper spine curvature/height
- Postoperative muscle and tissue pain
- Inflammatory conditions affecting soft tissues or nervous structures
- Scarring or soft tissue damage – affecting muscle, nervous tissue, or skin (Perineural fibrosis)
- Musculoskeletal spasms (back or leg)
- Abdominal wall weakness
    - o Herniation of bowel
    - o Core muscle weakness
    - o Deep incisional pain
- Injury to psoas muscle:
    - o Injury to lumbar plexus (leg weakness, leg numbness, dysesthesias and related syndromes)
    - o Injury to deep vessels (deep wound bleeding, excessive blood loss, deep vein thrombosis, vascular insufficiency and ischemia to limb or internal organs)
    - o Autonomic nervous dysfunction (RSD, causalgia, bladder or erectile dysfunction)

Possible anticipated, procedure-related risks associated with any lumbar disc surgery include:

- Spinal instability
    - o Spondylolisthesis acquisita (vertebral slippage)
    - o Retrolisthesis
    - o Spinal stenosis (narrowing of the spinal canal)
    - o Spondylosis
    - o Facet joint deterioration
    - o Infection of the bone, or surrounding soft tissue
    - o Degenerative changes in adjacent segment
    - o Loss of disc height
    - o Disc herniation
    - o Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery

  - o Loss of proper spine curvature/height
  - o Osteolysis
- Surgery at incorrect level
- Neurological injury:
  - o Cauda equina syndrome
    - Loss of bowel or bladder function
    - Incontinence (loss of bowel or bladder control)
  - o Epidural bleeding, hematoma, or fibrosis
  - o Perineural fibrosis
- Dural injury:
  - o Meningitis
  - o Dural tear, dural leak, and/or dural injury with or without cerebrospinal fluid (CSF) leakage
  - o Arachnoiditis
  - o Cerebrospinal fistula
  - o Headache
- Risks to neurological structures including:
  - o Compressive lumbar radiculopathy
    - Neurological deterioration
  - o Injury to nerves or nerve roots associated with the spinal cord (resulting in pain, weakness, paralysis (partial or complete), paresthesia, altered reflexes, numbness, tingling, or other changes in sensation)
- Remote neurological complications:
  - o Coordination abnormalities
  - o Dysphasia
  - o Gait disturbance
  - o Otitis media
  - o Tremors
  - o Stroke

Possible risks associated with the PerQdisc implant include the following below. Based on the preliminary data collected on PerQdisc patients implanted outside of the United States the following risks are potentially more likely to occur:

- Fracture, wear, or breakdown of the PerQdisc device
- Implant subsidence (sinking) into the vertebral endplate(s) (top of vertebrae)
- Implant migration outside of the vertebral space but not subsiding (sinking) into the vertebral endplate(s) (top of vertebrae)
- Additional surgery to revise, remove or replace the implant

- Improper placement of the PerQdisc device
- Back pain due to altered spinal biomechanics (structure, function, and motion)
- No pain relief or worsening of pre-operative symptoms
- Expulsion of the PerQdisc from the spinal disc

Additional potential PerQdisc risks include the following:

- Allergic or foreign body reaction to the implant materials
- Anatomical or technical difficulties at time of implantation
- Technical problems with bending or breakage of surgical instruments or device delivery system
- Development of new radiculopathy (pinching of nerve root, can present as, weakness, numbness and tingling)
- Periprosthetic and periarticular calcification and/or spontaneous fusion (bone growth around the
- implant location)
- Intra-operative findings that preclude implantation of the PerQdisc device (meaning the
- PerQdisc cannot safely be implanted due to items such as your anatomy or spine structure)
- Loss of neurological function or interference with neural structures
- Abnormal movement in the nucleus space.