

An introduction to

# Posterior fixation

## For the thoracolumbar spine

This booklet provides general information on posterior fixation procedure options for the thoracolumbar spine. It is not meant to replace any personal conversations that you might wish to have with your physician or other member of your healthcare team. Not all the information here will apply to your individual treatment or its outcome.



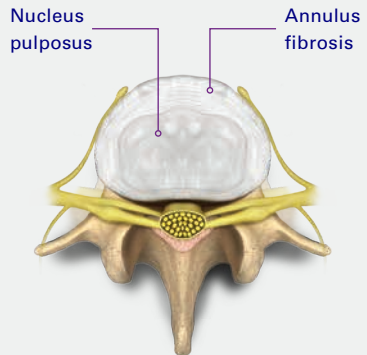
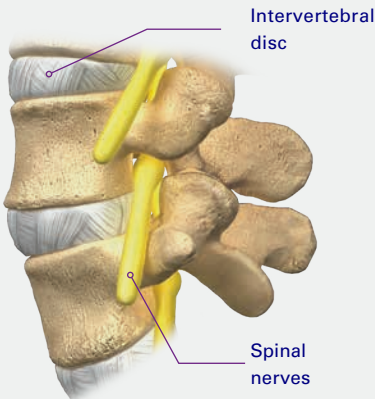
# About the spine

You have been provided with this patient information brochure to help you understand your back surgery using the Centaur Spinal System for Posterior Spinal Fusion (PSF) surgery. Your surgeon has decided that you need spine surgery after carefully examining you, reviewing your history and taking into account the results of other diagnostic studies.

Your spine is an important structure in your body. It gives you support. It allows you to move and bend freely. Without it, you could not sit or stand up. To provide support, your spine contains 24 bones known as vertebrae. They are arranged in a column, stacked one on top of the other. The vertebrae protect and support the spinal cord, which houses many nerves. The area of the spine in your mid to lower back is called the thoracic and lumbar spine. It is made up of 17 bones, called vertebrae (12 thoracic, 5 lumbar).

These vertebrae are connected by several joints, which allow you to bend, twist, and move your back. The main joint between two vertebrae is called a disc. The disc is comprised of two parts, a tough and fibrous outer layer (annulus fibrosis), and a soft, gelatinous center (nucleus pulposus). These two parts work in conjunction to allow the spine to bend, twist, and also provide shock absorption.

There are many primary causes of back problems. The majority of the symptoms are degenerative and caused by disc, bone, or ligaments pressing onto the nerve roots or cord.



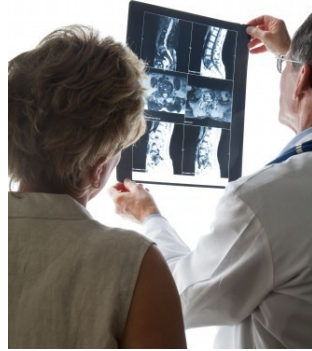
# Patient Information

This leaflet will help you understand more about:

- About your surgical treatment
- Posterior Spinal Fusion (PSF) surgery
- Information about the Centaur Spinal System
- What to expect from your surgery

The decision to receive medical treatment is individual to the patient and the patient's symptoms. The information presented within this leaflet may not apply to your condition, treatment or its outcome, as surgical techniques vary and complications may occur. It is important to discuss the viability of this procedure with your doctor to decide whether this treatment option is right for you.

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

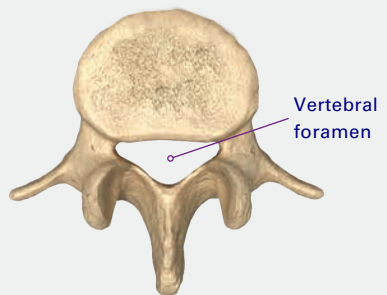
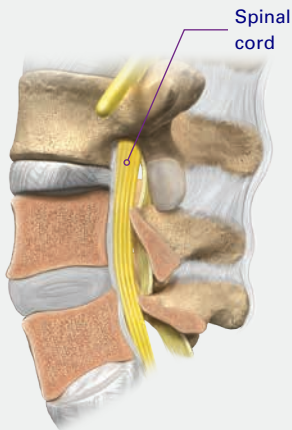
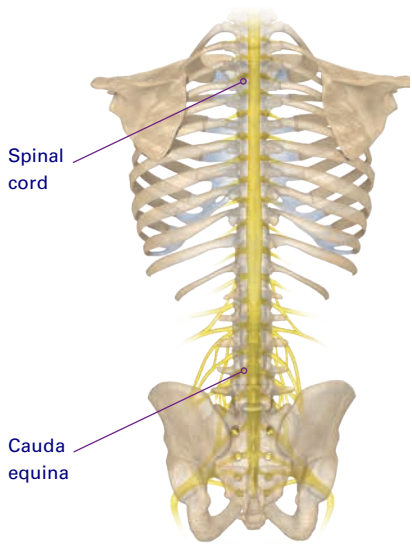


# About the spinal cord and the cauda equina

Each vertebra has an opening (vertebral foramen) through which a tubular nervous structure travels. Beginning at the base of the brain to the upper lumbar spine, this structure is called the spinal cord.

Below the spinal cord, in the lumbar spine, the nerves that exit the spinal cord continue to travel through the vertebral foramen as a bundle known as the cauda equina.

At each level of the spine, spinal nerves exit the bony spine then extend throughout the body.



# What can cause pain?

There are several possible causes of spine problems. The most frequent symptoms are caused by either instability or by disc, bone, or ligaments putting pressure on (compressing) the nerve roots, spinal cord, or cauda equina.

Some causes may include acute and chronic instabilities or deformities of the spine:

- Degenerative disc disease (DDD)
- Spinal stenosis
- Spondylolisthesis
- Spinal deformities
- Fracture
- Pseudarthrosis
- Tumor resection
- Trauma
- Failed previous fusion

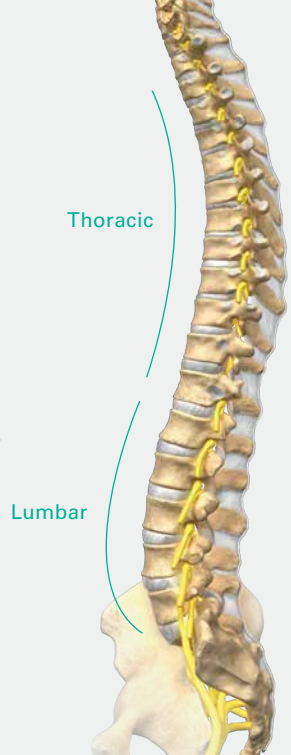
# What are treatment options?

Many symptoms can be treated without surgery including rest, heat, ice, medication, injections, and physical therapy.

If symptoms do not improve with conservative treatment, physicians may recommend spinal surgery. Surgery is reserved for those who do not gain relief from non-operative forms of treatment, patients whose symptoms are increasing or worsening, and/or patients that present with a spinal condition which indicates the need for surgery. It is important to speak with a physician about the best option.

# What is posterior fixation for the thoracolumbar spine?

Posterior fixation for the thoracolumbar spine is a procedure intended to provide immobilization and stabilization of spinal segments in skeletally mature patients throughout the healing process, allowing fusion to occur.



## Can posterior fixation be right for me?

Your physician might determine posterior fixation is a good option for your pathology and if you have gone through a period of non-surgical treatment.

Conversely, your physician may determine that posterior fixation is not a good option for you if you are not a good candidate for fusion surgery in general due to other medical conditions. These conditions can be but are not limited to, signs of inflammation or infection near the operative site, patient sensitivity to implant materials, patients with inadequate bone quality, and other indications.

# What to expect

## Before surgery

Your physician will review your condition and explain treatment options, including medications, physical therapy, and other surgeries. Should you have any questions regarding the procedure, do not hesitate to ask your surgeon. Your physician will provide thorough preoperative instructions.

## During surgery

After you are sedated, positioned face down, and surrounded by the appropriate surgical draping, images may be taken of your spine such as x-ray to identify the location of the operative disc space.

### Step 1: Approach

Your surgeon will make an incision down the midline of your back. Tissue is then retracted or pulled back laterally to expose the affected vertebral bodies. Once the exposure is complete your surgeon will then be ready to decompress the affected areas.

### Step 2: Decompression

Your surgeon may then choose to decompress portions of the affected vertebrae and discs. Decompression may be necessary if the symptoms are caused by a compression of the spinal cord and/or nerve roots.



### Step 3: Stabilization or fixation

Your surgeon will then use screws and rods, such as the Centaur Spinal System, to stabilize or fixate the affected vertebral bodies. The combination of screws and rods act as an internal brace or stabilization device to help hold everything in place. Your surgeon will determine the appropriate use of fixation implants during the procedure.

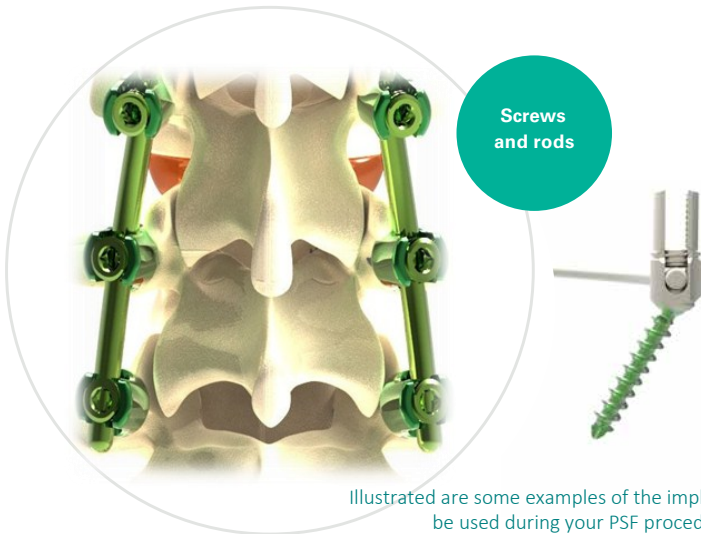
### Step 4: Fusion

Your surgeon will then tighten and lock down the construct (combination of screws and rods), which will allow the affected vertebral bodies to fuse. This means the bone will grow around the affected areas and heal. This can take various lengths of time depending on the severity of the condition. The area will eventually stabilize itself once fusion has occurred.

## What implants are used?

Below are some examples of the implants that may be used during your posterior fixation procedure such as the Centaur Spinal System that is comprised of screws, rods and tightening caps (pictured on the right).

*Refer to [What is the Centaur Spinal System?](#)*



Illustrated are some examples of the implants that may be used during your PSF procedure.



## After surgery

After surgery you will wake up in the recovery room, where your vital signs will be monitored and your immediate postoperative condition will be carefully observed. Once the medical staff feels that you are doing well, you will be returned to your room in the hospital.

Your physician will determine the best postoperative course for you. This will include any medications to take home, as well as a prescribed program of activities. Your physician will provide instructions on wound care, exercises, and limitations to postoperative activity.

## What are the potential risks of a posterior fixation procedure?

Keep in mind that all surgery presents risks and complications that are important to discuss with your surgeon prior to your surgery. Listening to your physician's guidance, both before and after surgery, will help your recovery.

Potential risks following a posterior fixation procedure include:

- Problems with anesthesia
- Infection, bleeding
- Nerve damage
- Problems with the implants or hardware
- Ongoing pain

This is not intended to be a complete list of the possible complications. Please contact your physician to discuss all potential risks.

# What is the Centaur Spinal System?

The Centaur Spinal System consists of implantable screw, rods and caps. The Centaur Spinal System implants are intended for instrumented Posterior Spinal Fusion by a qualified surgeon. Centaur screws and rods are made of medical grade titanium alloy. The Centaur screws and rods may be used to hold the vertebrae in place while the fusion (bones grow together) occurs.

These implants are available to your surgeon in a wide variety of shapes and sizes to match each patients' individual anatomy and clinical pathology. The materials used usually do not harm the human body and are commonly used in medical implants for bone surgery. The Centaur Spine System implants are intended to remain in your body. Non-clinical testing of the worst-case scenario has demonstrated that the implants of the Centaur Spinal System have been designed to withstand anticipated loads until fusion occurs or up to 2 years in-vivo (whichever occurs first).

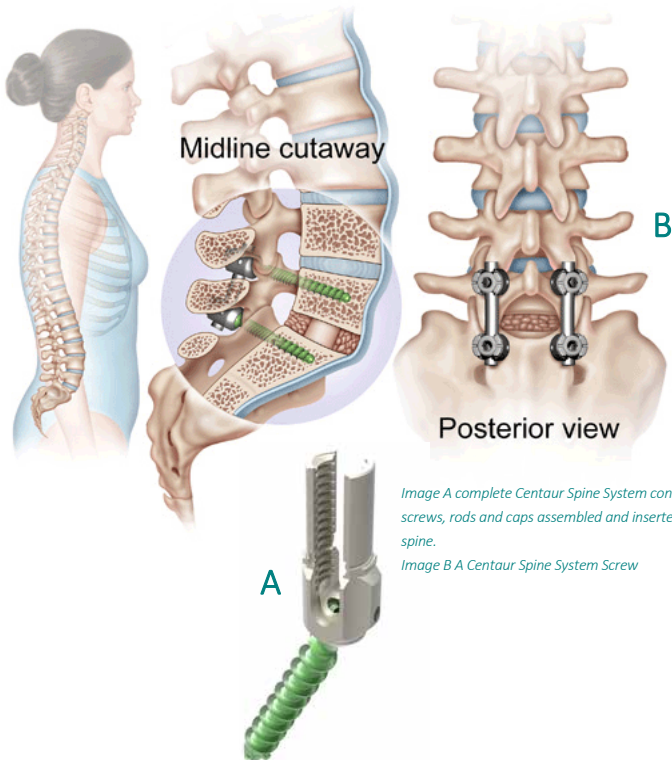


Image A complete Centaur Spine System construct - screws, rods and caps assembled and inserted into the spine.

Image B A Centaur Spine System Screw

## Talk to your Doctor

It is important to always follow your surgeons' recommendations. Your surgeon may advise you that some activities may increase the risk of loosening, bending or breaking the implants. If you have any questions about the Centaur Spinal System, please call or see your doctor, who is the only one qualified to treat your spinal condition.

Contact your doctor immediately after surgery if;

- You get a fever
- The wounds starts leaking fluids
- You have trouble swallowing or breathing
- You have new or increased back or leg pain or numbness

## What possible side-effects could occur?

Potential risks to any surgical procedure include unforeseeable complications caused by anesthesia, the surgical procedure, undiagnosed medical problems and rare allergic reactions. Most of these complications can be treated once they are detected but sometimes they require a longer period of hospitalization or recovery, additional medications, and sometimes even additional surgery. These risks will be explained by your surgeon. In general these complications happen very infrequently, but it is important to remember that surgery is a difficult process and therefore, unforeseeable complications do occur. As a patient it is important to understand and follow your doctors advice so that the best possible outcome can be achieved.

As with any surgical procedure, the following implant related side effects can occur;

- Implant material sensitivity; allergic reaction
- Discomfort or abnormal sensations
- Loosening, degradation, bending, failure, movement/migration or fracture of the implants

# MRI safety information

After your surgery, it is important to Inform your healthcare professional about your implants if you are having an MRI. Worst-case, non-clinical testing has demonstrated the Centaur Spinal System is MR Conditional.



After your surgery, you will have a Centaur spinal system implant/s and can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in injury. Full MRI safety information is available in the MRI Safety Information section of the Centaur spinal system instructions for use (IFU), which can be obtained at [www.prismsurgical.com.au](http://www.prismsurgical.com.au) or by calling +61 7 3720 8882.

# Contact Information

If a serious incident has occurred as a result of the devices listed in this leaflet, please report incident details immediately to the Australian sponsor;

- Prism Surgical Designs Pty Ltd  
[www.prismsurgical.com.au](http://www.prismsurgical.com.au)  
+61 7 3720 8882  
[enquiries@prismsurgical.com.au](mailto:enquiries@prismsurgical.com.au)
- Therapeutic Goods Administration (TGA) <https://www.tga.gov.au>

Please ask your surgeon if you would like additional information or if you have more questions about posterior spinal fusion surgery. Only your surgeon is qualified to treat your spine.

Prism Surgical Designs Pty Ltd is an Australian medical device company that develops, produces and markets instruments and implants for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.

