

# Simplify<sup>TM</sup> Disc

Cervical  
Artificial Disc  
Patient  
Information

A photograph of a male doctor in a white lab coat and a female patient looking at a tablet together. The doctor is pointing at the screen while the patient looks on. The image is framed by a white curved border at the top and a green curved border at the bottom right.

# Contents

---

Glossary of spine terms.....	1
What should I know about my spine? .....	2
Simplify™ Disc .....	3
Why do I need surgery? .....	3
How is the Simplify Disc procedure different from fusion surgery? .....	4
Who is a candidate for Simplify™ Disc (indications)? .....	4
Who is NOT a candidate for Simplify™ Disc (contraindications)? .....	5
What warnings and precautions should I pay attention to? .....	6
Risks and potential complications (adverse effects) with this type of surgery.....	7
What can I expect before surgery? .....	11
What can I expect during surgery? .....	11
What happens after surgery?.....	11
What are expected outcomes of the surgery?.....	12
Frequently asked questions after surgery .....	12
Consideration of options .....	12

# Glossary of spine terms

---

**Axial Rotation:** Turning the head side to side.

**Bone Graft:** Bone taken from one area of your body to be used in another area. For example, bone graft used in fusion surgery may be taken from another part of your body such as your hip (autograft) or from a cadaver donor (allograft).

**Cervical:** Neck. Related to the neck.

**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.

**Degenerative Disc Disease (DDD):** Not a disease, but rather a catch all term used to describe degenerative changes in the intervertebral disc(s) due to aging and wear-and-tear, which result in chronic pain and restricted movement.

**Disc:** The intervertebral disc is a combination of strong connective tissues that hold one vertebra to the next, and acts as a cushion between each vertebra.

**Extension:** Bending the head backward.

**Flexion:** Bending the head forward.

**Fusion:** A surgical procedure in which bone graft is placed between two bones (for example, two vertebra in the spine) so that they grow together and then move as one unit rather than separately.

**Heterotopic Ossification:** Unintended bone formation around or across the disc space between the spinal vertebrae.

**Instability:** When vertebrae move beyond their normal range of motion. This can be the result of an injury, degenerative disease or congenital condition (something you are born with).

**Kyphosis:** Exaggerated forward rounding of the upper spine.

**Lateral Bending:** Bending the head side to side (ear to shoulder).

**Lordosis:** Exaggerated inward curving of the spine, usually in the lumbar region.

**Thoracic:** Mid-upper back, area between the cervical (neck region) and the lumbar (lower back) spine.

**Vertebrae:** Bones that make up the spine.

**X-Ray:** An image produced by the use of radiation waves, showing bone and other tissues in the body.

## What should I know about my spine?

---

Your spine supports your entire body, allowing you to bend and move freely. Your spine allows you to walk, run and jump while holding the rest of you upright. It is very important to keep your spine in good health.

The spine contains 24 small bones called vertebrae plus the base of your spine, which is made up of the sacrum and coccyx bone, often referred to as the 'tail bone'. These bones are stacked one on top of the other in a column, which forms the spine. Each vertebra is shaped like a flattened disc with a hole on one side of it. Running through this hole is the spinal cord. The spinal cord contains the nerves that carry signals from your brain to the rest of your body. The spine protects your spinal cord from injury.

The spine is divided into four regions. The top seven vertebrae make up the cervical (or neck) region. The middle twelve make up the thoracic region (or chest). The lower five vertebrae make up the lumbar region (lower back) the most commonly known location of back pain. Finally, the base of your spine is made up of the sacrum and tailbone.

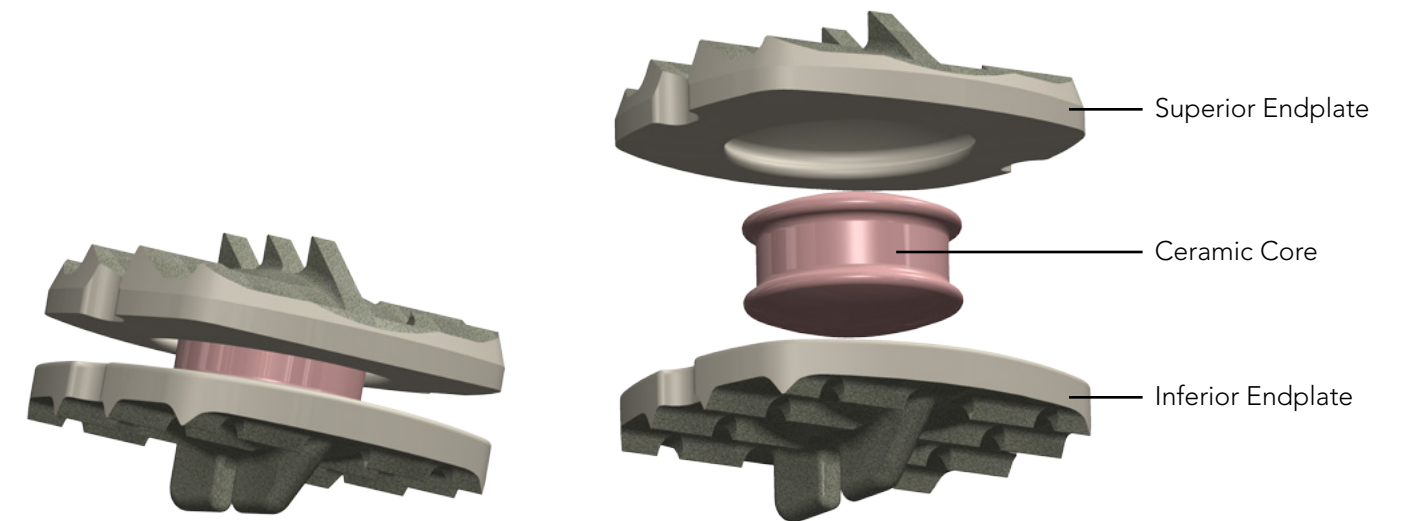
Separating the vertebral bones is a compressible cushion-like substance called the "disc". The disc prevents the bones from hitting each other and assists the spine in moving (flexing) through its various range of motions.

In healthy spines, the disc that separates each vertebra provides adequate cushioning for movement and mobility. A condition called Degenerative Disc Disease, or DDD, can occur, where the disc no longer functions normally because of wear and tear, or from being injured.

## Simplify™ Disc

---

Simplify™ Disc is designed to replace the unhealthy cervical disc and allow motion at the treated spinal level (segment) and help relieve pain. Simplify™ Disc is made of two PEEK (medical plastic) endplates and one mobile core made from surgical grade ceramic. The circular core is able to rotate but is held in place by a retaining ring of the upper endplate. It is this movement, which allows the artificial disc to rotate freely. There are also teeth on the superior endplate and ridges on both endplates that help secure them to the vertebral bone during the surgery and healing process.



Simplify™ Disc Assembled

Simplify™ Disc Components

## Why Do I Need Surgery?

---

Your surgeon has determined that the pain in your arms or neck is coming from the upper spine region and has diagnosed you with DDD. Your doctor may have used the terms C3, C4, C5, C6, or C7 to describe the bones in the cervical region. The "C" stands for Cervical and the number refers to the specific bone in that region. For example, a patient having fusion surgery at C4/C5 is having surgery on the bones at levels C4 and C5, and on the disc in between. Your surgeon will go through the specifics of your situation and help you better understand your condition.

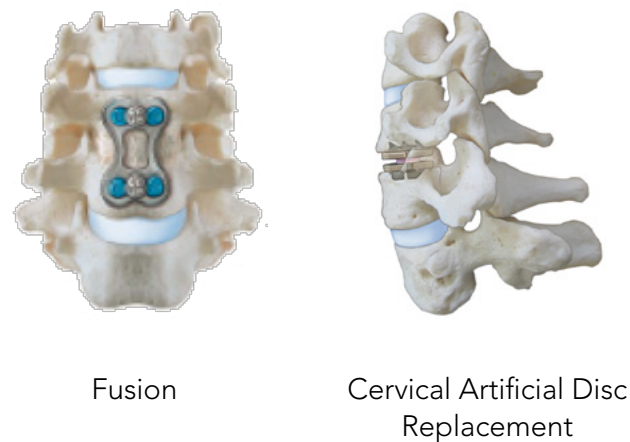
If you have been diagnosed with DDD and your pain has not improved after at least six weeks of conservative treatment or you have increasing symptoms, such as tingling or numbness or signs of a pinched nerve, then surgery is one option that may relieve your pain. One type of surgery is total disc replacement (TDR), and Simplify™ Disc is a type of cervical TDR.

## How is the Simplify™ Disc procedure different from fusion surgery?

---

Simplify™ Cervical Artificial Disc is an alternative to spinal fusion, which is the most common surgery performed for your condition. In spinal fusion surgery, the unhealthy disc is removed and replaced with bone graft material, locking in place the vertebral bones of the spine. After surgery, bone grows through the bone graft material to fuse and create one solid piece of bone. While fusion surgery may alleviate pain caused by DDD, the fusion procedure is designed to eliminate motion at that level of your spine. In addition, if your fusion procedure requires bone to be taken from your hip for the bone graft, there may be pain and increased healing time associated with the incision in your hip. Simplify™ Disc surgery does not require a bone graft.

In both spinal fusion and Simplify™ Disc procedures, the unhealthy disc is removed. In the Simplify™ Disc procedure, the surgeon inserts the device into the disc space after the disc is removed. A contrast material, which increases the visibility of the Simplify Disc, may be used if necessary. The device is inserted to restore the height of the spine, while potentially allowing for motion at the treated level. It is believed that maintaining motion may allow your spine to remain healthier longer, but this has not been proven.



## Who is a Candidate for Simplify™ Disc (indications)?

---

Only your doctor can decide whether you are a candidate to receive Simplify™ Disc. Simplify™ Disc should be used only in adult patients:

- Who have been diagnosed with DDD with pain from one unhealthy cervical level
- Who will have surgery at only one unhealthy cervical level
- Who have neck and/or arm pain that has not improved after at least six weeks of conservative treatment, increasing symptoms, or signs of a pinched nerve

Your doctor will determine if you are a candidate for Simplify™ Disc based on these and other criteria, and will confirm your need for surgery through diagnostic tests.

## Who is NOT a candidate for Simplify™ Disc (contraindications)?

---

The following conditions would exclude you from being a candidate for Simplify™ Disc:

- An active systemic infection or an infection at the operative site as this could impair the healing process or worsen the infection
- Known allergy to the implant materials (titanium, PEEK, ceramic) as sensitivity may cause an allergic reaction
- Osteoporosis/osteopenia (weak bone quality) defined as DEXA bone mineral density T-score worse than -1.5 as this may result in a bone fracture or cause the Simplify™ Disc to loosen
- Bridging osteophytes (advanced degenerative arthritis of the spine joint) as this impairs motion of the spine
- Cervical instability on X-rays showing too much relative motion between vertebral bodies or too much angulation of the disc space as instability may increase
- Severe facet disease or degeneration (spine joint wear and aging) as Simplify™ Disc is not indicated as a treatment for this condition
- Significant cervical anatomical deformity at the operative level or compromised cervical vertebral bodies (degenerative disease or due to current or past trauma as evident on X-rays) as Simplify™ Disc may loosen; or
- DDD symptoms necessitating surgical treatment at more than one cervical level as the Simplify™ Disc is only being implanted at one cervical level

## What warnings and precautions should I pay attention to?

---

Simplify™ Disc has not yet been approved for use in the U.S. by the FDA. The safety and effectiveness of this device has not been established. In the U.S. clinical study, Simplify™ Disc will be used only in patients that meet certain requirements. Only your doctor can decide if you are a good candidate for this procedure.

It is important to 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 your doctor needs to consider when deciding whether you are a good candidate for treatment with Simplify™ Disc. For example, patients cannot have significant cervical deformity at the operative level.

The Simplify™ Disc is placed close to nerves and blood vessels 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.

There is a possibility with artificial cervical discs that abnormal bone formation, known as heterotopic ossification, could develop around the disc which could reduce spine motion or result in fusion in that area of the spine.

This device should be used only by surgeons who are experienced with this procedure and trained on the Simplify™ Disc. A lack of adequate training and/or experience could lead to less successful outcomes or more complications.

## Risks and potential complications (adverse effects) with this type of surgery

---

As with any surgery, there are some possible complications that can occur when you have surgery with Simplify™ Disc. Complications can occur singly or in combination and may include:

### **Potential risks associated with general surgery include:**

- Adverse reaction or allergy to the anesthesia medications (difficulty with the drugs used to put you to sleep during the surgery)
- Heart and vascular complications
  - Cardiac event (e.g., heart attack)
  - Excessive bleeding or injury to blood vessels
  - Edema (swelling)
  - Hematoma or seroma (bleeding or bruising under the skin)
  - Hypotension or hypertension (decreased or increased blood pressure)
  - Ischemia (decreased blood flow)
  - Myocardial infarction (a heart attack from decreased blood flow to the heart)
  - Embolism including pulmonary embolism (a clot from blood or another source that travels and lodges in the lungs or elsewhere in the body)
  - Thrombosis (a blood clot)
  - Thromboembolism (a blood clot that breaks off from a thrombosis and travels to another part of the body)
  - Thrombophlebitis (a blood clot in a vein, usually in the leg)
  - Stroke (decreased blood flow to the brain)
- Wound complications
  - Infection of the surgical wound or surrounding soft tissues (e.g., abscess, cellulitis (skin infection))
  - Wound necrosis (death of tissue around the surgical wound)
  - Scarring of tissue around the surgical wound
  - Wound dehiscence (opening of the surgical wound)
- Gastrointestinal or urogenital complications (problems with the stomach and intestines or the urinary or genital systems)
  - Ileus (temporary interruption of bowel habits)
  - Nausea or vomiting
  - Difficulty with urination
  - Urinary tract infection
- Other
  - Pneumonia (lung infection)
  - Atelectasis (collapse of lung tissue)
  - Systemic infection (throughout the body)
  - Seizures or convulsions

*continued next page*

- Injury to nerves, muscles, or organs
- Pregnancy complications, including miscarriage or fetal birth defects
- Pain
- Psychological illness
- Inability to resume activities of normal daily living
- Death

**Potential risks associated with anterior cervical (neck) spine surgery include:**

- Risks to neurological structures
  - Dural injury (injury to the outer covering of the spine and brain) which may result in cerebrospinal fluid (fluid around the brain and spinal cord) leakage
  - Cerebrospinal fistula (abnormal opening between the brain and sinuses or the ear which may result in cerebrospinal fluid leakage)
  - Arachnoiditis (inflammation of the membrane surrounding the spinal cord)
  - Compressive neuropathy (symptoms due to a trapped or pinched nerve)
  - Neurologic deterioration - injury to nerves or nerve roots associated with the spinal cord resulting in:
    - Pain
    - Weakness
    - Paralysis
    - Altered reflexes
    - Numbness
    - Tingling
    - Other changes in sensation
  - Coordination abnormalities
  - Dysphasia (difficulty understanding language and speaking)
  - Gait disturbance (difficulty walking)
  - Headache
  - Otitis media (inflammation which may cause ear pain)
  - Tremors (involuntary movement of a body part)
  - Reflex Sympathetic Dystrophy (RSD) (symptoms including pain, swelling and/or increased sensitivity in the arms or legs)
- Risks to spine structures
  - Annular ossification (hardening of tissue around the bones of the spine)
  - Development of disc degeneration at treated level or adjacent levels (wear or bulging of a disc above or below the study treatment level)
  - Facet joint degeneration (wear of the facet joints which are small, paired joints located in the back part of your spine)
  - Infection of the disc, bone, or surrounding soft tissue
  - Inflammatory conditions, such as discitis (inflammation of the disc)
  - Loss of disc height or change in spine curvature
  - Scarring or soft tissue damage
  - Spinal instability (abnormal motion of the joints of the spine)
  - Spondylolisthesis (forward slippage of a bone in the spine)
  - Spinal stenosis (narrowing of the spinal canal)

*continued next page*

- Risks to structures of the neck
  - Airway obstruction (airway blockage preventing all or some air movement into and out of the lungs)
  - Dysphagia (difficulty swallowing),
  - Sore throat
  - Aspiration (the drawing of food or other foreign substances into the lungs during inhalation)
  - Dysphonia (difficulty speaking),
  - Hoarseness
  - Laryngeal palsy (paralysis of the nerve that controls the voice box),
  - Vocal cord paralysis
  - Esophageal perforation (injury to structures that connect the mouth and nasal cavities to the stomach)
  - Pharyngeal perforation (injury to structures that connect the mouth and nasal cavities to the stomach)
  - Tracheal perforation (windpipe injury)
  - Vessel damage and/or rupture (injury to blood vessels, including the vertebral arteries which carry blood from the heart to the brain and parts of the spine)
  - External chylorrhea (leakage of lymphatic fluids)
  - Fistula (abnormal opening or connection between tissues or organ)
  - Lymphadenopathy (enlargement of lymph nodes)

**Potential risks associated with cervical total disc replacement surgery (including with Simplify™ Disc):**

- Device Position and Condition
  - Breakage,
  - Disassembly (coming apart),
  - Loosening,
  - Malposition (incorrect placement),
  - Subsidence (collapse into the bone below)
  - Migration (movement)
  - Improper sizing of the device
- Anatomical difficulties during the surgery
- Adverse reaction or allergy to the device materials (PEEK, ceramic, titanium)
  - Autoimmune disease (an illness that occurs when body tissues are attacked by the immune system)
  - Metallosis (buildup of metal debris in soft tissues of the body)
  - Adverse tissue reaction (including soft tissue damage or death, inflammation or other cellular response)
  - Osteolysis (loss of bone mass) or vertebral inflammation related to wear debris (small particles of the device release into the tissue)
  - Tumor formation (development of a tumor from the body's response to the device materials)

*continued next page*

- Interference with radiographic imaging because of the presence of the device
- Adverse reaction or allergy to contrast media (a material that may be used during the implant of Simplify Disc™ to help with visualization)
- Device/joint noise
- Difficulties with surgical instruments
  - Improper positioning or placement of surgical instruments
  - Instrument damage or breakage
  - Improper cleaning of surgical instruments
  - Possibility that an instrument fragment may be left in the body
- The need for additional surgery at the treated spinal level or the level above or below the treated spinal level
- Vertebral fracture (breakage of a bone in the spine)
- The development of a new or recurrent spinal problem at the surgery level, or the development of a new spinal problem at the level above or below the treated spinal level
  - Pain
  - Neurological deterioration
  - Heterotopic ossification (abnormal bone growth around the device resulting in decreased spinal motion)
  - Spontaneous fusion (unintended fusion at the treated level or adjacent levels)

In addition to the listed risks, 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.

Although many of the significant risks are listed in this patient brochure, a more complete list is provided in the physician's package insert for the product, which your doctor has received. In particular, this patient brochure does not list many potential side effects that are less common. The physician's package insert also contains additional information regarding the risks that are listed in this patient brochure. It is important that you discuss with your physician any questions you have regarding risks possibly related to your planned surgery.

## What can I expect before surgery?

---

You should review the following with your doctor:

- Your overall health and your treatment options, including medications, physical therapy and other surgical options such as fusion, etc.
- Discuss what medications you are taking and whether you should stop taking any of them before surgery
- What you must do before and after surgery
- Ask your surgeon to tell you about the risks and benefits of this surgery

## What can I expect during surgery?

---

During the disc replacement surgery, you will be under general anesthesia. You will be lying on your back, and the surgeon will be making an incision into your neck in order to access your spine. The surgeon will remove the unhealthy disc and replace it with the Simplify™ Disc. A contrast material, which increases the visibility of the Simplify Disc, may be used if necessary.

## What happens after surgery?

---

It is very important that you follow your surgeon's instructions after surgery. Surgery with Simplify™ Disc is considered major surgery. As with any major surgery, you should expect to feel some discomfort and will have a period of rehabilitation. Your doctor will prescribe medication for any pain or nausea you may experience. You should expect to stay in the hospital for up to a few days. Prior to leaving the hospital, you will be given instructions on how to care for your incision, as well as how to plan for a return to normal activity. Follow your surgeon's instructions carefully, as he or she will recommend a gradual progression of activity level and that you avoid heavy lifting for 6 weeks and impact sports for 3 months. Your doctor may also refer you to a physical therapist for exercises to improve your strength and mobility while protecting your spine.

Contact your doctor immediately if you:

- Have a fever
- Have trouble swallowing or breathing
- Have fluid draining from your incision
- Have new or increased neck or arm pain, numbness, or weakness
- Have trouble breathing

## What are expected outcomes of the surgery?

---

The U.S. clinical study of Simplify™ Disc is being conducted to demonstrate the safety and effectiveness of the disc in helping to relieve pain and restore normal function. Outcomes will be based on reduction in pain, improvement in function, and lack of serious complications. Ask your doctor for more details about the clinical study and your expected results.

## Frequently asked questions after surgery

---

### **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 it is okay to do so.

### **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.

### **Will there be a scar?**

The surgeon will need to make a short incision in the front (anterior) part of your neck to access the disc space. The cut is usually made in the lines you already have in the skin on your neck, and the cut generally heals so that it is difficult to see.

### **Will Simplify™ Disc affect travel through airport security?**

Since the disc utilizes primarily non-metallic materials, it is very unlikely Simplify™ Disc will set off security detectors.

## Consideration of Options

---

You have been diagnosed with Degenerative Disc Disease, and your surgeon has recommended surgery to alleviate your symptoms. You should carefully consider whether to have spine surgery. If you decide to have spine surgery, you should discuss all options with your surgeon. Simplify Medical, Inc. has provided this brochure in an effort to inform you about one of your treatment options. However, this brochure is not a substitute for thoroughly discussing Simplify™ Disc and other treatment options with your surgeon. This brochure is intended to encourage you to have further discussions with your physician.

This patient brochure is not intended to provide medical advice with regard to a specific patient. Only your physician can provide medical advice after considering the unique clinical presentation and treatment needs of each patient.

For additional information, please visit our website at [www.simplifymedical.com](http://www.simplifymedical.com)

### **Limited Warranty and Disclaimer:**

*Simplify Medical, Inc., products are provided with a limited written warranty to the original purchaser that provides certain remedies in the event that a product contains any defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness for a particular purpose, are hereby disclaimed.*

### **Warning:**

Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training or experience. The prescribing physician (your surgeon) is provided with a copy of a package insert that contains more complete information regarding the warnings, precautions, contraindications, risks, and benefits of this product. This patient brochure is a brief summary of information and does not include a discussion of all pertinent warnings, precautions, contraindications, and risks. For this reason, this patient brochure should be used as a supplemental source of information that is intended to stimulate further discussion with your surgeon regarding the topics set forth in this patient brochure and should not be used as a substitute for discussing with your surgeon any questions you may have.

**Caution:** For investigational use only.





Simplify Medical, Inc.  
685 North Pastoria Avenue  
Sunnyvale, CA 94085  
t: 1.650.947.3472  
f: 1.650.947.3473  
info@simplifymedical.com  
www.simplifymedical.com

©2015 Simplify Medical, Inc. Simplify Medical,  
Simplify Disc and *Motion you can see* are trademarks  
of Simplify Medical.

32101-H