restor3d

Lumbar Interbody Fusion Device

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The restor3d TIDAL® Lumbar Interbody Fusion System are additively manufactured Titanium Alloy (Ti-6AL-4V per ASTM F2924) implants, designed for use as a lumbar interbody fusion device. They are provided sterile-packed. The system is comprised of various sizes to accommodate individual patient anatomy as well as multiple designs to support several surgical techniques (PLIF, ALIF, TLIF, OLIF, LLIF). Each approach includes several offerings that vary by footprint (width and depth/length), height, and lordotic angle. All sizes have a large central window(s) for packing autogenous bone graft and/or allogenic bone graft. The inferior and superior faces have endplate surface lattices as well as teeth to resist migration when placed in between the vertebral bodies.

restor3d has provided instrumentation to assist in the surgical placement of the fusion devices. It is important that the provided inserter and sizers be used to ensure accurate implantation of the implants. It is important not to overtighten when threading the implant onto the inserter as overtightening could result in failure to disengage the implant after insertion.

INDICATIONS FOR USE

The restor3d lumbar cages are intended to be used as an intervertebral body fusion device with bone graft for use in lumbar spine. They are indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels from L2-S1. DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants are used to facilitate fusion in the lumbar spine using autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbar spine.

CONTRAINDICATIONS

- Surgical procedures other than those listed in the indications for use.
- Patients with an active local or systemic infection.
- Conditions which tend to retard healing such as blood supply limitations or previous infections.
- Skeletally immature patients where the implanted device would cross open epiphyseal plates.
- Grossly distorted anatomy due to congenital abnormalities.
- Inadequate tissue coverage over surgical site.
- Insufficient quality or quantity of bone, comminuted bone surfaces or pathologic conditions such as cystic change or severe osteopenia that would impair the ability of the restor3d Lumbar Interbody Fusion Cage to securely fixate to the bone.
- Inadequate neuromuscular status (e.g. paralysis, inadequate muscle strength).
- Patients with conditions such as mental illness, senility or alcoholism that tend to restrict his or her willingness to follow postoperative instructions during the healing process.
- Patients with foreign body sensitivity, suspected or documented material allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted and sensitivity ruled out prior to implantation.

WARNINGS AND PRECAUTIONS

WARNINGS

- The restor3d Lumbar Interbody Fusion Device is supplied sterile for single use only.
- Do not resterilize this device. Resterilization could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Do not reuse this device. Reuse of this product may result in infection or other systemic complication that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect the function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage or contamination that

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could result in implant failure and should be discarded.
- Do not modify the implant. Modified devices may not perform as intended and could result in patient injury.
- Visual inspection of the instrument should be performed to determine if it is usable. Any indication of rolled or curled edges should warrant the instrument being unusable and should be returned to the manufacturer. Any instrument that has been damaged, mishandled, or removed from the sterile field may have surface damage or contamination that could result in failure and should be discarded and returned to the manufacturer.

PRECAUTIONS

- The restor3d Lumbar Interbody Fusion Device should be used only by those physicians who have been trained in the appropriate, specialized procedures. Knowledge of appropriate surgical techniques, instrumentation, proper selection and placement of implants and postoperative patient care and management are essential to a successful outcome.
- Correct selection of restor3d Lumbar Interbody Fusion Device components is extremely important. Carefully select the appropriate device size based on the needs of each individual patient.
- Never attempt to reuse. Once the restor3d Lumbar Interbody Fusion Device has been removed from the packaging, the device should be either used or discarded. Never attempt to reuse the implant, even though it may appear undamaged.
- The surgeon must make the final decision regarding implant removal.
- In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. Extreme care must be taken when removing the device.
- Use only restor3d instruments when handling and implanting the restor3d device. Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.
- Confirm lateral fluoroscopy shows proper sagittal alignment. When inserting the implant, care should be taken to avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.

MRI SAFETY INFORMATION

The restor3d Lumbar Interbody Fusion Device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the restor3d Lumbar Interbody Fusion Device in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects resulting from use of the restor3d Lumbar Interbody Fusion Device include, but are not limited to, the following:

- Loosening, cracking or fracture of the implant.
- Loss of fixation in bone.
- Pseudoarthrosis
- Soft tissue injury
- Vertebral endplate injury
- reoperation
- Fracture of bony structures.
- Deep or superficial infection.
- Degenerative changes or instability of segments adjacent to fused vertebral levels.
- Nerve damage due to surgical trauma or presence of the device.
- Sensitivity, allergies, or other reaction to the device material.
- Tissue reactions including macrophage and foreign body reactions adjacent to implants.
- Nonunion, delayed union or pseudoarthrosis, possibly requiring further surgery.
- Malalignment of anatomical structures (i.e. loss of normal spinal contours or change in height).
- Pain, discomfort and abnormal sensations due to presence of the implant.
- Hematoma or thrombosis.

Adverse effects may necessitate re-operation, revision or removal surgery. Implant removal should be followed by adequate postoperative management.

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IMPLANT MATERIALS

The restor3d Lumbar Interbody Fusion Device are manufactured from a medical grade of titanium alloy per ASTM F2924 (Ti-6Al-4V).

HANDLING AND STERILIZATION

Components labeled as sterile on their packaging have been sterilized and should always be stored unopened. These components should not be used if the date of surgery is beyond the packaging expiration date; resterilization of the implants is not recommended. Sterilized product should be stored in a clean, dry location at room temperature and out of direct sunlight.

A) STERILE IMPLANTS

The restor3d Lumbar Interbody Fusion Device has been sterilized by gamma radiation and is provided sterile in the unopened, undamaged package. If either the implant or the package appears damaged, is beyond the sterility expiration date, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize sterile implants.**

B) STERILE DISPOSABLE INSTRUMENTS

Instruments provided sterile have been sterilized by gamma radiation and are sterile in the unopened, undamaged package. If either the instrument or the package appears damaged, is beyond the sterility expiration date, or if sterility is questioned for any reason, the instrument should not be used. **Do not resterilize sterile instruments.**

C) NON-STERILE DISPOSABLE INSTRUMENTS

restor3d non-sterile disposable instruments are provided CLEAN but NOT STERILE. No further cleaning other than sterilization is required. For sterilization, remove all packaging material prior to sterilization. See part D below for the recommended manual instrument cleaning instructions and part E for the recommended steam autoclave cycle. Ensure that the instruments are at room temperature prior to use. Only sterile implants and instruments should be used in surgery.

D) INSTRUMENT CLEANING

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- After surgical procedure, remove debris from each instrument using a water moistened pad, exchanging pad if it becomes soiled.
- Disassemble all components as per manufacturer instructions (if appropriate).
- Rinse with cold tap water to remove gross contamination.
- Soak in an enzymatic detergent solution per manufacturer directions for 5 minutes.
- Scrub thoroughly with a soft brush and/or pipe cleaner
- Rinse with cold tap water for 4 minutes. While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Follow the manual validated cleaning process below. if needed, an equivalent automated cleaning process can be utilized after manual cleaning. Be familiar with equipment manufacturers' use and operations instructions.
- Use a 20 mL syringe to flush lumens and internal features.
- Soak in a detergent solution per manufacturer directions for 5 minutes
- Scrub thoroughly with a soft brush and/or pipe cleaner
- Rinse thoroughly/flush with reverse osmosis/deionized (RO/DI) water for 4 minutes.
- While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Sonicate for a minimum of 10 minutes in an enzymatic detergent solution per manufacturer directions.
- Rinse thoroughly/flush with reverse osmosis/deionized (RO/DI) water
- While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Sonicate for a minimum of 10 minutes in reverse osmosis/deionized (RO/DI) water.
- Rinse thoroughly/flush with reverse osmosis/deionized (RO/DI) water.
- While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Dry with a clean, soft, disposable cloth and allow to air dry for 20 minutes.
- Visually inspect for debris and cleanliness. Reclean if necessary.

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E) RECOMMENDED STEAM STERILIZATION CONDITIONS (NON-STERILE INSTRUMENTS)

The minimum recommended steam sterilization conditions for reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.

2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Time	Parameter	Minimum Set Point
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	30 minutes

3. After Sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage. These recommendations are consistent with ANSI/AAMI ST 79 guidelines and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

SURGICAL PROCEDURE / DIRECTIONS FOR USE

It is the responsibility of the surgeon to be familiar with the procedure before use of these products. As the manufacturer of this device, restor3d does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

1. Prepare, position, and drape the patient per standard procedure.
2. Expose the affected levels via a standard approach incision and tissue dissection.
3. Perform any necessary bone and tissue removal.
4. Remove disc material and prepare endplates using the appropriate instruments. Use a combination of curettes, rasps, osteotomes, disc shavers, or box chisels to remove the disc material and cartilage from the vertebral endplates.
5. Prepare the intervertebral disc space per surgeon preference.
6. Determine the correct implant size and shape with the implant trial(s).
7. Prepare the implant, including packing with bone graft material, if desired.
8. Place the implant on the inserter handle. Orient the implant and inserter in the correct alignment and carefully insert the implant into the distracted segment.
9. If necessary, lightly tamp the implant with the reusable tamp to obtain final position.
10. Radiographically verify implant position.
11. Remove the inserter handle from the disc space.

Complete surgical procedure with supplemental fixation as required.

TRAINING

Surgeons may obtain training from a qualified instructor prior to implantation this device to ensure thorough understanding of instrumentation, implantation and removal techniques. Please contact restor3d Customer Service toll-free in the U.S. at 984-888-0593 or email customerservice@restor3d.com to arrange training with a qualified instructor.

Caution:
U.S. federal law restricts this device to sale by or on the order of a physician.
For Symbols Glossary, please refer to
https://restor3d.com/resources/instructions

Manufacturer: Additive Device, Inc. d/b/a restor3d, inc.
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