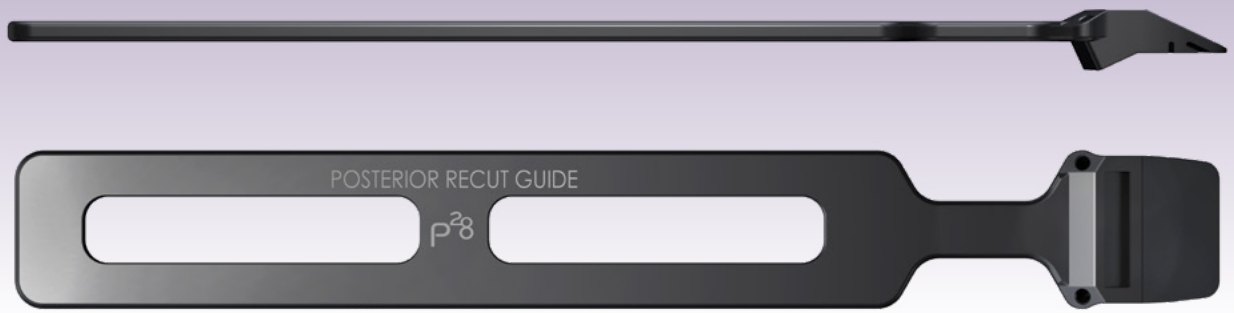
APEX 3D™
TOTAL ANKLE REPLACEMENT

POSTERIOR CHAMFER TALAR RECUT

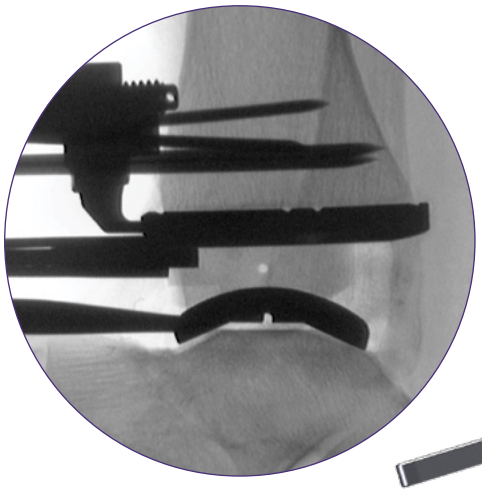
Auxiliary Surgical Technique Guide

Designed to correct talar bone resection to accommodate implant bone facing geometry

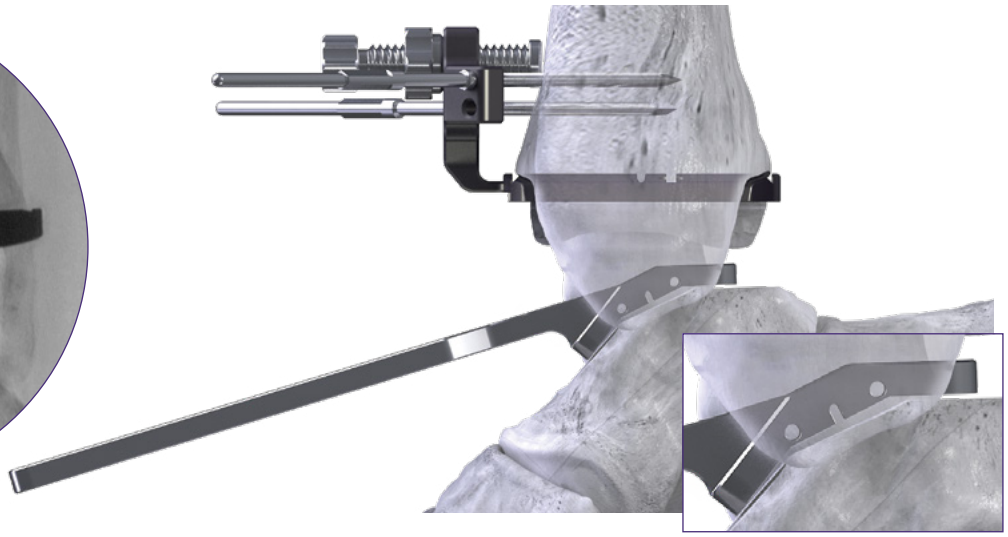


Exclusively foot & ankle
Paragon 28®

POSTERIOR RECUT - CHAMFER ONLY

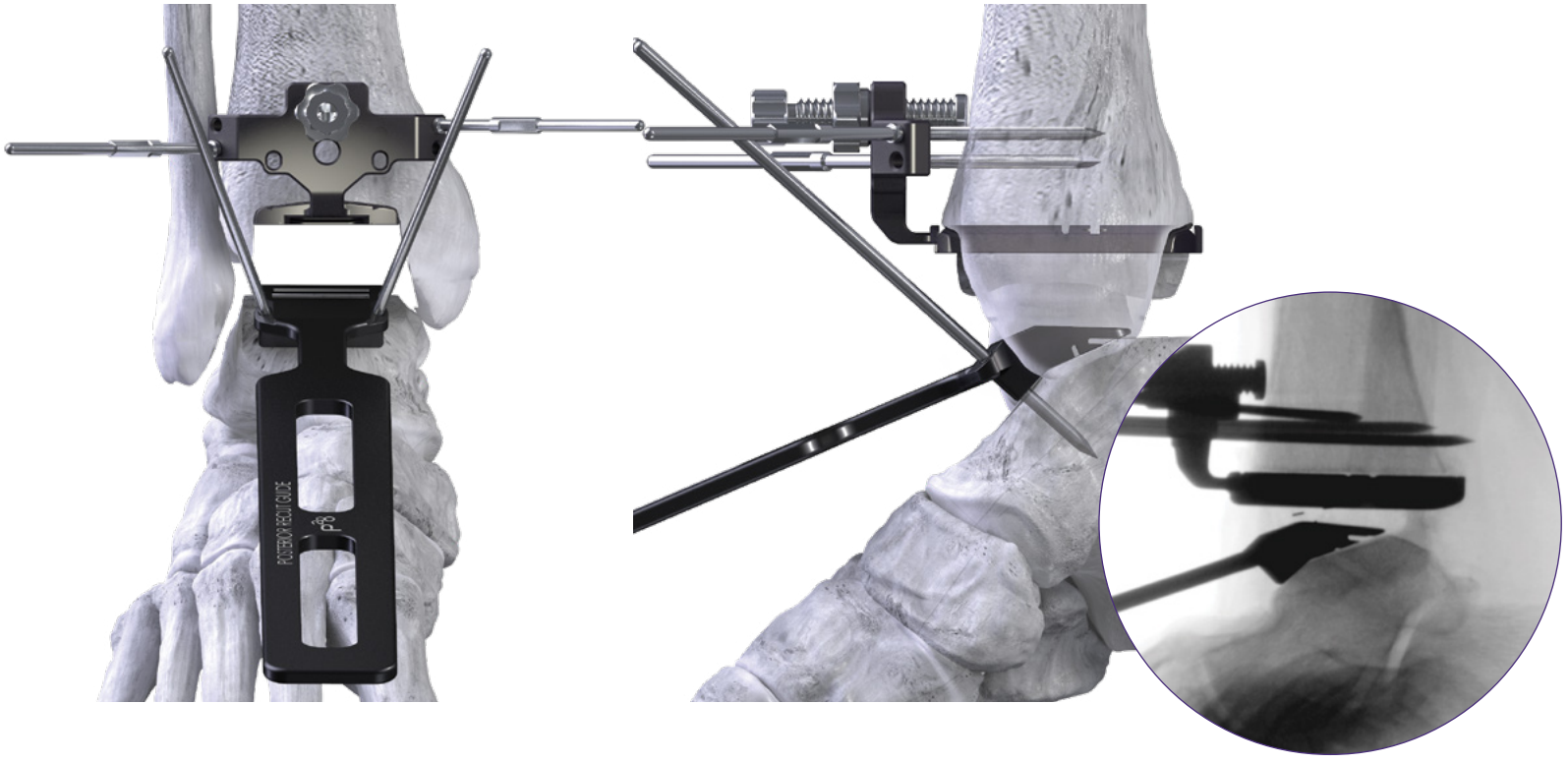


Chamfer Talus Trialing



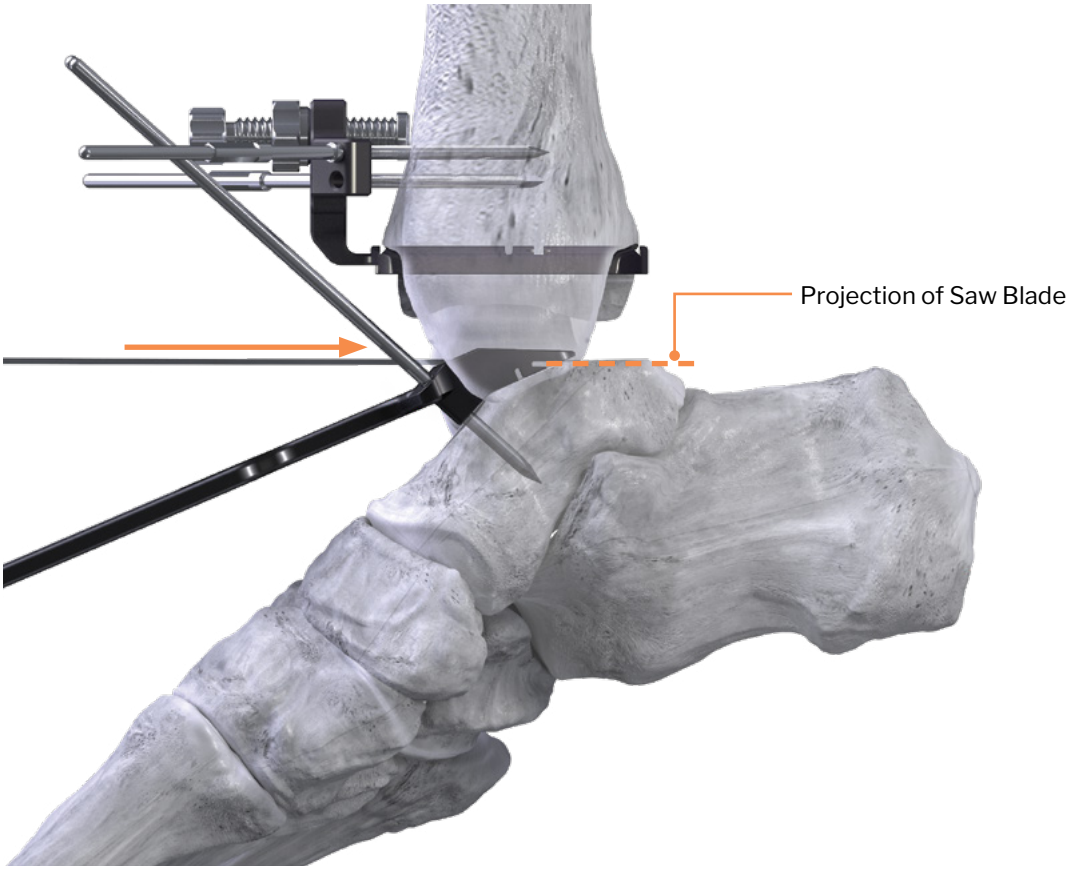
Chamfer Checker Diagnostic Evaluation

- The Posterior Chamfer Recut Guide can be utilized to correct bone resection if talar bone geometric incongruencies are noted during chamfer talus trialing or during the chamfer checker diagnostic evaluation process.



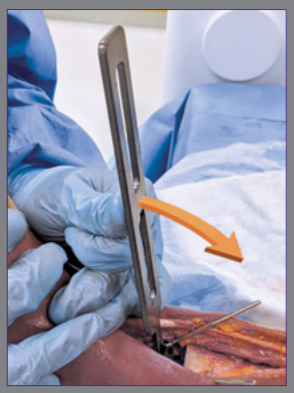
- Place the Posterior Recut Guide against the anterior and dorsal surface of the previously resected talar bone.
- Under a lateral view, ensure congruent dorsal/anterior contact of the Guide's position against the bone prior to pinning.
- By hand, place one (1) Ø2.4 mm x 110 mm Smooth Steinmann Pin into the medial anterior pin hole of the Guide, connect to power and advance, taking care not to penetrate the subtalar joint, then repeat for the lateral Fixation Pin.

POSTERIOR RECUT - CHAMFER ONLY



- Connected to power, advance the saw blade to resect the posterior talar bone .

Surgical note:



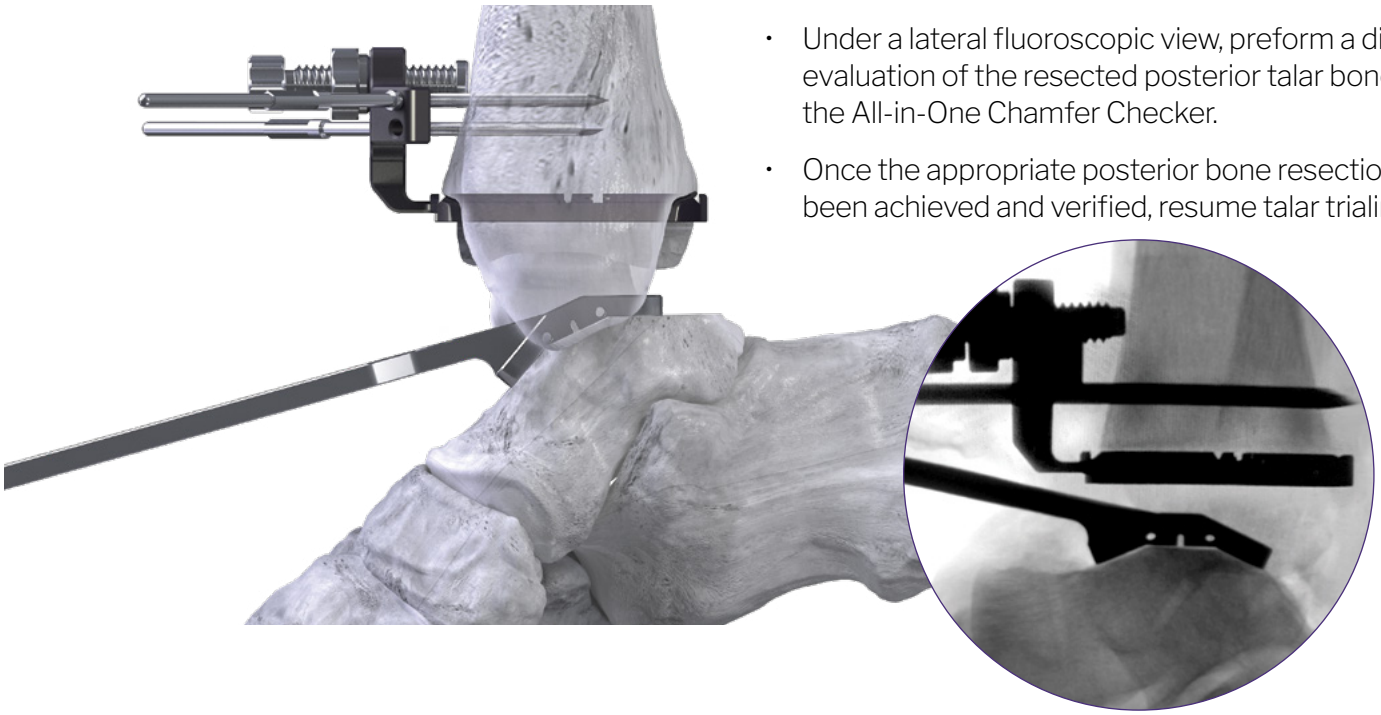
Prior to resection, slightly plantarflex the joint and apply counter pressure to the distal aspect of the guide to achieve congruent contact surface with the bone. A saw blade may be used to assess projection of bone resection.

- Remove Pins, Guide and resected talar bone .

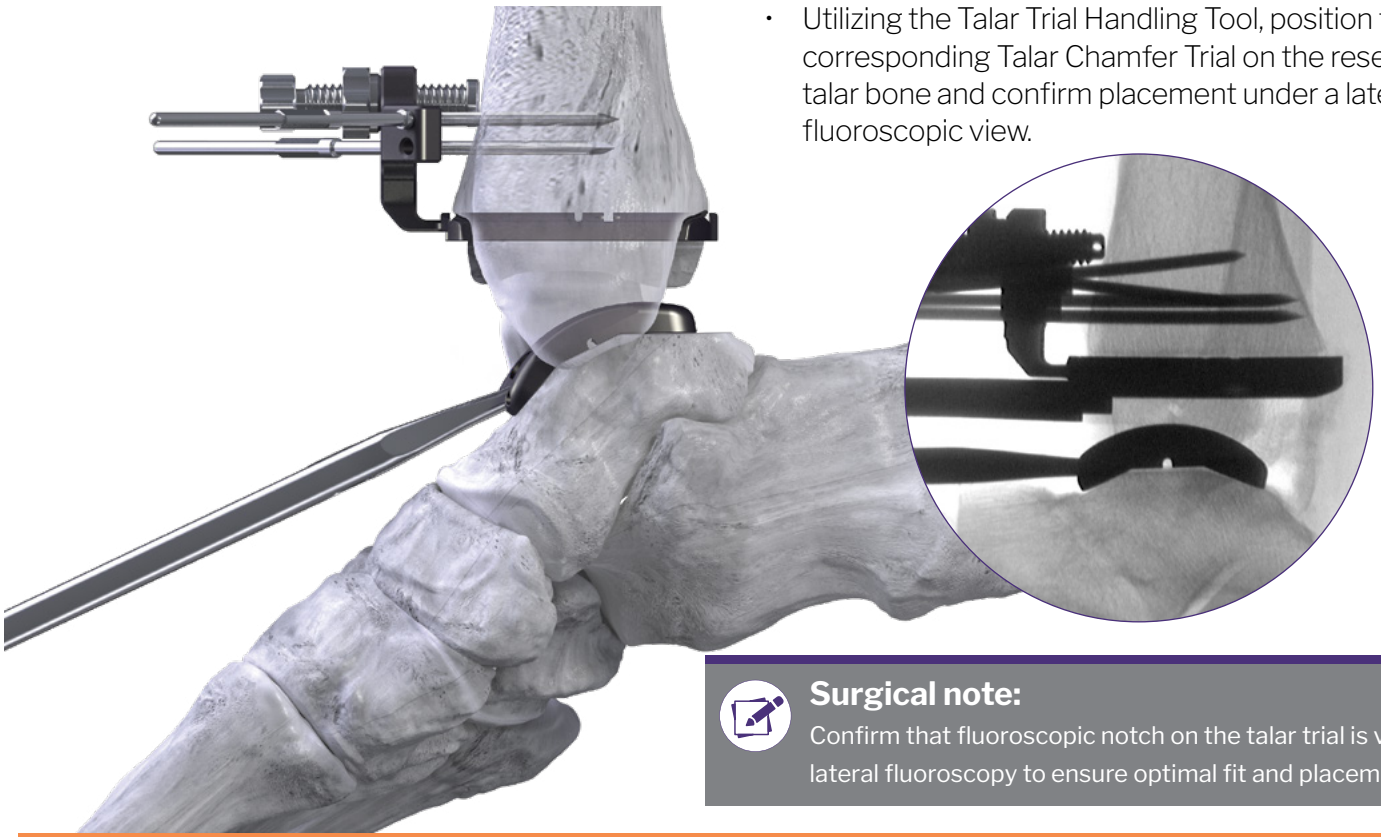
Surgical note:

Additional M/L bone remnants may need to be removed.

POSTERIOR RECUT - CHAMFER ONLY



- Under a lateral fluoroscopic view, preform a diagnostic evaluation of the resected posterior talar bone utilizing the All-in-One Chamfer Checker.
- Once the appropriate posterior bone resection has been achieved and verified, resume talar trialing.



- Utilizing the Talar Trial Handling Tool, position the corresponding Talar Chamfer Trial on the resected talar bone and confirm placement under a lateral fluoroscopic view.

Surgical note:
Confirm that fluoroscopic notch on the talar trial is visible on lateral fluoroscopy to ensure optimal fit and placement.

Attention:
Once congruent contact with the resected talar bone has been achieved, resume the procedure as reflected in section 8 of the Traditional Alignment Surgical Technique Guide [P10-STG-0001]

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

INDICATIONS FOR USE

The APEX 3D™ Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. Components are intended for cemented use only.

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 fixation or complications in post-operative treatment (e.g. dementia, senility, alcoholism)
- Corpulence; an overweight or corpulent patient 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 of 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 weight-bearing
- 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 exist. 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

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS (CONT.)

- 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
- 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

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 or surgical technique or incorrect patient information and consequent incorrect patient behavior.

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.

WARNINGS AND PRECAUTIONS (CONT.)

- 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 cement, metal, UHMWPE, and ceramic. Regarding the etiology, it has been hypothesized that 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, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis 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 component(s).

MR SAFETY INFORMATION

The APEX 3D™ Total Ankle Replacement System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the APEX 3D™ Total Ankle Replacement System in the MR environment is unknown. MR scanning of a patient who has this device may result in patient injury.

APEX 3D™
TOTAL ANKLE REPLACEMENT

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Exclusively foot & ankle Paragon 28®

www.Paragon28.com

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.