restor3d TIDAL Osteotomy Wedge System

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

1. DEVICE DESCRIPTION

The restor3d TIDAL Osteotomy Wedge System consists of a set of wedge-shaped devices intended to be used for angular correction of small bones in the ankle and foot. The restor3d TIDAL Osteotomy Wedge System are constructed from a medical grade titanium alloy. Restor3d offers in a variety of sizes Cotton Wedges, indicated for opening osteotomies of the medial cuneiform, as well as Evans Wedges, used in lateral column lengthening osteotomies. The restor3d TIDAL Osteotomy Wedges are intended to be used with ancillary plating fixation.

Restor3d has provided instrumentation to assist in the surgical placement of the wedges. It is important that the provided inserter and trials be used as they were designed for this specific application to ensure the accurate installation of the wedges. 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 not to impact the end of that trial as that is the location of the other size that will be trialed.

2. INDICATIONS FOR USE

The TIDAL Osteotomy Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The TIDAL Osteotomy Wedges are intended for use with ancillary plating fixation.

The TIDAL Osteotomy Wedges are not intended for use in the spine.

3. CONTRAINDICATIONS

The TIDAL Osteotomy Wedges are contraindicated for use in cases of:

- Infection
- Physiologically or psychologically inadequate patients
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for more conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity
- Malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless additional supplemental fixation or stabilization methods are utilized
- Foreign body sensitivity

4. WARNINGS AND PRECAUTIONS

WARNINGS

- 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 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.
- Plates and screws chosen to secure the fracture or osteotomy that could contact the implanted restor3d Osteotomy TIDAL Wedge should be manufactured from Titanium (or titanium alloy) to reduce the likelihood of galvanic corrosion.
- It is important that immobilization of the fracture or osteotomy site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established to reduce the likelihood of delayed or non-union of the fracture or osteotomy site.

PRECAUTIONS

- Correct selection of implant is extremely important. The potential for success in fracture fixation is increased by selecting the proper implant size, shape, and design. The patient's anatomy and indication will determine the size of the restor3d Osteotomy TIDAL Wedge 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 firm 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.
- The restor3d TIDAL Osteotomy Wedge 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 TIDAL Osteotomy Wedge 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.
- When inserting the implant, care should be taken to avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.

5. IMPLANT MATERIALS

The restor3d TIDAL Osteotomy Wedges are manufactured from a medical grade of Titanium alloy (Ti-6Al-4V).

6. STERILITY

Product	Cleaning Instructions	Sterilization Instructions
Non-sterile Reusable Instruments	See section 7	See LBL-50001
Non-sterile Disposable Instruments	N/A	See section 6, part E
Sterile Disposable Instruments	N/A	N/A

A) Sterile Implants

This implant has been sterilized by gamma radiation and is 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 E 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) Non-Sterile Reusable Instruments

Detailed reprocessing instruction are provided in MKG-10005 Sterilization Instructions. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Immediately re-sterilize all reusable instruments removed from the sterile field before handling.

E) Recommended steam sterilization conditions (non-sterile disposable 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

7. INSTRUCTIONS FOR REPROCESSING REUSABLE INSTRUMENTS

The Reusable Instrument Tray and its contents are provided non-sterile and must be cleaned and sterilized prior to use. All reusable instruments must be cleaned, inspected, and sterilized between uses. Always immediately clean and decontaminate all devices that have been soiled.

Reusable instruments can be used indefinitely if not damaged, worn, or deteriorated, and should be inspected before each use for these conditions. DO NOT use broken, damaged, malfunctioning, or deteriorated instruments. Examples of unacceptable wear or deterioration include any cracking, bending, corrosion, missing components, or visible wear which could impact function or performance (e.g., dull cutting edges).

General Guidance for Cleaning Instruments

Verify that all instruments required for use are present in the case. For manual cleaning, devices should be grouped according to similar metals before subsequent processing in order to prevent galvanic corrosion. In addition, it is not recommended to use chloride containing cleaning solutions since its use has been linked to corrosion of metallic instruments, especially stainless steel.

DETAILED INSTRUMENT REPROCESSING INSTRUCTIONS ARE PROVIDED IN MKG-10005 STERILIZATION INSTRUCTIONS.

8. ADVERSE EVENTS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- 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

9. SURGICAL PROCEDURE

A surgical technique is available which outlines the basic procedure for device implantation and the use of specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

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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