Axis Spine Technologies: ALIF Instructions for Use

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

LOT	LOT NUMBER	REF	CATALOG NUMBER
NON STERILE	NON-STERILE	MATL	MATERIAL

DESCRIPTION

The Axis Spine Technologies ALIF System is a device designed to be inserted within the intervertebral disc space in order to provide structural stability in skeletally mature individuals.
The ALIF System is a modular system that can be assembled in a variety of geometries to suit individual pathology and anatomical conditions.
The interior of the implant has openings that can be intra-operatively packed with autograft and includes a cover plate to retain the autograft and prevent screw loosening.
The ALIF System must be used with supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

INDICATIONS FOR USE

The ALIF System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1.
DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
The ALIF System must be used with supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.
For use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection localized to the site of the proposed implantation.
2. Signs of local inflammation.
3. Patients with known allergy or foreign body sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.
Potential risks identified with the use of this system, which may require additional surgery, include:

- Device component fracture
- Loss of fixation
- Pseudarthrosis (Nonunion or delayed union)
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons.
The ALIF device is intended for use only as indicated.
The ALIF Device is for single use only. No implant should be reused if it has come in contact with blood or other bodily fluids. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.
All sizers and instrumentation are provided non-sterile and must be steam sterilized prior to use.
All implants, sizers and instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to Axis Spine Technologies.
Interbody fusion devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudoarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
When implanted at two contiguous levels, the ALIF System must be implanted in the same orientation to prevent screw impingement or potential bone fracture.
Preoperative planning and patient anatomy should be considered when selecting implant size. Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.
It is important to select the appropriate length ALIF screw and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.
Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with

known or suspected sensitivity to the aforementioned materials. If fewer than the maximum number of screws accommodated by the device are used, then the system is intended to be used with additional supplemental fixation (cleared by the FDA) for use in the lumbar spine.
These devices can break when subjected to the increased load associated with delayed union or nonunion.
Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.
Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.
Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
Care should be taken to insure that all components are ideally fixated prior to closure.

PATIENT EDUCATION:
Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

MATERIALS
The ALIF System is manufactured from Ti6Al-4V ELI conforming to ASTM F136/ ISO 5832-3 and PEEK-Optima LT-1 (Polyether-etherketone) conforming to ASTM F2026.

MRI SAFETY INFORMATION:
The ALIF 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 the ALIF System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Compatibility: Do not use ALIF System with components of other systems. Unless stated otherwise, Axis Spine Technologies devices are not to be combined with the components of another system.

PRE-OPERATIVE WARNINGS
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the ALIF implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE 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 must be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weightbearing, muscular activity or sudden jolts or shock to the spine.
- The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.
- The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

METHOD OF USE
Please refer to the Surgical Technique for this device.

PACKAGING
Packages for each of the components should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Axis Spine Technologies.
All implants are provided non-sterile are single use and should be sterilized per instructions provided below.
Instruments provided non-sterile are reusable and should be reprocessed using instructions provided below.

CLEANING AND DECONTAMINATION
All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the Axis Spine Technologies Cleaning and Sterilization Instructions before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to Axis Spine Technologies. Contact your local representative or Axis Spine Technologies directly for any additional information related to cleaning of Axis Spine Technologies surgical instruments.

STERILIZATION
All non-sterile instruments and implants are sterilizable by steam autoclave using standard hospital practices, in addition to Axis Spine Technologies's validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the Axis Spine Technologies Cleaning and Sterilization Instructions.

INFORMATION
To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local Axis Spine Technologies representative.