EXACTECH | **EXTREMITIES**

Operative Technique Addendum

VANTAGE® TOTAL ANKLE

Mobile Bearing System
Flat Cut Talus
Decoupled Cut Technique Addendum

Exactech®

TABLE OF CONTENTS

NOTE

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

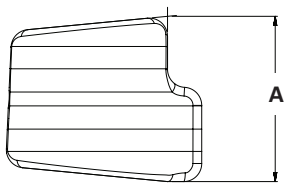
The Vantage Ankle Flat Cut Talus implants are inserted using steps similar to those used to insert the standard Vantage Ankle talar components. The steps described in this decoupled cut operative technique addendum address the steps specific to the Flat Cut Talus implants and related instrumentation.

INTRODUCTION

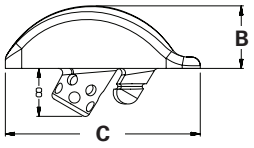
Thank you for considering the Vantage Ankle Flat Cut Talus implant. The Vantage Ankle Flat Cut Talus implant is the newest addition to the Vantage Ankle family and builds on the design history and research of our standard system. Created by the collaborative effort of engineering research and the global 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.

MOBILE 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

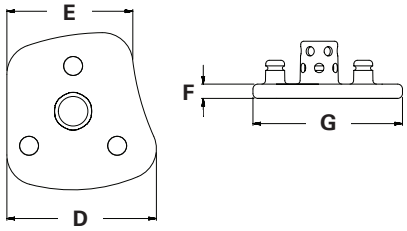


Cage Height - 8mm For All Sizes	Size 1	Size 2	Size 3	Size 4	Size 5
Thickness (mm) - B	11	11.3	11.6	12	12.3
A/P (mm) - C	34.3	36.9	38.8	40.6	43

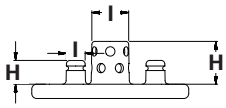


MOBILE BEARING TIBIA

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	3	3	3	3
A/P Length - G	33	36.5	40.6	44.7

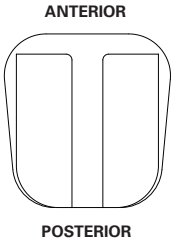


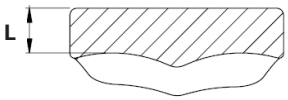
Peg and Cage Measurements (mm) - For All Sizes	Bone Cage	Pegs
Height - H	9	5
Diameter - I	8	4



MOBILE BEARING POLYETHYLENE LINER

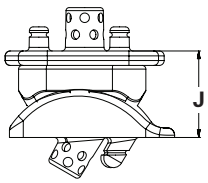
Labeled Thickness (mm) - For All Talus Sizes	Minimum Thickness (mm) - L
6	4
7	5
8	*6*
10	*8*
12	*10*





MOBILE BEARING FULL CONSTRUCT

Full Construct (mm)	Size 1	Size 2	Size 3	Size 4	Size 5
Resection Height with 6mm Liner - J	18	18.3	18.6	19	19.3



OPERATIVE TECHNIQUE OVERVIEW

Please reference Vantage Total Ankle Mobile Bearing Operative Technique (721-00-31) Surgical Approach Overview until figure 8.

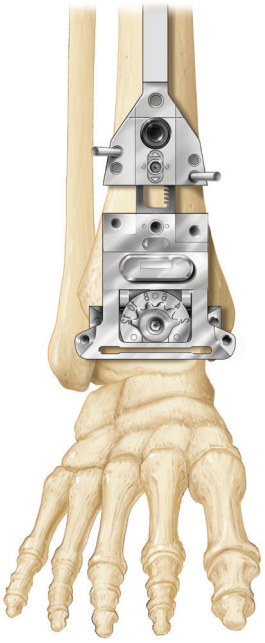


Figure A
Place the Adjustable Talar Cutting Block

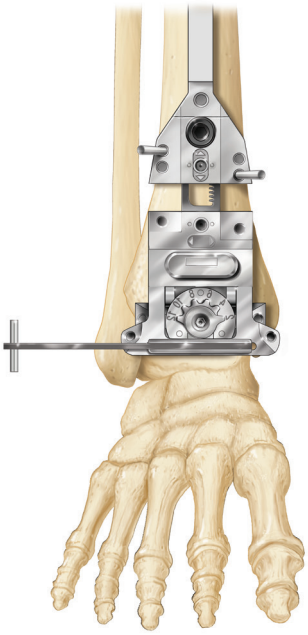


Figure B
Insert the Low-Profile Angel Wing

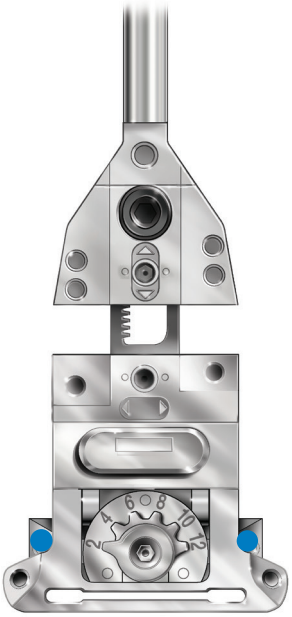


Figure C
Assess Slope and Pin Proximal Holes

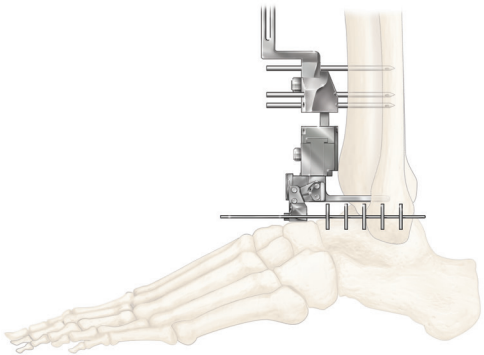


Figure D
Insert the Low-Profile Angel Wing and Assess Resection Height

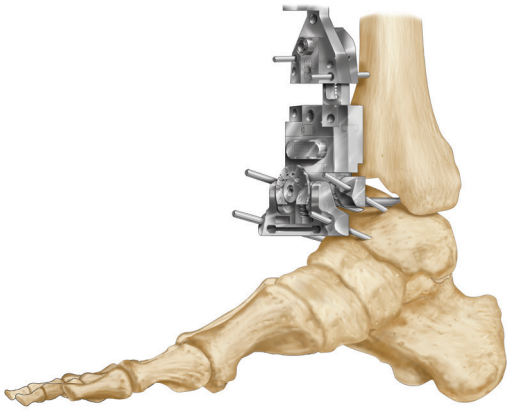


Figure E
Pin the Distal Holes of the Adjustable Cutting Block

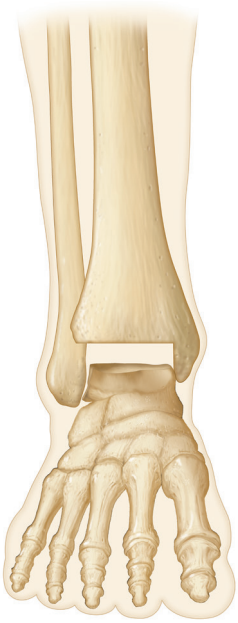


Figure F
Remove the Talar Resection

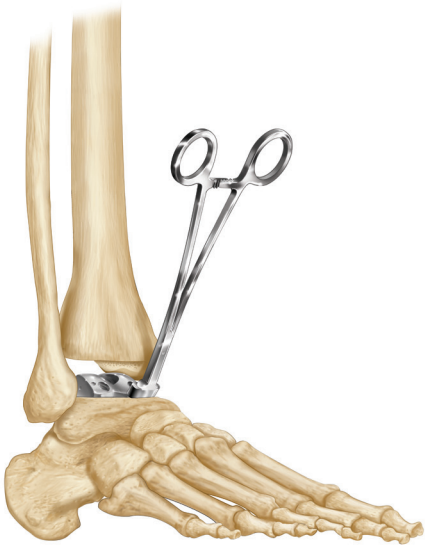


Figure G
Place Flat Cut Talus Trial With Scissor Inserter

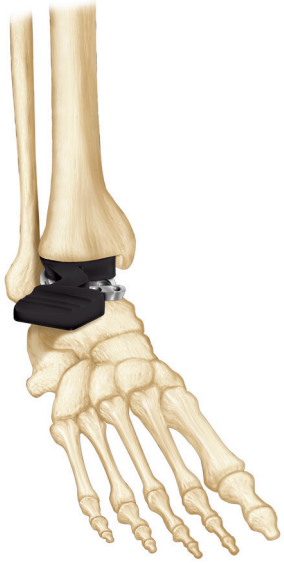


Figure H
Insert Gap Check Tool and Verify Resection Gap

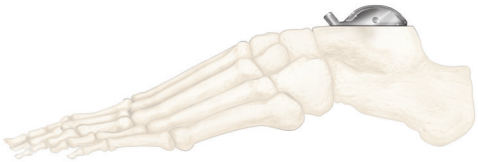


Figure I
Check the Talus Trial Position with a Lateral Shot

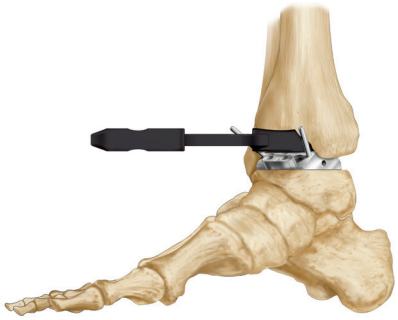


Figure J
Pin the Flat Cut Talus Trial

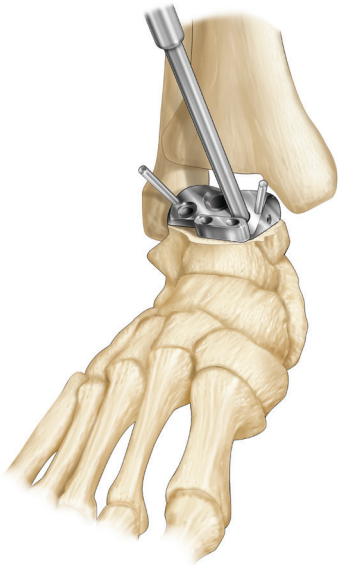


Figure K
Use Talus Drill to Clear Anterior Holes

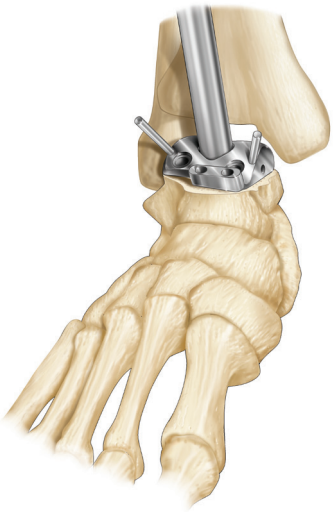


Figure L
Use Coring Drill to Prepare the Center Hole for the Bone Cage

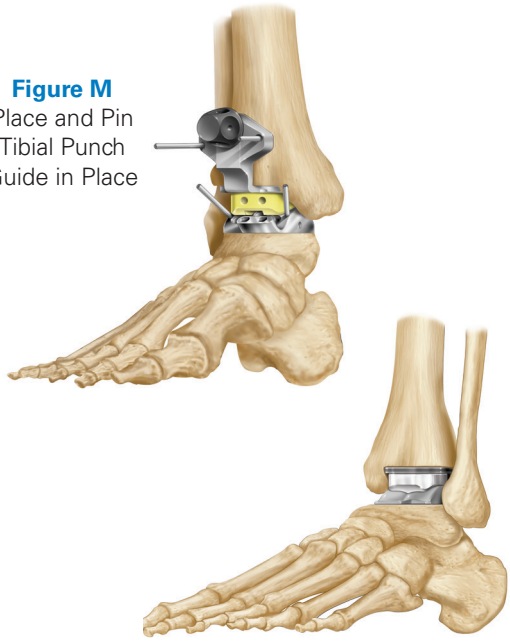


Figure M
Place and Pin Tibial Punch Guide in Place

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 Mobile Bearing Operative Technique (721-00-31) Overview figures 18 through 21 for the preparation of the tibial bone and implantation of the implant construct.

SYSTEM USE SPECIFICATIONS

INTENDED USE

The Vantage Mobile Bearing Ankle System is a non-constrained ankle replacement intended for the treatment of severe arthritis in the ankle. The implant assembly includes three components: a talus, tibia and polyethylene liner. The tibial and talar components are intended for press-fit fixation to the distal tibia and proximal talus, respectively. The Vantage Flat Cut Talus implant is provided as an optional variant of the standard curved-underside Vantage talar component.

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.

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

Note: *Please reference Vantage Total Ankle Mobile Bearing Operative Technique (721-00-31) through page 16.*

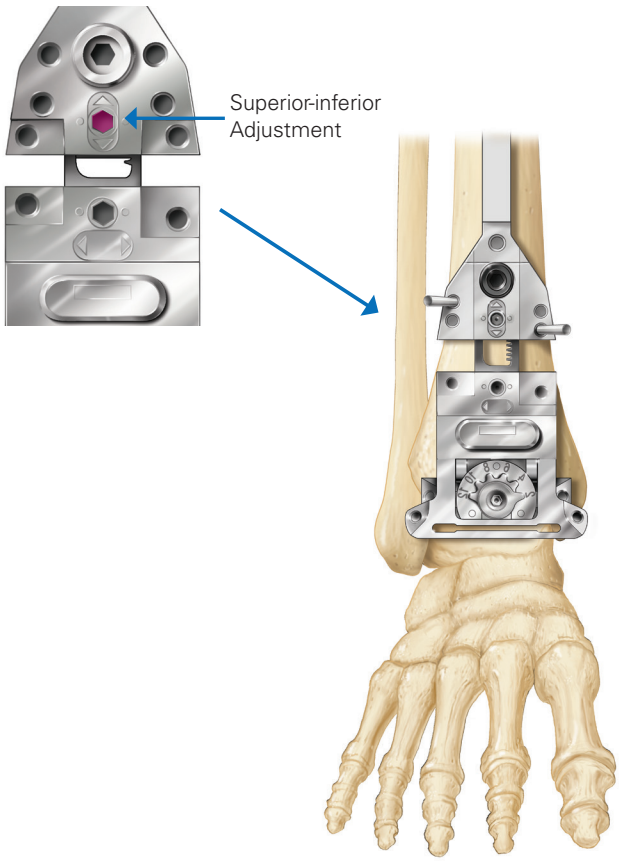


Figure 1
Place the Adjustable Talar Cutting Block

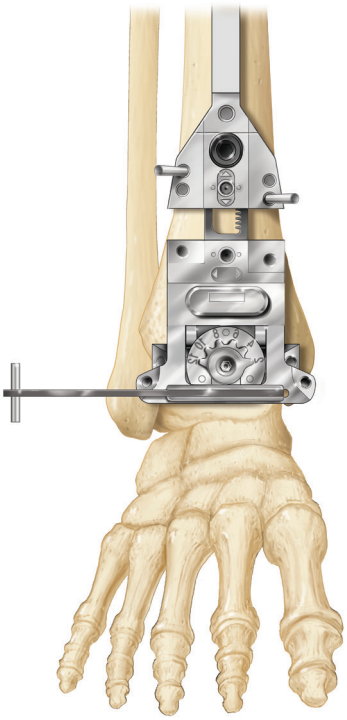


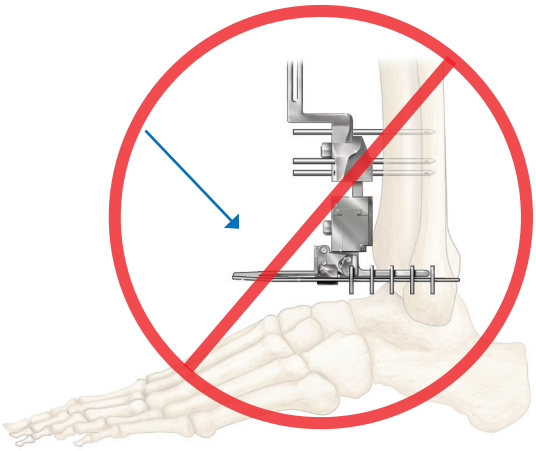
Figure 2
Insert the Low-Profile Angel Wing

After clearing the resected tibial bone, the **Adjustable Talar Cutting Block** is placed onto the **Alignment Guide** *(Figure 1)*. The adjustable talar cutting block should be extended as far as possible distally, using the Superior-Inferior Adjustment on the alignment guide. This will allow for proper tensioning of the soft tissues. Care should be taken to ensure the paddle is both contacting the talar bone and centered on it.

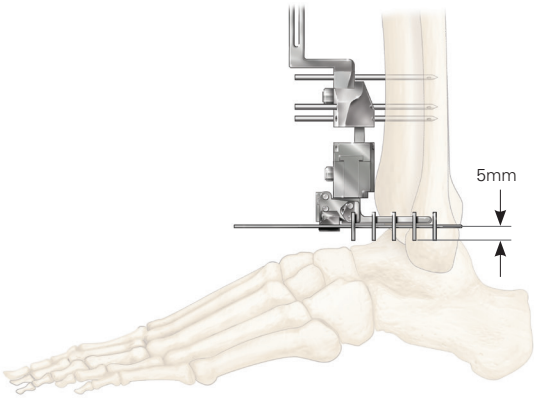
Insert the **Low-Profile Angel Wing** into the cutting slot of the block *(Figure 2)*. Hold the foot in neutral dorsiflexion and the heel in slight valgus.

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH



MALALIGNMENT



PROPER ALIGNMENT

Figure 3
Ensure Proper Alignment of the Guide to Gauge the Resection Slope

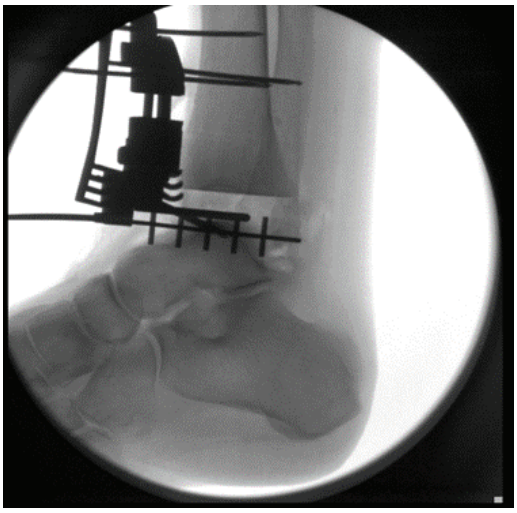


Figure 4
Review Lateral Fluoroscopic Image for Slope

A lateral fluoroscopic image should be taken at this point to assess the slope of talar cut *(Figures 3 and 4)*. Ensure that the Low-Profile Angel Wing is at its thinnest.

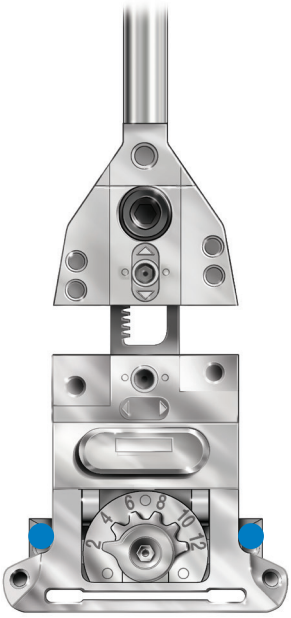


Figure 5
Pin Proximal Holes on Adjustable Talar Cutting Block

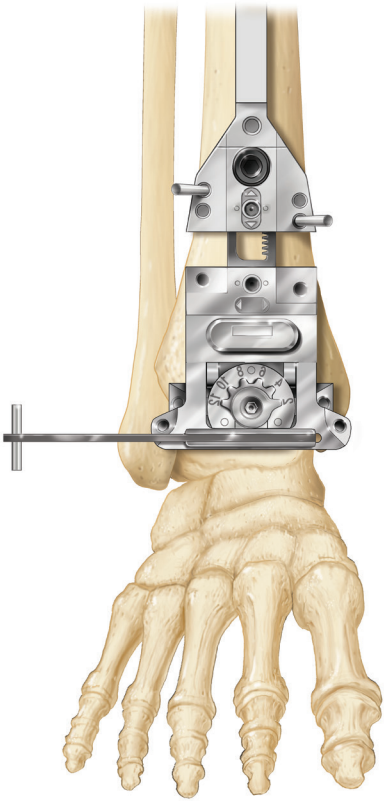


Figure 6
Insert the Low-Profile Angel Wing and Assess Resection Height

When the proper resection slope is achieved, two pins can be inserted into the proximal pin holes *(Figure 5)*.

Note: *This Adjustable Cutting Block uses a similar mechanism to the Alignment Guide and can be adjusted from 2-12 mm in 2 mm increments.*

Adjust the resection level of the block to 8mm, however, assess the state of the talar dome. In cases of severe talar dome collapse, adjust the resection level to 2-4mm.

Insert the Low-Profile Angel Wing for final resection height assessment *(Figure 6)*.

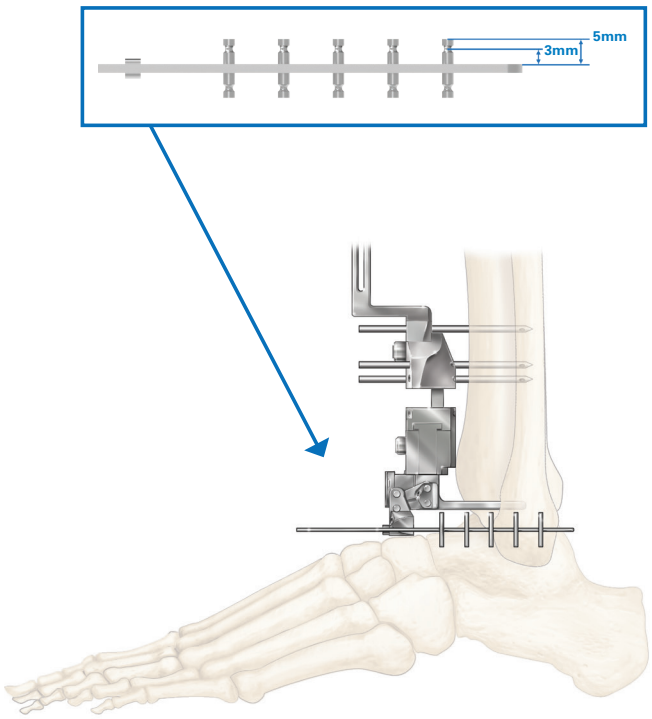


Figure 7
Review the Resection Height with a Lateral Fluoroscopic Image

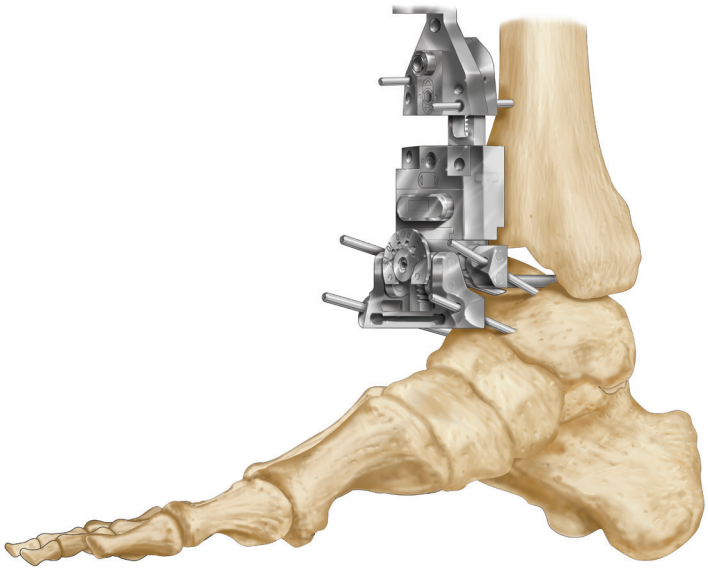


Figure 8
Pin the Distal Holes of the Adjustable Talar Cutting Block

A lateral fluoroscopic image should be taken at this point to assess the resection height of the talar cut. The level of the resection can be adjusted by using the superior-inferior adjustment of the block. For reference, the Low-Profile Angel Wing pins are 5mm tall and have notches located 3mm from the base of the device *(Figure 7)*.

When the proper orientation is achieved, the two distal talar block stabilizing pins are inserted, and the proximal pins are removed *(Figure 8)*.

Resect the talus with the oscillating saw.

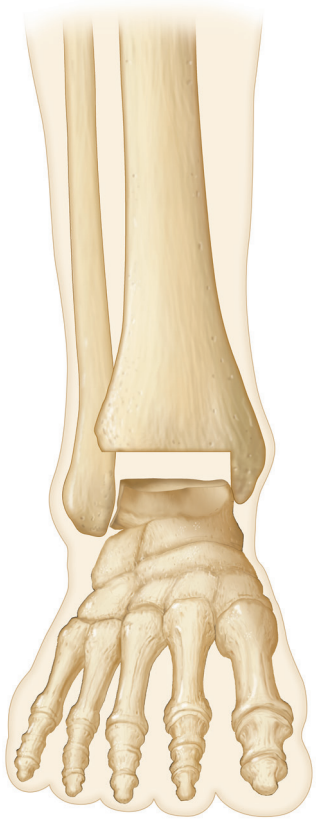


Figure 9
Remove the Talar Resection

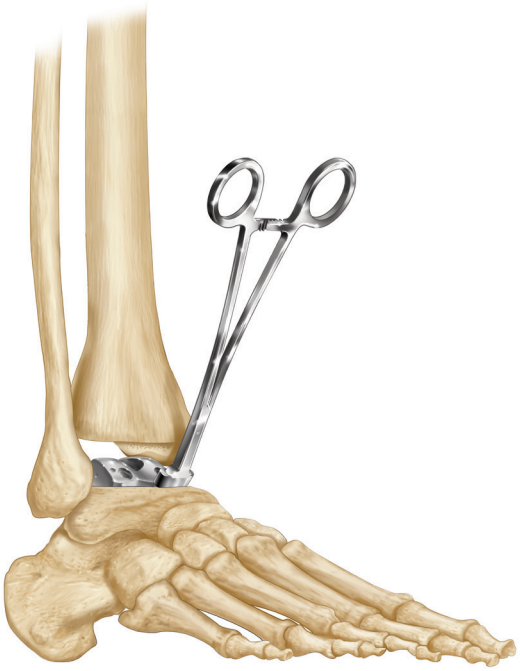


Figure 10
Place Flat Cut Talus Trial With Scissor Inserter

Clear the resected talar bone and ensure a rectangular opening *(Figure 9)*.

Attach the **Scissor Inserter** to the **Flat Cut Talus Trial** and place it on the cut surface *(Figure 10)*. 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.

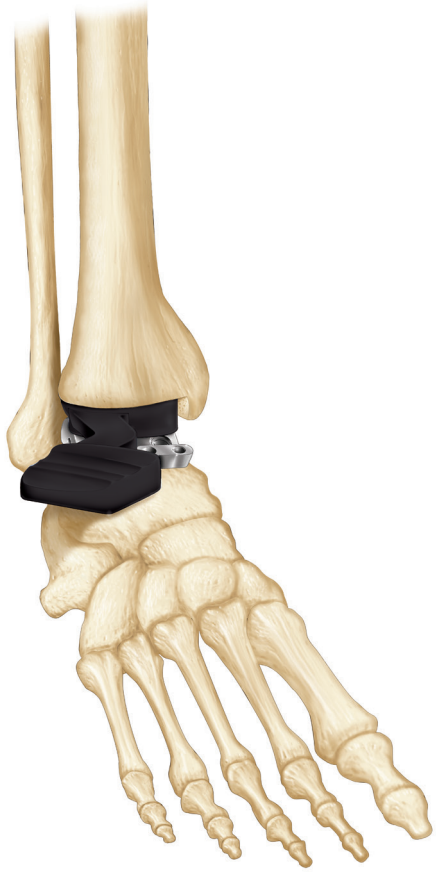


Figure 11
Insert the Flat Cut Mobile Bearing Gap Check Tool

Insert the corresponding size **Flat Cut Mobile Bearing Gap Check Tool** on top of the trial *(Figure 11)*.

SURGICAL PEARL
Do not remove the Alignment Guide until you verify there is sufficient resection with the Flat Cut Mobile 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 Mobile 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 Mobile 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.

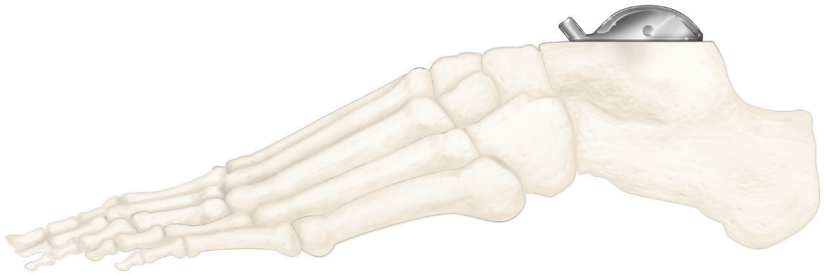


Figure 12
Ensure Proper Position of Talar Trial with Fluoroscopic Image

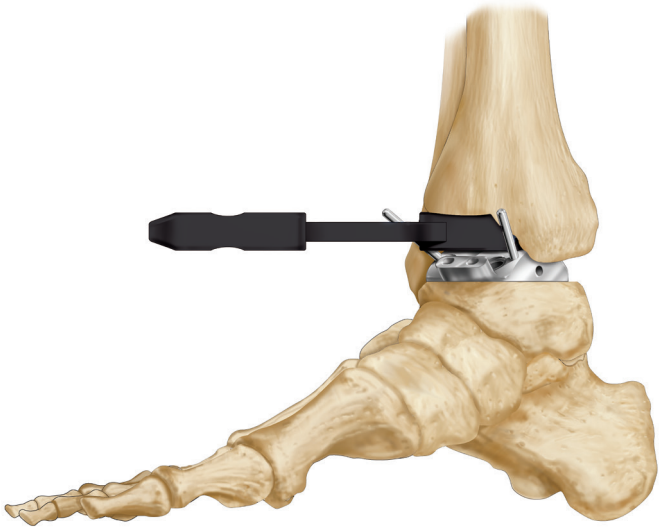


Figure 13
Pin the Flat Cut Talus Trial

A lateral fluoroscopic image should be taken to ensure complete coverage of the resected talus *(Figure 12)*.

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 13)*. The Flat Cut Mobile Bearing Gap Check Tool should then be removed taking care not to dislodge the pins.

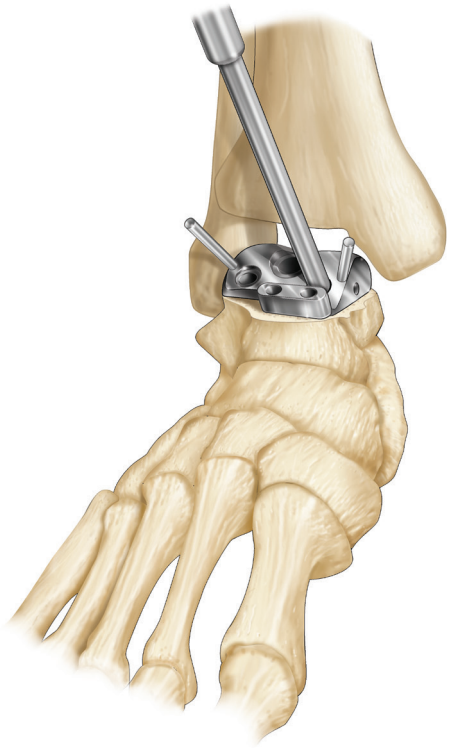


Figure 14
Use Talus Drill to Clear Anterior Holes

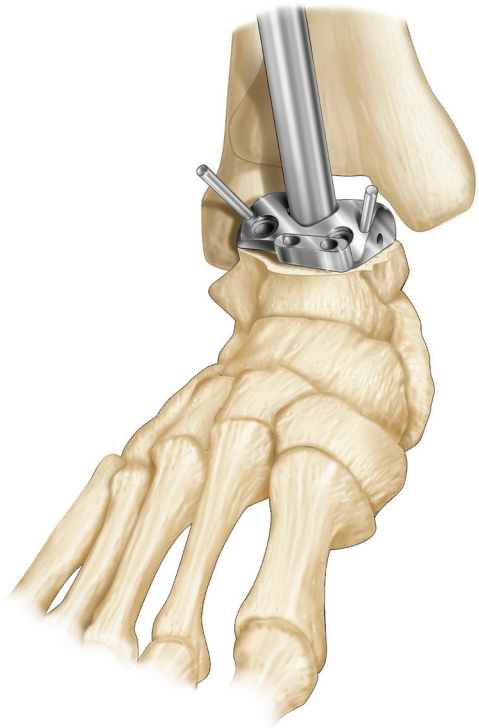


Figure 15
Use Coring Drill to Prepare the Center Hole for the Bone Cage

Attach the **Talus Drill** to a Zimmer-Hudson adapter and prepare the two anterior holes in the trial *(Figure 14)*.

Attach the **Coring Drill** to the Zimmer-Hudson adapter and prepare the center hole for the cage *(Figure 15)*.

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 could be used in the cage of the talar implant.

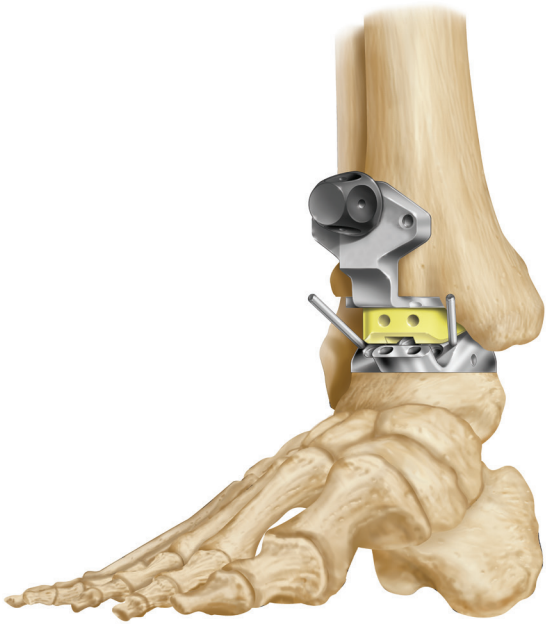


Figure 16
Place Appropriately-Sized Tibial Punch Guide

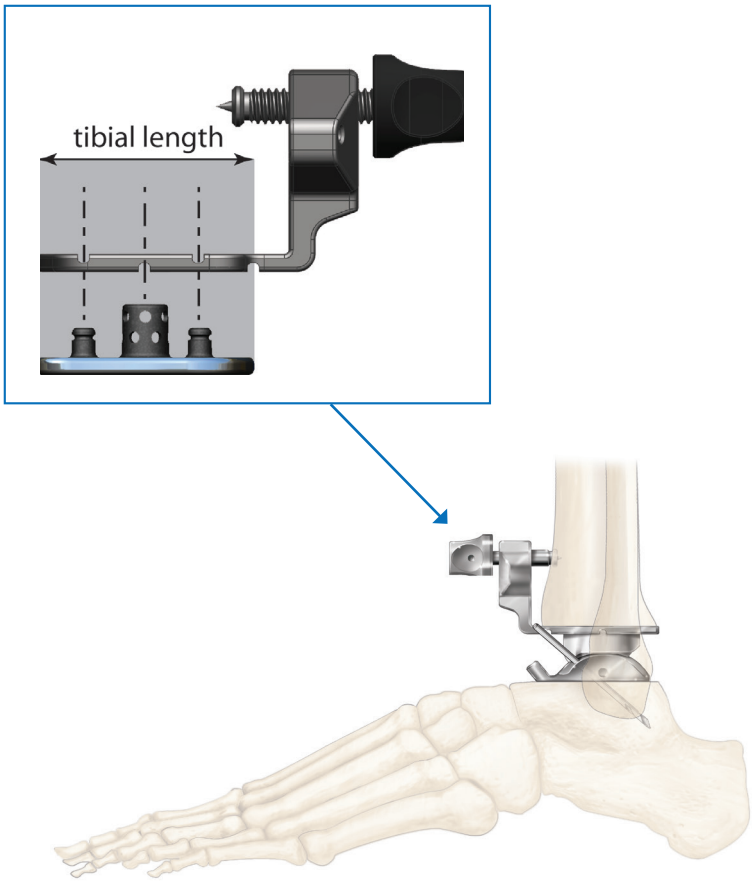


Figure 17
Confirm Tibial Size and Placement – Lateral View

Choose the appropriately-sized **Tibial Punch Guide** and **Liner Trial** and then place onto the talar trial *(Figure 16)*.

Check the A/P position of the tibial component. A lateral fluoroscopic image will show where the tibial plate cage will be located *(Figure 17)*.

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.

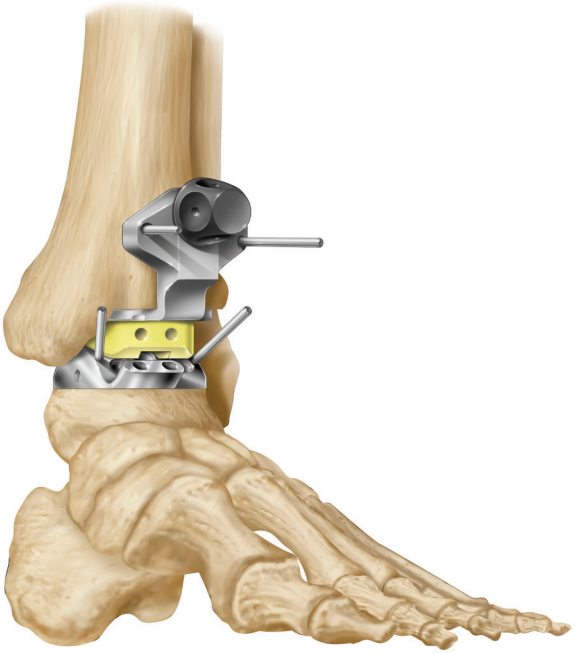


Figure 18
Pin Tibial Punch Guide in Place

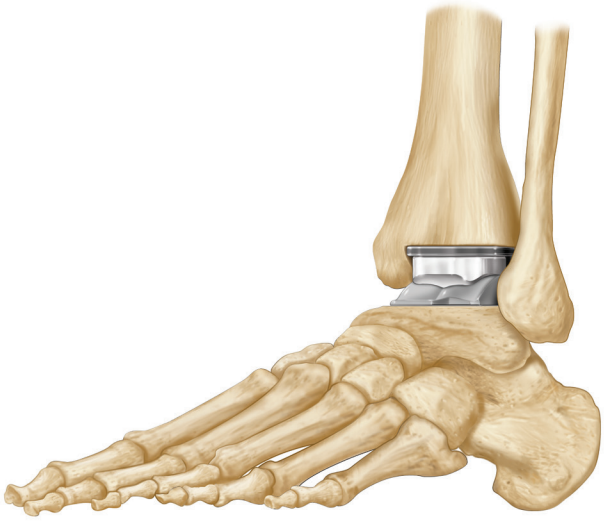


Figure 19
Final Assembly

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 18)*.

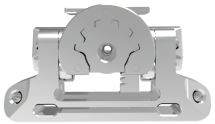
Remove the Flat Cut Talus Trial and liner trial to create space. Adjust the screw of the tibial punch guide so it touches the anterior cortex in order to prevent tilting. This forces the punch guide plate into the distal tibia for better stability.

Please reference the Vantage Total Ankle Mobile Bearing Operative Technique, 721-00-31, 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 19* for how the final implant assembly will look.

351-91-04	Stryker Oscillating Saw Blade
351-00-06	Adjustable Cutting Block, 2-12mm
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
351-10-23	Flat Cut Mobile Bearing Gap Check Tool, Sizes 1 and 2
351-10-24	Flat Cut Mobile Bearing Gap Check Tool, Sizes 3 and 4



IMPLANT LISTING

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

NOTES

NOTES

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

---

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.

 00-0000107 Rev. B 0421

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

Exactech®

GLOBAL HEADQUARTERS:
2320 NW 66TH COURT
GAINESVILLE, FL 32653 USA

+1 352.377.1140
+1 800.EXACTECH
+1 352.378.2617 FAX

www.exac.com