MARINER®

POSTERIOR FIXATION

PATIENT INFORMATION LEAFLET

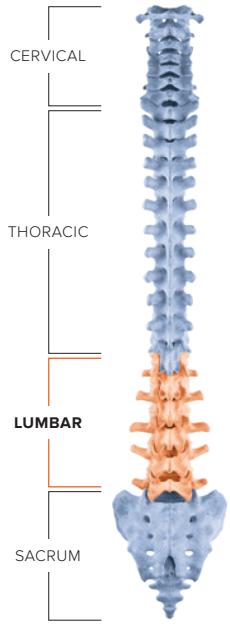
SeaSpine DEVICE TECHNOLOGIES

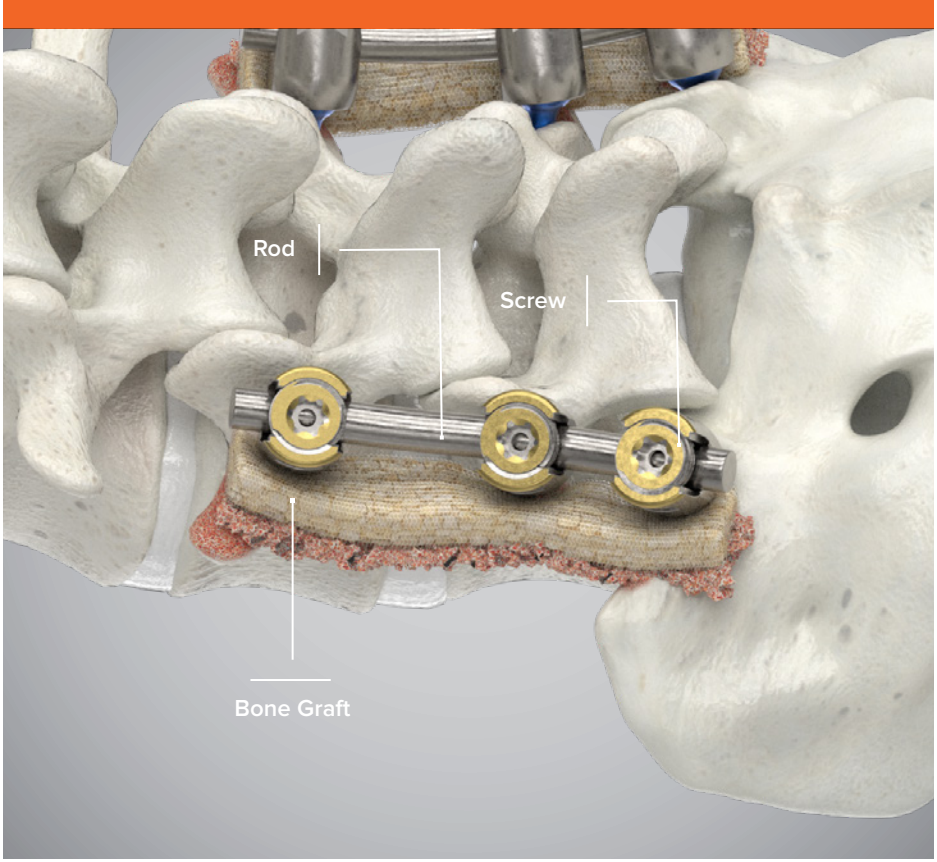
INTRODUCTION

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.





WHAT IS POSTERIOR FIXATION?

Posterior Fixation for the lumbar spine is a surgical procedure performed through an incision down the midline of your back. In this procedure, tissue is retracted or pulled back laterally to expose the affected vertebral bodies. Decompression may be necessary if the symptoms are caused by a compression of the spinal cord and/or nerve roots. Once decompressed, your surgeon will use screws and rods to stabilise or fixate the affected vertebral bodies.

The primary goal of this procedure is to relieve pressure on the nerve roots and/or spinal cord to provide realignment, immobilisation, and stabilisation 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.

Mariner® Posterior Fixation Spinal Implant

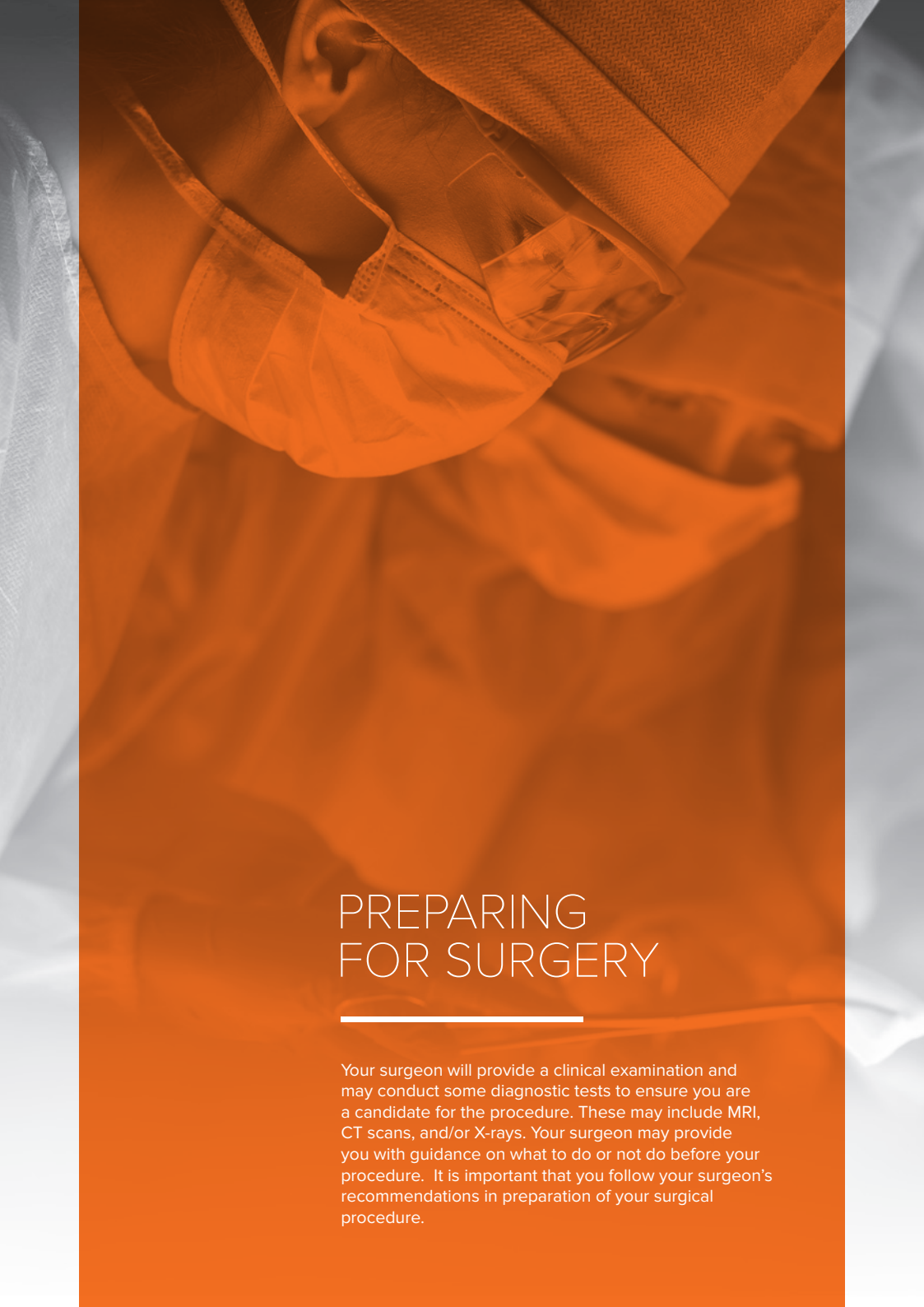
IS POSTERIOR FIXATION THE RIGHT PROCEDURE FOR ME?

Your surgeon may have indicated that you are a candidate for a Posterior Fixation procedure. Mariner® is intended for skeletally mature patients with Degenerative Disc Disease (DDD). Some patients may have had at least six weeks of non-operative 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.

The Posterior Fixation 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 combination 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 doctor, 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.

IMPLANT 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® Screw 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®

Mariner® Implants

PART NUMBER	PART DESCRIPTION
10-1025	Rod, 5.5 x 250mm
10-1045	Rod, 5.5 x 450mm
12-1030	Precontoured Rod, 5.5 x 30mm
12-1035	Precontoured Rod, 5.5 x 35mm
12-1040	Precontoured Rod, 5.5 x 40mm
12-1045	Precontoured Rod, 5.5 x 45mm
12-1050	Precontoured Rod, 5.5 x 50mm
12-1055	Precontoured Rod, 5.5 x 55mm
12-1060	Precontoured Rod, 5.5 x 60mm
12-1065	Precontoured Rod, 5.5 x 65mm
12-1070	Precontoured Rod, 5.5 x 70mm
12-1080	Precontoured Rod, 5.5 x 80mm
12-1090	Precontoured Rod, 5.5 x 90mm
12-1100	Precontoured Rod, 5.5 x 100mm
12-1110	Precontoured Rod, 5.5 x 110mm
12-1120	Precontoured Rod, 5.5 x 120mm
12-2041	Contoured Crossbar, Small, 5.5 Rod
12-2052	Contoured Crossbar, Medium, 5.5 Rod
12-2075	Contoured Crossbar, Large, 5.5 Rod
41-2441	Contoured Crossbar Small 6.0 Rod
41-4241	Contoured Crossbar Small 6.0 Rod
41-4252	Contoured Crossbar Medium 6.0 Rod
41-4275	Contoured Crossbar Large 6.0 Rod
41-1010	Set Screw
41-3010	Polyaxial Head
41-4010	Extended Polyaxial Head
41-5010	Deformity Head
41-5530-2	Cannulated Screw 5.50 x 30mm
41-5535-2	Cannulated Screw 5.50 x 35mm
41-5540-2	Cannulated Screw 5.50 x 40mm
41-5545-2	Cannulated Screw 5.50 x 45mm
41-5550-2	Cannulated Screw 5.50 x 50mm
41-6530-2	Cannulated Screw 6.50 x 30mm
41-6535-2	Cannulated Screw 6.50 x 35mm
41-6540-2	Cannulated Screw 6.50 x 40mm
41-6545-2	Cannulated Screw 6.50 x 45mm
41-6550-2	Cannulated Screw 6.50 x 50mm
41-6555-2	Cannulated Screw 6.50 x 55mm
41-6560-2	Cannulated Screw 6.50 x 60mm
41-7010	Trauma Head

PART NUMBER	PART DESCRIPTION
41-7530-2	Cannulated Screw 7.50 x 30mm
41-7535-2	Cannulated Screw 7.50 x 35mm
41-7540-2	Cannulated Screw 7.50 x 40mm
41-7545-2	Cannulated Screw 7.50 x 45mm
41-7555-2	Cannulated Screw 7.50 x 55mm
41-7560-2	Cannulated Screw 7.50 x 60mm
41-8535-2	Cannulated Screw 8.50 x 35mm
41-8540-2	Cannulated Screw 8.50 x 40mm
41-8545-2	Cannulated Screw 8.50 x 45mm
41-8550-2	Cannulated Screw 8.50 x 50mm
41-8555-2	Cannulated Screw 8.50 x 55mm
41-8560-2	Cannulated Screw 8.50 x 60mm
41-1250	Straight Rod 6.0 x 250mm
41-1450	Straight Rod 6.0 x 450mm
41-15351	Solid Screw 10.50 x 35mm
41-15401	Solid Screw 10.50 x 40mm
41-15451	Solid Screw 10.50 x 45mm
41-15501	Solid Screw 10.50 x 50mm
41-15551	Solid Screw 10.50 x 55mm
41-15601	Solid Screw 10.50 x 60mm
41-15701	Solid Screw 10.50 x 70mm
41-15801	Solid Screw 10.50 x 80mm
41-15901	Solid Screw 10.50 x 90mm
41-15101	Solid Screw 10.50 x 100mm
41-15111	Solid Screw 10.50 x 110mm

MARINER®

Mariner® Implants

PART NUMBER	PART DESCRIPTION
41-2030	Precontoured Rod 6.0 x 30mm
41-2035	Precontoured Rod 6.0 x 35mm
41-2040	Precontoured Rod 6.0 x 40mm
41-2045	Precontoured Rod 6.0 x 45mm
41-2050	Precontoured Rod 6.0 x 50mm
41-2055	Precontoured Rod 6.0 x 55mm
41-2060	Precontoured Rod 6.0 x 60mm
41-2065	Precontoured Rod 6.0 x 65mm
41-2070	Precontoured Rod 6.0 x 70mm
41-2080	Precontoured Rod 6.0 x 80mm
41-2090	Precontoured Rod 6.0 x 90mm
41-2100	Precontoured Rod 6.0 x 100mm
41-2110	Precontoured Rod 6.0 x 110mm
41-2120	Precontoured Rod 6.0 x 120mm
41-4525-1	Solid Screw 4.50 x 25mm
41-4530-1	Solid Screw 4.50 x 30mm
41-4535-1	Solid Screw 4.50 x 35mm
41-4540-1	Solid Screw 4.50 x 40mm
41-4545-1	Solid Screw 4.50 x 45mm
41-5530-1	Solid Screw 5.50 x 30mm
41-5535-1	Solid Screw 5.50 x 35mm
41-5540-1	Solid Screw 5.50 x 40mm
41-5545-1	Solid Screw 5.50 x 45mm
41-5550-1	Solid Screw 5.50 x 50mm
41-6010	Extended Deformity Head
41-6530-1	Solid Screw 6.50 x 30mm
41-6535-1	Solid Screw 6.50 x 35mm
41-6540-1	Solid Screw 6.50 x 40mm
41-6545-1	Solid Screw 6.50 x 45mm
41-6550-1	Solid Screw 6.50 x 50mm
41-6555-1	Solid Screw 6.50 x 55mm
41-6560-1	Solid Screw 6.50 x 60mm
41-7530-1	Solid Screw 7.50 x 30mm
41-7535-1	Solid Screw 7.50 x 35mm
41-7540-1	Solid Screw 7.50 x 40mm
41-7545-1	Solid Screw 7.50 x 45mm
41-7550-1	Solid Screw 7.50 x 50mm
41-7555-1	Solid Screw 7.50 x 55mm
41-7560-1	Solid Screw 7.50 x 60mm
41-8010	Extended Trauma Head

PART NUMBER	PART DESCRIPTION
41-8535-1	Solid Screw 8.50 x 35mm
41-8540-1	Solid Screw 8.50 x 40mm
41-8545-1	Solid Screw 8.50 x 45mm
41-8550-1	Solid Screw 8.50 x 50mm
41-8555-1	Solid Screw 8.50 x 55mm
41-8560-1	Solid Screw 8.50 x 60mm
41-8570-1	Solid Screw 8.50 x 70mm
41-8580-1	Solid Screw 8.50 x 80mm
41-8590-1	Solid Screw 8.50 x 90mm
41-8510-1	Solid Screw 8.50 x 100mm
41-8511-1	Solid Screw 8.50 x 110mm
41-9535-1	Solid Screw 9.50 x 35mm
41-9540-1	Solid Screw 9.50 x 40mm
41-9545-1	Solid Screw 9.50 x 45mm
41-9550-1	Solid Screw 9.50 x 50mm
41-9555-1	Solid Screw 9.50 x 55mm
41-9560-1	Solid Screw 9.50 x 60mm
41-9570-1	Solid Screw 9.50 x 70mm
41-9580-1	Solid Screw 9.50 x 80mm
41-9590-1	Solid Screw 9.50 x 90mm
41-9510-1	Solid Screw 9.50 x 100mm
41-9511-1	Solid Screw 9.50 x 110mm

MALIBU™

Malibu™ Implants

PART NUMBER	PART DESCRIPTION
10-1030	Rod 5.5 x 300mm
10-1060	Rod 5.5 x 600mm
10-3150	Bullet Nose Rod 5.5 x 150mm
10-3170	Bullet Nose Rod 5.5 x 170mm
10-3190	Bullet Nose Rod 5.5 x 190mm
10-3210	Bullet Nose Rod 5.5 x 210mm
10-3230	Bullet Nose Rod 5.5 x 230mm
11-2028	Crossbar xxsmall 5.5 Rod
11-2037	Crossbar xsmall 5.5 Rod
12-0010	Locking Cap
12-0020	Locking Cap 8.0+ (Gold)
12-0045	Rod Connector 5.5 x 5.5
12-0046	Rod Connector 6.35 x 6.35
12-0047	Rod Connector 5.5/6.35
12-0051	Closed Lateral Connector 5.5 x 30mm
12-0052	Closed Lateral Connector 5.5 x 45mm
12-0053	Closed Lateral Connector 5.5 x 60mm
12-1300	Precontoured Ti Rod 5.5 x 300mm
12-1400	Precontoured Ti Rod 5.5 x 400mm
12-1500	Precontoured Ti Rod 5.5 x 500mm
12-4525	Polyaxial Screw Dia 4.5 x 25mm
12-4530	Polyaxial Screw Dia 4.5 x 30mm
12-4535	Polyaxial Screw Dia 4.5 x 35mm
12-4540	Polyaxial Screw Dia 4.5 x 40mm

PART NUMBER	PART DESCRIPTION
12-5530	Polyaxial Screw 5.5 x 30mm
12-5535	Polyaxial Screw 5.5 x 35mm
12-5540	Polyaxial Screw 5.5 x 40mm
12-5545	Polyaxial Screw 5.5 x 45mm
12-5550	Polyaxial Screw 5.5 x 50mm
12-6535	Polyaxial Screw 6.5 x 35mm
12-6540	Polyaxial Screw 6.5 x 40mm
12-6545	Polyaxial Screw 6.5 x 45mm
12-6550	Polyaxial Screw 6.5 x 50mm
12-6555	Polyaxial Screw 6.5 x 55mm
12-7535	Polyaxial Screw 7.5 x 35mm
12-7540	Polyaxial Screw 7.5 x 40mm
12-7545	Polyaxial Screw 7.5 x 45mm
12-7550	Polyaxial Screw 7.5 x 50mm
12-7555	Polyaxial Screw 7.5 x 55mm
12-8500	Polyaxial Screw 8.5 x 100mm
12-8510	Polyaxial Screw 8.5 x 110mm
12-8535	Polyaxial Screw 8.5 x 35mm
12-8540	Polyaxial Screw 8.5 x 40mm
12-8545	Polyaxial Screw 8.5 x 45mm
12-8550	Polyaxial Screw 8.5 x 50mm
12-8555	Polyaxial Screw 8.5 x 55mm
12-8560	Polyaxial Screw 8.5 x 60mm
12-8570	Polyaxial Screw 8.5 x 70mm
12-8580	Polyaxial Screw 8.5 x 80mm
12-8590	Polyaxial Screw 8.5 x 90mm
13-5540	Polyaxial Reduct Screw 5.5 x 40mm
13-5545	Polyaxial Reduct Screw 5.5 x 45mm
13-6540	Polyaxial Reduct Screw 6.5 x 40mm
13-6545	Polyaxial Reduct Screw 6.5 x 45mm
13-6550	Polyaxial Reduct Screw 6.5 x 50mm
13-7540	Polyaxial Reduct Screw 7.5 x 40mm
13-7545	Polyaxial Reduct Screw 7.5 x 45mm
13-7550	Polyaxial Reduct Screw 7.5 x 50mm

MALIBU™

Malibu™ Implants

PART NUMBER	PART DESCRIPTION
15-2250	ESS Plus Rod 5.5 x 250mm
15-2450	ESS Plus Rod 5.5 x 450mm
15-3300	Prebent ESS Plus Rod 5.5 x 300mm
15-3400	Prebent ESS Plus Rod 5.5 x 400mm
15-3500	Prebent ESS Plus Rod 5.5 x 500mm
15-4525	Dlta Screw 4.5 x 25mm
15-4530	Dlta Screw 4.5 x 30mm
15-4535	Dlta Screw 4.5 x 35mm
15-4540	Dlta Screw 4.5 x 40mm
15-5525	Dlta Screw 5.5 x 25mm
15-5530	Dlta Screw 5.5 x 30mm
15-5535	Dlta Screw 5.5 x 35mm
15-5540	Dlta Screw 5.5 x 40mm
15-5545	Dlta Screw 5.5 x 45mm
15-5550	Dlta Screw 5.5 x 50mm
15-6530	Dlta Screw 6.5 x 30mm
15-6535	Dlta Screw 6.5 x 35mm
15-6540	Dlta Screw 6.5 x 40mm
15-6545	Dlta Screw 6.5 x 45mm
15-6550	Dlta Screw 6.5 x 50mm
15-6555	Dlta Screw 6.5 x 55mm
15-7535	Dlta Screw 7.5 x 35mm
15-7540	Dlta Screw 7.5 x 40mm
15-7545	Dlta Screw 7.5 x 45mm
15-7550	Dlta Screw 7.5 x 50mm
15-7555	Dlta Screw 7.5 x 55mm

PART NUMBER	PART DESCRIPTION
17-0565	Angled Hook 5.5 x 6.5mm Left
17-1565	Angled Hook 5.5 x 6.5mm Right
17-2595	Offset Hook 5.5 x 9.5mm Left
17-3595	Offset Hook 5.5 x 9.5mm Right
17-5550	Laminar Hook 5.5 x 5.0mm
17-5565	Laminar Hook 5.5 x 6.5mm
17-5580	Laminar Hook 5.5 x 8.0mm
17-5595	Laminar Hook 5.5 x 9.5mm
17-7050	Laminar Hook 7.0 x 5.0mm
17-7065	Laminar Hook 7.0 x 6.5mm
17-7080	Laminar Hook 7.0 x 8.0mm
17-7095	Laminar Hook 7.0 x 9.5mm
17-7550	Pedicle Hook 7.5 x 5.0mm
17-7565	Pedicle Hook 7.5 x 6.5mm
17-7580	Pedicle Hook 7.5 x 8.0mm
17-7595	Pedicle Hook 7.5 x 9.5mm
17-9050	Pedicle Hook 9.0 x 5.0mm
17-9065	Pedicle Hook 9.0 x 6.5mm
17-9080	Pedicle Hook 9.0 x 8.0mm
17-9095	Pedicle Hook 9.0 x 9.5mm
69-5535	Uni Planar Dlta Screw 5.5 Dia x 35mm
69-6540	Uni Planar Dlta Screw 6.5 Dia x 40mm
69-6545	Uni Planar Dlta Screw 6.5 Dia x 45mm

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. 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 Fixation surgery carries risks. Your surgeon will discuss with you the risks associated with you prescribed procedure.

SeaSpine DEVICE TECHNOLOGIES

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Date of Release December 31, 2021