

EXACTECH | EXTREMITIES

Operative Technique Addendum



VANTAGE[®]
TOTAL ANKLE

Flat Cut Talus - Fixed Bearing System
Coupled Cut Technique Addendum



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NOTE

This document presents the coupled cut addendum to the standard Vantage® Total Ankle System Fixed Bearing operative technique to include the Vantage Ankle Flat Cut Talus devices.

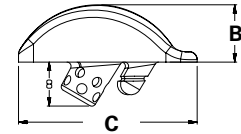
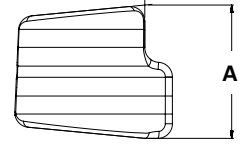
The Vantage Ankle Flat Cut Talus implants are inserted using steps similar to those used to insert the standard Vantage Ankle. The steps described in this coupled cut operative technique addendum address the steps specific to the Flat Cut Talus implants and related instrumentation.

INTRODUCTION

Thank you for considering the Vantage Ankle Flat Cut Talus System. The Vantage Ankle Flat Cut System is the newest addition to the Vantage Ankle family and builds on the design history and research of our standard system. Created by the collaborative effort of engineering research and the global thought leaders, the Vantage Ankle Flat Cut Talus provides a talar dome replacement option for patients who have suffered greater extent of talar bone damage due to severe rheumatoid, post-traumatic, or degenerative arthritis than can be adequately addressed by standard Vantage Ankle talar implants, but are still candidates for total ankle arthroplasty, per surgeon evaluation.

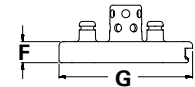
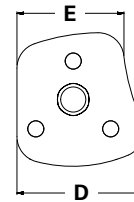
FIXED BEARING FLAT CUT TALUS

Length (mm)	Size 1	Size 2	Size 3	Size 4	Size 5
Medial/Lateral - A	29	31.2	33.5	35.7	38
Cage Height - 8mm For All Sizes					
Thickness (mm) - B	11	11.3	11.6	12	12.3
A/P (mm) - C	34.3	36.9	38.8	40.6	43

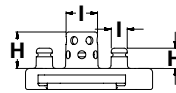


FIXED BEARING TIBIA

Measurements (mm)	Size 1	Size 2	Size 3	Size 4
Anterior Width - D	31.4	32.6	33.8	35.1
Posterior Width - E	26.4	27.8	29.1	30.5
Thickness - F	5.2	5.2	5.2	5.2
A/P Length - G	33	36.5	40.6	44.7

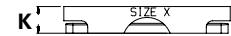
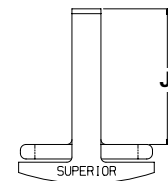


Peg and Cage Measurements (mm) - For All Sizes	Bone Cage	Pegs
Height - H	9	5
Diameter - I	8	4



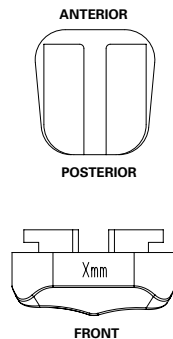
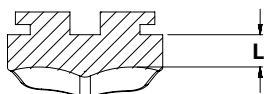
LOCKING CLIP

Locking Clip Measurements (mm)	Size 1	Size 2	Size 3	Size 4	Size 5
Length of Locking Feature - J	21.4	21.4	21.4	21.4	21.4
Thickness - K	3.4	3.4	3.4	3.4	3.4

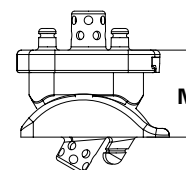


FIXED BEARING POLYETHYLENE (MM) - FOR ALL TALUS SIZES

Labeled Thickness (mm)	Minimum Thickness (mm) - L
6	4
7	5
8	6
10	8
12	10



Full Construct (mm)	Size 1	Size 2	Size 3	Size 4	Size 5
Resection Height with 6mm Liner - M	20.2	20.5	20.8	21.2	21.5



OPERATIVE TECHNIQUE OVERVIEW

Please reference Vantage Total Ankle Fixed Bearing Operative Technique (721-00-30) Surgical Approach Overview until *Figure 3*.



Figure A
Place the Coupled
Cutting Block

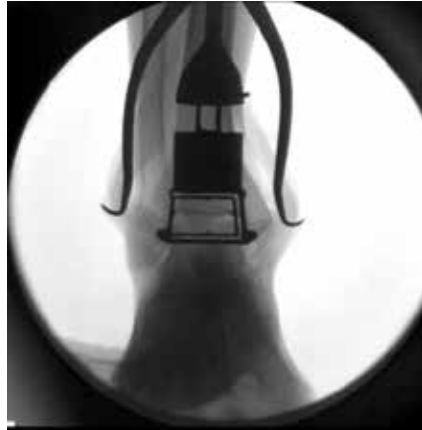


Figure B
Review Fluoroscopic Image for Alignment



Figure C
Adjust the Medial/Lateral Position



Figure D
Insert the Angel Wing to
Assess Slope



Figure E
Proximal Hole on the
Coupled Cut Block



Figure F
Remove the Tibia and Talar Resections



Figure G
Place Flat Cut Talus Trial With Scissor Inserter



Figure H
Insert Gap Check Tool and Verify Resection Gap



Figure I
Check the Talus Trial Position with a Lateral Shot



Figure J
Pin the Flat Cut Talus Trial



Figure K
Use Talus Drill to Clear Anterior Holes



Figure L
Use Coring Drill to Prepare the Center Hole for the Bone Cage

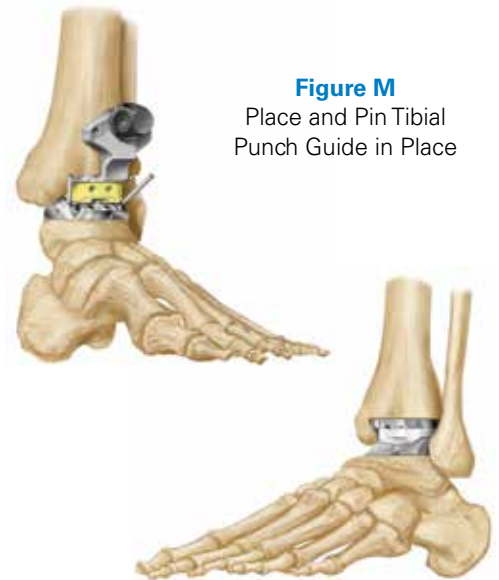


Figure M
Place and Pin Tibial Punch Guide in Place

Figure N
Final Implant

SURGICAL PEARL

Add bone graft to the flat cut talus central cage prior to impaction.

Please reference the Vantage Total Ankle Fixed Bearing Operative Technique (721-00-30) Overview figures 19 through 21 for the preparation of the tibial bone and implantation of the implant construct.

SYSTEM USE SPECIFICATIONS

INTENDED USE

The Vantage Ankle Flat Cut Talus System is a semi-constrained ankle replacement intended for the treatment of severe arthritis in the ankle. The implant assembly includes four components: the flat cut talus, tibia, polyethylene liner and locking piece. The tibial and talar components are cemented to the distal tibia and proximal talus, respectively.

INDICATIONS FOR USE

The Vantage Total Ankle 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.

The Vantage Total Ankle System is indicated for cemented use only.

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

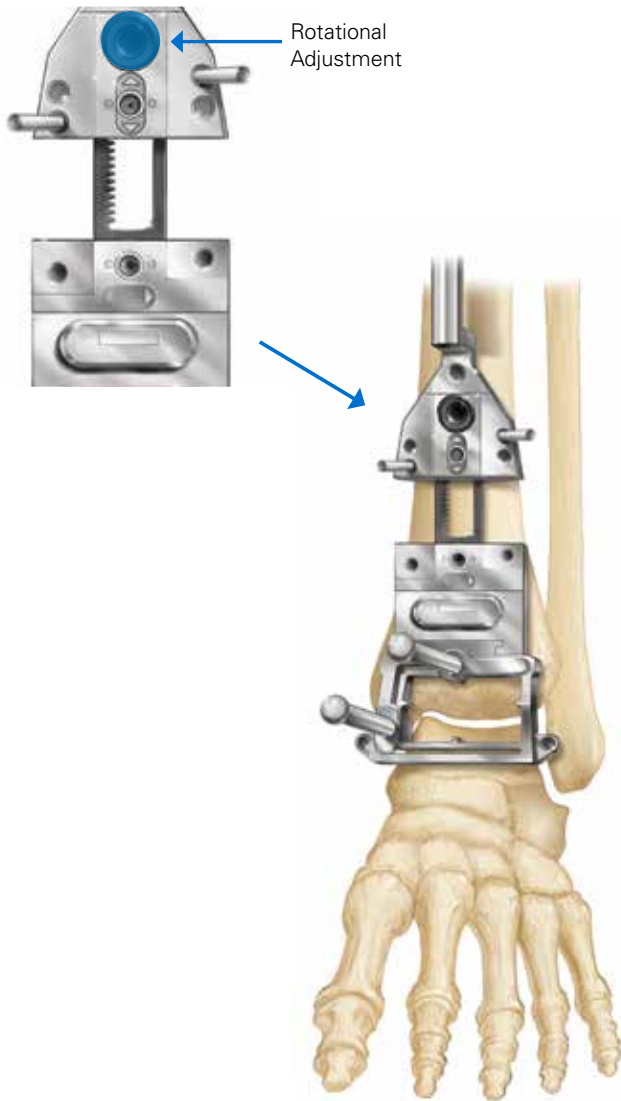


Figure 1
Place the Coupled Cutting Block

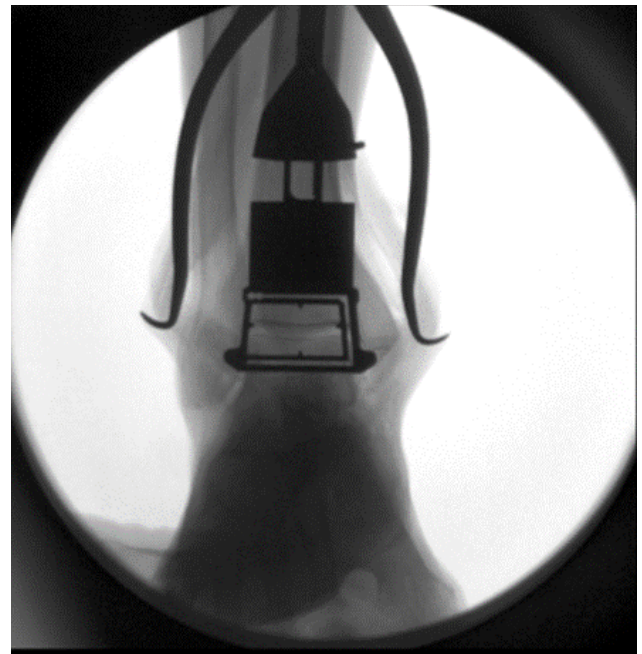


Figure 2
Review Fluoroscopic Image for Alignment

Please reference the Vantage Ankle Total Operative Technique 721-00-30 until page nine, then follow the directions below.

Note: *Since the instruction flow in this addendum is tight to the original operative technique (721-00-30), any change to the original operative technique should be evaluated for its impact on the content and instruction flow in this addendum.*

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 slot of the **Coupled Cut Block**. Adjust rotation of the distal block so the Medial Shim and Rotation Alignment Rod are

parallel. To lock the rotation, use the **1/8" Standard Hex Driver** in the central locking screw. 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 oriented with the second ray.*

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH

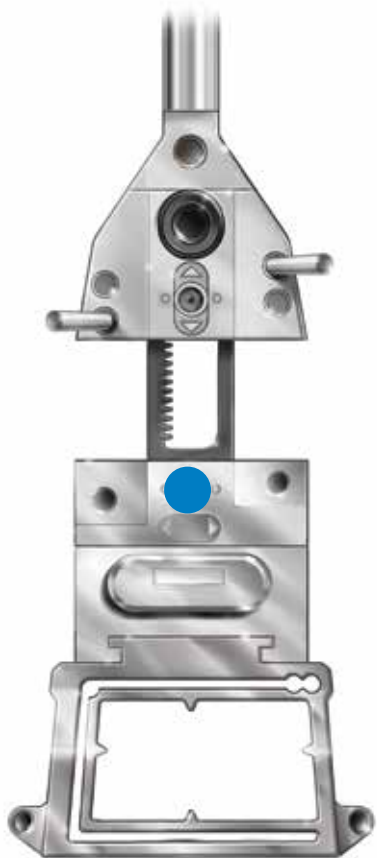
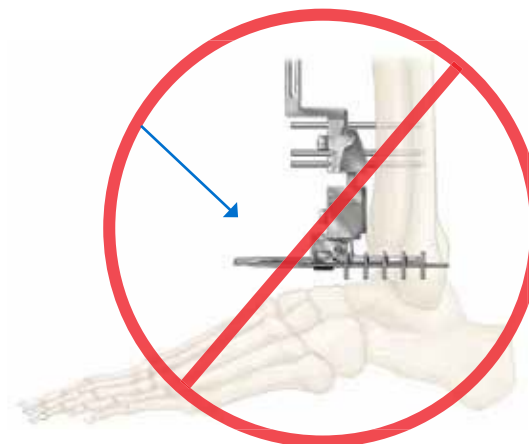
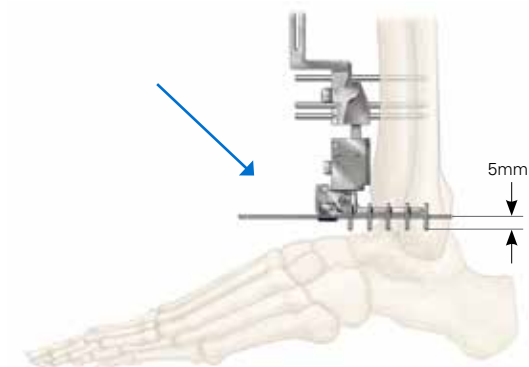


Figure 3
Adjust the Medial/Lateral Position



MALALIGNMENT





PROPER ALIGNMENT

Figure 4
Insert Angel Wing to Assess Slope

SURGICAL PEARL


In the case of a severe talar dome collapse, it is recommended to use a lamina spreader to distract the joint prior to adjusting the block.

 An anterior view fluoroscopic image should be taken to ensure alignment between the horizontal pointers and the joint line, and the vertical pointers and the center of the tibial axis. This can be achieved by adjusting the medial-lateral position of the Coupled Cut Block.

 A mortise fluoroscopic image should be taken to check the M/L position of the lateral holes on the tibial side of the Coupled Cut Block.

These indicate the width of the tibial components and will identify the largest component that fits between the malleoli. Select the appropriately-sized block based on the M/L coverage.

Insert the **Angel Wing** into the talar cutting slot of the Coupled Cut Block and make adjustments at the proximal pin to ensure the Angel Wing is perpendicular to the tibial axis.

 A lateral fluoroscopic image should be taken at this point to assess the slope of the Angel Wing relative to the tibial axis. Ensure the Angel Wing is at its thinnest.

The slope may be adjusted by sliding the proximal guide along the tubercle pin shaft. Ensure proper alignment of the Angel Wing.

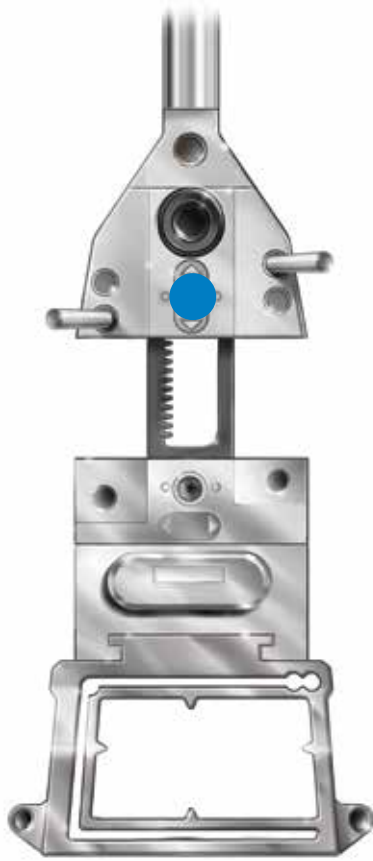


Figure 5
Adjust Superior/Inferior Position

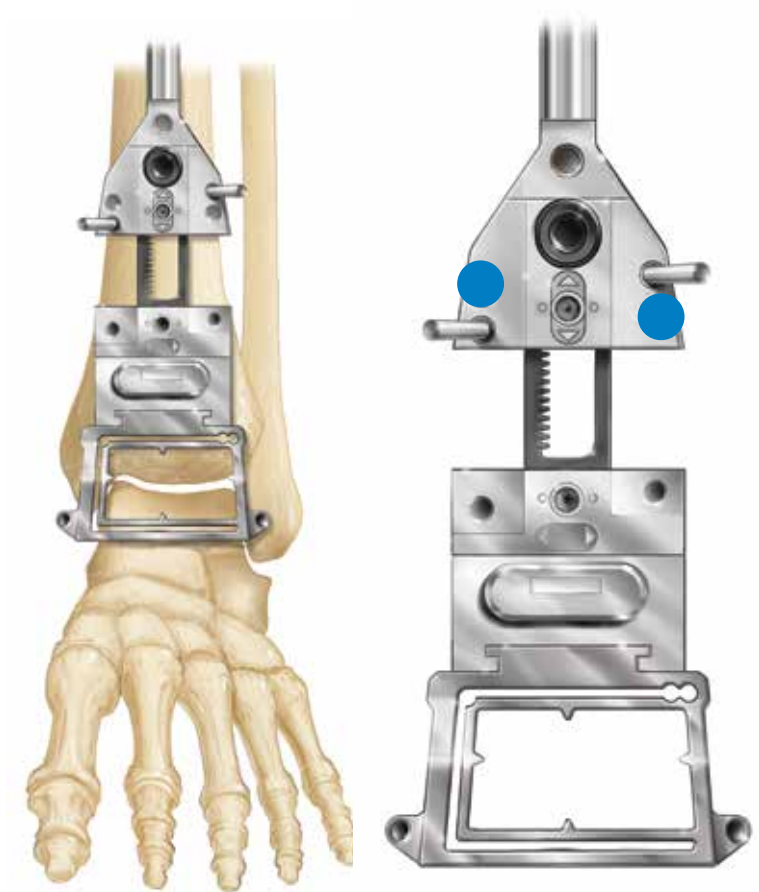


Figure 6
Pin the Proximal Holes on the Coupled Cut Block

The level of the cut may be adjusted using the superior-inferior adjustment on the guide.

Hold the foot in neutral dorsiflexion and heel in slight valgus. Adjust the Coupled Cut Block in the S/I direction, so that the resection level is roughly 2mm above the talar neck.

When the proper orientation is achieved, pin the upper portion of the block in any of the holes depending on the best bony purchase. Two pins are recommended.

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH

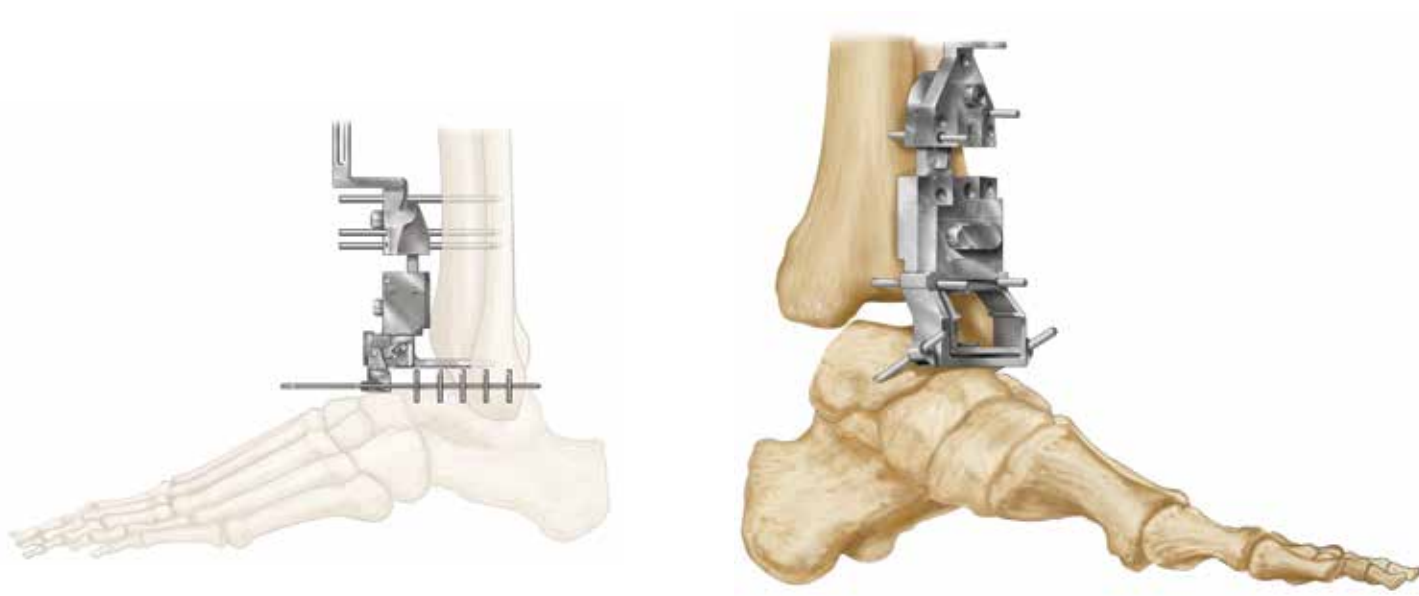


Figure 7

Pin the Coupled Cut Block

Insert two inferior, oblique stabilizing pins into the distal end of the cutting block.

Pin the tibial cutting slot of the Coupled Cut 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. Cut the bone along the medial malleoli. 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.

Cut the talus with the oscillating saw.

Note: Prior to removing the block, ensure that the resection cleared the bone on the medial and lateral borders of the talus. If not, move the block medially or laterally, and clear the remaining bone on the borders of the talus.

For tight ankles, this resection is recommended to make space for the implant assembly. In ankles with laxity, a shallower cut may be taken.



Figure 8
Remove the Tibia and Talus Resections



Figure 9
Place Flat Cut Talus Trial With Scissor Inserter

First clear the resected talar bone, then the tibia to ensure a rectangular opening (*Figure 8*).

SURGICAL PEARL

When removing the resected tibial bone, cut the bone into small pieces with the **Reciprocating Saw** and then a ronguers 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.

Attach the **Scissor Inserter** to the **Flat Cut Talus Trial** and place it on the cut surface (*Figure 9*). Check the M/L coverage to determine the appropriate size. Ensure the rotation of the trial is correct, the second ray of the foot is recommended as an indicator. If connected, the scissor inserter can be used to show the rotation of the trial.

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH



Figure 10

Insert the Flat Cut Fixed Bearing Gap Check Tool

Insert the corresponding size **Flat Cut Fixed Bearing Gap Check Tool** on top of the trial (*Figure 10*).

SURGICAL PEARL

Do not remove the Alignment Guide until you verify there is sufficient resection with the Flat Cut Fixed Bearing Gap Check Tool and trial. This will make the process easier if you need to recut.

Note: Certain images are shown without the Alignment Guide to provide better visibility of other instruments in specific surgical steps.

The Flat Cut Fixed Bearing Gap Check Tool represents the tibial shape. It will identify risk of impingement laterally with the fibula. Impingement at this point may be corrected by resecting more of the medial malleolus. The Flat Cut Fixed Bearing Gap Check Tool and trial stack-up represents the minimum implant stack-up thickness.

If all resections are complete and the resection is sufficient, the Alignment Guide may be removed.




Figure 11

Ensure Proper Position of Talar Trial with Fluoroscopic Image



Figure 12

Pin the Flat Cut Talus Trial

 A lateral fluoroscopic image should be taken to ensure complete coverage of the resected talus (Figure 11).

 **SURGICAL PEARL**

The circular fluoroscopic hole should be above the lateral process.

Once the desired position is achieved, two anterior pins should be placed into the Flat Cut Talus Trial for stability (Figure 12). The Flat Cut Fixed Bearing Gap Check Tool should then be removed taking care not to dislodge the pins.

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH



Figure 13

Use Talus Drill to Clear Anterior Holes



Figure 14

Use Coring Drill to Prepare the Center Hole for the Bone Cage

Attach the **Talus Drill** to a Zimmer-Hudson adapter and prepare the two anterior holes in the trial (*Figure 13*).

Attach the **Coring Drill** to the Zimmer-Hudson adapter and prepare the center hole for the cage (*Figure 14*).

The Coring Drill is cannulated. A pin or K-wire up to 3.2mm in diameter can be used to clear the bone from the drill. This bone can be used in the cage of the talar implant.



Figure 15

Place Appropriately-Sized Tibial Punch Guide

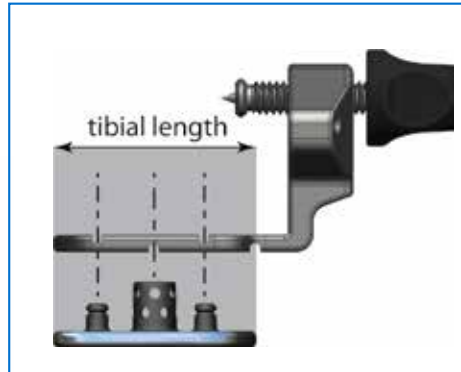



Figure 16

Confirm Tibial Size and Placement – Lateral View

Choose the appropriately-sized **Tibial Punch Guide** and **Punch Liner Trial** and then place onto the talar trial (*Figure 15*).

 Check the A/P position of the tibial component. A lateral fluoroscopic image will show where the tibial plate cage will be located (*Figure 16*). 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.

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH



Figure 17
Pin Tibial Punch Guide in Place



Figure 18
Final Assembly

Once the appropriate size has been selected, 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. This confirms proper alignment between the tibia and talus. Once the position is correct, place the **Oblique Pins** into the Tibial Punch Guide to lock the position (*Figure 17*).

Remove the Flat Cut Talus Trial and punch liner to create space.

Please reference the Vantage Total Ankle Fixed Bearing Operative Technique, 721-00-30, for the preparation of the tibial bone and implantation of the implant construct on pages 28-31.

SURGICAL PEARL

Add bone graft to the Flat Cut Talus central cage prior to impaction.

See *Figure 18* for how the final implant assembly will look.

INSTRUMENT LISTING

351-00-21	Flat Cut Talus Coupled Cut Block, Left, Size 1
351-00-22	Flat Cut Talus Coupled Cut Block, Left, Size 2
351-00-23	Flat Cut Talus Coupled Cut Block, Left, Size 3
351-00-24	Flat Cut Talus Coupled Cut Block, Left, Size 4
351-00-25	Flat Cut Talus Coupled Cut Block, Left, Size 5
351-00-26	Flat Cut Talus Coupled Cut Block, Right, Size 1
351-00-27	Flat Cut Talus Coupled Cut Block, Right, Size 2
351-00-28	Flat Cut Talus Coupled Cut Block, Right, Size 3
351-00-29	Flat Cut Talus Coupled Cut Block, Right, Size 4
351-00-30	Flat Cut Talus Coupled Cut Block, Right, Size 5

351-03-11	Flat Cut Talus Trial, Left, Size 1
351-03-12	Flat Cut Talus Trial, Left, Size 2
351-03-13	Flat Cut Talus Trial, Left, Size 3
351-03-14	Flat Cut Talus Trial, Left, Size 4
351-03-15	Flat Cut Talus Trial, Left, Size 5
351-04-11	Flat Cut Talus Trial, Right, Size 1
351-04-12	Flat Cut Talus Trial, Right, Size 2
351-04-13	Flat Cut Talus Trial, Right, Size 3
351-04-14	Flat Cut Talus Trial, Right, Size 4
351-04-15	Flat Cut Talus Trial, Right, Size 5



351-06-00	Flat Cut Talus Coring Drill
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351-10-21	Flat Cut Fixed Bearing Gap Check Tool, Sizes 1 and 2
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351-10-22	Flat Cut Fixed Bearing Gap Check Tool, Sizes 3 and 4
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IMPLANT LISTING

350-03-01	Flat Cut Talus, Left, Size 1
350-03-02	Flat Cut Talus, Left, Size 2
350-03-03	Flat Cut Talus, Left, Size 3
350-03-04	Flat Cut Talus, Left, Size 4
350-03-05	Flat Cut Talus, Left, Size 5
350-04-01	Flat Cut Talus, Right, Size 1
350-04-02	Flat Cut Talus, Right, Size 2
350-04-03	Flat Cut Talus, Right, Size 3
350-04-04	Flat Cut Talus, Right, Size 4
350-04-05	Flat Cut Talus, Right, Size 5



NOTES

AVAILABLE FOR SALE IN THE UNITED STATES AND NEW ZEALAND.

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

For additional device information, refer to the Exactech Vantage® Total Ankle Fixed Bearing System—Instructions for Use for a device description, indications, contraindications, precautions, and warnings. The Vantage Total Ankle Fixed Bearing System is not available for sale outside the United States, except New Zealand. 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.

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