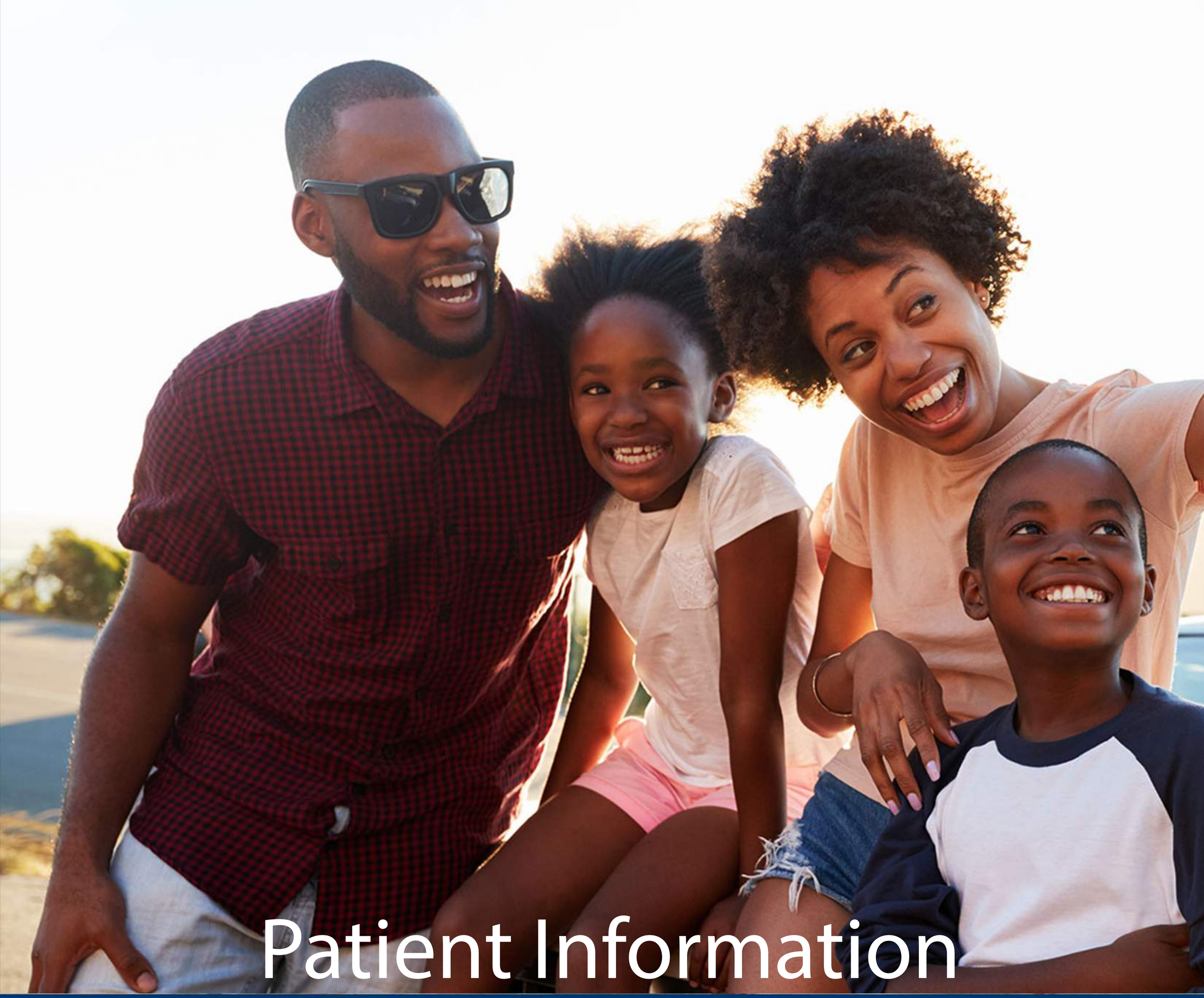

Patient Information

Spinous Process Fixation System

RNZ NEUROSCIENCE

Bringing world –class health care to your door-step

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SP-Fix™
Spinous Process Fixation System

Patient Information

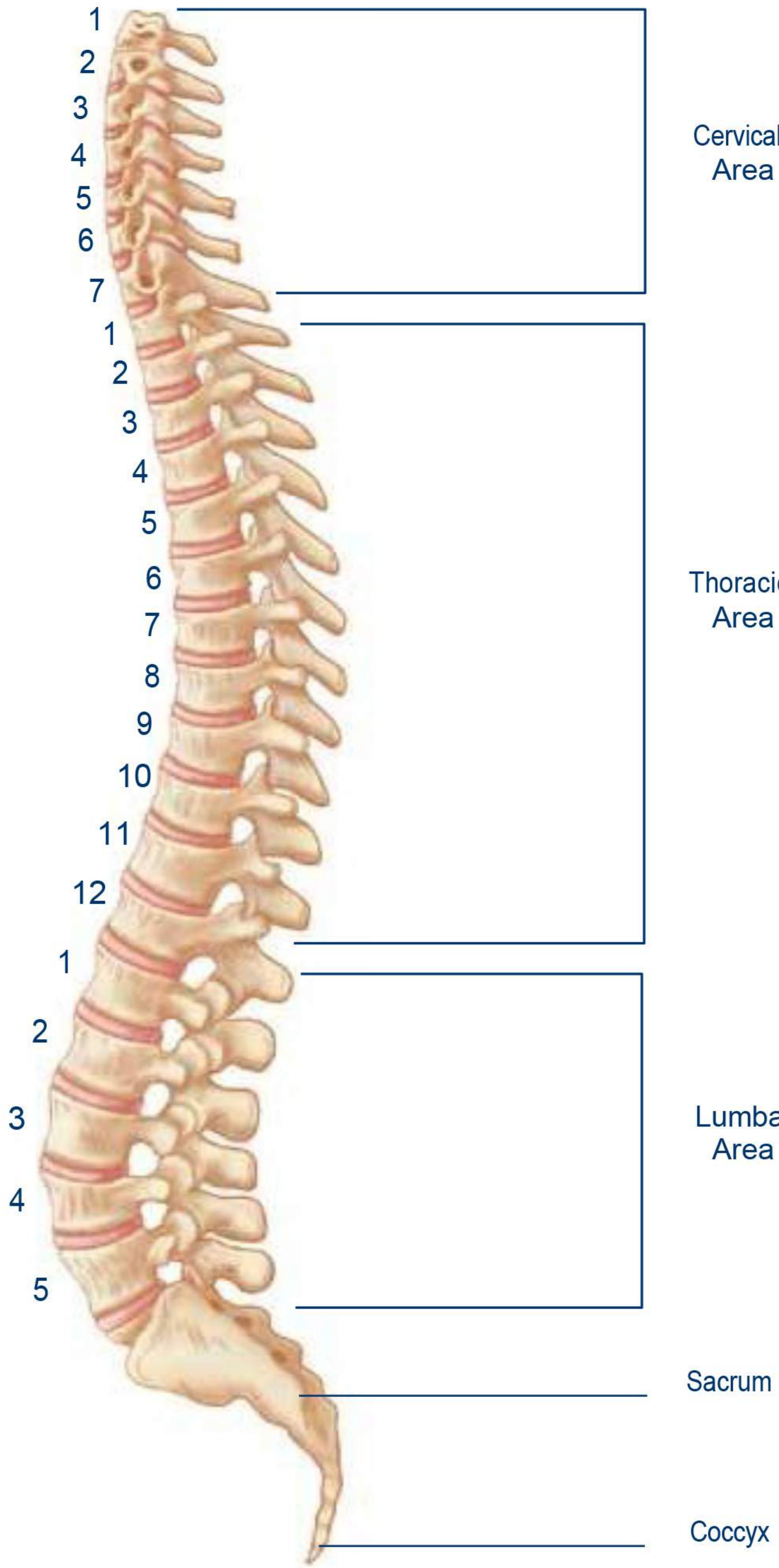
This brochure will help you understand more about:

- 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 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



Anatomy of the Spine

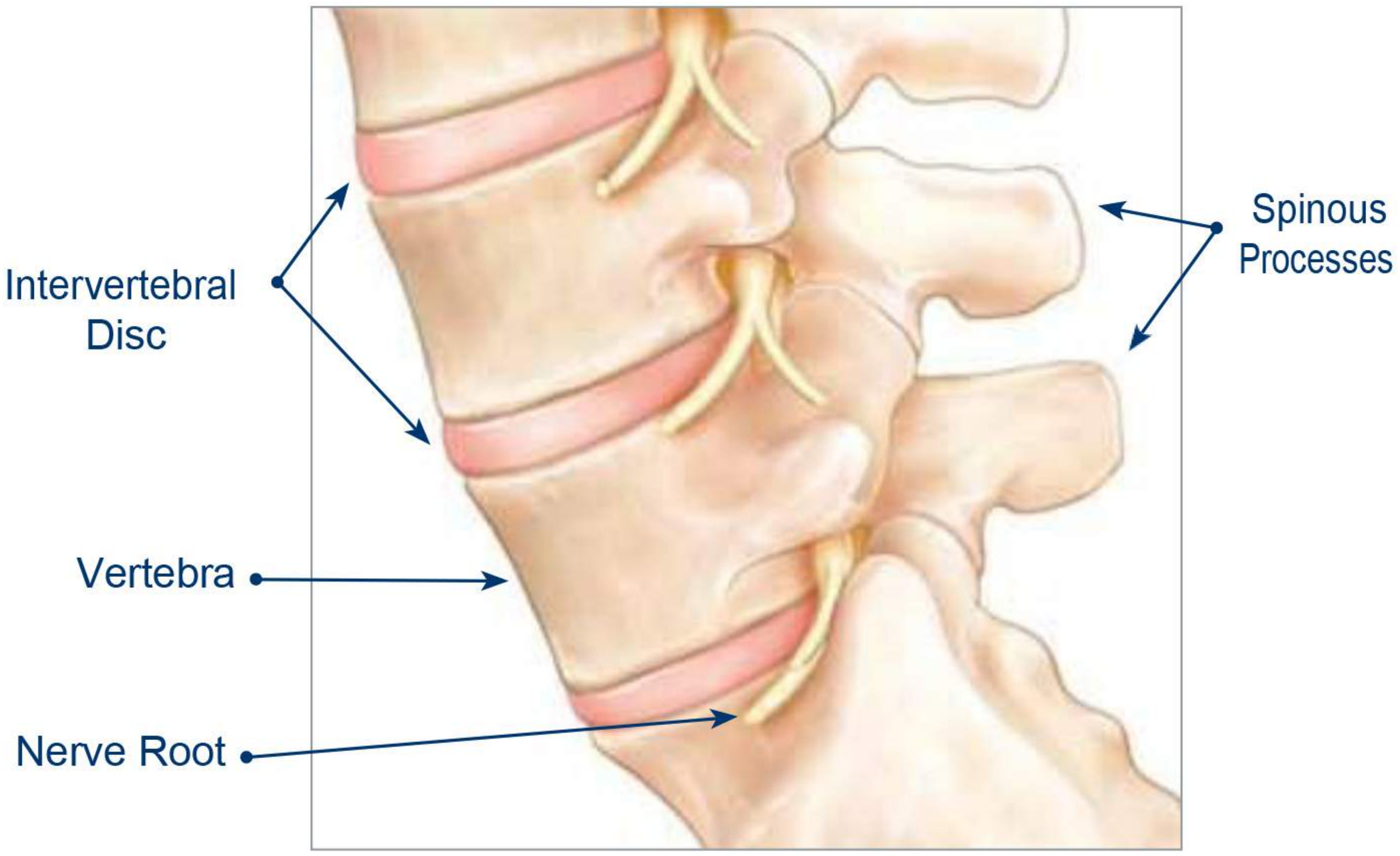
The spine is made up of vertebrae and is divided into 3 main sections:

- 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 and also feature bones called spinous processes. Spinous processes 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 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.

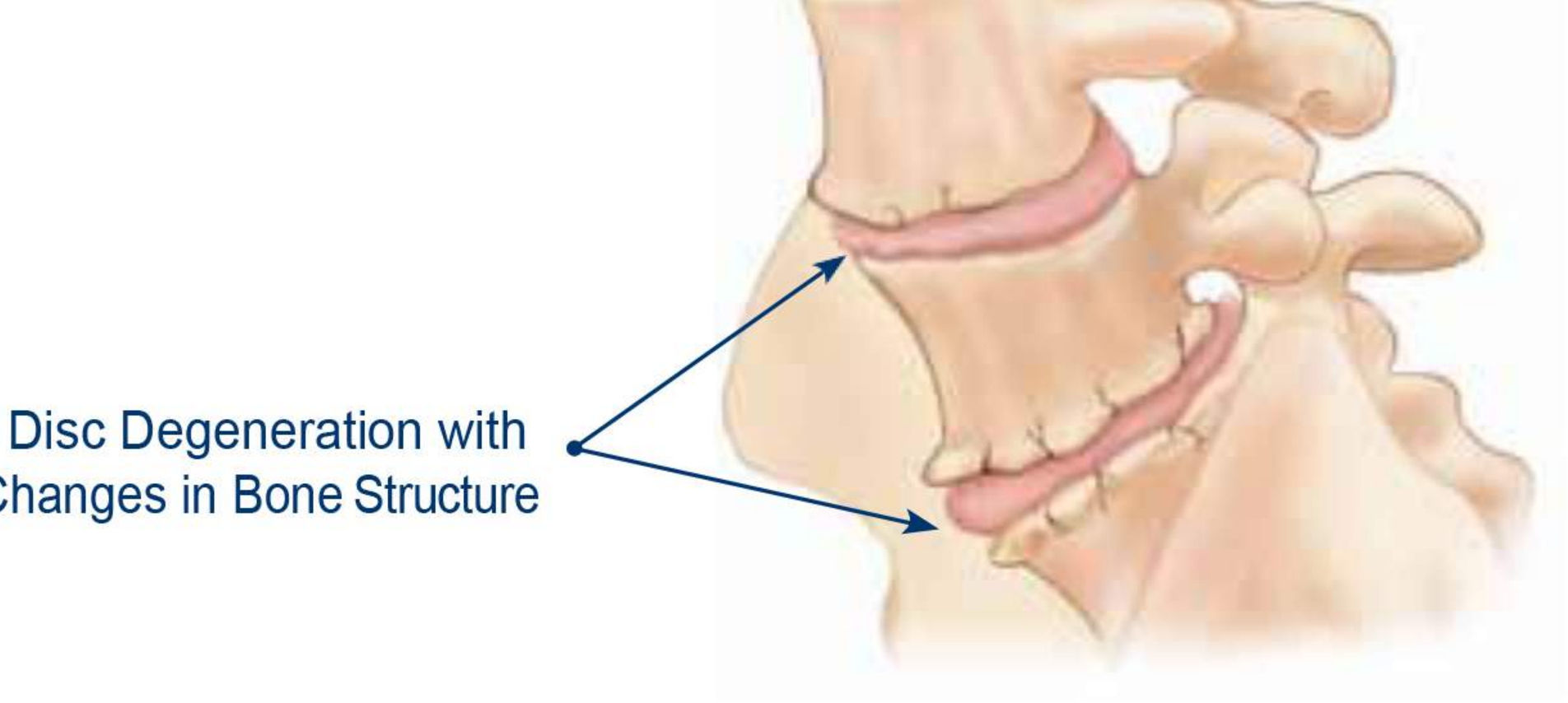


What is Degenerative Disc Disease?

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

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

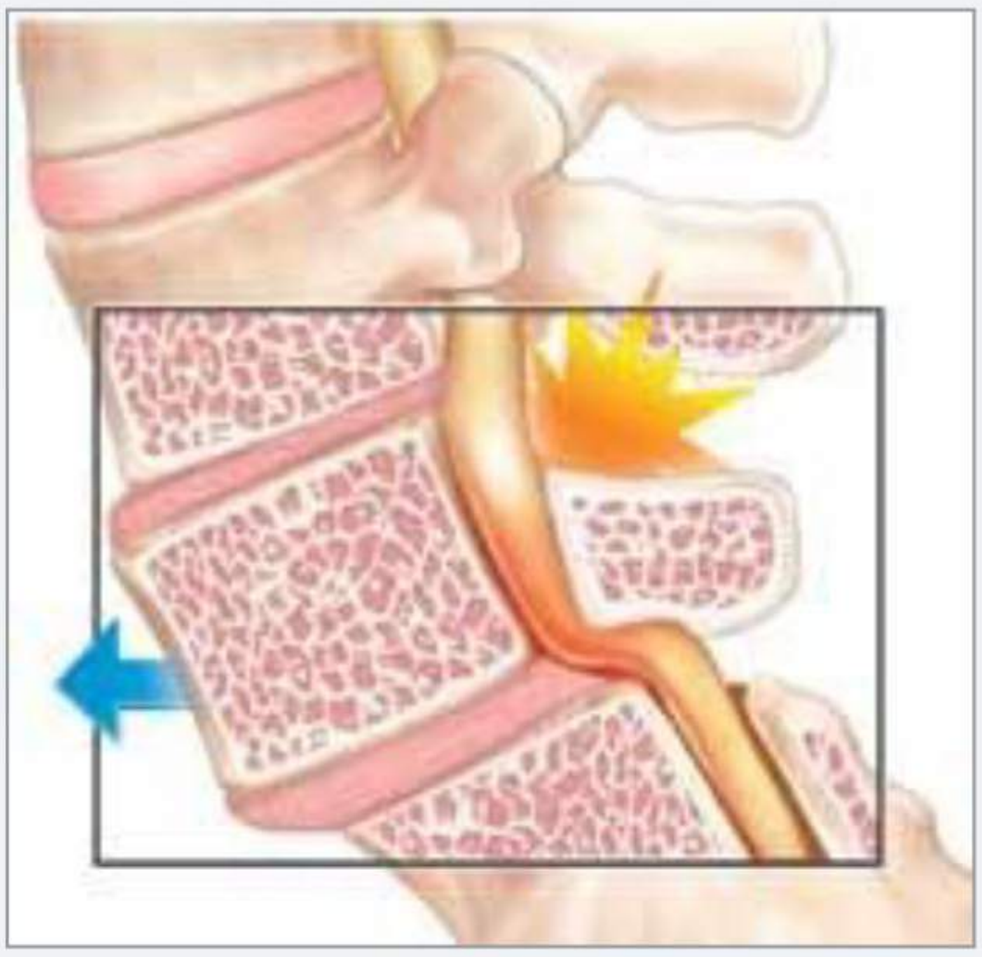


What is Spondylolisthesis?

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.

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.

Normal spine segment



Displaced vertebra causing pressure on nerve

Answers to your questions regarding SP-Fix™ Spinous Process Fixation System

How the SP-Fix™ Spinous Process Fixation System Works

The SP-Fix™ Spinous Process Fixation System is a fixation device designed to provide supplemental fixation in your spine and supports a minimally invasive surgical technique. SP-Fix™ is available in vari si o fit specific anatomy and comes in either a Plate and Barrel Assem Assembly. Your surgeon will recommend which procedure a est for you and your condition.

Plate and Barrel Assembly

Plate Assembly

How is the Procedure Performed?

Your surgeon may need to relieve excess pressure on the spinal cord or nerves . An incision will be made in your back over the affected area. Your surgeon will implant the device into your spine between your spinous processes. Once the device has been implanted, your surgeon will clamp the implant together, locking it to your spinous processes.

Bone graft material is placed around the final assembly to facilitate fusion. SP-Fix™ is designed to be used with other fixation devices such as pedicle screws, facet screws or an interbody device with a plate and screw along with SP-Fix™.

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

SP-Fix™ Plate and Barrel Assembly

SP-Fix™ Plate Assembly

What Should I Expect with My Recovery?

Treatment with SP-Fix™ Spinous Process Fixation 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.

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