SHORELINE® ACS

ANTERIOR CERVICAL DISCECTOMY AND FUSION

PATIENT INFORMATION LEAFLET

SeaSpine

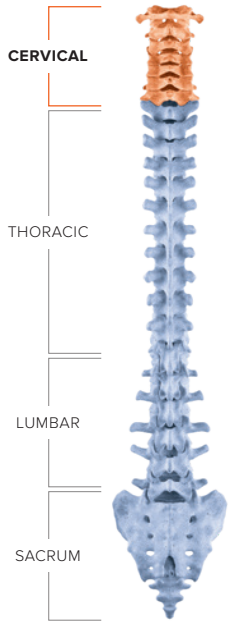
DEVICE TECHNOLOGIES

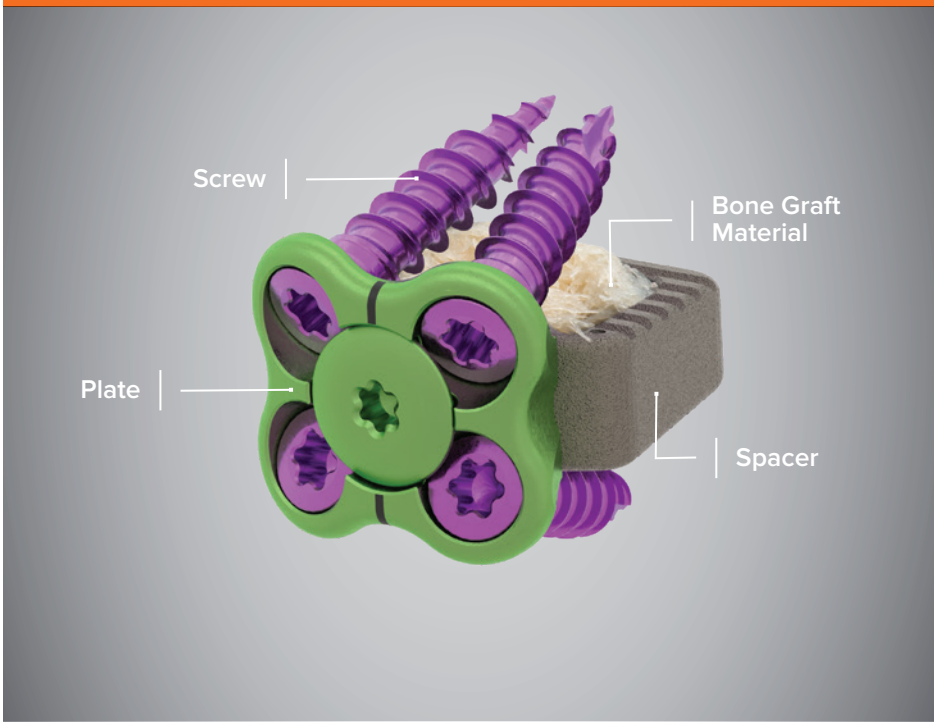
INTRODUCTION

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 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 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.

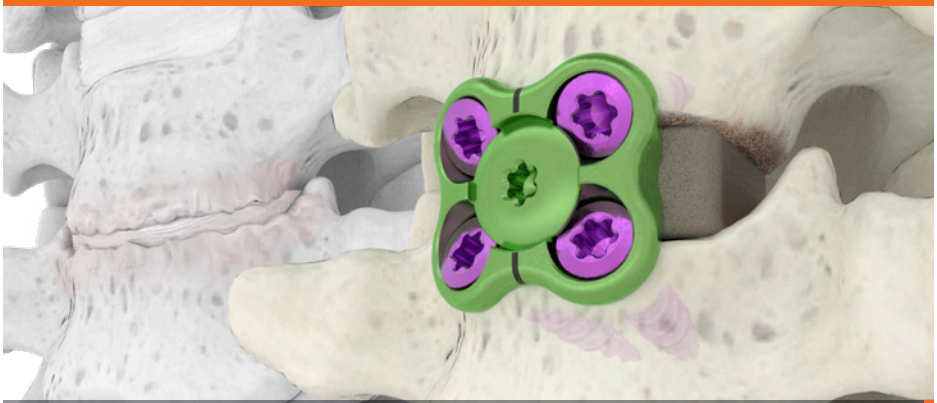




WHAT IS AN ANTERIOR CERVICAL DISCECTOMY AND FUSION?

An Anterior Cervical Discectomy and Fusion (ACDF) is a surgical procedure 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 the bones together 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.



Shoreline® ACS Spinal Implant

IS AN ANTERIOR CERVICAL DISCECTOMY AND FUSION THE RIGHT PROCEDURE FOR ME?

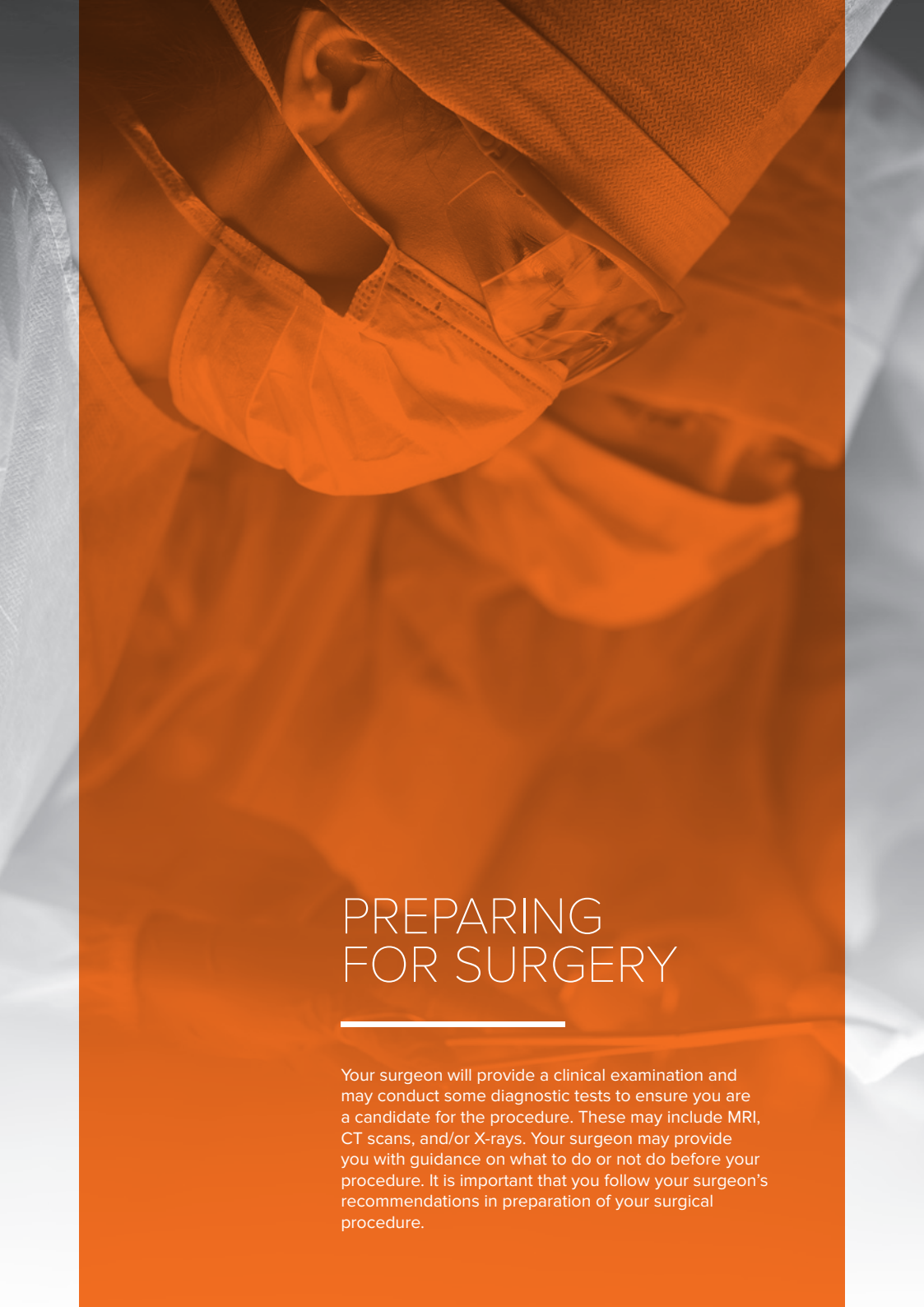
Your surgeon may have indicated that you are a candidate for an Anterior Cervical Discectomy Fusion (ACDF). Shoreline® ACS is intended for skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine (C2-C7). Some patients may have had at least six weeks of nonoperative treatment 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. 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 Anterior Cervical Discectomy and 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, 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 utilised 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 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

Shoreline® 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.

Shoreline 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]

IMPLANT MATERIALS

- Polyetheretherketone (PEEK) per ASTM F2026
- Commercially Pure Titanium per ASTM F67
- Tantalum per ASTM F560
- Titanium 6Al-4V per ASTM F136

Although the Shoreline® 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.

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

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

SHORELINE® ACS

TruProfile® Interbody

PART NUMBER	PART DESCRIPTION
85-0905S through 85-0912S	16 x 14 x 5mm through 12mm, 7° Interbody
85-1005S through 85-1012S	18 x 15 x 5mm through 12mm, 7°, Interbody
85-1105S through 85-1112S	20 x 15 x 5mm through 12mm, 7°, Interbody
85-1306S through 85-1312S	16 x 14 x 6mm through 12mm, 10°, Interbody
85-1406S through 85-1412S	18 x 14 x 6mm through 12mm, 10°, Interbody
85-1506S through 85-1512S	20 x 14 x 6mm through 12mm, 10°, Interbody
85-1707S through 85-1712S	16 x 14 x 7mm through 12mm, 15°, Interbody
85-1808S through 85-1812S	18 x 15 x 8mm through 12mm, 15°, Interbody
85-1908S through 85-1912S	20 x 15 x 8mm through 12mm, 15°, Interbody

No-profile Interbody

PART NUMBER	PART DESCRIPTION
85-0202S through 85-0212S	16 x 14 x 6mm through 12mm, 7°, No-profile Integrated Spacer
85-0306S through 85-0312S	18 x 15 x 6mm through 12mm, 7°, No-profile Integrated Spacer

No-profile Locking Cap

PART NUMBER	PART DESCRIPTION
85-2006 through 85-2008	6-7mm, No-profile Locking Cover, 8–12mm

TruProfile Plate

PART NUMBER	PART DESCRIPTION
85-0505 through 85-0512	5–12mm, 2-Hole Anterior Plate
85-0605 through 85-0612	5–12mm, 3-Hole Anterior Plate
85-0705 through 85-0712	5–12mm, 4-Hole Anterior Plate

TruProfile Locking Cover

PART NUMBER	PART DESCRIPTION
85-2105 through 85-2112	5mm, Locking Cover, 5–12mm
85-2305 through 85-2312	5–12mm, Locking Cover Backup

Screws

PART NUMBER	PART DESCRIPTION
85-3110 through 85-3118	Fixed – 3.5mm, Self-tapping, 10–18mm
85-3010 through 85-3018	Variable – 3.5mm, Self-tapping, 10–18mm
85-3312 through 85-3318	Fixed – 3.5mm, Self-drilling, 12– 18mm
85-3212 through 85-3218	Variable – 3.5mm, Self-drilling, 12–18mm
85-4010 through 85-4018	Variable – 4.0mm, Self-tapping, 10–18mm
85-4110 through 85-4118	Fixed – 4.0mm, Self-tapping, 10–18mm

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, Anterior Cervical Discectomy and Fusion surgery carries risks. Your surgeon will discuss the risks associated with your prescribed procedure.

SeaSpine DEVICE TECHNOLOGIES

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
EMEA INQUIRIES intlcustomer@seaspine.com
ALL OTHER INQUIRIES customerservice@seaspine.com

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

Date of Release December 31, 2021