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OSSERA™ AFX IMPLANT AND INSTRUMENTATION SYSTEM INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

The Ossera™ AFX consists of a set of implants intended to be used as an accessory to the DynaNail TTC Fusion System by providing stabilization of the hindfoot and ankle. The Ossera™ AFX will be available in a wide range of heights and diameters, permitting surgeons to choose a relevant size for the affected anatomy. The Ossera™ AFX is constructed from an implant grade titanium alloy.

restor3d has provided instrumentation to assist in the surgical placement of the Ossera™ AFX. It is important that the provided instrumentation is used as they were designed to ensure the accurate installation of the device.

INDICATIONS FOR USE

The Ossera™ AFX System is intended to be used as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The Ossera™ AFX System is intended for use as an accessory to the DynaNail TTC Fusion system. The Ossera™ AFX System is not intended for standalone use. The Ossera™ AFX System is intended for use with autograft and/or allogenic bone graft.

CONTRAINDICATIONS

The Ossera™ AFX is contraindicated for use in cases of:

- An active local or systemic infection
- An active soft tissue infection of the foot and ankle
- Skeletal immaturity where the implant would cross open epiphyseal plates
- Significant tibial malalignment (>10 degrees in either sagittal or coronal plate)
- A dysvascular limb
- Severe longitudinal deformity
- Conditions that restrict a patient's ability or willingness to follow post-operative instructions during the healing process
- Foreign body sensitivity, suspected or documented metal allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted and sensitivity ruled out prior to implantation.
- Possibility for more conservative treatment

POTENTIAL ADVERSE EFFECTS

Potential adverse effects resulting from the use of the Ossera™ AFX include, but are not limited to, the following:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or discoloration of the implant requiring revision surgery
- Loss of anatomic position with nonunion or malunion with rotation or angulation
- Bone resorption or over-production
- Allergic reaction to the implant material
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

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

WARNINGS

- The Ossera™ AFX is 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 complications 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.
- Appropriate surgical technique should be followed to limit contact between the Ossera™ AFX and DynaNail TTC Fusion System construct. Contact between the implants may result in component wear, which could lead to adverse local tissue reactions, implant loosening and osteolysis.
- It is important that immobilization of the fracture or osteotomy site be maintained until firm bony union (confirmed by clinical examination) is established to reduce the likelihood of delayed or non-union of the fracture or osteotomy site.
- Do not modify the implant. Modified devices may not perform as intended and could result in patient injury.
- Do not use beyond the expiration date listed on the label. The performance, safety, and/or sterility of the device cannot be assured beyond the expiration date.
- In the event that a device is opened and not used, dispose of it according to hospital policy and procedure.

PRECAUTIONS

- The Ossera™ AFX has not been evaluated for safety or effectiveness for primary arthrodesis. The safety and effectiveness of the Ossera™ AFX for primary arthrodesis is unknown. Use for primary arthrodesis may result in patient injury.
- Correct selection of implant is extremely important. The potential for success in arthrodesis is increased by selecting the proper implant size, shape, and design. The patient's anatomy and indication will determine the size of the Ossera™ AFX to be used.
- No partial weight-bearing or non weight-bearing device can be expected to withstand the unsupported stresses of full weight bearing. Until the bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at fracture site and delay healing.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant or fracture or osteotomy nonunion requiring revision surgery to remove the device. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.
- As an accessory to the DynaNail TTC Fusion System, the Ossera™ AFX is labeled as MR Unsafe. Scanning a patient who has this device may result in patient injury.

HOW SUPPLIED

A) **STERILE IMPLANTS**

The Ossera™ AFX 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 the sterile implant.**

B) **STERILE 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 IMPLANTS**

restor3d Ossera™ AFX Implants are provided to the hospital in a CLEAN but NOT STERILE packaging. Only sterile devices should be used in surgery. Unless otherwise indicated, these devices are NOT STERILE and MUST be sterilized prior to use. For sterilization, remove all packaging material prior to sterilization. See NON-STERILE IMPLANT AND DISPOSABLE

INSTRUMENT STEAM STERILIZATION CONDITIONS below for the recommended steam autoclave cycle. No further cleaning other than sterilization is required.

D) **NON-STERILE DISPOSABLE INSTRUMENTS**
restor3d Ossera™ AFX 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 NON-STERILE IMPLANT AND DISPOSABLE INSTRUMENT STEAM STERILIZATION CONDITIONS below for the recommended steam autoclave cycle. Only sterile implants and instruments should be used in surgery.

NON-STERILE IMPLANT STEAM STERILIZATION CONDITIONS

- The following steam autoclave cycle is validated for the non-sterile Ossera™ AFX implants.
- Prior to sterilization, implants and instruments should be double wrapped in 1-ply FDA-cleared sterilization wrap, placed in a stainless steel mesh sterilization basket and sterilized prior to surgical use.
    - Parts should be placed inside the basket in a single layer.
    - Do not stack more than two baskets.
    - Ensure the basket is thoroughly cleaned before placing the parts to be sterilized. If baskets are not visually cleaned, repeat cleaning and inspect again.
- Implants must be steam autoclaved using a full cycle, and repeated autoclaving will not adversely affect them, unless otherwise noted on the label. Detailed below is the cycle for steam sterilization of wrapped goods:
- Use a validated, properly maintained, and calibrated steam sterilizer following the manufacturer's recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following protocol in accordance with our validated results:
    - Sterilizer type: prevacuum
    - Preconditioning pulses: 4
    - Temperature: 132°C
    - Full cycle time: 4 minutes
    - Dry time: 70 minutes
    - Open door time: 30 minutes
    - Cool-down time: 30 minutes
    - Cool down phase should be completed outside of the chamber on a wire-rack
    - Do not rapidly cool polymeric instruments.
- Store sterile packaged devices in a manner that provides protection from dust, moisture, insects, vermin and extremes of temperature and humidity.

RESPONSIBILITIES OF THE USER

General: Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance. DO NOT ATTEMPT TO STERILIZE THE DEVICE IN THE PACKAGING MATERIALS SUPPLIED.

Sterility: The healthcare facility should conduct testing to ensure that the conditions essential to sterilization can be achieved and are acceptable for the steam sterilization process. ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities provides guidelines for design and personnel considerations, processing recommendations, care of sterilizers, quality control, and quality process improvement.

MR SAFETY INFORMATION

The Ossera™ AFX is labeled MR Unsafe.

TRAINING

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Surgeons may obtain training from a qualified instructor prior to implantation of 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.

Rx Only 

For symbols glossary, please refer to:
https://www.restor3d.com/resources/instruction

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