

EXACTECH | EXTREMITIES

Operative Technique Addendum



VANTAGE[®]
TOTAL ANKLE

**Fixed Bearing System Operative
Technique Addendum for
Supplemental Instrumentation**



TABLE OF CONTENTS

INTRODUCTION.....	1
Low-Profile Angel Wing.....	2
Corner Chisel	4
Constrained Ankle Distractor	5
Low-Profile Talar Implant Trials	6
OPTIONAL INSTRUMENTS – INSTRUCTIONS FOR USE	8
INTENDED USE.....	9
INDICATIONS FOR USE	9
INSTRUMENT LISTING	10



INTRODUCTION

This addendum details the surgical technique for optional Instrumentation provided with the Vantage® Total Ankle 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. Similarly, 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:

James K. DeOrio, MD

*Duke University
Durham, NC*

Mark E. Easley, MD

*Duke University
Durham, NC*

James A. Nunley, MD

*Duke University
Durham, NC*

Victor Valderrabano, MD, PhD

*Schmerzlinik Basel
Basel, Switzerland*

DETAILED OPERATIVE TECHNIQUE

LOW-PROFILE ANGEL WING



Figure 1
Insert Angel Wing

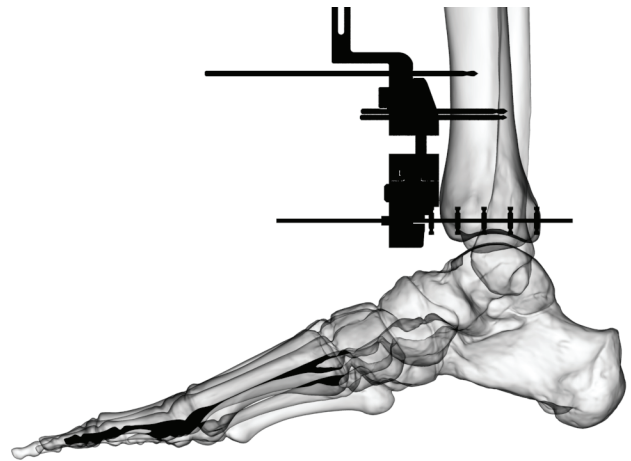
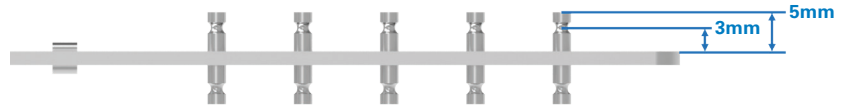


Figure 2
Adjust Slope

LOW-PROFILE ANGEL WING (351-10-17)

The **Low-Profile Angel Wing** is provided as an optional instrument and may be used to replace the standard Angel Wing (351-10-14).

The Low-Profile Angel Wing has pins which are 5mm in length from the base to the tip, whereas the standard Angel Wing has pins which are 7mm in length from the base to the tip. Additionally, the Low-Profile Angel Wing has notches on the pins located 3mm from the base of the device.

DETAILED OPERATIVE TECHNIQUE

LOW-PROFILE ANGEL WING

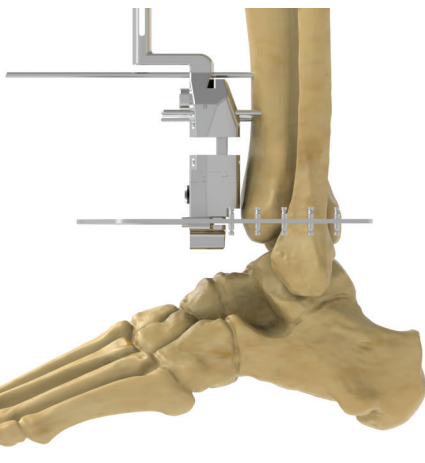
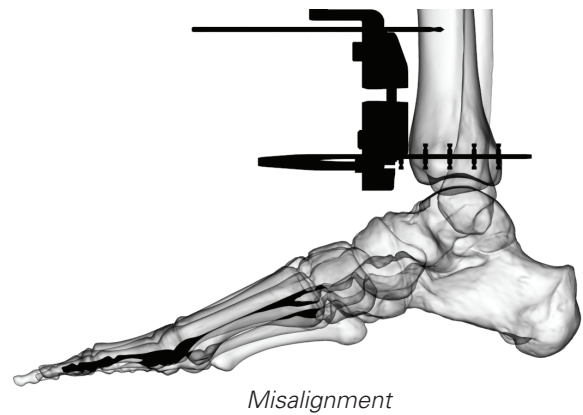
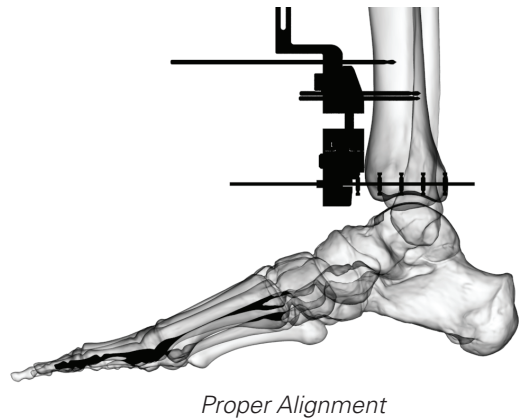


Figure 3
Pin Distal Alignment Guide

Figure 4
Verify Resection Level in Lateral X-ray

Note: The Low-Profile Angel Wing is intended for patients with ankle laxity because the device's shallower cut may result in a resection too small for the final implant construct in patients with typical ankle joint tension. In all cases, ensure proper radiographic alignment of the Low-Profile 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 Total Ankle Fixed Bearing Technique (721-00-30), pages 6 and 8 of the Vantage Flat Cut Ankle Coupled Cut Addendum (00-0000087), or pages 5-8 of the Vantage Flat Cut Ankle Decoupled Cut Addendum (00-0000057), replacing the standard Angel Wing with the Low-Profile Angel Wing. Figures 1-4 are used as a reference when using the Low-Profile 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 fixed bearing operative technique (721-00-30) up to page 16 or the Vantage Flat Cut Talus Coupled Cut Addendum (00-0000087) up to page 8 such that the tibial cut or coupled cuts 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*). Alternatively, if following the Flat Cut Talus Coupled Cut Addendum, remove the pins from the Coupled Cutting Block, disengage the Coupled Cutting Block from the Alignment Guide and clear the resected talar bone.

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 fixed 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 Flat Cut Talus Coupled Cut Addendum may be continued, beginning again with the placement of the Flat Cut Talar Trial on page 9, or the Vantage Flat Cut Talus Decoupled Cut Addendum (00-0000057) may be started on page 5, beginning with the placement of the Adjustable Talar Cutting Block.

Note: Do not impact Corner Chisel through either the Tibial Cutting Block or Coupled Cutting Block, as this action may result in wedging between the devices.

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

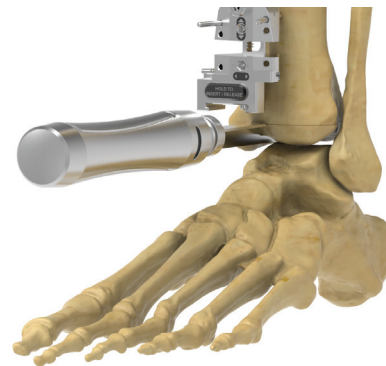


Figure 7
Clear Remaining Bone From the Medial
Corner of the Tibial Cut

DETAILED OPERATIVE TECHNIQUE

CONSTRAINED ANKLE DISTRACTOR

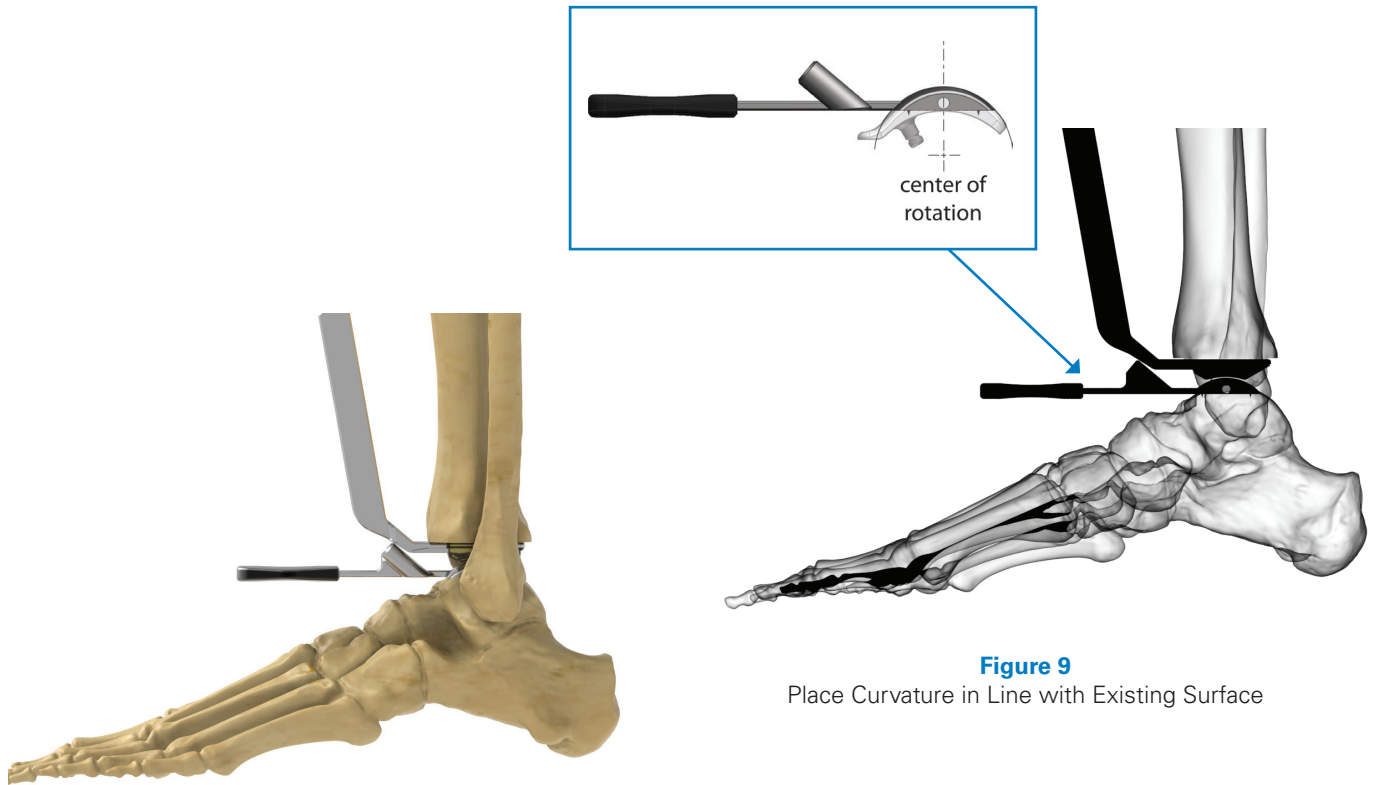


Figure 8

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 fixed bearing operative technique (721-00-30, pages 19-20) replacing the standard Ankle Distractor with the Constrained Ankle Distractor. Figures 8, 9 and 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

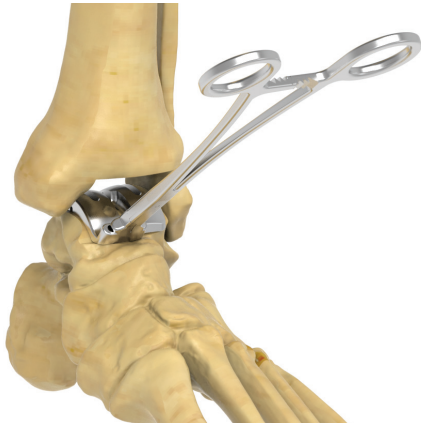


Figure 11

Attach Scissor Inserter to Talar Trial and Place in Joint

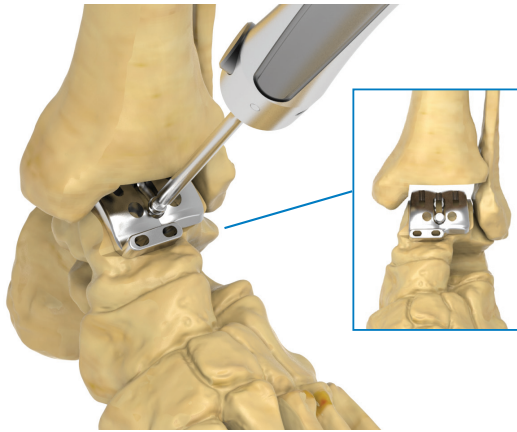


Figure 12

Place Talar Trial Screw



Proper Alignment



Misalignment

Figure 13

Verify Fluoroscopic Position Once Proper Alignment is Achieved

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 fixed bearing operative technique (721-00-30) 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.

DETAILED OPERATIVE TECHNIQUE

LOW-PROFILE TALAR IMPLANT TRIALS

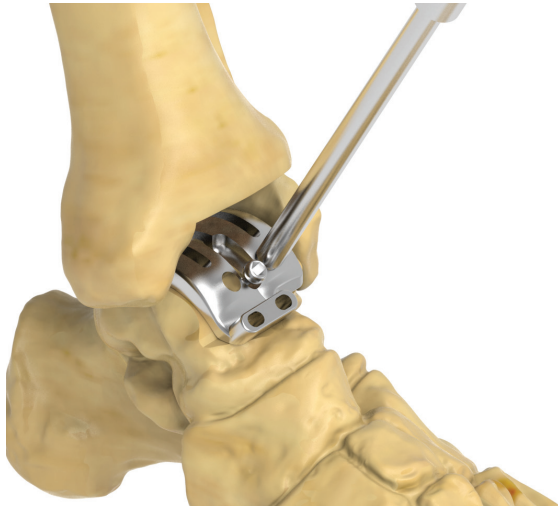


Figure 14
Drill Two Anterior Talar Holes

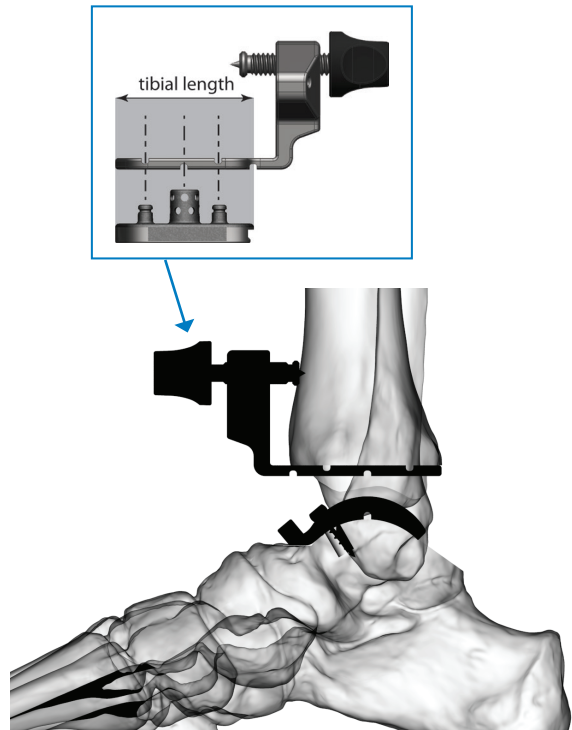


Figure 16
Confirm Tibial Size and Placement - Lateral View



Figure 15
Place Appropriately-Sized Tibial Punch Guide



Figure 17
Pin Tibial Punch Guide in Place

OPTIONAL IMPLANT/INSTRUMENTS – INSTRUCTIONS FOR USE



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

The left and right **Talar Component Size 5** are used the same as the other Talar Components. Please refer to the fixed bearing operative technique (721-00-30) on pages 27-28 for further details.



Sharp Peripheral Peg Punch (351-10-30)

The **Sharp Peripheral Peg Punch (351-10-30)** is an optional instrument and used the same as Peripheral Peg Punch (351-10-25) but has a sharp tip. For instructions for use, please follow steps on page 27 in the fixed bearing operative technique (721-00-30) replacing the standard Peripheral Peg Punch with the Sharp Peripheral Peg Punch option.



Radel Tibial Impactor Tip (351-17-02)

The **Radel Tibial Impactor Tip** is an optional instrument and can be used the same as the Tibial Impactor Tip (351-17-00). For further instructions for use, please follow steps on page 27 in the fixed bearing operative technique (721-00-30) replacing the standard Tibial Impactor Tip with the Radel Tibial Impactor.



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 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 fixed bearing operative technique (721-00-30) 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 19 in the fixed bearing operative technique (721-00-30) 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 that can be used the same way as the Talar Trial Screw (351-90-04). 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 22 in the fixed bearing operative technique (721-00-30) 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 fixed bearing operative technique (721-00-30) for additional 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 fixed bearing operative technique (721-00-30). The blades come in 10mm width (351-91-04), oscillating with Hall Connection (351-91-05) and reciprocating with Hall Connection (351-91-06) options.

INTENDED USE

The Vantage Fixed Bearing Ankle System is a semi-constrained ankle replacement intended for the treatment of end-stage arthritis in the ankle. The implant assembly includes four components: the talar, tibial, 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

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

17-4 PH SS (UNS S17400)

Nitronic 60 (UNS S21800)

316 SS (UNS S31600)

CoCr

455 SS (UNS S45500)

PPSU

INSTRUMENT LISTING

IMPLANT/CATALOG NUMBER

PART DESCRIPTION

350-01-05

Talar Component - Size 5 - Left

350-02-05

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

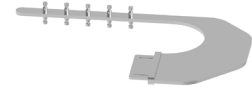
351-04-25

Low-Profile Talar Implant Trial - Size 5- Right



351-10-17

Low-Profile Angel Wing



351-10-18

Constrained Ankle Distractor



351-10-30

Sharp Peripheral Peg Punch



351-10-33

Corner Chisel



351-17-02

Radel Tibial Impactor Tip



INSTRUMENT LISTING

IMPLANT/CATALOG NUMBER	PART DESCRIPTION
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



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—Instructions for Use (700-096-157) 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.

The products discussed herein may be available under different trademarks in different countries. All copyrights, and pending and registered trademarks, are property of Exactech, Inc. This material is intended for the sole use and benefit of the Exactech sales force and physicians. It should not be redistributed, duplicated or disclosed without the express written consent of Exactech, Inc. ©2021 Exactech, Inc. 00-0001132 Rev. B 0821



EXACTECH, INC.
2320 NW 66TH COURT
GAINESVILLE, FL 32653 USA

+1 352.377.1140
+1 800.EXACTECH
+1 352.378.2617 (FAX)
www.exac.com