



ANTERIOR LUMBAR INTERBODY FUSION

Anterior Lumbar Interbody Fusion

Patient Information

This brochure will help you understand more about:

- ▶ **General conditions of the spine**
- ▶ **Information about surgical treatment**
- ▶ **Anterior Lumbar Interbody Fusion (ALIF)**
- ▶ **What to expect from surgery**

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

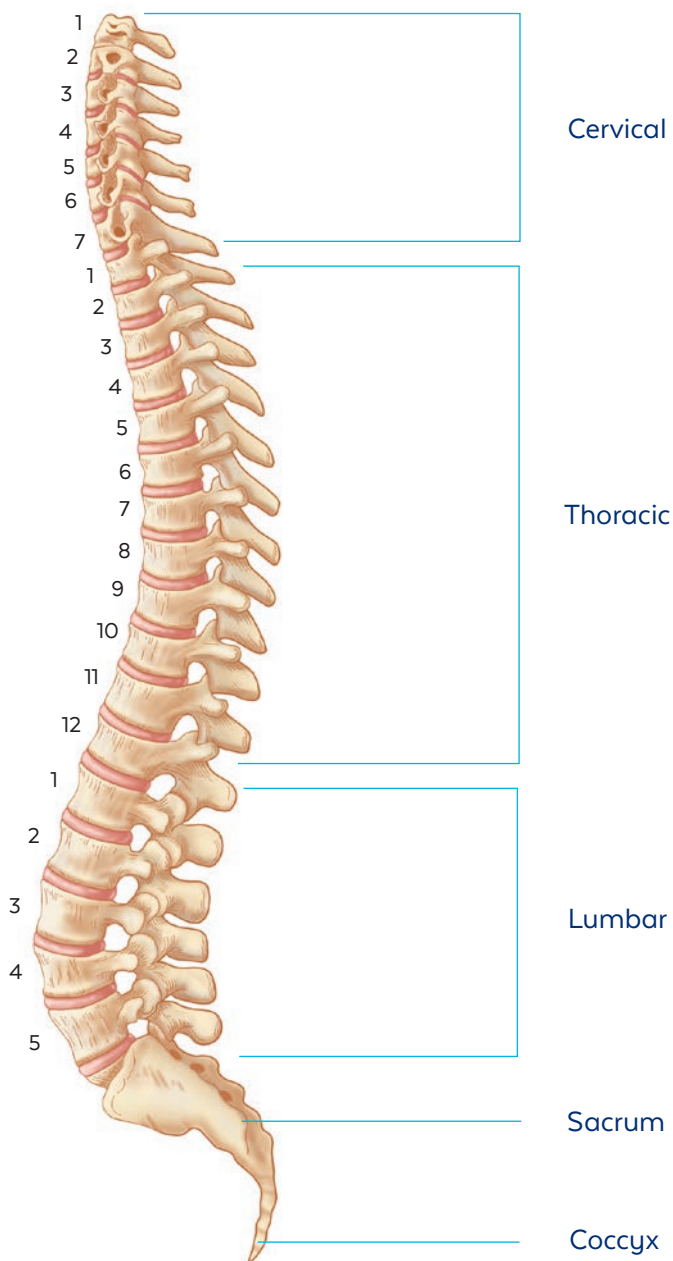
This brochure is intended to be an educational resource only and is not meant to be a warranty, or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, contraindications, warnings, precautions,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



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Anatomy of the Spine



The Healthy Spine

The spine is one of the most important structures in the human body. It supports much of the body's weight and protects the spinal cord, which carries information from the brain to the rest of the body. The spine is strong but flexible, allowing for a wide range of movements.

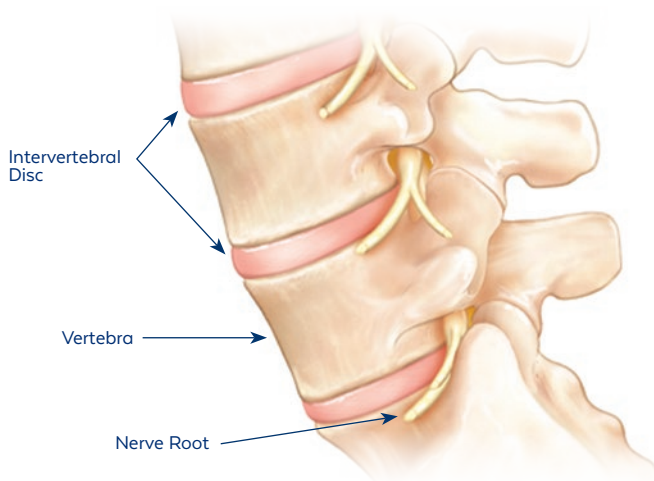
The spine is made up of vertebrae (bones) and is divided into three main sections:

- ▶ 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 (cavity that runs through each of the vertebrae and contains the spinal cord) and provide exit points for spinal nerves.

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



Conditions of the Lumbar Spine

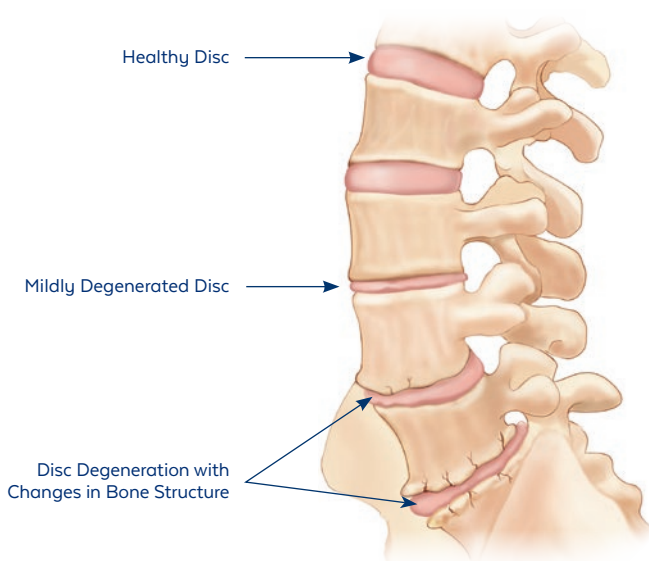
In the normal spine, intervertebral discs act as a cushion between the vertebrae. Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration of the discs in your low back. As a result, someone may experience one or more of the following conditions.

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. Disc degeneration 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, leading to abnormal motion or alignment of the spine, which may result in pain.

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



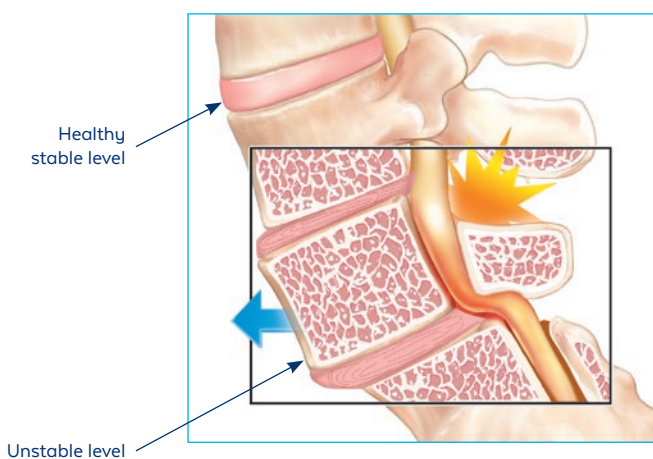
Spondylolisthesis

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 X-rays.



Normal spine segment



Displaced vertebra causing pressure on nerve

Conditions of the Lumbar Spine (Cont'd)

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.

Spinal Instability

Spinal instability occurs when the stabilizing structures of the spine become compromised by disease, age, or damage. Several factors can lead to spinal instability, including degeneration or trauma.

Spondylolysis

Spondylolysis occurs when a stress fracture through a specific part of the vertebrae causes weakness and instability.

Spinal Stenosis

Spinal stenosis describes the narrowing of areas in the spine that cover and protect the nerve roots and spinal cord. This can be caused by herniated (bulging) discs, osteophytes (bony projections), or ligaments compressing the spinal cord.

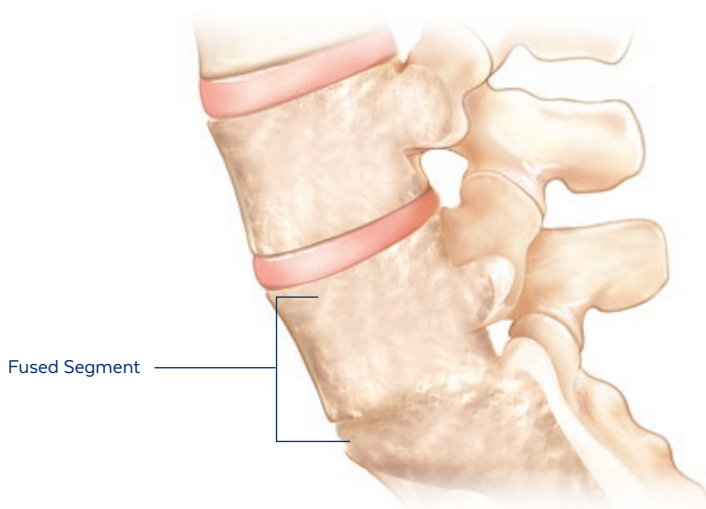
Symptoms of these conditions can include:

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

General Treatment Options

Symptoms due to spinal instability or other conditions may be treated with non-surgical methods for as long as possible. These treatments include rest, ice or heat, weight control, exercise, physical therapy, medication, and steroid injections.

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

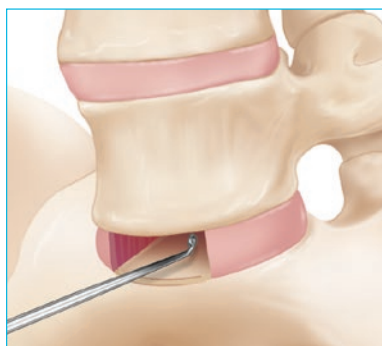


Surgical treatment involves removal of the affected discs and fusion (joining of two bones together) of the vertebral segments. Spinal fusion is accomplished by bone growth between the vertebrae, helping to minimize motion in the area, which may help reduce pain.

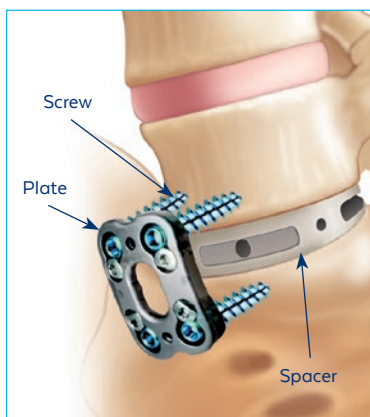
Depending on certain factors, the surgeon may decide to perform fusion using an anterior approach to the spine, which means an incision in the abdomen, or a posterior approach, which means an incision in the back. Sometimes the surgeon may use a combination of these two approaches.

What is Anterior Lumbar Interbody Fusion (ALIF)?

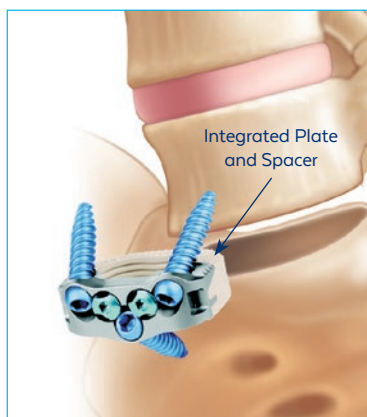
The primary goal of this procedure is to relieve pressure on either the nerve roots or spinal cord and/or treat a painful disc. The unhealthy disc is removed using surgical instruments.



An interbody fusion implant may be inserted to fill the vacant disc space. A plate and screws, or an integrated plate-spacer with fixation (i.e., screws or anchors), may be used to hold the vertebrae in place while fusion occurs. These devices may be used with pedicle screw and rod fixation (stabilization systems). Please refer to the pedicle screw fixation surgery brochure for more information on those devices.



Interbody spacer with lumbar plate and screws



Integrated plate-spacer with screws

Globus Medical offers a variety of implants for ALIF surgery.

Implant Type

Implant Name*

Lumbar Spine Conditions**

Interbody Spacers



HEDRON A™
MAGNIFY®
PATRIOT®
CONTINENTAL®
PATRIOT®
TransContinental®
PATRIOT®
TransContinental® M
SUSTAIN® Large
SUSTAIN®-R Large

Degenerative disc disease,
spondylolisthesis, retrolisthesis

Integrated Plate-Spacers
(and screws or anchors)



CORBEL®
HEDRON IA™
INDEPENDENCE®
INDEPENDENCE MIS®
INDEPENDENCE
MIS AGX™
MAGNIFY®-S
MONUMENT®

Degenerative disc disease,
spondylolisthesis, retrolisthesis

Lumbar Plates
(and screws)



CITADEL®
PLYMOUTH®
TRUSS®

Spine instability, fracture, tumor,
degenerative disc disease,
pseudarthrosis, spondylolysis,
spondylolisthesis, scoliosis,
kyphosis, lordosis, spinal stenosis,
failed previous spine surgery

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 typically composed of titanium alloys, polyetheretherketone (PEEK), commercially pure titanium, cobalt chromium alloy, hydroxyapatite, and/or tantalum. 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 during recovery?

Patients may notice improvement of some or all 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 return to normal activities as soon as possible. A positive attitude, reasonable expectations, and compliance with post-surgery instructions all help to 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. Lumbar plates 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.

Lumbar Interbody Spacers and Integrated Plate-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.

Lumbar Plates

These devices can be safety 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/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Quadrature Body Coil Only

Under the scan conditions defined above, these devices are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

The image artifact is not expected to extend beyond 55mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for these devices if you have an infection, congenital abnormality, tumors, degenerative diseases, 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, breakage, loosening, movement/migration, decrease in bone density or bone fracture, abnormal sensations, and allergic reaction to implant material.

Other general adverse effects that may be associated with any spinal surgical 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 conditions, 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 effect 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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M E D I C A L

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