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 you consider surgery to relieve your pain and discomfort. This patient brochure explains one option, surgery using the BRYAN® Cervical Disc. The purpose of this brochure is to give you background about cervical spine (neck) surgery and the BRYAN® Cervical Disc. Please read this brochure entirely before your cervical surgery.
Glossary

Disc Herniation - pushing out of the inner part of the intervertebral disc through a hole in the outer layer of the intervertebral disc

Foramen - an opening where spinal nerves pass through

Heterotopic Ossification – bone formation around or across the intervertebral disc space

Intervertebral Disc – connecting soft material between the vertebrae that provides cushioning and movement of the spine

Myelopathy – disease in the spinal cord

Radiculopathy – disease of the nerve roots in or near the spine as a result of pressure from an intervertebral disc, or irritation of the nerve roots due to disc or spinal joint disease

Spondylosis – bone formation on the soft material that connects the bones of the spine

What is the cervical spine?

The spinal column bones (vertebrae), which encircle and protect your spinal cord, are separated by shock-absorbing discs. These 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. The spine can be divided into four regions: cervical (neck), thoracic (middle back), lumbar (lower back), and the sacrum (tail bone) (Figure 1).

![Figure 1](image-url)
The cervical region of the spine is made up of seven vertebrae, C1–C7. The BRYAN® Cervical Disc is intended to treat the disc spaces between the C3 and C7 vertebral bodies (Figure 2).

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 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. Additionally, a loss of disc height may cause the formation of bone spurs, which can push against your spinal cord and/or nerves causing a condition called spinal cord and/or nerve root compression (Figure 3). This condition can also occur when a disc ruptures in the cervical spine, putting pressure on the spinal cord and/or nerve roots resulting in pain and other symptoms such as weakness or tingling in the neck and arms. Living with these symptoms can be disabling.
Why do I need surgery?

With the advice of your doctor, you have tried to relieve your symptoms with other treatments such as physical therapy and medications for at least six weeks, but these treatments have not relieved your pain or dysfunction. Your doctor has recommended that you may get relief of your symptoms by having surgery. One type of surgery is total disc replacement, and the BRYAN® Cervical Disc is one total disc replacement option.

What is the BRYAN® Cervical Disc?

The BRYAN® Cervical Disc is made of two metal (titanium) shells, and a plastic (polyurethane) central core. It is designed to provide motion by allowing movement between the metal components and the plastic component. It is inserted into the affected disc space of your neck. The device is designed to help relieve pain. It is intended to be used in patients with only one diseased disc requiring surgery in their neck (Figure 4).

Who should receive the BRYAN® Cervical Disc?

If you are an adult with good bone quality who has undergone at least six weeks of conservative (non-surgical) treatment, and if you are still experiencing symptoms related to reduced function of the upper extremities such as arm weakness, poor reflexes, and/or decreased nerve sensation along with any combination of the following conditions, you may be selected to receive the BRYAN® Cervical Disc:

» arm pain and/or tingling as a result of a disc herniation (radiculopathy);

» arm pain and/or tingling as a result of bony spurs (spondylotic radiculopathy);

» neck pain and/or trouble walking as a result of a disc herniation (myelopathy); or

» neck pain and/or trouble walking as a result of bony spurs (spondylotic myelopathy).
In addition to experiencing one or more of the symptoms described above, your surgeon should confirm the need for surgery by using diagnostic imaging such as computed tomography (CT), myelography and CT, and/or magnetic resonance imaging (MRI). The BRYAN® Cervical Disc is implanted via an open (through an incision) anterior (from the front) approach.

Who should avoid having cervical disc surgery? (Contraindications)

If you are experiencing any of the following conditions you should avoid having cervical disc surgery:

» active systemic (whole body) infection or infection at the operating site;
» allergy to titanium (metal part of device), polyurethane (plastic part of device), or ethylene oxide residues (used in making the device sterile);
» osteoporosis (loss of calcium from bone resulting in bones that break easily);
» moderate to advanced spinal arthritis (spondylitis);
» unstable cervical spine as seen on x-ray;
» diseased disc has much more movement than adjoining discs;
» deformed cervical spine or spinal column bones that are not healthy;
» significant loss of the normal curvature of your neck (lordosis);
» significant change in the curve of your neck (kyphosis); or
» more than one cervical disc that needs treatment.

What warnings and precautions should I pay attention to?

In the U.S. clinical trial, the BRYAN® 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 that needs to be treated with daily insulin therapy, they could not be pregnant, and they could not be taking certain medications such as steroids. Therefore, it is not known if the BRYAN® Device will perform as well in other types of patients as it did in patients who were studied in the U.S. clinical trial.

Heterotopic ossification (HO) is a complication associated with cervical total disc replacements (including among others, the BRYAN® Cervical Disc), and it has been reported in some studies outside of the United States. One of the consequences of HO can be reduced motion. It has also
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 BRYAN® Cervical Disc U.S. clinical study were instructed to use NSAIDS for two weeks postoperatively.

This device is placed close to nerves and important blood vessels and arteries in the cervical spine. There is a risk of nerve damage and/or serious or fatal bleeding if damage to these structures occurs during or after surgery.

It is important that you let your doctor know 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 this device 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 with the BRYAN® 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.

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

Like any surgery, there are some possible complications that may occur when you receive the BRYAN® Cervical Disc. Possible complications that may occur singly or in combination include:

» Allergic reaction to the implant material
» Implant loosening or failure
» Infection of your wound, at the operative site, and/or systemic infection
» Painful or difficult swallowing
» Impairment of or change in speech
» Trauma during surgery such as nerve or spinal cord injury, excessive bleeding and/or vertebral body (spinal bone) fractures
» Nerve damage
» Implant components bending, breaking, loosening, or moving
- Instruments bending or breaking
- Neck and/or arm pain
- Change in the curvature of your neck
- Nerve or spinal cord injury, possibly causing impairment or paralysis
- Numbness, tingling, or muscle weakness in your extremities
- Tear in the protective membrane (dura) covering the spinal cord
- Loss of motion (unintended fusion) at the treated level
- Development or progression of disease at other levels in your cervical spine
- Bleeding or collection of clotted blood (hematoma)
- Blood clots and blood flow restrictions, possibly resulting in stroke
- Swelling
- Reactions to anesthesia used during your surgery
- 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 may not make you feel better or may cause you to feel worse. If this happens you may need another surgery to help you feel better.

Not all of the adverse events listed above occurred in the U.S. clinical study. For the 242 patients who received the BRYAN® Cervical Disc in the clinical study, some of the most common events were neck and/or arm pain, difficulty swallowing, impairment of speech, and infection. Six patients had additional neck surgery after their disc replacement. 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, which your doctor has received. Please ask your doctor for more information about any additional risks possibly related to your planned surgery.

NOTE: Additional surgery may be necessary to correct some of the adverse effects.
What are the expected outcomes of the surgery?

In the U.S. clinical trial comparing the BRYAN® Cervical Disc to fusion, many different outcomes were measured. The outcomes were similar in both groups; however, two outcome measures were calculated to be statistically higher in the group receiving the BRYAN® Disc. The clinical importance of the differences in these outcome measures is not yet known. The rates of complications were about the same between the two groups in the first two years following surgery. The clinical benefit beyond two years has not been measured. Ask your doctor for more details about the clinical study and your expected results.

How is the BRYAN® Cervical Disc procedure different from anterior cervical discectomy and fusion?

The BRYAN® Cervical Disc is an alternative to anterior cervical discectomy and fusion (ACDF). In the ACDF procedure, after the disc is removed, the bones are fixed in position with the hope that they will eventually grow together creating one solid piece of bone. Fusion, which is the surgery that is most commonly done for your condition, is designed to treat your symptoms by eliminating the motion at the treated level (Figure 5). In both the ACDF and the BRYAN® Cervical Disc procedures, the unhealthy disc is removed. In the BRYAN® Cervical Disc procedure, the device is inserted into the disc space after the disc is removed. The BRYAN® Device is designed to allow motion at the treated level.

Figure 5
How do I prepare for surgery?

Items your doctor may cover with you:
» See your general practitioner 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.
» Be careful not to eat or drink the night before the surgery.
» 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.
» Be sure you read and understand this entire brochure.
» Ask your surgeon to tell you of the risks, as well as benefits, of this surgery.

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. During surgery, you will be under general anesthesia. 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 (Figure 6).
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 BRYAN® 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. 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.

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 check on how you are doing and to see if anything else needs to be done for your recovery
» 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, 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

Can I shower after surgery?
You will have a bandage 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. Your doctor will tell you when you may drive again.

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.

What if I have more questions?
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.

How can I contact someone at the manufacturer?
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