EXACTECH | **EXTREMITIES**

Operative Technique Addendum

VANTAGE® TOTAL ANKLE

Mobile Bearing System Operative Technique Addendum for Supplemental Instrumentation

Exactech®

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INTRODUCTION

This addendum details the surgical technique for optional Instrumentation provided with the Vantage® Total Ankle Mobile Bearing System. The Exactech Vantage Ankle was designed through a collaborative effort of engineering research and the expertise of global thought leaders in ankle arthroplasty. The 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 morphologies.

The Vantage Ankle is designed to address 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 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.

The Vantage Ankle was developed in conjunction with:

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DETAILED OPERATIVE TECHNIQUE

STANDARD ANGEL WING

Figure 1
Insert Angel Wing

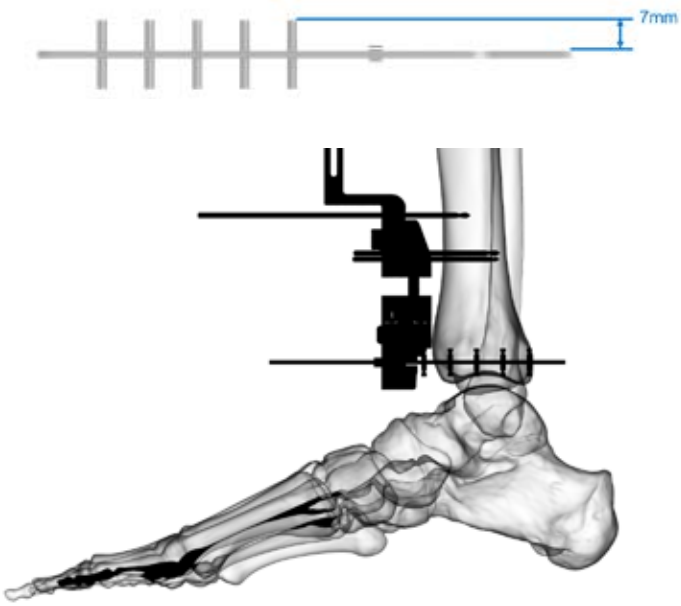


Figure 2
Adjust Slope

STANDARD ANGEL WING (351-10-14)

The standard **Angel Wing** is provided as an optional instrument and may be used to replace the Low-Profile Angel Wing (351-10-17).

The standard Angel Wing has pins which are 7mm in length from the base to the tip, whereas the Low-Profile Angel Wing has pins which are 5mm in length from the base to the tip. Additionally, the standard Angel Wing does not feature notched pins which are present on the Low-Profile Angel Wing.

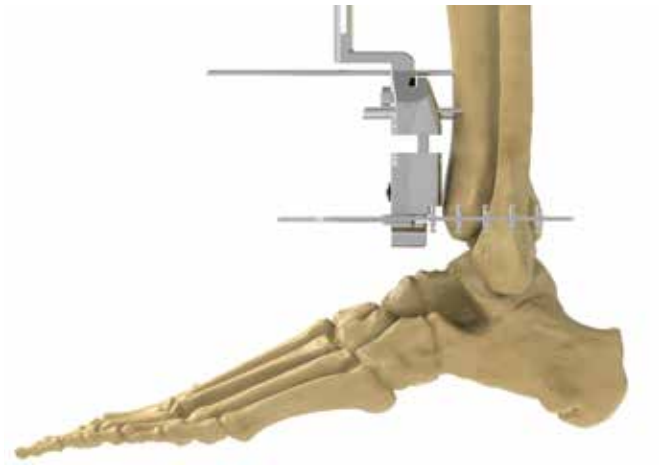
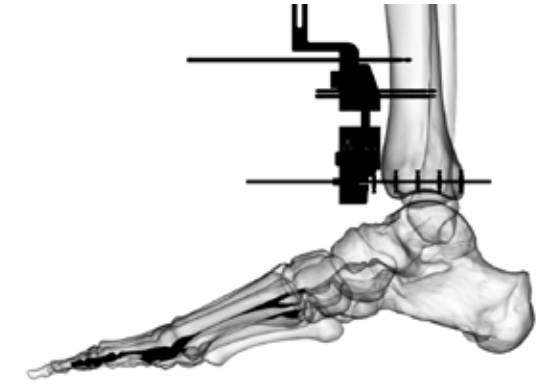
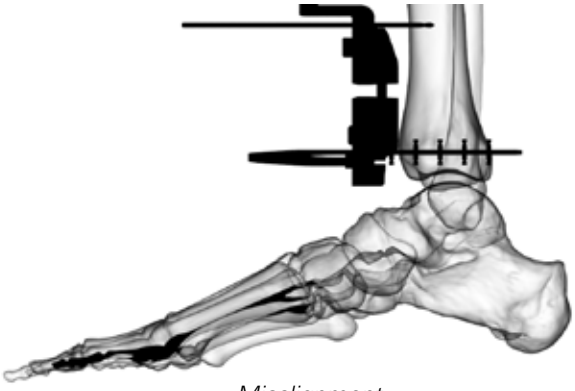


Figure 3
Pin Distal Alignment Guide



Proper Alignment



Misalignment

Figure 4
Verify Resection Level in Lateral X-ray

Note: *The standard Angel Wing is intended for patients with a tight ankle joint because the device's larger cut may result in a resection too large relative to the final implant construct in patients with typical ankle joint tension. In all cases, ensure proper radiographic alignment of the standard Angel Wing to accurately gauge resection height. In all cases, verify that the appropriate Gap Check Tool can fit into the resection prior to removal of the Tibial Alignment Guide.*

For instructions on the use of the instrument, follow the steps described on pages 12 and 14 of the standard Vantage Ankle Mobile Bearing Technique (721-00-31), or pages 5-8 of the Vantage Ankle Mobile Bearing Flat Cut Talus Decoupled Cut Addendum (00-0000107) replacing the Low-Profile Angel Wing with the standard Angel Wing. Figures 1-4 are used as a reference when using the standard Angel Wing.

DETAILED OPERATIVE TECHNIQUE

CORNER CHISEL

CORNER CHISEL (351-10-33)

The **Corner Chisel** is provided as an optional instrument to aid in clearing any bone that remains in the medial corner of the tibial resection. To use the Corner Chisel, first follow the standard mobile bearing operative technique (721-00-31) up to page 16, such that the tibial cut have been made, but the resected tibia remains in the surgical space *(Figure 5)*.

Note: *Ensure that the distal tibia has been fully resected through the posterior tibial cortex before proceeding. Attempting to use the Corner Chisel to punch through the posterior cortex may result in excessive forces that can force the corner chisel beyond the tibial bone and damage the posterior soft tissues. Additionally, a higher strike force may also increase the risk of fracturing the medial malleolus. The Corner Chisel should only be used to clear bone remaining in the medial corner of the completed tibial resection.*

Remove the pins from the Tibial Cutting Block and disengage the Tibial Cutting Block from the Alignment Guide *(Figure 6)*.

Next, mate the Corner Chisel to the Modular Impactor Handle. Thereafter, align the Corner Chisel to the medial corner and impact posteriorly until the corner is clear of bone, taking care not to damage the posterior soft tissues or fracture the medial malleolus *(Figure 7)*.

The assembly can then be removed from the surgical space, allowing for the removal of the resected tibia. Once the tibial resection has been removed, the standard mobile bearing operative technique can be continued, beginning again with the placement of the Talar Cutting Block, depicted on page 17 of the standard technique.

Alternatively, the Vantage Ankle Mobile Bearing Flat Cut Talus Decoupled Cut Addendum (00-0000107) may be started on page 5, beginning with the placement of the Adjustable Talar Cutting Block.

Note: *Do not impact Corner Chisel through the Tibial Cutting Block, as this action may result in wedging between the Corner Chisel and Tibial Cutting Block.*

Additionally, do not use Corner Chisel to lever off of the resection, as this action may damage both the remaining tibial bone and the instrument.

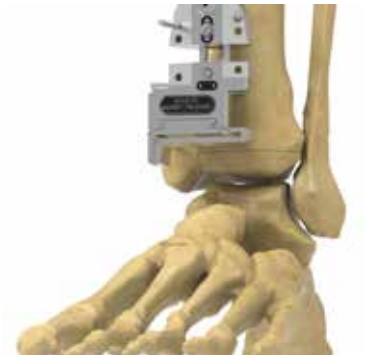


Figure 5
Resect the Tibia

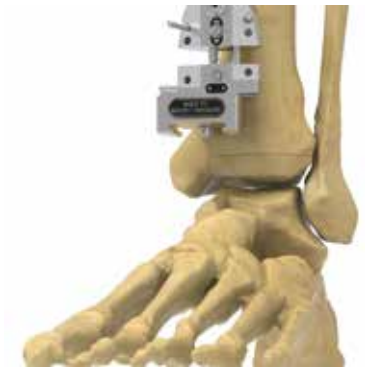


Figure 6
Remove Tibial Cutting Block Pins and Tibial Cutting Block

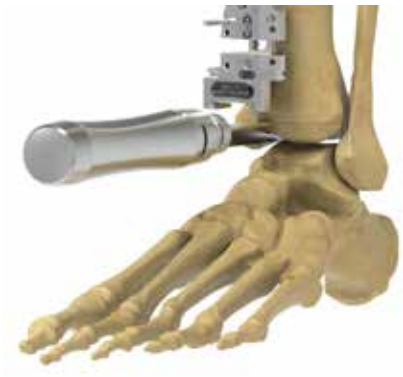


Figure 7
Clear Remaining Bone From the Medial Corner of the Tibial Cut

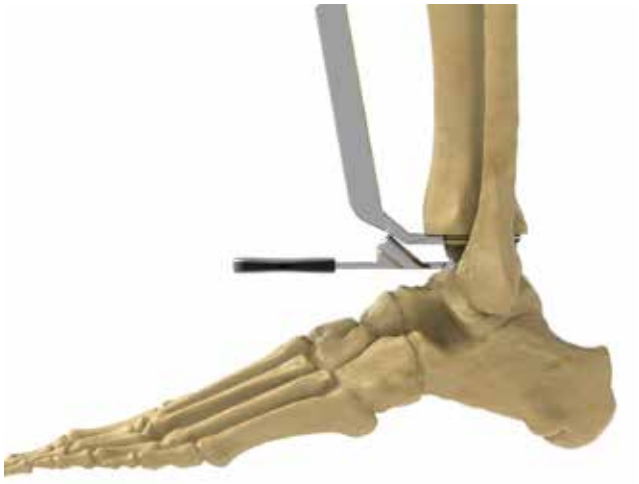


Figure 8
Place Talar Lollipop with Distractor Tool to Apply Soft Tissue Tension

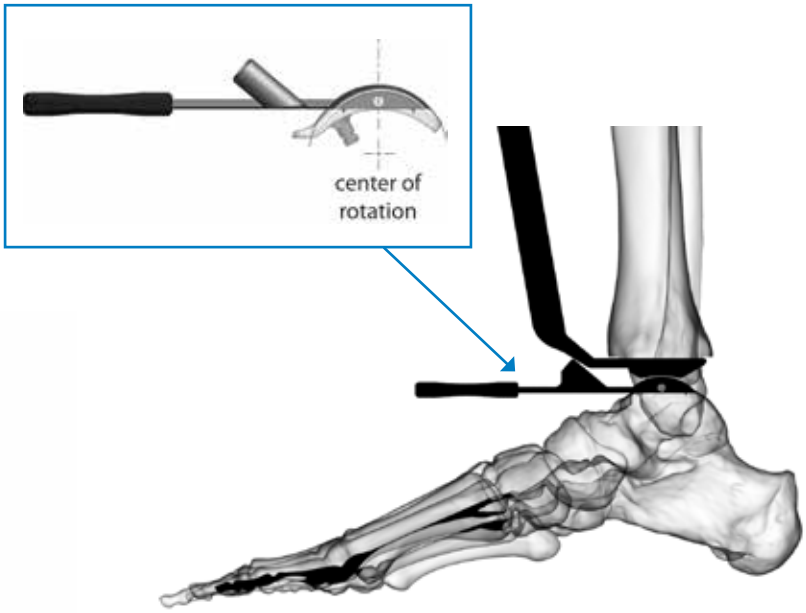


Figure 9
Place Curvature in Line with Existing Surface

CONSTRAINED ANKLE DISTRACTOR (351-10-18)

The **Constrained Ankle Distractor** is an optional instrument and may be used to replace the standard Ankle Distractor (351-10-16).

The Constrained Ankle Distractor features a distal articulating component which is rigidly fixed to the main body of the device, whereas the articulating component of the standard Ankle Distractor can translate anteriorly/posteriorly.

Note: *Do not use the Constrained Ankle Distractor in patients with an anteriorly subluxed talus. Because the distal articulating component of the distractor is rigidly attached to the main body, use on such a patient may concentrate distraction forces on the anterior tibia, resulting in damage to the bone.*

For instructions on the use of the Constrained Ankle Distractor, follow the standard mobile bearing operative technique (721-00-31, pages 19-20) replacing the standard Ankle Distractor with the Constrained Ankle Distractor. Figures 8 through 10 are used as reference when using the Constrained Ankle Distractor.

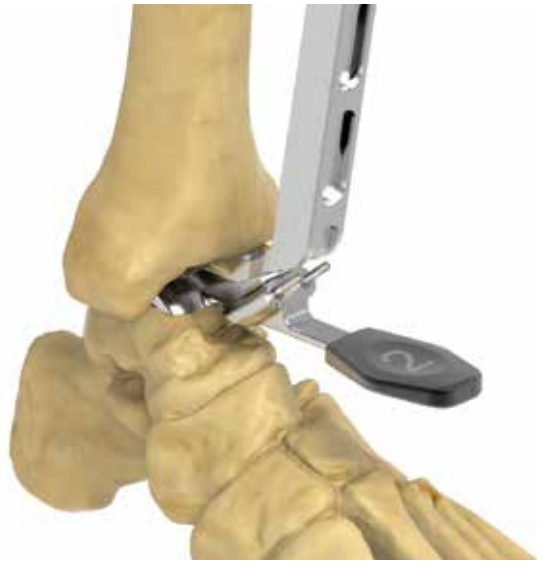


Figure 10
Place Anterior Pins Through Talar Lollipop

DETAILED OPERATIVE TECHNIQUE

LOW-PROFILE TALAR IMPLANT TRIALS

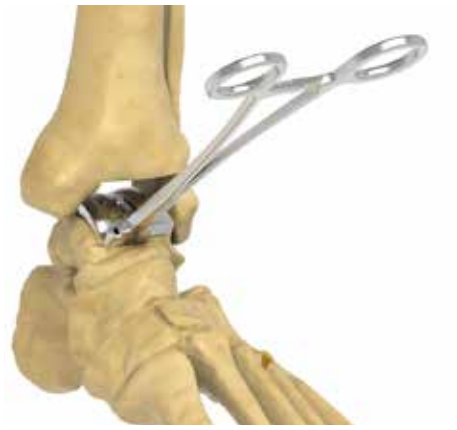


Figure 11
Attach Scissor Inserter to Talar Trial and Place in Joint

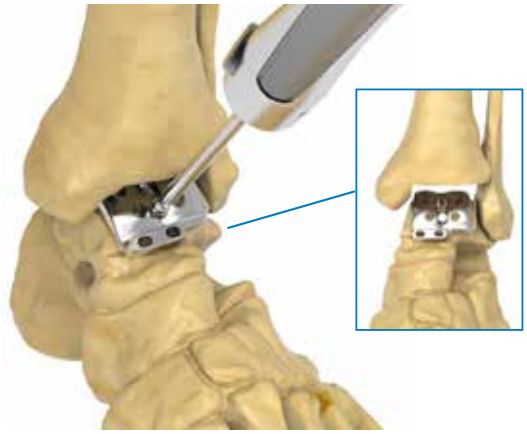
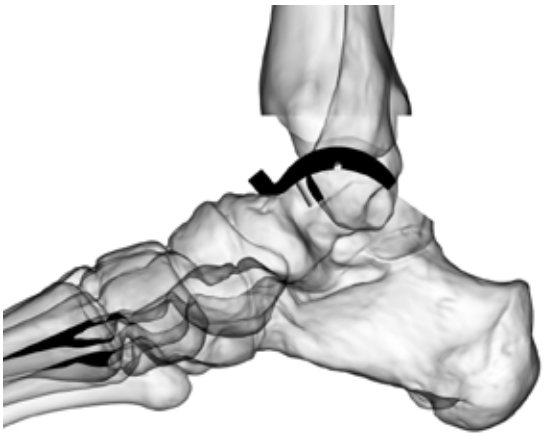
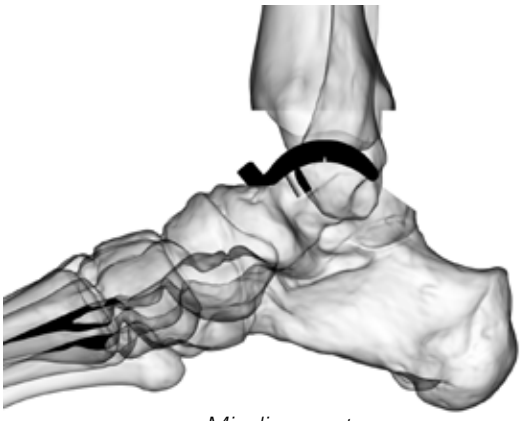


Figure 12
Place Talar Trial Screw



Proper Alignment



Misalignment

Figure 13
Verify Fluoroscopic Position Once Proper Alignment is Achieved

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LOW-PROFILE TALAR IMPLANT TRIALS

(351-03-21,22,23,24,25 AND 351-04-21,22,23,24,25)

The **Low-Profile Talar Implant Trials** are optional instruments and may be used to replace the function of the standard **Talar Implant Trials** (351-03-01,2,3,4,5 and 351-04-01,2,3,4,5). The Low-Profile Talar Implant Trials feature drill holes which are flush with the articular surface of the device, whereas the standard Talar Implant Trials have drill holes with flattened square standoffs.

For instructions on the use of the Low-Profile Talar Implant Trials, follow the steps described on pages 24-27 of the standard mobile bearing operative technique (721-00-31) replacing the standard Talar Implant Trials with the Low-Profile Talar Implant Trials. Figures 11 through 17 are used as references for use of the Low-Profile Talar Implant Trials.

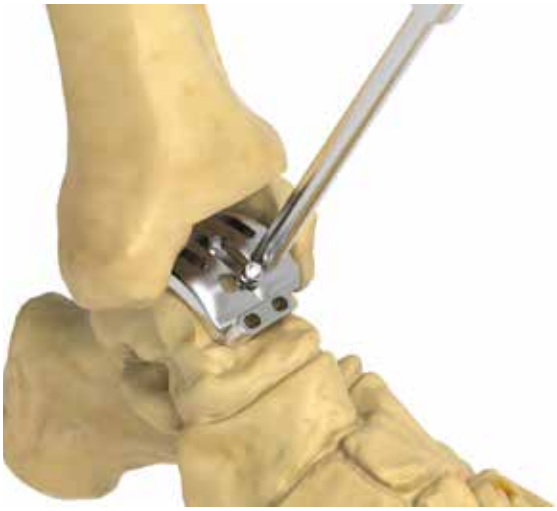

Figure 14
Drill Two Anterior Talar Holes

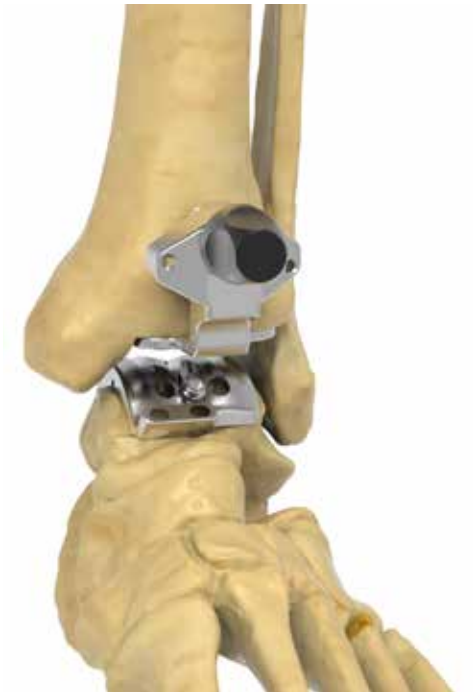

Figure 15
Place Appropriately-Sized Tibial Punch Guide

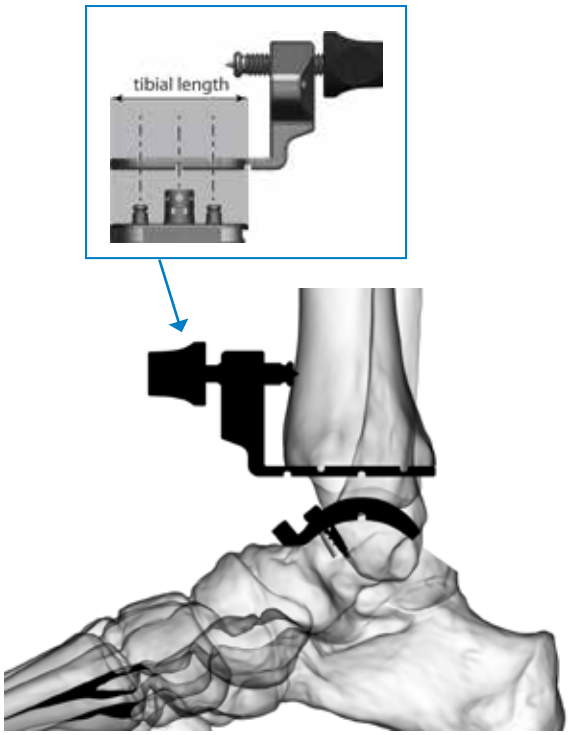

Figure 16
Confirm Tibial Size and Placement - Lateral View

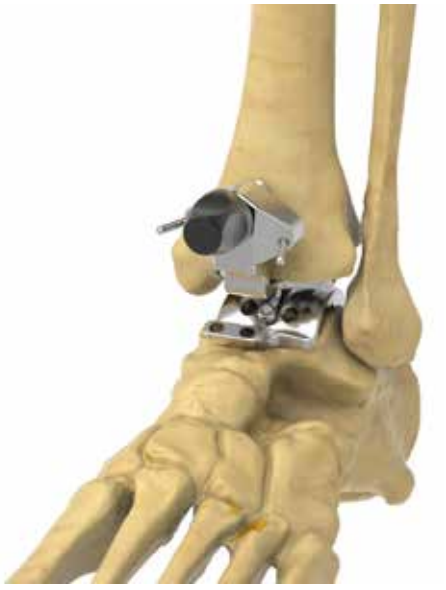

Figure 17
Pin Tibial Punch Guide in Place

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

Talar Component Size 5 Left & Right (351-01-05E & 351-02-05E)

The left and right **Talar Component Size 5** are used the same as the other Talar Components. Please refer to the mobile bearing operative technique (721-00-31) on pages 27-28 for further details.

2.4mm x 3.5" Threaded Pin (351-90-05) & 2.4mm x 3.5" Threaded Pin Pouch (351-90-25)

The **2.4mm x 3.5" Threaded Pin (351-90-05)** and **2.4mm x 3.5" Threaded Pin Pouch (351-90-25)** are optional instruments that can be used the same way as the 2.4mm x 3.5" Fluted Drill Bit (351-90-01). The only difference between the threaded options is that 351-90-25 is in a sterile pouch. For instructions for use, please follow steps in the standard mobile bearing operative technique (721-00-31) replacing the standard 2.4mm x 3.5" Fluted Drill Bit with either the 2.4mm x 3.5" Threaded Pin or 2.4mm x 3.5" Threaded Pin Pouch option.

2.4mm x 3.5" Threaded Olive Pin (351-90-06) & 2.4mm x 3.5" Threaded Olive Pin Pouch (351-90-26)

Both the **2.4mm x 3.5" Threaded Olive Pin (351-90-06)** and **2.4mm x 3.5" Threaded Olive Pin Pouch (351-90-26)** are optional instruments that can be used the same way as 2.4mm x 3.5" Olive Pin (351-90-03). The only difference between the threaded options is that 351-90-26 is in a sterile pouch. For instructions for use, please follow steps on page 21 in the standard mobile bearing operative technique (721-00-31) replacing the standard Olive Pin with either the 2.4mm x 3.5" Threaded Olive Pin or 2.4mm x 3.5" Threaded Olive Pin Pouch option.

Long Talar Trial Screw (351-90-07) & Long Talar Trial Screw Pouch (351-90-27)

The **Long Talar Trial Screw (351-90-07)** and **Long Talar Trial Screw Pouch (351-90-27)** are optional instruments 1" in length that can be used the same way as the Talar Trial Screw (351-90-04). The Long Talar Trial screw options are a quarter inch longer than its predecessor. The only difference between the screw options is that 351-90-27 is in a sterile pouch. For instructions for use with the Long Talar Trial Screw Pouch, please follow steps on page 25 in the standard mobile bearing operative technique (721-00-31) replacing the standard Talar Trial Screw with the Long Talar Trial Screw Pouch option.

Pin Puller (351-91-10)

The **Pin Puller** is an optional instrument that may be used to pull out any 2.4 mm pins throughout the total ankle procedure. Please refer to the mobile bearing operative technique (721-00-31) for more information.

Komet Saw Blades (351-91-04, 351-91-05, 351-91-06)

The **Komet Saw Blades (351-91-04, 351-91-05, 351-91-06)** are distributed and optional instruments that can be used wherever sawing occurs in the mobile bearing operative technique (721-00-31). The blades come in 10mm width (351-90-04), oscillating with Hall Connection (351-90-05) and reciprocating with Hall Connection (351-90-06) options.

INSTRUMENT LISTING

CATALOG NUMBER	PART DESCRIPTION
350-01-05E	Talar Component - Size 5 - Left
350-02-05E	Talar Component - Size 5- Right
351-01-05	Lollipop Guide - Size 5
351-03-21	Low-Profile Talar Implant Trial - Size 1- Left
351-03-22	Low-Profile Talar Implant Trial - Size 2- Left
351-03-23	Low-Profile Talar Implant Trial - Size 3- Left
351-03-24	Low-Profile Talar Implant Trial - Size 4- Left
351-03-25	Low-Profile Talar Implant Trial - Size 5- Left
351-04-21	Low-Profile Talar Implant Trial - Size 1- Right
351-04-22	Low-Profile Talar Implant Trial - Size 2- Right
351-04-23	Low-Profile Talar Implant Trial - Size 3- Right
351-04-24	Low-Profile Talar Implant Trial - Size 4- Right
351-04-25	Low-Profile Talar Implant Trial - Size 5- Right
351-10-14	Angel Wing
351-17-02	Radel Tibial Impactor Tip
351-10-18	Constrained Ankle Distractor
351-10-33	Corner Chisel

CATALOG NUMBER	PART DESCRIPTION
351-41-05	Liner Trial Mobile Bearing - Size 5 - Left - 6mm
351-41-15	Liner Trial Mobile Bearing - Size 5 - Left - 7mm
351-41-25	Liner Trial Mobile Bearing - Size 5 - Left - 8mm
351-41-35	Liner Trial Mobile Bearing - Size 5 - Left - 9mm
351-41-45	Liner Trial Mobile Bearing - Size 5 - Left - 10mm
351-41-55	Liner Trial Mobile Bearing - Size 5 - Left - 11mm
351-41-65	Liner Trial Mobile Bearing - Size 5 - Left - 12mm
351-42-05	Liner Trial Mobile Bearing - Size 5 - Right - 6mm
351-42-15	Liner Trial Mobile Bearing - Size 5 - Right - 7mm
351-42-25	Liner Trial Mobile Bearing - Size 5 - Right - 8mm
351-42-35	Liner Trial Mobile Bearing - Size 5 - Right - 9mm
351-42-45	Liner Trial Mobile Bearing - Size 5 - Right - 10mm
351-42-55	Liner Trial Mobile Bearing - Size 5 - Right - 11mm
351-42-65	Liner Trial Mobile Bearing - Size 5 - Right - 12mm
351-90-05	2.4mm x 3.5" Threaded Pin
351-90-06	2.4mm x 3.5" Threaded Olive Pin
351-90-07	Long Talar Trial Screw
351-90-25	2.4mm x 3.5" Threaded Pin Pouch
351-90-26	2.4mm x 3.5" Threaded Olive Pin Pouch
351-90-27	Long Talar Trial Screw Pouch
351-91-10	Pin Puller
351-91-04	Komet Saw Blade, 10mm
351-91-05	Oscillating Komet Saw Blade, Hall Connection
351-91-06	Reciprocating Komet Saw Blade, Hall Connection

THE VANTAGE TOTAL ANKLE INSTRUMENTATION DESCRIBED IN THE INSTRUMENT LISTING ABOVE CONSISTS OF THE FOLLOWING MATERIALS:

17-4 PH SS (UNS S17400)

316 SS (UNS S31600)

455 SS (UNS S45500)

Nitronic 60 (UNS S21800)

PPSU

CoCr

Radel

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

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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. 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.

 00-0001312 Rev. B 0821

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

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