restor3d Cervical Interbody Fusion Device

For Symbols Glossary, please refer to
https://restor3d.com/resources/instructions

INSTRUCTIONS FOR USE

1. DEVICE DESCRIPTION

The restor3d Cervical Fusion Device is a spinal intervertebral fusion device manufactured from medical grade titanium alloy. It is provided in a variety of footprint sizes as well as various heights and angles to accommodate variations in patient anatomy.

Restor3d has provided instrumentation to assist in the surgical placement of the fusion devices. It is important that the provided inserter and trials 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. If double sided trials are provided, it is important to take care when impacting the end of that trial as that is the location of the other size that will be trialed.

2. INDICATIONS FOR USE

The restor3d Cervical Interbody Fusion Device is indicated for use as an intervertebral body fusion device 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 level of the cervical spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the cervical spine (C3-C7) and are placed via an anterior approach using autogenous bone as graft material for the interior graft window. The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

3. 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 Cervical 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.

4. WARNINGS AND PRECAUTIONS

WARNINGS

- The restor3d Cervical 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 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.

PRECAUTIONS

- The restor3d Cervical 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 Cervical 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 Cervical 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.

5. MRI SAFETY INFORMATION

The restor3d Cervical 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 Cervical 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.

6. POTENTIAL ADVERSE EFFECTS

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

- Loosening, cracking or fracture of the implant.
- Loss of fixation in bone.
- 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.

7. IMPLANT MATERIALS

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

8. HOW SUPPLIED

A) <u>STERILE IMPLANTS</u>
The restor3d Cervical 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) <u>STERILE DISPOSABLE INSTRUMENTS</u>
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 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) RECOMMENDED STEAM STERILIZATION CONDITIONS (NON-STERILE INSTRUMENTS)

The following steam autoclave cycle is recommended for non-sterile disposable instruments; however, sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. Time and temperature parameters required for sterilization vary according to type of sterilizer and cycle design. Prior to sterilization, instruments should be placed in suitable packaging for the sterilization process (i.e., central supply wrap (CSR), paper/plastic pouches, rigid containers, etc.) and sterilized prior to surgical use.

Cycle Type	Minimum Temperature	Minimum Exposure Time Wrapped	Minimum Drying Time
Prevacuum (4 Preconditioning Pulses)	132°C (270°F)	4 minutes	55 minutes

9. 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. Expose the disc space and distract the segment per standard procedure.
2. Prepare the disc space per surgeon preference.
3. Determine the correct implant size and shape with the implant trial(s).
4. Prepare the implant, including packing with bone graft material, if desired.
5. Place the implant on the inserter handle.
6. Orient the implant and inserter in the correct alignment and carefully insert the implant into the distracted segment.
7. Verify implant position.

8. Remove the inserter handle from the disc space.
9. Complete surgical procedure as required.

10. 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.

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