PATIENT INFORMATION

## INTERSPINOUS PROCESS

# FIXATION

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GLOBUS MEDICAL

# Interspinous Process Fixation

## Patient Information

This brochure will help you understand more about:

- **General conditions of the spine**
- **Information about surgical treatment**
- **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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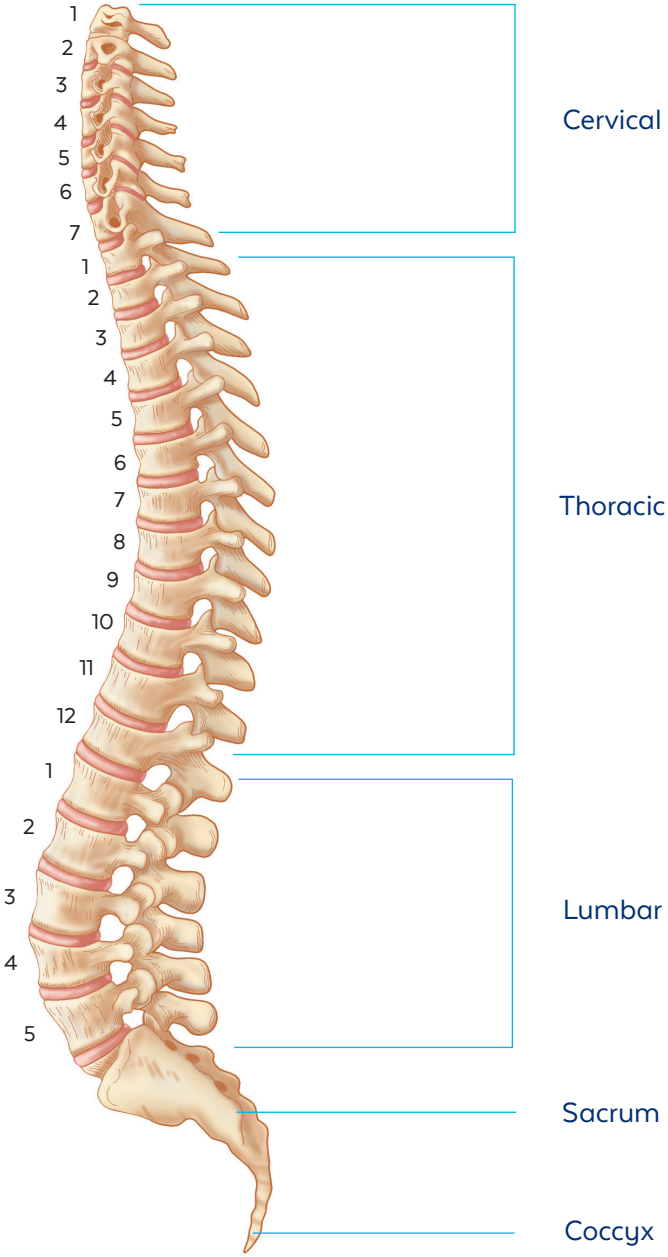
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Cervical
Thoracic
Lumbar
Sacrum
Coccyx

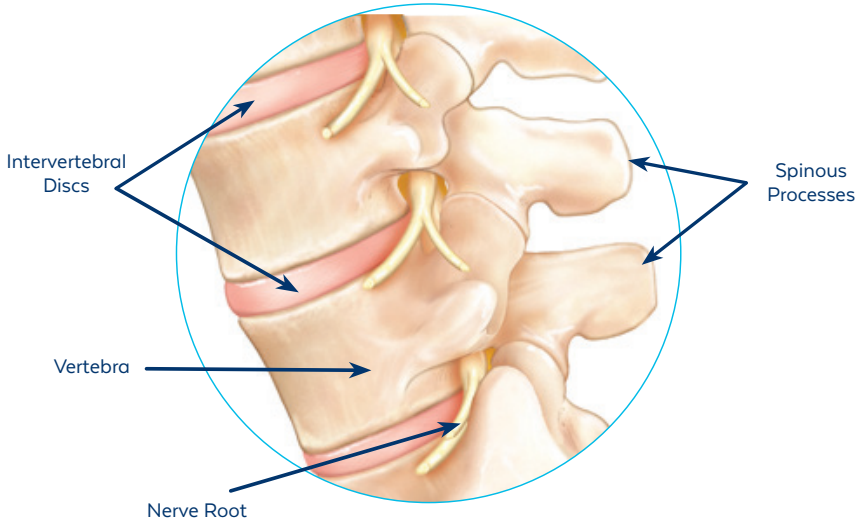
# Anatomy of the Spine

The spine is made up of vertebrae (bones) and is divided into 3 main sections:

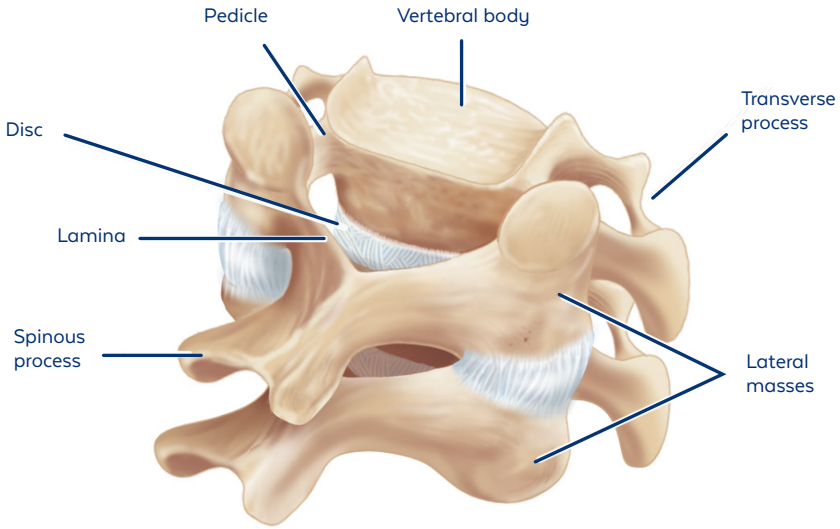
- Cervical (7 vertebrae)
- Thoracic (12 vertebrae)
- Lumbar (5 vertebrae)

Below the lumbar spine is the sacrum, which is composed of 5 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. Vertebrae feature bones called spinous processes, which are the bones you can feel in the middle of your back if you run your hand over your spine. Vertebrae also 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, which act as cushions or shock absorbers between the vertebral bodies. Nerves run between your vertebrae and carry signals through your body.




**Posterior (back) view of the spine**

# Conditions of the Spine

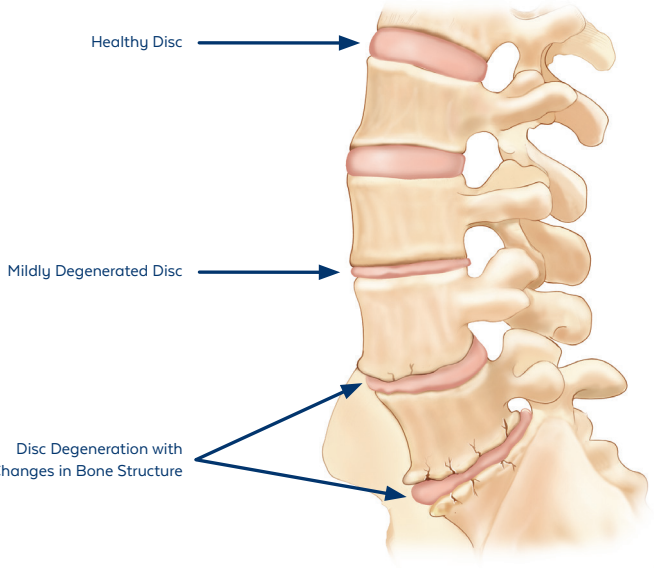
In the normal spine, the intervertebral discs act as a cushion between vertebrae. Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration of the discs in your back. As a result, someone may experience one or more of the following conditions.

### *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.

In the normal spine, your discs act as a cushion between vertebrae. 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.

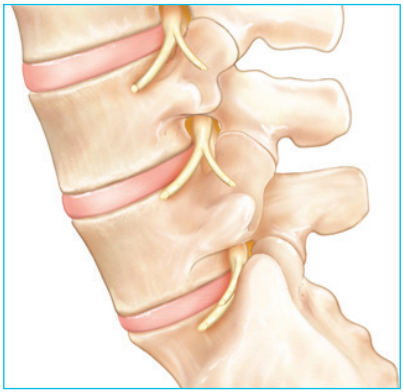
Symptoms include pain, burning, or numbness in the back or legs. This pain may increase with activities that involve sitting for extended periods, bending, or twisting.



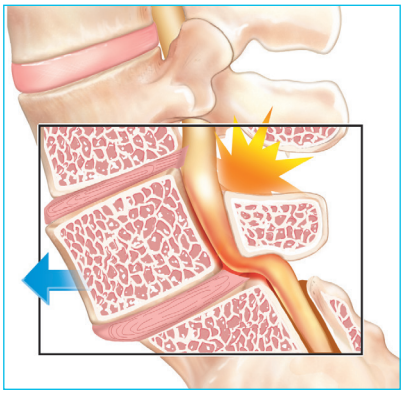
### *Spondylolisthesis*

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.

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

### *Trauma*

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

### *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.

Symptoms of these conditions can include:

- Tingling or numbness in the lower extremities
- Radiating pain, weakness, and/or numbness in your 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 of the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae. These implants may be used in conjunction with other implanst sujch as screws and rods to help give stability to the spine.

# What Is Interspinous Fixation?

Interspinous process fixation, or interspinous fixation, is a procedure in which a device is inserted into your spine between the bumps along your spine (spinous processes), at the back of your vertebrae, to help open open the space for your spinal cord.

A solid barrel style implant with fixation plates or an expandbale implant may be inserted between the spinous processes in certain areas of your spine. Standard or minimally invasive (small incisions) surgery may be used depending on your condition. A trial implant is inserted and then the actual implant is placed and secured between each level. Expandable implants are inserted and expanded to the correct amount. All implants are available in various widths and heights or expansion ranges to fit different patients. Your surgeon will recommend which procedure and implant is best for you and your condition.

Globus Medical offers the following implants for interspinous fixation procedures.

| **Implant Type** | **Implant Name*** | **Spine Conditions**** |
|---|---|---|
| Expandable  | AERIAL® | Degenerative disc disease, spondylolisthesis, fracture, dislocation, spinal tumor |
| Plate and Barrel Assembly  | SP-Fix® | Degenerative disc disease, spondylolisthesis, fracture, dislocation, spinal tumor |

*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 made of titanium alloy, cobalt chrome and/or polyetheretherketone (PEEK). 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.

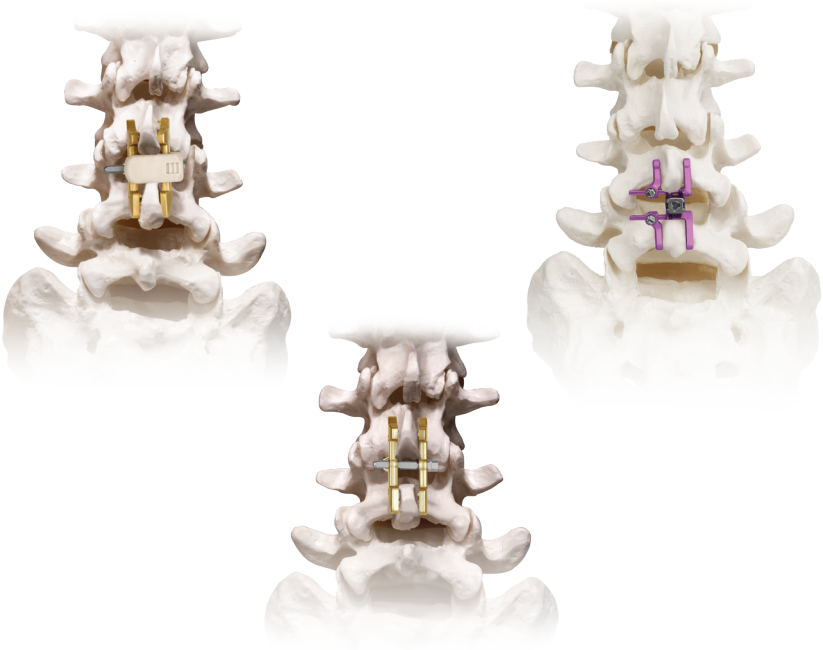
## How Is the Procedure Performed?

Your surgeon may need to relieve excess pressure on the spinal cord and/or nerves. An incision (surgical cut) will be made in your back over the affected area. Your surgeon then determines which size is best for you, using X-rays to see your spine.

Your surgeon will then implant the device into your spine between your spinous processes, to help open up the space around your spinal cord. Once the device has been implanted, your surgeon will clamp and lock the implant to the spinous processes.

Bone graft material may be placed around the implants to help with fusion. These devices may be used with other fixation devices such as pedicle screws and rods.

Speak to your surgeon about surgical options for your specific condition and what is best for you.



# Frequently Asked Questions

## What should I expect with my recovery?

Treatment with interspinous fixation may help you return to normal activities. Many patients recover in two to four weeks; however, recovery time varies among patients. Some patients may be able to get out of bed the day of surgery and be discharged the following day.

A positive attitude, reasonable expectations, and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.

## How long will my implant last?

The device lifetime for these devices is one year, in which it is expected that the devices will achieve their intended purpose (support fusion) and maintain their performance until fusion occurs. After fusion occurs, these devices are made to survive the life of the patient. These implants can be removed after fusion occurs; however, this is determined by the surgeon and the patient.

## Can I have an MRI after the devices are implanted?

MR compatibility is shown below for AERIAL® and SP-Fix®. Your radiologist may request this information prior to taking an MRI. These instructions are also provided in the device insert.

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*AERIAL®*

The AERIAL® devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under these defined scan conditions the AERIAL® 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 for the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MR system.

*SP-Fix®*

SP-Fix® devices can 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, SP-Fix® 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 device if you have an infection, congenital abnormality, tumors, certain allergies, a fever or high white blood cell count, rapid joint disease, defective posterior arches, rheumatoid arthritis, osteoporosis, osteopenia, or cancer, or are obese, pregnant, immunocompromised, mentally ill, or diabetic.

As with any surgical procedure, complications or adverse effects may occur following the placement of this device. These can include but are not limited to early or late implant bending, breakage, failure, loosening, movement/migration, decrease in bone density, intervertebral disc damage, abnormal sensation, loss of spinal mobility or function, bone fracture, and allergic reaction to implant material.

Other general adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, pseudarthrosis, pain, secondary surgery, change in spinal curvature bleeding, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, cardiovascular system compromise, respiratory problems, tissue damage, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, restriction of activities, paralysis, and death.

If you experience any of the above adverse effects, please contact a healthcare 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 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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