

Scandinavian Total Ankle Replacement (STAR)

Implant package contents provided sterile. Unless marked as sterile, instrument set contents provided non-sterile.

Small Bone Innovations, 1380
South Pennsylvania Ave
Morrisville, PA 19067
Phone: 215-428-1791
Fax: 215-428-1805

Information for Prescribers

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

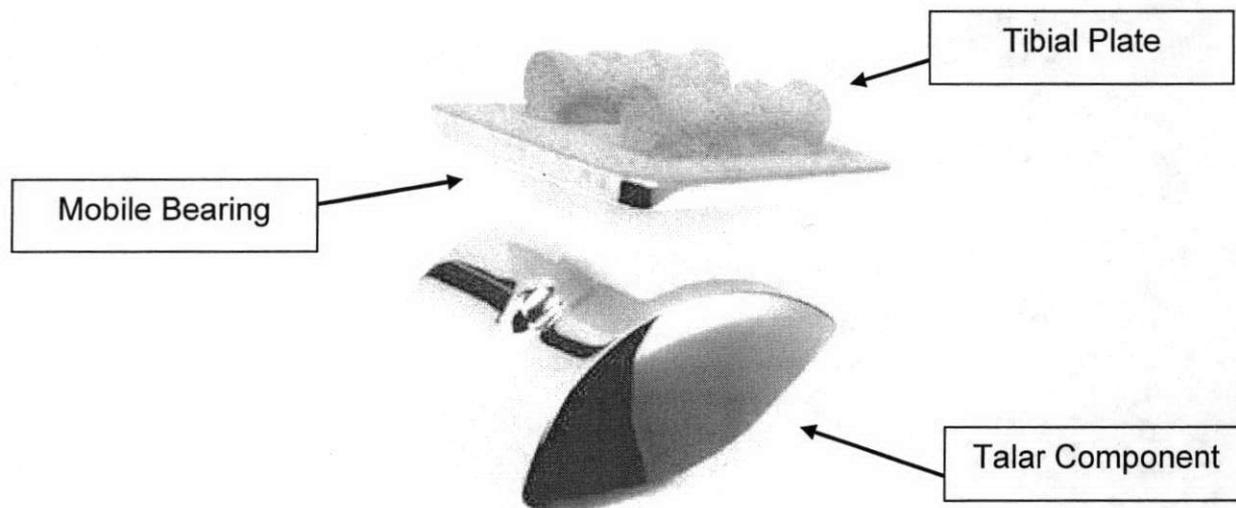
Rev. 9-18-08

Device Description

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.

Components

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

Tibial Plate

When viewed from the top, 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 side, 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.

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.

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 side, 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)	Cobalt-Chromium-Molybdenum Alloy with Titanium Plasma Spray Coating	Co-Cr-Mo (ASTM F75) Coating (ASTM F67)
	Small (32mm x 30mm)		
	Medium (32.5mm x 35mm)		
	Large (33mm x 40mm)		
	Extra Large (33.5mm x 45mm)		
Mobile Bearing	Thicknesses of 6, 7, 8, 9, 10 mm 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 F-138)
Talar Component	Extra-extra Small (28mm x 29mm)	Cobalt-Chromium-Molybdenum Alloy with Titanium Plasma Spray Coating	Co-Cr-Mo (ASTM F75) Coating (ASTM F67)
	Extra Small (30mm x 31mm)		
	Small (34mm x 35mm)		
	Medium (36mm x 35mm)		
	Large (38mm x 35mm)		

Indications for Use

The Scandinavian Total Ankle Replacement (STAR Ankle) is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.

Contraindications, Warnings, and Precautions

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 about 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 about the surgical site

Warnings and Precautions:

- 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 should 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.
- Always determine 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. Do not use implants or components 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.
- Immediately post-operative through two weeks, a 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.

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.

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

Potential Adverse Effects

The following adverse effects are among those that 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 postoperatively.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved ankle, and/or amputation of the ankle..
- Intraoperative or postoperative 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.

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

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 Centers	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, multi-center cohort to confirm the findings of the pivotal study	10	448 STAR Ankle patients

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** below.

Table 3. Study Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • 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 severe ankle conditions, confirmed by the patient medical history, radiograph studies and medication record 	<ul style="list-style-type: none"> • 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) • 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., hemochromatosis). 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.

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 consisted of adverse events and failures of the STAR Ankle, 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

	STAR	Control (Arthrodesis)
Efficacy Success	≥ 40 point improvement in Buechel Pappas Score	≥ 40 point improvement in Buechel Pappas Score
Safety Success	Clinical Safety Success: Absence of major complications, device failure, removal/revision	Clinical Safety Success: Absence of major complications, revision
	Radiographic Safety Success: Absence of radiolucencies, tilting or migration > 4mm	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

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).

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 were 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 was 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.

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 prespecified radiographic success criteria.

Table 5. Safety Success Rates at 24 Months

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 Months¹

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%)
<i>Medial Malleolus</i>	1 (1.5%)	8 (5.1%)	11 (2.6%)
<i>Fibula</i>	0 (0.0%)	6 (3.8%)	1 (0.02%)
<i>Tibia</i>	0 (0.0%)	1 (0.63%)	5 (1.2%)
<i>Other</i> ³	0 (0.0%)	0 (0.0%)	4 (1.0%)
Post-operative fracture	1 (1.5%)	14 (8.9%)	26 (6.3%)
<i>Medial Malleolus</i>	0 (0.0%)	7 (4.4%)	14 (3.4%)
<i>Fibula</i>	0 (0.0%)	2 (1.3%)	4 (1.0%)
<i>Tibia</i>	0 (0.0%)	3 (1.9%)	6 (1.4%)
<i>Other</i> 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%)
<i>Deep Peroneal Nerve</i>	0 (0%)	9 (5.7%)	22 (5.3%)
<i>Superficial Peroneal Nerve</i>	3 (4.5%)	9 (5.7%)	36 (8.6%)
<i>Medial Branch of the Superficial Peroneal Nerve</i>	1 (1.5%)	6 (3.8%)	3 (0.7%)
<i>Dorsomedial Cutaneous Nerve</i>	0 (0%)	0 (0%)	1 (0.2%)
<i>Posterior Tibial Nerve</i>	0 (0%)	1 (0.6%)	1 (0.2%)
<i>Saphenous Nerve</i>	0 (0%)	1 (0.6%)	3 (0.7%)
<i>Sciatic Nerve</i>	0 (0%)	0 (0%)	2 (0.5%)
<i>Medial Plantar Nerve</i>	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 demonstrates that the overall rate of surgical interventions was higher in the STAR group than in the arthrodesis control group in the pivotal study. The rate of interventions in the continued access arm was lower than that in the arthrodesis arm.

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	0	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 intraoperative (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).

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-operative		Discharge-6wk		6wk-3mo		3mo-6mo		6mo-12mo		12mo-24mo	
	STAR	Ctrl	STAR	Ctrl	STAR	Ctrl	STAR	Ctrl	STAR	Ctrl	STAR	Ctrl
	N=158	N=66	N=158	N=66	N=157	N=66	N=154	N=64	N=151	N=63	N=147	N=53
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Bone fracture	15 (9.5)	1 (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)	.
Complication												
ion	.	.	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)

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	%
Efficacy Success Rate ¹	7	47	14.9%	83	142	58.5%

¹Efficacy 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 ($p < 0.001$)). Total ankle replacements are designed to allow ROM, while the intent of arthrodesis is to eliminate ROM.

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*	7	51	13.7%	70	142	49.3%

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

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 ROM of the ankle when compared to ankle arthrodesis, which is designed to eliminate ROM. 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.

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.

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-operative and gradually increase until the patient is fully weight-bearing at 4 to 6-weeks post-operative. The ankle cast should typically be removed six weeks post-operative.

How Supplied

The implant is supplied sterile and is intended for single use only.

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. The recommended storage temperature is 18-20° C with 50-70% humidity. 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.

Sterilization/Resterilization of Instruments

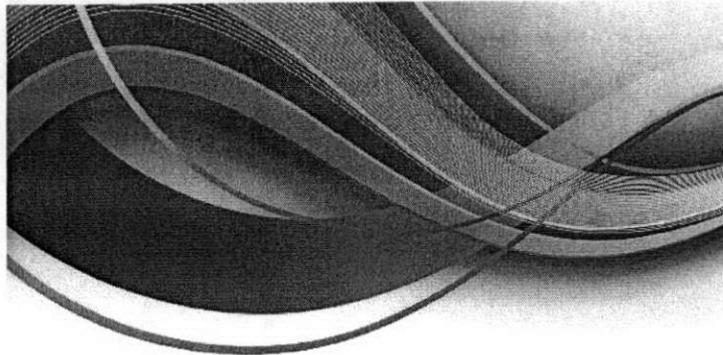
Implantation instruments are provided nonsterile for sterilization by the end user. Instruments can be steam sterilized (autoclaved) using the following validated procedure:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	132°-135° C (137° C maximum)	4 Minutes	30 Minutes

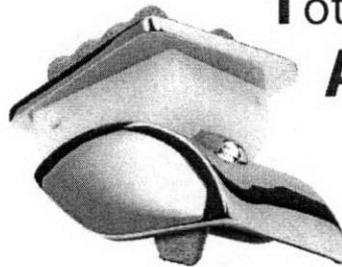
Prior to sterilization, as an essential pre-requisite to ensure effective sterilization, surgical instruments must be cleaned, disinfected, and inspected using a validated procedure after every use. The following validated cleaning/disinfecting procedure is recommended:

- Dry clean-up in the operating room and removal of all visible contamination from the instruments immediately after use;
- Manual pre-cleaning (brushing or ultrasonic) with cold water without any chemical additives;
- Disassemble whenever possible:
 - Remove the plastic connector from the alignment guide
 - Separate the rod from the remainder of the alignment guide
 - Remove the two set screws and disassemble the three remaining components of the guide block
 - Separate the adjustable twist drill from the stop
 - Separate the barrel from the remainder of the depth gauge
- Machine cleaning, consisting of:
 - Cleaning at 50° C to 60° C, using demineralized water and a highly alkaline cleaning agent
 - Rinse with water without chemical additives;
 - Acidic neutralization;
 - Rinse with dematerialized water without chemical additives;
 - Thermal disinfection at 93° C for a minimum of 3 minutes, using dematerialized water and adding a rinsing agent;
 - Drying;
 - Assembly and inspection/performance test of the instruments.

Link Orthopaedics
 300 Roundhill Drive
 Rockaway, NJ 07866
 Phone: 973.625.1333
 Phone: 800.932.0616
 Fax: 973.625.4445
www.linkorthopaedics.com



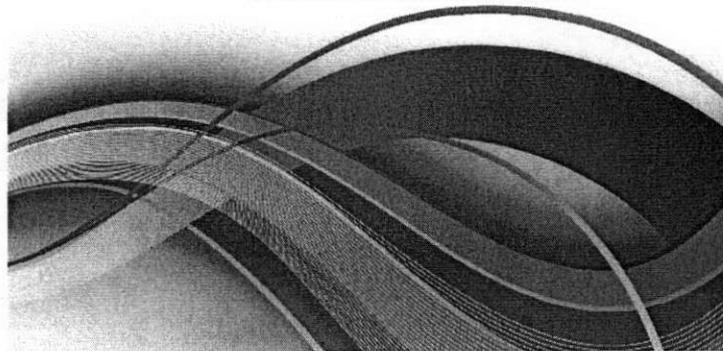
The **S.T.A.R.**[®]
Scandinavian
Total
Ankle
Replacement



Patient Information



SBi
SMALL BONE INNOVATIONS, INC.



Patient Information

This patient education brochure is presented by Small Bone Innovations, Inc.

Patient results may vary. Please consult your physician to determine if this product is right for you.

For more information about SBI's products or prescribing information, including warnings and contraindications, please consult the product labeling summary provided on the back inside cover of this brochure, or visit www.totalsmallbone.com

Page Topic

<i>Glossary of Terms</i>	3
<i>What Should I Know about Ankle Replacement?</i>	4
<i>What Is the S.T.A.R.® Ankle System and How Is It Implanted?</i>	4
<i>For What Conditions is S.T.A.R.® Approved (Indications for Use)?</i>	5
<i>Who Should Not Have the S.T.A.R.® Ankle (Contraindications)?</i>	6
<i>What Warnings Should I Know about When This Device Is Used?</i>	8
<i>What Are Some Precautions and Risks for This Device?</i>	9
<i>What are Some Alternatives to S.T.A.R.® Ankle Replacement Surgery?</i>	9
<i>How Do I Make My Choice for Ankle Therapy?</i>	10
<i>What Short-Term Lifestyle Changes Will I Have to Make?</i>	11
<i>What Long-Term Lifestyle Changes Will I Have to Make?</i>	11
<i>How Do I Know if the S.T.A.R.® Ankle is Working Properly?</i>	12
<i>What Have Clinical Studies Shown About This Device?</i>	12
<i>What Problems May I Expect?</i>	15
<i>When Should I Call My Surgeon?</i>	15
<i>Frequently Asked Questions and Answers about the S.T.A.R.® Ankle</i>	15

Caution: United States federal law restricts this device to sale by or on the order of a physician.

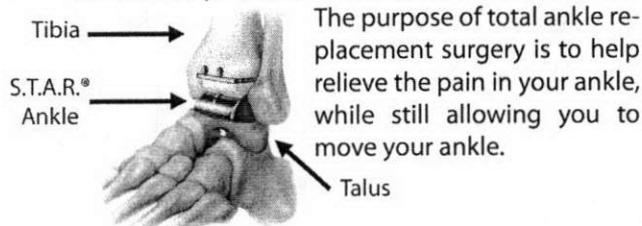
Glossary of Terms

- **Conservative treatment** is a term used to describe any treatment option that does not involve surgery. Conservative treatment options vary depending upon the seriousness of the issue, from pain medications to simple therapies to help lower pain, to physical therapy, ankle foot orthotics, molded ankle braces, and compression stockings.
- **Cortisone** is an artificially produced chemical that reduces swelling of the ankle joint. It is typically injected to help ease pain. It is not injected into the blood stream, but rather into the area of swelling. Cortisone has many different trade names (e.g., Celestone, Kenalog, etc.).
- **Degenerative arthritis ('OA')**, also known as osteoarthritis, is a medical condition in which swelling of the ankle joint results in pain. It is caused by:
 - 1) An abnormal wearing of the cartilage that covers these joints and acts as a cushion inside joints; and
 - 2) A decrease of the fluid that normally 'lubricates' those joints. As the bone becomes less protected by cartilage, patients are likely to have more pain when walking. As a result of this kind of arthritis, the involved joint(s) appear larger, and are stiff and painful. The joints usually feel worse the more they are used throughout the day.
- **Rheumatoid arthritis ('RA')**, unlike OA, is a longer-term disorder that causes the immune system to attack the ankle joint(s). This disease results in stiffness, swelling and damage to the joints. The condition can be disabling and painful, and can lead to loss of mobility. It could even lead to a total breakdown of the joint.
- **Ankle structures** are the supporting ligaments, cartilage and bone surrounding the ankle, which provide support for the ankle's motion.
- **Fuse/fusion/fusing** of the ankle joint refers to a surgery done for the treatment of ankle arthritis, where worn-out joint surfaces are removed. The ankle bones are then held together with metal implants. The bone surfaces then heal in this position. The joint remains stiff after ankle fusion, but the result is usually a pain-free joint.

What Should I Know about Ankle Replacement?

Replacement of the ankle joint with an artificial implant is designed to treat painful conditions of the ankle, such as arthritis. Arthritis is a condition that can take many forms. Your surgeon may have used a different name to describe it. At this time, your ankle does not work properly and is causing you pain. Sometimes, arthritis can be treated without surgery. For example, patients can take pain medicine, or other medicine(s) to treat arthritis and/or using a brace. However, if these types of treatments do not relieve your pain, surgery may be an option.

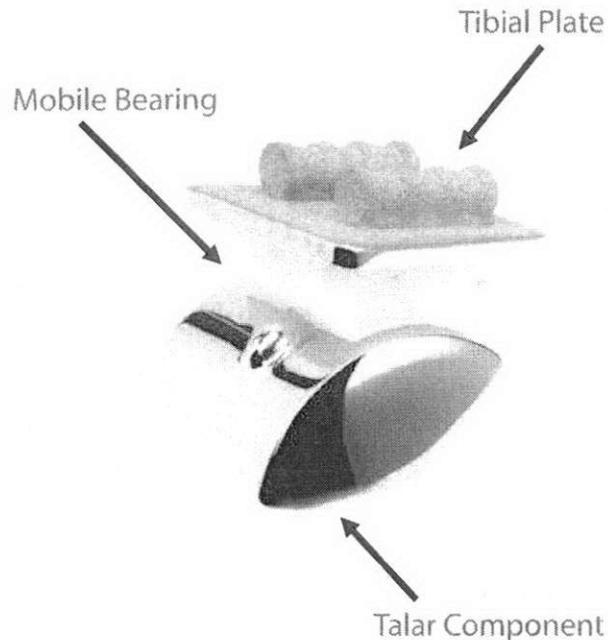
Your surgeon has asked you to consider the replacement of your ankle joint with an artificial implant called the "S.T.A.R.® Ankle." S.T.A.R.® stands for "Scandinavian Total Ankle Replacement." A well-known surgeon in Scandinavia designed this device. "Total" means that your entire ankle joint will be replaced.



What Is the S.T.A.R.® Ankle System and How Is It Implanted?

The S.T.A.R.® Ankle is made up of three parts. The first part covers the lower bone of the ankle joint, a bone called the talus bone. The second part covers the very bottom of your "shin bone." This is the long bone that runs from the bottom of your knee to the top of your ankle. This bone is also called the tibia bone. Both of these parts that cover your bone are made of a metal called cobalt chromium alloy. These parts are coated with another metal, pure titanium, in the places where they actually touch your bone. The third part of the S.T.A.R.® Ankle is called a Mobile Bearing and is placed in between the two metal parts. This part is made out of medical grade plastic called polyethylene. The plastic piece is designed to move in between the metal parts as you move your ankle.

The materials that the S.T.A.R.® Ankle is made of have been used in artificial hips and knees for many years. They have shown to be extremely well accepted by the body.



The S.T.A.R.® Ankle procedure requires the surgeon to make a cut along the front of the ankle to open the ankle joint. Approximately 3/8" of bone is then removed from the ankle joint to make space for the metal and medical grade plastic parts described previously. Unlike other ankle replacement systems, the S.T.A.R.® Ankle does not require the use of bone cement. The surgeon then shapes the bones of your ankle so the S.T.A.R.® Ankle replacement will fit in place.

For What Conditions is S.T.A.R.® Approved (Indications for Use)?

The Scandinavian Total Ankle Replacement (S.T.A.R.® Ankle) is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.

Who Should Not Have the S.T.A.R.® Ankle (Contraindications)?

- If you now have or have had a deep infection in your ankle joint or connected bones. Failing to tell this to your surgeon could lead to serious infection.
- If your problem ankle has already been fused, it is not possible to implant the S.T.A.R.® Ankle.
- If your surgeon does not think that he can get your foot flat to the ground, the S.T.A.R.® Ankle may not work correctly and could fail, break, loosen or cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.
- If your ankle is too deformed for ankle replacement, the S.T.A.R.® Ankle may not work correctly and could fail, break, loosen or cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.
- If there is not enough blood getting to the bones of your foot, implanting a S.T.A.R.® Ankle may cause additional damage to your bones, or the ankle replacement may fail to attach to your bones. This may lead to the need for additional treatment, including surgery to remove the ankle replacement.
- If you have nerve problems around the ankle and you cannot feel the position of your ankle or pain in your ankle or foot, this may lead to stress on the ankle that could damage the S.T.A.R.® Ankle. This damage may cause the implant to fail, loosen or break, or may cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.
- If you have poor bone quality that may not let the S.T.A.R.® Ankle attach to your bones, placing a S.T.A.R.® Ankle could cause more damage to your bones which may cause the implant to break, loosen or fail. This could lead to the need for additional treatment,

including surgery to reposition or remove the ankle replacement.

- If you have poor support from your ankle ligaments that your surgeon cannot fix. This could lead to stress on the S.T.A.R.® Ankle that could cause the implant to fail, loosen or cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- If your bones are not fully grown, putting in the S.T.A.R.® Ankle could damage your bones so that they do not fully grow.

- The clinical investigation of the S.T.A.R.® ankle was limited to patients weighing no more than 250 pounds. Therefore, if you weigh over 250 pounds, the clinical study does not show results for patients whose weight is similar to your weight.

- If you have poor skin and soft tissue quality around the surgical site. The operation to place the S.T.A.R.® Ankle could further damage your skin and soft tissues. This may require additional treatment, including surgery to try and repair or heal the soft tissues around your ankle, or possibly remove the ankle replacement.

- If you have had prior surgery and/or injury that has caused excessive damage to the bones in your ankle. Placing a S.T.A.R.® Ankle could cause further damage to your bones that may cause the implant to break, loosen or fail. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- If you have a medical condition resulting in the lack of normal muscle function around your problem ankle. If you do not have normal ankle muscle function, this may lead to stress on the ankle joint. This stress may damage the S.T.A.R.® Ankle. This could cause the implant to fail, loosen or break, or may cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- If you have emotional problems that may not allow you to cooperate before and after surgery. You are unable to follow the pre- and post-operative instructions and to keep the follow up appointments necessary for successful healing and for prevention of additional treatment or surgery.

- If your knee is too crooked to place the ankle replacement in the proper position, the S.T.A.R.® Ankle may not work correctly. It could fail, loosen or break, or cause damage to your bones. This could lead to the need for additional treatment. This may include surgery to reposition or remove the ankle replacement.

What Warnings Should I Know about When This Device Is Used?

The following conditions may lead to severe issues when undergoing a S.T.A.R.® Ankle replacement. Each must be discussed with your surgeon.

- Any known allergies to metals. Such allergies may cause an allergic reaction to the materials used in this device.

- Premature or excessive weight bearing on the S.T.A.R.® Ankle before the supporting bones are healed. This may result in failure of the ankle replacement. Please also see the section titled "What Short-Term Lifestyle Changes Will I Have to Make?" for additional information about weight bearing after surgery.

- Ongoing changes in your medical condition, including recent surgery. You and your surgeon will need to decide if your medical condition or surgery could make it more likely that the S.T.A.R.® Ankle may break, loosen or fail, or that your bones may be damaged. This could lead to the need for additional treatment, including surgery.





What Are Some Precautions and Risks for This Device?

The S.T.A.R.® Ankle requires special training for successful implantation. Please ask your surgeon whether he or she has been trained to implant the S.T.A.R.® Ankle.

It is important to follow your surgeon's advice regarding which activities you should not do after undergoing a S.T.A.R.® Ankle replacement. This advice will likely include no running, jumping, or heavy work. Not following this advice may result in early failure or loosening of the ankle replacement. It may also result in breakage of a bone which might require additional surgery.

What Are Some Alternatives to S.T.A.R.® Ankle Replacement Surgery?

You should discuss other methods for treating your ankle pain with your surgeon. Treatments for ankle arthritis range from a variety of conservative treatment methods to surgery. Initial treatment includes arthritis medicine(s), avoiding painful activities and using a specialized ankle brace. Physical therapy may be beneficial in some cases. A cortisone injection into the ankle joint may also help to relieve the pain, although usually this treatment is a temporary measure. When conservative therapy fails to relieve patient symptoms, surgical intervention may be recommended. One surgical procedure to relieve your ankle pain is to stop the movement of your ankle by fusing (joining) the ankle bones together. This surgery is referred to as "ankle fusion" or "arthrodesis".

There are different methods that can be used for ankle fusion. These methods involve using screws or other metal "hardware" to hold the ankle still until the bones around the joint grow together. Once an ankle is successfully fused, it never moves again. Another option for treating your ankle pain is a total ankle replacement, either with the S.T.A.R.® Ankle or with a different device. With all ankle replacements, the ankle joint is replaced by a prosthetic device, which attempts to mimic the movement of the ankle. Currently, there are several ankle replacements other than the S.T.A.R.® Ankle available in the United States (U.S.). **The S.T.A.R.® Ankle differs from other ankle replacements in that it uses a mobile bearing versus a fixed bearing and does not require the use of bone cement during implantation.**



How Do I Make My Choice for Ankle Therapy?

You should discuss total ankle replacement using the S.T.A.R.® Ankle with your surgeon. You should also discuss other methods, such as fusion surgery, for treating your ankle pain. Please ask your surgeon any questions you have so that you will make the best decision. It is important to fully understand the risks and benefits of each type of treatment before you make your decision.

What Short-Term Lifestyle Changes Will I Have to Make?

To prepare yourself for surgery, you may be asked to lose weight if you are overweight. Smokers will need to stop smoking 2 weeks before surgery.

For the first two weeks after surgery, you will likely not be able to bear any weight on your ankle. You need to keep your ankle elevated as much as possible and limit your activities. Once you are in your removable cast, you can do more activities, including walking. Over the next month you will be gradually allowed to go back to your normal daily activities. For all of these steps, however, you need to follow the specific advice of your surgeon.



What Long-Term Lifestyle Changes Will I Have to Make?

After an ankle replacement you can do as much walking and swimming as you are comfortable with. You can also participate in sports that do not put too much force on your ankle (called "non-impact athletics"), such as golf and hiking. You should not run, jump, perform heavy lifting or manual labor unless specifically allowed by your surgeon. These types of activities may cause the S.T.A.R.® Ankle replacement parts to wear out prematurely, loosen or even break. Ask your surgeon about specific activities that you are interested in. Things that you can do to increase the life of the S.T.A.R.® Ankle replacement include keeping your weight down and not smoking.

How Do I Know if the S.T.A.R.® Ankle is Working Properly?

For the first two weeks after surgery it is normal to have a moderate amount of pain. You may need to use pain medicine(s). This pain will slowly decrease over time, but it is not unusual to experience some discomfort for up to three months and swelling may continue for up to a year after surgery.

Contact your surgeon right away if at any time you notice:

- Fluid leaking from your wound;
- Redness around your wound;
- Pain or swelling that starts suddenly (especially after an ankle twist or fall); or
- Severe pain after the initial two weeks following your surgery.



What Have Clinical Studies Shown About This Device?

The clinical studies show the S.T.A.R.® Ankle is reasonably safe and effective for the treatment of ankle arthritis. One multicenter pivotal two-year clinical study was conducted to compare the safety and effectiveness of the S.T.A.R.® Ankle to ankle fusion. A total of 224 patients (158 S.T.A.R.®, 66 fusion) were enrolled in the study. Data from an additional series of 448 S.T.A.R.® Ankle patients (continued access cohort) were enrolled to add to the results of the pivotal study. All patients enrolled in these studies had ankle arthritis and failed six months of conservative therapy. In all studies, each patient's pain was recorded as well as how well their ankle functioned before and after the surgery.

In the pivotal study, the S.T.A.R.® Ankle showed favorable results when compared to ankle fusion. S.T.A.R.® patients had superior effectiveness compared to ankle fusion and had comparable safety results compared to ankle fusion. Outcomes for ankle range of motion and improvement in pain were shown to be better in S.T.A.R.® Ankle patients. Patient satisfaction at 2 years with the S.T.A.R.® Ankle was good to excellent in 86% of patients, compared to 85% of fusion patients. The continued access cohort also had favorable results further supporting the safety and effectiveness of the S.T.A.R. Ankle. In the continued access cohort, fewer patients needed a second operation compared to the pivotal study, which is most likely attributed to experience and improvements in the S.T.A.R.® ankle surgery technique. The clinical outcomes between the S.T.A.R.® Ankle and ankle fusion differ because the S.T.A.R.® Ankle is intended to preserve range of motion while ankle fusion is intended to prevent ankle motion.

Ask your surgeon for more details about the clinical study and its results and see the following section which describes the types of problems you may encounter.

What Problems May I Expect?

Like other joint implants, the S.T.A.R.® Ankle will wear with time and may need a replacement part, may need to be replaced or your ankle joint fused. The life span of the S.T.A.R.® Ankle is not easy to estimate, and depends on many things. This may include your body type, and any defect of your ankle joint and the activities in which you take part. If you are overweight, smoke, or take part in activities that put stress on your ankle, the life span of the S.T.A.R.® Ankle may be shorter.



The most common problems observed in the company's clinical studies were pain, nerve injury, wound healing problems, and bone fracture. Many of these problems occurred during the surgery to implant the device and did not affect the good to excellent clinical results seen with the S.T.A.R.® Ankle.

Following ankle replacement surgery, pain is often experienced while your ankle is healing. In the Pivotal Trial, 22% of S.T.A.R.® Ankle patients experienced pain during the period from just after surgery to three months after surgery. By 24 months after surgery, 12% of the patients reported pain. Of the patients reporting pain at 24 months, nearly all had less pain than before their ankle replacement surgery.

During ankle replacement surgery, nerve injuries including numbness around the surgical scar sometimes occur. In the S.T.A.R.® Ankle Pivotal Trial, 12% of patients reported a nerve injury during the period from just after surgery to three months after surgery. After that early post-operative period, the number of patients reporting a nerve injury was lower. By 24 months after surgery, only 2% of the patients reported a nerve injury or numbness. Nerve injury is not a common event during or after fusion surgery.

At any point during the 2 year Pivotal Trial, 18% of patients reported a bone fracture related to the S.T.A.R.® Ankle; half of these fractures occurred during surgery and were taken care of by the surgeon at the time of surgery. Other fractures occurred during the weeks following surgery. By 24 months after surgery, all but 1% of fractures were healed.

Following ankle replacement surgery, wound problems sometimes occur. In the S.T.A.R.® Ankle Pivotal Trial, 20% of patients experienced a wound problem during the period from just after surgery to three months after surgery. By 24 months after surgery, less than 1% of these problems persisted.

Based on two year results, problems with the S.T.A.R.® Ankle that required additional surgery occurred in about 17% of patients in the Pivotal Trial; about 8% involved the replacement or removal of all or part of the S.T.A.R.® Ankle. Of the ankle fusion patients, 11% required an additional surgery. In the continued access cohort, 8% of patients required an additional surgery; about 3% involved the replacement or removal of all or part of the S.T.A.R.® Ankle.

When Should I Call My Surgeon?

If at any time you notice fluid leaking from your wound or redness around your wound, you need to contact your surgeon right away. Also, if pain, severe pain, or swelling, not present before starts suddenly, please contact your surgeon immediately.

Will My Implant Set off a Metal Detector?

Due to the metal in your ankle replacement, MRI and metal detectors may be affected. A patient ID card will be provided to you by the manufacturer through your surgeon. The card will identify you as having a total ankle replacement that may activate these devices. You need to show this card when getting x-rays and MRIs. When passing through an electronic detection system you may use this card to notify security of your implant.

Frequently Asked Questions and Answers about the S.T.A.R.® Ankle

Q: How long will I be in the hospital after surgery?

A: Most patients are in the hospital for two or three days. Some patients have shorter stays in the hospital. However, a small number of patients may stay in the hospital for longer than five days.

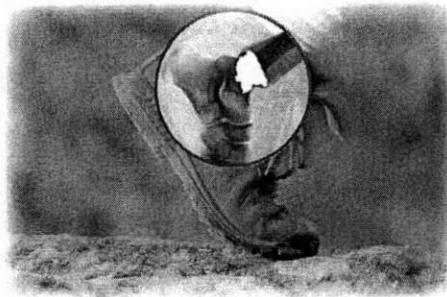


Q: Will my activity be restricted after surgery?

A: Typically, prior to putting any weight on your ankle, you will use crutches or a walker for a minimum of two weeks after surgery. Your doctor will let you know when you can begin putting some of your weight on your ankle. If your surgeon allows, you can put full weight on your ankle about four weeks after the operation. In most cases, your cast will be removed six weeks after the operation.

Q: Have the materials in the S.T.A.R.® Ankle been used in the human body before?

A: Yes, the S.T.A.R.® Ankle device uses the same materials (i.e., cobalt chromium alloy, titanium, and polyethylene) that have been used for the last 30 years in artificial hip and knee replacements.



Q: What are the similarities and differences between the S.T.A.R.® Ankle and fusion?

A: The S.T.A.R.® Ankle replacement is designed to maintain as much of your ankle's normal range of motion as possible while relieving your pain. Fusing the ankle hopes to relieve your pain by restricting the ankle's range of motion. Pain is common and occurred at similar rates in S.T.A.R.® and ankle fusion patients in a two-year study following surgery. There is also a slightly greater chance for reoperation with the S.T.A.R.® Ankle based on the results of this two year study. However, providing ankle motion allows you to perform your daily activities with more normal body motion. It is generally believed that providing ankle motion places less stress on your body as a whole.

Q: What will I be permitted to do after I have recovered from the ankle surgery?

A: After an ankle replacement, you can do as much walking and swimming as you like. You can also do as much non-impact athletics as you like, such as golf. You should not run, jump, perform heavy lifting or manual labor unless your surgeon allows it. These types of activities may cause the S.T.A.R.® Ankle to wear out prematurely, loosen or break. This may require further therapy, including surgery, to correct. Ask your surgeon about specific activities that you are interested in.

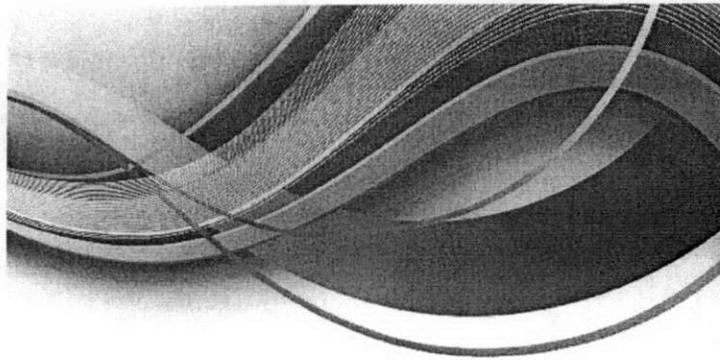
Q: What are the similarities and differences between the S.T.A.R.® Ankle and other ankle replacements?

A: During all total ankle replacement surgeries, metal components replace the bone surfaces in your ankle. In the S.T.A.R.® Ankle, the two metal parts are separated by a piece of polyethylene (a medical grade plastic) which moves between both metal parts. This polyethylene piece is called a Mobile Bearing, and helps to maintain the normal motion of the ankle as you do daily activities like walking and going up and down stairs. All other ankle implants in the United States have the plastic attached to one of the metal parts. The S.T.A.R.® Ankle is the only ankle replacement used in the United States that attaches directly to your bone without the need for bone cement. Ankle implants, other than the S.T.A.R.® ankle, require the use of bone cement, a type of grout, to attach the implants to the bone.

LIMITED WARRANTY

Implants

SBi warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. SBi does not warrant the outcome of the surgical procedure.



SBi

SMALL BONE INNOVATIONS, INC.

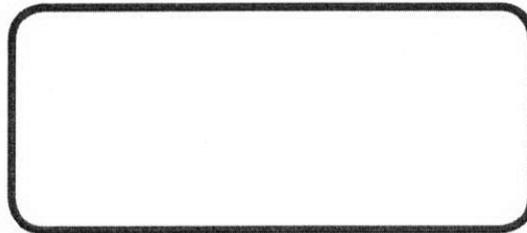
Small Bone Innovations, Inc.

1380 So. Pennsylvania Avenue
Morrisville, PA 19067

Customer Service: 800-778-8837

Fax: (215) 428-1795

www.totalsmallbone.com



Copyright © Small Bone Innovations, Inc. 2009. All rights reserved.

MKT 16020 Rev. D 6/09

