



Piranha™ Anterior Cervical Plate System

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System Contents:
Non-Sterile Implants--Single Use Only
Non-Sterile Instruments--Reusable

DESCRIPTION

The Spinal Elements Anterior Cervical Plate System consists of preassembled cervical plates, bone screws, and a locking shield. All components are made from titanium alloy (Ti-6Al-4V). The Spinal Elements Anterior Cervical Plate System is intended to provide stabilization of the cervical vertebrae for various indications (see below). The fixation construct is attached to the vertebral body of the cervical spine with bone screws using an anterior approach. Bone screws are available for variable or fixed angle implantation. The Spinal Elements Anterior Cervical Plate System is intended to be removed after solid fusion has occurred.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product. This document contains important information regarding the use of the Spinal Elements Anterior Cervical Plate System including indications, contraindications, warnings, precautions, and adverse effects. It should be read carefully in its entirety

INDICATIONS

The Spinal Elements Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) as an adjunct to fusion in the treatment of the following:

- Degenerative disc disease (DDD) – defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spinal Stenosis
- Tumors
- Trauma (i.e. fracture)

For product information or questions pertaining to sales and service, please contact Spinal Elements customer service or your local sales representative.

CONTRAINDICATIONS

The Spinal Elements Anterior Cervical Plate System is not designated or sold for any use except as indicated. DO NOT USE IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

Contraindications include, but are not limited to:

- Presence of overt infection and/or localized inflammation or foci or infections.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Suspected or documented metal allergy or intolerance.
- Any patient having inadequate tissue coverage over the operative site.
- Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
- Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
- Use in displaced, non-reduced fractures with bone loss.
- The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
- Any other medical or surgical condition which would preclude the potential benefit of surgery, such as elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis or a marked left shift in the WBC differential count.
- The physical contact of the Spinal Elements Anterior Cervical Plate System implants with metal implant made of anything other than implant grade titanium, such as stainless steel (ASTM F899) or other dissimilar metal.
- Situations with the absence or compromise of significant stabilizing elements.
- Use in the presence of any neural or vascular deficits or other compromising pathology, which may be further injured by device intervention.

MATERIALS

The Spinal Elements Anterior Cervical Plate System implants are manufactured from implant grade titanium (ASTM F136). Surgical instruments provided with the system are made of stainless steel.

CLEANING of INSTRUMENTS

1. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.
3. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with manufacturer's instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes. Pay particular attention to all crevices, recesses, pivots or threads on the devices.
4. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufactures recommended practices. Spinal Elements recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.
5. Sterilization: Place all instruments within the sterilization tray. Steam sterilize following AAMI standards and a validated cycle.
6. Conduct a final verification of the cleaning process by visually inspecting the device under normal room lighting conditions to verify that all of the foreign material has been removed.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case do not use and contact customer service or your Spinal Elements representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Spinal Elements representative for a replacement.

WARNINGS

Potential risks identified with the use of this device system, which may require additional surgery, include

- Device component fracture
- Loss of fixation

- No-union
- Fracture of the vertebra
- Neurological injury
- Vascular or visceral injury

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

STERILIZATION and HANDLING

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to clinical use. Instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be resterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery. The implants are for single use only.

The following sterilization cycle is approved for use:

Method	Cycle	Temperature	Exposure Time	Drying Times
Moist Heat	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

MAGNETIC RESONANCE ENVIRONMENT

The Anterior Cervical Plate 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 the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH A SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of the metal implants should only be done with proper equipment and should not occur at the point where the shield is positioned as the shield can

come off if bent at that point. It is recommended that contouring be gradual and that great care be used to avoid any notching, scratching, or reverse bending of the devices when contouring.. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

3. REMOVAL OF THE IMPLANT AFTER HEALING.

Metallic implants can loosen, fracture, corrode, migrate, possible increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed badequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the riskinvolved with a second surgery.

ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and follow the postoperative care regimen as instructed by his or her physician.

The Spinal Elements Anterior Cervical Plate System should be implanted only by surgeons who are completely experienced with the implantation of such devices and the required specialized spinal techniques. The Spinal Elements Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the cervical spine. A successful result is not achieved in every surgical case. Bone grafting must

be part of the spinal fusion procedure in which the system is used.

Reoperation to remove or replace implants may be required at any time due to medical reason or device failure. If corrective action is not taken, complications may occur.

These complications may include but are not limited to: Device corrosion with localized tissue reaction and pain. Device migration which may result in injury to soft tissue, visceral organs or joints. Loosening or disassembly of implant resulting in additional injury. Bending, loosening, or breaking of the implant making removal difficult, impractical or impossible. Abnormal sensations, discomfort or pain. Increased risk of infection. Bone loss due to stress shielding.

Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the Spinal Elements Anterior Cervical Plate System.

Proper patient selection and the patient's ability to comply with physician instructions and follow prescribed treatment regimen will greatly affect the results. It is important to screen patients and select and select optimal therapy given physical and/or mental activity requirements and/or limitations. If a surgical candidate exhibits any contraindication or is predisposed to any contraindication, DO NOT USE the Spinal Elements Anterior Cervical Plate System.

Patients who smoke have shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence.

Patients with poor bone quality are also poor candidates for surgery. The selection of patients for internal fixation requires consideration of the following to ensure the success of the procedure:

Patient's vocation or activity: If the patient's life style includes physical activities such as running, lifting, muscle strain, or excessive walking, the consequential forces can cause failure of the implant.
Patient's weight: An overweight patient can produce burden on the implant that can lead to failure of the implant.
Patient's mental condition: Various conditions that may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications include but are not limited to: senility, mental illness, alcoholism.
Patient's susceptibility to adverse conditions as a result of having a foreign material implanted in their body.

POSSIBLE ADVERSE EFFECTS

1. Occurrence of any adverse effects may require re-operation and removal of the implant.
2. Adverse effects may include but are not limited to:
3. Early or late loosening of components.
4. Disassembly, fretting, loosening, bending, breakage and/or migration of any component or component portion.
5. Foreign body reaction to the implants.
6. Pressure on the skin from component parts where there is inadequate tissue coverage over the implant, causing skin irritation.
7. Early or late infection.
8. Vertebral body fracture at, above, or below the level of surgery.

9. Implants cutting through bone, especially soft osteoporotic, osteopenic, or cancellous bone.
10. Bone forming around the implant, making removal difficult or impossible.
11. Non-union (pseudarthrosis) or bone fracture.
12. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
13. Neurovascular compromise including
14. Hemorrhage of blood vessels.
15. Cessation of growth of the operated portion of the bone.

LIMITED WARRANTY

Spinal Elements products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness are hereby disclaimed. If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Spinal Elements for current information.

INFORMATION



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