

ProDisc-C Total Disc Replacement. Patient Information.



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Patient Information

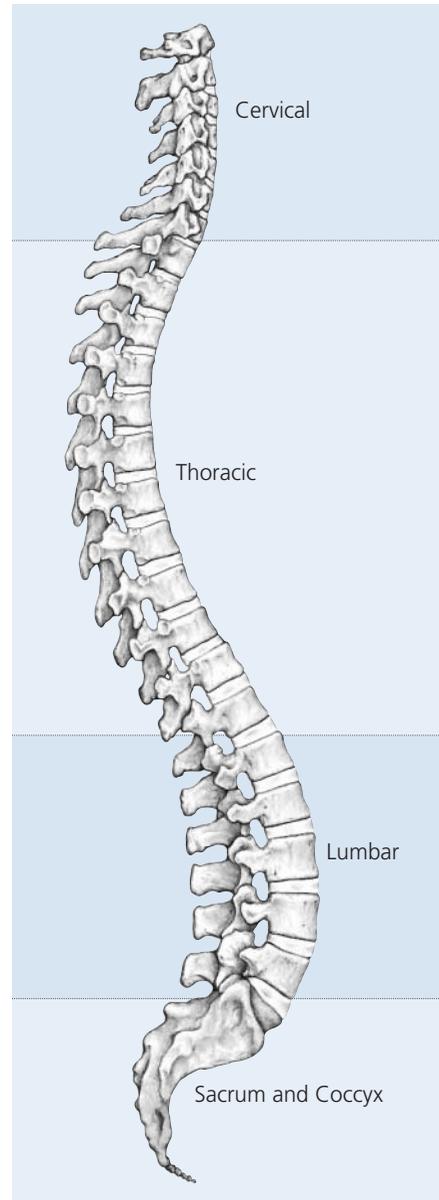
Why have I been given this information brochure?

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 brochure is provided to assist you in making a decision about the treatment of your arm and/or neck pain with the ProDisc-C Total Disc Replacement made by Synthes Spine.

What is important for me to understand about my spine?

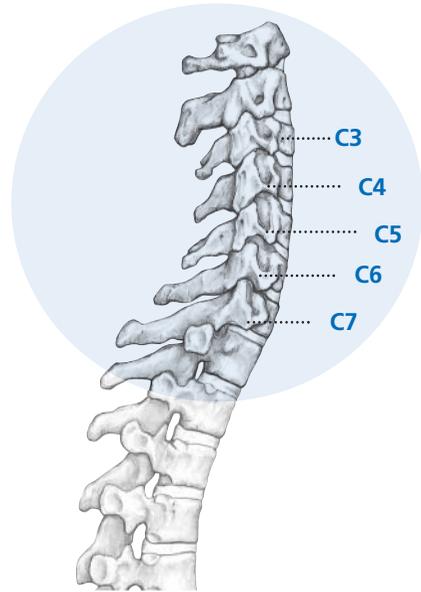
Your spine is the structure that supports and stabilizes your body and allows motion. It gives you the ability to perform activities such as walking, bending and sitting. It also provides protection for your spinal cord and nerve roots.

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 through your spine to many different parts of your body.



Your 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.



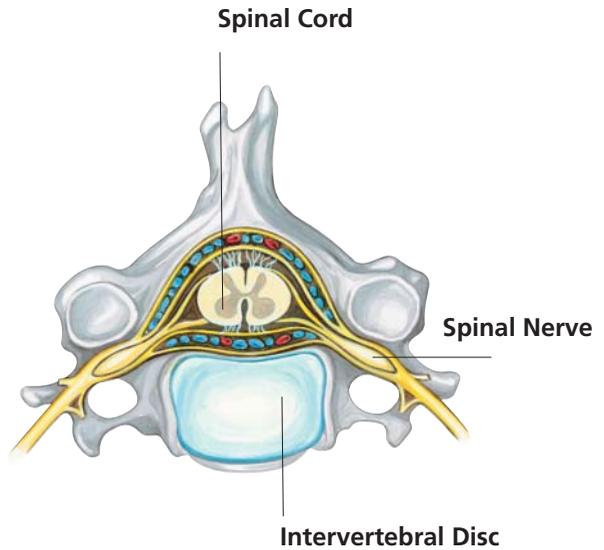
The ProDisc-C Total Disc Replacement is used to treat the lower cervical spine. Your doctor may refer to the involved cervical areas as C3, C4, C5, C6, or C7.

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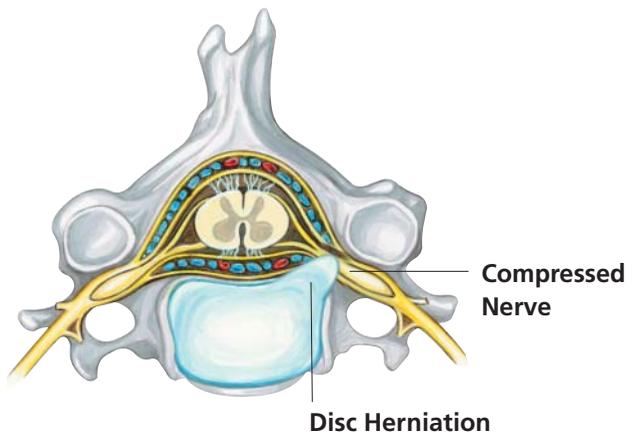
Why may I need surgery?

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



Healthy Cervical Disc



Herniated Cervical Disc

What is the ProDisc-C Total Disc Replacement?

The ProDisc-C Total Disc Replacement implant is composed of top and bottom metal (cobalt chromium molybdenum) endplates and a plastic inlay (ultra-high molecular weight polyethylene) that form a ball and socket joint.

The ProDisc-C Total Disc Replacement implant provides the possibility for motion by allowing the top endplate to move over the plastic ball attached to the bottom endplate. The materials used in the ProDisc-C Total Disc Replacement implant have been used in spinal disc replacement for over 20 years in Europe and are the most commonly used materials in knee and hip replacements worldwide.



How is surgery with the ProDisc-C Total Disc Replacement different from other surgical choices?

ProDisc-C 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 the ProDisc-C Total Disc Replacement procedures, the unhealthy 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 unhealthy 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-C 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-C Total Disc Replacement procedure does not require a bone graft.

Who should receive the ProDisc-C Total Disc Replacement, and what is it designed to do?

The ProDisc-C Total Disc Replacement is used to replace one unhealthy (diseased and/or degenerated) disc of the cervical spine after the unhealthy disc is removed.

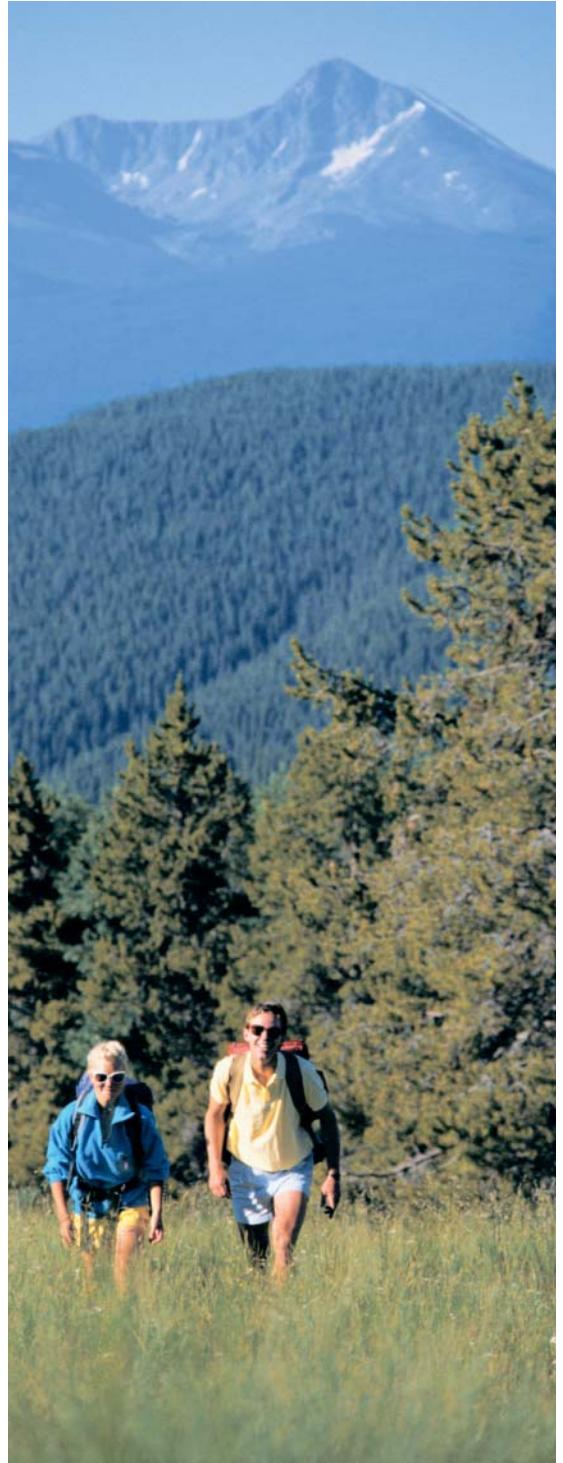
The ProDisc-C Total Disc Replacement is designed to reduce pain by removing the unhealthy disc while potentially allowing your neck to move after surgery. The ProDisc-C Total Disc Replacement should only be used in patients who are at least 22 years of age, have only one unhealthy disc, and have had 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 the ProDisc-C Total Disc Replacement?

You should not receive the ProDisc-C 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, and/or titanium) or plastic (polyethylene)
- Stiffening of the neck or severe degeneration
- Weakened bones at the treatment level due to past or present injury

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



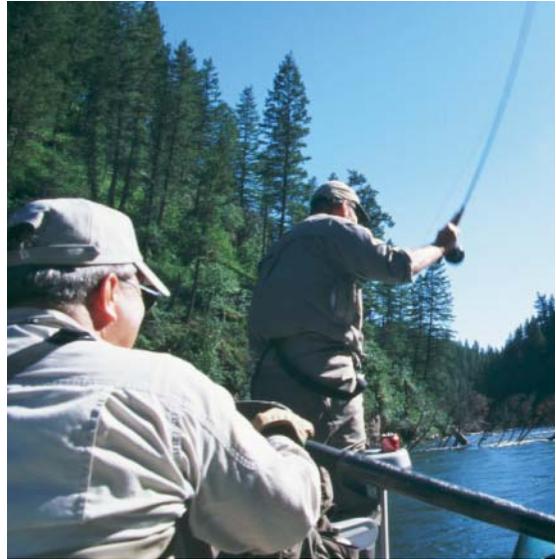
Patient Information

What warnings and precautions should I pay attention to?

It is important to select a surgeon who has attended a training course sponsored by the company who makes the ProDisc-C Total Disc Replacement (Synthes 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.



What are the potential risks with the ProDisc-C Total Disc Replacement?

As with any surgery, there are some possible problems that can occur when you have neck surgery, including surgery with the ProDisc-C Total Disc Replacement. 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
- Death
- 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
- Pain in your neck, arms, or other parts of your body
- Numbness or tingling in your extremities

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What are the potential risks with the ProDisc-C Total Disc Replacement? *continued*

- 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

In a U.S. clinical study of 103 patients who received ProDisc-C Total Disc Replacement, 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 were pain, headaches, and muscle aches. There may be other risks associated with treatment using the ProDisc-C Total Disc Replacement.

Although many of the major risks are listed in this patient information brochure, a more complete list is provided in the physician's package insert, which your doctor has received. Please ask your doctor for more information about any additional risks possibly related to your planned surgery.

What can I expect before the surgery?

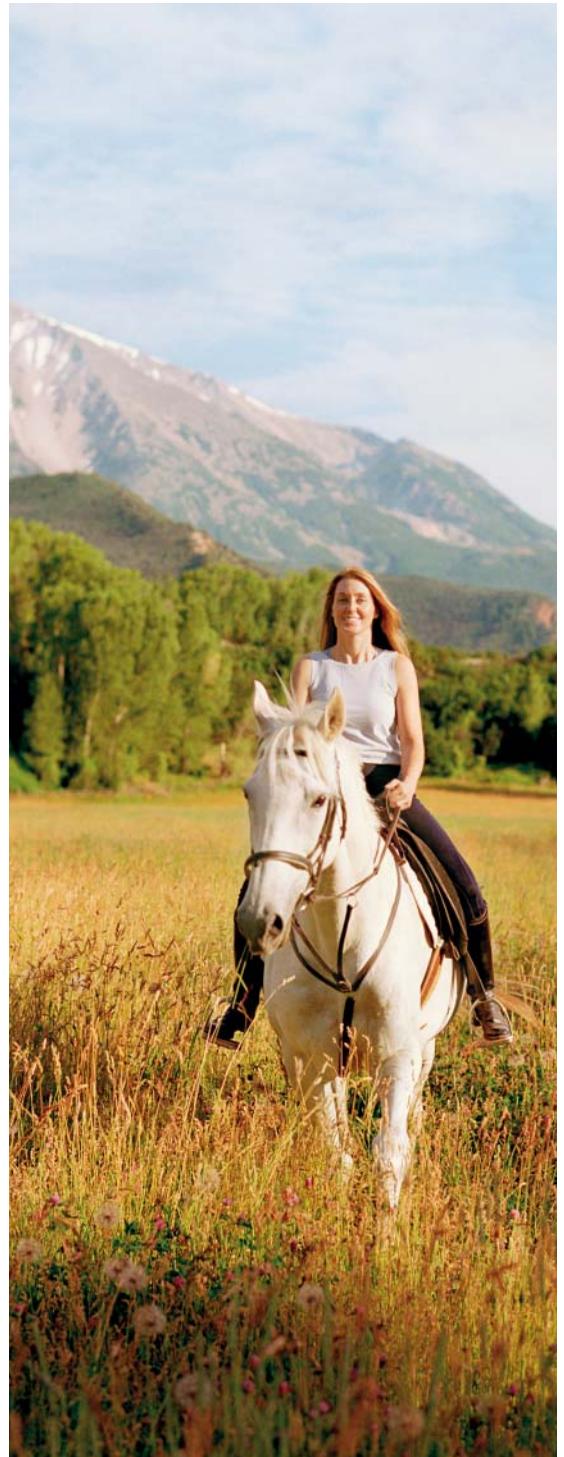
Your doctor will review your condition with you and explain what all of your possible choices are, including medications, physical therapy, and other surgeries such as removal of the diseased disc, fusion, etc.

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 to your unhealthy disc. Then the surgeon will remove the unhealthy disc. The surgeon will insert the ProDisc-C 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-C Total Disc Replacement is considered 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. On average, you should expect to stay in the hospital for a day or two.



Patient Information

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:

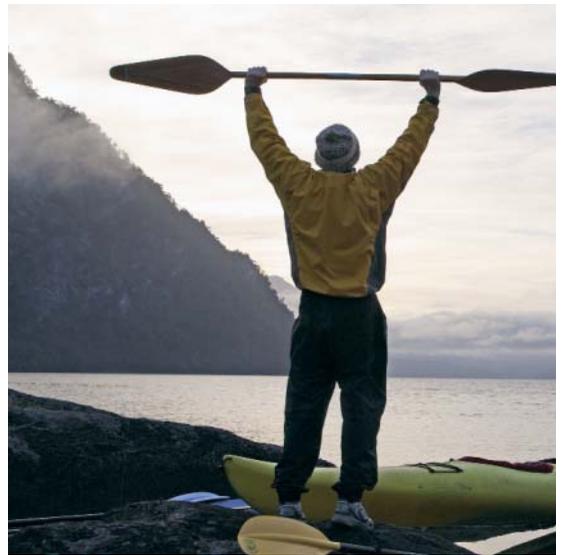
- have a fever
- notice fluid draining from your wound
- have trouble swallowing or breathing
- have trouble urinating
- have new or increased neck pain, arm pain, numbness, or weakness



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

What are the expected outcomes of the surgery?

The U.S. clinical study of the ProDisc-C Total Disc Replacement showed that ProDisc-C Total Disc Replacement 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 two years following surgery. The clinical benefit beyond two 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 candidate.

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.

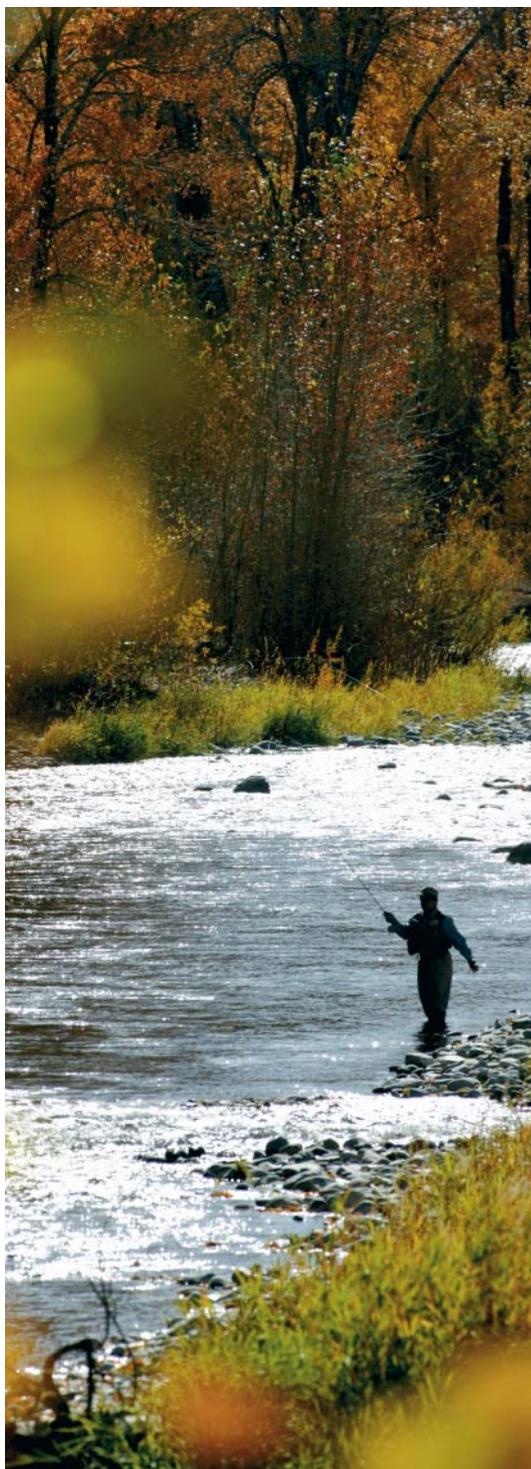
Conclusion

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-C Total Disc Replacement 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 brochure is not a replacement for professional medical advice. Only your doctor is qualified to diagnose and treat your neck and/or arm pain.

For information about obtaining insurance reimbursement for ProDisc-C Total Disc Replacement procedure, contact our **Patient Assistance Line (PAL) at 1-800-895-7764**.



Glossary

Alleviate	To make something less severe or more bearable, especially pain.
Degenerated	To fall below a normal or desirable state functionally, to decline in quality, to deteriorate.
Incision	During surgery, a cut into a body tissue or organ with a sharp instrument.
Intervertebral	Located between the spinal vertebrae.
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.
Lymph	A watery fluid derived from body tissues that contains white blood cells. Lymph acts to remove bacteria and certain proteins from the body tissues, transport fat from the small intestine and supply mature lymphocytes to the blood.
Lymphatic vessel	Any of the vascular channels that transport lymph throughout the lymphatic system, which is an interconnected system of spaces and vessels between body tissues and organs.
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. 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.

Glossary

Rehabilitation	To restore to good health or good condition through therapy and education.
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.
Ultra-High Molecular Weight Polyethylene	Hard plastic used between the metal endplates.

Limited Warranty and Disclaimer:

Synthes Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Warning: In the United States, this product has labeling limitations. See package insert for complete information.

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

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