

PRESTIGE[®] Cervical Disc System



Patient Information





This patient information brochure is designed to help you understand treatment for your neck pain and related problems. Your doctor has recommended you consider surgery to relieve your pain and discomfort using the PRESTIGE® Cervical Disc. The purpose of this brochure is to give you some background about cervical spine (neck) surgery and the PRESTIGE® Cervical Disc.

Your Cervical Spine

The vertebrae (spinal column bones), 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.

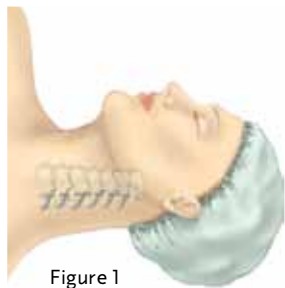


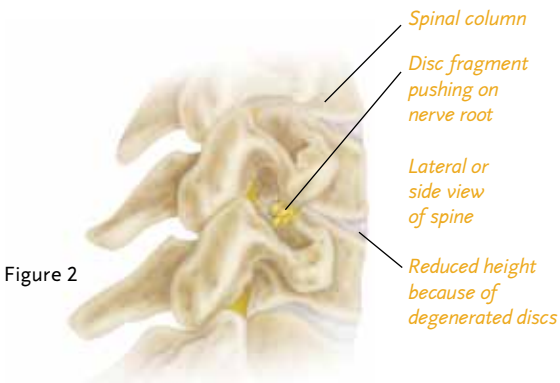
Figure 1

Why do I need surgery?

As discs lose their water content because of disease or age, they lose their height and bring the vertebrae closer together. The consequence 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 bone spurs, which can push against your spinal cord and/or nerves. When a disc ruptures in the cervical spine, it puts pressure on one or more nerve roots (called nerve root compression) or on the spinal cord, causing pain and other symptoms in the neck and arms. Living with this pain or weakness and tingling in the arms can be disabling.



Disc Degeneration



With the advice of your doctor, you may have tried other treatments for some time now which did not relieve your pain or dysfunction. Or perhaps your doctor has determined permanent damage would result without surgery. Your doctor has recommended that you consider the PRESTIGE® Cervical Disc, which provides for motion following surgery, instead of the more common fusion procedure.

What is the PRESTIGE® Cervical Disc?

The PRESTIGE® Cervical Disc is made of two-pieces of articulating, surgical grade, stainless steel. It is inserted into the affected disc space of your neck, acting like a joint, via a ball-and-trough mechanism, similar to that of a ball-and-socket. It is intended to be used in patients with only one diseased disc requiring surgery in their neck.

Who should avoid having cervical disc surgery?

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

What warnings should I pay attention to?

Heterotopic ossification (HO) is a fairly common complication associated with artificial hips and knees. The 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

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(NSAIDs), such as ibuprofen, may reduce the instance of HO. HO also has been reported in early cervical disc surgeries outside the United States. NSAIDs were not prescribed in these early cases. 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.

Metallic devices release metallic ions into the body. The long term effect of these ions in the body is not known.

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® Cervical Disc. Complications may occur singly or in combination and may include:

- Allergic reaction to the implant material
- Implants bending, breaking, loosening, or moving
- 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 extremities
- Tear in the protective membrane (dura) covering the spinal cord
- Loss of motion or fusion at the treated cervical level
- Development or progression of disease at other cervical levels

- Bleeding or collection of clotted blood (hematoma)
- Blood clots and blood flow restrictions, possibly resulting in stroke
- 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.

In the U.S. clinical study, there were a number of adverse effects. Some of the most common were trauma, difficulty swallowing, impairment of speech, and infection. There may be other risks associated with treatment using the PRESTIGE® device. Although many of the major risks are listed in this patient information brochure, a more comprehensive list is provided in the physician's package insert for the product. Please consult your doctor for more information and an explanation of these risks.

NOTE: Additional surgery may be necessary to correct some of the adverse effects.

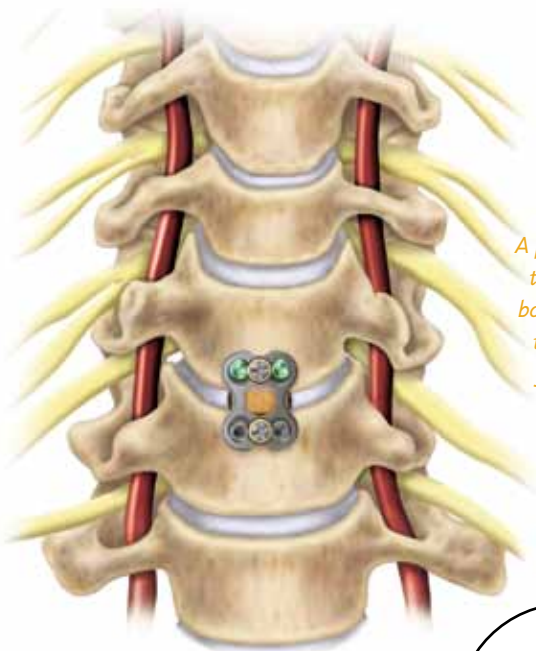


What should I expect from the surgery?

This surgical procedure is expected to relieve the symptoms of a nerve root or spinal cord compression caused by the damaged disc. The surgery associated with a PRESTIGE® 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?

Unlike a fusion, which is designed to treat your symptoms by eliminating the motion at the treated level (Figure 3), the PRESTIGE® Cervical Disc is designed to allow motion.



A plate is attached to the vertebral bodies to stabilize the bones until fusion occurs.

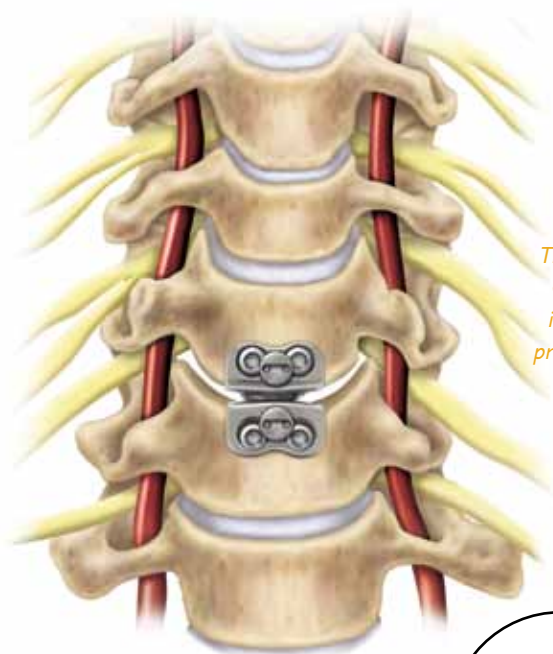
Vertebrae fuse (join together) restricting movement and flexibility.



Figure 3

What is involved in a PRESTIGE® Cervical Disc procedure?

This surgery involves the use of a medical device, designed to replace the disc which sits between the vertebrae in your neck (Figure 4). Your disc, which is damaged or diseased, is surgically removed through an incision (cut) 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® Cervical Disc into the disc space. The PRESTIGE® Cervical Disc is held in place by four bone screws and two lock screws. The device utilizes a patented ball-and-trough design which allows for motion to be preserved. *(Continued on Next Page)*



The PRESTIGE® Cervical Disc is designed to preserve motion.



Figure 4

The PRESTIGE® Cervical Disc maintained normal and healthy “segmentally” (naturally divided) motion 24 months after implantation. Patients also showed improvement of their nervous system. A nurse will show you how to care for your wound before you are sent home and your doctor will discuss a program to gradually increase your activity. You may be required to wear a neck brace after surgery. You may be told, while you recover, to avoid any activities that require repeated bending, lifting, twisting, to include athletic activities. Your doctor will schedule office visits to check on how you are doing and to see if anything else needs to be done for your recovery.

Preparing for Surgery

You may be told to see your general practitioner before surgery to check your overall health. Tell your doctor what medications you are taking, and ask if you should stop taking any medications before surgery. To make your recovery easier, prepare your home for life after surgery. Place important things within easy reach. Remove safety hazards that might cause you to lose your balance. Arrange for someone to help you at home and around the house after surgery. You will most likely be told not to eat or drink the night before the surgery. Be sure you read and understand this entire booklet. Your surgeon is required to let you know of the potential risks, as well as benefits, of this surgery.

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 increase your chances of a successful outcome. Recovering from neck pain and surgery is an ongoing process. How fast you recover depends on the type of surgery you had, your commitment to working closely with your physical therapist, and moving and exercising correctly, as recommended by your doctor.

In most cases, immediately after surgery, your heart and lung function will continue to be monitored, a drainage tube may have been left in your wound and your doctor may prescribe medicines to control pain and nausea.

Contact your doctor immediately if:

- You get a fever
- The wound starts leaking fluids
- You have trouble swallowing or breathing
- You have trouble urinating
- You have new or increased neck or arm pain or numbness

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.

What are the expected outcomes of the surgery?

Patients in the U.S. clinical study were found to be about 79% successful through two years. Success was based on several factors, such as reduced pain, improved function, and lack of serious adverse events.

Frequently Asked Questions

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 usually less than 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 get information that might help you pass through security more quickly and easily. Ask your surgeon to provide a patient identification card.

Talk to Your Doctor

While this brochure is meant to provide you with information 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® 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 find a doctor who is experienced in performing the specific surgery that you are considering.

For additional information visit:

www.sofamordanek.com

www.necksurgery.com

www.prestigedisc.com



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