Scandinavian Total Ankle Replacement System (STAR™ Ankle)

EN

INSTRUCTIONS FOR USE

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CONTENTS

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ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE

This IFU is for use with devices distributed in the US only. The corresponding OUS IFU is V15160.

1 Overview

The Scandinavian Total Ankle Replacement System (STAR Ankle) is comprised of a Tibial Plate, Mobile Bearing, and Talar Component.
The Mobile Bearing articulates with both the Tibial Plate and Talar Component as shown in the photograph of the three components of the STAR Ankle system below:

The STAR Ankle is designed to replace a portion of the distal tibial and proximal talar bones of the natural ankle joint. The device is designed to allow the patient to regain and/or retain some of his/her normal ankle mobility and function.

2 Components

The three components of the STAR Ankle are described below in **Table 1.**

2.1 Tibial plate

When viewed from the transverse plane, the Tibial Plate has a trapezoidal shape with rounded corners. This component is shaped to conform to the existing anatomy thereby reducing the need to remove excess bone around the joint. On the proximal surface of the Tibial Plate, two parallel cylindrical barrels are positioned equidistant from the center of the plate running anterior to posterior for bone fixation. When viewed from the sagittal plane, the plate is 2.5mm thick. The distal surface of the plate on which the mobile bearing articulates is flat and polished.

The Tibial Plate is surface treated on the bone-opposing surfaces with a titanium plasma spray coating. The Tibial Plate is intended to be press-fit without the use of cement, and should rest on anterior and posterior cortical bone.

2.2 Mobile bearing

The proximal surface of the Mobile Bearing is flat. The distal (talar) surface is concave and has a central radial groove running from anterior to posterior. The walls of the bearing component are straight. A 0.5mm stainless steel x-ray marker wire is placed 2mm from the proximal surface.

2.3 Talar component

The Talar Component is designed as an anatomical prosthesis to cover the talar dome, anterior, posterior, and medial and lateral facets. The Talar Component is designed to minimize the amount of bone that must be removed. From the apex of the dome, the walls slope outwards to conform to the normal bone anatomy. Viewed from the sagittal plane, the proximal surface of the Talar Component is dome-shaped to conform to the talar dome of the natural ankle. A small, raised half-cylindrical ridge runs from anterior to posterior in the medial-lateral center of the dome. The purpose of this ridge is to constrain the medial/lateral motion of the mobile bearing. As with the Tibial Plate, the Talar Component is also surface treated with a titanium plasma spray coating.

Table 1. Description of components

Component	Sizes	Material	Standard
Tibial Plate	Extra Small (30mm x 30mm) Small (32mm x 30mm) Medium (32.5 mm x 35mm) Large (33mm x 40mm) Extra Large (33.5mm x 45mm)	Cobalt-Chromium-Molybdenum Alloy with Titanium Plasma Spray Coating	Co-Cr-Mo (ASTM F75) Coating (ASTM F1580)
Mobile Bearing	Thicknesses of 6, 7, 8, 9 10mm Revision bearings in thicknesses of 11, 12, 13 and 14mm	Ultra-High Molecular Weight Polyethylene (UHMWPe) with stainless steel radiographic marker wires	UHMWPe (ASTM F648) Stainless Steel (ASTM F138)
Talar Component	Extra-extra Small (28mm x 29mm) Extra Small (30mm X 31mm) Small (34mm x 35mm) Medium (36mm x 35mm) Large (38mm x 35mm)	Cobalt-Chromium-Molybdenum Alloy with Titanium Plasma Spray Coating	Co-Cr-Mo (ASTM F75) Coating (ASTM F1580)

3 Indications for use

The Scandinavian Total Ankle Replacement (STAR Ankle) is intended for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis. For detailed information concerning the product(s), please refer to the dedicated operative technique.

4 Contraindications, warnings and precautions

4.1 Contraindications

- Active or prior deep infection in the ankle joint or adjacent bones.
- Skeletal immaturity.
- Bone stock inadequate to support the device including:
  - Severe osteoporotic or osteopenic condition or other conditions resulting in poor bone quality
  - Avascular necrosis of the talus
  - Prior surgery and/or injury that has adversely affected ankle bone quality.
- Malalignment or severe deformity of involved or adjacent anatomic structures including:
  - Hindfoot or forefoot malalignment precluding plantigrade foot
  - Significant malalignment of the knee joint.
- Insufficient ligament support that cannot be repaired with soft tissue stabilization.
- Neuromuscular disease resulting in lack of normal muscle function in the affected ankle.
- Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure.
- Charcot joint or peripheral neuropathy that may lead to Charcot joint of the affected ankle.
- Prior arthrodesis at the ankle joint.
- Poor skin and soft tissue quality at the surgical site.

4.2 Warnings and precautions

⚠ WARNING

- Only implant the STAR Ankle after adequate training and familiarity with the surgical technique manual, to avoid increased risk of device failure due to improper surgical technique.
- Do not use STAR Ankle components in combination with prosthesis components made by other manufacturers, because design, material, or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together.
- To ensure proper implantation of the STAR Ankle, use the instrumentation that is supplied with the system in accordance with the surgical technique manual.
- The trial prostheses **shall** not be implanted.
- Examine instruments for wear or damage before use. While rare, intra-operative instrument breakage may occur. Instruments that have experienced excessive use or force may be susceptible to breakage.
- The safety and efficacy of the STAR Ankle have not been studied in patients weighing > 250 lbs (113kg).
- Always confirm that the patient does not have a possible allergy to the implant/prosthesis material before selecting the STAR implant to minimize the risk of an allergic response.

- Discard all damaged or mishandled implants. Do not reuse implants and components. Although the implant may appear undamaged, it may have small defects and internal stress patterns which may lead to early failure of the device.
- Do not resterilize sterile packaged product. Do not use implants, components or sterile packaged instruments if the package is damaged or has been opened prior to planned use.
- Always exercise care in selecting the proper type and size of implant. Size and shape of the human bone place restrictions on the size and shape of the implant, potentially limiting device function.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load. Correct handling of the implant is extremely important.
- For a minimum of two weeks after surgery, the patient should not bear any weight on the implanted STAR Ankle. Certain vigorous physical activities (e.g., basketball, football) and trauma to the joint replacement may cause early failure of the STAR Ankle. Please refer to the section titled “Post-operative Management” for additional restrictions.
- Appropriate selection, placement and fixation of the STAR Ankle components are critical factors which affect implant service life.
- Improper selection, placement and fixation of the implant components may result in early implant failure. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- Single use is defined as use of one implant or instrument on a single patient in a single surgical procedure.
- Reuse of instruments designated as single use has been associated with necrosis of bone leading to implant failure. It may also lead to sepsis and/or communication of potentially lethal viruses.
- Reuse of implants designated as single use has been associated with sepsis and/or communication of potentially lethal viruses.

5 Patient education

- Warn the patient of the surgical risks, possible adverse effects and possible operative complications that may occur with joint arthroplasty.
- Warn the patient of the limitations of artificial joint replacement devices.
- Caution the patient to protect the joint replacement from unreasonable stresses and to follow the treating physician’s instructions. In particular, warn the patient to strictly avoid high impact activities such as running and jumping.
- Warn the patient that artificial joint replacement devices can wear out over time, and may require replacement.

6 Potential adverse effects of the device on health

Reported device related adverse effects
The most commonly reported adverse effects associated with the STAR Ankle are the following:

- Bone fracture (talus, tibia)
- Pain and nerve injury
- Mobile bearing fracture
- Device loosening (tibial plate, talar component)
- Instability
- Device subsidence.

A complete list of frequency and rate of complications and adverse events identified in the clinical study are provided in the Overall Safety section **(Table 5).**

7 Potential adverse effects

The following adverse effects may occur in association with total ankle replacement surgery including the STAR Ankle:

- Device failure
- Dislocation
- Loosening of any of the components
- Fatigue fracture of the implants
- Peripheral neuropathies, nerve damage, circulatory compromise
- Heterotopic bone formation
- Surgical complications including, but not limited to: vascular disorders, thrombophlebitis, hematoma or damage to blood vessels resulting in blood loss, or death
- Delayed wound healing
- Superficial or deep infection at any point in time post-operatively
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved ankle, and/or amputation of the ankle
- Intra-operative or post-operative bone fracture
- Wear deformation of the articular surface
- Damage to ligamentous, tendinous, and surrounding soft tissues
- Osteolysis and/or other periprosthetic bone loss
- Metal sensitivity reactions or allergic reactions or metallosis
- Limb length discrepancy
- Increased ankle pain and/or reduced ankle function
- Progression of adjacent joint arthritis
- Progressive mal-alignment
- Altered gait.

Any of these adverse effects may require medical or surgical intervention.

8 Clinical studies

One multicenter, prospective pivotal two-year clinical study was conducted to support the safety and efficacy of the STAR Ankle. Data from an additional series of patients (continued access cohort) supplement the results of the pivotal study. The bilateral cohort, composed of patients previously enrolled in the unilateral pivotal or continued access cohort who later developed disease in the contralateral ankle or patients diagnosed with bilateral disease (and excluded from enrollment into the pivotal cohort) also provided supplemental information in support of safety and effectiveness. The three cohorts are summarized in Table 2 below.

Table 2. Patient cohorts for the STAR Ankle in the US

Cohort	Definition	Number of Enrolled	Enrolled Patients
Pivotal	Non-randomized, concurrent, multi-center study to evaluate the safety and efficacy of the STAR Ankle compared to ankle arthrodesis at 2 years	10 STAR Ankle; 5 arthrodesis	158 STAR Ankle patients; 66 arthrodesis control patients
Bilateral	Single-arm multi-center cohort to evaluate the safety of bilateral STAR Ankle implantation	6	21 bilateral STAR Ankle patients
Continued Access	Single-arm, mulit-center cohort to confirm the findings of the pivotal study	10	448 STAR Ankle patients

8.1 Pivotal study

The pivotal study was a multi-center, non-randomized, concurrently controlled non-inferiority clinical study comparing the safety and efficacy of the STAR Ankle to arthrodesis. The control group in the STAR Ankle pivotal study consisted of concurrently recruited arthrodesis patients. A total of 224 patients (158 STAR; 66 arthrodesis), randomized in a 2:1 ratio, were enrolled in the study.
The study eligibility criteria are described in **Table 3.**

Table 3. Study inclusion/exclusion criteria

Inclusion Criteria	Exclusion Criteria
• Moderate or severe pain, loss of mobility and function of the ankle (Buechel-Pappas Scale total score of less than 50 and Buechel-Pappas pain score of 20 or less) • Primary arthrosis, post traumatic arthrosis or rheumatoid arthrosis • At least six months of conservative treatment for sever ankle conditions, confirmed by the patient medical history, radiograph studies and medication record	• Patients who have not reached skeletal maturity • Active or prior deep infection in the ankle joint or adjacent bones • Prior arthrodesis at the involved site • History of prior mental illness • Obesity (weight greater than 250 lbs (113kg)) • History of current or prior drug abuse or alcoholism • Hindfoot malpositioned by more than 35 degrees or forefoot malalignment which would preclude a plantigrade foot • Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure • Avascular necrosis of the talus • Inadequate skin coverage about the ankle joint • Patients under the age of 35 who are unwilling or unable to accept the physical limitations imposed by ankle arthroplasty, including limitations on certain vigorous physical activities (e.g. basketball, football, etc.) and on manual labor. • Juvenile onset Type I diabetes • Adult onset Type II diabetes when accompanied by neuropathic changes or a history of foot infection in either foot. • Pregnancy • Avascular necrosis of the tibia • Significant bone tumor of the foot or ankle • Severe deformity that would not normally be eligible for ankle surgery • Prior surgery and/or injury that has adversely affected the ankle bone stock • Severe osteoporotic or osteopenic condition or other conditions that may lead to inadequate implant fixation in the bone • Insufficient ligament support • Motor dysfunction due to neuromuscular impairment

The inclusion and exclusion criteria for the CA cohort were similar to those for the pivotal cohort except for inclusion of metabolic disorders (e.g., hemachromatosis). The exclusion criteria were also the same, with the exception that “motor dysfunction due to neuromuscular impairment” was expanded to include “motor dysfunction due to neuromuscular impairment, insulin dependent diabetes, peripheral neuropathy, or Charcot changes.”

Eligible patients for inclusion into the bilateral cohort were patients with bilateral disease requiring surgical intervention (and excluded from enrollment into the pivotal cohort) or patients who had either been previously enrolled in the unilateral pivotal or continued access cohorts but who had or later developed disease in the contralateral ankle. Other eligibility criteria were the same as for the pivotal study.

9 Composite clinical success

The primary efficacy endpoint was based on improvement in mean Buechel Pappas (BP) Score. Individual patient success criteria were also defined for efficacy, safety and overall patient success. Efficacy success was based on patient improvement in the Buechel Pappas score. The BP score is based on a 100-point scale consisting of subscales for pain (40 points), function (40 points), range of motion (15 points), and deformity (5 points). Safety endpoint success was a combination of clinical safety and radiographic success. Clinical safety success consists of no major complications (specific adverse events that were treated with surgery) and no revision or removal of the device, while Radiographic safety success was based on radiographic outcomes.

A composite overall clinical success criteria was used for the clinical study where an individual patient was defined as a success if at 24 months they were both an efficacy and safety success based on the following criteria outlined in **Table 4.**

Table 4. Composite success criteria

Inclusion Criteria	STAR	Control (Arthrodesis)
Efficacy Success	Greater-than or equal to 40 point improvement in Buechel Pappas Score	Greater-than or equal 40 point improvement in Buechel Pappas Score
Safety Success	**Clinical Safety Success:** Absence of major complications, device failure, removal/revision **Radiographic Safety Success:** Absence of radiolucencies, tilting or migration > 4mm	Clinical Safety Success: Absence of major complications, revision Radiographic Safety Success: Absence of non-union, mal-union, delayed union
Overall Patient Success	Patients meeting each of the above STAR efficacy and success criteria are considered to be an overall patient success	Patients meeting each of the above control efficacy and success criteria are considered to be an overall patient success

10 Patient accountability and demographics

Patient accountability demonstrated that there were 145 patients (96.7%) patients evaluated in the STAR treatment group and 48 (73.8%) patients in the Control treatment group evaluated at the study endpoint (24 months). There were no significant differences in demographic parameters noted between the two groups except for patient age at time of surgery (STAR mean age = 57.1 vs. 62.7 years for the control group).

11 Continued access and bilateral cohorts

Data for each of these cohorts were collected from multicenter single-arm registries in either patients with unilateral disease (continued access cohort) or bilateral disease (bilateral cohort). The protocols and patient demographics for the continued access and bilateral registries were similar to the pivotal study. At the time of database closure, data were available on 435 continued access patients and 16 bilateral patients. Certain refinements to the surgical technique and to the instrumentation were implemented in the continued access study.

In the Continued Access population, patient follow-up was approximately 92% (408/444) through 12 months and approximately 79% (328/416) through 24 months. There were 5 patient withdrawals from the study. Three (3) patients received a second STAR Ankle in their contralateral ankle and were transferred to the bilateral cohort. Four patients expired during the course of the study, though none of these deaths were considered device-related.

Patient demographics and baseline disease history for the continued access (CA) cohort were largely comparable to those of STAR Ankle patients in the pivotal study. Some differences in primary diagnoses were noted with a higher percentage of post-traumatic arthritis in the CA cohort as compared to the pivotal study (62.1% versus 48.1%) and a lower percentage of primary arthritis (21.5% versus 39.2%). Patients with a primary diagnosis of a metabolic disorder (9.2%) were also treated in the CA cohort.

While the general demographics of the CA cohort were comparable to those of the pivotal cohort, the CA cohort had a higher percentage of post-traumatic arthrosis as the primary diagnosis and a lower percentage of primary arthrosis in comparison to the STAR Ankle population enrolled in the pivotal study.

Data were available on a total of 16 patients in the bilateral study of the STAR Ankle and a total of 27 ankles. Four (4) of the 16 patients reported in this section were originally enrolled in the pivotal study but were transferred to the bilateral arm upon placement of a second STAR Ankle. Two (2) patient deaths occurred by 24 months. Neither of these deaths was considered to be device-related.

Most patient demographics and baseline medical history for the bilateral cohort were similar to those in the pivotal cohort. However, there were a lower percentage of patients with posttraumatic arthritis in the bilateral cohort (13.3% of first and no second bilateral ankles implanted were secondary to posttraumatic arthritis, as compared to 48.1% of pivotal study patients) and a lower percentage of bilateral patients that had surgery to the affected ankle prior to implantation of the STAR Ankle.

12 Primary safety endpoint

As shown in **Table 5**, the safety outcomes for the arthrodesis patients were comparable to the STAR Ankle pivotal patients at 24 months. Safety success was based on clinical success and radiographic success as defined more specifically in **Table 4** above. Some patients were clinically successful in spite of a lack of pre-specified radiographic success criteria.

Table 5. Safety success rates at 24 month

24 Month Success Rates	Pivotal					
	Control			STAR		
	n	N	%	n	N	%
Safety Success Rate	43	52	82.7%	108	142	76.1%

The rates of adverse events in the STAR continued access cohort as a whole were less when compared to the pivotal study, including rates of surgical interventions and major complications.

In addition to the above safety analysis, adverse events occurring up to 24 months at the operative site for both the pivotal and continued access cohorts are provided in **Table 6.**

Table 6. Adverse events and surgical interventions up to 24 months[1]

Adverse Events	Control (N=66)	STAR Pivotal (N=158)	STAR Continued Access (N=416)
Bone fracture[2]	2 (3.0%)	28 (17.7%)	46 (11.1%)
Intra-operative fracture	1 (1.5%)	15 (9.5%)	21 (4.8%)
Medial Malleolus	1 (1.5%)	8 (5.1%)	11 (2.6%)
Fibula	0 (0.0%)	6 (3.8%)	1 (0.02%)
Tibia	0 (0.0%)	1 (0.63%)	5 (1.2%)
Other[3]	0 (0.0%)	0 (0.0%)	4 (1.0%)
Post-operative fracture	1 (1.5%)	14 (8.9%)	26 (6.3%)
Medial Malleolus	0 (0.0%)	7 (4.4%)	14 (3.4%)
Fibula	0 (0.0%)	2 (1.3%)	4 (1.0%)
Tibia	0 (0.0%)	3 (1.9%)	6 (1.4%)
Other[4]	1 (1.5%)	2 (1.3%)	5 (1.2%)
Bony changes	0 (0%)	12 (7.6%)	17 (4.1%)
Pain	32 (48.5%)	69 (43.7%)	139 (33.4%)
Nerve injury	5 (7.6%)	32 (20.3%)	99 (23.8%)
Deep Peroneal Nerve	0 (0%)	9 (5.7%)	22 (5.3%)
Superficial Peroneal Nerve	3 (4.5%)	9 (5.7%)	36 (8.6%)
Medial Branch of the Superficial Peroneal Nerve	1 (1.5%)	6 (3.8%)	3 (0.7%)
Dorsomedial Cutaneous Nerve	0 (0%)	0 (0%)	1 (0.2%)
Posterior Tibial Nerve	0 (0%)	1 (0.6%)	1 (0.2%)
Saphenous Nerve	0 (0%)	1 (0.6%)	3 (0.7%)

Adverse Events	Control (N=66)	STAR Pivotal (N=158)	STAR Continued Access (N=416)
Sciatic Nerve	0 (0%)	0 (0%)	2 (0.5%)
Medial Plantar Nerve	0 (0%)	0 (0%)	1 (0.2%)
Numbness	1 (1.5%)	6 (3.8%)	27 (6.5%)
Wound problem	4 (6.1%)	32 (20.3%)	81 (19.5%)
Surgical intervention	7 (10.6%)	26 (16.5%)	33 (7.9%)
Revision or removal	6 (9.1%)	12 (7.6%)	14 (3.4%)
Other intervention	1 (1.5%)	18 (11.4%)	21 (5.0%)
Major complication	1 (1.5%)	14 (8.9%)	22 (5.3%)
Infection	1 (1.5%)	2 (1.3%)	4 (1.0%)
Bone problem	0 (0%)	8 (5.1%)	13 (3.1%)
Wound problem	1 (1.5%)	5 (3.2%)	7 (1.7%)
Wound problems and infection	0 (0%)	1 (0.6%)	0 (0%)

[1] Not all 435 continued access patients had reached their 24-month follow-up as of the time of database closure. To permit a reasonable comparison to the pivotal study data, with the exception of intra-operative fracture, the adverse event rate for the continued access cohort has been calculated using data from the 416 patients who have reached 24 months post-procedure only. For the comparison of intra-operative fracture rate, all 435 continued access patients were analyzed.
[2] See Table 8 below for a time course distribution of the fracture events in the pivotal study.
[3] The continued access STAR subjects experienced other intra-operative bone fractures as follows: medial tibia (1); posterior malleolus (1); talus (1); lateral malleolus (1).
[4] The control (arthrodesis) subjects experienced one post-operative navicular fracture (1). The pivotal STAR subjects experienced post-operative lateral/posterior malleolus fracture (1) and a fracture (bone unspecified) (1). The continued access STAR subjects experienced other post-operative bone fractures as follows: posterior distal tibia (1); posterior malleolus (1); talus (1); anterior tibia (1); and a fracture (bone unspecified) (1).

The majority of adverse events resolved; some resolved without treatment, while others required treatment. Table 7 summarizes the experience of events requiring surgical intervention. See Table 8 for a time course distribution of the more common adverse events and surgical interventions.

Table 7. Surgical interventions - Summary of interventions up to 24 months

	Control (N=66)	STAR Pivotal (N=158)	STAR Continued Access (N=416)
Surgical Interventions	9	33	43
Patients with Surgical Interventions	7 (10.6%)	26 (16.5%)	35 (8.4%)
Intervention Type			
Revision	3 (4.5%)	11 (7.0%)	10 (2.4%)
Removal	4 (6.1%)	2 (1.3%)	6 (1.4%)
Reoperation	0	8 (5.1%)	7 (1.7%)
Other Intervention	1 (1.5%)	10 (6.3%)	15 (3.6%)
Intervention Class by Subgroup			
Minor Operative Site Procedures	4 (6.1%)	9 (5.7%)	13 (3.1%)
Hardware Removal	4 (6.1%)	1 (0.6%)	3 (0.7%)
Excision Exostosis	0	5 (3.2%)	4 (1.0%)
Minor wound problem	0	3 (1.9%)	4 (1.0%)
Ligament Reconstruction	0	0	3 (0.7%)
Major Operative Site Procedures	3 (4.5%)	19 (12.0%)	14 (3.4%)
Component removal	0	10 (6.3%)	8 (1.9%)
Infection	1 (1.5%)	1 (0.6%)	2 (0.5%)
Fracture fixation (ORIF)	0	2 (1.3%)	4 (1.0%)
Repair nonunion	2 (3%)	0	1 (0.2%)
Fusion, adjacent joint	0	3 (1.9%)	0
Osteotomy for malalignment	0	3 (1.9%)	0
Major Procedure Not Device- Related	2 (3.0%)	3 (1.9%)	10 (2.4%)
Hardware removal	1 (1.5%)	0	0
Fusion, adjacent joint	1 (1.5%)	0	9 (2.2%)
Other		3 (1.9%)	1 (0.2%)

Numbers and rates are patient based
Five (5) patients died during the first 24 months of follow-up, four (4) in the STAR Ankle group and one (1) arthrodesis patient. One STAR patient suffered a fatal pulmonary embolism 7 days post-surgery. Four (4) patient deaths were determined by the study investigators and medical monitors not to be study-related.
Fractures occurred in 17.7% (28/158) of the STAR patients, many of which were intra-operative (9.5% - 15/158), and in 3.0% of the arthrodesis patients. One of these fractures (a medial malleolar fracture) failed to heal within 12 weeks of surgery.
Surgical interventions and major complications (defined as any surgical intervention to the treated ankle that was a result of an infection, wound problem, or bone problem such as osteolysis, cyst formation, or non-traumatic fracture) occurred in a higher percentage of STAR patients (20.3%; 32/158) than in study patients undergoing arthrodesis (10.6%; 7/66). **Table 7** demonstrates that the rate of surgical interventions was higher in the STAR group than in the arthrodesis control group in the pivotal study, and that the rate of interventions in the continued access arm was lower than that in the arthrodesis arm.

The same types of adverse events as seen in the pivotal and continued access cohorts were observed among the 16 bilateral patients for whom data were available at the time of database closure.
Table 8 shows the time course distribution for the more common adverse events and surgical interventions observed in the STAR pivotal trial.

Table 8. Time course of adverse events and surgical interventions up to 24 months (patient basis)

Adverse Events	Intra-operativ		Discharge-6wk		6wk-3mo		3mo-6mo		6mo-12mo		12mo-24mo	
	STAR N=158 n (%)	Control N=66 n (%)	STAR N=158 n (%)	Control N=66 n (%)	STAR N=157 n (%)	Control N=66 n (%)	STAR N=154 n (%)	Control N=66 n (%)	STAR N=151 n (%)	Control N=63 n (%)	STAR N=147 n (%)	Control N=53 n (%)
Bone fracture	15 (9.5)	(1.5)	6 (3.8)	-	2 (1.3)	-	6 (3.9)	-	1 (0.7)	-	2 (1.4)	1 (1.9)
Bony changes	1 (0.6)	-	-	-	-	-	1 (0.6)	-	3 (2.0)	-	8 (5.4)	-
Pain	12 (7.6)	3 (4.6)	12 (7.6)	4 (6.1)	15 (9.6)	1 (1.5)	20 (13.0)	15 (23.4)	17 (11.3)	13 (20.6)	18 (12.2)	10 (18.9)
Nerve injury	9 (5.7)	-	9 (5.7)	1 (1.5)	1 (0.6)	1 (1.5)	9 (5.8)	2 (3.1)	4 (2.6)	1 (1.6)	3 (2.0)	
Wound problem	2 (1.3)	-	28 (17.7)	4 (6.1)	4 (2.5)	1 (1.5)	1 (0.6)	0	-	-	1 (0.7)	1 (1.9)
Surgical intervention												
Revision/ removal	-	-	2 (1.3)	-	2 (1.3)	1 (1.5)	-	2 (3.1)	3 (2.0)	1 (1.6)	6 (4.1)	3 (5.7)
Other intervention	-	-	1 (0.6)	-	-	-	3 (1.9)	-	7 (4.6)	1 (1.6)	7 (4.8)	-

Adverse Events	Intra-operativ		Discharge-6wk		6wk-3mo		3mo-6mo		6mo-12mo		12mo-24mo	
	STAR N=158 n (%)	Control N=66 n (%)	STAR N=158 n (%)	Control N=66 n (%)	STAR N=157 n (%)	Control N=66 n (%)	STAR N=154 n (%)	Control N=66 n (%)	STAR N=151 n (%)	Control N=63 n (%)	STAR N=147 n (%)	Control N=53 n (%)
Major Complication				-								
Infection	-	-	2 (1.3)	-	-	1 (1.5)	-	-	-	-	-	-
Bone problem	-	-	1 (0.6)	-	-	-	2 (1.3)	-	1 (0.7)	-	4 (2.7)	-
Wound problems	-	-	4 (2.5)	-	1 (0.6)	-	-	-	-	-	-	1 (1.9)
Wound problems and infection	-	-	1 (0.6)	-	-	-	-	-	-	-	-	-

13 Primary efficacy endpoint: Total Buechel-Pappas (BP) score

Efficacy success rates based on all data available at 24 months for the pivotal cohort are shown in **Table 9.** As demonstrated in the table, statistically significant differences were noted in efficacy success rates between the STAR Ankle patients at 24 months as compared with the arthrodesis patients ($p<0.001$).

Table 9. Efficacy success rates at 24 months

24 Month Success Rates	Pivotal					
	Control			STAR		
	n	N	%	n	N	%
Overall Patient Success Rate[1]	7	49	14.9	83	142	58.5

[1] Efficacy success is defined as at least a 40 point improvement in Buechel-Pappas Score

Table 10 shows the primary efficacy endpoint results based on the mean Buechel-Pappas score at 24 months and the change in Buechel-Pappas score at 24 months from baseline. Comparisons between groups were made using the Wilcoxon Test, due to the non-normality of the Buechel-Pappas score distribution. All comparisons showed a statistically significantly higher score in the STAR Ankle group when compared with the arthrodesis group ($p<0.001$). The Buechel-Pappas score at 24 months remained statistically significantly higher in the STAR Ankle group when using various imputation methods to account for missing data including a multiple imputation method and a last observation carried forward method.

Table 10. Mean Buechel-Pappas score at 24 months

Buechel-Pappas Score	Pivotal					
	Control			STAR		
	N	Mean	Std Dev	N	Mean	Std Dev
24 Month	47	69.7	16.8	142	81.6	14.0
Improvement at 24 months	47	26.3	17.1	142	40.5	15.1

Prior to surgery, STAR Ankle patients had a higher level of pain than did arthrodesis patients. At all follow-up evaluations, pain levels in both groups dropped. There was a larger improvement in mean STAR Ankle patient pain VAS scores over the course of the study when compared to arthrodesis patients (51.8 (n = 144 STAR patients) versus 44.6 (n = 45 control patients) at 24 months).
As stated above in the discussion of Composite Clinical Success, the BP score allots 15 points to the ankle's range of motion (ROM). STAR pivotal patients experienced a significantly greater ROM relative to the arthrodesis patients (i.e., a 3.6 point improvement in the ROM subscore for the STAR pivotal patients compared to a 3.7 point worsening in the arthrodesis group ($p<0.001$)).

14 Overall patient success

Overall patient success rates based on all data available at 24 months for the pivotal study are shown in **Table 11.** As shown in the table, higher overall patient success rates were determined for the STAR Ankle patients at 24 months as compared with the arthrodesis patients. Higher patient success rates were primarily based on the higher BP component of the composite evaluation formula.

Table 11. Overall patient success rates at 24 months

24 Month Success Rates	Pivotal					
	Control			STAR		
	n	N	%	n	N	%
Overall Patient Success Rate[1]	7	51	13.7 %	70	142	49.3%

[1] See **Table 4** above for the composite success criteria defining overall patient success.

15 Clinical trial summary

Based upon the clinical data, the STAR Ankle showed favorable results when compared to ankle arthrodesis. In the majority of efficacy parameters measured (including overall patient success, total Buechel-Pappas score, 40 point or greater improvement in Buechel-Pappas score), the STAR ankle patient outcomes were non-inferior to the control procedure. In addition, the primary efficacy parameter of mean total Buechel-Pappas Score for the STAR Ankle was shown to be statistically superior to arthrodesis, and the

overall patient success rate was significantly higher in the STAR Ankle group than in the arthrodesis group. Patients receiving the STAR Ankle, which is designed to allow patients to regain and/or retain some of their normal ankle mobility and function, had a significant improvement in the range of motion of the ankle when compared to ankle arthrodesis patients. There was also a greater improvement in mean pain scores for the STAR ankle patients when compared to the arthrodesis patients. Data from the continued access cohort demonstrates lower rates of adverse events, surgical interventions and major complications as compared to STAR Ankle patients in the pivotal study.

16 Surgeon education

It is recommended that surgeons receive training prior to use of this device, which includes information on patient selection and appropriate surgical technique. The goal of the training program is to help surgeons develop the skills and experience with ankle arthroplasty using the STAR Ankle that is key to the success of this procedure as a safe and effective treatment for appropriately selected patients.

17 Post-operative management

For a minimum of two weeks after surgery, the patient should not bear weight on the operated ankle. The patient should keep the ankle elevated as much as possible while limiting all physical activities. Partial weight-bearing may begin at 2 to 3 weeks post-operation and gradually increase until the patient is fully weight-bearing at 4 to 6 weeks post-operation. The ankle cast should typically be removed six weeks post-operation.

18 How supplied

The implant is supplied sterile and is intended for single use only. It is sterilized by gamma radiation at 25kGy minimum.

19 Characteristics

The STAR Ankle System 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 STAR Ankle System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

20 Storage and handling of implant

- The implant is shipped in sterile packaging. The implant may be stored for up to 5 years from the date of its original packaging.
- The implant is sterile until the expiration date printed on the package and must be used before this date.
- The implant should be stored in its original, sealed packaging in clean, dry conditions. Avoid extreme or sudden changes in temperature. Avoid exposure to direct sunlight or dampness.

- Before removing the implants, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants should be considered UNSTERILE and should not be used.
- Upon removal from the package, compare the descriptions on the package with the package contents (product number and size).
- Take particular care that aseptic integrity is assured during removal of the implant from the last packaging.
- Select suitable measures so that the implant does not come into contact with objects that could damage or otherwise affect its surface.
- Damaged implants are no longer functionally reliable.
- Assure that all necessary implant components are available intact.
- Assure that all instruments necessary for the implantation procedure are available intact.

21 Explanation of symbols and abbreviations used on product labels

REF	Catalog Number
LOT	Batch code
	Date of manufacture
	Manufacturer
	Use by date
STERILE R	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Do not use if package is damaged
QTY	Quantity
℞ ONLY	Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician
	Non-sterile
STERILE EO	Sterilized using ethylene oxide
	Keep dry

	Consult instructions for use
	Fragile, handle with care
	Keep away from sunlight
	MR Conditional
	MR Safe
	MR Unsafe