



STABILIZATION SYSTEM

# TRANSITION<sup>®</sup>

Life moves us 

Outside the US Only



# TRANSITION<sup>®</sup> Stabilization System

## Patient Information

This brochure will help you understand more about:

- ▶ **General conditions of the spine**
- ▶ **Information about surgical treatment**
- ▶ **TRANSITION<sup>®</sup> Stabilization System**
- ▶ **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.

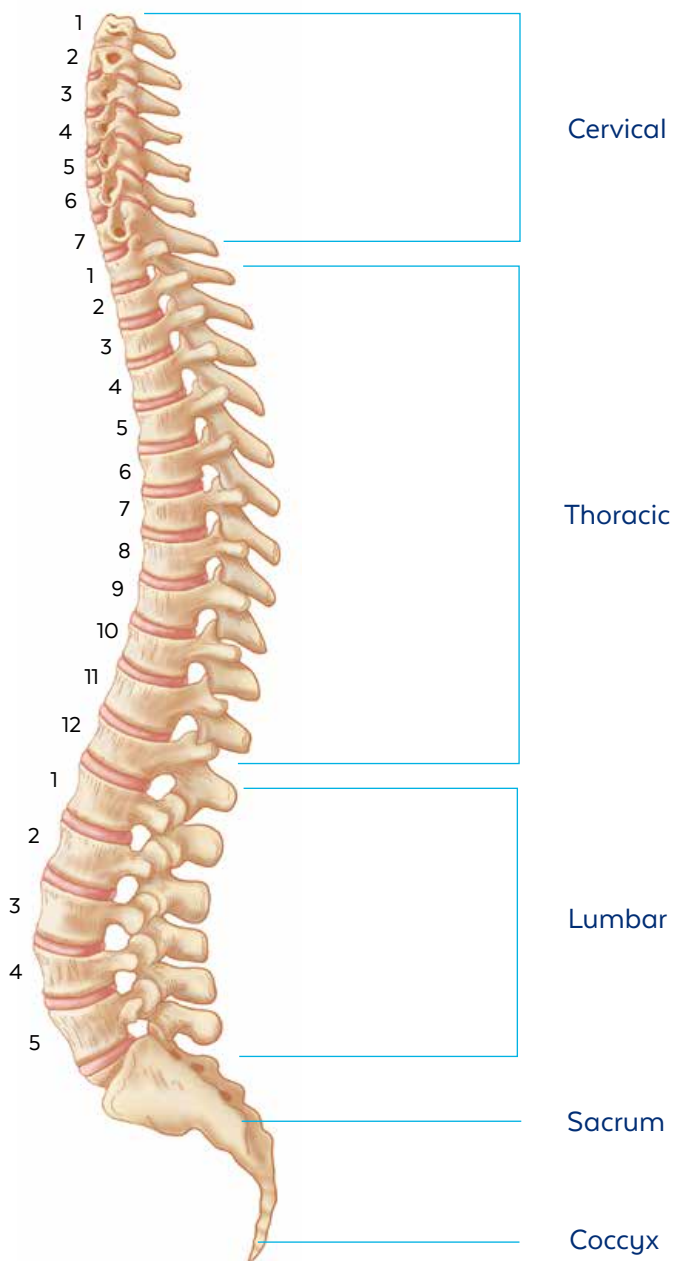
This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results, and other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

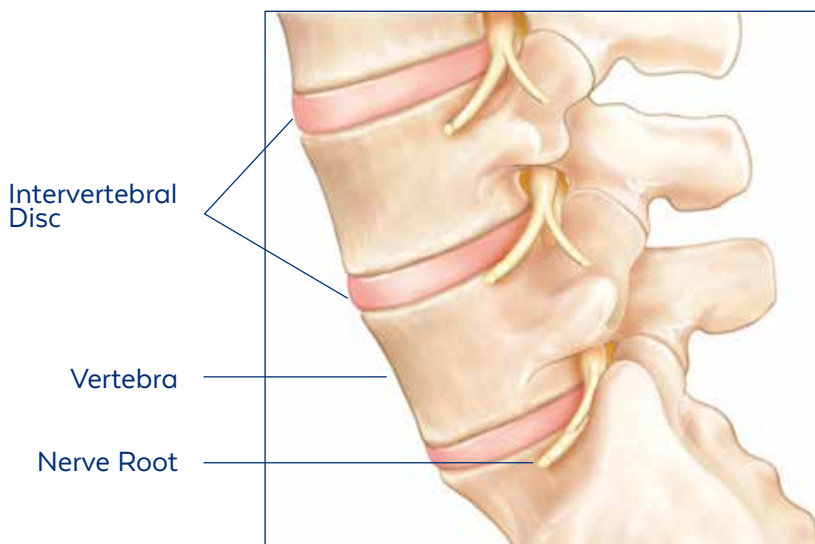
The spine is made up of vertebrae (bones) and is divided into three main sections:

- ▶ Cervical (7 vertebrae)
- ▶ 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, 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 (the 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 Spine

In the normal spine, 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***

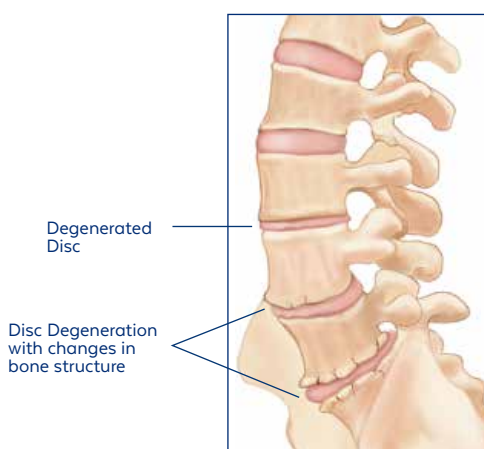
Degenerative changes in the spine may cause instability and pain in your back. Degenerative disc disease (DDD) involves the intervertebral disc and is part of the natural aging process. Disc degeneration can also result from torsional (twisting) injury to the lower back.

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, which can lead to abnormal motion or alignment of the spine that may result in pain.



Healthy Discs

Symptoms include pain, burning, or numbness in the back or legs.



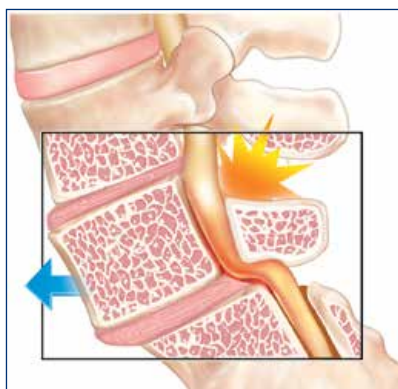
## **Spondylolisthesis**

Spondylolisthesis (spinal instability) is a condition in which one of the vertebrae slips forward or backward (retrolisthesis). If left untreated, this can lead to instability 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) are reviewed.



Normal spine segment

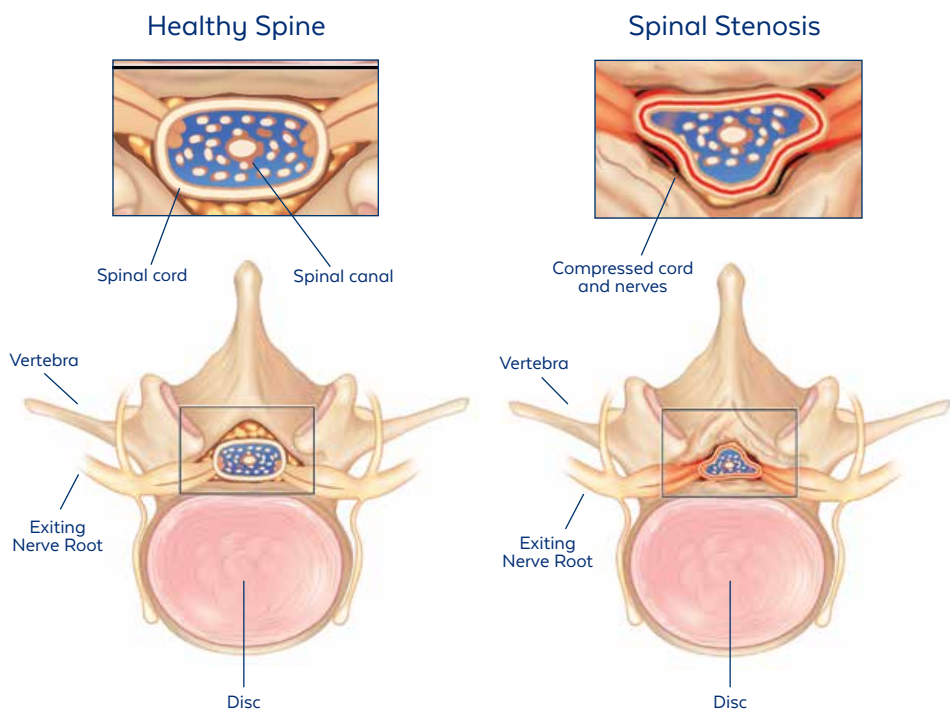


Displaced vertebra causing pressure on nerve

## Conditions of the Lumbar Spine (Cont'd)

### **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. 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**

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.

## **Spondylosis**

Age-related change of the bones and discs of the spine.

## **Pseudarthrosis**

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

## **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

## General Treatment Options

Symptoms due to spinal instability or the other conditions listed above may be treated with non-surgical methods for as long as possible. These treatments include rest, ice or heat, weight control, exercise, physical therapy, medication, and steroid injections.

If these non-surgical treatments do not bring relief after a period of time, your doctor may recommend surgical treatments to take pressure off the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae.



Surgery may involve only TRANSITION<sup>®</sup> implants to stabilize the spine in a less rigid manner than metal rods, or may include other implants to stabilize the spine to prevent any movement between vertebrae (spinal fusion). For spinal fusion, surgery may also include removal of the affected discs and placement of bone graft (from the patient's own body or a donor).

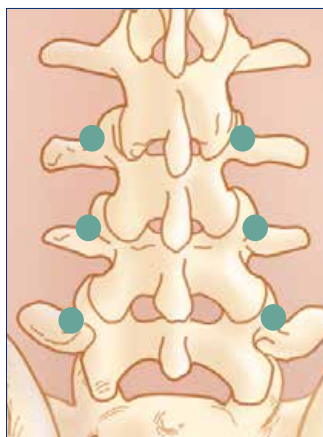
The surgeon may decide to use an anterior approach, which means making an incision in the abdomen, or a posterior approach, which means making an incision in the back. Sometimes the surgeon may use a combination of these two approaches.

# Treatment with the TRANSITION<sup>®</sup> Stabilization System

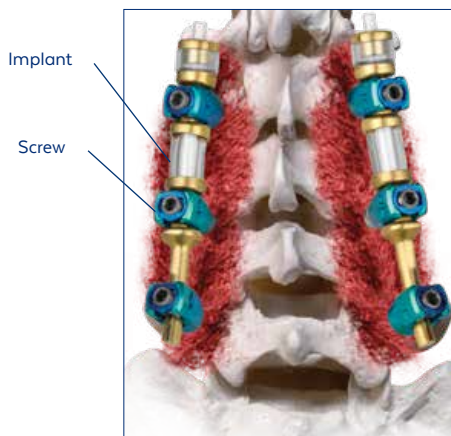
## ***How Is the Procedure Performed?***

Screws are placed on each side of the affected vertebrae in the part of the bone called the pedicle (bone tube that connects the back of the vertebrae to the front). The implants are then secured within the screws, connecting with the next vertebrae. Bone graft material may be placed around the final assembly to help with fusion.

Speak to your doctor about surgical options for your specific condition and what is beneficial for you.



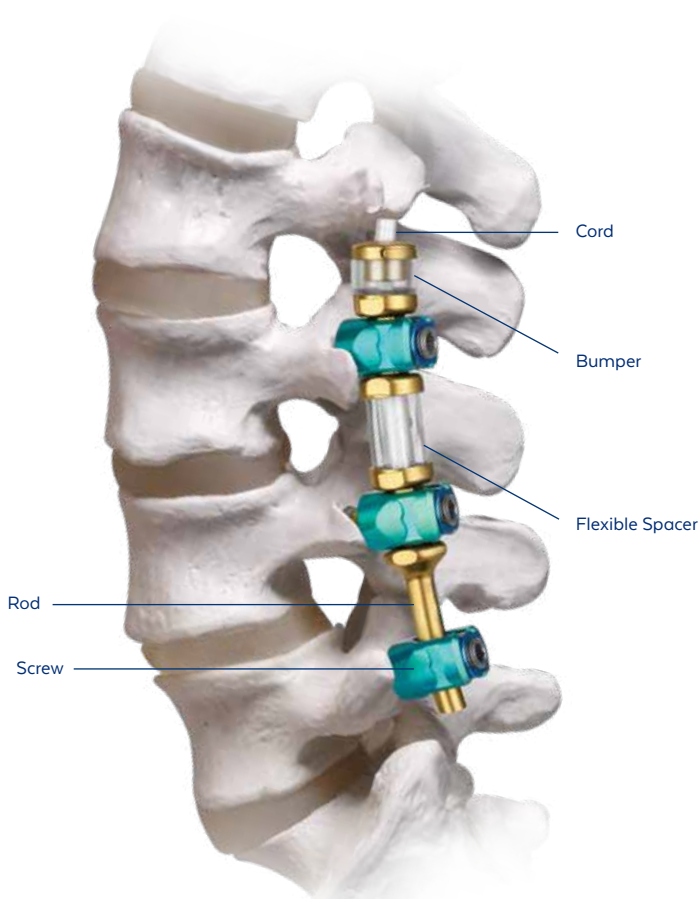
Points of screw placement



Final implant construct

## How TRANSITION® Works

TRANSITION® includes a cord, bumper, flexible spacer, and rod portion, which is placed into screws. The cord can bend and stretch more than a traditional metal rod, and is less stiff.



TRANSITION® implants are composed of titanium alloys, cobalt chromium alloy, polyethylene terephthalate (PET), polycarbonate urethane (PCU), and/or hydroxyapatite. 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?

Treatment with TRANSITION® may help you return to normal activities. Many patients recover in 2 to 4 weeks; however, recovery time varies among patients. Some patients may be able to get out of bed the day of surgery and may 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 this system 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. 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?

TRANSITION® implants have not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment, and have not been tested.

## Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this device if you have an infection, congenital abnormality, tumors, inadequate pedicles, tissue deficits, certain allergies, rheumatoid arthritis, osteopenia, osteoporosis, or cancer, or are obese, pregnant, or diabetic. 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 this device. These can include but are not limited to early or late implant bending, breakage, loss of fixation, failure, loosening, movement/migration, decrease in bone density or bone fracture, and 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, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, cardiovascular system compromise, respiratory problems, organ damage, joint inflammation, change in spinal curvature, complications due to bone grafting, reactions to anesthesia, restriction of activities, 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 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.

<b>Region</b>	<b>Authority</b>	<b>Website</b>
All	Globus Medical	<a href="https://www.globusmedical.com/international/about/contact/">https://www.globusmedical.com/international/about/contact/</a>
Australia	Therapeutic Goods Administration (TGA)	<a href="https://www.tga.gov.au/">https://www.tga.gov.au/</a>
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	<a href="https://www.medsafe.govt.nz/">https://www.medsafe.govt.nz/</a>
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	<a href="https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency">https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</a>
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

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