120 MONTH CLINICAL TRIAL RESULTS

CLINICAL DATA

Prestige LP™
Cervical Disc System

Medtronic
Further, Together

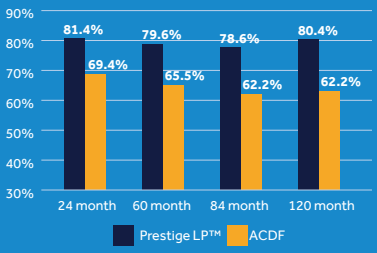
Prestige LP™ Cervical Disc System
2-Level Clinical Trial Results

Prestige LP™ Cervical Disc System exhibited statistical Superiority in Overall Trial Success Compared to ACDF for 2-Level Disc Replacement at 2 years.*

PRESTIGE LP 2- LEVEL CLINICAL TRIAL RESULTS (Data up to 120 months)

The Prestige LP™ Cervical Disc System Investigational Device Exemption (IDE) trial was a 2-level randomized, multi-centered, prospective clinical trial, which compared Prestige LP™ Cervical Disc to the control group, anterior cervical discectomy and fusion (ACDF). ACDF patients received allograft bone and an anterior cervical plate.

2-Level Overall Trial Success



Overall success required the following: neurologic success, NDI success, absence of serious, device-related adverse events, and no secondary surgeries at the treated levels classified as failure.

*Posterior probability of superiority = 99.3%.

KEY RESULTS AT 24 MONTHS

RETURN TO WORK

The median return-to-work time following surgery was 49 days for 2-level Prestige LP™ patients and 55 days for 2-level ACDF control subjects, respectively.

SECONDARY SURGERIES

Patients treated with Prestige LP™ for 2-level disease exhibited fewer secondary surgeries at the index level than patients treated with 2-level ACDF.*

*Not adjusted for multiplicity.

ADVERSE EVENTS

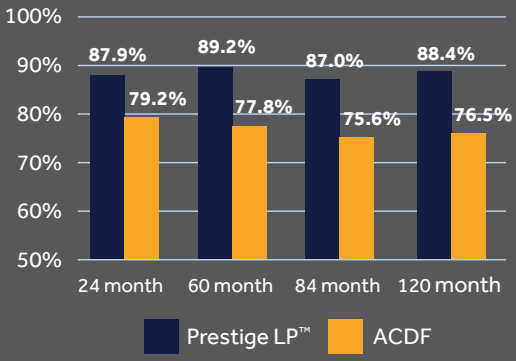
Patients treated with Prestige LP™ for 2-level disease exhibited numerically fewer serious implant or implant/surgical procedure associated adverse events than patients treated with 2-level ACDF.

	Surgery	24 MO	60 MO	84 MO	120 MO
Patient Accountability for 2-Level					
Prestige LP™ (n=209)	209 (100%)	199 (95.2%)	167 (82.3%)	154 (76.6%)	148 (86.0%)
ACDF (n=188)	188 (100%)	160 (88.9%)	140 (80.0%)	127 (73.8%)	118 (84.9%)

Note: The post-op numbers were based on the number of patients that were evaluated for overall success

NECK DISABILITY INDEX (NDI) SUCCESS

2-Level NDI Success*

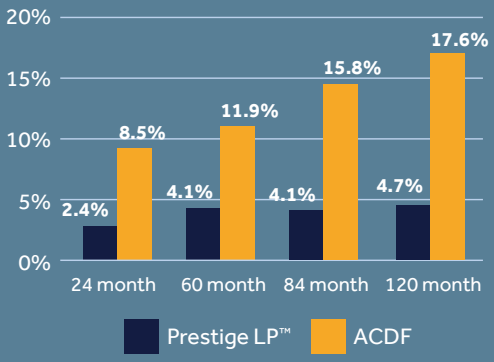


In addition, at 24 months postoperative, patients treated with Prestige LP™ Cervical Disc for 2-level disease exhibited statistically superior rates of NDI success compared to patients treated with 2-level ACDF (posterior probability of superiority = 99.0%).

*Not adjusted for multiplicity

SECONDARY SURGERIES

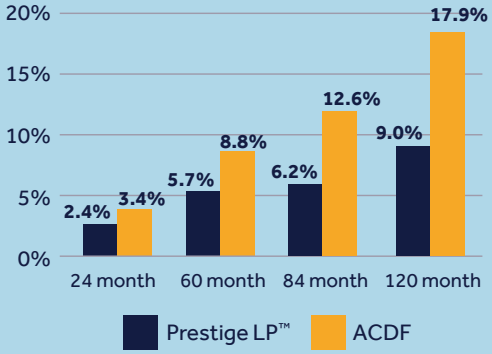
2-Level Subsequent Surgeries*



Prestige LP™ subjects required fewer secondary surgeries compared to ACDF subjects.

Cumulative Rate of Second Surgeries Involved in Adjacent Levels

(ACDF subjects, based on the cumulative rates up to 24 months, for which statistical assessment was performed.)



Risks of the Prestige LP™ Cervical Disc include, but are not limited to: development of new radiculopathy, myelopathy, or pain.

*Not adjusted for multiplicity

Prestige LP™ Cervical Disc System
1-Level Clinical Trial Results

Prestige LP™ Overall Trial Success Compared to ACDF

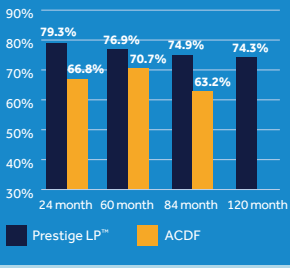
Without FSU (Functional Spinal Unit) considered as part of the endpoint, Prestige LP™ was shown to be statistically superior in overall success at 24 months.*

With FSU considered as part of the endpoint, Prestige LP™ was shown to be statistically non-inferior in overall success at 24 months.*

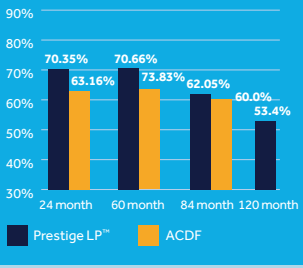
PRESTIGE LP 1- LEVEL CLINICAL TRIAL RESULTS (Data up to 120 months)

The Prestige LP™ Cervical Disc System Investigational Device Exemption (IDE) trial was a 1-level historically controlled, multi-centered, prospective clinical trial, which compared Prestige LP™ Cervical Disc to the control group, anterior cervical discectomy and fusion (ACDF). ACDF patients received allograft bone and an anterior cervical plate.

1-Level Overall Trial Success
Prestige LP™ vs. ACDF without FSU*



1-Level Overall Trial Success
Prestige LP™ vs. ACDF with FSU



Overall success required the following: neurologic success, NDI success, absence of serious, device-related adverse events, and no secondary surgeries at the treated levels classified as failure. This study included FSU (Functional Spinal Unit) success.

*Posterior probability of superiority and non inferiority = 99.5%.

KEY RESULTS AT 24 MONTHS

RETURN TO WORK

The median return-to-work time following surgery for the 1-level Prestige LP™ patients was 20 days sooner than the ACDF group.

SECONDARY SURGERIES

The rate of additional (secondary) surgeries at the index level was observed to be 5.0% in the Prestige LP™ group, as compared to 7.9% in the ACDF group at 24-months and they were not statistically different.

ADVERSE EVENTS

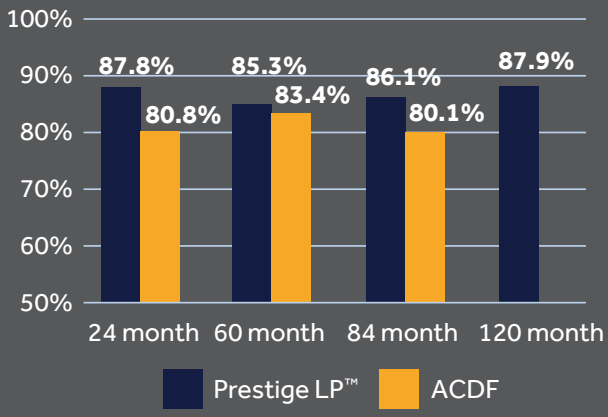
Patients treated with Prestige LP™ for 1-level disease exhibited similar serious implant/surgical procedure associated adverse events as patients treated with a 1-level ACDF.

	Surgery	24 MO	60 MO	84 MO	120 MO
Patient Accountability for 1-Level					
Prestige LP™ (n=280)	280 (100%)	271 (96.8%)	199 (71.6%)	211 (75.9%)	230 (83.3%)
ACDF (n=265)	265 (100%)	220 (83.7%)	188 (72.3%)	182 (70.0%)	-

Note: The post-op numbers were based on the number of patients that were evaluated for overall success

NECK DISABILITY INDEX (NDI) SUCCESS

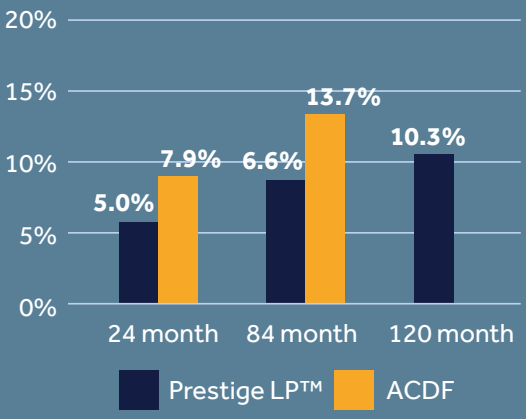
1-Level NDI Success



Compared to ACDF, the Prestige LP™ Cervical Disc was shown to be statistically non-inferior in NDI success at 24-months (posterior probability of non-inferior = essentially 100%).

SECONDARY SURGERIES

1-Level Subsequent Surgeries



Prestige LP™ subjects required fewer secondary surgeries compared to ACDF.

Risks of the Prestige LP™ Cervical Disc include, but are not limited to: development of new radiculopathy, myelopathy, or pain.

MEDTRONIC
LAUNCHED THE FIRST CERVICAL DISC ON THE US MARKET IN 2007.
PRESTIGE LP™ CERVICAL DISC SYSTEM BUILDS ON THAT SUCCESS.

THE PRESTIGE LP™ CERVICAL DISC SYSTEM
IS THE FIRST IN THE US WITH
10 YEAR 2-LEVEL CLINICAL DATA.

BRIEF **STATEMENT**

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 ≤ -1.0; allergy or sensitivity to titanium, aluminum or vanadium; marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3.5mm and/or >11° 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°) 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.

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Consult instructions for use at this website www.medtronic.com/manuals.
Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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