Altus Spine Cervical Plate System

NON STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT:

This document is designed to assist in using the Altus Spine Cervical Plate System. It is not a reference for surgical techniques.

CAUTION:

Federal law (USA) restricts this device to sale and use by or on the order of a physician.

Single Use!

As with all orthopedic implants, implants and implanted system components should **never** be reused under any circumstances. An implant, once used, should be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

DESCRIPTION:

The Altus Spine Cervical Plate System is a semi-constrained fixation system consisting of cervical plates, bone screws and the instruments necessary to implant the system. All implant components are made from a titanium alloy (Ti-6Al-4V). The Altus Spine Cervical Plate System is intended to provide stabilization of the cervical vertebrae for various indications (see below).

PRODUCT CONFIGURATIONS:

All components of the Altus Spine Cervical Plate System are provided non-sterile and must be cleaned and sterilized prior to use. All implantable portions of the Altus Spine Cervical Plate System are made from implant grade titanium meeting the requirements of ASTM Standard F-136.

The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping or self-drilling bone screws using an anterior approach. Bone screws are available for fixed or variable angle implantation. The Altus Spine Cervical Plate System is intended to be removed after solid fusion has occurred.

INDICATIONS FOR USE:

The Altus Spine Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spine fusions in 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), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudosarthrosis and/or failed previous fusions. The Altus Spine Cervical Plate System can be implanted in the sub-axial cervical spine from the C3 through C7 levels.

Warning:

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

CONTRAINDICATIONS:

The Altus Spine Cervical Plate System components are contraindicated in the following patients and/or situations:

1. Overt infection or distant foci of infection;
2. Local inflammation with or without fever or leukocytosis;
3. Pregnancy;
4. Diseases or conditions other than those specifically described in the indications section;
5. Use in the posterior elements (pedicles) of the cervical, thoracic or lumbar vertebrae;
6. Where attempted corrections exceeds the limits of physiological conditions;
7. Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions;
8. Metabolic disorders that may impair bone formation;
9. Inadequate bone stock to support the device, or severe osteopenia;
10. Inability to restrict high activity level;
11. Poor prognosis for good wound healing (e.g.: decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);
12. Failure, unwillingness, or inability to explant the device after bony fusion;
13. Morbid obesity;
14. Mental illness;
15. Drug or alcohol abuse;
16. Metal sensitivity or allergy to implant materials;
17. Presence of congenital abnormalities;
18. Spinal anatomy, tumors or any other complication which prevents secure implantation or decreases the useful life of the device;
19. Any circumstances not described in the indications for use.

WARNINGS:

1. Some metals, polymers, chemicals and other materials used with orthopedic implants have been shown 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.
2. Implantation of 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.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt and chromium) are present in medical grade stainless steel and cobalt chrome alloys.
4. Mixing different metal types can accelerate the corrosion process. Stainless steel and titanium implants must not be used together when building a construct. Component parts from other manufacturers should not be used with the Altus Spine Cervical Plate System. As with all spinal implants, components should never be reused under any circumstances.
5. The Altus Spine Cervical Plate System is not intended as the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without the development of a solid fusion mass the spinal implant will eventually bend, loosen or fracture.
6. Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS:

1. The implantation of cervical plate systems should be performed only by experienced spinal surgeons with specific training in the use of this cervical plate system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Surgical techniques for the Altus Spine Cervical Plate System are available upon request. This technique is not a substitute for training and is for general informational purposes only.
2. The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage. The implants and instruments must be cleaned and sterilized before use.
3. If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. The plates must not be repeatedly or excessively bent. Do not reverse bend the plate.
4. The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.
5. The patient should be instructed in the limitation of physical activities which would place excessive stresses on the implant or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in/out of bed or other daily activities while minimizing rotational and bending stresses.
6. The surgeon must consider removal of the implant after healing as the implant can loosen, fracture or corrode even after fusion has occurred. The risks and benefits of a second surgery must be carefully evaluated.

ADVERSE EFFECTS:

While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of materials foreign to the body that are placed within the body to support potential fusion of the spine. However, due to the many biological, mechanical and physiochemical factors that affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Possible adverse effects include, but are not limited to the following:

- Paralysis, complete or incomplete. Delayed onset may occur even when evoked potential was unaffected during surgery;
- Dural tear leading to cerebrospinal fluid fistula or pseudo menigocele;
- Other spinal cord injuries not otherwise described due to positioning of the spinal attachment device;
- Epidural bleeding;
- Abnormal sensations;
- Radioculopathy and/or mylopathy;
- Loosening, bending, breaking, disassembly and/or migration of the system components, or device failure;
- Collapse of a fracture and/or fusion site;
- Corrosion at the screw/plate interface contributing to breakage and/or pseudoarthrosis;
- Discomfort or pain, soft tissue erosion, esophageal erosion or perforation, or protrusion due to prominent implanted hardware;
- Attachment device pullout, especially with short constructs or osteoporotic bone;
- Implant or graft extrusion through the skin;
- Postural deformities, pain, skin breakdown or residual neural compression due to kyphosis or lordosis occurring at the top of the segment being implanted;
- Bone loss or fracture due to stress shielding;
- Foreign body reaction to the device including tumor formation, autoimmune disease, metallosis and/or scarring;
- Non-union, pseudoarthrosis, or delayed union;
- Cessation of growth at the fusion site;
- Discitis, arachnoiditis and/or other types of inflammation;
- Hemothorax;
- 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;
- Decubitus ulcer;
- Wound infection, deep or superficial, which may require implant removal and/or other medical interventions;
- Wound dehiscence, delayed wound healing or hematoma;
- Pain or discomfort, possibly severe in nature;
- Urinary tract infection;
- Blood vessel damage and/or blood loss or hemorrhage;
- Fracture(s) of the bone;
- Gastrointestinal, urological and/or reproductive system compromise including sterility, impotency and/or loss of consortium;
- Bone graft donor site pain;
- Sensitivity to a metal foreign body (including possible tumor formation);

- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height);
- Inability to resume activities of normal daily living;
- Reoperation or revision;
- Death.

CLEANING AND DECONTAMINATION:

All components of the Altus Spine Cervical Plate System are supplied non-sterile and must be sterilized prior to clinical use. All packaging should be sealed and intact upon receipt. If the packaging or product is damaged, it should not be used and should be returned immediately.

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile field must be first decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field.

1. Rinse the device with warm water for approximately two (2) minutes while brushing with a soft bristled brush to remove most or all of the visible gross debris from the device. Pay careful attention to any pivots, threads, recesses or crevices on the devices.
2. Ultrasonically clean the device with an enzymatic detergent for five (5) minutes. Scrub the devices using a cleaning brush to remove any visible debris from all crevices.
3. Rinse and flush the device for two (2) minutes with warm tap water.
4. Conduct final verification of the cleaning process by visually inspecting the device under normal room lighting conditions to verify that all of the foreign material has been removed.
5. Sterilization: Place instruments within the sterilization tray. Steam sterilize following AAMI standards and a validated cycle given below.
6. Please be advised that all instruments are to be thoroughly cleaned and sterilized in the tray where the instrument is already configured disassembled; if the instrument is cleaned and/or sterilized outside of the tray, and then the instrument must be disassembled for thorough cleaning and/or sterilization.

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.

STERILIZATION:

The Altus Spine Cervical Plate System is supplied clean but not sterile. Sterilize the devices using the cases and trays provided. Sterilization should be achieved by high temperature steam. All packaging materials should be removed prior to sterilization. The following cycle has been validated for a sterility assurance level (SAL) of 10^{-6} using the 4 minute autoclave sterilization cycle in legally marketed wrap cleared by the FDA.

METHOD	Steam
PROCESS	Pre-Vacuum
TEMPERATURE	270˚F (132˚C)
CYCLE TIME	4 Minutes
DRY TIME	20 Minutes

Use an FDA cleared wrap to maintain sterility.

After sterilization, remove the device from the sterilization packaging or tray using accepted sterile technique with powder free gloves. Ensure that the components are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

IMPLANT SELECTION:

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient. Patients' overweight may be responsible for additional stresses and strains on the device, which can speed up metal fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.
Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of plates only is recommended if necessary according to the surgical technique of each system. Plates should only be contoured with the proper contouring instruments. Incorrectly contoured plates, or plates which have been repeatedly or excessively contoured, must not be implanted. Refer to the Altus Spine surgical protocols for additional procedural information.

PREOPERATIVE:

- Surgical Technique Guides may be requested from an Altus Spine Representative.
- The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Altus Spine.
- To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Altus Spine Surgical Technique Guide.
- Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.
- Unless otherwise specified on the label, the instruments may be reused after decontamination, cleaning, and sterilization.

INTRAOPERATIVE:

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The plates should not be repeatedly or excessively bent. The plates should not be reverse bent in the same location.
- Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
- Caution: Do not over tap or use a screw that is either too long or too large. Over tapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed in this package insert.
- Before closing the soft tissues, all of the screws should be firmly locked to the plate. Recheck the tightness of all screws after finishing to be sure that all screws are locked to the plate. Failure to do so may cause screw loosening or other adverse effects.

POSTOPERATIVE:

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. The physician may recommend external support from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass. External immobilization by bracing or casting may be employed. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants that may lead to fixation or implant failure and accompanying clinical problems. The patient should also be instructed to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

PACKAGING:

The implants are delivered in packages; these must be intact at the time of receipt. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

PRODUCT COMPLAINTS:

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance, should notify Altus Spine or its representative. Moreover, if a device has malfunctioned, Altus Spine or its representative must be advised immediately.

If an Altus Spine product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor or Altus Spine Representative must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please include the device name, reference number, lot number of the component(s), your name and address, and an exhaustive description of the event to help Altus Spine understand the causes of the complaint. See below for contact information.

PRODUCT INFORMATION DISCLOSURE:

ALTUS SPINE HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. ALTUS SPINE EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALTUS SPINE SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. ALTUS SPINE NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. ALTUS SPINE INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

For further information or complaints, please contact:

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Product Complaints: complaintsdepartment@altus-spine.com	General Information: info@altus-spine.com
Website: www.altus-spine.com	

The below symbols may be found on the package label:

	Manufacturer		Do not reuse; single use only
	Non Sterile		Caution, see instructions
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner		Consult instructions for use