SeaSpine

REGATTA®

LATERAL LUMBAR INTERBODY FUSION

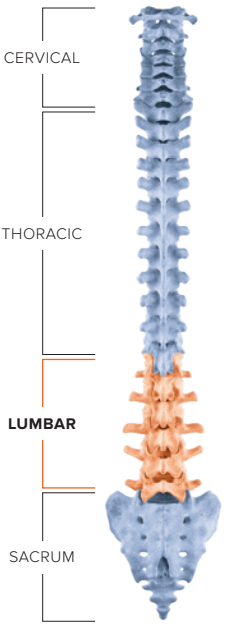
PATIENT INFORMATION BROCHURE

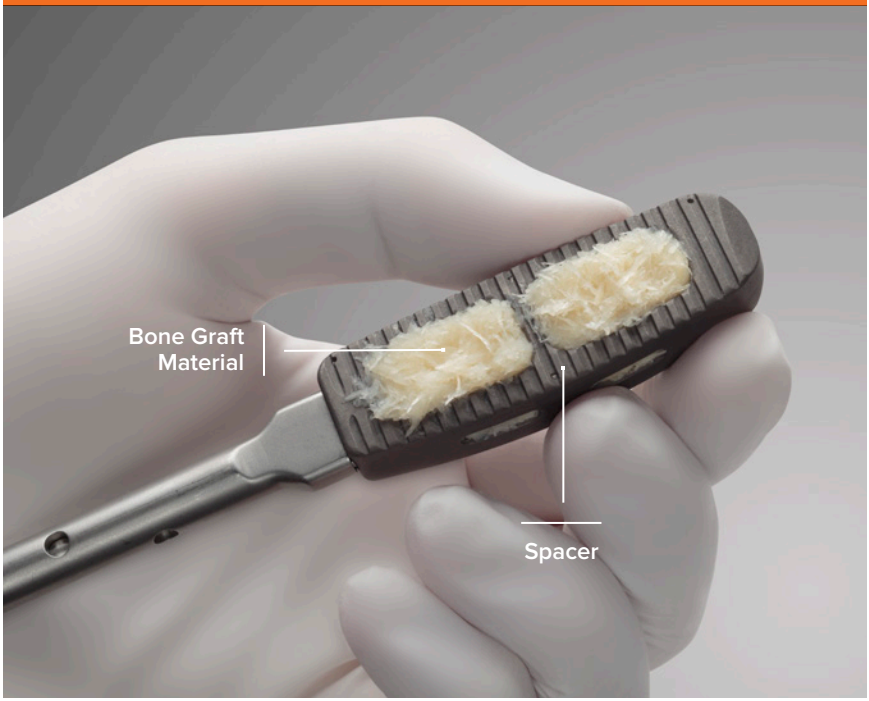
INTRODUCTION

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 center (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 stabilization.

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.

IS A LLIF 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 6 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.

SPONDYLOLISTHESIS

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

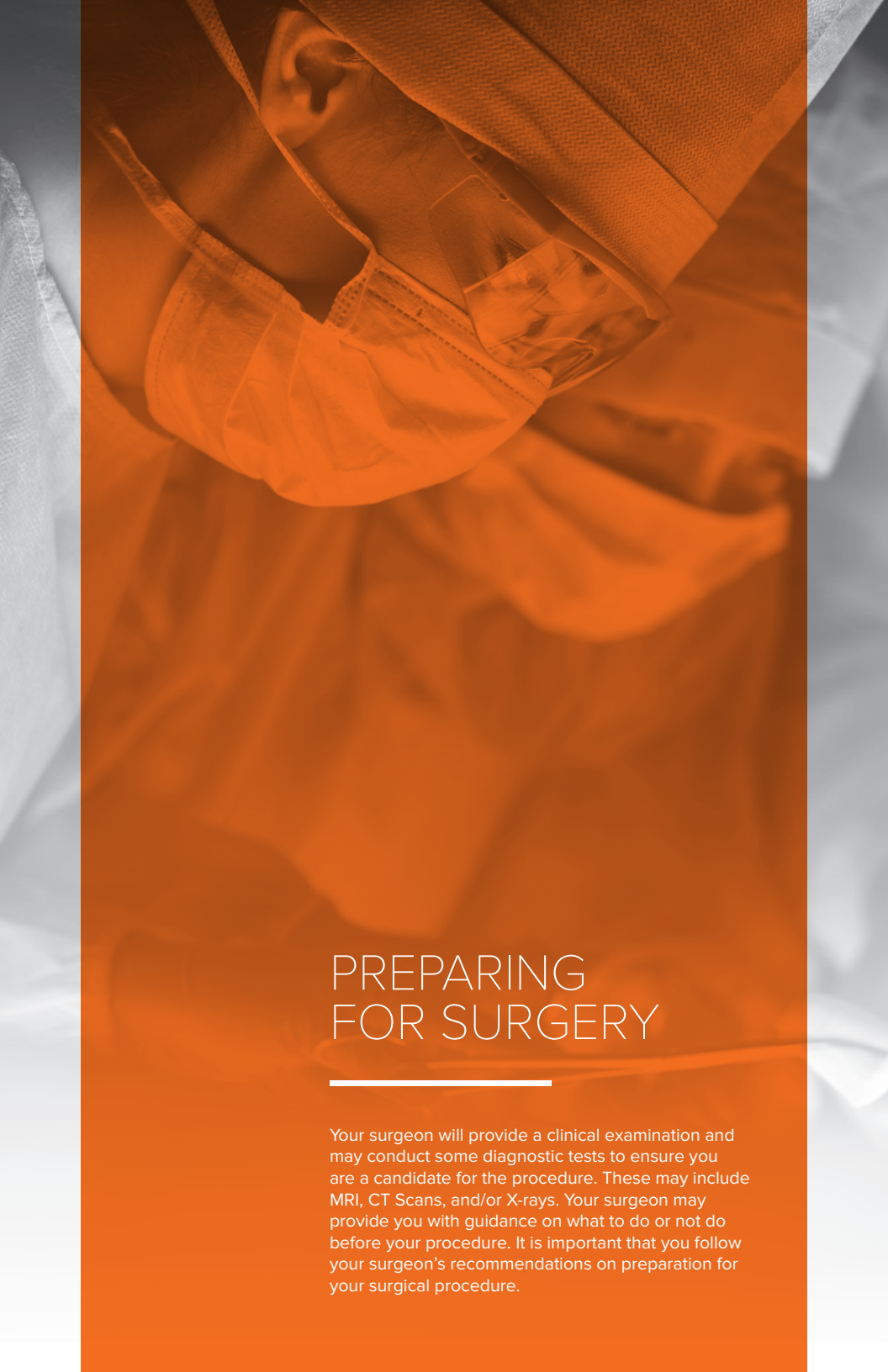
SPINAL STENOSIS

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 SeaSpine® Regatta Lateral Lumbar Interbody System may not be the right procedure for you. It is important to discuss with your surgeon your condition, 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 on preparation for 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 utilized 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 stabilize once fusion occurs.

STEP 4: FIXATION

Supplemental fixation is required. Some method of internal fixation will be used to act as a stabilization 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.

SeaSpine

For more information or to place an order, please contact:
TEL 866.942.8698 | FAX 877.558.6227
customerservice@seaspine.com | **seaspine.com**

Outside USA
TEL +1.760.727.8399 | FAX +1.760.727.8809
INTERNATIONAL INQUIRIES intlcustomer@seaspine.com
ALL OTHER INQUIRIES customerservice@seaspine.com