MATERIAL

Prestige LP™
Cervical Disc System

Medtronic
MATERIAL

The Prestige LP™ Cervical Disc is precision machined from a proprietary and state of the art titanium ceramic composite material.

WHAT IS A TITANIUM CERAMIC COMPOSITE?

It is composed of 2 materials:

- **Titanium Alloy** -(Ti6-Al4-V) - Standard medical grade “titanium alloy”
- **Titanium Carbide** - Hard ceramic metal material

Note
The mixing of these biocompatible materials retains the imaging characteristics of titanium alloy while improving it’s resistance to wear.

Titanium/Ceramic Ratio

10% Titanium Carbide
90% Titanium Alloy (Ti-6Al-4V)
The titanium carbide is **NOT a coating** on the implant. It is a component of the material mixture.

**Surface Treatments**

Commercially pure titanium thermal sprayed coating & roughed titanium ceramic for enhanced fixation
WHY IS THIS MATERIAL UNIQUE TO CERVICAL ARTHROPLASTY?

Imaging for Satisfactory Post-op Assessment

- Prestige LP™ Cervical Disc was specifically designed with a Titanium ceramic composite as a material that allows satisfactory postoperative assessment with MRI at the implanted surgical levels.*

Note
The Prestige LP™ Cervical Disc provides satisfactory post-operative MRI clarity.

In a study by Sekhon et. al, post-operative MR images of cervical arthroplasty patients were assessed for imaging quality by 8 blinded surgeons and scored using a Jarvik 4-point scale.¹

- Prestige LP™ Cervical Disc (n=5)
- ProDisc-C™ (n=5)
- PCM™ (n=5)
- BRYAN™ Cervical Disc ((n=5)


*CT myelogram may be required for adequate visualization

**MR Conditional at 1.5 and 3 Tesla

***MR Conditional per product labeling
Favorable Wear Properties
• Titanium Carbide improves the resistance to articulation wear.
  – Titanium ceramic composite has a lower steady state wear rate of combined motion than stainless steel.

2 Piece Design
• The Prestige LP™ Cervical Disc is a 2-piece design that does not have a separate articulating core that could migrate from the device
Metal Ion Sensitivity

- Does NOT contain:
  - Cobalt
  - Nickel
  - Chromium
Prestige LP™ Cervical Disc has been used in 40 countries representing 6 continents.

Medtronic is committed to this technology.

RISKS

- foreign body reaction to the implant including possible rumor formation, autoimmune disease, metallosis, and/or scarring
- implant migration, implant subsidence and loss of fixation
- bone formation (including heterotopic ossification) that may reduce spinal motion or result in a fusion, either at the treated or at adjacent levels
- sizing issues with components
- development of new radiculopathy, myelopathy, or pain
BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR THE PRESTIGE LP™ CERVICAL DISC:

The Prestige LP™ Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The Prestige LP™ Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the Prestige LP™ Cervical Disc.

The Prestige LP™ Cervical Disc should not be implanted in patients with active systemic infection or localized infection at the surgical site; osteoporosis or osteopenia defined as a DEXA bone mineral density T-score \( \leq -1.0 \); allergy or sensitivity to titanium, aluminum or vanadium; marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation \( >3.5\text{mm} \) and/or \( >11^\circ \) rotational difference from that of either level adjacent to the treated levels; severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height \( >50\% \), an absence of motion \( (<2^\circ) \) as this may lead to a limited range of motion and may encourage bone formation (e.g., heterotopic ossification, fusion); severe facet joint arthropathy; significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level(s) due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis); or significant kyphotic deformity or significant reversal of lordosis.
The Prestige LP™ Cervical Disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone adequate hands-on training in the use of this specific device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the Prestige LP™ Cervical Disc should use this device. Medtronic will offer hands-on training to physicians prior to their first use of the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

The safety and effectiveness of this device has not been established in patients with the following conditions: axial neck pain as the solitary symptom; skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 78; prior cervical spine surgery, including prior surgery at the index level or adjacent levels; more than two cervical discs or two non-adjacent cervical discs that require surgical treatment; facet joint pathology of involved vertebral bodies; spinal metastases; an endocrine or metabolic disease that affects bones such as Paget’s disease, osteomalacia, renal osteodystrophy, Ehlers-Danlos Syndrome, or osteogenesis imperfecta; chronic or acute renal failure or history of renal disease; taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids); diabetes mellitus requiring daily insulin management; serious mental illness; being treated for alcohol and/or drug abuse; and pregnant.

Devices with metal-on-metal articulating surfaces (such as the Prestige LP™ Cervical Disc) may release wear debris, metallic particles or metal ions locally near the device and/or systemically. The short and long term effects of the wear debris, metallic particles and metal ions on the body are not known, but certain groups of patients may be at a higher risk including patients who are pregnant, patients who are planning to get pregnant, and patients who have renal disease.
Patients in the clinical study of the Prestige LP™ Cervical Disc were instructed to use non-steroidal anti-inflammatory drugs (NSAIDs) for two weeks postoperatively. It has been reported in the literature that short-term postoperative use of NSAIDs may reduce the instance of heterotopic ossification (HO). To reduce the instance of HO, it is recommended that the Prestige LP™ device be implanted in subjects able to tolerate the use of NSAIDs for two weeks post-operatively.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.