

Timberline[®]

Lateral Fusion System

Patient Education



HIGHRIDGE

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Individuals represented in the brochure
are not actual patients.

Enjoying Life Without Back Pain

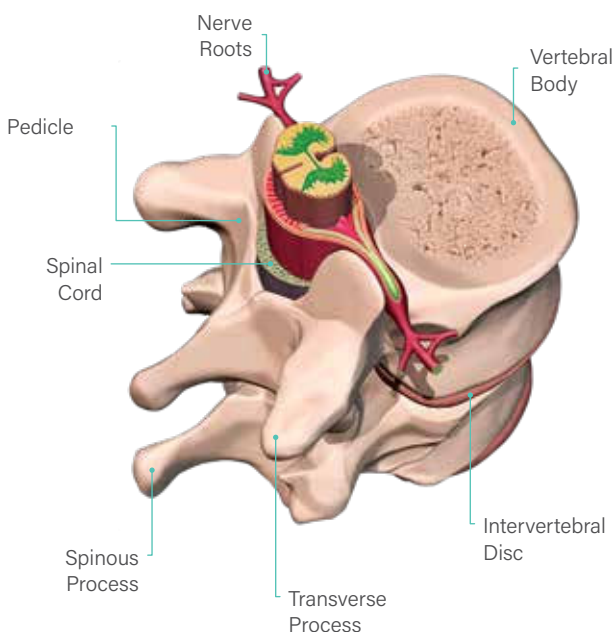
Chronic lower back pain can drastically affect your way of life, impacting your job, family, hobbies and overall well being. The cause could be some form of back injury or the result of daily wear and tear on your spine, but the good news is that there's something you can do about it. In fact, you may 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 Timberline Lateral Fusion System, a device designed for less invasive spine fusion for cases requiring an interbody device.

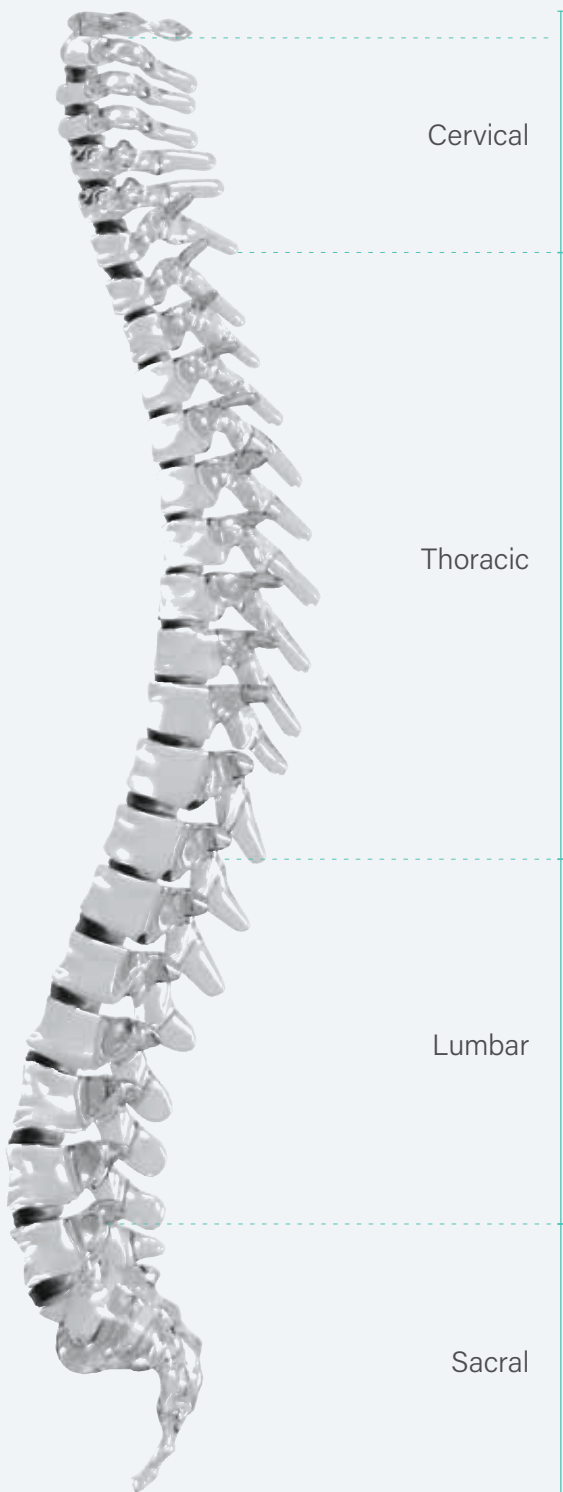
Note: Please talk with your doctor to determine the most suitable treatment option for you.



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.







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.

Spinal fusion with an interbody device

For more advanced cases of spinal degeneration, especially when the intervertebral disc is damaged, surgeons may implant a device between the vertebrae called an “interbody device” to provide increased stability and optimize the environment as the fusion takes hold.

These devices restore the spacing between the vertebrae and serve as a repository for bone graft, a substance that is used to help the body create new bone to strengthen the spine.

The most common surgical procedures for spinal fusion with an interbody device approach the spine from either the front (anterior) or the back (posterior) of the body. However, these traditional approaches can involve cutting through important stabilizing muscles, ligaments and other healthy tissues that are located along the front and back of the spine.

Surgery with the minimally invasive timberline lateral fusion system

The Timberline system enables one of the most minimally invasive procedures available for interbody spinal fusion. This is because it allows surgeons to access the spine from the side, called the lateral approach, and typically requires just one small incision of less than two inches.



Why the lateral approach?

The lateral approach overcomes many of the challenges associated with traditional anterior and posterior approaches. Patients can benefit from this procedure in several ways:

- **Smaller Incision** – The lateral approach typically involves a smaller incision when compared to traditional procedures, which usually means less blood loss and less soft tissue damage.
- **Muscle Preservation** – The lateral approach allows the surgeon to preserve key muscles of the back that play an important role in supporting the spine. Disrupting them during surgery could lead to longer recovery times and may increase the probability of developing further problems with the spine, long term.
- **Ligament Preservation** – This approach preserves the anterior and posterior longitudinal ligaments. These tough strands of elastic tissue act as tension bands to help stabilize the spine and are often removed or disrupted during traditional procedures.
- **Excellent Access** – Many surgeons believe that the lateral approach provides better access to the diseased levels of the spine, and allows them to better prepare the intervertebral disc space for a fusion.
- **Optimized Conditions for Fusion** – The implant size, and associated space for grafting material, that a surgeon can implant via the lateral approach is much larger than those used in traditional procedures. This provides more stability and surface area for fusion.

- **Quicker Recovery** – Due to the minimally invasive nature of the lateral approach, most patients are able to leave the hospital in less than 2 days compared to 3-5 days with traditional, more invasive procedures. Patients typically return to normal daily activities within approximately 4-6 weeks, whereas more invasive procedures may result in recovery times of up to 6 months.¹
- **Lower Complication Rate** – Studies have shown that the lateral approach has a lower complication rate than traditional procedures.^{*,1}



* The lateral approach is not appropriate for the L5–S1 segment, or patients with severe deformity.

1. Rodgers WB, et al. Intraoperative and Early Postoperative Complications in Extreme Lateral Interbody Fusion: An analysis of 600 cases. Spine. January 2011. 36(1): 26–33.

This study accounts for the use of supplemental fixation, which was used in 99.2% of the cases.

How is the procedure performed?

The patient is positioned on his or her side for the surgery. After making a small incision on the patient's side, the surgeon initiates a safe passage down to the spine using specially designed Timberline system instruments and a unique soft tissue retraction device. This lighted, translucent retractor system allows the surgeon to create precisely the amount of space needed to see the affected disc space, and successfully perform the procedure while minimizing interruption to the surrounding tissue. Fluoroscopy (real time x-ray) is used throughout the procedure to confirm correct positioning of the lateral retractor system and instrumentation.

The surgeon then removes the old intervertebral disc tissue and inserts one of the Timberline PEEK-OPTIMA® polymer LT1 implants along with bone-grafting material to help promote fusion. PEEK-OPTIMA LT1 is a high-performance biomaterial that has shown excellent durability in the body. The Timberline implant helps restore the proper disc height and supports the spine while the fusion takes hold.



The Timberline Lateral Fusion System is indicated for use with supplemental fixation. There are many minimally invasive options available. Consult with your surgeon about which option is best for you.



Is the Timberline System right for me?

The lateral approach is a great option for many patients needing an interbody fusion, but it is not for every fusion candidate. Your surgeon will help determine the best approach for you.

You may be a good candidate for a lateral approach fusion if you are suffering from one or more of the following conditions:



- Degenerative disc disease with instability.
- Degenerative spondylolisthesis (less than grade 2).
- Adjacent level disease.
- Recurrent disc herniation.
- Pseudoarthrosis.
- Degenerative Scoliosis.
- Post laminectomy instability.



Commonly Asked Questions

How long will I be in the hospital?

Only your doctor can determine the length of your stay, which is dependent on your specific situation. Due to the Timberline device's minimally invasive nature, surgeons are saying that patients may experience shorter hospital stays than with traditional fusion procedures.

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.

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

It is highly unlikely that your Timberline spinal implant will trigger security alarms at commercial airports. The Timberline implant is made of PEEK-OPTIMA LT1, which is a radiolucent material. Your surgeon may choose to utilize additional fixation devices to complement the Timberline implant. Consult with your surgeon.

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

When used as a lumbar intervertebral body fusion device, the Timberline system is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Timberline system is to be combined with supplemental fixation.

When used as a vertebral body replacement, the Timberline system is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The Timberline system may also be used in the thoracolumbar spine (i.e., T1– L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, or to restore the height of a collapsed vertebral body. The Timberline device is also indicated for treating fractures of the thoracic and lumbar spine. The Timberline system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.



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