S140 ANTERIOR CERVICAL PLATE SYSTEM

Instructions for Use

IFU 4140-001, Rev A

DESCRIPTION:
The Anterior Cervical Plate System consists of various shapes and sizes of plates, screws, and associated instruments. The plates are available in multiple lengths to accommodate single or multi-level surgeries. The plates and screws are manufactured from titanium alloy (ASTM F136) and the locking clip is manufactured from Nitinol (ASTM F2063). The Anterior Cervical Plate System requires the use of general and specific surgical instruments.

IMPORTANT NOTE:
This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIALS:
All plates and screw components of the Anterior Cervical Plate System are manufactured from Titanium Alloy (Ti-6Al-4V) according to ASTM F-136. The locking clip is manufactured from Nickel-Titanium alloy (NiTi) according to ASTM F2063.

INDICATIONS FOR USE:
The Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following conditions:

- degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- pseudoarthrosis
- tumor
- and failed previous fusion

WARNING: The Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

GENERAL CONDITIONS OF USE:
The safe implantation of anterior cervical plate systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Anterior Cervical Plate System should be performed only by experienced spinal surgeons with specific training in the use of anterior cervical plate systems. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Anterior Cervical Plate System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Under no circumstances should any component of the Anterior Cervical Plate System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. After spinal fusion occurs, these devices serve no functional purpose and may be removed. The decision to explant the surgical devices is made between the surgeon and the patient with due regard to the risks associated with a second surgery compared to the benefits of such.

CONTRAINDICATIONS:
Contraindications to using the Anterior Cervical Plate System are similar to those of other anterior cervical plate systems and consist of the following:

1. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the plate and screws and their fixation without risk of impairment to anatomical structures or physiologic performance.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
7. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

WARNINGS AND CAUTIONS:

1. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using the noted validated sterilization cycle parameters.
2. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
3. The Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The Anterior Cervical Plate System has not been tested for heating or migration in the MR environment.
4. If bony fusion does not occur within an expected period of time, the plates and screws may break due to the high and sustained loading of these devices. This has been noted in patients with pseudoarthrosis, delayed or non-union and can result in the need to revise the device(s).

POTENTIAL RISKS:
Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. 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.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that 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 among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. 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. Internal fixation devices, such as plates and screws that come into contact with other metal objects, must be made from like or compatible materials.

PATIENT SELECTION:
The following factors can be extremely important to the eventual success of the procedure:

1. 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.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative 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.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis 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:

Only experienced spinal surgeons with specific training in the use of anterior cervical plate systems should implant anterior cervical plate systems, because this is a technically demanding procedure presenting a risk of serious injury to the patient

1. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
2. Correct implant handling is vital. Only contour metal implants with proper equipment. Avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
3. Bending the construct. Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured, contour a new construct correctly rather than reverse bending the over-contoured construct.
4. Implant removal after healing. If the device is not removed after the completion of its intended use, any of the following complications may occur:
    a. Corrosion, with localized tissue reaction or pain;
    b. Implant migration resulting in injury;
    c. Risk of additional injury from postoperative trauma;
    d. Bending, loosening, and/or breakage, which could make removal impractical or difficult;
    e. Pain, discomfort, or abnormal sensations due to device presence;
    f. Possible increased risk of infection;
    g. Bone loss due to stress shielding. Carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove implant thus eliminating the risks involved in a second surgery.
5. 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. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient 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. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

ADVERSE AFFECTS:
In addition to the obvious risk that any orthopaedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopaedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopaedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While formation wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Titanium™ Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

HANDLING OF IMPLANTS

1. Receipt – Carefully unwrap and handle non-sterilized implants and instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and/or possible traceability to the manufacturer.

CLEANING - GENERAL
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can 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 possible improper functioning of the device. KYOCERA Instrument IFU 4001-001 provides more additional information about proper care and handling of the instruments in the Anterior Cervical Plate System.

ULTRASONIC CLEANERS – can be used with hot water per the manufacturers' recommended temperature, however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment.

CLEANING AND DECONTAMINATION OF INSTRUMENTS

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure. If cleaning must be delayed, place instruments in a covered container with appropriate enzymatic detergent to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood. Loosen and/or disassemble instruments with removable parts. All instruments must be thoroughly cleaned before use.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL® Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** The surgical instruments used with the Anterior Cervical Plate System do not require disassembly with the exception of the Screw Removal Tool Assembly (2140-001-015). Prior to cleaning, disassemble the Screw Removal Tool Assembly by removing the inner shaft. Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all hard to reach areas are accessed.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap.
4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
5. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
6. **Inspection:** After cleaning/disinfection, instruments should be visually inspected for contamination. If contamination is still visible, repeat steps 3, 4 and 5. If instruments continue to have visual contamination, do not use instruments and contact Kyocera Customer Service for further instructions.
7. **Preparation and Assembly:** After cleaning/disinfection and inspection, the inner shaft should be threaded (rotated) back into the Screw Removal Tool, and visually inspected. Do not use if any wear or damage is observed. Do not overtighten the inner shaft, two revolutions of the inner shaft is adequate to capture the inner shaft to the Screw Removal Tool. There is no additional mechanical testing required.

8. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. KYOCERA has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

STERILITY:
The Anterior Cervical Plate System components and instruments are provided non-sterile. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	30 minutes minimum; 40 minutes maximum

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

The packaging in which non-sterile implants and instruments are supplied should not be used for sterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

Do not sterilize implants in contact with instruments or implants of other materials. Metallic oxide could transfer to the implant, initiating an unacceptable conditioning.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling KYOCERA Medical Technologies, Inc. at (909) 557-2360.

Caution: Federal Law USA restricts this device to sale by or on the order of a physician.

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