Patient Information

Spinal Fusion Using the ST360°[™] or Silhouette[™] Pedicle Screw System





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Your doctor has recommended spinal fusion surgery using a pedicle screw system to correct a problem with your spine. The goal of spinal fusion surgery is to provide relief from the pain you've been having and make your spine more stable. After surgery, your ability to move should improve, and you can get back to doing the daily activities you may have been missing.

This brochure will help you understand:

- The healthy spine
- Problems of the back including degenerative disc disease
- Non-surgical and surgical treatments
- Fusion surgery and how pedicle screw systems, like the ST360°™ and Silhouette[™] Systems, work
- What you can expect before and after surgery

A glossary is also provided to help you become familiar with medical terms your doctor may use to describe your condition and treatment.

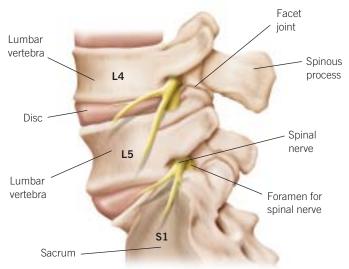


Illustration A. Normal Spine (side view)

Vertebrae are identified by number within its region of the spine. Discs form a jelly-like cushion between the vertebrae in the lumbar region of the spine.

The Healthy Spine

The **spine** is one of the most important structures in the human body. It supports much of the body's weight and protects the spinal cord, which carries communication from the brain to the rest of the body. The spine is strong but flexible, allowing a wide range of movements.

The spine extends from the base of the skull to the tailbone, and is made up of 33 bones, known as the **vertebrae**.

The first seven vertebrae are in the neck, or cervical region. The next 12 vertebrae have the ribs attached, protecting the heart and lungs. These are

called the thoracic vertebrae. Next is the low back area, called the lumbar region, which contains five vertebrae.

The remaining nine vertebrae are in the last two regions of the spine, the sacrum and the coccyx.

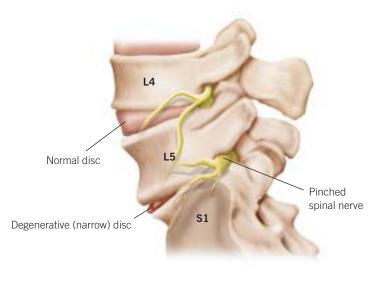
The vertebrae in the cervical, thoracic and lumbar regions are separated by **discs**. Discs serve as cushions between the vertebrae and help to protect the vertebrae and the nerves that run from the spinal cord to the rest of the body (see Illustration A).

The vertebrae in the sacrum and coccyx are fused segments, which means they do not have discs between them.

Problems of the Back

It is estimated that 80% of Americans have low back pain at some time in their lives. Most back pain is acute, meaning that it occurs for a short time and then heals. In some cases, however, the pain and symptoms can last for months or keep coming back; this is considered a chronic, or long-term, problem and requires a doctor's care.

Because the spine is so important for support and movement, a problem with the spine can disrupt even the simplest activities of life. Illustration B: Degenerative Disc Disease in the Lumbar Spine (side view)



When a disc degenerates, the space between the vertebrae narrows. This narrowing can pinch the nerves and cause pain.

Conditions of the Spine

There are a number of conditions that can cause pain and affect movement, including spinal **stenosis**, **scoliosis**, tumor, infections, fractures and **degenerative disc disease**. People with low back conditions may have symptoms such as pain or numbness that travels down one or both legs, weakness in their leg muscles, and problems or pain when they urinate. The pain often occurs when the nerves that run through the spine become pinched.

Degenerative Disc Disease

Degenerative disc disease (DDD) is one of the common causes of back pain. As people age, the discs can lose their elasticity, flexibility, and their ability to serve as shock absorbers for the spine.

DDD happens when the soft center of the disc dries out and shrinks. This narrows the openings through which the nerves run, pinching the nerves between the vertebrae (see Illustration B). Most people have very few problems when this happens. But for others, the pressure on the nerves is very painful.

People with degenerative disc disease may have symptoms that include back pain, leg pain and weakness in their legs.

Treatments

There are many treatments for spine conditions and degenerative disc disease. You may have already tried some or all of the non-surgical treatments, and they may have helped you for a time. Non-surgical treatments include rest, ice or heat, medication, steroid injections, exercise and physical therapy.

If these non-surgical treatments don't bring relief after a period of time, you and your doctor may decide that a surgical treatment, called **spinal fusion surgery**, may be right for you.

Spinal Fusion Surgery

Spinal fusion surgery takes pressure off of the nerves that are causing pain. This is done by restoring the alignment of the spine or the space between the vertebrae, and then stabilizing and fusing the spine. A spinal **fusion** is when bone grows between the vertebra, stopping any motion in the area, which reduces pain.

Depending on the condition of the spine, the doctor may use an anterior approach, which means the **incision** will be in the abdomen, or a posterior approach, which means the incision will be in the back. Sometimes the doctor may choose to use a combination of the two.

If the doctor uses a posterior approach, then a **pedicle screw system** is used to stabilize the spine while it fuses and heals. The pedicle screw system may be used alone or it can be combined with another stabilizing device.

During surgery, the doctor may relieve the nerve compression by removing the disc (called a **discectomy**). The doctor may also relieve pressure on the nerve by trimming or removing the roof, or lamina, of the vertebra to create more space for the nerve (called **laminectomy**).

The doctor then restores the space around the nerves and prepares to stabilize the spine with the pedicle screw system. There are a number of components in a pedicle screw system, and the doctor will choose the ones that will work best for your spine.

Illustration C: Pedicle Screws in a Lumbar Vertebra (top view)

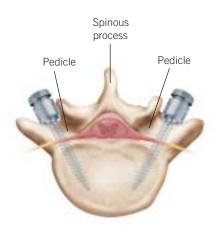
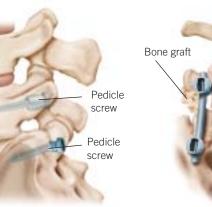


Illustration D: Pedicle Screws in the Lumbar Spine (side view)

Illustration E: Rods Connecting Pedicle Screws (back view)





A rod is placed between the screws on each side of the vertebrae to stabilize the spine. Bone graft is placed between and/or along the sides of the vertebrae.

A screw is placed on each side of the vertebra, in an area called the pedicle. Screws are placed in the vertebrae above and below the damaged disc. Often, a stabilizing device, made from bone or metal, is placed between the vertebrae to stabilize the spine.

The screws are placed through each side of the vertebrae in the part of the bone called the **pedicle** (see Illustrations C and D).

Rods are then attached to connect the screws and hold the spine in its restored position (see Illustration E). The pedicle screw system is now secure.

In the last step of the surgery, the doctor places **bone graft** (small chips of bone) alongside of the vertebrae to be fused or puts the graft in and around a device that's placed between the vertebrae (see Illustration E). Bone graft can come from either the patients' hip bone or from a **bone bank**, or from a combination of both.

Spinal Fusion

Stabilizing device

The pedicle screw system will hold the spine stable until the bone graft fuses with the vertebrae. Although bone fusion is a natural biological process, complete fusion can take up to one year (see Illustration F).

In some cases, people may have trouble fusing their spine. Many things, such as smoking or various medications, can interfere with successful fusion. Follow your doctor's advice to help increase your chances of proper final fusion. Your doctor will discuss with you the risks associated with your specific surgery. **Illustration F:** Spinal Fusion (side view)



Bone graft grows over time, fusing the vertebrae together and providing long-term stability.

What to Expect Before and After Surgery

Before Surgery

There are a few things you can do to prepare yourself for spinal fusion surgery. Eating well-balanced, nutritional meals in the weeks before surgery will help your body as it heals. If you smoke, quitting in the weeks before surgery is also helpful. Your doctor will tell you any other things you need to know that will help you prepare for surgery.

After Surgery

Recovery from spinal fusion surgery happens in stages as your body heals. The first stage of recovery involves the healing of the incision and soft tissues. This will happen over the first few weeks. Movement, such as walking, does a lot to help with healing. You can expect to be doing some walking as soon as the day after surgery, and you'll be expected to walk every day after that. Your doctor may also have you go to physical or occupational therapy for gentle exercise in the early weeks of recovery.

Your doctor will monitor and evaluate the bone fusion throughout your recovery. This will mean visits to the doctor's office, where x-rays will be taken to see how the bone is fusing. Your doctor will tell you what things you can do to help your recovery. It's common to have pain in both your back and your hip for a period of time after surgery. Your doctor will be able to help you manage the pain with medication. Be sure to talk to your doctor if you are having pain that is more than you were told to expect.

Most people can return to work and to many of their daily activities within six weeks of surgery. Complete fusion takes months, and recovery is different for each patient. Depending on how many levels of your spine are fused, you may notice some changes in the flexibility of your back. Your doctor will tell you what you can expect during your recovery.

Spinal fusion surgery using a pedicle screw system is designed to stabilize your spine, giving you the ability to move more easily and with less pain. For most people, spinal fusion surgery offers significant relief and improved ability to move and function in their daily lives.

Symptoms To Watch For After Surgery

As your doctor will explain, any surgery involves risk. After surgery, if you have any of these symptoms, you should contact your doctor:

- Signs of infection (fever, chills, redness around the incision, increased pain, a feeling of pressure in the spine)
- Bleeding or excessive drainage from the incision
- Sudden pain, or a significant increase in your pain level
- Loss of feeling in your hands or feet
- Increased or ongoing shortness
 of breath

This brochure is meant to help you understand spinal fusion surgery and pedicle screw systems like the ST360° and Silhouette Systems, so you can work with your doctor to make the treatment decision that is right for you. If you have any questions, please talk to your doctor.

Glossary

Bone bank: a laboratory where allograft bone (see bone graft) is stored for use in surgery.

Bone graft: there are two kinds of bone grafts. Autograft bone is bone that is harvested from one place in a person and then transplanted to another location in the same person. Allograft bone is bone donated from one person and harvested, processed, stored and then transplanted to another person.

Degenerative disc disease (DDD): loss of elasticity and flexibility of the disc. Although it can happen quickly, most DDD develops over time due to use or misuse.

Disc: a fluid-filled, jelly-like cushion between the vertebrae of the spine. Each disc is identified by the vertebrae that surround it. For example, the L4-5 disc is the disc between the L4 and L5 vertebrae. **Discectomy:** a surgical procedure that involves removing damaged disc material from between the vertebrae.

Fusion: the joining or healing of bones.

Incision: a cut made through the skin and into the body during surgery.

Laminectomy: a surgical procedure that relieves pressure on the spinal nerves by trimming or removing the lamina (roof) of the vertebra to create more space.

Pedicle: a stem-like area on the back of the vertebra that connects the main part of the vertebra to the structures (e.g. the lamina) that project from it. Each vertebra has two pedicles.

Pedicle screw system: a system of screws and rods that holds the vertebrae stable until fusion occurs. **Scoliosis:** a condition in which there is a sideways curve to the spine.

Spinal fusion surgery: a procedure to restore and maintain the space between the vertebrae by stabilizing the bones until they can grow together.

Spine: the bony column from the base of the skull to the tailbone. The structure is made up of vertebrae and contains five regions: the cervical, thoracic, lumbar, sacrum and coccyx.

Stenosis: a general term used to describe a condition in which the spinal canal narrows and presses on the nerve.

Vertebra (Vertebrae): one of 33 bones that form the spine. Each vertebra is identified by number within its region of the spine. For example, L1 is the first vertebra in the lumbar region.



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