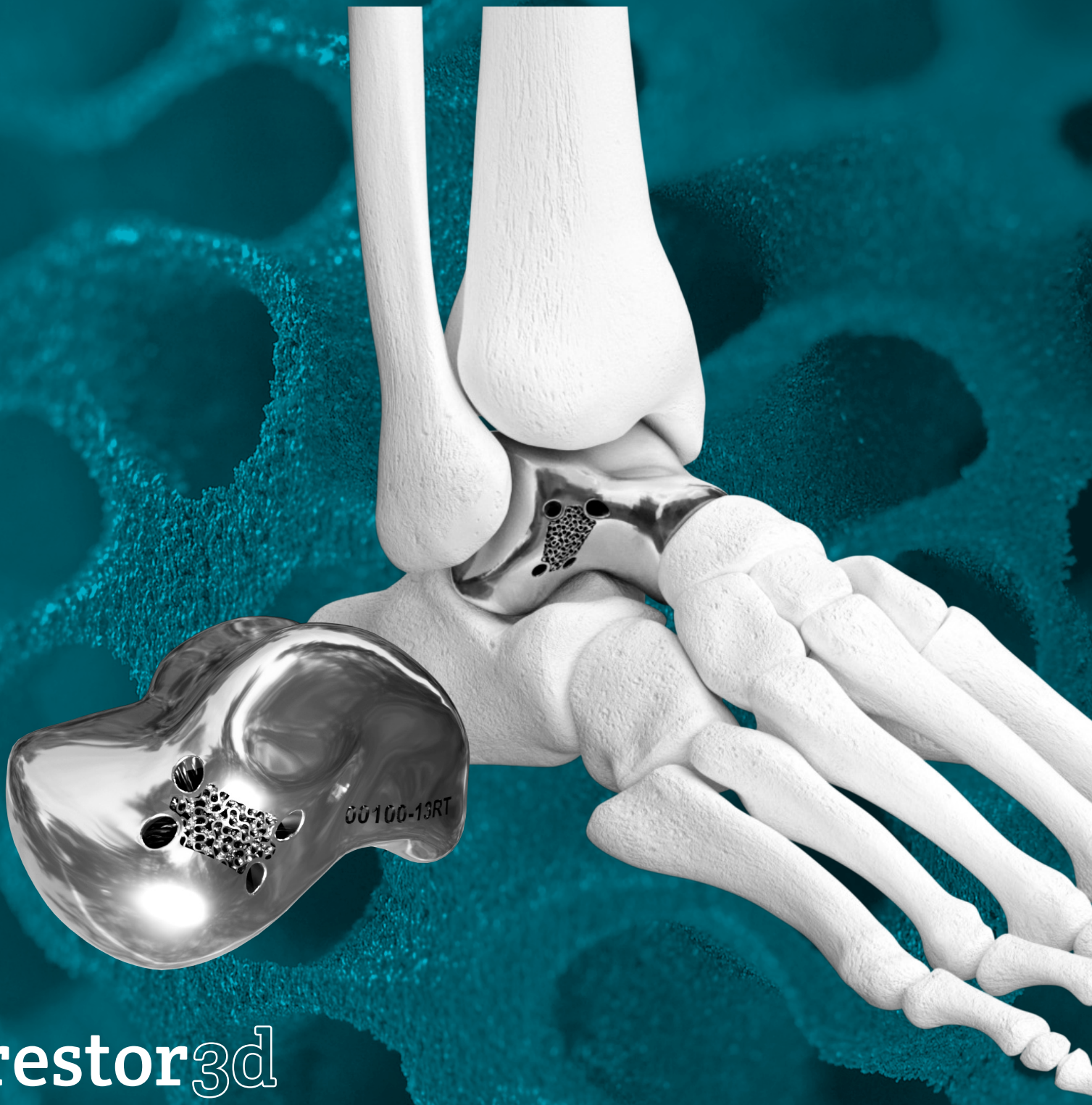
Patient Specific Total Talus Replacement

SURGICAL TECHNIQUE GUIDE



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Personalized Orthopaedics

Enabling Surgeons to Repair and

Reconstruct the Human Body

Backed by Science

Driven by Outcomes

Contents

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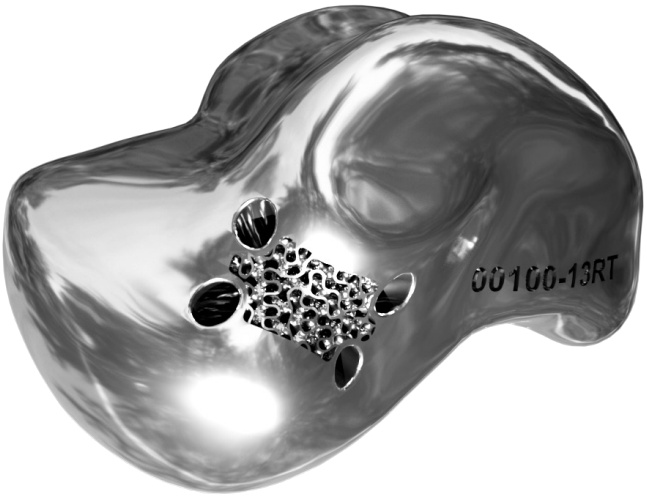
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Humanitarian Device: Authorized by Federal law for use in the treatment of avascular necrosis of the talus with or without talar collapse, cysts or non-union, large, uncontained, unstable, or cystic talar osteochondral defects with risk of collapse or talar osteochondral defects not responsive to traditional treatments, and non-union following talar fracture or talar extrusion unresponsive to more conservative treatments in adult patients. The effectiveness of this device for this use has not been demonstrated.

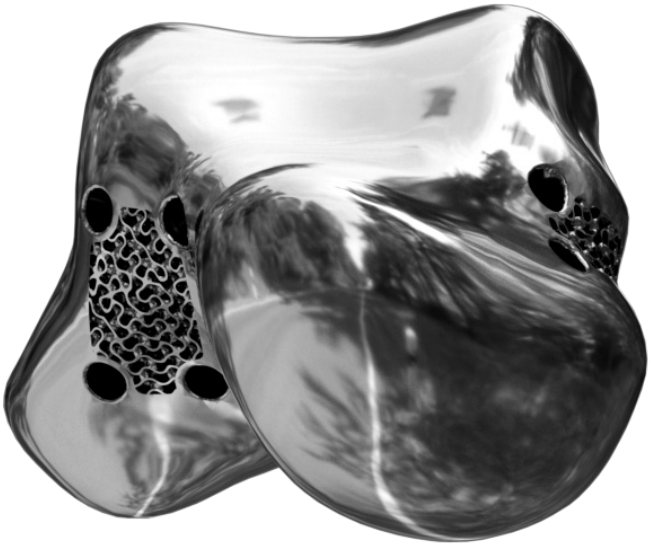
INTRODUCTION

The restor3d Total Talus Replacement Implant and Instrumentation System is designed to replace a native talus bone that has been affected by a disease state or injury. The implant is an additively manufactured Cobalt Chromium alloy construct produced by laser powder bed fusion. The data driven design of the implant enables the patient to maintain ankle range of motion, reduce pain and improve physical function.

The implant is patient specific and made available in multiple sizes to facilitate intraoperative flexibility. Non-sterile single-use disposable instrumentation including size trials and impactors are provided to assist in the surgical placement of the implant. It is important that the provided trials and impactors are used to ensure accurate implantation of the device.



MEDIAL VIEW



ANTERIOR VIEW

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INDICATIONS

The restor3d Total Talus Replacement implant is indicated for:

- avascular necrosis of the talus
- avascular necrosis of the talus in addition to talar collapse, cysts or non-union
- large, uncontained, unstable, or cystic talar osteochondral defects with risk of collapse or talar osteochondral defects not responsive to traditional treatment
- non-union following talar fracture or talar extrusion, unresponsive to more conservative treatments

The implant is patient specific and is designed from computed tomography (CT) scan. The anatomical landmarks necessary for the design and creation of the restor3d total talus replacement implant must be present and identifiable on CT scan. In addition to reading the information provided in this guide, please talk with your doctor. Your doctor will help you to understand the benefits and risks associated with the procedure and determine if you are a candidate for a Total Talus Replacement implant.

CONTRAINDICATIONS

If you have been diagnosed with or are experiencing any of the following conditions, it is recommended you do not receive a Total Talus Replacement implant:

- Surgical procedures other than those listed in the indications for use.
- Use of implant greater than 6 months from date of patient's CT scan.
- Degenerative changes in the tibiotalar, subtalar or talonavicular joints.
- Patients with an active local or systemic infection.
- Gross deformity in sagittal or coronal planes. More than 15 degrees of varus or valgus deformity in the coronal plane, or more than 50% subluxation anteriorly or posteriorly of the talus in the sagittal plane.
- Osteonecrosis of the calcaneus, distal tibia, or navicular.
- Known history of existing malignancy, or any systemic infection, local infection, or skin compromise at the surgical site.
- Blood supply limitations and previous infections that may prevent healing.
- Physical conditions that would eliminate adequate implant support or prevent healing, including inadequate soft tissue coverage.
- Conditions which may limit the patient's ability or willingness to restrict activities or follow directions post-operatively during the healing period.
- Presence of neurological deficit which would prevent patient post-operative compliance.
- Patients with foreign body sensitivity, suspected or documented material allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted, and sensitivity ruled out prior to implantation.

Consult the Total Talus Replacement Instructions for Use for potential adverse effects, warnings, and precautions prior to use.

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Surgical Technique

The following procedural steps provide a recommended technique guide for using the restor3d Patient Specific Total Talus Implant. The surgeon must consider the individual needs of the patient and make the appropriate adjustments when and as required.

Incision & Exposure

1 Prepare the insertion site using standard surgical technique. An anterior extensile incision is made between the tibialis anterior and extensor hallucis longus tendon. Dissection is taken down to the ankle and talonavicular joints with meticulous reflection of the capsule of each joint.

2 Raise full-thickness medial and lateral flaps to expose the talar head and neck as well as the distal tibia. Using a scalpel, release ligamentous and capsular tissues from the talar neck and body while ensuring preservation of superficial deltoid ligament slips and calcaneal-fibular ligament.

Osteotomy

3 Perform a biplanar osteotomy of the talar neck using a combination of bone saws, osteotomes, chisels, tamps and/or mallet at the junction of the talar body-neck and talar neck-head (Figure 1).

Resection

4 Using a clamp, distract the talar neck to release plantar soft tissue. Remove the talar neck (Figure 2).

FIGURE 1

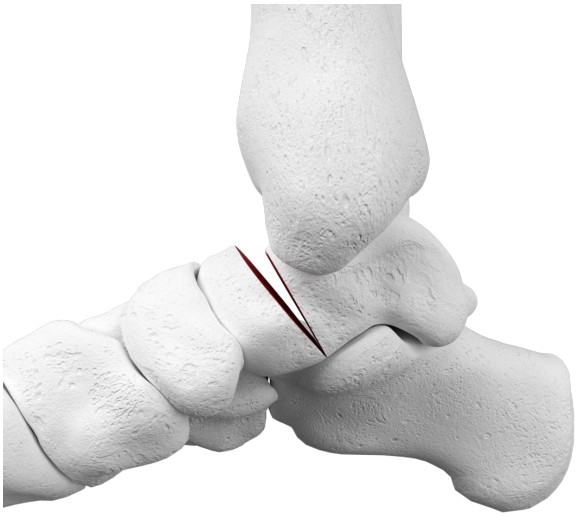

FIGURE 2

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Resection

5 Distract the talar head by placing a Cobb elevator into the talonavicular joint while protecting the cartilage on the navicular. While distracting, sharply release the remaining soft tissue attachments on the talar head allowing the talar head to be removed (Figure 3-4).

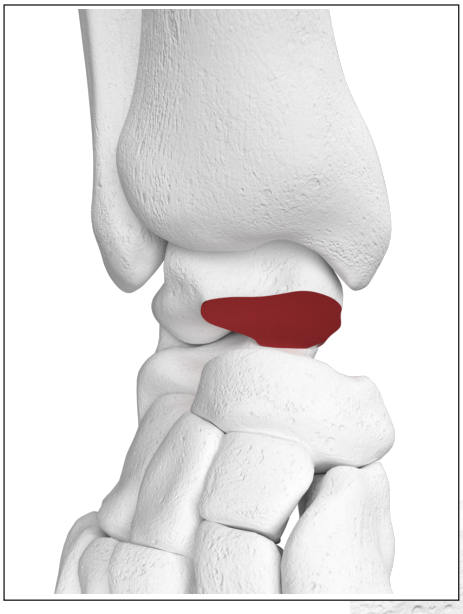

FIGURE 3

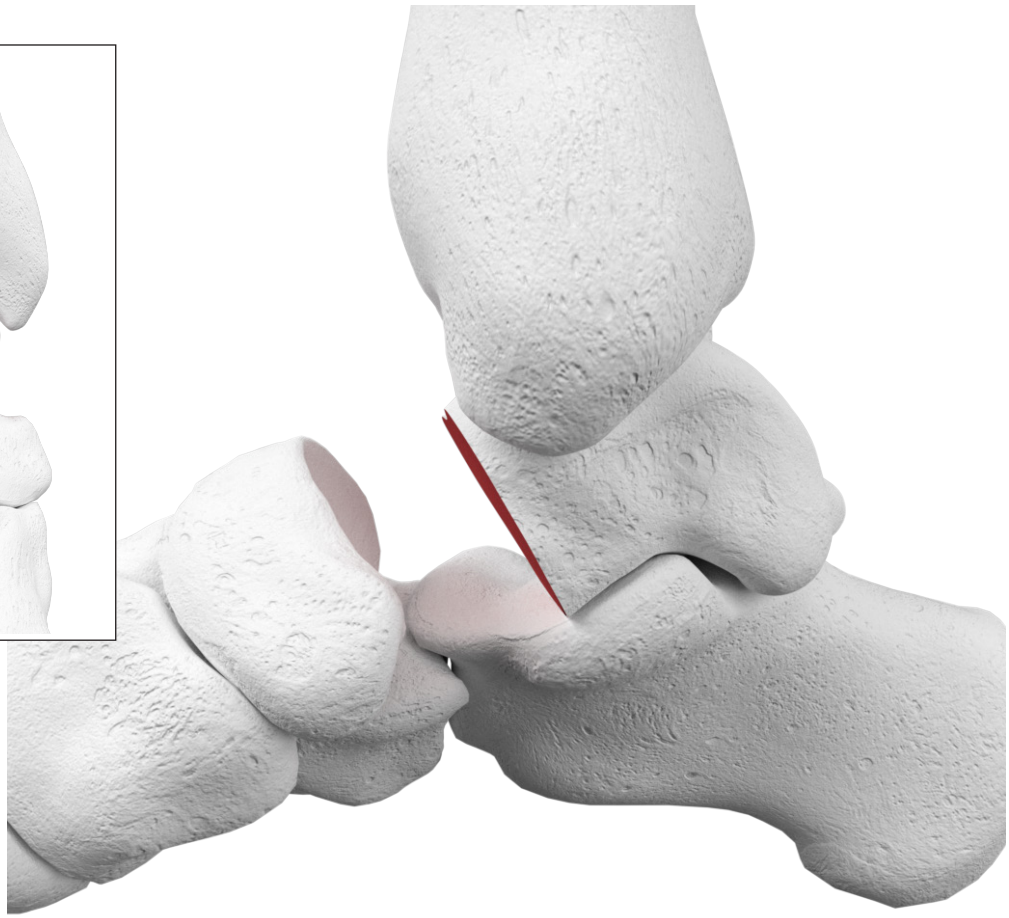

FIGURE 4

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Resection

6 Using a combination of bone saws, osteotomes, chisels, tamps and/or mallet, perform multiple osteotomies of the talar body under fluoroscopy to ensure the cartilage of the calcaneus and distal tibia are not violated. Remove the talar body (Figure 5-6).

7 Irrigate the surgical site with sterile saline and ensure all aspects of the talus are removed.

8 Meticulous dissection is vital throughout the talar resection to ensure preservation of all ligamentous and tendinous structures connecting the tibia and fibula to the calcaneus and navicular.

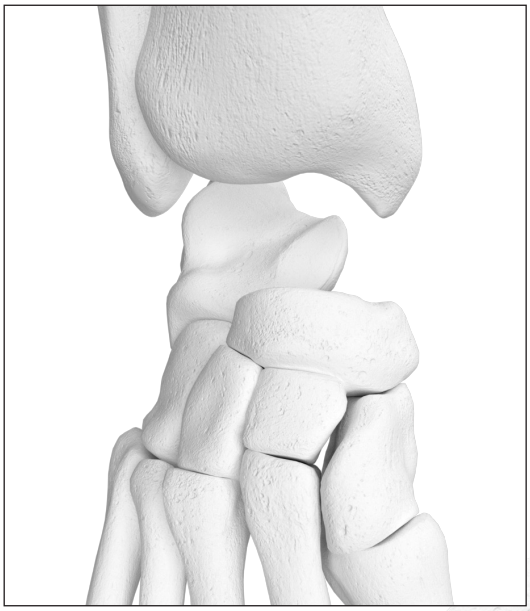

FIGURE 5

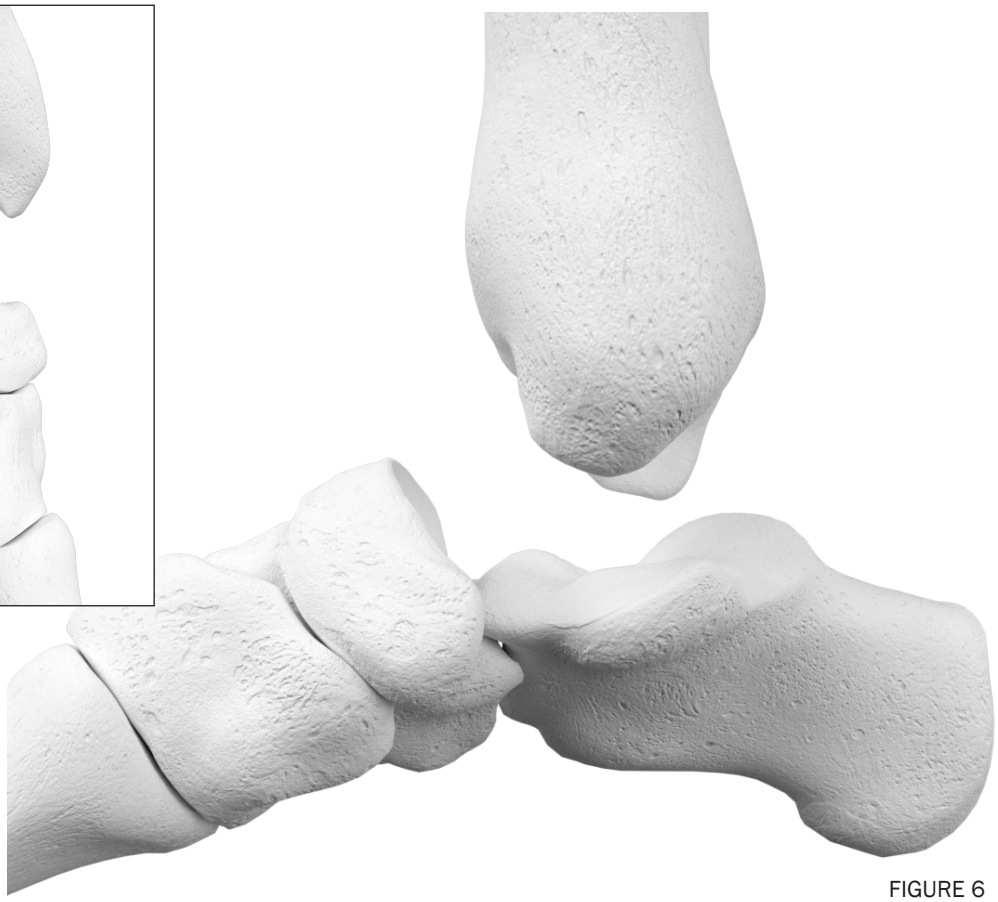

FIGURE 6

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Implant Sizing & Selection

9 Place the nominal size TTR implant trial provided into the surgical site and evaluate the range of motion under fluoroscopy (Figure 7-8). Assess articulation through dorsiflexion and plantarflexion of the ankle as well as inversion and eversion. Perform ankle stability testing.

If needed, remove the nominal size implant using the trial handle and trial other size(s) provided, checking articulation and range of motion

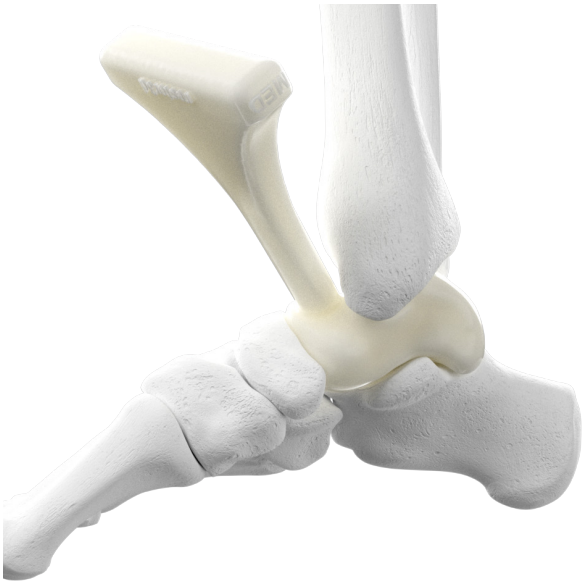

FIGURE 7

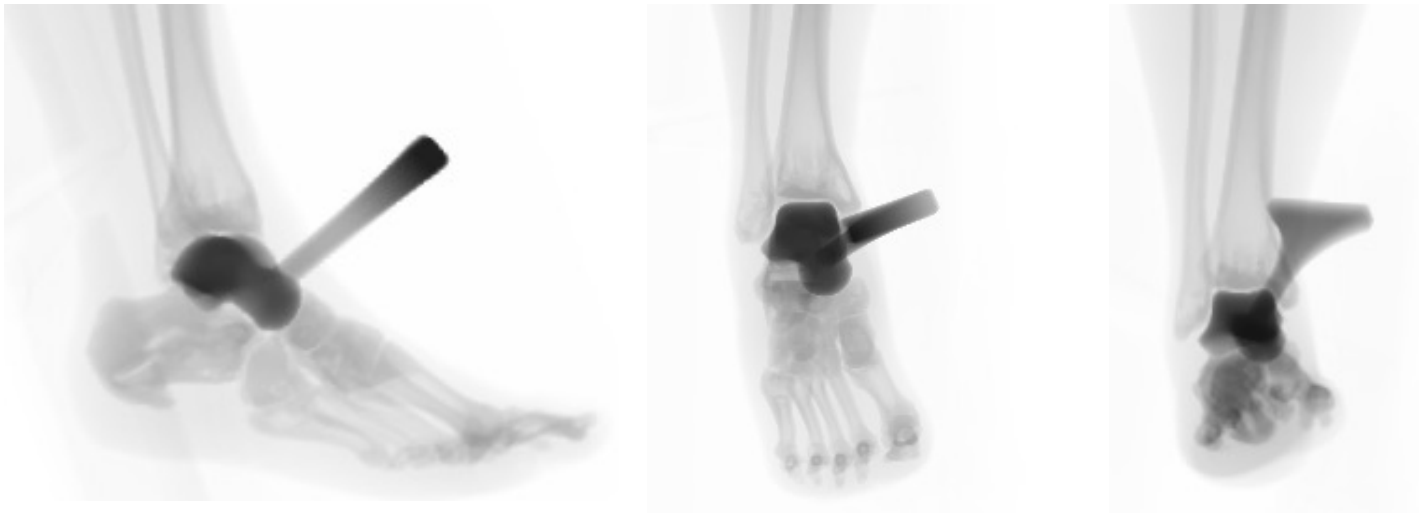

FIGURE 8

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Implantation

10 Insert the appropriately sized TTR Implant determined in step 9 (Figure 9). Use the provided impactor instruments to facilitate insertion. It is recommended to confirm the fit of the implant using fluoroscopy (Figure 10).

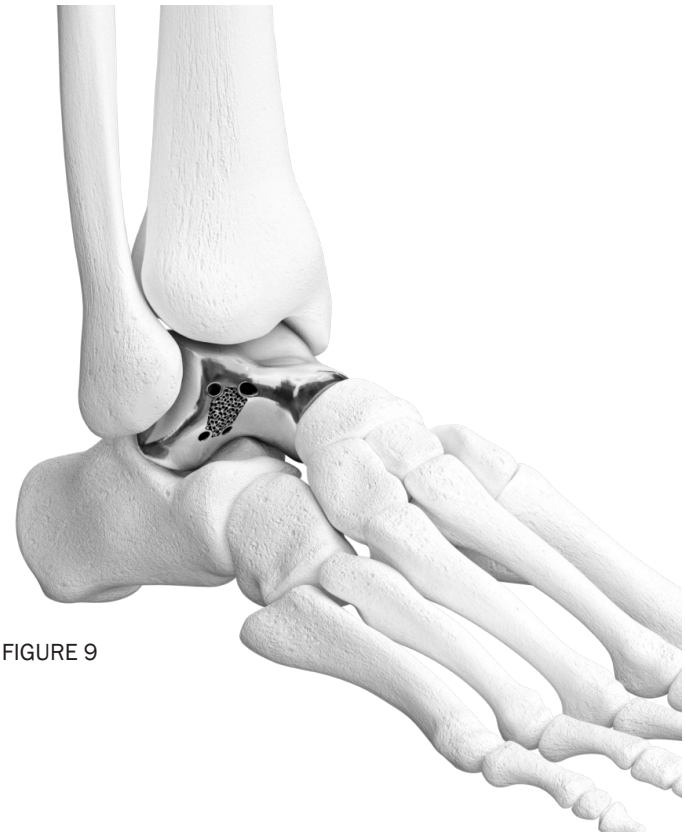
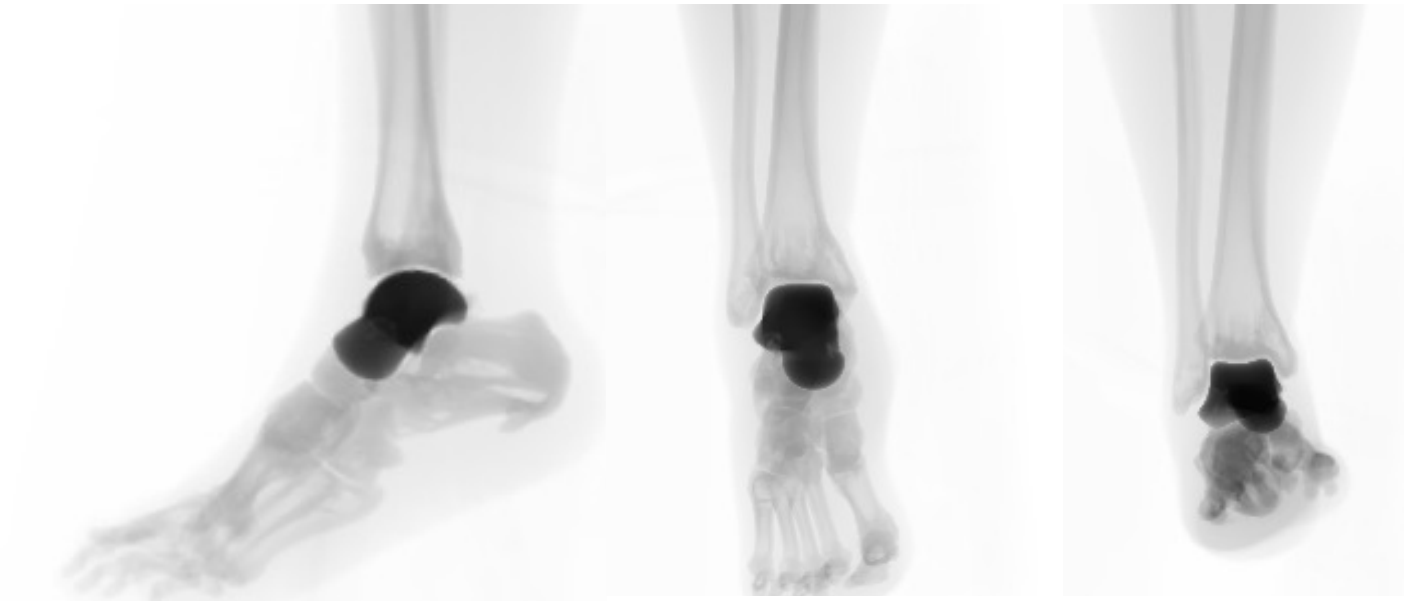


FIGURE 9



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Soft Tissue Suture Attachment

11 **Optional**. The anterior talofibular ligament, deltoid ligament or the talonavicular ligament may be augmented using the soft tissue attachments sites on the TTR implant if present.

Soft tissue attachments sites should be utilized if additional stability in the ankle is needed post implantation of the TTR implant.

To utilize, pass a suture tape or a size 2 braided suture using a CT2/T5 or common surgical needle through one of the eyelets of the device and then through the ligament (Figure 11). Then pass the suture through the other eyelet in the implant (Figure 12). Ensure the suture does not contact the porous area of the suture attachment feature.

12 Remove the needle from the suture and hold the ankle at maximum dorsiflexion and eversion before tying the suture. Ensure reapproximation of the lateral soft tissues to the implant specifically to the rough area adjacent to the eyelets. Cut the suture and assess ankle for stability in all planes (Figure 13).

NOTE: The remaining Patient Specific Total Talus Implants not implanted must be returned to restor3d or destroyed by the hospital.

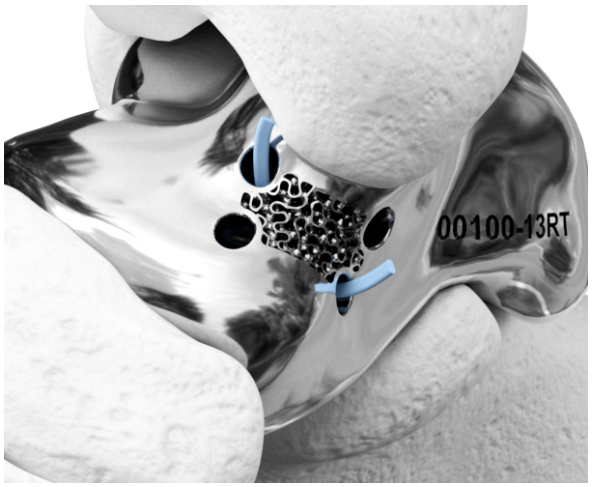


FIGURE 11

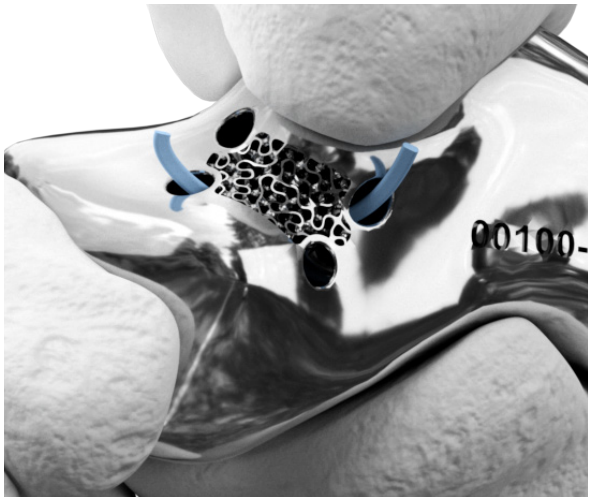
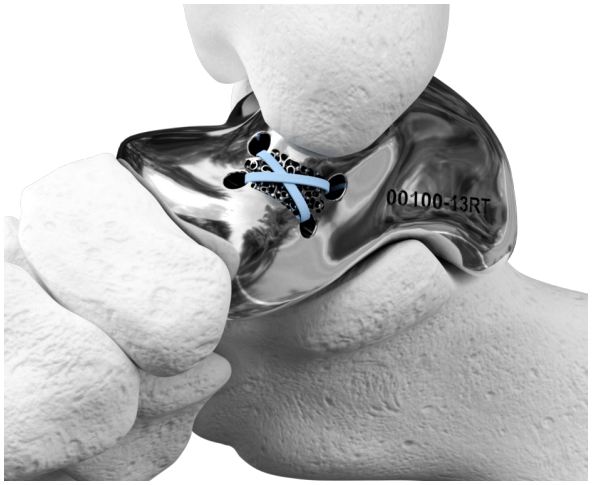


FIGURE 12



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