MERIDIAN® WITH REEF® A

ANTERIOR LUMBAR INTERBODY FUSION

PATIENT INFORMATION LEAFLET

SeaSpine

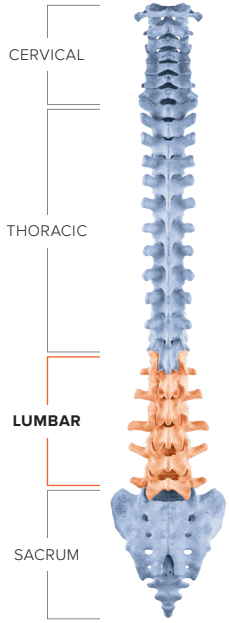
DEVICE TECHNOLOGIES

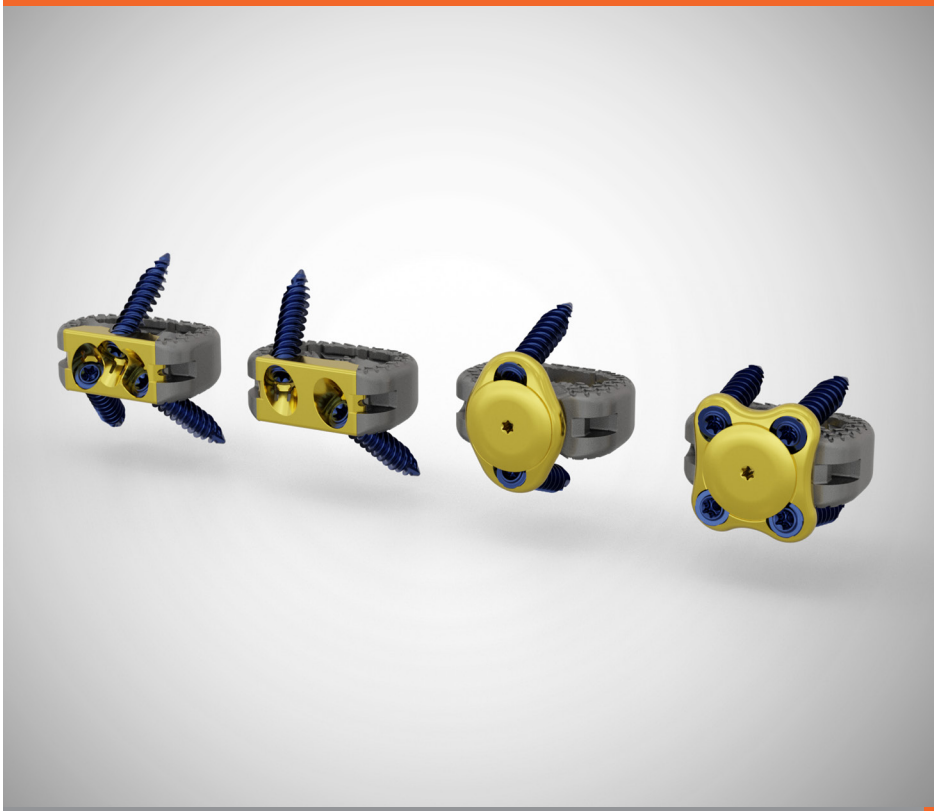
INTRODUCTION

The lumbar spine is made up of five bones called vertebrae. The bones and joints contain and protect the spinal cord, while also allowing motion such as, bending and twisting. The main joint between two vertebrae is called a disc. Each disc is comprised of two parts, a tough and fibrous outer layer (annulus fibrosus), and a soft, gelatinous centre (nucleus pulposus). These two parts play a vital role in allowing and restricting motion.

WHAT IS CAUSING MY PAIN?

Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration of the discs in your lower back. Your surgeon may have diagnosed a herniated disc, disc degeneration, spinal stenosis, or loss of disc height as compared to your other discs. Symptoms of these conditions can include loss of motor function and dexterity, tingling or numbness in the lower extremities, radiating pain, and weakness and/or numbness in your legs.





Meridian® Spinal Implants

WHAT IS AN ANTERIOR LUMBAR INTERBODY FUSION?

An Anterior Lumbar Interbody Fusion (ALIF) is an approach to spinal fusion through which the surgeon will access the lumbar spine via the anterior of the patient's body using a lower abdominal incision. In this procedure, the surgeon will remove the unhealthy disc and place a spacer and plate in its place.

The primary goal of this procedure is to relieve pressure on the nerve roots and/or spinal cord to provide realignment, immobilization, and stabilization of spinal segments in skeletally mature patients. The long-term goal of this surgery is to create fusion, which is the joining of two vertebral bodies.

IS AN ALIF THE RIGHT PROCEDURE FOR ME?

Your surgeon may have indicated that you are a candidate for a for an Anterior Lumbar Interbody Fusion (ALIF). This surgical procedure is intended for skeletally mature patients with Degenerative Disc Disease (DDD), spondylolisthesis, or spinal stenosis of the lumbar spine (L2–S1). Some patients may have had at least six months of nonoperative treatment from the beginning of their symptoms and are still experiencing arm pain and/or neurological symptoms.

DEGENERATIVE DISC DISEASE (DDD)

During the natural aging process, the disc between each vertebral body can lose their flexibility, height, and elasticity which can cause a tear in the tough outer layer of the disc, causing the disc to herniate, bulge, or leak the gelatinous core. The bulges or leakages can end up compressing the nerve roots and/or spinal cord, causing symptoms including, but not limited to lower back and/or leg pain.

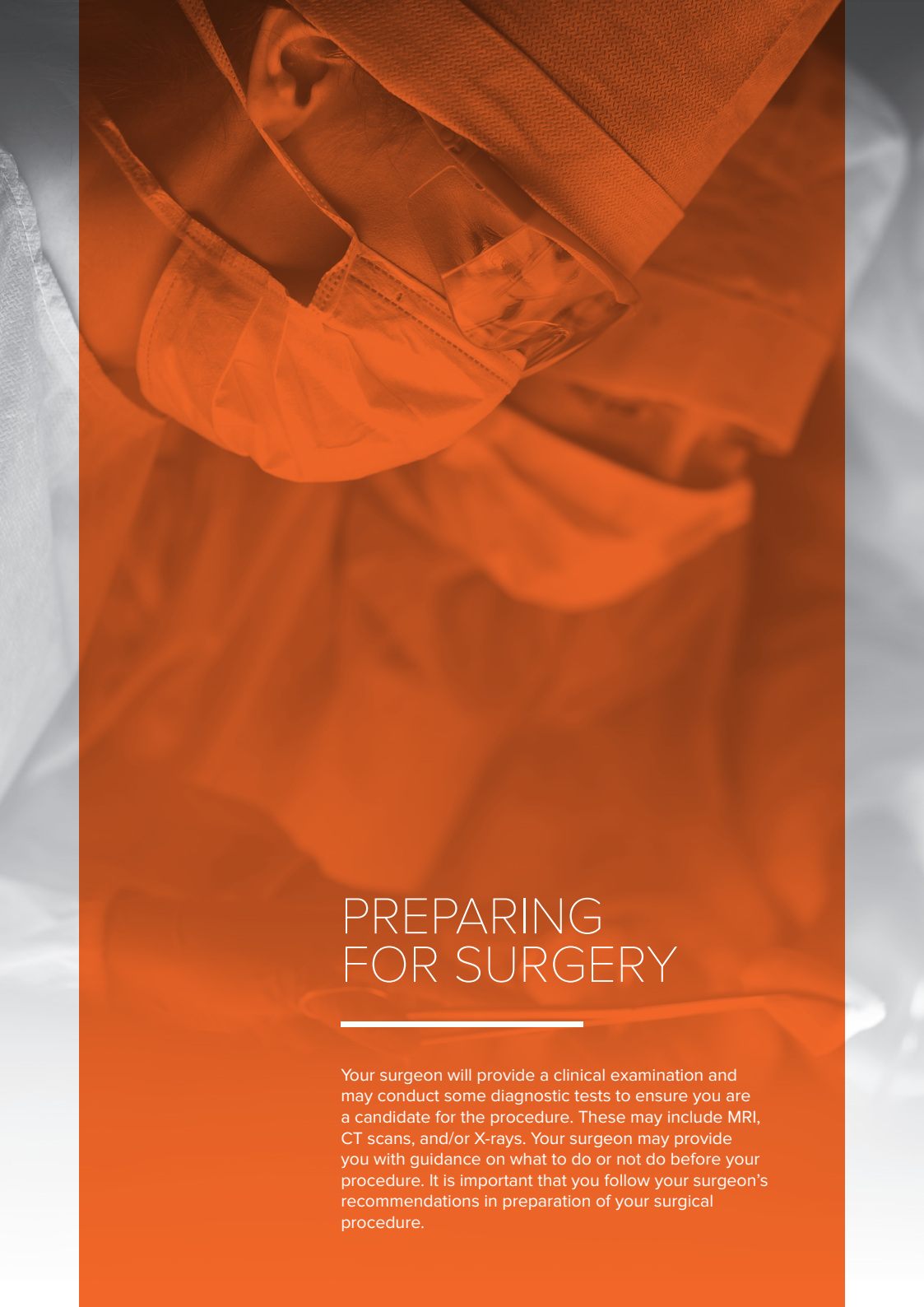
SPONDYLOLISTHESIS

This is a condition in which one vertebral body has slipped forward over another, resulting in compressed nerves, causing pain.

SPINAL STENOSIS

This condition is the narrowing of the spinal canal and nerve root canals, occurring most often in the lower back and the neck.

The Anterior Lumber Interbody Fusion may not be the right procedure for you. It is important to discuss your condition with your surgeon, and treatment options to establish the best treatment plan for you.



PREPARING FOR SURGERY

Your surgeon will provide a clinical examination and may conduct some diagnostic tests to ensure you are a candidate for the procedure. These may include MRI, CT scans, and/or X-rays. Your surgeon may provide you with guidance on what to do or not do before your procedure. It is important that you follow your surgeon's recommendations in preparation of your surgical procedure.

WHAT TO EXPECT DURING SURGERY

After you are sedated, positioned face up, and surrounded by the appropriate surgical draping, an X-ray image is taken to help identify the approach.

STEP 1: APPROACH

Your surgeon will make a small incision on one side of your abdomen. A retractor will be utilised to hold the skin incision open, providing access and visibility to the affected area. The size of the incision can vary based on the number of vertebral levels and/or complexity of your case.

STEP 2: DISC REMOVAL

Once your surgeon has found the affected disc space, they will remove the diseased or damaged disc and prepare the disc space for fusion.

STEP 3: IMPLANT PLACEMENT

An appropriate implant and/or plate, chosen by your surgeon, will be placed into the disc space to restore the proper disc height and provide support while bone grows between the vertebral bodies during the fusion (bone-healing) process. That segment of your spine will eventually stabilise once fusion occurs.

STEP 4: FUSION

With the completed construct, your vertebral bodies will then be allowed to fuse. Fusion means the bone will grow around the affected areas and will eventually stabilise itself. This healing process can take various lengths of time depending on the severity of the condition.

Your surgeon may discuss precautions or other measures that could be taken to avoid potential risk.

WHAT TO EXPECT 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 surgeon will determine the best postoperative course for you. The day after your surgery, your surgeon may instruct you to use a brace for a period of time to assist with the spinal fusion process. Supervised by trained medical professionals, your surgeon may ask you to carefully sit, stand, or walk. Your surgeon will also discuss with you any medications to take home, as well as a prescribed program of activities. Your surgeon will provide instructions on wound care, exercises, and limitations to postoperative activity.

WHAT ARE THE POTENTIAL RISKS?

POSSIBLE ADVERSE EVENTS

Like other spinal system implants, the following adverse events are possible. This list is not exhaustive.

- Delayed union or nonunion (pseudarthrosis).
- Bending, disassembly, or fracture of implant and components.
- Loosening of spinal fixation implants may occur due to inadequate initial fixation, latent infection, and/or premature loading, possibly resulting in bone erosion, migration, or pain.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Subsidence of the implant into adjacent bone.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Increased biomechanical stress on adjacent levels.
- Improper surgical placement of the implant causing stress shielding of the graft or fusion mass.
- Intraoperative fissure, fracture, or perforation of the spine.
- Postoperative fracture due to trauma, defects, or poor bone stock.
- Serious complications associated with any surgery may occur. These include, but are not limited to: wound complications, infection, genitourinary disorders, gastrointestinal disorders, vascular disorders, including thrombus; bronchopulmonary, disorders, including emboli; bursitis, haemorrhage, myocardial infarction, paralysis, or death.

Should you experience any pain or other symptoms outside of what was discussed with your surgeon, please contact your physician immediately.

TECHNICAL INFORMATION

Meridian implants may also have surface technology known as Reef Topography™ (RT). Reef Topography features undercut macrostructures that are meticulously machined into the implant to aid in graft material containment and to create an integrated scaffold for bone to grow into.[1]

- Designed to contain graft material before, during, and after implantation.
- Provides a conduit to central fusion aperture.
- The central aperture and endplate surface channels increase the surface area of the implant for cellular attachment, proliferation and bony ongrowth.[1]

[1] Walsh, W.R.et al. Novel titanium surface improves the osteogenic response of PEEK implants in a sheep model. 2017. Data is available upon request. Preclinical testing, such as animal studies, may not be indicative of human results.

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

TGA & SEASPINE®

CONTACT INFORMATION

A notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the TGA. Any serious incident that occurs in relation to the device should be reported to SeaSpine® via phone, fax, or email. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service: Complaints@seaspine.com and the Therapeutic Goods Administration (TGA): www.tga.gov.au/reporting-problems.

SeaSpine intends that this device should be used only by surgeons having received proper training in the use of the device.

This patient information leaflet has been designed to assist you in understanding a treatment option that your surgeon has advised may be suitable for you to treat your pain, and related problems. The aim of this leaflet is to provide you with information about one treatment option and how this may assist in alleviating your current pain and discomfort.

Reading this leaflet should not take the place of talking with your surgeon. Please read this leaflet in its entirety before your surgery and should you have any further questions ensure you discuss this with your surgeon before proceeding with your surgery.

As with any type of surgery, Anterior Lumbar Interbody Fusion surgery carries risks. Your surgeon will discuss with you the risks associated with you prescribed procedure.

SeaSpine DEVICE TECHNOLOGIES

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Warning: Applicable laws restrict these products to sale by or on the order of a surgeon.

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