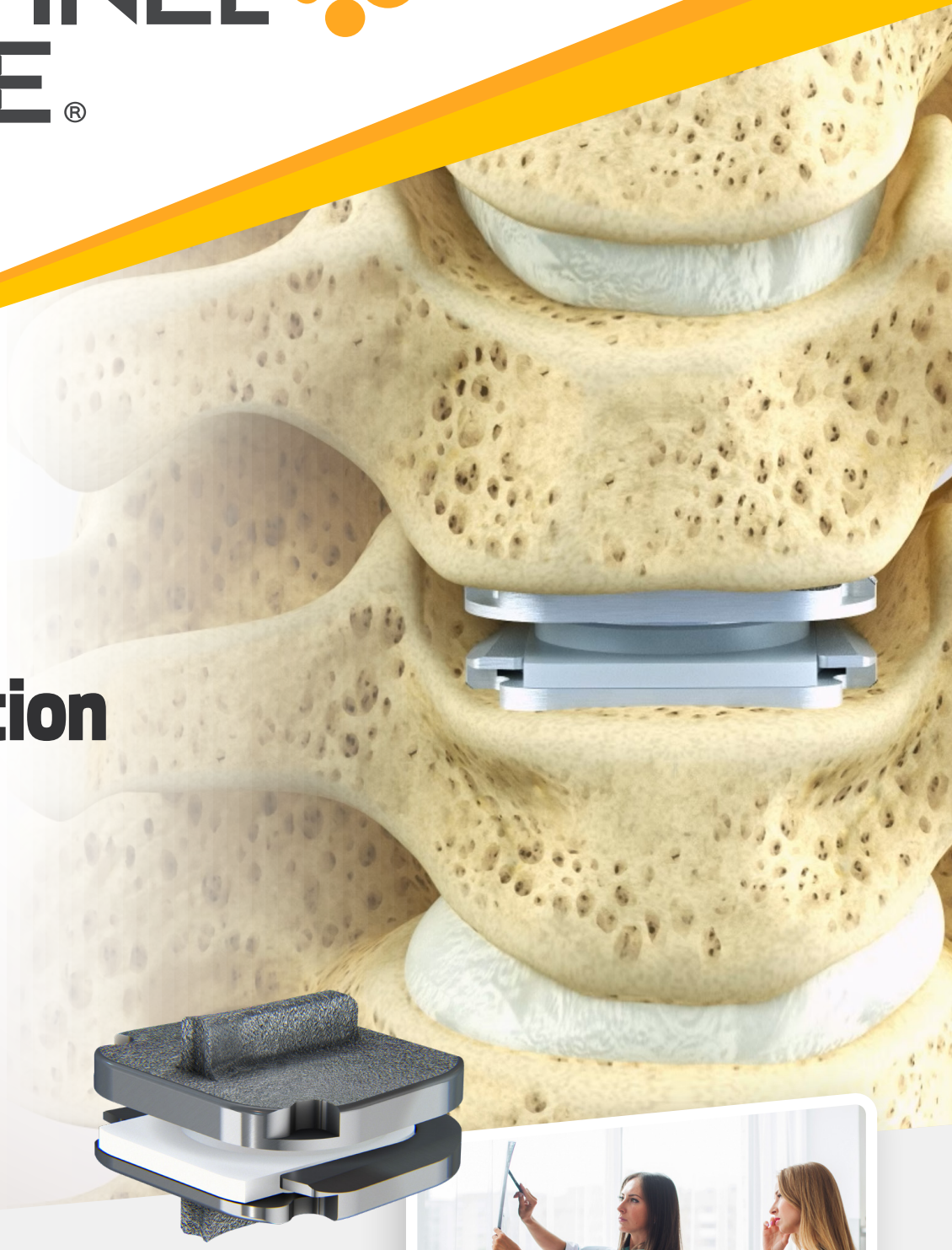
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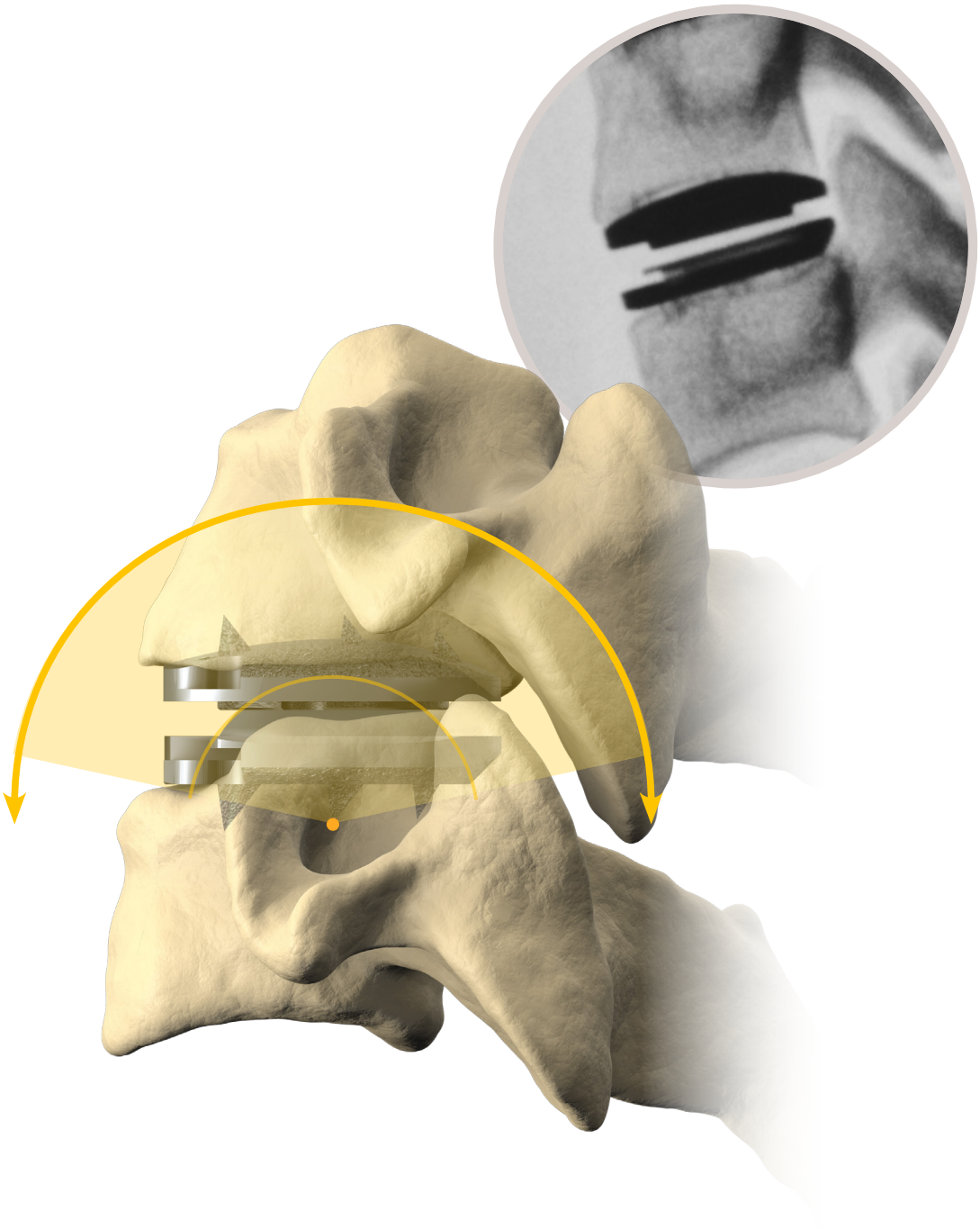
Patient Information Guide





prodisc®

For Cervical Total Disc Replacement



prodisc®

For Cervical Total Disc Replacement

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GLOSSARY

Alleviate:	To make something less severe or more bearable, especially pain.
Anterior:	Front of the body.
Anterior Cervical Disectomy and Fusion (ACDF):	A surgical procedure in which a damaged disc is removed and replaced with material to encourage a fusion between the two vertebrae.
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.
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.
Degenerated:	To fall or deteriorate below a normal or desirable state functionally, to decline in quality.
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 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.
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.
Incision:	During surgery, a cut into a body tissue or organ with a sharp instrument.
Intervertebral:	Located between the spinal vertebrae.
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 neck):	Bending the head from side to side.

Lordosis:	The natural curve of the spine in both the neck (cervical) and lower back (lumbar) regions. The spine's natural curves position the head over the pelvis and work as shock absorbers during movement. An excessive curve of the spine can be painful, sometimes affecting movement.
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.
Non-inferior:	A new treatment is not unacceptably worse than the comparator treatment.
Osteopenia:	Mild loss of bone mineral density (BMD), usually seen as a precursor to osteoporosis.
Osteoporosis:	A disease in which the bones deteriorate and become weakened, fragile, and easily broken. Bone mineral density (BMD) is reduced as minerals, such as calcium, leach out. Any bone can be affected by osteoporosis, but spinal or vertebral fractures can cause severe back pain and lead to loss of height and spinal deformity.
Pars Defect:	The pars is a short section of bone within a vertebra. A pars defect is a fracture (break) of the pars.
Ultra-High Molecular Weight Polyethylene (UHMWPE):	Hard plastic used between the metal endplates.
Rehabilitation:	To restore to good health or good condition through therapy and education.
Symptomatic Cervical Disc Disease (SCDD):	SCDD is a condition that can occur when the cervical discs no longer function normally because of aging, wear, or from being injured.
Spinal Arthroplasty:	The reconstruction of a damaged or diseased disc. also known as Total Disc Replacement.
Spinal Stenosis:	A condition that occurs when the space that holds the spinal cord and nerve roots becomes narrowed or restricted. Stenosis can squeeze nerves and the spinal cord, leading to pain in the lower back and legs, or in the neck, arms, and hands, depending on where the narrowing is occurring 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

Why Have I Been Given This Information Guide?

After reviewing your medical history and x-rays, and taking into account the results of other diagnostic studies, your doctor has decided that you may benefit from spine surgery. This patient information guide is provided to assist you in making a decision about the treatment of your arm and/or neck pain with one of the prodisc Cervical Total Disc Replacement devices (prodisc C, prodisc C Vivo, prodisc C SK, or prodisc C Nova) manufactured by Centinel Spine.

What is Important For Me to Understand About My Spine?

Your spine **(Figure 1)** is the structure that supports and stabilizes your body and allows motion. It gives you the ability to perform activities such as walking, bending and sitting. It also provides protection for your spinal cord and nerve roots.

Your spine is made up of bones called vertebrae that are stacked on top of each other to form a column. Each vertebra has a hole in the center through which the spinal cord passes. The spinal cord contains nerves that carry signals from your brain to the rest of the body. The vertebrae are separated by soft, cushioning intervertebral discs which maintain an appropriate space to support motion and allow nerves to pass though your spine to many different parts of your body.

The spine is divided into four regions. The cervical region (commonly called the neck) contains the seven upper-most vertebrae in your neck. The thoracic region (commonly known as the rib section) contains the twelve vertebrae in your mid-back. The lumbar region (commonly known as the lower back) contains the five vertebrae in your lower back. The sacrum and coccyx region (commonly called the tail bone) contains the bones in the base of the spine.

prodisc Cervical Total Disc Replacement devices are used to treat the lower cervical spine. Your doctor may refer to the involved cervical areas as C3, C4, C5, C6, or C7 **(Figure 2)**.

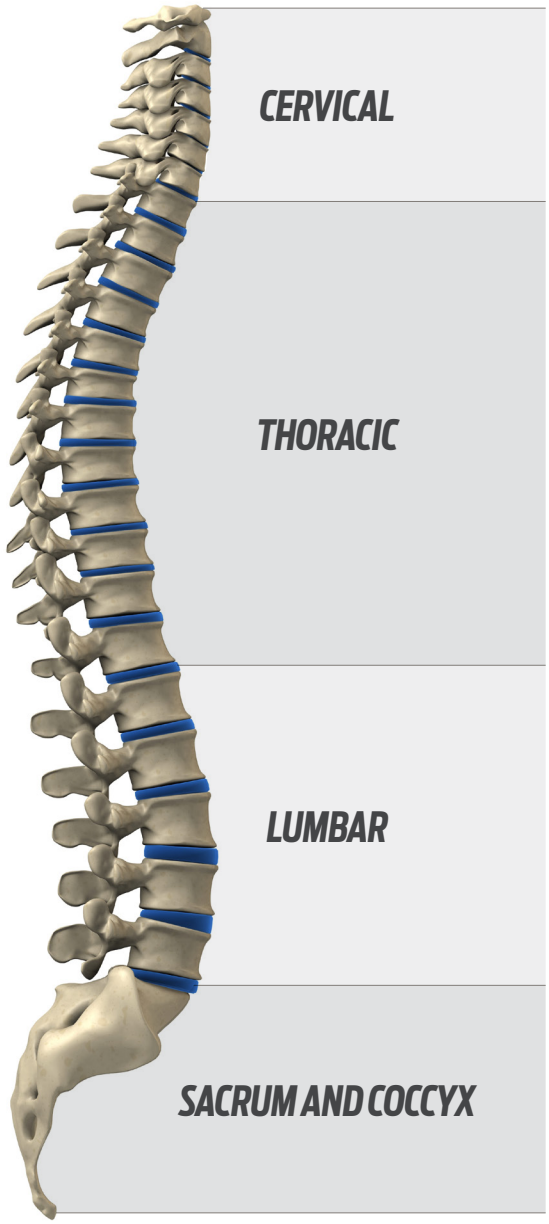


Figure 1: The Spinal Column

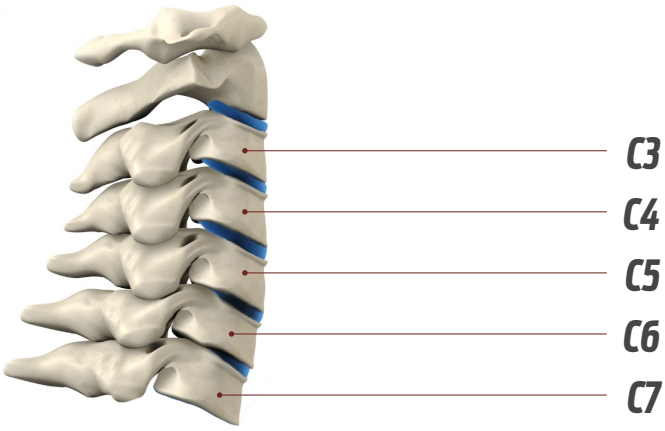


Figure 2: Levels of the Cervical Spine

Why Might I Need Surgery?

Your doctor has diagnosed you with **symptomatic cervical disc disease (SCDD)**.

Indications for all prodisc Cervical devices are: Symptomatic cervical disc disease (SCDD), which is defined as neck or arm (radicular) pain and/or a functional / neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays):

- herniated nucleus pulposus
- spondylosis (defined by the presence of osteophytes)
- loss of disc height

Your doctor may call your condition a **herniated disc**, **spondylosis**, or **radiculopathy**. Normally, the intervertebral disc between each pair of vertebrae provides the cushioning space that keeps the bones separated. Symptomatic cervical disc disease (SCDD) can occur when the discs no longer work normally because of wear or from being injured. This can cause the vertebral bodies to compress or lose height, and they may press on the nerves or the spinal cord. This can cause pain and/or numbness in the arms and neck and limit your ability to perform daily activities.

If you have been diagnosed with SCDD and your pain has failed to improve after at least six weeks of conservative (nonsurgical) treatment such as physical therapy or medication, you may get relief by having surgery. One type of surgery is total disc replacement surgery. A computed tomography (CT) scan, magnetic resonance imaging (MRI) and/or x-rays may be required to confirm the source of your pain and to help your doctor determine if you are a suitable candidate for surgery, including total disc replacement.

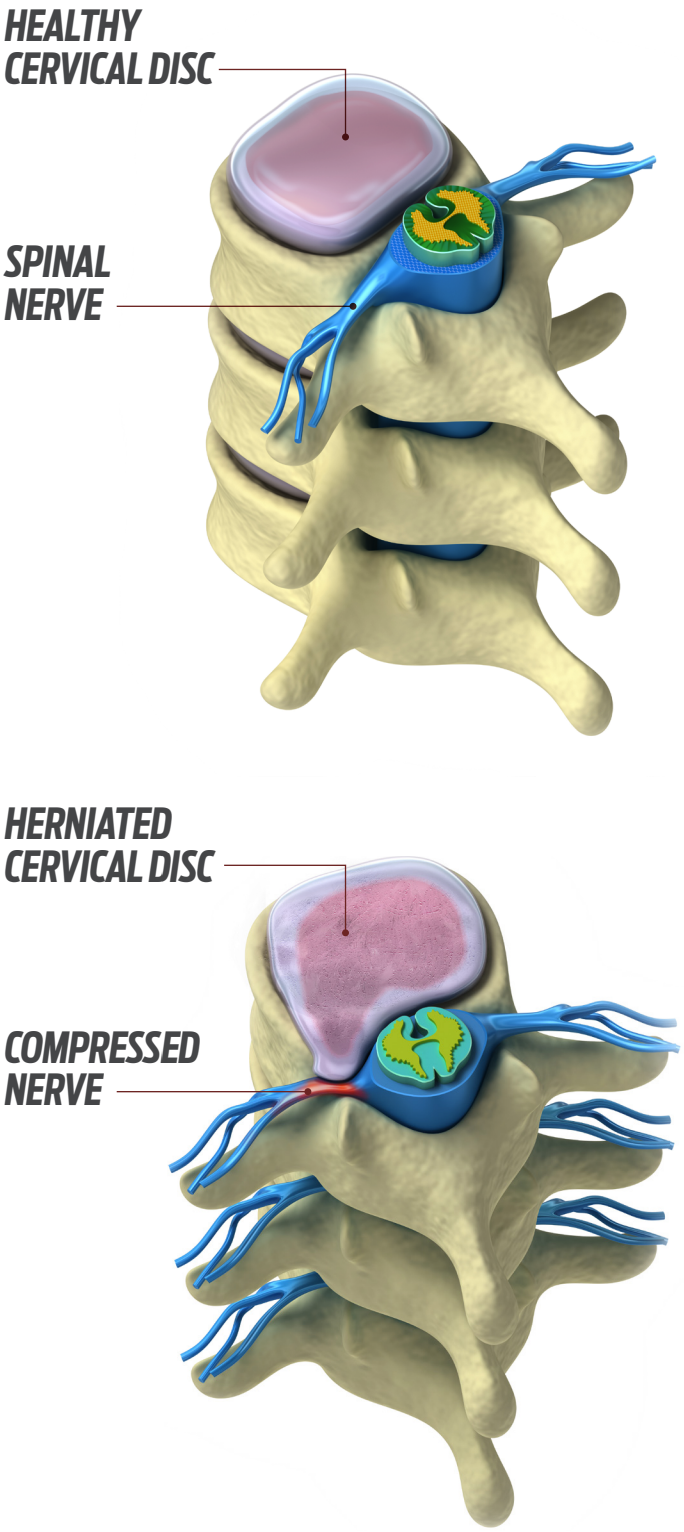


Figure 3: Healthy Disc vs. Damaged Disc

ABOUT prodisc® FOR CERVICAL TOTAL DISC REPLACEMENT

What Is the prodisc Cervical Total Disc Replacement Device?

There are several prodisc devices for Cervical Total Disc Replacement, including prodisc C, prodisc C Vivo, prodisc C SK, and prodisc C Nova. All prodisc Cervical Total Disc Replacement devices are composed of top and bottom metal cobalt chromium (CO-28Cr-6Mo) endplates, with a plastic inlay (ultra-high molecular weight polyethylene) **(Figures 4 - 7)**.

All prodisc Cervical Total Disc Replacement devices provide the possibility for motion by allowing the top endplate to move over the plastic ball attached to the bottom endplate **(Figure 8)**.

The materials used in the prodisc Cervical Total Disc Replacement devices have been used in spinal disc replacement for over 30 years and are the most commonly used materials in knee and hip replacements worldwide.

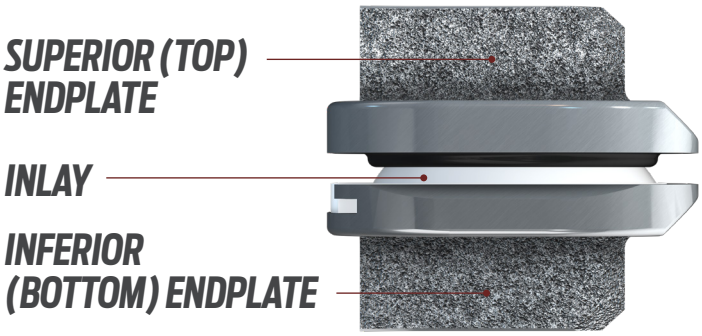


Figure 4: The prodisc C Implant

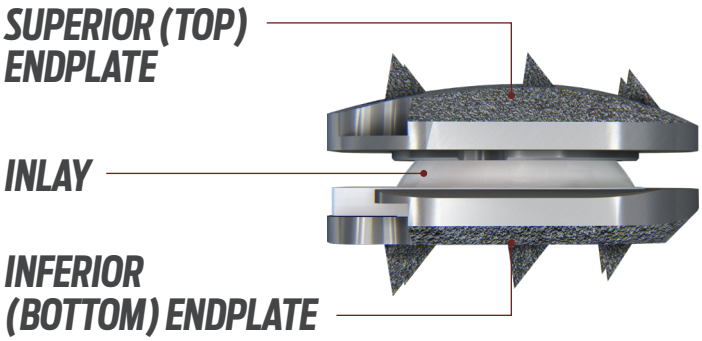


Figure 5: The prodisc C Vivo Implant

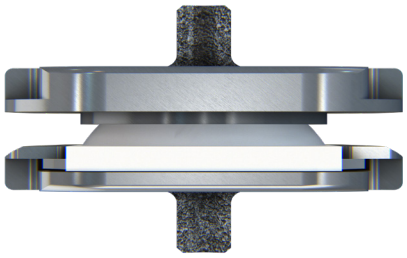


Figure 6a: The prodisc C SK Implant in A/P View

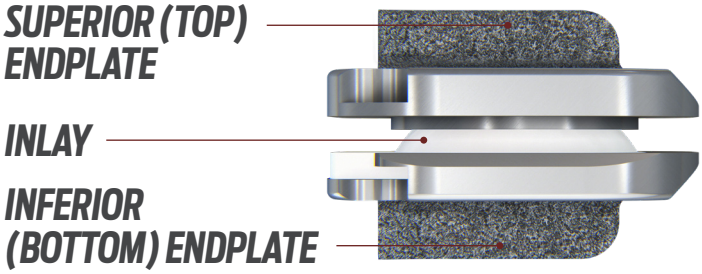


Figure 6b: The prodisc C SK Implant in Lateral View

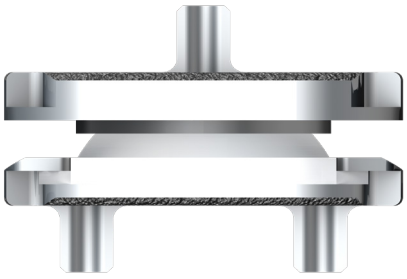


Figure 7a: The prodisc C Nova Implant in A/P View

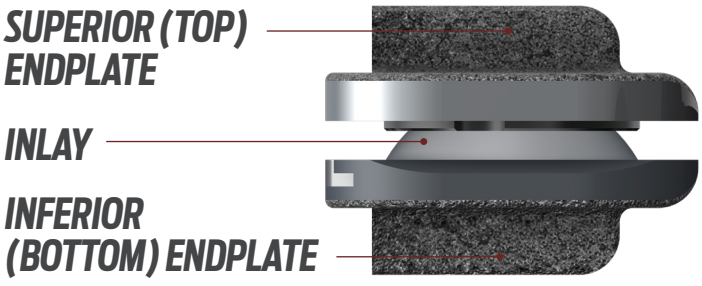


Figure 7b: The prodisc C Nova Implant in Lateral View

Each prodisc Cervical Total Disc Replacement device has features that help fixate it in the vertebral bone. prodisc C, prodisc C SK, and prodisc C Nova have superior and inferior keels, and prodisc C Vivo has spikes on both endplates. 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 and fixate the device in place.

All prodisc Cervical Total Disc Replacement devices are designed to allow motion in axial rotation (turning the head left and right) and flexion and extension (bending forward and backward, **Figure 9**) as well as lateral bending (bending side to side, **Figure 10**); however, not all patients will achieve motion after treatment with the prodisc Cervical Total Disc Replacement devices.

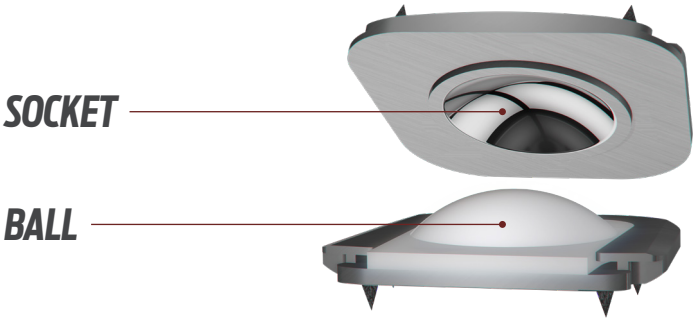


Figure 8: Ball and Socket

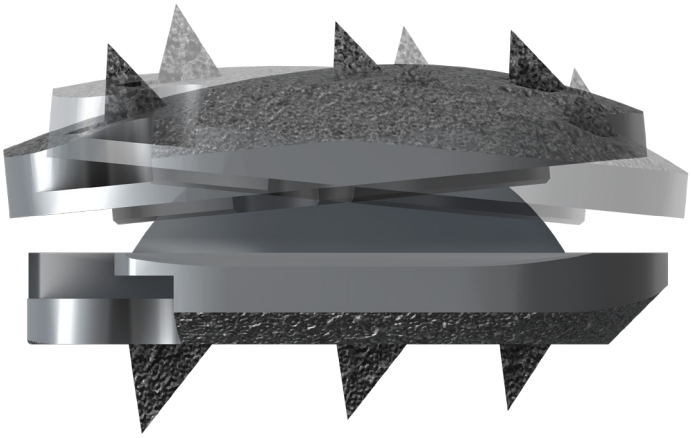


Figure 9: Illustrated Flexion/Extension Motion of prodisc C Vivo Total Disc Replacement

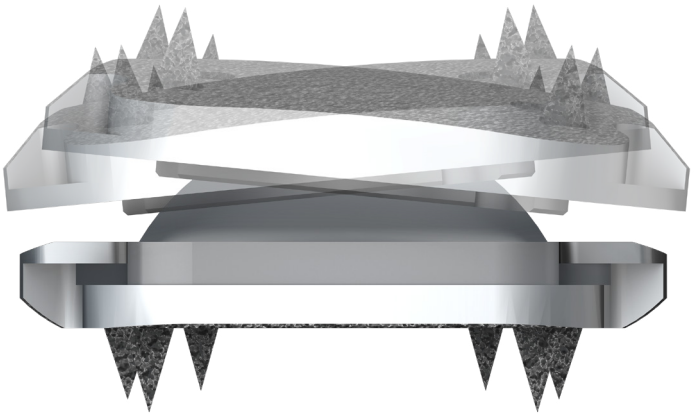


Figure 10: Illustrated Lateral Bending Motion of prodisc C Vivo Total Disc Replacement

How is Surgery with prodisc for Cervical Total Disc Replacement Different from Other Surgical Choices?

prodisc Cervical Total Disc Replacement surgery is an alternative to anterior cervical discectomy and fusion (ACDF), which is the surgery that is most commonly done for your condition.

In both the ACDF and prodisc Cervical Total Disc Replacement procedures, the symptomatic disc is removed and the height at that level of your spine is restored to relieve pressure on the nerves and/or spinal cord. In an ACDF procedure, after the symptomatic disc is removed, the bones are fixed in position with implants and bone graft.

In some ACDF procedures, the bone graft may come from your hip in a separate incision. After surgery, the two bones are supposed to grow together, creating one solid piece of bone and eliminating motion at that level of your spine. In the prodisc Cervical Total Disc Replacement procedure, the device is inserted into the disc space to restore the height at that level of your spine, while potentially allowing some motion. The prodisc Cervical Total Disc Replacement procedure does not require a bone graft.

Who Should Receive prodisc for Cervical Total Disc Replacement and What is it Designed To Do?

The prodisc Cervical Total Disc Replacement device is used to replace a symptomatic (diseased and/or degenerated) disc of the cervical spine after the symptomatic disc is removed.

The prodisc Cervical Total Disc Replacement is designed to reduce pain by removing the symptomatic disc while potentially allowing your neck to move after surgery.

The prodisc Cervical Total Disc Replacement should only be used in patients who are skeletally mature, have a symptomatic disc, and have had neck or arm pain for at least six (6) weeks that did not respond to nonoperative care (physical therapy, medication, etc.).



Who Should Not Receive prodisc for Cervical Total Disc Replacement?

You should not receive the prodisc Cervical Total Disc Replacement if you have any of the following:

- Any type of infection, especially infection in the spine and/or surrounding area
- Poor quality bone (osteoporosis or osteopenia)
- An unstable or overly weak neck
- Allergies or sensitivity to metals (cobalt, chromium, molybdenum, titanium, aluminum, or niobium) or plastic (polyethylene)*
- Stiffening of the neck or severe degeneration
- Weakened bones at the treatment level due to past or present injury

What Warnings and Precautions Should I Pay Attention To?

It is important to select a surgeon who has been trained by the company who makes the prodisc Cervical Total Disc Replacement devices (Centinel Spine).

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

It is very important that you let your doctor know about any allergies you have, any medications you take on a regular basis, if you are pregnant, or have any other treated or untreated illnesses, such as rheumatoid arthritis, cancer, cardiac disease, diabetes, hepatitis, osteoporosis, previous surgeries or injuries you may have that may impact whether this device is right for you.

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

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



What are the Potential Risks for the prodisc Cervical Total Disc Replacement Device?

As with any surgery, there are possible problems that can occur when you have neck surgery, including surgery with the prodisc Cervical Total Disc Replacement device. There is a risk that the surgery may not make you feel better or may cause you to feel worse. If this happens, you may need another surgery to help you feel better.

Specific possible problems that may occur include:

- Allergic reaction to the anesthesia used during your surgery
- Allergic reaction to the implant materials that may lead to implant loosening or failure
- Change in the curvature of your neck
- Difficulty or pain when you swallow
- Difficulty with, or change in, your speech
- The implant may not stay in place, or may break, bend, loosen, or move, potentially causing pain, paralysis, or damage to blood vessels, nerves, or the spinal cord
- Numbness or tingling in your extremities
- Muscle weakness in your extremities, or in general
- Failure of the device/procedure to make you feel better
- Fracture of the bones in your neck
- Seizures
- Infection (of your wound, your spine, or an infection in your blood)
- Inability to move your neck at the treated level (unintended fusion)
- Development or progression of disease at other levels in your cervical spine
- Bleeding or a collection of clotted blood (hematoma)
- Blood clots in your extremities, lungs, brain (stroke), or other parts of your body
- Swelling
- Complications of pregnancy, including miscarriage and fetal birth defects
- Inability to resume activities of normal daily living
- Death

In a U.S. clinical study of 103 patients who received the prodisc C Total Disc Replacement device, there were six (6) patients who did not get any relief of their symptoms and a number of other patients whose improvement was likely not significant enough for them to notice a difference. There were two (2) patients who needed additional surgery on their necks.

Throughout the course of the clinical study, patients reported health-related problems to their physicians. Some of the most common problems were pain, headaches, and muscle aches. There may be other risks associated with treatment using the prodisc Cervical Total Disc Replacement device.

Although many of the major risks are listed in this patient information guide, a more complete list is provided in the instructions for use, which is available on our website. Visit guides.centinelspine.com or scan the below QR Code to download the instructions for use.

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ABOUT THE SURGERY

What Can I Expect Before the Surgery?

Your doctor will review your condition with you and explain your possible choices, including medications, physical therapy, and other surgeries such as removal of the diseased disc, fusion, etc.

What Can I Expect During the Surgery?

During the total disc replacement surgery, you will be under general anesthesia. The surgeon will make a small incision in the front of your neck to get access to your symptomatic disc. Then the surgeon will remove the symptomatic disc. The surgeon will insert the prodisc Cervical Total Disc Replacement implant into the disc space. Finally, the surgeon will close the incision.

What Can I Expect After the Surgery?

Surgery with the prodisc Cervical Total Disc Replacement device is considered a major surgery. As with any major surgery, you should expect discomfort, as well as a period of rehabilitation. Your doctor may prescribe medicines to help you manage any pain or nausea you may experience. While many patients will have the surgery conducted without an overnight stay, some patients may have conditions that lead them to be monitored in a facility for a day or two.

After You Go Home

You and your doctor should talk about a plan to steadily bring you back to normal activity while the healing process occurs. It is very important that you follow your doctor's instructions. You can begin moving soon after surgery, but try not to do too much, too soon.

Your Doctor May Recommend the Following Instructions:

- A hard or soft collar may be used if your doctor thinks it is necessary
- Avoid prolonged or strenuous activity
- Avoid heavy physical activity until your doctor tells you it is okay
- You will be taught how to clean and care for your wound

After surgery, your doctor may refer you to a physical therapist who will teach you exercises to improve your strength and mobility while protecting your spine.

Contact Your Doctor Immediately If You:

- Have fever or chills
- Notice fluid draining from your wound
- Have trouble swallowing or breathing
- Have new or increased neck pain, arm pain, numbness, or weakness



What are the Expected Outcomes of the Surgery?

The U.S. clinical study of the prodisc C Total Disc Replacement device showed that the prodisc C Total Disc Replacement device was just as good as fusion surgery in helping to relieve pain and restore normal function. The rates of complications were about the same between the two groups in the first seven years following surgery. The clinical benefit beyond seven years has not been measured. Ask your surgeon for more details about the clinical study and its results.

Making the Choice for Surgery

You should discuss both surgical and nonsurgical treatment options with your doctor. If surgery is selected, your occupation, activity level, weight, and the condition of the spine will be considered when determining if you are an appropriate candidate. Only your doctor can decide if you are an appropriate surgical candidate.

Conclusion

You have been diagnosed with symptomatic cervical disc disease (SCDD) and your doctor believes that surgery is the best treatment option. After considering the alternatives, your doctor may recommend the prodisc Cervical Total Disc Replacement device as a treatment alternative.

If you would like additional information, or have more questions about total disc replacement surgery, please call or see your doctor.

This patient information guide is not a replacement for professional medical advice. Only your doctor is qualified to diagnose and treat your neck and/or arm pain.

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



Each of the prodisc Cervical Total Disc Replacement devices 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 QR code or visit: https://guides.centinelspine.com



CAUTION: Inform your doctor if you have an active infection or allergy to cobalt, chromium, molybdenum, polyethylene or titanium. Also inform your doctor if you have been diagnosed with osteoporosis, osteopenia, or if you have any other health issues.



WARNING: This product has labeling limitations. Please visit guides.centinelspine.com or scan the QR code to see the package insert for complete information.

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

When Can I Travel After prodisc Cervical 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:

rediscover®

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 the prodisc Cervical Total Disc Replacement device, please report to the manufacturer, Centinel Spine (complaints@centinelspine.com).

PATIENT INFORMATION

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

Please ask your surgeon for this information.

Lot #

Part#

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

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



Magnetic Resonance Imaging: The prodisc Cervical Total Disc Replacement 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 Code (right) to download the Instructions for Use.

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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 (right).

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CENTINEL SPINE®

US Headquarters: 900 Airport Rd, Ste. 3B, West Chester, PA 19380 USA
Email (US): info@centinelspine.com
Web: www.centinelspine.com

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LBL641 Rev 1 (05/2024)

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