PATIENT INFORMATION

POSTERIOR LUMBAR INTERBODY FUSION

PLIF

Life moves us

Outside the US Only

GLOBUS MEDICAL

Posterior Lumbar Interbody Fusion

Patient Information

This brochure will help you understand more about:

- **General conditions of the spine**
- **Information about surgical treatment**
- **PLIF 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 be a warranty or 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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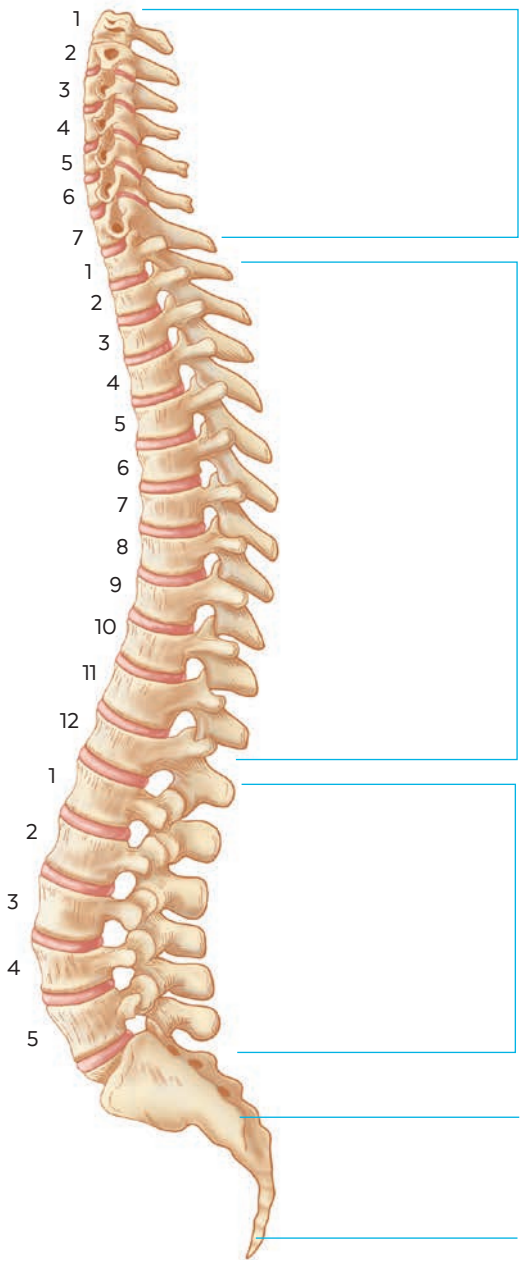
Anatomy of the Spine



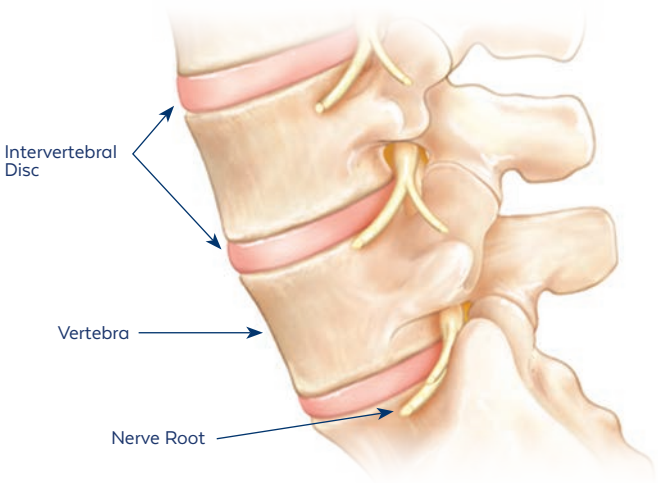
The spine is made up of vertebrae (bones) and is divided into 3 main sections:

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

Below the lumbar spine is the sacrum, which is comprised of 5 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.

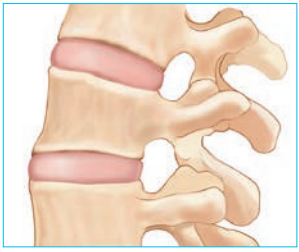
The individual vertebrae are separated by intervertebral discs, which act as cushions or shock absorbers between the vertebral bodies.



Conditions of the Lumbar Spine

In the normal spine, intervertebral discs act as cushions 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 lower back. As a result, someone may experience one or more of the following conditions.

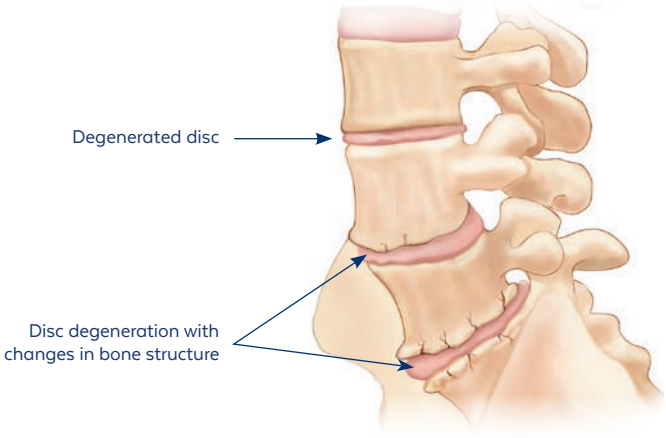
Degenerative Disc Disease



Healthy discs

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.

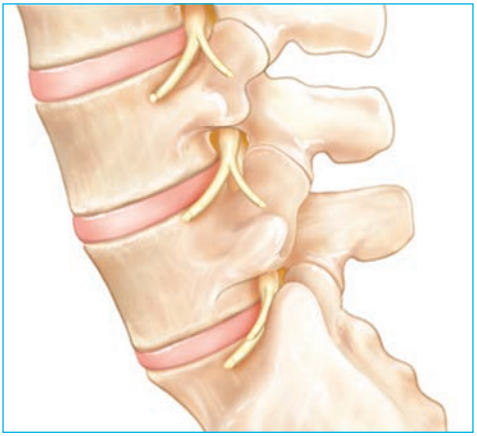
In the normal spine, your discs act as a cushion between vertebrae. Over time the discs can lose flexibility, elasticity, and height. When this happens, they lose their shock-absorbing characteristics, which can lead to abnormal motion or alignment of the spine that may result in pain.



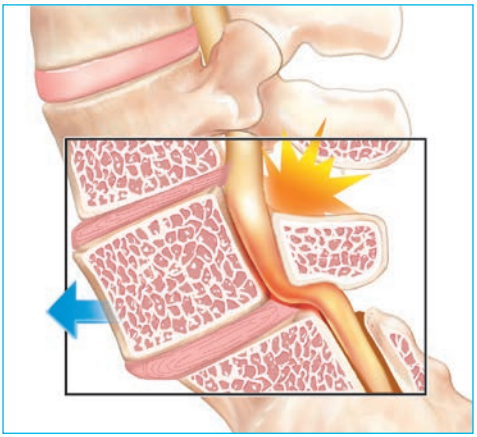
Symptoms may include pain, burning, or numbness in the back or legs. This pain may increase with activities that involve sitting for extended periods, bending, or twisting.

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.



Normal spine segment



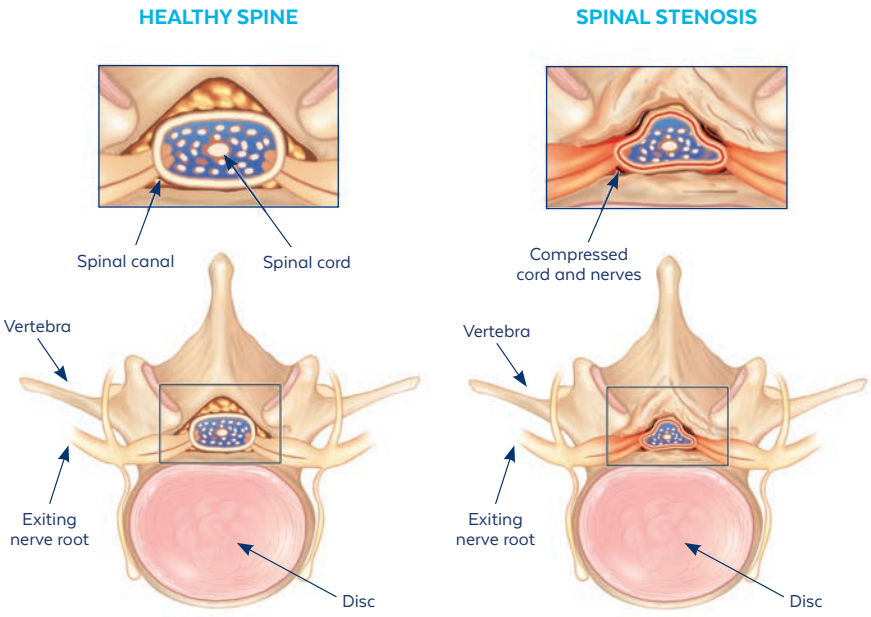
Displaced vertebra causing pressure on nerve

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.

Conditions of the Lumbar Spine (Cont'd)

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

Events such as car accidents, sports injuries, and other serious incidents that 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

Pseudoarthrosis refers to failed fusion (joining of bones).

Symptoms of these conditions can include:

- Tingling or numbness in the lower extremities
- Radiating pain, weakness, and/or numbness in the back, hips, legs, and/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.

Treating Spinal Conditions

There are a variety of surgical approaches to treating spinal conditions. The choice of which approach to use is dependent on many factors, which include patient symptoms, patient anatomy, prior surgery, and/or surgeon preference. PLIF is one of the options that your doctor may choose.

What is a PLIF?

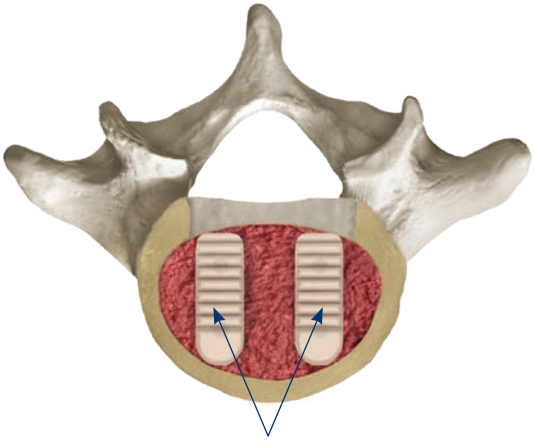
Posterior lumbar interbody fusion (PLIF) is a form of spine surgery in which the lumbar spine is approached through an incision on the back. This procedure is used to stabilize the spine by fusing two or more vertebrae together.

How is a PLIF Performed?

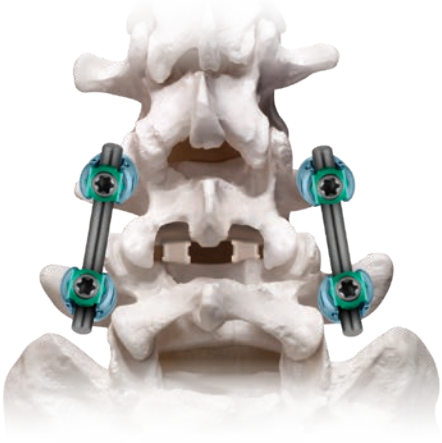
During the surgery the patient lies face down. First, the surgeon makes an incision in the skin of the back over the vertebra(e) to be treated. In a traditional PLIF, a 3-6 inch incision is typically required depending on the number of surgical levels. A small section of the bone and disc are removed to clear a pathway for the interbody spacers.

Two interbody spacers are inserted into the disc space to aid in supporting areas between the vertebrae where the disc was removed. The intended function of the spacers is to stabilize the segment and to improve overall alignment of the spine. Increasing disc height also provides more room for the nerves. The central chamber and surrounding area is packed with bone graft material to help promote bone growth (fusion) between adjacent 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 segment in place while fusion occurs and for stability. The screws are 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.

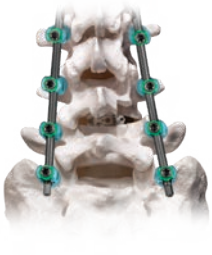


Posterior pedicle screw and rod construct

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

How is a PLIF Performed? (Cont'd)

Globus Medical offers a variety of implants for PLIF surgery.

Implant Type	Implant Name*	Lumbar Spine Conditions**
Interbody Spacers 	CALIBER® HEDRON-P® PATRIOT® CONSTITUTION® RISE® SABLE® SUSTAIN® Small SUSTAIN®-R Small SUSTAIN®-O SUSTAIN®-RT	Degenerative disc disease, spondylolisthesis, retrolisthesis
Pedicle Screws and Rods 	BEACON® CREO® PROTEX® REVERE® REVOLVE®	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 may diminish between 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 his/ her 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 3000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scanning conditions mentioned above, these 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 imagined with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Pedicle Screw and Rods

These devices have not been evaluated for safety and compatibility in the MR environment. These devices have not been tested for heating and 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, certain degenerative diseases, spondylolisthesis unable to be reduced to grade 1, fever or high white blood cell count, have had prior fusion at the levels to be treated, or are obese, osteoporotic, pregnant, or possess acquired bone friability (fragility). In addition, a patient whose activity level, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions may place undue stress on the implant during healing and that patient 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, decreased bone density or bone fractures, abnormal sensations, and allergic reaction to implant materials.

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, spinal infection, spinal cord and/or nerve damage, changes to the spinal curvature or loss of curvature, urinary retention or bladder control loss, reproductive system compromise, bursitis, vascular or visceral injury, decrease in bone density, 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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