Implantation of Open-Truss Ankle Fusion Device

Ankle Truss System™ (ATS)

4WEB Medical

March 7-8, 2023

ICD-10 Coordination & Maintenance Committee Meeting

Background & Clinical Need

Ankle bone defects may be associated with:

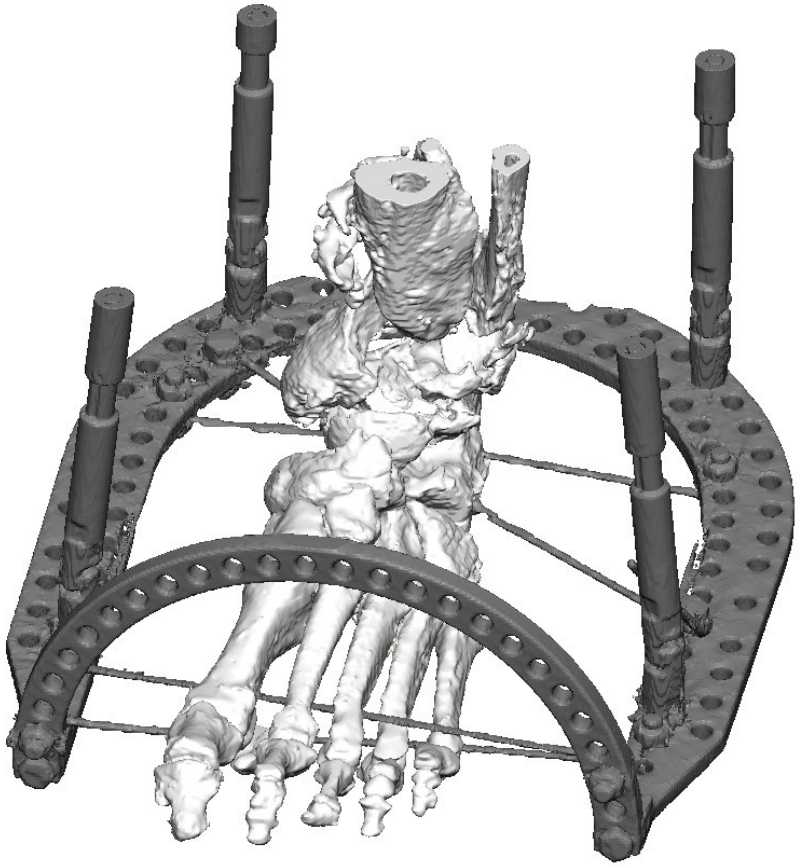
- Failed ankle replacement
- Failed previous arthrodesis

Standards of Care

- Intramedullary nails – can not address large ankle defects (e.g., failed ankle replacement) and may cause limb length discrepancy, malalignment, and malunion
- Grafting – high complication rates (67%) and high non-union rates (42%)

Clinical Need

- Provide structural support to allow bone fusion across ankle bone defects
- Preserve limb length and allows for realignment



Pellegrini, M. J., Schiff, A. P., Dekker, T. J., Easley, M. E., DeOrio, J. K., Nunley, J. A., & Adams, S. B. (2016). Subtalar arthrodesis in patients with avascular necrosis of the Talus. *Foot & Ankle Orthopaedics*, *1*(1).
Parry, E., & Catanzariti, A. R. (2021). Use of three-dimensional titanium trusses for arthrodesis procedures in foot and ankle surgery: A retrospective case series. *The Journal of Foot and Ankle Surgery*, *60*(4), 824–833.

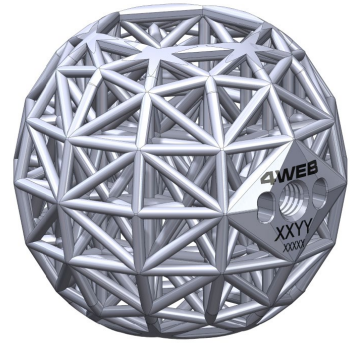
Ankle Truss System™ (ATS)

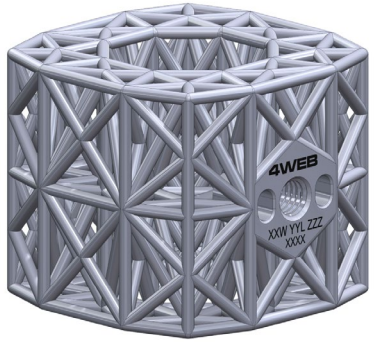
Device Purpose

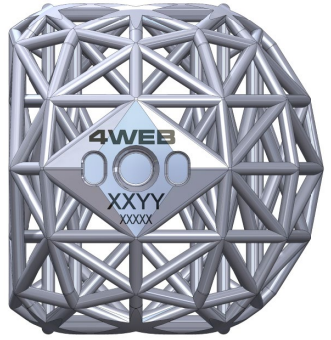
- Allow fusion across ankle bone defect via open-truss architecture
- Preserve limb length and salvage limb, avoiding need for amputation

Device Design

- Provides structural support across ankle bone defect and allows for packing with bone graft via open-truss architecture
- Features central hole that accommodates pre-market authorized intramedullary nail
- Provided in three configurations: cuboidal, spherical, spherical w/ flat
- Additively manufactured in Ti6Al4V to create surface roughness which has potential to stimulate biomechanical osteogenic response







4WEB Medical Ankle Truss System™.

Key Features & Benefits

1

Open truss architecture

- Allows for osteogenic ingrowth across the defect area
- Preserves limb length

2

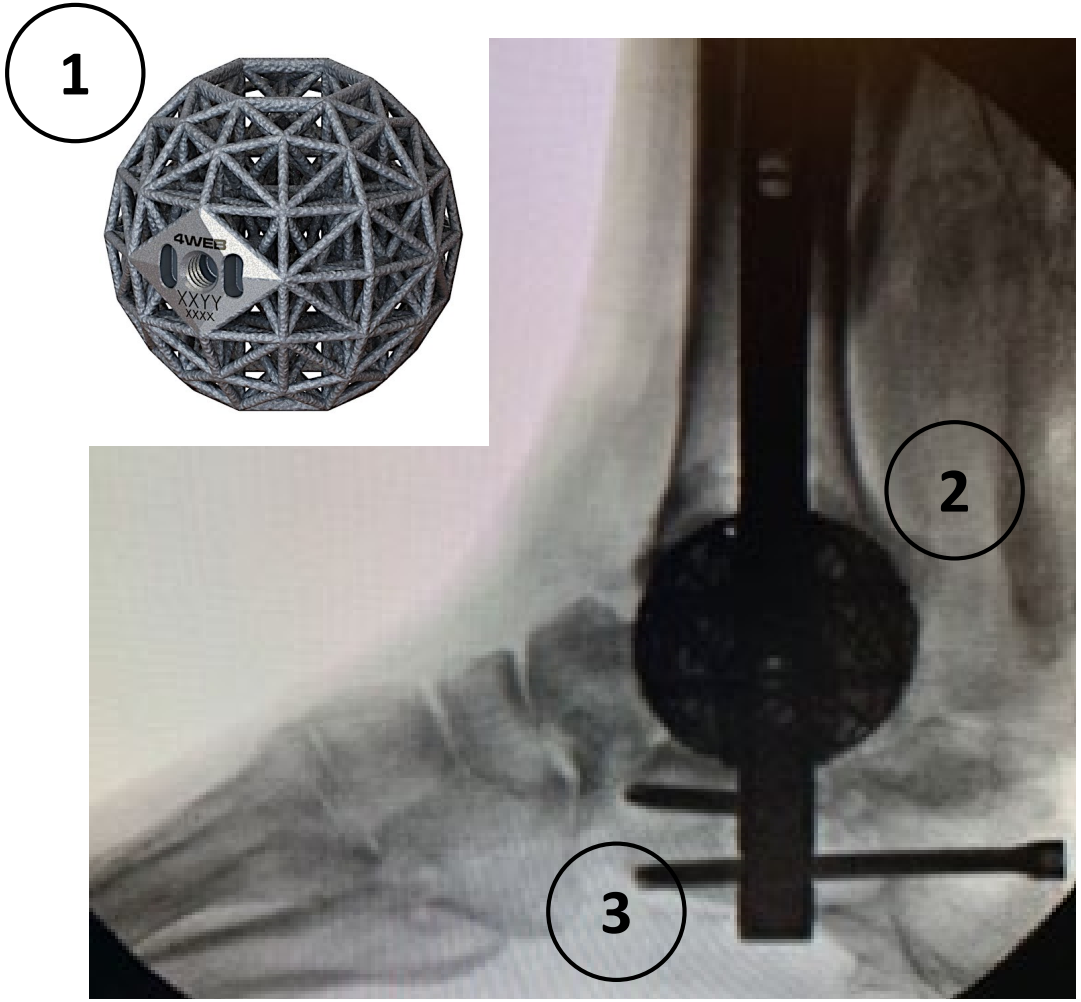
Device geometries

- Flexibility of device shapes (e.g., ArthroSphere™ and ArthroBlock™) fill various bone defect shapes and sizes
- Volume is scaled for a patient-matched fit

3

To be used in conjunction with nail fixation

- Central hole allows use of nail for fixation of the Ankle Truss System™
- Supports the nail intended use, as an accessory, to address bony defects



4WEB Medical Ankle Truss System™.

Implantation Procedure

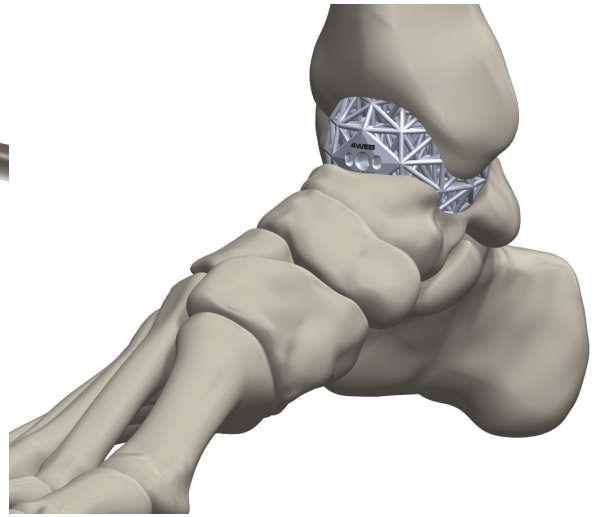
1. Anatomy prepared by performing resections/reaming via anterior or transfibular approach

2. Nail trajectory established (per nail surgical technique)

3. Appropriate implant size determined using Sizers or Ruler

4. Central hole plugged using Hole Plug; graft material packed into implant

5. Placement of Ankle Truss System™ device finalized; nail deployed through device



4WEB Medical Ankle Truss System™.

FDA Status & Documentation

FDA Status

- Breakthrough Device Designation was granted by the FDA on October 4, 2022
- FDA clearance is anticipated by June 30, 2023

Operative Note

- Documentation of the implant procedure may be found in the operative note

Potential Naming Conventions

- “4WEB Ankle Truss System”
- “ArthroCube” or “ArthroSphere”
- “Truss Implant” or “Truss Device”
- “4WEB Cage”