

MOTION

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Prestige LP™
Cervical Disc System




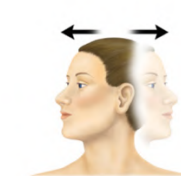
KINEMATICS/ MOTION:

The Cervical Spine incorporates 3 main motions:*

- 1** Flexion / extension
(with A/P translation)


- 2** Lateral bending

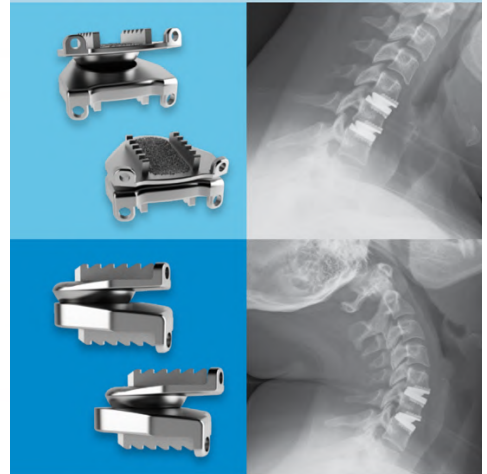

- 3** Axial rotation



*Panjabi MM, Duranceau J et al: Cervical Human Anatomy - Quantitative Three-Dimensional anatomy of the Middle and Lower Regions. Spine Vol 16, No.8:861-869, 1991

The Prestige LP™ Cervical Disc is designed to preserve physiologic motion of the cervical spine. The disc is designed to allow a minimum of 10 degrees lateral bending (from neutral) and a minimum of 10 degrees flexion/extension (from neutral), unlimited axial rotation (constrained by ligaments and posterior elements) and ±2mm A/P translation (sagittal plane).

FLEXION/EXTENSION (WITH A/P TRANSLATION)

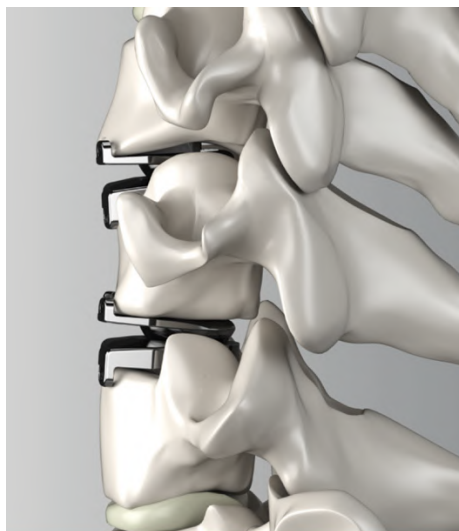


In the two-level US IDE trial, while angular motion varied from 0-22 degrees, the Prestige LP Cervical Disc provided an average of 6.92 degrees of angular motion (superior level) and 6.85 degrees (inferior level) at 24 months vs. 6.75 degrees (superior level) and 5.56 degrees (inferior level) preoperative.

AXIAL ROTATION



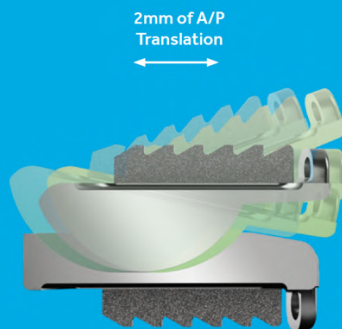
LATERAL BENDING



Cervical Spine COR

The centers of rotation in the cervical spine are located in the posterior portion of the motion segment.*

The Prestige LP™ ball and trough are located in the posterior portion of the device and designed to keep the center of rotation in the intended physiological area.



The variable center of rotation and the patients movement work together to facilitate clinical motion.

Risks

- foreign body reaction to the implant including possible tumor 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

*Amevo B, Worth D, Bodruk N. Instantaneous axes of rotation of the typical cervical motion segments: a study in normal volunteers. Clin Biomech 6:111-117, 1991

IMPORTANT PRODUCT INFORMATION

PRESTIGE LP™ CERVICAL DISC SYSTEM IMPORTANT PRODUCT INFORMATION

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 ≤ -1.0 ; allergy or sensitivity to titanium, aluminum or vanadium; marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3.5 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.