

Simplify. Cervical Artificial Disc

PATIENT LABELING



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I. Glossary of Terms

Annulus Fibrosus - A tough, tire-like outer band of the spinal disc. It surrounds a gel-like center, the nucleus pulposus.

Anterior Cervical Discectomy and Fusion (ACDF) - A surgical procedure in the neck where the damaged disc is removed. This reduces spinal cord and nerve pressure. This can relieve pain, weakness, numbness, and tingling. After the disc is removed, the bones on either side of the disc space are joined together. This is called spinal fusion.

Artificial Disc - An implant designed to replace a damaged spinal disc. It may maintain normal disc height and preserve motion.

Biomechanical - Relating to the mechanics of the human body. This focuses on the forces from muscles and gravity on the skeleton.

Cervical Spine - The spinal bones in your neck.

Cervical Intervertebral Disc - A shock-absorbing pad located between each bone. It helps maintain spacing, stability, and motion within the neck.

Cervical Disc Degeneration - Changes that occur as a result of natural aging and that can become painful and limit motion or cause instability of the spine.

Decompression - A procedure involving the relief of pressure on the spinal cord and nerve roots that is commonly caused by disc degeneration or disc herniation.

Discectomy - The removal of part or all of the spinal disc.

Disc Herniation - Occurs when part of the gel-like center pushes through a hole in the outer part of the spinal disc.

Facet Joints - Small, paired joints on the back of the vertebrae that provide stability and motion.

Incision - A cut in the skin made during surgery to access the surgical site.

MRI - Magnetic Resonance Imaging is a non-invasive medical imaging procedure. It uses a magnetic field and pulses of radio waves to produce pictures of structures inside the body.

Nerve - A fiber or bundle of fibers that sends messages to and from the brain. Nerves control movement throughout the body. Nerves also control touch, pain, and numbness.

Nerve Root - The part of the nerve that passes from the spinal cord through an opening between bones of the spine.

Nucleus Pulposus - The soft, gel-like center of the spinal disc.

PEEK- This is a type of medical grade plastic formally described as polyether ether ketone.

Vertebrae - The bones that form the spinal column or backbone. A single spinal bone is called a vertebra.

II. The Cervical Spine

The Cervical Spine

The cervical spine begins at the base of the head. It is made up of seven small bones. These are called vertebrae. They form a column that protects your spinal cord and nerve roots. The spinal cord and nerve roots carry signals to and from the brain, shoulders, arms, chest, and legs.

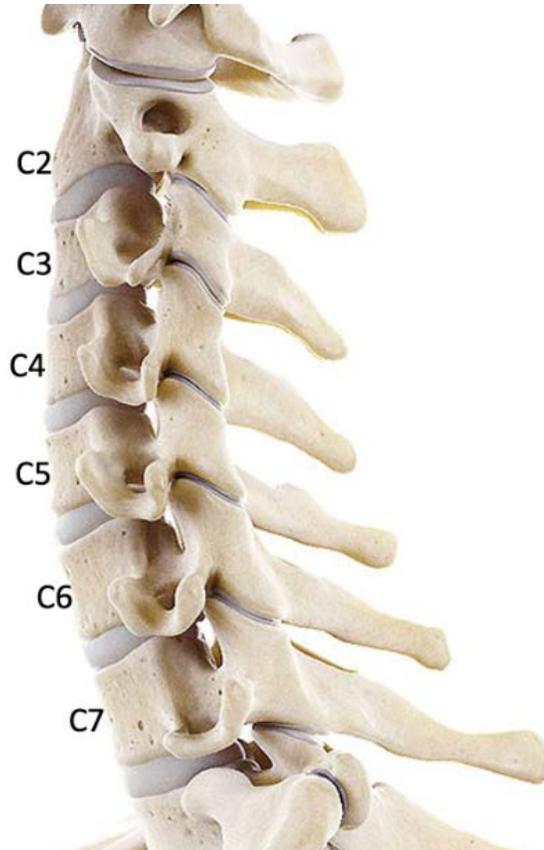


Figure 1: Cervical Spine

The Cervical Disc

The cervical disc is a pad located between each vertebra. This helps to absorb shock. Discs help keep spacing, stability, and motion in the spine. Each disc has a tough, tire-like outer band that surrounds a gel-like center. The center and outer band work together to absorb shock, stabilize the spine, and control motion between each vertebra.

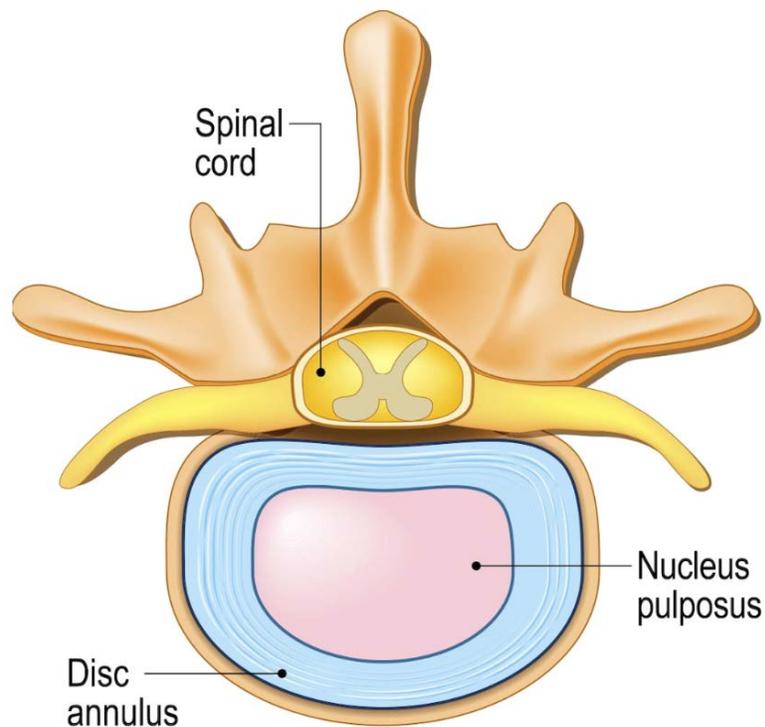


Figure 2: Cervical Disc Anatomy

III. What is Cervical Disc Degeneration?

As we age, the discs in our cervical spine begin to dry out, wear, and flatten. This brings the vertebrae closer together. This adds stress to the disc, nearby joints, muscles, and nerves. The decrease in disc height may lead to bony growths. These growths can push against your spinal cord and nerves. This process is known as cervical disc degeneration.

Disc Herniation

Disc herniation occurs when the outer layer of the disc tears or bursts due to stress. These tears can cause the gel-like center of the disc to bulge or eject out. This can put pressure on the nearby nerves or spinal cord.

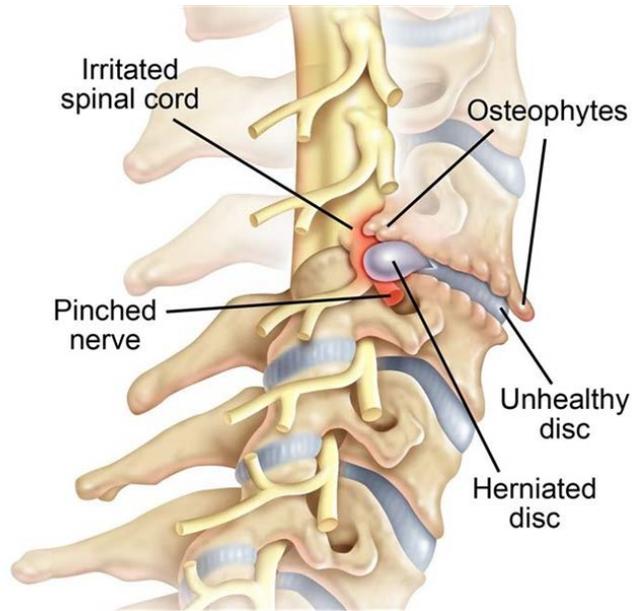


Figure 3: Cervical Disc Herniation

Bone Spurs

Bone spurs are small bony knobs that can form on vertebrae due to increased stress. These spurs often cause stiffness or pain in the neck. They may press against nearby nerves or the spinal cord. This can result in pain or weakness in certain parts of the body.

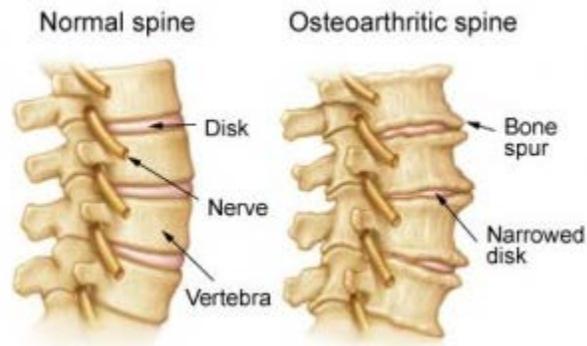


Figure 4: Normal Spine (Left) and Osteoarthritic Spine (Right)

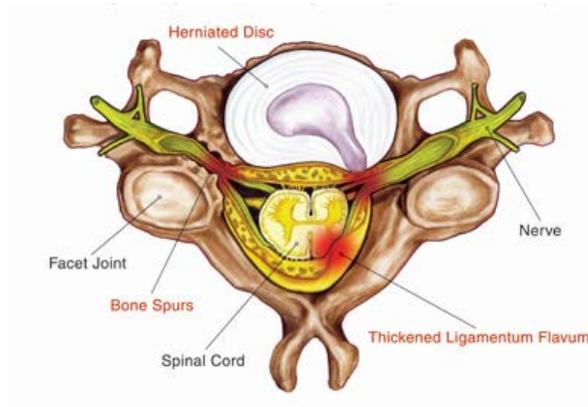


Figure 5: Spinal Nerve Compression-Bone Spurs with Herniated Disc

IV. Symptoms of Cervical Disc Degeneration

Many people experience cervical disc degeneration from aging. Few people experience severe symptoms. Usually, symptoms are mild. Symptoms include aches or stiffness in the neck and shoulder and occasional headaches. Disc herniation and bone spurs can pinch nerves, which can worsen symptoms. This can lead to painful conditions known as cervical radiculopathy and cervical myelopathy.

Cervical Radiculopathy is when pinched spinal nerves lead to pain, weakness, or numbness. This can be in the neck, shoulders, arms, and hands. Often, this feels like a shooting pain traveling down the arm.

Cervical Myelopathy is pressure on the spinal cord that can lead to problems with walking, neck pain, or hand control.

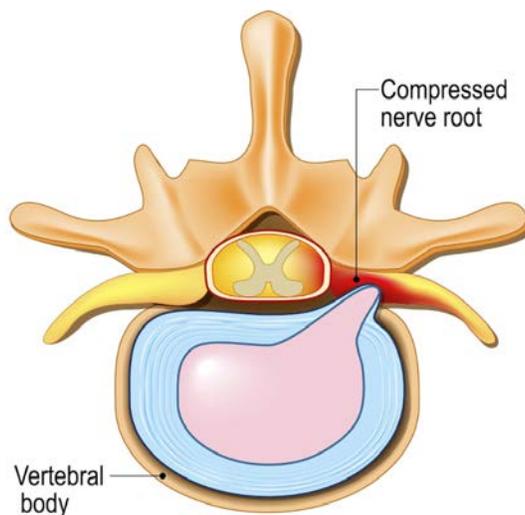


Figure 6: Herniated Disc with Radiculopathy

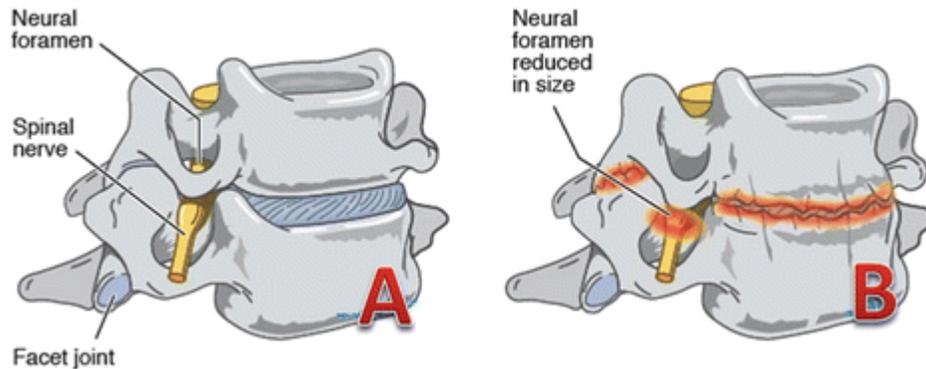


Figure 7: Normal (A) and Diseased (B) Cervical Spine Segments

V. Diagnosis and Treatment Options

Your doctor will take your health history and do a physical examination to understand your symptoms. From this, your doctor will determine if you have any nerve or spinal cord injury. This may be caused by cervical disc degeneration. Your posture, neck motion, reflexes, muscle strength, and locations of pain are all evaluated during the examination.

If degeneration is a possible cause of your symptoms, your doctor may order an x-ray or an MRI (magnetic resonance imaging). The MRI will evaluate your discs, nerves, and spinal cord.

For many patients, non-surgical treatments will provide relief. These treatments may include rest, physical therapy, and/or the use of pain relief medications. If pain or numbness keeps happening, surgical treatment options are considered.

Surgical treatment involves removing the free disc material and/or bone spurs. This is a procedure known as decompression. After decompression, a discectomy and fusion (ACDF-Anterior Cervical Discectomy and Fusion) or artificial disc replacement can be performed.

During ACDF, a spacer may be placed into the disc space. This restores your disc height. A metal plate may be used to prevent motion while fusion occurs.

For artificial disc replacement, the Simplify® Cervical Artificial Disc may be used if your symptoms are from 1 level in your neck. After the damaged disc is removed, the Simplify® Cervical Artificial Disc is placed into the disc space to restore height and preserve motion.



Figure 8: Simplify® Cervical Artificial Disc placed in the spine



Figure 9: Single Level ACDF in the Spine

Non-surgical and surgical treatments are designed to relieve your pain. Your doctor will determine the best treatment for you. It will be based on your condition.

VI. Artificial Disc Replacement Surgery

During an artificial disc replacement, your doctor will remove the damaged disc. Any disc or bony materials pushing against the spinal cord and nerves will also be removed. The disc space will be

filled with an implant called an artificial disc. This implant is designed to restore spacing between the vertebrae while preserving the motion of the spine.



Figure 10: Disc Sizing



Figure 11: Broaching

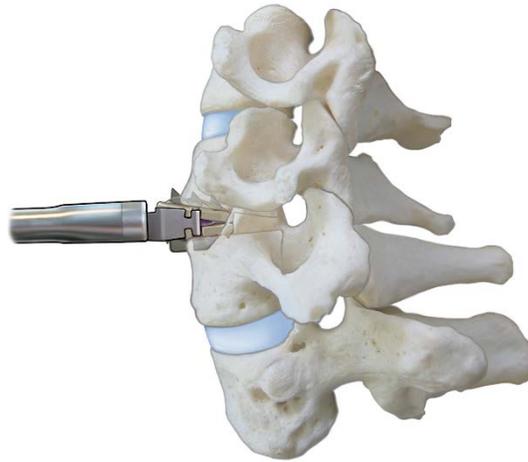


Figure 12: Disc Placement

VII. The Simplify® Cervical Artificial Disc

The Simplify® Cervical Artificial Disc is an artificial disc used for disc replacement. The disc is used in patients with cervical disc degeneration at one disc space. This degeneration may cause pain, numbness, or tingling.



Figure 13: The Simplify® Cervical Artificial Disc

The Simplify® Cervical Artificial Disc is made of two PEEK (plastic) endplates and a ceramic core. The endplates move along the core to provide motion. Each endplate is coated with rough titanium to help bone grow onto the plates. The coating helps to anchor the Simplify® Cervical Artificial Disc to the upper and lower vertebrae. The upper and lower endplates also feature teeth-like fins to fix the disc to the bone.

The implant is available in different sizes. The size will be decided by your doctor during surgery. The upper endplate has a ring that holds the endplate onto the core. This provides more reliability.

VIII. Am I a Candidate for Artificial Disc Replacement Surgery with the Simplify® Cervical Artificial Disc?

You will likely be treated non-surgically first. This often includes rest, physical therapy, and injections. If these treatments do not provide relief after 6 weeks, your doctor may suggest artificial disc replacement for you. If your symptoms get a lot worse before 6 weeks, your doctor may also suggest artificial disc replacement.

Please speak to your doctor to understand the benefits and risks of the Simplify® Cervical Artificial Disc. Your doctor will tell you if you are a candidate this procedure.

IX. Who Should Not Receive the Simplify® Cervical Artificial Disc (Contraindications)?

Simplify® Cervical Artificial Disc should not be used in patients with the following conditions:

- An active infection in your body or where surgery will take place.
- Degenerative disc symptoms that need surgery at more than one disc space.
- Osteoporosis/osteopenia defined as bone mineral density (DEXA) T-score less than -1.5.
- Known allergy to the implant materials. These include PEEK, ceramic, and titanium.
- Severe facet disease or facet degeneration.
- Bridging bone between the bones in your spine.
- The cervical spine is not stable enough as shown with X-rays.
- An unnatural shape (deformity) of the neck at the level where surgery will take place.
- Weak cervical bones at the level where surgery will take place. This can be from current or past trauma.
- Diseases that may affect your spine such as rheumatoid arthritis or ankylosing spondylitis.

X. What are the Warnings Associated with the Simplify® Cervical Artificial Disc?

The following warnings are associated with the Simplify® Cervical Artificial Disc:

- Simplify® Cervical Artificial Disc should only be used by doctors experienced with anterior cervical spinal surgery. The doctors should have hands-on training in the use of this device.
- Only doctors who are familiar with the Simplify® Cervical Artificial Disc parts and instruments should use this device. Doctors should be familiar with the procedure, applications, biomechanics, adverse events or complications, and risks.
- A lack of experience or training may lead to more chances of adverse events or complications. This could include neurological problems.
- Correct selection of the correct implant size and placement of Simplify® Cervical Artificial Disc is vital to make sure it works as expected. Information about correct implant size selection and placement is provided to your doctor.

- Removal of the implant may be needed during or after surgery. This could cause damage to your bones or nearby tissues. If an implant is removed during surgery, a new implant should be used in its place.
- Due to the closeness of vascular structures, neurological structures, and major organ systems to the implantation site, there are risks of serious or fatal bleeding. There are also risks of neurological damage or injury to nearby organs. Care must be taken to identify and protect these structures.
- There is a risk of extra bone growth with all artificial cervical disc implants. This could lead to less cervical motion or fusion at either the treated disc space or disc spaces that are next to your implant.

XI. What are the Precautions Associated with the Simplify® Cervical Artificial Disc?

Below is a list of precautions to be aware of as the safety and effectiveness of the Simplify® Cervical Artificial Disc has not been established in patients with the following conditions:

- Over the age of 60
- Previous spine surgery at the level currently requiring surgery (other than minimal extraction of part of vertebral bone with spine joints intact)
- More than one anterior neck surgery
- Only symptom is soreness of the neck muscles
- Very limited motion of the level requiring surgery
- Diseases which affect bone development or mineral levels
- Auto-immune diseases
- Insulin-dependent diabetes
- Current or extended use (greater than 6 months) of any drug that may interfere with bone or soft tissue healing

XII. What are the Risks of this Type of Surgery?

Complications may occur when you are treated with the Simplify® Cervical Artificial Disc. Potential complications can include, but may not be limited to, the following:

Risks Associated with Any Surgery:

General surgical risks are, but may not be limited to:

- Surgical wound healing complications. This includes infection near the surgical cut or in the blood.
- Lung problems including pneumonia, collapsed lung, and blood clots.
- A bad reaction to the drugs used to put you to sleep before surgery (anesthesia).
- Swelling of the vein at the site where fluids are given during and after surgery. This is usually on the lower arm.
- Continued bleeding after surgery. This may require another surgery or transmission of more blood (transfusion).
- Problems associated with the heart or blood movement. In rare instances, heart attack, stroke, or death can occur.

Risks Associated with Anterior Cervical Spine Surgery:

Anterior cervical surgical risks are, but may not be limited to:

- Injury or damage to the surgery site area. This includes the nerves, blood vessels, spinal cord, swallowing tubes, and skin.
- Hoarseness or problems with swallowing or talking.
- Partial paralysis or arm numbness, tingling, or weakness.
- Spinal cord damage or damage to the nerves at the back of the spine.
- Tear in the covering of the spinal cord with potential spinal fluid leakage.
- Bleeding and possible collection of blood or scarring on the covering of the spinal cord.
- Surgery at the wrong level.

Risks Associated with the Simplify® Cervical Artificial Disc:

Risks specific to cervical artificial discs, including the Simplify® Cervical Artificial Disc, are, but may not be limited to:

- Removal, revision, reoperation or additional fixation of the Simplify® Cervical Artificial Disc.
- Movement of the Simplify® Cervical Artificial Disc out of the disc space or into the bones.
- Device placement difficulties, including the wrong position or level.
- Development of poor stability at the surgery disc space or other cervical disc spaces.
- Additional surgery due to the Simplify® Cervical Artificial Disc loosening, breaking, or wearing.
- Fractures to the cervical bones in the spine.
- Loss of motion or spinal fusion at the treated disc space due to bone overgrowth.
- Development of pain at the surgery disc space.
- Allergic reaction to implanted materials.

This is not a full list of risks. There may be other risks with treatment using the Simplify® Cervical Artificial Disc. There is the possibility that this surgery may not be effective in relieving your symptoms. It is possible your symptoms could worsen.

If this happens, you may require additional surgery. You should discuss these risks and any concerns with your doctor before deciding to have artificial disc replacement surgery.

XIII. The Simplify® Cervical Artificial Disc U.S. Clinical Study

The Simplify® Cervical Artificial Disc was evaluated in a clinical trial conducted in the United States. It was studied for the safe and effective treatment of single-level degeneration of the cervical spine. Patients had degeneration that caused problems with nerve function due to pressure on the spinal cord and/or nerve roots.

The clinical trial involved 150 patients who received the Simplify® Cervical Artificial Disc. These patients were compared to 117 patients who received an anterior cervical discectomy and fusion (ACDF) procedure.

The ACDF procedure was done from the front of the neck. It involved removal of the disc followed by the stabilization of the disc space. This was done with a spacer and small metal plate. This plate served as a brace on the front of the bone to allow for the bone to grow together and fuse.

Patients in the Simplify® Cervical Artificial Disc study had to be between 18 and 60 years old. The patients had to be non-responsive to non-surgical treatments for at least six weeks. Patients also could have had neurological problems that had gotten a lot worse. A brief summary of some of the two year benefits and adverse effects from the Simplify® Cervical Artificial Disc clinical trial are presented below.

The clinical benefit of the Simplify® Cervical Artificial Disc beyond two years has not been measured. Please ask your doctor for more details about this clinical trial and the results.

XIV. What are the Expected Outcomes and Benefits of the Simplify® Cervical Artificial Disc?

For those patients that are candidates, the Simplify® Cervical Artificial Disc surgery offers another option of treatment. It may help stop the pain and other problems caused by a damaged cervical disc.

Artificial cervical disc replacement with the Simplify® Cervical Artificial Disc should relieve symptoms of spinal cord or nerve root compression resulting from cervical disc degeneration. Additionally, it may:

- Help movement of your neck in all directions.
- Minimize your neck and arm pain.
- Minimize tingling in your arms.
- Help you return to your normal activities of work, family, and recreation.

Below are the results from the Simplify® Cervical Artificial Disc clinical trial that followed patients two years after surgery. Please ask your doctor for more information if you have any questions related to this clinical study and its associated clinical results.

Two years after surgery, 93% Simplify® Cervical Artificial Disc patients achieved overall study success compared to 74% of ACDF patients.

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

- Through two years, 11% of the Simplify® Cervical Artificial Disc patients (16 out of 150 patients) experienced a serious adverse event compared to 14% of the patients (16 out of 117 patients) in the ACDF group.
- At two years, 98% of Simplify® Cervical Artificial Disc patients (135 out of 138 patients) demonstrated meaningful improvement in Neck Disability Index (NDI) as compared to 86% of ACDF patients (83 out of 96 patients). NDI is an outcome measurement designed to evaluate patient's neck function.
- A meaningful decrease in combined neck and arm pain was seen in 96% of Simplify® Cervical Artificial Disc patients (134 out of 139 patients), compared to 87% of ACDF patients (83 out of 95 patients).
- At two years, 134 Simplify® Cervical Artificial Disc patients and 95 ACDF patients were evaluated for neck range of motion (ROM) at the surgical disc space compared to their baseline motion. Motion was maintained for the Simplify® Cervical Artificial Disc patients (baseline average ROM was 7.29 degrees compared to 9.61 degrees at two years). ROM was reduced in the ACDF patients (baseline average ROM was 7.27 degrees compared to 0.72 degrees at two years).
- Prior to the study surgery, 42% (61 out of 147 patients) of the Simplify® Cervical Artificial Disc patients compared to 55% (64 out of 117 patients) of the ACDF patients were taking narcotics for treatment of their cervical spine condition. At two years, 11% (15 out of 139 patients) of the Simplify® Cervical Artificial Disc patients were taking narcotics compared to 37% (35 out of 95 patients) of the ACDF patients.
- Another surgery at the treated disc space was needed for 5 out of 117 ACDF patients (3%), compared to 4 out of 148 Simplify® Cervical Artificial Disc patients (3%).
- At two years, none of the Simplify® Cervical Artificial Disc patients experienced a device failure (0%) as compared to 7 out of the 90 ACDF patients (6.6%).
- At two years, 138 of the Simplify® Cervical Artificial Disc patients and 96 of the ACDF patients were asked if they would have surgery again. Of the Simplify® Cervical Artificial Disc patients, 90% (124 out of 138 patients) replied "Definitely Yes" as compared to 70% (67 out of 96 patients) ACDF patients.

XV. What are the Potential Adverse Effects of the Simplify® Cervical Artificial Disc?

During the Simplify® Cervical Artificial Disc clinical study, patients in the study experienced health-related problems that could be related to the surgical procedure, the patient's health, or the Simplify® Cervical Artificial Disc. Some of these problems were discussed earlier in the Risk of

Surgery section (*Section XII*). Listed below are adverse event rates from the U.S. study for the Simplify® Cervical Artificial Disc and ACDF patient groups.

Adverse Event Category	Simplify® Cervical Artificial Disc Group N=150	ACDF Patient Group N=117
Radiculopathy	19.3%	17.9%
Spasm	15.3%	4.3%
Inflammation	10%	10.3%
Pain (no narcotic given for pain)	9.3%	12.8%
Trauma (events related to a fall, car accident, etc.)	7.3%	6.0%
Pain (narcotic given for pain)	7.3%	17.9%
Adjacent Segment Degeneration (events related to progression of degeneration to the surrounding disc spaces)	6.7%	6.8%
Infection (not at the surgical site)	6.0%	4.3%
Dysphagia (difficulty swallowing) or dysphonia (difficulty speaking)	5.3%	2.6%
Numbness (increased numbness from before surgery or earlier follow-up visit)	4.7%	4.3%
Headache	4.0%	10.3%
Compressive Neuropathy (related to pressure on a nerve that results in pain, tingling, numbness, and weakness)	2.7%	7.7%
Cardiac Events (related to issues with heart function)	0.7%	0.9%
Pseudarthrosis (failure to fuse vertebrae)	0.7%	3.4%

A complete list of risks 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.**

XVI. How Do I Prepare for Surgery?

Please be sure to follow your doctor’s guidance as you prepare for surgery. Here is a list of topics that may be covered prior to the surgery:

- Review of your current condition and review of all possible treatment options.
- Evaluation of your overall health to ensure that it is safe for you to have surgery.
- Questions about the medicines that you are currently taking. Your doctor will decide if you should stop taking any of them prior to surgery.
- Instructions on not drinking or eating anything the night before surgery.
- Confirmation that you have someone to assist you at home after surgery
- Confirmation you can easily access important items you will need on a regular basis.
- The benefits of reading and understanding this entire information guide.
- Any additional questions you have about the risks and benefits of this surgery.

XVII. What Happens During a Simplify® Cervical Artificial Disc Surgery?

During the artificial cervical disc replacement surgery, you will be asleep under general anesthesia and a small opening will be made in the front of your neck to access your cervical spine. The degenerated disc will be removed and the affected nerve will be relieved of pressure. The Simplify® Cervical Artificial Disc will be inserted into the disc space using specialized instruments. After the Simplify® Cervical Artificial Disc is placed, the opening will be closed.

XVIII. What Happens After Simplify® Cervical Artificial Disc Surgery?

Ask your doctor to describe how you will feel after surgery and what will help you to recover. Removing your disc and replacing it with the Simplify® Cervical Artificial Disc is a major surgery. It is important to closely follow your doctor's instructions to recover quickly and to increase your chances of a successful result.

As with any major surgery, you should expect some discomfort and to go through a period of recovery. Patients are normally released from the hospital within one day. Listed below are some topics your doctor or other healthcare professionals may discuss with you after the surgery:

- Instructions on surgical wound care to be followed after leaving the hospital.
- Avoid repeated bending, twisting, and lifting.
- Use of oral medications to address pain or nausea.
- Possible recommendation that you wear a neck brace for limited period of time.
- Schedule follow-up office visits to monitor your progress.
- Guidance for gradually increasing limited activity at home.
- An exercise program under the direction of a physical therapist.

XIX. When Should I Call the Doctor After Surgery?

Some pain and discomfort after surgery is normal. The symptoms you had before surgery may not go away immediately. Talk to your doctor about when to call regarding problems after surgery.

If you have any of these problems at any time after surgery contact your doctor:

- You have a fever.
- The skin around the incision becomes red, swollen, or more painful.
- Excessive drainage or leaking from the incision.
- Trouble breathing, swallowing, or talking.
- Difficulty urinating.
- New or increased neck and/or arm pain, weakness, or numbness.

XX. Frequently Asked Questions

Will I Have a Large Scar?

The average incision is about one (1) inch long. When it heals, it is usually not noticeable.

What Happens if the Surgery is Not Effective?

If you experience new or increased neck or arm pain after surgery, it could be that the surgery was not effective. You may need additional surgery if your condition does not improve. Contact your doctor immediately if you experience neck or arm pain.

When Can I Shower After Surgery?

You will have to keep your surgical wound dry after surgery. Discuss with your doctor about when and how long you can shower after surgery.

Can I Receive an MRI After Surgery?

Yes. MRI machines can vary. You should consult your doctor regarding testing conditions.

When Can I Drive?

For a period of time after surgery, your doctor may recommend that you avoid certain activities. This can include driving. Talk to your doctor about activities that you may need to discontinue temporarily while you recover.

XXI. For More Information, Talk to Your Doctor

This guide is intended to provide you with useful information that will help you make an informed decision about your treatment options. However, it is not intended to replace medical advice from your doctor.

Your doctor is the only person qualified to diagnose and treat your spinal condition. If you have specific questions regarding the Simplify® Cervical Artificial Disc or its usefulness in your course of treatment, please contact your doctor.