



PATIENT INFORMATION GUIDE

# Total Talus Replacement

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restor3d

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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.

## Glossary

**Additive Manufacturing:** Commonly referred to as 3D Printing, Additive Manufacturing is the technology used to build three-dimensional objects by depositing materials layer upon layer using data from a computer aided design (CAD) model. The technology enables creation of patient specific designs, which often include complex shapes and customized sizes.

**Ankle Joint\*:** A joint in the lower limb formed by the bones of the leg (tibia and fibula) and the foot (talus). It allows the foot to move up (dorsiflexion) and down (plantarflexion).

**Arthrodesis or Fusion:** Uniting of two or more bones through surgery, allowing the bones to grow together resulting in immobilization.

**Avascular Necrosis (AVN) or Osteonecrosis:** The death of bone tissue from a lack of blood supply. It can lead to tiny breaks in the bone resulting in bone collapse.

**Calcaneus\*:** The large bone forming the heel (hindfoot). It forms a joint (articulates) with the cuboid bone of the foot and the talus bone of the ankle.

**Computerized Tomography (CT) Scan:** Combines a series of X-ray images taken from different angles around your body and uses a computer to create detailed, cross-sectional images (slices) of the bones, blood vessels and soft tissues inside your body.

**Dorsiflexion:** Movement of the foot in an upward direction (towards the shin and the body).

**Fibula\*:** The outer and typically smaller of the two parallel bones in the lower leg, between the knee and the ankle.

**Magnetic Resonance Imaging (MRI):** A medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in your body.

**Navicular\*:** A wedge-shaped bone at the inner foot connecting the talus (ankle bone) to the cuneiform bones in the foot.

**Patient Specific Device:** A personalized device that is unique to the patient. They are designed using imaging data (e.g. CT Scan) and made to fit the patient's anatomy.

**Plantarflexion:** Movement of the foot in a downward direction (away from the body).

**Subtalar (ST) Joint\*:** Formed by the talus and calcaneus and allows the foot to rotate inward (inversion) and outward (eversion).

**Talus\*:** The large, rotating bone in the ankle connecting the leg (tibia and fibula) and foot, allowing movement.

**Tibia\*:** The inner and typically larger of the two parallel bones in the lower leg, between the knee and the ankle, often referred to as the shin bone.

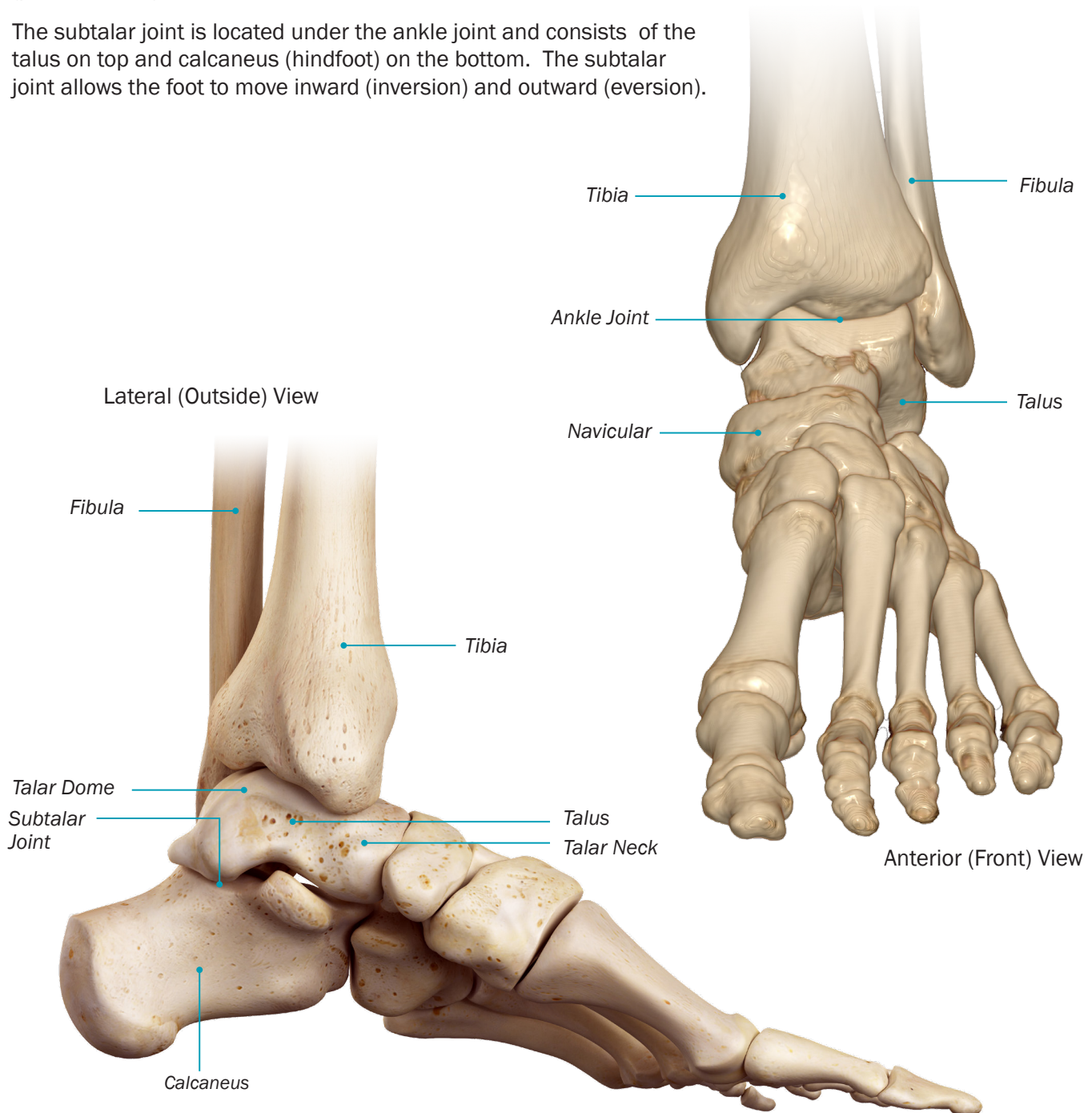
\*See Page 4 for a detailed image of the foot and ankle.

# Anatomy

## ANKLE BASICS

The ankle is made up of two joints: the ankle joint and the subtalar joint. There are three bones that make up the ankle joint: the fibula, tibia (shinbone), and talus. The tibia and fibula are lower leg bones between the knee and ankle, with the tibia on the inside of the leg and the fibula on the outside. The tibia and fibula rotate around the top of the talar dome. The ankle joint allows the foot to move up (dorsiflexion) and down (plantarflexion).

The subtalar joint is located under the ankle joint and consists of the talus on top and calcaneus (hindfoot) on the bottom. The subtalar joint allows the foot to move inward (inversion) and outward (eversion).



## Questions

### **AVASCULAR NECROSIS:**

#### ***What is avascular necrosis?***

Avascular necrosis (AVN) is the death of bone tissue due to a lack of blood supply. If left untreated, AVN can cause the bone to eventually collapse. If AVN involves the bones of a joint (like the talus) it often leads to destruction of cartilage, resulting in arthritis and pain. Avascular necrosis can be caused by a sudden, acute injury (e.g., traumatic), such as a broken bone or dislocated joint, or an injury that occurs slowly over time (e.g., atraumatic), such as long-term use of high-dose steroid medications or excessive alcohol intake. Anyone can be affected by AVN, but it is most common in people between the ages of 30 and 50.

#### ***What are the symptoms of avascular necrosis of the ankle?***

Many people have no symptoms in the early stages of avascular necrosis. As the condition gradually worsens over time, your affected joint might hurt when you put weight on it, and eventually you may feel pain when you are lying down. Pain may be dull, mild, or severe. Avascular necrosis of the talus can be quite devastating and can lead to total loss of the ankle joint with pain, arthritis, and deformity. In more severe cases, or following failure of ankle fusion, below-knee amputations may result. Therefore, when AVN of the talus is advanced, causing structural instability in the joint, a restor3d Total Talus Replacement device can be implanted to replace the dysfunctional talus.

#### ***What are the available diagnosis and treatment options?***

Your doctor will take X-rays if they suspect you may have avascular necrosis. Following X-rays, MRI or CT scans will likely be ordered. MRI and CT images are more sensitive than X-rays and are better at helping your doctor identify pathology (cause of the disease or condition).



*CT scan demonstrating avascular necrosis of the talus.*

## **AVASCULAR NECROSIS CONT:**

Your treatment options will depend on the severity of the disease. If AVN of the talus is noted in an early stage, non-operative or early-stage surgical treatment options (e.g., core decompression or bone grafting) may be available.

In late stage AVN, if the talus has begun to collapse or has fully collapsed, surgical intervention is required. Surgical treatment options may include an arthrodesis (fusion) of one or more joints in the foot and ankle, which assists in relieving pain, but at the expense of mobility. Alternatively, an amputation may be offered, where your doctor will surgically remove the lower portion of your limb below the knee.

A Total Talus Replacement is considered a joint sparing alternative to the above surgical interventions when less invasive surgical interventions are not suitable, as it allows you to maintain motion of your ankle joint while decreasing pain and increasing physical function.

## **OSTEOCHONDRAL DEFECTS:**

### ***What is an osteochondral lesion of the talus?***

Osteochondral lesions are tears or fractures in the articular cartilage in the ankle joint (between the tibia and fibula bones and the talus bone). Typically, osteochondral lesions are caused by an injury such as a bad sprain (or repetitive trauma) while twisting during impact sports such as soccer, football or golf.

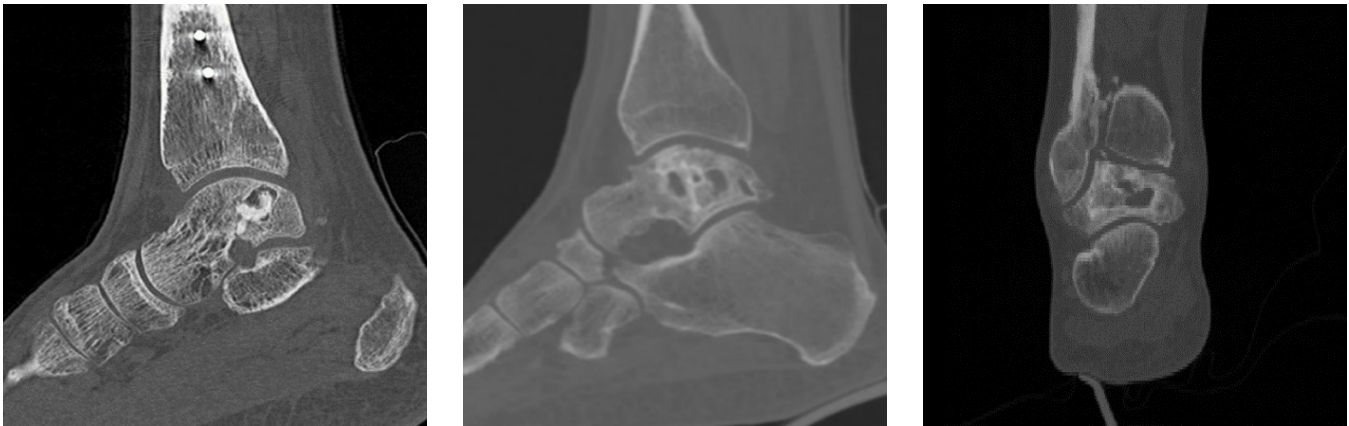
### ***What are the symptoms of an osteochondral lesion of the ankle joint?***

Osteochondral lesions can cause pain and swelling, and ankle instability (locking, clicking, or catching sensation). Pain and swelling will typically subside when the joint is at rest. Osteochondral lesions may also lead to the development of large subchondral cysts which reduces the structural integrity of the bone.

### ***What are the diagnosis and treatment options?***

While an X-ray may be initially ordered, it is challenging to diagnose an osteochondral lesion on an X-ray because these lesions can be masked by swelling and inflammation from the original injury. Most likely an MRI or CT scan will be ordered, and in some cases, both may be ordered.

## OSTEOCHONDRAL DEFECTS CONT.



*CT scan demonstrating subchondral cyst within the marrow cavity (left), and cyst formations with partial fragmentation and collapse of the medial talar dome articular surface (middle and right).*

Osteochondral lesions typically require surgery, which varies based on the size and severity of the lesion. Prior to surgery, nonsurgical interventions (e.g., wearing a cast or brace to reduce stress on the ankle, physical therapy to strengthen muscles and improve mobility, or steroid injections to minimize swelling) may be tried. Next, arthroscopic surgery may be performed. During this surgery, your surgeon will make a small incision, to view the defect with a camera, and “clean up” the area by removing the damaged cartilage. Your surgeon may also drill into the bone to cause bleeding which promotes healing, or if the damage is more severe, they may use a bone graft to replace the cartilage.

A Total Talus Replacement is considered a joint sparing alternative to the above surgical interventions when less invasive surgical interventions are not suitable, as it allows you to maintain motion of your ankle joint while decreasing pain and increasing physical function.

## TALAR FRACTURE OR EXTRUSION:

### ***What is a talar fracture or extrusion?***

Trauma to the lower extremity can result in fracture, dislocation, or complete extrusion of the talus. A talar fracture is a break in the talus bone while talar extrusion is when the talus is fully pushed out due to high force trauma. Depending on the severity and the state of the talus, a reconstruction involving replacement of the talus may be appropriate to prevent further deterioration of adjacent joints. While talar fractures can occur in all parts of the talus bone, most commonly, fractures occur in the neck (mid-portion between the body of the talus located under the tibia). Fractures most often occur from high impact traumas such as participation in sports (e.g., snowboarding accident), motor vehicle accident or severe falls (e.g., from a ladder).

## TALAR FRACTURE OR EXTRUSION CONT.:

### *What are the symptoms of talar fracture or talar extrusion?*

Most patients experience extreme acute pain, inability to bear weight on the impacted limb, and swelling, bruising, tenderness or fracture blisters.

### *What are the diagnosis and treatment options?*

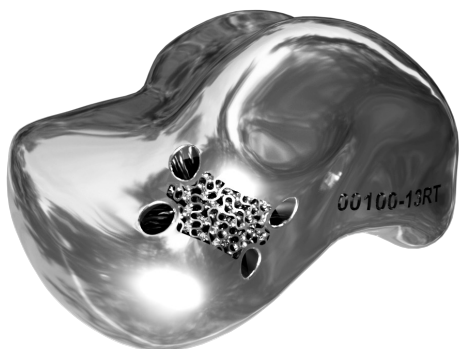
An X-ray is the most widely available imaging technique and can show if there is a broken bone, the number of pieces or fragments and if there is displacement. If more information is needed, your doctor may order a CT scan.



*CT scan of a nondisplaced vertical fracture of the talus (left) and complex fracture of the talus with depression of the posterior fracture segment (middle and right).*

Less severe talar fractures can be treated with non-surgical approaches (e.g., casting or rehabilitation), or fracture fixation using plates or screws and are less likely to develop post-traumatic secondary complications. Patients with non-union following talar fracture or extrusion who have been unresponsive to more conservative treatment may be eligible for a Total Talus Replacement implant. In some cases, a fracture may lead to avascular necrosis; these patients may be eligible for a restor3d Total Talus Replacement implant.

### **What is a 3D printed Total Talus Replacement implant?**



The restor3d Total Talus Replacement implant is a 3D printed patient specific implant that is designed and manufactured individually for each patient using data from CT images. The implant allows you to reduce pain, increase physical function and maintain range of motion avoiding an amputation (limb loss) or fusion (loss of joint mobility) for the treatment of your current condition. The restor3d Total Talus Replacement implant is designed to match your specific anatomy and is additively manufactured from a medical grade cobalt chromium metal alloy. The device has optional suture attachment sites to enable soft tissue reconstruction, as needed.



*X-ray of Total Talus Replacement implant.*

### **Who should be treated with a restor3d Total Talus Replacement implant?**

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 treatments
- 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.

### **Who should not receive a Total Talus Replacement implant?**

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.

## **Who should not receive a Total Talus Replacement implant Cont.**

- 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.

## **What are the warnings associated with a Total Talus Replacement implant?**

- The Total Talus Replacement Implant and Instrumentation (System) provided by restor3d is NONSTERILE. In-hospitalization sterilization is required before implantation.
- It is recommended that the surgeon evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a restor3d Total Talus Replacement implant.
- If the surgeon believes there are significant deformities on the affected side and/or the contralateral (healthy) side, then the patient may not be a suitable candidate for a patient specific restor3d Total Talus Replacement Implant.
- The implant must be used within 6 months from the date of the CT scan. If the patient's anatomy has changed significantly since the time of the CT scan, the implant should not be used, even if the time period of 6 months has not expired.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- The surgeon or surgical staff is obligated to examine the surgical implant and its packaging for damages prior to each application (i.e. use). If the implant or its packaging is damaged or deformed, it is not to be used.
- Improper selection, placement, positioning, alignment and fixation of the implant may result in unusual stress conditions and a subsequent reduction in the service life of the prosthetic implant.

## **What are the warnings associated with a Total Talus Replacement implant Cont.**

- Malalignment or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
- Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear.
- Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue, fracture and/or excessive wear.
- The surgeon is to be thoroughly familiar with the implant and surgical procedure prior to performing surgery. For further information, contact restor3d and consult the Surgical Technique Guide.
- The restor3d Total Talus Replacement System is patient specific and for single use only.
- Do not reuse the restor3d Total Talus Replacement System. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect the function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.
- This is a patient specific implant, do not use in a patient other than the one listed in the product labeling and/or the physician order form.
- The restor3d Total Talus Replacement System is provided in its final and complete form. Do not modify the Implant or System. Modified devices may not perform as intended and could result in patient injury.

## **What are the precautions associated with a Total Talus Replacement implant?**

- Surgical implants may only be used in surgeries, for which the designated application of the implant is explicitly necessary and defined.
- Correct selection of the implant is extremely important. Carefully select the appropriate device size based on the needs of each individual patient.
- Following surgery, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement of the implant and delay healing.
- Postoperative care is extremely important. The patient must be advised that noncompliance with postoperative instructions could lead to adverse effects. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological conditions.
- Patient specific Total Talus Replacement Implants are designed from patient data acquired from Computed Tomography (CT) scan. Over time, a patient's anatomy can change. If a significant amount of time has elapsed from the time of collection of the patient data (date of scan) to the time of surgery utilizing a Patient Specific Total Talus Replacement Implant, the implant may not fit the patient's anatomy correctly.
- Never attempt to reuse. Once the restor3d Total Talus Replacement Implant has been removed from the packaging, the device should be either used, discarded, or returned to restor3d. Never attempt to reuse the implant, even though it may appear undamaged.

## **What are the precautions associated with a Total Talus Replacement implant Cont.**

- Use only restor3d instruments when handling and implanting the restor3d device

## **What are the risks associated with this type of surgery?**

As with any surgery, there can be risks which include:

- Anesthesia
- Skin problems
- Bleeding
- Infection
- Blood clots
- Nerve/blood vessel damage

## **What are the potential adverse events of the restor3d Total Talus Replacement?**

Potential adverse effects resulting from use of the restor3d Total Talus Replacement Implant include, but are not limited to, the following:

- Infection, deep and superficial
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Increased pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Allergies or other reactions to implant materials
- Loss of anatomic position with rotation or angulation
- Bone resorption or over-production
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Embolism
- Migration of particle wear debris possibly resulting in a bodily response.

## **What are the expected outcomes and benefits of a Total Talus Replacement implant?**

The Total Talus Replacement Implant is expected to provide pain relief, improve physical function, and preserve motion and stability of the ankle joint.

You should speak to your doctor to see if you are a candidate for the Total Talus Replacement implant.

## Total Talus Replacement Clinical Data

Data from 27 patients were evaluated to demonstrate the safety and probable benefit of the Total Talus Replacement implant when used in the indicated population. The retrospective data collection under a protocol approved by appropriate Institutional Review Boards (IRBs)

The primary safety endpoints were: 1) the rate of adverse events (AEs), device or procedure related AEs, and serious AEs (SAEs), 2) the rate of subsequent surgical intervention (SSI), defined as any surgical procedure or service required after the initial implant of the TTR device, and 3) the rate of implant survivorship.

The primary probable benefit endpoint was improvement in pain, as measured by Pain Numerical Scale (NRS) and PROMIS 1.0 – Pain Interference scale, at last follow-up from baseline. The secondary probable benefit endpoints included physical function, as measured by the PROMIS 1.0 – Physical Function scale, and ankle range of motion (ROM).

A summary of the patient demographics is provided below in Table 1. Twenty-seven (27) patients were treated with 27 implants. None of the enrolled patients had a Total Talus Replacement implanted in both the left and right ankles.

Table 1: Patient Demographics.

<b>Age at Surgery</b> (in years) (n=27) Mean ± SD Range	49.9 ± 15.0 22-69
<b>Race</b> (n=27) Black/African American, n (%) White/Caucasian, n (%) Other, n (%)	1 (3.70%) 25 (92.6%) 1 (3.70%)
<b>Ethnicity</b> (n=27) Hispanic or Latino, n (%) Not Hispanic or Latino, n (%) Unknown, n (%)	1 (3.70%) 22 (81.5%) 4 (14.8%)
<b>BMI</b> (n=27) Mean ± SD Range	32.6 ± 6.80 21.2-51.2
<b>Smoking Status</b> (n=27) Current, n (%) Former, n (%) Never, n (%)	6 (22.2%) 10 (37.0%) 11 (40.7%)
<b>Alcohol Use Status</b> (n=27) Current, n (%) Former, n (%) Never Used, n (%)	15 (55.6%) 7 (25.9%) 5 (18.5%)
<b>Comorbid Conditions</b> (n=27) <sup>1</sup> Yes, n (%) No, n (%)	13 (48.1%) 14 (51.9%)
<b>Surgical History</b> <sup>2</sup> (n=27) Yes, n (%) No, n (%)	20 (74.1%) 7 (25.9%)

<sup>1</sup> Comorbid conditions included: 5 (18.5%) patients with a history of anxiety, 4 (14.8%) with depression, 1 (3.70%) with non-atrial arrhythmia, 1 (3.70%) with peripheral vascular disease, 1 (3.70%) with a history of stroke or CVA, 1 (3.70%) with diabetes mellitus, 1 (3.70%) with moderate to severe chronic kidney disease, 1 (3.70%) with leukemia, 1 (3.70%) with a history of drug abuse, and 1 (3.70%) patient with HIV or AIDS.

<sup>2</sup> Surgical history was not limited to the affected limb

## Safety

There was a total of ten (10) safety events reported in five (n=5, 18.5%) patients. The safety events include nine (9) subsequent surgical interventions (SSIs) across four (n=4, 14.8%) patients and one adverse event in one (n=1, 3.7%) patient that did not have an SSI. One (1/8, 12.5%) device that had soft tissue attachment sites (but not used) was linked to a patient who reported four (4) subsequent surgical interventions. The initial safety event for each patient was categorized for their relatedness to the device. The initial safety event for three (3, 11.1%) patients was determined to be unrelated to the subject device, and for two (2, 7.4%) patients was determined to be possibly procedure-related. None (0, 0%) were determined to be device-related. See Table 2 for an overview of safety events.

Table 2: Categorization of Initial Reported Safety Events.

	Possibly Device-Related	Possibly Procedure-Related	Unrelated
Serious Adverse Events <sup>1</sup> (n=4)	0	2	2
<i>Subsequent Surgical Interventions</i>	0	2	2
Adverse Events (n=1)	0	0	1
<b>Total<sup>2</sup> (n=5)</b>	<b>0</b>	<b>2</b>	<b>3</b>

<sup>1</sup> Serious adverse event totals are inclusive of subsequent surgical interventions.

<sup>2</sup> Sum of SAEs and AEs.

### Serious Adverse Events

The nine (9) SSIs included one patient who had four (4) SSIs, one patient who had three (3) SSIs, and two patients who had one (1) SSI following the index surgery. The study team potentially attributed the initial subsequent surgeries for two (2/27, 7.41%) of these patients to the implantation procedure. Importantly, to date, the study team has not received any reports of below the knee amputation (BKA), and all patients (27/27, 100%) were successfully able to salvage their limbs with the restor3d Total Talus Replacement implant.

### Adverse Events

Only one patient (1/27, 3.70%) reported an adverse event that did not result in an SSI, and this event was determined by the surgeon to not be related to the subject device.

### Implant Survivorship

Implants remained in place for 26 (96.3%) patients, demonstrating a high rate of implant survivorship. To date, no additional implants have been removed in the study population.

## Probable Benefits

### Perceived Pain – Pain Numerical Rating Scale (NRS)

Pain scores on Pain NRS were assessed at baseline (prior to treatment) and at the most recent follow-up time point. Twelve (12) patients had longitudinal (baseline and postoperative) data available on Pain NRS measures. Across all patients, irrespective of length of follow-up, there was a 1.75-point mean improvement in scores on Pain NRS (Figure 1).

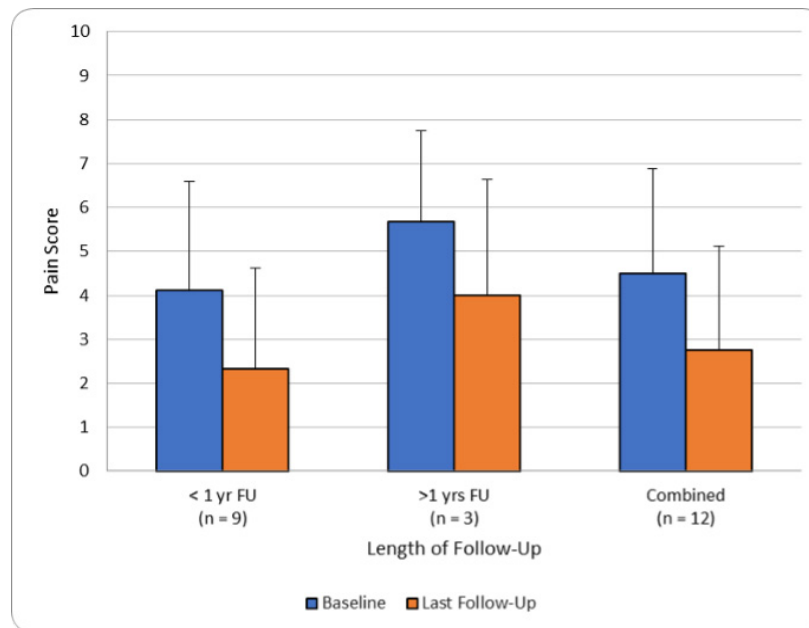


Figure 1. Pain NRS - baseline and last follow-up by duration of follow-up. Bars represent standard deviations

### Perceived Pain – PROMIS-Pain Interference

Pain T-scores on the PROMIS-Pain Interference measure were assessed at baseline (prior to treatment) and at the most recent follow-up time point. Nine (9) patients had longitudinal (baseline and postoperative) data available on the PROMIS-Pain Interference measure. In each follow-up group, T-scores improved from baseline to last follow-up (see Figure 2). Across all cohorts, the mean improvement in T-scores was 5.00 points. Importantly, pain T-scores continued to improve as the follow-up period increased through the 2-year post operation time point. Given that a T-score of 55 is within normal limits, these patients returned to pain levels similar to the general U.S. population.

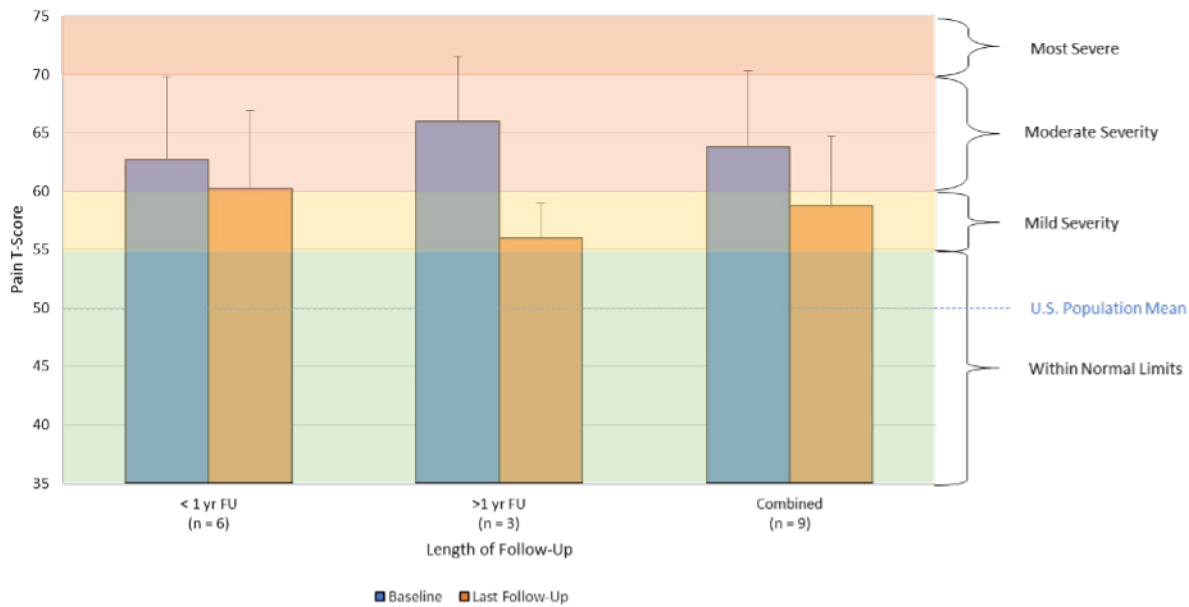


Figure 2: PROMIS-Pain Interference - Mean Baseline and Last Follow-Up Scores by Duration of Follow-Up.

### Physical Function

Physical function T-scores on the PROMIS-Physical Function measure were assessed at baseline (prior to treatment or within 30 days following surgery) and at the most recent follow-up time point. Ten (10) patients had longitudinal (baseline and postoperative) data available on the PROMIS-Physical Function measure. Across all patients, irrespective of follow-up duration, there was a 3.00-point improvement in T-scores from baseline to last follow-up, see Figure 3. When compared to the less than 1 year of follow-up, the patients who had more than 1 year of follow-up experienced greater improved physical functioning (mean T-score improved by 6.00 points).

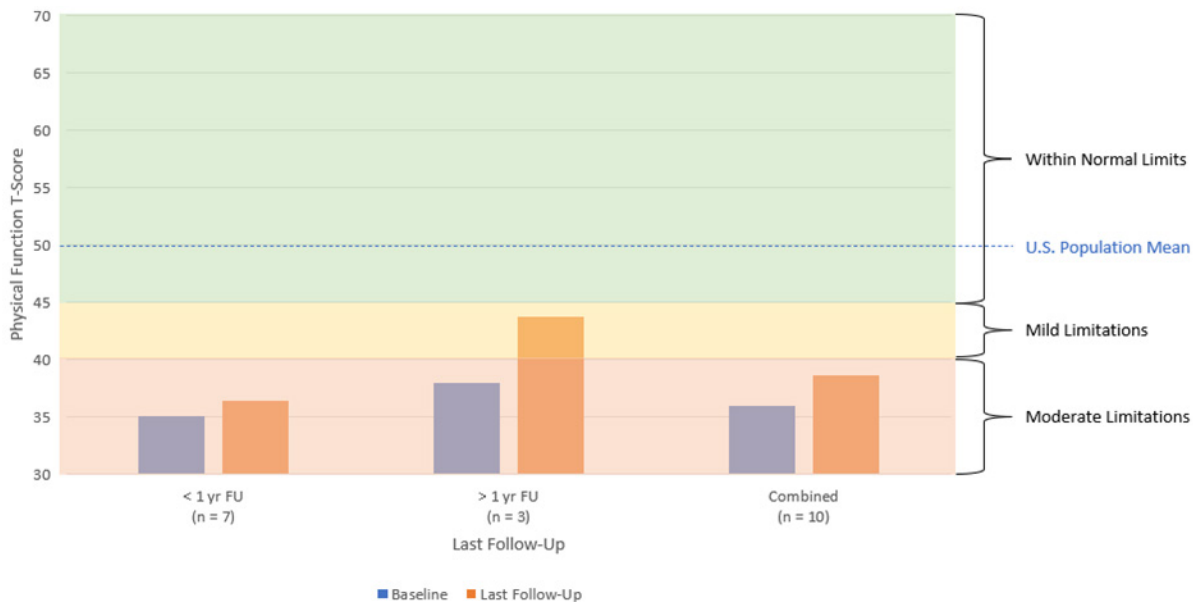


Figure 3: PROMIS-Physical Function scores by Follow-Up Duration.

### Range of Motion (ROM)

Plantarflexion and dorsiflexion were measured pre and postoperatively. Eight (8/22, 36.4%) patients had preoperative and postoperative plantarflexion scores available. As anticipated, patients in active recovery (in the less than 1-year postoperative group) reported a reduction in postoperative ROM. In the greater than 1-year postoperative group, there was no change from baseline plantarflexion, signifying that these patients returned to their preoperative ROM (see Figure 4).

One patient in the less than 1 year group had a 30-degree reduction in ROM impacting the overall mean of the combined cohorts. The results of this study demonstrate that patients are able to regain ROM over time.

Seven (7/22, 31.8%) patients had baseline and postoperative dorsiflexion measures available. Similar to published reports and across all cohorts, there was no change from baseline dorsiflexion, signifying that patients maintained range of motion postoperatively, see Figure 5.

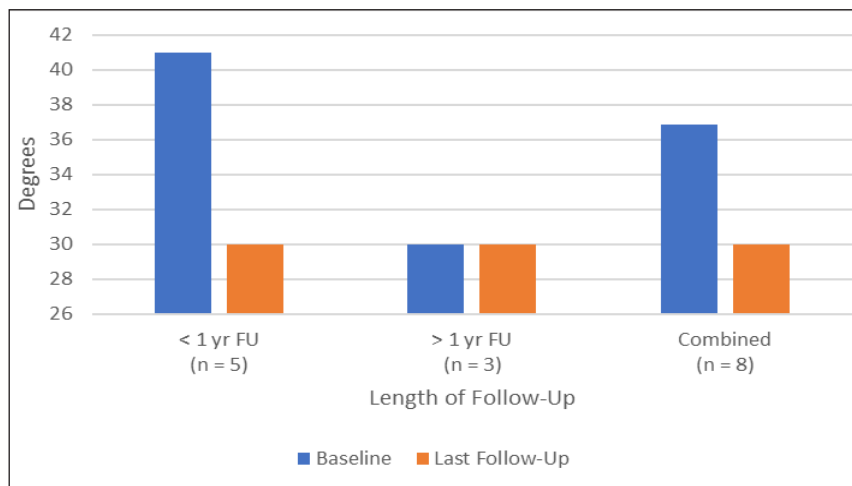


Figure 4. Degrees of plantarflexion by follow-up duration.

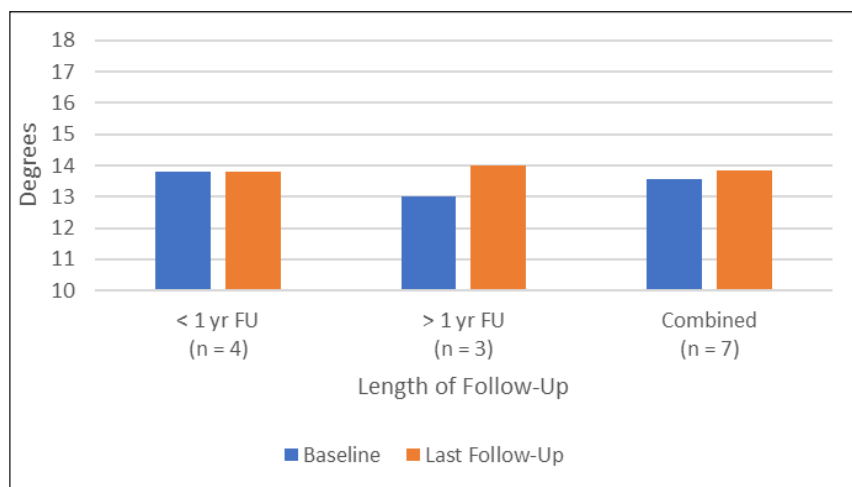


Figure 5. Degrees of dorsiflexion by follow-up duration.

Range of motion findings demonstrate the ability for the restor3d Total Talus Replacement implant to maintain mobility postoperatively. This finding is important because alternative interventions such as ankle fusion that reduce pain result in a substantial decrease in ROM, ultimately reducing the patient's physical function and quality of life.

## Conclusion

The patients who were treated with the restor3d Total Talus Replacement implant in the above study received a clinically meaningful probable benefit from the device for several reasons.

### Safety

- No (0, 0%) SAEs, SSIs or AEs were reported in patients where the soft tissue attachment sites were used, and the rate of patients with SSIs among the patients who had devices implanted with soft tissue attachment sites (1/8, 12.5%) was equivalent to the rate of patients with SSIs reported across the entire study population (4/27, 14.8%).
- No (0, 0%) adverse events were attributed to the subject device.
- More importantly, 26 (26/27, 96.3%) participants retained their implants, suggesting strong implant survivorship.
- No (0, 0%) patients reportedly received an amputation and all patients were successfully able to salvage their limb.

### Probable Benefit

- Patients reported an improvement in perceived pain from baseline to last follow-up on both Pain NRS and PROMIS-Pain Interference measurement tools.
- Patients demonstrated improved physical function as more postoperative time elapsed. Importantly, patients who had more than 1 year of follow-up reported a 6-point improvement in PROMIS-Physical Function T-scores, nearly reaching normal limits of the scale.
- By the 1-year postoperative time point, both plantarflexion and dorsiflexion returned to baseline.

Across the enrolled participants, not only did the restor3d Total Talus Replacement implant prevent below the knee amputation, but it also improved the quality of life for many patients through reduced pain, maintained ROM and improved physical functioning. These positive impacts afford patients the ability to return to work, maintain a healthy lifestyle through physical activity, and engage with friends and family.

## **What happens during the Total Talus Replacement surgery?**

After being administered anesthesia, your surgeon will make an incision on the front (anterior) of your ankle. The surgeon will use surgical instruments to remove your talus bone and will then insert the Total Talus Replacement implant that was designed to fit your anatomy. Your surgeon will confirm the fit of the implant under X-ray imaging and will then close the incision and apply a postoperative bandage.

## **What happens after a total talus replacement surgery?**

Your doctor will talk with you about your post-surgery recovery. It is recommended that you remain non-weight bearing in a splint/cast for three weeks or until incision is healed. Active Range of Motion will begin at three weeks if the incision is healed. You may then weight bear as tolerated in a Controlled Ankle Movement (CAM) boot for the following three weeks. At six weeks post-op, you may transition to weight bearing as tolerated in an Ankle Stabilizing Orthosis ankle brace and sneakers. Formal physical therapy should begin at 6 weeks post-op. Please follow the instructions from your doctor. Your doctor will continue monitoring your healing progression at regular intervals and will decide when you are able to resume certain physical activities.

## **When should I call the doctor after surgery?**

Please refer to the instructions in your discharge papers about when you should call regarding any problems after surgery. It is normal to experience some pain and discomfort after surgery. If you experience increased pain, surgical site infection, or any other medical issue at any time after surgery, please contact your doctor.

## **Talk to your doctor**

While this guide is intended to provide you with information to help you make an informed decision about your treatment options, it is not intended to provide medical advice or replace professional medical care. If you have any questions about the Total Talus Replacement implant, please call your doctor, who is the only qualified person to diagnose and treat your foot and ankle condition. As with any surgical procedure, it is advised to select a doctor who is experienced in performing the surgery you are considering.

If you have specific questions about the Total Talus Replacement implant, please contact your doctor. For additional information, please visit [restor3d.com](http://restor3d.com).



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