SECURE®-C

Cervical Artificial Disc

Patient Information

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Glossary

Alleviate:	To make something less severe or more bearable, especially pain
Anterior:	Front of the body
Axial Rotation:	(In the neck) Turning the head side to side
Bone Graft:	A transplant of bone taken from one area to another area
Cobalt Chromium Molybdenum Alloy (CoCrMo):	A metallic material used in implants
CT:	Computerized tomography (CT), which is an x-ray procedure that combines many x-ray images to create cross-sectional images (like slices) of the body
Degeneration:	Deterioration of tissue, which may include loss of function
Disc:	The soft tissue found between the bones of the spinal column that help cushion the spine
Discectomy:	A surgical procedure in which the central portion of a disc is removed
Extension:	(In the neck) Bending the head backward
Facet Joint:	Joints that connect the vertebrae together in the back of the spine and slide against one another during motion
Flexibility:	Motion or movement in a joint
Flexion:	(In the neck) Bending the head forward
Fusion:	Joining two bones together so that they no longer move
Herniated Disc:	A disc that, due to use, injury or disease, bulges outside its normal area, potentially causing pain and limiting function
Heterotopic Ossification:	Unintended bone formation around or across the disc space between the spinal bones (vertebrae)
Incision:	A surgical cut made in skin

Glossary

Lateral Bending:	(In the neck) Bending the head side to side (ear to shoulder)
MRI:	Magnetic Resonance Imaging (MRI), which is a radiographic (like an X-ray) procedure that uses magnets to create cross-sectional images (like slices) of the body
Myelopathy:	Disease of the spinal cord
Osteoporosis:	A condition in which the bones are thin or weak and become brittle and fragile
Osteopenia:	A condition in which the bones are somewhat thin or weak, which may develop into osteoporosis
Polyethylene:	A hard plastic material used in implants
Radiculopathy:	Disease of the 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
Rehabilitation:	The process of recovery from surgery to a more normal condition
Spondylosis:	A degenerative disease in which the vertebral joints of the spine become stiff and then fused
Synthetic Spacer:	Implant made of an artificial material (such as metal or plastic) that is commonly used in fusion surgeries to hold open the disc space
Systemic:	Pertaining to or affecting a particular body system
Vertebrae:	The bones of the spine that make up the spinal column, with a hole for the spinal cord to pass through
X-Ray:	An image produced by the use of radiation waves, showing bone and other tissues in the body

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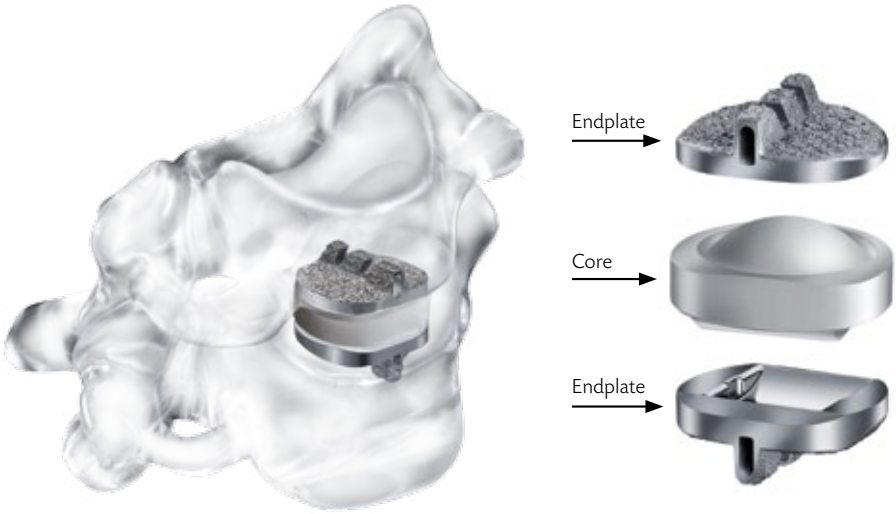
Patient Information

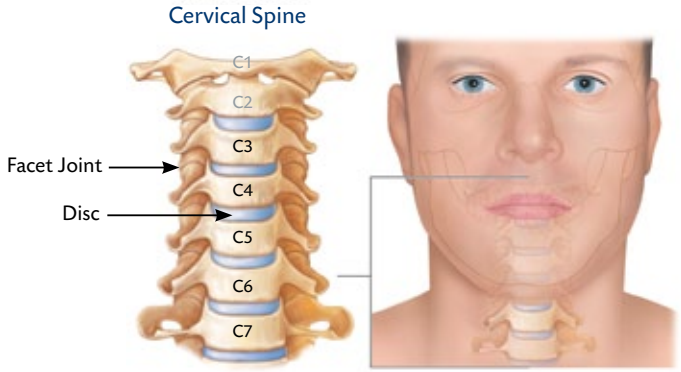
This brochure is intended to provide you with information about a treatment option for your arm pain and/or neurologic symptoms (such as weakness or numbness). After reviewing and discussing your medical history, x-rays, and the results of other evaluations you have completed, you and your doctor have determined that an option for improving your condition would be to undergo cervical spine (neck) surgery using the SECURE®-C Cervical Artificial Disc made by Globus Medical, Inc.

What is the SECURE®-C Cervical Artificial Disc?

The SECURE®-C Cervical Artificial Disc consists of two metallic endplates (cobalt chromium molybdenum alloy, CoCrMo) and a polyethylene (plastic) inner core. The materials used in the device are commonly used in orthopedic implants. The two endplates are secured to the top and bottom surfaces of the involved vertebrae (the bones in the spine) and the core fits between them. The implanted device is designed to allow motion at the treated level as the plastic core moves against the metallic endplates.

Specifically, SECURE®-C's design is intended to allow the neck to move in flexion/extension (bending the neck forward and backward), lateral bending (bending the neck side to side) and axial rotation (turning the head side to side). SECURE®-C is intended to treat a disc in the cervical spine (neck) between the C3 and C7 vertebral bodies. The device is provided in different sizes to fit different patients.

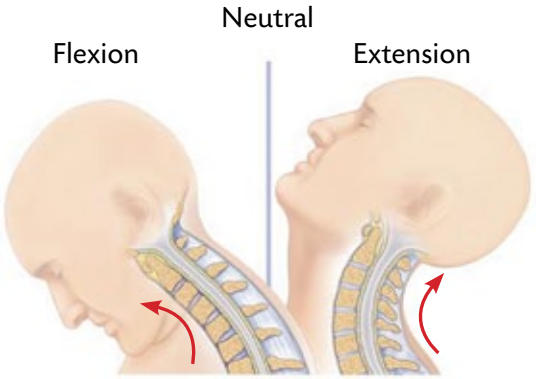




What is the cervical spine and how does it normally move?

Your spine is one of the most important parts of your body. It gives your body structure, support, stability, flexibility (motion or movement in a joint) and provides protection for your spinal cord. A normal spine allows you to move about freely and to bend with flexibility. Your neck, or cervical spine, is composed of seven bones (vertebrae) which are numbered C1 to C7 and are stacked on top of each other to form a column. Each vertebrae has a hole for the spinal cord which contains nerves that carry signals from your brain to the rest of your body. There is a disc between each vertebra which acts as a shock absorber and has a thick outer layer (annulus) that surrounds a soft gel-like center (nucleus).

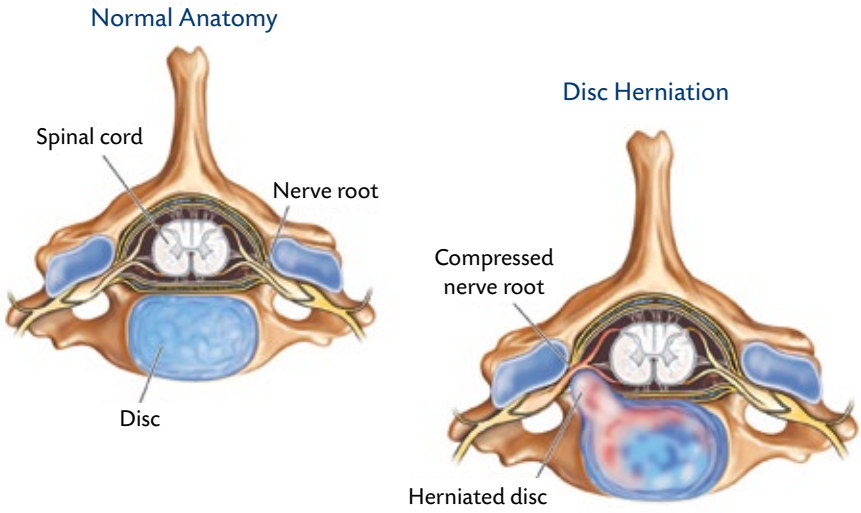
The natural motion of the spine involves movement between each bone, compression of the disc, and sliding of the facet joints (contact areas between the bones). The motion of the cervical spine is: flexion-extension (bending the head forward and backward), lateral bending (bending the head side-to-side) and axial rotation (turning the head). As an example, the image below illustrates flexion-extension motion in the cervical spine.



What is causing my arm and neck symptoms?

Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration (degeneration) of the discs in your neck. Degeneration commonly causes pain that radiates toward the shoulders and arms and/or weakness and numbness and may also cause neck pain. Your doctor has probably taken X-rays and an MRI or CT of your neck and may have found a herniated disc (a disc bulge as shown in the illustration below), spondylosis (degeneration of the vertebral joint causing stiffness), or narrowing of the disc as compared to your other discs. Your doctor may diagnose your condition as radiculopathy (disease or irritation of the nerves) or myelopathy (disease of the spinal cord) at one level.

Normal Disc Compared to Herniated Disc



Why may I need surgery?

Non-surgical treatment, such as physical therapy, injections, and possibly a neck brace, will be prescribed first by your doctor. If these treatments do not relieve your pain or dysfunction, you and your doctor may determine that you are a candidate for cervical disc replacement. If this option is selected, your surgeon will remove the diseased cervical disc and insert a disc replacement, such as the SECURE®-C Cervical Artificial Disc.

The SECURE®-C design permits motion in flexion and in extension.

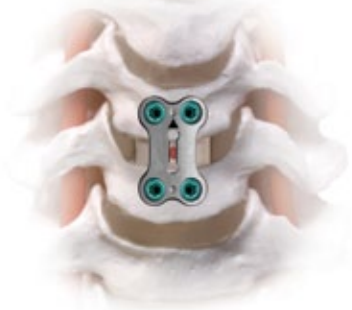
Flexion

Extension

How is surgery with the SECURE®-C Cervical Artificial Disc different from a fusion?

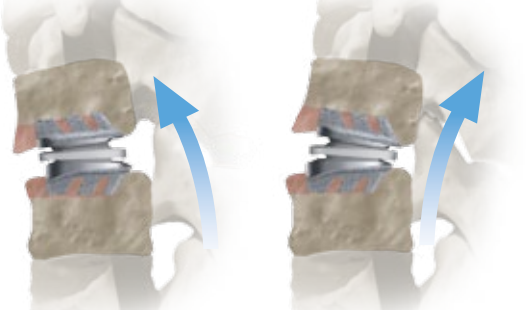
The current standard of care for the surgical treatment of cervical disc disease is fusion (joining of two bones together), which is known as anterior cervical discectomy and fusion (ACDF). In both an ACDF and a SECURE®-C Cervical Artificial Disc procedure, the unhealthy disc is removed and the height at that level is restored to relieve pressure on the nerves and/or spinal cord. In an ACDF, after the unhealthy disc is removed, it is replaced with a bone graft (bone taken from one area and moved to another) or synthetic spacer (artificial implant designed to hold open the disc space), and a cervical plate with screws is used for stabilization. The goal of this procedure is to permanently fuse two or more vertebrae together so they cannot move except as a single unit. This may alleviate (lessen or make more bearable) pain and other symptoms but has potential disadvantages, including loss of motion and flexibility.

Fusion



Restricts normal motion

SECURE®-C



Flexion (forward bending)

Extension (backward bending)

How is surgery with the SECURE®-C Cervical Artificial Disc different from a fusion? *(cont'd)*

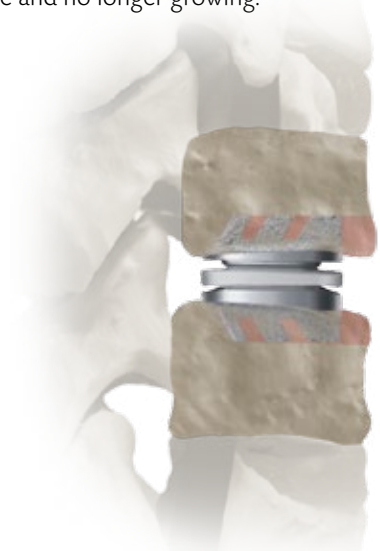
The SECURE®-C Cervical Artificial Disc has been developed to provide pain relief while potentially allowing motion of the cervical spine. In a SECURE®-C procedure, after the unhealthy disc is removed, it is replaced with the device alone (no bone graft). The device is designed to provide support for the vertebrae while potentially allowing motion in backward and forward bending, side-to-side bending, and turning.

Who should receive the SECURE®-C Cervical Artificial Disc?

The SECURE®-C Cervical Artificial Disc may be used to treat patients who meet the following requirements:

- 21 to 60 years old
- One diseased disc (C3-C7)
- Arm pain and/or neurological symptoms such as weakness or numbness with or without neck pain for at least six weeks that has not responded to non-surgical care such as medication and physical therapy
- Specific findings on imaging studies such as X-ray, CT, or MRI

In addition, in order to receive this device you must be old enough so that your bones are mature and no longer growing.



Who should not receive the SECURE®-C Cervical Artificial Disc? (Contraindications)

You should avoid having surgery with the SECURE®-C Cervical Artificial Disc if you are experiencing any of the following conditions:

- Active systemic (whole body) infection or an infection at the operating site, as undergoing surgery could interfere with your ability to heal and could increase the chance of spreading or worsening the infection
- Osteoporosis or osteopenia (thin or weak bones resulting from a loss of calcium) because this condition could increase the risk of bone fracture, or could cause the device to loosen
- Allergy to cobalt, chromium, molybdenum, or titanium (metals in the device), or polyethylene (plastic in the device) because this could cause an allergic reaction
- An unstable cervical spine as seen on X-ray and determined by your doctor, because the SECURE®-C surgery involves removal of the disc without the use of a stabilizing plate (as is routinely done for fusion) and may cause further instability
- Advanced spinal arthritis (severe spondylosis) as determined by your doctor, as your disc may have begun to turn into bone, which could severely limit any motion that could be achieved
- Severe facet joint arthropathy (deterioration of the facet joint between each vertebrae) as determined by your doctor, which is not treated by replacement of the disc
- Weakened bones or spinal deformity (abnormal curvature) at the affected level due to current or past trauma or disease as determined by your doctor, which could increase the risk of device loosening
- More than one cervical disc requiring treatment, as the device has only been evaluated in patients with one cervical disc requiring treatment

What are the WARNINGS and PRECAUTIONS associated with the SECURE®-C device?

WARNINGS

There was a clinical study in the United States to evaluate patients treated with the SECURE®-C Cervical Artificial Disc. To participate in the clinical study, patients had to meet certain criteria. For example, patients could not be included in the study if they were taking medications known to interfere with bone healing (such as steroids), if they had a prior surgery at the level being treated, if they had a prior fusion surgery next to the level being treated, or if they were pregnant. *As a result, it is unknown if the device will perform as well in other types of patients compared to those included in the study.*

The device is placed close to major blood vessels (including arteries) and nerves that are located in the cervical spine. There is a risk of nerve damage and/or serious or fatal bleeding if these structures are damaged during or after surgery.

Heterotopic Ossification (HO) is a potential complication associated with cervical total disc replacement devices. HO occurs when bone forms around or across the disc space, which could result in reduced motion. The short-term postoperative use of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, may reduce the chance of developing HO, but this has not been proven.

PRECAUTIONS

Because the clinical study evaluated patients that met certain criteria, the safety and effectiveness of the SECURE®-C device has not been established in patients with the following conditions:

- Intractable radiculopathy or myelopathy due to disease at more than one level or disease outside of the disc space;
- Patients whose bones are still growing;
- Under the age of 21 or over the age of 60;
- Prior fusion at an adjacent level of the spine;
- Prior surgery at the level of the spine to be treated;
- Progressive symptoms and signs of spinal cord or nerve compression with less than six weeks of non-surgical treatment;

What are the WARNINGS and PRECAUTIONS associated with the SECURE®-C device? *(cont'd)*

- Disease or degeneration of the facet joint at the level of the spine to be treated;
- Neck or arm pain of unknown cause;
- Neck pain alone;
- Paget's disease (enlarged bones), osteomalacia (weakened bones), or other metabolic bone disease (chemical imbalance);
- Rheumatoid arthritis (chronic joint inflammation) or other autoimmune disease (abnormal body response to normal substances);
- Neuromuscular disorders such as muscular dystrophy (progressive loss of muscle), spinal muscular atrophy(decreased muscle), amyotrophic lateral sclerosis (Lou Gehrig's disease);
- Severe insulin dependent diabetes;
- Systemic disease including AIDS, HIV, and hepatitis;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids);
- Active malignancy (cancer), including spinal metastases (spreading of cancer);
- Acute mental illness or substance abuse; and
- Pregnancy.

It is extremely important that you let your doctor know about any medications you are taking, any allergies you have, if you are pregnant (or intend to become pregnant) or if you have any other illnesses or medical conditions that may help your doctor decide if this device is right for you. Failure to fully inform your doctor about your overall state of health and existing medical conditions may create unnecessary complications if you are treated with this device.

What are the potential RISKS and ADVERSE EFFECTS associated with the SECURE®-C Cervical Artificial Disc?

Complications may occur when you are treated with the SECURE®-C Cervical Artificial Disc, as with any surgery. Possible complications may include but are not limited to the following:

- Nerve damage
- Neck and/or arm pain
- Allergic reaction to the implant material
- Implant components bending, breaking, loosening or moving
- Instruments bending or breaking
- Infection of your surgical wound, disc, bone, or surrounding soft tissue
- Systemic infection
- Nerve or spinal cord injury, possibly resulting in paralysis or permanent impairment
- Painful or difficult swallowing, or hoarseness
- Impairment or change in speech
- Injury to your throat or windpipe, or blocking of your airway
- Trauma during surgery (excessive bleeding, fracture, spinal cord or nerve injury)
- Poor implant sizing or placement
- Development or progression of disease at other levels in your cervical spine
- Tingling, numbness or weakening of muscles in your extremities
- Change in the curvature of your neck or the height of your cervical disc(s)
- Loss of motion (unintentional fusion) at the treated level
- Bone growth in your disc space, also called heterotopic ossification
- Bone loss or thinning
- Dural tear (tear in the protective membrane around the spine)
- Leakage of spinal fluid
- Reactions to the anesthesia used in your surgery
- Hematoma (collection of clotted blood)
- Swelling
- Scarring of tissue in or around your surgical wound
- Complications of pregnancy, including miscarriage or fetal birth defects
- Injury or damage to the blood vessels, heart, lungs, stomach, intestines, bowels, bladder, or other organs, during surgery
- Changes in mental status
- Inability to resume activities of normal daily living
- Death

What are the potential RISKS and ADVERSE EFFECTS associated with the SECURE®-C Cervical Artificial Disc? *(cont'd)*

In addition to the risks listed on the previous page, 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 in order to help you feel better.

Throughout the course of the U.S. clinical study, patients reported health related problems to their physicians. Some of the events listed on the previous page occurred in the U.S. clinical study. For the patients in the U.S. clinical study treated with the SECURE®-C Cervical Artificial Disc (236 patients) or with ACDF (144 patients), some of the more common events were:

- Neck pain in 50 out of 236 SECURE®-C patients (21.2%), and 41 out of 144 ACDF patients (28.5%);
- Arm pain in 32 out of 236 SECURE®-C patients (13.6%), and 24 out of 144 ACDF patients (16.7%);
- Both neck and arm pain in 26 out of 236 SECURE®-C patients (11.0%), and 28 out of 144 ACDF patients (19.4%);
- Abnormal sensation in the arms (dysesthesia) in 20 out of 236 SECURE®-C patients (8.5%), and 15 out of 144 ACDF patients (10.4%);
- Pain in the back and/or legs in 36 out of 236 SECURE®-C patients (15.3%), and 23 out of 144 ACDF patients (16.0%);
- Other musculoskeletal adverse events (excluding events related to the spine) in 30 out of 236 SECURE®-C patients (12.7%), and 9 out of 144 ACDF patients (6.3%); and
- Difficulty swallowing in 6 out of 236 SECURE®-C patients (2.5%), and 8 out of 144 ACDF patients (5.6%).

What are the potential RISKS and ADVERSE EFFECTS associated with the SECURE®-C Cervical Artificial Disc? *(cont'd)*

Six patients (2.5%) treated with SECURE®-C, and 14 patients (9.7%) treated with ACDF, had additional surgery at the same level within 2 years after their surgery. Four patients (1.7%) treated with SECURE®-C, and 6 patients (4.2%) treated with ACDF, had surgery at an adjacent level within 2 years after surgery. **No mechanical failures of the SECURE®-C device were observed in any study patients.** There may be other risks associated with treatment using SECURE®-C.

Although many of the major risks are covered in this patient brochure, a comprehensive list is provided in the package insert for the device, which your doctor has received. Please ask your doctor for more information about any additional risks that could be related to your planned surgery.

SECURE®-C may help to restore normal everyday motion in some patients

What are the expected outcomes and benefits of the SECURE®-C Cervical Artificial Disc?

The surgery may relieve your symptoms of pain, weakness and/or numbness, and the SECURE®-C Cervical Artificial Disc is designed to allow motion at the treated level. In the U.S. clinical study, 236 patients were treated with SECURE®-C and 144 patients were treated with ACDF. Some of the study results at two years after surgery are described below. The clinical benefit beyond two years has not been measured. Ask your doctor for more details about the clinical study and its results.

Two years after surgery, the overall success rate for SECURE®-C patients in the clinical study using the original success criteria was 90.1%, compared to 71.1% for ACDF patients, which showed that SECURE®-C is statistically superior to ACDF. The overall success rate at two years using the FDA-defined success criteria was 83.8% for SECURE®-C patients, compared to 73.2% for ACDF patients, which also showed that SECURE®-C is statistically superior to ACDF. In the study, 89.2% of SECURE®-C patients demonstrated meaningful improvement in an outcome measure designed to evaluate patient function known as the NDI (Neck Disability Index), compared to 84.5% of ACDF patients, two years after surgery. In addition, 96.0% of SECURE®-C patients in the study had the same or improved neurologic status, compared to 94.9% of ACDF patients, two years after surgery.

Moreover, 96% of SECURE®-C patients in the study were satisfied with the results of their surgery two years after the procedure, compared to 85% of ACDF patients. Eighty-two percent of patients treated with the SECURE®-C had four or more degrees of motion in flexion-extension (bending the head forward and backward), and 67% had either the same or more motion in flexion-extension at two years as before they were treated.

The rates of complications were about the same when comparing the group treated with the SECURE®-C and the group treated with the standard of care, ACDF, in the first two years following surgery. The rate of subsequent surgery at the index level for SECURE®-C patients (2.5%) is statistically superier to the rate for ACDF patients (9.7%), in the first two years after surgery.

What can I expect before surgery?

Review your medical history with your doctor as well as your current condition and all possible options for treatment (including medications, physical therapy and other surgeries such as a fusion). Discuss any medications you are currently taking, including non-prescription drugs, herbal supplements, and vitamins, as well as any allergies you have. You may be asked by your doctor to discontinue the use of certain medications prior to your surgery. Typically you should not eat or drink the night before surgery, but your doctor will give you detailed instructions as to exactly what to do the night before surgery and during your recovery.

You will want to prepare your home life accordingly to ensure a comfortable atmosphere suitable for easy recovery. This includes things like removing safety hazards that may cause you to fall or lose your balance. Place important things within easy reach (phone, etc.) during your recovery. You will want to arrange for someone to help you at home after surgery. Your doctor will also discuss with you any potential risks and benefits of the procedure. *Ensure that you have read and that you understand this entire brochure.*

What can I expect during surgery?

The SECURE®-C Cervical Artificial Disc is implanted by removing your diseased disc and inserting the device. The SECURE®-C device is implanted through an anterior (front) surgical approach to your neck. General anesthesia will be administered and an incision will be made in the anterior (front) part of your neck so that the front of the spine will be exposed. The incision is usually about one inch long. Your diseased disc will be removed. The surgeon will prepare the space from which the disc has been removed, using trials to determine the best implant size for you, and will insert the SECURE®-C Cervical Artificial Disc in that size. The two device endplates are secured to the top and bottom surfaces of the involved vertebrae and the core fits between them. After insertion, your incision will be closed.

What can I expect after surgery?

Ask your doctor about your specific recovery plan. Surgery with the SECURE®-C Cervical Artificial Disc is considered major surgery. You can expect to remain in the hospital for approximately one day. Usually your heart and lung function will continue to be monitored immediately after surgery and there may be a drainage tube in your wound. As with any surgery, you should expect some discomfort and a period of rehabilitation. Your doctor will most likely prescribe medicine to control nausea or pain. After your surgery, it is important to ask your doctor about the proper way to recover. Remember that recovering from pain and surgery is a continuing process. **It is very important to closely follow your doctor's specific post-operative care instructions in order to recover quickly and for the best outcome possible.**

Contact your doctor immediately if you experience any of the following:

- Nausea or vomiting
- Difficulty swallowing or breathing
- Severe pain that does not go away when you take your pain medicine
- Fever
- Trouble urinating
- Loose stitches or an open surgical wound
- Red streaks or pus draining from your wound
- A rash

Your doctor may recommend or discuss the following with you:

- Proper wound care
- Medication to help manage any post-surgical pain
- A cervical collar to wear for a few weeks following surgery
- A therapy program for active range of motion exercises
- Avoiding lifting above the shoulders and repetitive bending
- Avoiding rough or strenuous athletic activities

Frequently asked questions after surgery

When can I drive?
There is a possibility that you will be restricted from driving for a period of time after surgery. If this is the case, your doctor will tell you when you may drive again.

Can I shower after surgery?
You should be able to quickly shower but you will have a bandage on your neck. Try not to soak the dressing while in the shower. Also you should not use a hot tub or take long baths until your doctor tells you its okay to do so.

Will there be a scar?
Typically it's a small incision that will heal with a scar that is not very noticeable. However, this will vary from person to person.

What about traveling with this device?
It is advised that you contact authorities at your local airport prior to traveling after this device has been implanted. This is due to increased security measures. Airport personnel should be able to provide you with guidance and information that will help you pass through security more easily and quickly. Be sure to ask your doctor to provide a patient identification card that will indicate you have a metallic device implanted in your neck.

How can I contact the manufacturer of the device for user assistance?
Globus Medical, Inc. is the manufacture of the device. Contact information is provided below:

Globus Medical, Inc.
2560 General Armistead Avenue
Audubon, PA 19403
1-866-456-2871
www.globusmedical.com

Summary

In order to make the most informed treatment decision for your care, please discuss any questions you may have with your doctor. While discussing the SECURE®-C Cervical Artificial Disc as a possible treatment option for your symptoms, be sure to discuss other possible surgical and non-surgical treatment options for your medical condition. Inform your doctor if you have an active infection, or an allergy to cobalt, chromium, molybdenum, or titanium (metals in the device), or polyethylene (plastic in the device). Also, please inform your doctor if you have been diagnosed with osteoporosis, osteopenia, or if you have any other health issues.

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LIMITED WARRANTY AND DISCLAIMER:
Globus Medical products are sold with a limited warranty to the original purchaser against defects in materials and workmanship. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the United States, this product has labeling limitations. Refer to the package insert for complete information.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training and experience.

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