

# Implantation of Total Talar Prosthesis with Total Ankle Replacement

4WEB Medical

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ICD-10 Coordination & Maintenance Committee Meeting

# Background & Clinical Need

## Talar dysfunction may be associated with:

- Failed ankle arthroplasty
- Ankle arthritis
- Avascular necrosis
- Talar osteomyelitis
- Degenerative joint disease
- Talar trauma

## Standards of Care

- Ankle replacements – finite service life and are contraindicated for patients with talar dysfunction indications
- Partial resurfacing prostheses – only viable with sufficient talar bone stock

## Clinical Need

- Currently, there is no technology that replaces the talus and allows for function with ankle replacements



# Total Ankle Talar Replacement™ (TATR)

## Device Purpose

- Preserve ankle joint movement by mating to ankle replacement tibial components
- Preserve movement in talonavicular and talocalcaneal joints by mating to native anatomy
- Replace entire talar volume

## Device Design

- Incorporates dome contour on superior surface of talar volume
- Utilizes patient radiographic data (e.g., CT) to create talar volume
- Talar replacement is shaped to match patient anatomy at talonavicular and talocalcaneal joint surfaces
- Additively manufactured in cobalt chrome and polished to mirror finish



# Key Features & Benefits

1

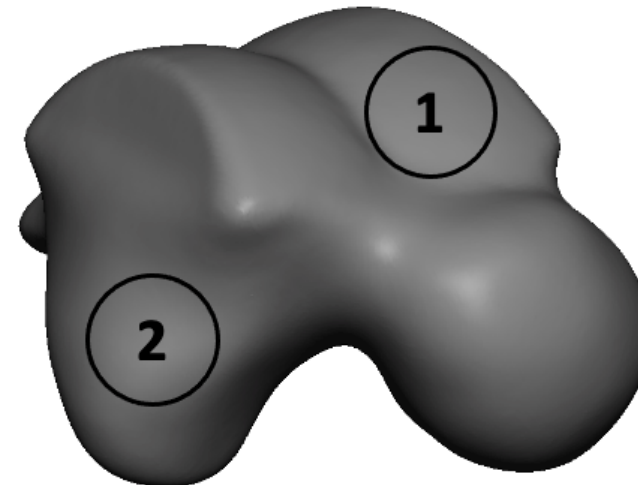
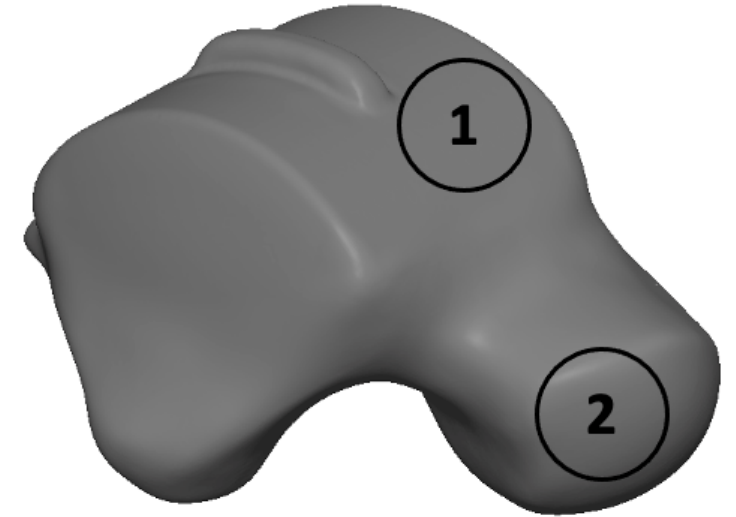
## **Talar dome mates to ankle replacement**

- Allows for implantation with ankle replacement tibial components
- Can be deployed concurrently with ankle replacements or retroactively as part of an ankle replacement revision
- Preserves ankle joint motion

2

## **Talar body & head mate to native anatomical structures**

- Preserves talocalcaneal and talonavicular joint motion
- Volume is patient-matched



# Implantation Procedure

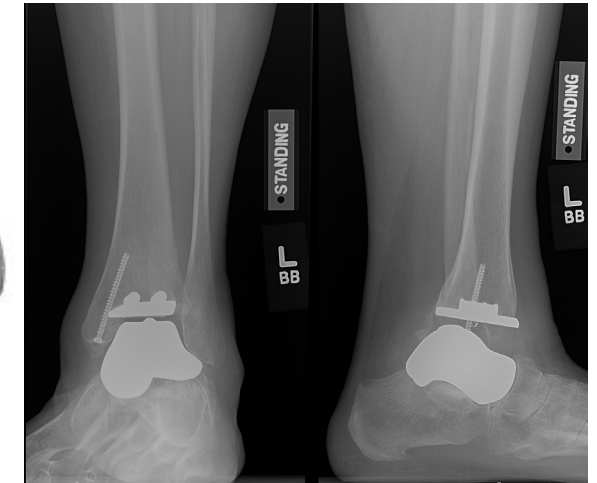
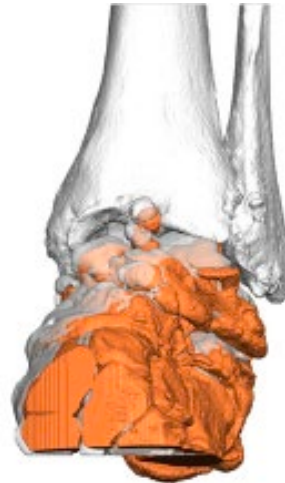
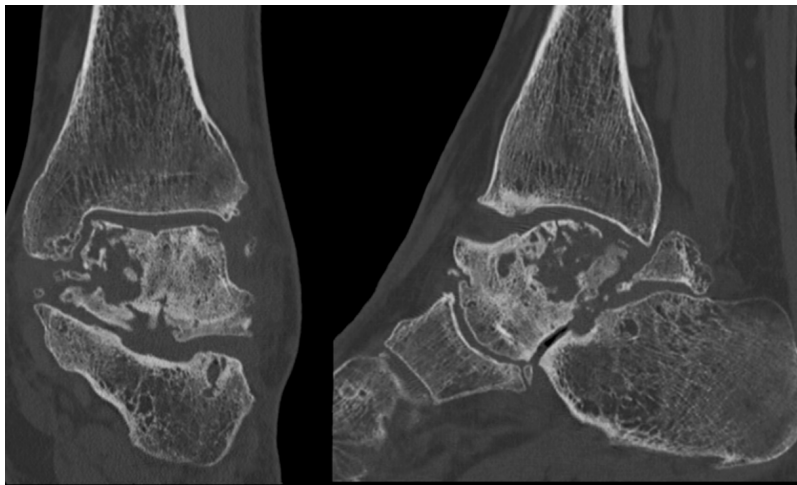
1. Tibial preparation and resection per ankle replacement surgical technique

2. Native talus removed

3. Total Ankle Talar Replacement™ trials used to determine appropriate implant fit

4. Total Ankle Talar Replacement™ device deployed

5. Ankle replacement components deployed



# FDA Status & Documentation

## **FDA Status**

- Breakthrough Device Designation is being pursued with the FDA
- 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 Total Ankle Talar Replacement”
- “4WEB TATR”
- “TATR”
- “Hybrid Total Talar and Total Ankle Replacement”
- “Total Talar Replacement”