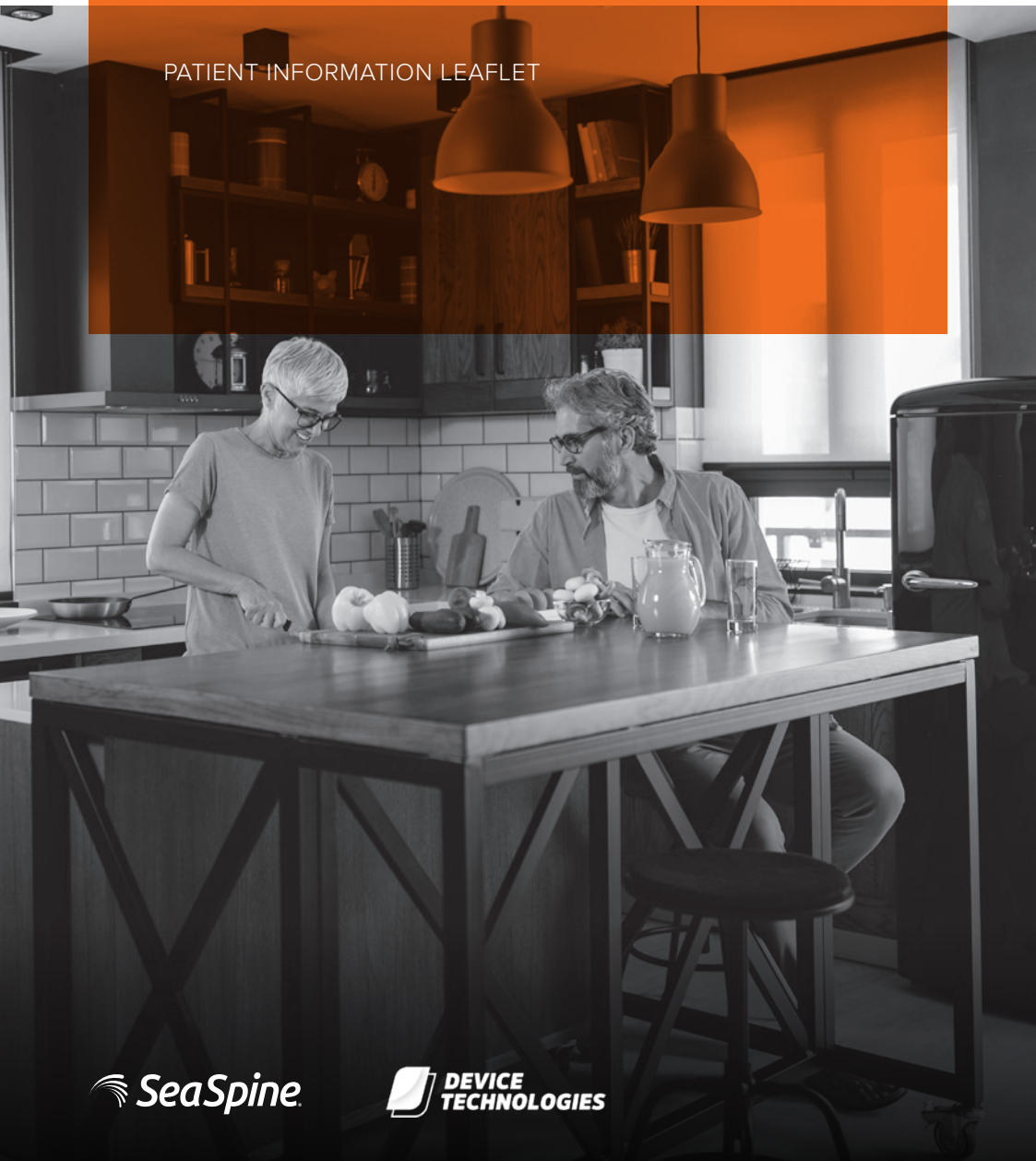
SIERRA™

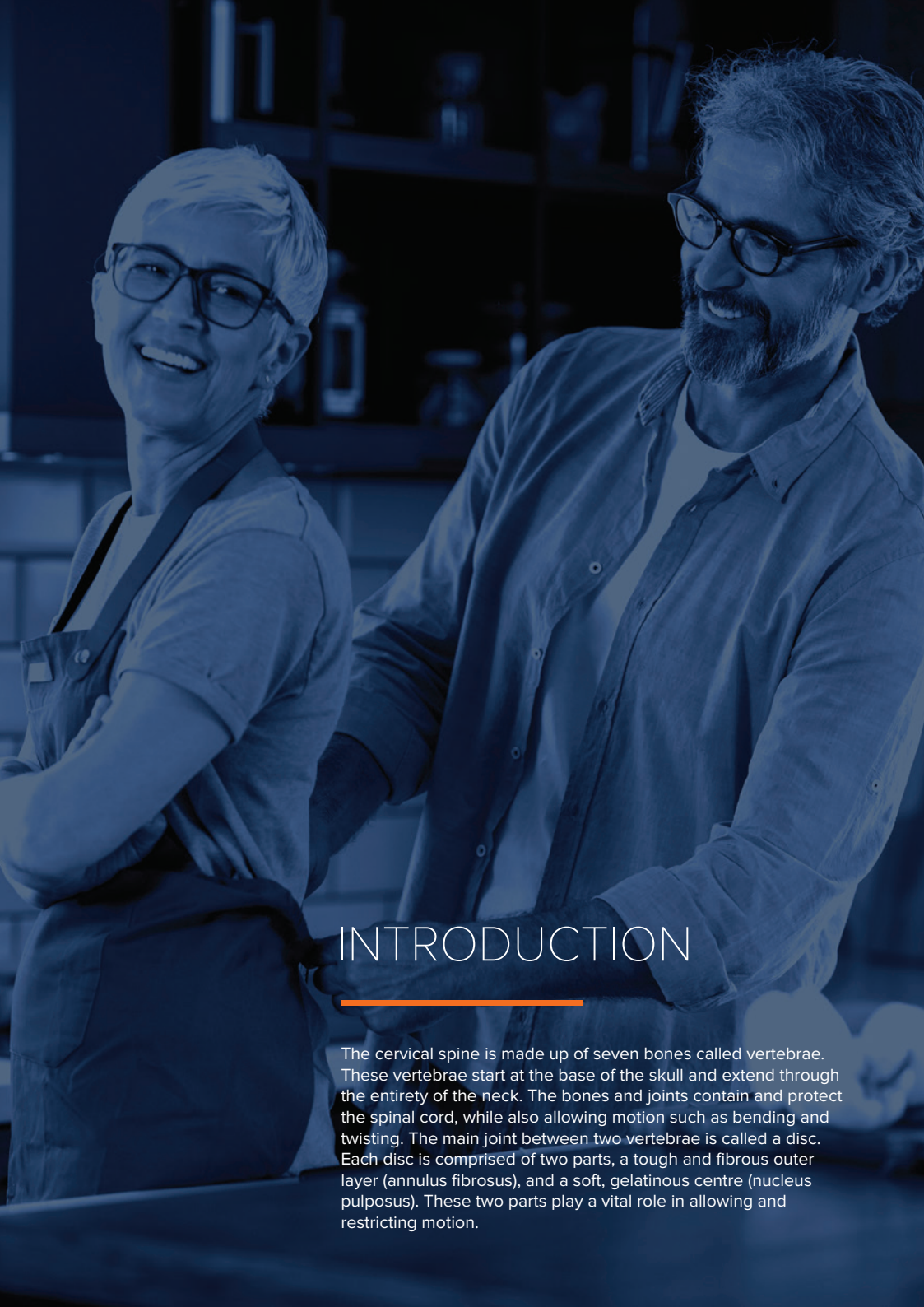
POSTERIOR CERVICAL FUSION

PATIENT INFORMATION LEAFLET



SeaSpine

DEVICE TECHNOLOGIES

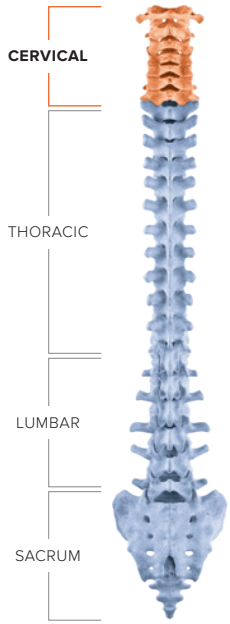


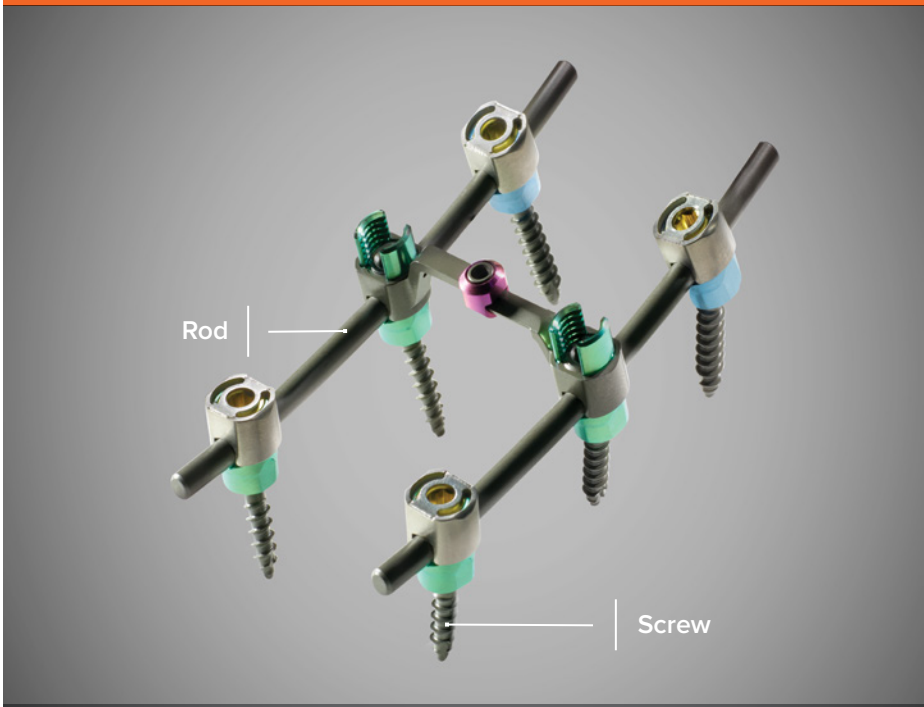
INTRODUCTION

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.





Sierra™ Posterior Cervical Fixation

WHAT IS A POSTERIOR CERVICAL FUSION?

Posterior Cervical Fusion is a surgical procedure that attempts to eliminate instability and relieve pain in the neck. In this procedure, an incision is made on the back of the neck. Tissue and muscles are retracted to expose the affected vertebral bodies. Decompression may be necessary if symptoms are caused by a compression of the spinal cord and/or never roots. Once the proper anatomy has been decompressed, your surgeon will use screws and rods to stabilize or fixate the affected vertebral bodies.

The primary goal of this procedure is to relieve pressure on the nerve roots and/ or spinal cord to provide realignment. Alignment, mmobilization, and stabilization of spinal segments in skeletally mature patients. The long-term goal of this surgery is to create fusion, which is the joining of two vertebral bodies.

Sierra™ Posterior Cervical Fixation

IS POSTERIOR CERVICAL FUSION THE RIGHT PROCEDURE FOR ME?

Your surgeon may have indicated that you are a candidate for Posterior Cervical Fusion. This surgical procedure is intended for skeletally mature patients with Degenerative Disc Disease (DDD), spondylolisthesis, or spinal stenosis of the cervical spine (C2-C7). Some patients may have had at least six months 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.

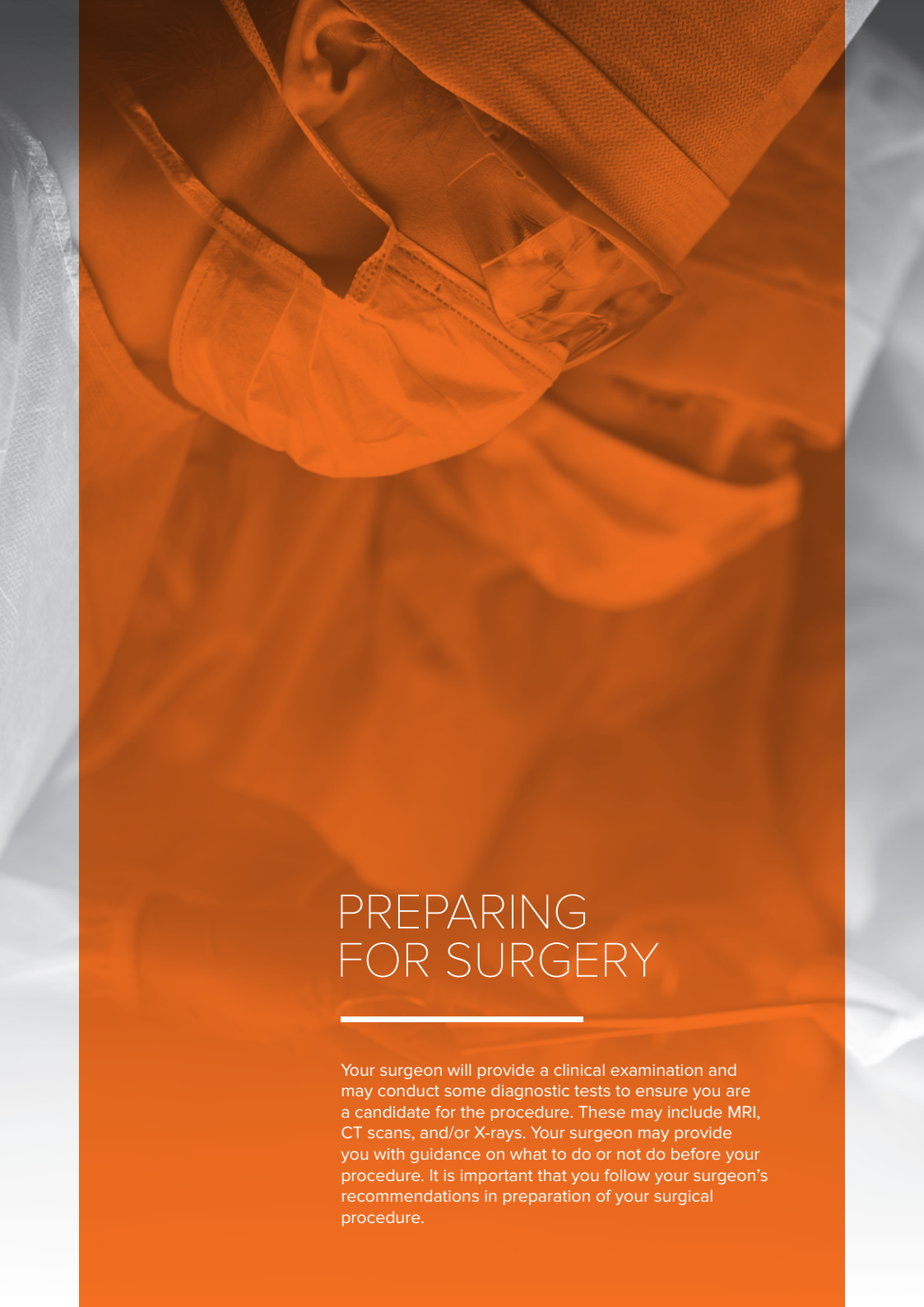
SPONDYLOLISTHESIS

This is a condition in which one vertebral body has 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 neck.

The Posterior Cervical 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

DURING SURGERY

After you are sedated, positioned face down, 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 down the back of your neck. The size of the incision can vary based on the number of levels and/or complexity of your case.

STEP 2: DECOMPRESSION

Your surgeon may decide that decompression of the affected vertebrae and discs may be necessary to reduce pressure from the cord or symptomatic nerve root. During decompression, a small section of the bone and disc are removed to clear a pathway for the interbody spacer.

STEP 3: STABILISATION OR FIXATION

Your surgeon will use a combination of screws and rods in a less invasive manner than the traditional screw placement to stabilise or fixate the affected vertebrae. This combination will act as a stabilisation device (internal brace) to help hold everything in place while fusion occurs. Your surgeon will determine the appropriate fixation implant, if necessary.

STEP 4: FUSION

With the completed construct tightened and locked down, your vertebral bodies will then be allowed to fuse. Fusion means the bone will grow around the affected areas and will eventually stabilise itself. This healing process can take various lengths of time depending on the severity of the condition.

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 physician will determine the best postoperative course for you. The day after your surgery, your physician 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 physician may ask you to carefully sit, stand, or walk. Your physician will also discuss with you any medications to take home, as well as a prescribed program of activities. Your physician 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, 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 physician immediately.

TECHNICAL INFORMATION

The SeaSpine® comprehensive posterior cervical systems offer a variety of screws and rods to accommodate varying patient pathologies. These screws and rods are comprised of various materials and 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.

IMPLANT MATERIALS

- Titanium Alloy (Ti Alloy) – ASTM F136
- Cobalt Chrome (CoCr) – ASTM F1537
- Titanium Alloy (Ti Alloy) – ASTM F136
- Cobalt Chrome (CoCr) – ASTM F1537

Although the Sierra™ 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 physician 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.

SIERRA™

Sierra™ Implant Set

PART NUMBER	PART DESCRIPTION
50-3510	Sierra Screw, DIA 3.5 x 10mm
50-3512	Sierra Screw, DIA 3.5 x 12mm
50-3514	Sierra Screw, DIA 3.5 x 14mm
50-3516	Sierra Screw, DIA 3.5 x 16mm
50-3518	Sierra Screw, DIA 3.5 x 18mm
50-3520	Sierra Screw, DIA 3.5 x 20mm
50-3522	Sierra Screw, DIA 3.5 x 22mm
50-4010	Sierra Screw, DIA 4.0 x 10mm
50-4012	Sierra Screw, DIA 4.0 x 12mm
50-4014	Sierra Screw, DIA 4.0 x 14mm
50-4016	Sierra Screw, DIA 4.0 x 16mm
50-4018	Sierra Screw, DIA 4.0 x 18mm
50-4020	Sierra Screw, DIA 4.0 x 20mm
50-4022	Sierra Screw, DIA 4.0 x 22mm
50-4024	Sierra Screw, DIA 4.0 x 24mm
50-4026	Sierra Screw, DIA 4.0 x 26mm
50-4028	Sierra Screw, DIA 4.0 x 28mm
50-4520	Sierra Screw, DIA 4.5 x 20mm
50-4524	Sierra Screw, DIA 4.5 x 24mm
50-4528	Sierra Screw, DIA 4.5 x 28mm
50-4532	Sierra Screw, DIA 4.5 x 32mm
50-7020	Sierra Lag Screw, DIA 3.5 x 20mm
50-7022	Sierra Lag Screw, DIA 3.5 x 22mm
50-7024	Sierra Lag Screw, DIA 3.5 x 24mm
50-7026	Sierra Lag Screw, DIA 3.5 x 26mm
50-7028	Sierra Lag Screw, DIA 3.5 x 28mm
50-7030	Sierra Lag Screw, DIA 3.5 x 30mm
50-7032	Sierra Lag Screw, DIA 3.5 x 32mm
50-7034	Sierra Lag Screw, DIA 3.5 x 34mm
50-7036	Sierra Lag Screw, DIA 3.5 x 36mm
50-7038	Sierra Lag Screw, DIA 3.5 x 38mm
50-7040	Sierra Lag Screw, DIA 3.5 x 40mm
50-7042	Sierra Lag Screw, DIA 3.5 x 42mm
50-7044	Sierra Lag Screw, DIA 3.5 x 44mm
50-7046	Sierra Lag Screw, DIA 3.5 x 46mm
50-7048	Sierra Lag Screw, DIA 3.5 x 48mm
50-7050	Sierra Lag Screw, DIA 3.5 x 50mm
50-9045	Sierra Hook, 4.5mm
50-9145	Sierra Offset Hook Left, 4.5mm
50-9245	Sierra Offset Hook Right, 4.5mm
50-9060	Sierra Hook, 6.0mm
50-9160	Sierra Offset Hook Left, 6.0mm
50-9260	Sierra Offset Hook Right, 6.0mm
50-0035	Closed Lateral Connector, 3.5 Rod
50-1000	Sierra Locking Cap

PART NUMBER	PART DESCRIPTION
50-2011SIE	Contoured Crossbar, Small, 3.5 Rod
50-2012	Contoured Crossbar, Medium, 3.5 Rod
50-2013	Contoured Crossbar, Large, 3.5 Rod
50-2014	Contoured Crossbar, XLarge, 3.5 Rod
50-2021SIE	S2S CrossBar, 24 - 29mm
50-2022	S2S CrossBar, 27 - 35mm
50-2023	S2S CrossBar, 33 - 47mm
50-1005	Sierra Set Screw
50-6120	Precontoured Rod, 3.5 x 20mm
50-6130	Precontoured Rod, 3.5 x 30mm
50-6140	Precontoured Rod, 3.5 x 40mm
50-6150	Precontoured Rod, 3.5 x 50mm
50-6160	Precontoured Rod, 3.5 x 60mm
50-6170	Precontoured Rod, 3.5 x 70mm
50-6180	Precontoured Rod, 3.5 x 80mm
50-6090	Rod, 3.5 x 300mm
50-6355	Transitional Rod, 3.5 / 5.5
50-8020	Occipital Plate, 25–35mm
50-8021	Occipital Plate, 30–40mm
50-8022	Occipital Plate, 35–45mm
50-8023	Occipital Plate, 40–50mm
50-8024	Occipital Plate, 45–55mm
50-8060	Occipital Clip
50-5006	Occipital Screw, 6mm
50-5008	Occipital Screw, 8mm
50-5010	Occipital Screw, 10mm
50-5012	Occipital Screw, 12mm
50-5014	Occipital Screw, 14mm
50-6260	Occipital Rod, 60°
50-6275	Occipital Rod, 75°
50-6290	Occipital Rod, 90°
51-4012	Sierra Extended Tab Screw, DIA 4.0 x 12mm
51-4014	Sierra Extended Tab Screw, DIA 4.0 x 14mm
51-4016	Sierra Extended Tab Screw, DIA 4.0 x 16mm
51-4018	Sierra Extended Tab Screw, DIA 4.0 x 18mm
51-4020	Sierra Extended Tab Screw, DIA 4.0 x 20mm
51-4022	Sierra Extended Tab Screw, DIA 4.0 x 22mm
51-4024	Sierra Extended Tab Screw, DIA 4.0 x 24mm
51-4026	Sierra Extended Tab Screw, DIA 4.0 x 26mm
51-4028	Sierra Extended Tab Screw, DIA 4.0 x 28mm
51-3510	Sierra Extended Tab Screw, DIA 3.5 x 10mm
51-3512	Sierra Extended Tab Screw, DIA 3.5 x 12mm
51-3514	Sierra Extended Tab Screw, DIA 3.5 x 14mm
51-3516	Sierra Extended Tab Screw, DIA 3.5 x 16mm
51-4010	Sierra Extended Tab Screw, DIA 4.0 x 10mm

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 physicians 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, the Posterior 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:
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