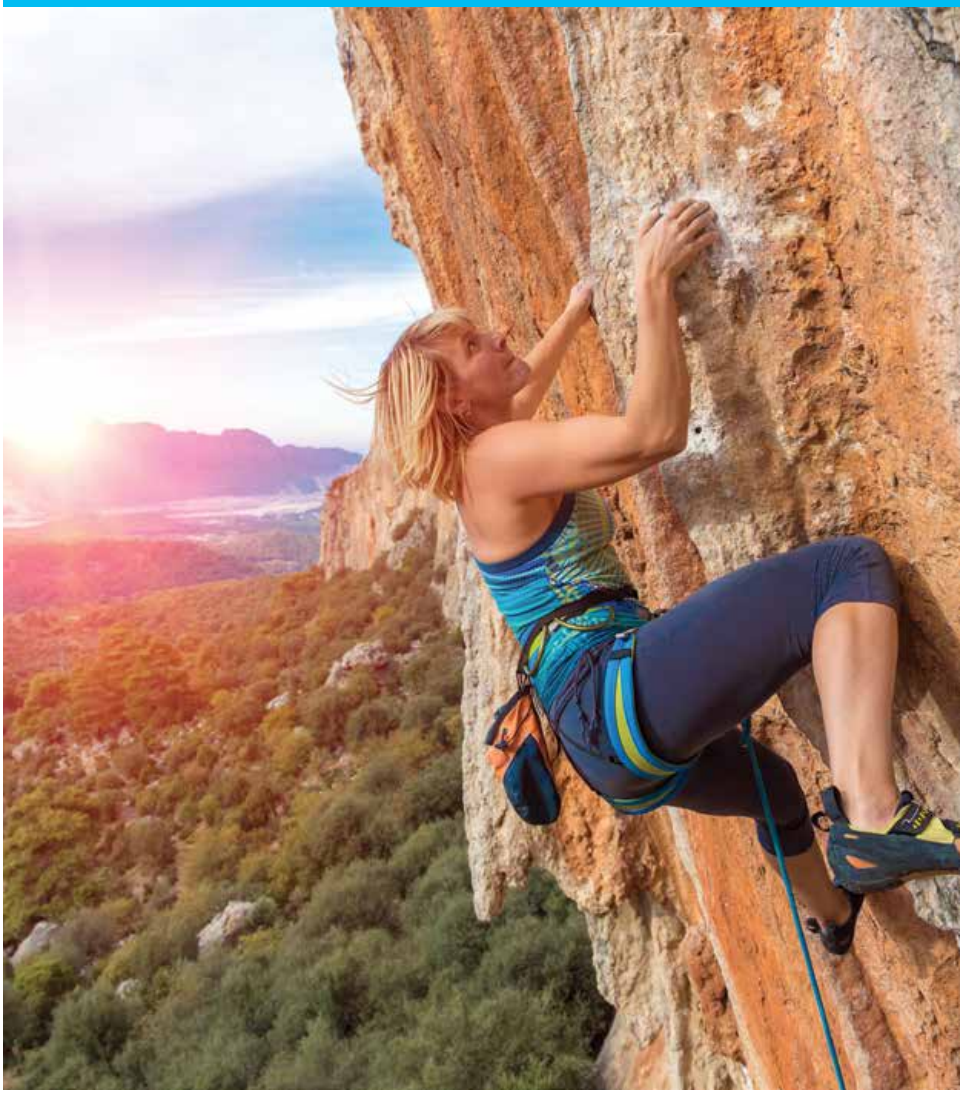
PATIENT INFORMATION



TRANSFORAMINAL LUMBAR INTERBODY FUSION

TLIF

Life moves us

Outside the US Only

GLOBUS MEDICAL

Transforaminal Lumbar Interbody Fusion

Patient Information

This brochure will help you understand more about:

- **General conditions of the spine**
- **Information about surgical treatment**
- **TLIF surgical technique**
- **What to expect from surgery**

The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment, or outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results, and other important medical information that pertains to this procedure.

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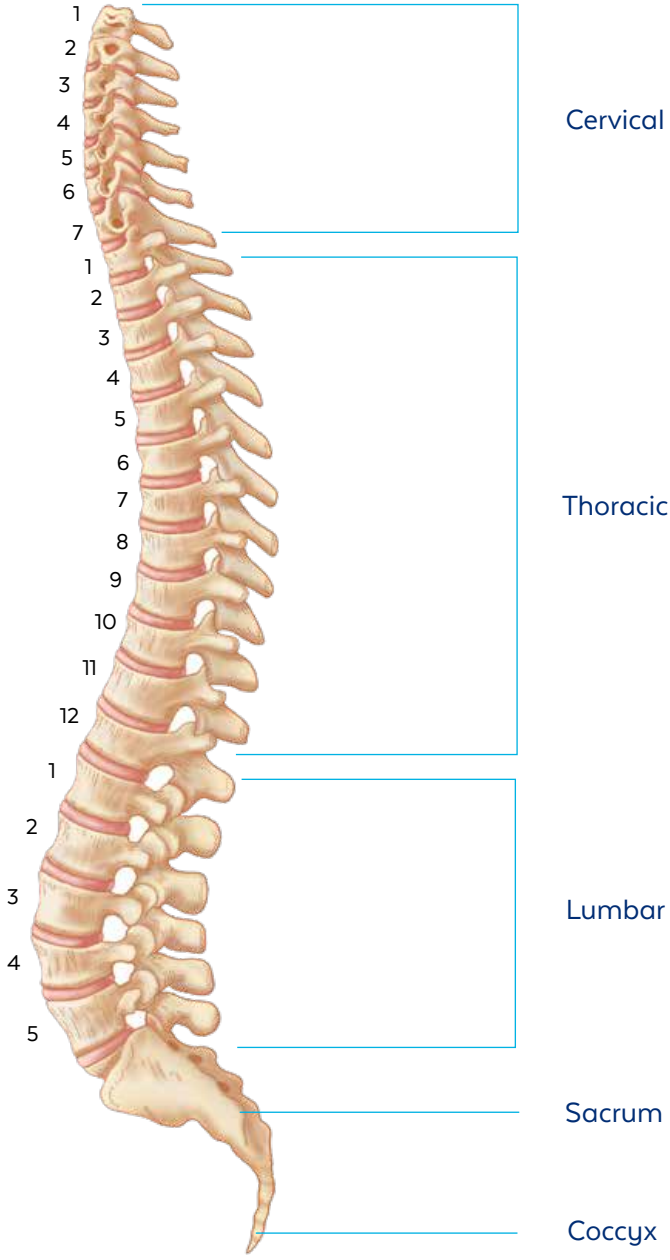
Anatomy of the Spine



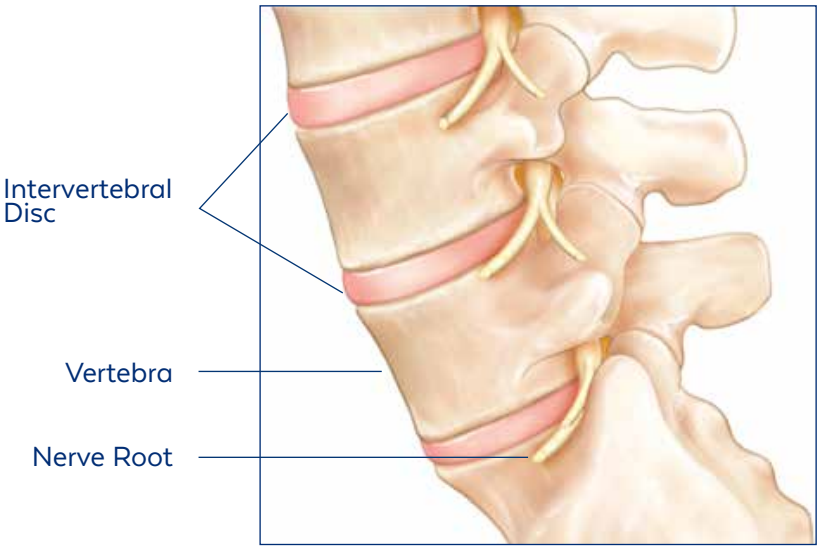
The spine is composed of vertebrae (bones) and is divided into three main parts:

- Cervical (7 vertebrae)
- Thoracic (12 vertebrae)
- Lumbar (5 vertebrae)

Below the lumbar spine is the sacrum, which is comprised of five fused vertebrae. At the end of the spine is the coccyx, or the tailbone.

The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. They also protect the spinal canal (the cavity that runs through each of the vertebrae and contains the spinal cord) and provide exit points for spinal nerves.

The individual vertebrae are separated by intervertebral discs, which act as cushions or shock absorbers between the vertebral bodies.



Conditions of the Lumbar Spine

In the normal spine, intervertebral discs act as a cushion between vertebrae. Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration of the discs in your low back. As a result, someone may experience one or more of the following conditions.

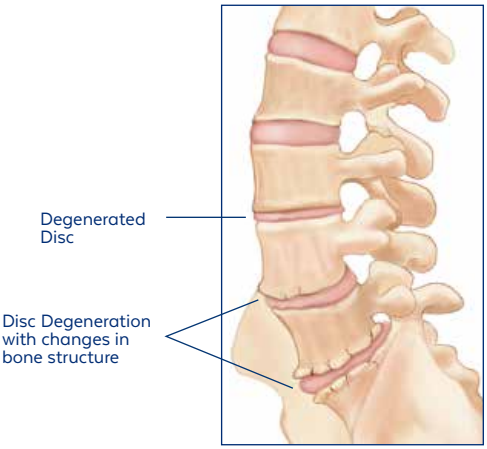
Degenerative Disc Disease

Degenerative changes in the spine may cause instability and pain in your back. Degenerative disc disease (DDD) involves the intervertebral disc and is part of the natural aging process. DDD can also result from torsional (twisting) injury to the lower back.

In the normal spine, your discs act as a cushion between vertebrae. Over time the discs can lose flexibility, elasticity, and height. When this happens, they lose their shock-absorbing characteristics, which can lead to abnormal motion or alignment of the spine that may result in pain.

Healthy Discs

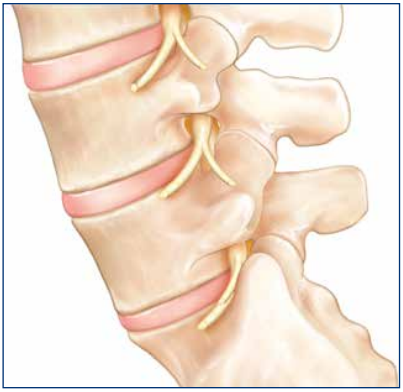
Symptoms include pain, burning, or numbness in the back or legs. This pain may increase with activities that involve sitting for extended periods, bending, or twisting.



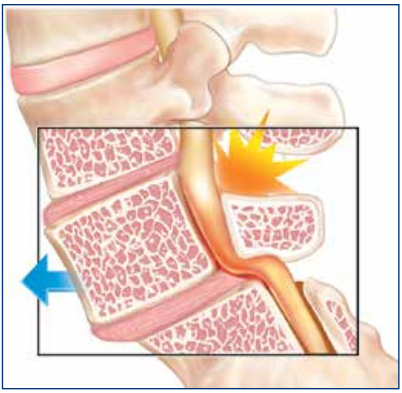
Spondylolisthesis

Spondylolisthesis is a condition in which one of the vertebrae slips forward or backward (retrolisthesis). If left untreated, this can lead to deformity of the spine and narrowing of the spinal canal.

Typical symptoms include low back pain, muscle spasms, thigh or leg pain, and weakness. Interestingly, some patients are asymptomatic and only learn of the disorder after spinal radiographs, such as X-rays.



Normal spine segment

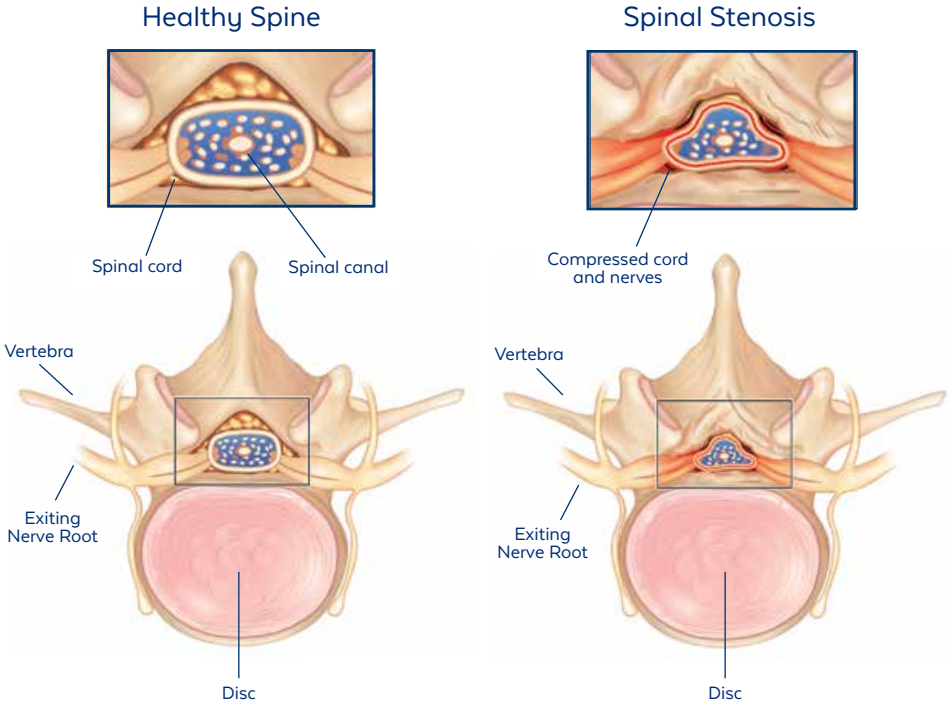


Displaced vertebra causing pressure on nerve

Conditions of the Lumbar Spine (Cont'd)

Lumbar Spinal Stenosis

Spinal stenosis is the narrowing of areas in the spine that cover and protect the nerve roots and the spinal cord. It is most commonly caused by age-related spinal degeneration. This narrowing can put pressure on the nerves and cause pain.



Symptoms often start gradually. Pain is likely to be present or worsen when you stand or walk, and lessen or disappear when you sit down or lean forward. Typically, people suffering from lumbar spinal stenosis will experience pain, tingling, weakness, or numbness that radiates from the lower back into the buttocks and legs.

Trauma

Traumatic events such as car accidents, sports injuries, and other serious incidents can cause injury to the spine, including fractures and dislocations.

Spinal Deformity

Spinal deformity is an abnormal curvature to the spine. The type of deformity depends on the curvature.

- Scoliosis: abnormal sideways curve
- Kyphosis: abnormal outwards curve that may create the appearance of a hunch back
- Lordosis: abnormal inward curve

Pseudarthrosis

Pseudarthrosis refers to failed previous fusion.

Symptoms of these conditions can include:

- Tingling or numbness in the lower extremities
- Radiating pain, weakness, and/or numbness in your back, hips, legs, or feet
- Bowel or bladder disturbances

These symptoms may be treated with non-surgical methods for as long as possible. These treatments include rest, ice or heat, weight control, exercise, physical therapy, epidural injections for pain management, and medication.

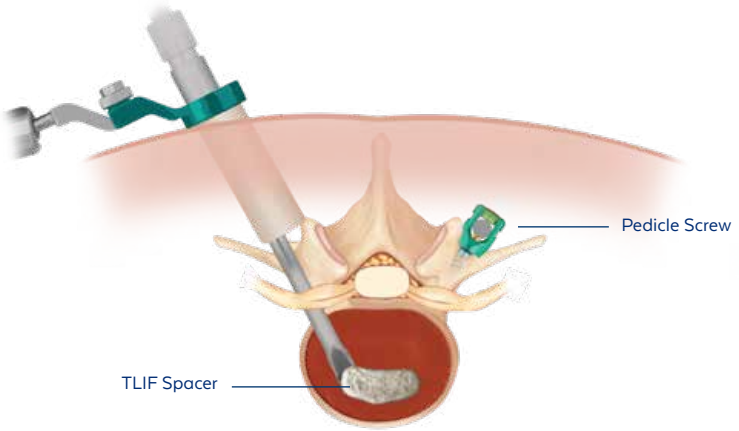
If these non-surgical treatments do not bring relief after a period of time, surgical treatments may be recommended to take pressure off the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae.

How Is a TLIF Performed?

During the surgery the patient lies face down, and the procedure is performed through an incision in the back. The length of the incision depends on how many levels are being treated. First, the surgeon will make an incision in the skin of the back over the vertebra(e) to be treated. In a traditional open TLIF, a 3-6 inch incision is typically required. A small section of the bone and disc is removed to clear a pathway for the interbody spacer.

An interbody spacer is inserted into the disc space to aid in supporting areas between the vertebrae where the disc has been removed. Its function is to stabilize the segment and help improve the overall alignment of the spine. This also provides more room for the nerves. The central chamber and surrounding area is packed with bone graft material to help promote bone growth between two vertebrae. The goal of this surgery is to fuse or grow bone between the vertebrae.

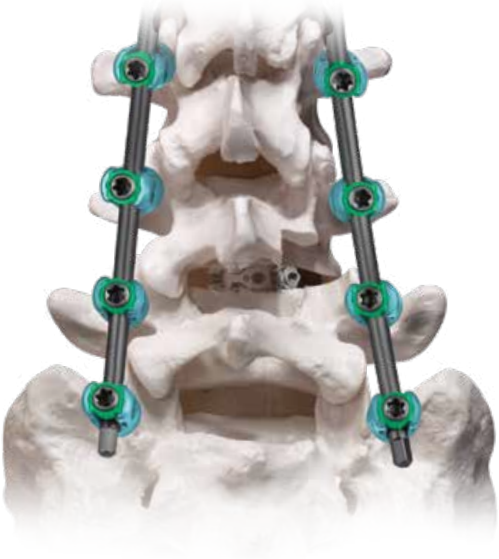
A variety of different interbody spacer options are available. Talk to your doctor about which implants and techniques may be best to treat your condition.



Pedicle screws and rods are used to hold the spinal column in place while fusion occurs.

The surgeon uses medical imaging to determine the precise screw location. The screws are then inserted into the vertebrae to be fused. Bone graft may be added along the sides of the vertebrae to help stimulate fusion. The surgeon then closes the incision and moves the patient into recovery.

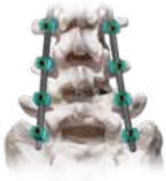
Over time, the vertebrae can grow together through fusion. This process varies among patients and can take anywhere from 6 months to a year.



Posterior pedicle screw and rod construct

How Is a TLIF Performed? (Cont'd)

Globus Medical offers a variety of implants for TLIF surgery.

Implant Type	Implant Name*	Lumbar Spine Conditions**
Interbody Spacers 	ALTERA® CALIBER® HEDRON T™ LATIS® RISE® SABLE® PATRIOT® CONSTITUTION® PATRIOT® SIGNATURE® SUSTAIN® Arch SUSTAIN®-R Arch	Degenerative disc disease, spondylolisthesis, retrolisthesis
Pedicle Screws and Rods 	CREO® REVERE® REVOLVE® PROTEX® BEACON®	Degenerative disc disease, spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis

Visit Globus Medical's website at https://www.globusmedical.com/international/
**These products may not be available in your region.*
***See definitions starting on page 6.*

These implants are composed of titanium alloys, polyetheretherketone (PEEK), commercially pure titanium, tantalum, stainless steel, hydroxyapatite, and/or cobalt chromium alloy. These materials are biocompatible and have a history of clinical use. If you have an allergy to any of these materials, please consult your physician.

Frequently Asked Questions

What Should I Expect With My Recovery?

Many patients will notice improvement of some or all of their symptoms, and pain from surgery may diminish 2 to 4 weeks after surgery. However, recovery time varies among patients.

It is the surgeon's goal for the patient to eventually return to their preoperative activities. A positive attitude, reasonable expectations, and compliance with your doctor's post-surgery instructions may all contribute to a satisfactory outcome.

How Long Will My Implant Last?

The device lifetime for these implants is one year, in which it is expected that the devices will achieve their intended purpose (to support fusion) and maintain performance until fusion occurs. After fusion occurs, the devices are made to survive the life of the patient. Pedicle screws and rods can be removed after fusion occurs; however, this is determined by the surgeon and patient.

Can I Have an MRI After the Devices Are Implanted?

MR compatibility is shown below for these devices. Your radiologist may request this information prior to taking an MRI. These instructions are also provided in the device insert.

Interbody Spacers

These devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the devices are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by these devices is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Pedicle Screws & Rods

These devices have not been evaluated for safety and compatibility in the MR environment, and they have not been tested for heating or migration in the MR environment.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this device if you have an infection, a congenital abnormality, tumors, degenerative diseases, spondylolisthesis unable to be reduced to grade 1, a fever or high white blood cell count, rheumatoid arthritis, osteoporosis, or cancer, have had prior fusions at the level(s) to be treated, or are obese, pregnant, diabetic, or not fully grown. In addition, a patient whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions may place undue stresses on the implant during healing and may be at a higher risk of implant failure.

As with any surgical procedure, complications or adverse effects may occur following the placement of these devices. These can include but are not limited to early or late implant bending, device fracture or failure, loss of fixation, subsidence, loosening, movement/migration, decrease in bone density or bone fracture, abnormal sensations, and allergic reaction to implant material.

Other adverse effects that may be associated with any spinal procedure include non-union or delayed union, pseudarthrosis (failed spinal fusion), pain, secondary surgery, bleeding, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, joint inflammation, changes in spinal curvature, loss of correction, cardiovascular system compromise, respiratory problems, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, restriction of activities, lack of effective treatment, paralysis, and death.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult your surgeon for additional information on this topic and how it applies to your particular medical condition.

If you experience a serious adverse event in relation to the implanted device, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Other	Report to your local health authority per local guidelines	

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.

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