EXACTECH | **EXTREMITIES**

Operative Technique

VANTAGE® TOTAL ANKLE

Total Ankle Mobile Bearing

exactech

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INTRODUCTION

The Exactech Vantage® Total Ankle was designed through a collaborative effort of engineering research and the expertise of global thought leaders in ankle arthroplasty. The design goal was to offer an anatomic and bone conserving total ankle replacement that addresses well-documented complications and the biomechanics of the native ankle.

The tibial component is an anatomic design that is right- and left-specific to respect the native anatomy of the tibia as well as provide for articulation of the fibula. Similarily, the talar component is left- and right-specific and designed with a bicondylar articulating surface that replicates the native anatomy with the goal of reproducing the natural biomechanics during the gait cycle. The talar component is designed to preserve bone through an arc-shaped talar interface that respects the diseased anatomy. The design is based on CT reconstruction studies that focused on the differences between a healthy and diseased talus morphology.

The Exactech Vantage Ankle is designed to minimize well-documented complications, such as cyst formations and subsidence around the implant. The tibial design does not violate the anterior cortex and the talar implant allows for an uniform load transfer from the implant to the prepared talar bone. To further address the risk of talar subsidence, the anterior talar shield supports the implant on the talar neck.

Thank you for considering the Exactech Vantage Ankle. We believe this product will significantly improve the surgeon's ability to focus on the biomechanics and fixation while addressing the well-documented complications that compromise patient outcomes.

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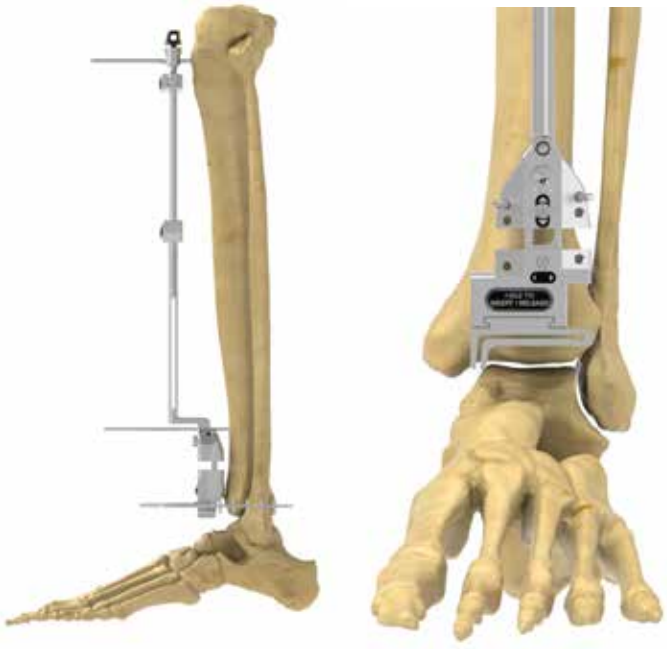

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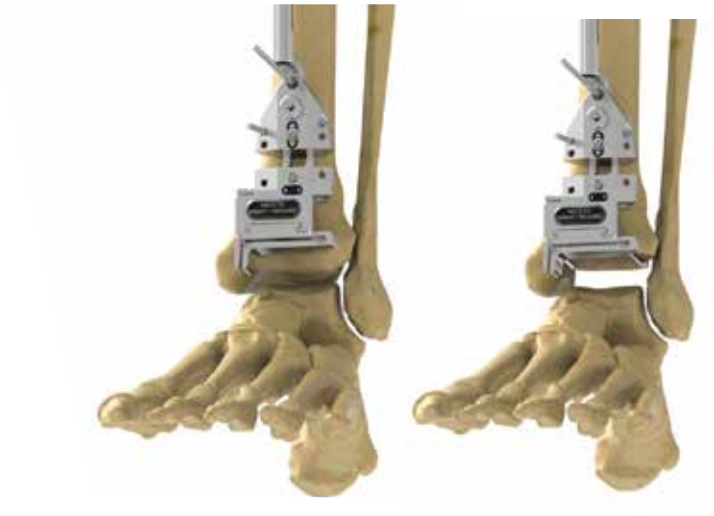

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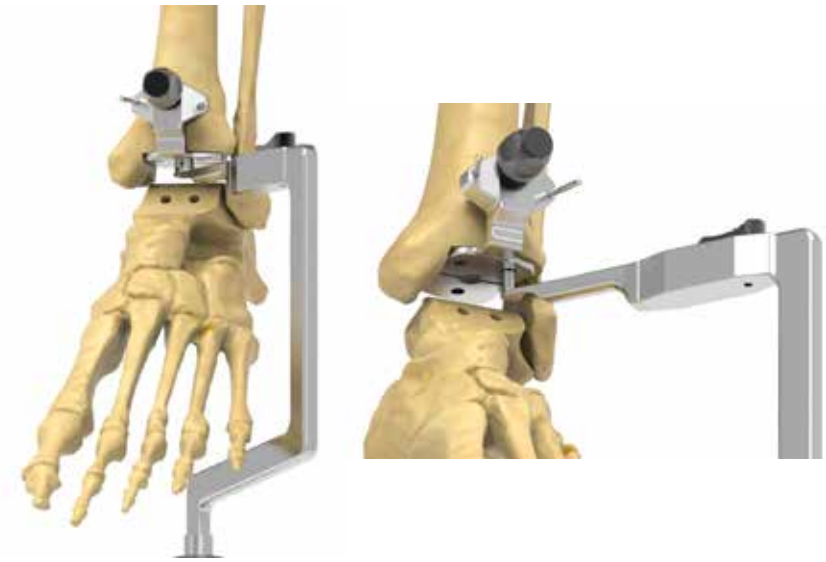

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DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH

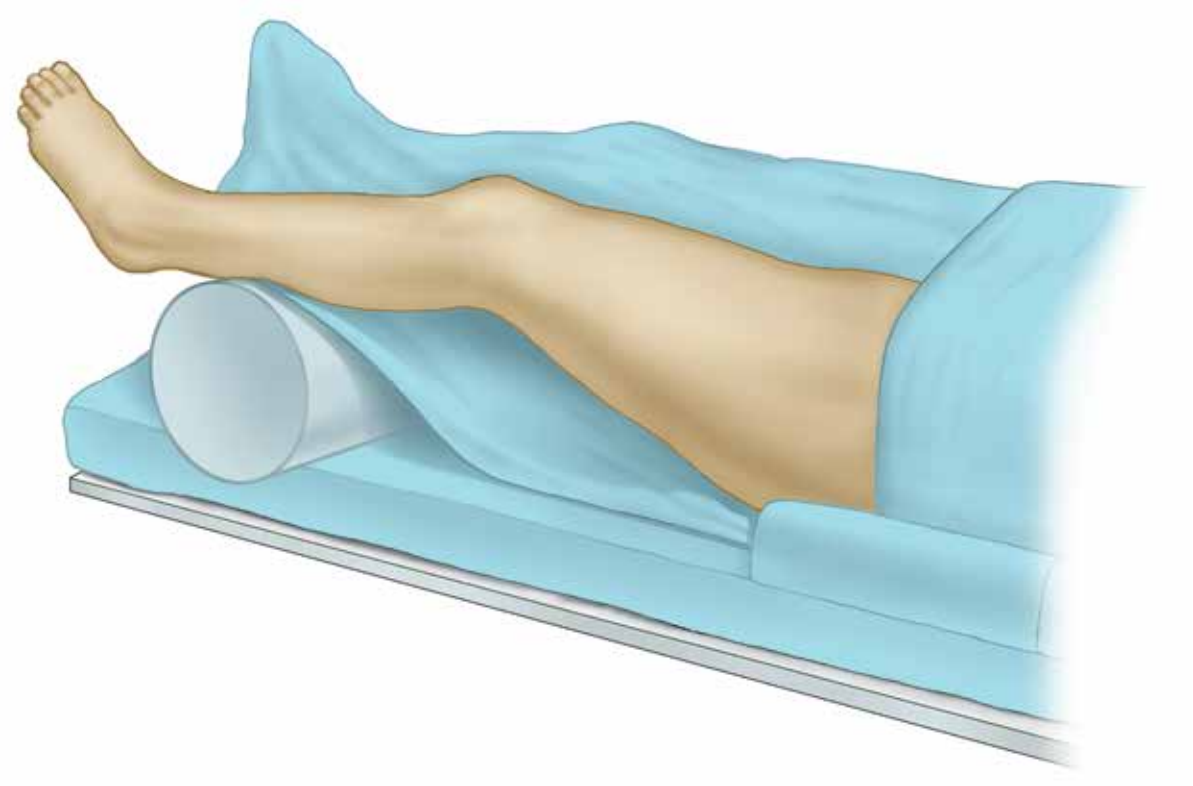


Figure 1
Position Patient

SURGICAL APPROACH

The patient is placed supine on the operating table. It is usually necessary to put a small bump under the ipsilateral hip so that the leg will not externally rotate; the patella should be facing directly anterior. Surgery is generally done under regional anesthesia but general anesthesia is certainly acceptable. If regional anesthesia is used, then a popliteal catheter or sciatic catheter will need to be carefully blocked out of the OR field so as not to interfere with the surgical technique. A thigh tourniquet will be utilized for all cases; it should be well padded and placed proximal to the popliteal catheter. Adhesive drapes are generally placed around the knee to block out the popliteal catheter and the thigh area.

The extremity is then prepped and draped into a sterile field, exposing the knee to the foot. Intravenous antibiotics and a sequential compression device on the opposite leg are used in all cases. The extremity is then exsanguinated with an esmarch bandage and a thigh tourniquet elevated to the appropriate level *(Figure 1)*.

Figure 2
Place Skin Incision 6-8cm Proximal to Tibiotalar Joint

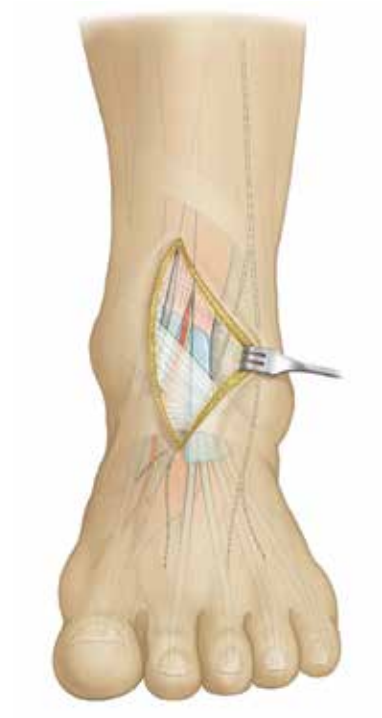


Figure 3
Retract for Initial Exposure

The skin incision is made 1cm lateral to the crest of the tibia and extends approximately 6-8cm proximal to the level of the tibiotalar joint and 6cm distal to the joint just past the talonavicular joint. After dividing the subcutaneous tissues, it is important to identify the superficial peroneal nerve as its distal course will frequently cross from lateral to medial directly over the ankle joint. Frequently, it will be necessary to sacrifice the small medial branch of the nerve, but never the entire superficial peroneal nerve *(Figure 2)*.

Next, the extensor retinaculum is exposed. The extensor hallucis longus sheath is opened through the extent of the skin incision. It is important not to open the anterior tibial tendon sheath as this is usually more difficult to close and may lead to bowstringing with wound closure. Bowstringing from inadequate retinacular closure has led to wound breakdown. Once the EHL tendon sheath is open, the deep peroneal nerve and artery will be located directly below the EHL tendon and muscle. It is important to protect these structures as they are gently and bluntly dissected from the tibia with a cuff of soft tissue and retracted laterally with EHL tendon and muscle. Care must be taken distally as the deep peroneal nerve and artery curve from the lateral to medial and will be in the area of the lateral talonavicular joint. These must be protected throughout the surgical procedure *(Figure 3)*.

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH

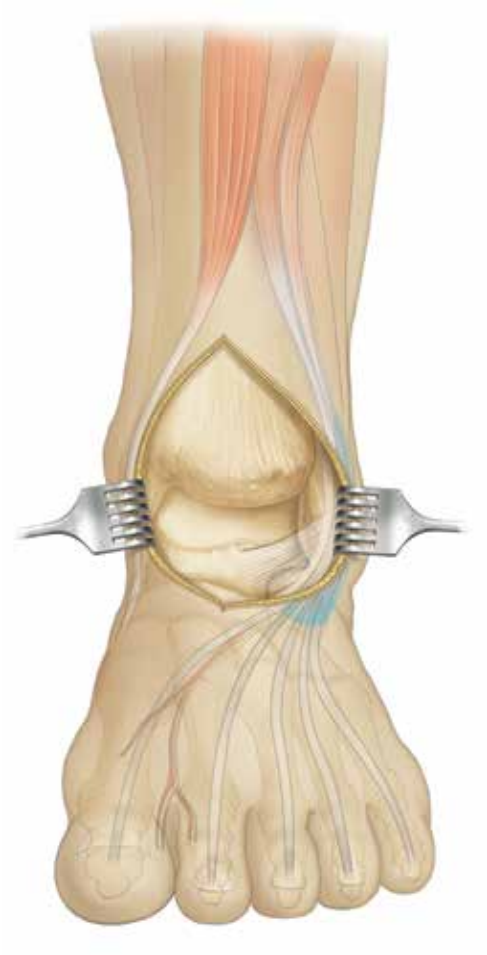


Figure 4
Expose Bony Anatomy

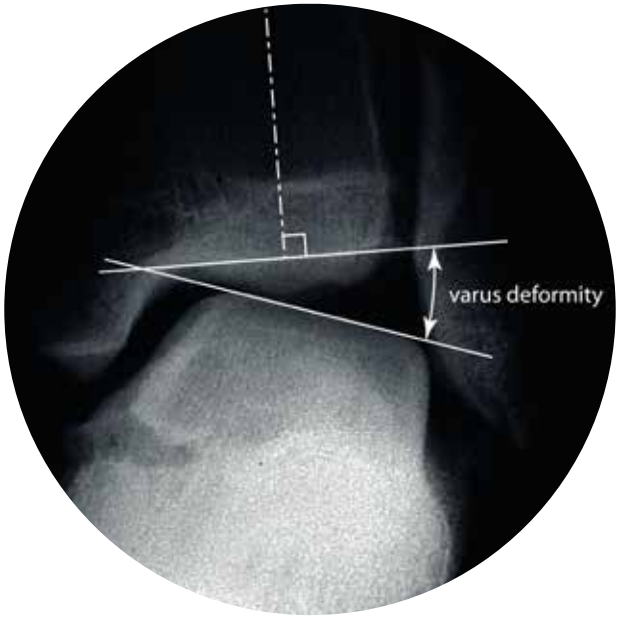


Figure 5
Address Varus Ankle

Next, a longitudinal incision is made in the capsule of the ankle joint, and the capsule is reflected medially to expose the entire medial malleolus and laterally to expose the syndesmosis. At this point, a deep retractor, generally a gelpi retractor, is placed to hold the soft tissues open and expose the ankle joint. A saw or osteotome is used to remove anterior osteophytes from the tibia, and this should be done perpendicular to the longitudinal axis of the tibia. Frequently, there are massive osteophytes on the neck of the talus and these should be removed with a Cushing Rongeur. Care must be taken not to remove too much bone from the neck of the talus and to avoid weakening it *(Figure 4)*.

If the preoperative radiographs demonstrate a varus deformity to the ankle, it may be necessary to perform a release of the deltoid ligament. This is done with a combination of sharp and blunt dissections, starting at the tip of the medial malleolus and releasing from anterior to posterior until all attachments of soft tissue to the medial malleolus and the posterior aspect of the tibial are released. This will free the tissue up as a cuff and allow for correction of moderate varus deformity *(Figure 5)*.

Figure 6
Place Alignment Guide – Anterior

Figure 7
Check Alignment Guide – Lateral

ANKLE ALIGNMENT

Once the ankle joint is exposed, a small 5mm incision is made over the tibial tubercle. With the **Tibial Cutting Block** attached, place the **Total Ankle Alignment Guide** onto the proximal tibial bone in the A/P direction. The guide should be adjusted to the height of the tibial tubercle using the button at the center of the shaft *(Figure 6)*.

SURGICAL PEARL
Distal alignment block should be opened to the 0 mark in order to allow for superior or inferior adjustments.

Use the medial shim to align the **Tibial Tubercle Pin** or **Tibial Tubercle Pin Pouch** prior to insertion, then place the Tibial Tubercle Pin through the proximal hole in the guide and into the anterior cortex of the tibia.

Once the length of the guide is adjusted and centered on the joint, adjust the medial-lateral position of the **Tibial Cutting Block** to align the center shaft of the alignment guide to the midline of the tibia. Place a provisional 2.4mm pin in the most proximal hole of the alignment guide. This pin will have a loose fit in the guide to allow for minor adjustments.

Small adjustments may be made to the slope once the pin is placed, however, errors larger than 10° will be difficult to correct at this stage *(Figure 7)*.

Figure 8
Adjust Tibial Block Rotation

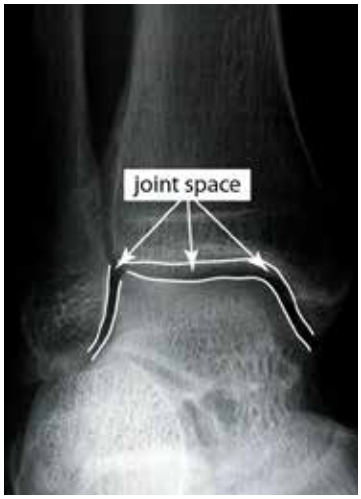


Figure 9a
Take a Fluoroscopic Image of the Mortise View (Optional Step)

Figure 9b
Ensure Proper Alignment of Tibial Cutting Block

To determine rotation, the second ray of the foot is recommended as an indicator of the A/P direction. To assess the orientation of the talus, place the **Medial Shim** into the medial gutter. This will indicate the rotation of the native talus. Place the **Rotation Alignment Rod** into the tibial cutting block. Adjust the rotation of the distal block by inserting the **1/8" Standard Hex Driver** in the Central Locking Screw, using it as a lever. The medial shim and alignment rod must be parallel *(Figure 8 and 9b)*.

This orientation will guide the direction of the tibial implant and prevent inadvertent resection of the posterior medial portion of the medial malleolus.

Note: *In lax ankles or those with valgus deformity, the medial shim may not stay in place. In these cases, it may be held against the medial malleolus or the alignment rod may be oriented with the second ray.*

An anterior fluoroscopic image may optionally be taken to ensure alignment between the cutting block and the medial gutter of the tibia in the mortise view *(Figure 9a)*.

Signifies fluoroscopic image

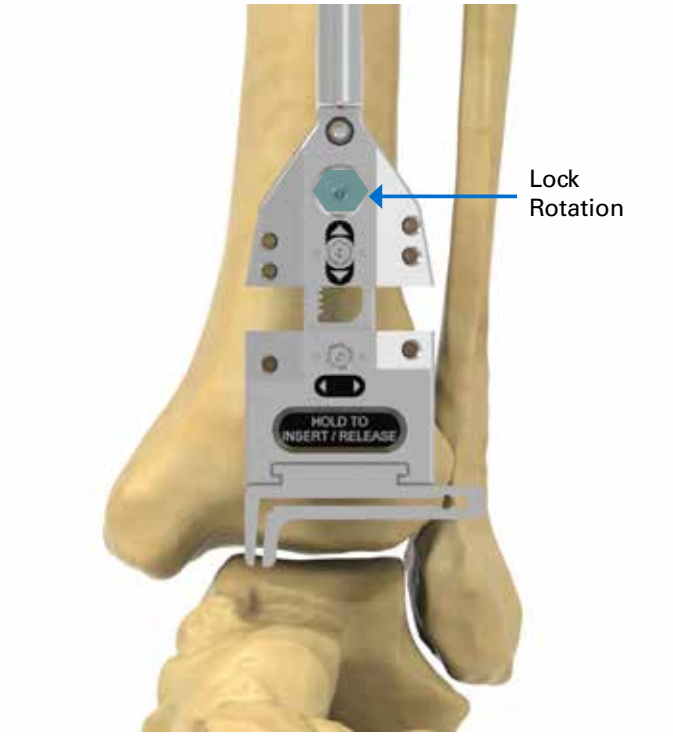


Figure 10
Lock Rotation

Figure 11
Adjust Varus/Valgus Alignment

To lock the rotation, use the 1/8" Standard Hex Driver in the Central Locking Screw and rotate clockwise until the guide is fully locked *(Figure 10)*.

Varus/valgus adjustments may be made at the proximal end of the alignment guide by sliding the shaft of the guide in the medial/lateral direction *(Figure 11)*.

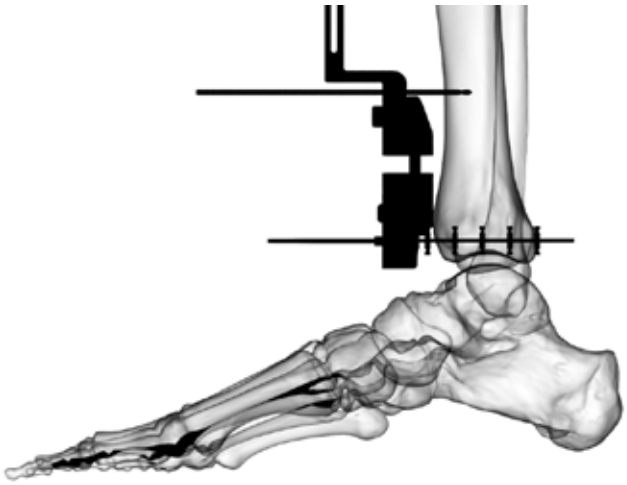


Figure 12
Adjust Resection Slope

Figure 13
Alignment Guide with Low-Profile Angel Wing - Lateral View

Insert the **Low-Profile Angel Wing** into the tibial cutting block, and make adjustments at the proximal pin to ensure a neutral cut *(Figure 12)*.

A lateral fluoroscopic image should be taken at this point to assess the slope of the tibial cut and the position of the cut relative to the plafond. The slope may be adjusted by sliding the proximal guide along the tibial tubercle pin shaft *(Figure 13)*.

Signifies fluoroscopic image

Figure 14
Pin the Proximal Block for Stability

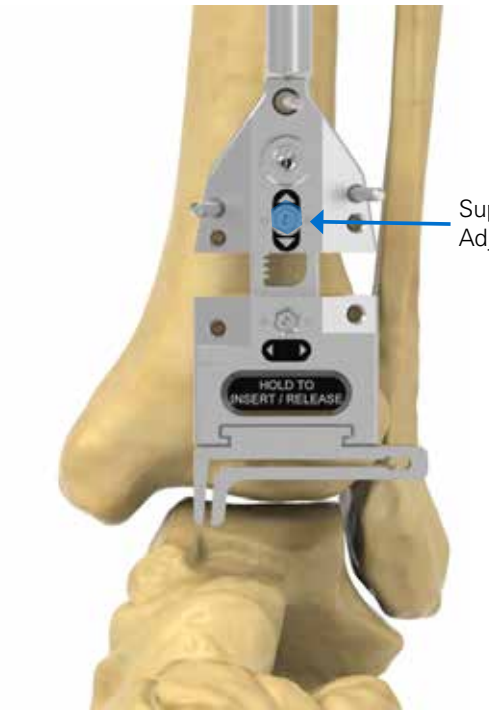


Figure 15
Adjust Superior-inferior Position

When the proper orientation is achieved, pin the upper portion of the block in any of the holes depending on the best bony purchase *(Figure 14)*.

SURGICAL PEARL
Proximal holes are symmetric, however the tibial bone tends to bow lateral, so care should be taken to ensure the bone is below the guide.

The level of the cut may be adjusted using the superior-inferior adjustment on the guide *(Figure 15)*.

Note: *To make superior-inferior and medial-lateral adjustments, insert the 1/8" Standard Hex Driver, press down, then rotate (Figure 15).*

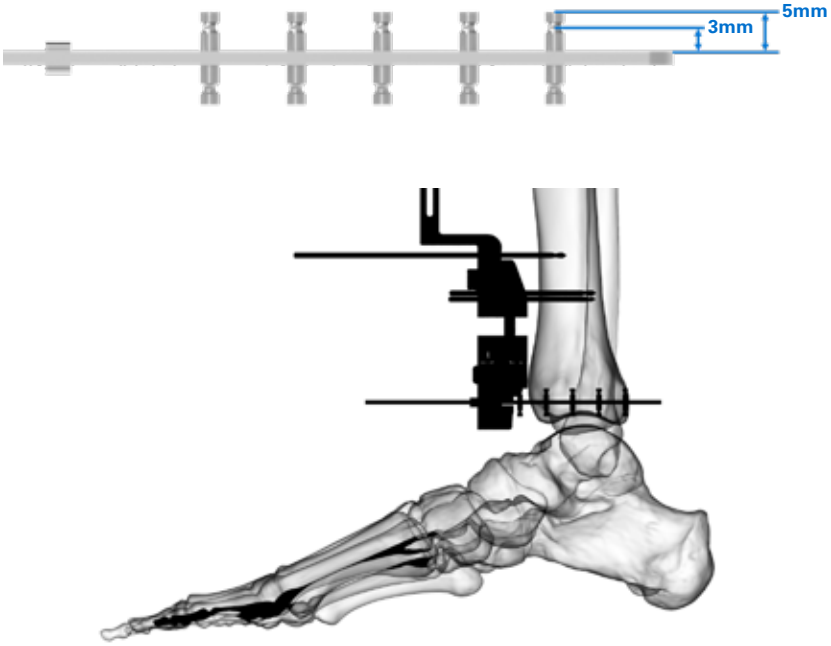


Figure 16
Adjust Resection Height

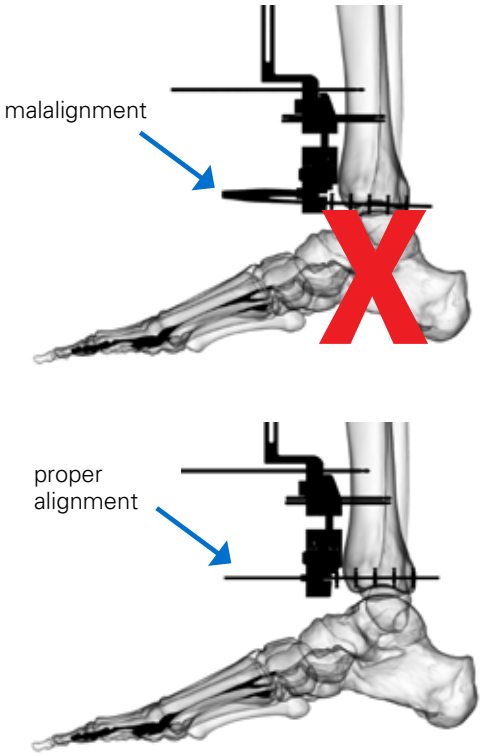


Figure 17
Ensure Proper Alignment of the Low-Profile Angel Wing to Gauge the Resection Depth

Adjust the tibial cutting block in the S/I direction so the pins on the low-profile angel wing guide are aligned with the top of the tibial plafond. This will place the tibial resection 5mm above the plafond *(Figure 16)*.

Note: *The pins of the Low-Profile Angel Wing are 5mm long from the base to the tip and have notches located 3mm from the base of each pin. Additionally, it has notches on the pins located 3mm from the base of the device.*

For tight ankles, this resection is recommended to make space for the implant assembly. In ankles with laxity, a shallower cut may be taken. Ensure proper alignment of the Low-Profile Angel Wing is achieved to accurately gauge the resection depth *(Figure 17)*.

Signifies fluoroscopic image

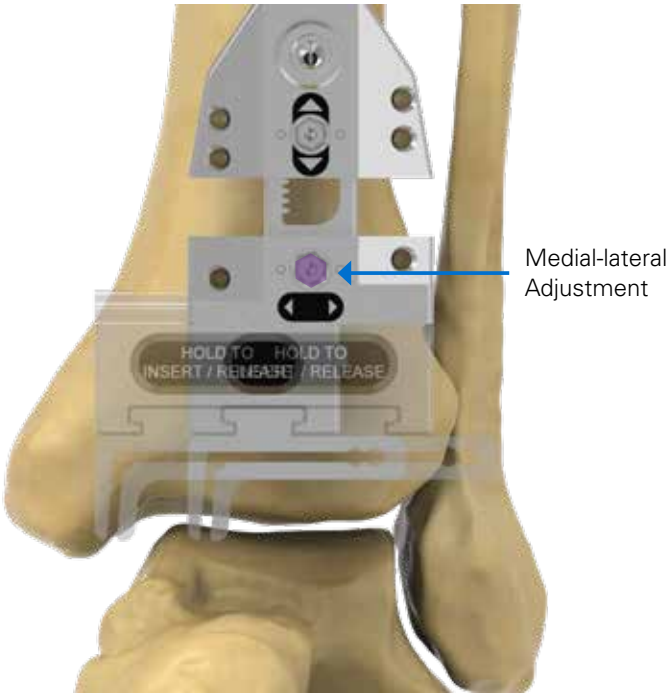


Figure 18
Adjust Medial-Lateral Position

Figure 19
Adjust Tibial Block Medial Laterally

Adjust the medial-lateral position of the **Tibial Cutting Block** to align the vertical slot on the cutting block with the medial gutter *(Figure 18)*.

Note: *Cutting blocks are aligned to medial gutter and width grows laterally. The widest option that stays medial of the fibula should be chosen.*

Align the c-arm and take an A/P fluoroscopic image to check the alignment of the tibial cutting block in the M/L direction, looking specifically at the lateral holes in the cutting block. These indicate the width of the tibial components and will identify the largest component that fits between the malleoli. Adjust the tibial cutting block in the M/L direction as needed to best fit the tibial geometry *(Figure 19)*.

Figure 20
Pin the Tibial Cutting Block

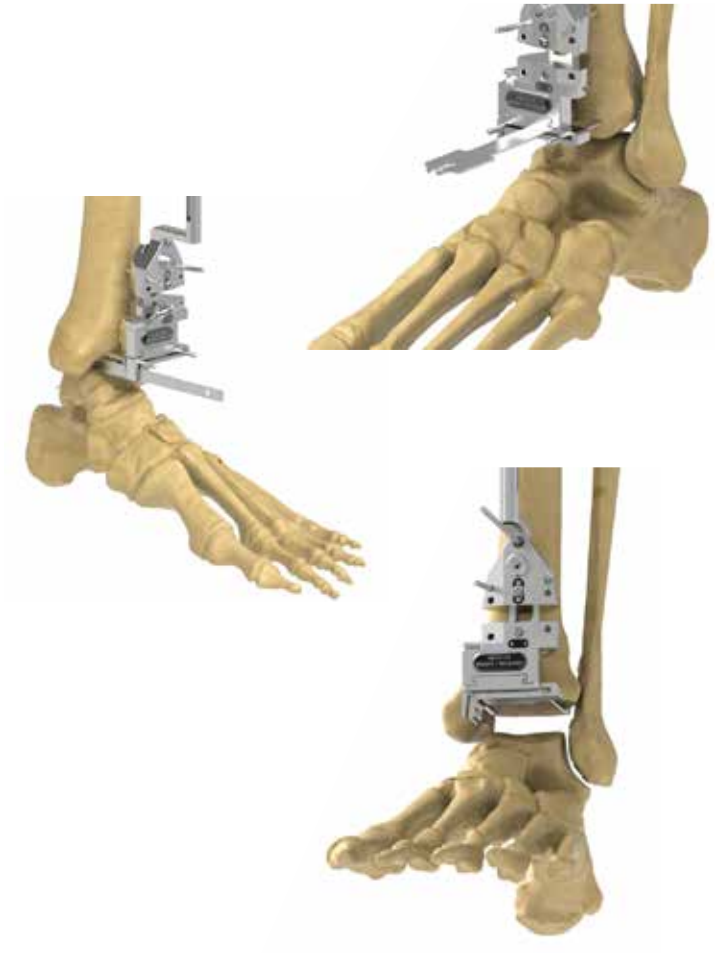


Figure 21
Resect the Tibia and Remove the Bone

Pin the tibial cutting block on the medial and lateral sides to protect the malleoli during the distal tibial resection.

Cut the distal tibia using an oscillating saw, taking care not to penetrate through the posterior capsule where the neurovascular bundle is located. A reciprocating saw may be used to cut the bone along the medial malleolus. A portion of the anterior lateral tibia may remain after the initial cut. This should be cleared to make room for the anterior flange of the tibial component *(Figure 20)*.

SURGICAL PEARL

When removing the resected tibial bone, cut the bone into small pieces with the reciprocating saw and then a rongeur to remove the bone until all the bone is cleared from the joint. Be sure to get any posterior bone fragments, as these can cause impingement post-operatively if not removed (Figure 21).

Figure 22
Place Talar Cutting Block

Figure 23
Pin Talar Block

After clearing the resected tibial bone, the **Talar Cutting Block** is placed onto the alignment guide. The alignment guide should be extended as far as possible distally to tension the soft tissues. Care should be taken to ensure the paddle is contacting the talar bone. The **Standard Talar 4mm Cutting Block** is recommended for tight ankles. The **2mm Talar Cutting Block** may be used to take additional talar bone if needed *(Figure 22)*.

Holding the foot in neutral dorsiflexion position and the heel in slight valgus, the two talar block stabilizing pins are inserted and the talar cut is made with the oscillating saw *(Figure 23)*.

Figure 24
Clear Tibial and Talar Resections

Figure 25
Verify Resection Gap

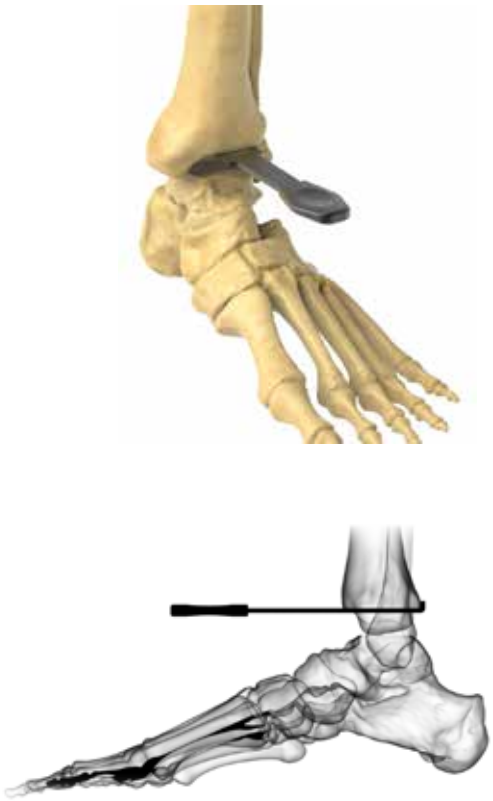


Figure 26
Assess Tibial Size
(Optional Step)

Clear the talar bone to ensure a rectangular opening. Use the **Gap Check Tool** to verify that a minimum amount of bone has been resected to accommodate the implant *(Figure 24)*.

SURGICAL PEARL
Do not remove alignment guide until you verify with the gap check tool. This will make the process easier if you need to recut.

The gap check tool represents the smallest tibial shape and minimum implant thickness. It will identify risk of impingement laterally with the fibula. Impingement at this point may be corrected by resecting more of the medial malleolus *(Figure 25)*.

Assess the tibia size using the A/P sizing tool; this step is optional *(Figure 26)*.

Signifies fluoroscopic image

Figure 27
Place Talar Lollipop with Distractor/
General Tool to Apply Soft Tissue Tension

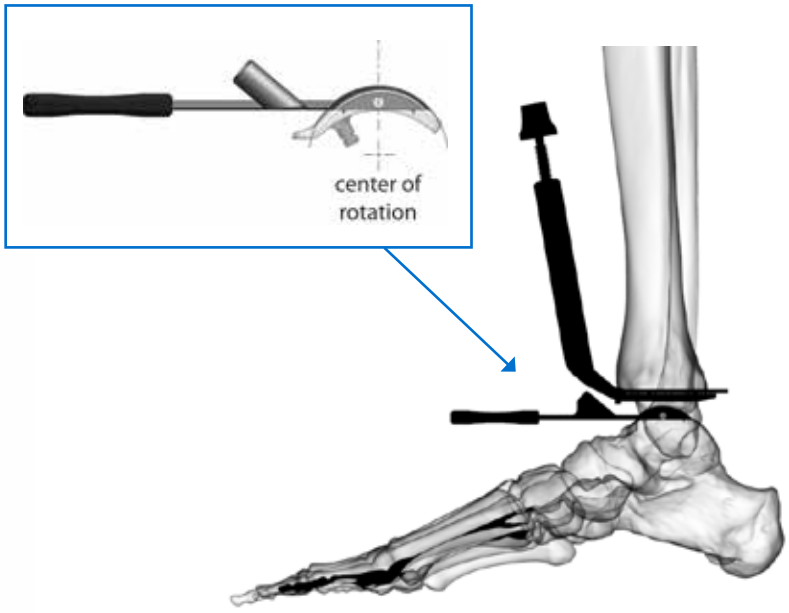


Figure 28
Place Curvature in Line with Existing Surface

The **Talar Lollipop** should be placed onto the resected talar dome to identify the proper coverage. The handle is meant to align in the A/P direction (second ray). The **Distraction Tool** (or any general OR distractor such as a lamina spreader) may be used to tension the soft tissue and hold the lollipop in place *(Figure 27)*. Check to ensure the lollipop covers the bone medial to lateral without overhang into the gutters in order to avoid impingement.

A lateral fluoroscopic image should be taken to ensure complete coverage of the resected talus *(Figure 28)*. A circular fluoroscopic hole should be above the lateral process.

SURGICAL PEARL
In mobile bearing, the medial-lateral coverage is the most important part of the lollipop to avoid impingement. Alignment of rotation will be accounted for in the mobile bearing insert.

Figure 29
Place Anterior Pins Through Talar Lollipop

Figure 30
Remove Talar Lollipop

Once the desired position is achieved, two anterior pins should be placed into the talus through the lollipop *(Figure 29)*.

The **Distractor** and **Lollipop** are then removed from the joint, leaving the two anterior pins *(Figure 30)*.

Signifies fluoroscopic image

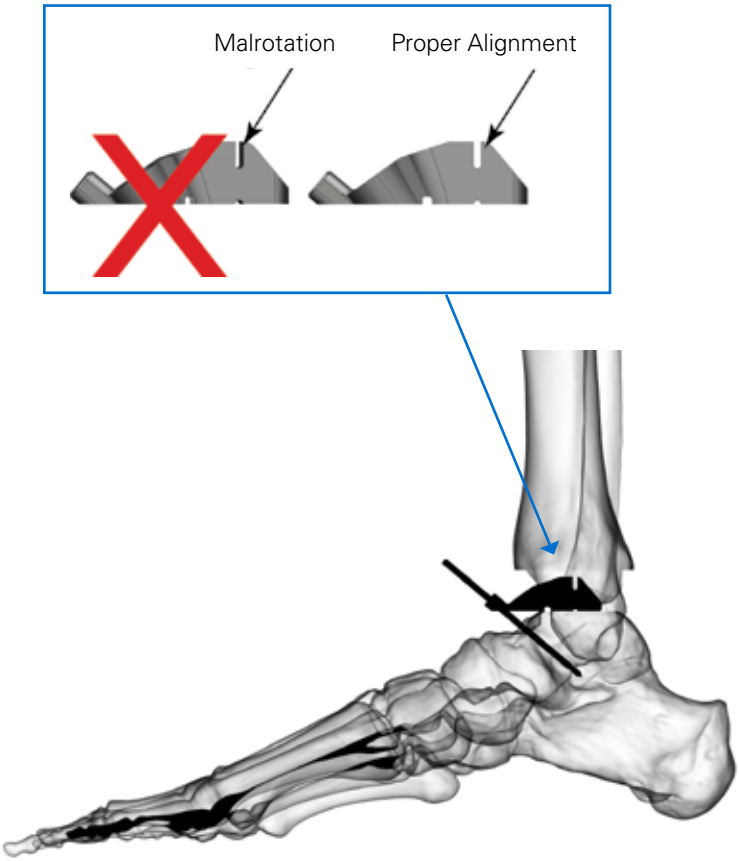


Figure 31
Place Talar Mill Block - Ensure Block Seats on Talar Surface

(Fluoroscopy image is optional.)

Figure 32
Check and Resect Posterior Chamfer Cut

The corresponding sized **Talar Mill Block** is placed over the anterior pins and held onto the cut talar surface. Ensure that the cutting block is in complete contact with the cut surface, as posterior lift off will bias the cut surface in dorsiflexion.

A lateral fluoroscopic image may optionally be taken to verify the block is in complete contact with the cut surface. A distractor should be used to hold the block in place and tension the joint prior to placing the 2.4mm pins *(Figure 31)*.

SURGICAL PEARL
If taking a lateral image of the mill block, the fluoroscopic notch should be directly above the lateral process.

Check the posterior chamfer slot on the talar cutting block to ensure the blade makes contact with the posterior bone prior to inserting the stabilizing pins. If the blade misses the bone posteriorly, a different block should be chosen or the block should be shifted anteriorly.

With the distractor in place, the two stabilizing **Olive Pins** are placed into the block to hold it to the talus during preparation. Alternatively, the sterile pins from the **2.4mm x 3.5" Fluted Olive Pin Pouch** may be used in place of the standard Olive Pins. If the olive pins are not providing stable fixation, any of the 2.4mm pins can be used.

The first posterior chamfer cut may be made using the oscillating saw through the posterior slot *(Figure 32 and 33)*.

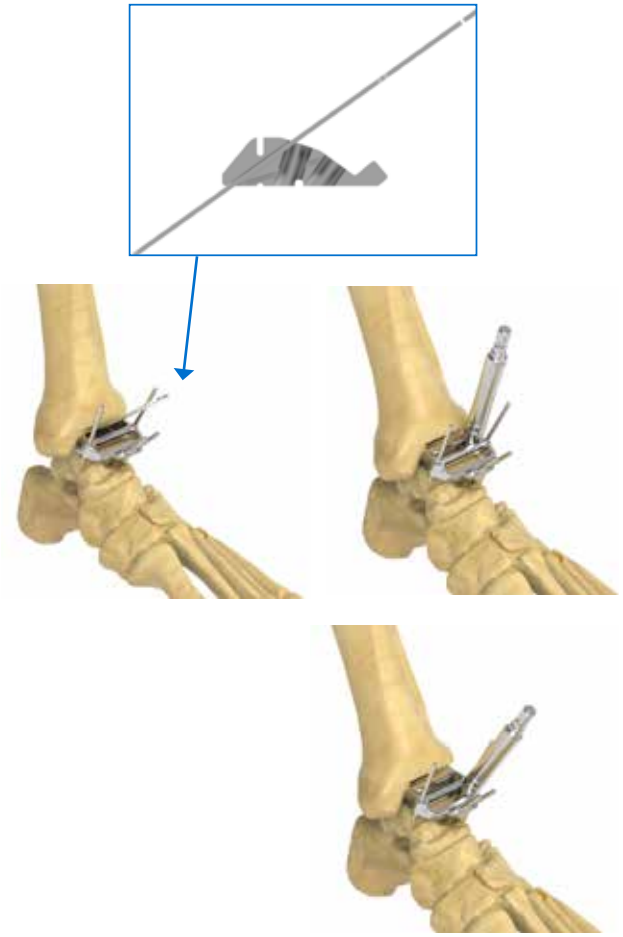


Figure 33
Make the First Posterior Chamfer Cut and Mill Both Slots

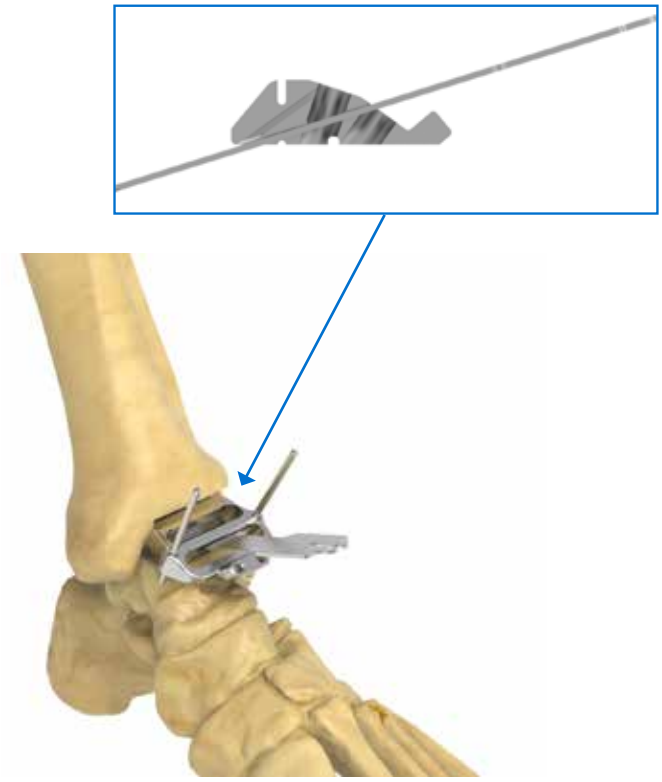


Figure 34
Remove Anterior Pins and Make Second Posterior Chamfer Cut

The **Anterior Mill Tool** should be used through the two anterior slots to create the faceted surfaces *(Figure 33)*.

SURGICAL PEARL

Milling in sequential shallow passes or drilling holes and connecting them is more effective than plunging to depth and attempting to pull the bit medial to lateral.

The anterior pins should be removed at this point to allow the saw to clear the second posterior chamfer cut *(Figure 34)*.

Figure 35
Remove Pins and Blocks to View Faceted Talar Surface

Figure 36
Remove High Spots with Talar Rasp

All pins and block are removed revealing a faceted talar surface *(Figure 35)*. Depending on osteophyte formation, the talar neck region may need to be cleared using a rongeur.

The **Curved Rasp** should be used to smooth high spots on the talar bone leaving a curved surface that will mate with the talar implant *(Figure 36)*. The Curved Rasp should be used to smooth high spots on the talar bone by applying pressure in a radial motion (anterior to posterior & posterior to anterior).

Figure 37
Place Talar Trial – Lateral View

Figure 38
Place Talar Trial – Anterior View

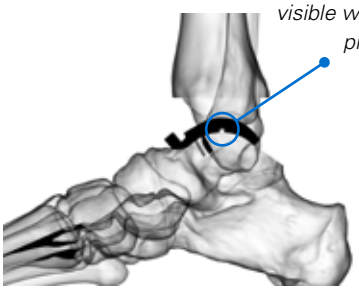
Using the **Scissor Inserter Handle**, the **Talar Trial** should be placed onto the cut surface to identify any osteophytes on the anterior talus that may need to be removed *(Figure 37)*.

The talar trial should now be centered on the cut talar surface *(Figure 38)*.

Signifies fluoroscopic image

Figure 39a
Place Talar Trial Screw to Hold Talar Trial

The radiographic indicator (circled below) will only be visible when the component is properly aligned.



Proper Alignment

Mis-alignment

Figure 39b
Verify Alignment in Lateral X-ray

Figure 39c
Drill Talar Peg Holes

The **Talar Trial Screw** or **Talar Trial Screw Pouch** is placed into the center slot to hold the trial component onto the bone during motion assessment *(Figure 39a)*.

Check the talar orientation using a lateral fluoroscopic image. Once the proper orientation is achieved, drill the talar holes *(Figure 39c)*.

Figure 40
Place Appropriately-Sized Tibial Punch Guide

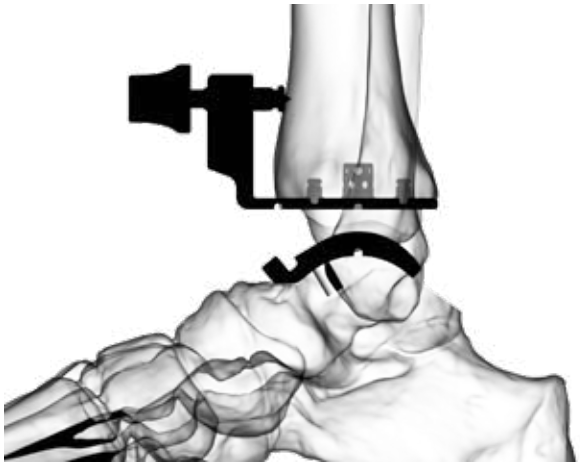


Figure 41
Confirm Tibial Size and Placement - Lateral View

Insert the **Tibial Punch Guide** that is appropriate for the native tibia and the **Tibial Liner Trial** that is appropriate for the selected talar trial. The liner trial may be inserted by hand simultaneously with the Tibial Punch Guide or after insertion of the Tibial Punch Guide with the aid of the Scissor Inserter Handle, based on surgeon preference. Articulate the joint and ensure the rotation of the tibial component is correct. Check the range of motion and look for evidence of lift-off during articulation *(Figure 40)*. This confirms proper alignment between the tibia and talus.

Check the A/P position of the tibial component. A lateral fluoroscopic image will show where the cage will be located.

Adjust using the anterior knob. The punch guide has markings for the anterior and posterior pegs as well as the center cage. The A/P size of the implant is marked by a large notch anteriorly and by the posterior edge of the punch guide *(Figure 41)*.

Signifies fluoroscopic image

Figure 42
Pin Tibial Punch Guide in Place

Once the position is correct, use any 2.4mm diameter pins to lock the position. The **Fluted Pin Pouch** (2.5" or 3.5" diameter) can be used the same as any 2.4mm pins and is packaged in its own sterile pouch. A final check of the articulation is used to validate placement and identify risk of talar impingement. This determines the rotation of the tibial component *(Figure 42)*.

Remove the tibial liner trial to create space.

Remove the talar trial component, leaving the punch guide attached to the distal tibia. Adjust the screw so it touches the anterior cortex in order to prevent tilting. This forces the punch guide plate into the distal tibia for better stability.

Figure 43
Center Cage Punch

Insert the **Center Cage Punch** into the punch guide. It may be helpful to angle the impactor toward the fibula during insertion.

Once in place, impact the punch into the distal tibia until it is fully seated in the guide *(Figure 43)*.

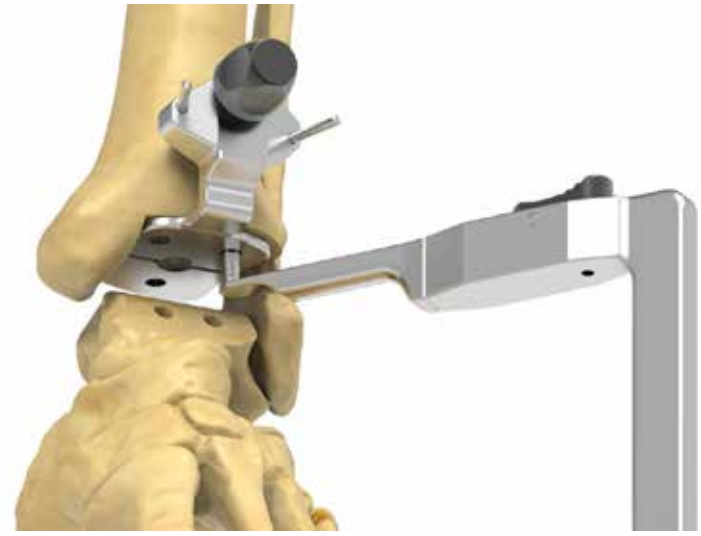


Figure 44
Punch Peripheral Pegs Through Guide

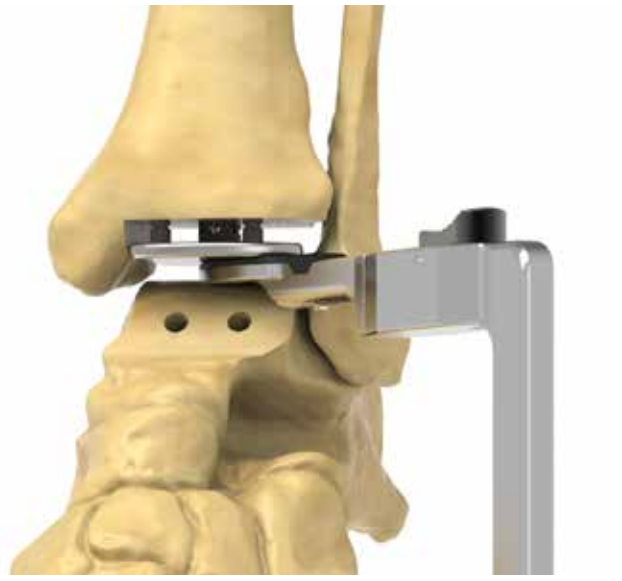


Figure 45
Impact Tibial Component

Repeat this process using the **Peripheral Peg Punch** on the three-peg holes *(Figure 44)*.

Note: *In cases of hard bone, you may remove the Tibial Punch Guide and re-punch the holes using the peripheral peg and center cage punches.*

Remove the punch guide and manually insert the tibial component into the joint. Assemble the **Radel Tibial Impactor Tip** onto the impactor handle assembly *(Figure 45)*.

Impact the tibial component up into the distal tibia ensuring that it is fully seated.

Note: *Apply impaction posterior during the tibial insertion to ensure that the posterior peg is fully seated.*

Figure 46
Impact Talus

Figure 47
Insert Tibial Liner Trial

Attach the **Talar Impactor Cover** to the **Talar Impactor Frame** and then to the impactor handle. This may require plantarflexion of the foot to seat the impactor tip. Ensure the component is fully seated onto the bone *(Figure 46)*.

Insert the Tibial Liner Trial with the Scissor Style Inserter Handle to verify the correct liner thickness for proper ligament tensioning *(Figure 47)*.

Figure 48a
Insert the Polyethylene

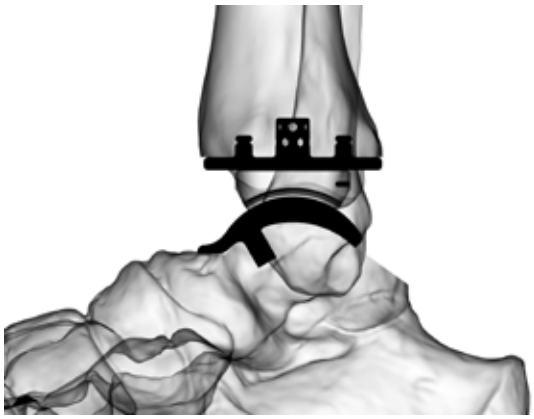


Figure 48b
Verify with X-ray

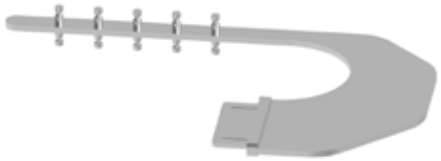
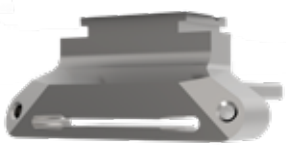
Figure 49
Final Implant Construct

Remove liner trial and insert the final liner component *(Figure 48a and 49)*.

Note: *Size and thickness are listed on the anterior portion of the polyethylene component. In a lateral X-ray, a radiographic marker should show on the posterior end of the polyethylene component (Figure 48b).*

The entire wound is irrigated with antibiotic solution and 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 short-leg cast are applied with the ankle in neutral position.

INSTRUMENT LISTING

CATALOG NUMBER	PART DESCRIPTION	
351-90-00	Tibial Tubercle Pin	
351-10-00	Tibial Alignment Guide	
351-90-01 351-90-02 351-90-08	2.4mm x 3.5" Fluted Drill Bit 2.4mm x 2.5" Fluted Drill Bit 2.4mm x 4.5" Fluted Drill Bit	
351-90-03	2.4mm x 3.5" Olive Pin	
351-90-04	Talar Trial Screw	
351-10-17	Low-Profile Angel Wing	
351-93-01	Modular Impactor Handle	
351-93-02	Hex Driver with Zimmer/Hudson Connection	
351-10-01 351-10-02 351-10-03 351-10-04	Tibial Cutting Block Size 1-2 - Left Tibial Cutting Block Size 1-2 - Right Tibial Cutting Block Size 3-4 - Left Tibial Cutting Block Size 3-4 - Right	
351-00-01 351-00-02	Talar Cutting Block Standard +4mm Talar Cut Talar Cutting Block +2mm Talar Cut	

351-10-09 (white) 351-10-10 (black)	Mobile Bearing Gap Check Tool Size 1-2 Mobile Bearing Gap Check Tool Size 3-4

CATALOG NUMBER	PART DESCRIPTION
351-10-15	A/P Sizing Tool
351-17-02	Tibial Radel Impactor
351-07-00	Talar Impactor Tip
351-10-13	Modular Impactor Arm
351-10-25	Peripheral Peg Punch
351-10-26	Center Peg Punch
351-10-11	Rotation Alignment Rod
351-10-12	Medial Shim
351-10-16	Ankle Foot Distractor

351-01-10	Scissor Style Inserter Handle	

CATALOG NUMBER	PART DESCRIPTION	
351-01-01	Lollipop Guide - Size 1	
351-01-02	Lollipop Guide - Size 2	
351-01-03	Lollipop Guide - Size 3	
351-01-04	Lollipop Guide - Size 4	
351-02-01	Mill Talar Block - Size 1	
351-02-02	Mill Talar Block - Size 2	
351-02-03	Mill Talar Block - Size 3	
351-02-04	Mill Talar Block - Size 4	
351-04-01	Talar Trial - Size 1 - Right	
351-04-02	Talar Trial - Size 2 - Right	
351-04-03	Talar Trial - Size 3 - Right	
351-04-04	Talar Trial - Size 4 - Right	
351-03-01	Talar Trial - Size 1 - Left	
351-03-02	Talar Trial - Size 2 - Left	
351-03-03	Talar Trial - Size 3 - Left	
351-03-04	Talar Trial - Size 4 - Left	
351-05-00	Talus Drill	
351-05-01	Rasp - Size 1	
351-05-02	Rasp - Size 2	
351-05-03	Rasp - Size 3	
351-05-04	Rasp - Size 4	
351-05-10	Talar Mill Bit	
351-11-01	Tibial Punch Guide - Left - Size 1	
351-11-02	Tibial Punch Guide - Left - Size 2	
351-11-03	Tibial Punch Guide - Left - Size 3	
351-11-04	Tibial Punch Guide - Left - Size 4	
351-12-01	Tibial Punch Guide - Right - Size 1	
351-12-02	Tibial Punch Guide - Right - Size 2	
351-12-03	Tibial Punch Guide - Right - Size 3	
351-12-04	Tibial Punch Guide - Right - Size 4	
351-07-03	Talar Impactor Frame	

351-07-04	Talar Impactor Cover

CATALOG NUMBER	PART DESCRIPTION
351-41-01	Liner Trial - Mobile Bearing - Size 1 - Left - 6MM
351-41-02	Liner Trial - Mobile Bearing - Size 2 - Left - 6MM
351-41-03	Liner Trial - Mobile Bearing - Size 3 - Left - 6MM
351-41-04	Liner Trial - Mobile Bearing - Size 4 - Left - 6MM
351-42-01	Liner Trial - Mobile Bearing - Size 1 - Right - 6MM
351-42-02	Liner Trial - Mobile Bearing - Size 2 - Right - 6MM
351-42-03	Liner Trial - Mobile Bearing - Size 3 - Right - 6MM
351-42-04	Liner Trial - Mobile Bearing - Size 4 - Right - 6MM
351-41-11	Liner Trial - Mobile Bearing - Size 1 - Left - 7MM
351-41-12	Liner Trial - Mobile Bearing - Size 2 - Left - 7MM
351-41-13	Liner Trial - Mobile Bearing - Size 3 - Left - 7MM
351-41-14	Liner Trial - Mobile Bearing - Size 4 - Left - 7MM
351-42-11	Liner Trial - Mobile Bearing - Size 1 - Right - 7MM
351-42-12	Liner Trial - Mobile Bearing - Size 2 - Right - 7MM
351-42-13	Liner Trial - Mobile Bearing - Size 3 - Right - 7MM
351-42-14	Liner Trial - Mobile Bearing - Size 4 - Right - 7MM
351-41-21	Liner Trial - Mobile Bearing - Size 1 - Left - 8MM
351-41-22	Liner Trial - Mobile Bearing - Size 2 - Left - 8MM
351-41-23	Liner Trial - Mobile Bearing - Size 3 - Left - 8MM
351-41-24	Liner Trial - Mobile Bearing - Size 4 - Left - 8MM
351-42-21	Liner Trial - Mobile Bearing - Size 1 - Right - 8MM
351-42-22	Liner Trial - Mobile Bearing - Size 2 - Right - 8MM
351-42-23	Liner Trial - Mobile Bearing - Size 3 - Right - 8MM
351-42-24	Liner Trial - Mobile Bearing - Size 4 - Right - 8MM
351-41-31	Liner Trial - Mobile Bearing - Size 1 - Left - 9MM
351-41-32	Liner Trial - Mobile Bearing - Size 2 - Left - 9MM
351-41-33	Liner Trial - Mobile Bearing - Size 3 - Left - 9MM
351-41-34	Liner Trial - Mobile Bearing - Size 4 - Left - 9MM
351-42-31	Liner Trial - Mobile Bearing - Size 1 - Right - 9MM
351-42-32	Liner Trial - Mobile Bearing - Size 2 - Right - 9MM
351-42-33	Liner Trial - Mobile Bearing - Size 3 - Right - 9MM
351-42-34	Liner Trial - Mobile Bearing - Size 4 - Right - 9MM

INSTRUMENT LISTING

CATALOG NUMBER	PART DESCRIPTION
351-41-41	Liner Trial - Mobile Bearing - Size 1 - Left - 10MM
351-41-42	Liner Trial - Mobile Bearing - Size 2 - Left - 10MM
351-41-43	Liner Trial - Mobile Bearing - Size 3 - Left - 10MM
351-41-44	Liner Trial - Mobile Bearing - Size 4 - Left - 10MM
351-42-41	Liner Trial - Mobile Bearing - Size 1 - Right - 10MM
351-42-42	Liner Trial - Mobile Bearing - Size 2 - Right - 10MM
351-42-43	Liner Trial - Mobile Bearing - Size 3 - Right - 10MM
351-42-44	Liner Trial - Mobile Bearing - Size 4 - Right - 10MM
351-41-51	Liner Trial - Mobile Bearing - Size 1 - Left - 11MM
351-41-52	Liner Trial - Mobile Bearing - Size 2 - Left - 11MM
351-41-53	Liner Trial - Mobile Bearing - Size 3 - Left - 11MM
351-41-54	Liner Trial - Mobile Bearing - Size 4 - Left - 11MM
351-42-51	Liner Trial - Mobile Bearing - Size 1 - Right - 11MM
351-42-52	Liner Trial - Mobile Bearing - Size 2 - Right - 11MM
351-42-53	Liner Trial - Mobile Bearing - Size 3 - Right - 11MM
351-42-54	Liner Trial - Mobile Bearing - Size 4 - Right - 11MM
351-41-61	Liner Trial - Mobile Bearing - Size 1 - Left - 12MM
351-41-62	Liner Trial - Mobile Bearing - Size 2 - Left - 12MM
351-41-63	Liner Trial - Mobile Bearing - Size 3 - Left - 12MM
351-41-64	Liner Trial - Mobile Bearing - Size 4 - Left - 12MM
351-42-61	Liner Trial - Mobile Bearing - Size 1 - Right - 12MM
351-42-62	Liner Trial - Mobile Bearing - Size 2 - Right - 12MM
351-42-63	Liner Trial - Mobile Bearing - Size 3 - Right - 12MM
351-42-64	Liner Trial - Mobile Bearing - Size 4 - Right - 12MM
351-90-08	2.4mm x 4.5" Fluted Pin
351-90-20	Tibial Tubercle Pin Pouch (sterile)
351-90-21	2.4mm x 3.5" Fluted Pin Pouch (sterile)
351-90-22	2.4mm x 2.5" Fluted Pin Pouch (sterile)
351-90-23	2.4mm x 3.5" Fluted Olive Pin Pouch (sterile)
351-90-24	Talar Trial Screw Pouch (sterile)
351-91-02	Komet Saw Blade, KMS0812.S63 STE
351-91-03	Reciprocating Komet Saw Blade, KM252R STE

THE VANTAGE TOTAL ANKLE INSTRUMENTATION SYSTEM CONSISTS OF THE FOLLOWING MATERIALS

17-4 PH Stainless Steel (Type 630) per ASTM A564/A564M or ASTM A693
Polyphenylsulfone (PPSU) in the following color codes (Black, Blue, Yellow, White, Red, Gray)
Nitronic 60 (UNS S21800)
440C Stainless Steel (UNS 44004) per ASTM A276
416 Stainless Steel (UNS S41600) per ASTM A194
316 Stainless Steel (UNS S31600) per ASTM A276
302 Stainless Steel (UNS S30200) per ASTM A276
304 Stainless Steel (Also called 18-8 Stainless Steel UNS S30400) per ASTM A276
420 Stainless Steel (UNS S42000) per ASTM A276
AlTiN Coating
Chrome Coating
DLC Coating

INTENDED USE

The Vantage Total Ankle Mobile Bearing System is a non-constrained ankle replacement intended for the treatment of end-stage arthritis in the ankle. The implant assembly includes three components: the talar, tibial and liner. The tibial and talar components are intended for press-fit fixation to the distal tibia and proximal talus, respectively.

INDICATIONS FOR USE

The Vantage Total Ankle Mobile Bearing System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic or degenerative arthritis. It is also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

CONTRAINDICATIONS FOR USE

Use of the Vantage Total Ankle System is contraindicated in the following situations:

- Excessive bone loss at the ankle joint site
- Severe osteoporosis
- Complete talar avascular necrosis
- Active osteomyelitis
- Infection at the ankle site or infection at distant sites that could migrate to the ankle
- Sepsis
- Vascular deficiency in the involved limb
- Cases where there is inadequate neuromuscular status (i.e. prior paralysis, fusion and/or inadequate abductor strength)
- Neuropathic joints
- Neurological or musculoskeletal disease or loss of function that may adversely affect movement of the lower limb, gait or weight bearing
- Poor soft tissue coverage around the ankle
- Charcot arthropathy
- Previous ankle arthrodesis with excision of the malleoli
- Excessive loads as caused by activity or patient weight
- Skeletally immature patients (patients less than 21 years old at the time of surgery)
- Dementia
- Known metal allergies
- Pregnancy

NOT AVAILABLE FOR SALE IN THE UNITED STATES

Exactech is proud to have offices and distributors around the globe. For more information about Exactech products available in your country, please visit www.exac.com

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For additional device information, refer to the Exactech Vantage® Total Ankle Mobile Bearing System–Instructions for Use (700-096-156) for a device description, indications, contraindications, precautions, and warnings. The Vantage Total Ankle Mobile Bearing System is not available for sale in the United States. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for comprehensive warnings, precautions, indications for use, contraindications, and adverse effects.

 721-00-31 Rev. C 0322

CE 2797 CE Mark is not valid unless there is a CE Mark on the product label.

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