



restor3d Ossera™ AFX are a treatment option for ankle fusion in patients at risk of limb loss.

The foot and ankle specific system consists of 3D printed Titanium alloy implants and reusable instrumentation including size trials, cannulated reamers, cut guides, and inserters. The fully interconnected porous implant architecture utilizes TIDAL™ technology for in-growth as early as 4 weeks⁴.



Specs and Benefits

Optimized for Foot & Ankle

Standardized implants in 3 unique geometries: dome, pill, and cylinder. Each available in numerous sizes to provide intraoperative flexibility.

Rapid Delivery

Reusable instrumentation and sterile packed implants are available immediately and eliminate the need for custom designed implants.

Better By Design

A foot and ankle specific system thoughtfully designed for reproducible results. Cannulated reamers and flat cut guides simplify bone preparation.

Scientifically Backed Osseointegration

restor3d's TIDAL Technology™ is incorporated into all Ossera™ AFX implants for research backed osseointegration potential and bony in-growth as early as 4 weeks⁴.

Data Based Size Optimization

Implant sizing determined through analysis of restor3d patient scans ensures an optimized fit for diverse anatomies.

Off The Shelf Implant Geometry

For Tibiotalocalcaneus Cage Contact

CYLINDER	
Diam. (mm)	Height (mm)
34	26, 32, 36, 40
36	32, 36, 40
38	32, 36, 40
40	32, 36, 40

For Tibiotalus Cage Contact

DOME		PILL	
Diam. (mm)	Height (mm)	Diam. (mm)	Height (mm)
36	31.4	36	34, 38
38	33.7	38	38, 42
40	36	40	40, 44
42	38.2	42	42, 46
44	40.4	44	44, 48



All implants feature a 15 mm central cannulation

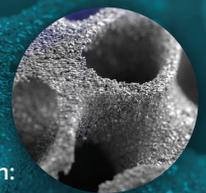


Lateral fibular relief provided on all cylinder, dome, pill & half-pill implants

TIDAL Technology™

Optimized porous architecture designed for osseointegration:

- 100% Interconnectivity and up to 80% porosity¹
- Mesoscale pores support graft retention and bony ingrowth²
- Direct bony apposition to implant surface guided by surface topography and curvature demonstrated in preclinical model^{2,3}



A Process Built for Every Patient & Surgeon

restor3d Ossera™ AFX are optionally available patient-specific to meet the needs of every patient and every surgeon. Surgical templating may be performed by a physician or restor3d using x-ray or CT based imaging.*

Self Submission

At the direction of a physician, implants of the desired geometry and dimensions can be ordered directly through r3id, or by contacting restor3d customer service. To place an order on r3id, follow these simple steps:

- 1 Create a new case on r3id
- 2 Select "Ossera™ AFX" from the cleared devices
- 3 Follow the prompts to select the desired nominal implant and alternate implants

Surgical Templating by restor3d

Patient imaging containing the full field of view of the affected region may be provided to restor3d for surgical templating of cylinder or rectangle implants. Scans are recommended to be less than 6 months old and must be in one of the following imaging modalities:

Calibrated x-rays

- File Type: Uncompressed DICOM
- Lateral and coronal views
- Must contain a calibration sphere, line, or PACS measurement for scale
- If scans contain a calibration sphere, the sphere must be half or more in view
- If scans contain a calibration line, the line must be fully in view
- Scans with measurements obtained from PACS must have the measurement viewable in the image

CT

The following CT scan parameters are recommended:

- File type: Uncompressed DICOM
- Field of view: less than or equal to 40cm
- kVp: 120
- Pixel Spacing: less than or equal to 0.5mm
- Slice Thickness: 1.25mm or less



example implant templating by restor3d



example coronal x-ray with calibration sphere

*restor3d surgical templating only available for cylinder and rectangle implants. The surgical template is intended to enable independent review of patient imaging and implant sizing options by the surgeon to inform his/her own decision making. The surgical template is not intended to be relied on to make a clinical diagnosis or treatment decision regarding an individual patient. The surgical template has been validated for visualizing an implant in the anatomy, at the same scale, using an overlay method.

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.
4. Data on file.