Talar Replacement Device

Instructions for Use

ATTENTION: Humanitarian Device. Authorized by Federal law for use in the treatment of talar dysfunction. The effectiveness of this device for this use has not been demonstrated. Operating surgeon, please read the following information prior to use of anatomical modeled implants.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

INTENDED USE:

This device is intended to replace a patient's dysfunctional native talus.

DEVICE DESCRIPTION:

The 4WEB Medical Talar Replacement (TR) Device is designed to replace the patient's native talus with an anatomically matched, physiologic volume. The anatomical matching allows for the prosthetic talus to articulate with adjacent boney anatomy while allowing the patient to maintain leg length, maintain mobility, and avoid quality of life limiting fusion procedures or amputations. The 4WEB Medical Talar Replacement devices are additively manufactured (laser sintering) cobalt-chromium (CoCr) alloy devices conforming to ASTM F75 and ASTM F3213. All surfaces of the device are polished to a mirror finished and passivated per ASTM A967. Three Talar Replacement Devices are provided: nominal, up to +10% and up to -10%.

INDICATIONS FOR USE:

The 4WEB Medical Talar Replacement Device is indicated for avascular necrosis of the talus in adult patients requiring replacement. The anatomical landmarks necessary for the design and creation of the 4WEB Medical Talar Replacement Device must be present and identifiable on computed tomography scan.

CONTRAINDICATIONS:

The 4WEB Medical Talar Replacement device should not be implanted in patients meeting any of the following conditions:

- 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.
- Gross deformity in sagittal or coronal planes. More than 15 degrees of varus and valgus deformity in the coronal plane, or more than 50% subluxation anteriorly or posteriorly of the talus in the sagittal plane.
- Patients with an active local or systemic infection.
- 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 made, and sensitivity ruled out prior to implantation.

WARNINGS AND PRECAUTIONS:

Warnings

- Surgeons must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Talar Replacement Device. 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 Talar Replacement Device.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implant 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, and alignment 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 pre-closure 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 4WEB Medical Talar Replacement Device.
- The surgeon is to be thoroughly familiar with the implant and surgical procedure prior to performing surgery. For further information, contact 4WEB Medical and consult the Surgical Technique.
- Do not reuse the 4WEB Medical Talar Replacement Device. 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.
- Do not implant trials.

Precautions

- Surgical implants and trials 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 Talar Replacement devices are designed from patient data such as radiograph (Xray), CT scan, or magnetic resonance imaging (MRI). Over time, a patient's anatomy can change. If greater than 6 months has elapsed from the time of collection of the patient data

(date of scan) to the time of surgery utilizing a Talar Replacement Device, the implant may not fit the patient's anatomy correctly.

- Never attempt to reuse. Once the 4WEB Medical Talar Replacement Device has been removed from the packaging, the device should be either used, discarded, or returned to 4WEB Medical. Never attempt to reuse the implant, even though it may appear undamaged.
- Use only 4WEB Medical instruments when handling and implanting the 4WEB Medical Talar Replacement Device.

ADVERSE EVENTS

Adverse events may be related to surgery in general, ankle surgery specifically or the device. These may 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
- Osteosclerosis of adjacent bones
- Cartilage wear and/or arthritis of the joints/bones articulating with 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
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

MRI SAFETY INFORMATION:

The 4WEB Medical Talar Replacement Device 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 the 4WEB Medical Talar Replacement Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING:

All 4WEB Medical Talar Replacement devices and instrumentation are supplied non sterile for steam sterilization prior to use in the operating room.

Wrapping Technique

Double wrap instruments in accordance with local institution's procedures using standard wrapping techniques such as ANSI/AAMI ST79. Label the contents of the wrapped product using an indelible marker or other sterilization compatible label system. Biological or Chemical Indicators (Bis or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped product. The indicators should be tested according to the BI or CI manufacturer's directions.

STORAGE AND SHELF LIFE:

4WEB Medical's Talar Replacement Device 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.

STERILIZATION:

• Use a validated, properly maintained and calibrated steam sterilizer.

• Effective steam sterilization can be achieved using the following cycle to achieve an SAL of 10^{-6}

Cycle	Temperature	Duration	Dry Time
Gravity	121° C (250° F)	30 min	45 min
Prevacuum	132° C (270° F)	4 min	45 min

NOTE: STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the Talar Replacement Device, methods of application, instruments and surgical technique. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. Correct positioning of the Talar Replacement Device should be checked intraoperatively with x-ray. The size of the Talar Replacement Device must be chosen on the basis of the patient's anatomy. The implants are for single-implant use only. An explanted implant must never be re-implanted. Stresses and fracture, even though not noticeable by visual inspection, may have been created during initial implantation. Following implantation, the product number and manufacturing lot number of the device that has been implanted must be reported in the patient's surgical file. The remaining two TR devices not implanted must be returned to 4WEB Medical or destroyed by the hospital. If destroyed, a Certificate of Destruction must be provided to 4WEB Medical.

PRODUCT COMPLAINTS:

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any Talar Replacement Device should notify 4WEB Medical, or, where applicable, their distributor.

SURGICAL TECHNIQUE MANUAL:

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. 4WEB Medical 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. To receive additional copies of the Surgical Technique Manual, contact your local sales representative or the company at the address below.

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CLINICAL DATA:

4WEB Medical completed a retrospective chart review study which examined the clinical and radiographic outcomes of 30 patients (31 devices) who had been implanted with a talus replacement with the goal of demonstrating safety and probable benefit of the TR Device when used in the indicated population. The data collected was approved by appropriate Institutional Review Boards (IRBs).

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.

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"). Implant survivorship was also evaluated based on the SSSIs and AEs reported for each patient and assessed qualitatively through review of follow-up notes written by the medical provider.

Three probable benefits were evaluated using the clinical data. The primary probable benefit endpoint was improvement in pain, as measured by the Visual Analog Scale (VAS), at last follow-up compared to baseline. The secondary probable benefit endpoints included measuring ankle range of motion (ROM) at last follow-up compared to baseline and evaluating physical function as measured using the American Orthopaedic Foot & Ankle Society Ankle-Hindfoot Rating system (AOFAS) at last follow-up compared to baseline.

A summary of the patient demographics is provided in Table 1. Thirty (30) patients (31 devices) were treated in the study. None of the enrolled patients had bilateral procedures (i.e., a 4WEB Medical TR Device implanted in both the left and right ankles). One patient had an initial 4WEB Medical TR Device that was removed and replaced with another 4WEB Medical TR Device for a total of 31 devices.

Table 1: Patient Demographics

Age (n=29)	
Mean +/-SD (years)	47.2 +/- 14.2
Range	22 - 71
Gender (n=30)	
Male, n (%)	14 (46.7%)
Female, n (%)	16 (53.3%)
BMI (n=26)	
Mean +/-SD	30.1 +/- 7.1
Range	19.5 – 51.9
Smoking Status (n=27)	
Current, n (%)	4 (14.8%)
Former, n (%)	10 (37.0%)
Never a smoker, n (%)	13 (48.1%)
Laterality (n=31)	
Left, n (%)	15 (48.3%)
Right, n (%)	16 (51.7%)
Both, n (%)	0 (0%)
Race (n=30)	
White, n (%)	16 (53.3%)
Black, n (%)	1 (3.3%)
Not Reported, n (%)	13 (43.3%)
Ethnicity (n=30)	
Hispanic or Latino, n (%)	2 (6.7%)
Not Hispanic or Latino, n (%)	13 (43.3%)
Not Reported, n (%)	15 (50.0%)
Prior Surgeries (n=29)	
0, n (%)	13 (44.8%)
1, n (%)	8 (27.6%)
2, n (%)	5 (17.2%)
≥ 3, n (%)	3 (10.3%)
Primary Indication*	
Avascular Necrosis (AVN), n (%)	29 (93.5%)
Revision of previous talus replacement, n(%)	2 (6.5%)

*Indication information is available for all 31 procedures

Safety
4WEB Medical utilized a Clinical Events Committee (CEC) to analyze the safety objectives for the retrospective chart review study. The CEC was comprised of an independent group of experts whose purpose was to advise 4WEB Medical on the safe and effective conduct of this retrospective review, monitor patient safety and the scientific integrity of the retrospective review, and to adjudicate any AEs.

The CEC concluded that no definitive device-related side effect or symptoms were observed for patients who received a 4WEB Medical TR Device. The CEC identified a total of eleven AEs, with one SAE being possibly linked to the device, four SAE's not related to the device but potentially the procedure, and one AE not related to the device but potentially the procedure. These six safety events (potentially device or procedure related) include five SSSI's reported (5/31, 16.1%). The remaining four AE's and one SAE were unrelated to both device and procedure, as shown in Table 2.

Table 2: Categorization of Reported Safety Events

Item	Possibly Device-Related	Possibly Procedure Related	Unrelated
Adverse Events (AE) (n=5)	0	1	4
Serious Adverse Events (SAE) (n=6)	1	4	1
Subsequent Secondary Surgical Interventions (SSSI) (n=5)	*1*	*4*	*0*
Total (n=11)	**1**	**5**	**5**

The five secondary surgeries included one patient with a valgus (turned outward) 4WEB Medical TR Device position which was revised with another 4WEB Medical TR Device, two patients with varus (turned inward) 4WEB Medical TR Device positions which were revised with either an ankle fusion or a tendo-Achilles lengthening procedure, one patient where their device shifted after implantation which required a second 4WEB Medical TR Device, and a patient who developed arthritis on their tibia which was revised with another 4WEB Medical TR Device. The CEC concluded that none of these SSSIs were directly linked to the 4WEB Medical TR Device or the talar replacement surgery.

The AEs not requiring a secondary surgery included four patients who reported pain during their post operative follow-ups, all of which were treated in office or with medication, and one patient who began to lose the arch of their foot at their two-year follow-up. The one remaining SAE not related to the device or procedure was one patient who fell and fractured their hip nineteen months post operation.

Implants remained in place for 27 out of 31 (87.1%) devices, demonstrating a high rate of implant survivorship.

Probable Benefits
The primary probable benefit endpoint was the reduction in baseline level pain following surgery using the VAS for pain. Pain scores were collected through retrospective chart review and included scores from VAS, ranging from 0 – 10. Of the 30 subjects, pre and post operative VAS pain scores were reported for 20 out of 30 (66.7%) of the enrolled patients. A baseline VAS was available for 20 out of 30 (66.7%) patients and a follow-up score was available for 23 out of 30 (76.7%) patients. Figure 1 and Table 3 present the mean VAS pain changes from baseline for the different follow-up cohorts.

At baseline, the mean VAS pain score for the twenty subjects was 6.4 ± 2.3 and scores ranged from 0 – 10, with 10 representing maximum pain intensity. The mean VAS pain score at last follow-up (n=23) was 3.8 ± 2.8. Mean change from baseline for the twenty subjects with pre- and postoperative VAS

pain score was -3.1 ± 3.3. For the cohort analysis, mean improvement for subject with pre- and postoperative VAS pain scores for the <1 year, 1 year, and 2 years cohorts were -2.7 ± 1.2, -3.2 ± 4.1, and -3.2 ± 2.9 respectively.

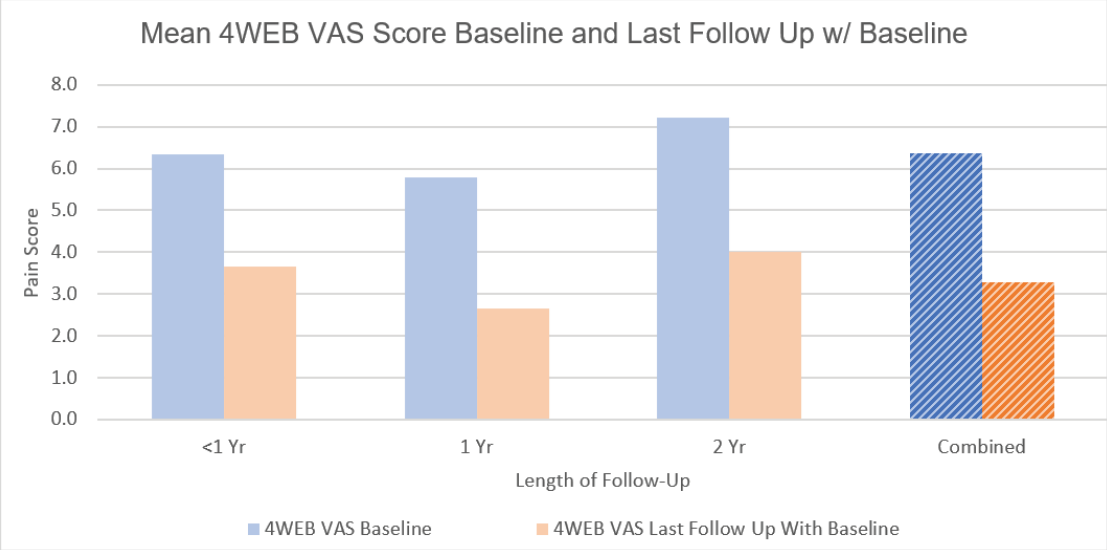


Figure 1: VAS Pain – Mean Baseline and Last Follow-Up w/ Baseline by Duration of Follow-Up

Table 3: VAS Pain Mean Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=3)	6.3	3.2	4 – 10	2.7 , 10.0
	Last Follow Up w/ Baseline (n=3)	3.7	4.0	0 – 8	-0.9 , 8.2
	Last Follow-Up (n=5)	4.6	3.4	0 – 8	1.6 , 7.6
	Change from Baseline (n=3)	-2.7	1.2	-4 – (-2)	-4.0 , -1.4
1 Year	Baseline (n=10)	5.8	2.5	5 – 9	4.2 , 7.4
	Last Follow Up w/ Baseline (n=10)	2.7	2.4	0 – 7	1.2 , 4.1
	Last Follow-Up (n=10)	2.7	2.4	0 – 7	1.2 , 4.1
	Change from Baseline (n=10)	-3.2	4.1	-8 – 5	-5.7 , -0.6
2 Year	Baseline (n=7)	7.2	1.6	5 – 9	6.0 , 8.4
	Last Follow up w/ Baseline (n=7)	4.0	2.6	1 – 8	2.1 , 5.9
	Last Follow-Up (n=8)	4.5	2.8	1 – 8	2.6 , 6.4
	Change from Baseline (n=7)	-3.2	2.9	-7 – 0	-5.4 , -1.1
Combined	**Baseline (n=20)**	**6.4**	**2.3**	**0 – 10**	**5.4 , 7.4**
	Last Follow Up w/ Baseline (n=20)	**3.3**	**2.6**	**0 – 8**	**2.1 , 4.4**
	Last Follow Up (n=23)	**3.8**	**2.8**	**0 – 8**	**2.6 , 4.9**
	Change from Baseline (n=20)	**-3.1**	**3.3**	**-8 – 5**	**-4.5 , -1.7**

The secondary probable benefit endpoints assessed included the range of motion (ROM) of the ankle joint in dorsiflexion (DF) and in plantar flexion (PF). Similar to pain, patients demonstrated an improvement in dorsiflexion and plantar flexion movement in their affected ankle joint after talar replacement.

Of the 30 patients, eleven (11/30, 36.7%) patients had pre- and postoperative dorsiflexion available, with a mean ROM of 9.5 ± 5.7 degrees at last follow up, an improvement of 4.3 degrees on average over the baseline ROM. Figure 2 and Table 3 present mean outcomes for all patients with dorsiflexion

ROM data, as well as by cohort based on duration of follow-up period (i.e., < 1 years, 1 year, and 2 years).

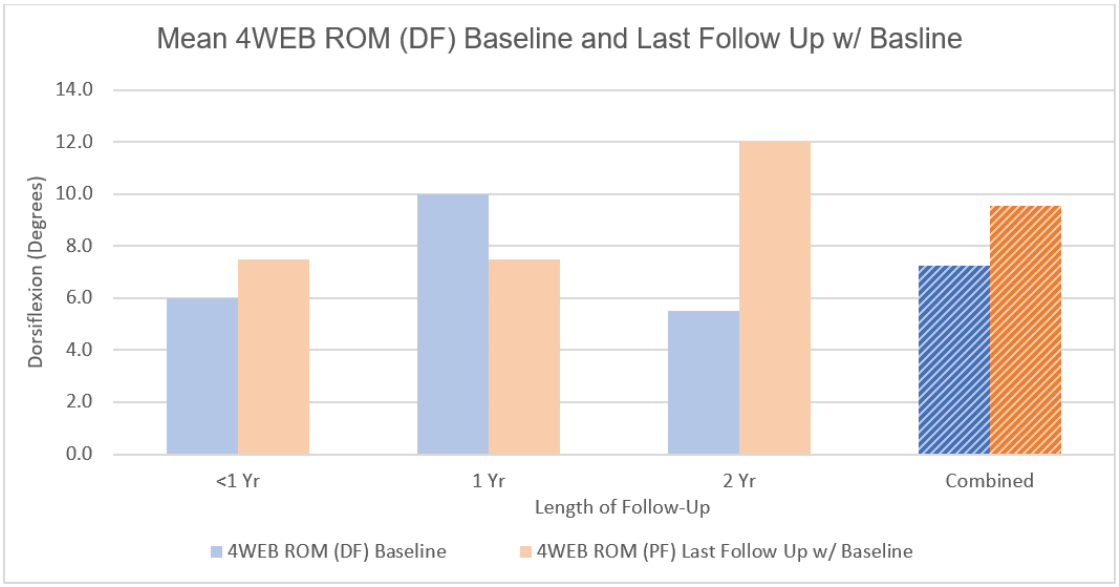


Figure 2: ROM (DF) – Mean Baseline and Last Follow-Up w/ Baseline by Duration of Follow-Up

Table 4: Ankle Dorsiflexion ROM Mean Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=5)	6.0	6.5	0 – 15	0.3 , 11.7
	Baseline w/ Follow Up (n=2)	2.5	3.5	0 – 5	-2.4 , 7.4
	Last Follow Up w/ Baseline (n=2)	7.5	3.5	5 – 10	2.6 , 12.4
	Last Follow Up (n=3)	11.7	7.6	5 – 20	3.0 , 20.3
	Change from Baseline (n=2)	5.0	0.0	5 – 5	N/A , N/A
1 Year	Baseline (n=6)	10.0	11.4	-5 – 20	0.9 , 19.1
	Baseline w/ Follow Up (n=4)	8.8	13.1	-5 – 20	-4.1 , 21.6
	Last Follow Up w/ Baseline (n=4)	7.5	2.9	5 – 10	4.7 , 10.3
	Last Follow Up (n=5)	8.0	2.7	5 – 10	5.6 , 10.4
	Change from Baseline (n=4)	-1.3	10.3	-10 – 10	-11.4 , 8.9
2 Year	Baseline (n=6)	5.5	10.0	-5 – 20	-2.5 , 13.5
	Baseline w/ Follow Up (n=5)	3.6	9.9	-5 – 20	-5.0 , 12.2
	Last Follow up w/ Baseline (n=5)	12.0	7.6	5 – 20	5.4 , 18.6
	Last Follow Up (n=7)	10.0	7.6	0 – 20	4.3 , 15.7
	Change from Baseline (n=5)	8.4	8.4	0 – 22	1.1 , 15.7
Combined	**Baseline (n=17)**	**7.2**	**9.3**	**-5 – 20**	**2.8 , 11.7**
	Baseline w/ Follow Up (n=11)	**5.3**	**10.0**	**-5 - 20**	**-0.6 , 11.2**
	Last Follow Up w/ Baseline (n=11)	**9.5**	**5.7**	**5 – 20**	**6.2 , 12.9**
	Last Follow Up (n=15)	**9.7**	**6.1**	**0 – 20**	**6.6 , 12.8**
	Change from Baseline (n=11)	**4.3**	**9.0**	**-10 – 22**	**-1.0 , 9.6**

The same subset of patients had plantar flexion ROM scores available in their medical records. Of the 30 patients, eleven (11/30, 36.7%) had both pre- and postoperative data available. These patients had a mean plantar flexion ROM of 38.6 ± 13.1 degrees at last follow up, representing an

improvement of 0.5 degrees on average over their baseline ROM and an increase of 2.7 degrees over the average of all baseline scores. Figure 3 and Table 5 present mean outcomes for the combined patients with plantar flexion ROM, as well as by cohort based on duration of follow-up period (i.e., < 1 years, 1 year, and 2 years).

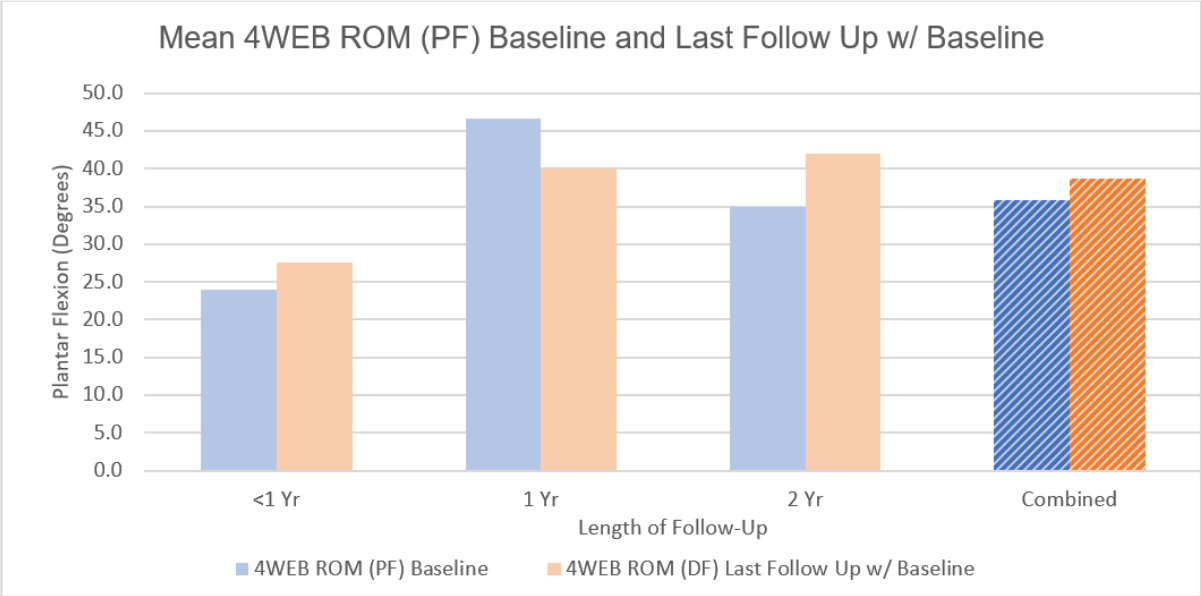


Figure 3: Ankle ROM (Plantar Flexion) – Mean Baseline and Last Follow-Up w/ Baseline by Duration of Follow-Up

Table 5: Ankle Plantar Flexion ROM Mean Baseline, Last Follow-Up, and Change from Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=5)	24.0	13.9	10 – 40	11.8 , 36.2
	Baseline w/ Follow Up (n=5)	25.0	21.2	10 – 40	-4.4 , 54.4
	Last Follow Up w/ Baseline (n=2)	27.5	17.7	15 – 40	3.0 , 52.0
	Last Follow Up (n=3)	31.7	14.4	15 – 40	15.3 , 48.0
	Change from Baseline (n=2)	2.5	3.5	0 – 5	-2.4 , 7.4
1 Year	Baseline (n=6)	46.7	5.2	40- 50	42.5 , 50.8
	Baseline w/ Follow Up (n=4)	50.0	0.0	50 – 50	50.0 , 50.0
	Last Follow Up w/ Baseline (n=4)	40.0	11.5	30 – 50	28.7 , 51.3
	Last Follow Up (n=5)	36.0	13.4	20 – 50	24.2 , 47.8
	Change from Baseline (n=4)	-10.0	11.5	-20 – 0	-21.3 , 1.3
2 Year	Baseline (n=6)	35.0	20.7	0 – 50	18.4 , 51.6
	Baseline w/ Follow Up (n=5)	34.0	23.0	0 – 50	13.8 , 54.2
	Last Follow Up w/ Baseline (n=5)	42.0	13.0	20 – 50	30.6 , 53.4
	Last Follow Up (n=7)	35.7	16.2	10 – 50	23.7 , 47.7
	Change from Baseline (n=5)	8.0	23.9	-10 – 50	-12.9 , 28.9
Combined	**Baseline (n=17)**	**35.9**	**16.7**	**0 – 50**	**27.9 , 43.8**
	Baseline w/ Follow up (n=11)	**38.2**	**18.9**	**0 - 50**	**27.0 , 49.3**
	Last Follow Up w/ Baseline (n=11)	**38.6**	**13.1**	**15 – 50**	**30.9 , 46.4**
	Last Follow Up (n=15)	**35.0**	**14.0**	**10 - 50**	**27.9 , 42.1**
	Change from Baseline (n=11)	**0.5**	**18.5**	**-20 - 50**	**-10.5 , 11.4**

The final secondary probable benefit endpoint was the American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Score. The AOFAS Hindfoot Score is a nine-question survey filled out by both the patient and surgeon where the pain, function, and alignment of the subject's ankle are rated. The AOFAS scores range from 0-100, with the higher score representing better physical function. Of the 30 patients included in the study, thirteen (13/30, 43.3%) patients had pre- and postoperative AOFAS Hindfoot Scores available. Figure 4 and Table 6 present the mean change for AOFAS average combined score by cohort based on duration of follow-up period (i.e., < 1 years, 1 year, and 2 years). Patients showed an increase in AOFAS Hindfoot Score post-operatively for all cohorts. The mean change from baseline in AOFAS Hindfoot Score was an increase in 23.1 points.

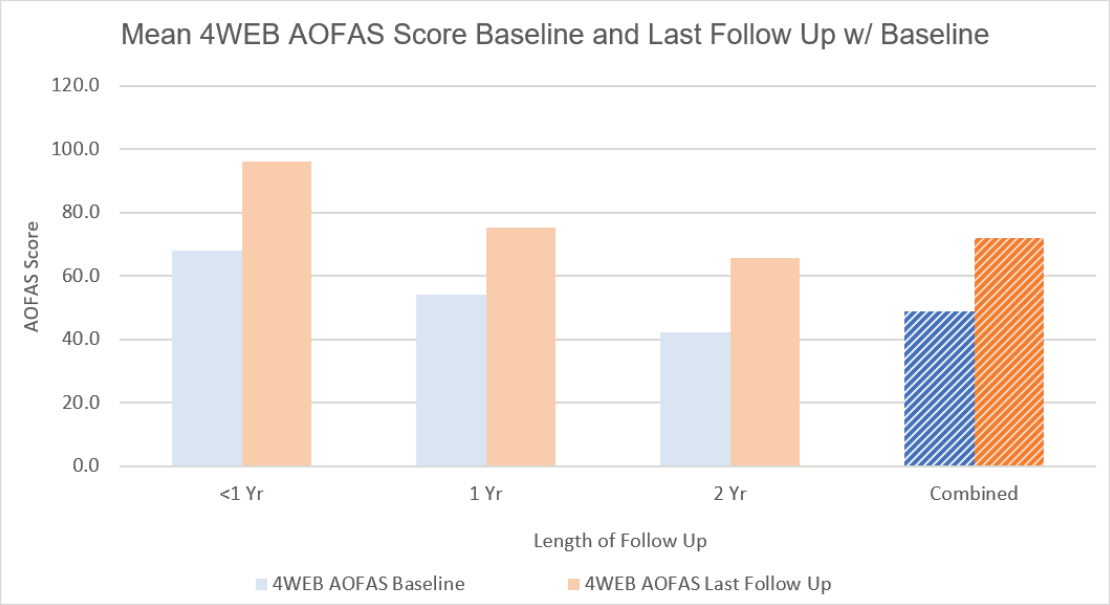


Figure 4: Mean AOFAS Hindfoot Score Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-Up

Table 6: Mean AOFAS Baseline, Last Follow-Up and Change From Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=1)	68.0	0.0	68	68.0 , 68.0
	Last Follow Up (n=1)	96.0	0.0	96	96.0 , 96.0
	Change from Baseline (n=1)	28.0	0.0	28	28.0 , 28.0
1 Year	Baseline (n=5)	54.0	12.7	39 – 70	42.9 , 65.1
	Last Follow Up (n=5)	75.4	23.1	47 – 98	55.1 , 95.7
	Change from Baseline (n=5)	21.4	28.6	-17 – 59	-3.6 , 46.4
2 Year	Baseline (n=7)	42.3	22.8	0 – 67	25.4 , 59.2
	Last Follow Up (n=7)	65.9	19.9	33 – 87	51.1 , 80.6
	Change from Baseline (n=7)	23.6	29.1	-8 – 79	2.0 , 45.1
Combined	**Baseline (n=13)**	**48.8**	**19.5**	**0 – 70**	**38.2 , 59.4**
	Last Follow Up (n=13)	**71.8**	**21.2**	**33 – 98**	**60.3 , 83.4**
	Change from Baseline (n=13)	**23.1**	**26.4**	**23 – 79**	**8.7 , 37.4**

Conclusions

The information presented above supports the probable benefit of the 4WEB Medical Talar Replacement Device for the treatment of AVN of the talus. Additionally, the data collected supports a reasonable assurance of the device's safety. The patients who were analyzed as part of the retrospective clinical study showed meaningful probable benefit in the form of improved range of motion, improved functionality, and a reduction in pain. These improvements in functionality allow for a patient to return to a normal lifestyle by preserving their ankle mobility, ability to work, and overall physical health. Moreover, the safety of the device was demonstrated through a low rate of reoperation and no documented device related adverse events.

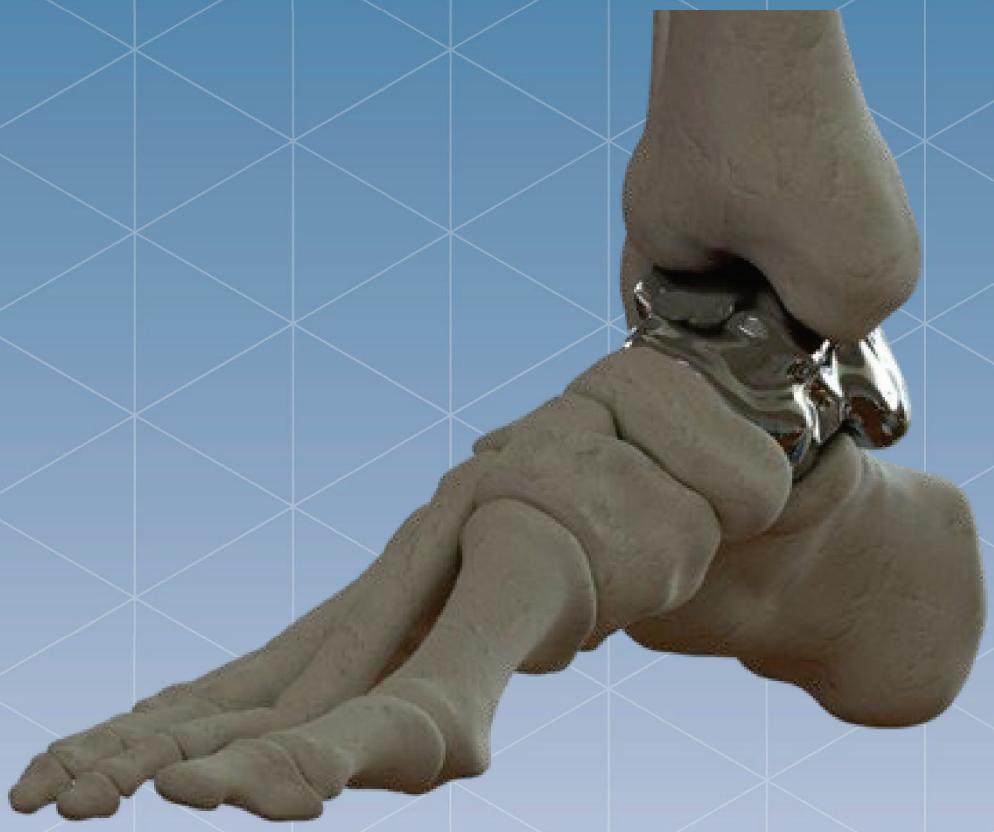
Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied.			
Symbol	**Ref. Number**	**Title**	**Description of Symbol**
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.1.5	Lot number	Indicates the manufacturer's lot number so that a specific medical device can be identified.
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42 EEC, and 98/79 EC.
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	21 CFR 801.109	Prescription only	Requires prescription in the United States.

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.

SURGICAL TECHNIQUE GUIDE

Talar Replacement Device



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4WEB® MEDICAL

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

TALAR REPLACEMENT DEVICE OVERVIEW

The 4WEB Medical Talar Replacement (TR) Device is a solid anatomical replica of a patient's native talus that replaces a patient's damaged or diseased talus. The device is designed using 3D modeling software of a patient's computed tomography (CT) scans. Anatomical matching allows the prosthetic talus to be well positioned within the ankle, congruent with articulating surfaces, preserve joint mobility, and maintain leg length.

The 4WEB Medical TR device is made of cobalt-chromium (CoCr) alloy conforming to ASTM F75 and F3213 and is manufactured via laser sintering additive techniques. All surfaces of the device are polished to a mirror finish.

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

SURGICAL PROCEDURE

▲ ACCESS AND EXPOSURE

Make a straight incision over the anterior ankle between the extensor hallucis longus (EHL) and extensor digitorum longus (EDL) tendons (Figure 1). Dissect to the ankle and talonavicular joints.

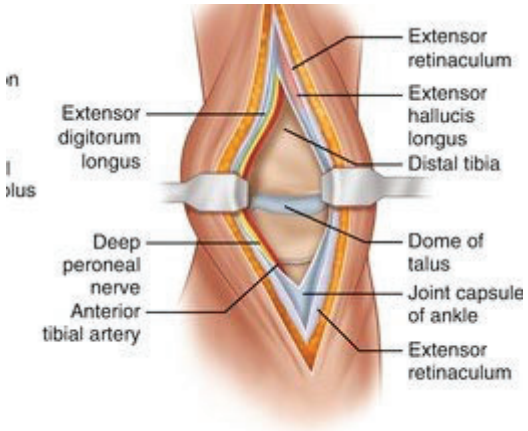

Figure 1

Once the ankle joints have been exposed, open the anterior capsule of the tibiotalar joint and perform an anterior ligament release.

▲ REMOVAL OF EXISTING TALUS

Begin by removing the talar neck. Perform a wedge osteotomy at the intersection of the talar body and the talar neck (Figure 2). Using a combination of bone saws, osteotomes, chisels, tamps, and/or mallet, remove the talar segment.

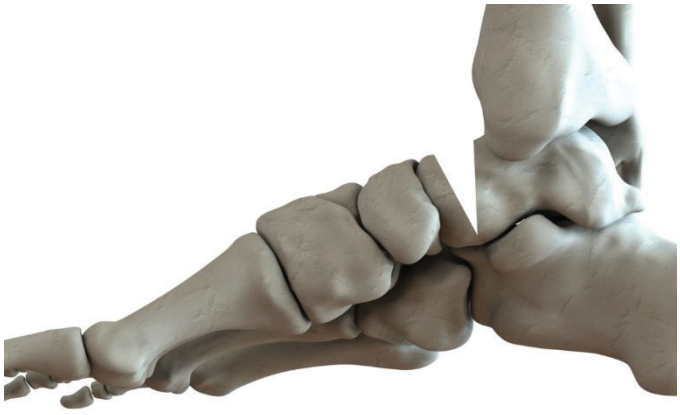

Figure 2

Release any plantar soft tissue and remove the talar neck (Figure 3).

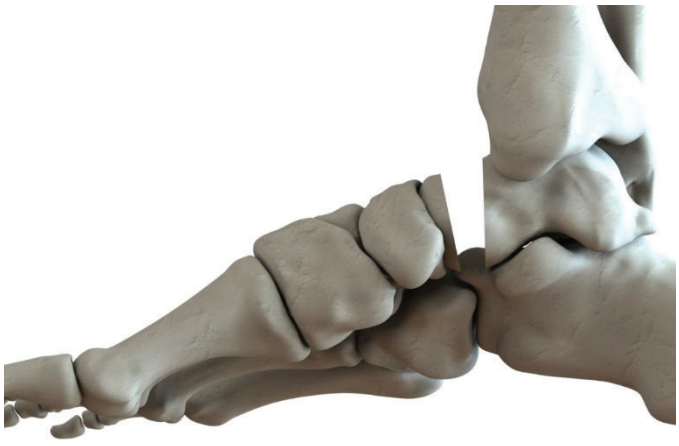

Figure 3

Continue to resect the talus with a series of osteotomies. Distract the talar head from the talonavicular joint taking care not to damage the cartilage on the navicular. While distracting, sharply release the remaining soft tissue attachments on the talar head allowing the talar head to be removed (Figure 4).

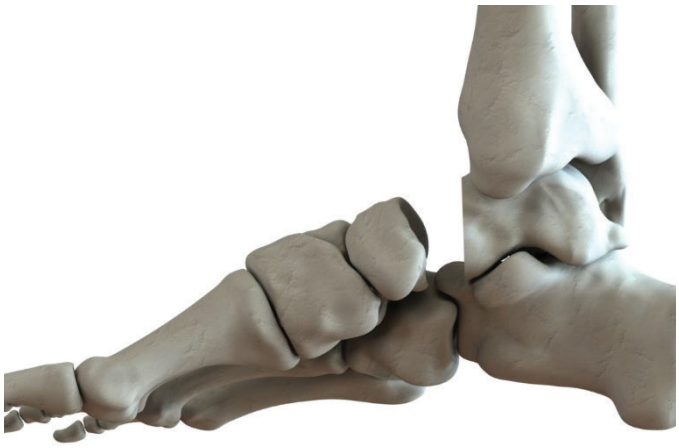

Figure 4

Using fluoroscopy, perform additional osteotomies to remove the remaining talar body while preserving the calcaneus and distal tibia cartilage (Figure 5).

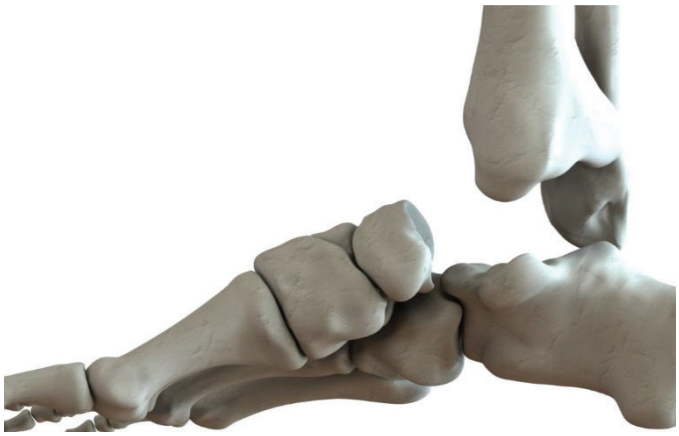

Figure 5

Use sterile saline to irrigate the surgical site and ensure all aspects of the talus have been removed. It is vital that all ligamentous and tendinous structures connecting the tibia and fibula to the calcaneus and navicular have been preserved.

IMPLANT SIZING

Three sizers have been provided with the 4WEB Medical Talar Replacement device: one correlating to the nominally sized implant, one up to 10% larger, and one up to 10% smaller.

Place the nominal sized implant trial into the surgical site (Figure 6) and evaluate the range of motion under fluoroscopy. Evaluate the fit of the trial by articulating the ankle in dorsiflexion, plantar flexion, inversion, and eversion.

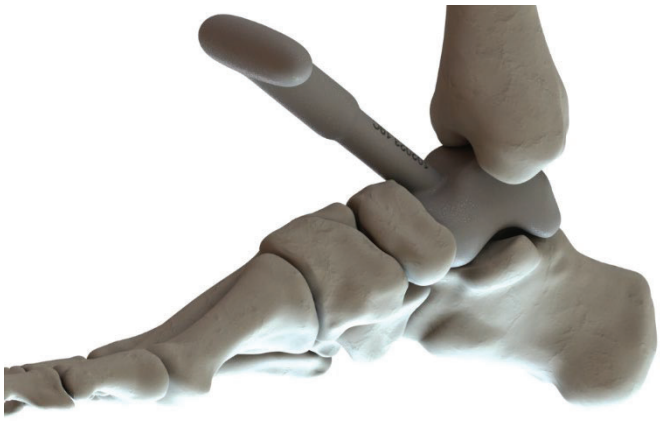

Figure 6

If the necessary, remove the nominal sized trial and use the larger or smaller trial to determine the appropriate TR device for implantation.

IMPLANT INSERTION

Insert the appropriate 4WEB Medical TR Device based on the trial size determined to be the best fit (Figure 7). It is recommended to confirm the fit of the implant using fluoroscopy.

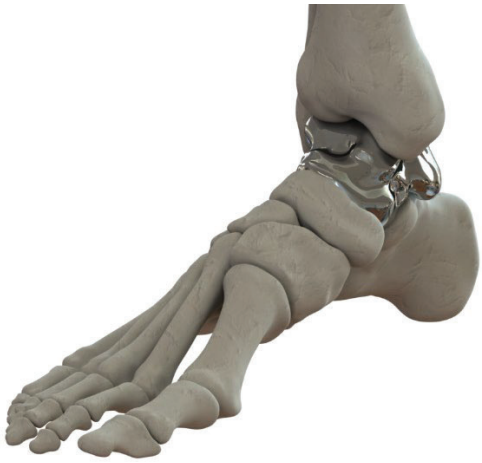

Figure 7

Note: The remaining two TR devices not implanted must be returned to 4WEB Medical or destroyed by the hospital. If destroyed, a Certificate of Destruction must be provided to 4WEB Medical.

▲ 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 regular shoes and begin working with physical therapy.

INSTRUCTIONS FOR USE - Talar Replacement Device

ATTENTION: Humanitarian Device. Authorized by Federal law for use in the treatment of talar dysfunction. The effectiveness of this device for this use has not been demonstrated. Operating surgeon, please read the following information prior to use of anatomical modeled implants.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

INTENDED USE:
This device is intended to replace a patient's dysfunctional native talus.

DEVICE DESCRIPTION:
The 4WEB Medical Talar Replacement Device is designed to replace the patient's native talus with an anatomically matched, physiologic volume. The anatomical matching allows for the prosthetic talus to articulate with adjacent boney anatomy while allowing the patient to maintain leg length, maintain mobility, and avoid quality of life limiting fusion procedures or amputations. The 4WEB Medical Talar Replacement devices are additively manufactured (laser sintering) cobalt-chromium (CoCr) alloy devices conforming to ASTM F75 and ASTM F3213. All surfaces of the device are polished to a mirror finished and passivated per ASTM A967. Three Talar Replacement Devices are provided: nominal, up to +10% and up to -10%.

INDICATIONS FOR USE:
The 4WEB Medical Talar Replacement Device is indicated for avascular necrosis of the talus in adult patients. The anatomical landmarks necessary for the design and creation of the 4WEB Medical Talar Replacement Device must be present and identifiable on computed tomography scan.

CONTRAINDICATIONS:
The 4WEB Medical Talar Replacement device should not be implanted in patients meeting any of the following conditions:

- 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.
- 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.
- Patients with an active local or systemic infection.
- 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 made, and sensitivity ruled out prior to implantation.

WARNINGS AND PRECAUTIONS:

Warnings

- Surgeons must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Talar Replacement Device. 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 Talar Replacement Device.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implant 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, and alignment 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 pre-closure 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 4WEB Medical Talar Replacement Device.
- The surgeon is to be thoroughly familiar with the implant and surgical procedure prior to performing surgery. For further information, contact 4WEB Medical and consult the Surgical Technique.
- Do not reuse the 4WEB Medical Talar Replacement Device. 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.
- Do not implant trials.

Precautions
- Surgical implants and trials 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 Talar Replacement devices are designed from patient data such as radiograph (Xray), CT scan, or magnetic resonance imaging (MRI). Over time, a patient's anatomy can change. If greater than 6 months has elapsed from the time of collection of the patient data (date of scan) to the time of surgery utilizing a Talar Replacement Device, the implant may not fit the patient's anatomy correctly.
- Never attempt to reuse. Once the 4WEB Medical Talar Replacement Device has been removed from the packaging, the device should be either used, discarded, or returned to 4WEB Medical. Never attempt to reuse the implant, even though it may appear undamaged.
- Use only 4WEB Medical instruments when handling and implanting the 4WEB Medical Talar Replacement Device.

ADVERSE EVENTS:
Adverse events may be related to surgery in general, ankle surgery specifically or the device. These may 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

- Osteosclerosis of adjacent bones
- Cartilage wear and/or arthritis of the joints/bones articulating with 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
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

MRI SAFEY INFORMATION:
The 4WEB Medical Talar Replacement Device 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 the 4WEB Medical Talar Replacement Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING:
All 4WEB Medical Talar Replacement devices and instrumentation are supplied non-sterile for steam sterilization prior to use in the operating room.

Wrapping Technique
Double wrap instruments in accordance with local institution's procedures using standard wrapping techniques such as ANSI/AAMI ST79. Label the contents of the wrapped product using an indelible marker or other sterilization compatible label system. Biological or Chemical Indicators (Bis or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped product. The indicators should be tested according to the BI or CI manufacturer's directions.

STORAGE AND SHELF LIFE:
4WEB Medical's Talar Replacement Device 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.

STERILIZATION:
• Use a validated, properly maintained and calibrated steam sterilizer.
• Effective steam sterilization can be achieved using the following cycle to achieve an SAL of 10^{-6}

Cycle	Temperature	Duration	Dry Time
Gravity	121° C (250° F)	30 min	45 min
Prevacuum	132° C (270° F)	4 min	45 min

NOTE: STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the Talar Replacement Device, methods of application, instruments and surgical technique. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. Correct positioning of the Talar Replacement Device should be checked intraoperatively with x-ray. The size of the Talar Replacement Device must be chosen on the basis of the patient's anatomy. The implants are for single-implant use only. An explanted implant must never be re-implanted. Stresses and fracture, even though not noticeable by visual inspection, may have been created during initial implantation. Following implantation, the product number and manufacturing lot number of the device that has been implanted must be reported in the patient's surgical file. The remaining two TR devices not implanted must be returned to 4WEB Medical or destroyed by the hospital. If destroyed, a Certificate of Destruction must be provided to 4WEB Medical.

PRODUCT COMPLAINTS:

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any Talar Replacement Device should notify 4WEB, or, where applicable, their distributor.

SURGICAL TECHNIQUE MANUAL:

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. 4WEB Medical 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. To receive additional copies of the Surgical Technique Manual, contact your local sales representative or the company at the address below.

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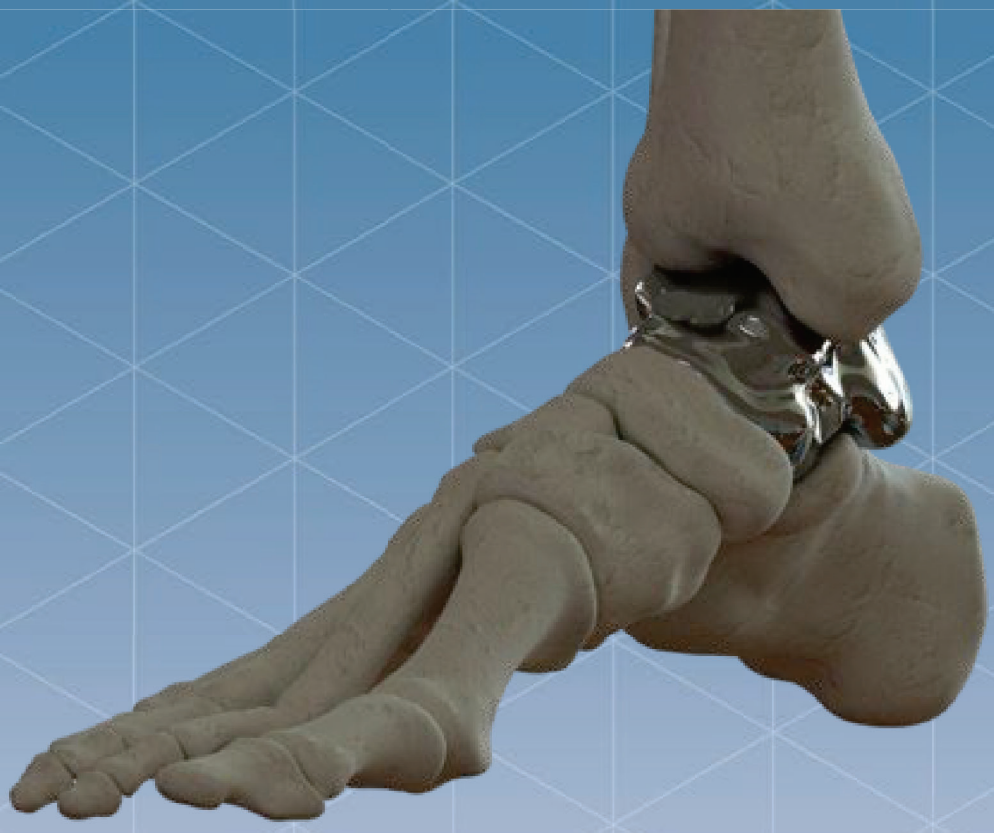
ST-TRD-01 | REV 4

Talar Replacement Device

Patient Information Guide



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4WEB MEDICAL

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GLOSSARY

- **ADDITIVE MANUFACTURING** Also known as 3D Printing or AM, additive manufacturing refers to the process that builds a three-dimensional object by depositing materials layer by layer using a model from a computer aided design program. Additive manufacturing allows for the creation of complex geometries, including the 4WEB Medical Talar Replacement (TR) Device.

- **ANKLE JOINT** A joint in the lower limb formed by two bones from the leg (tibia and fibula) and the one bone from the foot (talus). It allows for the foot to be moved in both dorsiflexion (up) and plantarflexion (down). Please see the image on page 4 showing relation between these three bones forming the ankle joint.

- **ARTHRODESIS/FUSION** Arthrodesis or fusion are terms used to describe the immobilization of a joint when the bones grow solidly together.

- **AVASCULAR NECROSIS** Also known as AVN or osteonecrosis, avascular necrosis is a condition resulting in the death of bone tissue from a lack of blood supply. AVN can lead to tiny breaks in the bone resulting in a bone 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 on page 4 showing the calcaneus.

- **CT SCAN** A computerized tomography (CT) scan takes multiple x-ray images from various angles around your body and uses a computer to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside your body.

- **DORSIFLEXION** Movement of the foot in an upward (towards the shin) direction.

- **FIBULA** The outer bone of the lower leg. The fibula is one of three bones in the ankle joint. Please see the image on page 4 showing the fibula.

- **MAGNETIC RESONANCE IMAGING (MRI)** Refers to the 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 located in the ankle between the talus and cuneiform bones. Please see the image on page 4 showing the navicular.

- **PATIENT SPECIFIC IMPLANT** An implant that is unique to the patient it has been designed for. A patient specific implant has been created using CT Scans to match the exact anatomy of the patient.

- **PLANTARFLEXION** Movement of the foot in a downward (towards the ground) direction.

- **SUBTALAR JOINT** Formed by the talus and calcaneus, the subtalar joint allows for the foot to rotate inward (inversion) and outward (eversion). Please see the image on page 4 showing the subtalar joint.

- **TALUS** The large bone in the ankle connecting the leg and foot. The talus enables movement of the foot relative to the leg. Please see the image on page 4 showing the talus.

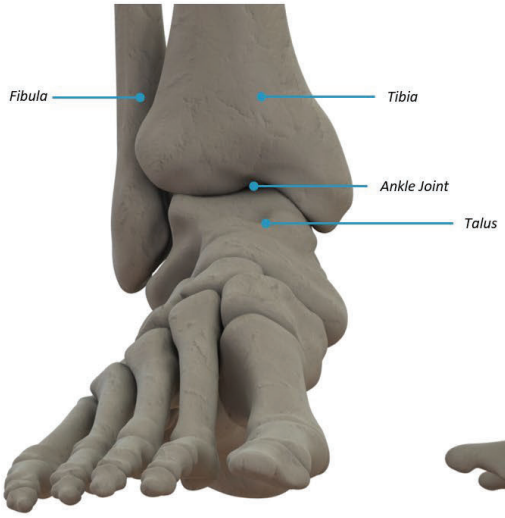
- **TIBIA** Often referred to as the shin bone, the tibia is the inner bone of the lower leg. The tibia is typically larger than the fibula and is one of three bones in the ankle joint. Please see the image on page 4 showing the tibia.

ANATOMY OF THE ANKLE

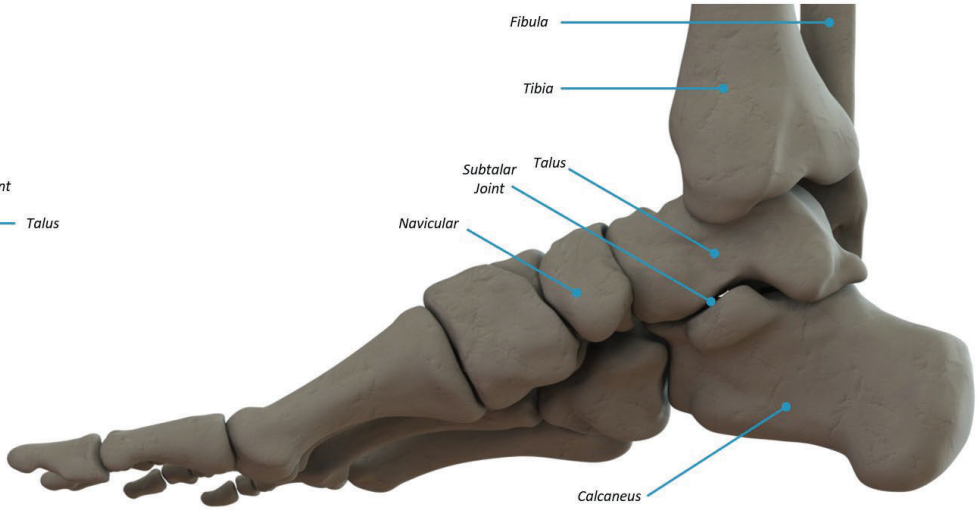
The ankle is comprised of two joints: the ankle joint and the subtalar joint. The ankle joint allows for the foot to move upward (dorsiflexion) and downward (plantarflexion). The bones comprising the ankle joint are the tibia (shin bone), the fibula, and the talus. The tibia and fibula rotate around the top of talus, also known as the talar dome.

The two bones that make up the subtalar joint are the calcaneus (heel) and talus. The subtalar joint is located below the ankle joint and allows for the foot to move inward (inversion) and outward (eversion). See the images below detailing these bones and joints.

Anterior (Front) View



Medial (Inside) View



QUESTIONS

What is Avascular Necrosis?

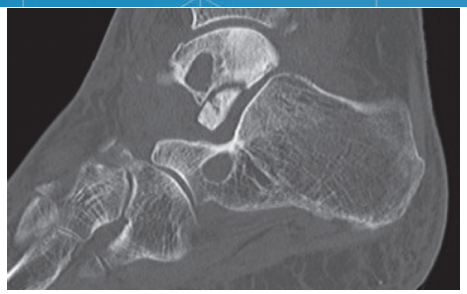
Avascular Necrosis (AVN) is the death of bone tissue due to a lack of blood supply. If left untreated, AVN can cause the bone to eventually collapse. If AVN involves the bones of a joint (like the talus) it often leads to destruction of cartilage, resulting in arthritis and pain. Avascular necrosis can be caused by an acute injury (like a broken bone) or an injury that occurs slowly over time (like 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 AVN in 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 pain, arthritis, deformity, and amputation.

How is AVN diagnosed?

Your doctor will take X-rays if they suspect you may have AVN. Following the X-rays, an MRI or CT will likely be ordered as they are more sensitive imaging techniques that will help your doctor better identify the extent of the disease.



CT Scan showing AVN

How is AVN treated?

Your treatment options will depend on the severity of the AVN. If AVN is noted in early on, non-operative or early stage surgical treatment options such as core decompressions or bone grafting may be available.

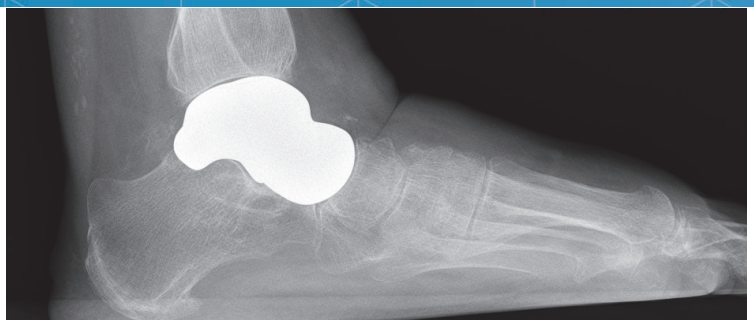
In late stage AVN, if the talus has begun to collapse or has fully collapsed, surgical intervention is required. Surgical treatment options may include an arthrodesis, or fusion, of one or more joints in the foot and ankle. An arthrodesis eliminates movement at that joint, which assists in relieving pain. Another option is an amputation, where your doctor will surgically remove the lower portion of your limb below the knee.

One additional treatment option is available: a talus replacement surgery. During this procedure the talus bone is removed and replaced with a 4WEB Medical Talar Replacement (TR) Device. This is considered a joint-sparing procedure, as it allows you to maintain the function of your ankle while decreasing pain.

What is a Talar Replacement Device?

The 4WEB Medical Talar Replacement Device is an exact replica of the native talus it is replacing. The Talar Replacement Device is an 3D printed implant that is designed and manufactured individually for each patient using data from their CT scans. The device allows you to regain ankle function, maintain ankle joint and subtalar joint motion, and reduce pain while avoiding a fusion or amputation. The implant is made from cobalt-chromium metal alloy and is produced using additive manufacturing techniques.

4WEB Medical Talar Replacement Device



X-ray of a 4WEB Medical Talar Replacement Device

Who should receive a Talar Replacement Device?

The 4WEB Medical Talar Replacement Device is indicated for adult patients with avascular necrosis of the talus. In addition to reading the information provided in this guide, please talk with your doctor to help you understand the benefits and risks associated with talar replacement surgery.

Who should not receive a Talar Replacement Device?

The 4WEB Medical Talar Replacement device should not be implanted in patients meeting any of the following conditions:

- Use an implant greater than 6 months from date of patient's computed tomography (CT) scan.
- Degenerative changes in the tibiotalar, subtalar or talonavicular joints.
- Gross deformity in sagittal or coronal planes. More than 15 degrees of varus and valgus deformity in the coronal plane, or more than 50% subluxation anteriorly or posteriorly of the talus in the sagittal plane.
- Presence of an active infection.
- 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 performed, and sensitivity ruled out prior to implantation.

What are the warnings associated with the Talar Replacement Device?

- Surgeons must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Talar Replacement Device. 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 Talar Replacement Device.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implant 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, and alignment 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 pre-closure 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 4WEB Medical Talar Replacement Device.
- The surgeon is to be thoroughly familiar with the implant and surgical procedure prior to performing surgery. For further information, contact 4WEB Medical and consult the Surgical Technique.
- Do not reuse the 4WEB Medical Talar Replacement Device. 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.
- Do not implant trials.

What are the precautions associated with the Talar Replacement Device?

- Surgical implants and trials 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 Talar Replacement Devices 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 greater than 6 months has elapsed from the time of collection of the patient data (date of scan) to the time of surgery utilizing a Talar Replacement Device, the implant may not fit the patient's anatomy correctly.
- Never attempt to reuse. Once the 4WEB Medical Talar Replacement Device has been removed from the packaging, the device should be either used, discarded, or returned to 4WEB Medical. Never attempt to reuse the implant, even though it may appear undamaged.
- Use only 4WEB Medical instruments when handling and implanting the 4WEB Medical Talar Replacement Device.

What are the risks associated with talar replacement surgery?

As with any surgery, there are inherent risks which may include the following:

- Anesthesia
- Skin Problems
- Bleeding
- Infection
- Blood Clots
- Nerve/blood vessel damage

What are the adverse effects associated with the 4WEB Medical Talar Replacement Device?

Adverse events may be related to the surgery in general, but also talar replacement surgery specifically as well as the Talar Replacement Device. These may 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
- Osteosclerosis of adjacent bones
- Cartilage wear and/or arthritis of the joints/bones articulating with 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
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

What are the expected outcomes and benefits of a Talar Replacement Device?

The Talar Replacement Device is intended to provide pain relief, preserve ankle mobility, and improve physical function. You should speak with your doctor to see if you are a candidate for a 4WEB Medical Talar Replacement Device.

CLINICAL DATA

4WEB Medical completed a retrospective chart review study which examined the clinical and radiographic outcomes of 30 patients (31 devices) who had been implanted with a talus replacement with the goal of demonstrating safety and probable benefit of the TR Device when used in the indicated population. The data collected was approved by appropriate Institutional Review Boards (IRBs).

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"). Implant survivorship was also evaluated based on the SSSIs and AEs reported for each patient and assessed qualitatively through review of follow-up notes written by the medical provider.

Three probable benefits were evaluated using the clinical data. The primary probable benefit endpoint was improvement in pain, as measured by the Visual Analog Scale (VAS), at last follow-up compared to baseline. The secondary probable benefit endpoints included measuring ankle range of motion (ROM) at last follow-up compared to baseline and evaluating physical function as measured using the American Orthopaedic Foot & Ankle Society Ankle-Hindfoot Rating system (AOFAS) at last follow-up compared to baseline.

A summary of the patient demographics is provided in Table 1. Thirty (30) patients (31 devices) were treated in the study. None of the enrolled patients had bilateral procedures (i.e., a 4WEB Medical TR Device implanted in both the left and right) ankles). One patient had an initial 4WEB Medical TR Device that was removed and replaced with another 4WEB Medical TR Device for a total of 31 devices.

Table 1: Patient Demographics

Age (n=29)	
Mean +/-SD (years)	47.2 +/- 14.2
Range	22 - 71
Gender (n=30)	
Male, n (%)	14 (46.7%)
Female, n (%)	16 (53.3%)
BMI (n=26)	
Mean +/-SD	30.1 +/- 7.1
Range	19.5 – 51.9
Smoking Status (n=27)	
Current, n (%)	4 (14.8%)
Former, n (%)	10 (37.0%)
Never a smoker, n (%)	13 (48.1%)
Laterality (n=31)	
Left, n (%)	15 (48.3%)
Right, n (%)	16 (51.7%)
Both, n (%)	0 (0%)
Race (n=30)	
White, n (%)	16 (53.3%)
Black, n (%)	1 (3.3%)
Not Reported, n (%)	13 (43.3%)
Ethnicity (n=30)	
Hispanic or Latino, n (%)	2 (6.7%)
Not Hispanic or Latino, n (%)	13 (43.3%)
Not Reported, n (%)	15 (50.0%)
Prior Surgeries (n=29)	
0, n (%)	13 (44.8%)
1, n (%)	8 (27.6%)
2, n (%)	5 (17.2%)
≥ 3, n (%)	3 (10.3%)
Primary Indication*	
Avascular Necrosis (AVN), n (%)	29 (93.5%)
Revision of previous talus replacement, n(%	2 (6.5%)

* Indication information is available for all 31 procedures

Safety

4WEB Medical utilized a Clinical Events Committee (CEC) to analyze the safety objectives for the retrospective chart review study. The CEC was comprised of an independent group of experts whose purpose was to advise 4WEB Medical on the safe and effective conduct of this retrospective review, monitor patient safety and the scientific integrity of the retrospective review, and to adjudicate any AEs.

The CEC concluded that no definitive device-related side effect or symptoms were observed for patients who received a 4WEB Medical TR Device. The CEC identified a total of eleven AEs, with one SAE being possibly linked to the device, four SAEs not related to the device but potentially the procedure, and one AE not related to the device but potentially the procedure. These six safety events (potentially device or procedure related) include five SSSI's reported (5/31, 16.1%). The remaining four AE's and one SAE were unrelated to both device and procedure, as shown in Table 2.

Table 2: Categorization of Reported Safety Events

Item	Possibly Device-Related	Possibly Procedure Related	Unrelated
Adverse Events (AE) (n=5)	0	1	4
Serious Adverse Events (SAE) (n=6)	1	4	1
Subsequent Secondary Surgical Interventions (SSSI) (n=5)	*1*	*4*	*0*
Total (n=11)	**1**	**5**	**5**

The five secondary surgeries included one patient with a valgus (turned outward) 4WEB Medical TR Device position which was revised with another 4WEB Medical TR Device, two patients with varus (turned inward) 4WEB Medical TR Device positions which were revised with either an ankle fusion or a tendo-Achilles lengthening procedure, one patient where their device shifted after implantation which required a second 4WEB Medical TR Device, and a patient who developed arthritis on their tibia which was revised with another 4WEB Medical TR Device. The CEC concluded that none of these SSSIs were directly linked to the 4WEB Medical TR Device or the talar replacement surgery.

The AEs not requiring a secondary surgery included four patients who reported pain during their post operative follow-ups, all of which were treated in office or with medication, and one patient who began to lose the arch of their foot at their two-year follow-up. The one remaining SAE not related to the device or procedure was one patient who fell and fractured their hip nineteen months post operation.

Implants remained in place for 27 out of 31 (87.1%) devices, demonstrating a high rate of implant survivorship.

Probable Benefits

The primary probable benefit endpoint was the reduction in baseline level pain following surgery using the VAS for pain. Pain scores were collected through retrospective chart review and included scores from VAS, ranging from 0 – 10. Of the 30 subjects, pre and post operative VAS pain scores were reported for 20 out of 30 (66.7%) of the enrolled patients. A baseline VAS was available for 20 out of 30 (66.7%) patients and a follow-up score was available for 23 out of 30 (76.7%) patients. Figure 1 and Table 3 present the mean VAS pain changes from baseline for the different follow-up cohorts.

At baseline, the mean VAS pain score for the twenty subjects was 6.4 ± 2.3 and scores ranged from 0 – 10, with 10 representing maximum pain intensity. The mean VAS pain score at last follow-up (n=23) was 3.8 ± 2.8. Mean change from baseline for the twenty subjects with pre- and postoperative VAS pain score was -3.1 ± 3.3. For the cohort analysis, mean improvement for subject with pre- and postoperative VAS pain scores for the <1 year, 1 year, and 2 years cohorts were -2.7 ± 1.2, -3.2 ± 4.1, and -3.2 ± 2.9 respectively.

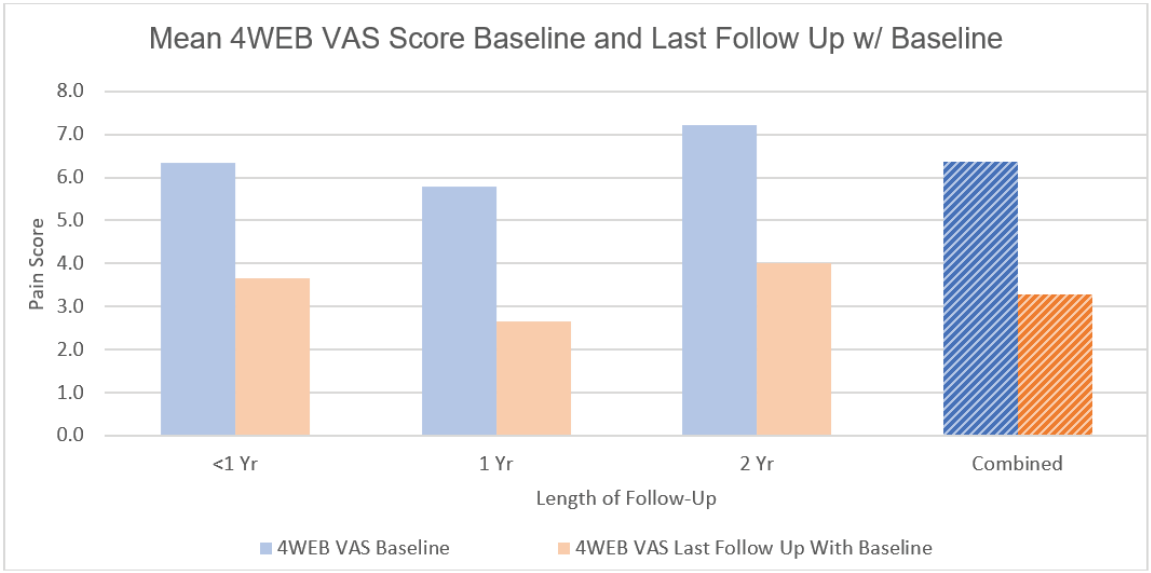


Figure 1: VAS Pain – Mean Baseline and Last Follow-Up w/ Baseline by Duration of Follow-Up

Table 3: VAS Pain Mean Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=3)	6.3	3.2	4 – 10	2.7 , 10.0
	Last Follow Up w/ Baseline (n=3)	3.7	4.0	0 – 8	-0.9 , 8.2
	Last Follow-Up (n=5)	4.6	3.4	0 – 8	1.6 , 7.6
	Change from Baseline (n=3)	-2.7	1.2	-4 – (-2)	-4.0 , -1.4
1 Year	Baseline (n=10)	5.8	2.5	5 – 9	4.2 , 7.4
	Last Follow Up w/ Baseline (n=10)	2.7	2.4	0 – 7	1.2 , 4.1
	Last Follow-Up (n=10)	2.7	2.4	0 – 7	1.2 , 4.1
	Change from Baseline (n=10)	-3.2	4.1	-8 – 5	-5.7 , -0.6
2 Year	Baseline (n=7)	7.2	1.6	5 – 9	6.0 , 8.4
	Last Follow up w/ Baseline (n=7)	4.0	2.6	1 – 8	2.1 , 5.9
	Last Follow-Up (n=8)	4.5	2.8	1 – 8	2.6 , 6.4
	Change from Baseline (n=7)	-3.2	2.9	-7 – 0	-5.4 , -1.1
Combined	**Baseline (n=20)**	**6.4**	**2.3**	**0 – 10**	**5.4 , 7.4**
	Last Follow Up w/ Baseline (n=20)	**3.3**	**2.6**	**0 – 8**	**2.1 , 4.4**
	Last Follow Up (n=23)	**3.8**	**2.8**	**0 – 8**	**2.6 , 4.9**
	Change from Baseline (n=20)	**-3.1**	**3.3**	**-8 – 5**	**-4.5 , -1.7**

The secondary probable benefit endpoints assessed included the range of motion (ROM) of the ankle joint in dorsiflexion (DF) and in plantar flexion (PF). Similar to pain, patients demonstrated an improvement in dorsiflexion and plantar flexion movement in their affected ankle joint after talar replacement.

Of the 30 patients, eleven (11/30, 36.7%) patients had pre- and postoperative dorsiflexion available, with a mean ROM of 9.5 ± 5.7 degrees at last follow up, an improvement of 4.3 degrees on average over the baseline ROM. Figure 2 and Table 4 present mean outcomes for all patients with dorsiflexion ROM data, as well as by cohort based on duration of follow-up period (i.e., < 1 years, 1 year, and 2 years).

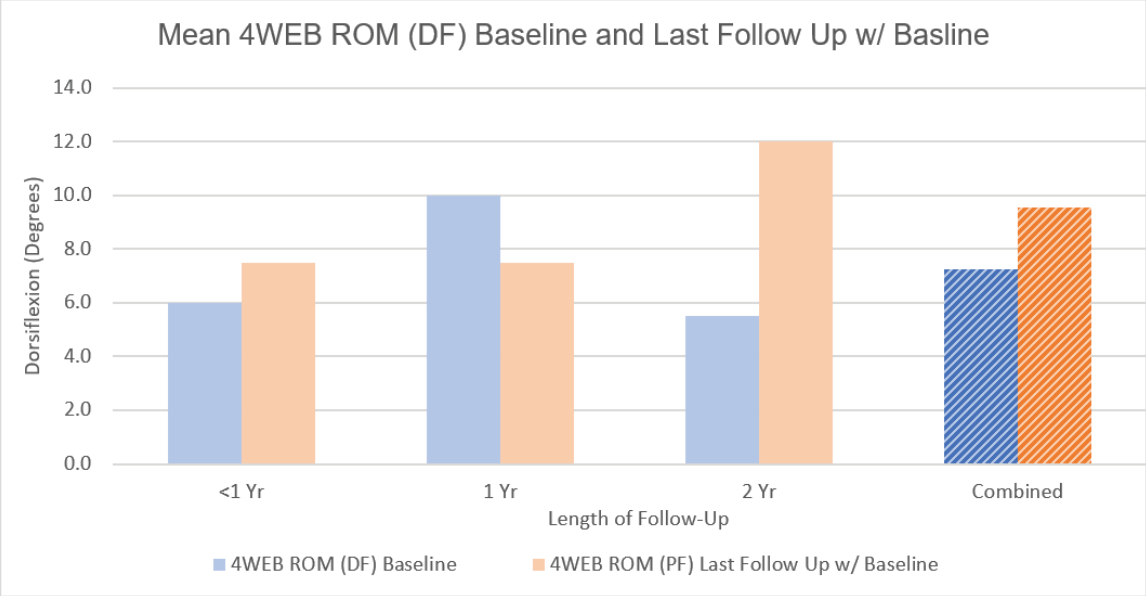


Figure 2: ROM (DF) – Mean Baseline, and Last Follow-Up w/Baseline by Duration of Follow-Up

Table 4: Ankle Dorsiflexion ROM Mean Baseline, Last Follow-Up and Change From Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=5)	6.0	6.5	0 - 15	0.3 , 11.7
	Baseline w/ Follow Up (n=2)	2.5	3.5	0 - 5	-2.4 , 7.4
	Last Follow Up w/ Baseline (n=2)	7.5	3.5	5 - 10	2.6 , 12.4
	Last Follow Up (n=3)	11.7	7.6	5 - 20	3.0 , 20.3
	Change from Baseline (n=2)	5.0	0.0	5 – 5	N/A , N/A
1 Year	Baseline (n=6)	10.0	11.4	-5 - 20	0.9 , 19.1
	Baseline w/ Follow Up (n=4)	8.8	13.1	-5 - 20	-4.1 , 21.6
	Last Follow Up w/ Baseline (n=4)	7.5	2.9	5 – 10	4.7 , 10.3
	Last Follow Up (n=5)	8.0	2.7	5 - 10	5.6 , 10.4
	Change from Baseline (n=4)	-1.3	10.3	-10 - 10	-11.4 , 8.9
2 Year	Baseline (n=6)	5.5	10.0	-5 - 20	-2.5 , 13.5
	Baseline w/ Follow Up (n=5)	3.6	9.9	-5 - 20	-5.0 , 12.2
	Last Follow up w/ Baseline (n=5)	12.0	7.6	5 - 20	5.4 , 18.6
	Last Follow Up (n=7)	10.0	7.6	0 - 20	4.3 , 15.7
	Change from Baseline (n=5)	8.4	8.4	0 – 22	1.1 , 15.7
Combined	**Baseline (n=17)**	**7.2**	**9.3**	**-5 – 20**	**2.8 , 11.7**
	Baseline w/ Follow Up (n=11)	**5.3**	**10.0**	**-5 - 20**	**-0.6 , 11.2**
	Last Follow Up w/ Baseline (n=11)	**9.5**	**5.7**	**5 - 20**	**6.2 , 12.9**
	Last Follow Up (n=15)	**9.7**	**6.1**	**0 - 20**	**6.6 , 12.8**
	Change from Baseline (n=11)	**4.3**	**9.0**	**-10 - 22**	**-1.0 , 9.6**

The same subset of patients had plantar flexion ROM scores available in their medical records. Of the 30 patients, eleven (11/30, 36.7%) had both pre- and postoperative data available. These patients had a mean plantar flexion ROM of 38.6 ± 13.1 degrees at last follow up, representing an improvement of 0.5 degrees on average over their baseline ROM and an increase of 2.7 degrees over the average of all baseline scores. Figure 3 and Table 5 present mean outcomes for the combined patients with plantar flexion ROM, as well as by cohort based on duration of follow-up period (i.e., < 1 years, 1 year, and 2 years).

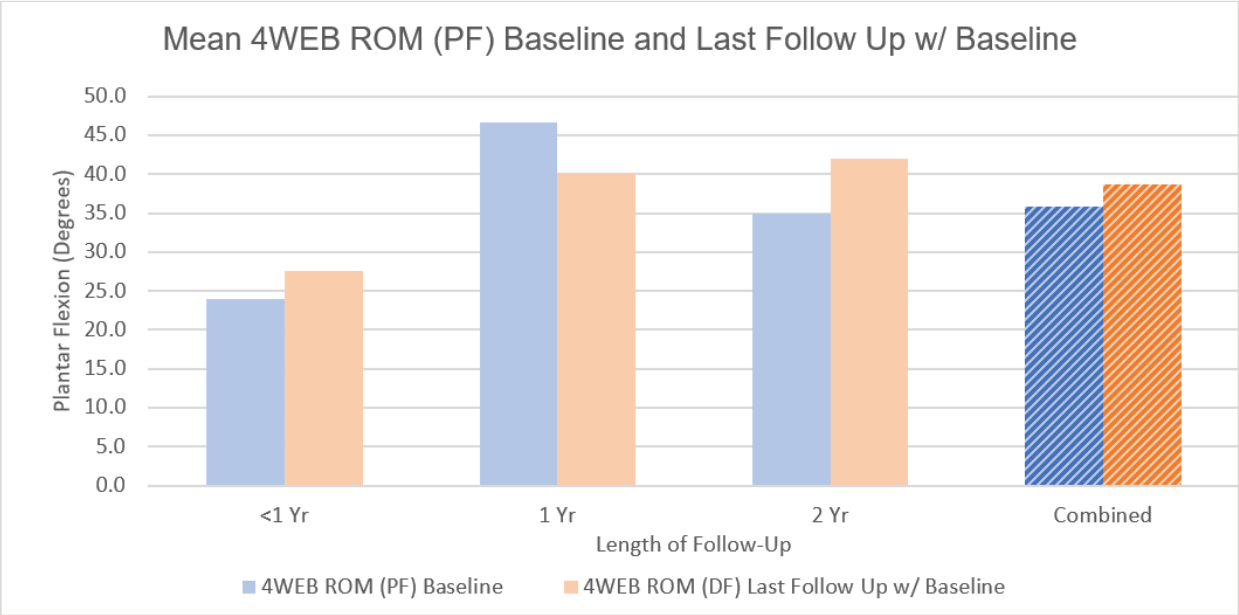


Figure 3: Ankle ROM (Plantar Flexion) – Mean Baseline and Last Follow-Up w/Baseline by Duration of Follow-Up

Table 5: Ankle Plantar Flexion ROM Mean Baseline, Last Follow-Up, and Change From Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI
<1 Year	Baseline (n=5)	24.0	13.9	10 – 40	11.8 , 36.2
	Baseline w/ Follow Up (n=5)	25.0	21.2	10 – 40	-4.4 , 54.4
	Last Follow Up w/ Baseline (n=2)	27.5	17.7	15 – 40	3.0 , 52.0
	Last Follow Up (n=3)	31.7	14.4	15 – 40	15.3 , 48.0
	Change from Baseline (n=2)	2.5	3.5	0 – 5	-2.4 , 7.4
1 Year	Baseline (n=6)	46.7	5.2	40- 50	42.5 , 50.8
	Baseline w/ Follow Up (n=4)	50.0	0.0	50 – 50	50.0 , 50.0
	Last Follow Up w/ Baseline (n=4)	40.0	11.5	30 – 50	28.7 , 51.3
	Last Follow Up (n=5)	36.0	13.4	20 – 50	24.2 , 47.8
	Change from Baseline (n=4)	-10.0	11.5	-20 – 0	-21.3 , 1.3
2 Year	Baseline (n=6)	35.0	20.7	0 – 50	18.4 , 51.6
	Baseline w/ Follow Up (n=5)	34.0	23.0	0 – 50	13.8 , 54.2
	Last Follow Up w/ Baseline (n=5)	42.0	13.0	20 – 50	30.6 , 53.4
	Last Follow Up (n=7)	35.7	16.2	10 – 50	23.7 , 47.7
	Change from Baseline (n=5)	8.0	23.9	-10 – 50	-12.9 , 28.9
Combined	**Baseline (n=17)**	**35.9**	**16.7**	**0 – 50**	**27.9 , 43.8**
	Baseline w/ Follow up (n=11)	**38.2**	**18.9**	**0 - 50**	**27.0 , 49.3**
	Last Follow Up w/ Baseline (n=11)	**38.6**	**13.1**	**15 – 50**	**30.9 , 46.4**
	Last Follow Up (n=15)	**35.0**	**14.0**	**10 - 50**	**27.9 , 42.1**
	Change from Baseline (n=11)	**0.5**	**18.5**	**-20 - 50**	**-10.5 , 11.4**

The final secondary probable benefit endpoint was the American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Score. The AOFAS Hindfoot Score is a nine-question survey filled out by both the patient and surgeon where the pain, function, and alignment of the subject's ankle are rated. The AOFAS scores range from 0-100, with the higher score representing better physical function. Of the 30 patients included in the study, thirteen (13/30, 43.3%) patients had pre- and postoperative AOFAS Hindfoot Scores available. Figure 4 and Table 6 present the mean change for AOFAS average combined score by cohort based on duration of follow-up period (i.e., < 1 years, 1 year, and 2 years). Patients showed an increase in AOFAS Hindfoot Score post-operatively for all cohorts. The mean change from baseline in AOFAS Hindfoot Score was an increase in 23.1 points.

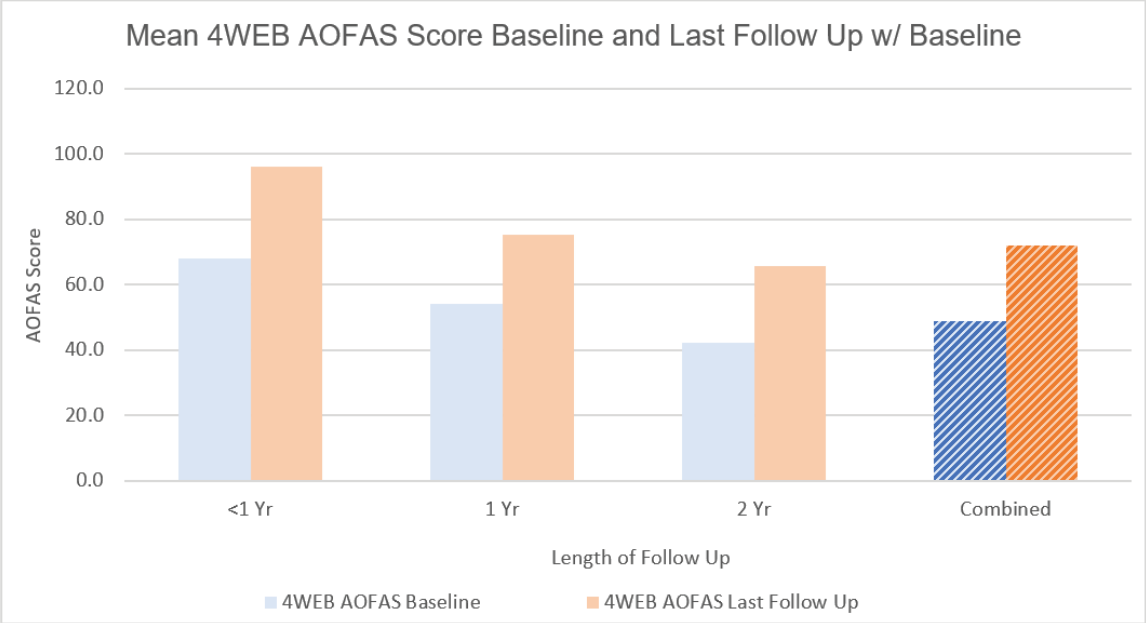


Figure 4: Mean AOFAS Hindfoot Score Baseline, Last Follow-Up and Change from Baseline by Duration of Follow-Up

Table 6: Mean AOFAS Baseline, Last Follow-Up and Change From Baseline by Duration of Follow-Up

Cohort	Assessment	Mean	SD	Range	95% CI		
<1 Year	Baseline (n=1)	68.0	0.0	68	68.0	,	68.0
	Last Follow Up (n=1)	96.0	0.0	96	96.0	,	96.0
	Change from Baseline (n=1)	28.0	0.0	28	28.0	,	28.0
1 Year	Baseline (n=5)	54.0	12.7	39 - 70	42.9	,	65.1
	Last Follow Up (n=5)	75.4	23.1	47 - 98	55.1	,	95.7
	Change from Baseline (n=5)	21.4	28.6	-17 - 59	-3.6	,	46.4
2 Year	Baseline (n=7)	42.3	22.8	0 - 67	25.4	,	59.2
	Last Follow Up (n=7)	65.9	19.9	33 - 87	51.1	,	80.6
	Change from Baseline (n=7)	23.6	29.1	-8 - 79	2.0	,	45.1
Combined	**Baseline (n=13)**	**48.8**	**19.5**	**0 - 70**	**38.2**	**,**	**59.4**
	Last Follow Up (n=13)	**71.8**	**21.2**	**33 - 98**	**60.3**	**,**	**83.4**
	Change from Baseline (n=13)	**23.1**	**26.4**	**23 – 79**	**8.7**	**,**	**37.4**

Conclusions

The information presented above supports the probable benefit of the 4WEB Medical Talar Replacement Device for the treatment of AVN of the talus. Additionally, the data collected supports a reasonable assurance of the device's safety. The patients who were analyzed as part of the retrospective clinical study showed meaningful probable benefit in the form of improved range of motion, improved functionality, and a reduction in pain. These improvements in functionality allow for a patient to return to a normal lifestyle by preserving their ankle mobility, ability to work, and overall physical health. Moreover, the safety of the device was demonstrated through a low rate of reoperation and no documented device related adverse events.

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LA-TRD-15 | REV 4

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

CT

The quality of the CT is a critically important aspect of creating patient specific devices. Adherence to the following protocol will reflect in the quality of the resulting digital reconstruction and, consequently, in the accuracy of the final device or model.

CT SCAN PARAMETERS

SCAN SPACING	Less than 1.5mm (equal to slice thickness)
SLICE THICKNESS	Less than 1.5mm (equal to scan spacing)
AGING TIMEFRAME	Less than 6 months
FIELD OF VIEW (FOV)	Set Field of View (FOV) to include entire area of interest
GANTRY TILT	0 Degrees
PIXEL RESOLUTION	Less than 0.75mm
ARCHIVE MEDIA	Digital Upload, CD, DVD, or Flash Drive
FILE TYPE	DICOM
SERIES	Original / Primary / Axial (No reformatted data)
ALGORITHM (EXAMPLES)	GE: Standard (not bone or detail) Siemens: H30s Toshiba: FC20 Philips: B

X-RAY

In certain cases, X-ray may be used in addition to other radiographic imaging. Adherence to the following protocol will reflect in the quality of the resulting digital reconstruction and, consequently, in the accuracy of the final device or model.

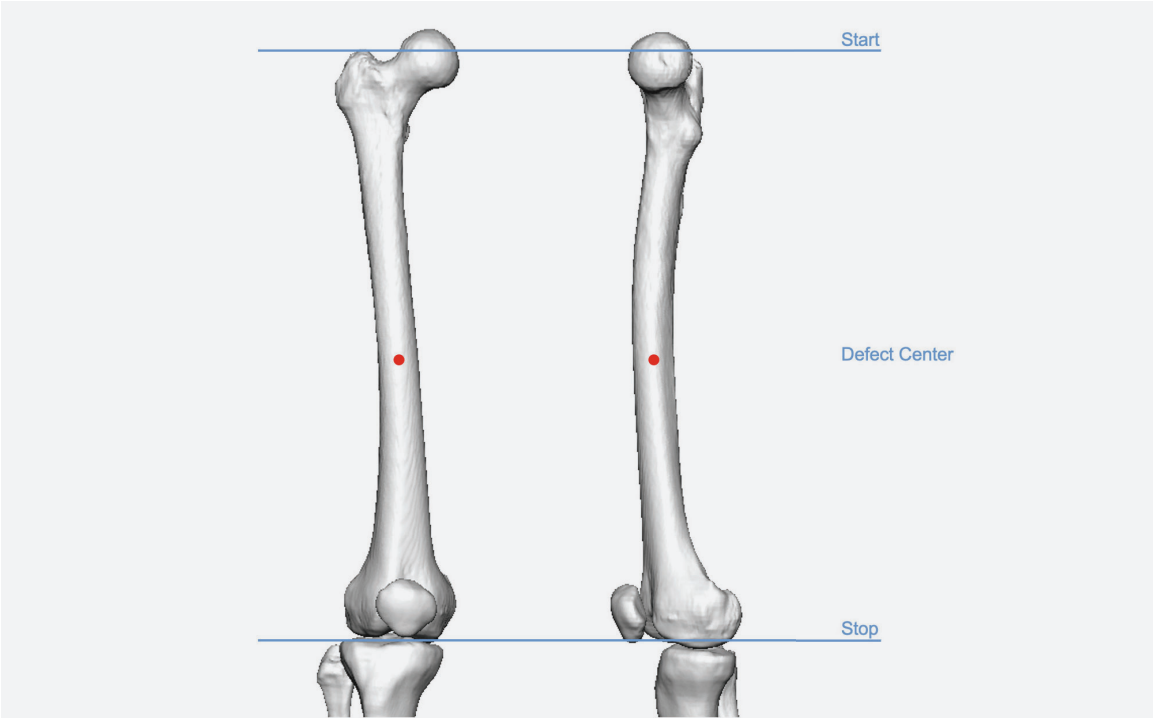
X-RAY PARAMETERS

SOURCE TO IMAGE DISTANCE	180-228cm
IMAGE SPACING	< 0.50mm
AGING TIMEFRAME	Less than 6 months
FIELD OF VIEW (FOV)	Set Field of View (FOV) to include entire area of interest; Anterior-Posterior & Lateral required
ARCHIVE MEDIA	CD, DVD, or Flash Drive
FILE TYPE	DICOM

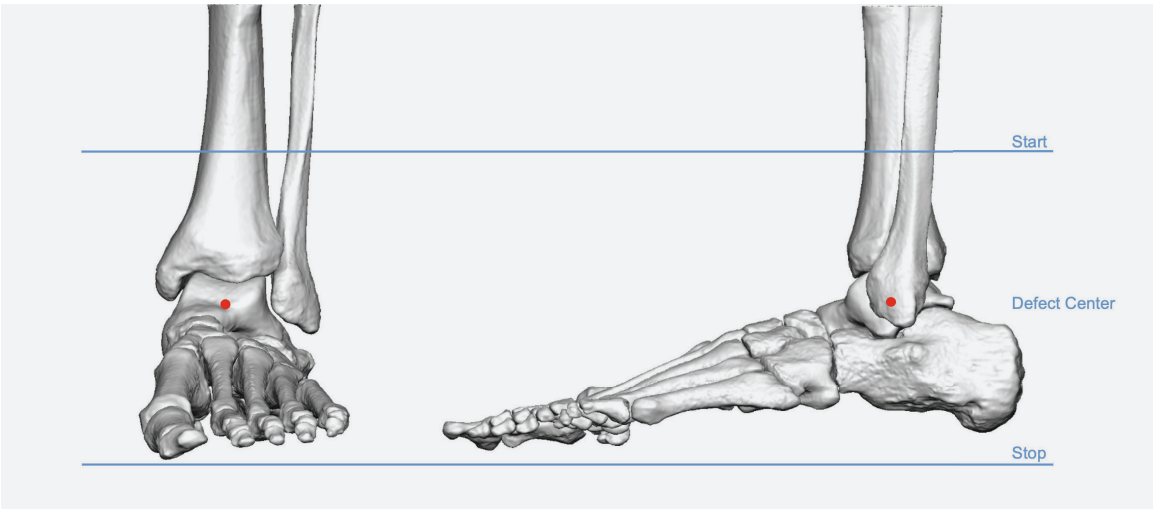
DATA TRANSFER

Archive the entire study in uncompressed DICOM format to upload via 4WEB File Share.
Contact 4WEB Medical at psi@4webmedical.com or +1.800.285.7090 for details.

REGION OF INTEREST: LONG BONE – EXAMPLE IMAGE



REGION OF INTEREST: FOOT & ANKLE – EXAMPLE IMAGE



Images not to scale

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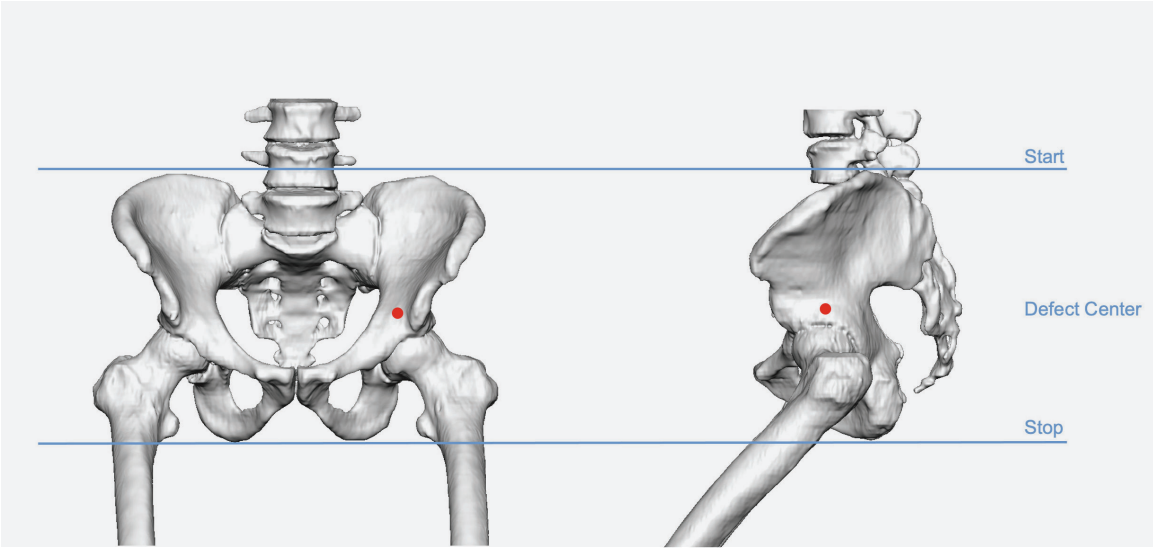
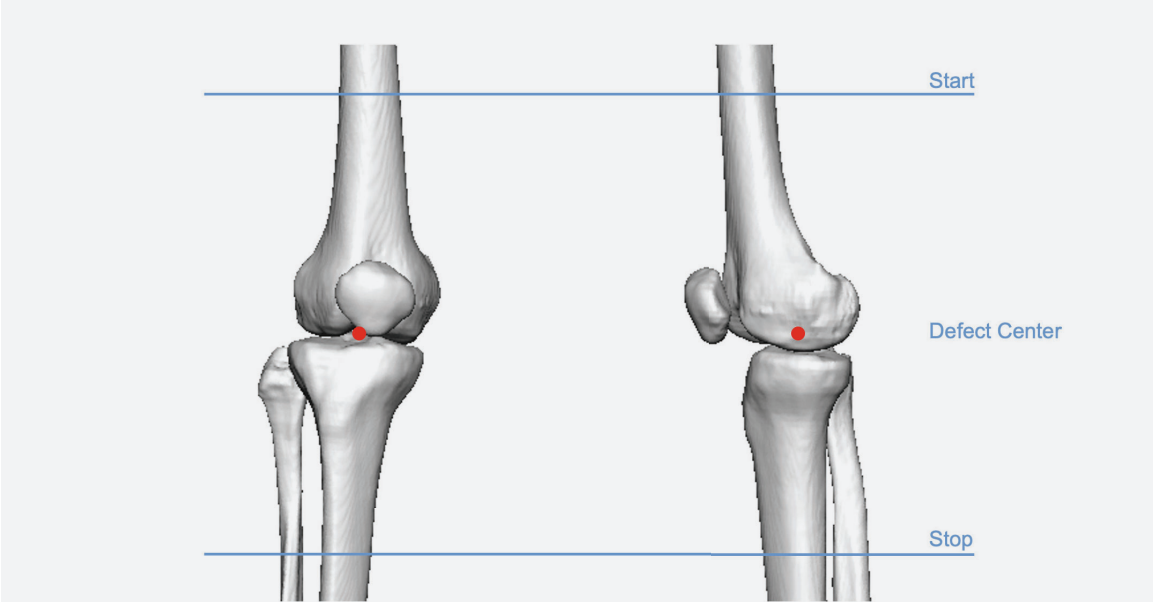
REGION OF INTEREST: PELVIS – EXAMPLE IMAGE



REGION OF INTEREST: KNEE – EXAMPLE IMAGE



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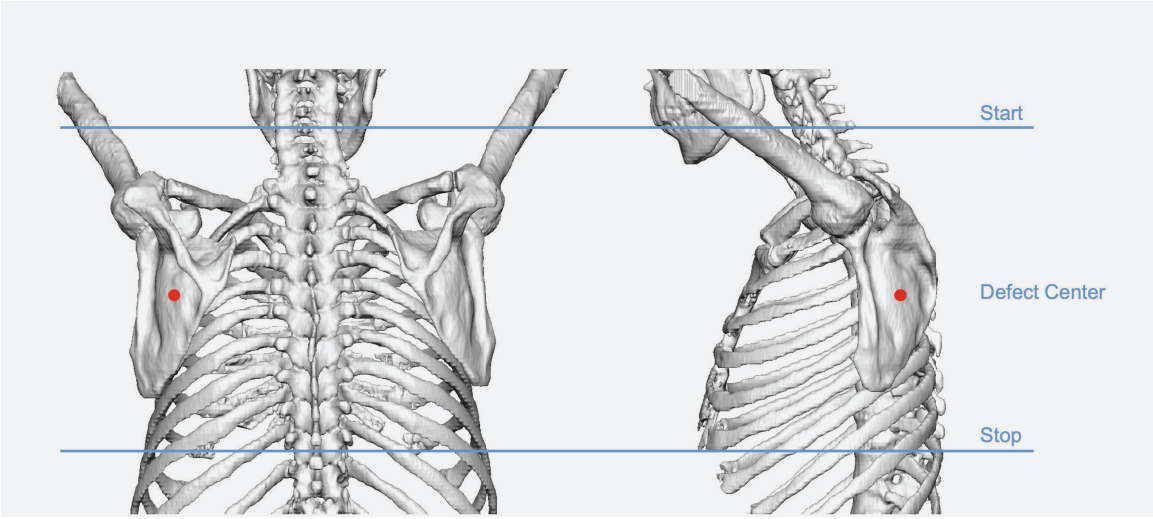
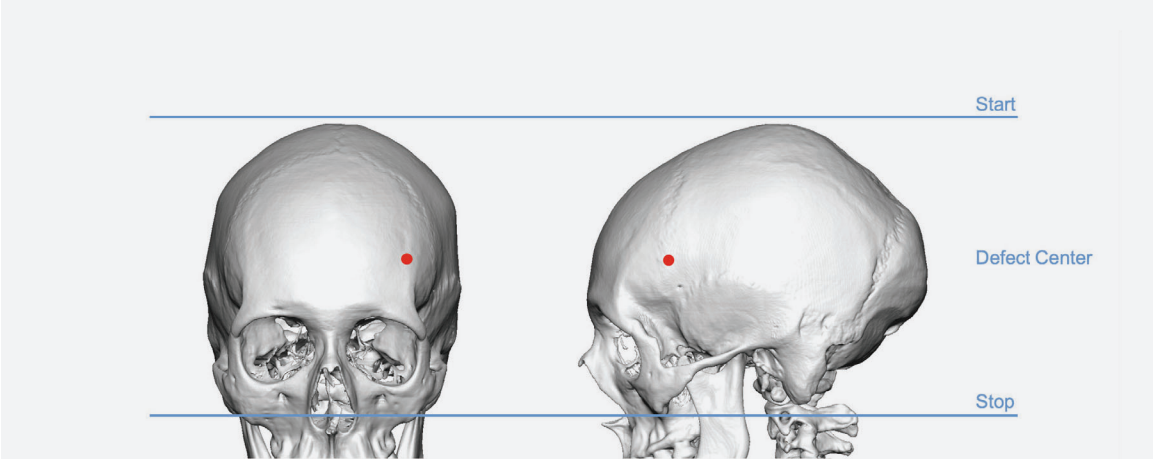
REGION OF INTEREST: SCAPULA – EXAMPLE IMAGE



REGION OF INTEREST: CRANIOMAXILLOFACIAL – EXAMPLE IMAGE



Images not to scale

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KEY POINTS

- Use a 3D scanning routine that provides high-resolution images as would be suitable for image-guided surgery, stereotactic planning, or other 3D applications. **It may be useful to consult with your CT vendor's Application Specialist for advice on optimal parameters for your machine that provide the best scan with acceptable radiation dose levels.**
- Provide images in the original scanning plane. If the 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.
- Do not use gantry tilt during image acquisition. Images acquired with gantry tilt then post-processed to reorient images (i.e. "take out" tilt) are NOT acceptable.
- Ensure that scans are free from motion artifact. Image distortion from patient motion can severely compromise the accuracy of a 3D model or implant.
- Image artifact caused by metallic implants can obscure region of interest. **Take steps to minimize artifact from the presence of metal.**
- Do not encrypt data as some encryption methods do not allow for permanent decryption which may render the DICOM data unusable for 3D processing.
- Acquire scans at a high spatial resolution. Series should be acquired with thin, contiguous image slices **(equivalent thickness and spacing of 1.5mm or less)** and as small a field of view (FOV) as possible while still including the patient's anatomy of interest.
- For requests requiring anatomical recreations, **bilateral scans are strongly recommended.**
- The field of view (FOV) must remain constant throughout scan.
- Start axial scan at least 5.0cm from region of interest (see examples).
- Region of interest should be at least 1.0cm from the border of the field of view to avoid possible border distortion.
- The CT bed Z height must not be altered between slices.

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