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OMEGA LUMBAR INTERBODY FUSION DEVICE PACKAGE INSERT (OMEGA LIF/OMEGA XP)

This package insert covers the Omega LIF System and Manual Surgical Instruments that are used for the implantation of this system. Specific sections for implants and instrumentation highlight important user information for only those devices.

GENERAL INFORMATION

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.

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

WARNING

Implants provided sterile are sterilized through gamma irradiation. Do not re-sterilize implants provided sterile. Devices provided non-sterile must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
5. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.



4. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

MAGNETIC RESONANCE ENVIRONMENT

Omega LIF System have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

SINGLE USE

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death. All implants are single use.

STERILITY

All devices provided sterile have been gamma irradiation sterilized and are for single use only. Do not re-sterilize sterile devices. All devices provided non-sterile must be sterilized prior to use. Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by Spinal Elements.

SHELF LIFE

The product expiration date is indicated by the hourglass symbol on the product label. **Caution:** Do not use sterile devices if the packaging providing the sterile barrier has been compromised. Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to Spinal Elements.

CLEANING AND MAINTENANCE

GENERAL INFORMATION

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments. All devices provided non-sterile must be cleaned and sterilized prior to use. Do not clean devices provided sterile.

MANUAL CLEANING INSTRUCTIONS

Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended

for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

Spring-Loaded Awls should be disassembled before cleaning by compressing the button and removing the external shaft from the handle. Follow the cleaning instructions listed in the Manual Surgical Instruments section of this insert. Pay special attention to the lumens of the external shafts of disassembled instruments and all guide sleeves.

An instrument lubricant should be applied to the engagement collar of AO Quick Release Handles after cleaning.

An instrument lubricant should be applied to all hinged instruments after cleaning.

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.

Disassemble all components to provide maximum exposure for cleaning.

All devices must be processed manually prior to automated cleaning.

Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.

Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents.

Caution: Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. An automated system may be used as a follow-up method to manual cleaning.

INSTRUCTIONS

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

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

Preparation for decontamination (72-06)

The OmegaLIF Inserter (Part No. 72-06-00) must be disassembled before cleaning. Disassemble the OmegaLIF Inserter as follows:

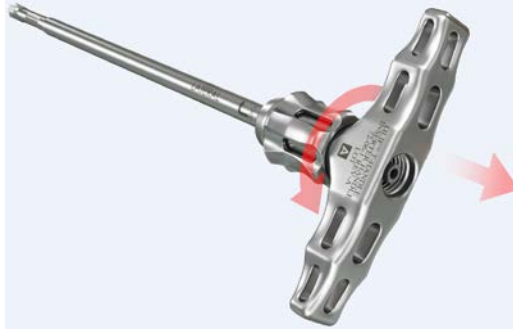


OmegaLIF Inserter Assembly PN: 72-06

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.

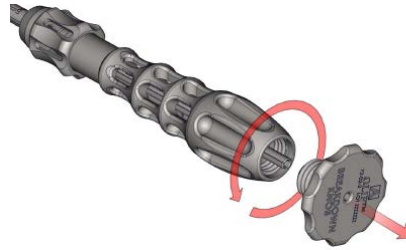


Preparation for decontamination (72-02)

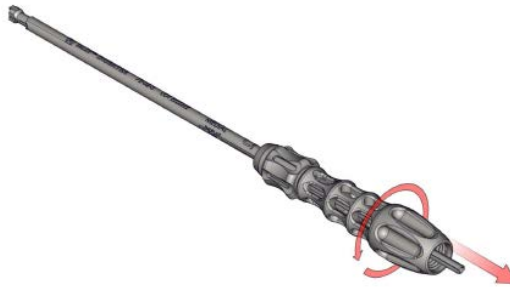
The OmegaLIF Inserter (Part No. 72-02-00) must be disassembled before cleaning. Disassemble the OmegaLIF Inserter as follows:



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



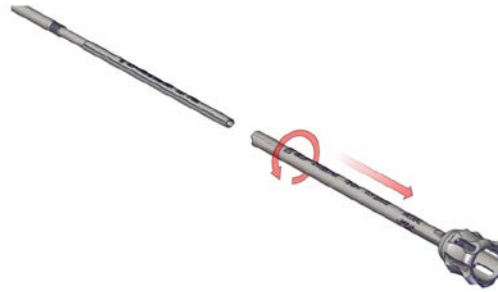
2. Rotate OMEGALIF Handle while pulling backwards to align the Handle and Inner Shaft keyways. Continue to pull the Handle to remove from the Inner Shaft.



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 ¹ |
| 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 ² |
| Dry Time | 7 minutes | N/A | 115.5° C |

¹Cold tap water line

²Purified 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 is only acceptable as an adjunct to full sterilization for reusable surgical instruments. 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.

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.

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.

| | Method | Cycle Type | Sterilization Temperature | Exposure Time | Dry Time |
|----------------|--------|------------|---------------------------|---------------|------------|
| Wrapped | Steam | Pre-vacuum | 270°F (132°C) | 4 minutes | 30 minutes |

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAM ST 79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. These parameters were validated to a sterility assurance level (SAL) of 10⁻⁶. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Information



Catalog Number



Material



Batch Code



Packaged Quantity



Manufacturer



Date of Manufacture



Caution, Consult
Accompanying
Documents



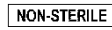
Do Not Re-Use



Sterilized using
irradiation



Use-by date



Device Not Sterile



Prescription Only



Instruction for Use are provided electronically at ifu.spinalelements.com

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Patents: patent.spinalelements.com

For additional information regarding any of Spinal Elements’ devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

CAUTION: Federal Law (USA) restricts these devices for sale by or on the order of a physician.