

OPTIMUS

CUSTOM SPINE OPTIMUS: STAND-ALONE ANTERIOR LUMBAR DEVICE

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

**CONSISTS OF STERILE AND NON-STERILE PRODUCT
NON-STERILE PRODUCT MUST BE STERILIZED PRIOR TO USE
SINGLE USE ONLY**

DEVICE DESCRIPTION

OPTIMUS consists of fixation plates, end caps, and bone screws for stand-alone anterior intervertebral body fusion. OPTIMUS is available in a variety of heights (9-13mm posterior), angles (6, 10 and 14 degrees) and two footprints (25x32mm and 29x36mm) to accommodate variations in patient anatomy. The end caps, which attach to the fixation plate, come in either PEEK or titanium and are plasma sprayed with CP-titanium. The bone screws are \varnothing 5mm and are available in three lengths (24, 28, and 32mm).

MATERIALS

OPTIMUS is fabricated from the following materials:

- PEEK-OPTIMA™ LT1 (PEEK-OPTIMA™ is a trademark of Invibio, Ltd.) per ASTM specification F-2026 (end caps)
- Titanium alloy (Ti6Al4V) per ASTM specification F-136 (fixation plate, end caps, and bone screws)
- CP-Titanium per ASTM specification F-1580 (end caps plasma sprayed surface coating)

INDICATIONS

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient should be skeletally mature and have had six months of non-operative treatment.

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is a stand-alone system intended to be used with bone screws, autogenous bone graft and requires no additional supplementary fixations. One device is used per intervertebral space.

CONTRAINDICATIONS

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, open wounds, pregnancy, and other medical conditions which would prohibit beneficial surgical outcome.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Prior fusion at the level(s) to be treated
- Any case not described in the indication for use

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

PRECAUTIONS AND WARNINGS

- **STERILE AND NON-STERILE PRODUCT.** Implants and Instruments that are provided non-sterile must be sterilized before use.
- **IMPLANT SELECTION AND USE.** The selection of the proper size, shape, and design of the implant for each patient is extremely important and crucial to the success of the procedure. Implants are subject to repeated stresses in use, and their strength is limited by the size and shape of the human spine. If healing is delayed, or does not occur, the stresses and strains on the implants may cause fracture or deformation of the implants due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Improper selection, placement, positioning and fixation of these devices may contribute to early failure.
- **SINGLE USE.** An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life and compromise device performance or patient safety. Reuse of a single use device can also cause cross-contamination leading to patient infection.
- **ADEQUATE INSTRUCTIONS TO PATIENT.** 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 and damage nerves or blood vessels.
- **PATIENT CONDITIONS.** Based on fatigue testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
- **PATIENTS WITH PREVIOUS SURGERY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- **SYSTEM COMPATIBILITY.** While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals (i.e., titanium and stainless steel) may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of Optimus should not be used in conjunction with components from any other manufacturer's spinal system.
- **INSTRUMENTATION.** Specialized instruments are provided by Amendia and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can

occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, and number of procedures. Instruments should be examined for wear or damage prior to surgery. Return damaged instruments back to manufacturer for refurbishment services.

- **HANDLING.** The implants and instruments used as part of this systems are provided non sterile and should be stored in their original packaging or in the sterilization container provided. Implants and instruments should be stored in such a manner when not in use, and until they are cleaned and sterilized according to the recommended guidelines. Inspect implant and instruments prior to use for visual damage.
- **ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES**
When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the material that make up the implants, be checked before they are implanted.
- **METAL COMPONENTS**
Some of the alloys utilized to produce orthopedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such phenomena.
- The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill, and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which 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.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the substantial possibility of bone erosion, migration and/or pain.

- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders; including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of the bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

RECOMMENDED MANUAL CLEANING PROCEDURES

- The instruments should be thoroughly cleaned before any decontamination. Cleaning should remove all dried infectious residual matter.
- Prepare hospital grade enzymatic detergent according to manufacturer’s instructions.
- End caps must be removed from containment caddies for manual processing.
- Loosen and disassemble instruments with removable components in accordance with the table below:

<u>Part Number</u>	<u>Instrument</u>	<u>Disassembly Instructions</u>
139020 139021 139022	Insertor assembly with Insertion Head	Ensure the Stabilizer [139022] shaft has been unthreaded from the Insertion Head [139020] and removed from the Insertor [139021]
139021 139022 13901X	Insertor assembly with Screw Guide	Ensure the Stabilizer [139022] shaft has been unthreaded from Screw Guide [13901X] and removed from the Insertor [139021]

- Perform cleaning per the steps listed in the table below:

<u>Step</u>	<u>Solution</u>	<u>Time (Minutes)</u>	<u>Temperature</u>	<u>Instruction</u>
1	Hospital Grade Enzymatic Detergent	5 Minutes	Room Temperature (27°-43°C)	Immerse and soak for required time.
2	Hospital Grade Enzymatic Detergent	14-15 Minutes	Room Temperature (27°-43°C)	Clean thoroughly – Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulation holes. Inspect for visible soil on exposed surfaces.

3	Demineralized Water	2-3	Room Temperature (27°-44°C)	Rinse thoroughly for required time immediately after Step 2.
4	Air	As Required	Ambient	Allow to air dry in clean area. Blow instrument lumens with clean air using filtered air source or syringe.

- DO NOT USE SODA TO CLEAN DEVICES MADE OF ALUMINUM.
- DO NOT USE SODIUM CHLORITE TO CLEAN DEVICES MADE OF STAINLESS STEEL.
- Verify that all instruments and implants are visually clean. If not, repeat the cleaning process from the beginning until they are clean.

DECONTAMINATION CONSIDERATIONS

- For patients presenting a risk factor of transmissible subacute spongiform encephalopathy (previous histories of growth hormone treatment, genetic history, previous history of high-risk neurosurgical interventions), the World Health Organization (WHO) recommends special inactivation procedures. Consult WHO and local regulatory authorities for further information.

RECOMMENDED AUTOMATED CLEANING PROCEDURE FOR END CAP CONTAINMENT CADDIES

- Prepare hospital grade enzymatic detergent according to manufacturer’s instructions.
- End caps may remain in containment caddies for automated processing.
- Run washer per the parameters below:

<u>Cycle</u>	<u>Solution</u>	<u>Time</u>	<u>Temperature</u>
Pre-Wash	Cold Tap water	300 secs	Cold
Wash 1	Hospital Grade Enzymatic Detergent Wash	300 secs	65.5°C
Wash 2	Hospital Grade Enzymatic Detergent Wash	300 secs	65.5°C
Rinse	Demineralized Water	10 secs	82.2°C
Dry	Potable Tap Water	7 mins	115.5°C

- Inspect device for visible soil, if not, repeat the cleaning process from the beginning until they are clean.

RECOMMENDED STERILIZATION PROCEDURES FOR MEDICAL DEVICES PROVIDED NON STERILE

- Use a validated, properly maintained and calibrated steam sterilizer.
- Remove all devices from their packaging prior to sterilization.
- Sterilize the devices by steam autoclaving procedure regularly used in the hospital.

Recommendation: The system should be sterilized using an FDA cleared wrap and sterilized utilizing the following parameters based on the recommendations of the AAMI Guidelines St79 for steam sterilization:

<u>Method</u>	<u>Cycle Type</u>	<u>Temperature</u>	<u>Exposure Time</u>	<u>Dry Time</u>
Steam	Pre-Vacuum	132°C (270°F)	4 Minutes	30 Minutes

	Wrapped			
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- Other alternative sterilization methods and cycles are possible but must be validated.
- Autoclave must be validated to guarantee the recommended sterilization temperature is reached all along the exposure time.
- EtO sterilization, cold sterilization, irradiation, plasma techniques are not recommended for the inactivation of prions.
- If paper-filter sterilization boxes are used, it is advisable to verify whether the filters are intact before sterilization. If after sterilization it remains water in the sterilization boxes, sterilization cannot be considered as efficient.

NOTE: These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained and calibrated. Ongoing test must be performed to confirm inactivation of all forms of viable microorganisms.

MAGNETIC RESONANCE (MR) COMPATIBILITY

OPTIMUS 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 OPTIMUS in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

FURTHER INFORMATION

A surgical technique brochure is available on request through your Amendia agent or directly from Amendia. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

COMPLAINTS

Any professional (e.g. Customer or user) who has experienced dissatisfaction in the services or who has any complaints about Amendia products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify the representative or distributor.

When filing a complaint form, please provide maximum information such as the identification of the product (name, reference, lot number), the nature of the complaint or the description of the incident, the consequences, and all technical elements that could be helpful in the future investigation, such as: the device, x-rays, etc... should be addressed.

For further information or complaint, please contact:

**3115 Melrose Dr., Suite 200
 Carlsbad, CA 92010 ·
 U.S.A. ·
 760.607.0121**