Altus Spine Lumbar Interbody Fusion System

NON STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT:

This document is designed to assist in using the Altus Spine Lumbar Interbody Fusion 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 Lumbar Interbody Fusion System consists of various shapes (i.e., square, rectangular D-shaped, etc.) of devices. Each device has a hollow chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the device have a pattern of teeth to provide increased stability and to help prevent movement of the device.

PRODUCT CONFIGURATIONS:

All components of the Altus Spine Lumbar Interbody Fusion System are provided non-sterile and must be cleaned and sterilized prior to use. All implantable portions of the Altus Spine Lumbar Interbody Fusion System are made from implant grade titanium meeting the requirements of ASTM Standard F136 or Polyetheretherketone (PEEK) conforming to ASTM F2026. Because the PEEK material is radiolucent to aid the surgeon in determining if fusion in the operative site has occurred, tantalum wire markers (ASTM F560) are inserted to provide a visual aid in determining the implant's location, inter- and post-operatively.

The device is to be combined with a cleared supplemental fixation system, such as the Altus Spine Pedicle Screw System.

INDICATIONS FOR USE:

The Altus Spine Lumbar Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Altus Spine Lumbar Interbody Fusion System is to be combined with cleared supplemental fixation systems, such as the Altus Spine Pedicle Screw System.

CONTRAINDICATIONS:

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

Altus Spine Lumbar Interbody Fusion System components are contraindicated in the following patient situations:

1. When there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy of foreign body sensitivity to any of the implant material;
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant;
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patients;
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk or implant failure.

WARNINGS:

1. Correct selection of the implant is extremely important. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitation on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implants devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of which can lead to fatigue fracture. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come in contract with other metal objects, must be made from like or compatible metals.
4. Correct handling of the implant is extremely important. PEEK implants are designed to support physiologic loads. Excessive torque, when applied to long-handled insertion tools, can cause splitting or fracture of the implants. When an implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.
5. 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 implant systems should be performed only by experienced spinal surgeons with specific training in the use of this implant 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. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: 1) Corrosion, with localized tissue reaction or pain; 2) Migration of implant position resulting in injury; 3) Risk of additional injury from postoperative trauma; 4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; 5) Pain, discomfort, or abnormal sensations due to the presence of the device, 6) Possible increased risk of infection; and 7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

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
- Implant material sensitivity, or allergic reaction to a foreign body (including possible tumor formation)
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia
- Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period
- Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Spinal cord impingement or damage
- Fracture of bony structures
- Reflex sympathetic dystrophy
- Degenerative changes or instability in segments adjacent to fused levels
- 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
- Paralysis
- Death

CLEANING AND DECONTAMINATION:

All components of the Altus Spine Lumbar Interbody Fusion 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. Disassemble all instruments prior to cleaning.
2. 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.
3. 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.
4. Rinse and flush the device for two (2) minutes with warm tap water.
5. 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.
6. Sterilization: Place instruments within the sterilization tray. Steam sterilize following AAMI standards and a validated cycle given below.

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 Lumbar Interbody Fusion 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
PULSES	3
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.

Other sterilization methods and cycles may be suitable; however, the hospital should validate any alternative sterilization methods used.

Interbody Fusion System components should not be used with components of spinal systems from other manufacturers.

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. 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.
- Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
- 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 Lumbar Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The Altus Spine Lumbar Interbody Fusion 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 DISPOSAL:

All products that are damaged, deformed, corroded, or unable to be cleaned must be returned to Altus Spine for proper disposal.

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:

	ALTUS SPINE 1340 Enterprise Drive, Suite 200 West Chester, PA 19380 USA
Customer Support Phone: 1.610.355.4156	**Customer Service Fax:** 1.610.300.3049
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	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