

# TIDAL™ Subtalar Wedge System

Addresses Subtalar Arthrosis, Calcaneal  
Fracture Neglect, and Malunion

**SURGICAL TECHNIQUE**



# restor3d

# restor<sup>3d</sup>

Personalized Orthopaedics  
Enabling Surgeons to Repair and  
Reconstruct the Human Body

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Backed by Science  
Driven by Outcomes



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## Contents

Product Overview .....	2
TIDAL™ Subtalar Wedge System Features .....	2
Sizing Options .....	2
Disposable Instrumentation .....	3
TIDAL Technology.....	3
Indications & Contraindications.....	4
Subtalar Wedge Surgical Technique .....	5
Explant Information.....	7
Ordering Information – Implants.....	7
Ordering Information – Instrumentation .....	7

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 each 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](mailto:customerservice@restor3d.com). You can also visit [www.restor3d.com](http://www.restor3d.com).

## Product Overview

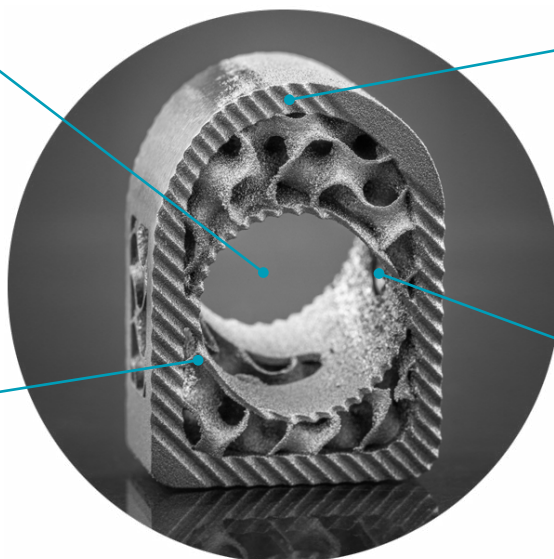
restor3D's TIDAL™ Subtalar Wedge System features TIDAL Technology and is manufactured from medical grade titanium alloy (Ti-6Al-4V). The wedge system is available in varied footprints and heights and is designed for internal bone fixation in the ankle, such as ankle fusion and subtalar fusion.

Central aperture for the packing of graft material or the placement of a fixation device

Hierarchical surface topography provides expulsion resistance

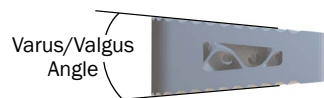
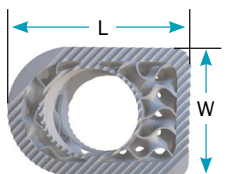
Featuring proprietary porous TIDAL technology that encourages better fusion

Threaded hole for use with restor3d single-use inserter



Available in multiple footprints and heights to accommodate various patient anatomies

## Sizing Options



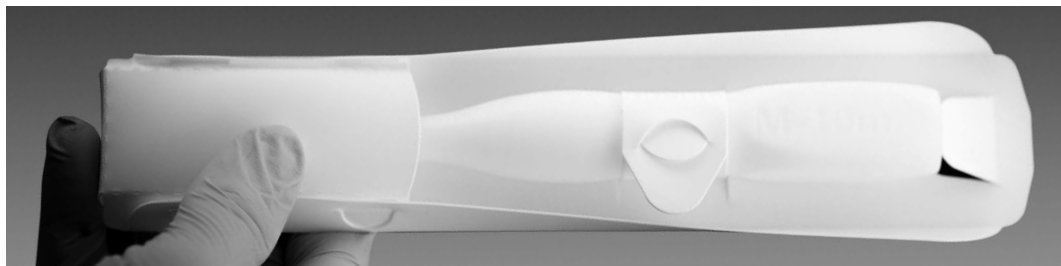
AP LENGTH (MM)	ML WIDTH (MM)	HEIGHT (MM)	VARUS/VALGUS CORRECTION	CENTRAL HOLE DIAMETER
27mm	19mm	10mm, 14mm	0°, 10°	13mm
27mm	23mm	10mm, 14mm	0°, 10°	13mm

See implants ordering information page for more information. AP = Anterior-Posterior | ML = Medial-Lateral.



## Disposable Instrumentation

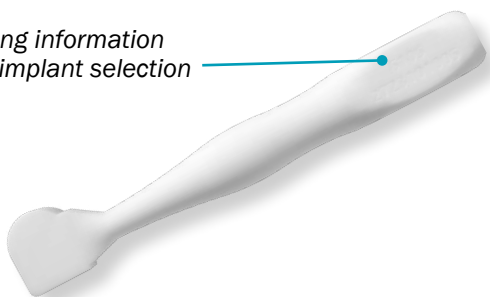
Instrumented with single-use, sterile-packed trials and inserters. The restor3d TIDAL™ Subtalar Wedges are designed to interface with a threaded inserter to allow for accurate placement. Once implant is in place, simply unscrew the inserter to release.



### Sizing Trials

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

Sizing information for implant selection

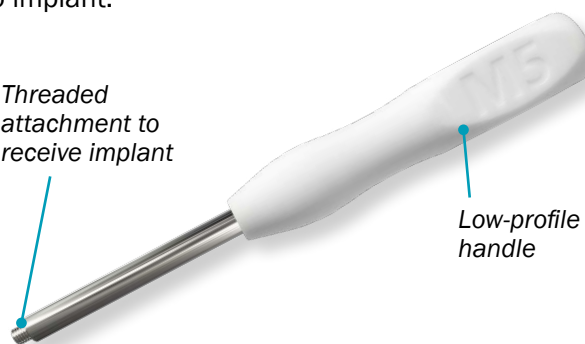


### Inserter

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

Threaded attachment to receive implant

Low-profile handle

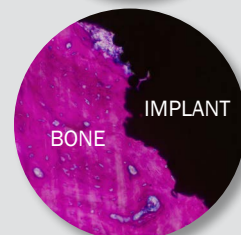


## TIDAL Technology

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<sup>1</sup>
- Mesoscale pores support graft retention and bony ingrowth<sup>2</sup>
- Direct bony apposition to implant surface guided by surface topography and curvature demonstrated in preclinical model<sup>2,3</sup>



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 TIDAL™ Subtalar Wedges are intended to be used for internal bone fixation in the ankle, such as ankle fusion and subtalar fusion.

The restor3d TIDAL™ Subtalar Wedges are intended for use with supplemental fixation.

The restor3d TIDAL™ Subtalar Wedges are not intended for use in the spine.

For a complete list of the indications for restor3d's Utility Wedge, see the restor3d TIDAL™ Utility Wedge System IFU (MKG-20007).

## Contraindications

The restor3d TIDAL™ Subtalar 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

## Subtalar Wedge Surgical Technique

### 1. Surgical Approach

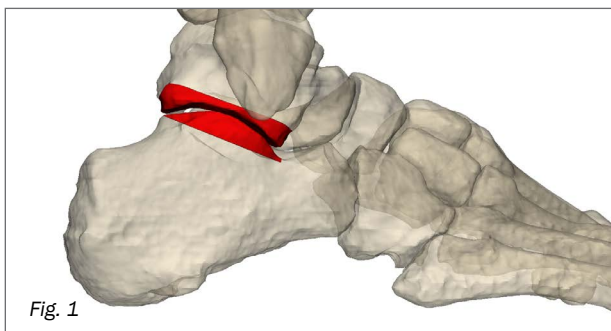
Plan an incision that will allow the addressing of any calcaneal deformity, removal of any hardware present, correcting of any calcaneal malunion and lateral wall exostosis, and access to the subtalar joint for distraction arthrodesis. Common incisions include those made along the curve of the peroneals, sinus tarsi, or an extensile lateral incision.

Release the calcaneofibular ligaments laterally and mobilize the peroneal tendons and sural nerve. Identify and safeguard the flexor hallucis longus tendon, as it protects the neurovascular bundle. Release the talocalcaneal interosseous ligament to allow for improved mobilization and distraction of the joint.

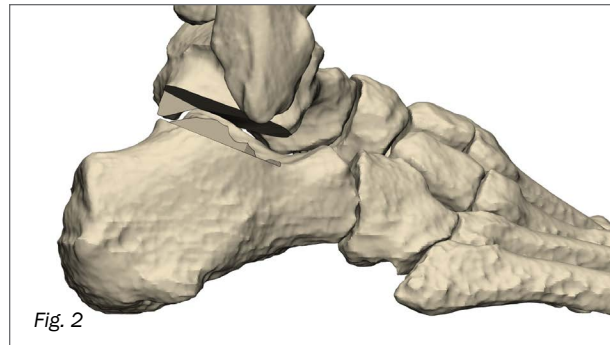
### 2. Prepare the joint.

Correct any bony malunion (i.e.- varus) or nonunion at this time. Remove any large exostosis, which is posterior and superior to the calcaneal tuberosity or lateral calcaneal wall. Realign and stabilize any bony malalignment prior to preparing the joint for fusion.

Distract the subtalar joint and remove the remaining cartilage on either side of the posterior facet (Fig. 1). Prepare the subchondral bone for fusion by cracking or scaling and drilling the bone surfaces for better surface integration in the fusion.

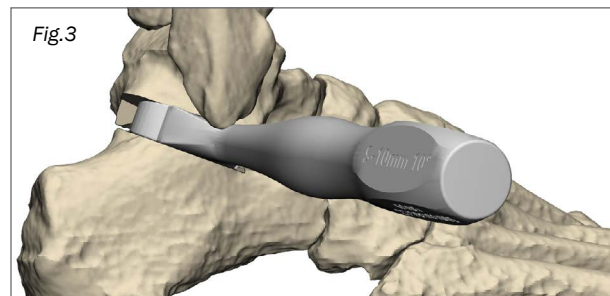


When preparing the joints, pay attention to create a flat surface on the calcaneus and talus to ensure the appropriate bone-implant apposition (Fig. 2).



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

Introduce the implant trials into the osteotomy site until the desired correction is achieved (Fig. 3). Trials are available for each size of implant offered. Implant heights range from 10mm to 16mm, each with correction angles varying from 0 degrees to 10 degrees.



Take care to ensure that the selected trial is congruent to the osteotomy site, allowing for the optimal bone ingrowth into the wedges. Use fluoroscopy to determine the necessary heights of the implant and visually assess that the correction is adequate. Pay particular attention to the coronal plane alignment. Use fluoroscopy to verify that the selected trial allows for the desired amount of correction, and then remove the trial and select the corresponding Subtalar Wedge.

**NOTE: At this time, ensure that the skin incision will close without tension after the correction and joint distraction.**

#### 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 window, in addition to porous lattice, can be packed with graft material (Fig. 4).



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

Attach the wedge to the 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. 5).

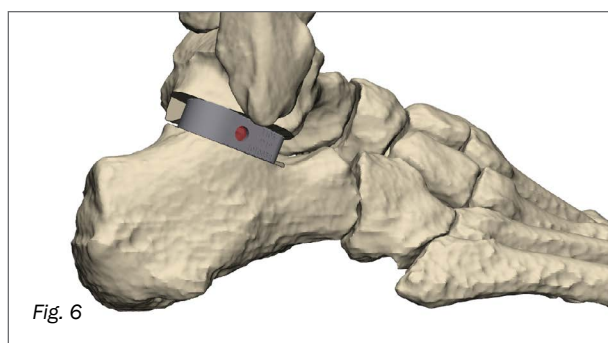
*PRECAUTION: Take care not to overtighten when threading the implant onto the inserter, as overtightening could result in failure to disengage the implant after insertion.*



Place the wedge and inserter combination into the joint until flush with bone and fully seated. If a pin-based distractor or laminar spreader was used to maintain access to the osteotomy site, remove it now. If needed, use a bone tamp to strike either the wedge or the inserter surface

to allow for adjustments in the placement and positioning of the wedge.

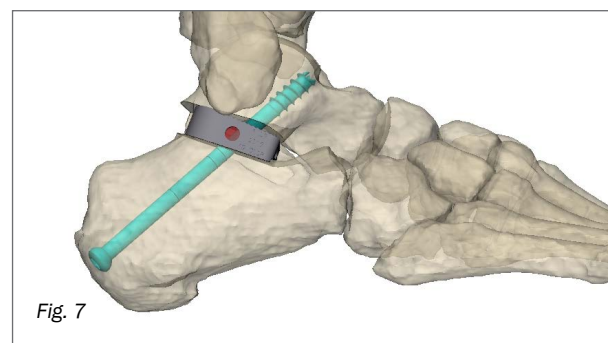
Unscrew the inserter from the wedge and inspect the surface of the Subtalar Wedge to ensure there is congruent contact along its surface (Fig. 6). Use fluoroscopy to confirm the correct final placement of the wedge.



#### 6. Implant Fixation

The restor3d TIDAL™ Subtalar Wedge is intended for use with supplemental fixation. It is recommended that the selected supplemental fixation is manufactured from titanium or titanium alloy in order to avoid galvanic corrosion.

Once final placement is confirmed, insert a screw, or other fixation, through the calcaneus, the wedge, and into the talus to secure the wedge in place (Fig. 7). Autograft, and/or allograft bone, and/or orthobiologic can be inserted around the wedge at this time if desired.



Use layers of sutures to close the incision with the surgeon's preferred technique.



## 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

### TIDAL™ Subtalar Wedge


IMPLANT	PRODUCT CODE (LEFT)	PRODUCT CODE (RIGHT)	FOOTPRINT	AP LENGTH	ML WIDTH	HEIGHT	ANGLE
	1105-2719100005L	1105-2719100005R	Small Footprint	27mm	19mm	10mm	0°
	1105-2719101005L	1105-2719101005R					10°
	1105-2719140005L	1105-2719140005R				14mm	0°
	1105-2719141005L	1105-2719141005R					10°
	1105-2723100005L	1105-2723100005R	Large Footprint	27mm	23mm	10mm	0°
	1105-2723101005L	1105-2723101005R					10°
	1105-2723140005L	1105-2723140005R				14mm	0°
	1105-2723141005L	1105-2723141005R					10°

## Ordering Information – Instrumentation

### Subtalar Wedge Sizing Trial

INSTRUMENT	PRODUCT CODE	FOOTPRINT	AP LENGTH	ML WIDTH	HEIGHT	ANGLE
	6105-2719100005	Small Footprint	27mm	19mm	10mm	0°
	6105-2719101005					10°
	6105-2719140005				14mm	0°
	6105-2719141005					10°
	6105-2723100005	Large Footprint	27mm	23mm	10mm	0°
	6105-2723101005					10°
	6105-2723140005				14mm	0°
	6105-2723141005					10°

### Subtalar Wedge Inserter

INSTRUMENT	PRODUCT CODE
	6100-INSRTRM5



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