TIDAL® Osteotomy Wedge System

Cotton Wedges

SURGICAL TECHNIQUE

restor3d

restor3d

Personalized Orthopaedics
Enabling Surgeons to Repair and
Reconstruct the Human Body

Backed by Science
Driven by Outcomes

Contents

Product Overview 2

Indications & Contraindications.....4

Standard and Anatomic Cotton Wedge Surgical Technique.....5

Explant Information.....7

Ordering Information – Implants.....7

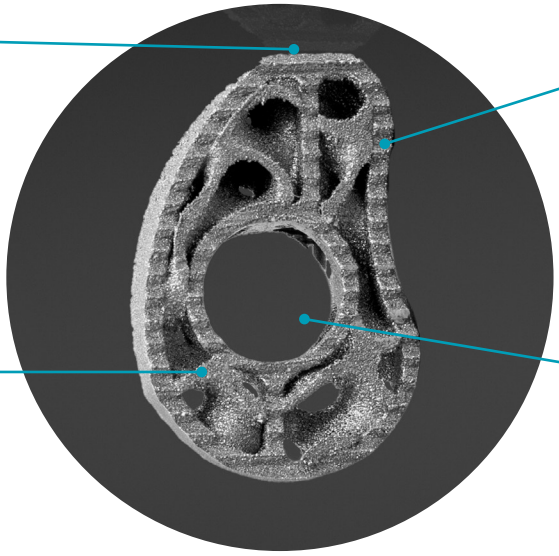
Ordering Information – Instrumentation 8

IMPORTANT NOTE: restor3d, as the manufacturer of this device, 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 procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. restor3d is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient. Always refer to the package insert, product label and/or product instructions prior to using any restor3d product.

For further product information or to arrange a product demonstration, please contact your local restor3d representative or call Customer Service toll-free in the U.S. at (984) 888-0593 or email customerservice@restor3d.com. You can also visit www.restor3d.com.

Product Overview

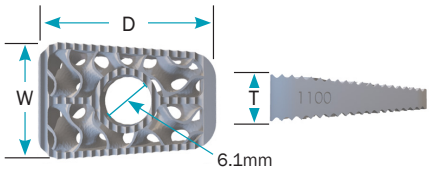
restor3D's TIDAL® Osteotomy Wedge System is designed for internal bone fixation for fractures or osteotomies in the ankle and foot. The Cotton Wedges are for plantar flexion opening wedge osteotomies of the medial cuneiform. Manufactured using laser powder bed fusion of medical grade titanium alloy, the restor3d Cotton Wedges are available in a variety of footprints and thicknesses to accommodate varying patient anatomy.



Available in multiple footprints and thicknesses to accommodate the range of patient anatomy

Sizing Options

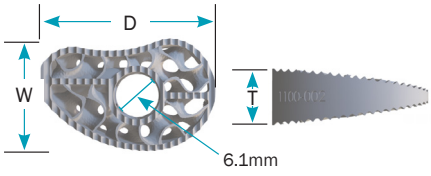
Standard Cotton Wedge



WIDTH (MM)	DEPTH (MM)	THICKNESS* (MM)	CENTRAL HOLE DIAMETER (MM)
14	16	4-6	6.1
14	20	4-6	6.1

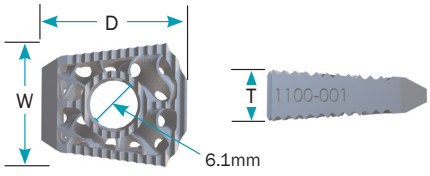
**Thickness of Standard Cotton Wedges are in 1mm increments.*

Anatomic Cotton Wedge



WIDTH (MM)	DEPTH (MM)	THICKNESS (MM)	CENTRAL HOLE DIAMETER (MM)
12	18	5, 6, 7, 8, 10, 12	6.1
14	22	5, 6, 7, 8, 10, 12	6.1

Standard Cotton with Bevel



WIDTH (MM)	DEPTH (MM)	THICKNESS* (MM)	CENTRAL HOLE DIAMETER (MM)
14	16	4-6	6.1
14	20	4-6	6.1

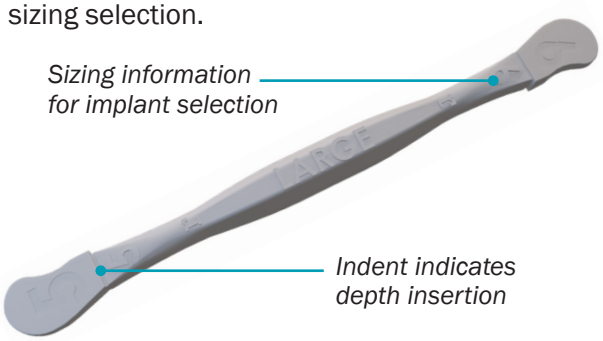
**Thickness of Standard Cotton Wedges are in 1mm increments.*

Single-Use Instrumentation

Osteotomy Wedges are instrumented with single-use, sterile-packed trials and inserters. restor3d's TIDAL® Osteotomy Wedges are designed to interface with a threaded inserter to allow for accurate placement. Once the implant is definitively positioned, simply unscrew the inserter to release. Inserter is only provided with the Anatomic Cotton Wedges.

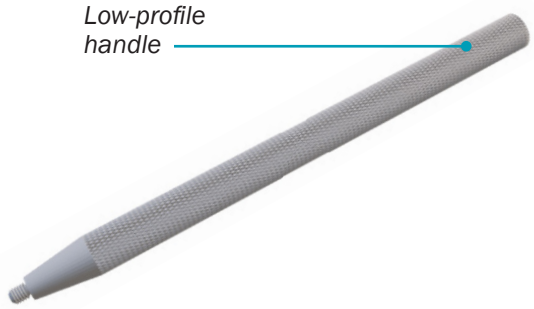
Sizing Trials

- Radiodense material for clear visibility under fluoroscopy.
- Accurately replicates correction with the patient's anatomy prior to final implant selection.
- Double sided trials facilitate streamlined implant sizing selection.



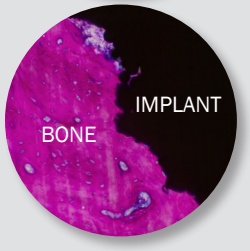
Inserter

- Ergonomic, low-profile handle to maximize visibility at the implantation site.
- Rigid fixation with robust attachment to implant.



TIDAL Technology™

Backed by scientific research and development



restor3d's TIDAL Technology™ is an optimized porous architecture designed for osseointegration. Derived from sinusoidal functions, TIDAL Technology™ guides bone growth through the fully interconnected structure with maximized surface area.

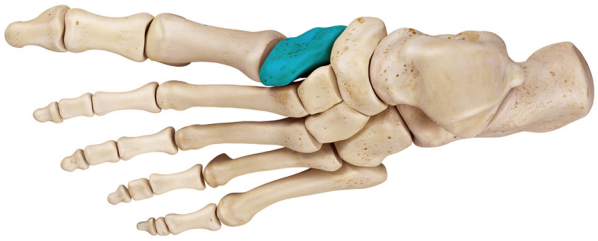
- 100% interconnectivity and up to 80% porosity[1]
- Mesoscale pores support graft retention and bony ingrowth[2]
- Direct bony apposition to implant surface guided by surface topography and curvature demonstrated in preclinical model[2,3]

1. Kelly, et al. Acta Biomaterialia (2019) 94, 601-626.
2. Kelly, et al. Journal of the Mechanical Behavior of Biomedical Materials (2021) 116, 104380.
3. Kelly, et al. Biomaterials (2021) 279, 121206.

Indications

The TIDAL® Cotton 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



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

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

Contraindications

The restor3d 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

Standard and Anatomic Cotton Wedge Surgical Technique

1. **Make an incision to expose the medial cuneiform.**

   Make a 2-3 cm incision dorsally over the body of the medial cuneiform.

   Use blunt dissection to expose the first metatarsal cuneiform and navicular medial cuneiform joints, taking care to retract both the extensor hallucis longus and tibialis anterior tendons.

2. **Perform an osteotomy and distract to allow for access into the site.**

   Make a transverse osteotomy on the dorsal surface of the medial cuneiform to avoid articular injury. Leave the plantar cortex intact to provide stability to the osteotomy while also aiding in the correction of a plantar deformity.

   A pin based distractor or laminar spreader may provide controlled distraction of the osteotomy. Once access is secured, distract the osteotomy to your desired correction. The trials may be used to hold distraction of the anatomy intraoperatively.

3. **Determine the correct implant size and shape with the implant trial(s).**

   Trial selection depends on the thickness, width, and depth of the osteotomy site, the preparation technique, and the patient's anatomy. Based on the preoperative imaging and surgical technique, choose a trial of the appropriate size and carefully insert it into the osteotomy site (Figs. 5 and 6). Sequentially trial until desired correction is achieved. Verify correct sizing via fluoroscopy and select the implant that corresponds to the footprint and thickness determined using the implant trial(s).

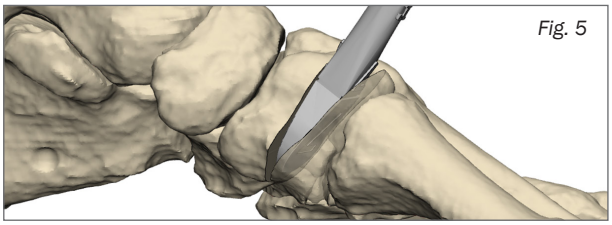


Fig. 5

Fig. 6

4. **Prepare the implant, including packing with bone graft material, if desired.**

   If desired, pack the interior of the wedge with bone graft material. Note that the large, central graft window, in addition to porous lattice, can be packed with graft material (Fig. 7).

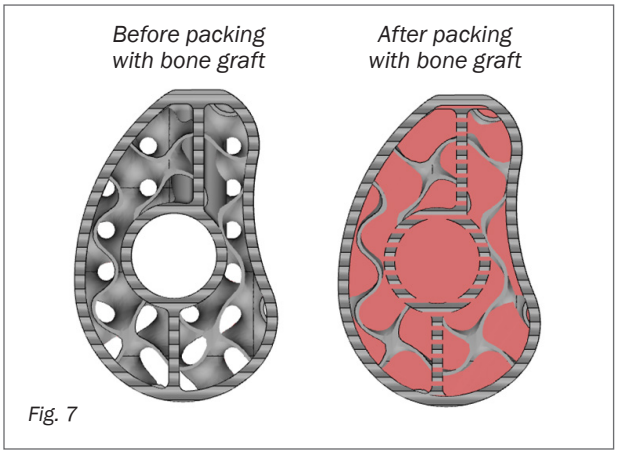


Fig. 7

5. **Place the implant on the inserter handle (if using an Anatomic Cotton Wedge). The Standard Cotton wedge does not come with an inserter.**

   If using an Anatomic Cotton Wedge, attach the wedge to the restor3d inserter by threading the inserter's tip into the corresponding threaded hole on the wedge. Thread the implant onto the inserter until some resistance is felt and the implant is held flush against the inserter and securely in place (Figs. 8 and 9).

   PRECAUTION: Take caution to not overtighten when threading the implant onto the inserter as overtightening could result in failure to disengage the implant after insertion.

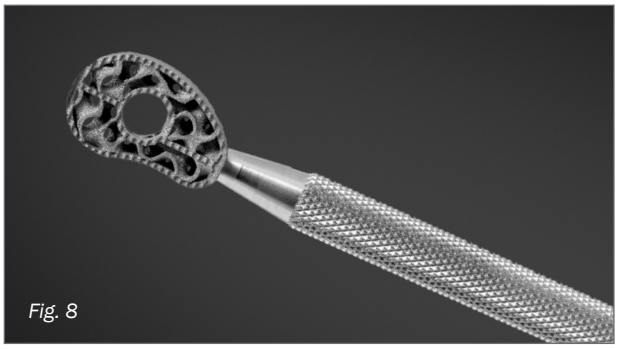


Fig. 8

   If using a Standard Cotton Wedge (which is not designed for use with an inserter) use a tamp to place the implant in the osteotomy site (Fig. 9).

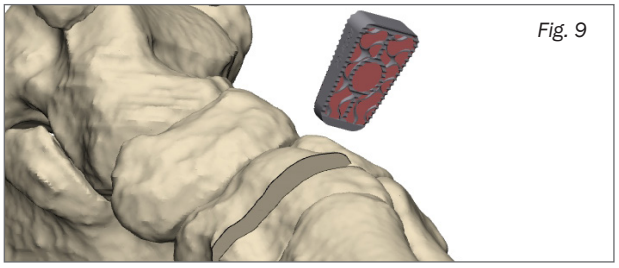


Fig. 9

6. **Orient the implant and inserter (if provided) in the correct alignment and carefully insert the implant into the distracted segment.**

   Carefully insert the implant into the osteotomy site (Figs. 10 and 11). If necessary, use light impaction to advance the implant until it is flush with bone. If a pin-based distractor or laminar spreader was used to maintain access to the osteotomy site, remove it now.

   PRECAUTION: When inserting the implant, take care to avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.

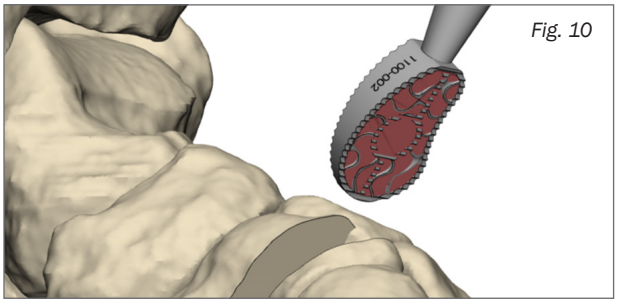


Fig. 10

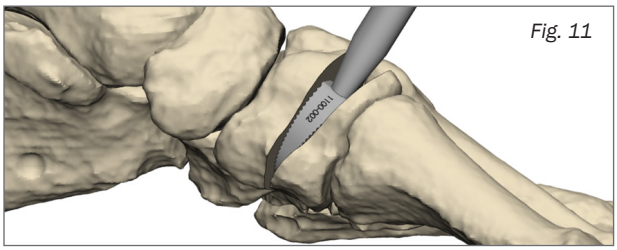


Fig. 11

7. **Verify implant position.**

   Confirm the final position of the implant via fluoroscopy.

8. **Remove the inserter (if using an Anatomic Cotton Wedge) and inspect implant.**

   If using an Anatomic Cotton Wedge, unscrew inserter from the wedge. Inspect the wedge to ensure there is congruent contact with bone along its surface.

9. **Implant fixation.**

   restor3d osteotomy wedges are intended for use with ancillary fixation. It is recommended that the selected ancillary fixation is manufactured from titanium in order to avoid galvanic corrosion.

10. **Complete surgical procedure as required.**

Explant Information

If this implant needs to be removed due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering Information – Implants

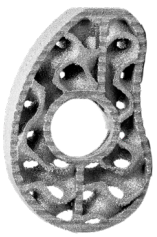
Standard Cotton Wedge

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	1100-16140407	Small Footprint	16mm	14mm	4mm	7°
	1100-16140507				5mm	
	1100-16140607				6mm	
	1100-20140407	Medium Footprint	20mm		4mm	
	1100-20140507				5mm	
	1100-20140607				6mm	

Standard Cotton with Bevel

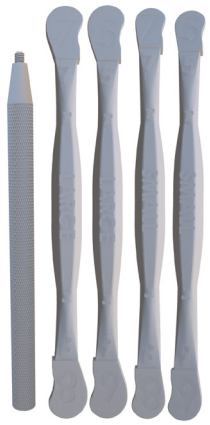
IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	1100-001-16140407	Small Footprint	16mm	14mm	4mm	7°
	1100-001-16140507				5mm	
	1100-001-16140607				6mm	
	1100-001-20140407	Medium Footprint	20mm		4mm	
	1100-001-20140507				5mm	
	1100-001-20140607				6mm	

Anatomic Cotton Wedge

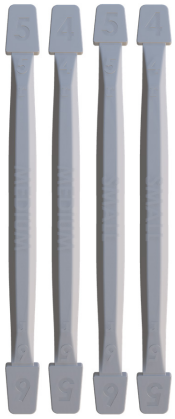
IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS
	1100-002-18120513	Small Footprint	18mm	12mm	5mm
	1100-002-18120616				6mm
	1100-002-18120719				7mm
	1100-002-18120822				8mm
	1100-002-18121028				10mm
	1100-002-18121234				12mm
	1100-002-22140510	Large Footprint	22mm	14mm	5mm
	1100-002-22140613				6mm
	1100-002-22140715				7mm
	1100-002-22140818				8mm
	1100-002-22141023				10mm
	1100-002-22141228				12mm

Ordering Information – Instrumentation

Anatomic Cotton Wedge Kit

KIT CONTENTS	PRODUCT CODE	DESCRIPTION	THICKNESS
	4100-002-0101	Anatomic Cotton Kit (5mm-8mm)	5mm-8mm
	4100-002-0102	Anatomic Cotton Kit (10mm/12mm)	10mm / 12mm

Standard and Beveled Cotton Wedge Kit

KIT CONTENTS	PRODUCT CODE	DESCRIPTION	FOOTPRINTS
	4100-0101	Cotton Kit	Small and Medium

restor3d

Durham, NC
Phone: (984) 888-0593
Email: customerservice@restor3d.com
www.restor3d.com

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
© 2023 restor3d, Inc. Marks noted with ® or TM are trademarks of restor3d, Inc. Other marks mentioned herein may be trademarks of restor3d, Inc. or of their respective owners. Patents: www.restor3d.com/patents. All Rights Reserved.
Printed in the USA. LBL-70057 Rev 02 APR2023