

# Prestige LP™

Cervical Disc System

Adjacent  
Two-Level  
Patient  
Information



Medtronic



# Prestige LP™

Cervical Disc System

## Adjacent Two-Level Patient Information

This patient information brochure is designed to help you understand one treatment option for your arm pain and/or neurologic symptoms (such as weakness or numbness). 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 at two adjacent (next to each other) levels. 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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Frequently Asked Questions

Talk to your doctor

# GLOSSARY

**Adjacent Discs** – disc levels located next to each other

**Anterior** – front

**Anterior Cervical Discectomy And Fusion (ACDF)** – fusion surgery from the front of the neck where unhealthy cervical spinal disc(s) are removed and replaced with bone or an implant. For more information, see page 17.

**Artificial Cervical Disc** – a medical implant used to replace a diseased or damaged disc in the cervical spine.

**Autoimmune Disease** – a disease in which the body's tissues are attacked by its own immune system.

**Cervical Spine** – the first seven bones in the spine (in the neck)

**CT** – Computerized tomography, which is an x-ray procedure that combines many images to create cross-section images (likes slices) of the body.

**Degeneration** – deterioration of tissue, which may include loss of function.

**Disc Herniation** – when the inner disc material pushes out (bulges outside its normal area) through a weakness or hole in the outer layer of the disc, potentially causing pain and limiting function.

**Dura** – tough protective tissue layer that surrounds the spinal cord

**Facet joint** – joint in the back of the spine that connects the vertebrae together.

**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

**Implant** – a medical device that is put into the body to fix or take the place of a damaged body part.

**Incision** – a cut in the skin made during surgery.

**Intervertebral (Disc)** – the soft tissue between the spinal bones that helps hold the bones apart, acts as a cushion, and allows the bones to move.

**Joint** – where two or more bones meet, normally to allow movement.

**Kyphosis** – outward curvature of the spine

**Lordosis** – inward curvature of the spine

**Metallosis** – condition in which metal particles builds up in the soft tissues of the body.

**MRI** – Magnetic Resonance Imaging (MRI), a procedure that uses magnets to create cross sectional images (likes slices) of the body.

**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

## GLOSSARY (CONTINUED)

**Nerves** – fibers that move messages to and from the brain.

**Osteopenia** – a condition in which bones are somewhat thin or weak and which may develop into osteoporosis.

**Osteoporosis** – a condition in which bones are thin, weak and brittle, making them more likely to break.

**Radiculopathy** – damage to nerves in or near the spine as a result of pressure from a disc or irritation of the nerves due to disc or spinal joint disease.

**Seroma** – a fluid collection.

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

**Spinal Cord** – the bundle of spinal nerves that starts at the bottom of the brain and runs to the lower back.

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

**Vertebrae** – the bones that form the spinal column (backbone) and include a hole for the spinal cord to pass through.

**X-ray** – a tool used by doctors that produces images by using radiation waves (often used to take images of bones).

## WHAT IS THE CERVICAL SPINE?

The top seven vertebrae (bones) in your neck make up the cervical spine and begin at the base of your skull. The vertebrae in your cervical spine encircle and protect your spinal cord and support your skull **(Figure 1)**. A shock absorbing intervertebral disc (disc) between each vertebra helps to cushion the vertebrae allowing them to move **(Figure 2)**. Nerves branching from the spinal cord (spinal nerves) pass through openings in the vertebrae to other parts of your body.

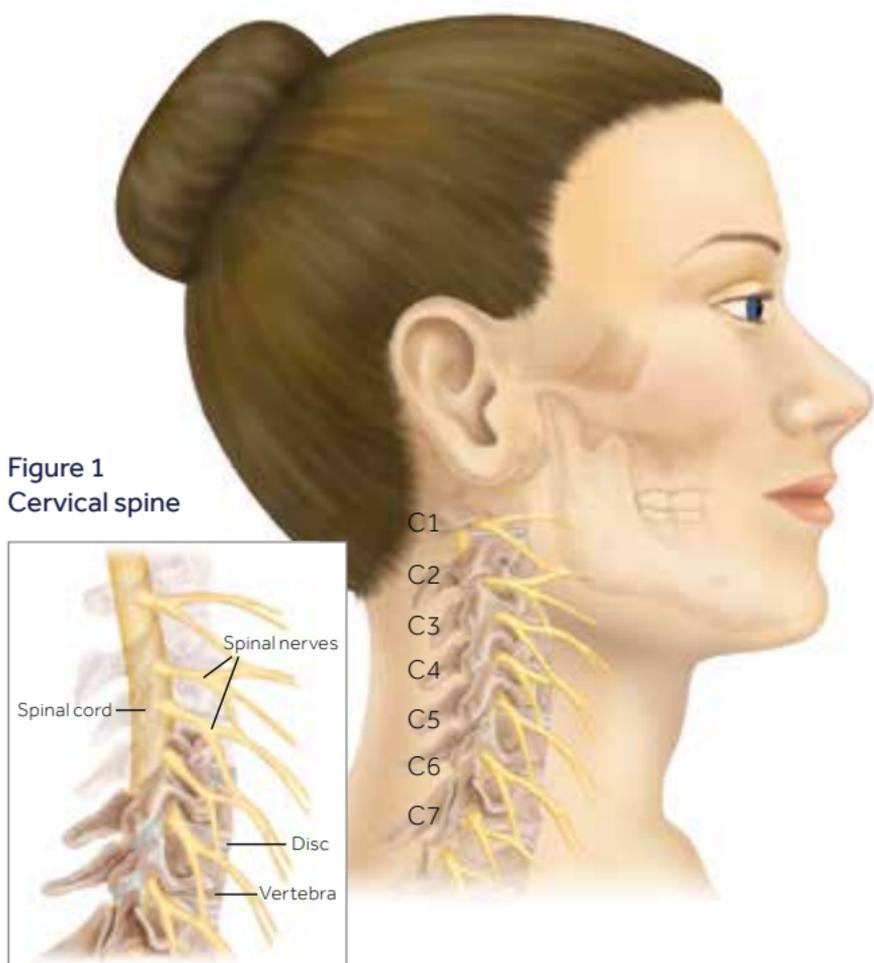
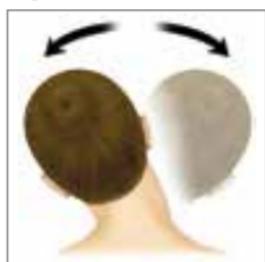


Figure 1  
Cervical spine

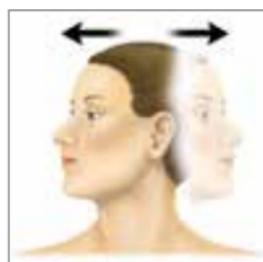
Figure 2



Bend side-to-side  
(lateral bend)



Bend forward-to-back  
(flexion and extension)



Turn left-to-right  
(rotation)

## WHAT IS DISC DEGENERATION?

As discs lose their water content because of disease or age, they lose their height which brings 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 spinal nerves passing from the spinal cord to other parts of your body (**Figure 3**). Additionally, a loss of disc height may cause the formation of bony growths which can push against your spinal cord and/or nerves. Also, when the inner part of the disc pushes out through a weakness in the outer layer of the disc (disc herniation), it may put pressure on one or more of the spinal nerve roots (called nerve root compression) or on the spinal cord. These situations may cause arm pain and/or neurologic symptoms (such as weakness, numbness, or tingling). Living with these symptoms can be disabling.

## WHY MAY I NEED SURGERY?

With the advice of your doctor, you have tried non-surgical treatments which did not relieve your pain or symptoms for at least six weeks. Your doctor has recommended that you consider the Prestige LP Cervical Disc.

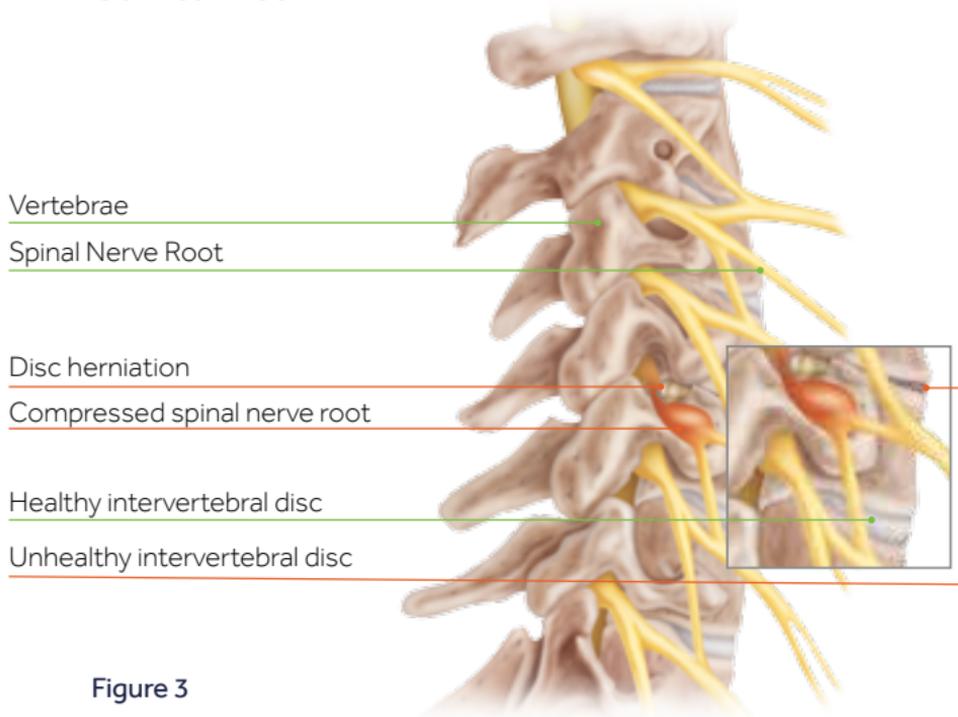


Figure 3

## WHAT IS THE PRESTIGE LP CERVICAL DISC?

The Prestige LP Cervical Disc is an artificial cervical disc for the neck. It consists of two plates that are attached to the vertebral bodies on either side of the disc and are made of a mixture of metals commonly used in spine surgery (titanium, aluminum, vanadium) and a ceramic material (titanium carbide). It is inserted at the affected levels in your neck after removing the diseased disc material at two adjacent disc levels. It is designed to maintain motion at the treated levels in the cervical spine and to help relieve symptoms such as pain. It is intended to be used in patients who have two adjacent (next to each other) diseased cervical discs that require surgery.



Figure 4  
Prestige LP Cervical Disc



## WHO SHOULD RECEIVE THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS? (INDICATIONS)

Treatment with the Prestige LP Cervical Disc at two adjacent levels may be an option if you:

- Are an adult (between 21 and 78 years old) and your spinal bones are mature and of good quality.
- Have arm pain and/or neurological symptoms such as weakness, numbness or tingling with or without neck pain as a result of damaged discs at two adjacent levels that are irritating:
  - your spinal cord possibly causing trouble walking (myelopathy) and/or
  - your spinal nerve roots possibly causing pain, loss of feeling, loss of movement, weakness or tingling down your arm and possibly into your hand (radiculopathy).
- Have two diseased cervical discs next to each other (between level C3 and level C7) that your doctor has determined require surgery.
- Have tried at least six weeks of non-surgical treatment and still have the same symptoms or are getting worse even with the other treatments.
- Your doctor has confirmed that you need surgery by using diagnostic imaging such as computerized Tomography (CT), CT with Myelography (a method of using X-rays and a special dye called contrast material to identify spinal conditions), and/or magnetic resonance imaging (MRI). The imaging needs to show at least one of the following at each affected level:
  - the inner part of the disc squeezing through the outer part of the disc (herniated nucleus pulposus);
  - degeneration of the spine from wear and tear (spondylosis) which may include bony growths (osteophytes) on your spinal bones; and/or
  - loss of disc height compared to the unaffected levels of the spine above and below the affected levels.

## WHO SHOULD NOT RECEIVE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS? (CONTRAINDICATIONS)

If you are experiencing or have been diagnosed with any of the following conditions or symptoms, you should not have surgery with the Prestige LP Cervical Disc at two adjacent levels:

- active systemic (whole body) infection or infection at the surgery site, as undergoing surgery could interfere with your ability to heal or increase the chance of worsening the infection;
- allergy to the materials the Prestige LP Cervical Disc is made of: titanium, aluminum, or vanadium. Talk to your doctor if you have any metal allergies because surgery with the Prestige LP Cervical Disc could cause an allergic reaction;
- weak or brittle bones or low bone mineral density (osteoporosis or osteopenia) because this could increase the risk of bone fracture or cause the Prestige LP Cervical Disc to loosen;
- stiffness of the cervical spine (neck) due to disc degeneration (spondylosis) as determined by your doctor, could limit motion or cause extra bone to form (heterotopic ossification);
- a cervical spine (neck) that shows an unhealthy amount of movement (instability), at the affected levels on X-rays as determined by your doctor, as the removal of the affected discs could lead to additional instability;
- severe disease or degeneration in the joints in the back of the cervical spine (facet joints) as determined by your doctor based on imaging;
- deformed cervical spine or spinal column bones at one or both of the surgery levels that are not healthy due to trauma or an inflammatory disease such as ankylosing spondylitis or rheumatoid arthritis as determined by your doctor, as this could limit movement or increase the risk of the Prestige LP Cervical Disc loosening;

## **WHO SHOULD NOT RECEIVE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?** (CONTRAINDICATIONS) (CONTINUED)

- inward curvature of the cervical spine (lordosis) or outward curvature of the cervical spine (kyphosis), as this could limit motion;
- more than two cervical discs that need treatment or two non-adjacent (not next to each other) cervical discs that need treatment, as the Prestige LP Cervical Disc has only been studied in patients who need surgery at one or two adjacent cervical levels.

## **WHAT ARE THE WARNINGS FOR USING PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?**

Take time to understand the possible dangers from artificial cervical disc surgery, including surgery with the Prestige LP Cervical Disc. Talk to your doctor about possible dangers and complications of surgery with the Prestige LP Cervical Disc. In particular, please be aware that:

- Implanting an artificial disc such as the Prestige LP Cervical Disc in the neck is serious surgery. The Prestige LP Cervical Disc is inserted very close to important nerves and blood vessels. Your doctor will be careful to find and protect these nerves and blood vessels, but there is a risk of damage to nerves or blood vessels during the surgery. A small cut to a blood vessel can cause dangerous bleeding (hemorrhage) or even death. Damage to a nerve can cause long-term loss of movement (paralysis) or feeling.

## WHAT ARE THE WARNINGS FOR USING PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS? (CONTINUED)

- As with any artificial disc surgery, there are steps your doctor should take to make the surgery as safe as possible. The Prestige LP Cervical Disc should only be used by doctors who:
  - are skilled in neck surgery;
  - are trained in the proper use of the Prestige LP Cervical Disc, how it works and how to choose the correct Prestige LP Cervical Disc size; and
  - understand the risks and complications of surgery with the Prestige LP Cervical Disc.
  - If your doctor does not have the proper training and experience, there may be a higher chance of problems during or after the surgery.
- Implants with metal surfaces (such as the Prestige LP Cervical Disc) may release metallic particles or ions into the body, including the area around the implant and also the blood stream. The short and long term effect of these particles and ions in the body is 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 kidney disease.
- Heterotopic ossification (HO), unintended bone formation around or across a joint such as the disc space between the vertebrae, may occur after artificial cervical disc surgery including surgery with the Prestige LP Cervical Disc. A possible consequence of HO is reduced motion although HO has not necessarily been shown to cause harmful results. Not all patients who have surgery with the Prestige LP Cervical Disc will develop HO. It has been reported in the literature that using Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen, for a short time after artificial cervical disc surgery may reduce the chances of HO. Patients in the clinical trial of the Prestige LP Cervical Disc were instructed to use NSAIDs for two weeks after their surgery.

## WHAT ARE THE PRECAUTIONS FOR USING PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?

Below is a list of precautions to be aware of.

The safety and effectiveness of the Prestige LP Cervical Disc has not been tested in the following groups of patients:

- Patients with neck pain alone without arm pain;
- Patients who do not have mature bones or who are young (under the age of 21) or elderly (over the age of 78);
- Patients who have had previous cervical spine surgery at one or both of the affected levels or at the levels adjacent to (next to) the affected levels;
- Patients with more than two cervical discs that need treatment or two non-adjacent (not next to each other) cervical discs that need treatment;
- Patients who have disease or damage of the facet joints at either of the levels of the spine requiring treatment;
- Patients who have cancer that has spread to the spine (spinal metastases);
- Patients who have an endocrine or metabolic disease that affects bones such as Paget's disease, osteomalacia, renal osteodystrophy, Ehlers-Danlos Syndrome, or osteogenesis imperfecta;
- Patients who have kidney failure or a history of kidney disease;
- Patients who are taking medications that may interfere with bone and tissue healing, such as steroids;
- Patients with insulin dependent diabetes;
- Patients with serious mental illness;
- Patients who are being treated for alcohol and/or drug abuse; and
- Patients who are pregnant;

## WHAT ARE THE PRECAUTIONS FOR USING PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS? (CONTINUED)

Before surgery:

- 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 may be right for you.
- You should discuss both surgical and nonsurgical treatment options with your doctor. If surgery is selected, your job, activity level, weight, your overall health, and the condition of your spine will help your doctor determine if surgery with the Prestige LP Cervical Disc at two adjacent levels is an option for you.
- You may be asked questions to help decide if you may have a low bone mineral density. Based on your answers, your doctor may order a bone test (DEXA). The Prestige LP Cervical Disc has not been tested in patients with osteoporosis or osteopenia.
- If you decide to have surgery with the Prestige LP Cervical Disc, your doctor will estimate which Prestige LP Cervical Disc sizes are most likely right for the levels being treated. Choosing the correct device size is important so that the Prestige LP Cervical Disc stays in place and works correctly. Your doctor should not start surgery without the Prestige LP Cervical Disc sizes that are most likely right for you or without Prestige LP Cervical Disc instruments that are in good working condition.
- Ask your doctor to see a full list of the potential risks and complications.
- If you have any questions, talk to your doctor.

## **WHAT ARE THE PRECAUTIONS FOR USING PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS? (CONTINUED)**

During surgery:

- Your doctor will keep the Prestige LP Cervical Disc clean (sterile) and undamaged and will use it as described in the instructions for use.
- The Prestige LP Cervical Disc can only be used in one patient. It cannot be re-used, re-cleaned, or re-sterilized.

After surgery:

- Take care to follow your doctor's directions. Right after surgery, you should not:
  - Do any heavy lifting;
  - Bend or twist your neck multiple times;
  - Do any challenging activities such as athletic activities.
- You may need to limit your activities for weeks to months depending on how you heal. Your doctor will give you specific instructions.
- Your doctor may instruct you to use a Non-Steroidal Anti-Inflammatory (NSAID), such as ibuprofen, for a short time after your surgery, which may reduce your chance of developing HO

## **WHAT ARE THE POTENTIAL RISKS OF SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?**

Like any surgery, there are possible risks (complications) that may occur if you are treated with the Prestige LP Cervical Disc at two adjacent levels.

Complications may occur singly or in combination and may include:

## **WHAT ARE THE POTENTIAL RISKS OF SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?** (CONTINUED)

- Risks due to surgery:
  - Reactions to anesthesia or an allergic reaction;
  - Wound, local, and/or bodily (systemic) infection;
  - Problems with wound healing including pain;
  - Tissue swelling, damage to tissues or collections of fluid (seroma) or thickened blood (hematoma)
  - Problems with the heart or blood vessels including bleeding, a heart attack, problems with blood pressure, blood clots, or a stroke;
  - Problems with the lungs (including pneumonia or lung tissue collapse);
  - Problems with the digestive, urinary, or reproductive systems;
  - Neurological problems including nerve damage, paralysis, seizures, or changes in mental state;
  - Complications of pregnancy including miscarriage or birth defects;
  - Inability to resume normal activities; and
  - Death
- Risks due to neck (anterior cervical spine) surgery:
  - Injury to or swelling of nearby organs and structures including the spinal cord, nerves, vocal cords, vertebrae, blood vessels, dura (protective tissue that surrounds the spinal cord), trachea (windpipe), or esophagus;
  - Difficulty swallowing (dysphagia) or sore throat;
  - Impairment of or change in speech (dysphonia);
  - Neurological complications including muscle weakness, paralysis, changes in sensation (including numbness or tingling), or change in bowel or bladder function;

## **WHAT ARE THE POTENTIAL RISKS OF SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?** (CONTINUED)

- Neck pain, arm pain, or headache;
- Change in the curvature of the neck; and
- Development of new or worsening disease at other cervical levels.
- Risks specific to surgery with a cervical artificial disc, including the Prestige LP Cervical Disc:
  - Problems during placement of the implant, incorrect positioning of the implant, or the implant breaking, loosening, or moving;
  - Development of new or worsening pain;
  - Problems with the surgical instruments bending or breaking;
  - Reaction (including allergic reaction) to the implant materials or metallic particles or ions around the implant or elsewhere in the body which may lead to the implant breaking or loosening, damage to the surrounding bone, tumor formation, autoimmune disease, metallosis, scarring or other symptoms;
  - Degeneration of other parts of the spine;
  - Unintended bone formation that may reduce motion or cause unintended fusion;
  - Need for another surgery; and
  - Interference with radiographic imaging.

There is also the risk that the surgery may not be effective in relieving your symptoms or may cause worsening of your symptoms. If this occurs, you may need another surgery to help you feel better.

There may be other risks associated with treatment using the Prestige LP Cervical Disc at two adjacent levels. Although many of the major risks are listed in this patient information brochure, please talk with your doctor for more information and an explanation of all of the risks.

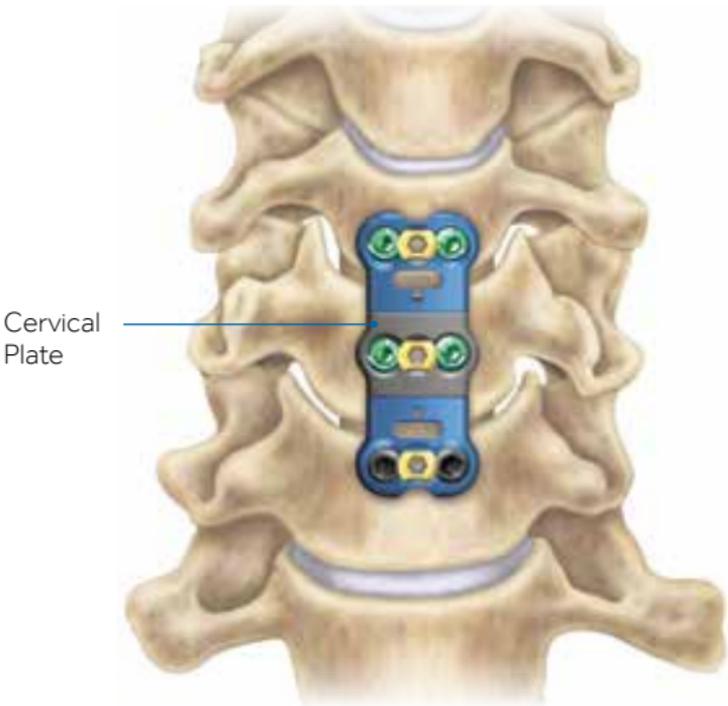
## HOW IS THE SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS DIFFERENT FROM FUSION AT TWO ADJACENT LEVELS?

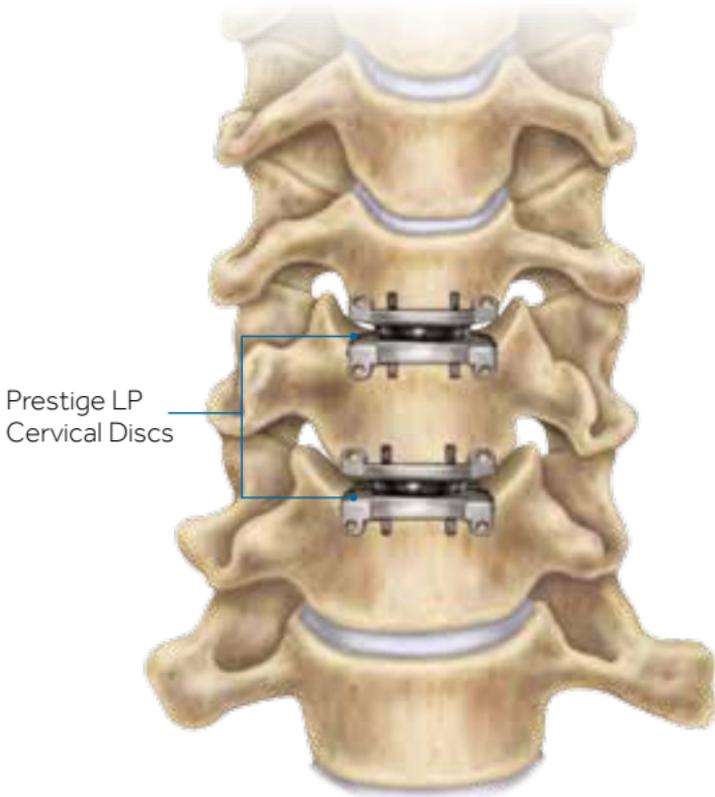
Two-level anterior cervical discectomy and fusion (ACDF) is a cervical fusion surgery done from the front of the neck in which two spinal disc at adjacent levels are removed to address the patient's symptoms. The two adjacent disc spaces may then be stabilized with a device, such as a plate, to serve as an internal brace while fusion occurs. ACDF, which is the surgery that is most commonly performed for your condition, is designed to treat symptoms by eliminating motion at the two adjacent treated levels.

In both ACDF and the Prestige LP Cervical Disc procedure, the unhealthy discs are removed. The difference is that:

- In the ACDF procedure, after the unhealthy discs are removed, the empty disc spaces are filled with spacers made of either bone or medical grade plastic. Then often a plate with screws is placed on the front of the vertebrae to hold the spacers in place and to serve as an internal brace while bone grows between the vertebrae (fusion).
- The Prestige LP Cervical Disc procedure is an alternative to ACDF. In the Prestige LP Cervical Disc procedure, the unhealthy discs are removed, and the Prestige LP Cervical Discs are inserted into the two adjacent empty disc spaces. The Prestige LP Devices are designed to allow motion at the two adjacent treated levels (**Figure 5**).

Figure 5  
ACDF Procedure





Prestige LP  
Cervical Discs

Prestige LP Cervical Discs  
in the cervical spine

# WHAT COMPLICATIONS OCCURRED IN THE UNITED STATES CLINICAL TRIAL OF THE PRESTIGE LP CERVICAL DISC USED AT TWO ADJACENT LEVELS?

In order to be used in the United States at two adjacent levels, the Prestige LP Cervical Disc was evaluated in a clinical trial to determine whether it is a safe and effective treatment for arm pain and/or neurological symptoms due to damaged discs at two adjacent levels that are irritating the spinal cord (myelopathy) and/or spinal nerve roots (radiculopathy).

## Adverse Event (Complication)

Cervical neck pain

Cervical arm pain

Non-cervical neck or arm pain (including shoulder pain, finger pain, and arm injuries)

Pain in an area other than the neck or arms (including back pain, headache, and leg pain)

Problems with the implant (including incorrect positioning or the implant breaking, loosening, or moving)

Cervical heterotopic ossification

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

Events involving the cervical part of the nervous system (including arm weakness, numbness or tingling and unsteadiness in walking)

Events involving the treated levels of the cervical spine (including degeneration of the disc or vertebrae, disc herniation, a break in the vertebrae, and changes in spinal alignment)

Events involving the surgery wound other than infection

Through two years after surgery, 5 out of 209 patients (2.4%) treated with the Prestige LP Cervical Disc at two adjacent levels and 15 out of 188 patients (8.0%) treated with ACDF at two adjacent levels had additional surgery at the same levels. In addition, 5 out of 209 patients (2.4%) treated with the Prestige LP Cervical Disc at two adjacent levels and 6 out of 188 patients (3.2%) treated with ACDF at two adjacent levels had additional surgery at a level adjacent to the levels originally treated.

The trial was prospective (looking forward in time) and involved 397 patients (209 patients who received the Prestige LP Cervical Disc at two adjacent levels and 188 patients who underwent a fusion procedure, ACDF, at two adjacent levels).

Throughout the course of the clinical trial, patients in both the PRESTIGE LP Cervical Disc group and the ACDF fusion group reported health-related problems to their doctors. Some of the important adverse events (complications) and their rates two years after surgery in each group were:

Patients Treated with PRESTIGE LP Cervical Disc at Two Adjacent Levels	Patients Treated with ACDF at Two Adjacent Levels
83 out of 209 patients (39.7%)	80 out of 188 patients (42.6%)
76 out of 209 patients (36.4%)	76 out of 188 patients (40.4%)
36 out of 209 patients (17.2%)	36 out of 188 patients (19.1%)
125 out of 209 patients (59.8%)	113 out of 188 patients (60.1%)
13 out of 209 patients (6.2%)	10 out of 188 patients (5.3%)
22 out of 209 patients (10.5%)	21 out of 188 patients (11.2%)
14 out of 209 patients (6.7%)	21 out of 188 patients (11.2%)
66 out of 209 patients (31.6%)	59 out of 188 patients (31.4%)
29 out of 209 patients (13.9%)	17 out of 188 patients (9.0%)
17 out of 209 patients (8.1%)	14 out of 188 patients (7.4%)

A complete list of risks is provided in the package insert for the Prestige LP Cervical Disc, which your doctor has received. Please ask your doctor for more information about any additional risks that could be related to your planned surgery.

## WHAT BENEFITS OCCURRED IN THE UNITED STATES CLINICAL TRIAL OF THE PRESTIGE LP CERVICAL DISC USED AT TWO ADJACENT LEVELS?

Surgery with the Prestige LP Cervical Disc may relieve the arm pain and/or neurological symptoms (such as weakness, numbness, or tingling) you are experiencing due to the damaged discs you have at two adjacent levels that are irritating your spinal cord (myelopathy) and/or spinal nerve roots (radiculopathy). In addition, the Prestige LP Cervical Disc is designed to allow motion at the two levels where you have surgery, unlike ACDF fusion surgery which is designed to treat symptoms by eliminating motion.

Some of the results from the clinical trial of the Prestige LP Cervical Disc at two years after surgery are described below. The clinical benefit beyond two years has not been fully evaluated. Ask your doctor for more details about this clinical trial and its results.

- Two years after surgery, 162 out of 199 (81.4%) patients treated with the Prestige LP Cervical Disc at two adjacent levels achieved overall success, compared to 111 out of 160 (69.4%) patients treated with ACDF at two adjacent levels. Overall Success was determined 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 for the treatment of arm pain and/or neurological symptoms due to damaged discs at two adjacent levels that are irritating the spinal cord (myelopathy) and/or spinal nerve roots (radiculopathy).

Other key results from the trial at two years after surgery include:

- Considering all of the patients treated with the Prestige LP Cervical Disc at two adjacent levels, 100 out of 196 (51.0%) had more than four degrees of motion at both treated levels while bending the head forward to backward (flexion-extension) and did not have evidence of an unintended fusion at either treated level.

## WHAT BENEFITS OCCURRED IN THE UNITED STATES CLINICAL TRIAL OF THE PRESTIGE LP CERVICAL DISC USED AT TWO ADJACENT LEVELS? (CONTINUED)

- Through two years after surgery, the rate of complications considered severe and related to the implant or the implant and the surgical procedure was lower in patients treated with the Prestige LP Cervical Disc at two adjacent levels (4 out of 209 (1.9%)) than in patients treated with ACDF at two adjacent levels (11 out of 188 (5.9%)).
- Through two years after surgery, the rate of another surgery at the treated levels was lower in patients treated with the Prestige LP Cervical Disc at two adjacent levels (5 out of 209 (2.4%)) than in patients treated with ACDF at two adjacent levels (15 out of 188 (8.0%)).
- Two years after surgery, 182 out of 199 (91.5%) patients treated with the Prestige LP Cervical Disc at two adjacent levels had a neurologic exam that was either the same or improved, compared to 137 out of 159 (86.2%) patients treated with ACDF at two adjacent levels.
- Two years after surgery, similar numbers of patients in both treatment groups had returned to work. Patients receiving Prestige LP Cervical Disc at two adjacent levels had an average return to work that was 6 days sooner than the ACDF group.

## HOW DO I PREPARE FOR SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?

- 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 all of your possible treatment options 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 medications 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 discuss the possible risks, as well as the possible benefits, of this surgery.

## **WHAT CAN I EXPECT DURING SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?**

During surgery, you will lie on your back on an operating table and be put into a deep sleep (general anesthesia). Once you are asleep, your neck area will be washed and a clean (sterile) sheet will be taped around your neck. A cut (incision) about an inch long will be made in the front of your neck and your doctor will move the structures in your neck to the side so he or she can see your spine. Your doctor will surgically remove your two damaged or diseased discs and insert a Prestige LP Cervical Disc into each disc space. The muscle and skin incisions will be sewn together and you will be moved to the recovery room and woken up.

## **WHAT CAN I EXPECT AFTER SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS?**

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 at two adjacent levels 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.

After surgery, your doctor or nurse may:

- prescribe medicines to control pain and nausea;
- 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;

## **WHAT CAN I EXPECT AFTER SURGERY WITH THE PRESTIGE LP CERVICAL DISC AT TWO ADJACENT LEVELS? (CONTINUED)**

- discuss a program to gradually increase your activity;
- tell you to wear a neck brace after surgery;
- tell you to avoid activities that require repeated bending, lifting, twisting, such as athletic activities; and
- schedule office visits to assess your progress and to see if anything else needs to be done for your recovery.

After surgery, your doctor may refer you to a physical therapist to 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.

Contact your doctor immediately if:

- you get a fever;
- your 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; or
- you have new or increased neck or arm pain, numbness, or weakness.

## FREQUENTLY ASKED QUESTIONS

### **How long can I expect the device to last?**

Despite extensive testing, there is not enough long-term data in humans to predict the lifetime of the Prestige LP Cervical Disc.

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

If you continue to experience the same or new 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 bandage on your neck. You may shower quickly but try not to soak the bandage. 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. Talk to your doctor for specific recommendations.

### **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 doctor to request a patient identification card from Medtronic and provide you with a copy.

## **FREQUENTLY ASKED** QUESTIONS (CONTINUED)

### **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](http://www.necksurgery.com).

### **Can I receive an MRI after surgery?**

Yes, patients can receive an MRI any time after surgery with the Prestige LP Cervical Disc. As MRI machines vary, please tell all of your doctors that you have Prestige LP Cervical Discs and talk to your doctors 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](http://www.necksurgery.com)

## **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.

# Medtronic

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**medtronic.com**

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



Consult instructions for use at this website: [www.medtronic.com/manuals](http://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.

**Caution: U.S.A. law restricts this device for sale by or on the order of a physician.**