

PRESTIGE[®] LP

Cervical Disc System

Patient Information







Medtronic

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Patient Information

This patient information brochure is designed to help you understand one treatment option for your neck pain and related problems. After reviewing your medical history, x-rays, and the results of other tests you have completed, your doctor has recommended that you consider surgery to relieve your pain and discomfort.

This patient brochure explains one option, surgery using the PRESTIGE[®] LP Cervical Disc. The purpose of this brochure is to give you background about cervical spine (neck) surgery and the PRESTIGE[®] LP Cervical Disc. Please read this entire brochure before your cervical surgery.

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Glossary

Anterior cervical discectomy and fusion (ACDF) – surgery from the front of the neck where a spinal disc, soft tissue before the bony part of the spine, is removed to address symptoms; the disc space may be held in place with a device, such as a plate, to serve as a brace while fusion occurs

Cervical Spine – the part of the spine that is made up of spinal bones in the neck

Disc Herniation – pushing out of the inner part of the disc material through a hole in the outer layer of the disc

Dura – tough tissue layer that surrounds the spinal cord

Foramen – an opening in the spinal column through which nerves pass

Fusion – joining two bones together so that they no longer move

Hematoma – a mass of usually thickened blood that forms as a result of a broken blood vessel

Heterotopic Ossification – unintended bone formation around a joint such as the disc space between the spinal bones

Intervertebral Disc – the soft tissue found between the spinal column that helps cushion the spine

Kyphosis – outward curvature of the spine

Lordosis – inward curvature of the spine

Myelopathy – disease in the spinal cord

Myelography – a method of using X-rays and a special dye called contrast material to make pictures of the bones and the fluid-filled space between the bones in the spine to identify spinal conditions

Osteoporosis – A disease that causes bones to become thin and brittle, making them more likely to break

Radiculopathy – damage or trouble with nerve function that results if one of the nerve roots near the cervical vertebrae is squeezed.

Spinal Column – the series of spinal bones extending from the skull to the pelvis

Spondylosis – a degenerative disease in which the spinal joints become stiff

Vertebrae – spinal bones forming the backbone

Your Cervical Spine

The bones in your cervical spine (neck) which encircle and protect your spinal cord, are separated by shock absorbing discs (**Figure 1**). The discs give your spine the flexibility to move. Nerves branching from the spinal cord pass through openings in the vertebrae to other parts of your body.

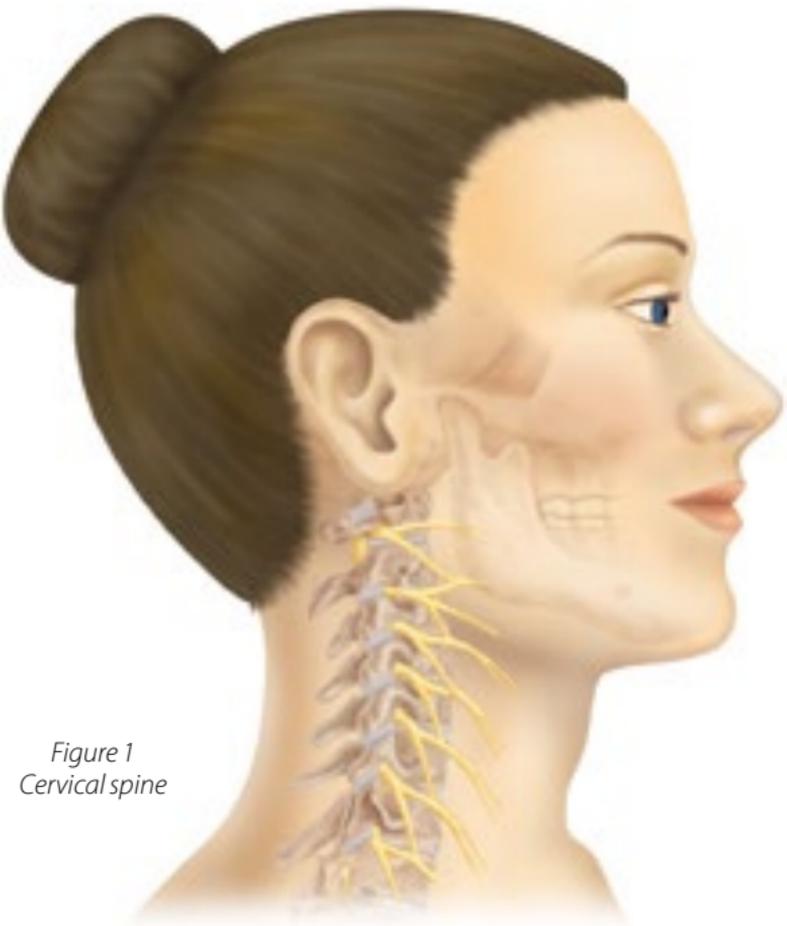


Figure 1
Cervical spine

What is disc degeneration?

As discs lose their water content because of disease or age, they lose their height and bring the vertebrae closer together. The result is a weakening of the shock absorption properties of the disc and a narrowing of the openings for the nerves in the sides of the spine (**Figure 2**). Additionally, a loss of disc height may cause the formation of bony growths which can push against your spinal cord and/or nerves. When the inner part of a disc pushes out through a hole in its outer layer (herniates) in the cervical spine, it may put pressure on one or more nerve roots (called nerve root compression) or on the spinal cord; this may cause pain and other symptoms in the neck and arms. Living with this pain or weakness and tingling in the arms can be disabling.

Why may I need surgery?

With the advice of your doctor, you have tried other treatments for at least six weeks which did not relieve your pain or symptoms. Your doctor has recommended that you consider the PRESTIGE® LP Cervical Disc, which is designed to allow motion following surgery, instead of the more common fusion procedure.

Vertebrae

Nerve root

Cervical disc herniation

Compressed nerve root

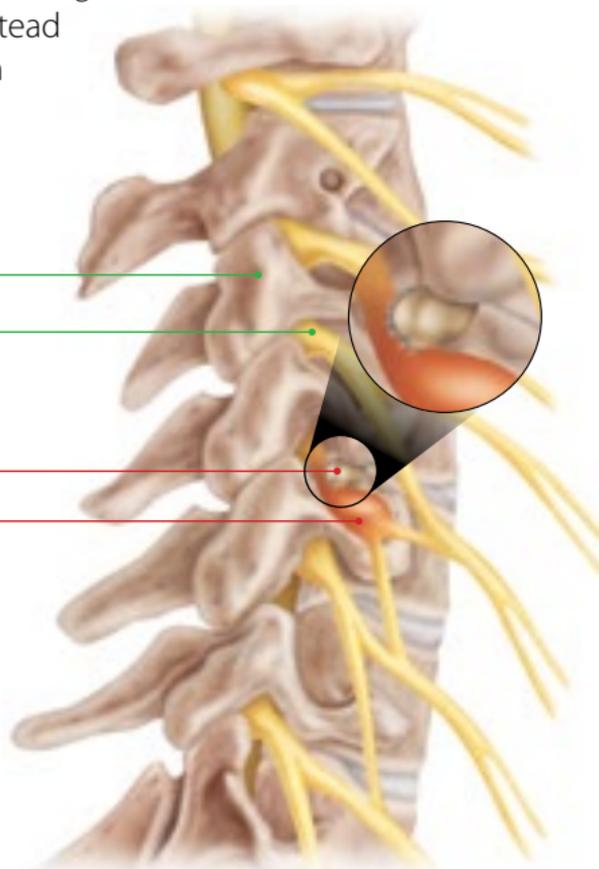


Figure 2
Compressed nerve root
resulting from a cervical
disc herniation

What is the PRESTIGE® LP Cervical Disc?

The PRESTIGE® LP Cervical Disc is made of two pieces of metal. It is inserted into the affected disc space of your neck after removing diseased disc material. It is designed to act like a pivoting joint. Designed to help relieve symptoms such as pain, it is intended to be used in patients with only one diseased disc requiring surgery in their neck.



Figure 3
PRESTIGE® LP Cervical Disc

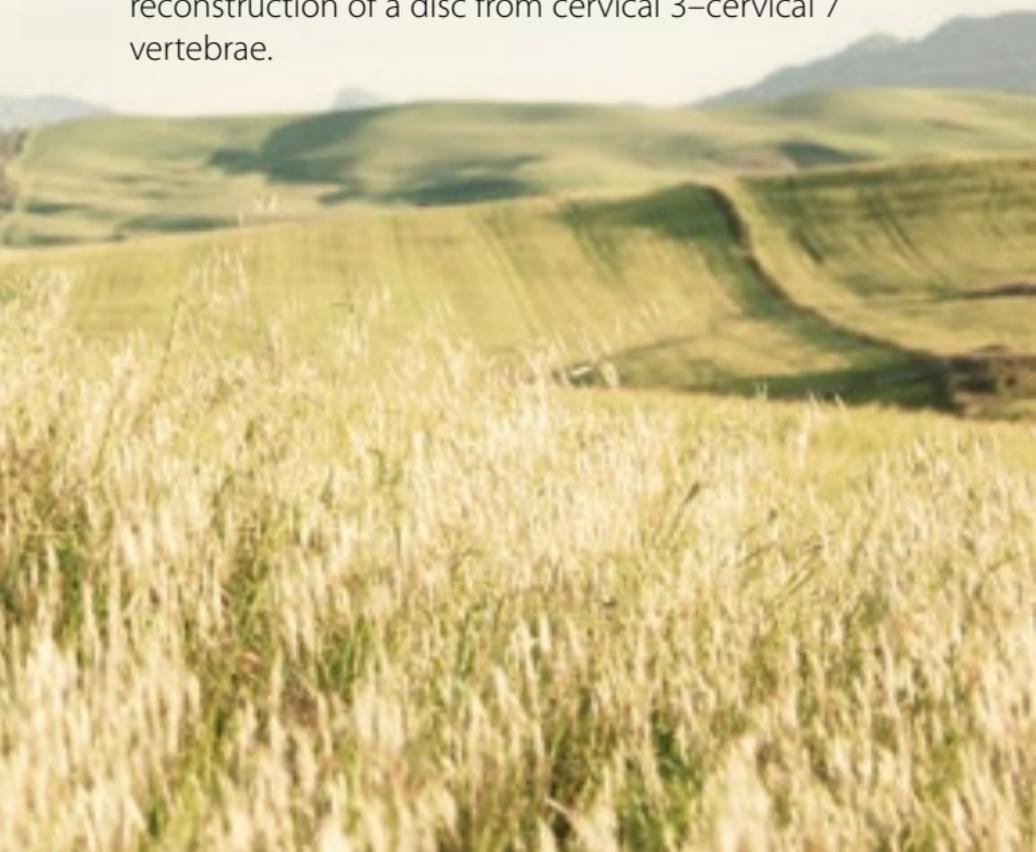


Who should receive the PRESTIGE® LP Cervical Disc?

You may be selected to receive the PRESTIGE® LP Cervical Disc if you:

- » Are skeletally mature (21–78 years old) with good bone quality
- » Have undergone at least six weeks of non-operative treatment, and are still experiencing symptoms related to reduced function of the upper extremities such as arm weakness, poor reflexes, and/or decreased nerve sensation
- » Have arm pain and/or tingling as a result of damage or trouble with nerve function that results if one of the nerve roots near the cervical vertebrae is squeezed (radiculopathy); and/or neck pain and/or trouble walking as a result of disease in the spinal cord (myelopathy).

In addition, your surgeon should confirm the need for surgery by using diagnostic imaging such as computed tomography (CT), myelography (a method of using X-rays and a special dye called contrast material to identify spinal conditions) and CT, and/or magnetic resonance imaging (MRI). The PRESTIGE® LP Cervical Disc is implanted via an open (through an incision) anterior (from the front) approach and is indicated for patients who need single-level reconstruction of a disc from cervical 3–cervical 7 vertebrae.



Who should not have cervical disc surgery? (Contraindications)

If you are experiencing or have been diagnosed with any of the following conditions or symptoms, you should not have cervical disc surgery:

- » active systemic (whole body) infection or infection at the operating site, as undergoing surgery could interfere with your ability to heal or increase the chance of worsening the infection
- » allergy to titanium, aluminum, or vanadium, as the PRESTIGE® LP Disc contains titanium, aluminum and vanadium and could cause an allergic reaction
- » weak or brittle bones (osteoporosis or osteopenia) because this could increase the risk of bone fracture or cause the implant to loosen;
- » stiffness of the spinal joints due to disc degeneration (spondylosis), as this could limit motion;
- » unstable cervical spine as seen on x-ray, as the removal of the diseased disc could lead to additional instability;
- » diseased disc has much more movement than adjoining discs, as this could lead to instability;
- » deformed cervical spine or spinal column bones that are not healthy, as this could limit movement or increase the risk of device loosening;
- » significant loss of the normal curvature of your neck (lordosis) or change in the curve of your neck (kyphosis), as this could limit any motion that could be achieved
- » more than one cervical disc that needs treatment, as the device has only been studied in patients requiring one cervical level of surgical treatment

To what warnings and precautions should I pay attention?

In the U.S. clinical trial, the PRESTIGE® LP Cervical Disc was used only in patients who met certain requirements. Examples of these requirements are that patients in the study could **not have diabetes**, which needs to be treated with daily insulin therapy; **not be pregnant**; and **not be taking certain medications such as steroids**. Below is a list of warnings to be aware of:

- » Heterotopic ossification (HO) is when unintended bone formation occurs around or across a joint such as the disc space between the vertebrae. This is a fairly common occurrence associated with artificial hips and knees. **A possible consequence of HO is reduced motion.** Not all patients will develop HO. It has been reported in the literature that short-term postoperative use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen, may reduce the instance of HO. Patients in the clinical study were instructed to use NSAIDs for two weeks postoperatively.
- » This device is placed close to nerves and blood vessels in the cervical spine. **There is a risk of nerve damage, or serious or fatal bleeding**, if damage to these structures occurs during or after surgery.
- » Implants with metal surfaces release metallic ions into the body. **The long term effect of these ions in the body is not known.**

Below is a list of precautions to be aware of as the safety and effectiveness of the PRESTIGE® LP device has not been established in patients with the following conditions:

- » Neck pain alone without arm pain;
- » Patients who are not skeletally mature (under the age of 21 or over the age of 78);
- » Previous cervical spine surgery, including a repeat surgery at the level requiring treatment;
- » Previous cervical fusion at a level above or below the level of the spine requiring treatment;
- » Disease or damage of the facet joint at the level of the spine requiring treatment;
- » Spinal metastases (spreading of cancer);
- » Diseases of the bone caused by low mineral levels or genetic problems such as Paget's disease, osteomalacia, osteopenia, or other metabolic bone disease;
- » Local or systemic bacterial infection;
- » Kidney failure or history of kidney disease;
- » Taking medications known to potentially get in the way with bone/soft tissue healing, such as steroids;
- » Pregnancy
- » Severe insulin dependent diabetes; and
- » Extreme obesity as defined by the NIH Clinical Guidelines Body Mass Index (i.e., BMI ≥ 40)

It is important that you inform your doctor about any allergies you have, any medications you take on a regular basis, if you are pregnant, or if you have any other treated or untreated illnesses that may help your doctor decide if the PRESTIGE® LP Cervical Disc is right for you.

You should discuss both surgical and nonsurgical treatment options with your doctor. If surgery is selected, your occupation, activity level, weight, your overall health, and the condition of your spine will help to determine if you are an appropriate candidate for surgery to receive the PRESTIGE® LP Cervical Disc. Only your doctor can decide if you are an appropriate candidate.

This device should be used only by surgeons who are experienced in this procedure and have undergone hands-on training with this specific device. A lack of adequate experience and/or training may lead to less successful outcomes or more complications. If you have questions, talk to your doctor.



What are the risks and adverse effects of this type of surgery?

Like any surgery, there are some possible complications that may occur when you receive the PRESTIGE® LP Cervical Disc.

Complications may occur singly or in combination and may include:

- » allergic reaction to the implanted material
- » implants bending, breaking, loosening, or moving
- » injury due to surgical instruments bending or breaking
- » wound, local, and/or bodily (systemic) infections
- » neck and/or arm pain
- » difficulty swallowing
- » impairment of or change in speech
- » nerve or spinal cord injury, possibly causing impairment or paralysis
- » numbness or tingling in arms or legs
- » tear in the protective tissue (dura) covering the spinal cord
- » loss of motion or unintended fusion at the treated cervical level
- » development or progression of disease at other cervical levels
- » bleeding or collection of thickened blood (hematoma)
- » blood clots and blood flow restrictions, may possibly result in stroke
- » trauma during surgery, such as nerve or spinal cord injury, excessive bleeding and/or vertebral body (spinal bone) fractures
- » change in the curvature of the neck
- » tissue swelling
- » reactions to anesthesia
- » changes in mental status
- » complications of pregnancy, including miscarriage and fetal birth defects
- » inability to resume activities of normal daily living, including sexual activity
- » death

There is also the risk that this surgical procedure will not be effective, and may not relieve or may cause worsening of preoperative symptoms.

There may be other risks associated with treatment using the PRESTIGE® LP Cervical Disc. Although many of the major risks are listed in this patient information brochure, please consult your doctor for more information and an explanation of these risks.

WARNING: Additional surgery may be necessary to correct some of the adverse effects such as: allergic reaction, implants bending/loosening/breaking/moving, infection, neck and/or arm pain, nerve or spinal cord injury, numbness or tingling in arms or legs, tear in the protective tissue (dura) covering the spinal cord, loss of motion or unintended fusion at the treated cervical level, development or progression of disease at other cervical levels, bleeding or collection of thickened blood (hematoma), trauma during surgery, such as nerve or spinal cord injury, excessive bleeding and/or vertebral body (spinal bone) fractures, change in the curvature of the neck and tissue swelling.

US Clinical Study

The PRESTIGE® LP Cervical Disc has been evaluated in a clinical trial in the United States for the safe and effective treatment of single-level radiculopathy (damage or trouble with nerve function that results if one of the nerve roots near the cervical vertebrae is squeezed) and/or myelopathy (disease in the spinal cord).

The study was prospective (looking forward in time) and involved 545 patients. 280 patients received the PRESTIGE® LP Cervical Disc. The outcomes of those patients receiving the PRESTIGE® Cervical Disc were compared to 265 patients who had received anterior cervical discectomy and fusion (ACDF) in a study that had been done earlier. ACDF is a surgery from the front of the neck where a spinal disc is removed to address symptoms; the disc space may then be stabilized with a device, such as a plate, to serve as a brace while fusion occurs.

Patients in the study had to be at least 18 years of age and not helped by nonsurgical treatment for at least six weeks.

Some of the results at 24 months after surgery are described below. Ask your doctor for more details about this clinical study and its results.

Twenty-four months after surgery, 159 out of 226 PRESTIGE® LP Cervical Disc patients (70.4%) achieved overall success, compared to 108 out of 171 ACDF patients (63.2%). Overall Success is decided by combining the results from five different measurements of safety and effectiveness. This demonstrates that PRESTIGE® LP Cervical Disc is an effective surgical alternative to ACDF.

Other study results include:

- » While motion varied from 0.19°–26.43°, the PRESTIGE® LP Cervical Disc provided an average of 7.51° degrees of motion at 24 months compared to 5.67° prior to surgery.
- » Patients receiving PRESTIGE® LP Cervical Disc had a median return to work that was 20 days sooner than the ACDF group
- » The rate of additional surgeries at the index level (the cervical disc level that was surgically treated) was observed to be 5.0% in the PRESTIGE® LP Cervical Disc group and 7.9% in the ACDF group at 24 months

Some of the most common adverse events at 24 months in this US clinical study and the rates in each patient group were:

Adverse Event

Pain including stiffness, strain, tightness occurring in an area other than the cervical pain (other pain)

Neck and/or arm pain

Events involving the nervous system (neurological) such as unsteadiness in walking

Events occurring in the spine (spinal event) such as a fracture (break) in the vertebrae.

Trauma adverse events such as injury from motor vehicle accident, fall, etc.

Events pertaining to the stomach or intestines (gastrointestinal)

Infections

Difficulty swallowing (dysphagia) and/ or difficulty speaking (dysphonia)

Events associated with excretion and/or reproduction (urogenital)

Respiratory adverse events

Cervical heterotopic ossification

Wound (non-infectious) adverse events

Cardiac disorders such as heart attack

Implant events including breakage, displacement, malpositioning and other events

Other events not associated with any pre-defined categories

PRESTIGE® LP Cervical Disc**Patient Group****ACDF Patient Group**

146 out of 280 patients (52.1%)	132 out of 265 patients (49.8%)
144 out of 280 patients (51.4%)	124 out of 265 patients (46.8%)
136 out of 280 patients (48.6%)	108 out of 265 patients (40.8%)
83 out of 280 patients (29.6%)	55 out of 265 patients (20.8%)
61 out of 280 patients (21.8%)	35 out of 265 patients (13.2%)
35 out of 280 patients (12.5%)	38 out of 265 patients (14.3%)
34 out of 280 patients (12.1%)	27 out of 265 patients (10.2%)
26 out of 280 patients (9.3%)	22 out of 265 patients (8.3%)
26 out of 280 patients (9.3%)	9 out of 265 patients (3.4%)
24 out of 280 patients (8.6%)	17 out of 265 patients (6.4%)
27 out of 280 patients (9.6%)	15 out of 265 patients (5.7%)
25 out of 280 patients (8.9%)	13 out of 265 patients (4.9%)
16 out of 280 patients (5.7%)	18 out of 265 patients (6.8%)
16 out of 280 patients (5.7%)	5 out of 265 patients (1.9%)
93 out of 280 patients (33.2%)	81 out of 265 patients (30.6%)

What are the expected outcomes of the surgery?

This surgical procedure is expected to relieve the symptoms of a nerve root or spinal cord compression caused by the damaged disc. The PRESTIGE® LP Cervical Disc is designed to preserve motion at the operated disc level, unlike a fusion surgery that does not allow for motion.

How is this procedure different from a fusion?

In both the ACDF and the PRESTIGE® LP Cervical Disc procedures, the unhealthy disc is removed. In the ACDF procedure, after the unhealthy disc is removed, the disc space may be stabilized with a device, such as a plate, to serve as a brace while fusion occurs (**Figure 4**). Fusion, which is the surgery that is most commonly performed for your condition, is designed to treat your symptoms by eliminating the motion at the treated level. The PRESTIGE® LP Cervical Disc procedure is an alternative to ACDF. After the unhealthy disc is removed, the device is inserted into the disc space. The PRESTIGE® LP Device is designed to allow motion at the treated level.

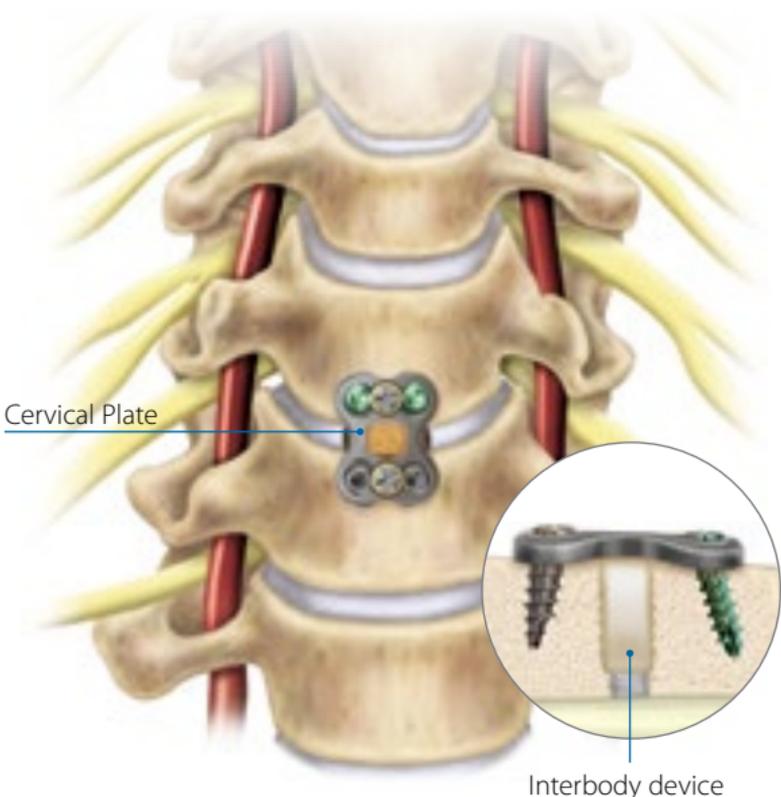


Figure 4
Cervical plate and interbody device

How do I prepare for surgery?

Items your doctor may cover with you:

- » See your doctor before surgery to check your overall health.
- » Tell your doctor what medicines you are taking and ask if you should stop taking any of these medicines before surgery.
- » Your doctor will review your condition with you and explain what all of your possible choices are including medications, physical therapy, and other surgeries such as removal of the diseased disc, fusion, etc.
- » Do not to eat or drink the night before the surgery.
- » Prepare your home for life after surgery – place important things such as medication and personal hygiene items within easy reach.
- » Remove safety hazards, such as clutter on the floor, that may cause you to trip or lose your balance.
- » Arrange for someone to help you at home and around the house after surgery.
- » Be sure you read and understand this entire brochure.
- » Ask your surgeon to inform you of the risks, as well as the benefits, of this surgery

What is involved in a PRESTIGE® LP Cervical Disc procedure?

This surgery involves the use of an artificial cervical disc, designed to replace the disc which sits between the vertebrae in your neck (**Figure 5**). During surgery, you will be under general anesthesia. Your disc, which is damaged or diseased, is surgically removed through an incision (opening) made in the front of your neck. Typically, this incision is about an inch long. Your surgeon will prepare a space and insert a PRESTIGE® LP Cervical Disc into the disc space. The device pieces move with respect to one another and are designed to allow for motion.

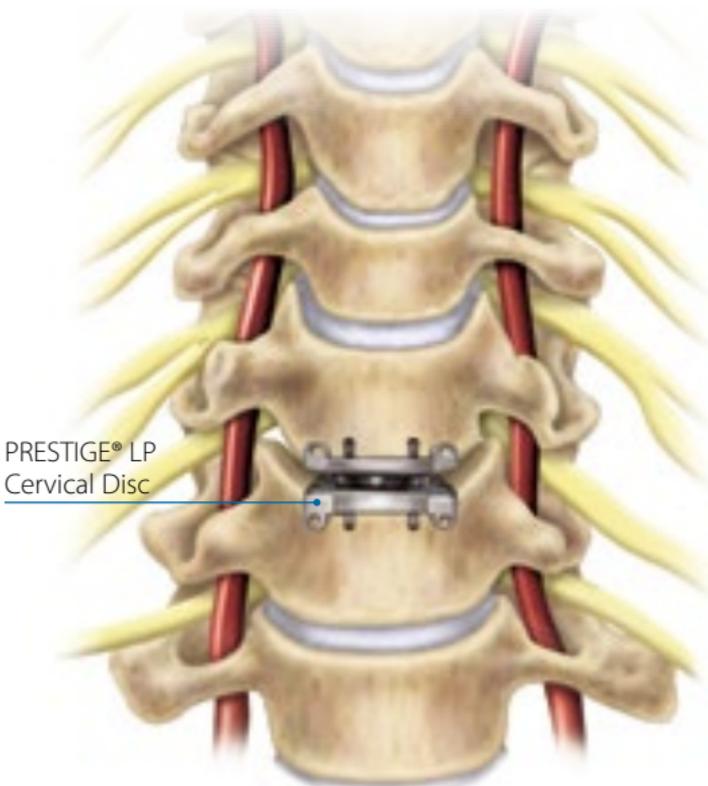


Figure 5
PRESTIGE® LP Cervical Disc in the cervical spine

What can I expect after surgery?

Ask your doctor about your specific recovery plan following surgery. It is important to follow your doctor's instructions carefully to recover from surgery as quickly as possible and to increase your chances of a successful outcome. Surgery with the PRESTIGE® LP Cervical Disc is considered major surgery. You can expect to stay in the hospital approximately one day. As with any major surgery, you should expect some discomfort and a period of rehabilitation.

A nurse or doctor will:

- » show you how to care for your wound before you are sent home
- » show you how to take care of a drainage tube in your wound, if that is part of your therapy
- » discuss a program to gradually increase your activity
- » perhaps require you to wear a neck brace after surgery
- » advise you to avoid any activities that require repeated bending, lifting, twisting, such as athletic activities
- » schedule office visits to assess your progress and to see if anything else needs to be done for your recovery
- » prescribe medicines to control pain and nausea.

Contact your doctor immediately and comply with instructions if:

- » you get a fever
- » the wound starts leaking blood (red streaks) or pus (a thick yellowish or greenish liquid, which may consist of bacteria)
- » you have trouble swallowing or breathing
- » you have trouble urinating
- » you have new or increased neck or arm pain, numbness, or weakness.

After surgery, your doctor may refer you to a physical therapist who will teach you exercises to improve your strength and increase your mobility. The goal of physical therapy is to help you become active as soon as possible, using safe body movements that protect your spine. This often includes neck strengthening exercises. You may also be taught different ways of positioning your neck to avoid reinjuring your spine.

Frequently Asked Questions

How long can I expect the device to last?

Despite extensive testing, there are not yet enough long-term data in humans to predict the lifetime of the device.

What happens if the device and/or surgery are not effective?

If you experience neck or arm pain, it is possible that either the surgery was not effective or that the device has failed. If the pain does not resolve, you may need additional surgery. Contact your doctor immediately if you experience neck or arm pain.

Can I shower after surgery?

You will have a dressing on your neck. You may shower quickly but try not to soak the dressing. Do not use a hot tub.

Will I have a large scar?

The incision is typically about one inch long and usually heals so that it is barely noticeable.

When can I drive?

For a period of time after your surgery, you may be cautioned about activities such as driving.

Can I travel?

Because of increased airport security measures, please call your local airport authority before traveling to obtain information that may help you pass through security more quickly and easily. Your device may set off airport security detectors, so ask your surgeon to request a patient identification card from Medtronic and provide you with a copy.

How can I find a qualified surgeon?

An updated list of surgeons who are trained to use the PRESTIGE® LP Cervical Disc is available at www.necksurgery.com.

Can I receive an MRI after surgery?

Yes, patients can receive an MRI any time after implantation. As MRI machines vary, it is important to consult your physician about appropriate testing conditions.

How can I contact someone at the manufacturer?

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

Toll Free Number: 1-800-876-3133

For additional information visit:

www.necksurgery.com

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Talk to your doctor

While this brochure is meant to provide you with information that you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice. If you have any questions about the PRESTIGE® LP Cervical Disc, please call or see your doctor, who is the only one qualified to diagnose and treat your spinal condition. As with any surgical procedure, you should select a doctor who is experienced in performing the specific surgery that you are considering.

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