PATIENT INFORMATION

FACET FIXATION

Life moves us

Outside the US Only

GLOBUS MEDICAL

Facet Fixation

Patient Information

This brochure will help you understand more about:

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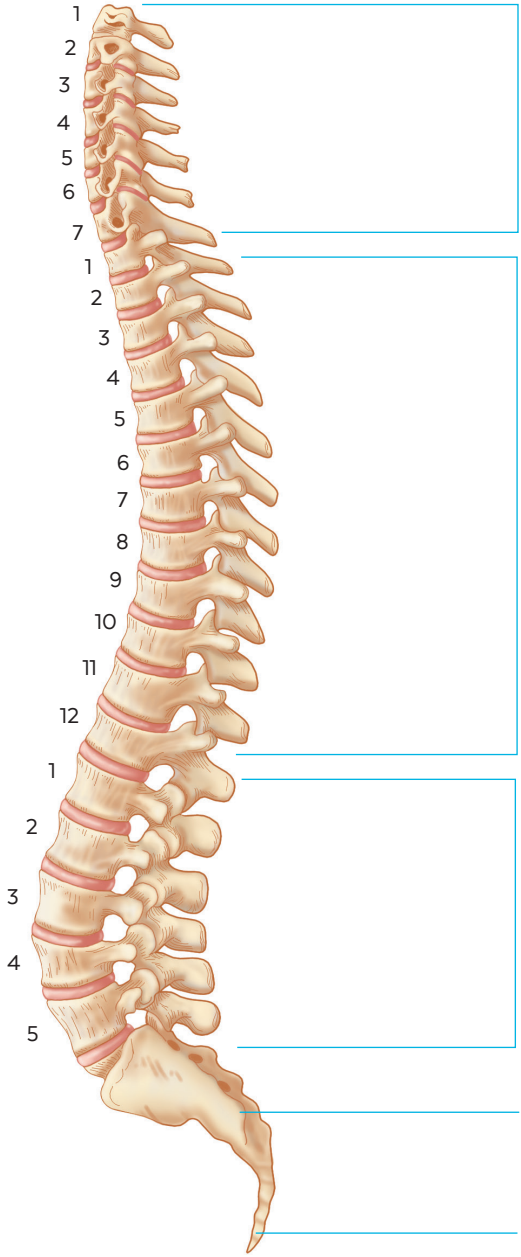
Anatomy of the Spine



The Healthy Spine

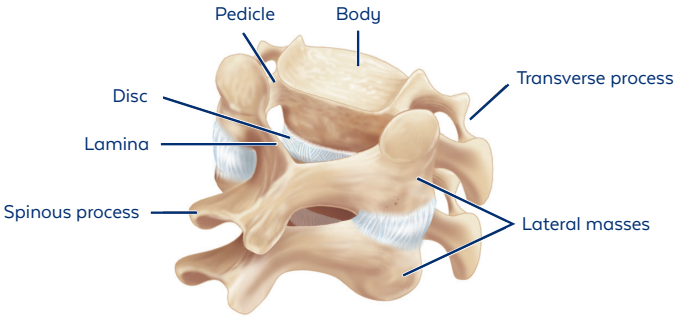
The spine is composed of vertebrae (bones) divided into three main parts:

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

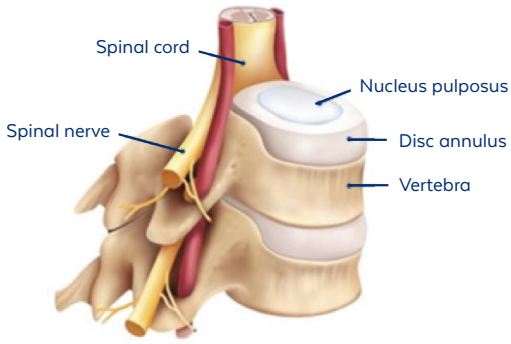
Below the lumbar spine is the sacrum, which is comprised of five fused (joined) vertebrae. At the end of the spine is the coccyx, commonly referred to as the tailbone.

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 successively 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 between the vertebrae.



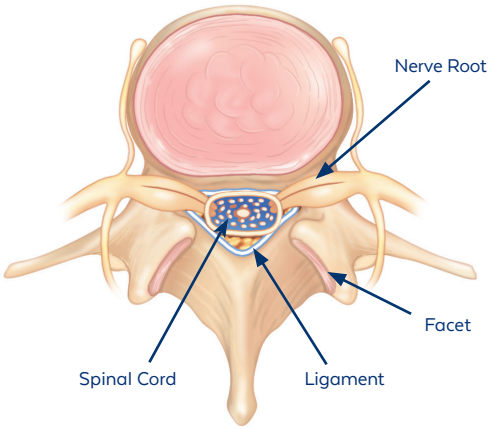
Posterior (back) view of spine

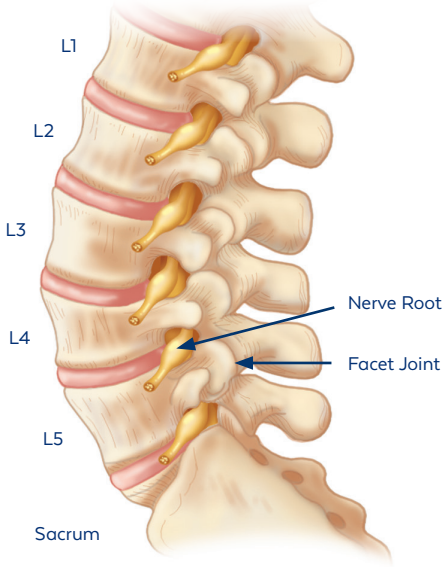


Anterior (front) view of spine

Facet Joints

On the back side of each vertebra are two pairs of facets, each having an upper and lower portion. These facets connect one vertebra to another, forming a joint (a flexible location where two or more bones are joined). Facet joints support the spine while also allowing for motion of the spine. To aid in motion, facets are surrounded by connective tissue and fluids to lubricate the joint, allowing the facets to move against each other smoothly.

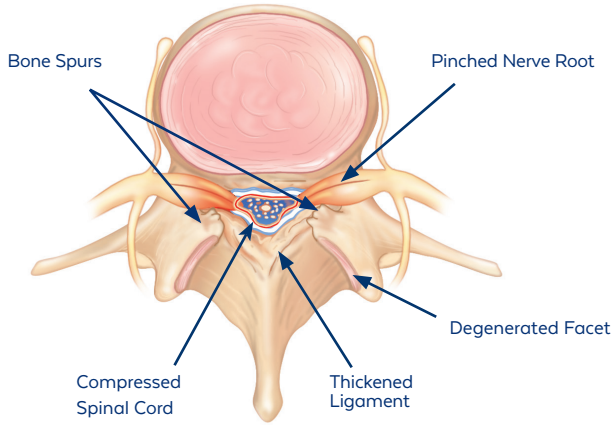


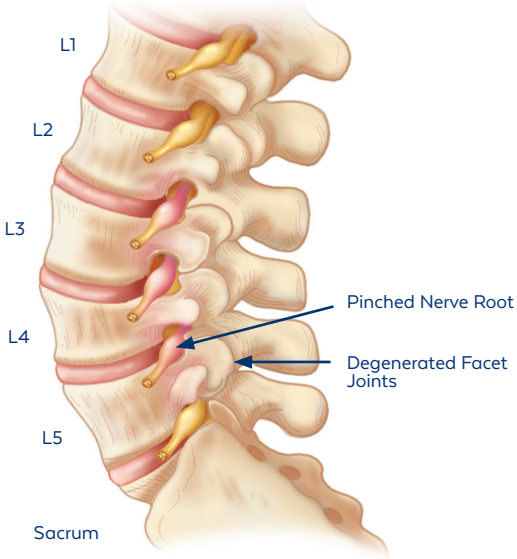


Conditions of the Spine

In the normal spine, intervertebral discs act as a cushion between vertebrae and the facet joints to help stabilize the spine while also allowing motion. Facets bear a large amount of weight and stress, particularly in the lower back.

Age, genetics, injury, and daily wear and tear can contribute to damage and deterioration in the spine. As a result, one may experience one or more of the following conditions.





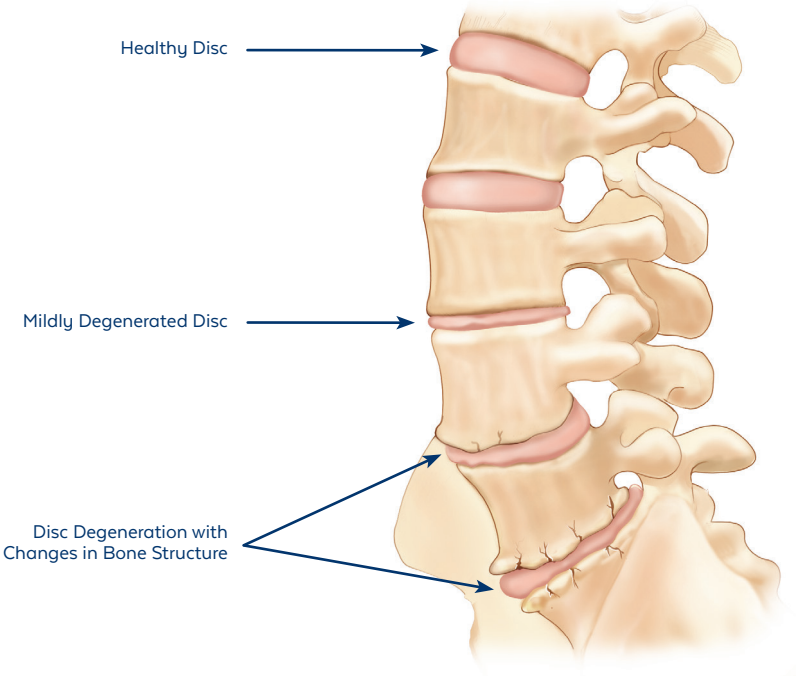
Conditions of the Spine (Cont'd)

Degenerative Disc Disease (DDD)

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.

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 that may result in pain.

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



Spinal Stenosis

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

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

Traumatic events such as car accidents, sports injuries, and other serious incidents can cause injury to the spine, including fractures and dislocations.

Pseudoarthrosis

Pseudoarthrosis refers to failed previous fusion (joining of bones).

Spinal Instability

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

Spondylolisthesis

Spondylolisthesis is a condition in which one of the vertebrae slips forward or backwards (retrolisthesis). If left untreated, this can lead to deformity of the spine and narrowing of the spinal canal.

Typical symptoms include lower back pain, muscle spasm, thigh or leg pain, and weakness. Interestingly, some patients are asymptomatic and learn of the disorder after spinal radiographs, such as X-rays.

Spondylolysis

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

Symptoms may include the following:

- Localized pain or burning
- Radiating pain in the back or legs
- Numbness or tingling in the back or legs

Symptoms may increase with activities that involve bending, twisting, or sitting for extended periods of time. They may be treated with non-surgical methods for as long as possible. Treatments include rest, ice or heat, weight control, exercise, physical therapy, injections for pain management, and medication.

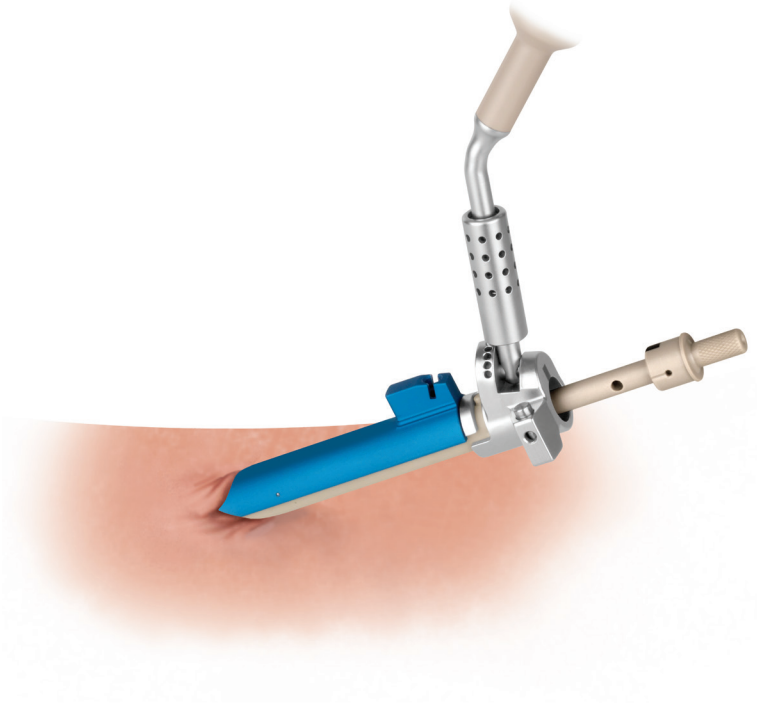
If non-surgical treatments do not bring relief after a period of time, surgical treatments may be recommended.

What Is Facet Fixation?

Facet fixation may be utilized as a treatment option to stabilize the spine and help reduce pain, often by implanting a screw through two facet joints. The screw locks the vertebrae together on both sides. This holds the joint in place and prevents movement. Over time the joint will fuse. Other options for fixation include pedicle screws and rods, or spinal plates. Your surgeon will determine which type of fixation is right for you.

How Is Facet Fixation Performed?

During the surgery, the patient lies face down. The skin is cleaned and an incision (surgical cut) is made so the surgeon can access the spine.



Spinal screws are implanted in the facet joint to help hold the spinal column in place. The goal of the surgery is to lock the vertebrae together to limit motion, which gives more stability to the spine and may help reduce pressure on the spinal cord and help relieve the associated pain.

Globus Medical offers the following implants for facet fixation procedures.

Implant Type	Implant Name*	Spine Conditions**
Screws 	ZYFUSE® CORRIDOR®	Degenerative disc disease, spondylolisthesis, spondylolysis, fracture, dislocation, 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 8.*

These implants are composed of medical grade titanium alloy and are available with hydroxyapatite coating. 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. Screws 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?

These devices 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, congenital abnormality, rheumatoid arthritis, osteoporosis, osteopenia, a high white blood cell count, or are pregnant, obese, 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, device fracture or failure, loss of fixation, subsidence, breakage, loosening, movement/migration, bone fracture, and allergic reactions to implant materials.

Other adverse effects that may be associated with spinal surgery procedures include pseudarthrosis, pain, secondary surgery, decrease in bone density, discomfort or abnormal sensations, organ damage, nerve damage, tissue damage, cardiovascular system compromise, incisional complications, numbness and tingling at the spinal cord end region, blocking of blood vessels, bruises, swelling caused by excessive body fluids, bone grafting complications, presence of blood clots in veins and lungs, sexual dysfunction, impotence, scar formation, paralysis, and death.

If you experience any of the above adverse effects, please contact a health care professional. This list does not include all possible contraindications and side 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 of the health authorities are listed below for your 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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