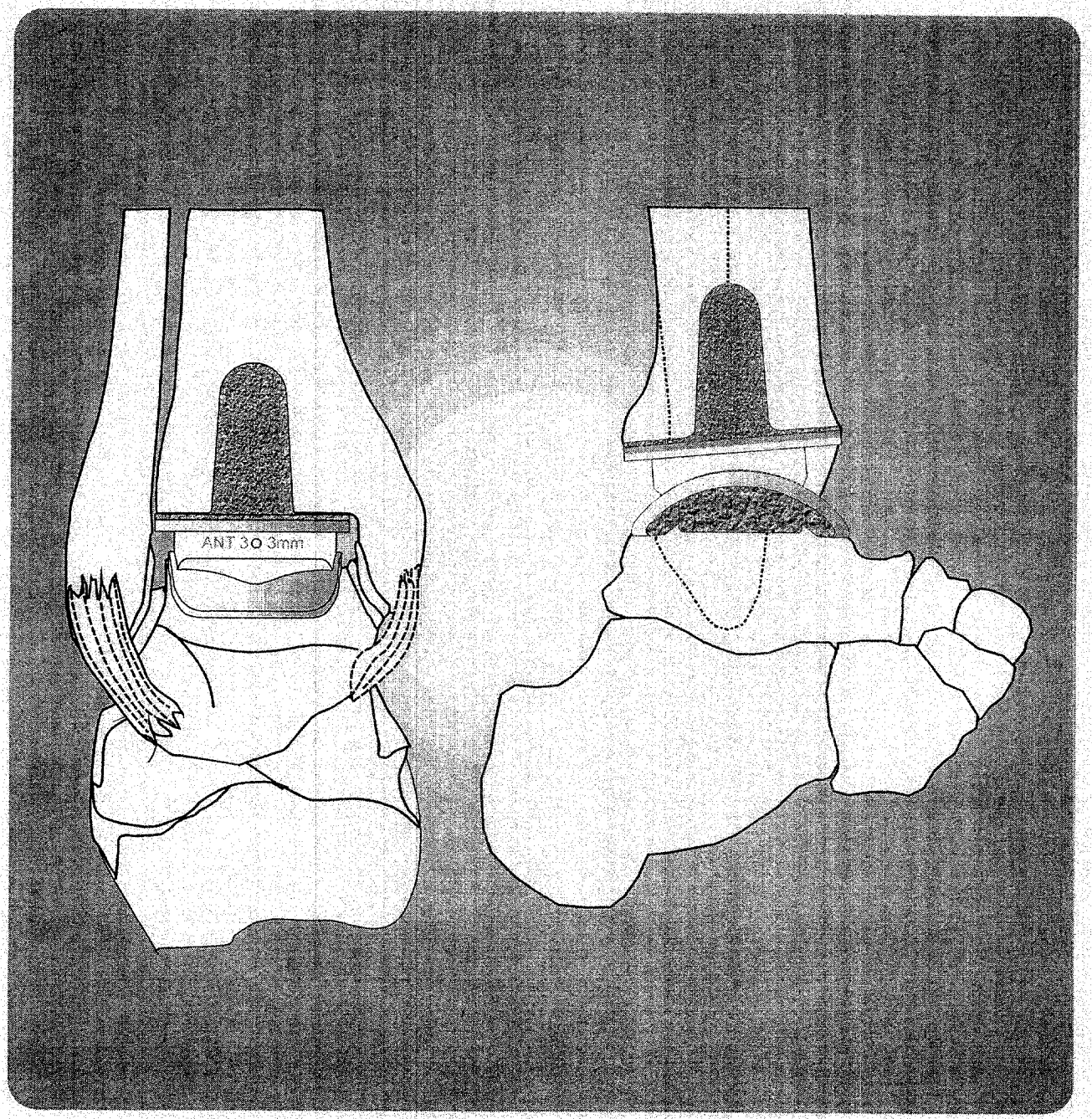
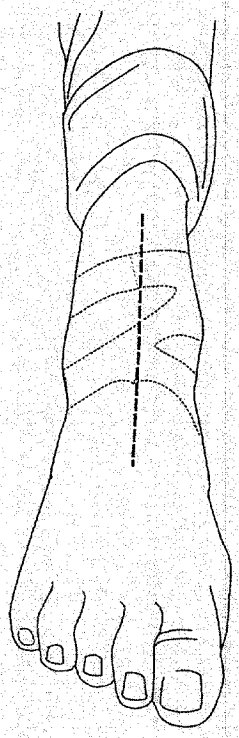
APPENDIX C – Surgical Procedure and Instrumentation


ANT 3O 3mm



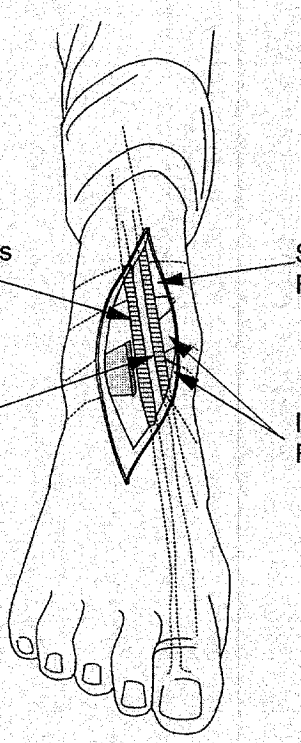
WARNING
Only patients with viable or reconstructable ligamentous and malleoli supports should be considered for the Buechel-Pappas Ankle Replacement system.

1. Skin Incision

Place the patient in a supine position on the operating table with a sandbag under the buttock of the affected extremity. Inflate a thigh tourniquet to 350 mm Hg* after the ankle and foot are exsanguinated with an Esmarch elastic wrap up to the level of the midcalf.

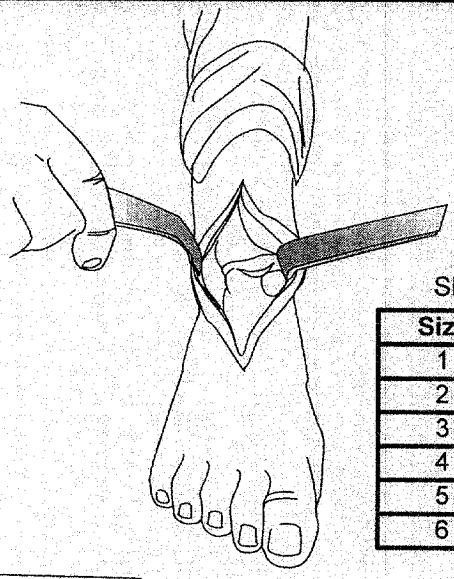
Use a 14 centimeter midline, straight anterior skin incision centered on the ankle joint.

WARNING
The tourniquet should not be applied for longer than a 2 hour period.



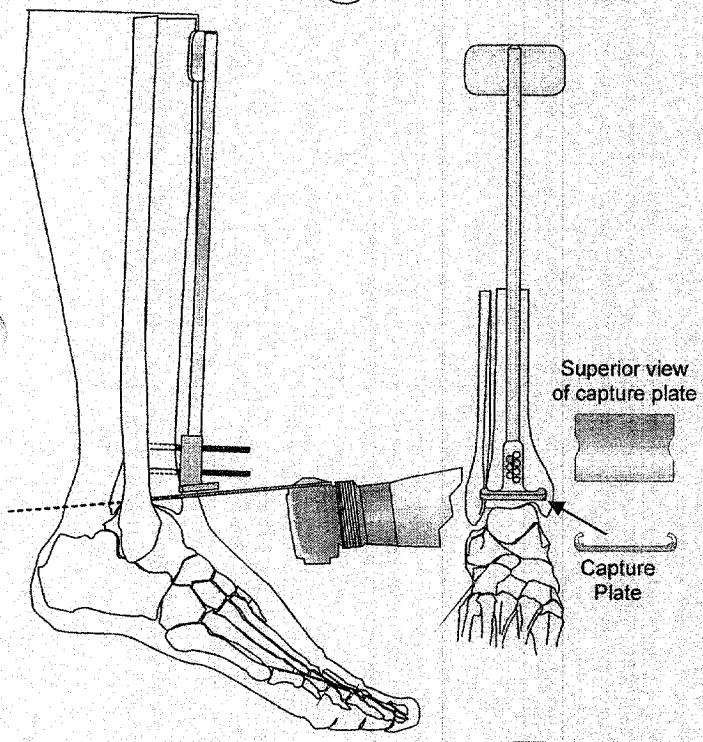
2. Deep Exposure

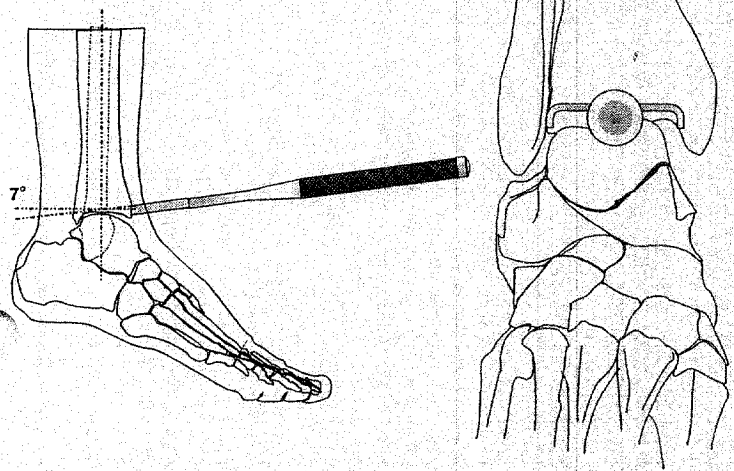
Find and protect the superficial peroneal nerve in the subcutaneous tissue. Incise the superior and inferior extensor retinaculi between the tibialis anterior and the extensor hallucis longus tendons. Continue the incision in the bed of the retracted anterior tibialis tendon, down to the bone of the tibia and talus



SIZING TABLE

Size	Color
1	Pink
2	Lt. Blue
3	Gray
4	Blue
5	Purple
6	Black





3. Ankle Joint Exposure

Subperiosteally elevate the capsule and soft tissues medially and laterally from the tibia and talus to expose the ankle joint and protect the dorsalis pedis artery and deep peroneal nerve. Retractors should be placed outside the medial and lateral malleoli to completely expose the anterior ankle joint.

4. Distal Tibial Resection

4a. Initial Selection of Tibial Component Size.
The initial size is the largest that fits the medial and lateral margins of the tibial resection which are the shoulder of the medial malleolus and the lateral border of the talus. The size of the Tibial Marking Osteotome size should be selected so as to produce such a tibial resection.

Note: All size dependent instruments such as the Tibial Marking Osteotome have colored rings at the ends of the handles to help in identifying sizes more efficiently. The chart at the left identifies these colors and sizes.

4b. Tibial Resection
Place the 7 degree inclined cutting surface of the Tibial Resection Guide 10 to 12mm above the talar dome and pin the guide into place with the proximal portion of the guide resting on the mid-tibial crest. A capture plate can be applied to the guide to assist in the tibial resection. Use a power saw to complete the transverse cut perpendicular to the tibial shaft, taking care not to under cut the medial malleolus or injure the posterior neurovascular bundle.

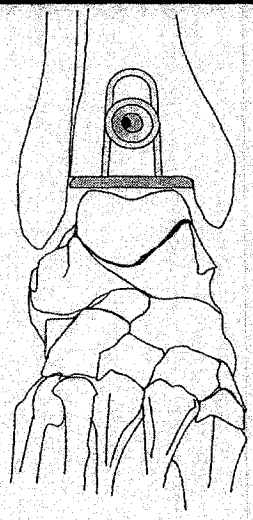
Note: Pre-drill the pin holes with a 1/8" drill in hard bone conditions.

Note: Tibial resection beyond 12mm above the talar dome is necessary only when advanced pathology is present.

4c. Finalizing the Tibial Cut
Place the Tibial Radiusing Osteotome of the proper size with the instrument cutting blade on the distal tibial cut. Center the blade on the tibia medial malleolar cut. Impact the Tibial Radiusing Osteotome to mark out and begin the cut on the medial malleolus. Be sure to radius the angle of the medial malleolar cut to avoid a stress fracture either by using a power burr or the marking osteotome itself.

The vertical cut may be completed with a small saw blade or fine osteotome. Posterior bony fragments may be removed with curettes and a pituitary rongeur.

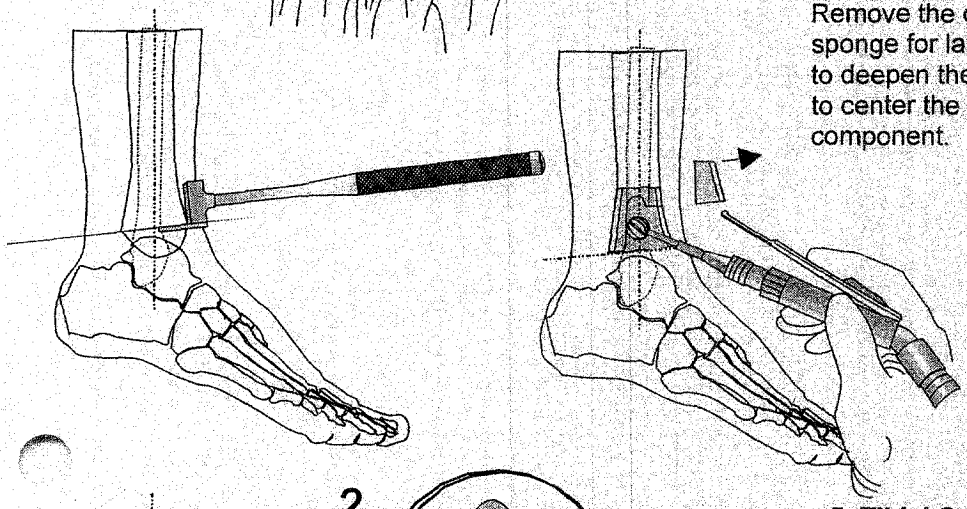
Note: The distal tibia should be morselized with multiple vertcal cuts to allow ease of removal without levering on the medial malleolus

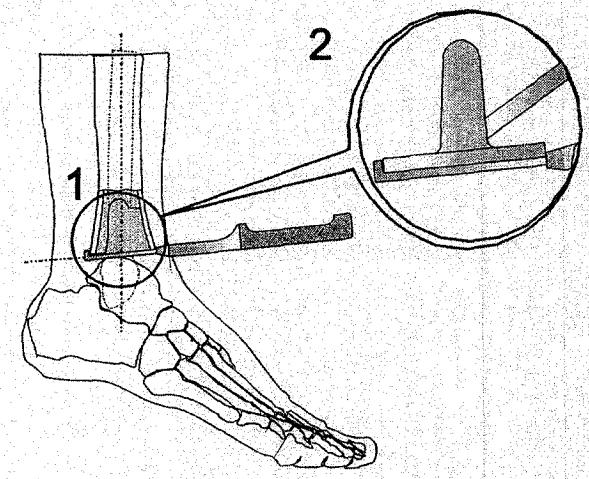


4d. Preparation of Tibial Window
Place the Base Plate of the appropriate size Tibial Window Osteotome on the previous tibial resection surface and center it over the talus. The dimension of the Tibial Window Osteotome is the same as the Tibial Stem dimension.

Impact the Tibial Window Osteotome to outline the cortical tibial window. Use a power saw to complete the cuts down to the center of the tibial shaft in the lateral plane. A narrow osteotome and a 3mm drill may be used to open the superior portion of the window.

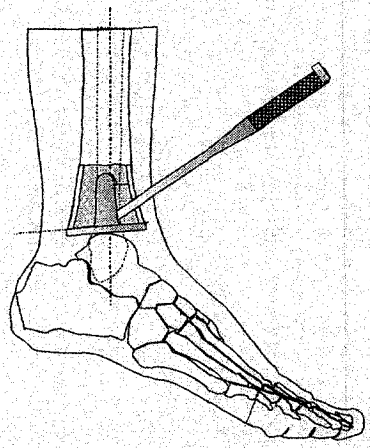
4e. Shaft Preparation
Remove the cortical window and place it in a blood soaked sponge for later reinsertion. Use the 10mm Spherical Burr to deepen the central channel in the tibial canal to a depth to center the stem and the loading plate of the tibial component.





5. Tibial Component Trial Fit

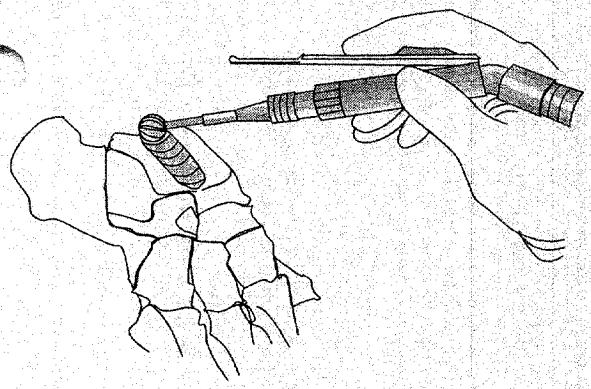
Place the Tibial Component Trial of the selected size through the anterior cortical window of the tibia and press it into position so that the Loading Platform is flush with the resected tibial surface and the Anchoring Stem is centered inside the tibial shaft. Good fit of the tibial component is described as a component with a centrally aligned stem and a plate which avoids contact with the fibula and whose medial edge is immediately adjacent to the medial edge of the distal tibial resection and whose A/P dimension covers the distal tibial resection. A larger component can be used to increase the dimensions of the plate if needed, particularly to provide full A/P coverage.

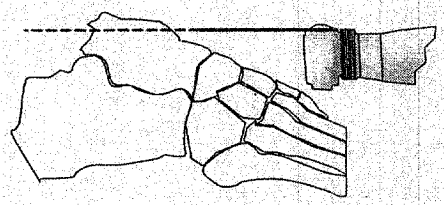


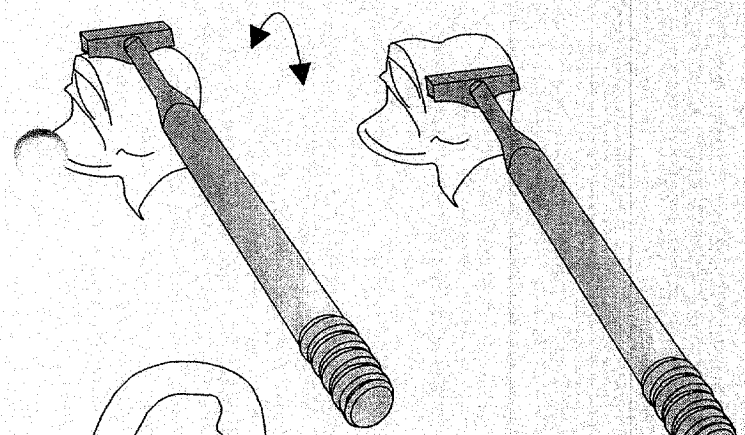
Note: A simple depth gauge can be used to center the Tibial Component in the A-P plane by:
1. Measuring the resected tibial width
2. Using this dimension on the trial to determine the variation (if any) between the trial and resected tibia.

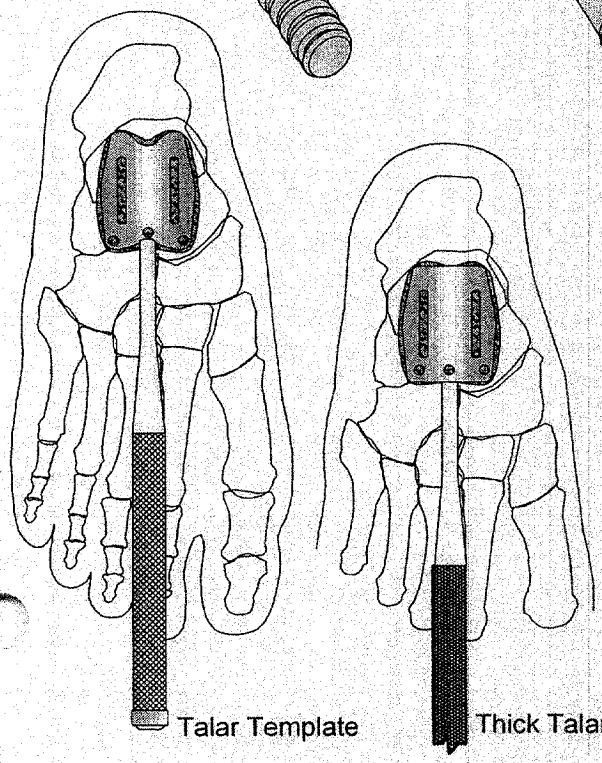
Once this reference dimension is made, the Tibial Trial is then recessed that distance from the anterior border which will center the component in the tibia.

If the component seems grossly loose, bone graft around the stem can be used to enhance fixation and stability.









Talar Template

Thick Talar Template

6. Talar Preparation

6a. Talar Size Selection

For proper fit the Talar Component should cover the talar dome without overhang of the medial and lateral edges. Take care to insure that these edges are within the medial and lateral surfaces of the talus to insure that the Talar Component edges to not contact the maleolli. A somewhat smaller talar component is preferable to one with any overhang.

WARNING

Oversizing of the talar component can result in M/L contact of the maleolli that may cause excessive bearing wear.

6b. Talar Dome Preparation

Use the 10mm Spherical Burr to deepen the central portion of the talar trochlea and to roughly shape the upper surface of the talus to match the bispherical undersurface of the Talar Template of appropriate size. The front edge of the talar component should lie at the same level as the anterior tibial shaft.

The Thick Talar Component is to be used if there is enough talar erosion or bone loss in which grafting or cement alone will not provide the adequate base for support. Also, in some cases the lateral view of the talus may look flat (almost horizontal) instead of its normal curved shaped. In this situation, it may not be feasible to fashion the talar dome to receive the standard talar component. It is important that the underside of the prosthesis be supported by the appropriate bone stock. This is defined as healthy bone which matches the underside shape of the component to ensure proper loading and fixation. In these cases where the talar component may only be supported on the anterior and posterior edges due to the lack of talar curvature and/or ability to fashion this curvature, the thick prosthesis should be used to allow full area contact at the bone/prosthesis interface.

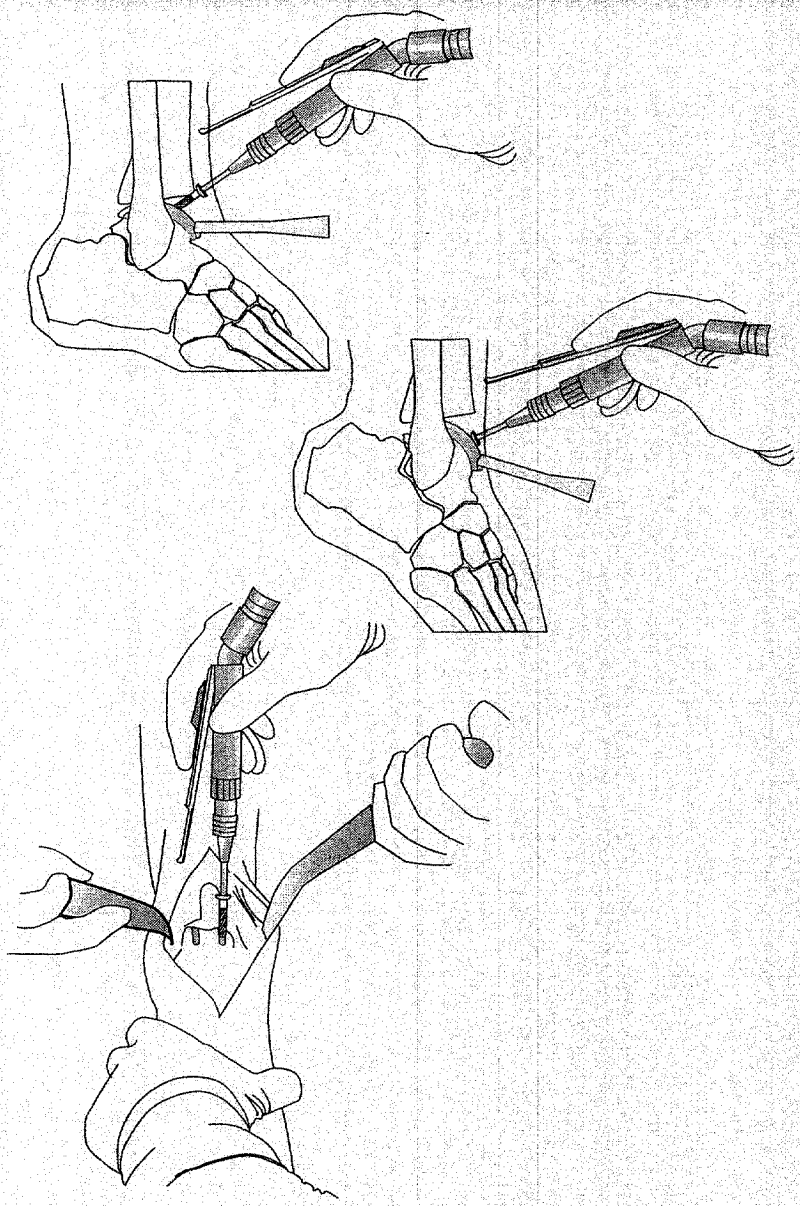
Move the Talar Shaping Rasp from anterior to posterior until a smooth surface, matching the Talar Template, has been prepared.

Note: If the thick talar component is to be used, this last step is omitted.

Center the Talar Template onto the prepared talar surface. Any exostoses which do not allow complete contact of the Talar Template with the talar dome should be removed.

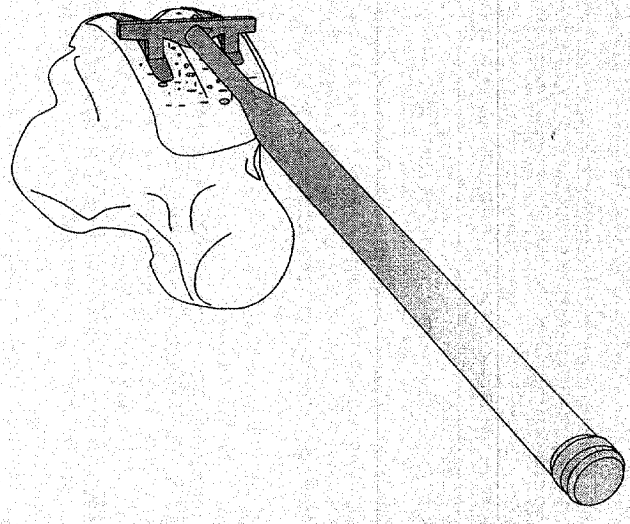
After fashioning the talar dome, the Talar Template is used to check the fit of the component as well as provide a guide for burring slots for the fixation fins. Insure that the medial and lateral edges of the Talar Template do not overhang the edges of the talus to avoid contact with the malleoli. If the talar dome bone stock seems to be insufficient to support the Talar Template, bone grafting or cement can be used to augment the deficient site. If there is a gross amount of instability and bone loss, the Thick Talar Template and prosthesis should be used to augment the fixation.

Once adequate fit is obtained, the talar template is pinned into place for the burring procedure, through the fixturing holes. One central pin is recommended.

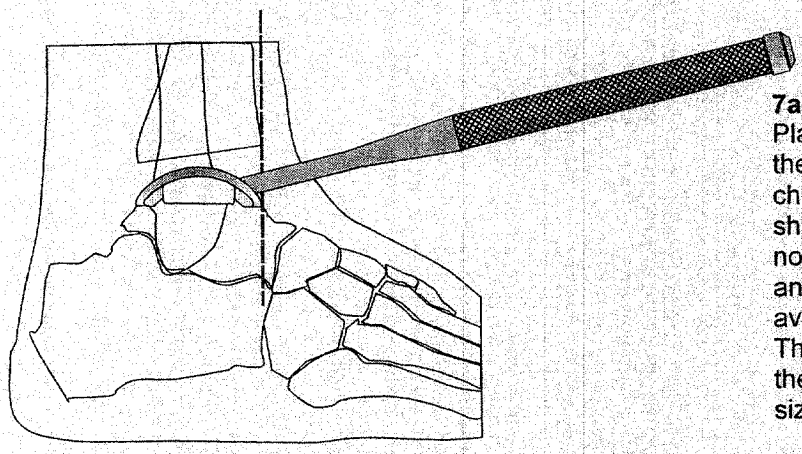


6c. Fixation Fin Channel Preparation
Plantarflex the ankle and use the Talar Slot Burr to prepare the two fixation channels through the Talar Template to allow full seating of the Fixation Fins of the Talar Component.

The template can be removed once the outline of the channels has been completed. Final channel depth is easier to prepare with the template removed.



Check the depth of the fixation channels with the Talar Channel Depth Template. Full seating from anterior to posterior assures complete seating of the Talar Component Trial.



7. Trial Component Fit

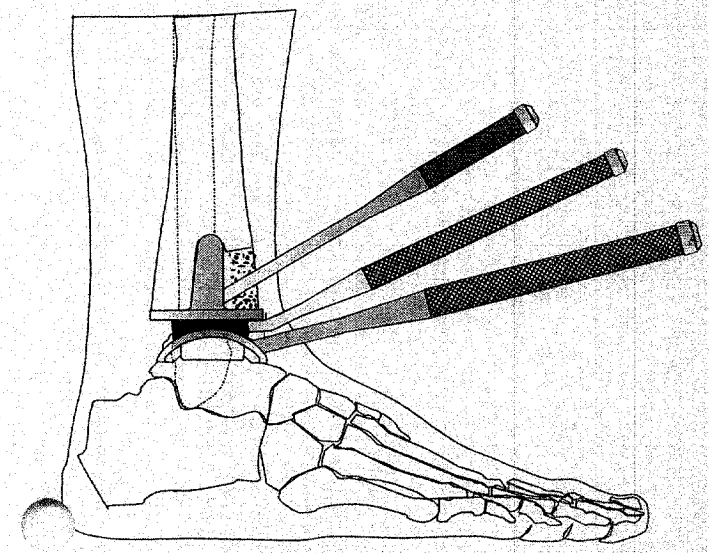
7a. Talar Component Trial Fit.
Place the Talar Component Trial of appropriate size onto the prepared talus and press the Fixation Fins into the channels. The anterior edge of the Talar Component Trial should lie in the plane of the anterior distal tibia, should not overhang the talus on its medial and lateral edges and should be centered on the talar dome. Take care to avoid anterior placement of the Talar Component Trial. The size of the talar component does not need to match the tibial size. In fact, the talar component is often one size smaller than the tibial component.

7b. Final Trial Component Fit
First insert the Talar Component Trial into position. Then insert the Tibial Component Trial. Finally insert the Sliding Cylindrical Bearing Trial between the Tibial and Talar Trials to determine the correct ligament tension. These bearings are available in 2mm increments and should be used to provide an unrestricted flexion/extension arc without causing an equinous deformity.

Check component alignment. All components should be centered and properly oriented.

Note: X-Ray evaluation of trial components position may be useful to confirm proper placement at this time.

WARNING
Improper alignment can substantially increase the risk of failure of the device due to accellerated wear and associated cysts, loosening and even fracture.

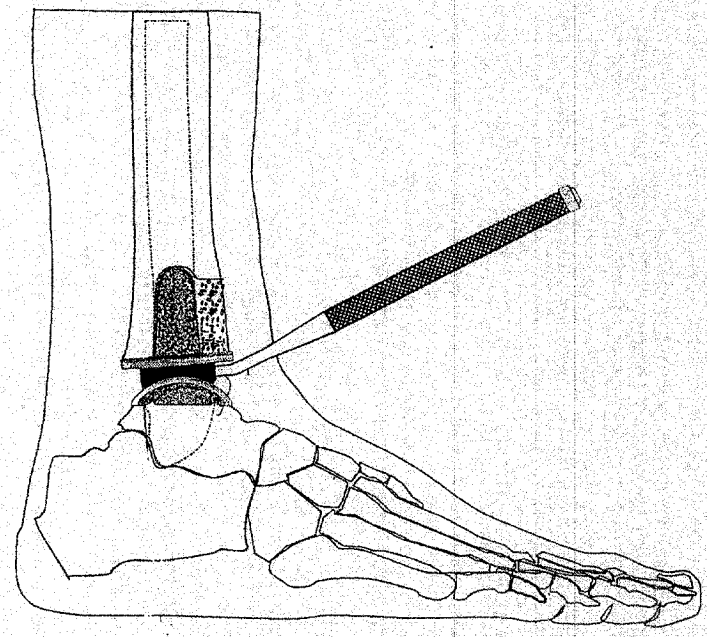


Check for ROM. All plantar and dorsi flexion and rotational and translational motions should be unrestircted. Any restricting tissues or bone particles should be removed..

WARNING
During a check of the ROM and axial rotation check for impingement of the Trial Bearing with the maleolli. Rubbing of the Bearing against tissue can produce undesirable wear debris and result in loosening or cysts.

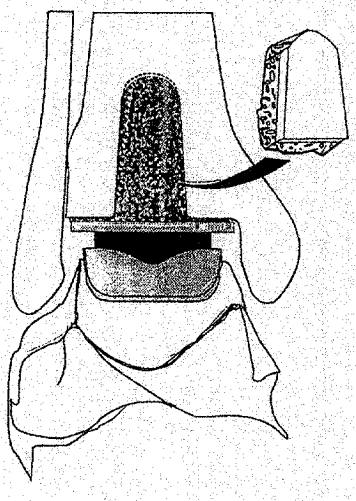
Check for stability. Varus-Valgus stress on the ankle should not allow any opening of the bearing medially or laterally. If opening occurs, consider a thciker bearing for improved medial-lateral stability.

Note: The bearing size must match the talar size. For example, if a size 3 talar component and size 4 tibial component are used, a size 3 bearing of appropriate thickness must be used.



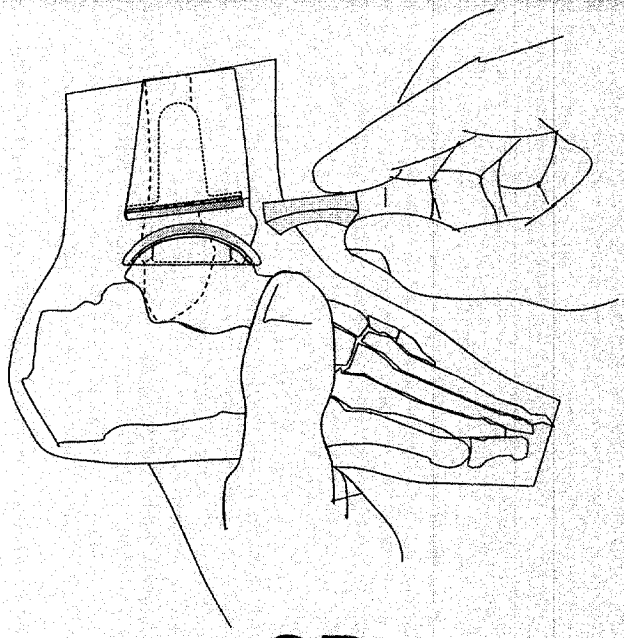
8c. Trial Bearing Fit
Place the Bearing Trial selected previously between the Tibial and Talar Components to provide seating compression on the components and to confirm the final dimension of the Bearing to be used.

WARNING
During a check of the ROM and axial rotation check for impingement of the Trial Bearing with the maleolli. Rubbing of the Bearing against tissue can produce undesirable wear debris and result in loosening or cysts.



8d. Restoration of Bone Window
Wedge the bone window back into its original position and impact it into place.

Note: Remove excess cancellous bone, if necessary, using a bone biter or rongeur to allow flush seating of the graft anteriorly. This cancellous bone can be used to graft the tibial component and also to be used as wedges between the window and tibia to lock the graft into place.

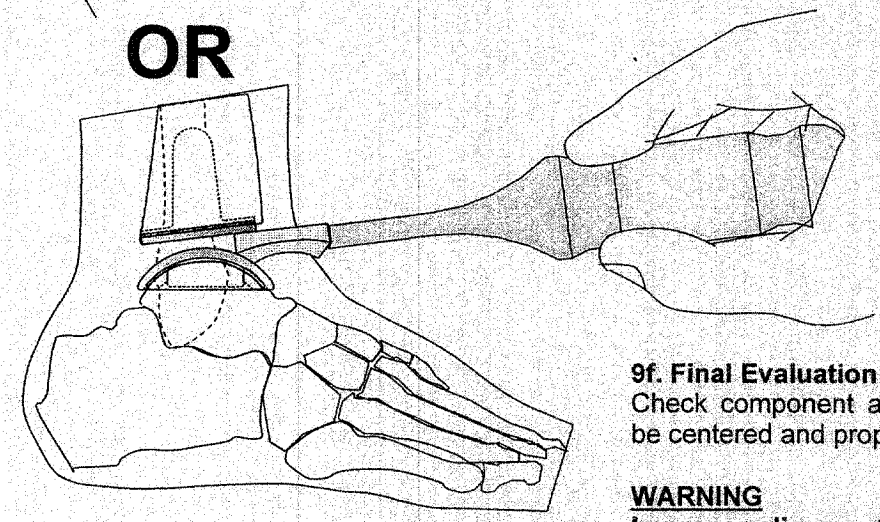


9e. Final Bearing Fit
Insert the appropriate Sliding Cylindrical Bearing between the Talar and Tibial Components by distracting the ankle joint and placing thumb pressure on the bearing.

If distraction alone is not enough to engage the bearing the Bearing Pusher may be used to provide more leverage to seat the bearing.

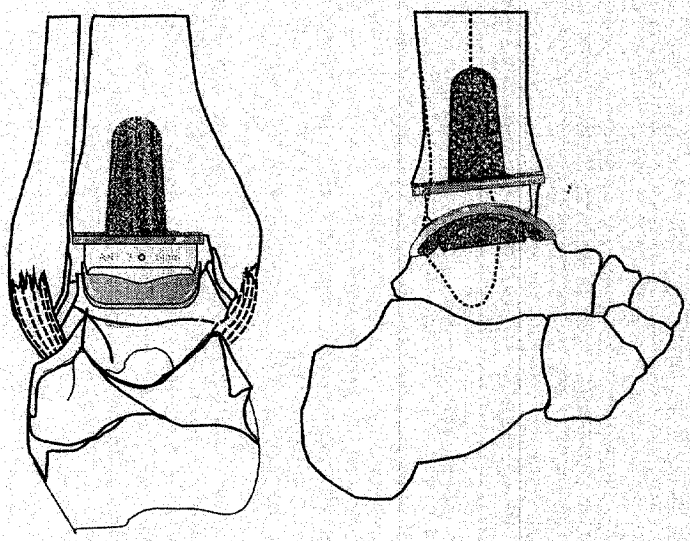
Note: The bearing size must match the talar size. For example, if a size 3 talar component and size 4 tibial component are used, a size 3 bearing of appropriate thickness must be used.

OR



9f. Final Evaluation
Check component alignment. All components should be centered and properly oriented.

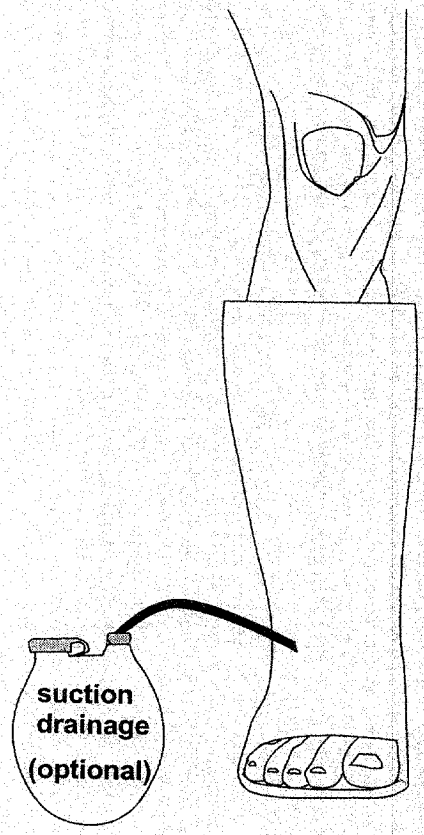
WARNING
Improper alignment can substantially increase the risk of failure of the device due to accellerated wear and associated cysts, loosening and even fracture.



Check the ROM. All flexion, extension, rotational and translational motions should be unrestricted. Any restricting tissues or bone particles should be completely removed and the wound irrigated thoroughly.

Note: If Achilles contracture prevents dorsiflexion to neutral alignment, consider a three puncture percutaneous Achilles tendon lengthening to avoid a persistent equinus deformity.

WARNING
Finally during the motion evaluation check for impingement of the Bearing with the maleolli. Rubbing of the Bearing against tissue can produce undesirable wear debris and result in loosening or cysts.



10. Closure and Postoperative Immobilization

If desired, place a small suction drain to exit laterally above the ankle at the level of the tibial window The drain is to exit a separate stab wound at the level of the prosthesis and should be placed 3 cm lateral to the incision for proper would healing. Routine drain use is unnecessary.

Close the retinaculum over the extensor tendons and the subcutaneous tissue with 2-0 absorbable suture. Close skin with 3-0 nylon suture or staples. Apply a very well-padded, short leg plaster cast in neutral position prior to moving the patient to the recovery room.

Postoperative Protocol

After surgery apply nasal oxygen for 48 hours (3-4 L/min) to aid in wound healing. Maintain short leg cast immobilization for at least six weeks before permitting ankle motion. This allows for proper soft tissue healing and early ingrowth fixation. After six weeks, x-rays should be taken to assure proper implant placement and healing of the cortical window. If the above are satisfactory, the cast is removed and an ankle air stirrup is applied to stabilize the joint. Dangling of the operated extremity at bedside can begin on the first postoperative day and can be continued alternately with elevation until throbbing in the ankle and foot are minimal (usually requires 3-5 days). Quad setting and straight leg raising should also begin on the first postoperative day, along with general upper extremity strengthening exercises. If used, remove the suction drain after 24 hours. Consider the use of Indomethacin 25mg tid for 10 days to inhibit heterotopic bone formation.

Balance weight bearing may begin on the third to fifth postoperative day and may be increased as pain subsides. If skin healing has occurred, active flexion/extension exercise can begin after six weeks. Apply an ankle air-stirrup and compression stockings at this time for medial/lateral support and edema control. Continue progressive ambulation with weight bearing to tolerance in the ankle stirrup until a painless, normal walking cycle has been achieved. This usually requires an additional six to twelve weeks. Active resistive, flexion-extension, inversion and eversion exercises should begin when postoperative pain and swelling are gone. These exercises should be continued until strength and stability allow for normal ambulatory activities without support. Ankle swelling may persist for 6 to 12 months following surgery.