Altus Spine Pedicle Screw System

NON STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT:

This document is designed to assist in using the Altus Spine Pedicle Screw 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 Pedicle Screw System is a system of screws, rods and cross connectors for use in spinal fixation. The components are assembled by the surgeon into a construct to stabilize the spine during spinal fusion procedures.

PRODUCT CONFIGURATIONS:

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

Components of the Altus Spine Pedicle Screw System can be described as a posterior fixation system that consists of:

1. Standard, multi-angle and cannulated screws with locking caps;
2. Rods;
3. Instruments;
4. Implants, and
5. Instrument Case.

INDICATIONS FOR USE:

The Altus Spine Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The Altus Spine Pedicle Screw System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the Altus Spine Pedicle Screw System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

CONTRAINDICATIONS:

Altus Spine Pedicle Screw System components are contraindicated in the following patient situations:

1. Recent infection (systemic, spinal or localized);
2. Morbid obesity;
3. Mental illness;
4. Drug or alcohol abuse;
5. Fever or leukocytosis;
6. Pregnancy;
7. Metal sensitivity or allergy to implant materials;
8. Severe osteopenia;
9. Presence of congenital abnormalities;
10. Spinal anatomy, tumors or any other complication which prevents secure implantation or decreases the useful life of the device;
11. Any condition where the device will interfere with anatomical structures or physiological performance (including inadequate tissue coverage over the operative site) for pedicle screw cases;
12. Missing or congenitally deformed pedicles of the fifth lumbar (L5) vertebrae;
13. Patients unable or unwilling to follow postoperative care instructions;
14. Any circumstances not described in the indications for use.

WARNINGS:

1. The safety and effectiveness of the pedicle screw spinal system has been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for other conditions are unknown.
2. 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 Pedicle Screw System. As with all spinal implants, components should never be reused under any circumstances.
3. The Altus Spine Pedicle Screw 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.
4. 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 pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
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. The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.
4. 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.
5. 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:

- Bending, loosening or fracture of the implants or instruments
- Loss of fixation
- Sensitivity to a metal foreign body (including possible tumor formation)
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which might result in skin breakdown and/or wound complications
- Non-union or delayed union
- Infection
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage)
- Gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium)
- Pain or discomfort
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra)
- Hemorrhage of the blood vessels and/or hematomas
- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height)
- Bursitis
- Bone graft donor site pain
- Inability to resume normal daily living activities
- Reoperation or revision
- Death

CLEANING AND DECONTAMINATION:

All components of the Altus Spine Pedicle Screw 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 Pedicle Screw 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}.

METHOD	Steam
PROCESS	Pre-Vacuum
PULSES	3
TEMPERATURE	270˚F (132˚C)
CYCLE TIME	4 Minutes
DRY TIME	20 Minutes

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 rods only is recommended if necessary according to the surgical technique of each system. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods, which have been repeatedly or excessively contoured, must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Altus Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

PREOPERATIVE:

- Surgical Technique Guides may be requested by a distributor or from Altus Spine directly.
- 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. For example, the forces exerted when repositioning the instrument in-situ must not be excessive as this is likely to cause injury to the patient.
- 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 rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field.
- 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/bolt may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
- To assure maximum stability, two or more Pedicle Screw System cross-connectors on two bilaterally placed, continuous rods should be used whenever possible.
- Before closing the soft tissues, all of the locking screws should be tightened firmly. Recheck the tightness of all locking screws after finishing to be sure that none loosened during the tightening of the other implants. Failure to do so may cause loosening of the other components.

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.

MR Environment:

The Altus Spine Minimally Screw System has not been evaluated for safety and compatibility in the MR environment. The Altus Spine Pedicle Screw System has not been tested for heating or migration in the MR environment.

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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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