



**Patient
Information**



Natural motion is back.

Charité
ARTIFICIAL DISC
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DePuySpine
a Johnson & Johnson company

Your surgeon has provided you with this patient information brochure to help you make an informed decision on your back surgery using the CHARITÉ™ Artificial Disc from DePuy Spine. Your surgeon has decided that you need spine surgery after carefully examining you, reviewing your history and x-rays, and taking into account the results of other diagnostic studies.

Your spine is an important structure in your body. It gives you support. It allows you to move and bend freely. Without it, you could not sit or stand up.

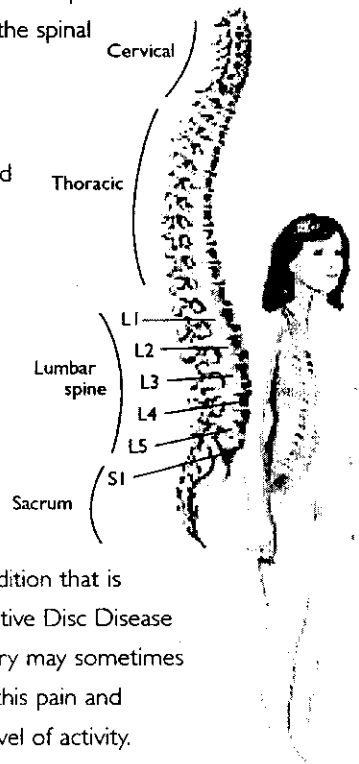
To provide support, your spine contains 24 small bones known as vertebrae. They are arranged in a column, stacked one on top of the other. The vertebrae protect and support the spinal cord, which houses many nerves.

Your spine has three main parts: the neck or cervical area, the central or thoracic area, and the lower back or lumbar area.

Doctors number the bones in the lower back (lumbar spine) L1, L2, L3, L4, and L5 and S1 in the sacrum.

Soft discs between each bone allow your back to move and bend. When the discs wear out or are injured, they cannot function normally and may cause pain or limit your daily activities. This can produce a condition that is

called Degenerative Disc Disease or DDD. Surgery may sometimes help to reduce this pain and restore some level of activity.



WHAT are the surgical options?

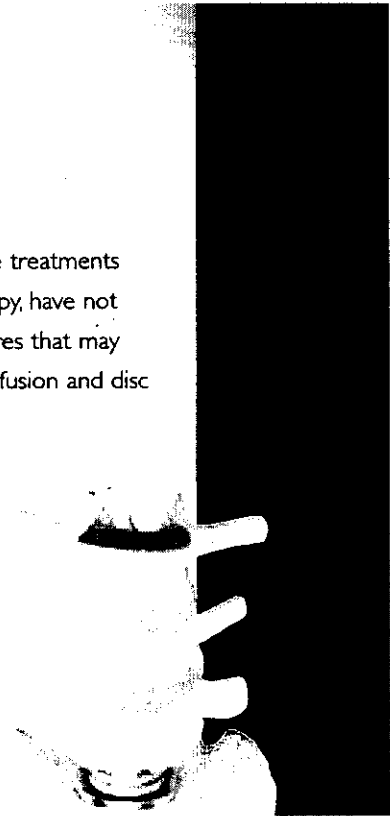
If your surgeon tells you that you have DDD and conservative treatments such as pain medication, use of a back brace, or physical therapy, have not made you feel better, there are two types of surgical procedures that may help to reduce your pain and restore activity. These are spinal fusion and disc replacement. During a spinal fusion surgery, the surgeon will remove the disc and pack bone graft into the space between the two vertebrae and along the back of the vertebrae. As you heal, the bone graft helps to create a solid bony bridge across the disc space connecting the two vertebrae. During disc replacement surgery, the surgeon will remove the disc and replace it with an artificial disc.

WHAT is the CHARITÉ Artificial Disc?

The CHARITÉ Artificial Disc is a three-piece medical device consisting of a sliding core sandwiched between two metal endplates. The sliding core is made from a medical grade plastic and the endplates are made from medical grade cobalt chromium alloy. These materials usually do not harm the human body and are used in many other medical implants such as total knee replacement implants.

WHAT are the benefits of disc replacement surgery?

There are many potential benefits of disc replacement surgery with the CHARITÉ Artificial Disc over spinal fusion surgery. Laboratory testing shows that the CHARITÉ Artificial Disc design allows your spine to move. In the clinical study, patients were observed to have motion between 0 and 21 degrees in flexion/extension (bending forwards and backwards). When a fusion surgery is performed, although your pain symptoms may go away, the vertebrae surrounding the disc space are immobilized.



The CHARITÉ Artificial Disc implanted in the spine.

Another benefit to disc replacement surgery with the CHARITÉ Artificial Disc is that no bone graft is required. Often times with spinal fusion surgery, the bone graft used to pack the disc space is bone that the surgeon has taken from the patient's hip. This means that the patient has two incisions that must heal as well as pain in the hip and back during recovery from surgery.

WHO is a candidate for the CHARITÉ Artificial Disc?

The CHARITÉ Artificial Disc is an alternative to spinal fusion for patients that have one diseased disc (DDD) between L4 and L5 or between L5 and S1. DDD is defined as a disc that has worn out or become injured and causes back pain. The disc deterioration is confirmed by history and x-rays.

Patients with DDD whose vertebrae (bones) have moved less than 3mm (0.12in) may still receive the CHARITÉ Artificial Disc. Patients receiving the CHARITÉ Artificial Disc should have had at least six months of treatment such as pain medication, a back brace, or physical therapy.

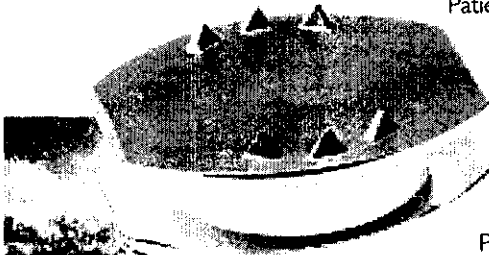
Patients who have had some types of minor lower back surgery may still receive the CHARITÉ Artificial Disc.

Ask your doctor if you are a candidate for the CHARITÉ Artificial Disc.

WHO should not receive it?

The CHARITÉ Artificial Disc should not be used if:

- you have either an infection throughout your body or localized to your spine; or,
- you have disc deterioration or instability at more than one spinal level; or,
- if you have poor bone quality (osteoporosis or osteopenia).



Your occupation or activity levels, 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 surgery with the CHARITÉ Artificial Disc. If any of these factors apply to you, please discuss them with your doctor.

WHAT happens during the surgery?

When undergoing surgery with the CHARITÉ Artificial Disc, you will be lying on your back and the surgeon will operate on your spine through an incision near the belly button. During the disc replacement surgery, the surgeon will remove the diseased disc and replace it with the CHARITÉ Artificial Disc.

There are alternative treatments to this surgery. You should discuss these other possibilities with your surgeon before you make your decision.



WHAT should I expect after surgery?

After your surgery with the CHARITÉ Artificial Disc, it is important that you follow your surgeon's instructions for recovery. Make sure you get and keep your surgeon's name and telephone number.

In most cases, immediately after surgery, your heart and lung function will continue to be monitored, and your doctor will prescribe medicines to control pain and nausea. The average hospital stay for disc replacement surgery patients in the study for the CHARITÉ Artificial Disc was about four days. A nurse will show you how to care for your wound before you are sent home, and your doctor will discuss a program to gradually increase your activity. It is possible that you will be asked to wear a back brace or elastic bandage to support your abdominal muscles after surgery.

Contact your doctor immediately after surgery if:

- you get a fever
- the wound starts leaking fluids
- you have trouble swallowing or breathing
- you have trouble urinating
- you have new or increased back or leg pain or numbness

WHAT possible complications could occur?

As with any surgery, there are some possible complications that can occur when you have disc replacement surgery with the CHARITÉ Artificial Disc. 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
- death
- implants that bend, break, loosen or move
- infection
- pain or discomfort
- paralysis
- side effects from anesthesia
- slow movement of the intestines
- spinal cord or nerve damage
- spinal fluid leakage
- the need for additional surgery
- tears of the dura (a layer of tissue covering the spinal cord)
- problems with your blood vessels other than bleeding
- incision problems



WHAT other information is important to know?

The U.S. clinical study of the CHARITÉ Artificial Disc from DePuy Spine has demonstrated that patients who received the CHARITÉ Artificial Disc had pain relief and restored function no worse than patients who had fusion surgery two years after the surgery. The rates of complications were about the same between the two groups. Disc patients had a higher rate of incision infections, and fusion patients had a higher rate of pain at the site where bone graft was taken. Ask your surgeon for more details about the clinical study and its results.

DePuy Spine hopes that this patient information brochure has given you the information that you need in order to make an informed decision about your treatment options. If you have any questions or would like additional information about artificial disc surgery, please call or see your doctor.

For more information visit our website at:

- or call DePuy Spine at 1-866-DISC-523 (1-866-347-2523)
- www.allaboutbackandneckpain.com
- www.charitedisc.com

This patient information guide is not designed as a replacement to professional medical care or advice. Only your surgeon is qualified to diagnose and appropriately treat your back pain and related problems.





You may wish to record important information regarding your CHARITÉ Artificial Disc. Please ask your surgeon for this information.

Lot #

Endplate _____

Sliding Core _____

Endplate _____

LIMITED WARRANTY AND DISCLAIMER: DePuy 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 USA, 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 or experience.

DePuy Spine is a joint venture with Biedermann Motech GmbH.

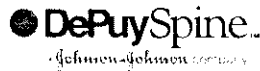
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www.allaboutbackandneckpain.com

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