Aspen®
MIS Fusion System

Patient Education

HIGHRIDGE

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Individuals represented in the brochure are not actual patients.

Enjoying life without back pain

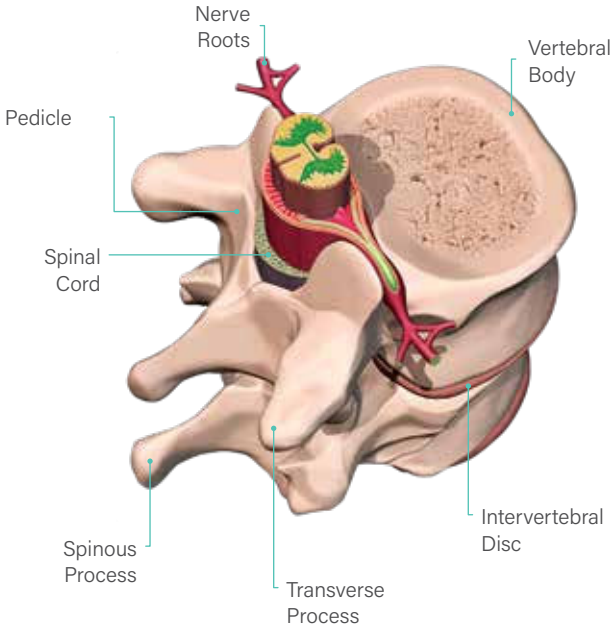
Chronic lower back pain can drastically affect your way of life, impacting your job, family, hobbies, and overall well being. The cause could be the result of daily wear and tear on your spine or some form of back injury, but the good news is there's something you can do about it.

In fact, you may be reading this today because your doctor recommended minimally invasive spinal fusion to relieve the chronic pain. If so, you may be a candidate for treatment with the Aspen MIS Fusion System, a device designed specifically to be less invasive so that you can get back to living your life as soon as possible.

Note: Please talk with your doctor to determine the most suitable treatment option for you.

Introduction to your spine

Your spine is composed of 24 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 — a section also known as the sacral region. In between each set of vertebrae is a soft tissue known as the disc, which acts as a shock absorber for the vertebrae allowing your spine to bend and move. Encased and protected by your vertebrae are your spinal cord and nerve roots. And along the back of the spinal column, near the surface of your skin and farther away from the delicate nerves, are small, bony protuberances called spinous processes.




Cervical
Thoracic
Lumbar
Sacral

Back pain isn't limited to your back

Lower back pain is a very common condition. Affecting 4 out of 5 adults at some point in their lives, it's a leading cause of doctor visits in the United States and is often due to the natural degeneration of the spine that occurs with aging.

In severe cases, this spinal degeneration causes weakness or instability of the spine and can lead to debilitating pain and discomfort in the back and/or legs. While many people may not typically associate leg pain with a back problem, spinal conditions are a common culprit. This is because the degenerative process can cause nerves around the spine to become pinched, leading to symptoms that travel down through the legs.

Spinal degeneration is associated with a range of symptoms, including:

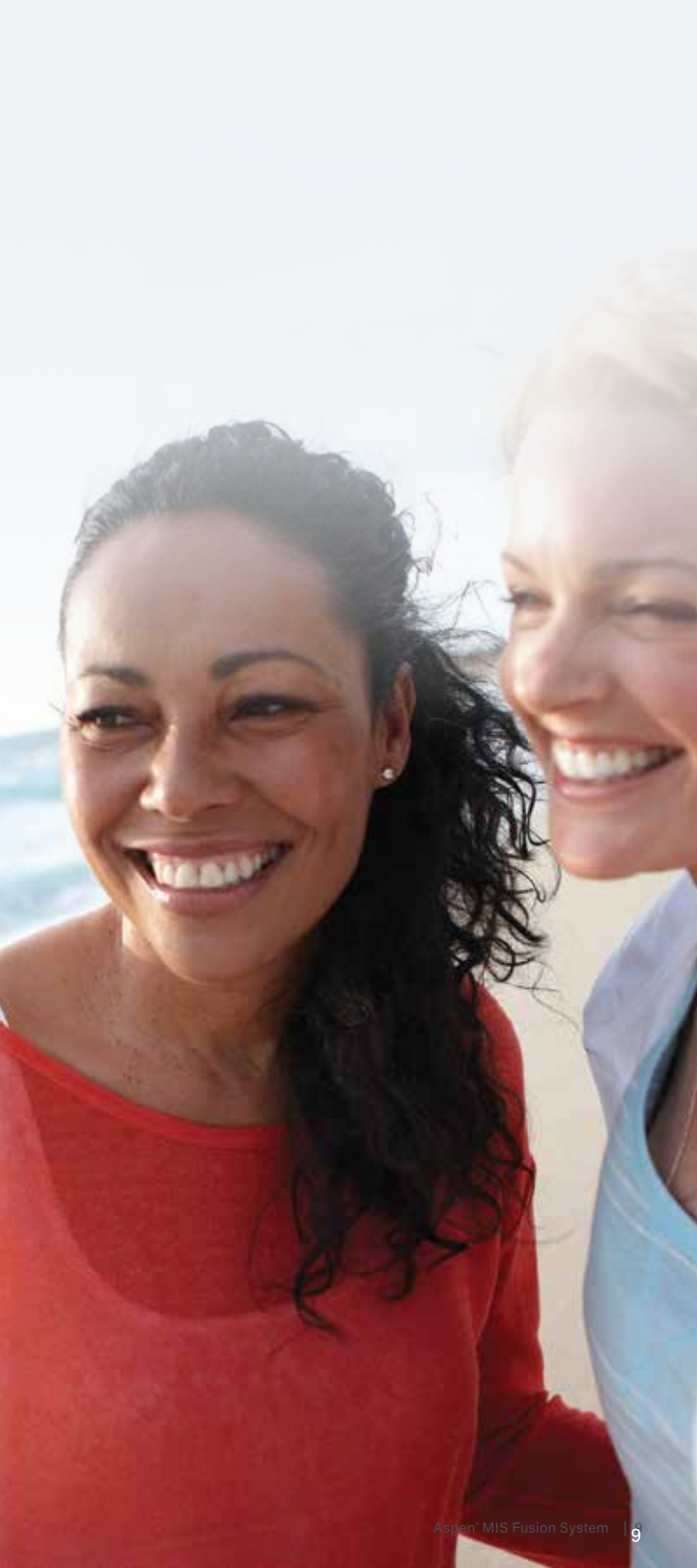
- Low back pain that intensifies with prolonged sitting, standing or exercise.
- Decreased range of motion and difficulty bending or twisting.
- Tightness in the hamstrings.
- Shooting or burning pain in the legs.
- Weakness in the legs or feet.
- Numbness or tingling in the legs.

The potential of spinal fusion

Conservative measures such as medication, physical therapy, and steroid injections are the first line of treatment for back and leg pain. However, if conservative measures are no longer successful, your surgeon may recommend a procedure known as spinal fusion.

During this surgical procedure, two or more spinal vertebrae are fused together to restrict movement and decrease the pain caused by instability. Most often, surgeons will use metal implants to act as an internal brace to immobilize the vertebrae while they heal.

Traditionally, they will use implants called pedicle screws and rods, which can involve a large incision and result in damage to the surrounding muscle tissue in order to secure them to the spine. But many patients do not need this invasive instrumentation.



A simpler alternative

The Aspen MIS Fusion System offers a minimally invasive implant option for spinal fusion. It has been shown to be comparable to screws in stabilizing the spine, which helps to address symptoms of back and leg pain at their source.1

The Aspen device is a small, clip-like titanium implant that attaches to the spinous process, the bony parts of the spine located closest to the skin and farther away from delicate nerve roots. Because of this, it can be implanted through a small 1 ½-inch incision while preserving surrounding muscle and tissue. The center of the Aspen device is also specifically designed to hold bone graft material that helps the body produce new bone to strengthen the spine.

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

Due to its minimally invasive nature, surgeons are reporting that patients who utilize the Aspen device may experience a less painful and quicker recovery compared to patients with traditional pedicle screw fixation. Studies show the Aspen device provides robust stabilization and promotes fusion while requiring a smaller incision, less muscle trauma, less blood loss, and a shorter surgery time.[1,2,3]

"The operation was very quick, very successful. I was up and [walking] around in a matter of hours. I'm able to do practically everything I've ever done in my life." – Dee, age 81

"Before my surgery I really had a lot of pain. Now I don't have any pain — it's so great." – Joanne, age 69

"The next day [after surgery] I walked by myself with absolutely zero pain. Within a month I was as mobile as I've ever been." – Tommy, age 71

Is the Aspen System right for me?

You may be a candidate for fusion with the Aspen MIS Fusion System if you suffer from chronic back and leg pain and have not found relief from conservative treatments.

Your doctor may have diagnosed you with a condition related to spinal degeneration, or perhaps even already recommended that you consider surgical options.

Many patients who need a single level fusion to address a degenerative condition are candidates for surgery with the Aspen device. For people who may not be able to physically handle a more extensive pedicle screw fusion procedure or long recovery —like the elderly or those who are ill — the Aspen device may be a particularly good option. Your doctor will help determine the best treatment for your condition.

Commonly Asked Questions

How long will I be in the hospital?
Only your doctor can determine the length of your stay. Patients treated with Aspen MIS Fusion System typically spend 2½ to 3½ days in the hospital.[3,4]

Will I be in pain after surgery?
Because the surgery is less invasive, causing less trauma to the muscles and tissue, you may experience 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 may be able to walk and lie down, but sitting could be uncomfortable. Use ice packs regularly and rest your back. Your doctor will prescribe pain medication to be used as needed. Slowly increase activities and follow your doctor's instructions carefully to ensure the best possible outcome. Studies have shown Aspen patients experience a statistically significant improvement in pain scores during the first year following surgery.[4]

Will this device activate security alarms at airports or other establishments?
It is highly unlikely that your Aspen spinal implant will trigger security alarms at commercial airports.

Will I feel the device through my skin?
Due to the small size and placement of the device, it is very unlikely that you would feel the device through your skin.

Will my insurance cover this surgery?
Please consult with your doctor and contact your insurance agent with questions regarding your specific insurance qualifications.

Indications for Use

The Aspen system is intended to be used to help provide immobilization and stabilization of spinal segments to aid in the fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Aspen MIS Fusion System is a posterior, non-pedicle supplemental fixation device intended for use at a single level in the non-cervical spine (T1-S1). It has been engineered for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation) and/or tumor.

The Aspen MIS Fusion System is intended for use with bone graft material and is not intended for standalone use.

References

1. Karahalios DG, et al. Biomechanics of a lumbar interspinous anchor with anterior lumbar interbody fusion. J Neurosurg Spine. April 2010. 12(4): 372–380. 2. Panchal R, DenHaese R, Hill C, et al. Anterior and Lateral Lumbar Interbody Fusion With Supplemental Interspinous Process Fixation: Outcomes from a Multicenter, Prospective, Randomized, Controlled Study. Int J Spine Surg 2018;12(2):172–184. 3. Kee Kim, MD. The Aspen MIS Fusion System versus Pedicle Screw Fixation, A comparison of Supplemental Posterior Fixation in ALIF and LLIF: Interaoperative Outcomes in a Prospective Randomized Multi-Center Trial. Presented at SMISS Global Forum 2014. www.smiss.org 4. Vokshoor A, Khurana S, Wilson D, et al. Clinical and Radiographic Outcomes after Spinous Process Fixation and Posterior Fusion in an Elderly Cohort. Surg Technol Int 2014; 25:271-276.

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Results are not necessarily typical, indicative, or representative of all recipient patients. Results will vary due to health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities and restrictions will differ from patient to patient. Talk to your surgeon about whether fusion surgery is right for you and the risks of the procedure, including the risk of infection, loosening or failure.