REEF® TO & REEF TA

POSTERIOR LUMBAR INTERBODY FUSION

PATIENT INFORMATION LEAFLET

SeaSpine

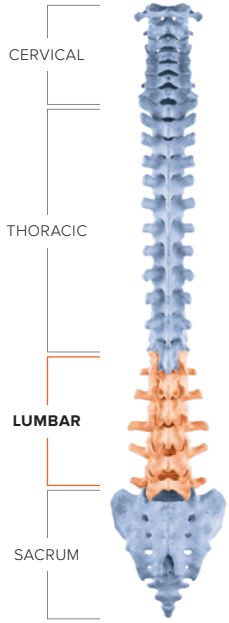
DEVICE TECHNOLOGIES

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.



Reef® TO and Reef TA Spinal Implants

WHAT IS A POSTERIOR LUMBAR INTERBODY FUSION?

A Posterior Lumbar Interbody Fusion (PLIF) for the lumbar spine is a surgical procedure that attempts to eliminate instability and relieve pain in the lower back and lower extremities. This procedure is performed through an incision down the midline of your back tissue. The unhealthy disc is removed, then replaced with a synthetic spacer, screws and rods for added stabilisation.

The Reef® TO (TLIF Oblique) and Reef TA (TLIF Articulating) Implants are intervertebral spacers that are used to fill the area where your disc has been removed. These spacers are used in conjunction with bone graft to help promote fusion within the disc space. It is then fixed in place by screws and rods to encourage fusion.

The primary goal of this procedure is to relieve pressure on the nerve roots and/or spinal cord. The long-term goal of this surgery is to create fusion, which is the joining of two or more vertebral bodies.

IS A POSTERIOR LUMBAR INTERBODY FUSION THE RIGHT PROCEDURE FOR ME?

Your surgeon may have indicated that you are a candidate for a for a Posterior Lumbar Interbody Fusion (PLIF). 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.

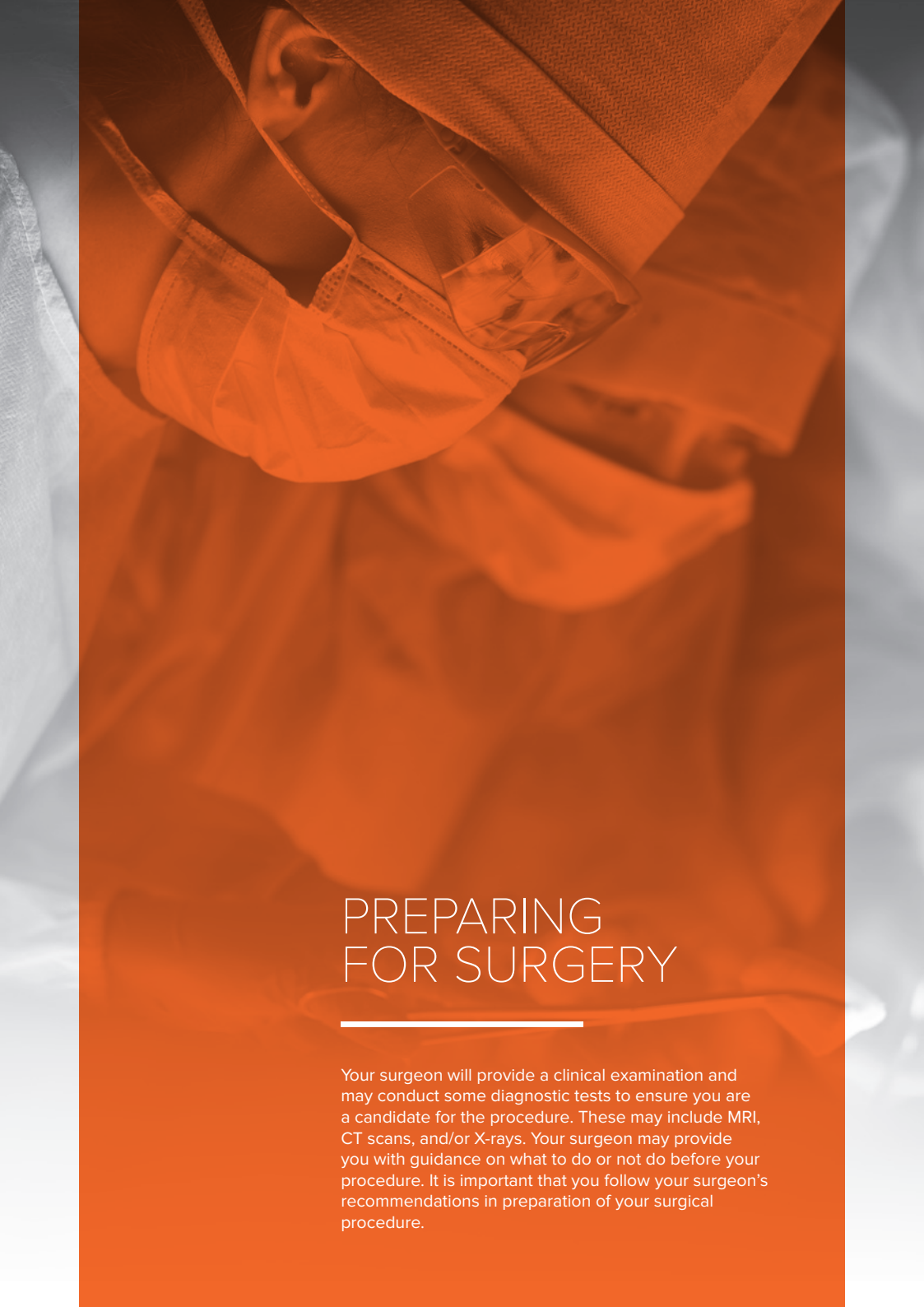
SPONDYLOLISTHESIS

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 Posterior 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 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. The size of the incision can vary based on the number of vertebral levels and/or complexity of your case.

STEP 2: SCREW PLACEMENT AND DECOMPRESSION

Your surgeon will place screws in the affected vertebrae which will be utilised for stabilisation at the end of the procedure. Your surgeon will then remove any bony anatomy that is causing your back and/or leg pain to help reduce pressure from the cord or symptomatic nerve roots.

STEP 3: DISC REMOVAL AND IMPLANT PLACEMENT

Your surgeon will then remove the diseased or damaged disc and prepare the disc space for fusion. An appropriate implant, 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

Your surgeon will now stabilize the spine by connecting rods to the previously placed screws. 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, 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 surgeon immediately.

TECHNICAL INFORMATION

Reef® TO (TLIF Oblique) & Reef TA (TLIF Articulating) implants are made of a biocompatible material known as PEEK, with small tantalum and titanium markers* used to help the surgeon clearly see the implant through X-ray images.

These implants also have less than one-micron (submicron) thick layer of commercially pure titanium, known as NanoMetalene®.

- Submicron titanium layer bonded to entire PEEK implant.
- Titanium surfacing resists wear debris.[1]
- Radiolucent for post-op fusion assessment.[2]
- Mechanical properties of PEEK unaltered, providing stiffness on par with bone.[1]

Reef TO & TA implants also feature a surface technology known as Reef Topography™ (RT). Reef Topography (RT) 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.[3]

- Endplate undercut macrostructures and aperture undercut macrostructures result in ~3x increase in mechanical stability†,[4]
- Reef Topography drives earlier and improved biomechanical stability†,[4]

Although the Reef® TO and Reef TA implants are 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.

† Preclinical testing, such as animal studies, may not be indicative of human results.

[1] Results from mechanical testing. Data on file. TR-0010-11-01

[2] Results from imaging study. Data on file. TR-0010-11-01

[3] Walsh, et al. The in vivo response to a novel Ti coating compared with polyether ether ketone: evaluation of the periphery and inner surfaces of an implant. Spine Journal 2018 Jul; 18(7): 1231-1240

[4] Results from preclinical in vivo testing. Data on File. D0003269

REEF® TO

9 x 24mm Implants

PART NUMBER	PART DESCRIPTION
TO1-924074	Interbody, 9 x 24 x 7mm, 5°
TO1-924084	Interbody, 9 x 24 x 8mm, 5°
TO1-924094	Interbody, 9 x 24 x 9mm, 5°
TO1-924104	Interbody, 9 x 24 x 10mm, 5°
TO1-924114	Interbody, 9 x 24 x 11mm, 5°
TO1-924124	Interbody, 9 x 24 x 12mm, 5°
TO1-924134	Interbody, 9 x 24 x 13mm, 5°
TO1-924144	Interbody, 9 x 24 x 14mm, 5°
TO1-924154	Interbody, 9 x 24 x 15mm, 5°
TO1-924081	Interbody, 9 x 24 x 8mm, 10°
TO1-924091	Interbody, 9 x 24 x 9mm, 10°
TO1-924101	Interbody, 9 x 24 x 10mm, 10°
TO1-924111	Interbody, 9 x 24 x 11mm, 10°
TO1-924121	Interbody, 9 x 24 x 12mm, 10°
TO1-924131	Interbody, 9 x 24 x 13mm, 10°
TO1-924141	Interbody, 9 x 24 x 14mm, 10°
TO1-924151	Interbody, 9 x 24 x 15mm, 10°

9 x 28mm Implants

PART NUMBER	PART DESCRIPTION
TO1-928074	Interbody, 9 x 28 x 7mm, 5°
TO1-928084	Interbody, 9 x 28 x 8mm, 5°
TO1-928094	Interbody, 9 x 28 x 9mm, 5°
TO1-928104	Interbody, 9 x 28 x 10mm, 5°
TO1-928114	Interbody, 9 x 28 x 11mm, 5°
TO1-928124	Interbody, 9 x 28 x 12mm, 5°
TO1-928134	Interbody, 9 x 28 x 13mm, 5°
TO1-928144	Interbody, 9 x 28 x 14mm, 5°
TO1-928154	Interbody, 9 x 28 x 15mm, 5°
TO1-928091	Interbody, 9 x 28 x 9mm, 10°
TO1-928101	Interbody, 9 x 28 x 10mm, 10°
TO1-928111	Interbody, 9 x 28 x 11mm, 10°
TO1-928121	Interbody, 9 x 28 x 12mm, 10°
TO1-928131	Interbody, 9 x 28 x 13mm, 10°
TO1-928141	Interbody, 9 x 28 x 14mm, 10°
TO1-928151	Interbody, 9 x 28 x 15mm, 10°
TO1-928161	Interbody, 9 x 28 x 16mm, 10°

9 x 24mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TO1-924095	Interbody, 9 x 24 x 9mm, 15°
TO1-924105	Interbody, 9 x 24 x 10mm, 15°
TO1-924115	Interbody, 9 x 24 x 11mm, 15°
TO1-924125	Interbody, 9 x 24 x 12mm, 15°
TO1-924135	Interbody, 9 x 24 x 13mm, 15°
TO1-924145	Interbody, 9 x 24 x 14mm, 15°
TO1-924155	Interbody, 9 x 24 x 15mm, 15°
TO1-924165	Interbody, 9 x 24 x 16mm, 15°

9 x 28mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TO1-928105	Interbody, 9 x 28 x 10mm, 15°
TO1-928115	Interbody, 9 x 28 x 11mm, 15°
TO1-928125	Interbody, 9 x 28 x 12mm, 15°
TO1-928135	Interbody, 9 x 28 x 13mm, 15°
TO1-928145	Interbody, 9 x 28 x 14mm, 15°
TO1-928155	Interbody, 9 x 28 x 15mm, 15°
TO1-928165	Interbody, 9 x 28 x 16mm, 15°

9 x 28mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TO1924112	Interbody, 9 x 24 x 11mm, 22°
TO1924122	Interbody, 9 x 24 x 12mm, 22°
TO1924132	Interbody, 9 x 24 x 13mm, 22°
TO1924142	Interbody, 9 x 24 x 14mm, 22°
TO1924152	Interbody, 9 x 24 x 15mm, 22°
TO1924162	Interbody, 9 x 24 x 16mm, 22°

11 x 28mm Implants

PART NUMBER	PART DESCRIPTION
TO1-128074	Interbody, 11 x 28 x 7mm, 5°
TO1-128084	Interbody, 11 x 28 x 8mm, 5°
TO1-128094	Interbody, 11 x 28 x 9mm, 5°
TO1-128104	Interbody, 11 x 28 x 10mm, 5°
TO1-128114	Interbody, 11 x 28 x 11mm, 5°
TO1-128124	Interbody, 11 x 28 x 12mm, 5°
TO1-128134	Interbody, 11 x 28 x 13mm, 5°
TO1-128144	Interbody, 11 x 28 x 14mm, 5°
TO1-128154	Interbody, 11 x 28 x 15mm, 5°
TO1-128091	Interbody, 11 x 28 x 9mm, 10°
TO1-128101	Interbody, 11 x 28 x 10mm, 10°
TO1-128111	Interbody, 11 x 28 x 11mm, 10°
TO1-128121	Interbody, 11 x 28 x 12mm, 10°
TO1-128131	Interbody, 11 x 28 x 13mm, 10°
TO1-128141	Interbody, 11 x 28 x 14mm, 10°
TO1-128151	Interbody, 11 x 28 x 15mm, 10°
TO1-128161	Interbody, 11 x 28 x 16mm, 10°

11 x 32mm Implants

PART NUMBER	PART DESCRIPTION
TO1-132084	Interbody, 11 x 32 x 8mm, 5°
TO1-132094	Interbody, 11 x 32 x 9mm, 5°
TO1-132104	Interbody, 11 x 32 x 10mm, 5°
TO1-132114	Interbody, 11 x 32 x 11mm, 5°
TO1-132124	Interbody, 11 x 32 x 12mm, 5°
TO1-132134	Interbody, 11 x 32 x 13mm, 5°
TO1-132144	Interbody, 11 x 32 x 14mm, 5°
TO1-132154	Interbody, 11 x 32 x 15mm, 5°
TO1-132101	Interbody, 11 x 32 x 10mm, 10°
TO1-132111	Interbody, 11 x 32 x 11mm, 10°
TO1-132121	Interbody, 11 x 32 x 12mm, 10°
TO1-132131	Interbody, 11 x 32 x 13mm, 10°
TO1-132141	Interbody, 11 x 32 x 14mm, 10°
TO1-132151	Interbody, 11 x 32 x 15mm, 10°
TO1-132161	Interbody, 11 x 32 x 16mm, 10°

11 x 28mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TO1-128105	Interbody, 11 x 28 x 10mm, 15°
TO1-128115	Interbody, 11 x 28 x 11mm, 15°
TO1-128125	Interbody, 11 x 28 x 12mm, 15°
TO1-128135	Interbody, 11 x 28 x 13mm, 15°
TO1-128145	Interbody, 11 x 28 x 14mm, 15°
TO1-128155	Interbody, 11 x 28 x 15mm, 15°
TO1-128165	Interbody, 11 x 28 x 16mm, 15°

11 x 32mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TO1-132115	Interbody, 11 x 32 x 11mm, 15°
TO1-132125	Interbody, 11 x 32 x 12mm, 15°
TO1-132135	Interbody, 11 x 32 x 13mm, 15°
TO1-132145	Interbody, 11 x 32 x 14mm, 15°
TO1-132155	Interbody, 11 x 32 x 15mm, 15°
TO1-132165	Interbody, 11 x 32 x 16mm, 15°

REEF® TA

9 x 28mm Implants, 8°

PART NUMBER	PART DESCRIPTION
TA1-928098	Interbody, 9 x 28 x 9mm, 8°
TA1-928108	Interbody, 9 x 28 x 10mm, 8°
TA1-928118	Interbody, 9 x 28 x 11mm, 8°
TA1-928128	Interbody, 9 x 28 x 12mm, 8°
TA1-928138	Interbody, 9 x 28 x 13mm, 8°
TA1-928148	Interbody, 9 x 28 x 14mm, 8°
TA1-928158	Interbody, 9 x 28 x 15mm, 8°
TA1-928088	Interbody, 9 x 28 x 8mm, 8°

9 x 32mm Implants, 8°

PART NUMBER	PART DESCRIPTION
TA1-932088	Interbody, 9 x 32 x 8mm, 8°
TA1-932098	Interbody, 9 x 32 x 9mm, 8°
TA1-932108	Interbody, 9 x 32 x 10mm, 8°
TA1-932118	Interbody, 9 x 32 x 11mm, 8°
TA1-932128	Interbody, 9 x 32 x 12mm, 8°
TA1-932138	Interbody, 9 x 32 x 13mm, 8°
TA1-932148	Interbody, 9 x 32 x 14mm, 8°
TA1-932158	Interbody, 9 x 32 x 15mm, 8°

9 x 28mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TA1-928095	Interbody, 9 x 28 x 9mm, 15°
TA1-928105	Interbody, 9 x 28 x 10mm, 15°
TA1-928115	Interbody, 9 x 28 x 11mm, 15°
TA1-928125	Interbody, 9 x 28 x 12mm, 15°
TA1-928135	Interbody, 9 x 28 x 13mm, 15°
TA1-928145	Interbody, 9 x 28 x 14mm, 15°
TA1-928155	Interbody, 9 x 28 x 15mm, 15°
TA1-928165	Interbody, 9 x 28 x 16mm, 15°

9 x 32mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TA1-932095	Interbody, 9 x 32 x 9mm, 15°
TA1-932105	Interbody, 9 x 32 x 10mm, 15°
TA1-932115	Interbody, 9 x 32 x 11mm, 15°
TA1-932125	Interbody, 9 x 32 x 12mm, 15°
TA1-932135	Interbody, 9 x 32 x 13mm, 15°
TA1-932145	Interbody, 9 x 32 x 14mm, 15°
TA1-932155	Interbody, 9 x 32 x 15mm, 15°

11 x 36mm Implants, 8°

PART NUMBER	PART DESCRIPTION
TA1-136088	Interbody, 11 x 36 x 8mm, 8°
TA1-136098	Interbody, 11 x 36 x 9mm, 8°
TA1-136108	Interbody, 11 x 36 x 10mm, 8°
TA1-136118	Interbody, 11 x 36 x 11mm, 8°
TA1-136128	Interbody, 11 x 36 x 12mm, 8°
TA1-136138	Interbody, 11 x 36 x 13mm, 8°
TA1-136148	Interbody, 11 x 36 x 14mm, 8°
TA1-136158	Interbody, 11 x 36 x 15mm, 8°

11 x 36mm Implants, 15°

PART NUMBER	PART DESCRIPTION
TA1-136095	Interbody, 11 x 36 x 9mm, 15°
TA1-136105	Interbody, 11 x 36 x 10mm, 15°
TA1-136115	Interbody, 11 x 36 x 11mm, 15°
TA1-136125	Interbody, 11 x 36 x 12mm, 15°
TA1-136135	Interbody, 11 x 36 x 13mm, 15°
TA1-136145	Interbody, 11 x 36 x 14mm, 15°
TA1-136155	Interbody, 11 x 36 x 15mm, 15°
TA1-136165	Interbody, 11 x 36 x 16mm, 15°

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

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

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