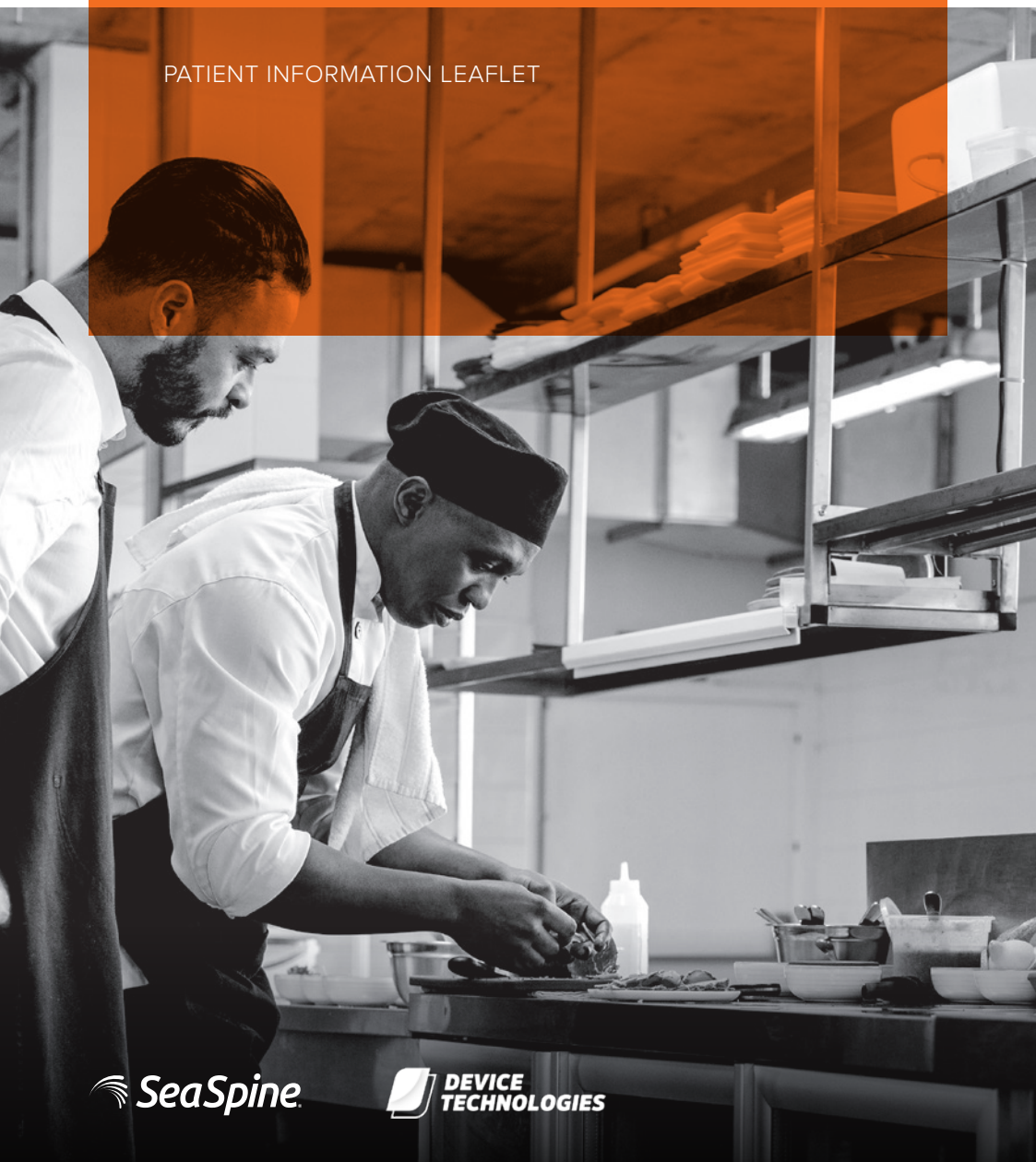
REGATTA®

LATERAL LUMBAR INTERBODY FUSION

PATIENT INFORMATION LEAFLET



SeaSpine

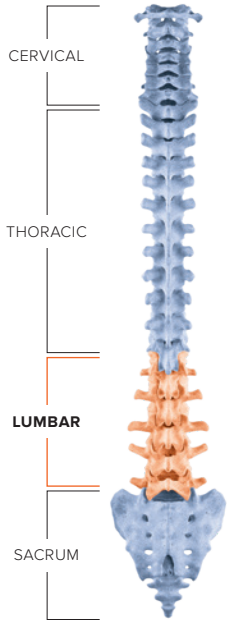
DEVICE TECHNOLOGIES

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.



WHAT IS A LATERAL LUMBAR INTERBODY FUSION?

A Lateral Lumbar Interbody Fusion (LLIF) is a minimally invasive surgical procedure performed through an incision on the side of the body. In this procedure, the unhealthy disc is removed, then replaced with a spacer, screws and/or a plate for added stabilisation.

The Regatta® System is comprised of an intervertebral spacer that is used to fill the area where your disc has been removed. This spacer is used in conjunction with bone graft or bone graft substitute to help promote fusion within the disc space. It is then fixed in place by screws and sometimes accompanied by a plate to provide supplemental fixation.

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 vertebral bodies. The lateral approach of this surgery provides a less invasive approach to the afflicted area, leading to less incisional pain.

Regatta® Lateral Lumbar Interbody

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

Your surgeon may have indicated that you are a candidate for a Lateral Lumbar Interbody Fusion (LLIF). Regatta® is intended for skeletally mature patients with Degenerative Disc Disease (DDD), spondylolisthesis, spinal stenosis, or scoliosis in the lumbar spine (L1-L5). Some patients may have had at least six weeks 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 is slipped forward over another, resulting in compressed nerves, causing pain.

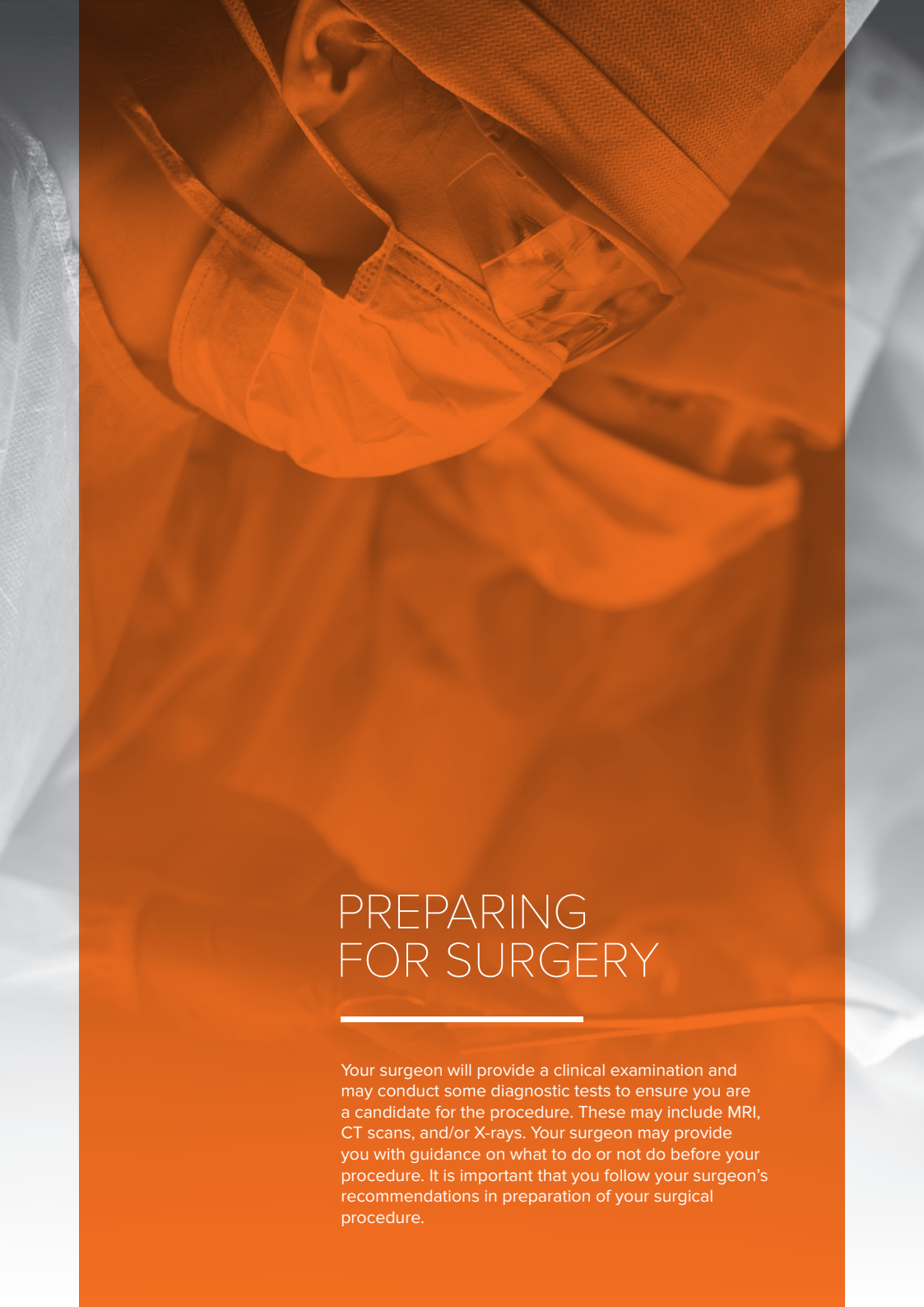
SPINAL STENOSIS

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

SCOLIOSIS

This condition is an abnormal curve of the spine caused by misalignment of the bones. In adults this occurs from aging discs, arthritis, or previous spine surgery.

The Lateral Lumbar 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 on your side, 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 on the lateral (side) of your body. Dilators will be used to direct the path to the affected disc space while monitoring the local nerves. Once the optimal path has been determined, a retractor will be utilised to hold the skin incision open, providing access and visibility to the affected area.

STEP 2: DISC REMOVAL

The diseased or damaged disc is removed to reduce pressure from the cord or symptomatic nerve root.

STEP 3: IMPLANT

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

STEP 4: FIXATION

Supplemental fixation is required. Some method of internal fixation will be used to act as a stabilisation device (internal brace) to help hold everything in place while fusion occurs. This could be a combination of screws and plates that are affixed to the adjacent vertebrae. Your surgeon will determine the kind of fixation used.

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, 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

Regatta® implants are made of a biocompatible material known as PEEK, with small tantalum markers used to help the surgeon clearly see the implant through X-ray images.

These implants also have a one-micron 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]

Although the Regatta implant 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.

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

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

REGATTA®

Regatta® 18mm Narrow Lateral Implants

PART NUMBER	PART DESCRIPTION
36-180840-00	18 x 8 x 40mm, 0°
36-181040-00	18 x 8 x 40mm, 0°
36-181240-00	18 x 8 x 40mm, 0°
36-181440-00	18 x 8 x 40mm, 0°
36-180840-10	18 x 8 x 40mm, 0°
36-181040-10	18 x 8 x 40mm, 0°
36-181240-10	18 x 8 x 40mm, 0°
36-181440-10	18 x 8 x 40mm, 0°
36-181040-15	18 x 8 x 40mm, 0°
36-181240-15	18 x 8 x 40mm, 0°
36-181440-15	18 x 8 x 40mm, 0°
36-180845-00	18 x 8 x 40mm, 0°
36-181045-00	18 x 8 x 40mm, 0°
36-181245-00	18 x 8 x 40mm, 0°
36-181445-00	18 x 8 x 40mm, 0°
36-180845-10	18 x 8 x 40mm, 0°
36-181045-10	18 x 8 x 40mm, 0°
36-181245-10	18 x 8 x 40mm, 0°
36-181445-10	18 x 8 x 40mm, 0°
36-181045-15	18 x 8 x 40mm, 0°
36-181245-15	18 x 8 x 40mm, 0°
36-181445-15	18 x 8 x 40mm, 0°
36-180850-00	18 x 8 x 50mm, 0°
36-181050-00	18 x 10 x 50mm, 0°
36-181250-00	18 x 12 x 50mm, 0°
36-181450-00	18 x 14 x 50mm, 0°
36-180850-10	18 x 8 x 50mm, 10°
36-181050-10	18 x 10 x 50mm, 10°
36-181250-10	18 x 12 x 50mm, 10°
36-181450-10	18 x 14 x 50mm, 10°
36-181050-15	18 x 10 x 50mm, 15°
36-181250-15	18 x 12 x 50mm, 15°
36-181450-15	18 x 14 x 50mm, 15°
36-180855-00	18 x 8 x 55mm, 0°
36-181055-00	18 x 10 x 55mm, 0°
36-181255-00	18 x 12 x 55mm, 0°
36-181455-00	18 x 14 x 55mm, 0°
36-180855-10	18 x 8 x 55mm, 10°
36-181055-10	18 x 10 x 55mm, 10°
36-181255-10	18 x 12 x 55mm, 10°
36-181455-10	18 x 14 x 55mm, 10°
36-181055-15	18 x 10 x 55mm, 15°
36-181255-15	18 x 12 x 55mm, 15°
36-181455-15	18 x 14 x 55mm, 15°
36-180860-00	18 x 8 x 60mm, 0°
36-181060-00	18 x 10 x 60mm, 0°
36-181260-00	18 x 12 x 60mm, 0°
36-181460-00	18 x 14 x 60mm, 0°
36-180860-10	18 x 8 x 60mm, 10°
36-181060-10	18 x 10 x 60mm, 10°
36-181260-10	18 x 12 x 60mm, 10°
36-181460-10	18 x 14 x 60mm, 10°
36-181060-15	18 x 10 x 60mm, 15°
36-181260-15	18 x 12 x 60mm, 15°
36-181460-15	18 x 14 x 60mm, 15°
36-180860-00	18 x 8 x 60mm, 0°
36-181060-00	18 x 10 x 60mm, 0°
36-181260-00	18 x 12 x 60mm, 0°
36-181460-00	18 x 14 x 60mm, 0°
36-180860-10	18 x 8 x 60mm, 10°
36-181060-10	18 x 10 x 60mm, 10°
36-181260-10	18 x 12 x 60mm, 10°
36-181460-10	18 x 14 x 60mm, 10°
36-181060-15	18 x 10 x 60mm, 15°
36-181260-15	18 x 12 x 60mm, 15°
36-181060-15	18 x 14 x 60mm, 15°

Regatta 23mm Wide Lateral Implants

PART NUMBER	PART DESCRIPTION
36-230840-00	23 x 8 x 40mm, 0°
36-231040-00	23 x 10 x 40mm, 0°
36-231240-00	23 x 12 x 40mm, 0°
36-231440-00	23 x 14 x 40mm, 0°
36-230840-10	23 x 14 x 40mm, 0°
36-231040-10	23 x 10 x 40mm, 10°
36-231240-10	23 x 12 x 40mm, 10°
36-231440-10	23 x 14 x 40mm, 10°
36-231040-15	23 x 10 x 40mm, 15°
36-231240-15	23 x 12 x 40mm, 15°
36-231440-15	23 x 14 x 40mm, 15°
36-230845-00	23 x 8 x 45mm, 0°
36-231045-00	23 x 10 x 45mm, 0°
36-231245-00	23 x 12 x 45mm, 0°
36-231445-00	23 x 14 x 45mm, 0°
36-230845-10	23 x 8 x 45mm, 10°
36-231045-10	23 x 10 x 45mm, 10°
36-231245-10	23 x 12 x 45mm, 10°
36-231445-10	23 x 14 x 45mm, 10°
36-231045-15	23 x 10 x 45mm, 15°
36-231245-15	23 x 12 x 45mm, 15°
36-231445-15	23 x 14 x 45mm, 15°
36-230850-00	23 x 8 x 50mm, 0°
36-231050-00	23 x 10 x 50mm, 0°
36-231250-00	23 x 12 x 50mm, 0°
36-231450-00	23 x 14 x 50mm, 0°
36-230850-10	23 x 8 x 50mm, 10°
36-231050-10	23 x 10 x 50mm, 10°
36-231250-10	23 x 12 x 50mm, 10°
36-231450-10	23 x 14 x 50mm, 10°
36-231050-15	23 x 10 x 50mm, 15°
36-231250-15	23 x 12 x 50mm, 15°
36-231450-15	23 x 14 x 50mm, 15°
36-230855-00	23 x 8 x 55mm, 0°
36-231055-00	23 x 10 x 55mm, 0°
36-231255-00	23 x 12 x 55mm, 0°
36-231455-00	23 x 14 x 55mm, 0°
36-230855-10	23 x 8 x 55mm, 10°
36-231055-10	23 x 10 x 55mm, 10°
36-231255-10	23 x 12 x 55mm, 10°
36-231455-10	23 x 14 x 55mm, 10°
36-231055-15	23 x 10 x 55mm, 15°
36-231255-15	23 x 12 x 55mm, 15°
36-231455-15	23 x 14 x 55mm, 15°
36-230860-00	23 x 8 x 60mm, 0°
36-231060-00	23 x 10 x 60mm, 0°
36-231260-00	23 x 12 x 60mm, 0°
36-231460-00	23 x 14 x 60mm, 0°
36-230860-10	23 x 8 x 60mm, 10°
36-231060-10	23 x 10 x 60mm, 10°
36-231260-10	23 x 12 x 60mm, 10°
36-231460-10	23 x 14 x 60mm, 10°
36-231060-15	23 x 10 x 60mm, 15°
36-231260-15	23 x 12 x 60mm, 15°
36-231460-15	23 x 14 x 60mm, 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, Lateral 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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Warning: Applicable laws restrict these products to sale by or on the order of a surgeon.

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