Ocata Anterior Cervical System®

Product Instructions for Use

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Non-Sterile Product ***SINGLE USE***

BEFORE USING THIS PRODUCT READ THE FOLLOWING THOROUGHLY.

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

Important Information on the Ocata Anterior Cervical System

Description:

The Ocata Anterior Cervical System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.

The Ocata Anterior Cervical System consists of a variety of shapes and sizes of bone plates, screws (available in self-drilling or self-tapping configurations), and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The Ocata Anterior Cervical System implant components are made from Ti-6Al-4V ELI titanium alloy in accordance with ASTM F136. Do not use any of the Ocata Anterior Cervical System components with the components from any other system or manufacturer.

Indications, Contraindications, and Possible Adverse Effects:

Indications:
The Ocata Cervical System is intended for anterior interbody screw fixation of the cervical spine from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine as an adjunct to fusion for 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), trauma (including fractures and dislocations), tumors, spondylolisthesis, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. This device system is intended for anterior cervical intervertebral body fusions only.

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

Contraindications:
Contraindications for use of the Ocata Anterior Cervical System include:

- Infection, local to the operative site
- Local inflammation, with or without fever or leukocytosis
- Pregnancy
- Diseases or conditions other than those specifically described in the **Indications** section
- Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
- Where attempted correction exceeds the limits of physiological conditions
- Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
- Metabolic disorders that may impair bone formation
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Any case not needing a bone graft and fusion or where fracture healing is not required
- Inability to restrict high activity level
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Obesity
- Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
- Any medical or surgical condition, which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Suspected or documented metal allergy or intolerance

Contraindications may be relative or absolute and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Potential Adverse Events:

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery. Possible operative/postoperative adverse reactions that may require medical or surgical intervention (e.g., implant removal with or without re-instrumentation) include:

- Loosening, disassembly, bending, breakage and/or migration of any or all of the components.
- Foreign body (allergic) reactions to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing implant or graft extrusion through the skin, irritation, and/or pain.
- Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
- Collapse of a fracture and/or fusion site.
- Device failure.
- Attachment device pullout, especially with short constructs and osteoporotic bone.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Wound infection, deep or superficial, which may require implant removal and/or other medical interventions.
- Laminar erosion.
- Dural tears leading to cerebrospinal fluid fistula or pseudo meningocele.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation. Delayed onset has occurred even when evoked potential was unaffected during surgery.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise. Urinary tract infection.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, micro fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseudarthrosis). Delayed union. Malunion.
- Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, epidural bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium.
- Development of respiratory problems, deep vein thrombosis, thrombophlebitis, and/or pulmonary embolism that may be fatal; may be due to patient position and/or length of the surgical procedure.
- Change in mental status.
- Pain, possibly severe in nature.
- Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:

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. The Ocata Anterior Cervical System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Ocata Anterior Cervical System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning 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 the Ocata Anterior Cervical System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. The implants are not prostheses.

Physician Note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

Other preoperative, intraoperative, and postoperative warnings are as follows:
Some metals, polymers, chemicals, and other materials utilized with orthopedic implants have been known to cause cancer and other adverse body reactions, or reports in the literature have suggested such causation. Any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; surgical candidates suffering from this disease should be warned accordingly.

Implantation foreign material in tissues can elicit an inflammatory reaction. Current literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.

Metal sensitivity has been reported following exposure to orthopedic implants.

The Ocata Anterior Cervical System instrumentation should only be used after the surgeon has had adequate training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the Ocata Anterior Cervical System is available upon request. This technique is not a substitute for training and is for general informational purposes only.

Components from other anterior cervical plating systems should not be used with the Ocata Anterior Cervical System because compatibility has not been established.

Do not use implants made from dissimilar metals (such as cobalt chromium-molybdenum alloy or stainless steel) in contact with components of the Ocata Anterior Cervical System; otherwise, galvanic corrosion may occur.

If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant(s) surface. The plates must not be repeatedly or excessively bent. Do not reverse bend the plate.

All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include mechanical malfunction and transmission of infectious agents

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

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

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

Implant Selection:

The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be subject to additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery.

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

- The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The Ocata Anterior Cervical System™ components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
- All sets should be carefully checked for completeness and all components should be carefully inspected prior to all surgeries.

Intraoperative:

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Imaging system should be used whenever possible to facilitate surgery.
- Misuse of the instruments or implant components may cause injury to the patient or operative personnel.
- Autogenous bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Before closing the soft tissues, all of the screws should be verified to be seated and locked into the plate. Recheck the tightness of all screws after finishing, ensuring that none has loosened during the tightening of the other screws and all remain locked.

Postoperative:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- The Ocata Anterior Cervical System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: corrosion, with localized tissue reaction or pain, migration of implant position possibly resulting in injury, risk of additional injury from post-operative trauma, bending, loosening and/or breakage, which could make removal impractical or difficult, pain, discomfort, or abnormal sensations due to the presence of the device, possible increased risk of infection, and/or bone loss due to stress shielding.
- While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Ocata Anterior Cervical System components should ever be reused under any circumstances.

Packaging:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Kalitec Medical.

Cleaning and Decontamination:

Implants and instruments of the Ocata Anterior Cervical System are supplied clean and NOT STERILE, and must be sterilized prior to use.

All instruments and implants must be thoroughly cleaned (prior to cleaning disassembly of the screwdriver is required) using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Kalitec Medical. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Some device materials may develop changes in mechanical, physical or chemical characteristics under conditions of repeated use, cleaning and re-sterilization that may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications.

The instruments should be inspected and checked following a thorough cleaning to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Precleaning:

Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Manual Cleaning:

Prepare an enzymatic cleaning solution per manufacturer's specifications. Separate dissimilar metal instruments and disassemble all instruments. Fully immerse and soak all instruments in enzymatic cleaner for 15 minutes. Fill all cannulations with enzymatic detergent. Use a small soft-bristle brush to remove visible soil from all surfaces of the instrument while fully immersed in the solution paying special attention to remove soil from hinges, jaws, tips, box locks, and ratchets. Agitate the instruments in the solution while scrubbing. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Actuate any movable parts to loosen any trapped soil. Rinse instruments under warm (38-49°C) running water until all evidence of detergent is removed. Place the instrument into a bath containing warm (38-49°C) water. Agitate the instruments by hand for at least three minutes. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Prepare an enzymatic cleaning solution to the manufacturer's specifications using distilled water. Ultrasonicate devices for 10 minutes, ensuring the devices are completely submerged. Rinse instruments under warm running water for at least one minute or until all evidence of detergent is removed. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Dry with clean lint-free cloth and/or allow to air dry.

Automated Cleaning:

Automated cleaning should be performed after manual removal of debris using the manual cleaning process identified above.

The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with the approved efficacy (e.g., FDA approval, complying with and validated according to the ISO 15883 series) should be used.

Place the instruments in a suitable washer/disinfector basket and process following the minimum recommended wash cycle parameters below:

Cycle	Description
1	Prewash- Cold tap water- 2 minutes
2	Enzymatic wash – Hot tap water - 43C min, 5 minutes using enzymatic detergent
3	Detergent wash - Hot tap water – 55C min- 5 minutes using neutral detergent
4	Rinse 1 - Hot tap water - 2 minutes
5	Rinse 2 - Pure water - 90C- 1 minute
6	Dry – Hot air – 90C- 15 minutes

Sterilization:

The Ocata Anterior Cervical System instruments and implants are provided non-sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the process parameters below:

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

Note: *Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.*

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to Kalitec Medical.

Product Complaints:

Any Health Care Professional who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Kalitec Medical or its representative. Further, if any of the implanted Ocata Cervical System components ever malfunctions, Kalitec Medical or its representative should be notified immediately.

If any Kalitec Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Kalitec Medical should be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Kalitec Medical understand the cause of the complaint.

Further Information:

If further information is needed or required, please contact:

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