PRISM SURGICAL

# PATIENT INFORMATION LEAFLET

## Anterior Lumbar Interbody Fusion

with the

Aurora® and Australis® Spinal System

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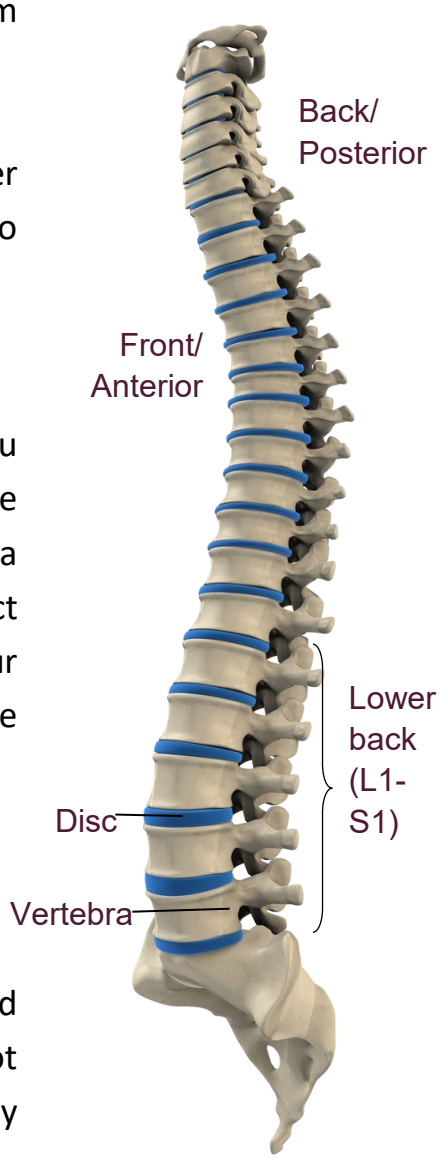
# General Information

You have been provided with this patient information brochure to help you understand your back surgery using the Aurora and Australis Spinal Systems for Anterior Lumbar Interbody Fusion (ALIF) from Prism Surgical.

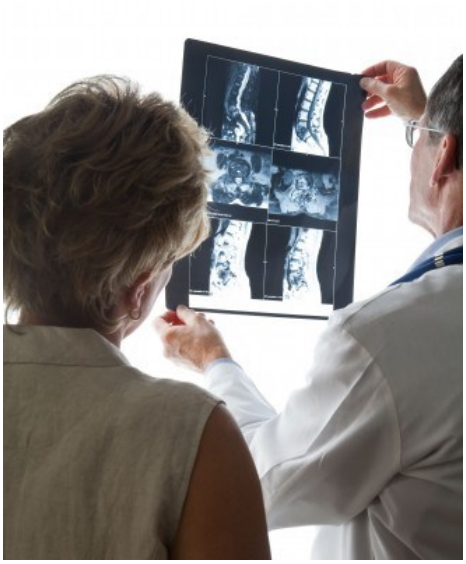
Your surgeon has decided that you need spine surgery after carefully examining you, reviewing your history and taking into account the results of other diagnostic studies.




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 vertebra. 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. Your spine has three main parts: the neck or cervical area, the central or thoracic area, and the lower back or lumbar area. Doctors number the bones in the lower back (lumbar spine) L1, L2, L3, L4, and L5 and S1 in the sacrum.

Soft discs between each bone allow your back to move and bend. When the discs wear out or are injured, they cannot function normally and may cause pain or limit your daily activities. This condition is often called Degenerative Disc Disease or DDD. Surgery may sometimes help to reduce this pain and restore some level of activity for patients with DDD. Other pathologies may also require fusion surgery in the anterior lumbar spine such as spondylolisthesis, and pseudoarthrosis.

# Patient Information



This leaflet will help you understand more about;

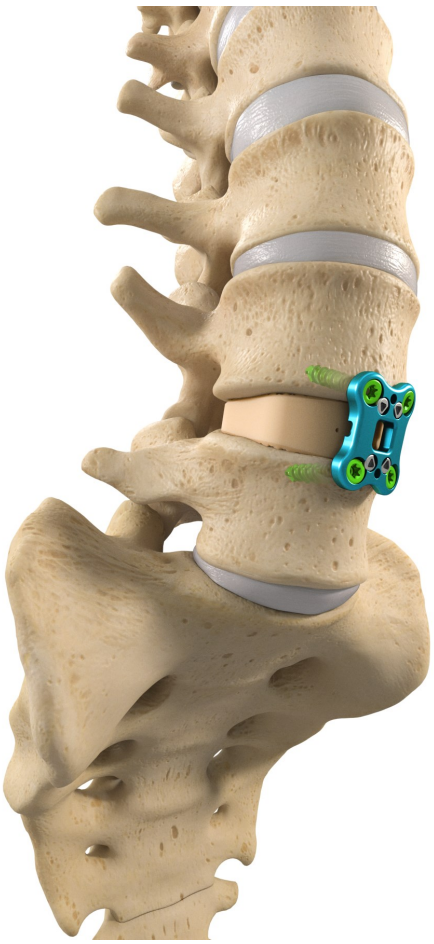
- About your surgical treatment
- Anterior Lumbar Interbody Fusion (ALIF)
- Information about the Aurora-Australis Spinal System
- What to expect from your surgery

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.

# What is an Anterior Lumbar Interbody Fusion (ALIF)?

The primary goal of this procedure is to relieve pressure on either your nerve roots or spinal cord and/or treat your painful disc. Your ALIF surgery will be performed under general anesthesia. When undergoing ALIF surgery with the Aurora-Australis Spinal System, your surgeon will operate on your spine through an incision near the belly button approaching your spine from the front. During surgery, your surgeon will remove the diseased disc and replace it with an Australis ALIF cage filled with bone grafting (fusion) material.  Plate and screws may be used to hold the vertebrae in place while the fusion (bones grow together) occurs.



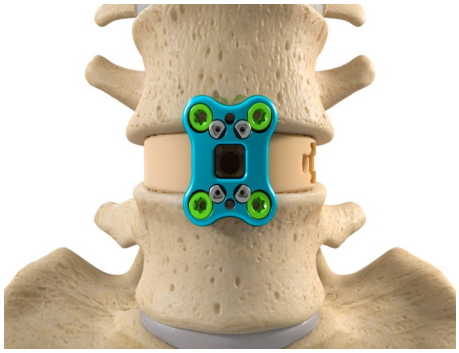
# What is the Aurora and Australis Spinal System?

The Aurora and Australis Spinal System consists of implantable cages, plates and screws. The Aurora-Australis Spinal System implants are intended for Anterior Lumbar Interbody Fusion Surgery (ALIF) in skeletally mature patients by a qualified surgeon. The Australis ALIF cage is made of Polyetheretherketone (PEEK), a medical grade plastic. The Australis cage has three medical grade titanium alloy pins to prevent migration and two 1mm tantalum beads that allow visualization of the cage under fluoroscopy. The Australis cage is intended to replace the painful disc that has been removed by your surgeon.

*Right: Australis ALIF cage implanted in the spine*

The Aurora ALIF plate and screws are made of medical grade titanium alloy. The Aurora plate and screws may be used to hold the vertebrae in place while the fusion (bones grow together) occurs.

*Right: Aurora ALIF plate and screws implanted in the spine.*



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

# 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 Aurora Australis 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 trouble urinating
- 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 Aurora-Australis Spinal System is MR Conditional.


After your surgery, you will have an Aurora and/or Australis 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 Aurora and Australis spinal system instructions for use (IFU), which can be obtained at 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 following;

- Prism Surgical Designs Pty Ltd
  www.prismsurgical.com.au
  +61 7 3720 8882
  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 anterior lumbar interbody fusion surgery. Only your surgeon is qualified to treat your spine.

SURGEON INFORMATION

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.

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