X·STOP®

A Patient's Guide

KYPHON
AHEAD OF THE CURVE™

Lumbar Spinal Stenosis & X-STOP Interspinous Process Decompression

This patient information guide is made possible through cooperation between your physician and Kyphon Inc. It is not designed as a replacement to professional medical care or advice. Only your surgeon is qualified to diagnose and appropriately treat your pain and related problems.

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Dear Patient,

This brochure is intended to help you understand the nature of a medical condition called lumbar spinal stenosis and a new therapy that is available, X-STOP® Interspinous Process Decompression (IPD®).

Your doctor has made this brochure available in order to answer common questions and to help you make an informed and careful decision about your treatment.

As you read this brochure, bear in mind that all forms of medical treatment – and particularly surgery – are highly personal matters.

That means that no matter how common your medical condition may be, your doctor will recommend treatment based on your individual needs.

There are always risks associated with any type of surgery. Your doctor will help explain the risks associated with all treatments discussed in this brochure.

This brochure is yours to keep. And we hope that you've chosen to read it in the comfort of your home, with family members and as many times as necessary.

So always remember, if you have any questions about your medical condition or the treatment options discussed in this brochure – please ask your doctor.

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Glossary of Terms

Analgesic: A drug that alleviates pain without causing loss of consciousness.

Anesthesia: A drug that blocks pain impulses from nerves. With general anesthesia you are unconscious, or asleep. With local anesthesia you are conscious, or awake.

Artifact: An abnormality in an image resulting in distortion and interference.

CAT or CT Scan (Computerized Axial Tomography): A test that uses X-rays and computer analysis to create the three-dimensional pictures of the inside of your body.

Cauda Equina Syndrome: The cauda equina is a bundle of nerves at the bottom of the spinal cord. Cauda equina syndrome is severe compression of the cauda equina resulting in loss of bowel or bladder function, loss of sensation in the buttocks and groin, and weakness in the legs.

Corticosteroid: A medicine that reduces swelling, or inflammation.

Degenerative: Undergoing degeneration: growing less healthy over time.

Extension: Bending backward, standing upright.

Facet: Surfaces where two vertebrae meet and articulate (move) forming a joint.

Facetectomy: An operation to remove part of the facet. To prevent a degenerated facet from pinching a nerve.

Flexion: Bending forward, or sitting.

Foramen: A natural opening or passage in bone for nerves and blood vessels.

Foraminotomy: An operation to make the foramen larger. To provide more space for the nerves and blood vessels.

Glossary of Terms (continued)

Fusion: An operation to permanently join the vertebrae together.

Interspinous Ligament: Spinal ligament that extends from one spinous process to the other.

Interspinous Process Decompression (IPD®): An operation in which an implant, called the X-STOP® device, is placed between your spinous processes.

Interspinous Space: The space between the spinous processes of the vertebrae.

Intervertebral Disc: Tissue found between the bones of the spinal column, called vertebrae. The discs help cushion the spine from stress during everyday activities (i.e., walking, bending, sitting, etc.).

Lamina: A part of a vertebra. For each vertebra, two lamina connect the pedicles to the spinous processes — forming the roof of the spinal canal.

Laminectomy: An operation to remove the lamina. The purpose is to allow more room for the spinal cord and nerves.

Laminotomy: An operation to remove part of the lamina. This is done to allow more room for the spinal cord and nerves.

Ligaments: A band of tissue linking two bones in a joint.

Lumbar: The lower part of the spine between the ribs and hipbones.

Lumbar Spinal Stenosis: A degenerative spinal disease that causes narrowing of the spinal canal. This narrowing pinches the nerves and causes pain symptoms.

MRI (Magnetic Resonance Imaging): A test that uses magnetic fields to create detailed pictures of the inside of your body.

Myelogram: A diagnostic procedure in which a dye is injected into the spinal canal before an X-ray is performed. The dye makes the spinal canal and nerve roots easier to see on X-ray film.

Glossary of Terms (continued)

Nerves: Fibers containing nerve cells that send messages between the brain and the rest of the body.

Nerve Compression: Pressure on a nerve; may cause nerve damage and muscle weakness.

Nerve root: The start of the nerve as it leaves the spinal cord (and passes through the foramen).

Osteophyte: A bony outgrowth on the edge of a vertebra, also known as a bone spur.

Pedicle: A part of a vertebra. It connects the lamina with the vertebral body.

Spinal Canal: The bony channel that contains the spinal cord.

Spinal Cord: A bundle of nerves that carries messages between the brain and the rest of the body.

Spinous Process: A part of the vertebra. A spinous process protrudes from each vertebra. The spinous processes create the "bumps" you feel in the middle of your back.

Spinal Stenosis: Narrowing of the spinal canal.

Supraspinous Ligament: Spinal ligament that passes over and attaches to the tips of the spinous processes.

Spondylolisthesis: A condition in which one vertebra slips forward in relation to the vertebra below it.

Vertebra: A bone of the spinal column. There are five (5) lumbar vertebrae.

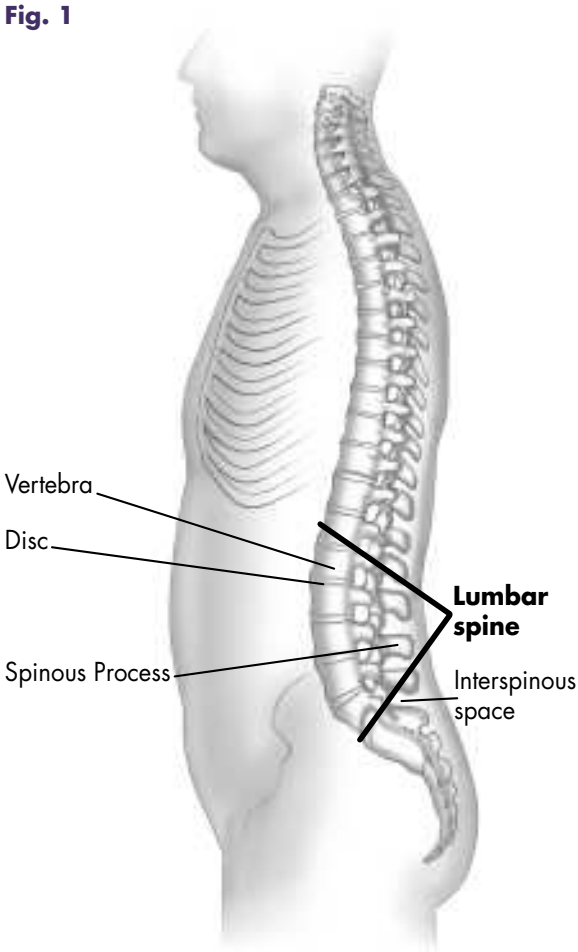
X-ray: A test that uses radiation to produce pictures of the inside of the body.

X-STOP: A titanium implant that fits between the spinous processes.

Anatomy of the Spine

Your spine consists of a column of 24 bones called vertebrae that extend from your skull down to your hips (Fig. 1). Between the vertebrae are discs of soft tissue. The vertebrae join together like links in a chain, providing support for your head and body while the discs act as cushions, or "shock absorbers." In addition to providing support, the spine encloses and protects a cylinder of nerve tissues called the spinal cord. The spinal cord is surrounded by a bony channel called the spinal canal.

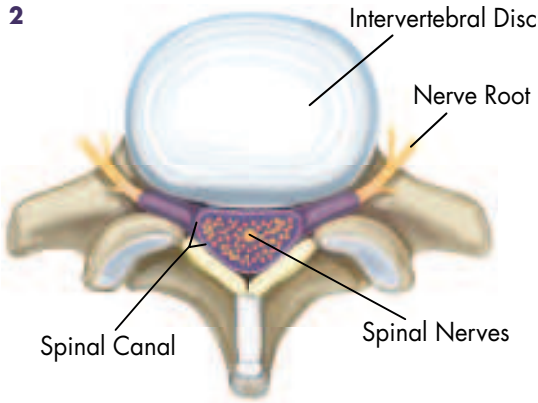
Fig. 1



Anatomy of the Spine (continued)

Normally there is space between the spinal cord and the borders of the spinal canal so that the nerves are free and are not pinched (Fig. 2).

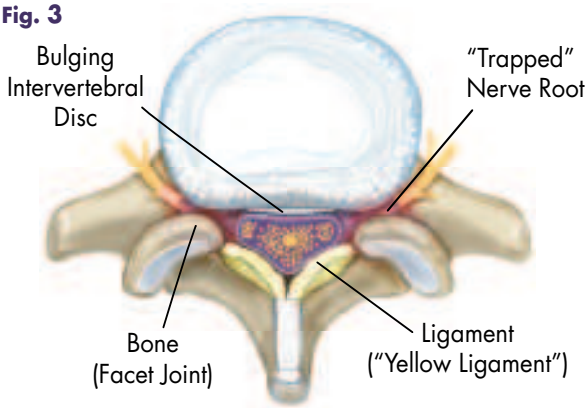
Fig. 2



Healthy

As we age the ligaments and bone that surround the spinal canal can thicken. This thickening results in narrowing of the spinal canal, which is called "spinal stenosis." The spinal cord and nerve fibers that exit the spinal canal (nerve roots) become crowded and pinched due to this narrowing. This results in pain and numbness in the back and legs (Fig. 3).

Fig. 3



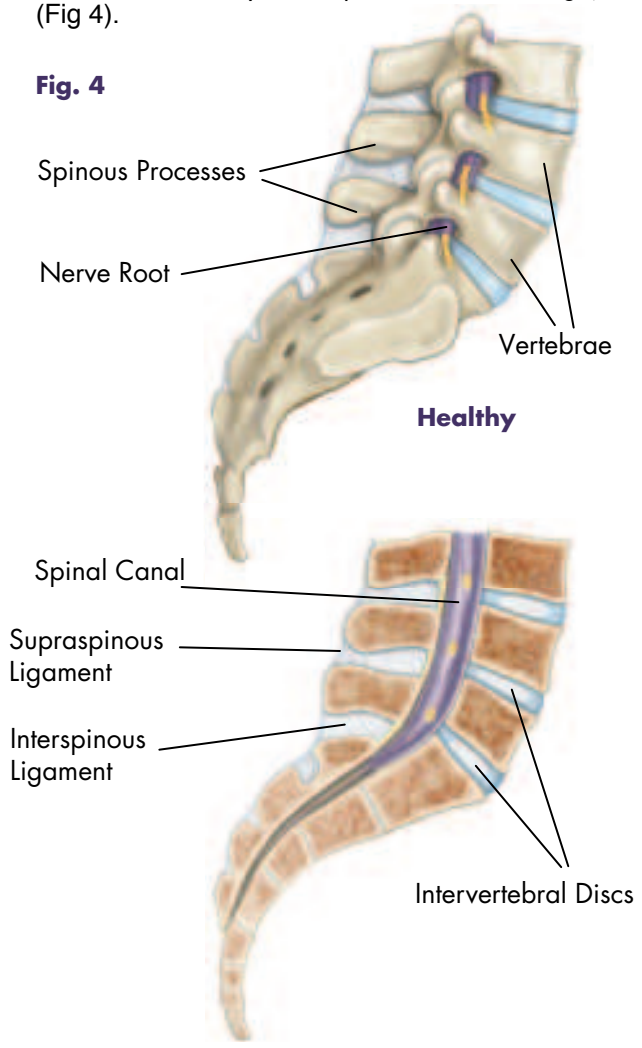
Stenotic

What is Spinal Stenosis?

Spinal stenosis is a narrowing of the spinal canal. Some patients are born with this narrowing, but most often spinal stenosis is the result of a degenerative condition that develops in people over the age of 50. Spinal stenosis is the gradual result of aging and "wear and tear" on the spine from everyday activities.

Degenerative or age-related changes in our bodies can lead to compression of nerves (pressure on the nerves that may cause pain and/or damage). (Fig 4).

Fig. 4



As we age:

- the ligaments of the spine can thicken and calcify (harden from deposits of calcium)
- bones and joints may also enlarge
- bone spurs, called osteophytes, may form
- discs may collapse and bulge (or herniate)
- one vertebra may slip over another (called spondylolisthesis)

Fig. 5

Symptoms of Spinal Stenosis

If you suffer from lumbar spinal stenosis you may feel various symptoms, including:

- dull or aching back pain spreading to your legs
- numbness and "pins and needles" in your legs, calves or buttocks
- weakness, or a loss of balance, and
- a decreased endurance for physical activities

Fig. 6 Standing or walking causes symptoms

Symptoms (continued)

Symptoms increase after walking a certain distance or standing for a time. Symptoms can improve when you:

- sit
- bend or lean forward (see Figure below)
- lie down, or
- put your foot on a raised rest

Fig. 7 Leaning forward while walking relieves symptoms

Diagnosing Lumbar Spinal Stenosis

Before confirming a diagnosis of stenosis, it is important for your doctor to rule out other conditions that may produce similar symptoms. In order to do this, most doctors use a combination of techniques, including:

- **History** - Your doctor will begin by asking you to describe any symptoms you have and how the symptoms have changed over time. Your doctor will also need to know how you have been treating these symptoms, including medications you have tried.
- **Physical Examination** - Your doctor will then examine you and check for any limitations of movement in your spine, problems with balance, and signs of pain. Your doctor will also look for any loss of reflexes, muscle weakness, sensory loss, or abnormal reflexes.
- **Tests** - After examining you, your doctor may use a variety of tests to confirm the diagnosis. Examples of these tests include:

  X-ray - shows the structure of the vertebrae and the outlines of joints.

  MRI (Magnetic Resonance Imaging) - provides a three-dimensional view of your back and can show the spinal cord, nerve roots, and surrounding spaces, as well as signs of degeneration, tumors or infection.

  CAT Scan (Computerized Axial Tomography) - depicts the three-dimensional shape and size of your spinal canal and bony structures surrounding it.

  Myelogram - highlights the spinal cord and nerves after a dye is injected into your spinal column, which appears white on an X-ray film.

Precaution:

Radiological evidence of stenosis must be correlated with your symptoms before the diagnosis can be confirmed.

Treatment Options

Once a diagnosis of spinal stenosis is confirmed, the process of treating the condition usually begins with a regimen of non-invasive, "conservative" therapy.

Non-surgical Treatment of Stenosis

There are a number of ways a doctor can treat stenosis without surgery, including:

- Medications, such as non-steroidal anti-inflammatory drugs (NSAIDs) to reduce swelling and pain, and analgesics to relieve pain.
- Corticosteroid injections (epidural steroids) to reduce swelling and treat acute pain that radiates to the hips or down the leg. Pain relief from an epidural injection may be temporary and patients are usually advised to get no more than 3 injections per 6-month period.
- Rest or restricted activity.
- Physical therapy and/or exercises to help stabilize the spine, build endurance and increase flexibility.

While some patients obtain relief from symptoms with these treatments, others do not.

Surgical Treatment of Stenosis

Decompression

Non-surgical treatments may temporarily relieve pain. More severe cases of stenosis may require surgery.

The most common surgical procedure for stenosis is a decompressive laminectomy sometimes accompanied by fusion. Often referred to as "unroofing" the spine, this procedure involves the removal of various parts of the vertebrae, including:

- the lamina, as well as the attached ligaments, that cause compression of the spinal cord and nerve roots, and/or
- enlarged facets, osteophytes and bulging disc material

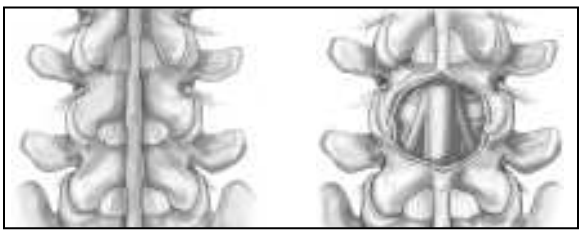
The goal of the surgery is to relieve pressure on the spinal cord and nerves by increasing the area of the spinal canal and neural foramen.

Other types of surgery to treat stenosis include:

- **Laminotomy** - only a small portion of the lamina is removed to relieve local pressure on the spinal cord and nerve roots.

Fig. 8 Laminectomy Procedure

Bone is removed and spinal cord is exposed



Pre-Op Post-Op

- **Foraminotomy** - the foramen (the opening through which the nerve roots exit the spinal canal) is enlarged to increase space for the nerves. This surgery can be done alone or with a laminotomy.
- **Facetectomy** - part of the facet joint is removed to increase space for the nerves.

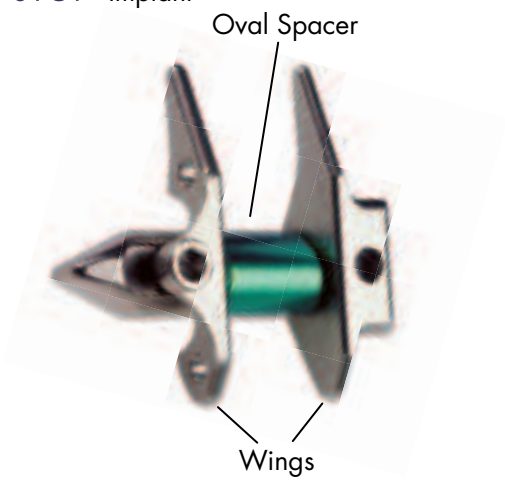
What is the X-STOP Device?

The X-STOP® device is a titanium metal implant designed to fit between the spinous processes of the vertebrae in your lower back. It is designed to remain safely and permanently in place without attaching to the bone or ligaments in your back. (Fig. 9).

Warning:

The X-STOP implant is manufactured from a titanium alloy of metal. Please inform your doctor if you think you are allergic to titanium or titanium alloy.

Fig. 9 X·STOP© Implant



The oval spacer fits between the spinous processes and the wings are designed to prevent the implant from moving.

Caution:

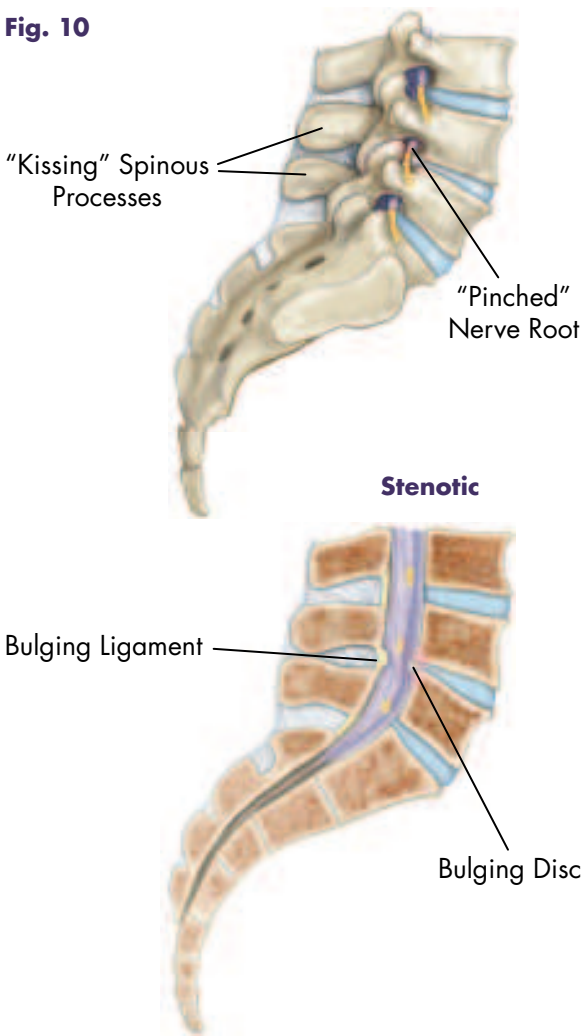
The X-STOP implant is manufactured from a titanium alloy which is known to produce artifacts if you undergo an MRI exam. If you have an MRI exam, after you have had X-STOP IPD surgery, inform your doctor that you have the X-STOP implant. Failure to inform your doctor may affect the quality of diagnostic information obtained from these scans. The X-STOP implant is MRI safe.

What is IPD?

Interspinous Process Decompression (IPD®)

IPD is a surgical procedure in which an implant, called the X-STOP device, is placed between two bones called spinous processes in the back of your spine.

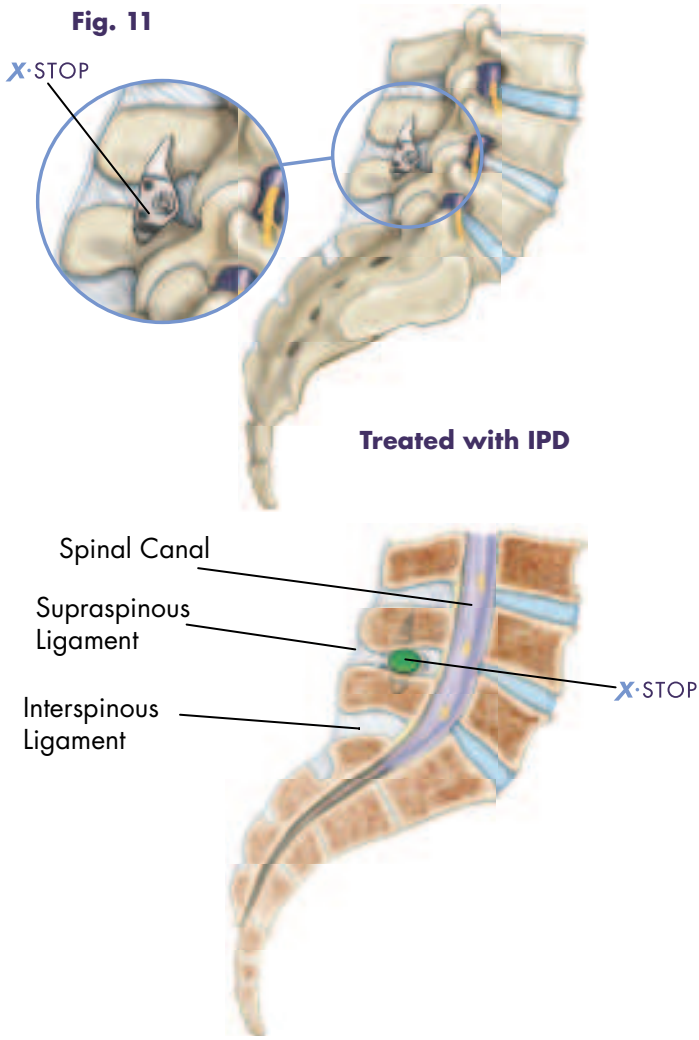
Fig. 10



Surgical Treatment with IPD®

With IPD surgery there is no removal of bone or soft tissue. The X-STOP implant is not positioned close to nerves or the spinal cord, but rather behind the spinal cord between the bony spinous processes. (Fig 11).

Fig. 11



The X-STOP® IPD® Procedure

The procedure may be performed in either the operating room or special procedures room at the hospital. Using local anesthesia and with the help of X-ray guidance, the X-STOP implant is inserted through a small incision in the skin of your back. Alternatively, your surgeon may elect to use general anesthesia.

You will be placed on your side during the procedure so that you can bend your spine when the X-STOP implant is inserted.
The surgery to implant the X-STOP device typically lasts 45 minutes to an hour-and-a-half. During this time you may be awake and able to communicate with your doctor.

Why May the X-STOP® IPD® Procedure Work?

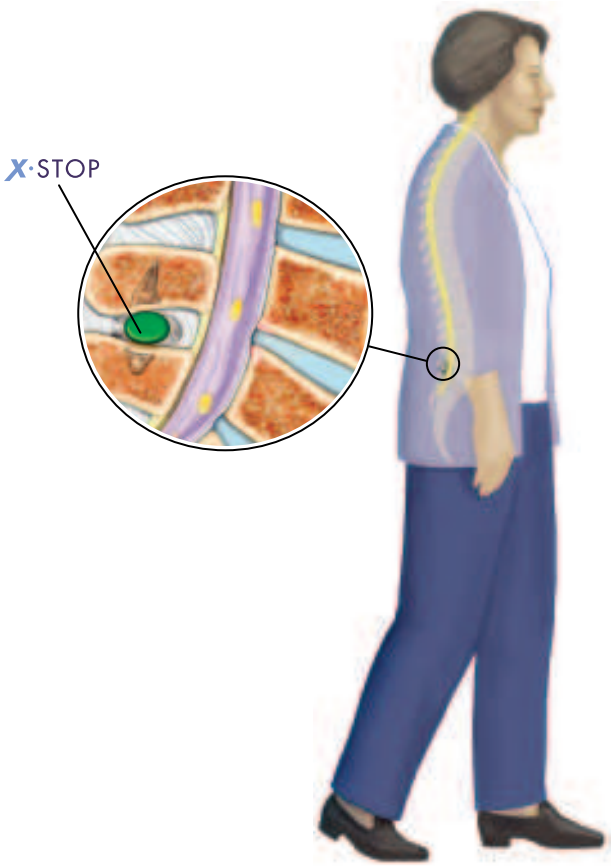
The X-STOP implant is designed to keep the space between your spinous processes open, so that when you stand upright the nerves in your back will not be pinched or cause pain. With the X-STOP implant in place, you should not need to bend forward to relieve your symptoms. (Fig. 13).

Fig. 12 Bending forward relieves symptoms

IPD offers several benefits compared to traditional surgery for lumbar spinal stenosis, including:

- the option of local anesthesia
- the potential to be an outpatient procedure
- usually no removal of bone or soft tissue allowing for potentially quicker recovery
- fully reversible procedure that does not limit any future non-surgical and surgical treatment options

Fig. 13 After IPD, you may no longer need to bend forward to relieve your symptoms because they may be reduced or gone completely



Pre-operative Considerations

Are you a candidate for the X-STOP IPD procedure?

The X-STOP system is indicated for patients aged 50 or older who have lumbar spinal stenosis. A diagnosis of lumbar spinal stenosis should be confirmed by a doctor with X-ray, MRI or CT scans. The X-STOP system is indicated for patients with moderately impaired ability to function, who experience relief from their pain symptoms when bending forward. Patients receiving the X-STOP implant should have already been under a doctor's care and getting non-surgical treatment for their symptoms for at least 6 months. The X-STOP implant may be implanted at one or two levels of the lumbar spine.

Who should not receive it?

The X-STOP system should not be used if you have:

- an allergy to titanium or titanium alloy
- spinal anatomy that would prevent implantation of the device or cause the device to be unstable in your body
- cauda equina syndrome, which is a spinal nerve compression that causes bowel or bladder dysfunction
- bone fractures or a diagnosis of severe osteoporosis
- an infection in your blood or anywhere near your lower back where the surgery is planned.

Preparing for Surgery

If you and your surgeon elect to go ahead with the X-STOP IPD procedure, there are several things you can do to help you achieve the best possible outcome for your surgery. You can increase the likelihood of a successful outcome by eating well-balanced nutritional meals as far in advance of your procedure as possible. Poor nutrition can reduce the body's ability to heal itself.

Possible Complications

Spinal surgery is not without risk.

Specific information on the rates of complications for the X-STOP IPD system and spinal surgery should be discussed with your doctor.

Complications that may be associated with X-STOP IPD surgery include, but are not limited to, the following:

- implant dislodgement (movement out of place)
- implant not positioned correctly
- fracture of the spinous process
- foreign body reaction (ex. allergic reaction)
- additional surgery, which could include removal of the X-STOP implant
- mechanical failure of the implant.

Complications related to any type of surgery may include, but are not limited to, the following:

- reactions to anesthesia
- heart attack
- infection, which could require medication or an operation
- blood vessel damage/bleeding
- bruising (hematoma)
- pneumonia
- blood clots
- wound closure problems
- spinal cord or nerve damage
- pain or discomfort
- paralysis
- stroke
- death

Please consult your doctor about the complication rates related to surgery.

Post-operative Care

You may feel immediate relief from pain following this procedure. You may be able to walk the same day and you may be discharged from the hospital within 24 hours. Although X-STOP IPD surgery can typically be performed on an outpatient basis, your physician may recommend a short hospital stay.

Following your discharge, physical therapy may be recommended. Your doctor may ask you to return for an examination approximately six weeks later. While your doctor may recommend some limitation in your physical activities in the weeks following your operation, you should be able to travel and engage in light activity as soon as you feel able to. Physical activity limitations may include:

- no bending backward
- no heavy lifting
- no stair climbing
- no sports such as swimming, golf, tennis, racquetball, running or jogging.

Post-operative medication is generally not required. Walking is usually acceptable as long as it is comfortable and does not exceed one hour in duration. Normal activity can usually be resumed with the doctor's recommendation within two to six weeks after the procedure.

It is important for you to realize that you have undergone a surgical operation and that you should not participate in strenuous activities until your doctor has indicated you may do so. You must follow your doctor's directions carefully in order to fully recover from your surgery.

If you are planning to have other diagnostic procedures or treatments, not related to your X-STOP IPD surgery, please tell your doctor that you had X-STOP IPD surgery.

Caution:

It is important to follow your doctor's instructions carefully in order to fully recover from surgery. Failure to follow post-operative care recommendations may result in recurrence of symptoms and discomfort. A stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon post-operatively.

X-STOP IPD: Clinical Study Results

The X-STOP IPD system was tested in a carefully controlled research study that took place in nine hospitals across the United States. In this study, 100 patients with lumbar spinal stenosis had surgery with the X-STOP device. These patients were compared to 91 patients who did not have surgery, but were treated by their doctors in other ways (for example, with medications, corsets, physical therapy, etc.).

Approximately half of the patients who received the X-STOP device in this two-year research study experienced a degree of pain relief and ability to increase their activity levels that was sufficient to be considered a successful outcome at two years after the surgery. The clinical benefit beyond two years has not been measured.

The likelihood of needing an additional operation during the study was low. During the study, 6% of patients did not have a satisfactory treatment outcome and decided to have a laminectomy operation (removal of part of the vertebra in the spine), at which time the X-STOP implant was removed. In addition, the implant dislodged (moved out of proper position) in one patient after a fall, and the implant was later removed. A second operation was also required in three other X-STOP procedure patients for the following conditions: drainage of a collection of blood, drainage of fluid around the wound, and removal of damaged tissue with secondary closure of the wound (allowing the wound to close on its own).

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

Summary

This brochure has been designed to help you understand X-STOP IPD surgery for spinal stenosis and to give you the information you need to be an active participant in your own care.

We hope that you take the time to discuss alternative treatments with your doctor and that you learn as much as you can about your own particular medical situation.

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

It's important that you understand exactly what the procedure entails – including the risks, benefits and alternative treatments – before you decide to proceed. Always remember that your final decision to go ahead is up to you.

Notes:

You may wish to record important information regarding your X-STOP implant(s). Please ask your surgeon for this information.

X-STOP LOT # _____

X-STOP LOT # _____

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Facts About Lumbar Spinal Stenosis

This brochure will provide you with information regarding a new treatment for lumbar spinal stenosis called X-STOP IPD (Interspinous Process Decompression) procedure.

You may be suffering from lumbar spinal stenosis if:

- you have difficulty walking distances
- you experience pain while standing
- your pain is relieved when you sit down or bend forward
- your pain is mostly in your buttocks and thighs

The X-STOP IPD procedure offers several benefits compared to traditional surgery for lumbar spinal stenosis, including:

- the option of local anesthesia
- usually no bone or soft tissue removal
- has the potential for an outpatient procedure
- fully reversible procedure that does not limit any future non-surgical and surgical treatment options

Your doctor will answer any questions you have regarding lumbar spinal stenosis and the X-STOP IPD procedure as a treatment for you.

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