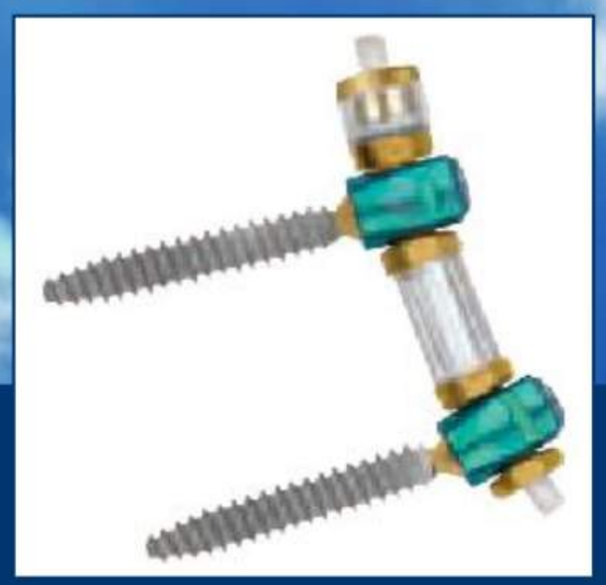
PATIENT INFORMATION

Stabilization System

RNZ NEUROSCIENCE

Bringing world –class health care to your door-step

Table of Contents

TRANSITION®
Stabilization System

Patient Information

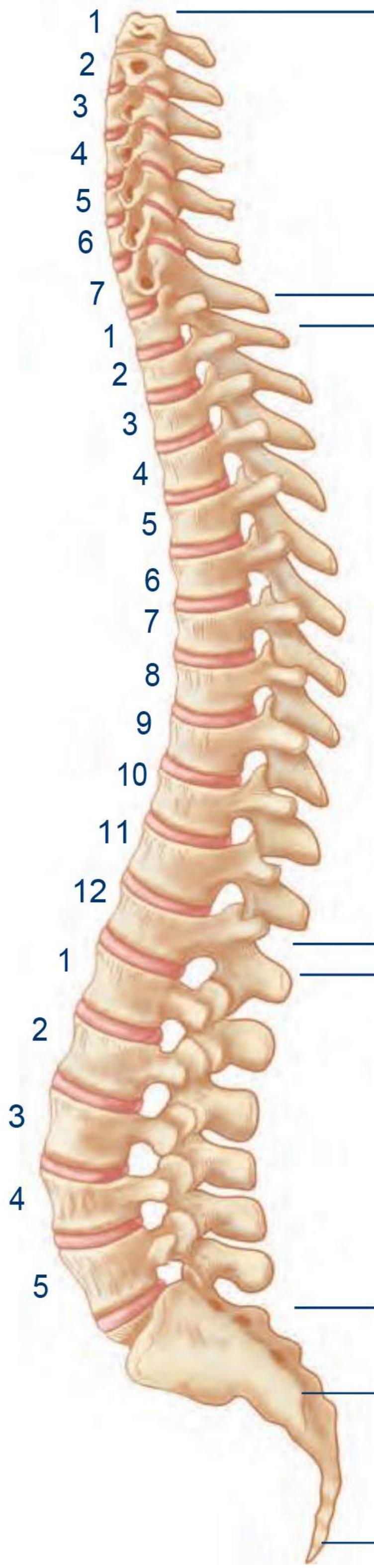
This brochure will help you understand more about:

- General conditions of the spine
- Information about surgical treatment
- TRANSITION® 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 its 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.

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.

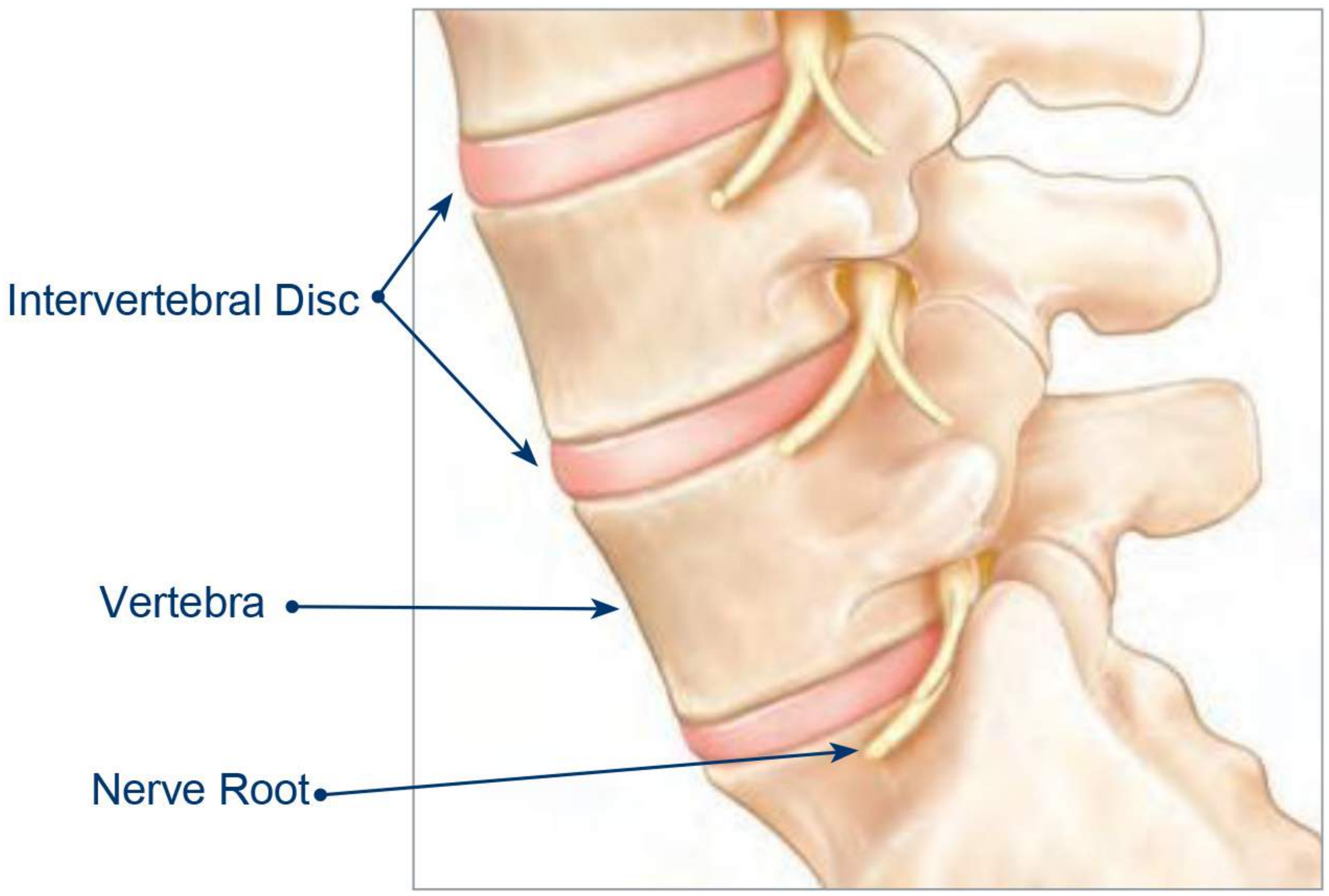
The spine is made up of vertebrae and is divided into 3 main sections:

Cervial (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 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.

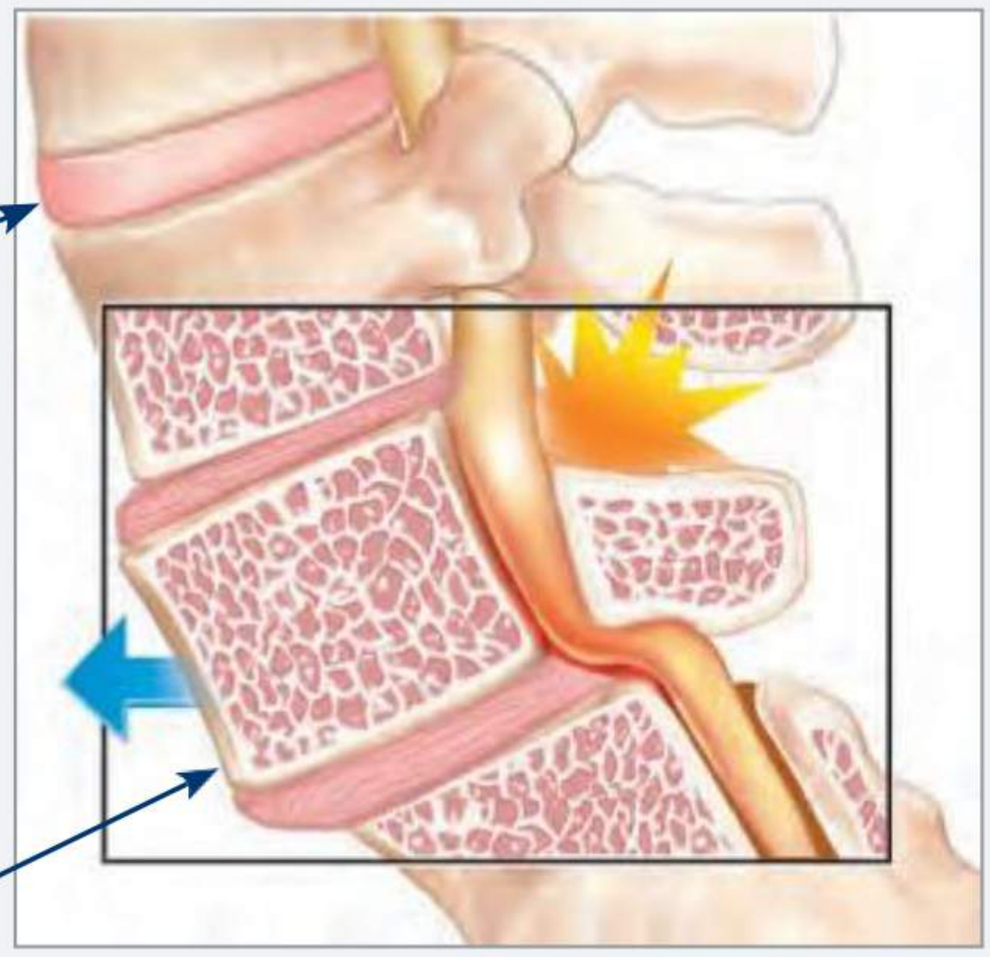


What is Spondylolisthesis?

Spondylolisthesis (spinal instability) is a condition in which one of the vertebrae slips forward or backward. 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 are reviewed.

Normal spine segment

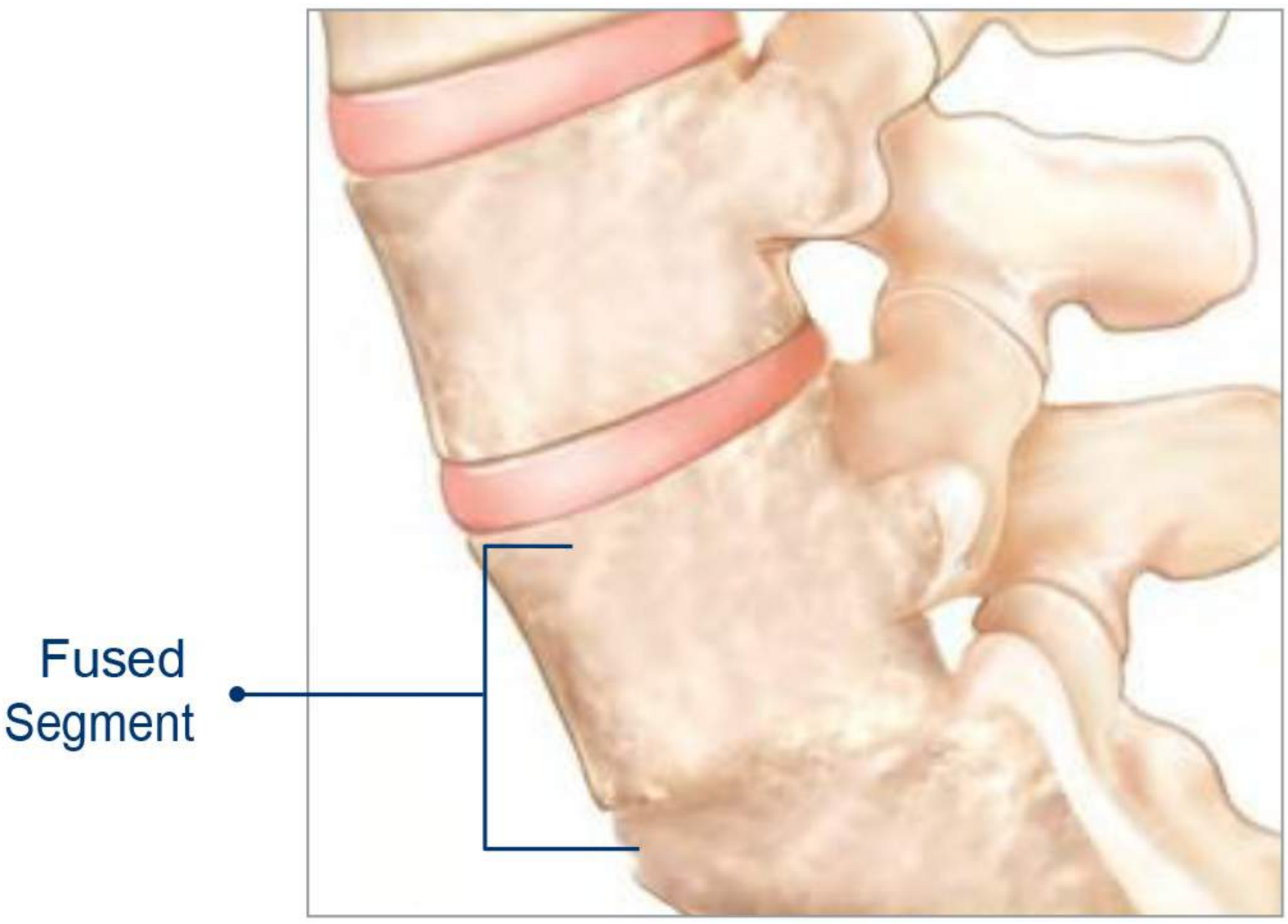


Displaced vertebra causing pressure on nerve

General Treatment Options

Symptoms due to spinal instability maybe 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.



Surgical treatment involves removal of the affected discs and fusion of the vertebral segments. Spinal fusion is accomplished by bone growth between the vertebrae, to minimize motion in the area, which may help reduce pain.

Depending on certain factors, the surgeon may decide to fuse using an anterior approach, which means an incision in the abdomen, or a posterior approach, which means an incision in the back. Sometimes the surgeon may use a combination of these two approaches.

The TRANSITION® Stabilization System uses the same surgical approach of traditional fusion surgery, but employs flexible material to stabilize the spine in a more natural manner.

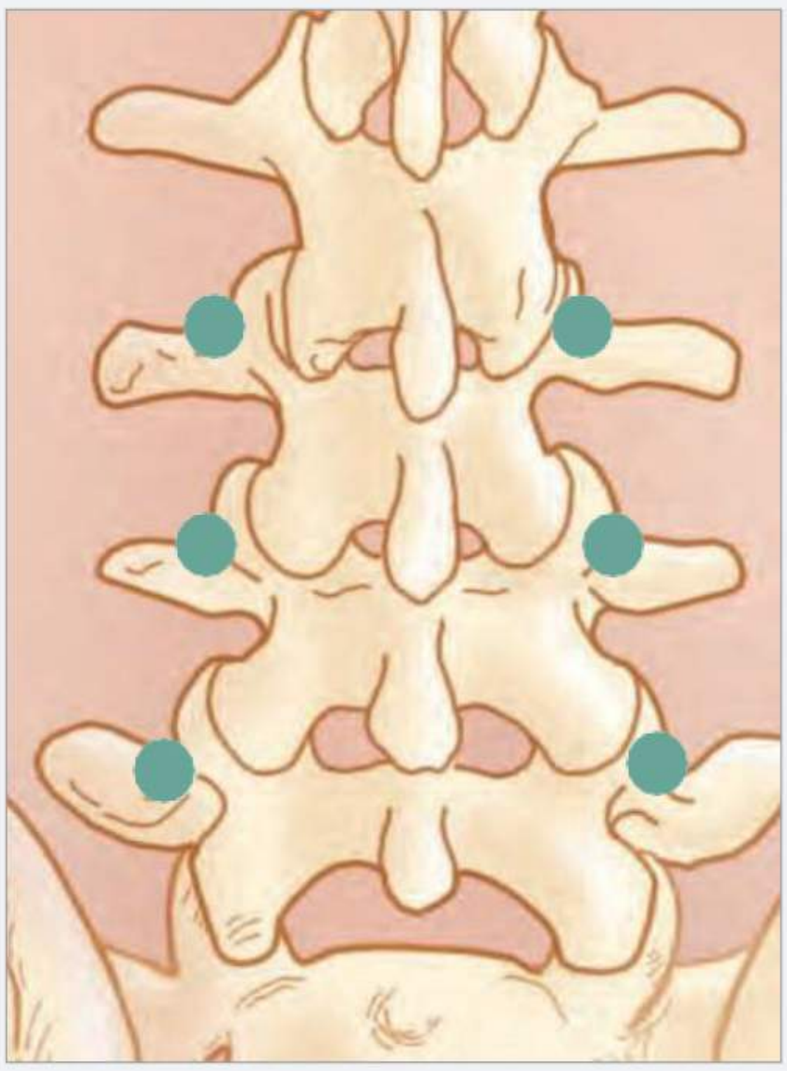
Treatment with the
TRANSITION Stabilization System

The goal of this treatment is to stabilize the spine to facilitate fusion, which may help relieve pain and allow patients to return to normal activities.

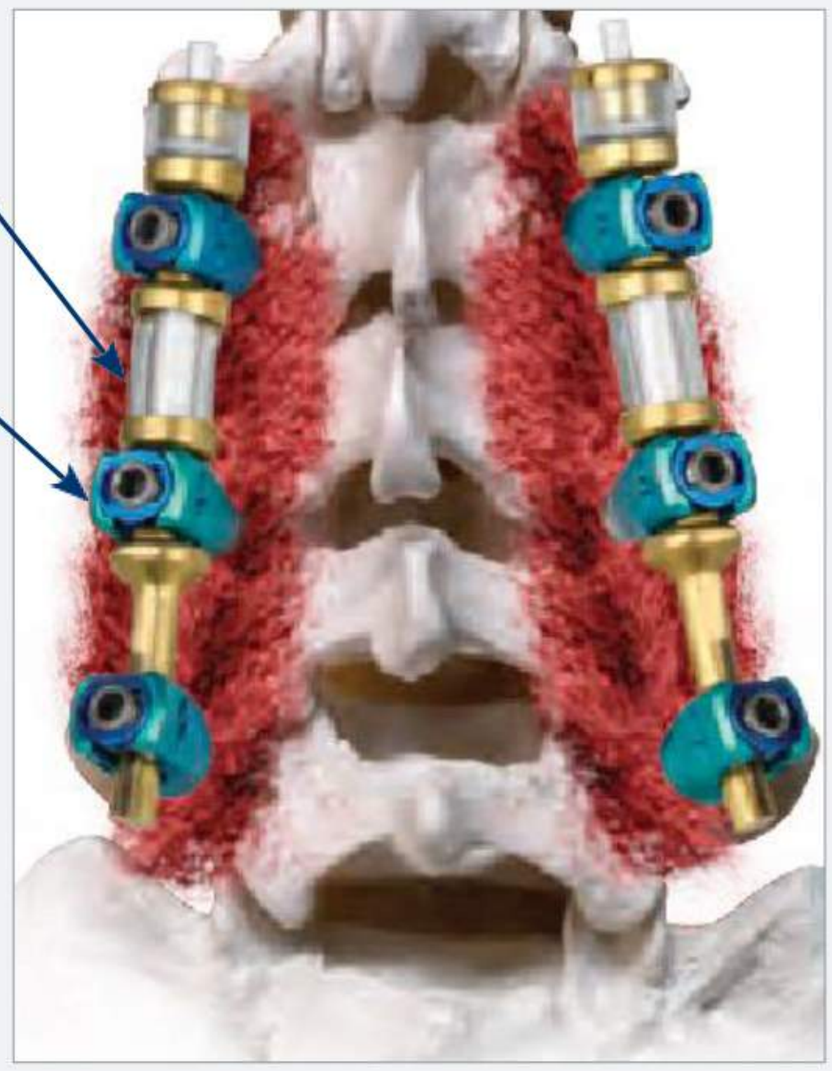
How is the Procedure Performed?

To help stabilize the spine, screws are placed on each side of the affected vertebrae in the part of the bone called the pedicle. The implants are then secured in the screw heads, connecting adjacent vertebrae. Bone graft material is placed around the final assembly to facilitate fusion. Excess spinal cord and/or nerve pressure may be relieved by this stabilization and associated 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 the TRANSITION® Stabilization System Works

The TRANSITION® Stabilization System is an implant designed to provide stabilization of segments for the treatment of acute and chronic instabilities in the spine . TRANSITION® incorporates a central cord, compressible bumper and flexible spacer. The system acts as a semi-rigid ligament with the ability to both bend and stretch, stabilizing your spine in a less rigid manner compared to other treatment options.

Compressed

Central Cord
The end is a flexible cord. This cord runs through the center of the implant.

Compressible Bumper
The bumper compresses slightly allowing the implant to stretch.

Flexible Spacer
The spacer works with the cord to allow the implant to bend.

Neutral

What Should I Expect with My Recovery?

Treatment with the TRANSITION® Stabilization System may help you return to normal activities. Many patients recover in 2–4 weeks; however, recovery time varies between 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 .

Contraindications, Complications, Warnings, and Precautions

You may be contraindicated for this device if you have an infection, a congenital abnormality, are obese, pregnant, mentally ill, diabetic, suffer from rheumatoid arthritis, osteoporosis, or cancer.

As with any surgical procedure, complications 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, bone fracture, and allergic reaction to implant material.

Other general complications associated with any spinal surgical procedure include non-union or delayed union, pseudarthrosis, pain, second surgery, bleeding, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, cardiovascular system compromise, respiratory problems, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, paralysis, and death.

This list does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

WARNING: The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with autogenous bone graft is being performed at all instrumented levels.

www.rnzglobal.com

info@rnzglobal.com

Bringing world –class health care to your door-step