

About The PRESTIGE® Cervical Disc

The PRESTIGE® Cervical Disc is an artificial disc replacement which is designed to maintain motion for patients suffering from the symptoms of degenerative cervical disc disease or acute unresolved cervical disc herniation.



The PRESTIGE® Cervical Disc offers patients with radiculopathy and myelopathy related to [degenerative cervical disc disease \(DDD\)](#) in the cervical spine an alternative to spinal fusion surgery. Constructed of stainless steel in a unique, two-piece ball-and-trough configuration, the device is designed to maintain motion at the treated vertebral segment.

Each vertebra in the spine is separated by a shock absorbing disc, which is made up largely of water. As discs lose water content because of disease, injury or age, they compress, or lose height, which causes the vertebrae to move closer together. This reduces the disc's shock absorbing qualities, which may lead to bone spurs and narrowing of the nerve openings. If a disc ruptures, it can place pressure on the surrounding nerve roots and the spinal cord, resulting in pain, numbness and/or weakness.

Your doctor may recommend surgery if non-surgical treatment fails to provide relief from these symptoms. Traditionally, a procedure called an anterior cervical discectomy with fusion (ACDF) has been the "gold standard" for surgically treating DDD in the cervical spine. Using bone grafts and instrumentation such as metal plates and screws, this procedure fuses, or creates a bond between, two or more adjacent vertebrae, ideally stabilizing the segment and providing relief. Many patients have achieved excellent results with ACDF; however, a potential disadvantage associated with spinal fusion is the loss of motion and flexibility in the treated vertebral segment.

The PRESTIGE® Cervical Disc replaces a diseased or damaged disc and is designed to maintain motion. Made of stainless steel, the device has two articulating components (a ball on top and a trough on the bottom) that are inserted into the disc space and attached to the vertebral bodies on either side. The PRESTIGE® Cervical Disc was designed to

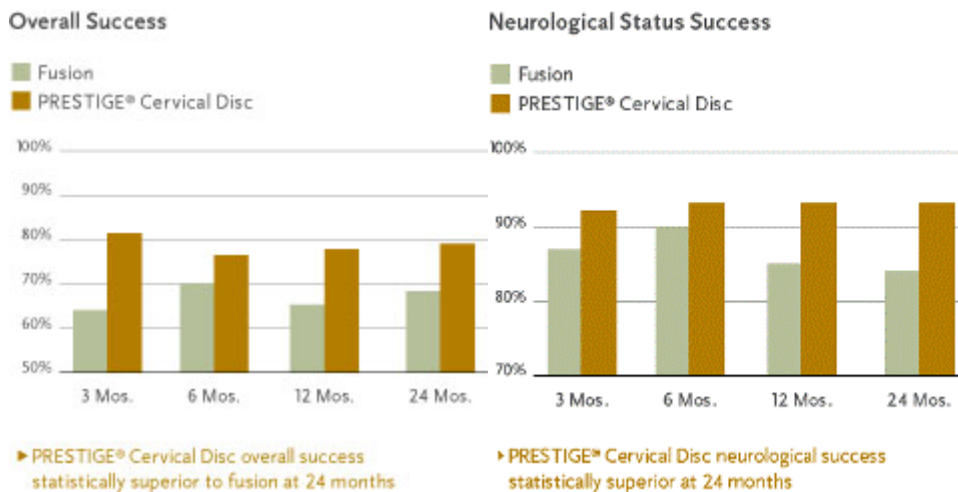
allow for the following motions of a natural intervertebral disc: flexion, extension, side bending and rotation. The PRESTIGE® Cervical Disc is available in a variety of sizes that allow Dr. Chang to closely match a patient's anatomy.

Clinical Research

In the largest clinical trial of its kind, the PRESTIGE® Cervical Disc proved to be a safe, effective alternative to fusion for patients with degenerative disc disease in the cervical spine.

The [PRESTIGE® Cervical Disc](#), used in a procedure called cervical disc arthroplasty, or cervical artificial disc replacement, has been studied in the most rigorous manner possible. Its safety and effectiveness as an alternative to anterior cervical discectomy with fusion (ACDF) for the treatment of degenerative disc disease (DDD) with myelopathy or radiculopathy has been evaluated in a Level 1, multi-center prospective randomized controlled study that involved 541 patients — the most extensive clinical study of its kind ever conducted and completed for the cervical spine.

The goal of the PRESTIGE® Cervical Disc clinical trial was to compare the outcomes associated with cervical artificial disc replacement with the PRESTIGE® Cervical Disc and ACDF. It was conducted at 32 study sites across the United States and treatment took place between October 2002 and August 2004. Patients in the study, who had to be at least 18 years of age with documented DDD conditions/symptoms with associated neurologic involvement that had not responded to non-surgical treatment for at least 6 weeks, were randomly assigned to the PRESTIGE® Cervical Disc or ACDF investigational groups.



- 276 patients in the PRESTIGE® Cervical Disc study group received an anterior cervical discectomy and decompression followed by placement of the PRESTIGE® Cervical Disc.
- 265 patients in the fusion control group received an anterior cervical discectomy and decompression with the placement of an interbody ring allograft and the ATLANTIS® Cervical Plate System (also by Medtronic).
- Patients in both groups underwent tightly-controlled radiographic and clinical examinations pre-operatively, and at routine follow-up periods post-operatively.

According to the study, patients who underwent cervical artificial disc replacement with the PRESTIGE® Cervical Disc achieved equivalence to all treatment outcome parameters and superiority in neurologic success and overall success at 24 months, compared to the outcomes of patients in the ACDF treatment group.

Some key findings of the PRESTIGE® Cervical Disc clinical trial include:

- At the 12 and 24 months follow-up points, the PRESTIGE® Cervical Disc patient group reported more improvement in their neck pain and a greater ability to go about their daily activities than the fusion control group.
- Patients receiving the PRESTIGE® Cervical Disc maintained sagittal (front and back) angular motion averaging more than 7 degrees in the normal physiologic range of motion. Pre-operatively, the PRESTIGE® Cervical Disc group had a mean angular motion of 7.55 degrees, which increased to an average of 7.59 degrees at 12 and 24 months post-operatively.
- On average, patients receiving the PRESTIGE® Cervical Disc had a median return to work that was 16 days faster than those in the ACDF treatment group.
- Patients in the PRESTIGE® Cervical Disc group experienced no implant failures or migrations.
- Fewer patients in the PRESTIGE® Cervical Disc group required secondary surgical procedures than those in the ACDF investigational group.

The PRESTIGE® Cervical Disc is the first artificial disc to be approved by the U.S. Food and Drug Administration for use in the cervical spine, and the first of a family of spinal artificial discs under development by Medtronic. Constructed of two pieces of stainless steel in a ball-and-trough configuration, the device is designed to be inserted into the remaining intervertebral disc space after a diseased or damaged disc has been removed.

Traditionally considered the "gold standard" for the treatment of [degenerative disc disease](#) in the cervical spine, ACDF involves removing the affected disc material then fusing, or creating a bond between, the vertebrae on either side of the disc space. The procedure has been successful in many patients; however, a potential disadvantage associated with spinal fusion is the loss of motion and flexibility in the treated vertebral segment.