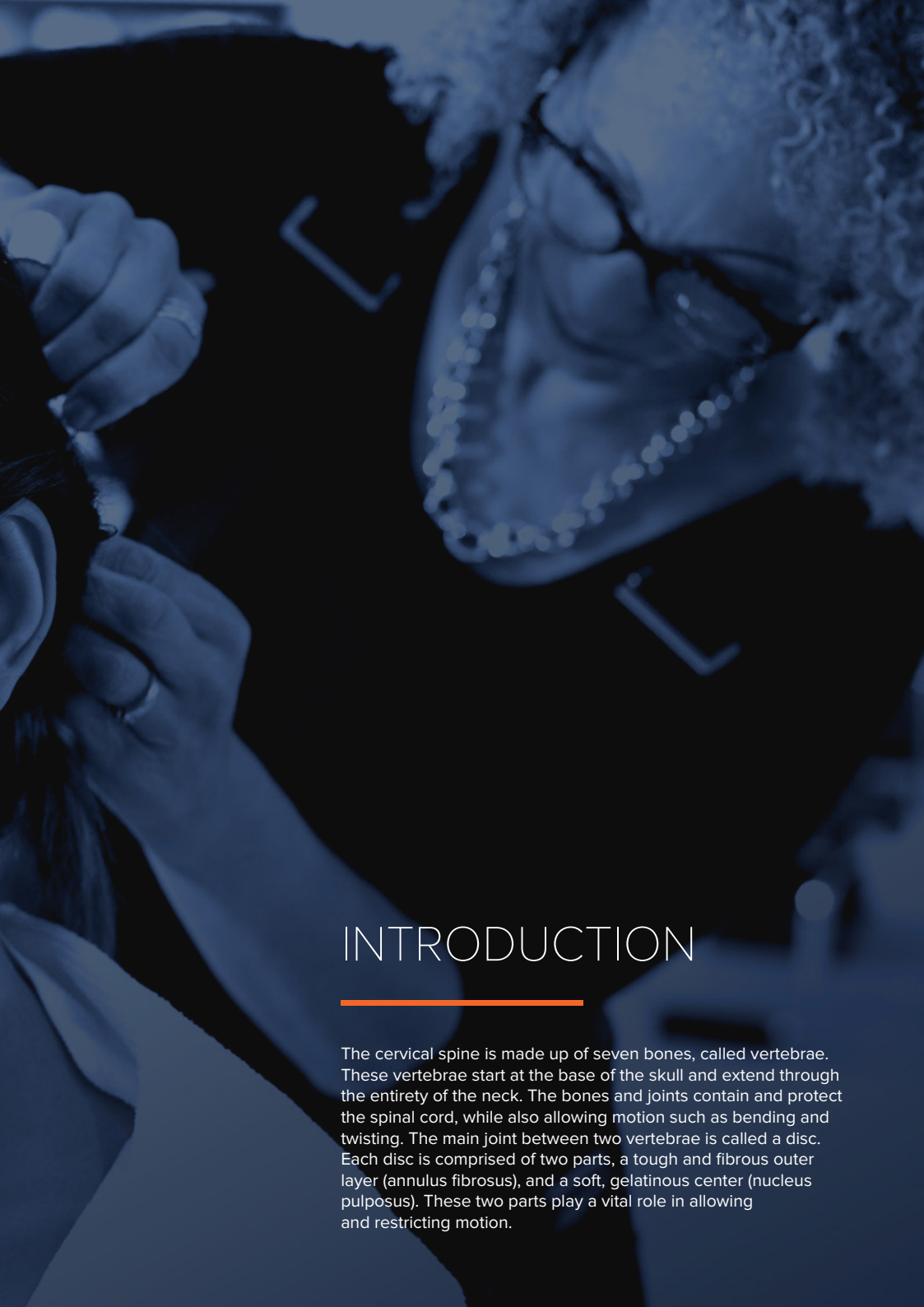
ADMIRAL™ ACP

ANTERIOR CERVICAL FIXATION SYSTEM

PATIENT INFORMATION LEAFLET

SeaSpine

DEVICE TECHNOLOGIES

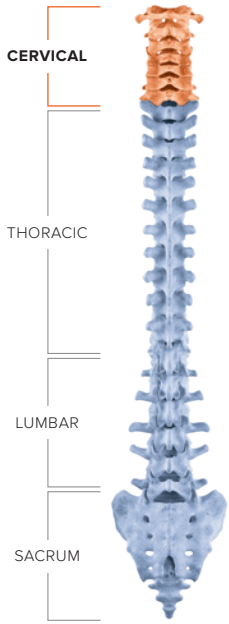


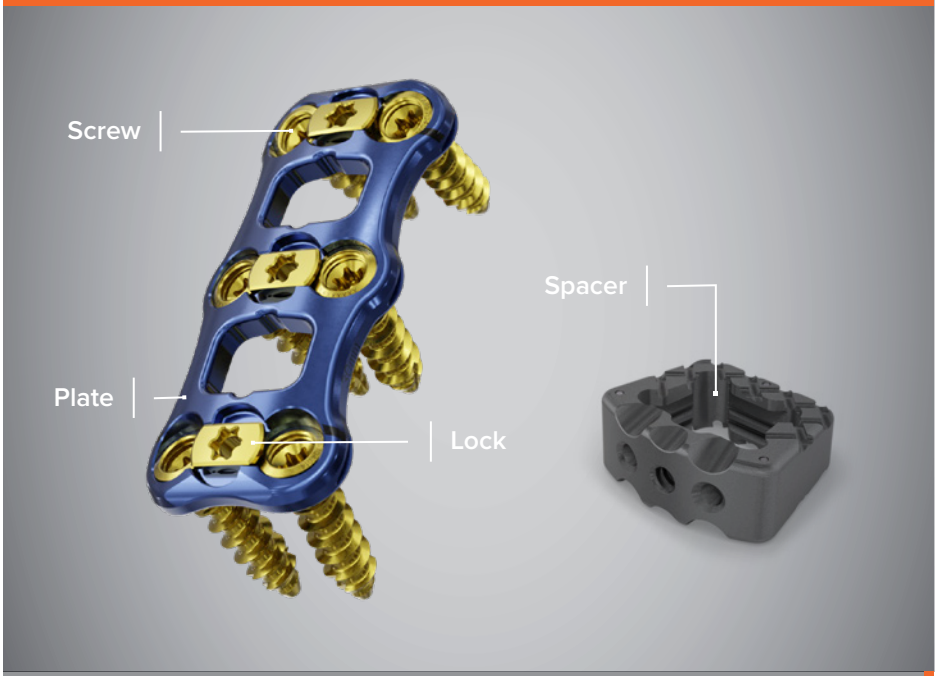
INTRODUCTION

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.



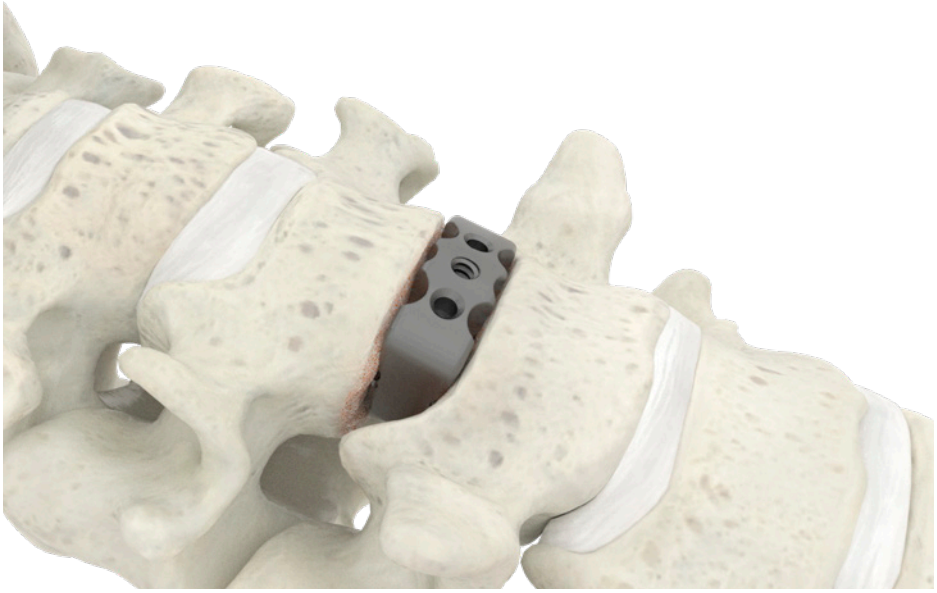


Admiral® & Shoreline RT® Spinal Implants

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 on the anterior (front) portion of the neck to reach and remove the unhealthy disc, then replaced with a spacer and fixated with a plate and screws. Bone graft or bone graft substitute is inserted to fuse together the bones above and below the disc.

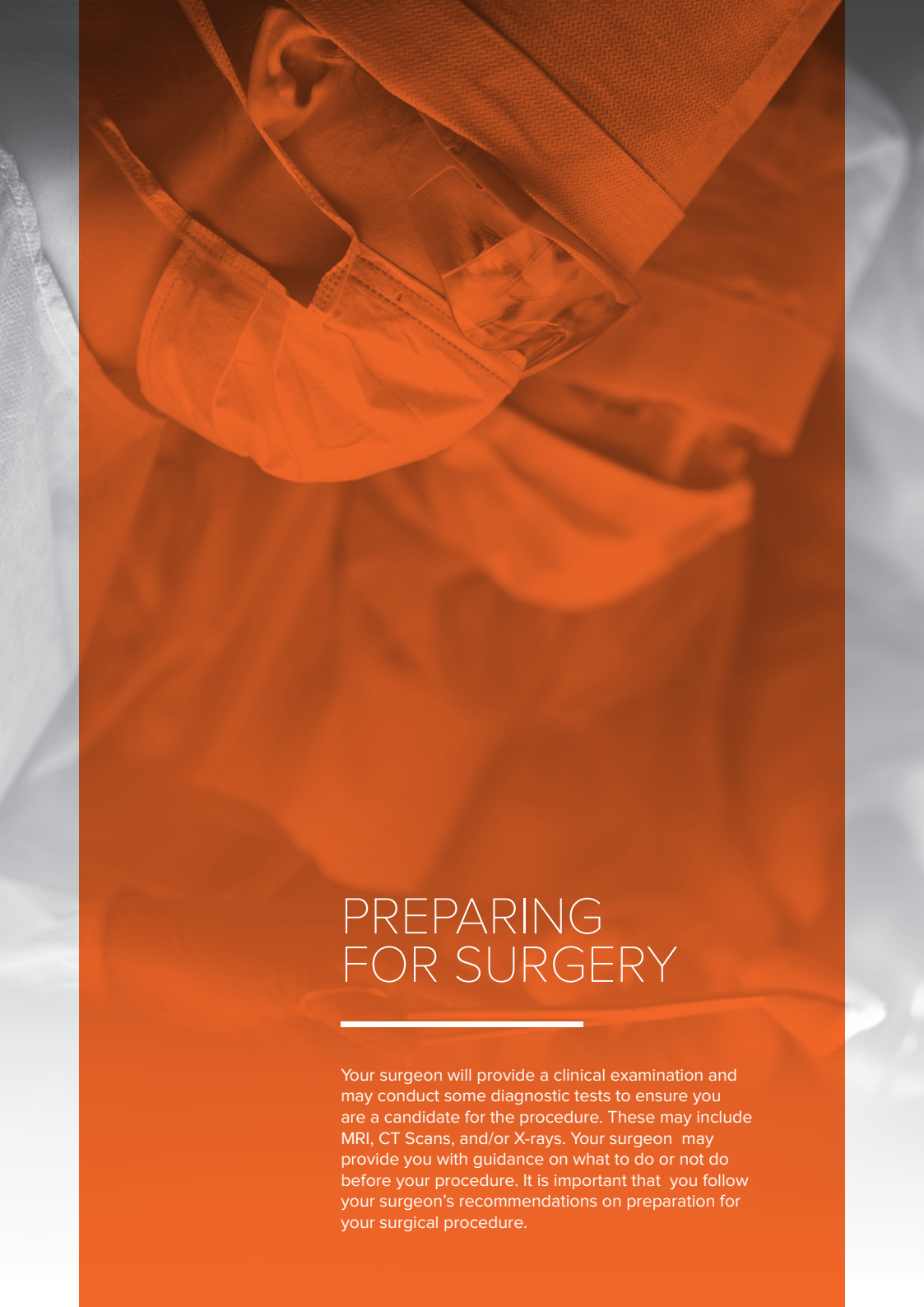
The primary goal of this procedure is to relieve pressure on the nerve roots and/or spinal cord. The long-term goal of this surgery is to create fusion, which is the joining of two vertebral bodies. The anterior cervical (front of the neck) access of this surgery provides a less invasive approach to the afflicted area and can potentially lead to less incisional pain than other approaches.



IS AN ACDF THE RIGHT PROCEDURE FOR ME?

Your surgeon may have indicated that you are a candidate for an ACDF. The Admiral™ Anterior Cervical Plate (ACP) System is intended for skeletally mature patients with a variety of indications. Most commonly, degenerative disc disease (DDD) of the cervical spine (C2-T1). DDD occurs during the natural aging process and is the result of a disc between the vertebral bodies losing height which can then lead to compression of the nerve roots or spinal cord. This compression on the nerve roots can cause symptoms including, but not limited to, neck and/or arm pain, numbness, and tingling. Some patients who 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 may be eligible for an ACDF.

The Admiral ACP 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.

A representation of what your procedure may look like post operatively depending on the total number of levels treated pictured above. 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, cardiovascular disorders, numbness, tingling, pulmonary embolism, paralysis, or death.

TECHNICAL INFORMATION

Admiral™ ACP is a comprehensive and complete anterior cervical plating system designed to strike the optimal balance between strength, profile, and construct rigidity. The System implant components are made from titanium alloy such as described by ASTM F136. This material is not compatible with other metal alloys. 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.

Although the Admiral 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 willprovide 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.

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/reporting-problems.

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, Anterior Cervical 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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INTERNATIONAL INQUIRIES intlcustomer@seaspine.com

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

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