



VERTEBRAL BODY REPLACEMENT

Vertebral Body Replacement

Patient Information

This brochure will help you understand more about:

- ▶ **General conditions of the spine**
- ▶ **Information about surgical treatment**
- ▶ **Vertebral body replacement procedure**
- ▶ **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.

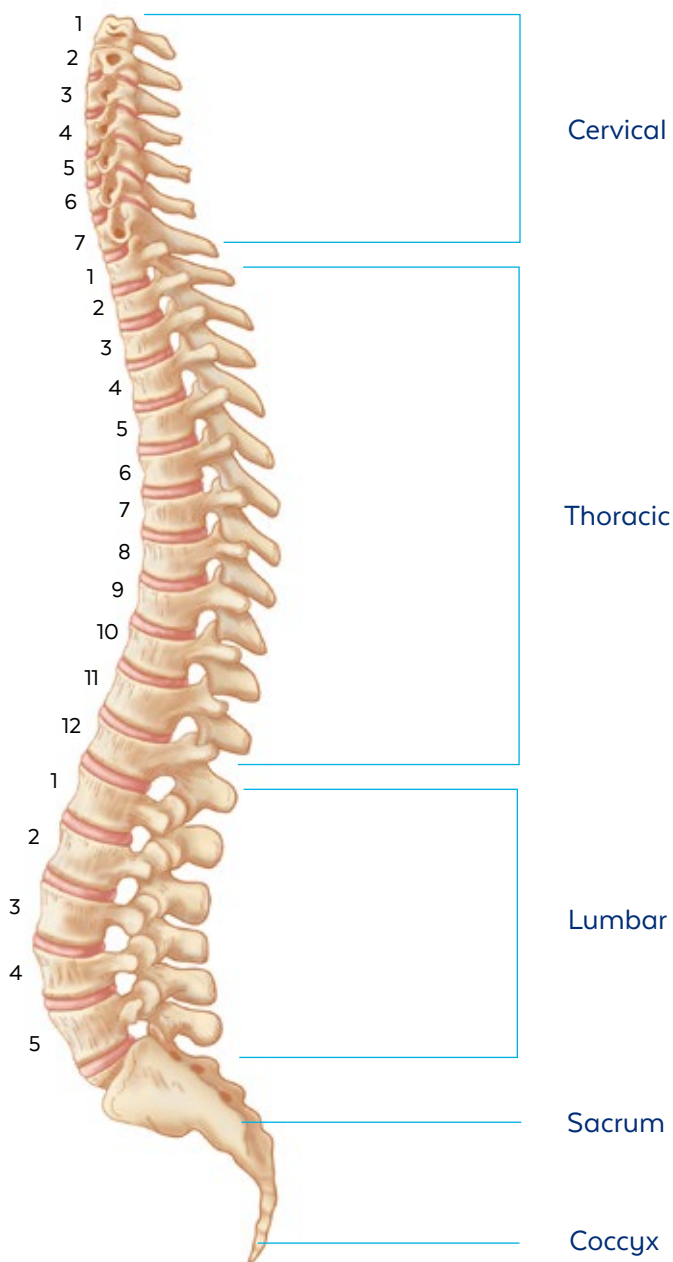
This brochure is intended to be an educational resource only and is not meant to be a warranty, or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, contraindications, warnings, precautions,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



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Anatomy of the Spine



The Healthy Spine

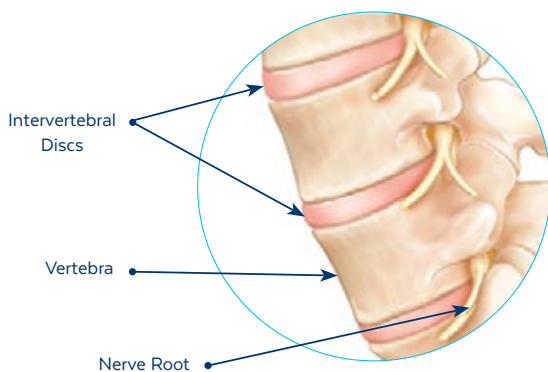
The spine is one of the most important structures in the human body. It supports much of the body's weight and protects the spinal cord, which carries information from the brain to the rest of the body. The spine is strong but flexible, allowing for a wide range of movements.

The spine is made up of vertebrae (bones) and is divided into four distinct regions:

- ▶ **Cervical Spine:** The cervical spine is in your neck. It starts at the base of your skull and contains 7 vertebrae.
- ▶ **Thoracic Spine:** The thoracic spine is your mid-back. It contains 12 vertebrae that connect to the ribs and sternum, making this portion very stable.
- ▶ **Lumbar Spine:** The lumbar spine is your lower back. It contains 5 vertebrae, which are the largest and strongest, and carries most of your body weight.
- ▶ **Sacrum and Coccyx:** The sacrum consists of 5 fused vertebrae, and 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.

Each individual vertebra is separated by intervertebral discs, which act as cushions or shock absorbers between the vertebral bodies.

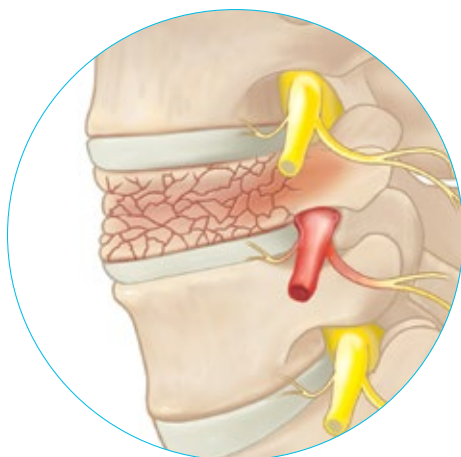


Conditions of the Spine

In the normal spine, vertebrae protect the spinal cord, bear weight, and are an attachment for important muscles and ligaments. Intervertebral discs act as cushions between vertebrae. Age, genetics, injury, and daily wear and tear can contribute to damage and deterioration in your spine. As a result, someone may experience one or more of the following conditions.

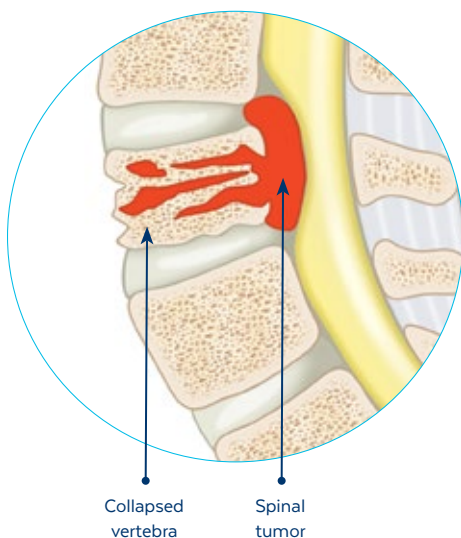
Trauma

Injury to the spine can occur from acute events such as motor vehicle accidents, sports injuries, or falls, where external forces are applied, causing vertebrae to fracture or dislocate. Injured vertebrae may cause mild or severe compression on the spinal cord and/or nerve roots.



Tumor

Spinal tumors can affect parts of the spinal column. They can be cancerous or non-cancerous, and often damage vertebrae and surrounding tissue. As tumors continue to grow, they can increasingly impact everyday function.



Degeneration of the Spine

Degenerative Disc Disease

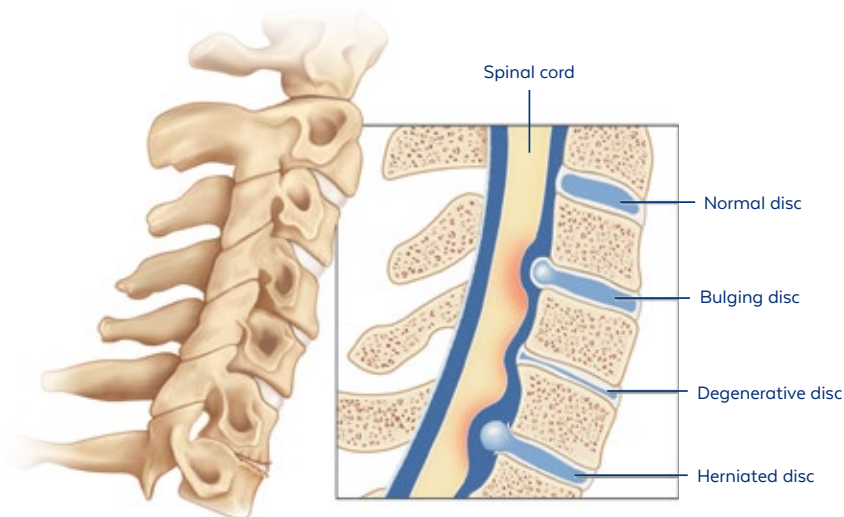
Over time, discs can lose flexibility, elasticity, shock absorbency, and height, resulting in degenerative disc disease. This can lead to abnormal motion or alignment and instability of the spine. Symptoms may include neck or back pain and/or pain or numbness in the upper or lower extremities.

Herniated Discs

Degeneration 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 (protrusion), break open (extrusion), or break into pieces (sequestration), putting 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 spinal cord. Symptoms of cervical stenosis can include loss of motion or dexterity, tingling or numbness in the arm or hand, radiating pain, weakness, and/or numbness in the shoulders, arms, and neck. In the lumbar spine, symptoms of stenosis can include back pain, tingling, or numbness in the lower extremities.



Narrowing of cervical spine canal due to disc herniation (spinal stenosis)

Conditions of the Spine (Cont'd)

Other Conditions of the Spine

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.

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.

Spondylolisthesis

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

Spondylolysis

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

General Treatment Options

In some cases, 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.

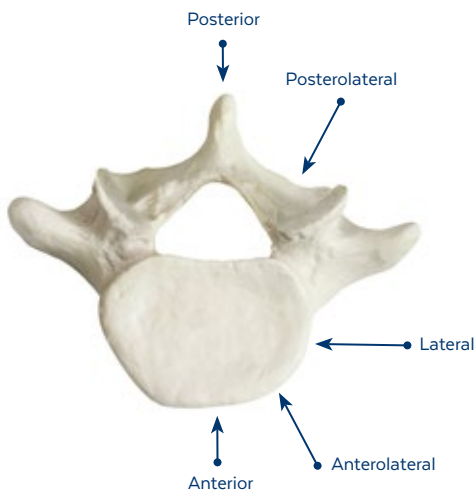
If non-surgical treatments do not bring relief after a period of time, surgical treatment may be recommended to relieve pressure on the nerves.

In other cases, surgical treatment may be required right away to remove diseased or damaged tissue and relieve pressure on the nerves.

What Is a Vertebral Body Replacement?

The primary goal of a Vertebral Body Replacement is to remove the diseased or damaged tissue and relieve pressure on the spinal cord and nerve roots. The spine is stabilized by replacing the affected vertebrae and fusing (joining) the segment together to prevent motion.

The vertebral body replacement procedure can be done from the front, side, or back depending on the region of the spine being treated. Your surgeon will choose the most appropriate surgical approach for treatment. In the cervical spine, an anterior approach may be used. In the thoracolumbar spine, an anterior, anterolateral, lateral, posterior, or posterolateral approach may be used.



What Is a Vertebral Body Replacement? (Cont'd)

During surgery, the patient is positioned depending on the chosen surgical approach. Surgical instruments are used to access the spine and remove damaged bone, as well as any relevant diseased tissue. The intervertebral discs are also removed above and below the involved vertebrae.



A vertebral body replacement device is then inserted to fill the empty space for stabilization of the spine. Pedicle screws and rods or a plate with screws and/or rods are used to hold the spine in place while fusion (bones growing together) occurs. The surgeon uses medical imaging to determine the precise location of these devices. If pedicle screws are implanted, the screws are inserted into the left and right sides of the vertebrae to be fused. A rod connects the screws to stabilize the spine on each side. Caps secure each rod to the screws. Bone graft may be added along the side of the vertebrae to stimulate fusion. Alternatively, a plate with screws may be implanted to stabilize the spine.

In some cases, a plate and screws may be used in addition to pedicle screws and rods to hold the vertebrae in place while fusion occurs.



Static implant with pedicle screws and rods



Expandable implant with plate and screws



Expandable implant with integrated fixation and pedicle screws and rods

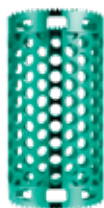
Once the surgery is complete, the surgeon closes the incision and moves the patient into recovery. Over time, the vertebrae can grow together through fusion. This process varies among patients and can take anywhere from 6 months to a year to completely fuse.

What Is a Vertebral Body Replacement? (Cont'd)

Globus Medical offers a variety of implants for vertebral body replacement surgery.

Implant Type

Static Spacers



Implant Name*

NIKO®
COLOSSEUM®

Spine Conditions**

Collapsed, damaged, or unstable vertebral body due to tumor or trauma

Expandable Spacers



FORTIFY®
FORTIFY® R
FORTIFY® VA
XPand®
XPand®-R

Collapsed, damaged, or unstable vertebral body due to tumor or trauma

Expandable Spacers with Integrated Fixation (and screws)



FORTIFY® I
FORTIFY® IR

Collapsed, damaged, or unstable vertebral body due to tumor or trauma

Implant Type

Plates
(and screws)



Implant Name*

ASSURE®
PROVIDENCE™
UNIFY®
VIP®
XTEND®
CITADEL®
GATEWAY®
PLYMOUTH®
TRUSS®

Spine Conditions**

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

Pedicle Screws & Rods



CREO®
BEACON®
PROTEX®
REVERE®
REVOLVE®

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 titanium alloys, polyetheretherketone (PEEK), commercially pure titanium, tantalum, stainless steel, hydroxyapatite and/or cobalt chromium alloy. 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 will notice improvement of some or all of their 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 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.

Please consult your physician to discuss clinical indications and contraindications for this type of surgery.

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. Plates and 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?

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.

Vertebral Body Replacement Devices

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.

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.

Pedicle Screws & Rods

These devices have not been evaluated for safety and compatibility in the MR environment. These devices have not been tested for heating or migration in the MR environment.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for these devices if you have an infection, inflammation, a congenital abnormality, degenerative diseases, prior fusions at the level(s) to be treated, a fever or high white blood cell count, rheumatoid arthritis, osteoporosis, or cancer, or are obese, pregnant, or diabetic. 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 a device. These can include but are not limited to early or late implant bending, breakage, device fracture or failure, loss of fixation, subsidence, loosening, movement/migration, decrease in bone density or bone fracture, abnormal sensations and allergic reaction to implant material.

Other adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, 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 adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult with 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.



GLOBUS
M E D I C A L

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