FORTOS-C™

Anterior Cervical Plating System

IFU 008 Rev 1 (CN3654 1/2021)

DEVICE DESCRIPTION:

The FORTOS-C™ Anterior Cervical Plating System implant 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 implantation of the FORTOS-C Anterior Cervical Plating System is via an anterior surgical approach.

The FORTOS-C Anterior Cervical Plating System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The FORTOS-C Plates include a blocking mechanism that cover the heads of the bone screws to reduce the potential for screw back-out. The blocking mechanisms come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The FORTOS-C Anterior Cervical Plating System implant components are made from titanium alloy such as described by ASTM F136. This material is not compatible with other metal alloys. Do not use any of the FORTOS-C Anterior Cervical Plating System components with the components from any other system or manufacturer.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EFFECTS

INDICATIONS:

The FORTOS-C Anterior Cervical Plating System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. 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.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POTENTIAL ADVERSE EFFECTS: All of the possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

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. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. 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.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. 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.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseud-arthrosis). Delayed union. Mal union.
15. Loss of spinal mobility or function. Inability to perform the activities of daily living.
16. Bone loss or decrease in bone density, possibly caused by stress shielding.
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retro pulsed graft.
19. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
20. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium
21. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
22. Change in mental status.
23. Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse effects.

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 FORTOS-C Anterior Cervical Plating System is only a temporary implant used for the correction and stabilization of the spine. 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 FORTOS-C Anterior Cervical Plating 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 FORTOS-C Anterior Cervical Plating 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.

MAGNETIC RESONANCE ENVIRONMENTS:

The FORTOS-C Anterior Cervical Plating System has not been evaluated for safety and compatibility in the MR environment. The FORTOS-C Anterior Cervical Plating System has not been tested for heating or migration in the MR environment.

PHYSICIAN NOTE:

Although 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.

CAUTION:

FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS:

IMPLANT SELECTION:

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic 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 metal fatigue and consequent breakage, bending, 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.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. 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.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. 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 FORTOS-C Anterior Cervical Plating System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Refer to the surgical technique guide for instruction on how to implant the FORTOS-C construct.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. 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. 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.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. 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.
6. Bone cement should not be used 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.
7. Before closing the soft tissues, all screws should be fully seated in the plate and below the blocking mechanism. Recheck the tightness of all screws. Caution: Excessive torque on the screw threads may cause the threads to strip in the bone, reducing fixation. Carefully rotate each blocking mechanism over the heads of the bone screws. Rotate each blocking mechanism to reach its stop position. Failure to cover the screw heads with the blocking mechanism may result in screw back out.

POSTOPERATIVE:

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

1. 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.
2. 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.
3. 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.
4. 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.
5. The FORTOS-C Anterior Cervical Plating 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 may 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:
    a. Corrosion, with localized tissue reaction or pain.
    b. Migration of implant position possibly 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 the presence of the device.
    f. Possible increased risk of infection.
    g. Bone loss due to stress shielding.

    The surgeon makes the final decision on implant removal. If safe and practical, bone fixation devices can 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.

6. The FORTOS-C Anterior Cervical Plating System implants should never 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 should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used.

DECONTAMINATION AND CLEANING:

All instruments and implants must be disassembled (if applicable), and thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field, or (if applicable) returned to Centinel Spine. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Follow the enzymatic cleaner of detergent manufacturer's instruction for use for correct exposure time, temperature, water quality, and concentration.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. No visual contamination shall be present after cleaning, so the instruments shall be re-cleaned if they are not visually clean.

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

STERILIZATION:

Unless noted otherwise on the package labeling, the FORTOS-C Anterior Cervical Plating System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Item	**Exposure time at 132 °C (270 °F)**	**Drying times**
Wrapped Tray	4 min	20-30 min

Remove all packaging materials prior to sterilization. Use only FDA-cleared wraps. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and sterilize before handling or returning to Centinel Spine.

PRODUCT COMPLAINTS:

Please contact Centinel Spine regarding any deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of FORTOS-C Anterior Cervical Plating System.

Centinel Spine should be notified immediately if malfunction or deterioration in the characteristics and / or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, user or other person, or to a serious deterioration in their state of health.

When reporting a complaint, please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint.

complaints@centinelspine.com

FURTHER INFORMATION:

Recommended directions for use of this system (surgical techniques) are available. Please contact:

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SYMBOLS: