



Anterior and Posterior
Offset Poly Trials



AUXILIARY SURGICAL TECHNIQUE GUIDE

PRODUCT INFORMATION

The Paragon 28® APEX 3D Total Ankle Replacement System is a cemented, fixed bearing device comprised of a tibial component, a talar component and a Vitamin E Ultra-High Molecular Weight Polyethylene component. Implants are available in varying sizes and design configurations intended for both primary and revision applications. For additional information regarding Indications for Use, Contraindications, Warnings, Precautions, etc. please visit: <https://www.paragon28.com/ifus/>



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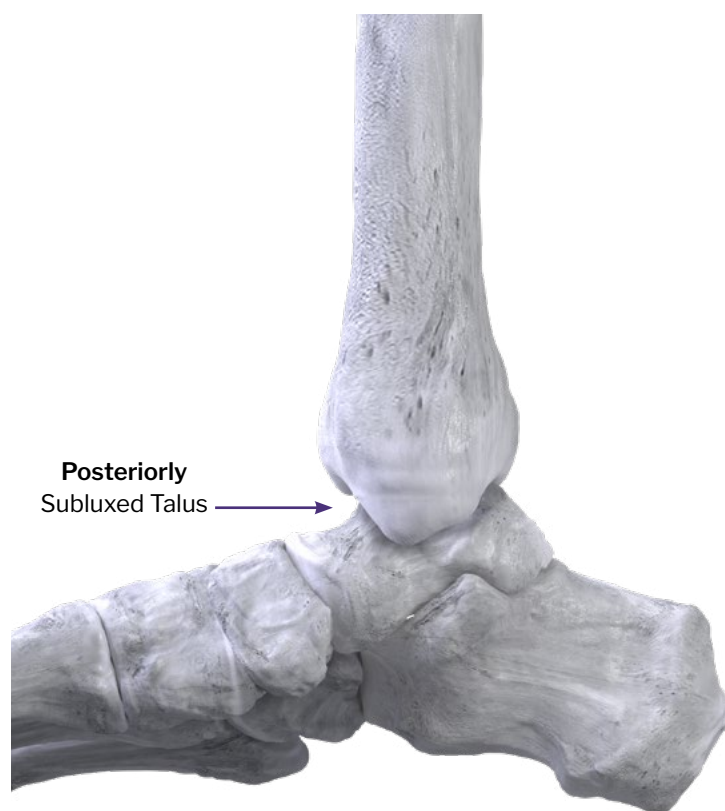
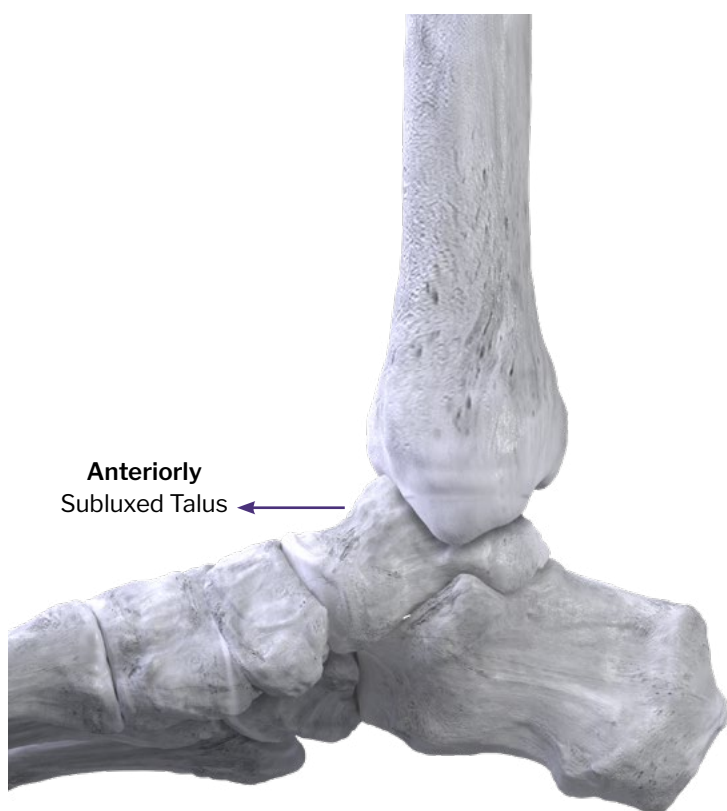
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ANTERIOR AND POSTERIOR SUBLUXED TALUS

To accommodate patients with either an anterior or posterior subluxated talus, the APEX 3D Total Ankle Replacement System has introduced uniquely designed biased poly insert options to shift the tibial insert articulation to accommodate the center of rotation of the subluxated talus.

Malalignment in the sagittal plane may potentially lead to edge loading and contact stresses on the poly. The biased tibial insert allows the talus to maintain its reduced position.



Anteriorly biased Poly Trial



Posteriorly biased Poly Trial



Offset Poly Insert Size Options:	1	2	3	4	5
Anterior or Posterior Offset:	3.0 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm
Offset is distance from the center of the Tibial Base					

ANTERIOR & POSTERIOR OFFSET POLY TRIALS



The Poly can be rotated 180° to accommodate both Anterior and Posterior subluxation

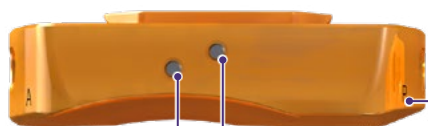


Anterior Offset Identifier



Posterior Offset Identifier

Anterior Subluxed Position



Talar Alignment Fluoroscopic Marker

Tibial Alignment Fluoroscopic Marker

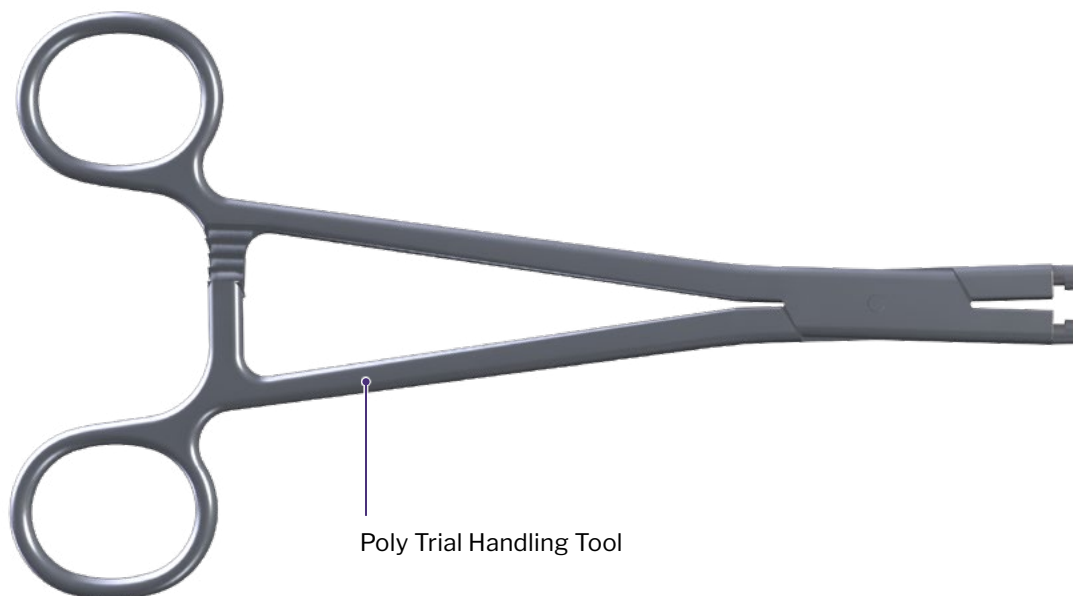
Posterior Offset Identifier

Posterior Subluxed Position



Tibial Alignment Fluoroscopic Marker

Talar Alignment Fluoroscopic Marker



Poly Trial Handling Tool

Universal Dovetail Connection

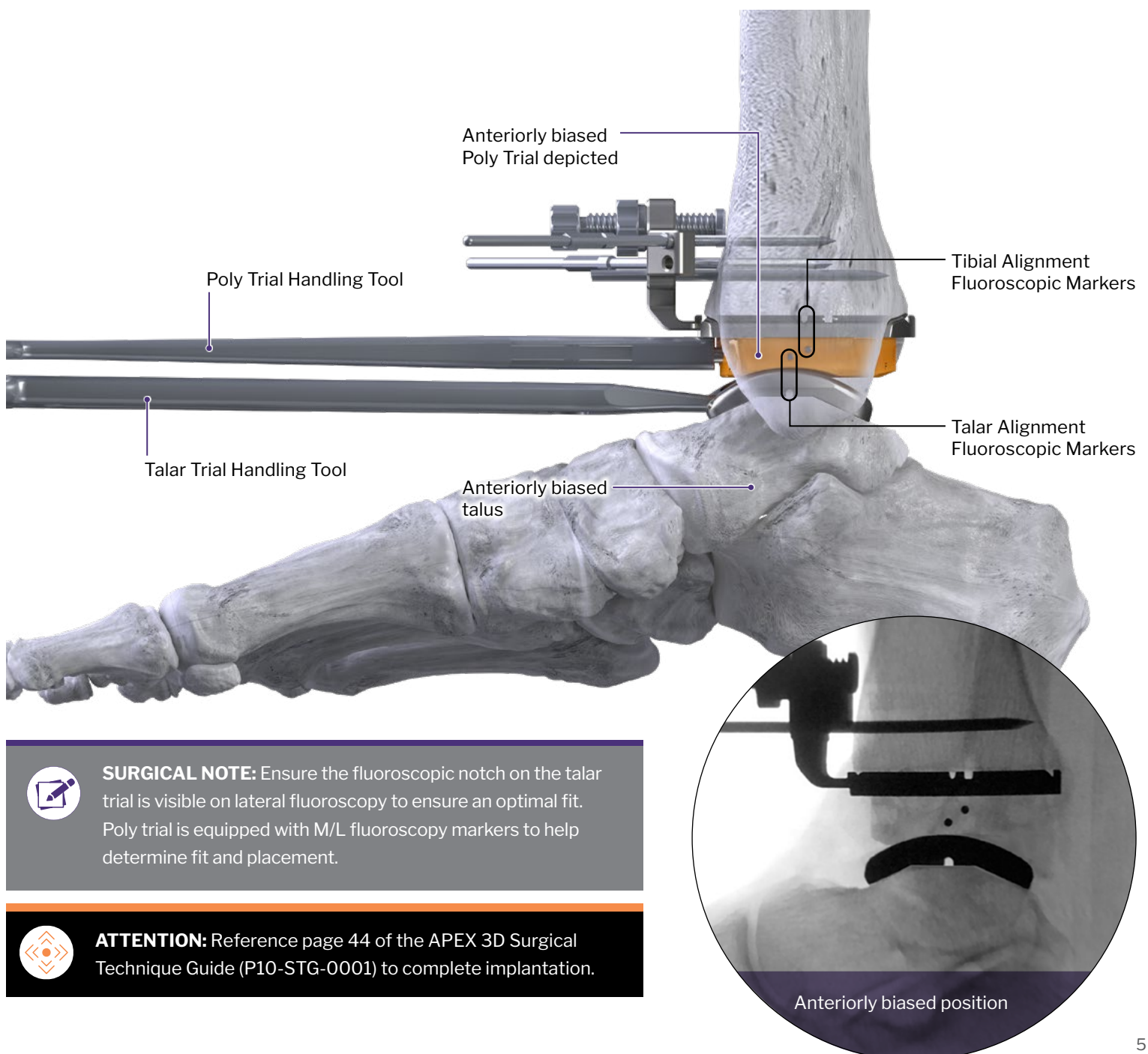


Handling Tool Insertion Feature

ANTERIOR SUBLUXED TALUS

If it is determined through a lateral fluoroscopic evaluation of the Neutral Poly Trial that the patient may benefit from the use of an Anterior Offset Poly Insert, the Offset Poly Trial can be used to evaluate and make a final determination.

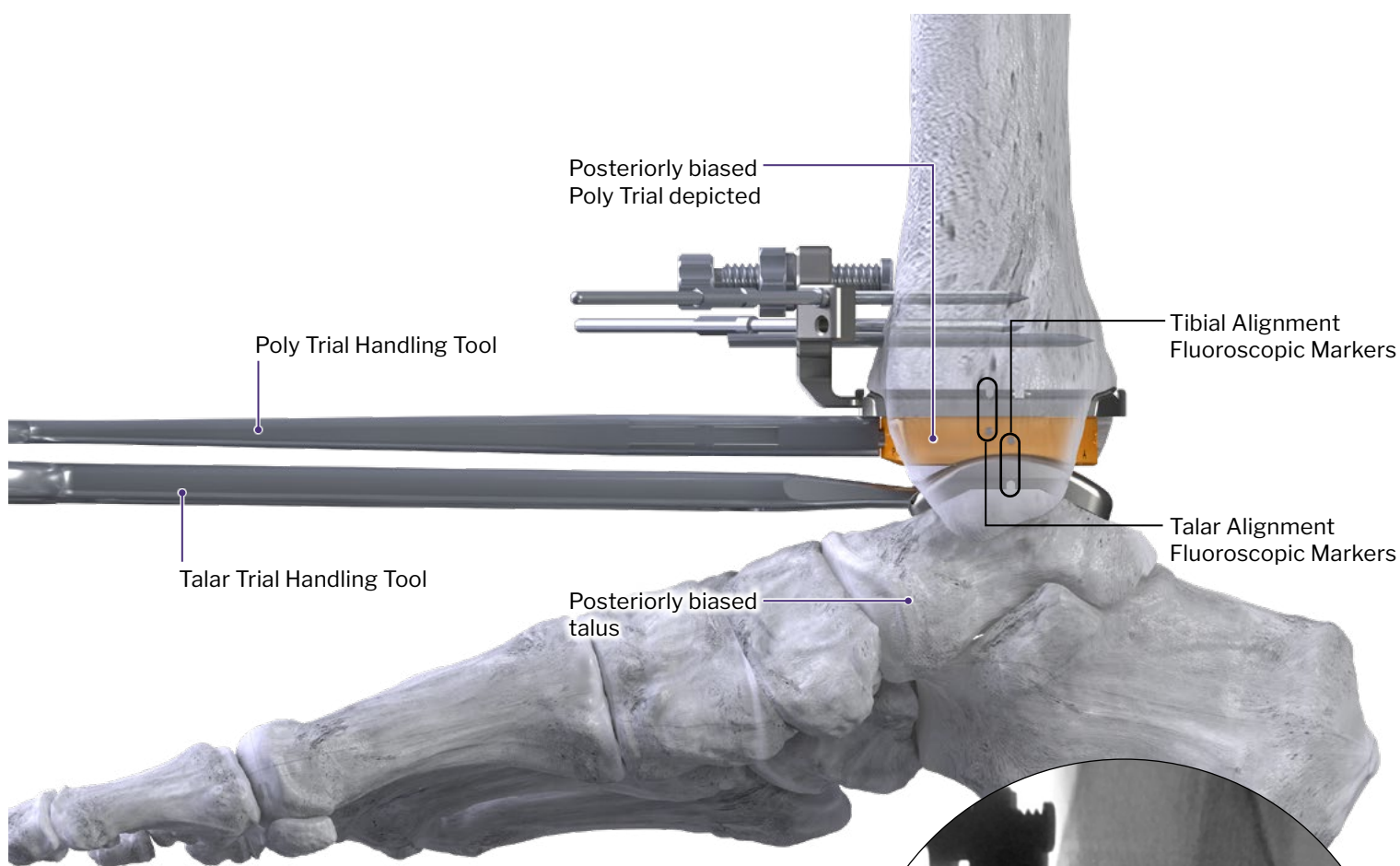
- Attach the Offset Poly Trial in the anterior orientation to the Poly Trial Handling Tool. Insert the Trial into the joint such that the dovetail of the Poly Trial connects with the dovetail of the Tibial Trial.
- Put the tibiotalar joint through gentle range of motion evaluation to ensure adequate placement and correct Poly Trial thickness.
- Confirm that the talar and Poly Trial components are size matched.
- Utilizing a lateral fluoroscopic view, confirm both the Tibial and Talar alignment Markers are in line with their associated Offset Poly Trial alignment markers.



POSTERIOR SUBLUXED TALUS

If it is determined through a lateral fluoroscopic evaluation of the Neutral Poly Trial that the patient may benefit from the use of a Posterior Offset Poly Insert, the Offset Poly Trial can be used to evaluate and make a final determination.

- Attach the Offset Poly Trial in the posterior orientation to the Poly Trial Handling Tool. Insert the Trial into the joint such that the dovetail of the Poly Trial connects with the dovetail of the Tibial Trial.
- Put the tibiotalar joint through gentle range of motion evaluation to ensure adequate placement and correct Poly Trial thickness.
- Confirm that the talar and Poly Trial components are size matched.
- Utilizing a lateral fluoroscopic view, confirm both the Tibial and Talar alignment Markers are in line with their associated Offset Poly Trial alignment markers.



SURGICAL NOTE: Ensure the fluoroscopic notch on the talar trial is visible on lateral fluoroscopy to ensure an optimal fit. Poly trial is equipped with M/L fluoroscopy markers to help determine fit and placement.



ATTENTION: Reference page 44 of the APEX 3D Surgical Technique Guide (P10-STG-0001) to complete implantation.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

All possible complications listed here are not typical of Paragon 28®. Inc. products but in principle, may be observed with any total joint replacement implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication of surgical technique or incorrect patient information and consequent incorrect patient behavior

CONTRAINDICATIONS

Use of the APEX 3D™ Total Ankle Replacement System is contraindicated in cases of inflammation, cases of active or suspected sepsis/infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixations or complications in post-operative treatment (e.g. dementia, senility, alcoholism)
- Corpulence; an overweight or corpulent patient that can strain the prosthesis to such a degree that stabilization or prosthesis failure can occur
- Excessive loads as caused by activity or patient weight
- Female childbearing age, for whom a negative pregnancy test is not obtained
- Steroid use
- Inadequate neuromuscular status (e.g. prior paralysis, neuropathy, neuropathic joint, fusion and/or inadequate abductor strength)
- Muscular atrophy
- Osteomyelitis
- Poor bone stock, poor skin coverage, or excessive bone loss around the joint which would make the procedure unjustifiable
- Sepsis
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery)
- Suspected or documented metal allergy or intolerance
- Musculoskeletal disease that may adversely affect gait or weightbearing
- Neurologic disorder/instability and non-compliance that may adversely affect gait or weight bearing
- Vascular deficiency in the ankle joint

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other

pathologies

- Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Metabolic disorders that may impair bone formation
- Osteomalacia
- Poor prognosis for good wound healing
- Presence of tumors
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count
- Uncooperative patient or patient with neurological disorders, incapable of following instructions

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exists. The risks and complications with these prosthetic components include:

- Asymptomatic, progressive bone resorption (osteolysis) due to foreign body reaction to particulate matter (See Important Physician Information section for more information)
- Sensitivity, allergy or other reactions to prosthetic component materials
- Peripheral neuropathies or nerve damage resulting in pain or numbness of the affected limb
- Loosening or migration of the prosthetic components
- Subluxation or dislocation of the prosthetic components with resulting reduction in range of movement
- Bending, disassembly and/or breakage of the prosthetic components
- Fractures resulting from unilateral joint loading
- Fatigue fracture of the prosthetic components as the result of trauma, strenuous activity, Improper alignment, incomplete implant seating, or duration of service
- Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock
- Drop in blood pressure intra-operatively due to the use of bone cement
- Thrombosis, embolism or myocardial infarction
- Wound hematoma and delayed wound healing
- Acute post-operative wound infections and late infections with possible sepsis

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

- Pain, a feeling of malaise or abnormal sensations due to the prosthetic components
- Inadequate range of motion due to improper selection or positioning of components or periarticular calcification
- Temporary and protracted functional neurological perturbation
- Corrosion with localized tissue reaction and pain
- Bone loss due to stress shielding
- Secondary necrosis of the talus

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WARNINGS AND PRECAUTIONS

- This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.
- The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
- Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component.
- Periodic long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- Re-operation to remove or replace prosthetic components may be required at any time due to medical reasons or device failure if corrective action is not taken, complications may occur.
- Patients need to be informed regarding expectations pertaining to performance and limitations following surgery. The prosthesis does not replace normal bone, has a finite service life, and future revision surgeries may be necessary. Protection of the prosthesis from full weight bearing is needed until adequate fixation and healing is achieved. Certain activities and loading trauma should be limited to prevent unreasonable stresses that could lead to breaking or damage of the prosthetic components.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility.
- Never modify an implant.
- The implants and guide wires are intended for single use only.
- Instruments and implants are to be treated as sharps
- Do not implant the instruments
- **Do not use other manufacturer's instruments or implants in conjunction with the APEX 3D™ Total Ankle Replacement Device.**
- **Do not re-sterilize the APEX 3D™ Total Ankle Replacement Implants or Instruments.**

IMPORTANT PHYSICIAN INFORMATION

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris (rate of debris generation) the phagocytic action results in the release of cytokines and intercellular mediators (IL-1, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific bases for the causes of this phenomenon and the potential ways to reduce its occurrence. Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions that are progressive may necessitate replacement of the prosthetic components(s)

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

MRI SAFETY INFORMATION



A patient with the Paragon 28® APEX 3D™ Total Ankle Replacement System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28® APEX 3D™ Total Ankle Replacement System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

OFFSET POLY INSTRUMENT CADDY

Part #	Description	Use
P10-931-I1[0/1][0/6/7/8/9]	Poly Trial Insert, Size 1, X mm, 3.00 mm ANT/POST Offset	Reusable
P10-931-I2[0/1][0/6/7/8/9]	Poly Trial Insert, Size 2, X mm, 3.25 mm ANT/POST Offset	Reusable
P10-931-I3[0/1][0/6/7/8/9]	Poly Trial Insert, Size 3, X mm, 3.5 mm ANT/POST Offset	Reusable
P10-931-I4[0/1][0/6/7/8/9]	Poly Trial Insert, Size 4, X mm, 3.75 mm ANT/POST Offset	Reusable
P10-931-I5[0/1][0/6/7/8/9]	Poly Trial Insert, Size 5, X mm, 4.00 mm ANT/POST Offset	Reusable

- All offset poly inserts are sterile packed and single-use

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.




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DISCLAIMER

The purpose of the APEX 3D™ Total Ankle Replacement System Surgical Technique Guide is to demonstrate the use of the APEX 3D™ Total Ankle Replacement System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.