



## Omega Lumbar Interbody Fusion Device Package Insert

**CAUTION:** Federal law (USA) restricts these devices to sale by or on the order of a physician. Implants and disposable instruments single use only.

### **DESCRIPTION:**

The Omega LIF System devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion in the lumbar spine. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various sizes, and are designed to expand in height intra-operatively to accommodate variations in surgical approach and patient anatomy. Each cage has a hollow center to allow placement of autograft inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

The Omega LIF System devices are made from Titanium alloy Ti6Al4V ELI, ASTM F136.

### **INDICATIONS:**

The Omega LIF Lumbar Cages are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Omega LIF implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage

### **PRECAUTIONS:**

Intervertebral body fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the Omega LIF cages. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.

Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.

Postoperative external immobilization is recommended, at the surgeon's discretion, as is a comprehensive postoperative core stabilization physical therapy program. Instructions to the patient to reduce stress on the implant(s) are an equally important component of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure and delayed/non-union.

### **CONTRAINDICATIONS:**

- Spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system)
- Reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis)
- Fractures
- Tumors
- Scoliosis
- Active infection
- Allergy to Titanium

- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Suspected or documented allergy or intolerance to composite materials
- Any case not needing a fusion
- Any case not described in the indications
- Any patient unwilling to cooperate with postoperative instructions
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
- Spondylolisthesis unable to be reduced to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count

**POSSIBLE ADVERSE EFFECTS:**

**Note:** A further surgery might become necessary to correct adverse effects.

This list may not include all complications caused by the surgical procedure itself.

1. Bending or fracture of implant. Loosening of the implant.
2. Implant material sensitivity, or allergic reaction to a foreign body.
3. Infection, early or late.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensations due to the presence of the device.
6. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
7. 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.
8. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
9. Bursitis.
10. Paralysis.
11. Death.
12. Spinal cord impingement or damage.
13. Fracture of bony structures.
14. Reflex sympathetic dystrophy.
15. If a pseudarthrosis occurs coupled with the Interbody Innovations cages, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.

**Warning:** An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

The risk of device expulsion and migration is higher without the use of supplemental fixation.



Never reuse an implant under any circumstances. Even when a removed device appears undamaged, it may contain small defects or residual stresses. These defects and stresses may lead to implant failure. Any retrieved devices should be handled in a manner such that they may not be reused in another surgical procedure.

The Omega LIF® 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 Omega LIF in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**Packaging:** Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to AMENDIA.

**STERILIZATION:**

OmegaLIF Implants are supplied sterile using gamma irradiation.

Products not clearly marked as sterile should be assumed non-sterile. Implants and instruments used in surgery not clearly labeled as sterile must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization where applicable.

Only sterile products should be placed in the operative field.

**Recommended Sterilization Procedures for Omega LIF® System Instrumentation Provided Non-Sterile:**

**Manufacturer:** Amendia, Inc.

**Method:** Manual Cleaning and Steam Sterilization

**Device(s):** Trays/Implants/Instruments

**Cautions:**

The Omega LIF® System products provided **NON-STERILE** must be cleaned and sterilized before use.

**Limitations on Reprocessing:**

Repeated processing has limited effect on **REUSABLE** instruments.

End of life is normally determined by wear and damage due to use.

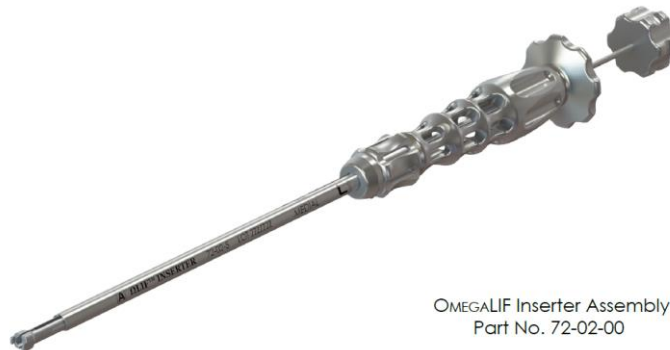
**CLEANING INSTRUCTIONS:**

**Point of Use:**

Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.

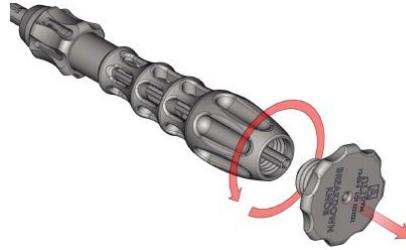
**Preparation for decontamination:**

**The OmegaLIF Inserter (Part No. 72-02-00) must be disassembled before cleaning.** Disassemble the OmegaLIF Inserter as follows:



OMEGALIF Inserter Assembly  
Part No. 72-02-00

1. Rotate OMEGALIF Breakdown Knob counter-clockwise to remove from bottom of Handle.



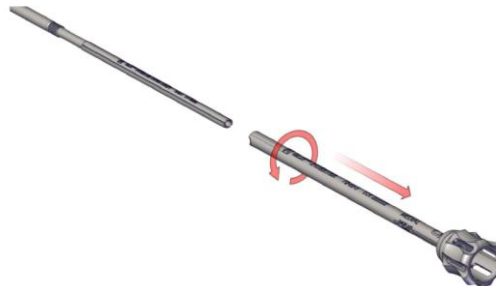
2. Rotate OMEGALIF Handle while pulling backwards to align the Handle and Inner Shaft keyways. Continue to pull the Handle to remove from the Inner Shaft.



3. Use the knob to rotate the OMEGALIF Outer Sleeve counter-clockwise while pulling backwards to unthread Sleeve from Inner Shaft.



4. Gently rotate and wriggle the Outer Sleeve to align with the Inner Shaft's keyway. Pull backwards again to slide Outer Sleeve off the shaft.





These instruments can be cleaned either manually, or manually with an additional automated cycle. It is preferred to use both manual and automatic cleaning methods, however, due to the somewhat limited availability of automated cleaning equipment it is possible to use just the manual cleaning procedures. These procedures are as follows:

**Cleaning agent:**

Endozime AW Plus is to be prepared as follows:

Add ½ ounce of Endozime® AW plus to 1 gallon of warm tap water (17mL/4liter, 27°-44°C)

**Manual Cleaning instructions:**

- (1) Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
- (2) Immerse in enzymatic detergent and clean thoroughly for at least 14 minutes at <43°C.
  - (2.1) Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
- (3) Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)
- (4) Allow instrument to air dry in a clean area. Blow lumens with clean air using filtered air source or syringe.

**Automated Cleaning instructions:**

- (1) Manually pre-clean the instruments
  - (1.1) Immerse and soak for a minimum of 5 minutes in enzymatic detergent at <43°C.
  - (1.2) Immerse in enzymatic detergent and clean thoroughly for 14 minutes at <43°C.
    - (3.1.2.1) Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
  - (1.3) Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)
- (2) Place instruments in an automated washer. Ensure the instruments stay in place and do not touch or overlap so that the design features are accessible for cleaning and do not retain liquid.
- (3) Run the washer per the parameters below:

**Washer Parameters**

Cycle	Time	Parameters	Temperature
Pre-Wash	300 seconds		Cold <sup>1</sup>
Wash 1	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C
Wash 2	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C
Purified Water Rinse	10 seconds	Non-Recirculated Purified Water	82.2° C <sup>2</sup>
Dry Time	7 minutes	N/A	115.5° C

<sup>1</sup>Cold tap water line

<sup>2</sup>Purified water tank temperature set at 82.2° C/180° F

- (4) Once cleaned, put all instruments in tray before sterilization. The OMEGALIF Inserter must remain disassembled post cleaning, placed in tray for sterilization, and assembled during procedure.

**Note: See Surgical Technique Guide for OMEGALIF Inserter reassembly instructions.**

**Disinfection:**

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

**Maintenance, inspection, and testing;**

Carefully inspect each device to ensure that all visible blood and soil have been removed.

Inspect lumens to confirm that all foreign material has been removed.

Visually inspect for damage and/or wear.

Note: If any damage or wear is noted that impairs the function of the instrument, contact your Amendia representative for a replacement.

**Packaging:**

This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization. The tray should be wrapped using FDA-cleared sterilization wrap or other FDA-cleared accessory that has been validated to allow sterilant penetration and subsequently maintain sterility.

**STERILIZATION INSTRUCTIONS:**

Visually inspect all components for any remaining debris prior to sterilization.



The Omega LIF® Intervertebral Body Fusion system components provided **NON-STERILE** should be autoclave sterilized using the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave.

**Omega LIF® system components should be sterilized utilizing a pre-vacuum steam autoclave for a minimum of 4 minutes at 270°F (132°C.)**

**Drying:**

A minimum drying time of 20 minutes, after sterilization, is recommended.

Drying times may vary according to load size and should be increased for large loads.

Dry, thoroughly and promptly, after both cleaning and sterilization

**Storage:**

Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature

The instructions provided above have been validated by Amendia as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

**Product Complaints:** Any health care professional (e.g. customer or user) who has experienced dissatisfaction in the services of AMENDIA or who has any complaints about AMENDIA products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify this to the sales representative, distributor, or AMENDIA customer service. Further, if any of the devices, instruments or components ever malfunction, (i.e. do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately. If any AMENDIA product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

CAUTION

Federal Law restricts this device to sale by or on the order of a Physician.

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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.