# restor3d Utility Wedge System

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

## INSTRUCTIONS FOR USE

### 1. DEVICE DESCRIPTION

The restor3d Utility 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 Utility Wedges are constructed from an implant grade titanium alloy. Restor3d offers in a variety of sizes Lapidus Wedges, indicated for lengthening and opening osteotomies of the metatarsal cuneiform, as well as Subtalar Wedges, used in hindfoot osteotomies. The restor3d Utility Wedges are intended to be used with supplemental 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.

### 2. INDICATIONS FOR USE

The restor3d Utility Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Metatarsal Cuneiform osteotomies
- Nonunion of arthrodesis of the Midfoot including Metatarsal Cuneiform osteotomies (TMT or Lapidus)
- Hindfoot osteotomies such as Ankle fusion and Subtalar fusion

The restor3d Utility Wedges are intended for use with supplemental fixation.
The restor3d Utility Wedges are not intended for use in the spine.

### 3. CONTRAINDICATIONS

The restor3d Utility 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*

- The restor3d Utility Wedge 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.
- Plates and screws chosen to secure the fracture or osteotomy that could contact the implanted restor3d Utility 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.
- 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*

- 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 Utility 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.

**5. MRI SAFETY INFORMATION**

The restor3d Utility 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 restor3d Utility 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.

**6. POTENTIAL ADVERSE EFFECTS**

Potential adverse effects resulting from use of the restor3d Utility Wedge 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.

**6. IMPLANT MATERIALS**

The restor3d Utility Wedge is manufactured from an implant grade titanium alloy (Ti-6AL-4V).

**7. HOW SUPPLIED**

A) STERILE IMPLANTS

The restor3d Utility Wedge 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 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.

Lapidus Wedge:

1. Expose the first TMT Joint and release the plantar ligaments.
2. Prepare the joint in accordance with the accepted surgical technique.
3. Determine the correct implant size and shape with the implant trials.
4. Prepare the implant, including packing with bone graft material, if desired.
5. Orient the implant in the correct alignment and carefully insert implant into the joint.
6. Verify implant position
7. Complete surgical procedure as required.

Subtalar Wedge:

1. Expose the subtalar joint and distract the joint per standard procedure.
2. Prepare the joint in accordance with the accepted surgical technique
3. Determine the correct implant size and shape with the implant trials.
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 implant into the joint.
7. Verify implant position.
8. Insert a screw through the calcaneus, wedge, and into the talus.
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.**

Manufacturer: restor3d, Inc.
311 W Corporation St
Durham, NC 27701
Phone: 984-888-0593
Email: customerservice@restor3d.com
www.restor3d.com