PATIENT INFORMATION

LATERAL LUMBAR INTERBODY FUSION

LLIF

Life moves us

Outside the US Only

GLOBUS MEDICAL

Lateral Lumbar Interbody Fusion

Patient Information

This brochure will help you understand more about:

- **General conditions of the spine**
- **Information about surgical treatment**
- **LLIF 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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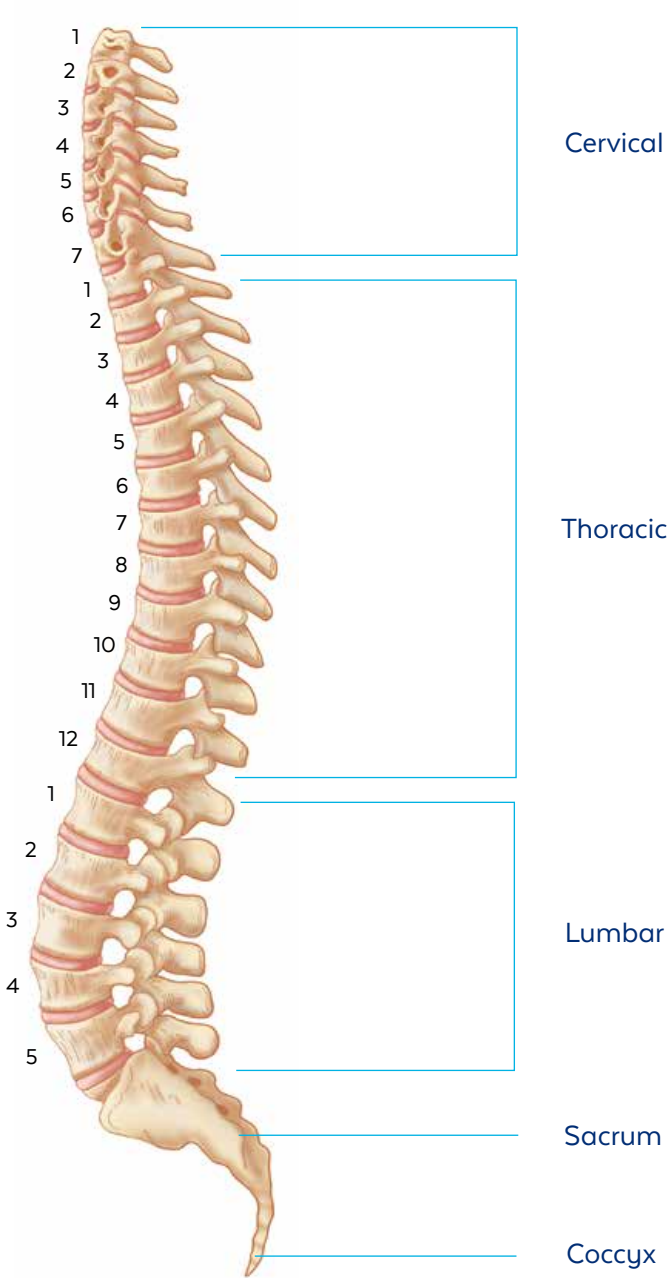
Anatomy of the Spine



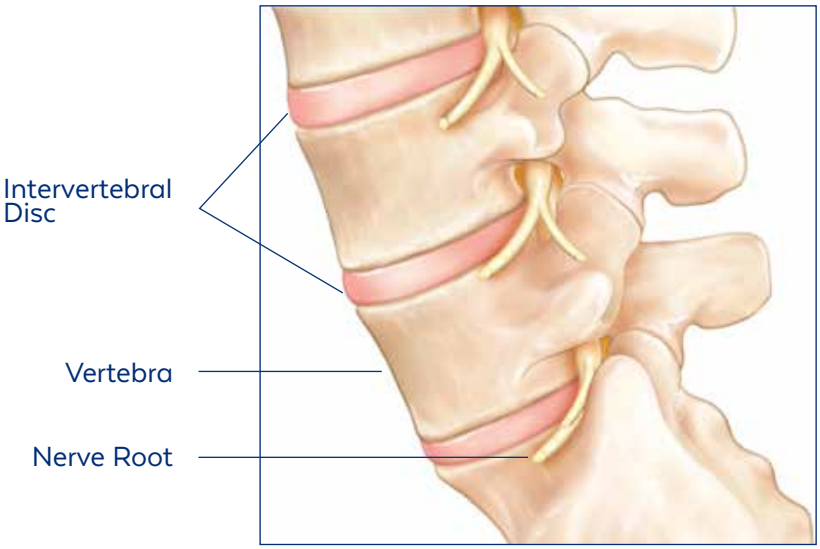
The spine is made up of vertebrae (bones) and is divided into three main sections:

- 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 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

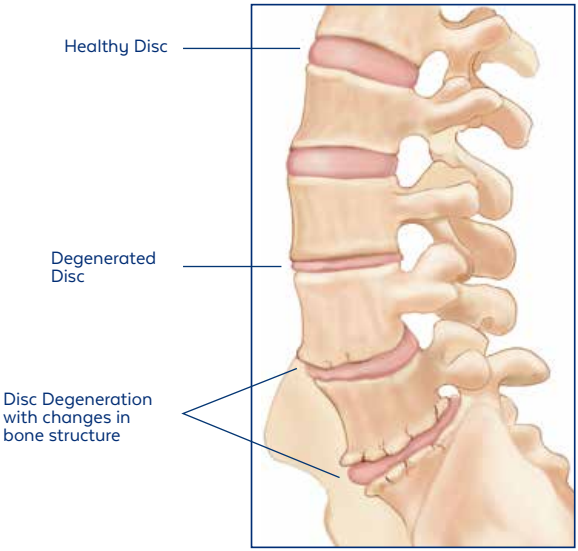
In the normal spine, intervertebral discs act as cushions between vertebrae. Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration of the discs in your lower back. As a result, someone may experience one or more of the following conditions.

Degenerative Disc Disease

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. Degenerative discs can also result from torsional (twisting) injury to the lower back.

In the normal spine, your discs act as cushions 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.

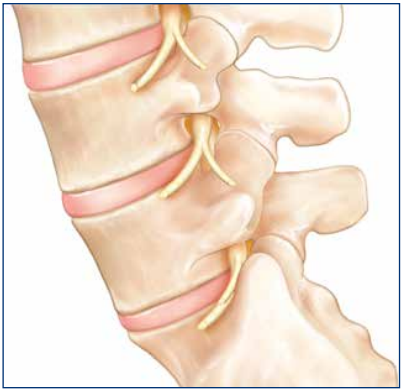
Symptoms include pain, burning, or numbness in the back or legs. These symptoms may increase with activities that involve bending, twisting, or sitting for extended periods of time.



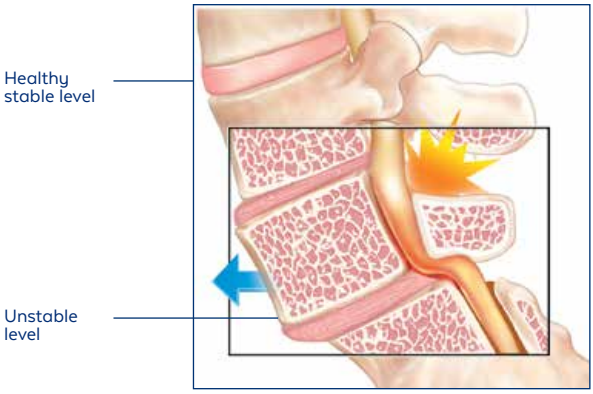
Spondylolisthesis

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 radiographs, such as X-rays.



Normal spine segment



Displaced vertebra causing pressure on nerve

Conditions of the Lumbar Spine (Cont'd)

Spinal Stenosis

Narrowing of areas in the spine that cover and protect the nerve roots and the spinal cord. This can be caused by herniated discs, osteophytes (bony projections), or ligaments compressing the spinal cord and/or nerves.

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

Spondylolysis

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

Subluxation

Subluxation is partial dislocation or a slight misalignment of the vertebrae.

Symptoms of these conditions can include:

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

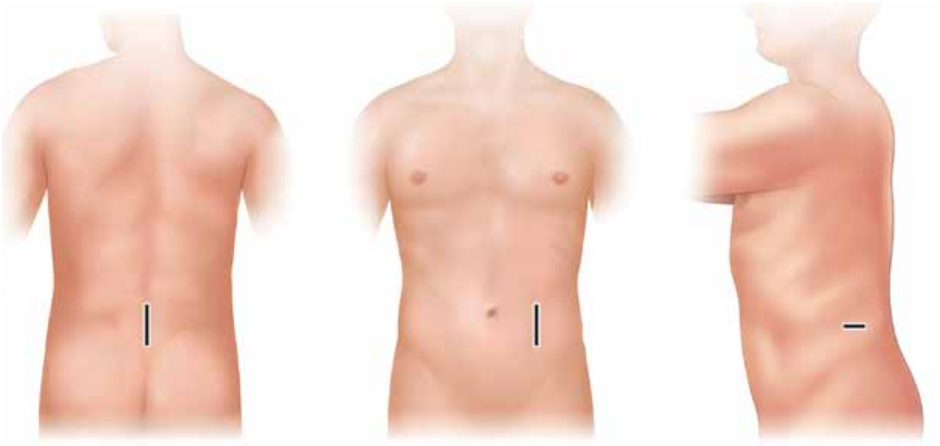
If these non-surgical treatments do not bring relief after a period of time, surgical treatments may be recommended to take pressure off the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae.

What Is Fusion?

Back pain commonly originates in levels of the spine where bones have slipped or the discs or facet joints are damaged. Fusion is a means of stabilizing the spine by joining two vertebrae together. This is accomplished by removing the disc from the diseased segment and implanting a spacer within that area. The spacer is packed with bone graft material, which helps to "fuse" the two vertebral segments together and restore structural stability to the spine.

What Is Lateral Lumbar Interbody Fusion?

Lateral lumbar interbody fusion (LLIF) is a method of spine surgery in which the lumbar spine is approached through the patient's side. This surgery may be performed using a traditional open or a minimally invasive (small incisions) technique to access the spine. Through the use of X-ray imaging, the LLIF technique permits the surgeon to separate muscles and gain access to the spine.



Posterior Approach
(Open)

Anterior Approach
(Open)

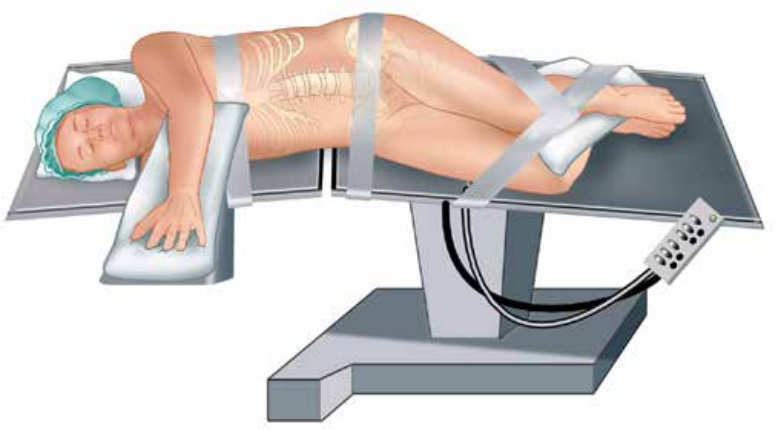
LLIF Approach
(MIS)

Actual incision size will vary by surgical procedure and by patient.

How Is an LLIF Performed?

Patient Positioning

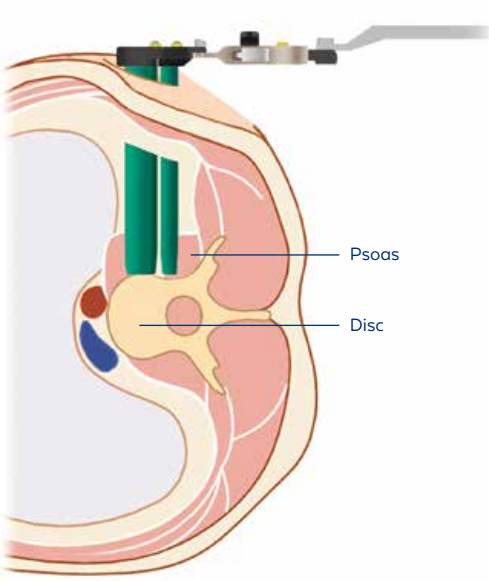
To begin this procedure, the patient is positioned on their side and secured to the operating table. X-ray imaging is used to confirm the operative levels. The skin is then cleaned and an incision is typically made on the left side.



How Is an LLIF Performed? (Cont'd)

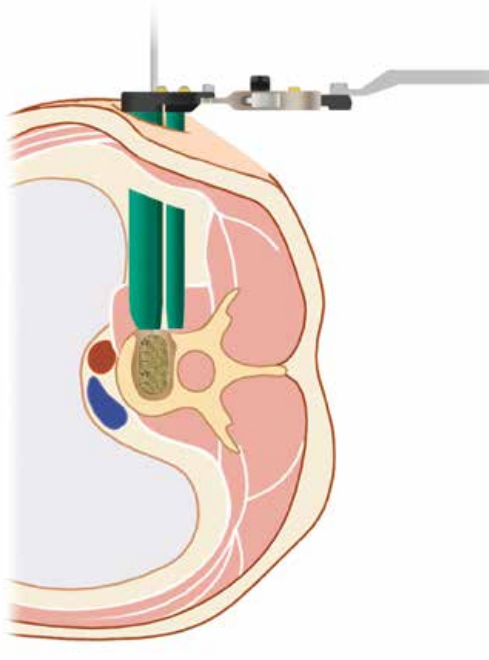
Disc Space Access

The surgeon uses several tubes to gradually clear a path through the soft tissue and access the disc space. X-ray imaging is used to confirm the placement of the instruments. A retractor is then placed over the tubes and positioned on the vertebral body. The purpose of the retractor is to hold back the tissue and provide a pathway for the instruments. Nerve monitoring equipment can be used to determine the placement of instruments in relation to the spinal nerves.



Interbody Spacer Insertion

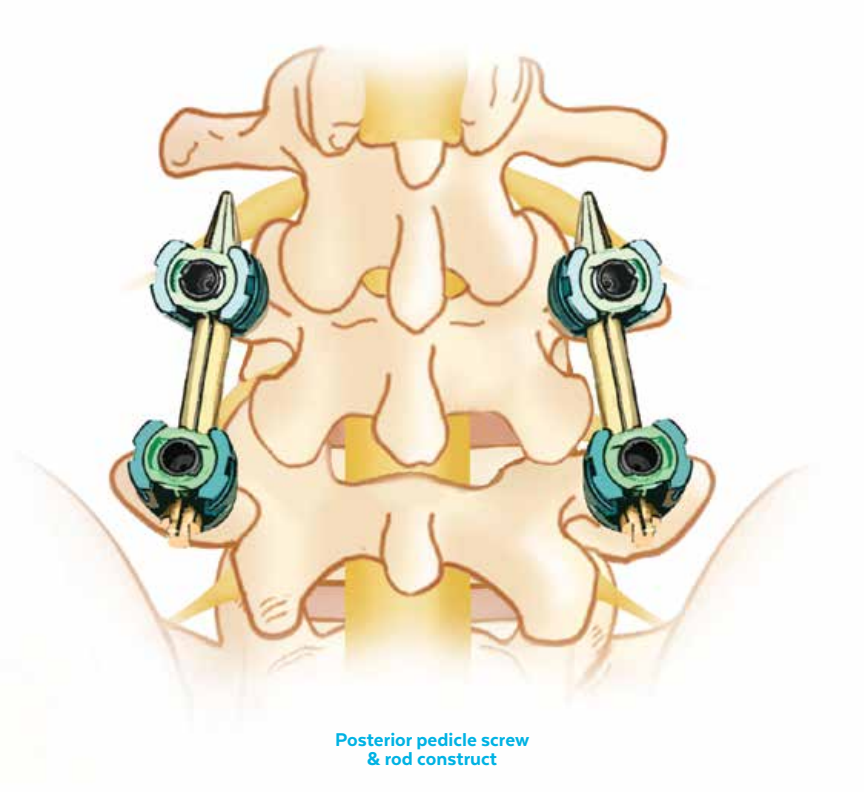
Once the retractor is safely in place and there is visibility to the spine, disc material is removed and the space is prepared for fusion. An interbody spacer is inserted into the prepared disc space. X-ray imaging is then used to confirm accurate placement and the retractor is removed.



A minimally invasive surgical approach is described here. Open surgery uses the same steps, but is performed through a larger incision rather than a narrow retractor.

Pedicle Screws and Rods

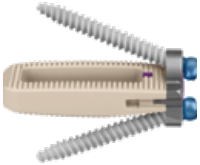
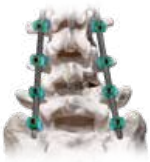
Pedicle screws and rods are used to stabilize the spine. X-ray imaging may be used to determine the precise screw location. The screws are inserted into the spine and a rod is secured. Bone graft may be added along the side of the vertebrae. The surgeon then closes the incision and moves the patient into recovery.



Posterior pedicle screw & rod construct

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

Globus Medical offers a variety of implants for LLIF surgery.

Implant Type	Implant Name*	Lumbar Spine Conditions**
Interbody Spacers 	CALIBER®-L PATRIOT® TransContinental® RISE®-L LATIS® HEDRON L™	Degenerative disc disease, spondylolisthesis, retrolisthesis
Integrated Plate-Spacers (and screws or anchors) 	ELSA® ELSA®-ATP InterContinental®	Degenerative disc disease, spondylolisthesis, retrolisthesis
Lumbar Plates (and screws) 	CITADEL® GATEWAY® PLYMOUTH® TRUSS®	Spine instability, fracture, tumor, degenerative disc disease, pseudarthrosis, spondylolysis, spondylolisthesis, scoliosis, kyphosis, lordosis, spinal stenosis, failed previous spine surgery
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 polyetheretherketone (PEEK), titanium alloys, 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. Pedicle screws and 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 on the following page 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

MR compatibility is shown below for these devices. Your radiologist may request this information prior to taking an MRI.

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 (30T/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions mentioned above, the lumbar spacers are expected to produce a maximum rise in temperature that is less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to be more than 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.

Lumbar Plates

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

- 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 this procedure if you have an infection, congenital abnormality, tumors, degenerative diseases, rheumatoid arthritis, certain allergies, osteoporosis, fever, high white blood cell count, or cancer, have had prior fusions at the level(s) to be treated, or are obese, pregnant, diabetic, or not yet 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, reduced bone density or bone fracture, abnormal sensations and allergic reaction to implant material.

Other general complications 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, cardiovascular system compromise, organ damage, change in spinal curvature, loss of correction, joint inflammation, 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 effect with your implant, 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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