

**BRYAN® Cervical Disc
Patient Education Brochure**

(Draft)

(Final version will include graphics & layout)

Text on inside cover page

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 BRYAN® Cervical Disc. The purpose of this brochure is to give you some background about cervical spine (neck) surgery and the BRYAN® 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.

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 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 BRYAN® Cervical Disc, which provides for motion following surgery, instead of the more common fusion procedure.

What is the BRYAN® Cervical Disc?

The BRYAN® Cervical Disc is made of two titanium shells, which articulate with a polyurethane central core. It is inserted into the affected disc space of your neck, acting like a joint. The device is designed to alleviate pain and replicate normal motion of the cervical spine.

Who should avoid having cervical disc surgery?

The BRYAN® Cervical disc should not be implanted in patients with an active infection or with an allergy to titanium, polyurethane, or ethylene oxide residues.

What warnings and precautions should I pay attention to?

The BRYAN® 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. Additional surgery may be necessary to correct some of the adverse events. Heterotopic ossification (HO) is a fairly common complication associated with artificial hips and knees, and can range in severity from a small amount of bone noted as an incidental findings on an X-ray to a massive bone formation around a joint resulting in total ankylosis (stiffening of a joint). 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. 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.

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

Like any surgery, there are some possible complications that may occur when you receive the BRYAN® 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 of 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 a 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 BRYAN® Cervical Disc. 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 the BRYAN® Cervical Disc is designed to preserve motion at the operated disc level, unlike a fusion surgery that does not allow for motion.

In the U.S. clinical trial comparing the BRYAN® disc to fusion, the group of patients who received the BRYAN® disc had more successful outcomes than the fusion patients on a pain and function questionnaire called the Neck Disability Index. The BRYAN® disc patients also had a higher rate of "overall success," or the main trial outcome that includes several key safety and effectiveness measures.

How is this procedure different from a fusion?

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

What is involved in a BRYAN® 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 BRYAN® Cervical Disc into the disc space. The BRYAN® Cervical Disc allows for motion to be preserved. The BRYAN® Cervical Disc maintained normal and healthy "segmental" (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 to 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 to leaking fluids
- You have trouble swallowing or breathing
- You have trouble urinating
- You have new or increased neck or leg 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.

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 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 BRYAN® 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.medtronic.com

www.necksurgery.com

www.bryandisc.com