FUSE ACP Anterior Cervical Plate System

℞ Only

A. DEVICE DESCRIPTION

The FUSE ACP Anterior Cervical Plate System is intended for anterior cervical intervertebral body screw fixation from C2 to T1. Rigid fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

Implant components consist of a variety of shapes and sizes of plates, bone screws and associated instruments. Locking caps are pre-assembled to the plates. They cover the heads of the bone screws to reduce the potential for screw back-out. With this locking mechanism, implant components can be rigidly locked into many different configurations to suit the individual pathology and anatomical conditions of the mature patient.

They are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

Implants must not be used with the components from any other system or manufacturer in a construct.

B. INDICATIONS

The FUSE ACP Anterior Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1.

The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2) Spondylolisthesis
3) trauma (including fractures),
4) Spinal Stenosis
5) tumors
6) deformity (defined as kyphosis, lordosis, or scoliosis),
7) pseudarthrosis, and/or 8) failed previous fusions.

C. CONTRAINDICATIONS

The FUSE ACP Anterior Cervical Plate System is not designed, intended or sold for uses other than those indicated.

Should not be used if patient has or shows following conditions.

1. Any abnormality present which affects the normal process of bone fusion including, but not limited to;
   - Rapid joint disease, disc disease, osteomalacia, or osteoporosis involving the spine
   - Bone absorption, osteopenia, primary or metastatic tumors involving the spine
   - Certain metabolic disorders affecting osteogenesis
2. Any medical or surgical condition which would preclude the potential benefit of spinal surgery with implantation including, but not limited to;
   - Presence of tumors, congenital abnormalities leading grossly distorted anatomy, elevation of sedimentation rate unexplained by other diseases
   - Elevation of white blood cell count (WBC), or marked left shift in the WBC differential count
   - Radio- or chemotherapy for cancer, kidney dialysis
3. Unstable burst and compression fractures of vertebral body
4. Active systemic infection or infection localized to the site of operation or adjacent to the spine or spinal structures
5. Marked local inflammation
6. Immature patient
7. Pregnancy
8. Suspected or documented allergy, intolerance or oversensitive to any of the implant materials.
9. Old age, mental defect, alcoholic, medicinal poisoned or neurological disk muscle disorder which may cause fail during surgery, complications after surgery or disability of following post-operative instructions.
10. Anomalous neural anatomy
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. Any patient unwilling to co-operate with postoperative instructions.
13. Fever or leukocytosis.
14. Morbid obesity who can show abnormal reaction caused failure of fusion which places unsafe load level on the device during the healing period or failure of the device itself due to excess weight near surgery area. Obesity is defined according to the W.H.O. standards.
15. Diagnosis result came out to be other than indication for use and physician judge that the product cannot be used on the patient.
16. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
17. Any case not needing a bone graft and fusion or where fusion is not required.
18. Open wounds.
19. Any case not described in the indications.
20. Any case requiring the mixing of metals from different components
21. Grossly distorted anatomy due to congenital abnormalities

These contra-indications are relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

This device system is intended for anterior cervical intervertebral body fusions only. Although not absolute contraindications, conditions to be considered as potential factors for not using this device include Severe bone resorption.

D. POTENTIAL COMPLICATIONS AND ADVERSE SIDE EFFECTS

The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon should be discussed with the patient preoperatively. A listing of possible adverse events or complications include but are not limited to:

1. Inappropriate or improper surgical placement of other fixation device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
2. Implant migration, Disassembly, bending, dislocation and/or breakage of any or all of the device components may result from inadequate implantation, latent infection, premature loading of the device or trauma.
3. Early or late loosening of any or all of the components.
4. Displacement of a screw due to incorrect positioning or implant size.
5. Additional surgery (revision surgery) may be necessary to correct some of these anticipated adverse events.
6. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
7. Bone loss or decrease in bone density, possibly caused by stress shielding or unbalanced physical pressure.
8. Heterotopic bone formation.
9. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
10. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Vertebral endplate injury or subsidence of the device into vertebral body(ies).
13. Bursitis, hemorrhage, hematoma, thrombus, occlusion, seroma, edema, embolism, stroke, excessive bleeding, myocardial infarction, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
14. Superficial or deep-set infection and inflammatory phenomena at the implantation site - Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures also have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.
15. Soft tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
16. Neuropathy, neurological deficits (transient or permanent), monoplegia, bilateral paraplegia, reflex deficits, arachnoiditis, and/or muscle loss.
17. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tinglinpag sensation, sensory loss and/or spasms.
18. Neurological damage (a breach of the dura mater, lesion of a spinal root) from surgical trauma
19. Delayed union(late bone fusion), Non-union(cessation of any potential growth of the operated portion of the spine or no visible fusion mass or pseudoarthrosis) or Mal-union
20. Loss of spinal mobility or function.
21. Inability to perform the activities of daily living.
22. Change in mental status.
23. Death.
24. Infection
25. Dysphagia
26. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
27. Bronchopulmonary disorders or development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
28. Damage or transformation of the product, collapse of vertebra body because of dislocation or expulsion of the implant before bone fusion, which requires another surgical procedure.
29. Damage or transformation of the product due to heavy physical exercise or pressure.
30. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
31. Foreign body (allergic) reaction to implants, debris, corrosion products, including inflammation, staining, tumor formation and/or autoimmune disease.
32. Fracture, microfracture, resorption, damage, penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
33. Discontinued growth of fused bone at, above and/or below the surgery level
34. Retropulsed graft
35. Gastrointestinal complications such as gastritis, ileus
36. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
37. Loss of bowel and/or bladder control or other types of urological system compromise.
38. Graft donor site complications including pain, fracture, infection, or wound healing problems.

Other than above listed events may occur. The surgeon must warn the patient of these adverse events as deemed necessary. And when some of the events such as device component fracture, loss of fixation, non-union, fracture of the vertebrae, and necrosis of bone, neurological injury and vascular or visceral injury etc., may require for additional surgical procedure.

E. WARNINGS AND CAUTIONS

⚠WARNIG

1. While the expected life of spinal implant components is difficult to estimate, its life span is finite. These components are made of foreign materials and placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, these devices are affected and cannot be expected to withstand the activity level and loads of normal healthy bone.
2. Do not use this product other than its indication. Cannot be inserted other than indicated area and cervical vertebrae is not allowed.
3. The FUSE ACP Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended 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 Pinehurst Anterior cervical Plate 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.
4. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues. The implant must be discarded.
5. This product is one time use only and can never be re-used in any occasions. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for implants which have been reused.
6. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
7. All instruments are delivered non-sterilized and therefore, must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
8. A wrong choice of implant size may cause damage to the product and may become the reason of unsuccessful surgery. Therefore, product's design and size should be selected after full consideration of patient's weight, amount of exercise, area of vertebral checked by X-ray, levels of implantation, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system. Please refer to "the choice of implant".
9. It cannot be used with other product without validation regarding safety and effectiveness. If it is used with other product, Solco Biomedical Co., Ltd do not take any responsibility.
10. Where material oversensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
11. It is important for surgeon and medical staff to be well-informed of the following information and give it to patient before the procedure, in order to be warned of the potential consequences and ensure success of the surgical implantation:
    - Clinical data show that patients who smoke tend to have less optimum bony consolidation, as well as patients who are undernourished, alcoholic, obese, or patients with drug abuse, muscle weakness or nerve paralysis.
    - To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
    - The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting and crushing.
    - Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations.
    - These implants do not present any known risk of interference with other medical equipment.
    - Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.
12. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.
13. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

⚠CAUTION

1. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
2. The benefit of spinal fusions utilizing any intervertebral body fusion device has not been adequately established in patients with stable spines.
3. A condition of senility, mental illness, or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
4. Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. Knowledge and experience in spinal surgery are pre-requisites.
5. 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.
6. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Also, patients who smoke or abuse alcohol are poor candidates for spinal fusion as someone who should be advised and warned of the consequences of the fact that an increased incidence of non-union has been reported with such patients.
7. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions or many extenuating circumstances may compromise the results.
8. Non-Sterilized implants must be placed on sterilization for use.
9. Never reuse the implant under any circumstances. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.
10. The compatibility needs to be verified before use with other product.
11. The products must be stored away from contact with metal or abrasive materials to prevent cracks or scratches. The product maybe damaged from loads due to scratches not visible with naked eyes.
12. The use of implants may interfere with the anatomical structure or physiological performance of the patient. It should be reviewed carefully about radiological diagnosis and its side effects before the procedure.
13. FUSE ACP Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of FUSE ACP Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
14. Without solid bone fusion, this device cannot be expected to support the cervical spine indefinitely and may fail due to bone-metal interface, metal or bone failure.
15. Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

F. Surgical Procedure

1. Pre-operative preparations

a. This Instructions for Use has to be read with the related surgical technique before use these implants
b. Inspection and tentative assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage or preparation for the surgery.
c. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
d. All instruments are delivered non-sterilized and therefore, must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.

e. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
f. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients must be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient must understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it.
g. Patients must be advised of all above potential complications and adverse side effects as risks. For example, patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients must be advised of this fact and warned of the potential consequences.
h. The type of construct to be assembled for the case should be determined by surgeon prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
i. 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.

2. The choice of Implant

a. Product's design and size must be selected by surgeon considering patient's weight, amount of exercise, and area of segment to be operated. Accurate decision to determine transplant size and operation techniques must be made by surgeon. Mistake to select wrong product may damage the product and cause unsuccessful surgery. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
b. Alterations will produce defects in surface finish and eventual breakage of the implant due to internal stresses which may become the focal point. Therefore, cutting, contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If such alteration occurred during insertion or adjustment, they must not be implanted and must be replaced with new one.
c. FUSE ACP Anterior Cervical Plate System is NOT compatible with implants from other manufacturers unless otherwise specified. If it is used with any other product, Solco biomedical Co., Ltd does not take any responsibility.
d. All damaged, expired or mishandled implants. Such implants must be handled by hospital personnel trained in the general procedures involving contaminant removal. Never reuse an implant, even though it may appear undamaged. If too much impact has been applied to the product or the product has been contacted to contaminated object or ground, then do not use the product and replace with the new one which is sterilized.

3. Intra-operative

a. After fully disinfect operation spot, use appropriate surgical instrument to incise skin.
b. Operation must be made by surgeon and must consider the patient's condition (Quality of bone, pathology, safety of spine).
c. This product should be inserted according to surgical technique manual and special medical literature. Then Surgeon should use proper surgical instrument according to surgical method and purpose.
d. In order to avoid damage, make sure there is enough space for inserting the implant in the intervertebral body.
e. The rotated with excessive torque by the locking guide driver, the locking guide may be detached or damaged.
f. It is advised not to move patient from surgery area until the implant and adjacent bones are fully fixed by surgical implantation.

4. Post-operative

a. The product cannot always withstand activity and load levels equal to those placed on normal and healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result. Physician and/or surgeon are required to give a notice to the patient of this information as well as temporary restrictions such as limit on physical activities and few other restrictions to avoid re-surgery due to damage of product.
b. Reprocessing implants and instruments is required after surgical use as instructed by the manufacturer. Cleaning, sterilization, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

5. Removal

a. Before removing the product, risk of an additional surgery to patient and difficulty of removing the product should be considered.
b. To remove the product surgeon can use the included removal Tool in the tray and an additional instrument.

G. PACKAGING

1. This product is disposable, supplied as non-sterilized and individually packed, packed by transparent PE bag. The packing should not be damaged before usage.
2. Packing should be removed before sterilization.
3. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

H. CLEANING

In accordance with the reprocessing manual, Instrument should be cleaned and sterilized before use.
Implant should not be cleaned and only non-sterilized implant should be sterilized before use.
Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

1. Cleaning before sterilization
   If the packing is not damaged, the instruments do not need to be washed. Otherwise, they must be washed with a damp gauze pad or wipe to remove all gross visible soil. The cleaning has to be done before sterilization; ultrasonic wash with water soluble neutral cleaner is advised. Cleaner's composition and cleaning method must follow by the reprocessing manual. The solution must be within pH range 6-8.
2. Avoid cleaning the product in high temperature for long period.
3. Use of corrosive object including abrasive sponges and metal brushes must be avoided.
4. Verify that the product is in operating condition without any foreign substance in them after cleaning.
5. Unacceptable cleaning agents
   It is inadequate to use strong acidic or basic cleaning solution such as sulphuric acid, nitric acid, or chloric acid. Sodium hydroxide (NaOH) is also prohibited.
6. Cautions when cleaning
   Forbid using abrasion product or instrument. After cleaning, product's capability and condition, existence of foreign substance in implant should be checked. For this each hospital's cleaning instrument and method need to be verified.

I. Drying

Surgical instrument and product should be dried without any water before sterilization.

J. STERILIZATION

All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization.
For storage before sterilization and surgery, use sterilized storage tray. To achieve a sterility assurance level of not less than 10-6, all non-sterile implants and instruments must be autoclave sterilized using the following validated cycle parameter

The individual products are recommended to be steam sterilized by the hospital in a gravity displacement

Method	Cycle Type	Temperature	Exposure time	Drying Time
Steam	Gravity (Wrapped)	132℃ (270℉)	15 min	30 min
Steam	Pre-vaccuum (Wrapped)	132℃ (270℉)	4 min	30 min

If different sterilization method is used, verification is required to show that the sterilization method is valid enough to be safe for usage.
Depend on sterilization method, hospital should check the certification and needs to check sterilization time and temperature regularly.
If sterilization is done with paper filter, filter should be changed every time it's used. If water is remained on sterilized tray and product you need to sterilize it again.

K. STORAGE

1. If non used product is exposed to waste, it must be sterilized and dried for storage. Product must be stored at a dry room temperature of 1 to 25° C and must be away from direct ray of light.
2. The product must be stored away from contact with metal or abrasive materials or corrosive environments to prevent damages such as cracks, scratches nick or notch. Also, the product maybe damaged from loads due to scratches not visible with naked eyes.

L. COMPLAINTS

If you are unsatisfied with the product or have complaints, please contact our representative.
Especially if you suspect the product is having problems, please notify us immediately. If our products have caused damage, side effect, fatal injury to patient, please contact us immediately with the provider's information via fax, telephone, or letter.
For all other complaints, please provide us product catalog number, lot number, your contact information including your name and telephone number, and detailed information about problems you are having.
For more information, please contact us below.

SYMBOL TRANSLATION

Symbol	Description	Symbol	Description
	DO NOT REUSE		MANUFACTURER
LOT	BATCH CODE or LOT NUMBER		DATE OF MANUFACTURE
REF	CATALOGUE NUMBER		WARNING
NON STERILE	NON STERILE		CAUTION, CONSULT ACCOMPANYING DOCUMENT
Mat :	MATERIAL	QTY	QUANTITY
	CONSULT INSTRUCTIONS FOR USE		KEEP AWAY FROM SUNLIGHT
	USED BY DATE		DO NOT USE IF PACKAGE IS DAMAGED
	KEEP DRY		TEMPERATURE LIMIT
Rx only	PRESCRIPTION ONLY	DIST. BY	Distributed by

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