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PIRANHA™ ANTERIOR CERVICAL PLATE SYSTEM
IMPLANTS AND INSTRUMENTATION

This package insert covers the Piranha™ Anterior Cervical Plate System and Manual Surgical Instruments that are used for the implantation of this system.

GENERAL INFORMATION

The Spinal Elements Anterior Cervical Plate System consists of cervical plates, bone screws, and a locking shield. All components are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. 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.

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
- Sponylolisthesis
- Spinal Stenosis
- Tumors
- Trauma (i.e. fracture)

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:

1. Presence of overt infection and/or localized inflammation or foci or infections.
2. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
3. Suspected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
6. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
7. Use in displaced, non-reduced fractures with bone loss.
8. The presence of marked bone absorption or sever metabolic bone disease that could compromise the fixation achieved.
9. 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.
10. 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.
11. Situations with the absence or compromise of significant stabilizing elements.
12. Use in the presence of any neural or vascular deficits or other compromising pathology, which may be further injured by device intervention.

WARNINGS

Implants and instruments are provided non-sterile. Instruments must be cleaned and sterilized before use. Implants may be processed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced surgeons with training in the use of spinal devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of the device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion. Bone grafting must be part of the spinal fusion procedure in which the system is used.

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.

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 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 risk involved with a second surgery.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

MAGNETIC RESONANCE ENVIRONMENT

The Piranha 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.

POSSIBLE ADVERSE EFFECTS

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, persistent CSF leakage, meningitis.

8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
9. Neurovascular compromise including hemorrhage of blood vessels.
10. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
11. Loss of bladder control or other types of urological system compromise.
12. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
13. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
14. Bone forming around the implant, making removal difficult or impossible
15. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.
16. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
17. Non-union (pseudo-arthrosis), delayed union, mal-union.
18. Pressure on the skin from component parts where there is inadequate tissue coverage over the implant, causing skin irritation.
19. Cessation of any potential growth of the operated portion of the spine.
20. Loss of or increase in spinal mobility or function.
21. Bone loss or decrease in bone density, possibly caused by stress shielding.
22. Inability to perform the activities of daily living.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. All implants and instruments should be inspected prior to use. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be sterilized before use.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. Caution should be taken not to over-tighten threaded components, including instruments, implants, and interfaces between implants and instruments.
6. Implants should not be reused (used in additional patients) under any circumstances.
7. Forming or bending of the plates should be kept to a minimum. Bending of the plate near the screw holes should be avoided. Distortion of the screw holes may prevent proper locking of the screw. If bending of the plate is performed, only benders supplied with the system should be used for such bending. Notching of the plate may reduce its fatigue life. Care should be taken to avoid bending the plate multiple times in the same location.
8. If the surgeon experiences difficulty in inserting screws (hard bone, etc.), drilling and/or tapping prior to screw insertion is recommended.
9. A drill guide should be used to limit the angle of drilling and subsequent insertion of screws. Insertion angles greater than what drill guides allow may prevent adequate locking of the screw.

10. To help prevent screws from disassociating from the plate postoperatively, the cam lock mechanism for each screw should be engaged. The cam lock is activated by using the screwdriver to turn the cam lock one quarter turn over the screw.
11. Before the closing of the soft tissues, all screws should be secured to the plate by activating the cam lock mechanism as described.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Anterior cervical plate implant components are for temporary internal fixation during the formation of a spinal fusion. Implants are not meant to support a load for an indefinite period. After the formation of a fusion, the device may be removed.

CLEANING AND MAINTENANCE

GENERAL INFORMATION

All devices must be free of packaging material prior to reprocessing. All instruments must be free of bio-contaminants prior to reprocessing. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

CLEANING AND MAINTENANCE

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.
Disassemble all components to provide maximum exposure for cleaning.
All devices must be processed manually prior to automated cleaning.
Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.
Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents.
Caution: Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. An automated system may be used as a follow-up method to manual cleaning.

AUTOMATED CLEANING INSTRUCTIONS

All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

PRE-AUTOMATED WASHER: MANUAL CLEANING

1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at <43°C. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.

3. Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)

AUTOMATED CLEANING

4. Transfer the instruments into the automated washer for processing. Position the instruments to allow for proper drainage. Ensure the instruments stay in place and do not touch or overlap so that the design features are accessible for cleaning and do not retain liquid. Process per the cycle below. These are minimum validated parameters:

Phase	Recirculation Time	Water Temp	Detergent Type (if applicable)
Pre-wash	300 seconds	Cold tap water	N/A
Wash 1	300 seconds	65.5°C	Endozime AW Plus or equivalent per manufacturer's instructions
Wash 2	300 seconds	65.5°C	Endozime AW Plus or equivalent per manufacturer's instructions
PURW Rinse	10 seconds	82.2°C	N/A
Drying	7 minutes	115.5°C	N/A

5. If needed, dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
6. Visually examine devices to ensure all visible soil has been removed.
7. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.

MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at <43°C. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
3. Rinse thoroughly for 2 minutes with warm distilled, de-ionized, or reverse osmosis water. (27°-44°C)
4. Allow instrument to air dry in a clean area. Blow lumens with clean air using filtered air source or syringe.

Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed. Visually inspect for damage and/or wear.
Note: If any damage or wear is noted that impairs the function of the instrument, contact your Spinal Elements representative for a replacement.

STERILIZATION

Devices provided non-sterile and must be sterilized before use. Non-sterile devices should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. These sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization

wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

INFORMATION

REF	Catalog Number	MAT	Material
LOT	Batch Code	QTY	Packaged Quantity
	Manufacturer		Date of Manufacture
	Caution, Consult Accompanying Documents		Do Not Re-Use

NON-STERILE Device Not Sterile

℞ Only Prescription Only

Instruction for Use are provided electronically at ifu.spinalelements.com

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Patents: patent.spinalelements.com

For additional information regarding any of Spinal Elements' devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.