

PEDICLE SCREW AUGMENTATION

Pedicle Screw Augmentation

Patient Information

This brochure will help you understand more about:

- ▶ **General spine anatomy**
- ▶ **General conditions of the spine**
- ▶ **Spinal stabilization with Pedicle Screw Augmentation**
- ▶ **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.

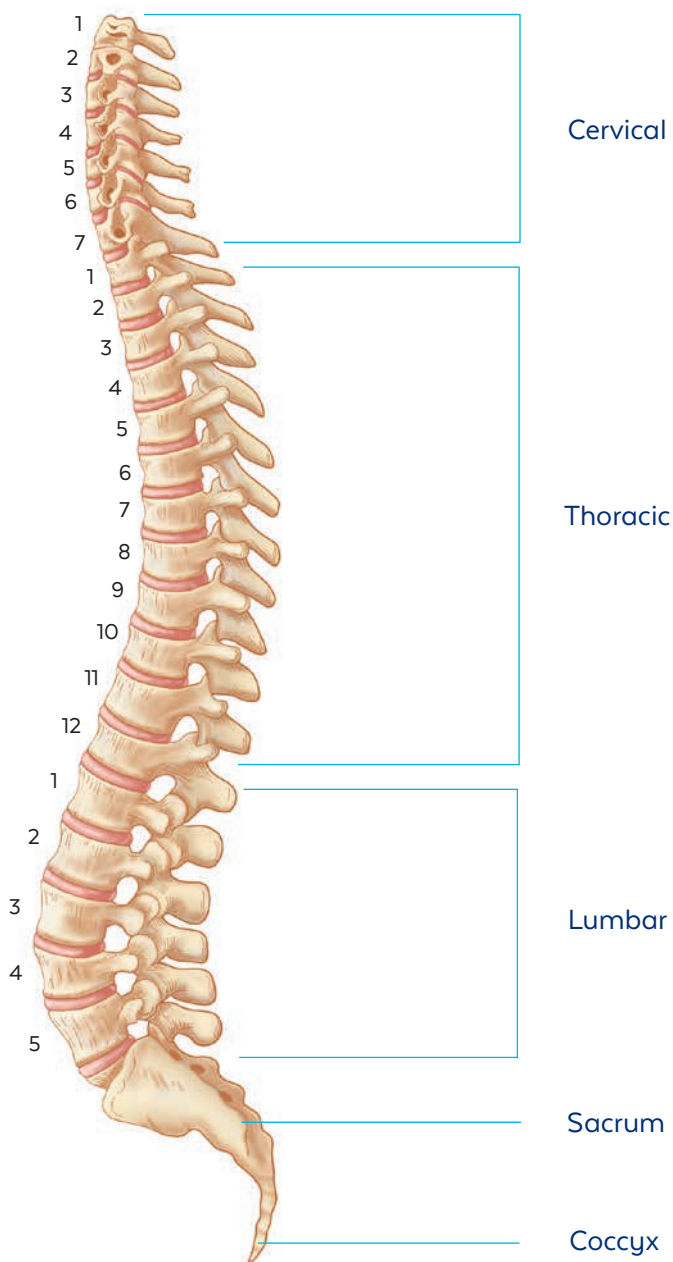
This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results and other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



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Anatomy of the Spine



The 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.

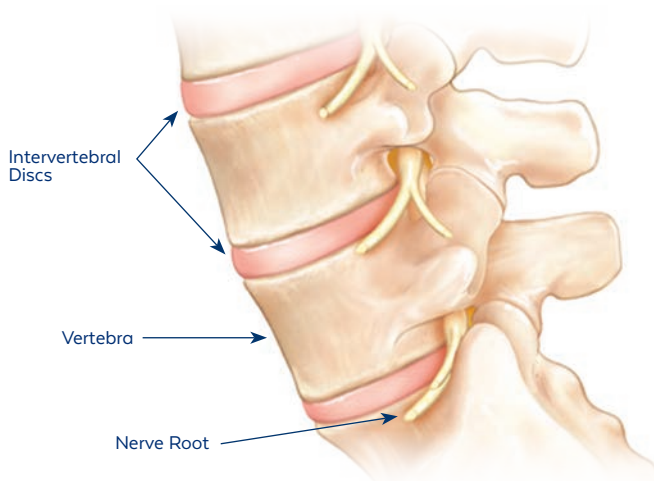
The spine is made up of vertebrae (bones) and is divided into three main sections:

- ▶ Cervical (7 vertebrae in the neck)
- ▶ Thoracic (12 vertebrae in the mid-back)
- ▶ Lumbar (5 vertebrae in the lower back)

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.

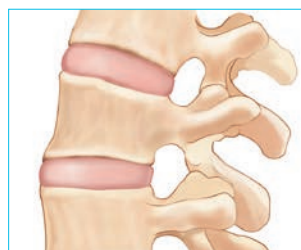


Conditions of the Lumbar Spine

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

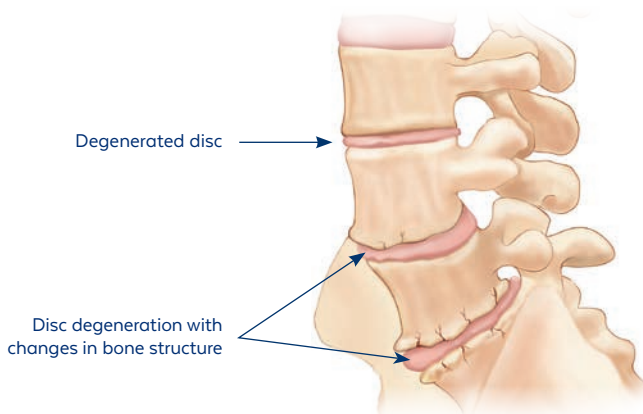
Degenerative Disc Disease

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.



Healthy discs

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.



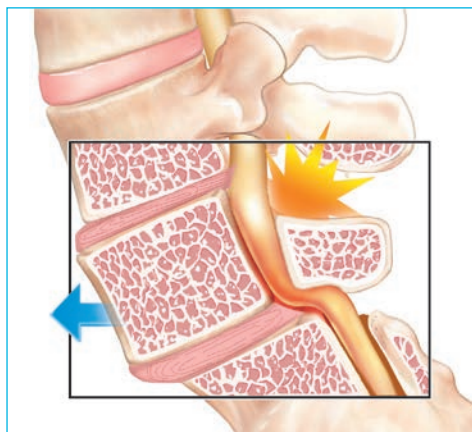
Symptoms include pain, burning, or numbness in the back or legs. This pain may increase with activities that involve sitting for extended periods, bending, or twisting.

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



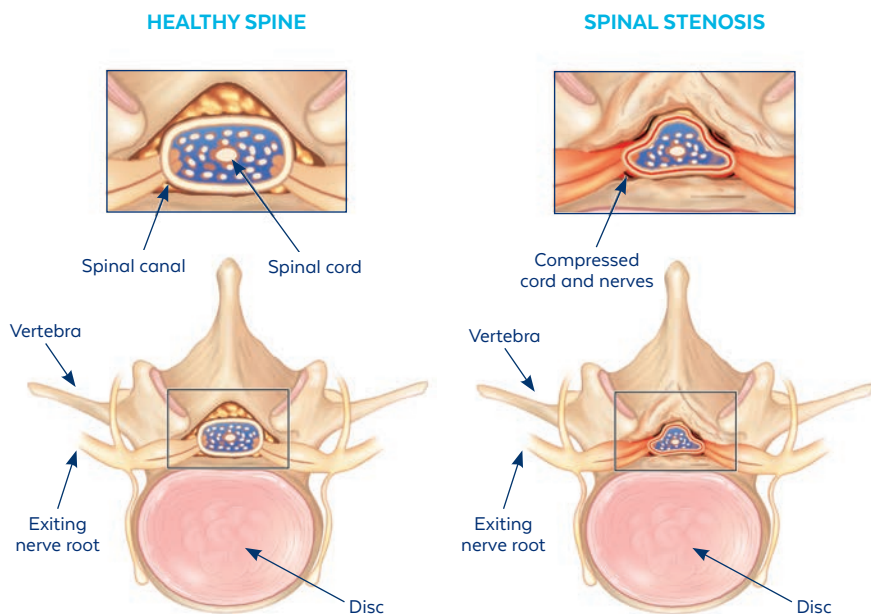
Displaced vertebra causing pressure on nerve

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)

Lumbar Spinal Stenosis

Spinal stenosis is the narrowing of areas in the spine that cover and protect the nerve roots and 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 over time. 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

Spinal Instability

Spinal instability is a condition that 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.

Pseudarthrosis

Pseudarthrosis refers to failed previous 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. The doctor will also choose between a minimally invasive approach or a more traditional open approach.

What Is Spinal Stabilization?

Spine stabilization refers to the surgical procedures that correct spinal instability and deformity. Stabilization allows for bony fusion (joining of two bones) to occur across vertebral segments for definitive long-term stabilization. The degree of stabilization necessary will depend on the severity of the condition and the surgeon's assessment. Treatment commonly involves the installation of hardware (implants), such as screws and rods, to help fuse segments of the spine. A variety of implants are available and are tailored to specific spinal conditions, surgical approaches, and goals.

What Is Minimally Invasive Spine Surgery?

Minimally invasive surgery (MIS) uses small incisions and may result in less trauma to surrounding tissues. X-ray imaging is used frequently in MIS surgery, which helps the surgeon locate anatomy and place the implants.

The decision to receive minimally invasive surgery is individualized to the patient and the patient's symptoms. It is important to discuss with your physician whether minimally invasive surgery is right for you.

Questions to Ask Your Surgeon

- ▶ Am I a candidate for minimally invasive spine surgery?
- ▶ How can I benefit from minimally invasive spine surgery?
- ▶ Which lumbar interbody fusion approach will be used?
- ▶ What can I expect the day of surgery?
- ▶ What can I expect post-surgery?



Open Incision

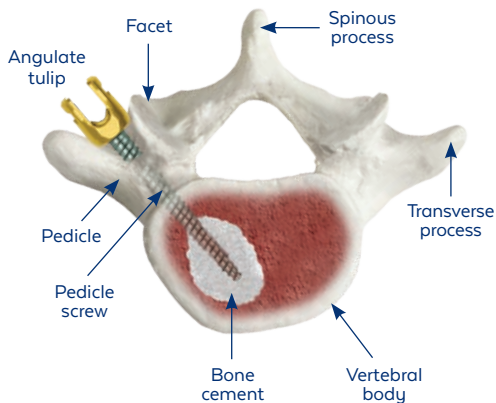


MIS Incisions

Actual incision size may vary by procedure.

What Is Pedicle Screw Augmentation?

The goal of this treatment is to facilitate fusion in patients who have weakened bone. Screws are placed on each side of the affected vertebrae in the pedicle which connects the front and back of the vertebra. When the patient's bone is weakened due to osteoporosis, spinal tumors, or other conditions, bone cement may be used to add support to the screws. The cement is inserted through the central hole along the screw and comes out through small holes into the bone. The bone cement fills open spaces and helps hold the screws in place. The screws are then secured with a rod to connect the next vertebrae.



What Is Pedicle Screw Augmentation? (Cont'd)

Globus Medical offers a variety of implants for pedicle screw augmentation.

Implant Type

Fenestrated Pedicle
Screws and Rods



Implant Name*

CREO®
REVLOK®

Spine Conditions**

Degenerative disc disease,
spondylolisthesis, fracture,
dislocation, scoliosis,
kyphosis, spinal tumor,
pseudarthrosis

Bone Cement



FORTRESS®

Vertebral body fractures,
cement augmentation of
pedicle screws

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.

The fenestrated pedicle screw and rod systems are composed of titanium alloys, commercially pure titanium, stainless steel, hydroxyapatite, and/or cobalt chromium alloy. The bone cement is composed of polymethyl methacrylate (PMMA)/methyl methacrylate-styrene copolymer, N:N Dimethyl-p-toluidine, hydroquinone, benzoyl peroxide, and barium sulfate. 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 notice improvement of some or all of their symptoms, and pain may diminish a few weeks after surgery. However, recovery time varies among patients.

Typically, 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 (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?

Bone cement can be safely scanned and does not require any special conditions for an MRI. The pedicle screw and rod systems have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this procedure if you have an infection, a congenital abnormality, severe cardiac or pulmonary insufficiencies, thrombophilia, certain allergies, nonpathological fractured vertebrae, severe vertebral body collapse, rheumatoid arthritis, osteoporosis, diabetes, cancer, or are obese, pregnant, or mentally ill. In addition, a patient whose mental or physical impairment places undue stresses on the implant during healing 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, breakage, loosening, movement/migration, loss of fixation, subsidence, device fracture or failure, cement leakage, embolism or clots, bone separation, extra skeletal bone formation, decrease in bone density or bone fraction, abnormal sensations and serious allergic reaction to implant material.

Other adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, pseudarthrosis, pain, secondary surgery, bleeding, infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, urinary complications, tissue damage, joint inflammation, cardiovascular system compromise or cardiac event, respiratory problems, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, 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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M E D I C A L

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

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