

S.T.A.R.®

Surgical Technique



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Description

Overview

The S.T.A.R.® Ankle system includes three functional components, and a set of customized accessory instruments that are used in the surgical procedure.

The three principal components of the prosthesis are:

- a metal tibial component with a highly polished flat articulation surface, and two cylindrical fixation bars positioned on its back side for anchoring the implant in the subchondral bone of the tibia.
- an ultra high molecular weight polyethylene mobile bearing featuring a plane surface to articulate with the Tibial Component and a concave undersurface articulating with the convex Talar Component.
- a metal talar component available in five different sizes for the right and left sides.

The mobile bearing articulates on the tibial and talar metal implant surfaces, as shown in the photograph of the three components of the S.T.A.R.® Ankle system below:

The S.T.A.R.® Ankle is designed to replace a portion of the tibial and talar components of the normal ankle joint, while preserving range of motion as much as possible. There are two bearing surfaces in the S.T.A.R.® Ankle:

(1) the interface between the upper side of the mobile bearing and the facing surface of the tibial plate, and (2) the interface between the lower surface of the mobile bearing and the facing surface of the talar component. The tibial plate has one flat surface and one surface with two raised cylindrical barrels oriented in the anterior / posterior direction. The upper flat surface of the mobile bearing slides against the flat surface of the tibial plate. The projecting cylinders of the tibial plate serve to fix the device to bone at the distal tibia. The lower surface of the mobile bearing is concave, fitting against the convex upper surface of the talar component. The mobile bearing design of the device is intended to reduce the shear and torque forces on the bearing, which can lead to loosening of either metal component, and to decrease stress at the metal / bone interface. The sloped sides are designed to improve the weight bearing characteristics of the talar component.

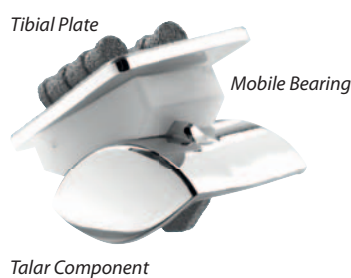
Components

Tibial Plate

When viewed from the top, the tibial plate has a trapezoidal shape with rounded corners. This component is manufactured from cobalt chromium molybdenum (CoCrMo) per ASTM F-75 and ISO 5832-4. This wedge is shaped to conform to the existing anatomy and, thereby, reduces the need to remove excess bone from inside 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. These cylinders must be inserted into hard subchondral bone.

When viewed from the side, the plate is 2.5 mm thick. The distal surface of the plate on which the mobile bearing articulates is flat and polished. The flat surface is designed to match the distal tibial cut.

Tibial plates are available in five sizes with varying widths and lengths: extra-small (30 mm × 30 mm), small (32 mm × 30 mm), medium (32.5 mm × 35 mm), large (33 mm × 40 mm), and extra large (33.5 mm × 45 mm).



The tibial plate is coated on the bone-opposing surfaces with a titanium plasma spray with a double titanium plasma spray and calcium phosphate coating. The tibial plate is intended to be press-fit without the use of cement, and should rest on anterior and posterior cortical bone. Also there are tibial plates in same sizes available to be used cemented when needed. Cemented implants are not coated.

Mobile Bearing

The polyethylene mobile bearing is manufactured from Ultra High Molecular Weight Polyethylene ("UHMWPE"), which is machined from medical grade extruded plate stock and conforms to to ASTM F-648 and ISO 5834-2. The proximal surface of the mobile bearing is flat. The distal or talar surface is concave and has a central radial groove running from anterior to posterior. The walls are straight, and a 0.5 mm stainless steel x-ray marker wire is placed 2mm from the proximal surface. The wall height varies to provide spacer thicknesses of 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm. Revision mobile bearings are available in sizes in sizes of 11 mm, 12 mm, 13 mm, 14 mm, 15 mm and 16 mm.

Talar Component

The talar component is designed as an anatomical prosthesis to cover the talar dome, anterior, posterior, and medial and lateral facets. Like the tibial plate, this component is manufactured from CoCrMo. 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. The component is offered in five sizes: extra-extra-small (28 mm × 29 mm), extra-small (30 mm × 31 mm), small (34 mm × 35 mm), medium (36 mm × 35 mm), and large (38 mm × 35 mm), and in both left and right-sided configurations.

Viewed from the side, the proximal surface of the talar component is dome-shaped to conform to the talar dome of the normal 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 available for cementless use with a titanium plasma spray and a calcium phosphate coating as well as for cemented use without coatings.

Indications / Contraindications

Indications

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

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 / Precautions

- Only implant the S.T.A.R.® 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 S.T.A.R.® 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 S.T.A.R.® 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 S.T.A.R.® 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 S.T.A.R.® 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 S.T.A.R.® Ankle. Certain vigorous physical activities (e. g., basketball, football) and trauma to the joint replacement may cause early failure of the S.T.A.R.® Ankle. Please refer to the section titled “Post-operative Management” for additional restrictions.
- Appropriate selection, placement and fixation of the S.T.A.R.® 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.

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.



Surgical Procedure

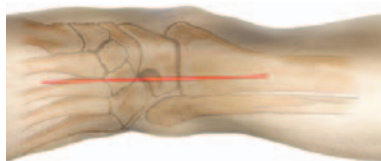


FIGURE 1



FIGURE 2

A small bump is placed beneath the ipsilateral hip to rotate the ankle so that the line of the medial malleolus is perpendicular to the operating table. After the foot and ankle have been correctly positioned, the leg is elevated for about 2 minutes, and a high thigh tourniquet is inflated with an appropriate amount of pressure for the size of the patient's leg and foot. A longitudinal 20 cm incision is centered over the ankle immediately lateral to the anterior tibial tendon (FIGURE 1). The incision is deepened to the ankle joint while retracting the extensor hallucis longus and the neurovascular bundle laterally (FIGURE 2).

The superficial branch of the peroneal nerve in the foot is visible and must be retracted carefully to the lateral aspect of the ankle. It is frequently necessary to sacrifice one small branch of this nerve that innervates the great toe. The tendon sheath of the extensor hallucis longus is now incised in line with the skin incision. Every effort is made to avoid opening the tendon sheath of the anterior tibial tendon, since this may cause difficulty in closure. After the tendon sheath of the extensor hallucis longus is opened, the deep peroneal nerve and artery are identified and are gently retracted. The ankle capsular tissues are incised in line with the skin incision and then are elevated and mobilized exposing the medial malleolus, and lateral malleoli. If the capsule is of sufficient quality save it to close over the prosthesis. It is important to avoid the release of the anterior talofibular ligament as this may lead to lateral instability. The ankle joint is distracted slightly, and hypertrophic synovium, intraarticular loose bodies or periarticular spurs are resected. Osteophytes on the anterior distal tibia are removed to visualize the tibial plafond.

Self-retaining retractors should be avoided when possible, to eliminate excess pressure on the skin edges. Hand retractors should be frequently repositioned to minimize the risk of tissue trauma.

Placement of the Tibial Alignment Guide

A 3.2 mm self drilling pin is inserted into the anterior tibial tubercle and perpendicular to the long axis of the tibia. The proximal portion of the tibial alignment guide is positioned over this fixation pin and the superior screw on the guide is tightened, locking the tibial alignment guide superiorly. The tibial cutting guide is positioned on an adjustable bar. (FIGURE 3) The guide is extended half of the length of the bar to allow for proximal and distal adjustments depending upon how much of the plafond requires resection. The distal aspect of the tibial alignment guide is positioned on the bar approximately 5 mm proximal to the tibial plafond. (This will allow a cut just proximal to the proximal extent of the articular surface.)

A T Guide can be inserted into the cutting block to aid in assessing the rotational and varus / valgus orientation of the tibial cutting guide (FIGURE 3). An osteotome can also be placed along the medial gutter of the ankle joint to aid in visualization when setting proper rotational orientation of the guide. Attach the parallel alignment rod to the midportion of the tibial alignment guide to confirm that the tibial alignment guide is parallel to the tibial diaphysis in both A/P and lateral planes with use of the C-arm (FIGURE 3). The distal portion of the alignment guide is secured with the use of 2.4 mm drill pins. Initially, secure the guide with a single pin to allow varus/valgus adjustment. Then placed at least two additional pins staggered to avoid stress riser in the Tibia and at least one oblique pin to affix the guide securely to the bone. The level of the tibial resection is checked with the use of the angel wing (FIGURES 4, 5, 6).

The angel wing is placed in the cutting slot of the tibial resection guide to set the cutting guide for a minimum of 5 mm distal tibial resection. There are 7 pegs each extending 5 mm from the central blade of the angel wing that are used to gauge the amount of tibial resection. For reference, the pegs are spaced every 10 mm's. The inferior tip of the closest peg is adjusted (using C-arm lateral view) to align with the most superior aspect of the distal tibial plafond (FIGURE 5). This adjustment is made by using the gear key on the tibial cutting guide, dialing it distal or proximal. The set screw is then tightened to lock the guide prior to cutting.

(In very loose ankle joints, there may be increased ability to distract the talus inferiorly. In this case, the surgeon may choose to remove only 4 mm of bone from the distal tibia. With a very tight ankle joint, where there is little ability to distract the talus distalward, one may need to resect 6 or 8 mm of distal tibial bone.)

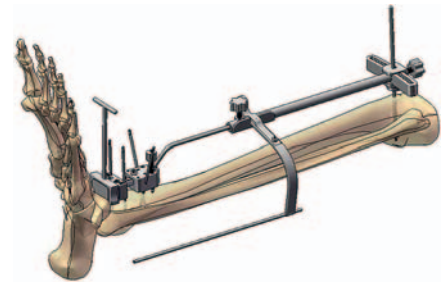


FIGURE 3

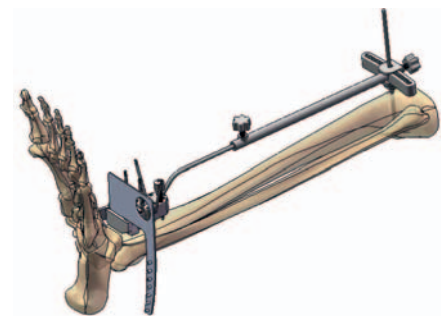


FIGURE 4

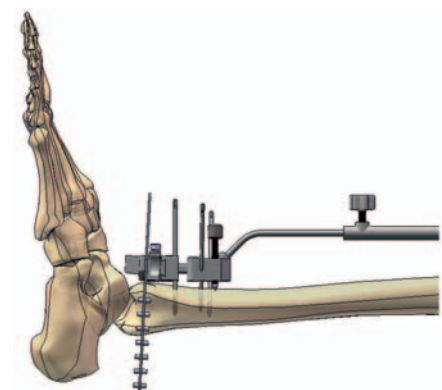


FIGURE 5

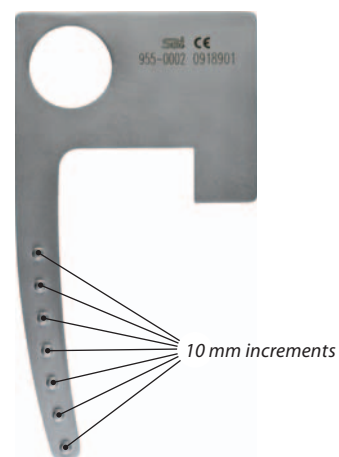


FIGURE 6 | Angel Wing

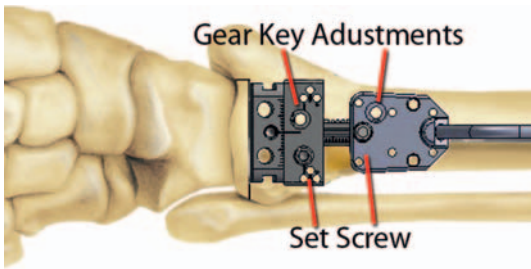


FIGURE 7



FIGURE 8 | Gear Key

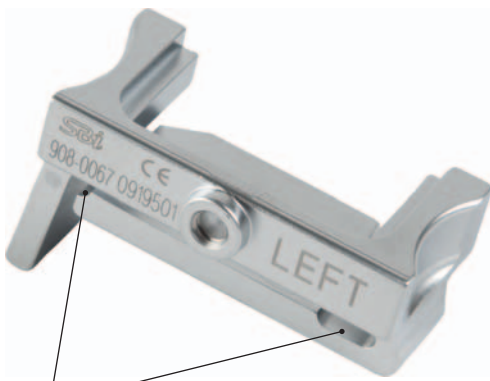


FIGURE 9a | Holes for pins to protect malleoli

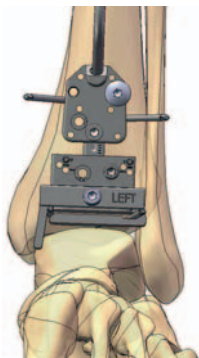


FIGURE 9b

Placement of the Tibial Alignment Guide

Medial and lateral adjustment of the cutting guide is done using the gear key to minimize the risk of notching either of the malleoli. (FIGURES 7 & 8). If additional stability is needed to secure the cutting guide 2.4 mm pins are placed in the most proximal pin holes. There are additional pin holes situated in two millimeter increments proximally. If additional tibial resection is necessary, the cutting guide can be moved proximally and secured on these pins. The saw capture is next placed on the distal tibial cutting guide. And the medial pin is placed in the slot defining the end of the tibial cut and protecting the medial malleolus from notching. The lateral pin is then placed angled toward the center of the tibia to protect the fibula from notching. (FIGURES 9 & 10)

At this point, it is recommended to insert two K-wires into the medial malleoli to help prevent accidental fracture.

The transverse distal tibial cut is then made. The saw should be directed at a 90 degree angle to the long axis of the tibia (FIGURE 10). Angling of the saw either medially or laterally may lead to notching of the malleoli if protecting pins are not used. Following this, a reciprocating saw is used to cut upward in a proximal direction along the inner edge of the medial malleolus to connect the transverse tibial osteotomy. Care should be taken not to penetrate too deeply with the saw blade during the transverse or vertical saw cuts.

All resected tibial bone is removed. This may be done as a single piece, or more commonly in several smaller pieces. The resection is checked using both AP and lateral fluoroscopic views to insure resection of the distal tibia is complete and at the appropriate angles.

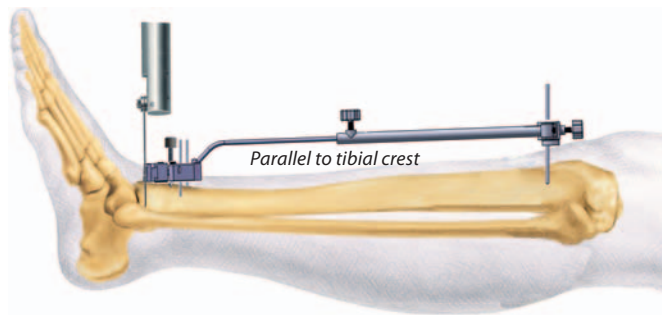


FIGURE 10

Preparation of the Talus

The appropriate talar cutting guide is next inserted onto the tibial alignment guide. (FIGURES 11 a / b & 12). The goal of the talar resection is to remove approximately 4 mm of bone from the talar dome. During the initial talar cut, the foot is held in a neutral or slightly plantigrade position as the talus is pushed cephalad against the prepared surface of the tibia (or the tibial spacer block). Cutting guides of size "1", "2" and "3" corresponds to 2 mm, 4 mm and 6 mm thickness of the spacer respectively. Size "1" can also be marked as 2 mm, Size "2" can also be marked as 4 mm and Size "3" can also be marked as 6 mm.

Care should be taken to hold the foot perpendicular to the long axis of the tibia. Holding the foot and ankle in excessive dorsiflexion will shift the final position of the talar implant anteriorly. Holding the foot and ankle in excess plantarflexion will result in positioning the talar component posteriorly.

During talar dome resection, it is important to protect the malleoli. Pins can be placed in the ends of the cutting slot and malleable retractors or other angled retractors can be placed in the medial and lateral gutters.

The angel wing can also be used here to verify the correct position of the talus prior to placement of fixation pins. Fixation pin holes are available on the medial and lateral aspects of the talar cutting guide to aid in maintaining the position of the talus during the talar osteotomy. After the osteotomy of the talus is completed, the bone fragment of the talar dome is removed and the joint is evaluated to assess the space following removal of both tibial and talar articular surfaces. A joint space evaluator instrument is placed into the prepared joint space. (FIGURE 13) One end of the instrument measures 12 mm while the other end measures 9 mm. The 12 mm end of the joint space evaluator is positioned between the cut surfaces. A minimum of 12 mm is required as this is the space required for a 6 mm bearing with tibial and talar implants. If the 12 mm joint space evaluator does not fit, further tibial resection is required. The tibial cutting guide has pin holes marked for 2 mm and 4 mm recuts. (FIGURE 14) The cutting guide can be repositioned, and additional bone resected.

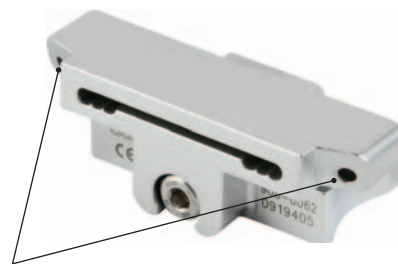


FIGURE 11 a | Pin holes for securing position of block relative to talus



FIGURE 11 b | Tibial spacer block for joints sizes "1", "2" and "3" are available

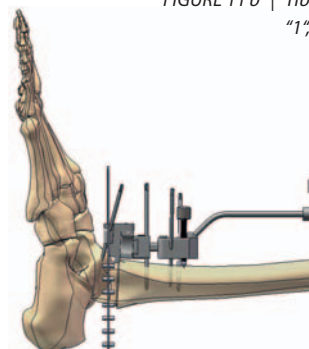


FIGURE 12

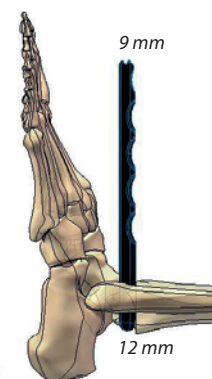


FIGURE 13 | Joint space evaluator

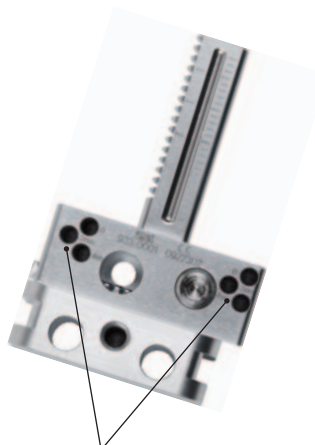


FIGURE 14 | Pin holes for recuts



FIGURE 15



FIGURE 16a

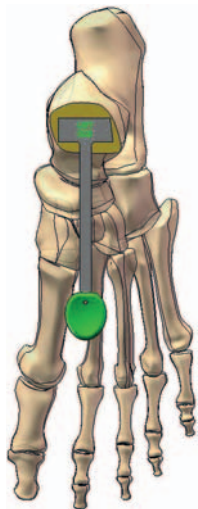


FIGURE 16b

Preparation of the Talus

After insuring there is enough space for at least a 6 mm polyethylene bearing, the foot is plantar flexed to achieve better exposure of the talus. The talar sizer (FIGURE 15) is centered on cut surface of the dorsal talus to confirm that there is a minimum 12 mm A/P depth on this cut. (FIGURE 16 a / b, Table 1) (All of the talar implants have a 12 mm inside Anterior/Posterior dimension. The medial/lateral width varies depending upon the size of the talar component).

An appropriate sized talar component for a patient will leave 3 mm of exposed talar surface on both the medial and lateral sides of the guide.

Using a skin marker, outline the anterior corners of the talar sizer to aid in placement of the appropriate size datum.

The above chart shows the outside dimensions of the talar components. A measurement of the distance between malleoli may be taken to ensure the appropriate size is selected. When the measurement is in-between sizes, select the smaller size.

Talar Component Outside Largest Dimension					
	XXS	XS	S	M	LG
ML Dimension	28	30	34	36	38
AP Dimension	29	31	35	35	35

Table 1

Next select the appropriate size datum (FIGURE 17) and mount it on the datum holder/distractor. (FIGURE 18)

The holder / distractor with the datum attached is inserted into the ankle joint. (FIGURE 18) The datum is positioned within the outline marked on the talar from the sizer. Confirm the handle of the distractor is in line with the second metatarsal. This appropriately aligns the talar rotational position. Next using the C-arm, a lateral fluoroscopic view is obtained to confirm that the posterior top corner of the datum is beneath the center of the tibial prepared surface. The posterior top corner of the datum represents the center of the talus. Compress the handle on the distractor to firmly hold the datum in place. (FIGURE 18) Using shoulder pins, (FIGURE 19) the datum is secured to the talus. Start with the shortest pin (10 mm). If the datum needs to be repositioned or if the bone quality is poor, move to the longer pins. Pins should be advanced slowly into the bone using the pin driver (FIGURE 20) and the last few turns should be done by hand to avoid stripping the threads in the bone.

It is critical at this point to insure that the datum is securely fixed, as your next four cuts are all based off of the position of the datum. (FIGURE 21)

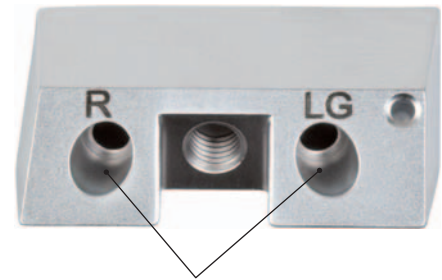


FIGURE 17 | Holes for threaded fixation pins with shoulders

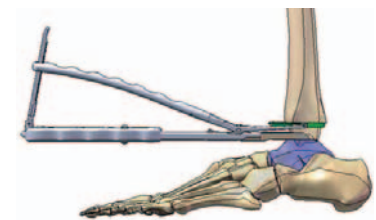


FIGURE 18



FIGURE 19

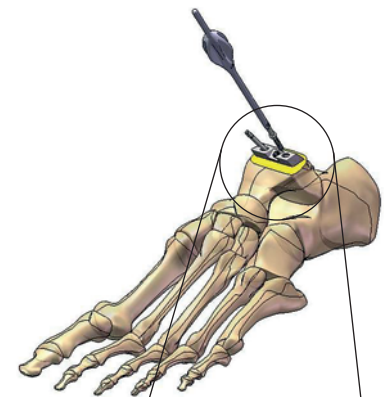


FIGURE 20

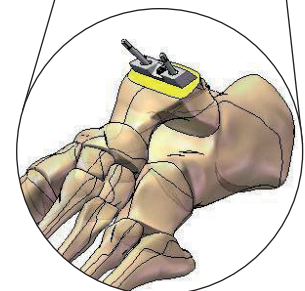


FIGURE 21



FIGURE 22 | A/P Talar Cut Guide

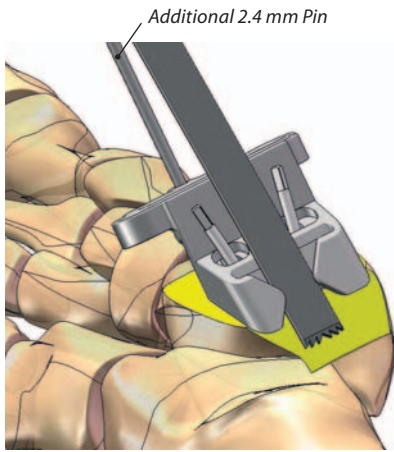


FIGURE 23



FIGURE 24 | Anterior talar mill:
Use with wire driver, drill or TPS

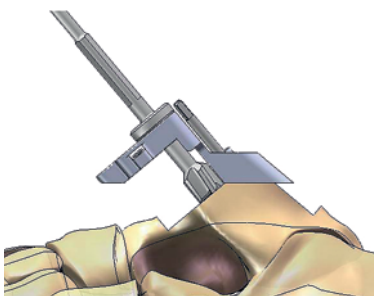


FIGURE 25

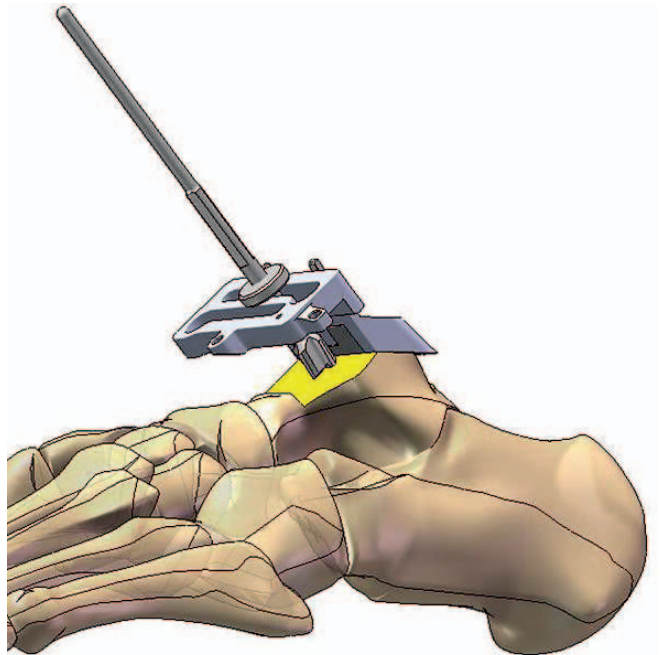


FIGURE 26

Anterior / Posterior Cut Guide

The posterior talar cut can be completed with or without the A/P talar cut guide. (FIGURE 22) When using the A/P talar cutting guide it is attached to the datum using the locking bolt. (FIGURE 23) An Additional 2.4 drill tip pin can be placed in the center for additional support if required. After this cut is completed, attention is directed to the anterior aspect of the talus.

The anterior talar mill (FIGURE 24) is used to prepare the anterior aspect of the talus. The mill is inserted until the collar abuts the A/P cutting guide. (FIGURE 25) A sweeping motion is made through both of the superior / inferior windows in the talar cutting guide to remove the anterior bone. (FIGURE 26) Take care to protect the soft tissues surrounding the medial and lateral aspects of the talus while using the mill. The A/P cutting guide, and all bone fragments are now removed.

Medial / Lateral Cut Guide

Next, the M/L talar cut guide (FIGURE 27) is secured to the datum using the locking bolt. Using the reciprocating saw with the depth marking (FIGURE 28), the medial and lateral edges of the talus are cut.

The saw blade is advanced only to the depth indicated by the marking on the saw blade to minimize risk of soft tissue damage. (FIGURE 29) Ideally 2 to 3 mm of bone is removed from the medial and lateral sides of the talus. The cuts should penetrate distally about 10 mm on the medial side, and about 17 mm on the lateral side. The blade is rotated until the top edge of the saw blade lines up with the line on the M/L talar cut guide. (FIGURES 30 a/b) The blade is advanced anteriorly to complete the cut.

Be cautious not to “lever” the blade too firmly against the guide and risk loosening of the fixation pins. Additional pin fixation holes may be used for extra stability if necessary.



FIGURE 27 | M/L Cut Guide: Additional pin fixation holes if necessary

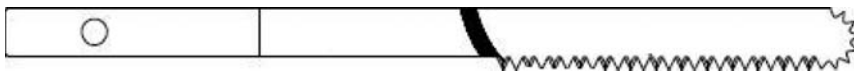


FIGURE 28 | Saw Blade with Depth Marking

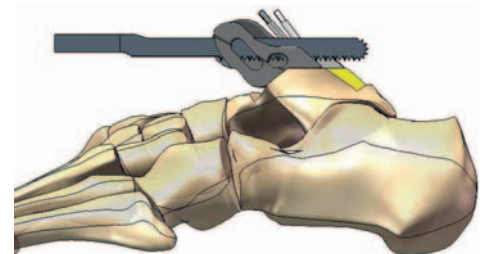


FIGURE 29

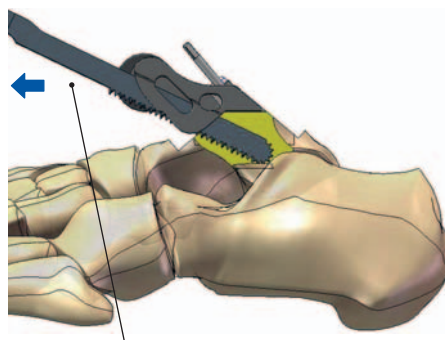


FIGURE 30 a | Move anterior to complete cut

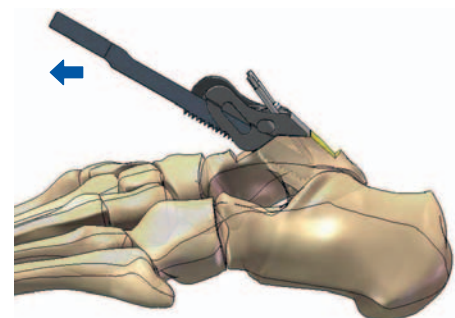


FIGURE 30 b



FIGURE 31 a



FIGURE 31 b



FIGURE 31 c

Use of the Extra Small (XS) and Extra Extra Small (XXS) talar instruments

Because of the small size, the datum is incorporated into the guides for the XS and XXS talar resection guides. (FIGURES 31 a/b)

The talar sizer is used to mark the orientation of the talar component. (FIGURE 31 c) Next the A/P cutting guide with datum (one piece) is loaded on the forceps. (FIGURE 32 a) It is positioned in line with the second metatarsal and centered medial-laterally. Next a lateral view on the C-arm is taken to ensure placement of the A/P cutting guide directly over the center of the talus. The A/P guide is now secured with threaded shoulder pins, and the posterior cut is made with the oscillating saw. Next the anterior surface is milled.

The A/P guide is removed using the pin driver. The M/L guide is loaded on the forceps and placed on the talus. (FIGURE 32 b) The guide will sit flush against the milled anterior surface. (FIGURE 32 c) Make sure the M/L guide is centered in the Medial and Lateral plane. (FIGURE 32 b) Pin it in place using the shoulder pins. (FIGURE 32 d) Make the medial and lateral cuts as previously described.



FIGURE 32 a



FIGURE 32 b

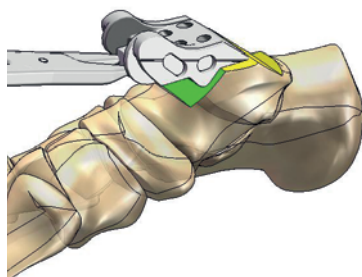


FIGURE 32 c



FIGURE 32 d

The talar window trial is used to check that all talar cuts are complete and accurate. (FIGURES 34 a7b) If the window trial does not fit, the bone rasp is used to remove excess unresected bone. (FIGURE 37)

Preparation of the Keel

Place two 2.4 mm pins in the anterior holes on talar window trial for additional stability during keel preparation. (FIGURE 35) The straight keel mill (FIGURE 36) is placed in the center slot of the window trial. The mill can be utilized with a drill or wire driver. The straight mill is pushed into the talar surface until it is flush with the stop on the mill and moved anteriorly on the slot. (FIGURES 37 a/b)



FIGURE 33 | Rasp

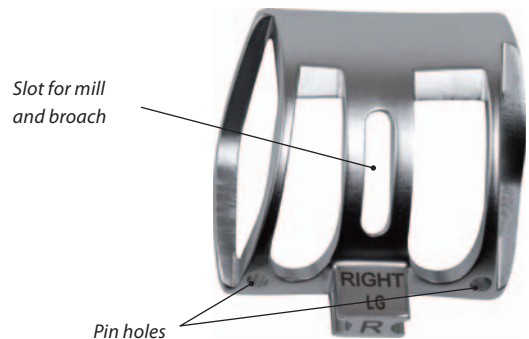


FIGURE 34 a | Window Trial



FIGURE 34 b



FIGURE 35



FIGURE 36 | Keel Mill

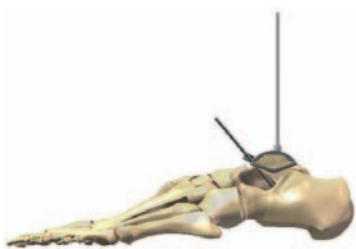


FIGURE 37 a



FIGURE 37 b



FIGURE 38

The talar window trial is removed, and the keel broach is used to finish preparation of the keel slot. (FIGURE 38) When the keel broach is properly inserted to depth its angled top surface will align in the same plane as the posterior cut and the vertical face lines up with the edge formed by the intersection of the anterior and superior cut surfaces. (FIGURE 39)

Replace the talar window trial to protect the talar cut surface during the final tibial preparation.

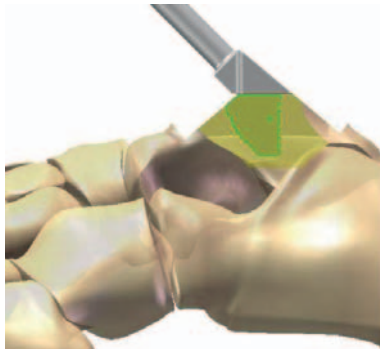


FIGURE 39



FIGURE 40

Final Tibial Preparation

Use the ruler to measure the anterior-posterior dimension of the cut surface of the tibia. Determine the appropriate size of the tibial component such that the component will rest on cortical bone on both the anterior and posterior aspects of the tibia. (TABLE 2)

The tibial size chosen is independent of the talar component size. The corresponding barrel guide is placed against the prepared tibial surface in the position that gives best anterior and posterior cortical coverage. The barrels need to be lined up in the M/L plane to be centered over the talar component. (FIGURE 41 a/b) A joint space evaluator, bearing trial, or joint space distractor may be used to apply pressure to the tibial barrel guide to keep it flush against the prepared tibial surface. (The bearing trial allows easier access for drilling the barrel holes). The height adjustment pin is used to help stabilize the barrel guide while it is pinned with 2.4 mm pins. The superior most pin may later be used to help guide the Tibial component insertion (FIGURE 46 b). The barrel holes are drilled down to the stop using the 6.5 mm drill bit. After drilling the first barrel hole, place the barrel hole plug in the hole to insure precise spacing as the second hole is prepared. After drilling the barrel holes, the key hole broach is inserted into the barrel hole guide to remove the excess bone between the barrel hole and the distal tibial surface. (FIGURE 42)

All of the talar and tibial preparation is completed at this point. One can now assess the balance of the joint, and ligament tightness by doing trial reductions using the trial bearings.



FIGURE 41 a

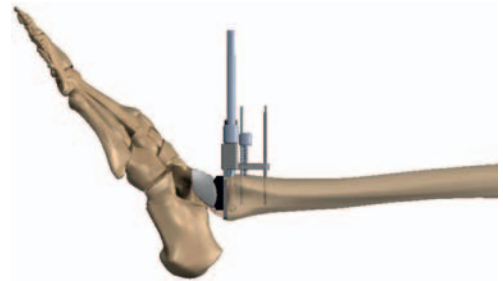


FIGURE 41 b

Tibial Components					
	XS	S	M	L	XL
Width	30	32	32,5	33	33.5
Depth	30	30	35	40	45

Tabel 2

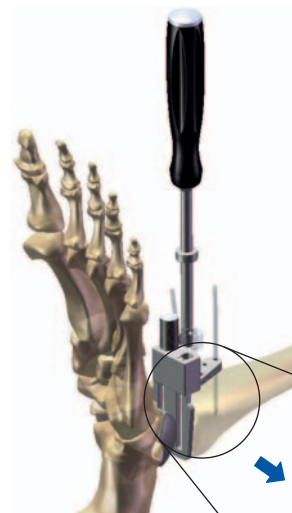
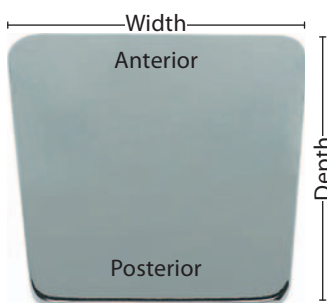


FIGURE 42 a

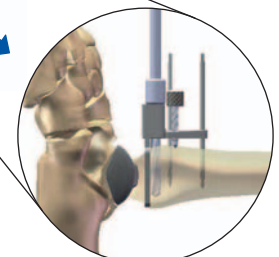


FIGURE 42 b



FIGURE 44 | Joint Space Evaluator with Notched End



FIGURE 45 (shows cementless use of implant)



FIGURE 46 a (shows cementless use of implant)



FIGURE 46 b (shows cementless use of implant)

Talar Component Implantation for cementless use of Implants

The talar component keel is inserted over the anterior chamfer into the prepared keel slot. The implant is moved posteriorly so that the posterior edge of the keel aligns with the posterior edge of the prepared slot. The notched end of the joint space evaluator is placed on the anterior edge of the talar component for support during impaction. (FIGURE 44) The talar impactor is then used to evenly seat the implant. (FIGURE 45)

Tibia Component Implantation for cementless use of Implants

Next the tibial component is mounted onto the tibial inserter locking it securely with the thumb screw. (FIGURE 46 a) The tibial component is inserted into the barrel holes, making sure the barrels are correctly aligned with the prepared holes. A mallet is used to gently drive the tibial component down to its ideal position. As the tibial component is being impacted, be sure it does not separate from the tibial cut. This can be accomplished by placing a poly trial against the tibial component after it has been driven down about half way. The anterior edge of the component should be flush with the anterior tibial cortex. A sponge is placed over the talar component to protect it while inserting the tibial component. Once the tibial implant is fully seated the thumb screw of the inserter is loosened and the tibial impactor is removed. Mobile bearing trials are then used to assess the appropriate height (6 - 10 mm) for a trial reduction and to evaluate joint tension. After a satisfactory reduction is accomplished, the trial bearing is replaced by the appropriate final mobile bearing implant.

Closure

The entire wound is irrigated with antibiotic solution and, if needed, a closed suction drainage system is placed. The deep tissue and extensor retinaculum are closed in an interrupted fashion. The subcutaneous tissue is closed. Skin edges are approximated with an interrupted skin closure. A sterile compression dressing and posterior splint is applied with the ankle in a neutral position.

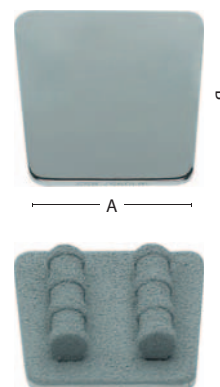
Implant Dimensions

Tibial Components

Material: CoCrMo Alloy

Components for cementless use are double coated with titanium plasma spray and calcium phosphate.

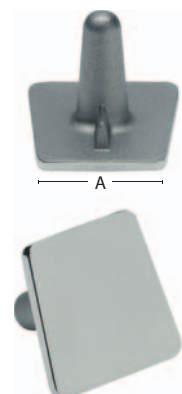
Item No. Cementless	Size	A mm	B mm
400-230	X-Small	30	30
400-231	Small	32	30
400-232	Medium	32.5	35
400-233	Large	33	40
400-234	X-Large	33.5	45



Item No. Cemented	Size	A mm	B mm
400-128	X-Small	30	30
400-130	Small	32	30
400-132	Medium	32.5	35
400-134	Large	33	40
400-136	X-Large	33.5	45

Revision Tibial Components

Item No. Cemented	Size	A mm	B mm
400-300	X-Small	30	30
400-302	Small	32	30
400-304	Medium	32.5	35
400-306	Large	33	40
400-307	X-Large	33.5	45



Mobile Bearings

Material: UHMWPE and Stainless Steel

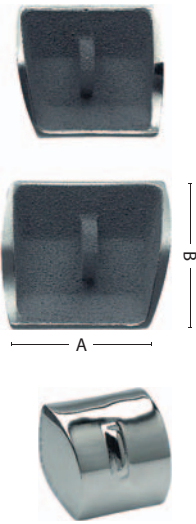
Item No.	Height	Item No.	Height
Primary		Revision	
400-140	6 mm	99-0028/11	11 mm
400-141	7 mm	99-0028/12	12 mm
400-142	8 mm	99-0028/13	13 mm
400-143	9 mm	99-0028/14	14 mm
400-144	10 mm	99-0028/15	15 mm
		99-0028/16	16 mm



Talar Components

Material: CoCrMo Alloy

Components for cementless use are double coated with titanium plasma spray and calcium phosphate.



Item No. Cementless	Size	Side	A mm	B mm
400-211	XX-Small	Right	28	29
400-213	X-Small	Right	30	31
400-215	Small	Right	34	35
400-217	Medium	Right	36	35
400-219	Large	Right	38	35
400-212	XX-Small	Left	28	29
400-214	X-Small	Left	30	31
400-216	Small	Left	34	35
400-218	Medium	Left	36	35
400-220	Large	Left	38	35

Item No. Cemented	Size	Side	A mm	B mm
400-097	XX-Small	Right	28	29
400-099	X-Small	Right	30	31
400-101	Small	Right	34	35
400-103	Medium	Right	36	35
400-105	Large	Right	38	35
400-098	XX-Small	Left	28	29
400-100	X-Small	Left	30	31
400-102	Small	Left	34	35
400-104	Medium	Left	36	35
400-106	Large	Left	38	35

Postoperative Treatment

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 unless a ligamentous reconstruction was carried out, in which case the cast is left on for a total of 8 weeks.

Obtaining X-ray

Suggestions for obtaining X-rays for patient follow-up:

All X-rays should be taken using image intensification to provide straight frontal and lateral views. In the frontal views, the cylindrical anchoring segments of the Tibial Glide Plate must show as circular dots. The X-ray marking wire in the Sliding Core must form a straight horizontal line parallel to the Tibial Component. The Talar Component with its lateral wings appears as a rectangle where both the medial and the lateral part of the joint can be seen into. In the lateral projection, the Tibial Component should render the distal plateau as a straight line. The Talar Component shows only a straight line. The Talar Component shows only a straight view of one side wing of the Talar Cap.

Additional Information

More detailed information about our implants can be supplied upon request.

Materials used for our orthopaedic implants:

- CoCrMo alloy, ISO 5832-4/ASTM F75
- Commercially Pure Titanium, ASTM F1580
- Stainless Steel, ISO 5832-1/ASTM F138 / ASTM F139
- UHMWPE, ISO 5834-2/ASTM F648
- Calcium phosphate coating, ASTM F1609

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