

Instructions for Use

Additive Orthopaedics Patient Specific Talus Spacer

Description: The Additive Orthopaedics Patient Specific Talus Spacer is an additively manufactured implant made from cobalt chromium metal alloy and produced by laser sintering. The device allows the patient to regain motion and reduce pain without an amputation or fusion until the time a fusion potentially becomes necessary.

System Components:

Total Talus Cobalt Chrome Cobalt-28 Chromium-6 Molybdenum (meeting the requirement of ASTM F75) in 3 sizes: small, nominal, and large.

Indications for Use:

The Additive Orthopaedics Patient Specific Talus Spacer is indicated for avascular necrosis of the ankle joint. The anatomical landmarks necessary for the design and creation of the Additive Orthopaedics Patient Specific Talus Spacer must be present and identifiable on computed tomography scan.

Contraindications:

- Use of implant greater than 6 months from date of patient's computed tomography (CT) scan.
- Degenerative changes in the tibiotalar, subtalar or talonavicular joints.
- Presence of an active 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.
- Sensitivity or allergy to the metal implant. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.

Humanitarian Device. Authorized by Federal law for use in the treatment of avascular necrosis of the ankle joint in adult patients. The effectiveness of this device for this use has not been demonstrated.

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

Potential Adverse Effects

- Infection, deep and superficial
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Deep and superficial infections
- 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
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

Precautions

- Surgical implants may only be used for surgeries, for which the designated application of the implant is explicitly necessary and defined.
- Correct selection of the implant is extremely important. That patient's anatomy and indication will determine the size of the implant to be used.
- No partial weight-bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight-bearing. 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 breakage of the implant or surrounding bones in the ankle joint. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.
- Patient Specific Talus Spacers are designed from patient data such as radiograph (X-ray), CT scan, or magnetic resonance imaging (MRI). 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 Talus Spacer, the implant may not fit the patient's anatomy correctly.

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Warnings

- Surgeon's must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Patient Specific Talus Spacer. If the surgeon believes there are deformities on the affected side or the contralateral side, then the patient may not be a suitable candidate for a Patient Specific Talus Spacer.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- The trained expert staff is obligated to examine the surgical implant and its packaging for damages prior to each application, i.e., use in case of the implant or its packaging being 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.
- 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.
- Do not modify the Additive Orthopaedics Patient Specific Talus Spacer.
- The surgeon is to be thoroughly familiar with the Patient Specific Talus Spacer and surgical procedure prior to performing surgery. For further information, contact Additive Orthopaedics and consult the Surgical Technique Guide.
- Do not reuse the Additive Orthopaedics Patient Specific Talus Spacer. 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 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.

MR Safety Information

The Additive Orthopaedics Patient Specific Talus Spacer has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Additive Orthopaedics Patient Specific Talus Spacer in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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Directions for Use

This outlines the basic procedure for device implantation, which is described more fully in the Surgical Technique Guide. It is the responsibility of the surgeon to be familiar with the procedure before use of the products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. As the manufacturer of this device, Additive Orthopaedics does not practice medicine and does not recommend this or any other surgical technique for use on any specific patient.

1. Prepare the insertion site using standard surgical techniques. A straight skin incision is made over the anterior ankle, similar to the anterior approach used for a total ankle replacement.
2. The anterior capsule of the tibiotalar joint is then opened, and the talus divided into sections using a chisel. Once divided, the talus is then resected.
3. Assess articulations through dorsiflexion and plantarflexion of the ankle as well as inversion and eversion. Flexibility at the midfoot is also demonstrated through multiple planes of movement.
4. Once the proper size is determined insert the corresponding Patient Specific Talus Spacer.
5. It is recommended to confirm the fit of the implant using fluoroscopy.

How Supplied

Additive Orthopaedics Patient Specific Talus Spacers are provided to the hospital non-sterile. Only sterile devices should be used in surgery. Additive Orthopaedics Patient Specific Talus Spacers have been cleaned and inspected. Unless otherwise indicated, these devices are NOT STERILE and MUST be sterilized prior to use. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged package.

Disclaimer

Additive Orthopaedics has verified through laboratory testing that its Patient Specific Talus Spacers are suitable for the specific sterilization methods and cycles for which they have been tested.

Health care personnel bear the ultimate responsibility for ensuring that any particular packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that requirements and conditions essential to sterilization can be achieved.

In the event that health care personnel fail to properly sterilize the device as required, Additive Orthopaedics does not accept responsibility or liability for any damages or otherwise arising from a lack of sterility of an implantable device supplied in a clean but non-sterile condition.

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Cleaning and Decontamination

Non-sterile Additive Orthopaedics Patient Specific Talus Spacers are supplied in a cleaned condition in clean packaging materials. Further cleaning other than sterilization is not required. Use care in handling a device once the device is removed from the packaging in order to prevent any inadvertent contamination, damage, or otherwise jeopardize the integrity of the device.

Sterilization

Double wrap devices in accordance with local procedures, using standard techniques such as those described in ANSI/AAMI ST46-1993. Be sure to sterilize in FDA cleared sterilization wraps or pouches.

Recommendations for Sterilization

These instructions are recommended for the care, maintenance and sterilization of Additive Orthopaedics Patient Specific Talus Spacers. They are intended to assist health care personnel in safe handling practices, effective sterilization of Patient Specific Talus Spacers. The instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective processing of implants. Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR), may be directly involved in handling devices. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective processing and to prevent damage or misuse of devices.

Responsibilities of the User

General. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance. **DO NOT ATTEMPT TO STERILIZE THE DEVICE IN THE PACKAGING MATERIALS SUPPLIED.**

Sterility. Users should conduct testing in the health care facility to ensure that the conditions essential to sterilization can be achieved and are acceptable for the steam sterilization process. ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities provides guidelines for design and personnel considerations, processing recommendations, care of sterilizers, quality control, and quality process improvement.

Sterility

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sterilized prior to use. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged package.

Additive Orthopaedics implantable devices can be steam autoclaved, and repeated autoclaving will not adversely affect them, unless otherwise indicated on the labeling.

Implantable devices may be autoclaved using a full cycle. Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Additive Orthopaedics under laboratory conditions.

The validation protocols were performed in accordance with AAMI ST79:2017 Steam Sterilization and Sterility Assurance in Health Care and AAMI ST79-2017 Containment Devices for Reusable Medical Device Sterilization. Be sure to sterilize in FDA cleared sterilization wraps or pouches. In accordance with our validation results, the following cycles are recommended for wrapped goods:

- Use a validated, properly maintained and calibrated steam sterilizer following the manufactures recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following cycles:
- Dynamic Air Removal Steam Exposure Temperature
 - 132C (270F) Exposure Time- 4 minutes
 - Minimal drying time- 30 minutes, Minimal cooling time- 30 minutes
- Store sterile packaged implants in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity

Storage and Shelf Life

Additive Orthopaedics Patient Specific Talus Spacers that have been wrapped to maintain sterility should be stored in a constant, well-regulated environment for temperature and humidity. Devices should not be subject to environmental extremes including temperature and moisture. Care must be exercised in the handling of wrapped devices to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped devices based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of a contaminating event increases over time, with handling, and whether woven or non- woven materials, pouches, or container systems are used as the packaging method.

Clinical Data

Data from 32 cases in 31 patients were evaluated to demonstrate the safety and probable benefit of the Patient Specific Talus Spacer when used in the indicated population. The data collection was approved by the Duke University Institutional Review Board.

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The primary safety endpoint was the proportion of patients who underwent a secondary subsequent surgical intervention (“SSSI”). Other safety endpoints assessed included adverse events (“AEs”), device or procedure related AEs, AEs by severity, and serious AEs (“SAEs”).

The probable benefit endpoint was the reduction in baseline level pain following surgery using the Visual Analog Scale (“VAS”) for pain. The secondary probable benefit endpoints assessed included ankle range of motion (“ROM”) and Foot and Ankle Outcome Scores (“FAOS”). FAOS subscales, pain, symptom (stiffness, swelling, etc.), activities of daily living (“ADL”), ability to perform sports and recreational activities (“Sport/Rec”); and foot/ankle-related quality of life (“QoL”) were also assessed.

A summary of the patient demographics is provided below in **Table 1**. Thirty-one (31) patients were treated for a total of 32 operations; 1 patient had a Patient Specific Talus Spacer implanted in both the left and right ankles.

Table 1: Patient Demographics

Age (n=31)	
Mean±SD	43 ± 15.3
Range	20-69
Gender (n=31)	
Male, n (%)	8 (25.8%)
Female, n (%)	23 (74.2%)
BMI (n=31)	
Mean±SD	31 ± 6.96
Range	20-48
Smoking Status (n=31)	
Current, n (%)	4 (12.9%)
Former, n (%)	3 (9.7%)
Never a smoker, n (%)	24 (77.4%)
Laterality (n=32)	
Left, n (%)	17 (54.8%)
Right, n (%)	13 (41.9%)
Both, n (%)	1 (3.2%)
Prior Surgeries (n=31)	
0, n (%)	15 (48.4%)
1, n (%)	9 (29.0%)
2, n (%)	5 (16.1%)
≥ 3, n (%)	2 (6.5%)

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Safety

Adverse event data was collected during the study. Three (3) related adverse events were reported in 3 cases: 2 pain events related to the treatment and 1 scar tissue formation event related to the treatment that resulted in a superficial peroneal neuroma. A table of related adverse events is provided below:

Table 2: Related Adverse Events

	AEs	Total Patients with AEs n (%)
Any AE	3	3 (9%)
General Disorders and Administration Site Conditions		
Chills	0	0%
Impaired Healing	0	0%
Mechanical Complication of the implant		
Pain	2	2 (6%)
Pyrexia	0	0%
Wound Necrosis	0	0%
Infections and Infestations		
Infection	0	0%
Superficial	0	0%
Deep	0	0%
Injury, poisoning and procedure complications		
Loosening of the device	0	0%
Fracture	0	0%
Injury	0	0%
Joint Injury	0	0%
Post procedural haematoma	0	0%
Musculoskeletal and connective tissue disorders		
Myositis	0	0%
Soft Tissue Necrosis	0	0%
Scar Tissue	1	1 (3.1%)
Skin and Subcutaneous tissue disorders		
Blister	0	0%
Skin Necrosis	0	0%

In addition, there were 3 reoperations reported in 3 of 32 cases (9.4%). Two (2) of the reoperations are unrelated to the Patient Specific Talus Spacer or the associated procedure, and are most likely due to pre-existing comorbidities, while 1 reoperation

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was related to the treatment and is associated with the scar tissue reported in **Table 2** above. In one patient, irrigation and debridement of tissue near the surgical site was required 6 months after the surgery to promote healing of the infected tissue and contracture with tibial anterior release. The infection was associated with a prior surgery for a vascularized pedicle graft. Approximately 3 years after the procedure, a below the knee amputation was performed to address an underlying neurological condition. The reoperation for this patient is not related to the treatment. Another patient underwent surgical treatment of superficial peroneal neuroma (“SPN”) after implantation of the device. Although neuromas are generally uncommon, they may occur after direct trauma or operation. This event was classified as possibly related to the treatment procedure. The third patient experienced progression of talus AVN to tibial AVN, after implantation of the Patient Specific Talus Spacer. This patient presented pre-operatively with cancer with widespread AVN in lower right extremity. The patient ultimately underwent revision surgery with a total ankle replacement (“TAR”). Chronic pain, including prior to the Patient Specific Talus Spacer procedure, was a long-term problem for this patient, thus it was not related to the treatment.

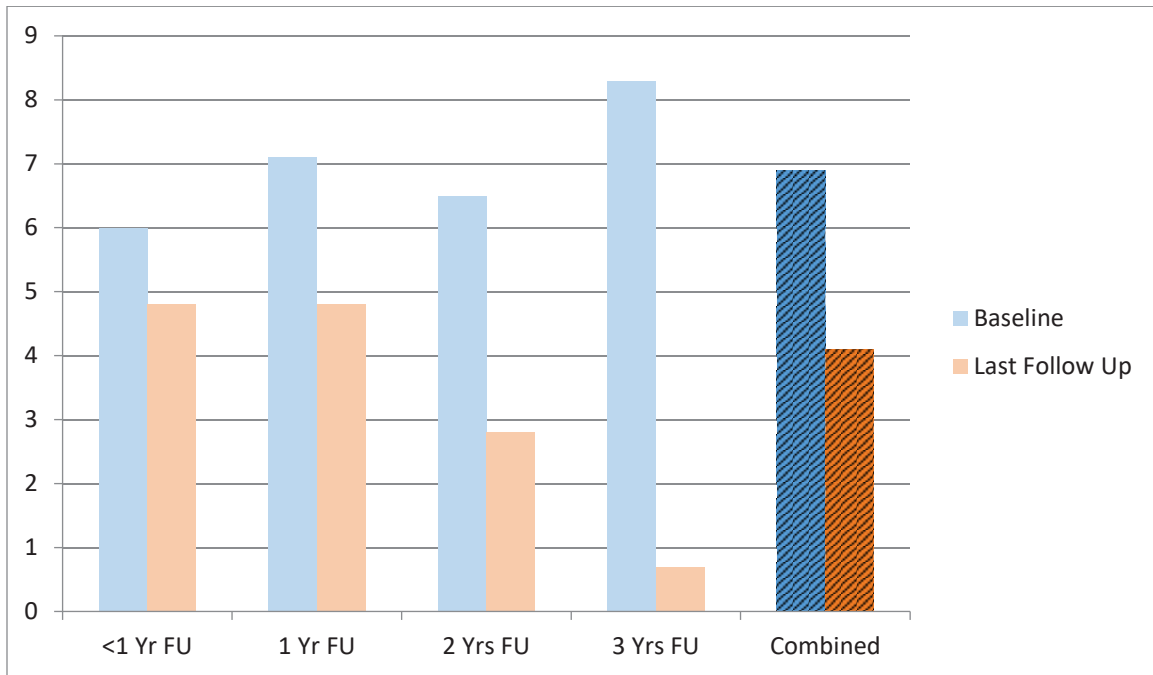
Probable Benefits

VAS pain scores were assessed prior to treatment and at the most recent follow-up time point, as shown in **Figure 1**. The total study population, as well as each cohort, experienced mean improvement on VAS pain; across cohorts the magnitude of the improvement was positively correlated with the duration of follow-up.

At baseline, the mean VAS score for the study population was 6.9 cm \pm 2.0 and scores ranged from 3-10 cm, with 10 representing maximum pain intensity. Mean change from baseline for the entire study population was -2.8 cm \pm 3.1. For the cohort analysis, mean improvement from for the <1 year, 1 year, 2 years, and 3 years cohorts was -1.2 cm \pm 2.7, -2.2 cm \pm 2.8, -3.7 cm \pm 2.3, and -7.7 cm \pm 3.2. Thus, improvement on VAS pain was consistent across duration of follow up. As anticipated, due to the lengthy recovery period associated with this patient population, VAS pain outcomes improved on average the longer the follow-up period.

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Figure 1: VAS Pain (cm) - Mean Baseline and Last Follow-Up by Duration of Follow-up

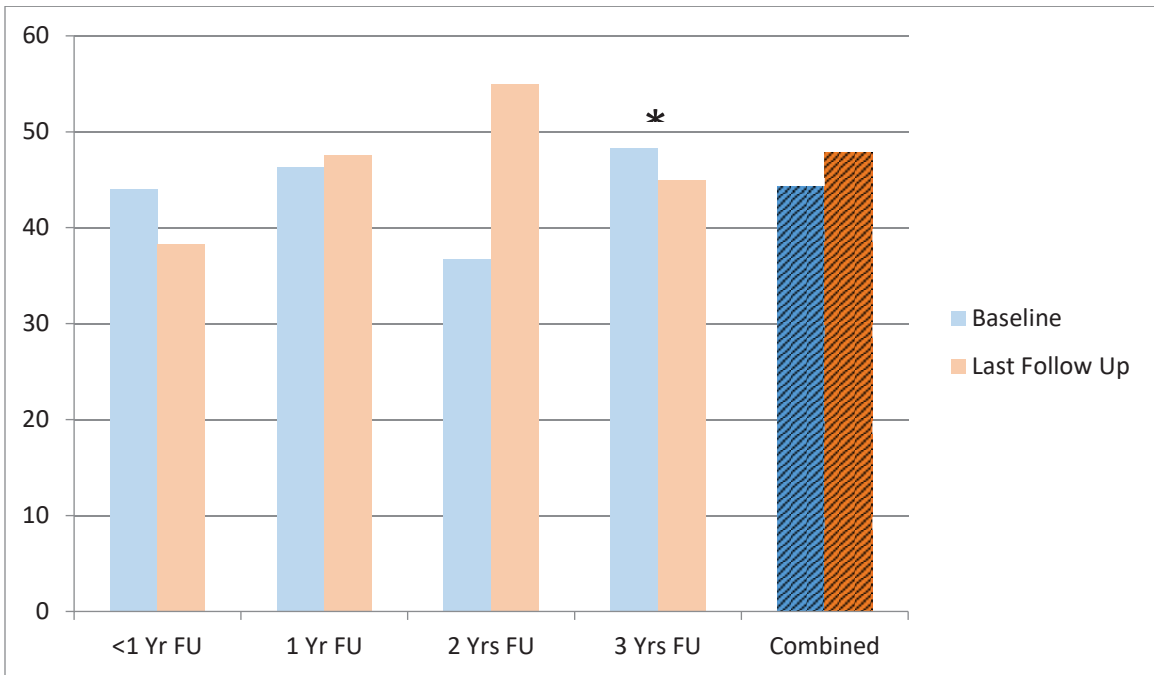


Ankle ROM values were assessed for each patient, and reported based on the last follow-up data (**Figure 2**). The data summary presents outcomes for the entire study population, as well as by cohort based on duration of follow-up period (i.e., < 1 year, 1 year, 2 years, and 3 years).

As anticipated, patients still in active recovery from the device procedure (i.e., < 1 year of follow up) reported deterioration from baseline; the other cohorts either reported mean improvement or no change. When patients with < 1 year of follow up are excluded from the study population the mean improvement for the remaining subjects is 5.9 degrees. Patients with 2-year follow-up data showed the greatest mean improvement in ankle ROM compared to baseline (25 degrees).

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Figure 2: Ankle ROM - Mean Baseline and Last Follow-Up by Duration of Follow-up

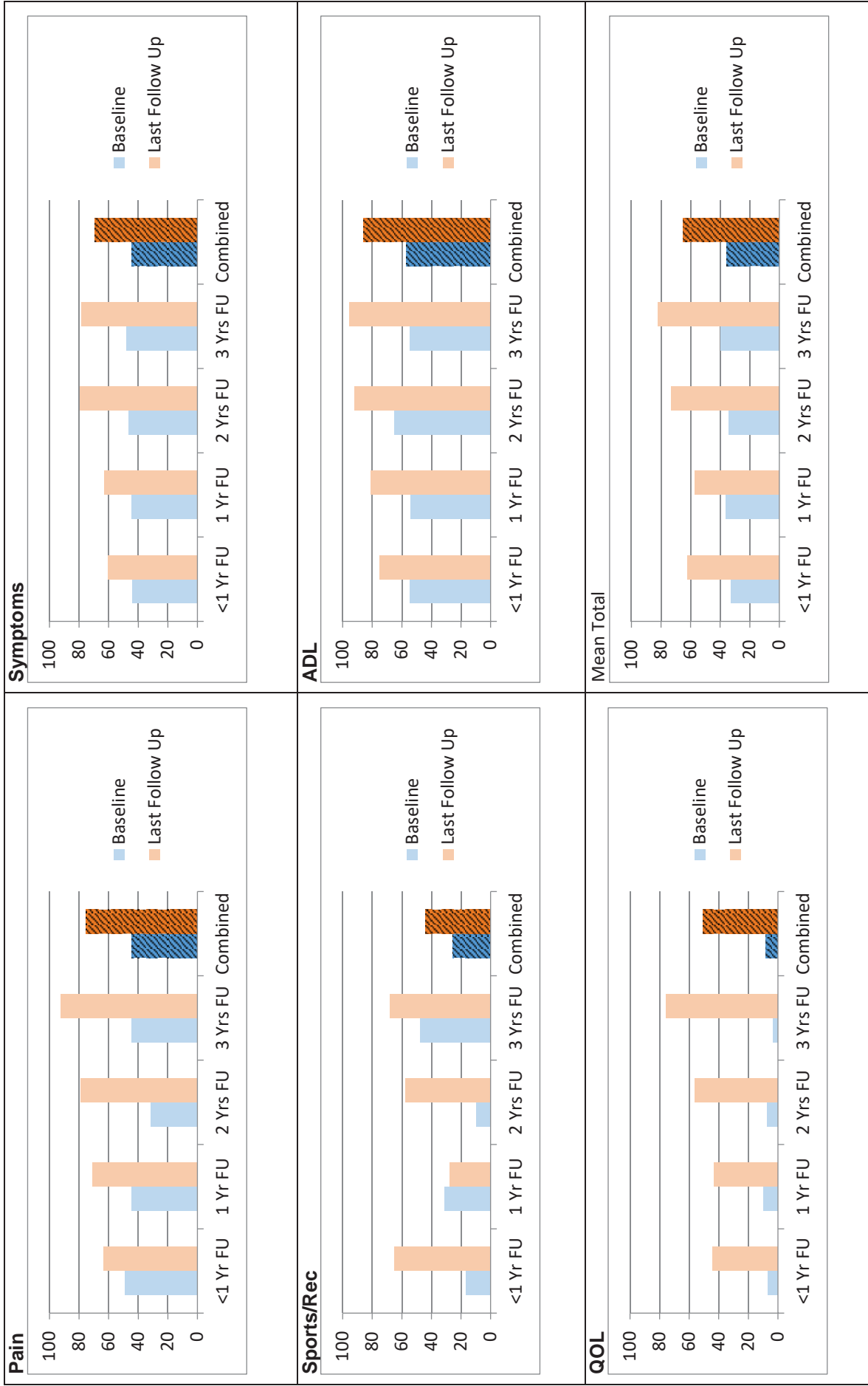


*In the 3 Yr Cohort, while mean ROM at last follow up is lower than baseline, the mean change from baseline to last follow up still showed improvement.

Average combined FAOS score, as well as each separate subscale (Pain, Symptoms, Sport/Rec, ADL, and QoL), were assessed pre-operatively and post-operatively. The mean change for FAOS average combined score and each subscale are reported with the last follow-up data combined (**Figure 3**). The data summary presents outcomes for the entire study population. As seen in **Figure 3** below, patients showed an increase for each subscale at the last follow up.

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Figure 3: Mean FAOS Subscales Mean Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-up







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Conclusion






The patients who were implanted with the Patient Specific Talus Spacer in the above study received a clinically meaningful probable benefit from the device. As discussed above, baseline VAS pain score were reduced by -2.8 cm postoperatively, from 6.9 cm (moderate to severe pain) to 4.1 cm (mild pain). ROM also improved on average, especially when limiting the analysis to those patients who had at least 1 year of follow-up and thus had adequate time to rehabilitate. Functional outcomes based on FAOS subscales also improved, with average improvement on all subscales exceeding the associated MIC threshold except Sport/Rec. Moreover, the rate of reoperation was low, with 9.4% of cases resulting in reoperation. Improvement in pain and function measures, accompanied by a low rate of reoperation, is particularly meaningful to AVN talus patients who have limited options and high risk of needing to undergo fusion or amputation. The favorable probable benefit to risk profile of the device is further demonstrated by the activity levels reported for some patients post-operatively, which include returning or continuing in their career, engaging in recreational activities, and returning to walking.

Packaging and Labeling

- Additive Orthopaedics LLC devices should be accepted only if the factory packaging and labeling arrive intact.
- Contact customer service if the package has been opened or altered.

Symbol	Description
	Catalog number
	Lot number
	Manufactured by (legal manufacturer of device)
	Date of Manufacture

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	Do not re-use/single use only
	Expiration date/use-by date
Symbol	Description
Rx only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if package damaged
	Non-sterile
	Caution, consult accompanying documents

Recommended CT Scanners:

- GE/Lightspeed RT 16*
- GE MEDICAL SYSTEMS BrightSpeed*
- GE MEDICAL SYSTEMS Discovery CT750HD*
- GE MEDICAL SYSTEMS LightSpeedVCT*
- Siemens/Sensation 64*
- Siemens/Sensation 65*
- Siemens/Somatom Definition AS*
- Siemens/Somatom Definition Flash*

**The average exposure time for the patient is 1681 ms. Please refer to the manufacturer's instructions for use for more information regarding patient dose. The CT Scanners use a helical CT image acquisition with a reconstruction algorithm of Moderate / Soft Tissue or Equivalent.*

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Additive Orthopaedics understands the concern about keeping the radiation doses to patients as low as possible; therefore, please use these guidelines as appropriate for your patients.” For general radiation safety concerns, you may wish to additionally reference publicly available information such as Imaging Wisely or FDA’s Computed Tomography webpage <http://www.fda.gov/Radition-EmittingProducts/RadiationEmittingProducttsandProcedures/MedicalImaging/MedicalXRays/ucm115317.htm>)

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PATIENT SPECIFIC TALUS SPACER

SURGICAL TECHNIQUE GUIDE



ADDITIVE ORTHOPAEDICS

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- Presence of an active infection.
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- 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.
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- Presence of neurological deficit which would prevent patient post-operative compliance.
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Potential Adverse Effects

- Infection, deep and superficial
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Deep and superficial infections
- Allergies or other reactions to implant materials
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- No partial weight-bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight-bearing. 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.
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Warnings

- Surgeon's must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Patient Specific Talus Spacer. If the surgeon believes there are deformities on the affected side or the contralateral side, then the patient may not be a suitable candidate for a Patient Specific Talus Spacer.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- The trained expert staff is obligated to examine the surgical implant and its sterile packaging for damages prior to each application i.e. use. In case of the implant or its packaging being 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.
- 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.
- Do not modify the Additive Orthopaedics Patient Specific Talus Spacer.
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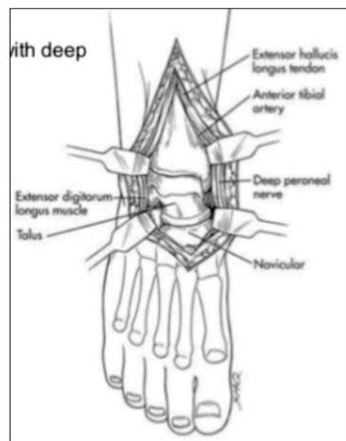
- This is a patient specific implant, do not use in a patient other than the one listed in the product labeling and/or the physician order form.

Procedural Steps

The following procedural steps provide a recommended procedure for using the Additive Orthopaedics Patient Specific Talus Spacer. The content provided puts forth technique guidance, however, the surgeon must consider the individual needs of the patient making the appropriate adjustments when and as required.

Skin Incision / Exposure

1. Prepare the insertion site using standard surgical techniques. A straight skin incision is made over the anterior ankle, similar to the anterior approach used for a total ankle replacement, between the extensor hallucis longus (EHL) and extensor digitorum longus (EDL) interval.

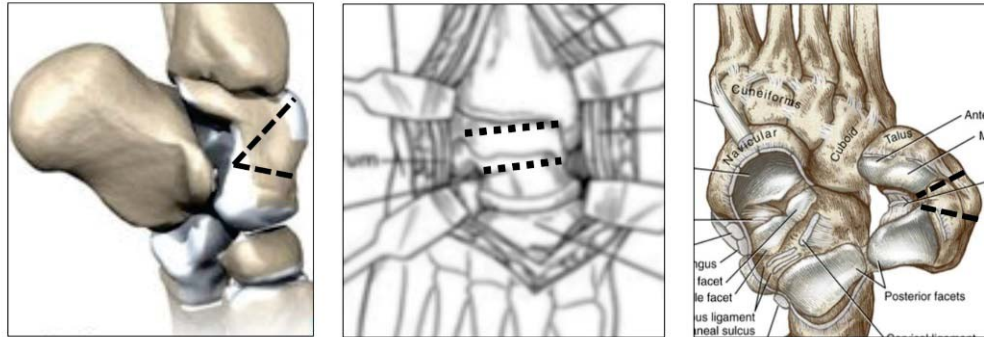


2. Open the anterior capsule of the tibiotalar joint. Perform an Anterior Ligament release.



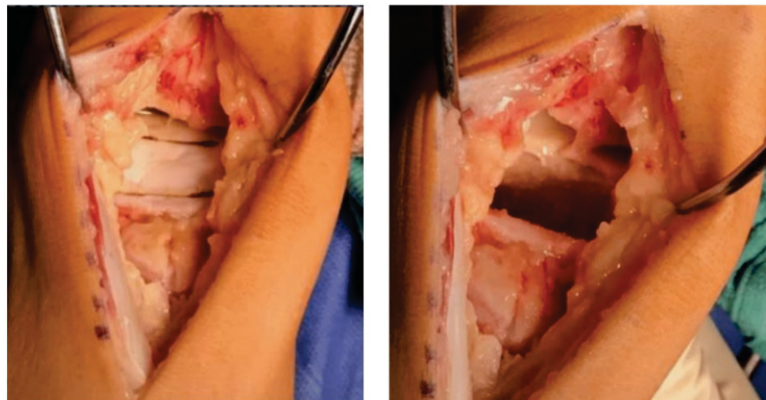
Dorsal Closing Wedge Osteotomy

3. Perform a dorsal closing wedge osteotomy at the talar neck and remove the bone wedge. The dorsal wedge osteotomy will sever the plantar interosseous/cervical ligament attachments.



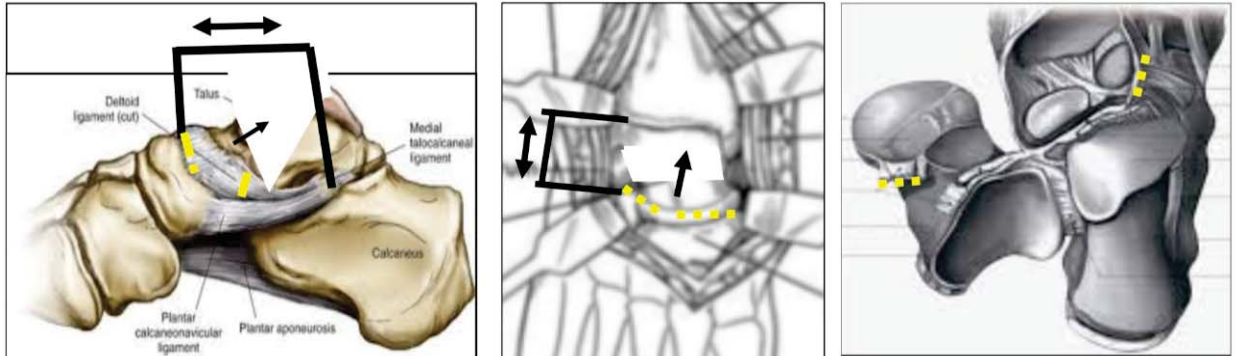
Middle Talus Resection

4. Use a combination of bone saws, osteotomes, chisels, tamps and/or mallet to resect the middle talar segment. Note: these instruments are not provided by Additive Orthopaedics.



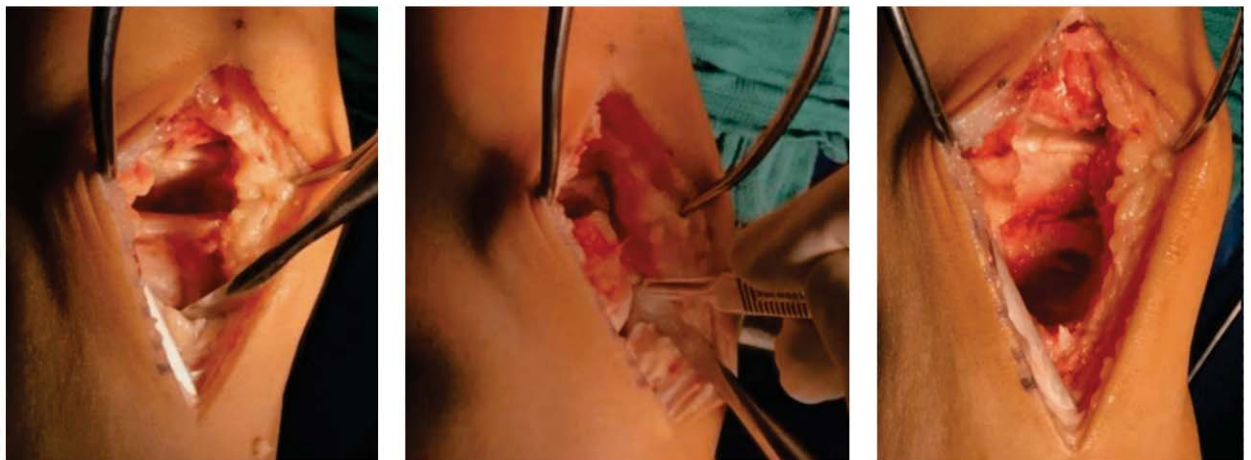
Anteromedial Interosseous Talocalcaneal Ligament Release

5. Release the anterior talonavicular. Distract the anterior segment posteriorly with tension on the interosseous talocalcaneal ligament. Release and remove the anterior segment.



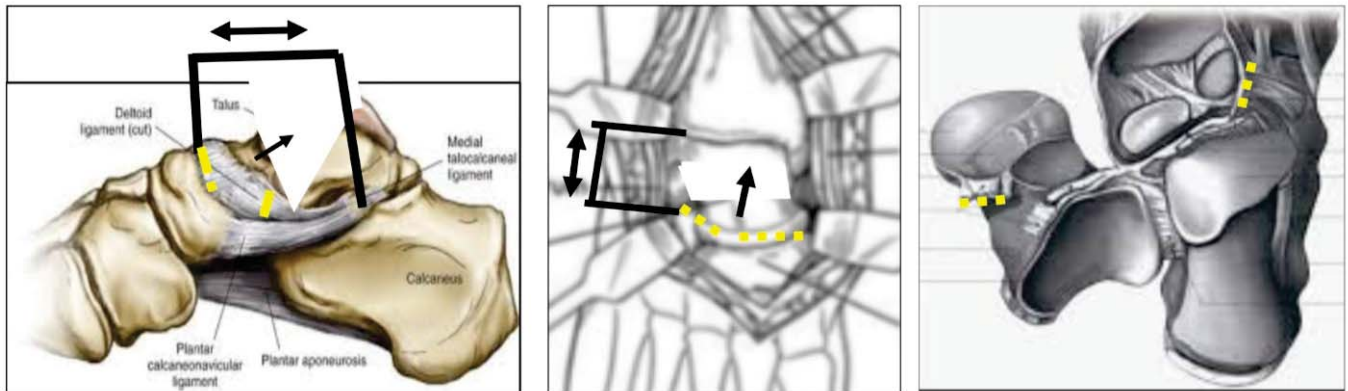
Anterior Talus Resection

6. Use a combination of bone saws, osteotomes, chisels, tamps and/or mallet to resect the anterior talar segment



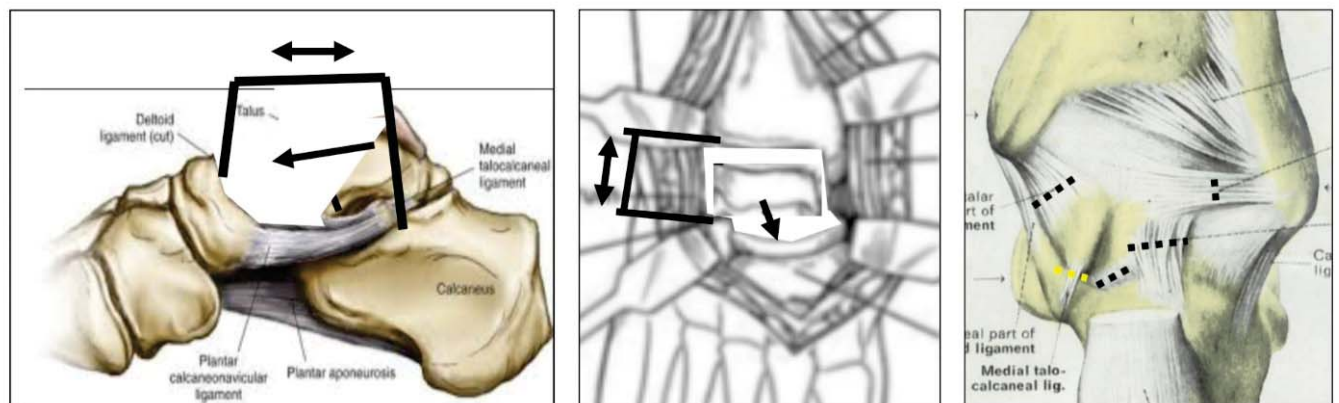
Posterior Interosseous Talocalcaneal Ligament Release

7. Release the lateral talocalcaneal ligament, Distract the posterior talar segment superiorly. Ligate the sinus tarsi artery in sulcus tarsi, and release the interosseous talocalcaneal ligament and any cervical attachment, if present.



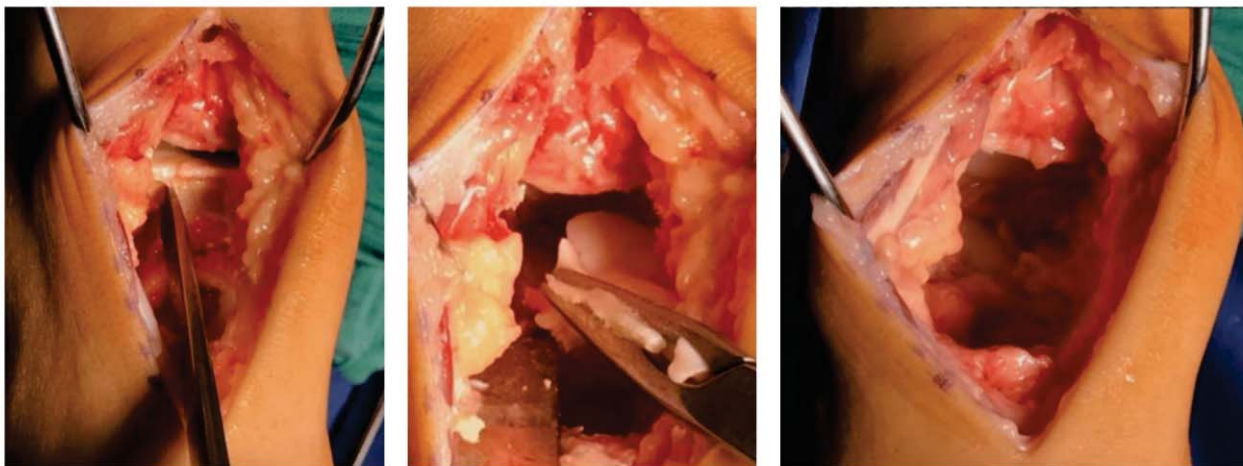
Release of Ligamentous Attachments within the Posterior Process of the Talus

8. Distract posterior segment anteriorly, plantarflex the ankle and release the posterior talofibular ligament and the posterior tibiotalar segment of the deltoid ligament. The posterior segment can now be distracted superiorly and an inferior approach used to release the posterior talocalcaneal ligament and median talocalcaneal ligament. The posterior segment can now be resected.



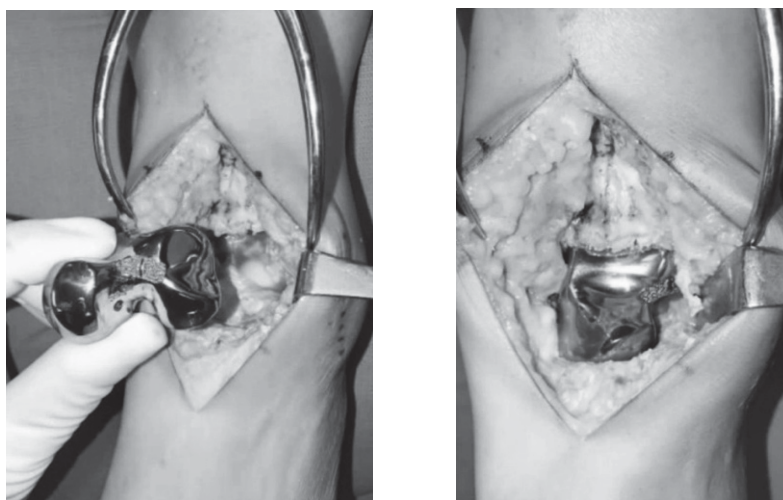
Posterior Talus Segment Resection

9. Use a combination of bone saws, osteotomes, chisels, tamps and/or mallet to resect the posterior talar segment.



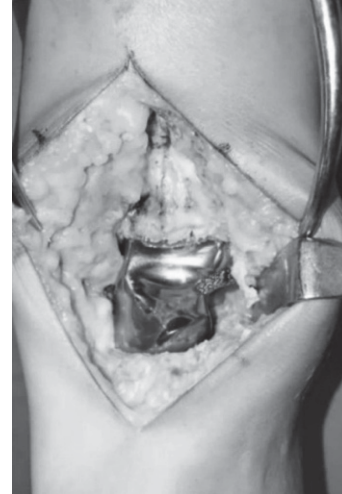
Implant Sizing and Selection

10. Insert the nominal size Patient Specific Talus Spacer. Assess articulations through dorsiflexion and plantarflexion of the ankle as well as inversion and eversion. Flexibility at the midfoot should also be demonstrated through multiple planes of movement. If needed, remove the nominal size implant and trial the small and/or large implants one at a time, checking articulations and range of motion. It is important to evaluate the patient's bone quality to ensure bone quality is adequate before implanting the Patient Specific Talus Spacer.



Implantation of Patient Specific Talus Spacer

11. Insert the appropriately sized Patient Specific Talus Spacer determined in step 10. It is recommended to confirm the fit of the implant using fluoroscopy.



Post Operative

It is recommended that the patient remain non-weightbearing in a cast or splint for 3 weeks. The patient may then weight bear as tolerated in a CAM walker boot for the following 3 weeks. At 6 weeks post-op, the patient may return to a regular shoe and begin working with physical therapy.

Note: The remaining two Patient Specific Talus Spacers that are not implanted must be returned to Additive Orthopaedics –or– destroyed by the hospital. If destroyed, a Certificate of Destruction must be provided to Additive Orthopaedics.

The enclosed surgical procedure is furnished for informational purposes only. Each surgeon must evaluate the appropriateness of the device and techniques based on his or her own medical training, clinical judgment and surgical experience. Proper surgical techniques and procedures are the responsibility of the medical professional. Additive Orthopaedics, LLC. cannot recommend a device or procedure that is suitable for all patients. Indications, contraindications, warnings, and precautions are listed in the implant Instructions for Use and should be reviewed by the physician and operating room personnel.

Humanitarian Device. Authorized by Federal law for use in the treatment of avascular necrosis of the ankle joint in adult patients. The effectiveness of this device for this use has not been demonstrated.



PATIENT SPECIFIC TALUS SPACER

PATIENT INFORMATION GUIDE



ADDITIVE ORTHOPAEDICS

PO Box 310, Little Silver, NJ 07739

gameplan@additiveorthopaedics.com

www.additiveorthopaedics.com

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 ankle joint. The effectiveness of this device for this use has not been demonstrated

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Glossary

Additive Manufacturing: Also known as 3D Printing, Additive Manufacturing is the technology process that builds a three-dimensional object by depositing materials layer by layer using data from computer aided design (CAD) models. It allows for the creation of complex geometries and patient specific designs.

Ankle Joint: A joint in the lower limb formed by the bones of the leg (tibia and fibula) and the foot (talus). It allows dorsiflexion and plantarflexion (up and down movement) of the foot. Please see the image of the foot and ankle on page 3.

Arthrodesis: Also known as a fusion, it is the surgical immobilization of a joint so the bones grow solidly together.

Avascular Necrosis: The death of bone tissue due to a lack of blood supply. Also called AVN or osteonecrosis, it can lead to tiny breaks in the bone and the bone's eventual collapse.

Calcaneus: The large bone forming the heel. It articulates with the cuboid bone of the foot and the talus bone of the ankle. Please see the image of the foot on page 3.

CT Scan: A computerized tomography (CT) scan combines a series of X-ray images taken from different angles around your body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside your body. CT scan images provide more-detailed information than plain X-rays.

Dorsiflexion: Movement of the foot in an upward direction.

MRI: Magnetic Resonance Imaging (MRI) is 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 bone in the ankle located between the talus and the cuneiform bones. Please see the image of the foot on page 3.

Patient Specific Implant: An implant that has been designed to match the patient's own anatomy. They are used in the medical field to repair a range of bone structures because they can be made to fit the patient's physical characteristics

Plantarflexion: Movement of the foot in which the foot or toes flex downward toward the sole of the foot.

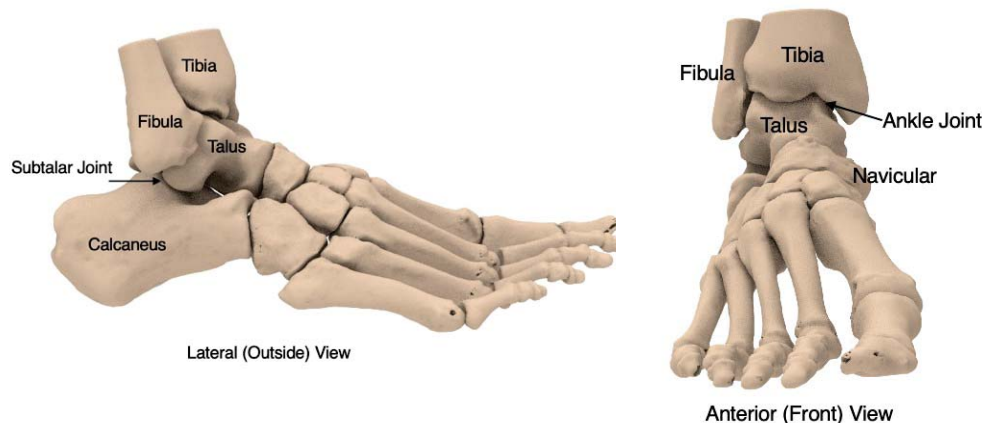
Talus: The large bone in the ankle connecting the leg and foot, and enabling movement. Please see the image of the foot on page 3.

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

The Ankle Joint

The ankle is made up of two joints: the ankle joint and the subtalar joint. The ankle joint is comprised of three bones: the tibia (shinbone); the fibula; and the talus. The ankle joint allows dorsiflexion and plantarflexion of the foot, or movement in an up-and-down motion.

The subtalar joint, which consists of the talus on top and calcaneus on the bottom, is located beneath the ankle joint. The subtalar joint allows the foot to move in a side-to-side motion. Along with articular cartilage, ligaments, tendons, and muscles of your lower leg, these components work together to provide the stability, strength, and movement to allow you to walk, run, and jump.



What is Avascular Necrosis?

Avascular necrosis (AVN) is the death of bone tissue due to a lack of blood supply. Eventually the bone will 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 bad injury, such as a broken bone or dislocated joint, or an injury that occurs slowly over time, 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.



Example X-ray of a patient with a talus fracture due to a traumatic injury

Symptoms of Avascular Necrosis of the Ankle Joint

Many people have no symptoms in the early stages of avascular necrosis. As the condition worsens, your affected joint might only hurt when you put weight on it. Eventually, you may feel pain when you are lying down. Pain may be dull, mild, or severe and usually develops gradually. Avascular necrosis of the ankle joint can be quite devastating and can lead to total loss of the ankle joint with pain, arthritis, and deformity.

Diagnosis and Treatment Options

Your doctor will take X-rays if he or she suspects you may have avascular necrosis. Following X-rays, Magnetic Resonance Imaging (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.

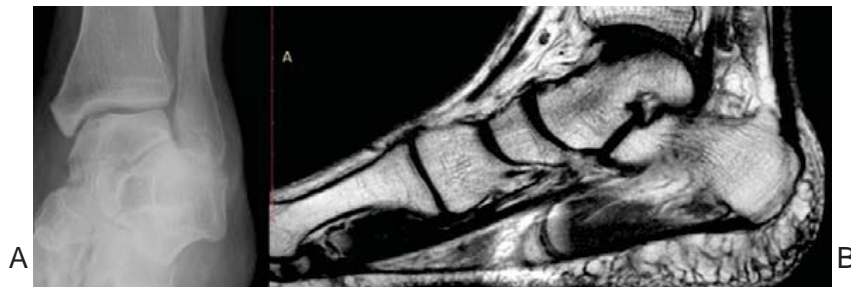


Figure A shows AVN of the talus as viewed on X-ray.
Figure B shows AVN of the talus as visualized on MRI.

Your treatment options will depend on the severity of the avascular necrosis. If AVN is noted in an early stage, non-operative or early stage surgical treatment options may be available. Early stage surgical intervention may include core decompression or bone grafting.

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, or fusion, of one or more joints in the foot and ankle. An arthrodesis eliminates movement at that joint, which assists in relieving pain. Another option is an amputation, where your doctor will surgically remove the lower portion of your limb below the knee. An additional treatment option is available, which is a talus replacement surgery. During this procedure the talus bone is removed and replaced with Patient Specific Talus Spacer. This is considered a joint-sparing procedure, as it allows you to maintain motion of your ankle joint.

What is a 3D Printed Patient Specific Talus Spacer?

The Patient Specific Talus Spacer is an additively manufactured, or 3D printed, patient specific implant that is designed and made individually for each patient using CT image data. The device allows you to regain motion and reduce pain until the time a fusion potentially becomes necessary. The talus implant is designed to match your specific anatomy. The implant is made from cobalt chromium metal alloy and produced by laser sintering.



Additive Orthopaedics Patient Specific Talus Spacer



Additive Orthopaedics Patient Specific Talus Spacer as visible on X-ray

Who should be treated with a Patient Specific Talus Spacer?

The Additive Orthopaedics Patient Specific Talus Spacer is indicated for avascular necrosis of the ankle joint. 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 Patient Specific Talus Spacer implant.

Who should not receive a Patient Specific Talus Spacer?

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

- Use of implant greater than 6 months from date of patient's CT scan.
- Degenerative changes in the tibiotalar, subtalar or talonavicular joints.
- Presence of an active 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.
- Sensitivity or allergy to the metal implant. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.

What are the Warnings Associated with a Patient Specific Talus Spacer?

- Surgeons must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Patient Specific Talus Spacer. If the surgeon believes there are deformities on the affected side or the contralateral side, then the patient may not be a suitable candidate for a Patient Specific Talus Spacer.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- The trained expert staff is obligated to examine the surgical implant and its packaging for damages prior to each application, i.e., use in case of the implant or its packaging being 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.
- 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.
- Do not modify the Additive Orthopaedics Patient Specific Talus Spacer.
- The surgeon is to be thoroughly familiar with the Patient Specific Talus Spacer and surgical procedure prior to performing surgery. For further information, contact Additive Orthopaedics and consult the Surgical Technique Guide.
- Do not reuse the Additive Orthopaedics Patient Specific Talus Spacer. 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 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.

What are the Precautions Associated with a Patient Specific Talus Spacer?

- Surgical implants and anatomical models may only be used for surgeries, for which the designated application of the implant is explicitly necessary and defined.
- Correct selection of the implant is extremely important. That patient's anatomy and indication will determine the size of the implant to be used.
- No partial weight-bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight-bearing. 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 breakage of the implant or surrounding bones in the ankle joint. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.
- Patient Specific Talus Spacers are designed from patient data such as radiograph (X-ray), CT scans, or magnetic resonance imaging (MRI). 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 Talus Spacer, the implant may not fit the patient's anatomy correctly.

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 Effects of a Patient Specific Talus Spacer?

As with any surgical procedure, complications may occur when you are treated with a Patient Specific Talus Spacer. Various adverse events that could be related to this type of device or procedure include:

- Infection, deep and superficial
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Deep and superficial infections
- 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
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

What are the Expected Outcomes and Benefits of a Patient Specific Talus Spacer?

The Patient Specific Talus Spacer is expected to provide pain relief and preserve motion and stability of the ankle joint.

You should speak to your doctor to see if you are a candidate for a Patient Specific Talus Spacer.

Patient Specific Talus Spacer Clinical Data

Data from 32 cases in 31 patients were evaluated to demonstrate the safety and probable benefit of the Patient Specific Talus Spacer when used in the indicated population. The data collection was approved by the Duke University Institutional Review Board.

The primary safety endpoint was the proportion of patients who underwent a secondary subsequent surgical intervention (“SSSI”). Other safety endpoints assessed included adverse events (“AEs”), device or procedure related AEs, AEs by severity, and serious AEs (“SAEs”).

The probable benefit endpoint was the reduction in baseline level pain following surgery using the Visual Analog Scale (“VAS”) for pain. The secondary probable benefit endpoints assessed included ankle range of motion (“ROM”) and Foot and Ankle Outcome Scores (“FAOS”). FAOS subscales, pain, symptom (stiffness, swelling, etc.), activities of daily living (“ADL”), ability to perform sports and recreational activities (“Sport/Rec”); and foot/ankle-related quality of life (“QoL”) were also assessed.

A summary of the patient demographics is provided below in **Table 1**. Thirty-one (31) patients were treated for a total of 32 operations; 1 patient had a Patient Specific Talus Spacer implanted in both the left and right ankles.

Table 1: Patient Demographics

Age (n=31) Mean±SD Range	43 ± 15.3 20-69
Gender (n=31) Male, n (%) Female, n (%)	8 (25.8%) 23 (74.2%)
BMI (n=31) Mean±SD Range	31 ± 6.96 20-48
Smoking Status (n=31) Current, n (%) Former, n (%) Never a smoker, n (%)	4 (12.9%) 3 (9.7%) 24 (77.4%)
Laterality (n=32) Left, n (%) Right, n (%) Both, n (%)	17 (54.8%) 13 (41.9%) 1 (3.2%)
Prior Surgeries (n=31) 0, n (%) 1, n (%) 2, n (%) ≥ 3, n (%)	15 (48.4%) 9 (29.0%) 5 (16.1%) 2 (6.5%)

Patient Specific Talus Spacer Clinical Data

Safety

Adverse event data was collected during the study. Three (3) related adverse events were reported in 3 cases: 2 pain events related to the treatment and 1 scar tissue formation event related to the treatment that resulted in a superficial peroneal neuroma. A table of related adverse events is provided below:

Table 1: Related Adverse Events

	AEs	Total Patients with AEs n (%)
Any AE	3	3 (9%)
General Disorders and Administration Site Conditions		
Chills	0	0%
Impaired Healing	0	0%
Mechanical Complication of the implant		
Pain	2	2 (6%)
Pyrexia	0	0%
Wound Necrosis	0	0%
Infections and Infestations		
Infection	0	0%
Superficial	0	0%
Deep	0	0%
Injury, poisoning and procedure complications		
Loosening of the device	0	0%
Fracture	0	0%
Inury	0	0%
Joint Injury	0	0%
Post procedural haematoma	0	0%
Musculoskeletal and connective tissue disorders		
Myositis	0	0%
Soft Tissue Necrosis	0	0%
Scar Tissue	1	1 (3.1%)
Skin and Subcutaneous tissue disorders		
Blister	0	0%
Skin Necrosis	0	0%

Patient Specific Talus Spacer Clinical Data

In addition, there were 3 reoperations reported in 3 of 32 cases (9.4%). Two (2) of the reoperations are unrelated to the Patient Specific Talus Spacer or the associated procedure, and are most likely due to pre-existing comorbidities, while 1 reoperation was related to the treatment and is associated with the scar tissue reported in **Table 1** above. In one patient, irrigation and debridement of tissue near the surgical site was required 6 months after the surgery to promote healing of the infected tissue and contracture with tibial anterior release. The infection was associated with a prior surgery for a vascularized pedicle graft. Approximately 3 years after the procedure, a below the knee amputation was performed to address an underlying neurological condition. The reoperation for this patient is not related to the treatment. Another patient underwent surgical treatment of superficial peroneal neuroma (“SPN”) after implantation of the device. Although neuromas are generally uncommon, they may occur after direct trauma or operation.

This event was classified as possibly related to the treatment procedure. The third patient experienced progression of talus AVN to tibial AVN, after implantation of the Patient Specific Talus Spacer. This patient presented pre-operatively with cancer with widespread AVN in lower right extremity. The patient ultimately underwent revision surgery with a total ankle replacement (“TAR”). Chronic pain, including prior to the Patient Specific Talus Spacer procedure, was a long-term problem for this patient, thus it was not related to the treatment.

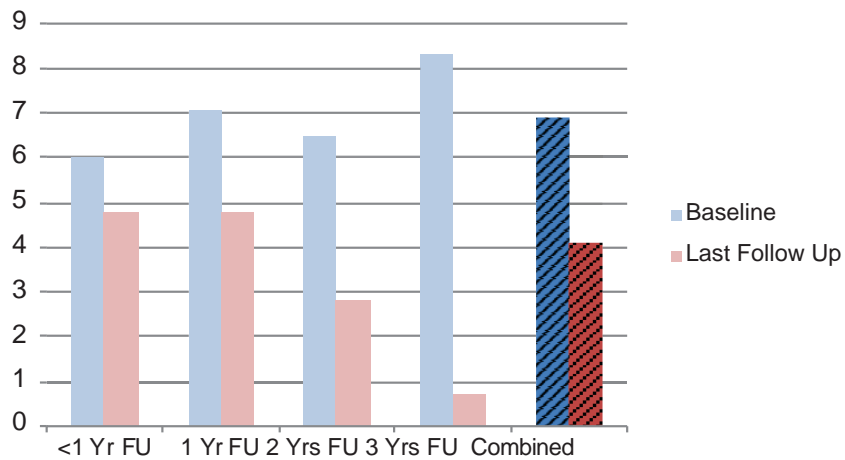
Patient Specific Talus Spacer Clinical Data

Probable Benefits

VAS pain scores were assessed prior to treatment and at the most recent follow-up time point, as shown in **Figure 1**. The total study population, as well as each cohort, experienced mean improvement on VAS pain; across cohorts the magnitude of the improvement was positively correlated with the duration of follow-up.

At baseline, the mean VAS score for the study population was $6.9 \text{ cm} \pm 2.0$ and scores ranged from 3-10 cm, with 10 representing maximum pain intensity. Mean change from baseline for the entire study population was $-2.8 \text{ cm} \pm 3.1$. For the cohort analysis, mean improvement from for the <1 year, 1 year, 2 years, and 3 years cohorts was $-1.2 \text{ cm} \pm 2.7$, $-2.2 \text{ cm} \pm 2.8$, $-3.7 \text{ cm} \pm 2.3$, and $-7.7 \text{ cm} \pm 3.2$. Thus, improvement on VAS pain was consistent across duration of follow up. As anticipated, due to the lengthy recovery period associated with this patient population, VAS pain outcomes improved on average the longer the follow-up period.

Figure 1: VAS Pain (cm) - Mean Baseline and Last Follow-Up by Duration of Follow-up

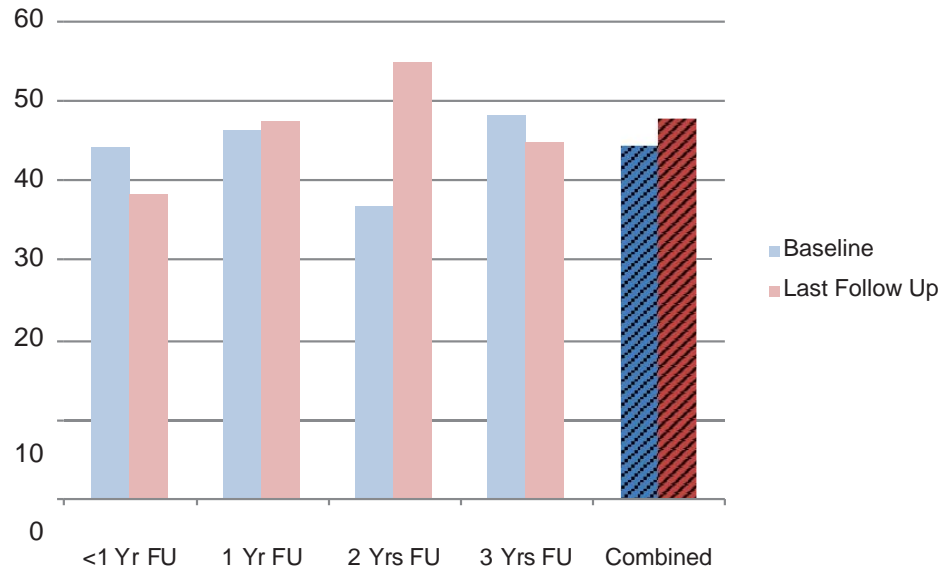


Patient Specific Talus Spacer Clinical Data

Ankle ROM values were assessed for each patient, and reported based on the last follow-up data (Figure 2). The data summary presents outcomes for the entire study population, as well as by cohort based on duration of follow-up period (i.e., < 1 year, 1 year, 2 years, and 3 years).

As anticipated, patients still in active recovery from the device procedure (i.e., < 1 year of follow up) reported deterioration from baseline; the other cohorts either reported mean improvement or no change. When patients with < 1 year of follow up are excluded from the study population the mean improvement for the remaining subjects is 5.9 degrees. Patients with 2-year follow-up data showed the greatest mean improvement in ankle ROM compared to baseline (25 degrees).

Figure 2: Ankle ROM - Mean Baseline and Last Follow-Up by Duration of Follow-up

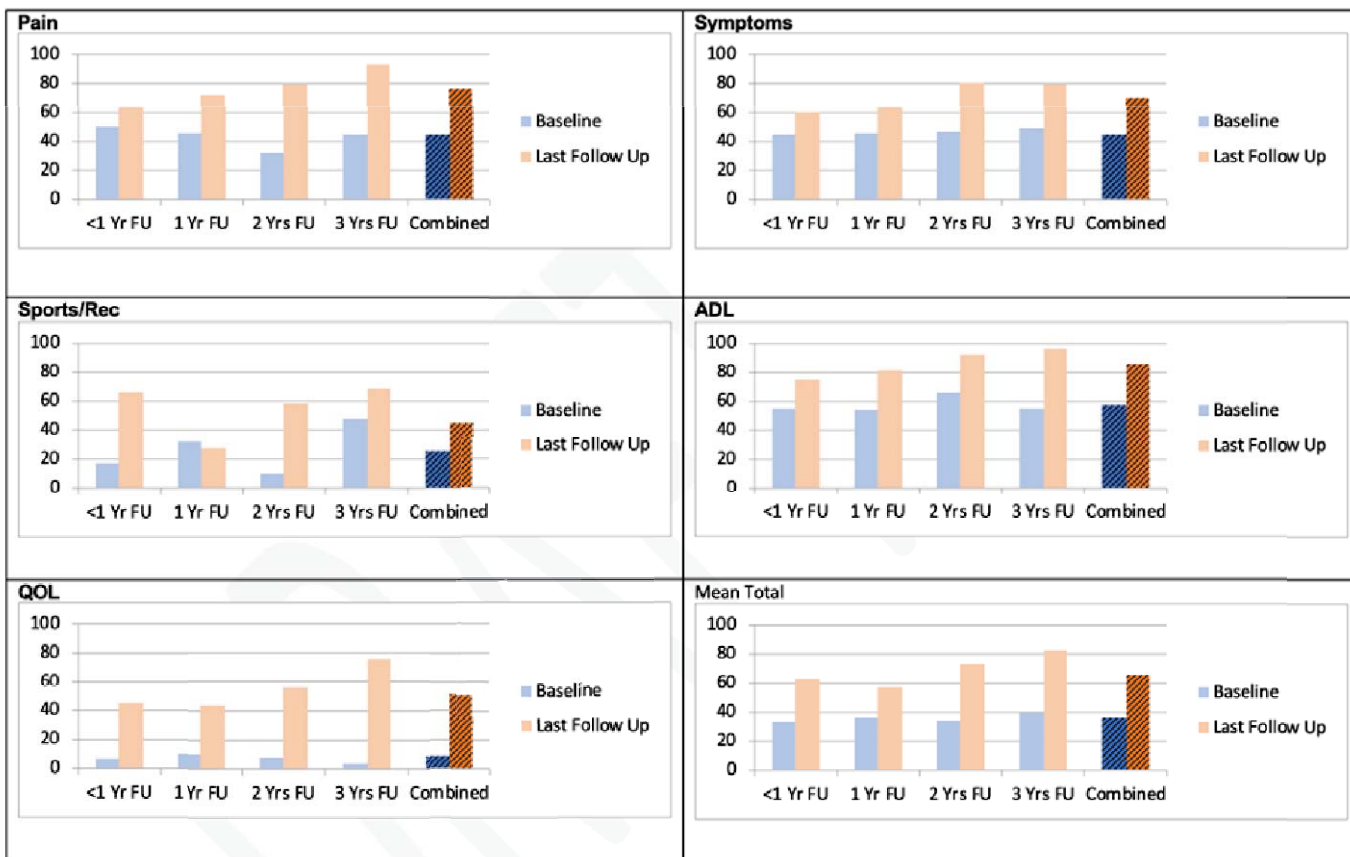


*In the 3 Yr Cohort, while mean ROM at last follow up is lower than baseline, the mean change from baseline to last follow up still showed improvement.

Average combined FAOS score, as well as each separate subscale (Pain, Symptoms, Sport/Rec, ADL, and QoL), were assessed pre-operatively and post-operatively. The mean change for FAOS average combined score and each subscale are reported with the last follow-up data combined (Figure 3). The data summary presents outcomes for the entire study population. As seen in Figure 3 below, patients showed an increase for each subscale at the last follow up.

Patient Specific Talus Spacer Clinical Data

Figure 3: Mean FAOS Subscales Mean Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-up



Conclusion

The patients who were implanted with the Patient Specific Talus Spacer in the above study received a clinically meaningful probable benefit from the device. As discussed above, baseline VAS pain score were reduced by -2.8 cm postoperatively, from 6.9 cm (moderate to severe pain) to 4.1 cm (mild pain). ROM also improved on average, especially when limiting the analysis to those patients who had at least 1 year of follow-up and thus had adequate time to rehabilitate. Functional outcomes based on FAOS subscales also improved, with average improvement on all subscales exceeding the associated MIC threshold except Sport/Rec. Moreover, the rate of reoperation was low, with 9.4% of cases resulting in reoperation. Improvement in pain and function measures, accompanied by a low rate of reoperation, is particularly meaningful to AVN talus patients who have limited options and high risk of needing to undergo fusion or amputation. The favorable probable benefit to risk profile of the device is further demonstrated by the activity levels reported for some patients postoperatively, which include returning or continuing in their career, engaging in recreational activities, and returning to walking.

What Happens During a Patient Specific Talus Spacer Surgery?

After being administered anesthesia, your surgeon will make an incision on the anterior, or front, of your ankle. He or she will use surgical instruments to remove your talus bone, and will then insert the Patient Specific Talus Spacer that was designed for your anatomy. Your surgeon will confirm the fit of the implant under X-ray imaging, and will then close the incision and apply a post-operative bandage.

What Happens After a Patient Specific Talus Spacer Surgery?

Your doctor will talk with you about your post-surgery recovery. Your doctor will want to see you back at the office to check your incision and your wound at one week and two weeks post-operative. You will remain non-weightbearing with a cast or splint on your foot for 3 weeks. Then you will be weightbearing as tolerated with a CAM walker boot for 3 weeks. At 6 weeks from your surgery you will be back in a regular shoe doing physical therapy. Your doctor will continue monitoring your healing progression on regular intervals for the first year then annually after one year. Please discuss with your doctor when you may resume certain physical activities.

When Should I Call the Doctor After Surgery?

Please talk to your doctor 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 device or replace professional medical care. If you have any questions about the Patient Specific Talus Spacer, 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 Patient Specific Talus Spacer, please contact your doctor. For additional information, please visit www.additiveorthopaedics.com

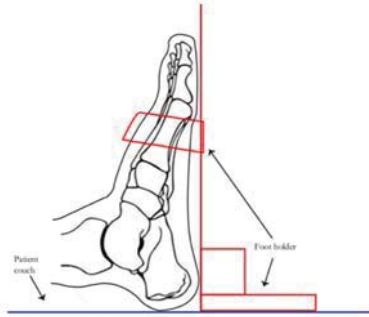
gameplan@additiveorthopaedics.com

www.additiveorthopaedics.com

Disclaimer: The quality of the CT scan is the most important aspect of creating case-specific anatomical models, implants, and prostheses. Additive Orthopaedics understands the concern about keeping the radiation doses to patients as low as possible; therefore, please use these guidelines as appropriate for your patients. It is the physician's responsibility to ensure that the hospital and patient are properly informed about any risks associated with this treatment. Additive Orthopaedics does not practice medicine and these are only recommended guidelines to ensure the data for surgeon prescription anatomic models, implants or prostheses are in the proper format and delivery for customization. We understand concerns about keeping the radiation dose to your patients as low as reasonably achievable, therefore, please apply these guidelines as appropriate to your patients. Please refer to the manufacturer's instructions for use for more information regarding patient dose.

Key Guidelines (Prepare patient by removal of jewelry in/around area being scanned. Place patient supine on the scanner table, instruct the patient not to move.)

- Use a 3D scanning routine that provides high resolution images as comparable to image guided surgery, stereotactic planning, or other 3D applications. Please use DICOM Compliant Scanners. Set reconstruction algorithm to Moderate / Soft Tissue or Equivalent. 512x512 matrix. Please see the system IFU for all tested manufactures, models, and protocols. We understand concerns about keeping the radiation dose to your patients as low as reasonably achievable, therefore, please apply these guidelines as appropriate to your patients. Please refer to the manufacturer's instructions for use for more information regarding patient dose.
- Acquire scans at high spatial resolution. Series should be acquired with thin, contiguous image slices (equivalent thickness and spacing of 1mm or less* For foot defects, please include the entire foot plus 10cm above (proximal) to the ankle joint. A minimum of 25-35cm FOV is required to capture all of the required bone regions (soft tissue not required). The physician should determine whether or not it is necessary to also include the opposite, non-afflicted foot / extremity, based on the condition.
- Provide images in the original scanning plane. If software post-processing is performed to reorient or reformat the scan volume, then a series of thin slice images in the original acquisition plane MUST be included. There should be no secondary reconstructions or reformatting including no iterative reconstruction (IR) nor metal artifact reduction (MAR). Set gantry tilt at 0 degrees during image acquisition at all times, regardless of patient's ability to put their foot at 90 degrees. Images acquired with gantry tilt and then post-processed to reorient images (i.e. "take out" tilt) are not acceptable. Minimum detector rows should be at least 16, the minimum technique parameters are 100-120kV and 150-174mAS. Manual: 150mA with Rot Time- 0.75s, Pitch= 0.6 and Kernel / Algorithm= Moderate / soft tissue or equivalent.
- Please ensure that scans are free from motion artifact. Patient must remain completely still through the entire scan. If patient motion occurs, the scan must be restarted. Image distortion from patient motion can severely compromise the accuracy of a model. NOTE: 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.

<p>Preferred Scanning Parameter *</p> <p><u>Scan Spacing:</u> Less than 1mm (equal to slice thickness)</p> <p><u>Slice Thickness:</u> *Less than 1mm (equal to scan spacing) Scanners requiring less than 1mm are: Siemens/Sensation 65 [0.6mm] GE/LightSpeed RT16 [0.625mm] Siemens/Somatom Definition FLASH [0.75mm] Planmed/Planmed Verity [0.4mm]</p> <p><u>FOV/Length:</u> 25-35cm capturing the required bone regions/ the entire foot 10cm proximal to the ankle joint</p> <p>Algorithm: Standard Moderate / Soft Tissue or Equivalent (examples) : Siemens: H30s Toshiba: FC20 Philips: B</p> <p><u>Gantry Tilt:</u> 0°</p> <p><u>Archive Media:</u> CD or DVD</p> <p><u>File Type:</u> DICOM (uncompressed)</p> <p><u>Series:</u> Original/Primary/Axial (No recon, reformat or post process data. Including no iterative recon or metal artifact reduction.)</p>	<p style="text-align: center;">PATIENT POSITIONING</p> <p style="text-align: center;">Supine, toes pointing straight up; use a foot holder if available</p> 	<p>Recommended CT Scanners:</p> <ul style="list-style-type: none"> • GE/Lightspeed RT 16* • GE MEDICAL SYSTEMS BrightSpeed* • GE MEDICAL SYSTEMS Discovery CT750HD* • GE MEDICAL SYSTEMS LightSpeedVCT* • Siemens/Sensation 64* • Siemens/Sensation 65* • Siemens/Somatom Definition AS* • Siemens/Somatom Definition Flash*
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Note: Please save protocol as Additive Ortho (date in format xx/xx/xxxx), and in the Study Description field, put AdditiveOrtho. Scans must be less than 30 days old. *If scanner cannot meet above parameters or if there are any questions regarding the protocol, please contact Additive Orthopaedics for further instructions by calling 732.882.6633. Disk should include Patient Physician's name, and Anatomy Scanned. CT scan must be sent to Additive Orthopaedics within one month of the date of the scan.

SHIPPING AND CONTACT: Additive Orthopaedics
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