

Medtronic

AM I A CANDIDATE FOR THE PRESTIGE® CERVICAL DISC?

You might be a candidate for the PRESTIGE® Cervical Disc if you have:

- Intolerable neck pain
- Pain radiating down your arms
- Numbness or weakness in your hands and extremities
- Exhausted non-surgical therapies

If non-surgical treatment options have failed to relieve your pain, there is a treatment you should know about. It's called the PRESTIGE® Cervical Disc.

The PRESTIGE® Cervical Disc is an artificial disc replacement that offers an alternative to spinal fusion. Although spinal fusion often provides good outcomes, a potential disadvantage is loss of motion and flexibility at the treated level.

Proven safe and effective in the largest clinical trial of its kind, the PRESTIGE® Cervical Disc is designed to maintain motion in the neck. That's a benefit patients have never had before.

For more information about the PRESTIGE® Cervical Disc, talk to your doctor.



Dear Doctor,

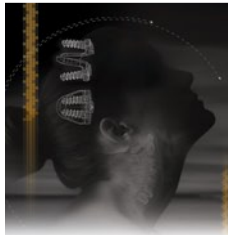
If you are unfamiliar with the PRESTIGE® Cervical Disc, we would be happy to have a local Medtronic Sales Representative deliver information to you. Please call us at 1-800-876-3133 to request your information. If you are a Primary Care Physician, there is an available list of surgeons in your area who are trained in the use of the PRESTIGE® Cervical Disc at www.necksurgery.com.

Sincerely,
Medtronic

listen. respond. deliver.



Medtronic



BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR THE PRESTIGE® CERVICAL DISC:

The PRESTIGE® Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from levels C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® Device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.

The PRESTIGE® Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.

The PRESTIGE® Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, such as neurological complications.

The safety and effectiveness of this device has not been established in patients with the following conditions: more than one cervical level with DDD; not skeletally mature; clinically significant cervical instability; prior fusion at adjacent cervical level; severe facet joint pathology of involved vertebral bodies; prior surgery at treated level; osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture; spinal metastases; chronic or acute renal failure or history of renal disease; taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids); pregnant; cervical instability; severe insulin dependent diabetes; and were not refractory to at least six weeks of unsuccessful conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care.

Implanted metal alloys release metallic ions into the body (especially those devices with metal-on-metal articulating surfaces). The long term effect of these ions on the body is not known.

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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