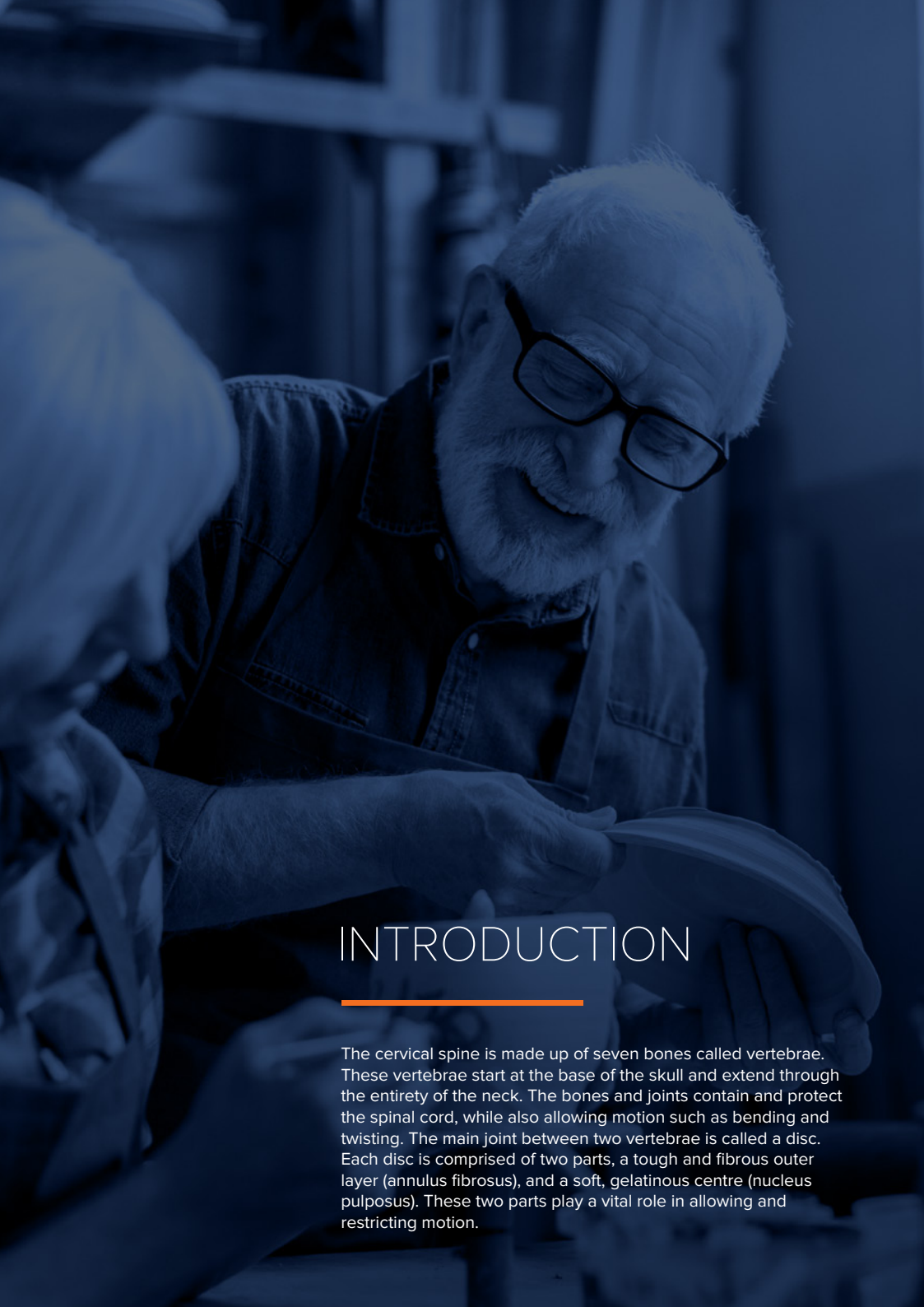
NORTHSTAR® OCT

POSTERIOR CERVICAL FUSION

PATIENT INFORMATION LEAFLET

SeaSpine

DEVICE TECHNOLOGIES

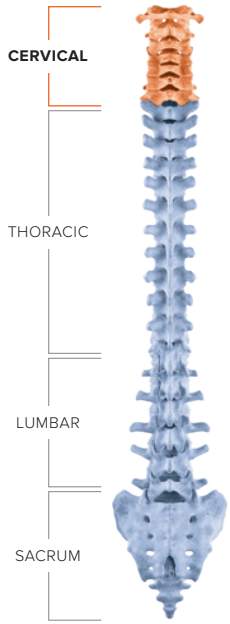


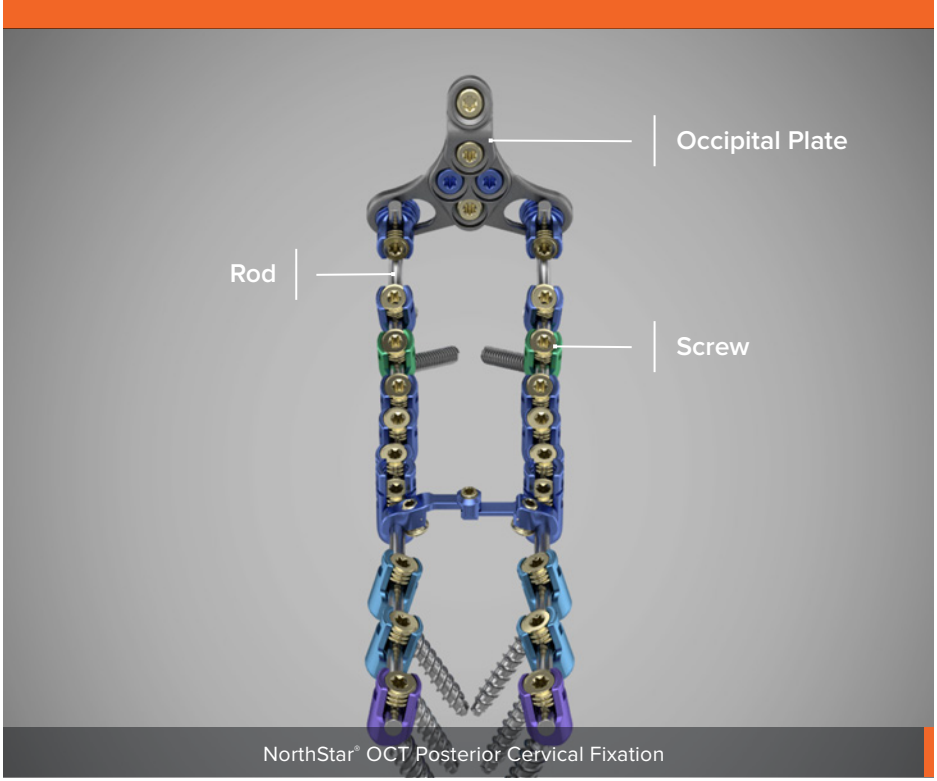
INTRODUCTION

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.





NorthStar® OCT 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 nerve 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. Immobilization, 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.

NorthStar® OCT Posterior Cervical Fixation

IS A POSTERIOR CERVICAL FUSION THE RIGHT PROCEDURE FOR ME?

Your surgeon may have indicated that you are a candidate for a 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.

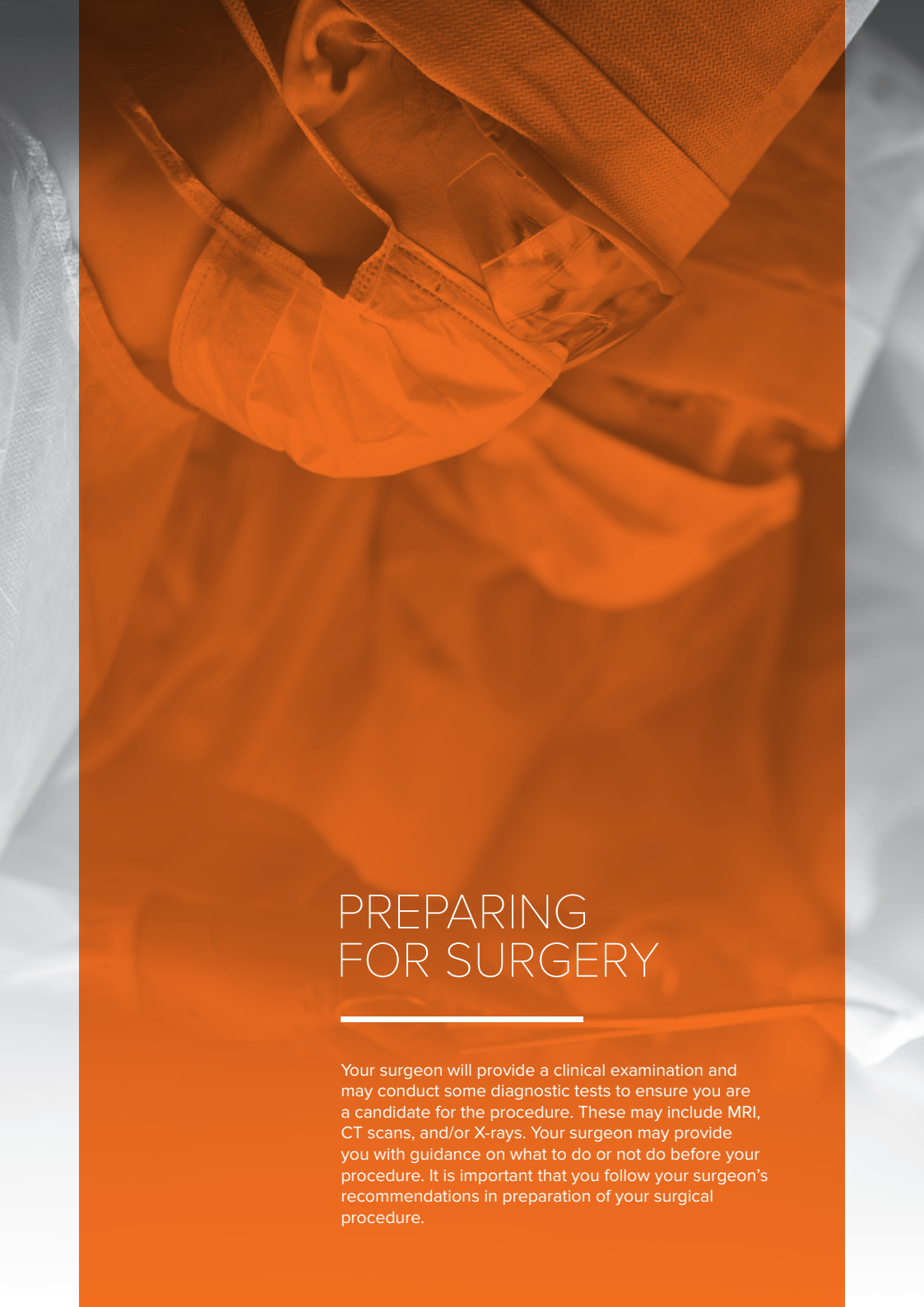
SPONDYLOLISTHESIS

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 the 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) – Ti-6Al-4V

Although the NorthStar® OCT 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.

NORTHSTAR® OCT

NorthStar® OCT Implant Set

PART NUMBER	PART DESCRIPTION
PC1-003508	Polyaxial Screw, 3.5 x 8mm
PC1-003510	Polyaxial Screw, 3.5 x 10mm
PC1-003512	Polyaxial Screw, 3.5 x 12mm
PC1-003514	Polyaxial Screw, 3.5 x 14mm
PC1-003516	Polyaxial Screw, 3.5 x 16mm
PC1-003518	Polyaxial Screw, 3.5 x 18mm
PC1-003520	Polyaxial Screw, 3.5 x 20mm
PC1-003522	Polyaxial Screw, 3.5 x 22mm
PC1-003524	Polyaxial Screw, 3.5 x 24mm
PC1-003526	Poly. Screw, 3.5 x 26mm
PC1-003528	Polyaxial Screw, 3.5 x 28mm
PC1-003530	Polyaxial Screw, 3.5 x 30mm
PC1-003532	Polyaxial Screw, 3.5 x 32mm
PC1-003534	Polyaxial Screw, 3.5 x 34mm
PC1-004010	Polyaxial Screw, 4.0 x 10mm
PC1-004012	Polyaxial Screw, 4.0 x 12mm
PC1-004014	Polyaxial Screw, 4.0 x 14mm
PC1-004016	Polyaxial Screw, 4.0 x 16mm
PC1-004018	Polyaxial Screw, 4.0 x 18mm
PC1-004020	Polyaxial Screw, 4.0 x 20mm
PC1-004022	Polyaxial Screw, 4.0 x 22mm
PC1-004024	Polyaxial Screw, 4.0 x 24mm
PC1-004026	Polyaxial Screw, 4.0 x 26mm
PC1-004028	Polyaxial Screw, 4.0 x 28mm
PC1-004030	Polyaxial Screw, 4.0 x 30mm
PC1-004032	Polyaxial Screw, 4.0 x 32mm
PC1-004034	Polyaxial Screw, 4.0 x 34mm
PC1-203520	Smooth Shank Polyaxial Screw, 3.5 x 20mm
PC1-203522	Smooth Shank Polyaxial Screw, 3.5 x 22mm
PC1-203524	Smooth Shank Polyaxial Screw, 3.5 x 24mm
PC1-203526	Smooth Shank Polyaxial Screw, 3.5 x 26mm
PC1-203528	Smooth Shank Polyaxial Screw, 3.5 x 28mm
PC1-203530	Smooth Shank Polyaxial Screw, 3.5 x 30mm
PC1-203532	Smooth Shank Polyaxial Screw, 3.5 x 32mm
PC1-203534	Smooth Shank Polyaxial Screw, 3.5 x 34mm
PC1-203536	Smooth Shank Polyaxial Screw, 3.5 x 36mm
PC1-203538	Smooth Shank Polyaxial Screw, 3.5 x 38mm
PC1-203540	Smooth Shank Polyaxial Screw, 3.5 x 40mm
PC-1400000	NorthStar OCT Set Screw
PC1-503530	Contoured Ti Rod, 3.5 x 30mm
PC1-503540	Contoured Ti Rod, 3.5 x 40mm
PC1-503550	Contoured Ti Rod, 3.5 x 50mm
PC1-503560	Contoured Ti Rod, 3.5 x 60mm
PC1-503570	Contoured Ti Rod, 3.5 x 70mm
PC1-503580	Contoured Ti Rod, 3.5 x 80mm
PC1-503590	Contoured Ti Rod, 3.5 x 90mm
PC1-503500	Contoured Ti Rod, 3.5 x 100mm
PC1-503502	Contoured Ti Rod, 3.5 x 120mm
PC1-503503	Straight Ti Rod, 3.5 x 200mm
PC1-504030	Contoured Ti Rod, 4.0 x 30mm

PART NUMBER	PART DESCRIPTION
PC1-504040	Contoured Ti Rod, 4.0 x 40mm
PC1-504050	Contoured Ti Rod, 4.0 x 50mm
PC1-504060	Contoured Ti Rod, 4.0 x 60mm
PC1-504070	Contoured Ti Rod, 4.0 x 70mm
PC1-504080	Contoured Ti Rod, 4.0 x 80mm
PC1-504090	Contoured Ti Rod, 4.0 x 90mm
PC1-504000	Contoured Ti Rod, 4.0 x 100mm
PC1-504002	Contoured Ti Rod, 4.0 x 120mm
PC1-504003	Straight Ti Rod, 4.0 x 200mm
PC-1013501	Rod-to-Rod Connector, 3.5mm SM
PC-1013502	Rod-to-Rod Connector, 3.5mm MD
PC-1013503	Rod-to-Rod Connector, 3.5mm LG
PC-1014001	Rod-to-Rod Connector, 4.0mm SM
PC-1014002	Rod-to-Rod Connector, 4.0mm MD
PC-1014003	Rod-to-Rod Connector, 4.0mm LG
PC1-104524	Polyaxial Screw, Favored Angle 4.5 x 24mm
PC1-104526	Polyaxial Screw, Favored Angle 4.5 x 26mm
PC1-104528	Polyaxial Screw, Favored Angle 4.5 x 28mm
PC1-104530	Polyaxial Screw, Favored Angle 4.5 x 30mm
PC1-104532	Polyaxial Screw, Favored Angle 4.5 x 32mm
PC1-104534	Polyaxial Screw, Favored Angle 4.5 x 34mm
PC1-105524	Polyaxial Screw, Favored Angle 5.5 x 24mm
PC1-105526	Polyaxial Screw, Favored Angle 5.5 x 26mm
PC1-105528	Polyaxial Screw, Favored Angle 5.5 x 28mm
PC1-105530	Polyaxial Screw, Favored Angle 5.5 x 30mm
PC1-105532	Polyaxial Screw, Favored Angle 5.5 x 32mm
PC1-105534	Polyaxial Screw, Favored Angle 5.5 x 34mm
PC1-513512	Straight CoCr Rod, 3.5 x 120mm
PC1-513520	Straight CoCr Rod, 3.5 x 200mm
PC1-514012	Straight CoCr Rod, 4.0 x 120mm
PC1-514020	Straight CoCr Rod, 4.0 x 200mm
PC1-523555	Transition Ti Rod, 3.5 to 5.5mm, 500mm
PC1-523560	Transition Ti Rod, 3.5 to 6.0mm, 500mm
PC1-524055	Transition Ti Rod, 4.0 to 5.5mm, 500mm
PC1-524060	Transition Ti Rod, 4.0 to 6.0mm, 500mm
PC1-014500	In-line Hook, 4.5mm
PC1-016000	In-line Hook, 6.0mm
PC1-024500	Angled Offset Hook, Right, 4.5mm
PC1-026000	Angled Offset Hook, Right, 6.0mm
PC1-034500	Angled Offset Hook, Left, 4.5mm
PC1-036000	Angled Offset Hook, Left, 6.0mm
PC1-020015	Top-loading Lateral Offset
PC1-023540	Parallel Top-loading
PC1-023560	Parallel Top-loading to 5.5/6.0mm
PC1-043540	Dual, Parallel, Top-loading
PC1-043560	Dual, Parallel, Top-loading to 5.5/6.0mm
PC1-063535	Parallel, Side-loading/Variable
PC1-063555	Parallel, 5.5/6.0mm Side-loading/Variable
PC2-120002	Curved Bone Probe
41-1010	Set Screw

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 the risks associated with your prescribed procedure.

SeaSpine DEVICE TECHNOLOGIES

For more information or to place an order, please contact:
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ALL OTHER INQUIRIES customerservice@seaspine.com

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

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