

ProDisc-L Total Disc Replacement. Patient Information.



Patient Information

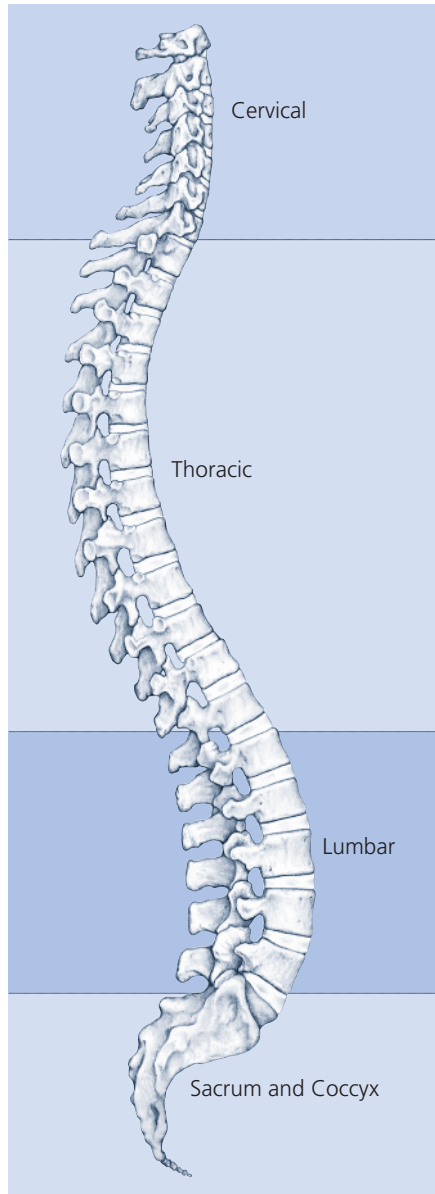
Introduction

After reviewing your history and x-rays, and taking into account the results of other diagnostic studies, your surgeon has decided that you need spine surgery. You have been provided this patient information brochure to assist you in making an informed choice regarding the treatment of your back pain with the ProDisc-L Total Disc Replacement from Synthes Spine.

Your spine 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.

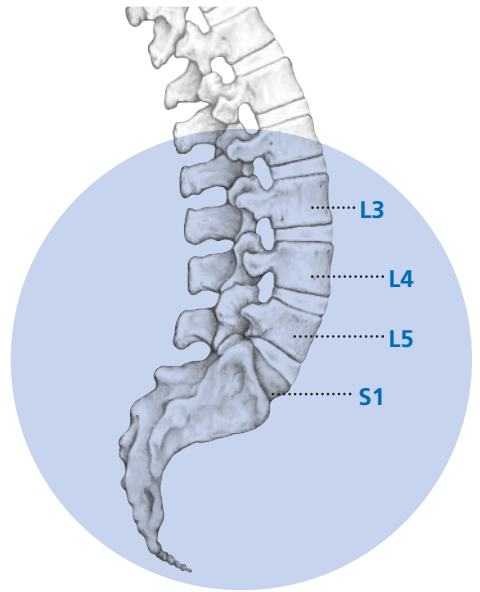


The vertebrae are separated by a cushioning disc. Passing through the hole of each vertebra is the spinal cord. The spinal cord contains nerves that carry signals from your brain to the rest of your body. Your spine protects your spinal cord from injury.

Diagnosis

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.

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 no longer function normally because of wear, or from being injured. This can cause pain that limits your ability to perform daily activities. Surgery for this condition may provide relief.



Patient Information

Treatment

You have been diagnosed with Degenerative Disc Disease and all the treatments you have tried so far have not made you feel better. Your surgeon believes that you may benefit from surgery. The traditional method of treatment has been spinal fusion. In spinal fusion surgery, the unhealthy 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. 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 the vertebrae surrounding the disc space are immobilized.



You have another option.

The ProDisc-L Total Disc Replacement is designed to replace your unhealthy disc.

The ProDisc-L Total Disc Replacement is a ball and socket implant consisting of two metal endplates and one plastic inlay. The plastic inlay snap-locks into the lower endplate and provides the ball that rides in the socket of the upper endplate that is intended to allow motion. There are also fins on the endplates that lock them into the vertebral bone.

There are several potential advantages associated with ProDisc-L Total Disc

Replacement over spinal fusion surgery. A United States clinical trial established that patients receiving the ProDisc-L Total Disc Replacement achieved pain relief equal to spinal fusion while maintaining some motion in their spine in many cases. It is believed that maintaining motion may allow your spine to remain healthier longer, but this has not been proven.

The ProDisc-L Total Disc Replacement surgery does not require a bone graft. This means that you may avoid the pain and healing time associated with the second incision that might be needed if you were to have a fusion procedure which required bone to be taken from your hip.

Making the Choice

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

- Must be suffering from Degenerative Disc Disease (DDD) at only one level between L3 and S1. DDD is defined as a disc that is worn out or has become injured and is causing pain. This determination is made based on history, physical examination and x-rays;



Patient Information

Making the Choice continued

- Should have had at least six months of conservative treatment without relief of symptoms (e.g., medications, physical therapy, etc.);
- Vertebrae must be dimensionally large enough to support the device;
- Must not have an active infection, either throughout your body or localized to your spine;
- Must have good bone quality (no osteoporosis or osteopenia);
- Must not be allergic to cobalt, chromium, molybdenum, polyethylene, titanium or tantalum;
- Must be old enough that the bones in your body are mature and no longer growing;
- Must not have spinal anatomy that would prevent implantation of the device or cause the device to be unstable in your body, as determined by your doctor.

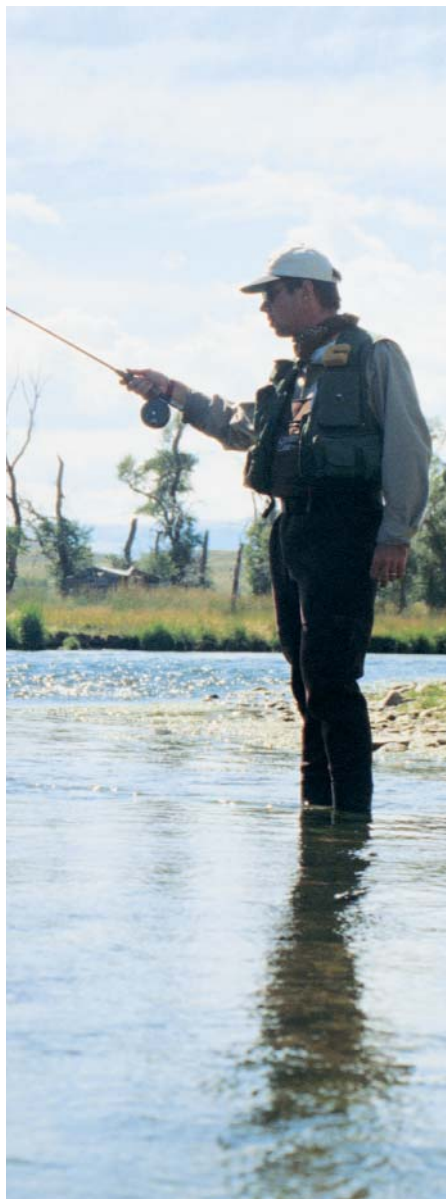
Your occupation or activity level, your weight, the condition of other levels of your spine, whether or not you are pregnant, and any allergies you have may influence whether you should have the ProDisc-L Total Disc Replacement surgery. If any of these factors apply to you or if you think that you have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

Surgery

During disc replacement surgery, you will be 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 surgeon will remove the unhealthy disc and replace it with the ProDisc-L implant.

After Surgery

Surgery with the ProDisc-L Total Disc Replacement 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 was about 3.5 days (range: 1.0–8.0 days). 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 normal activity. It is very important that you follow your surgeon's instructions. Try not to do too much, too soon.



Patient Information

After Surgery *continued*

Contact your doctor immediately if you:

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

Caution: Please be sure to tell your doctor that you had surgery with the ProDisc-L before you have a magnetic resonance imaging (MRI) taken. The metal in the ProDisc-L can affect the quality of the images taken.



Complications

As with any surgery, there are some possible complications that can occur when you have total disc replacement surgery with the ProDisc-L implant. Complications can occur singly or in combination and may include:

- Allergic reaction to the implant materials
- Bladder problems
- Bleeding, which may require a blood transfusion
- Blood clot (emboli) in the blood stream or lungs
- Death
- Difficulty with bowel movement or other problems with your bowels

Warning: Overloading of the spine by engaging in extreme activities (i.e., heavy weight-lifting) may result in failure of the implant.

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- Failure of implant/procedure to improve your symptoms and/or ability to function
 - Failure of incision to heal properly or other incision problems
 - Fracture of the vertebrae
 - Fusion
 - Implant failure (e.g., implants that bend, break, loosen or move)
 - Impotence or retrograde ejaculation
 - Infection
 - Injury to internal structures such as your kidney, ureter, bowel, blood vessels, or lymphatic vessels
 - Need for additional surgery which could include removal of the ProDisc-L implant
 - Pain or discomfort
 - Paralysis
 - Phlebitis (swelling of veins)
 - Pneumonia
 - Problems with your blood vessels other than bleeding
 - Seizures
 - Side effects from anesthesia
 - Spinal cord or nerve damage
 - Spinal fluid leakage
 - Spinal instability
 - Tears of the dura (a layer of tissue covering the spinal cord)
 - Wear debris (load-bearing implants that allow motion have been shown to potentially generate wear debris over time. Early and/or long-term effects of wear debris in the human spine are not yet known)

Patient Information

Information about the U.S. Clinical Study of the ProDisc-L Total Disc Replacement

The U.S. clinical study of the ProDisc-L Total Disc Replacement demonstrated that patients who received the ProDisc-L implant had improvement in function, which was the same as patients who had fusion surgery when evaluated two years after surgery. The rates of complications were approximately the same between the two groups. Ask your surgeon for more details about the clinical study and its results.



Conclusion

You have been diagnosed with Degenerative Disc Disease and your surgeon believes that you need surgery to make you feel better. You should carefully consider whether to have spine surgery. If you decide to have spine surgery, you should discuss all the available options with your surgeon.

The ProDisc-L Total Disc Replacement has been determined to be safe and effective in the treatment of Degenerative Disc Disease at one level in the lower back. Synthes Spine has provided this brochure 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.

Call Synthes Spine at 1-800-895-7764 or visit our website at www.synthesprodisc.com

This patient information brochure is not a replacement for professional medical advice. Only your surgeon is qualified to diagnose and treat your back pain.

You may wish to record important information regarding your ProDisc-L Total Disc Replacement.

Please ask your surgeon for this information.

Lot No.

Superior Endplate

Inlay

Inferior Endplate

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 U.S.A., this product has labeling limitations. See package insert for complete information.

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



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