



SURGICAL TECHNIQUE GUIDE

WHITE • PEARL

PREFERRED ANGLE ANTERIOR CERVICAL PLATE

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Disclaimer:

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon before and during surgery as to the best mode of treatment for each patient. Please reference the 510K or package insert for additional information and a complete list of intended indications, warnings, precautions, and other medical information.

FEATURES & BENEFITS

The White Pearl Preferred Angle ACP is a pioneering fixation system that is ideal for the treatment of degenerative or traumatic cervical disorders. Its flexibility allows for placement by guidewire for a minimally invasive or traditional open-style theater.

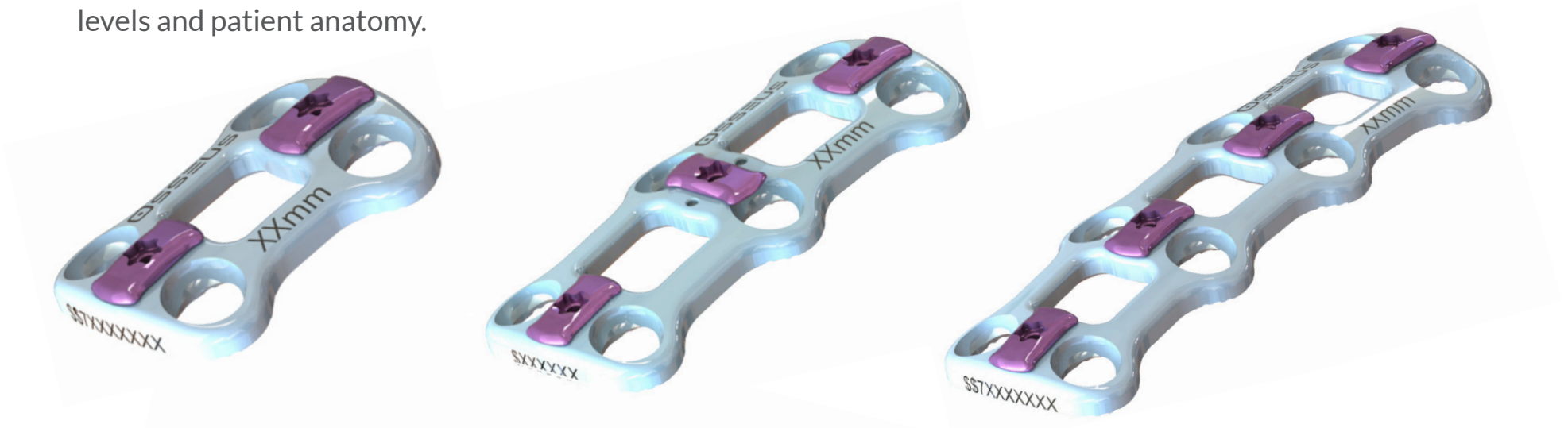
- Pre-lordosed low profile plates
- Cannulated design for precise plate placement
- Manual lock with visual and tactile confirmation
- Cortical and traditional screw options
- ± 20 degrees of cephalad/caudal angulation



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1. Choosing Plate

Following decompression and graft insertion, Surgeon will chose appropriate plate based on the number of levels and patient anatomy.



2. Plate Placement and Fixation

Place the Wire Inserter midline of the chosen anchor vertebrae and penetrate the cortical bone. Insert the K-Wire through the Inserter, into the vertebral body, and remove the inserter.



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Slide the plate cannulation (in the locking mechanism) over the K-Wire and ensure the plate is centered on the vertebral body.



Load a fixation pin or screw onto the Fixation Pin Inserter and insert at the chosen level to temporarily fixate the plate. Remove the K-Wire. NOTE: Discard fixation pin and K-Wire after use.

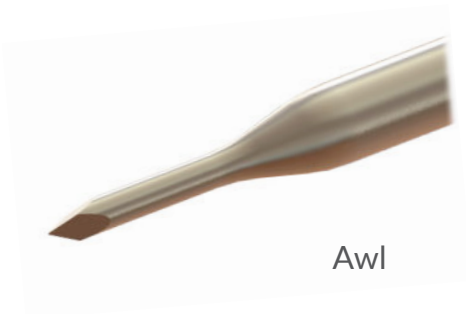


Optional use of plate bender for special anatomic conditions. Insert the plate into the bender and gently squeeze the handles. Do not bend on the locking mechanism.

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3. Awl, Tap, or Drill

Use the bone awl to puncture the cortical bone and follow with the screw tap.



Awl



Tap



Drill

NOTE: Awl and drills must be used with a Drill Guide.

If using the drill, place the chosen drill guide securely against the plate and align with the bone screw hole.

Choose appropriate length drill and drill until positive stop bottoms out on the guide.

*Drills are 1mm shorter than their associated screw length.



Variable



Double



Fixed

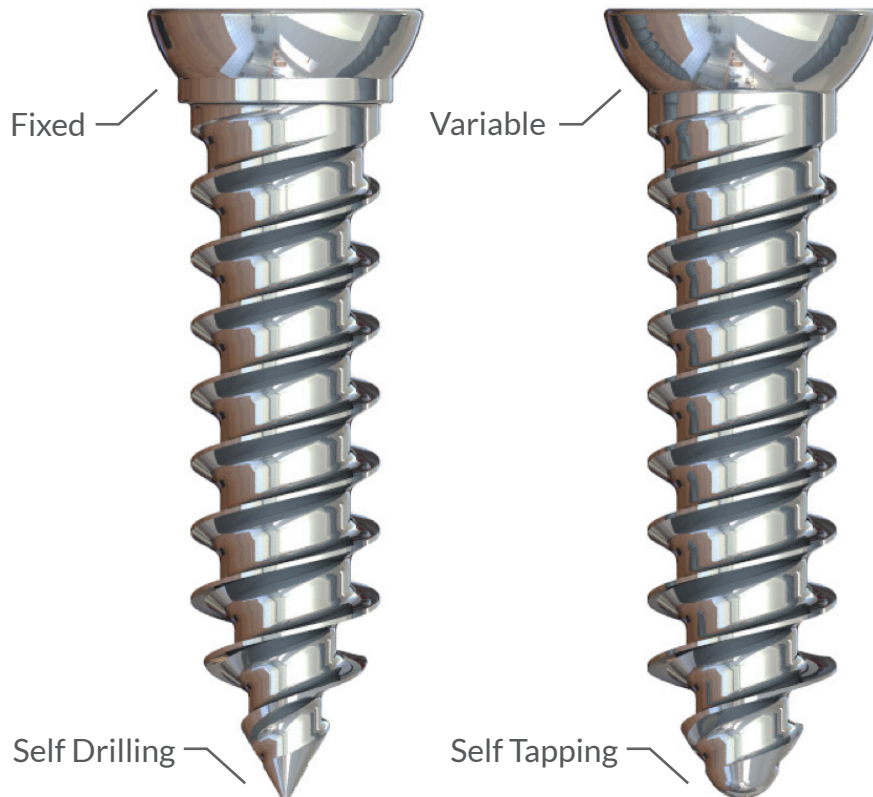
NOTE: Drill should be discarded after use.

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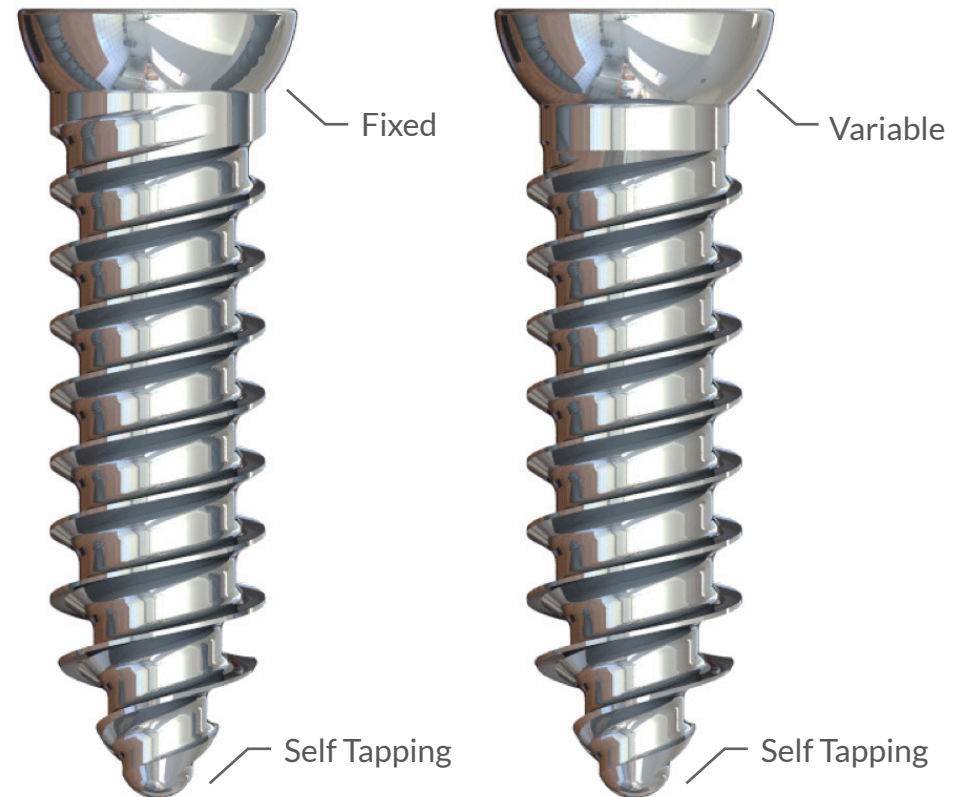
4. Screw insertion

Surgeon should choose screw type and length based on preference and patient anatomy. Attach selected screw to the screwdriver by pushing the tip of the driver into the screw while it is still in the caddy.

Ø3.75mm



Ø4.25mm



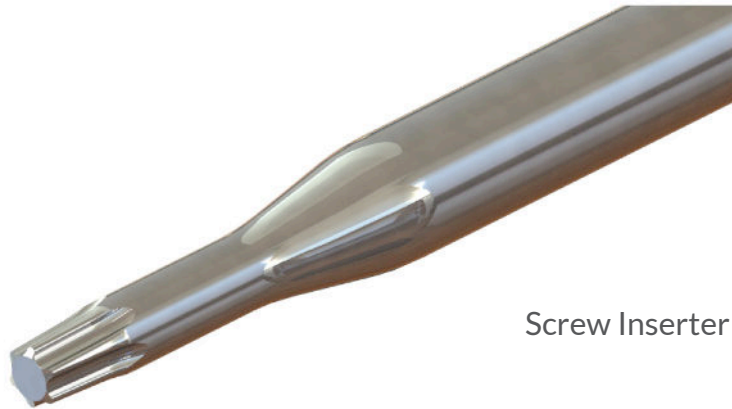
Insert the screw into the selected prepared pilot hole and repeat at all remaining levels. Confirm bone screw positions with fluoroscopy.

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5. Final Locking

Place the screw inserter into the mating hex feature in the locking mechanism and turn clockwise 90 degrees. Tactile and visual confirmation will be apparent when properly locked.

REMOVAL: Place screw inserter into the mating hex feature in the locking mechanism and turn 90 degrees counter clockwise. Repeat on all locks. Insert screwdriver into bone screws and turn counter clockwise. Repeat at all remaining bone screws. Remove plate.



Screw Inserter



Locking Mechanism

IMPORTANT PRODUCT INFORMATION

CERVICAL PLATES

Catalog No.	Description
2100-1108	CERV PLATE, 1-LEVEL, 8.5mm, CANN, PREF ACP
2100-1110	CERV PLATE, 1-LEVEL, 10mm, CANN, PREF ACP
2100-1112	CERV PLATE, 1-LEVEL, 12mm, CANN, PREF ACP
2100-1114	CERV PLATE, 1-LEVEL, 14mm, CANN, PREF ACP
2100-1116	CERV PLATE, 1-LEVEL, 16mm, CANN, PREF ACP
2100-1118	CERV PLATE, 1-LEVEL, 18mm, CANN, PREF ACP
2100-1120	CERV PLATE, 1-LEVEL, 20mm, CANN, PREF ACP
2100-1122	CERV PLATE, 1-LEVEL, 22mm, CANN, PREF ACP
2100-1124	CERV PLATE, 1-LEVEL, 24mm, CANN, PREF ACP
2100-1126	CERV PLATE, 1-LEVEL, 26mm, CANN, PREF ACP
2100-2120	CERV PLATE, 2-LEVEL, 20mm, CANN, PREF ACP
2100-2122	CERV PLATE, 2-LEVEL, 22mm, CANN, PREF ACP
2100-2124	CERV PLATE, 2-LEVEL, 24mm, CANN, PREF ACP
2100-2126	CERV PLATE, 2-LEVEL, 26mm, CANN, PREF ACP
2100-2128	CERV PLATE, 2-LEVEL, 28mm, CANN, PREF ACP
2100-2130	CERV PLATE, 2-LEVEL, 30mm, CANN, PREF ACP
2100-2132	CERV PLATE, 2-LEVEL, 32mm, CANN, PREF ACP
2100-2134	CERV PLATE, 2-LEVEL, 34mm, CANN, PREF ACP

Catalog No.	Description
2100-2137	CERV PLATE, 2-LEVEL, 37mm, CANN, PREF ACP
2100-2140	CERV PLATE, 2-LEVEL, 40mm, CANN, PREF ACP
2100-2143	CERV PLATE, 2-LEVEL, 43mm, CANN, PREF ACP
2100-2146	CERV PLATE, 2-LEVEL, 46mm, CANN, PREF ACP
2100-3134	CERV PLATE, 3-LEVEL, 34mm, CANN, PREF ACP
2100-3136	CERV PLATE, 3-LEVEL, 36mm, CANN, PREF ACP
2100-3139	CERV PLATE, 3-LEVEL, 39mm, CANN, PREF ACP
2100-3142	CERV PLATE, 3-LEVEL, 42mm, CANN, PREF ACP
2100-3145	CERV PLATE, 3-LEVEL, 45mm, CANN, PREF ACP
2100-3148	CERV PLATE, 3-LEVEL, 48mm, CANN, PREF ACP
2100-3151	CERV PLATE, 3-LEVEL, 51mm, CANN, PREF ACP
2100-3154	CERV PLATE, 3-LEVEL, 54mm, CANN, PREF ACP
2100-3157	CERV PLATE, 3-LEVEL, 57mm, CANN, PREF ACP
2100-3160	CERV PLATE, 3-LEVEL, 60mm, CANN, PREF ACP
2100-3163	CERV PLATE, 3-LEVEL, 63mm, CANN, PREF ACP
2100-3166	CERV PLATE, 3-LEVEL, 66mm, CANN, PREF ACP
2100-3169	CERV PLATE, 3-LEVEL, 69mm, CANN, PREF ACP

IMPORTANT PRODUCT INFORMATION

CERVICAL SCREW VARIATIONS

Ø3.75mm, Self-Drilling, Variable

Catalog No.	Description
2100-0110	CERV SCREW, VARIABLE, SELF-DRILLING, 3.75x10mm, DBL LEAD, PREF ACP
2100-0112	CERV SCREW, VARIABLE, SELF-DRILLING, 3.75x12mm, DBL LEAD, PREF ACP
2100-0114	CERV SCREW, VARIABLE, SELF-DRILLING, 3.75x14mm, DBL LEAD, PREF ACP
2100-0116	CERV SCREW, VARIABLE, SELF-DRILLING, 3.75x16mm, DBL LEAD, PREF ACP

Ø3.75mm, Self-Drilling, Fixed

Catalog No.	Description
2100-0210	CERV SCREW, FIXED, SELF-DRILLING, 3.75x10mm, DBL LEAD, PREF ACP
2100-0212	CERV SCREW, FIXED, SELF-DRILLING, 3.75x12mm, DBL LEAD, PREF ACP
2100-0214	CERV SCREW, FIXED, SELF-DRILLING, 3.75x14mm, DBL LEAD, PREF ACP
2100-0216	CERV SCREW, FIXED, SELF-DRILLING, 3.75x16mm, DBL LEAD, PREF ACP

Ø3.75mm, Self-Tapping, Variable

Catalog No.	Description
2100-0310	CERV SCREW, VARIABLE, SELF-TAPPING, 3.75x10mm, DBL LEAD, PREF ACP
2100-0312	CERV SCREW, VARIABLE, SELF-TAPPING, 3.75x12mm, DBL LEAD, PREF ACP
2100-0314	CERV SCREW, VARIABLE, SELF-TAPPING, 3.75x14mm, DBL LEAD, PREF ACP
2100-0316	CERV SCREW, VARIABLE, SELF-TAPPING, 3.75x16mm, DBL LEAD, PREF ACP

IMPORTANT PRODUCT INFORMATION

CERVICAL SCREW VARIATIONS

Ø3.75mm, Self-Tapping, Fixed

Catalog No.	Description
2100-0410	CERV SCREW, FIXED, SELF-TAPPING, 3.75x10mm, DBL LEAD, PREF ACP
2100-0412	CERV SCREW, FIXED, SELF-TAPPING, 3.75x12mm, DBL LEAD, PREF ACP
2100-0414	CERV SCREW, FIXED, SELF-TAPPING, 3.75x14mm, DBL LEAD, PREF ACP
2100-0416	CERV SCREW, FIXED, SELF-TAPPING, 3.75x16mm, DBL LEAD, PREF ACP

Ø4.25, Self-Tapping, Variable

Catalog No.	Description
2100-0710	CERV SCREW, VARIABLE, SELF-TAPPING, 4.25x10mm, DBL LEAD, PREF ACP
2100-0712	CERV SCREW, VARIABLE, SELF-TAPPING, 4.25x12mm, DBL LEAD, PREF ACP
2100-0714	CERV SCREW, VARIABLE, SELF-TAPPING, 4.25x14mm, DBL LEAD, PREF ACP
2100-0716	CERV SCREW, VARIABLE, SELF-TAPPING, 4.25x16mm, DBL LEAD, PREF ACP

Ø4.25mm, Self-Tapping, Fixed

Catalog No.	Description
2100-0810	CERV SCREW, FIXED, SELF-TAPPING, 4.25x10mm, DBL LEAD, PREF ACP
2100-0812	CERV SCREW, FIXED, SELF-TAPPING, 4.25x12mm, DBL LEAD, PREF ACP
2100-0814	CERV SCREW, FIXED, SELF-TAPPING, 4.25x14mm, DBL LEAD, PREF ACP
2100-0816	CERV SCREW, FIXED, SELF-TAPPING, 4.25x16mm, DBL LEAD, PREF ACP

IMPORTANT PRODUCT INFORMATION

IMPLANT AND INSTRUMENT LIST

Catalog No.	Description
2100-6010	10mm DRILL
2100-6012	12mm DRILL
2100-6014	14mm DRILL
2100-6030	VARIABLE DRILL GUIDE
2100-6040	FIXED DRILL GUIDE
2100-6050	DOUBLE DRILL GUIDE
2100-6090	AWL
2100-6060	3.0x8mm TAP
2100-6080	SCREW INSERTER
2100-6082	QC SCREW INSERTER
2100-6190	FIXATION PIN INSERTER
2100-6070	FIXATION PIN
2100-6170	FIXATION SCREW
2100-6110	PLATE BENDER
2100-6120	NEURO CALIPERS
2100-6140	IN-LINE QUICK CONNECT HANDLE
2100-6150	WIRE INTRODUCER

IMPORTANT PRODUCT INFORMATION

Indications for Use: The White Pearl Preferred Angle Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spinal stenosis.

Single Use Only.

PRECAUTIONS: Intervertebral body fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the [company] cages. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

CONTRAINDICATIONS: Spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system) - Reduced bone density, which does not guarantee a sufficient resting stability (e.g. osteoporosis) - Fractures - Tumors - Active infection - Allergy to tantalum or PEEK - Signs of local inflammation - Fever or leukocytosis - Morbid obesity - Pregnancy - Mental illness - Suspected or documented allergy or intolerance to composite materials - Any case not needing a fusion - Any case not described in the indications - Any patient unwilling to cooperate with postoperative instructions - Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery - These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth - Spondylolisthesis unable to be reduced to Grade 1 - Any case where the implant components selected for use would be too large or too small to achieve a successful result - Any case that requires the mixing of metals from two different components or systems - Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality - Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance - Prior fusion at the level to be treated - Any other condition which would preclude the potential benefits of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marketed left shift in the WBC differential count.

ST WP-001
Revision B

IMPORTANT PRODUCT INFORMATION

Warning: An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results.

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

The risk of device expulsion and migration is higher without the use of supplemental fixation.

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON

The White Pearl Preferred Angle Anterior Cervical Plate System was developed to promote the fixation and stabilization of vertebral spine, however, built only to assist the bone regeneration and not to substitute the structures of human skeleton. To provide biomechanical stability, the implants provide a natural way to the regeneration of bone tissues. The system is implanted by the anterior approach.

The implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

The White Pearl Preferred Angle Anterior Cervical Plate consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6Al-4V ELI). The White Pearl Preferred Angle Anterior Cervical Plate is intended to provide stabilization of the cervical vertebrae for various indications. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and/or self-drilling bone screws using an anterior approach. Bone screws are available for fixed angle or variable angle implantation.

INDICATIONS

The White Pearl Preferred Angle Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudarthrosis,
- failed previous fusion,
- spinal stenosis

LEANING/DISINFECTION

Preparation for cleaning:

Clean the device until there is no visual contamination of the instruments directly after application (within a maximum of 2 h).

For this use only running water or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency, be suitable for the disinfection of instruments and be compatible with the instruments (see "Material Resistance"). For manual removal of impurities only a soft brush or a clean soft tissue is to be used, in no case metal brushes or steel wool.

Rinse all lumens five (5) times by application of a single-use syringe (minimum volume 10ml).

Manual cleaning:

1. Soak instruments for a minimum of one (1) minute in enzymatic detergent.
 2. Use a cleaning brush and/or cloth to remove visible soil.
 3. Rinse thoroughly with warm water.
 4. Check the instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.
- Devices with challenging design features (cannulations, T-handle interfaces, hinged instruments, instruments with crevices):
1. Immerse instrument and soak for a minimum of five (5) minutes in enzymatic detergent.
 2. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features:
 - a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
 - b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
 - c. Scrub around hinged/mating surface areas with a brush or pipe cleaner.
 - d. Scrub crevices using a cleaning brush or pipe cleaner.
 3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
 4. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.

Automatic washing:

Pre-cleaning:

Devices without challenging design features:

- Pre-cleaning is not required for used reusable medical devices and containment devices that do not have dried-on soil. They can be placed directly into the automatic washer for cleaning.

Devices with challenging design features:

1. Immerse in enzymatic detergent for five minutes and scrub cannulas, holes, hinged mating surfaces, joints, and crevices with tight-fitting brushes (pipe cleaners, etc.) and where possible, use a twisting action.
2. Sonicate in fully opened position for a minimum of ten (10) minutes in warm enzymatic detergent.
3. Rinse with warm water.

Automatic Washing Cycle:

1. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations and holes positioned to drain).
2. Run the automatic wash cycle - Minimum cycle parameters:
 - five-minute cold prewash
 - five-minute enzyme wash at 43° C minimum temperature
 - five-minute detergent wash at 55° C minimum temperature
 - one-minute rinse at 45° C minimum temperature
3. Check instruments for visible soil (see "Verifying cleaning"). Repeat cleaning if soil is visible and reinspect.

Verifying cleaning:

1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.
Note: Rinse the instruments thoroughly with warm water following hydrogen peroxide testing.
3. Repeat cleaning if not visibly clean and re-inspect.

Inspection and function testing:

Device/Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

Maintenance:

- For devices with hinged/mating surfaces, surgical-grade lubricant should be added to the hinged area while in the open position.
- If the any of instruments exhibit any of the flaws listed above adequately dispose of the devices.

STERILIZATION

Implants and instruments of the Osseus White Pearl Preferred Angle Anterior Cervical Plate System are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Cycle:	Pre-Vacuum
Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	40 Minutes
Condition:	Wrapped
Wrap:	The wrap should be FDA cleared for the proposed cycle specifications

USAGE

WARNING: The safety and effectiveness of the anterior cervical plate system have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the cervical spine, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTION: The implantation of the White Pearl System should be performed only by experienced spinal surgeons with specific training in the use of this anterior cervical system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and

metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need for an additional surgery to remove the device. Refer to the individual system surgical technique manuals for additional important information. A surgical technique can be obtained from the local representative or Osseus Fusion Systems, LLC.

White Pearl components should not be used with components from other manufacturers. Stainless steel components may interfere with the quality of imaging obtained using MRI, and may cause galvanic corrosion.

The White Pearl Preferred Angle Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The White Pearl Preferred Angle Anterior Cervical Plate System has not been tested for heating or migration in the MR environment. The safety of White Pearl Preferred Angle Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation is contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity (The patient must not weigh more than 150 kg), certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

INFORMATION TO THE PATIENTS

The surgeon must discuss with the patient all physical and psychological limitations inherent to the use of implants, including the rehabilitation stage, physiotherapy and the use of orthopedic devices, according to medical prescription. The surgeon must warn about the risk of physical activities.

Patients with vigorous work or activities (lift weight, run, jump, or any excessive muscular work) that require a compressive resistance in the spine must be warned about the necessity of a substitution in future, to avoid the risks of fail. Smokers show a tendency of failure in the bone fusion and must be warned about this condition. Patients with degenerative disease in advanced stage can be susceptible to a shorter life time of the fixation system so this surgical technique is faced as a palliative technique.

Titanium alloy is non-ferromagnetic materials and do not offer any restriction about environment or equipment (X-ray, computerized axial tomography and magnetic resonance).

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

- CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
- IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
- MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase.
- PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
 - The patient's weight.** An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

- The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
- A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
- Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
- Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

- SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should only be done with proper equipment. The operating surgeon should 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. Bending of screws will significantly decrease the fatigue life and may cause failure.
- CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur: 1) Corrosion, with localized tissue reaction or pain; 2) Migration of implant position resulting in injury; 3) Risk of additional injury from postoperative trauma; 4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; 5) Pain, discomfort, or abnormal sensations due to the presence of the device; 6) Possible increased risk of infection; and 7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
- ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

POSSIBLE ADVERSE EFFECTS

- Bending or fracture of implant.
- Loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Infection, early or late.
- Nonunion, delayed union.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
- Bursitis.
- Paralysis.
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Death.
- Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malposition of implant adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
- Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
- Damage to lymphatic vessels and/or lymphatic fluid exudation.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.

Symbol	Used For	Symbol	Used For
	Single use only		Catalog number
	Lot number		Use by YYYY-MM-DD or YYYY-MM
	See package insert for labeling limitations		Do not use if package is damaged or open
	Non-sterile. To be sterilized prior to use.		CAUTION: USA law restricts this device to sale by or on the order of physician.