Cabo™ Anterior Cervical Plate System - English

Rx Only: Caution: Federal Law restricts this device to sale by or on the order of physician

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DESCRIPTION

The Cabo™ ACP (Anterior Cervical Plate) 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 Cabo ACP System is via an anterior surgical approach.

The Cabo ACP 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 Cabo Plates include locking pins that cover the heads of the bone screws to reduce the potential for screw back-out. The locking pins come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The Cabo ACP 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 Cabo ACP System components with the components from any other system or manufacturer. The manufacturer expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS FOR USE

The Cabo ACP 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, pseudarthrosis, and failed previous fusion.

IMPLANT MATERIALS

Titanium 6Al-4V ELI per ASTM F136

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- 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.
- 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.
- Suspected or documented metal allergy or intolerance.
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- Graft donor site complications including pain, swelling, or wound healing problems.
- Atelactasia, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise including fertility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

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

POSSIBLE ADVERSE EVENTS

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

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction 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 skin penetration, irritation, and/or pain. Burstitis Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomingocele, fistula, persistent CSF leakage, meningitis.
- 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, neuraoma, or tingling sensation.
- 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.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, 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. Mal union.
- 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.

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 Cabo ACP 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 Cabo ACP 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 Cabo ACP 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.

MRI SAFETY

The device 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 the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
CLEANING AND DECONTAMINATION

All instruments that have been previously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field. The following recommendations are for the manual cleaning and decontamination of surgical instruments. These recommendations are considered guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user. Automated cleaning systems differ between hospitals and therefore must be qualified by the hospital.

Manual Cleaning Procedure

Step Procedure
1 Remove all gross visible soil with a damp gauze pad or wipe.
2 Prepare an enzymatic cleaning solution (such as Prolystica® 2X Enzymatic) per manufacturer’s instructions.
3 Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
4 Transfer the instruments to fresh cleaning solution (such as Prolystica® 2X Enzymatic). Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solution. Be sure that thorough scrubbing also includes any lumens with an appropriate size brush. Actuate device to allow access to hard to reach areas.
5 Thoroughly rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.

Automated Cleaning Procedure

Step Procedure
1 Remove all gross visible soil with a damp gauze pad or wipe. Special attention will be required to examine products with tight crevices, voids, and lumens. Lumens may require pre-cleaning with dampened soft bristle brushes and tight crevices, voids, lumens should be flushed with a syringe.
2 Prepare an enzymatic cleaning solution (such as Prolystica® 2X) per manufacturer’s instructions. Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
3 Transfer items to a washer and run a cycle with the parameters listed in the following steps.
4 PRE-WASH: Cold tap water [2 minutes].
5 ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer’s recommendations, hot tap water [4 minutes].
6 DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer’s recommendations, hot tap water (66°C/150°F) [2 minutes].
7 RINSE 1: Rinse, hot tap water [2 minutes].
8 RINSE 2: Purified water rinse (66°C/180°F) [15 seconds].
9 DRYING: Hot air dry (82°C/180°F) [12 minutes].
10 Remove items from the washer and remove any residual moisture with a lint free clean cloth.

PRECAUTION: 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 The implants, components and instrumentation in the Cabo ACP System are to be sterilized by the hospital prior to surgery.

Double wrap trays using FDA-cleared sterilization wraps (2 wraps). The recommended sterilization cycle will provide a Sterility Assurance Level of (SAL 10^-6). Following AAMI ST79 guidelines, the validated sterilization cycle for a fully loaded tray is:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Steam Pre-vacuum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Exposure Time</td>
<td>270°F (132°C) for 4 minutes</td>
</tr>
<tr>
<td>Drying Time</td>
<td></td>
<td>20-30 minutes</td>
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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 must be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to SeaSpine.

SURGICAL TECHNIQUE

This package insert is designed to assist in using the product and is not intended to provide information on surgical technique. Contact a SeaSpine Representative, customerservice@seaspine.com or +1-760-727-8399 for a Surgical Technique Guide.

IMPLANT SELECTION Verify that all parts and necessary instruments are present prior to surgery, including sizes larger and smaller than those that are expected for use. The construct should be assembled prior to surgery.

PREOPERATIVE WARNINGS

- 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.
- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned 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 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 personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The Cabo ACP 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.

INTRAOPERATIVE WARNINGS

- Any available 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 neurologic 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.
- 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 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.
- Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

POSTOPERATIVE WARNINGS

- 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 component 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 Cabo ACP 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:
  
  • Corrosion with localized tissue reaction or pain
  • Migration of implant position possibly resulting in injury
  • Risk of additional injury from postoperative 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
  • 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.

• Implants should never be reused under any circumstances. A used implant should be discarded. While the implant may appear undamaged, it may have small defects or internal stress patterns and if implanted, could fail to perform as intended and pose safety risks to the patient. The risks include, but are not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.

COMPLAINTS
Immediately notify SeaSpine or a SeaSpine representative by phone, fax or email regarding complaints, malfunctions or adverse events associated with this product. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service.

PRODUCT INFORMATION DISCLOSURE
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