PATIENT INFORMATION

LAMINOPLASTY

Life moves us

Outside the US Only

GLOBUS MEDICAL

Laminoplasty

Patient Information

This brochure will help you understand more about:

- **General conditions of the spine**
- **Information about surgical treatment**
- **Laminoplasty**
- **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 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 you and your 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 related to this procedure.

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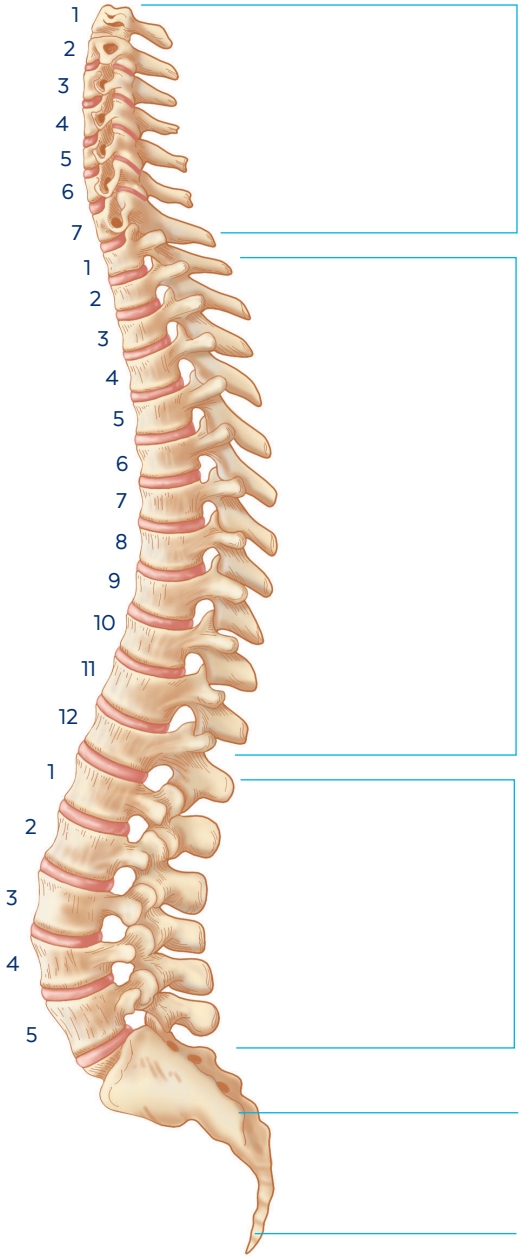
Anatomy of the Spine



The Healthy Spine

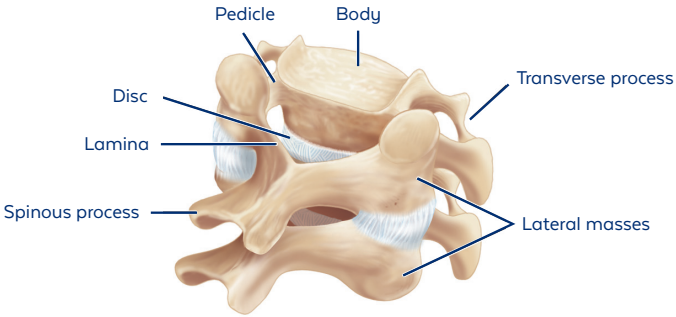
The spine is composed of vertebrae (bones) divided into three main parts:

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

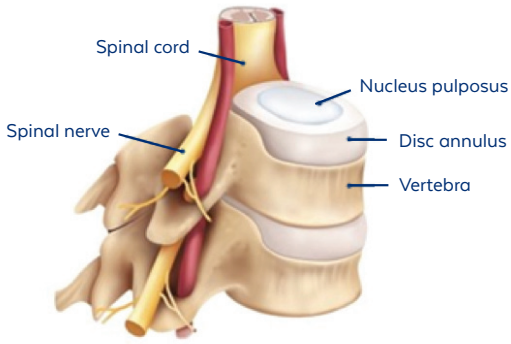
Below the lumbar spine is the sacrum, which is comprised of five fused vertebrae. At the end of the spine is the coccyx, commonly referred to as the tailbone.

The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. They 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 that act as cushions or shock absorbers.



Posterior (back) view of spine



Anterior (front) view of spine

Conditions of the Spine

In a healthy spine, the disc acts as a cushion between vertebrae. Age, genetics, injury, and daily wear and tear can contribute to damage and deterioration of the intervertebral disc and narrowing of the spinal canal. As a result, someone may experience one or more of the following conditions.

Degenerative Disc Disease (DDD)

Over time, the disc can lose flexibility, elasticity, and height. A degenerated disc results in less shock-absorbing ability, which can lead to abnormal motion or alignment and instability of the spine.

Herniated Disc

Degeneration (deterioration of the tissue) can cause cracks and tears in the outer layer of the intervertebral disc, where material inside the disc can be forced out, causing the disc to bulge or herniate, break open, or break into pieces, placing pressure on a nerve root or the spinal cord.

Spinal Stenosis

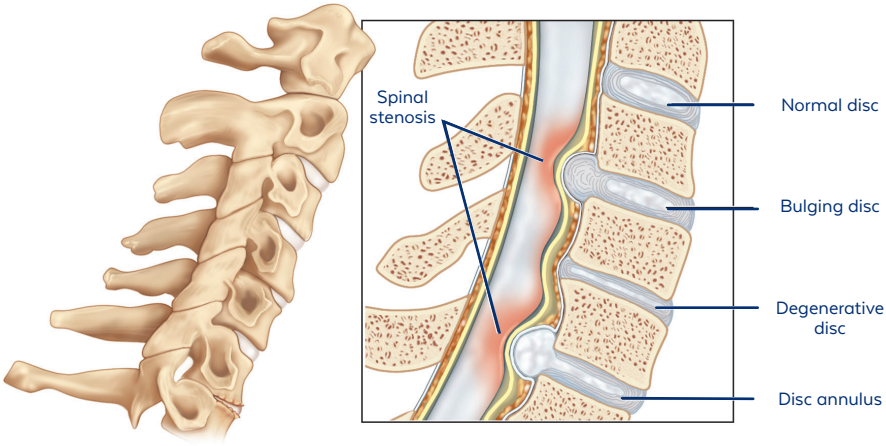
Spinal stenosis results from the narrowing of areas in the spine that cover and protect the nerve roots and the spinal cord. This can be caused by a herniated disc, osteophytes (bony spurs), or ligaments compressing the spinal cord.

Symptoms of these conditions may include:

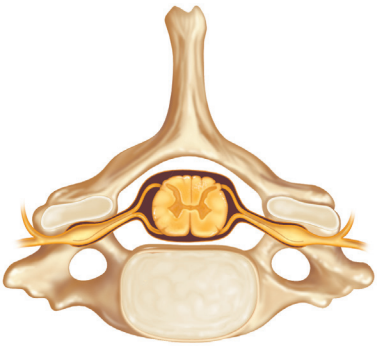
- Loss of motion and dexterity
- Tingling or numbness in the arm or hand
- Incontinence
- Radiating pain
- Weakness and/or numbness in shoulders, arms, and neck
- Difficulties with balance and gait

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

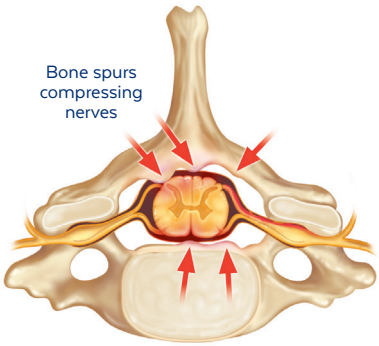
If non-surgical treatments do not bring relief after a period of time, surgical treatment may be recommended to relieve the pressure off the nerves causing pain. Your doctor may perform a physical examination, evaluate your symptoms, and order tests such as X-rays and MRIs to determine which surgical method is best for your condition.



Narrowing of the spinal canal due to disc herniation (spinal stenosis)



Healthy spinal canal



Narrowing of the spinal canal due to spinal stenosis

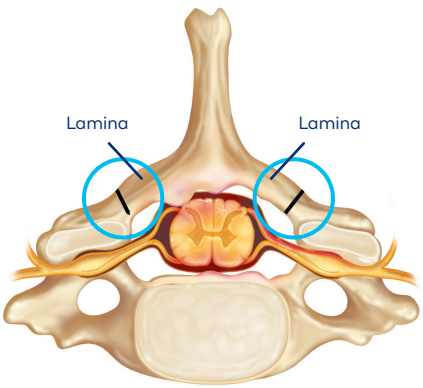
What Is Laminoplasty?

The lamina is a bony structure at the rear of the vertebra. Each vertebra includes two laminae that form a “roof” over the spinal canal to protect the back of the spinal cord, as shown below. When the spinal canal narrows due to stenosis, or the disc is degenerated or herniated, the spinal cord may be compressed (squeezed) in that region.

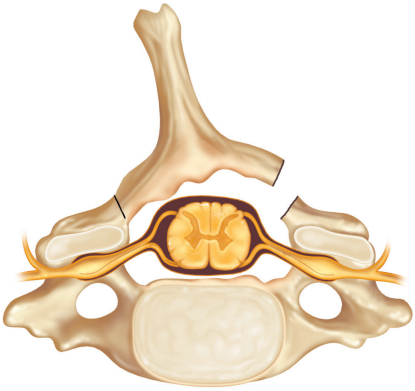
Laminoplasty is a surgical procedure in which a portion of the lamina is cut and repositioned to open the space below the lamina and help relieve the symptoms caused by spinal cord compression.

Decompression (removing pressure) is achieved by opening and lifting up the lamina to relieve pressure on the spinal cord. People who undergo laminoplasty may have multiple regions of compression along their spine.

In a common technique called open door laminoplasty, the surgeon creates a groove down one side of the vertebra to create a hinge, then carefully cuts through the other lamina to create an opening. The lamina is then opened (like a door) to widen the spinal canal and help relieve pressure. An implant such as a laminoplasty plate with a built-in spacer may be used to hold the lamina open, as shown below.



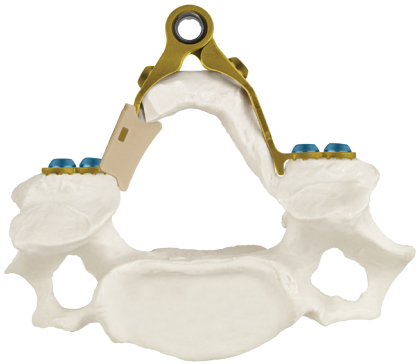
Cuts made into the laminae



Opened lamina

Globus Medical offers a variety of implants for laminoplasty surgery.

Implant Type	Implant Name*
Laminoplasty Fixation* (plates, screws)	RELIEVE® CANOPY® HAVEN®



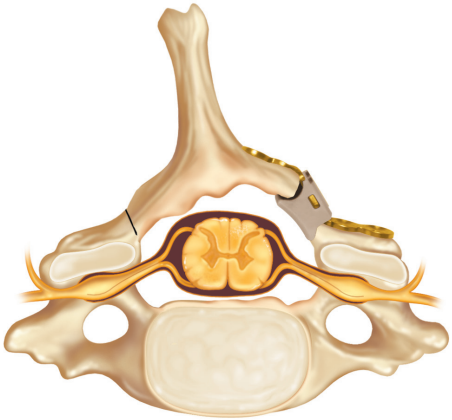
Visit Globus Medical's website at https://www.globusmedical.com/international/
**These products may not be available in your region.*

These implants are composed of polyetheretherketone (PEEK), titanium, titanium alloys, 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.

After Surgery

After the procedure, some patients may experience relief in their symptoms immediately, while others may take more time to improve. The length of stay in the hospital depends on multiple factors, including the patient's overall health, extent of the surgery, and the treatment plan. A neck collar may be prescribed.

It is important to work closely with your surgeon to determine an appropriate recovery plan.



Laminoplasty plate and spacer used to stabilize the lamina

Frequently Asked Questions

What May I Expect From Surgery?

Between 2 and 4 weeks after surgery, patients may notice improvement of some or all symptoms and reduced postoperative pain. 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-surgical instructions may all contribute to a satisfactory outcome.

When Will I Be Able to Return to Work?

The amount of recovery time needed prior to returning to work varies depending on your job and you as an individual. For jobs that require strenuous physical activity, a longer recovery period may be required. Please consult your surgeon for an individual recommendation.

How Long Will I Have Restricted Activities?

As with any surgery, the duration of time between the procedure and return to normal activities is different for every patient. Your surgeon may provide a list of activities you should avoid during the first 6 weeks after surgery.

How Long Will My Implant Last?

The expected lifetime of these devices is difficult to determine, but it is not indefinite. While these devices are made of synthetic materials and are designed to survive the life of the patient, there are many factors that may affect the device lifetime. Therefore, these devices cannot be expected to indefinitely withstand the applied loads of the spine.

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.

RELIEVE® 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 2 W/kg (normal operating mode)
- Quadrature body coil only

Under the scan conditions defined above, the 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 caused by these devices 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.

CANOPY® and HAVEN® have not been evaluated for safety and compatibility in the MR environment. CANOPY® and HAVEN® 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, an allergy to implant materials, severe osteoporosis, degenerative diseases, diabetes, rheumatoid arthritis, or are obese. 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 device breakage, loss of fixation, non-union, fracture of the vertebrae, neurological injury, vascular injury, or visceral injury.

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	

Notes

Notes

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.

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com/international

Customer Service:
Phone: 1-866-GLOBUS1 (or 1-866-456-2871)
Fax: 1-866-GLOBUS3 (or 1-866-456-2873)

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