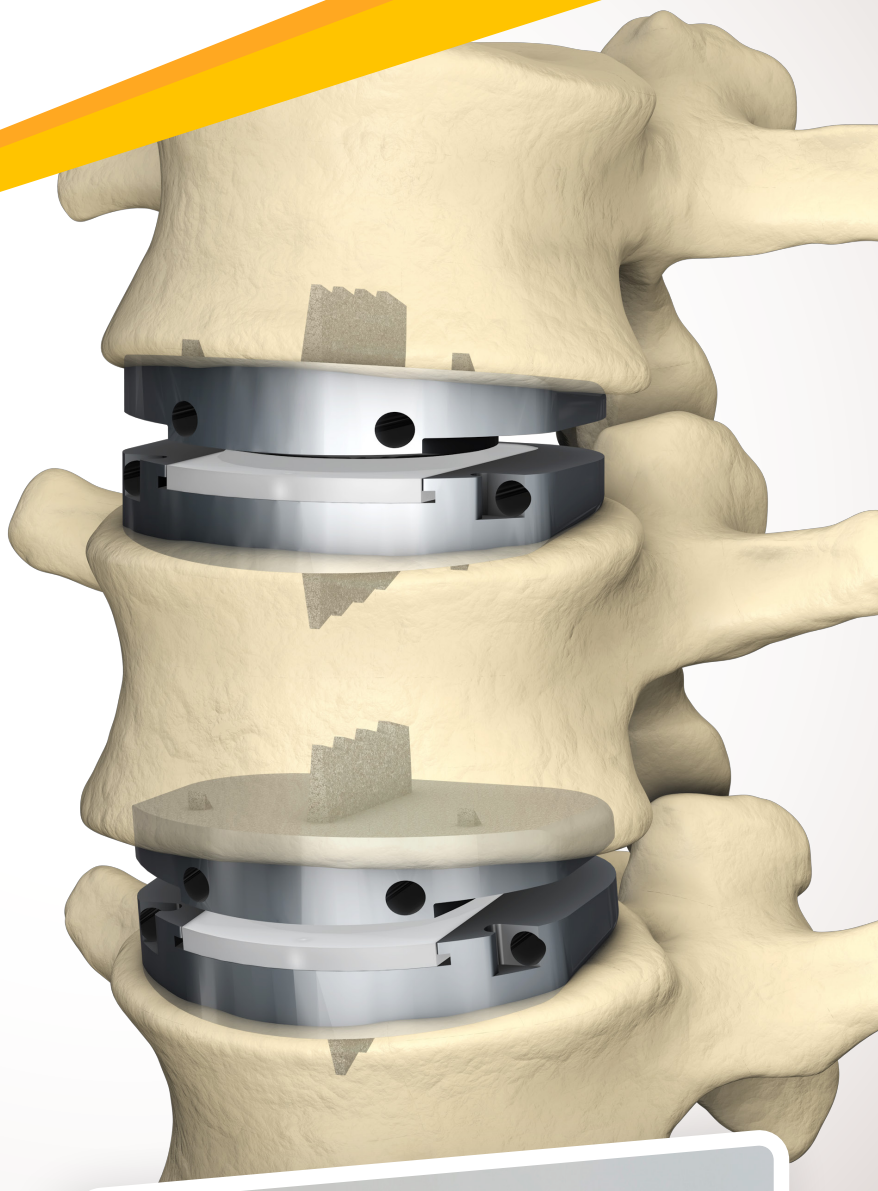
CENTINEL SPINE®

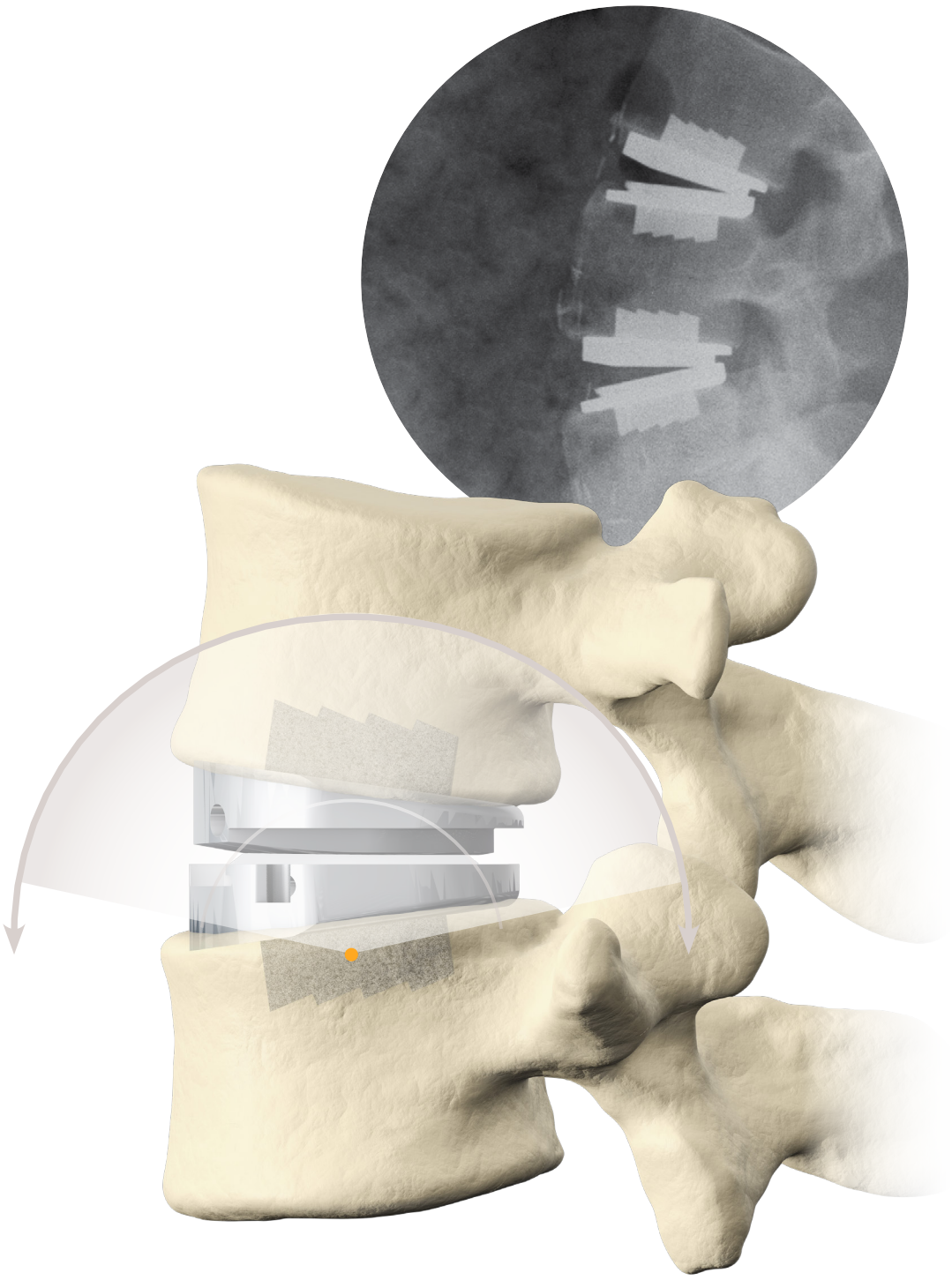
Patient Information Guide





prodisc® L

Total Disc Replacement



prodisc® L
Total Disc Replacement

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GLOSSARY

Anterior:	Front of the body.
Anterior Lumbar Interbody Fusion (ALIF):	A surgical procedure to remove and replace a degenerative disc in the lumbar (lower back) spine. During the procedure, an incision is made in the front of the body (abdomen) to access the anterior spine. The diseased disc is removed and an interbody device is implanted between the two vertebrae, supporting the spine while it heals forming a fusion.
Artificial Disc Replacement Device:	A medical implant designed to replace a worn out disc.
Bone Graft:	A transplant of bone taken from one area to another area.
Body Mass Index (BMI):	An estimation of an individual's body fat based on height and weight.
Cobalt chromium molybdenum alloy (CoCrMo):	A metallic material used in implants.
Computerized Tomography (CT):	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.
Degenerative Disc Disease (DDD):	DDD is a condition that can occur when the spinal discs no longer function normally because of aging, wear, or from being injured.
Disc:	The soft tissue found between the bones of the spinal column that helps cushion the spine.
Discectomy:	A surgical procedure in which the soft tissue (central) portion of a disc is removed.
Extension (In the lower back):	Bending backwards.
Facet Joint:	Joints that connect the vertebrae together in the back of the spine and slide against one another during motion.
Flexion (In the lower back):	Bending forwards.
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.
Incision	A surgical cut made in the skin.

Investigational Device Exemption (IDE):	Allows an investigational device to be used in a clinical study to collect safety and effectiveness data.
Lateral Bending (In the lower back):	Bending side to side.
Magnetic Resonance Imaging (MRI):	A radiographic (like an X-ray) procedure that uses magnets to create cross-sectional images (like slices) of the body.
Medical Device:	An instrument, apparatus, or implant designed to diagnose, prevent, or treat a disease or other condition. A medical implant is a medical device placed inside the body by means of surgery.
Osteoporosis:	A disease 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, and which may develop into osteoporosis.
Pars Defect:	The pars is a short section of bone within a vertebra. A pars defect is a fracture (break) of the pars.
Polyethylene:	A hard plastic material used in implants
Rehabilitation:	The process of recovery from surgery to a more normal condition.
Spinal Arthroplasty:	The reconstruction of a damaged or diseased disc. Also known as Total Disc Replacement.
Spinal Stenosis:	Narrowing inside the spinal canal, which mainly occurs from a combination of aging and degenerative changes in the spine.
Spondylolisthesis:	A vertebrae that has slipped on the vertebrae below. This usually occurs when a vertebra has a bony defect (spondylolysis) on both sides of the bony ring.
Spondylosis:	A degenerative condition in which the vertebral joints of the spine may stiffen or fuse.
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.

INTRODUCTION

After reviewing your history and x-rays, examining you, and taking into account the results of other diagnostic studies, your surgeon has decided that you need spine surgery. This patient information guide explains one of your treatment options (the prodisc L Total Disc Replacement device made by Centinel Spine). This guide may assist you in making an informed choice regarding the treatment of your back pain.

Your spine **(Figure 1)** is very important, it provides balance and allows you to move and bend. You would be unable to sit or stand without the support it provides to your body.

The spine is made up of twenty-four bones, called vertebrae. Each of these bones has a hole in it, similar to a donut. They are stacked one on top of the other, forming a column.

The spine is divided into four areas. The bones of your neck are called cervical vertebrae. The middle section of your back is the thoracic region. Your lower back is the lumbar area. The base of your spine is made up of the sacrum and coccyx bone, commonly called the tail bone.

The vertebrae are separated by cushioning discs. Passing through the hole in each vertebra is the spinal cord. The spinal cord contains nerves that carry signals from your brain to the rest of your body. Your spine protects your spinal cord from injury

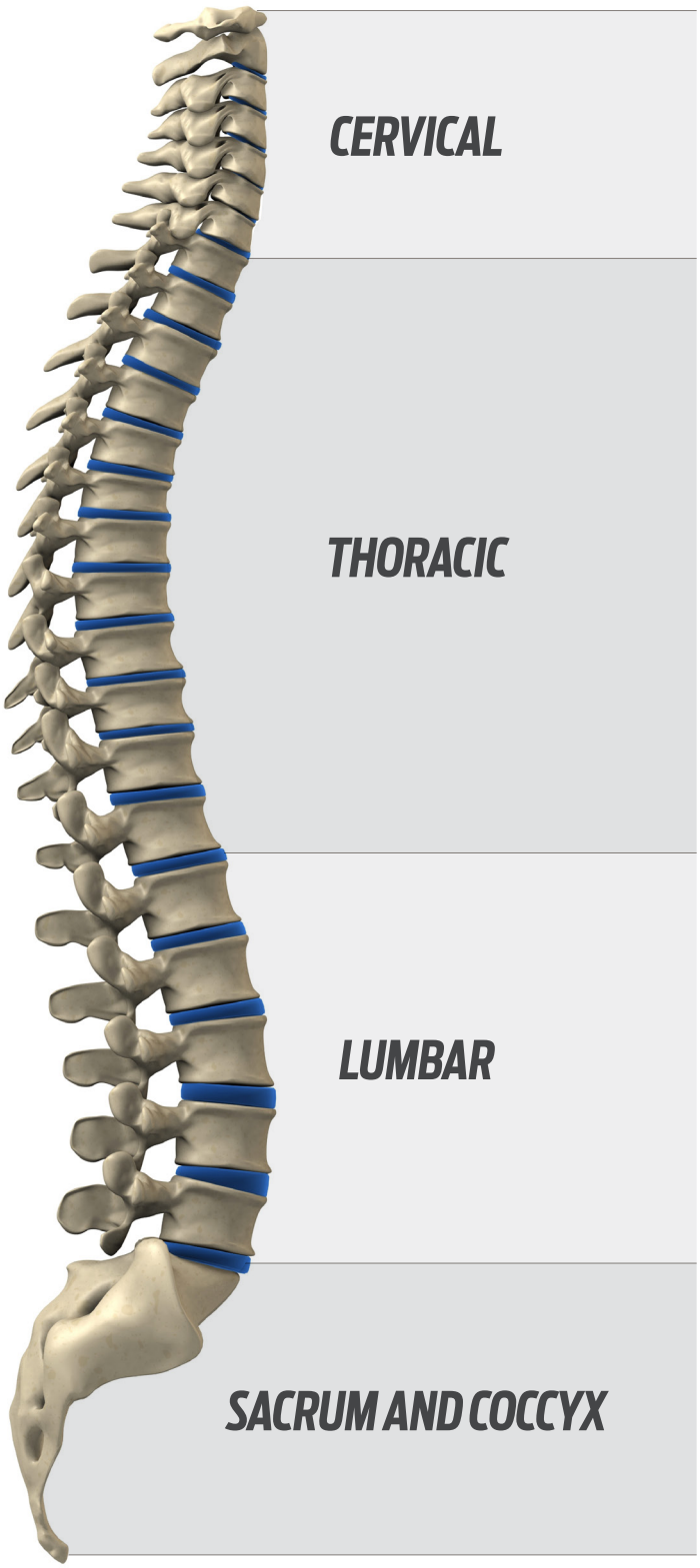


Figure 1: The Spinal Column

What Is Degenerative Disc Disease?

Normally, the disc sandwiched between each vertebra provides the cushioning space that keeps the bones separated. Degenerative Disc Disease, or DDD, is a condition that can occur when the discs in your spine no longer function normally because of aging, wear, or from being injured. This can cause pain that limits your ability to perform daily activities. This condition can often be treated non-surgically with medications, physical therapy, spinal injections, chiropractic care, braces, exercise programs, or rest.

However, in some cases, the symptoms may not improve or may get worse, and then your doctor may suggest surgery. The traditional surgery for DDD has been spinal fusion surgery. In spinal fusion surgery, the symptomatic disc is removed, the bones are held in position with medical devices, and a bone graft is placed in the area. In most cases, the bone for the graft is obtained from the patient's hip bone through a separate incision. After surgery, bone is supposed to grow between the two vertebrae, creating one solid piece of bone. If you have fusion surgery, it may take your pain away, but you may have less motion in your back.

Another option your doctor may consider is surgery with an artificial disc replacement device. The prodisc L Total Disc Replacement is a type of artificial disc replacement device.

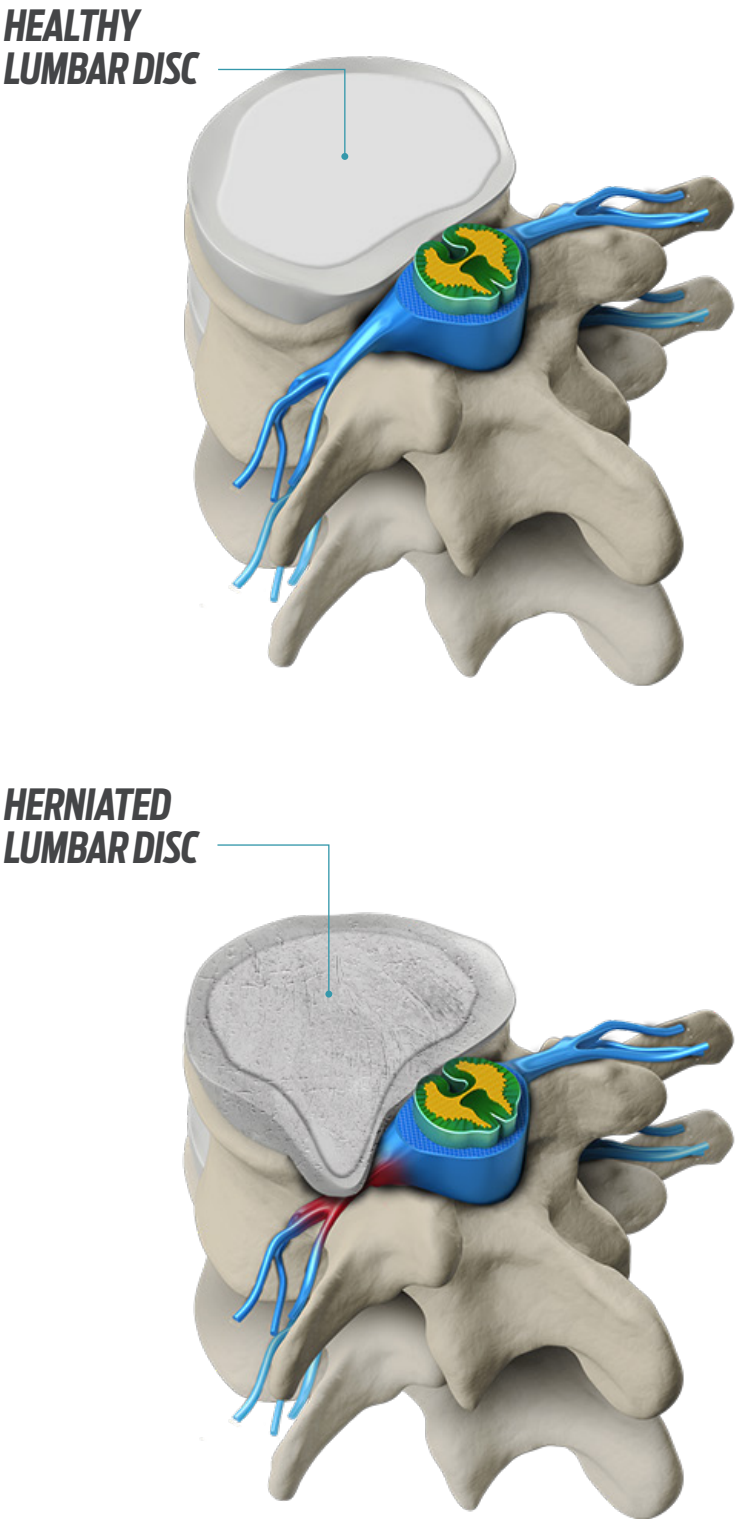


Figure 2: Healthy Disc vs. Damaged Disc

What is the prodisc L Total Disc Replacement?

The prodisc L Total Disc Replacement device is an artificial disc replacement implant for the lower spine designed to replace your symptomatic disc.

All of the materials used to make the prodisc L Total Disc Replacement device are materials frequently used in spine surgery. The prodisc L Total Disc Replacement device is a ball and socket implant consisting of two Cobalt Chromium Molybdenum alloy (metal) endplates and a polyethylene (plastic) inlay. The polyethylene inlay snap-locks into the lower endplate and provides the ball that rides in the socket of the upper endplate **(Figures 4 and 5)**.

Expected Device Lifetime: prodisc L has been tested for a 10-year life span, in actual clinical use, it has been shown to have a 1% reoperation rate.[1] The decision for a potential removal will be based upon your physician's assessment, which can vary from patient to patient.

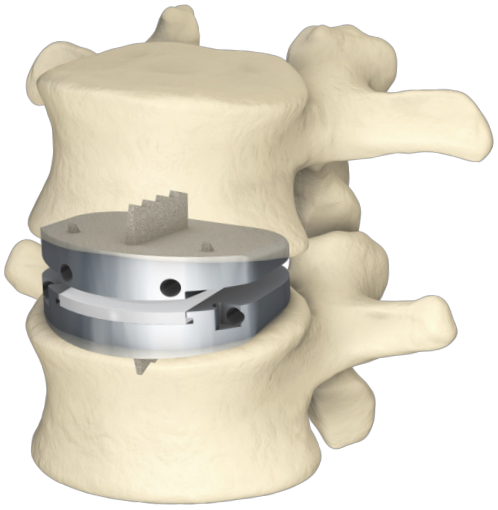


Figure 3: prodisc L Total Disc Replacement Device Placed In-Between Two Lumbar Vertebrae

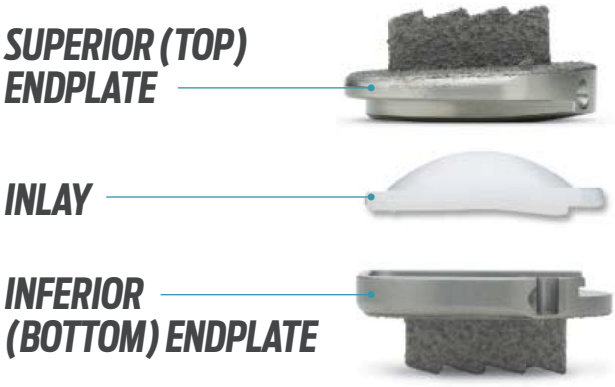


Figure 4: prodisc L Implant



Figure 5: Ball and Socket

There are also keels (fins) on both endplates that are designed to help fixate it in the vertebral bone **(Figure 6)**. The metal surfaces that are in contact with the bone are also coated with a highly porous titanium layer (a metal). This coating is designed to help the bone attach to the metal endplates.

The prodisc L Total Disc Replacement device is designed to allow motion in flexion and extension (bending forward and backward, **Figure 8**) as well as lateral bending (bending side to side, **Figure 7**); however, not all patients will achieve motion after treatment with the prodisc L Total Disc Replacement device.

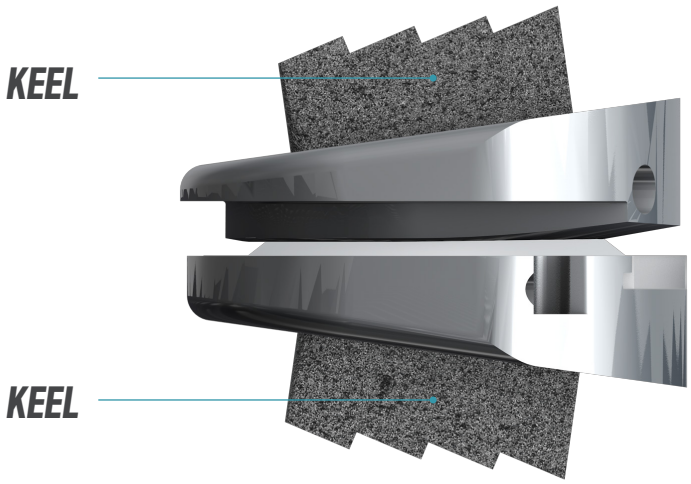


Figure 6: Assembled Version with Keels

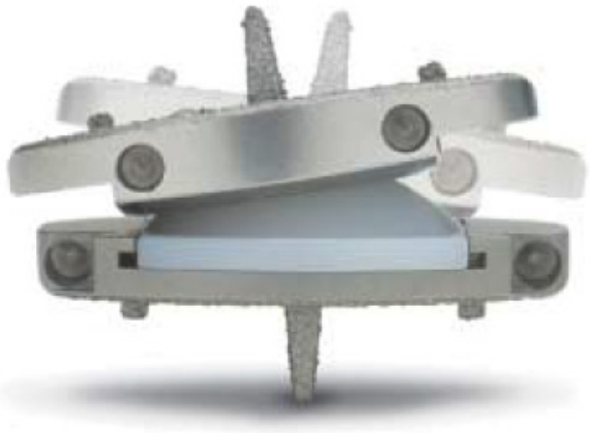


Figure 7: Illustrated Lateral Bending Motion of prodisc L Total Disc Replacement Device



Figure 8: Illustrated Flexion/Extension Motion of prodisc L Total Disc Replacement Device

Who Should Receive a prodisc L Total Disc Replacement Device (Indications)?

Your doctor has diagnosed that the pain in your lower back is coming from the bottom of the lumbar area and, possibly, the top of the sacrum. You may hear your doctor refer to the involved lumbar areas as L3, L4, and L5 and the sacrum as S1 **(Figure 9)**.

Your doctor may recommend the prodisc L Total Disc Replacement device because it is designed to allow some motion in the disc space. The prodisc L Total Disc Replacement surgery does not require bone graft. This means that you would not need to have bone taken from your hip.

You should discuss the options available to you with your doctor. Only your doctor can decide whether you are a candidate for the prodisc L Total Disc Replacement device. In order to be a candidate, you must meet the following requirements:

- Have a diagnosis of degenerative disc disease (DDD) at only one or two levels between L3 and S1.
- Have had at least six months of non-surgical treatment without relief of your symptoms (e.g., medications, physical therapy, etc.).
- Have specific findings on imaging studies such as X-ray, CT, or MRI.
- Be old enough so that your bones are mature and are no longer growing.

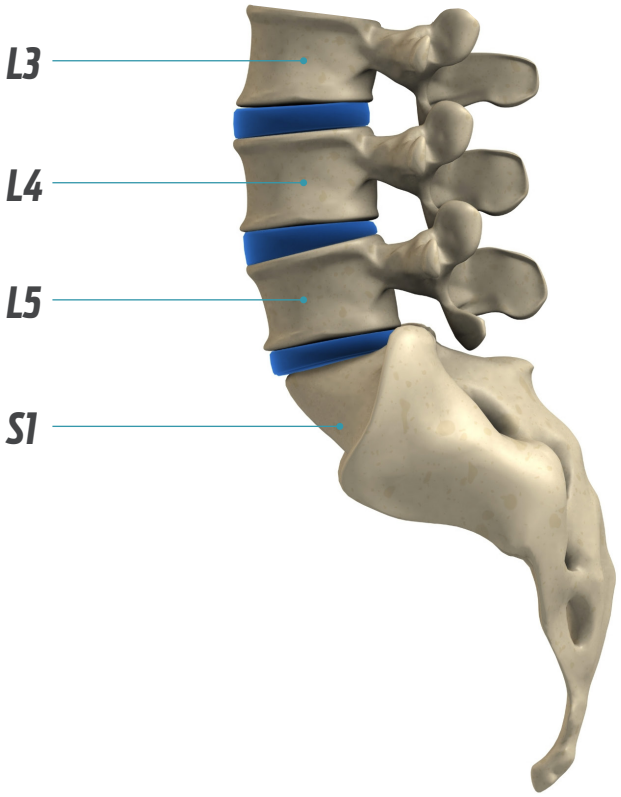


Figure 9: Levels of the Lower Spine



Who Should Not Receive a prodisc L Total Disc Replacement Device (Contraindications)?

You should not have surgery with the prodisc L Total Disc Replacement device if you have any of the following conditions:

- Active whole body (systemic) infection or an infection at the surgery site, such as a skin rash or infected cut because undergoing surgery could interfere with your ability to heal and could increase the chance of spreading or worsening the infection.
- Osteopenia or osteoporosis. These conditions could increase the risk of your bone breaking or could cause your implant to loosen.
- Narrowing inside your spinal canal (spinal stenosis) because you may still have pain when moving even after surgery.
- Known allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium, and tantalum). Talk to your doctor if you have a metal allergy because use of the prodisc L Total Disc Replacement device could cause an allergic reaction.
- Low back and/or leg pain caused by single nerve root compression ("pinched nerve"), because your pain may be treated with a different surgical procedure.
- A fracture (break) in a specific location within your vertebrae (referred to as a pars defect) which could cause instability within your spine.
- Vertebral bodies smaller than the smallest implant size available. Correct sizing of the implant is necessary for the device to function.
- Damaged lumbar vertebral bodies at the affected levels. This may lead to poor performance of the device.
- Too much forward slippage of your upper vertebral body with respect to your lower vertebral body (spondylolisthesis) as determined by your doctor which could cause instability in your spine.

What are the Warnings for prodisc L Total Disc Replacement?

Correct placement of the device is very important for the device to work properly. Use of the prodisc L Total Disc Replacement device should only be undertaken by experienced surgeons who have had hands-on training in the use of this specific device. A lack of experience may lead to a higher number of complications.



***NOTE:** For more information about sensitivities to metals, please scan the QR code or visit:

SCAN TO LEARN MORE

https://www.centinelspine.com/dropbox/prodisc_reprocessing/CENT_MaterialCompositionofCentinelSpineMotionPreservationDevices_LBL081.pdf

What are the Precautions for prodisc L Total Disc Replacement?

There was a clinical study in the United States to evaluate patients treated with the prodisc L Total Disc Replacement device.

Because the clinical study of the prodisc L Total Disc Replacement device only evaluated patients who met certain criteria, the safety and effectiveness of the prodisc L Total Disc Replacement device has not been tested in patients with the following conditions:

- More than two consecutive vertebral levels with DDD or levels outside L3-S1.
- Prior fusion surgery at any vertebral level.
- Facet joint disease or degeneration.
- Back or leg pain of unknown cause.
- Diseases of the bone caused by low mineral levels or genetic problems (Paget's disease, osteomalacia, or other metabolic bone diseases).
- Very overweight (BMI greater than 40 or weight more than 100 lbs. over ideal body weight).
- Pregnancy.
- Taking medications (such as steroids) which are known to get in the way of bone or soft tissue healing.
- Diseases that cause the vertebrae to swell or grow together and limit movement, such as rheumatoid arthritis or other autoimmune diseases.
- Whole body (systemic) disease including AIDS, HIV, and hepatitis.
- Active malignancy (cancer).

Your occupation, activity level, weight, overall health, the condition of other levels of your spine, whether or not you are pregnant, and any allergies you have may influence whether or not you should have the prodisc L Total Disc Replacement surgery. Please inform your doctor if any of these factors apply to you or if you think you have any special health issues.

This device is placed close to major blood vessels and nerves. There is a risk of nerve damage and/or serious or fatal bleeding if these structures are damaged during surgery.

It is very important that you carefully follow your doctor's instructions after surgery. Extreme activities like lifting very heavy weights may result in failure of the device.

During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that your physician keeps you well informed.

Under no circumstances may implant components from different suppliers be combined.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or surgical techniques, the limitations of treatment methods, or inadequate asepsis.



What are the Potential Risks and Adverse Effects of Having This Procedure?

As with any surgery, there are possible complications that can occur. Although many of the major risks are covered in this patient information, 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 which your doctor has access to via the Centinel Spine website at www.centinelspine.com.

Risks associated with any surgical procedure:

- Allergic reaction to anesthesia.
- Infection (wound, local and/or systemic) or abscess (a localized collection of pus surrounded by inflamed tissue).
- Problems with the wound including wound dehiscence (opening of the wound along the surgical suture line) or wound necrosis (dead tissue within the wound).
- Edema (abnormal excess accumulation of fluid in soft tissues).
- Heart and vascular (relating to the blood vessels) complications including bleeding, ischemia (a deficient supply of blood to a body part), abnormal blood pressure, hematoma (collection of clotted blood in tissue as a result of a broken blood vessel), thrombosis (formation of a blood clot within a blood vessel), and embolism (sudden obstruction of a blood vessel by a clot or abnormal particle circulating in the blood).
- Pulmonary (relating to the lungs) complications.
- Gastrointestinal complications including ileus (blockage of the intestines).
- Genitourinary (relating to the genital or urinary organs) complications.
- Neurological complications including nerve damage, paralysis (loss of movement), seizures, changes to mental status, and reflex sympathetic dystrophy (a painful disorder marked by burning pain, swelling, and motor and sensory disturbances especially of an extremity).
- Complications of pregnancy including miscarriage and congenital defects.
- Inability to resume activities of daily living.
- Death.

Risk specifically associated with lumbar spinal surgery:

- Injury to surrounding organs and structures including the spinal cord, nerves, lymphatic vessels (thin walled structures that carry lymph), soft tissue, dura (membrane that surrounds the spinal cord), intestines, kidneys, and ureters.
- Neurological difficulties, including trouble with bowel and/or bladder function, impotence or other issues with sexual function, muscle weakness or paralysis, paresthesias (a sensation of tingling, tickling, prickling, pricking, or burning of the skin) or other changes in sensation, or pain.
- Broken vertebrae (bones that make up the spinal column).
- Hematoma (collection of clotted blood in tissue as a result of a broken blood vessel) in the epidural space (the space inside the spinal canal but just outside of the dura) or the retroperitoneal space (the space between the space where the abdominal organs are located and the back abdominal wall).
- Scarring, adhesions, or swelling including in the peritoneum (the membrane that lines the abdominal cavity).
- Hernia (the bulge of an organ through the structure or muscle that usually contains it).

Risks associated with a total disc replacement device (including the prodisc L Total Disc Replacement:

- An issue with the device including poor positioning of the device, movement of the device out of place, sinking of the device into the adjacent bone resulting in loss of disc height, device breakage, device disassembly (coming apart), or early or late loosening of the device. Any of these issues may cause pain or injury to surrounding organs and structures including nerve or spinal cord compression or damage (which could cause paralysis) or damage to blood vessels (which could cause a lot of bleeding).
- The need for additional surgery which could include removal of the prodisc L Total Disc Replacement device.
- Deterioration (worsening) in neurologic status.
- Failure of the device to improve symptoms and function.
- Problems during placement of the device including trouble sizing the device or issues with the device instruments including the possibility that part of an instrument may remain in your body.
- Reaction of your body to wear debris from the device (particles of either plastic or metal that come off the device) or the entire device which may lead to loosening of the device, tumor formation, autoimmune disease, metallosis (an inflammatory reaction that can occur around metal implants), scarring, or other symptoms.
- A change in the alignment or curvature of your spine including spondylolisthesis (movement of one vertebra compared to the vertebra below it), a change in lordosis (change in the normal curvature of the spine), or instability of the spine.
- Degeneration of other parts of your spine including the facet joints (joints that connect the vertebrae together in the back of the spine) or adjacent discs.
- Spinal stenosis (narrowing of the spinal canal causing symptoms)
- Loss of bone or formation of extra bone including the potential for unintended fusion at either the treated level or another level.

In addition to the risks listed, 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.

The prodisc L Total Disc Replacement U.S. Clinical Studies

The prodisc L Total Disc Replacement device was evaluated in United States clinical trials for the safe and effective treatment of single-level and two-level degeneration of the lumbar spine that causes problems with nerve function due to pressure on the spinal cord and/or nerve roots. The one-level clinical trial involved a total of 162 patients who received the prodisc L Total Disc Replacement device compared to 80 who received a lumbar fusion procedure. The two-level clinical trial involved a total of 161 patients who received the prodisc L Total Disc Replacement device compared to 68 who received a lumbar fusion procedure. In lumbar fusion surgery, the symptomatic disc is removed, the bones are fixed in position with implants, and bone graft is placed in the area. In most cases, the bone for the graft is obtained from the patient's hip bone through a separate incision.

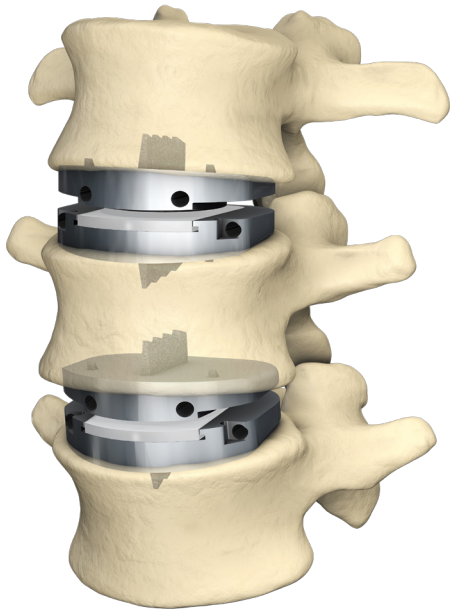
In both studies, patients participating in the prodisc L Total Disc Replacement study had to be between 18 and 60 years old and not responsive to non-surgical treatments, such as physical therapy, for at least six months. A summary of the 60-month benefits and adverse effects from the prodisc L Total Disc Replacement clinical trial have been published.[2] The clinical benefit of the prodisc L Total Disc Replacement beyond five years was not evaluated in the clinical studies.

What are the Results from the prodisc L Total Disc Replacement Studies?

In a U.S. clinical study of 162 patients that received one-level prodisc L, 1 (0.6%) was revised by the time of the five-year followup visit[3], and in a separate study of 161 patients that received two-level surgery with prodisc L, 5 (3%) had another surgery on the index level by the five-year followup[2].

What is the Expected Lifetime?

prodisc L has been tested for a 10-year life span. In actual clinical use, it has been shown to have a less than 1% reoperation rate.[1] The decision for a potential removal will be based upon your physician's assessment, which can vary from patient to patient.





What are the Potential Benefits of prodisc L Total Disc Replacement?

In the U.S. clinical studies, the potential benefits of the prodisc L Total Disc Replacement device were also evaluated through five years post-surgery. Some of the study results are described above and in the Summary of Safety and Effectiveness Data available on the US FDA website.[2,3] Ask your doctor for more details about the clinical study and its results.

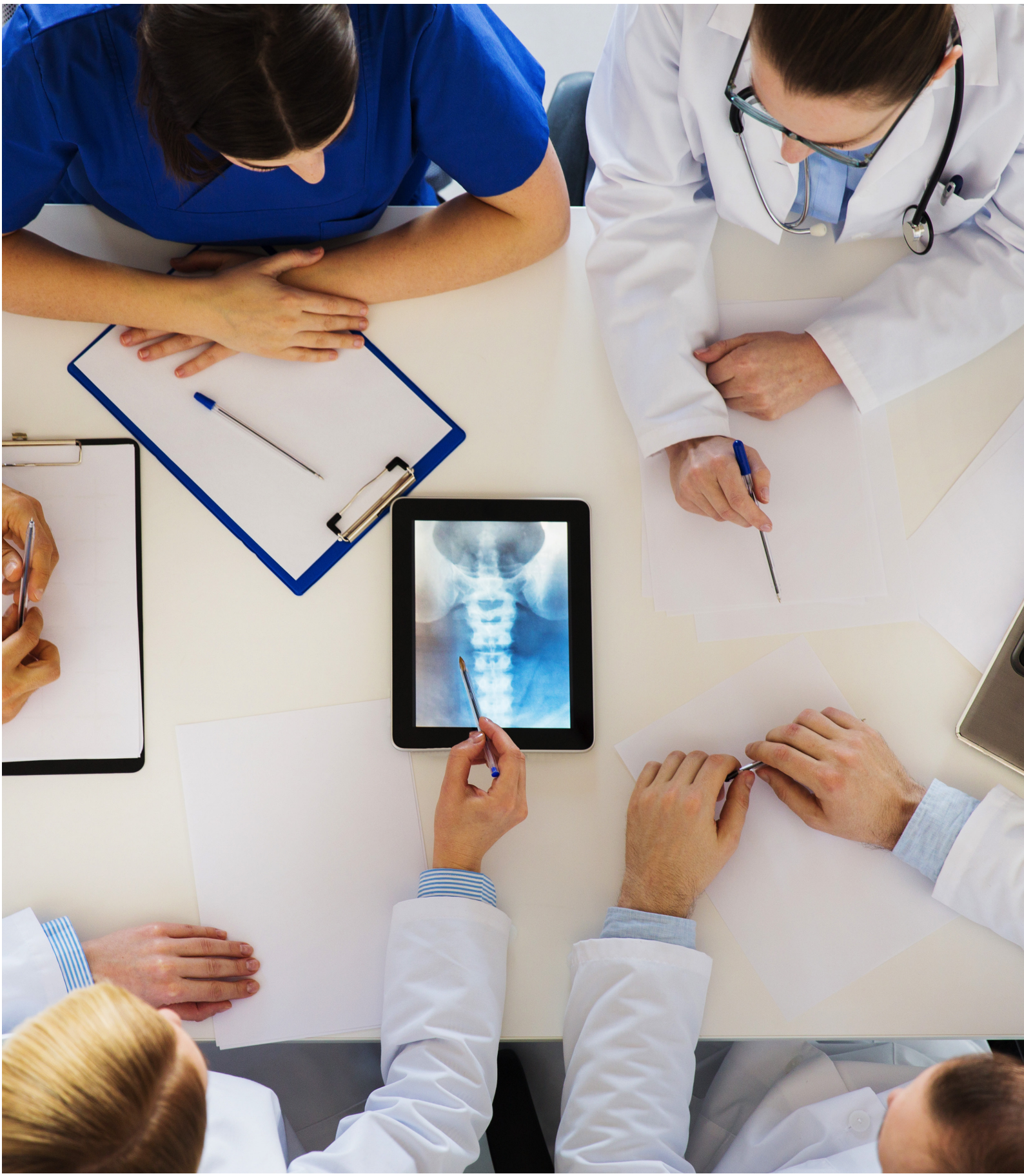
For those patients that are candidates, the prodisc L Total Disc Replacement surgery offers another option of treatment that may help stop the pain and other problems associated with a damaged lumbar disc at two levels.

Artificial lumbar disc replacement with the prodisc L Total Disc Replacement device is expected to relieve symptoms of spinal cord and/or nerve root compression resulting from lumbar disc degeneration at two levels. Additionally, it may:

- Help movement of your back in all directions (forward, backwards, side to side, rotating)
- Minimize your back and/or leg pain
- Minimize tingling in your leg
- Help you return to your normal activities of work, family, and recreation

How to Choose the Correct Treatment

Spinal fusion and prodisc L Total Disc Replacement both treat DDD. Consult with your doctor about your options and the best course of treatment for you.



What happens before your surgery?

Your medical history is extremely important to the success of the operation. Before surgery, your doctor will consider your occupation and activity level, your overall health, the condition of other levels of your spine, any medications you are taking, and any allergies you have to determine the best course of treatment for you. Your doctor will also discuss the procedure at length as well as its potential risks and benefits.

In order to be adequately prepared for your recovery following surgery, it may be necessary to make some minor adjustments within your home and arrange for someone to help you. This includes moving any overhead items to an area that can be easily reached and moving items that could potentially cause you to lose your balance or fall.

What happens during your surgery?

Your doctor will remove the prodisc L Total Disc Replacement implant pieces from their inner packaging, being careful to keep them clean (sterile) and undamaged.

You will be placed under general anesthesia. Even though you are having lower back surgery, your surgery will be performed through an incision in your abdomen. You will be lying on your back.

During your surgery, the doctor will remove the symptomatic disc. Trials will be used to determine the appropriate implant size and your symptomatic disc will be replaced with the prodisc L Total Disc Replacement device. After insertion, your incision will be closed.



What happens after your surgery?

Surgery with the prodisc L Total Disc Replacement device is considered major surgery. As with any major surgery, you should expect some discomfort as well as a period of rehabilitation. Your doctor may prescribe medicines to help you manage any pain or nausea you may experience. You should expect to stay in the hospital for at least a few days. The average hospital stay for disc replacement surgery patients in the clinical study for the prodisc L Total Disc Replacement device was about 3.5 days (range: 1.0–10.0 days).[2] Prior to going home, you will be taught how to care for your incision, and you and your doctor should discuss a plan to gradually bring you back to your normal activity level. Your doctor may carry out follow-up examination of your lumbar disc prosthesis at regular intervals. It is very important that you follow your surgeon's instructions. Try not to do too much, too soon.

When to Call Your Doctor

Contact your doctor immediately if you:

- Have a fever or chills
- Notice fluid draining from your incision
- Have trouble swallowing or breathing
- Have trouble urinating
- Have new or increased back or leg pain
- Have numbness
- Have weakness

CAUTION: Please be sure to tell your doctor that you had surgery with the prodisc L Total Disc Replacement device before you have magnetic resonance imaging (MRI) taken. The metal in the prodisc L Total Disc Replacement device can affect the quality of the images taken.



The prodisc L Total Disc Replacement device is labeled MR Conditional, meaning the implant can be scanned only under certain conditions. For instructions for conducting an MRI, package inserts, or other documents, please scan the appropriate QR code or visit: guides.centinelspine.com

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SCAN OUTSIDE U.S.

WARNING: Extreme activities like lifting very heavy weights may result in failure of the device. Call your doctor immediately if you have any new or increased pain, numbness, or weakness in your back or legs.

When Can I Travel After prodisc L Total Disc Replacement Surgery?

Ask your doctor when you can start driving after surgery. The amount of time needed to recover from surgery differs from patient to patient.

Contact your local airport if you will be traveling following implantation of your device. Due to increased security, airport personnel will be able to provide appropriate guidance on passing through security with a metallic device in your spine.



Where Can I Find Out More Information?

CENTINEL SPINE has provided this guide in an effort to inform you about your treatment options. If you would like additional information or have more questions about artificial disc surgery, please contact your doctor.

VISIT OUR WEBSITE AT:

www.rediscovermylife.org

PLEASE NOTE: This patient information guide is not a replacement for professional medical advice. Only your surgeon is qualified to diagnose and treat your spine-related pain.

If you experience any serious incident in relation to prodisc L, please report to the manufacturer, Centinel Spine (complaints@centinelspine.com).

- If you are a resident in Germany (or other EU countries), please also report to **the local competent authority**.
- If you are a resident in Australia, please also report to the Therapeutic Goods Administration (https://www.tga.gov.au/reporting-problems).

PATIENT INFORMATION

You may wish to record important information regarding your prodisc L Total Disc Replacement device.

Please ask your surgeon for this information.

	Part #	Lot #
Superior Plate		
Inlay		
Inferior Plate		

Implant Identification & Information Card: Download, print, and fold this wallet-sized information card to identify the device, manufacturer, and implant material composition—as well as provide MRI safety information, surgery details, and metal-detection notification to the appropriate authorities or when traveling. Visit rediscovermylife.org/resources.php or scan the QR code.

SCAN TO LEARN MORE

Warning: This product has labeling limitations. See package insert for complete information.

Caution: International law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) that has appropriate training experience.

MR

Magnetic Resonance Imaging: The prodisc L Total Disc Replacement device is labeled MR conditional, where it has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. For more information, please refer to the Instructions for Use. Visit guides.centinelspine.com or scan the QR Codes (right) to download the Instructions for Use.

SCAN FOR U.S.

SCAN OUTSIDE U.S.

References:

[1] Periodic Update Safety Report for prodisc L is on file with Centinel Spine.

[2] A complete Summary of Safety and Effectiveness (SSED) and labeling information for the prodisc L Total Disc Replacement may be obtained at www.fda.gov by searching PMA number P050010/S020 (https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010S020B.pdf)

[3] A complete Summary of Safety and Effectiveness (SSED) and labeling information for the prodisc L Total Disc Replacement may be obtained at www.fda.gov by searching PMA number P050010 (https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010B.pdf)

Device Models and Descriptions

INTERNATIONAL DEVICE MODELS	
Model #	**Description**
SSX544K	prodisc L, Inferior Endplate, Large, 00°
SSX672K	prodisc L, Inferior Endplate, Large, 03°
SSX674K	prodisc L, Inferior Endplate, Large, 08°
SSX524K	prodisc L, Inferior Endplate, Medium, 00°
SSX662K	prodisc L, Inferior Endplate, Medium, 03°
SSX664K	prodisc L, Inferior Endplate, Medium, 08°
SSX646	prodisc L, Inlay, Large, 10mm
SSX647	prodisc L, Inlay, Large, 12mm
SSX648	prodisc L, Inlay, Large, 14mm
SSX626	prodisc L, Inlay, Medium, 10mm
SSX627	prodisc L, Inlay, Medium, 12mm
SSX628	prodisc L, Inlay, Medium, 14mm
SSX670K	prodisc L, Superior Endplate, Large, 03°
SSX540K	prodisc L, Superior Endplate, Large, 06°
SSX542K	prodisc L, Superior Endplate, Large, 11°
SSX660K	prodisc L, Superior Endplate, Medium, 03°
SSX520K	prodisc L, Superior Endplate, Medium, 06°
SSX522K	prodisc L, Superior Endplate, Medium, 11°

U.S. DEVICE MODELS	
Model #	**Description**
PDL-L-IP00S	prodisc L, Inferior Endplate, Large, 00°
PDL-L-IP03S	prodisc L, Inferior Endplate, Large, 03°
PDL-L-IP08S	prodisc L, Inferior Endplate, Large, 08°
PDL-M-IP00S	prodisc L, Inferior Endplate, Medium, 00°
PDL-M-IP03S	prodisc L, Inferior Endplate, Medium, 03°
PDL-M-IP08S	prodisc L, Inferior Endplate, Medium, 08°
PDL-L-PT10S	prodisc L, Inlay, Large, 10mm
PDL-L-PT12S	prodisc L, Inlay, Large, 12mm
PDL-L-PT14S	prodisc L, Inlay, Large, 14mm
PDL-M-PT10S	prodisc L, Inlay, Medium, 10mm
PDL-M-PT12S	prodisc L, Inlay, Medium, 12mm
PDL-M-PT14S	prodisc L, Inlay, Medium, 14mm
PDL-L-SP03S	prodisc L, Superior Endplate, Large, 03°
PDL-L-SP06S	prodisc L, Superior Endplate, Large, 06°
PDL-L-SP11S	prodisc L, Superior Endplate, Large, 11°
PDL-M-SP03S	prodisc L, Superior Endplate, Medium, 03°
PDL-M-SP06S	prodisc L, Superior Endplate, Medium, 06°
PDL-M-SP11S	prodisc L, Superior Endplate, Medium, 11°



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