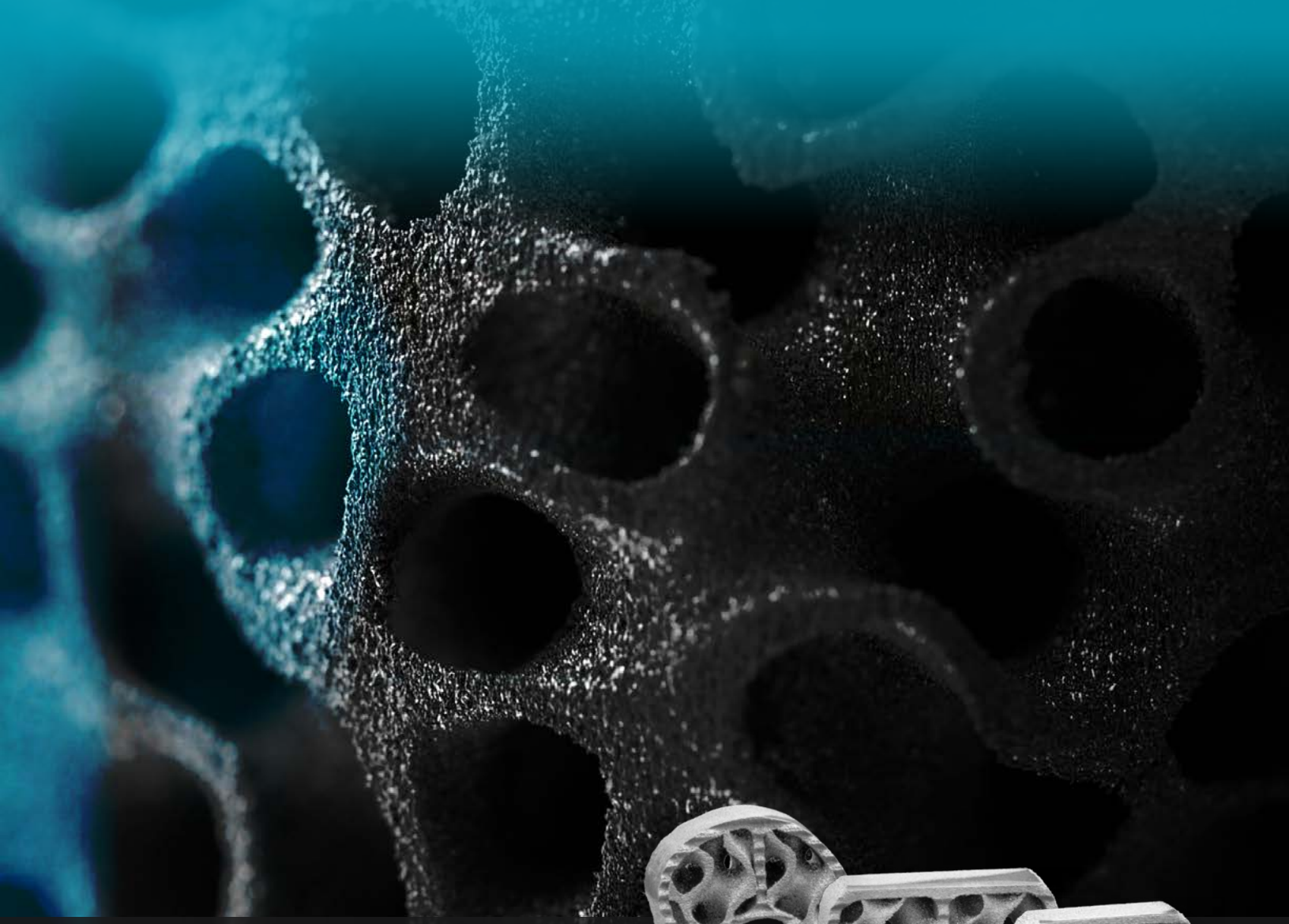

TIDAL™ Osteotomy Wedge System

Evans and Cotton Wedges

SURGICAL TECHNIQUE

restor3d

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Personalized Orthopaedics
Enabling Surgeons to Repair and
Reconstruct the Human Body

Backed by Science
Driven by Outcomes

THIS IS AN INTERACTIVE DOCUMENT

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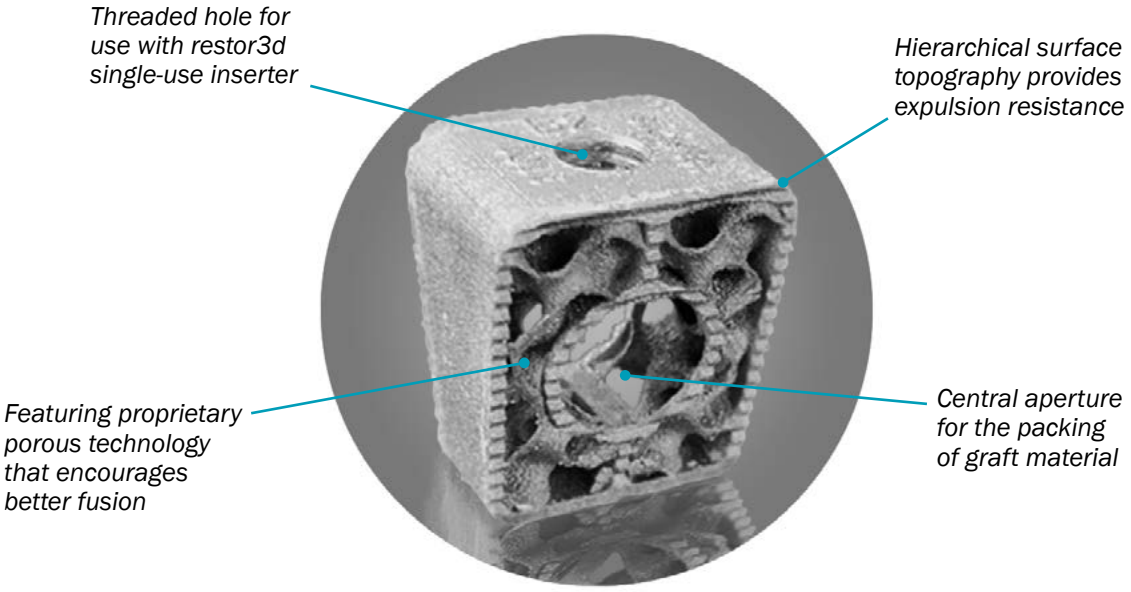
For further product information or to arrange a product demonstration, please contact your local restor3d representative or call Customer Service toll-free in the U.S. at (984) 888-0593 or email customerservice@restor3d.com. You can also visit www.restor3d.com.

Product Overview

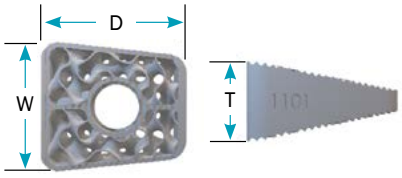
restor3D's TIDAL™ Osteotomy Wedge System is designed for internal bone fixation for fractures or osteotomies in the ankle and foot. The Evans Wedge is for lateral column lengthening osteotomies. The Standard and Anatomic Cotton Wedges are for plantar flexion opening wedge osteotomies of the medial cuneiform. 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.



Available in multiple footprints and thicknesses to accommodate various patient anatomies

Sizing Options

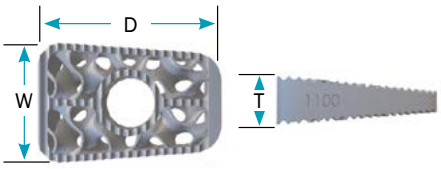
Evans Wedge



WIDTH (MM)	DEPTH (MM)	THICKNESS* (MM)
16mm	18mm	8mm-12mm
18mm	20mm	8mm-12mm
20mm	22mm	8mm-12mm

**Thickness of Evans Wedges are in 2mm increments.*

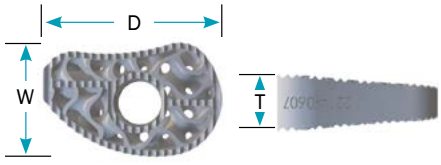
Standard Cotton Wedge



WIDTH (MM)	DEPTH (MM)	THICKNESS* (MM)
14mm	16mm	4mm-6mm
14mm	20mm	4mm-6mm

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

Anatomic Cotton Wedge

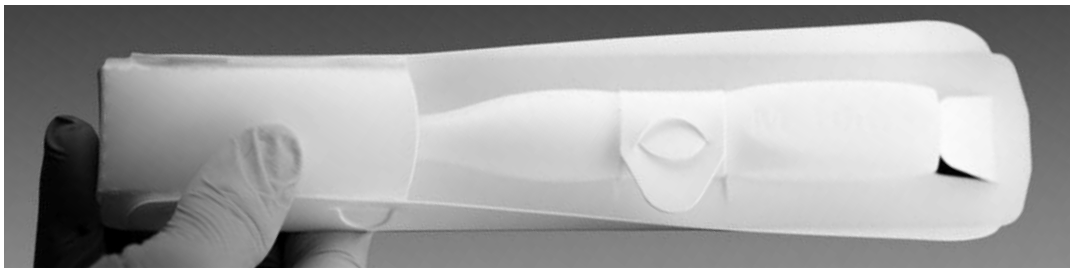


WIDTH (MM)	DEPTH (MM)	THICKNESS* (MM)
14mm	22mm	5mm-8mm

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

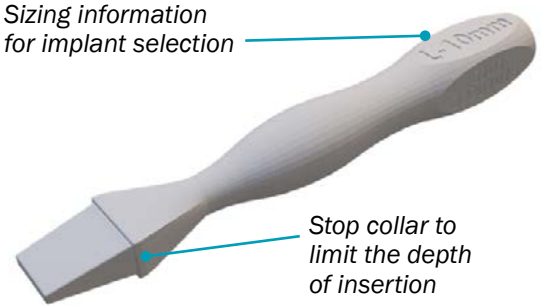
Disposable Instrumentation

Instrumented with single-use, sterile-packed trials and inserters. The restor3d TIDAL™ Osteotomy Wedges are designed to interface with a threaded inserter to allow for accurate placement. Once implant is in place, simply unscrew the inserter to release. Inserter is only provided with Evans Wedges and Anatomic Cotton Wedges.



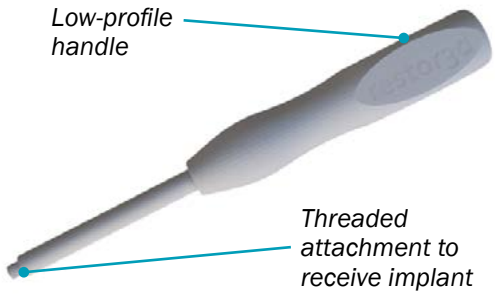
Sizing Trials

- Radiodense material for clear visibility intraoperatively.
- Allows for determination of the correct size of implant.
- Provided in all sizes to match implant offering.



Inserter

- Ergonomic, low-profile handle to maximize visibility of fusion site.
- Rigid fixation with threaded attachment to implant.

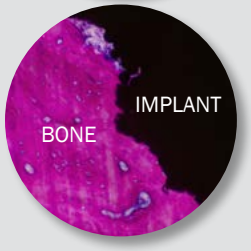


TIDAL Technology

Backed by years of 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.

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Indications

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.

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

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.

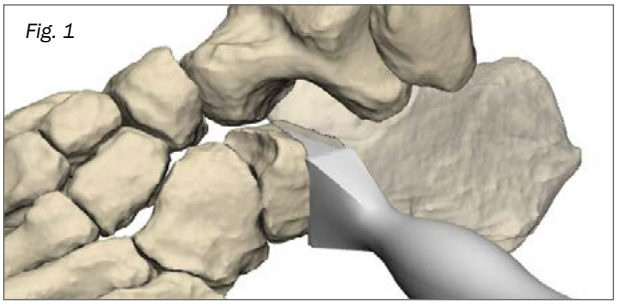

Fig. 1

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).

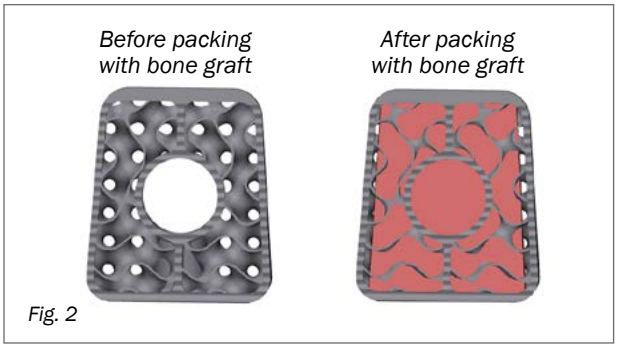

Fig. 2

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

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.

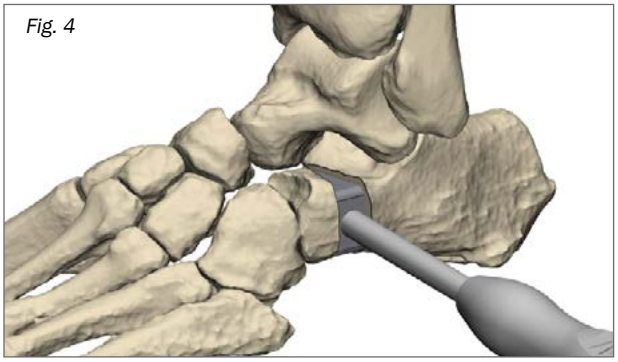

Fig. 4

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 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.**

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 in order to avoid articular injury. Leave the plantar cortex intact in order to provide stability to the osteotomy while also aiding in the correction of a plantar deformity.

   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. 5). 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. 5

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. 6).

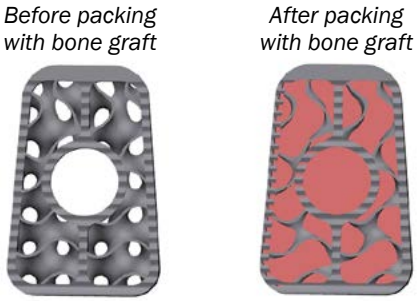

Fig. 6

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.

   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. 7).

   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.

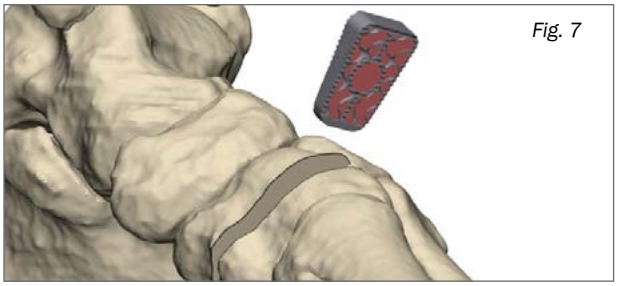

Fig. 7

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 (Fig. 8). 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.

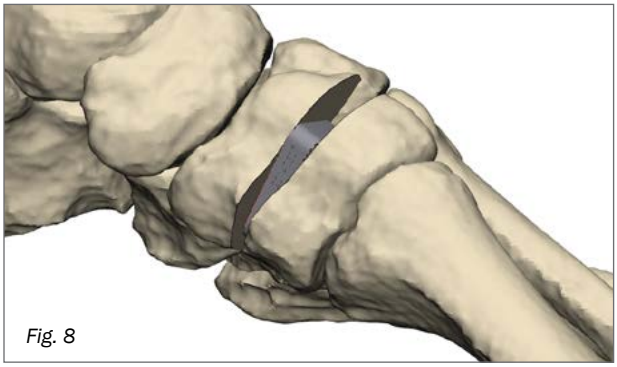

Fig. 8

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

Evans Wedge

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	1101-18160818	Small Footprint	18mm	16mm	8mm	18°
	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	

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	14mm	4mm	
	1100-20140507				5mm	
	1100-20140607				6mm	

Anatomic Cotton Wedge

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	1100-002-22140507	Anatomic Footprint	22mm	14mm	5mm	7°
	1100-002-22140607				6mm	
	1100-002-22140707				7mm	
	1100-002-22140807				8mm	

Ordering Information – Instrumentation

Evans Wedge Sizing Trial

INSTRUMENT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	6101-18160818	Small Footprint	18mm	16mm	8mm	18°
	6101-18161018				10mm	
	6101-18161218				12mm	
	6101-20180818	Medium Footprint	20mm	18mm	8mm	
	6101-20181018				10mm	
	6101-20181208				12mm	
	6101-22200818	Large Footprint	22mm	20mm	8mm	
	6101-22201018				10mm	
	6101-22201218				12mm	

Standard Cotton Wedge Sizing Trial

INSTRUMENT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	6100-16140407	Small Footprint	16mm	14mm	4mm	7°
	6100-16140507				5mm	
	6100-16140607				6mm	
	6100-20140407	Medium Footprint	20mm	14mm	4mm	
	6100-20140507				5mm	
	6100-20140607				6mm	

Anatomic Cotton Wedge Sizing Trial

INSTRUMENT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	THICKNESS	ANGLE
	6100-002-22140507	Anatomic Footprint	22mm	14mm	5mm	7°
	6100-002-22140607				6mm	
	6100-002-22140707				7mm	
	6100-002-22140807				8mm	

Osteotomy Wedge Inserter (only provided with Evans Wedges and Anatomic Cotton Wedges)

INSTRUMENT	PRODUCT CODE	CORRESPONDING IMPLANT
	6101-INSRTRM5	Evans Wedges
	6101-INSRTRM3	Anatomic Cotton Wedges

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