SeaSpine

SHORELINE®

ANTERIOR CERVICAL SYSTEM

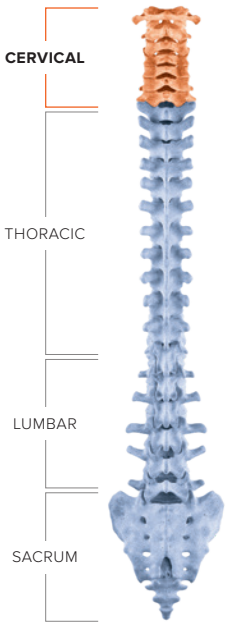
PATIENT INFORMATION BROCHURE

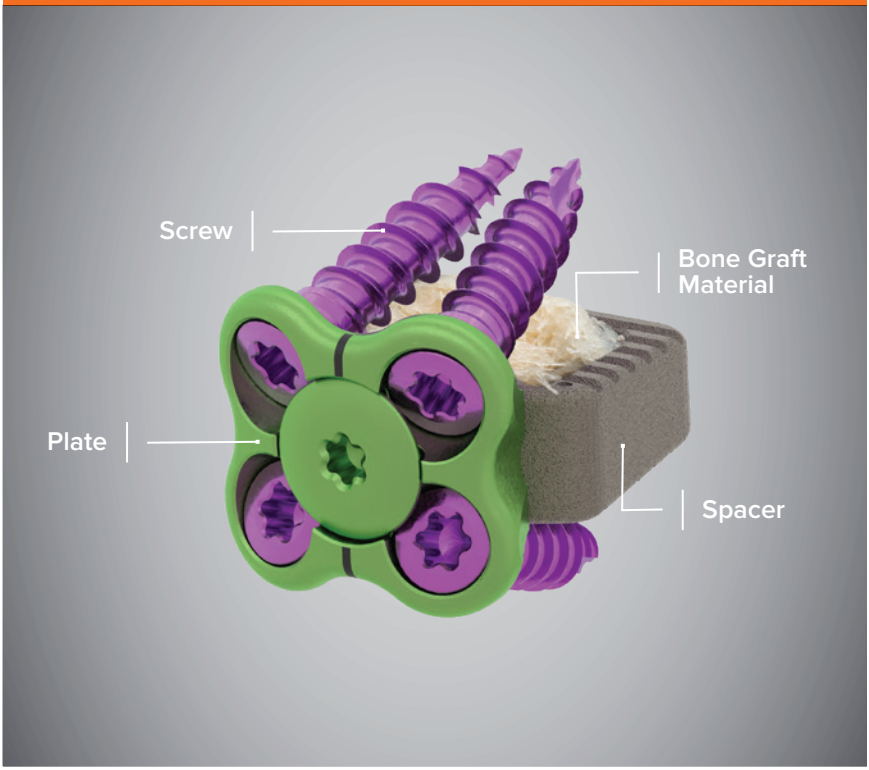
INTRODUCTION

The cervical spine is made up of seven bones, called vertebrae. These vertebrae start at the base of the skull and extend through the entirety of the neck. 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 neck. 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 arm or hand, and radiating pain, weakness and/or numbness in your shoulders, arms and neck.

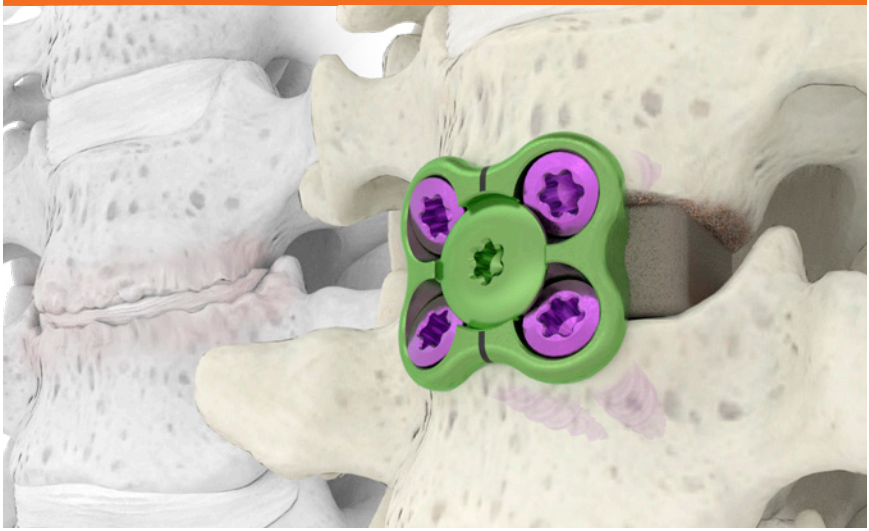




WHAT IS AN ANTERIOR CERVICAL DISCECTOMY AND FUSION?

An Anterior Cervical Discectomy and Fusion (ACDF) is a surgery to remove a herniated or degenerative disc in the neck. In this procedure, an incision is made in the neck area to reach and remove the unhealthy disc, then replaced with a spacer and fixated with screws and/or a plate. Bone graft or bone graft substitute is inserted to fuse together the bones above and below the disc.

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 anterior cervical (front of the neck) access of this surgery provides a less invasive approach to the afflicted area, leading to less incisional pain.



IS AN ACDF THE RIGHT PROCEDURE FOR ME?

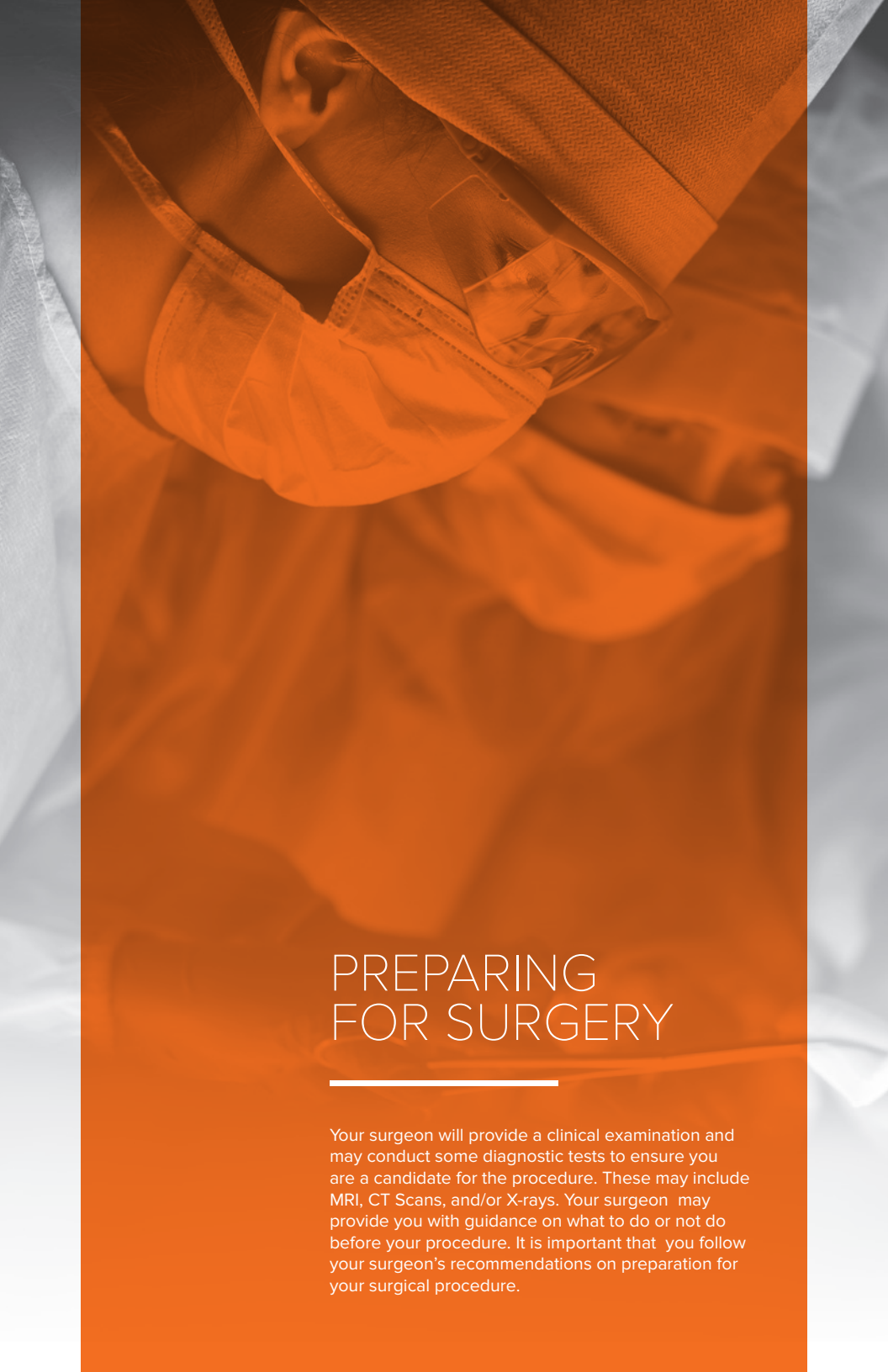
Your surgeon may have indicated that you are a candidate for an Anterior Cervical Discectomy Fusion (ACDF). Shoreline ACS is intended for skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine (C2-C7). Some patients may have had at least 6 weeks of nonoperative treatment from the beginning of their symptoms and are still experiencing arm pain and/or neurological symptoms.

The Shoreline system is comprised of an intervertebral spacer that is used to fill the area where your disc has been removed. This spacer is made with a patented NanoMetalene® technology which is a very thin layer of titanium molecularly bonded to a strong medical grade plastic known as PEEK. This spacer is used in conjunction with bone graft to help promote fusion within the disc space. It is then fixed in place by screws and is sometimes accompanied by a plate to provide further fixation.

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 SeaSpine Shoreline Anterior Cervical 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, and covered by surgical draping, an X-ray image is taken of your spine to identify the location of the operative disc space.

STEP 1: APPROACH

The surgeon will make a small incision on the anterior (front) of your neck. 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

Once the operative level has been exposed, the surgeon will then begin to remove the damaged or diseased disc.

STEP 3: IMPLANT

An appropriately sized 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.

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.

For more information or to place an order, please contact:
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