# Tibiotalocalcaneal Fusion with Internal Fixation Device

## Restor3d TIDAL™ Fusion Cage

*restor3d*

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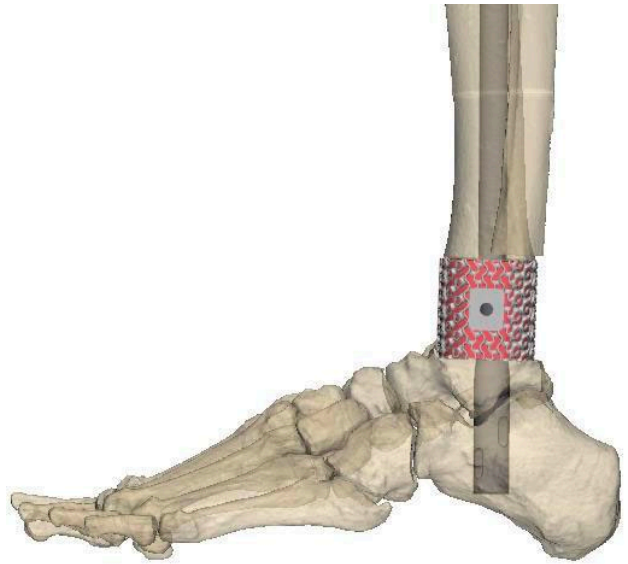
# What is the TIDAL™ Fusion Cage?

The TIDAL™ Fusion Cages are porous cages used in tibiotalocalcaneal arthrodesis that vary in shape and size to accommodate individual patient anatomy. The cage is used following the resection of the bone, talectomy, or preparation of the joint, to span the defects in the ankle and/or hindfoot. The intramedullary nail is then placed, per the surgical technique of the nail, through the central clearance hole of the Fusion Cage.

# What does the TIDAL™ Fusion Cage Treat?

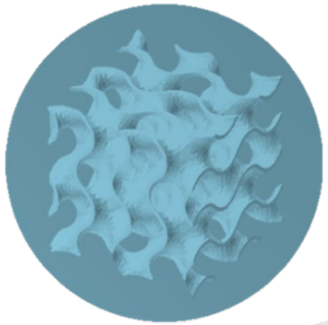
The restor3d TIDAL™ Fusion Cage System is used in the case of ankle arthrodesis when there is insufficient talus and/or distal tibia to support traditional TTC fusion and is intended for tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle procedures such as:

- Post-traumatic and degenerative arthritis
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints
- Revision after failed ankle arthrodesis with subtalar involvement
- Failed total ankle arthroplasty
- Non-union ankle arthrodesis
- Rheumatoid hindfoot
- Talectomy
- Avascular necrosis of the talus
- Neuroarthropathy
- Neuromuscular disease and severe deformity
- Charcot Foot



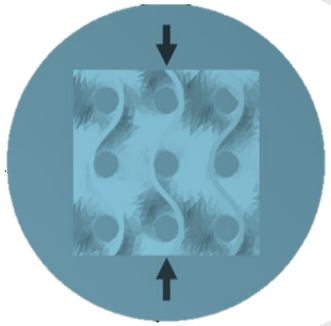
# What is TIDAL™ Technology

- Sheet-based porous lattice
- Manufactured via 3D Printing (laser powder bed fusion) of medical grade titanium alloy



Sheet-based architecture **maximizing surface area and porosity** with 100% interconnectivity [1,2]

Mesoscale pores support graft retention and **bony ingrowth** [3]



**High strength and fatigue resistance** compared to strut-based architectures of the same porosity [4,5,6]


1. Kelly, C.N., A.T. Miller, S.J. Hollister, R.E. Guldberg, and K. Gall, Design and structure–function characterization of 3D printed synthetic porous biomaterials for tissue engineering. Advanced healthcare materials, 2018. 7(7): p. 1701095.
2. Pham, A., C. Kelly, and K. Gall, *Free boundary effects and representative volume elements in 3D printed Ti–6Al–4V gyroid structures.* Journal of Materials Research, 2020. 35(19): p. 2547-2555.
3. Kelly, C.N., A.S. Lin, K.E. Leguineche, S. Shekhar, W.R. Walsh, R.E. Guldberg, and K. Gall, *Functional repair of critically sized femoral defects treated with bioinspired titanium gyroid-sheet scaffolds.* Journal of the Mechanical Behavior of Biomedical Materials, 2021. 116: p. 104380.
4. Kelly, C.N., C. Kahra, H.J. Maier, and K. Gall, *Processing, Structure, and Properties of Additively Manufactured Titanium Scaffolds with Gyroid-Sheet Architecture.* Additive Manufacturing, 2021: p. 101916.
5. Barber, H., C.N. Kelly, K. Nelson, and K. Gall, *Compressive anisotropy of sheet and strut based porous Ti–6Al–4V scaffolds.* Journal of the mechanical behavior of biomedical materials, 2021. 115: p. 104243.
6. Kelly, C.N., J. Francovich, S. Julmi, D. Safranski, R.E. Guldberg, H.J. Maier, and K. Gall, *Fatigue behavior of As-built selective laser melted titanium scaffolds with sheet-based gyroid microarchitecture for bone tissue engineering.* Acta biomaterialia, 2019. 94: p. 610-626.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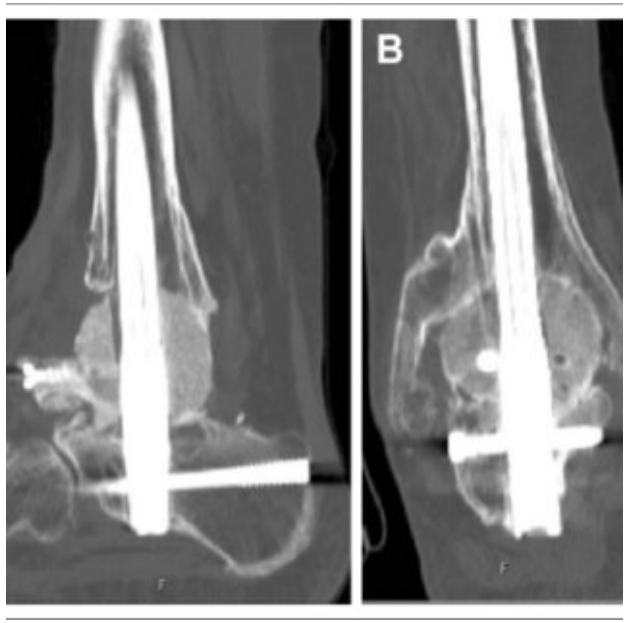
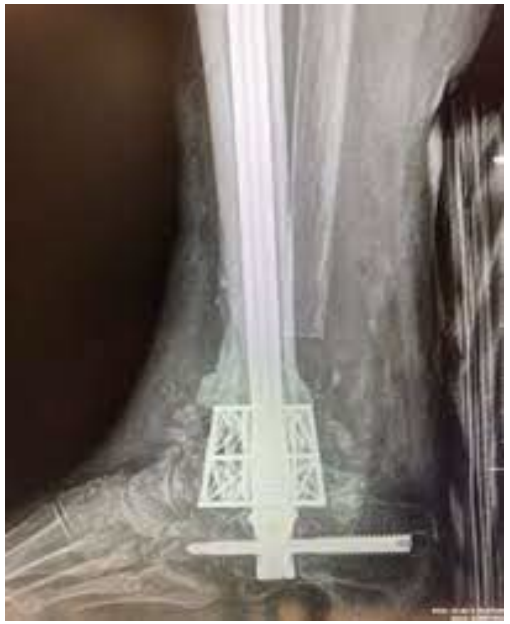
# Alternative Options

- Bulk Femoral Head Allograft
  - Complications: graft resorption, collapse, non-union

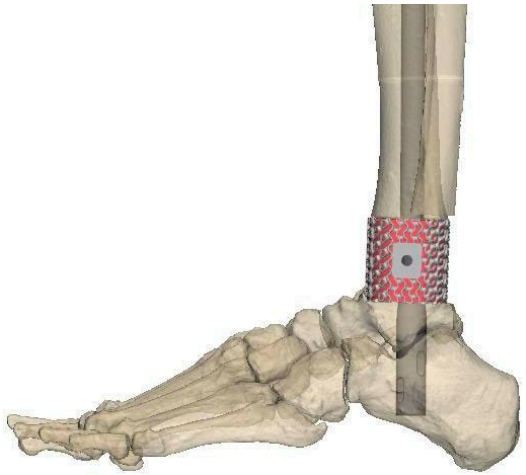



- Other Cage technologies
  - Complications: cage mechanical failure, non-union



# How does it work?

- The TIDAL™ Fusion Cage consists of a set of implants intended to be used for tibiotalocalcaneal arthrodesis by providing stabilization of the hindfoot and ankle in conjunction with an intramedullary nail for fixation.
- The TIDAL™ Fusion Cages are available in a wide range of heights and diameters, permitting surgeons to choose a relevant size for the affected anatomy.
- The TIDAL™ Fusion Cage is available in spherical and cylindrical configurations for preference on bone preparation options.
- The TIDAL™ Fusion Cages are constructed from an implant grade titanium alloy.



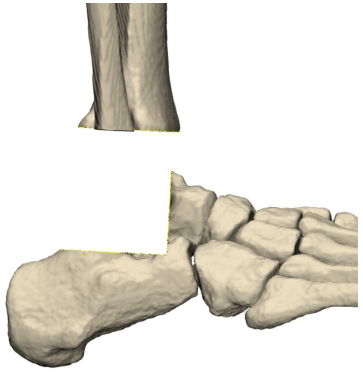
# Naming Conventions

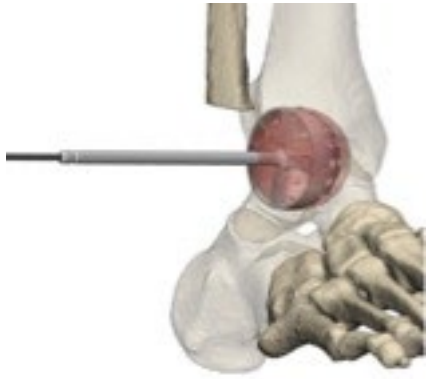
Some terms currently being used to describe the technology are: Fusion Cage, Ankle Fusion Cage, Ankle Cage, Cage, Porous Cage, Spacer, Porous Spacer

The device will be documented in the medical record in the operative notes

# Procedure Description: Bone Preparation

1. Perform a fibular osteotomy above the ankle joint line.
2. Remove the affected anatomy using either bone saws or reamers



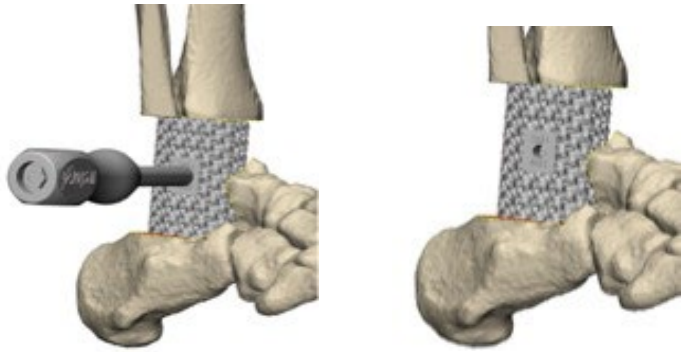


If using a reamer, place a guide wire in the middle of the affected anatomy and ream over the k-wire.

3. Introduce the trial implants into the surgical site. Trials are available for each size and shape of implant offered. Use trial implant to verify size, shape and final construct alignment. Central hole on the trial is sized to accept up to a 14mm reamer. Reaming should be carried out via nail manufacturer's instructions for use.
4. Once the implant shape and size has been selected, the corresponding implant is attached to the inserter. Bone graft material may be packed into the porous lattice and through the central hole.

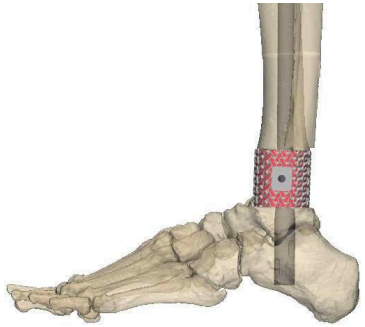
# Procedure Description: Implantation

5. Place the implant and inserter combination into the surgical site until the correct alignment is sustained. Unscrew the inserter from the implant.





6. The restor3d TIDAL™ Fusion Cage is indicated to be used with supplemental fixation. Follow the manufacturer's instructions for use for intramedullary (IM) nail fixation. Confirm final images under fluoroscopy.



6. Close operative site according to surgical technique.

# Known Complications

Some rare adverse events have been recorded in the clinical data submitted for premarket submission:

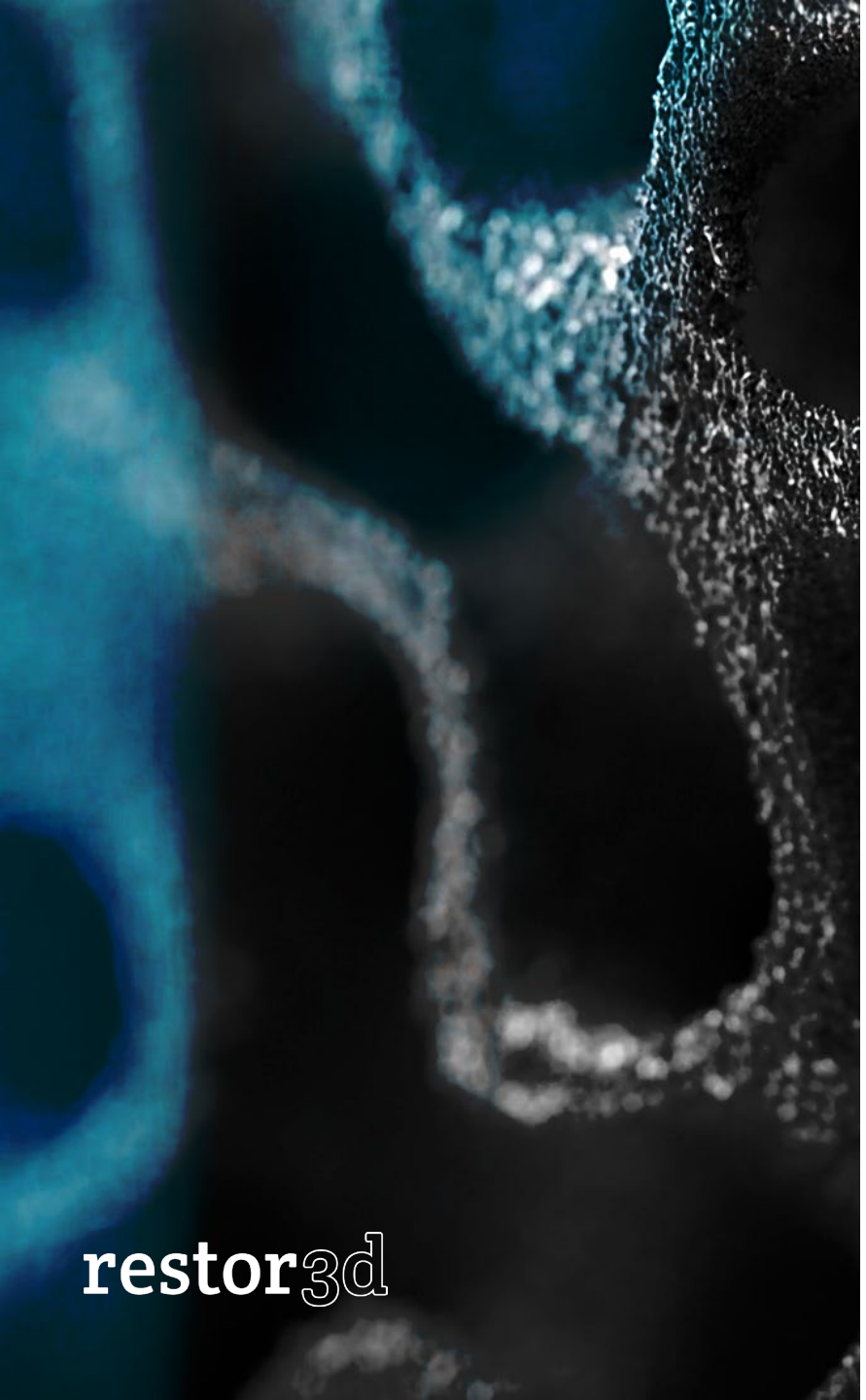
- Device did not fit correctly
- Implant felt loose following implantation
- Revision of associated fixation hardware (i.e., intramedullary nail)
- Infection

Potential adverse effects resulting from the use of the TIDAL™ Fusion Cage include, but are not limited to, the following:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or discoloration of the implant requiring revision surgery
- Loss of anatomic position with nonunion or malunion with rotation or angulation
- Bone resorption or over-production
- Allergic reaction to the implant material
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

# Summary:

- The restor3d TIDAL™ Fusion cage has advantages over other treatment options in tibiotalocalcaneal arthrodesis surgery.
- Restor3d TIDAL™ Fusion cage has Breakthrough Status and is being evaluated by the FDA. The anticipated approval date is first quarter (Q1) 2024.
- The device is used in the case of ankle arthrodesis when there is insufficient talus and/or distal tibia to support traditional TTC fusion.
- The restor3d TIDAL™ Fusion Cage offers a new treatment option for patient populations who have significant failure in TTC fusion procedures, especially for Charcot arthropathy patients and diabetic neuropathy patients.
- The unique design of the TIDAL™ Fusion Cage and its porous structure helps patients recover faster by encouraging better fusion.




# Questions?

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