MARINER® OUTRIGGER®

POSTERIOR REVISION

PATIENT INFORMATION LEAFLET

SeaSpine

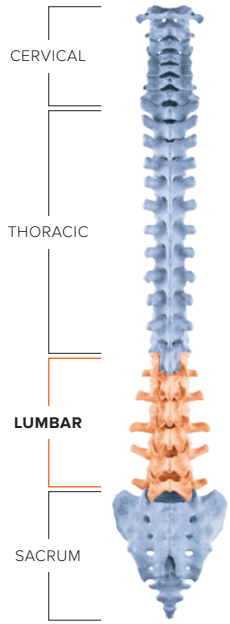
DEVICE TECHNOLOGIES

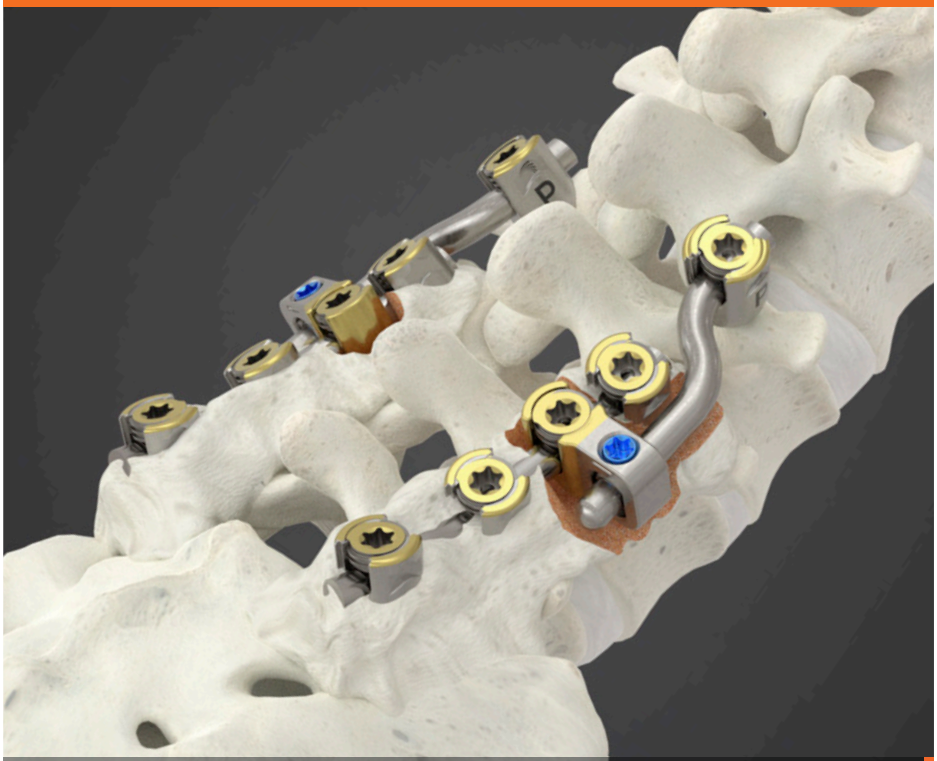
INTRODUCTION

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.





Mariner® Outrigger® Posterior Fixation Spinal Implant

WHAT IS A POSTERIOR REVISION?

Posterior Revision for the lumbar spine is a surgical procedure performed in certain patients to correct the problems of earlier spine surgery. Revision surgery is indicated in patients with chronic pain even after surgery. Failed back syndrome or failed back surgery is a condition used to describe persistent back pain following back surgeries.

The primary goal of revision spine surgery is to reduce pain and resume normal activities. The revision spine surgery is performed in certain conditions, such as re-herniation of a disc, infection, non-fusion, hardware failure, non-surgery related spine degeneration, flat back syndrome, instability, or adjacent segment degeneration.

IS A POSTERIOR REVISION THE RIGHT PROCEDURE FOR ME?

Your surgeon may have suggested that you are a candidate for a posterior revision procedure. Mariner® Outrigger® is intended for skeletally mature patients to assist with fusion surgery for conditions such as failed previous fusion, Degenerative Disc Disease (DDD), spondylolisthesis, and spinal stenosis.

FAILED PREVIOUS FUSION

Failed previous fusion, or pseudarthrosis, happens when a spinal fusion is unsuccessful. In cases of pseudarthrosis, not enough bone formation occurs during the mending period.

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.

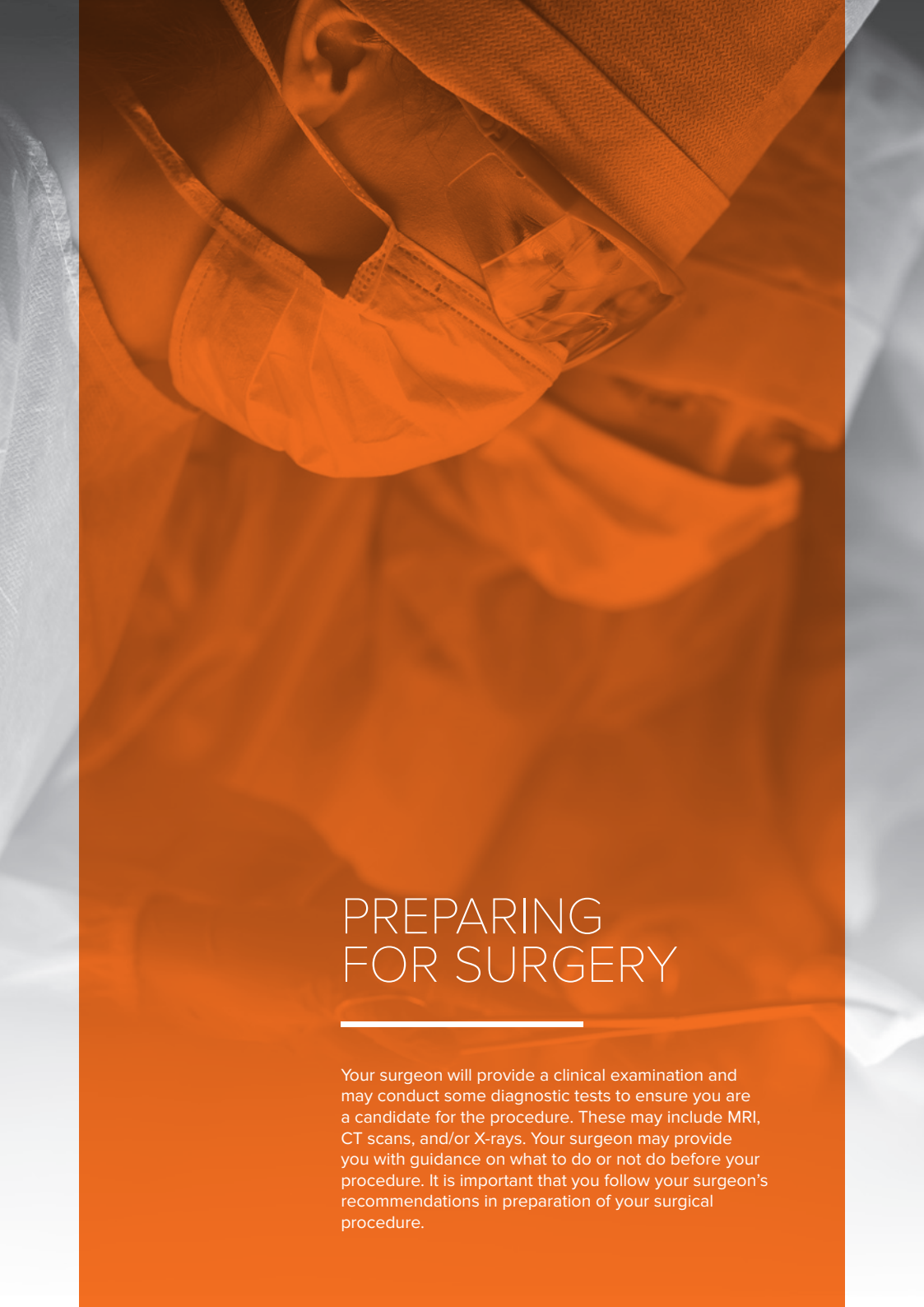
SPONDYLOLISTHESIS

This is a condition in which one vertebral body is 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 Posterior Revision procedure 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

DURING SURGERY

After you are sedated, positioned face down, and surrounded by the appropriate surgical draping, an X-ray image is taken of your spine to identify the location of the operative disc space.

STEP 1: APPROACH

Your surgeon will make a small incision down the midline of your back. A retractor will be utilised to hold the skin incision open, providing access and visibility to the affected area.

STEP 2: DECOMPRESSION

Your surgeon may decide that decompression of the affected vertebrae and discs may be necessary to reduce pressure from the cord or symptomatic nerve root.

STEP 3: STABILISATION OR FIXATION

Your surgeon will use a combination of screws and rods to stabilise or fixate the affected vertebrae. This will act as a stabilisation device (internal brace) to help hold everything in place while fusion occurs. Your surgeon will determine the appropriate fixation implant, if necessary.

STEP 4: FUSION

With the completed construct tightened and locked down, 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.
- Pressure on skin where inadequate tissue coverage exists over the implant, with potential extrusion through the skin.
- 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, hemorrhage, myocardial infarction, paralysis or death.

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

TECHNICAL INFORMATION

SeaSpine® offers a wide range of rod materials to accommodate each patient's needs. With straight and pre-contoured rod options, there are rods available for the most complex cases. The different rod characteristics, such as rod stiffness, bending strength and springback will allow your surgeon to pick the correct rod for your case. Although rare, metal sensitivities and allergic reactions to foreign materials have been reported for orthopedic implant patients. The most common sensitivities, in order of their frequency, are to nickel, cobalt, and chromium. Implant sensitivity reactions to titanium and titanium alloy are much less common.

MATERIALS

- Titanium Alloy (Ti Alloy) – ASTM F136
- Cobalt Chrome (CoCr) – ASTM F1537
- Extra Strength & Stiffness (ESS) – ASTM F562
- Extra Strength & Stiffness + (ESS+) – ASTM F562

Although the Mariner® Outrigger® system is intended to be kept in use for the lifetime of the patient, it is important to comply with your surgeon's postoperative instructions. Surgeons should advise patients to limit or restrict physical activity, especially lifting, twisting, or any type of sports participation. Your surgeon will provide clarity on the length of time to restrict physical activity, and any other postoperative warnings that you should abide by. Postoperative compliance is important for your recovery.

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.

MARINER® OUTRIGGER®

Mariner® Outrigger® Implants

PART NUMBER	PART DESCRIPTION
99-1000-030	Axial, Closed, 30mm
99-1010-12	Parallel, Closed, 8mm
99-1010-14	Parallel, Closed, 8mm
99-1011-12	Parallel, Closed, 16mm
41-1010	Set Screw
99-1014-12	Parallel, Top-Loading, 10mm
99-1014-14	Parallel, Top-Loading, 10mm
99-1015-12	Parallel, Top-Loading, 20mm
99-1015-14	Parallel, Top-Loading, 20mm
99-1012-12	Parallel, Side-Loading, 8mm
99-1012-14	Parallel, Side-Loading, 8mm
99-1016-12	Parallel, Closed/Side-Loading, 8mm
99-1016-14	Parallel, Closed/Side-Loading, 8mm
99-1017-12	Parallel, Closed/Side-Loading, 16mm
99-1018-12	Parallel, Top/Side-Loading, 10mm
99-1023-12	Parallel, Side-Loading/Closed, Variable 8mm
99-1024-12	Parallel, Top Loading/Closed, Variable 10mm
99-1025-12	Parallel, Closed, Variable 8mm
99-1030-100	Z-Rod, Dia. 5.5mm, Titanium, 100mm
99-1030-400	Z-Rod, Dia. 5.5mm, Titanium, 400mm
99-1130-100	Z-Rod, Dia. 6.0mm, Titanium, 100mm
99-1130-400	Z-Rod, Dia. 6.0mm, Titanium, 400mm
99-1050-060-12	L Con, Side-Loading, R, 8mm, 60mm
99-1050-120-12	L Con, Side-Loading, R, 8mm, 120mm
99-1051-060-12	L Con, Side-Loading, L, 8mm, 60mm
99-1051-120-12	L Con, Side-Loading, L, 8mm, 120mm
99-1052-060-12	L Con, Side-Loading, R, 16mm, 60mm
99-1052-120-12	L Con, Side-Loading, R, 16mm, 120mm
99-1053-060-12	L Con, Side-Loading, L, 16mm, 60mm
99-1053-120-12	L Con, Side-Loading, L, 16mm, 120mm
99-1054-060-12	L Con, Closed, R, 8mm, 60mm
99-1054-120-12	L Con, Closed, R, 8mm, 120mm
99-1055-060-12	L Con, Closed, L, 8mm, 60mm
99-1055-120-12	L Con, Closed, L, 8mm, 120mm
99-1022-120	Closed, Axial Rod, Long, 120mm

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.

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, Posterior Lumbar Interbody Fusion surgery carries risks. Your surgeon will discuss with you the risks associated with you prescribed procedure.

SeaSpine DEVICE TECHNOLOGIES

For more information or to place an order, please contact:
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EMEA INQUIRIES intlcustomer@seaspine.com
ALL OTHER INQUIRIES customerservice@seaspine.com

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

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