

INFORMATION FOR THE PATIENT ABOUT SURGICAL DECOMPRESSION AND STABILIZATION OF THE SPINE



ASPEN™
Spinous Process Fixation System



AGING AND THE SPINE

Daily wear and tear, along with disc degeneration due to aging and injury, are common causes of painful compression of the nerves in the lower back. Your doctor may have diagnosed you with degenerative disc disease or spondylolisthesis and has now recommended spinal surgery to relieve pressure and prevent further damage to your lower spine. You may be a candidate for the Aspen™ Spinous Process Fixation System, a unique device that is designed for less invasive spine surgery to treat degenerative spinal conditions.

The following information will address the basic anatomy of the spine, specific problems that may occur within the spine, as well as the benefits and risks associated with the Aspen device. Please consult your doctor to fully explain the most suitable treatment option for you.

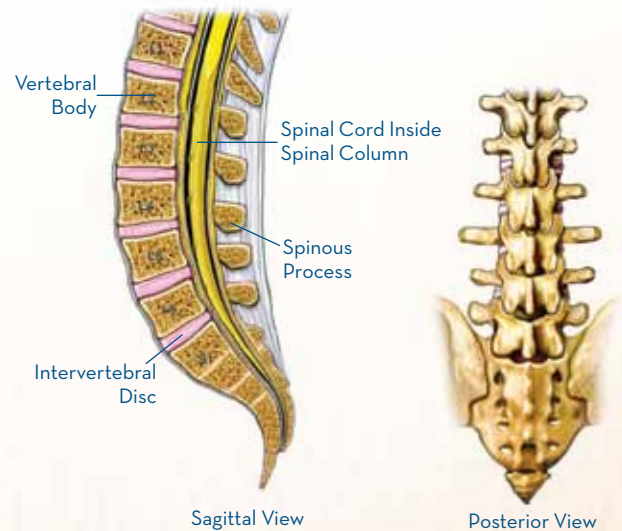
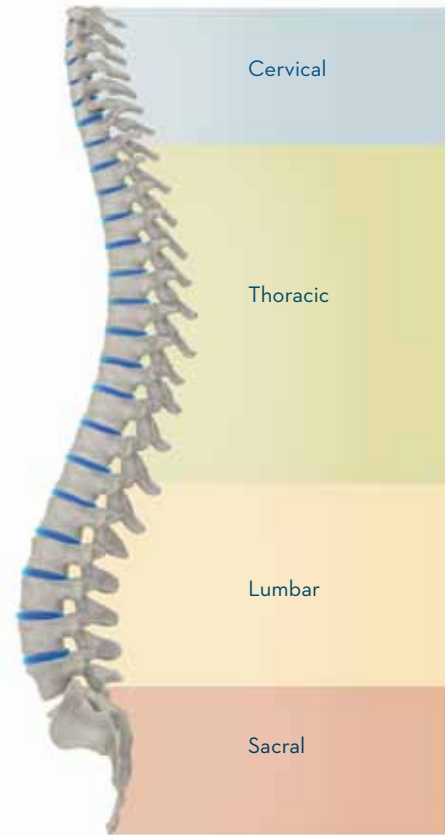


INTRODUCTION TO YOUR SPINE

Your spine is composed of 24 individual bones known as vertebrae. These 24 vertebrae are divided into three sections: cervical (neck), thoracic (chest) and lumbar (lower back). The base of your spine consists of a series of fused vertebrae known as the sacrum and coccyx. In between each set of vertebrae is a soft tissue known as the disc that acts as a shock absorber for the vertebrae, allowing your spine to bend and move. Your spinal cord and additional root nerves are encased and protected by the bony spinal canal in the center of the spinal column.

Symptoms of Degenerative Disc Disease:

- Pain in the lower back intensified by lifting, bending or twisting
- Pain heightened by prolonged sitting and/or standing
- Pain radiating through hips and legs



CHRONIC LOW BACK PAIN

Lower back pain is one of the most common conditions experienced by patients. In fact, it affects four out of five adults and is a leading cause of doctor visits in the United States.¹ As you age, several parts of the spine are adversely affected. Over time, the ligaments encasing the spine become thick and hard. The small joints which allow your spine to move can enlarge and compress the nerve roots and discs in the lower back. A lifetime of wear weakens these joints and with time, one vertebra can actually slip onto another. In addition, bone spurs can develop. Two common degenerative conditions associated with chronic low back pain are degenerative disc disease and spondylolisthesis.

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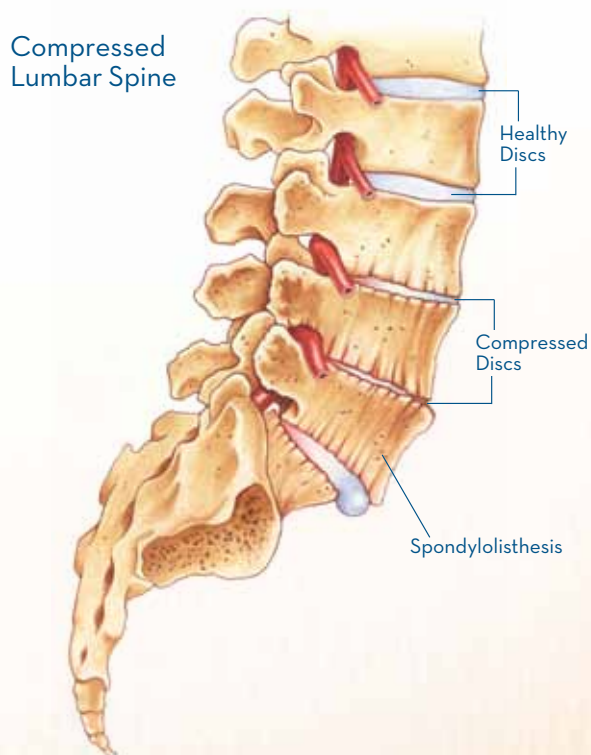
Many of these symptoms can be alleviated temporarily by frequent changes in position to help relieve pressure and pain.

Symptoms of Spondylolisthesis:

- Dull or aching pain that spreads from the back to the buttocks and continues to radiate down the legs
- Numbness or tingling in the buttocks and/or legs
- Pain heightened by standing or walking for an extended period of time
- Overall weakness or decrease in stamina

Many of these symptoms can be temporarily alleviated by sitting, leaning forward, reclining or rest.

The pain associated with these conditions can be alleviated or lessened through several modern minimally invasive techniques created to relieve pressure and pain, while stabilizing the spine. Only your doctor can offer a full diagnosis and determine the best treatment option concerning your condition.



¹ Bigos S, et al. Acute Low Back Problems in Adults, Clinical Practice Guideline No. 14. Rockville, MD: U.S. Public Health Service, U.S. Dept. of Health and Human Services, AHCPR Pub. No. 95-0642, Dec. 1994.

THE ASPEN SPINOUS PROCESS FIXATION SYSTEM: RELIEVING PRESSURE AND RESTORING PROPER SPINAL ALIGNMENT

The Aspen Spinous Process Fixation System from Lanx is a posterior supplemental fixation device created for single level placement in the noncervical spine. The device is intended for use with bone graft material and is not intended for stand-alone use. It is designed for plate attachment to the spinous processes to achieve supplemental fusion in patients who suffer from degenerative disc disease, spondylolisthesis, trauma and/or tumor.

Spinous processes are the small, bony protuberances along the back of the spinal column near the surface of your skin. Because spinous processes are located so close to the skin, minimal operative intervention is required.

A small incision is made in the lower back. The Aspen device is then inserted and precisely positioned behind the spinal elements and in between two spinous processes. This placement reestablishes alignment and stabilizes the spine.

The Aspen device is affixed to the small, bony protuberances along the back of your spine known as spinous processes.



POSSIBLE CANDIDATES FOR THE ASPEN SPINOUS PROCESS FIXATION SYSTEM MAY INCLUDE:

Patients with a confirmed diagnosis from their physician of degenerative disc disease, spondylolisthesis, trauma and/or tumor.

Patients often experience the following symptoms:

- Chronic low back pain that is often relieved by sitting
- Low back pain often radiating through the hips and legs
- Impaired ability to function within the moderate range of motion in the spine
- Those who may have undergone at least six months of non-surgical treatment, including medications, injections, physical therapy, restriction of activities or prescribed bed rest



FREQUENTLY ASKED QUESTIONS

How long will I be in the hospital?

Only your doctor can determine the length of your stay. Recovery from any spinal operation is an ongoing process.

Will I be in pain after surgery?

Because the surgery is less invasive, causing less trauma to the muscles and tissue, you will have less pain than if you were to undergo more invasive surgery. Your doctor will prescribe appropriate pain medication to be used as needed.

What should I expect following my surgery?

You will be able to walk and lie down, but sitting may be uncomfortable. Use ice packs regularly and rest your back. Your doctor will prescribe pain medication to be used as needed. Slowly increase activities. Follow your doctor's instructions carefully to ensure the best possible outcome.

Will this device activate security alarms at airports or other establishments?

It is highly unlikely that your Lanx titanium spinal implant will trigger security alarms. If you do experience issues traveling, upon request, Lanx will provide your doctor with an implant identification card that he/she will fill out and give to you post surgery.

Will my insurance cover this surgery?

Please consult with your doctor and contact your insurance agent with questions regarding your specific insurance qualifications.

GLOSSARY OF TERMS

Disc: soft tissue located between the vertebrae that acts as a shock absorber in the spine, allowing the spine to bend and move

Degenerative Disc Disease: gradual deterioration of the disc; gradual wear and tear of the discs in the spine causing the discs to lose their flexibility and shock absorbing capabilities. Degenerative disc disease is a naturally occurring process that happens with age

Lumbosacral Spine: the lower portion of the spine, including the vertebrae in the lumbar and sacral regions

Spinous Process: the small, bony protuberance located along the back of the spinal column that acts as an attachment site for muscles and ligaments

Spinal Fusion: a surgical procedure to stabilize the spine by fusing together two or more vertebrae, using bone grafts and metal rods and screws

Spondylolisthesis: a condition that occurs when one vertebra slips forward onto the adjacent vertebra

Vertebrae: 24 bones located in the spine, 7 cervical (neck), 12 thoracic (chest) and 5 lumbar (lower back)

Contraindications Associated with the Aspen Device

- Allergy to titanium or foreign body sensitivity
- Known or suspected infection/immune system incompetence
- Any abnormality present which affects the normal process of bone remodeling, including but not limited to severe osteoporosis, bone absorption, osteopenia or active infection at the site
- Morbid obesity
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Open wounds
- Pregnancy
- Any medical or surgical condition which could preclude the potential benefit of spinal surgery
- Any case requiring the mixing of two different component systems
- Fever or leukocytosis (elevated white blood cell count)
- Signs of local infection or previous inflammation
- Previous history of infection
- Alcoholism or heavy smoking
- Senility, mental illness or substance abuse of such severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications
- Inability to follow post-operative instructions
- Inadequate tissue coverage over the operative site
- Incompetent or missing posterior arch

Possible Complications

As with any surgical procedure, complications may occur following the placement of the Aspen device. These can include but are not limited to:

- Early or late implant bending, breakage, failure, loosening or movement/migration
- Bone fracture, spinous process
- Allergic reaction to implant material

Other general complications associated with any spinal surgical procedure include:

- Non-union or delayed union, pseudoarthrosis
- Pain
- Second surgery
- Bleeding
- Infection, early and late
- Tissue or nerve damage
- Incisional complications or scar formation
- Damage to blood vessels and cardiovascular system compromise
- Complications due to the use of bone grafting
- Respiratory problems
- Reactions to anesthesia
- Death

This booklet was designed to provide important information about less invasive spine surgery and the Aspen Spinous Process Fixation System from Lanx.

At Lanx, our mission is to improve the quality of care for patients worldwide by providing surgeons with innovative spinal products.

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