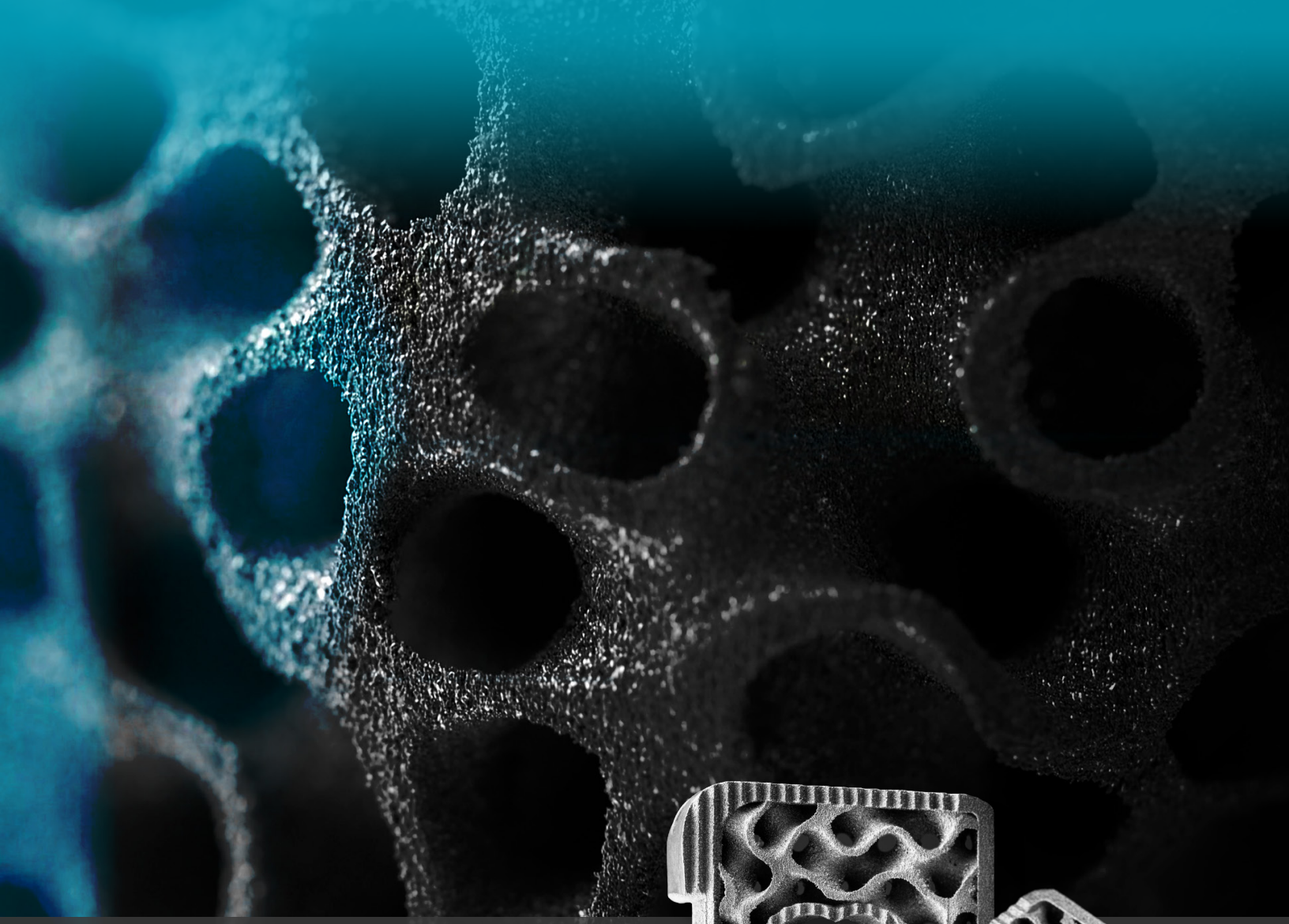


Evans Wedge System

Featuring TIDAL Technology

Designed for Lateral Column Lengthening Osteotomies

SURGICAL TECHNIQUE

restor3d

restor3d

Personalized Orthopaedics
Enabling Surgeons to Repair and
Reconstruct the Human Body

Backed by Science
Driven by Outcomes

THIS IS AN INTERACTIVE DOCUMENT

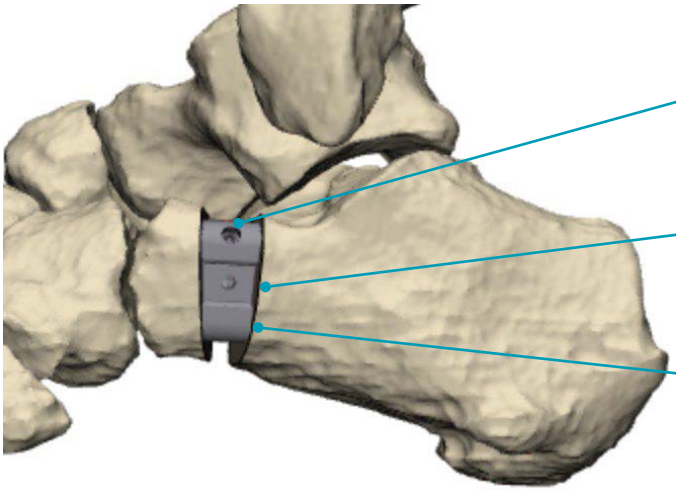
Contents

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 Evans Wedge System featuring TIDAL Technology is designed for internal bone fixation for fractures or osteotomies in the foot and ankle. The Evans Wedge is intended to be used for lateral column lengthening osteotomies. Manufactured using laser powder bed fusion of medical grade titanium alloy, a variety of footprint sizes and thicknesses are provided to accommodate differences in patient anatomy.



Dorsal instrument port increases ease of implant positioning

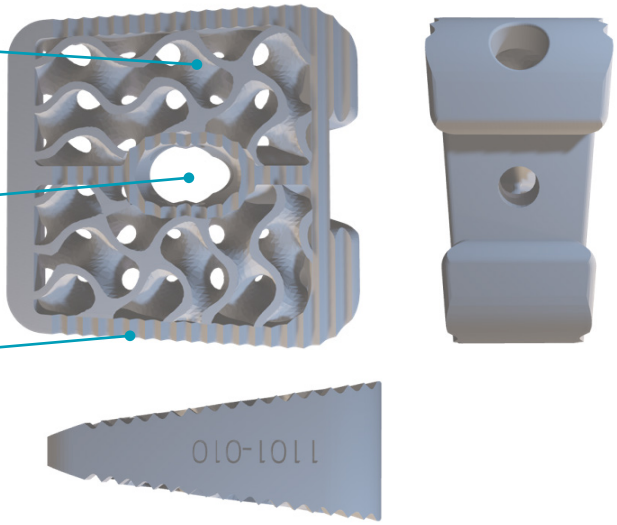
Lateral recess ensures a low profile to reduce soft tissue irritation

Plantar taper prevents dorsal translation of the anterior process

Proprietary TIDAL Technology maximizes graft packing and encourages bone growth through the implant

Angled window accommodates pin or screw fixation through the implant

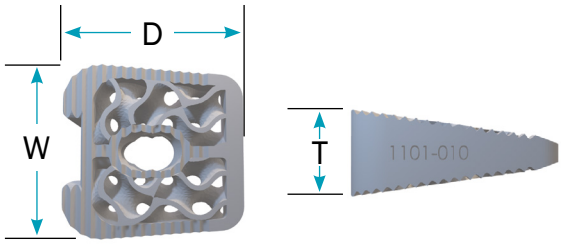
Optimized surface topography increases expulsion resistance



Sizing Options

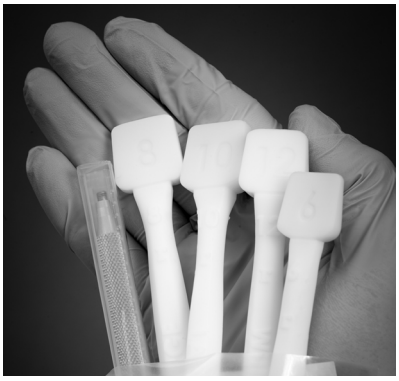
Anatomic Evans Wedge

FOOTPRINT	WIDTH (MM)	DEPTH (MM)	THICKNESS (MM)
Medium	20mm	20mm	6, 8, 10, 12
Large	22mm	22mm	6, 8, 10, 12



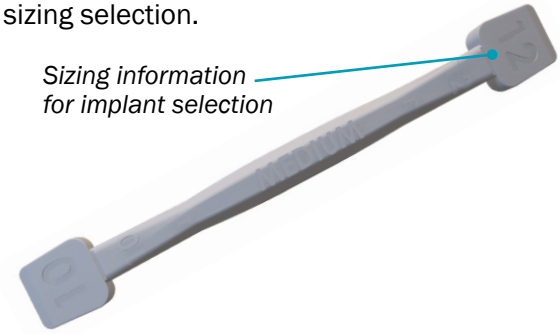
Disposable Instrumentation

Evans Wedges are instrumented with single-use, sterile-packed trials and inserters. restor3d's Evans Wedge System featuring TIDAL Technology is designed to interface with a threaded inserter to allow for accurate placement. Once the implant is definitively positioned, simply unscrew the inserter to release. For the Anatomic Evans Wedges, the inserter is included with trials corresponding to implant sizes in a single-use, sterile pack kit.



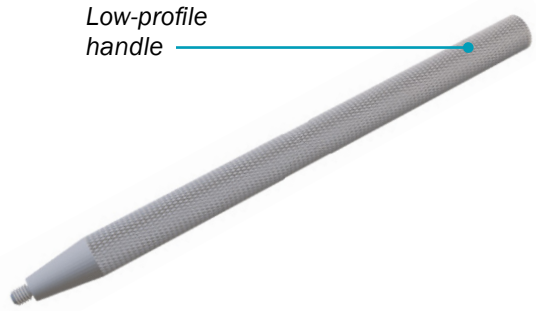
Sizing Trials

- 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.

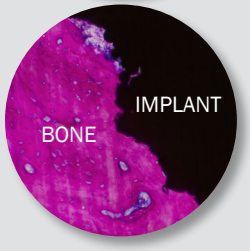


TIDAL Technology

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]

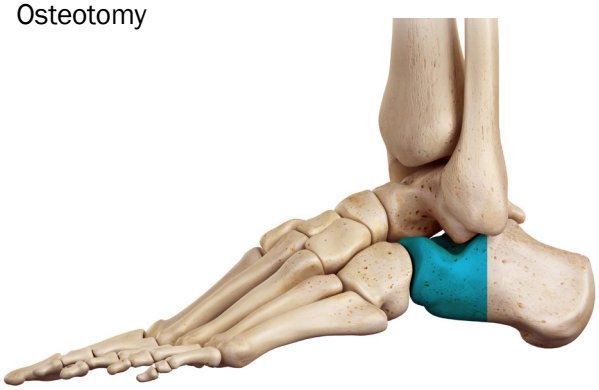


1. Kelly, et al. Acta Biomaterialia (2019) 94, 601-626.
2. Kelly, et al. Journal of the Mechanical Behavior of Biomedical Materials (2021) 116, 104380.
3. Kelly, et al. Biomaterials (2021) 279, 121206.

Indications

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

- Evans Lengthening Osteotomy or Calcaneal Z Osteotomy



The restor3d Utility Wedges are intended for use with supplemental fixation.

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

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:

- Evans Lengthening Osteotomy or Calcaneal Z Osteotomy

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

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

Contraindications

The restor3d TIDAL® Osteotomy Wedges and 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

Evans Wedge Surgical Technique

1. **Make an incision to expose the calcaneocuboid joint.**

   Make a 2-3 cm longitudinal incision lateral to the anterior process and just below the sinus tarsi.

   Expose the calcaneocuboid joint via blunt dissection, taking care to retract the peroneal tendons and sural nerves.

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

   Starting 10-15 mm proximal to the calcaneocuboid joint in order to avoid articular damage, use an oscillating saw to make the osteotomy. Use an osteotome to finish the cut. Gain accessibility and controlled distraction to the osteotomy site through use of either a pin-based distractor or laminar spreader. Once access is secured, distract the osteotomy to your desired correction.

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 (Fig. 1). 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).

   NOTE: Trials are designed to be line-to-line with the implants.

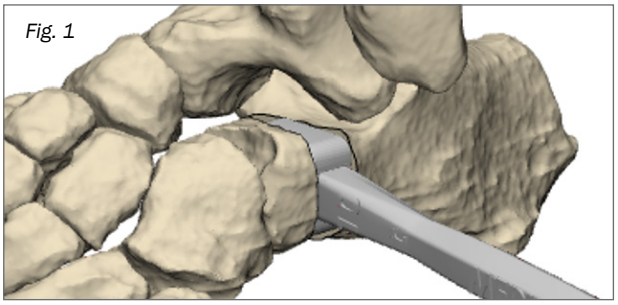


Fig. 1

4. **Prepare the implant, including packing with bone graft material, 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. 2).

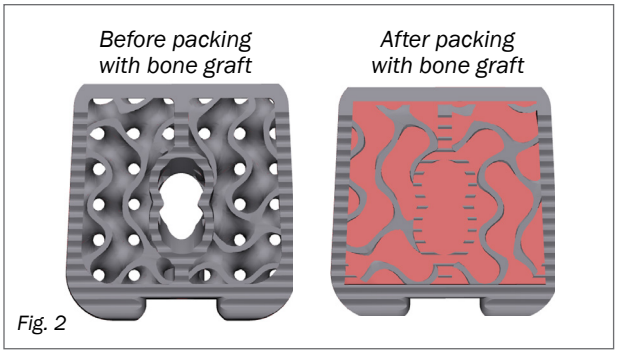


Fig. 2

5. **Place the implant on the inserter handle.**

   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 (Fig. 3)*.

   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.

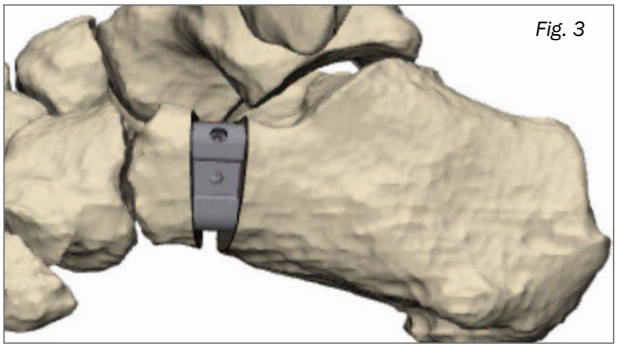


Fig. 3

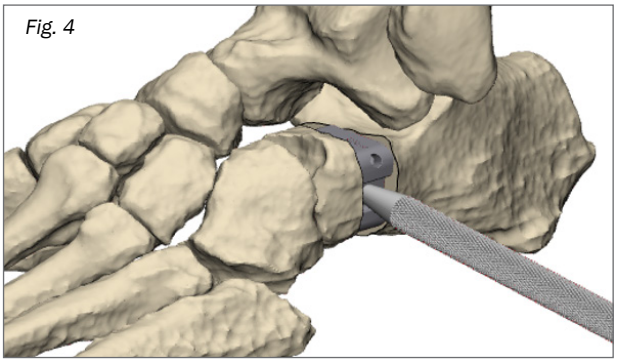
*TIP: Pinch the ends of the tube packaging containing the inserter when opening the instrument kits.

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

   Carefully insert the implant into the osteotomy site (Fig. 4). 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. 4



7. **Verify implant position.**

   Confirm the final position of the implant via fluoroscopy.

8. **Remove the inserter and inspect implant.**

   Unscrew inserter from the wedge. Inspect the wedge to ensure there is congruent contact with bone along its surface.

9. **Implant fixation.**

   restor3d Utility Wedges are intended for use with supplemental fixation. restor3d Osteotomy Wedges are intended for use with ancillary plating 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

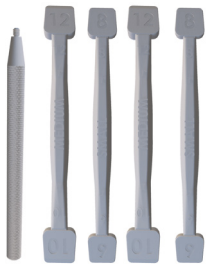
If this implant needs to be removed due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering Information – Anatomic Evans Wedge

Anatomic Evans Wedge

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS
	1101-010-202006	Medium Footprint	20mm	20mm	6mm
	1101-010-202008				8mm
	1101-010-202010				10mm
	1101-010-202012				12mm
	1101-010-222206	Large Footprint	22mm	22mm	6mm
	1101-010-222208				8mm
	1101-010-222210				10mm
	1101-010-222212				12mm

Anatomic Evans Wedge Kit

INSTRUMENT	PRODUCT CODE	DESCRIPTION	FOOTPRINTS
	4101-010-0101	Anatomic Evans Wedges	Medium and Large

Ordering Information – Additional Implants and Instruments

Standard Evans Wedge

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS
	1101-18160818	Small Footprint	18mm	16mm	8mm
	1101-18161018				10mm
	1101-18161218				12mm
	1101-20180818	Medium Footprint	20mm	18mm	8mm
	1101-20181018				10mm
	1101-20181218				12mm
	1101-22200818	Large Footprint	22mm	20mm	8mm
	1101-22201018				10mm
	1101-22201218				12mm

Ordering Information – Additional Implants and Instruments *(continued)*

Beveled Evans Wedge

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS
	1101-009-18160818	Small Footprint	18mm	16mm	8mm
	1101-009-18161018				10mm
	1101-009-18161218				12mm
	1101-009-20180818	Medium Footprint	20mm	18mm	8mm
	1101-009-20181018				10mm
	1101-009-20181218				12mm
	1101-009-22200818	Large Footprint	22mm	20mm	8mm
	1101-009-22201018				10mm
	1101-009-22201218				12mm

Standard and Beveled Evans Wedge Sizing Trial

INSTRUMENT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS
	6101-18160818	Small Footprint	18mm	16mm	8mm
	6101-18161018				10mm
	6101-18161218				12mm
	6101-20180818	Medium Footprint	20mm	18mm	8mm
	6101-20181018				10mm
	6101-20181218				12mm
	6101-22200818	Large Footprint	22mm	20mm	8mm
	6101-22201018				10mm
	6101-22201218				12mm

Evans Wedge Inserter

INSTRUMENT	PRODUCT CODE	CORRESPONDING IMPLANT
	6100-INSRTRM5	Standard and Beveled Evans Wedges

restor3d

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