

VertiFlex®

Superion® InterSpinous Spacer



Caution: Federal Law restricts this device to sale by or on the order of a physician.

This brochure will provide you with information about the Superion® InterSpinous Spacer, a new treatment for moderate lumbar spinal stenosis.

Your doctor will answer any questions you have regarding moderate lumbar spinal stenosis and the Superion® Spacer as a treatment for you.

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INTRODUCTION

Now that you have completed at least 6 months of nonsurgical treatment with no relief from your moderate lumbar spinal stenosis symptoms, your doctor has reviewed your medical history, x-rays, and other tests. Your doctor has advised that you should consider surgery to relieve your leg pain. This brochure can help you make a better choice on how to treat your pain.

WHAT IS THE SUPERION® SPACER?

One surgical option your doctor may offer is the Superior® InterSpinous Spacer (Superion® Spacer). The Superior® Spacer (please see Figure 1 below) is made of a mixture of metal elements (titanium alloy). This implant fits between the bones (spinous processes) in your lower back. These are the bony structures located in the back of the spine. These bones can be felt by placing your fingers down the center of the back. The Superior® Spacer may help relieve your symptoms by limiting movement of your spine that may be causing your symptoms. This may help reduce the pain in your back, groin, or legs. Devices made from metal mixture (alloy) are often used in bone procedures in the body.



Figure 1: The completely open (deployed) Superior® Spacer viewed from above. (A 10¢ coin is shown for scale.) The implant fits between the bones (spinous processes) and the wings are designed to keep the implant from moving.

A clinical study evaluated the Superior® Spacer. The study was done in thirty-one (31) hospitals across the United States. 391 patients were in the study. Some patients got the Superior® Spacer. The rest of the patients got the control device. The control device is FDA approved. You will learn more about this study in the rest of this brochure.

Once placed, the Superior® Spacer rests between two bones (spinous processes), as shown below in Figures 2 and 3.

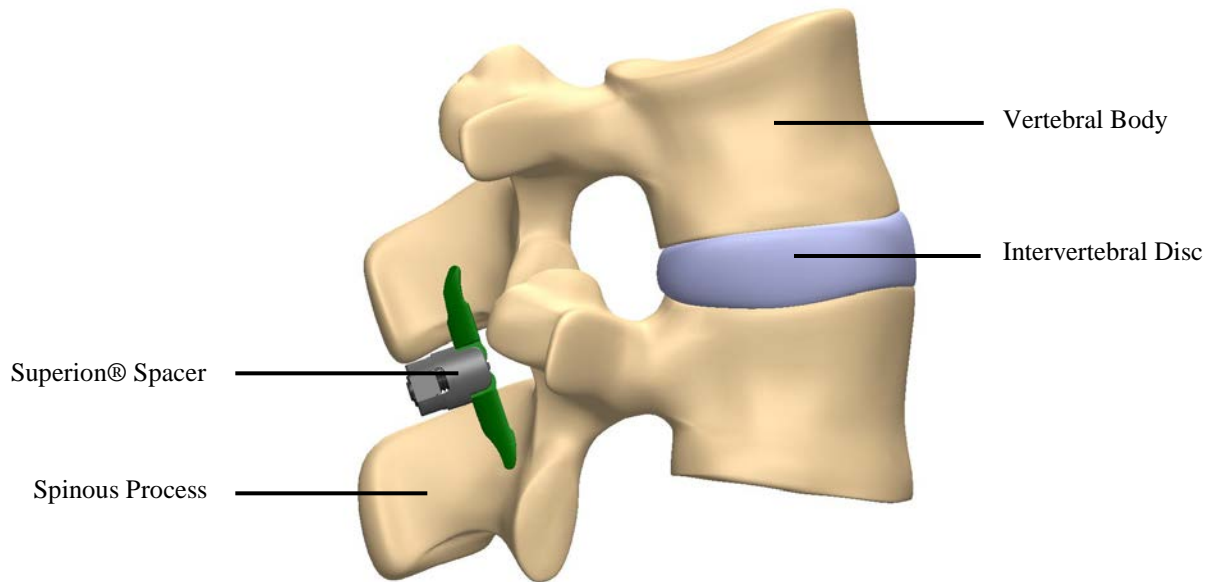


Figure 2: Superior® Spacer shown implanted in the spine viewed from the right side

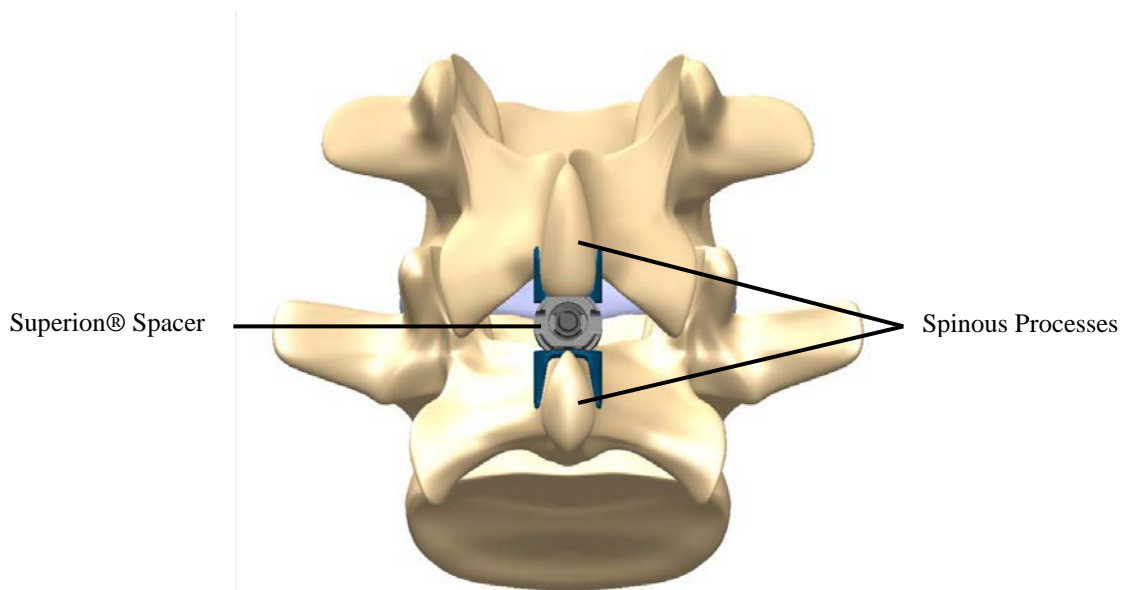


Figure 3: Superior® Spacer shown implanted in the spine viewed from the back

WHAT IS SPINAL STENOSIS?

Spinal stenosis is a narrowing of the passageways in the spine. These passageways contain the spinal cord and nerve roots. This narrowing can be caused by a few things. These include thickening of tissue (ligaments) that connects two bones, bulging of discs between the bones, or overgrowth of bone. The spinal cord and the nerve roots that exit the spinal canal can become pinched. This can cause pain, numbness, tingling and/or weakness in the back and legs. This

pain is usually more noticeable when you walk. This pain is lessened when you bend forward or sit. Refer to Page 12 of this brochure for additional information about spinal stenosis.

WHAT ARE MY TREATMENT OPTIONS?

There are ways to treat your moderate lumbar spinal stenosis. Some are:

- Non-surgical ways
 - Your doctor can inject you with a drug (steroids) to lower swelling and treat pain in your hips or down the leg. Pain relief from this treatment may not last long. You should not have more than three injections in a six month time.
 - You can rest and reduce your activity level.
 - You can take physical therapy and exercise.
 - You may be prescribed pain medications.
- Surgical ways
 - Decompression surgery only. This surgery removes the bone and other tissues around your nerves causing the pain. This surgery helps relieve pressure on your spinal cord and nerves.
 - Implantation of a device that goes between the bones in your back (spinous processes) like Superior® or other commercially available interspinous distraction devices. No surgical decompression is used in this surgery.
 - Decompression surgery with spinal fusion. In spinal fusion, decompression surgery is first performed to remove the bone and tissue that is causing the pain. Your doctor then puts some of your bone (bone graft) between two bones (usually vertebrae) in the area of the decompression surgery. The bone graft is usually either spinal bone removed during the decompression surgery or bone from your hip removed through a separate cut. The purpose of the bone graft is to cause new bone to grow between the two bones to “fuse” them. This is supposed to stop motion in that portion of the spine that may be contributing to your symptoms. Your doctor also uses screws and rods to hold the bones in place. The rods and screws are usually left in your spine unless a problem happens later. If a problem happens with the rods and screws, they are removed or replaced surgically.

Discuss your options with your doctor and select the treatment method that best seems to meet your current pain level and lifestyle.

ARE YOU A CANDIDATE FOR THE SUPERION® PROCEDURE?

To be a candidate for treatment with the Superior® Spacer:

- You must have pain, numbness, and/or cramping in the legs related to moderate lumbar spinal stenosis in your lower back. One sign of having spinal stenosis is that it is hard to walk a long way, such as ½ mile, without symptoms. Another sign is pain in your lower

back, groin, and/or legs while standing. This pain goes away or is relieved when you bend forward.

- You must have been treated by a doctor for at least 6 months with “non-surgical treatments” with no relief from your symptoms. These treatments are described below in ‘What Are My Treatment Options?’.

WHO SHOULD NOT HAVE THE SUPERION® SPACER? (CONTRAINDICATIONS)

- Tell your doctor if you have been told you have abnormal curvature of your back (scoliosis) or have had fractures in your bones (spinous processes). The Superior® Spacer may not function properly if you have been diagnosed with scoliosis or spinous process fractures. You may need other surgery to relieve your pain. Your doctor should not implant this device if you have scoliosis or spinous process fractures. (The Superior® Spacer is not allowed for use in patients with abnormal back curvature or instability)
- Tell your doctor if you have ever had a broken bone. Tell your doctor if you have problems with bone density (osteoporosis). These conditions may lead to more bone fractures in your back.
- Tell your doctor if you already had a fusion or decompression surgery in the same place in your lower back.
- Tell your doctor if you think you have an infection. An infection makes it risky to have the Superior® Spacer. You might need another surgery to remove it because infections near the implant are hard to treat. Your doctor should not implant this device in you if you have an infection. (It is not allowed for use in patients with infections).
- Tell your doctor if you think you have ever had any allergy to or reacted to any metal or an implant. The Superior® Spacer is made from a metal mixture (titanium alloy). You could be allergic to it. An allergic reaction to the Superior® Spacer might mean you would need more surgery to remove it. Your doctor should not implant this device in you if you might be allergic to it. (It is not allowed for use in patients who are allergic to titanium or titanium alloy.)
- Tell your doctor if you have ever had a problem with going to the bathroom due to your back pain or weakness in your legs. Tell your doctor if you have had a recent problem with sexual dysfunction that has come on suddenly. These events may be symptoms of *cauda equina* syndrome. This is a severe spinal nerve compression that causes loss of bowel or bladder function, loss of sensation in the buttocks and groin, and/or weakness in the legs. Your doctor should not implant this device if you have *cauda equina* syndrome. (The Superior® Spacer is not allowed for use in patients with *cauda equina* syndrome.)
- Your doctor may not use the Superior® Spacer if your “Body Mass Index” (BMI) is too high. BMI is related to your height and weight.

WHAT WARNINGS SHOULD I KNOW?

Do not do any strenuous physical activity for 6 weeks after your surgery. Examples of strenuous physical activity include lifting more than 10 pounds, aerobic dancing, and jumping rope. Do not play sports until your doctor tells you that you can. Sports include swimming, golf, tennis, racquetball, running, and jogging, among other activities. Your Superior® Spacer may move or break part of your spine if you are too active too soon after surgery. This could cause pain. You could need more surgery. Each patient is different. Ask your doctor what it is acceptable for you to do after surgery.

Tell your doctor after surgery if you have fluid leaking from your cut, redness around your cut, or separated edges at the site of the cut. These problems can lead to serious infection. The problems could require more surgery if your doctor does not treat them. You may need to ask another person to look at your cut to see if it is leaking, if there is redness around your wound, or if the edges of the skin around the wound are separated.

Tell your doctor as soon as possible after your surgery if you have pain or swelling in your back, or if you feel numbness in your legs or buttocks. These symptoms can be a sign that the Superior® Spacer is not working properly. You may need more surgery.

If you fall, tell your doctor. A fall may hurt you seriously or cause the Superior® Spacer to move.

WHAT ARE PRECAUTIONS FOR THE USE OF THE SUPERION® SPACER?

Follow all of your doctor's instructions after your surgery. This will help you recover better. Each patient is different. Your doctor will know what's best for you. If you don't do what your doctor says after surgery it may delay your recovery and cause you more pain.

If a doctor sends you to have an MRI (Magnetic Resonance Imaging) exam, tell him or her you have a Superior® Spacer. This is important because there are special instructions for an MRI on someone with an implanted Superior® Spacer. You will be given a patient information card to carry.

A fracture to the bone in your lower back (spinous process) may happen if you are very active right after surgery.

This is an important surgery. Your physician should have a lot of training with the surgery and Superior® Spacer.

There are some things on your X-ray that should be seen by your physician if the Superior® Spacer is used. Please talk to your physician about your X-rays.

Not all patients with moderate lumbar stenosis were studied. The following patients were not in the Superior® Spacer study:

- Patients with low back pain but no leg pain,
- Patients with stenosis at more than 2 levels,
- Patients who already had surgery on their lower back,
- Patients with nerve diseases,
- Patients with bone diseases (Paget's disease),
- Patients with bone tumors,
- Patients who were very obese,
- Patients who were pregnant,
- Patients with permanent damage to their nerves,
- Patients with low blood flow to heart (angina),
- Patients with rheumatoid arthritis,
- Patients with diseases in their blood vessels,
- Patients with advanced diabetes,
- Patients with other diseases that made it difficult to walk.

WHAT PROBLEMS HAPPENED FROM SUPERION® SURGERY? (RISKS)

Some of the most common adverse events at 3 years in this US clinical study and the rates in the Superior® device patient group were:

Risks Related to Surgery Seen Before 3 Years After Implant		
Hazard	Harm	How Often this Hazard Harmed Them
Fracture, damage or remodeling of nearby anatomy, including bony structures or soft tissues during or after surgery	Spinous process fracture	18 of 190 patients
Tears in the tissue surrounding and protecting the spinal cord (dural leaks)	Dural leaks	3 of 190 patients
Fever or infection	Infection	2 of 190 patients
Instruments used during surgery may break or not work properly which may cause damage to the operative site or nearby bones or soft tissue	Implant sinks into bone (subsidence)	2 of 190 patients
	Unintentional bending of the device during surgery preventing device placement	1 of 190 patients
	Device moved from position in spinous processes (dislodgement) so device no longer between bones	1 of 190 patients
	Device moved from correct alignment (migration) so not in the right place	1 of 190 patients
Loss of bladder and/or bowel functions	Genital and urinary organs (genitourinary) do not work normally	1 of 190 patients
New or worsened back or leg pain	Back pain	1 of 190 patients
	Leg pain	1 of 190 patients
Reactions to the drugs or anesthesia (the medicine they used to put you to sleep) used during and after surgery	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Surgery at the wrong side or level	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Blood loss, blood vessel damage, inflammation of the blood vessel in your leg (phlebitis) or a localized collection of blood outside the blood vessels (hematoma)	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	

Blood transfusion (blood is given to you through an IV to replace blood lost during surgery) which may cause failure of your circulation, blood type mismatch and problems, damage to your kidneys, or cause you to get hepatitis or infection with HIV	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Heart attack (myocardial infarction)	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Stroke	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Blood clot formation in one or more of the deep veins in your body (deep vein thrombosis), abnormal collection of fluid in the lungs (pulmonary embolism), or blood clot (thrombosis) formation in other vessels	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Lung infection (pneumonia)	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Injury to muscle, soft tissues or nerves	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Wound swelling, draining or delayed healing	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Discomfort or need for rehabilitation or physical therapy associated with recovery from surgery	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Inability to perform certain tasks, such as lifting, exercising etc.	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.
Death	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.

Risks Related to Device Use Seen Before 3 Years After Implant		
Hazard	Harm	How Often this Hazard Harmed Them
Additional surgery to remove or replace the implant due to more leg, butt, groin, and/or leg pain, or extra bone growth.	Device removal and decompression	26 of 190 patients
	Device removal and fusion	13 of 190 patients
	Supplemental decompression	4 of 190 patients
	Fusion (no device removal)	3 of 190 patients
	Irrigation & debridement and device removal	1 of 190 patients
	Device removal	1 of 190 patients
Fracture of the part of your spine that you can feel through the skin on your back (spinous process)	Spinous process fracture	16 of 190 patients
Movement of the implant from the original position so that it becomes ineffective or causes damage to nearby bony or soft tissues including nerves	Implant sinks into bone (subsidence)	4 of 190 patients
	Device moved from correct alignment (migration) so device not in right place	1 of 190 patients
	Device moved from position in spinous processes (dislodgement) so device no longer between bones	1 of 190 patients
Implant may break during surgery	Unintentional bending of the device during surgery preventing device placement	1 of 190 patients
Pain and discomfort associated with the operative site or presence of implants	Back pain	1 of 190 patients
	Leg pain	1 of 190 patients
Implant may loosen, wear out, change shape permanently (deform), break or disassemble which may require another operation to remove the implant and may require another method of treatment	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Sensitivity or allergy to the implant material	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Poor positioning of the implant	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Wearing of the implant material against bone or another part of the implant that creates very small particles	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Scar tissue may form at the implant site	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	
Other unexpected reactions	We did not see anyone harmed like this in our study of 190 patients, but this harm is possible.	

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The information in these tables is based on the first 3 years of study. It is unknown what adverse events may develop after 3 years. It is also unknown how many subjects may develop them. In this study, we did not observe some adverse events we thought were possible. The harm possible from them and their frequencies are unknown based on this clinical trial. It is unknown whether they will happen and how often they will happen with more widespread use of this device.

HOW HAVE WE TESTED THE SUPERION® SPACER IN CLINICAL TRIALS?

The Superior® Spacer is designed to keep your spine positioned so that when you stand upright the nerves in your back will not be pinched or cause pain. In addition, the Superior® Spacer is intended to allow you to continue to move your back more than with a fusion surgery. You should not need to bend forward to relieve your pain with the Superior® Spacer in place.

A controlled research study tested the Superior® Spacer. The study happened in thirty-one (31) hospitals across the United States. Patients had moderate lumbar spinal stenosis, similar to you. Doctors treated these patients for at least 6 months by to relieve their pain without surgery. The patients did not get better, so they entered the study. Study patients received the Superior® Spacer or a control (X-STOP®) device. The control device is already approved. Patients did not know which treatment they would get before surgery. 391 patients entered this study. 190 patients received a Superior® Spacer. 201 patients received an X-STOP® device. The study results were reported to the U.S. Food and Drug Administration (FDA).

In the clinical study, 81 out of every 100 Superior® patients had significant pain relief at two years after treatment. These results are based on information reported by the patient about their back and leg pain. In addition, Superior® Spacer study patients lost less blood during the implant surgery than X-STOP® subjects. 51 out of every 100 patients were study successes when treated with the Superior® Spacer. A study success meant the patient had pain relief, did not require more surgery or treatments, and did not have movement of the device from the correct position and alignment or bone (spinous process) fracture. 48 out of 100 patients were study successes when treated with the X-STOP® device. The study showed that the Superior® device was just as effective and safe as the X-STOP® device. We did not directly compare the Superior® Spacer to any other treatment method. The clinical study was not meant to look at the benefit of treatment beyond two years after surgery for FDA approval. However, patients in this study continue to be seen for at least 5 years. These results will be reported to FDA.

Please talk with your doctor for more details about the clinical study and its results.

WHAT CAN I EXPECT BEFORE MY SUPERION® SPACER SURGERY?

You and your doctor may choose for you to have surgery with the Superior® Spacer. If so, there are several things you can do to help you have the best possible results for your surgery.

Your doctor will give you specific instructions prior to your surgery that you should follow. You can also increase your chances of a successful outcome by eating well-balanced nutritional meals before your surgery. Poor nutrition can reduce the body's ability to heal.

WHAT CAN I EXPECT DURING MY SUPERION® SPACER SURGERY?

The implantation of the Superior® Spacer is done through a narrow tube (cannula). The narrow tube is a little smaller than the diameter of a 10¢ coin (13mm). The surgery is done in the operating room at the hospital. The surgery is also done in an out-patient surgical center. The Superior® Spacer goes through a small cut in the skin of your back. You will be given drugs. The drugs will make you sleep during surgery. You will not feel the surgery.

You will be placed on your stomach during the surgery. This will let your doctor slightly bend your spine when the Superior® Spacer is inserted. The surgery to implant the Superior® Spacer typically lasts about one hour.

First, your doctor will make a small (1/2 inch) cut in the skin over your back. Then, the doctor will insert the narrow tube (cannula) to divide the soft tissues under the skin (supraspinous ligament, a fibrous band which runs across the top of your spinous processes). This will access the surgical area of the spine. The space between the bones (spinous process) in your back will be measured through the narrow tube (cannula) to pick out the correct Superior® Spacer size.



Figure 4: From left: Surgeon creates a 1/2 inch incision with a scalpel; A narrow tube (cannula) is inserted to separate the soft tissue (supraspinous ligament) to get to the spine; A tool (gauge) is inserted to measure the space between the bones (spinous processes).

Next, the Superior® Spacer goes through the narrow tube (cannula) between two bones (spinous processes) in the back of your spine in the closed position. After insertion, the wings of the device are opened and locked in the final position.

If you are having the Superior® Spacer implanted at two levels, you will have two scars. The surgery is the same, except the surgeon needs more time (about 20 minutes) to put the second Superior® Spacer in your spine.



Figure 5: From left: The correct size implant is loaded onto the inserter; Surgeon inserts the device in the closed position and opens the wings of the device to lock it into the final position; The inserter is removed and the cut is closed up with stitches (the supraspinous ligament may be stitched as well).

The appearance of the Superior® Spacer as it is opened to the locked position is shown below in Figure 6:

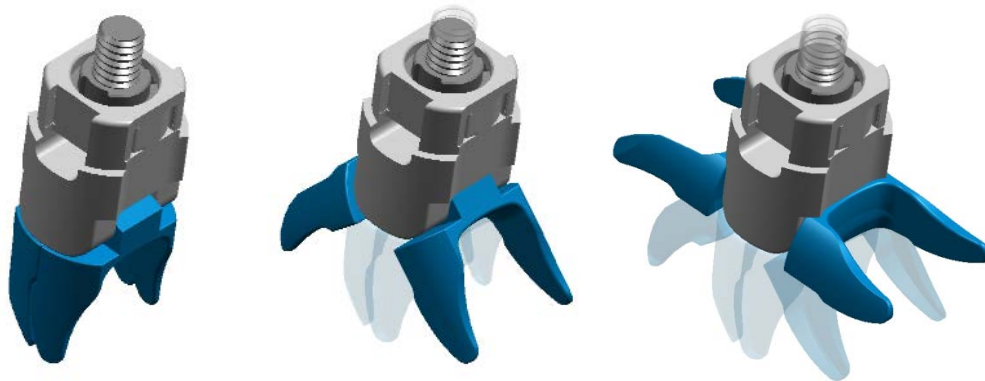


Figure 6: Superior® Spacer in closed (left), mid-extension (middle) and final fully extended and locked (right) positions

WHAT CAN I EXPECT AFTER MY SUPERION® SPACER SURGERY?

You may need physical therapy after the doctor says you can leave the hospital. Your doctor may ask you to return for a visit about four to six weeks later. Your doctor will also ask you to reduce your physical activities in the first 6 weeks after your operation. In the clinical study, patients were allowed to travel and engage in light activity such as walking as soon as they felt they could do so comfortably. It is important for you to realize that you have had a surgical operation. You should not participate in some activities until your doctor has said you may do so. Please ask your doctor when you can start doing certain activities, such as exercise or sports. Your results may be different from patients in the clinical study.

WHEN SHOULD I CALL MY DOCTOR?

Ask your doctor to describe how you will feel after surgery. Some pain and discomfort is normal. The problems you had before surgery may not lessen right away. Talk to your doctor about when to call with problems after surgery.

If you have any of these problems at any point after surgery, call your doctor.

- Signs that your cut (incision) may not be healing (infection):
 - The incision is draining. Although you can expect some wetness.
 - The skin around the incision becomes red, warm, swollen, or increasingly painful.
 - You have a fever.
- Pain or problems with your bladder or bowels (example: going to the bathroom).
- More pain, numbness, or weakness in the back, groin, buttocks, or legs than you had before surgery.

WHERE CAN I FIND OUT MORE INFORMATION?

If you have any questions about the Superior® Spacer, you may ask your doctor. For additional information, you may call the VertiFlex information hotline at (866) 355 – 4675. You may also find additional information at www.vertiflexspine.com.

WILL MY IMPLANT SET OFF A METAL DETECTOR?

The metal in the Superior® Spacer is made from a mixture of metal elements (titanium alloy). The metal might affect MRI and metal detectors. A patient ID card will be given to you by your surgeon. This card tells people you have a Superior® Spacer implant inside you. This card should be shown when you have x-rays and MRIs. You should use this card to tell security that you have this device in your spine when you pass through an electronic detection system.

MORE ABOUT YOUR CONDITION

Your spine is very important. It supports the structure of your body and protects your spinal cord. Your spinal cord relays information to and from your brain from other parts of your body. It is also responsible for the most basic movements of your body. These movements include nodding your head, sitting, standing, and walking.

Your spine consists of a flexible column of 24 bones called vertebrae. These vertebrae are stacked one on top of the other and extend from your skull down to your hip bones (See Figure 7). Discs of soft tissue are between each of the vertebrae. The vertebrae join together like links in a chain. These provide support for your head and body while the discs act as cushions, or "shock absorbers." In addition to providing support, the spine surrounds and protects a cylinder of nerve tissues called the spinal cord. The spinal cord is surrounded by part of the vertebrae. The vertebrae create a channel called the spinal canal.

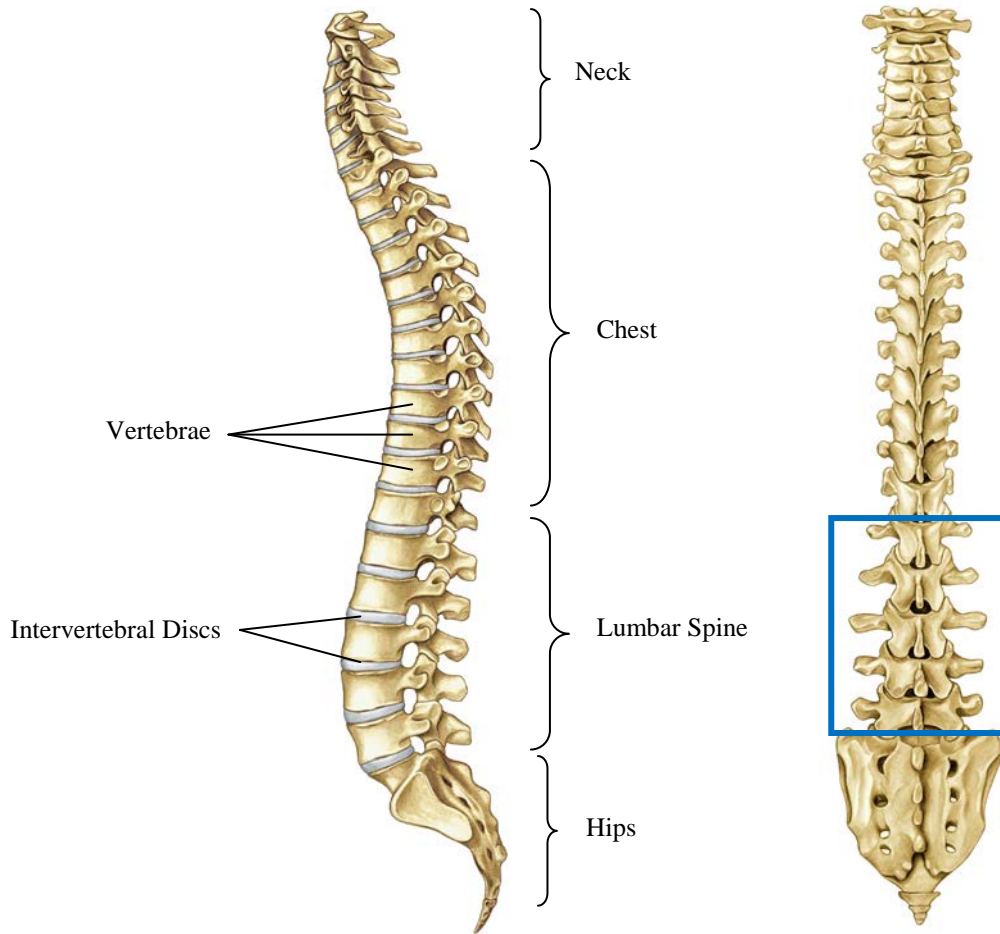


Figure 7: The Spine – Side View and Rear View (blue box on the right shows the part of the spine where the Superior® device goes)

Normally there is space between the spinal cord and the borders of the spinal canal. In this case, the nerves are free and are not pinched (See Figure 8).

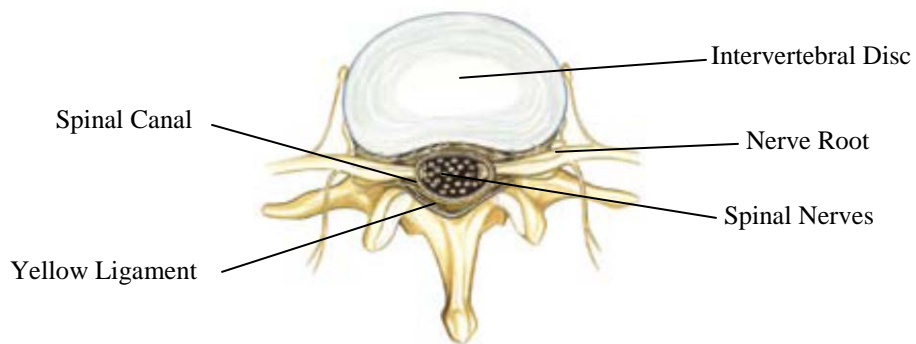


Figure 8: Healthy Spinal Column (Top View)

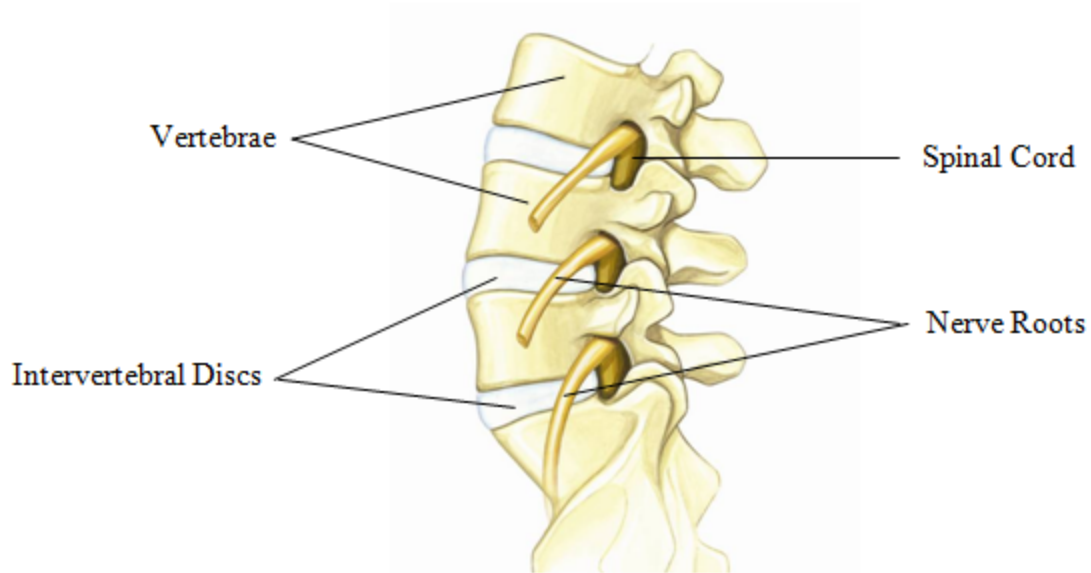


Figure 9: Healthy Spine (Side View)

What is Spinal Stenosis?

Spinal stenosis is defined as a narrowing of the spinal canal. This narrowing happens from thickening of ligaments (tissue that connects bones), bulging of discs, or overgrowth of bone (osteophytes) (See Figure 10). The spinal cord and nerve fibers that exit the spinal canal (nerve roots) can become crowded and pinched. This may lead to pain, numbness, tingling, and/or weakness in the back and legs. This pain is especially noted while walking.

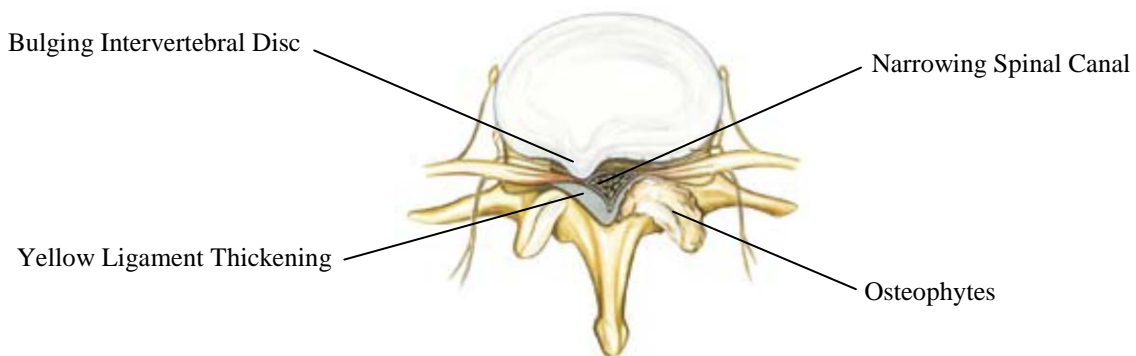


Figure 10: Spinal Column with Stenosis (Top View)

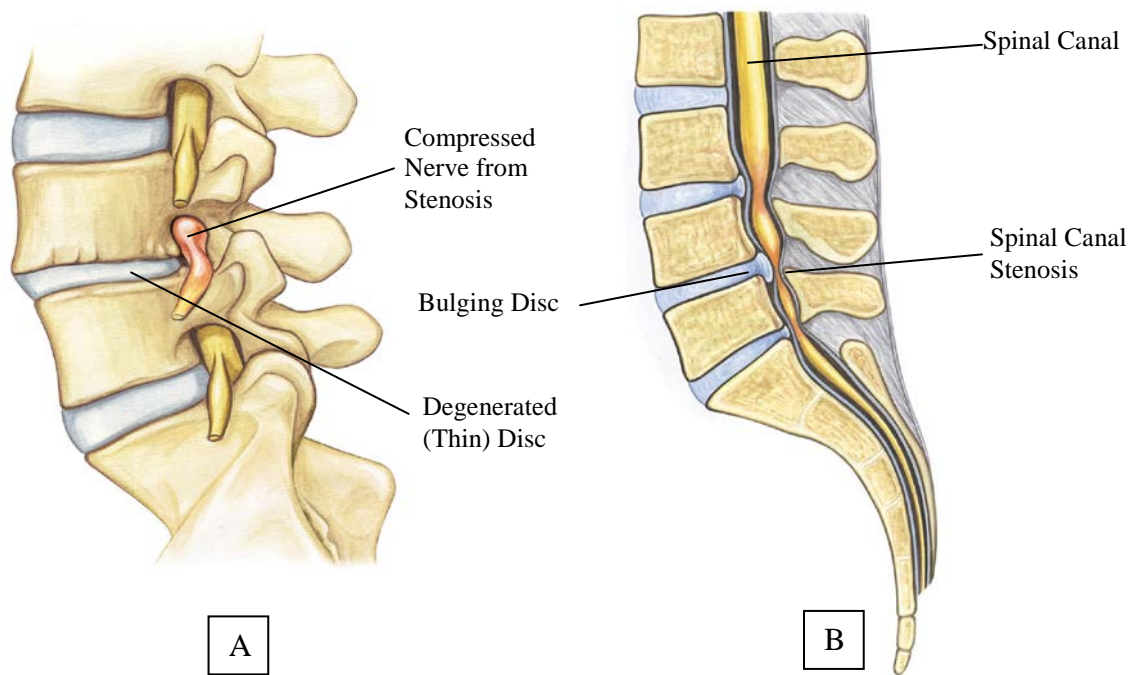


Figure 11: Stenotic Spine (Side Views, both can be treated with Superiorion®)
A: Lateral Spinal Stenosis
B: Central Spinal Stenosis

Spinal stenosis is the result of aging and “wear and tear” over time on the spine from everyday activities. This wear and tear on the spine can lead to degenerative changes in bone and ligaments. The degenerative changes can put pressure on the nerves that may cause pain and/or damage.

HOW DO I KNOW IF I HAVE SPINAL STENOSIS?

If you suffer from lumbar spinal stenosis you may feel various symptoms. These symptoms may include:

- You may feel a dull or aching pain spreading to your groin, buttocks or legs.
- You may feel a numbness or "pins and needles" in your legs, calves, or buttocks.
- You may feel a decreased endurance for physical activities.
- These symptoms may worsen in extended (upright) position, and are relieved in flexion (bending forward), may occur or worsen when walking but are relieved at rest, and may not be associated with back pain.

Before saying you have stenosis, it is important for your doctor to rule out other conditions that may produce similar symptoms. Your doctor will ask you to describe any symptoms you have. Your doctor will ask you how these symptoms have changed over time. Your doctor will ask

you about the treatments you have had for these symptoms. These may include medications. More radiology tests, like MRIs or x-rays, may be needed to show that you have spinal stenosis.

SUMMARY

This brochure has been designed to help you understand the Superior® Spacer as an option to treat your spinal stenosis. It also should give you the information you need to be an active participant in your own care.

We hope that you take the time to discuss all possible treatments with your doctor. You should also learn as much as you can about your own pain and what is causing it.

We also want to make sure that you understand all of the risks of surgery and the potential complications after surgery.

It is important that you understand exactly the procedure for the Superior® Spacer surgery before you decide to proceed. This includes the risks, benefits, and other treatment options. Always remember that the final decision to have surgery is up to you.