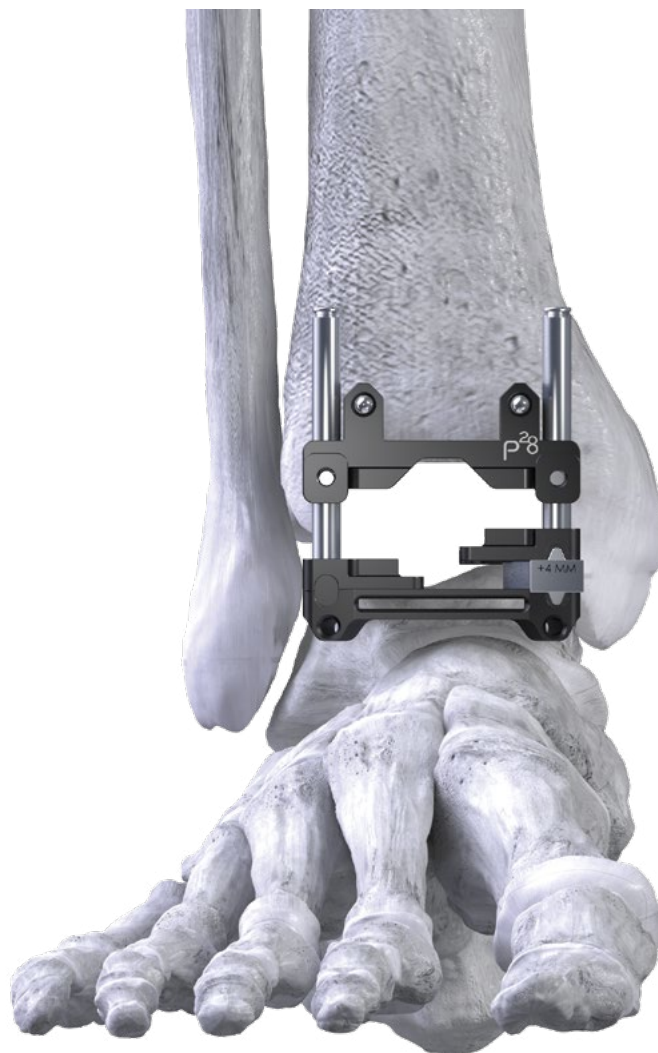
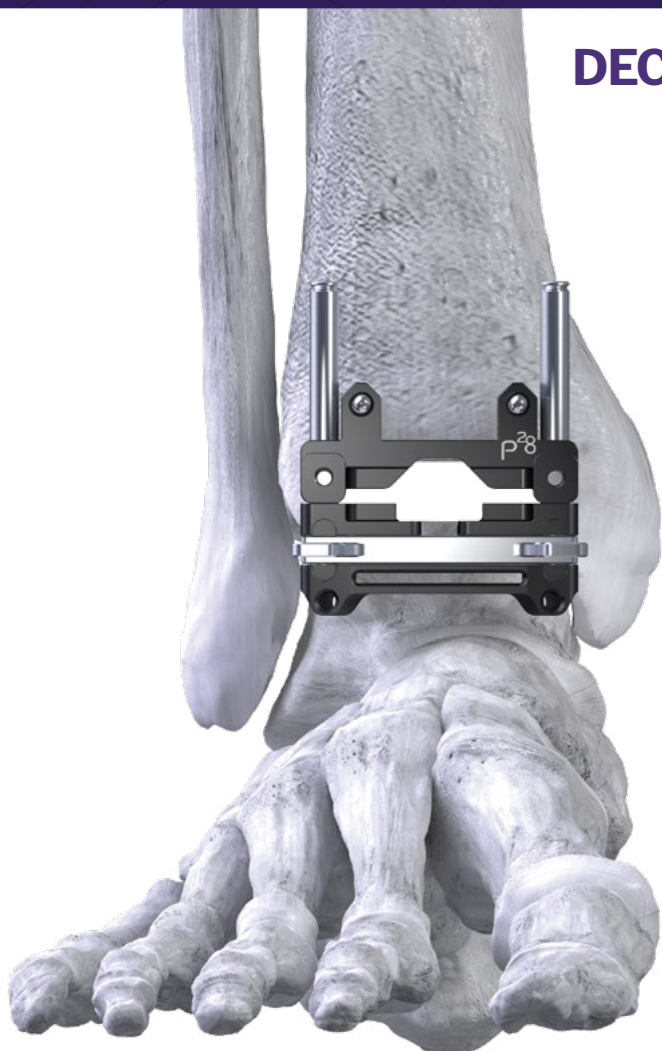


DECOUPLED TALAR BONE PREPARATION

Auxiliary Surgical Technique Guide



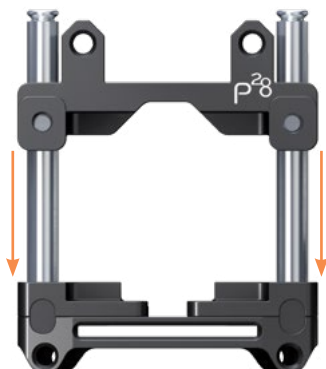
Designed to provide incremental talar bone resection adjustments when addressing joint line corrections, ankle laxity, defects in talar morphology and during chamfer talus to flat-cut talus conversions.

DECOUPLED TALAR BONE RESECTION GUIDE

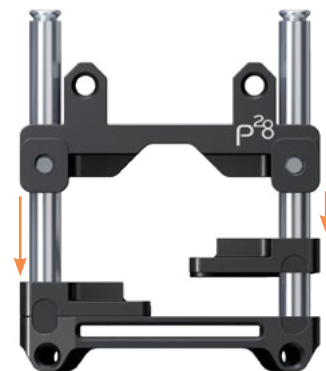
The Decoupled Talar Resection Guide can be utilized to adjust the talar bone resection level in 1mm increments. (Shims are offered in 1mm – 7mm thicknesses)



Collapsed Position



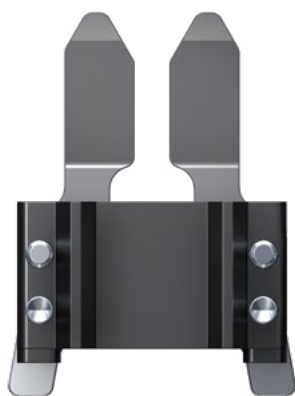
Distraction



Modular Distraction

SHIM SPECIFICATIONS

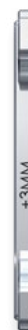
- **Coupled** Chamfer-Cut Resection Baseline: 5.75 mm Talus Bone Removal
- **Coupled** Flat-Cut Bone Resection Baseline: 9 mm Talus Bone Removal



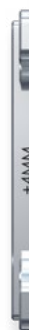
No Shim=
2 mm talar
bone removal



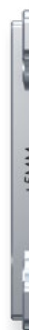
1 mm Shim=
3 mm talar
bone removal



2 mm Shim=
4 mm talar
bone removal



3 mm Shim=
5 mm talar
bone removal



4 mm Shim=
6 mm talar
bone removal



5 mm Shim=
7 mm talar
bone removal



6 mm Shim=
8 mm talar
bone removal

+2MM

+3MM

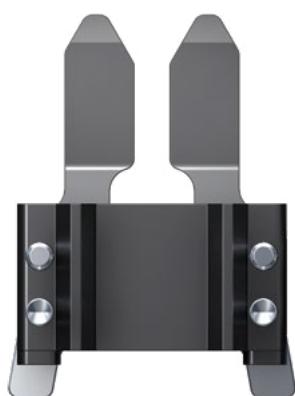
+4MM

+5MM

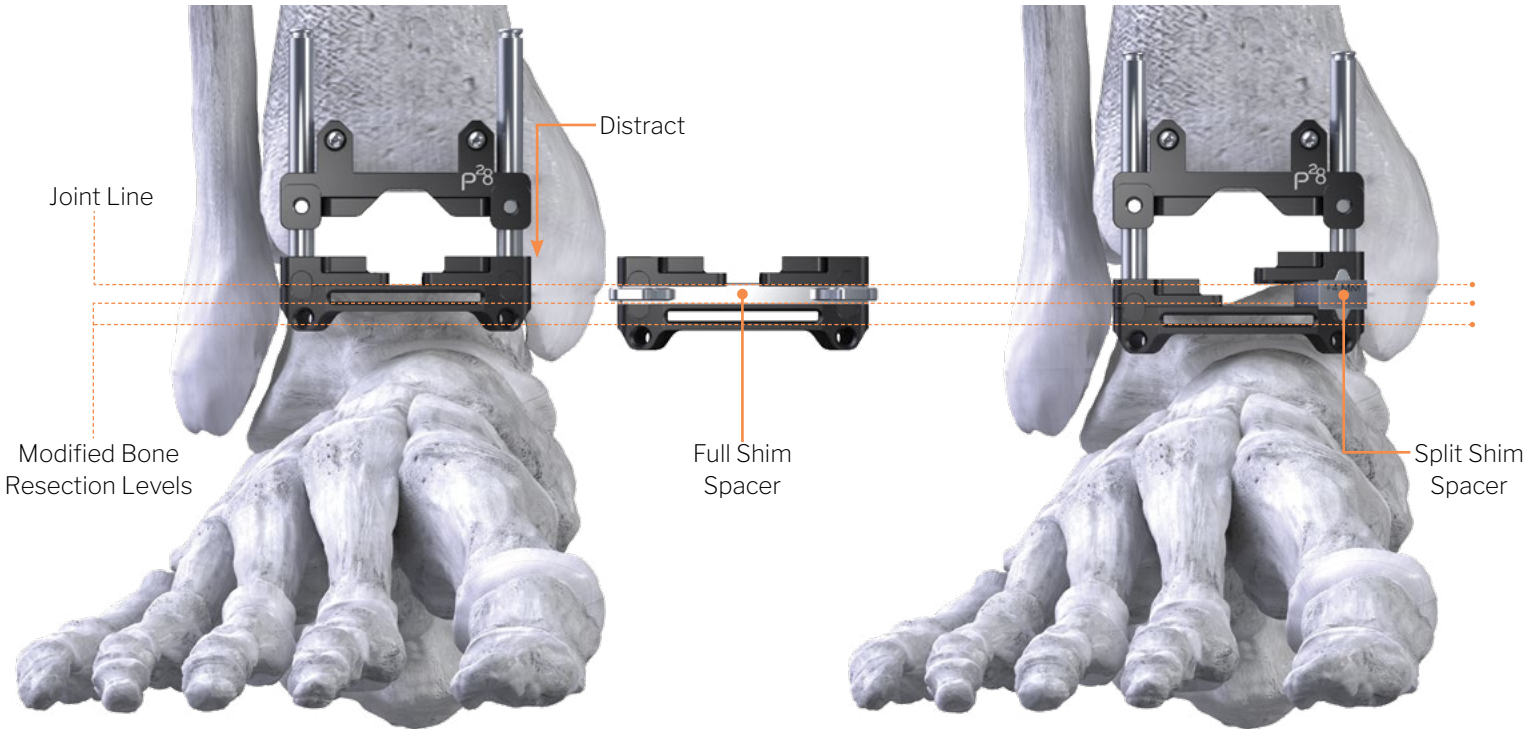
+6MM

+7MM

+7MM



DECOUPLED TALAR BONE RESECTION



- In the collapsed position, slide the proximal portion of the resection guide over the two (2) M/L Ø2.4 mm guide pins located on the anterior aspect of the tibia.
- Evaluate and adjust the anticipated talar bone resection level by distracting the distal portion of the guide until the desired level has been achieved, then insert the appropriately sized Shim below the modular talar paddle(s). (Note: Lamina spreaders should be utilized. Minor adjustment may be required.)
- By hand, place one (1) Ø2.4mm x 110mm Smooth Steinmann Pin into the medial or lateral distal converging pin hole of the guide based on the localized area of tension. Connect to power and advance, then repeat for the opposite side.
- Cut pins with the provided Pin Cutters to allow access for the saw blade. (Note: To allow for removal, do not cut pins flush. Shims should be removed prior to bone resection.)
- Resect the talar bone with saw blade connected to power ensuring uniform bone resection.



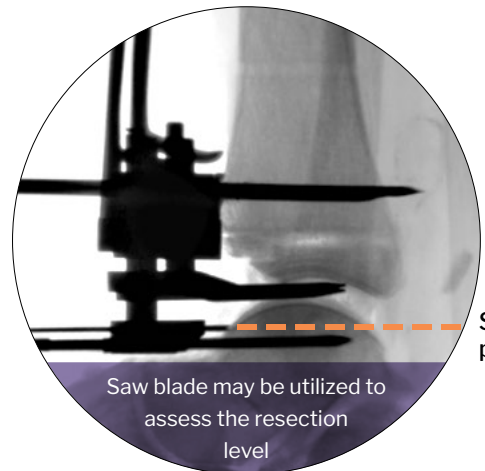
SURGICAL NOTE:

Full Shims can be utilized to address joint line corrections, ankle laxity, or during chamfer talus to flat-cut talus conversions. Split Shims can be utilized to address defects in talar morphology.



ATTENTION:

If ARC Tibia™ & Chamfer Talus bone preparation were selected, resume the surgical technique steps as reflected on page 19 of P10-STG-0001 Rev. B // If Flat Tibia & Flat Talus bone preparation was selected, refer to page 52.



Saw blade projection

Saw blade may be utilized to assess the resection level

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

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

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.	

ALIGNMENT CASE CONTENTS:

PART #	DESCRIPTION	USE
P10-901-24TH	T-Handle	Reusable
P10-901-OS01	Tibial Osteotome, ARC	Reusable
P10-901-RGA1	Resection Gap Checker, ARC/Chamfer-Cut	Reusable
P10-901-RGA2	Resection Gap Checker, ARC/Flat-Cut	Reusable
P10-901-RGF1	Resection Gap Checker, FLAT/Chamfer-Cut	Reusable
P10-901-RGF2	Resection Gap Checker, FLAT/Flat-Cut	Reusable
P10-901-RSP[1-6]	Tibial Rasp, ARC, Size 1-6	Reusable
P10-902-3010	Ø3.0 Pin, 316LVM, Fluted, 100 mm	Single-Use
P10-902-3016	Ø3.0 Pin, 316LVM, Fluted, 160 mm	Single-Use
P10-902-2425	Shoulder Threaded Pin 2.4 x 25 mm	Single-Use
P10-912-2450	Shoulder Threaded Pin 2.4 x 50 mm	Single-Use
P10-940-JL01	Joint-Line, Pin-Guide	Reusable
P10-940-JL10	Joint-Line, Pin Tube	Reusable
P10-941-AL01	Tibial Alignment Guide, Telescoping Rod	Reusable
P10-941-AL02	Tibial Alignment Guide, Telescoping Base	Reusable
P10-941-AL03	Tibial Alignment Guide, Distal Body	Reusable
P10-941-AL04	Tibial Alignment Guide, Lateral Rod	Reusable
P10-941-AL05	Tibial Alignment Guide, Fast-Track	Reusable
P10-841-AL07	Tibial Alignment Guide, Joint Line Pointer ("JLP"), GEN II	Reusable
P10-841-AW01	Alignment Wing, Gen II	Reusable
P10-941-PSI1	V-V Alignment Guide	Reusable
P10-942-3513	Arc Resection Drill, SS, Ø3.5 mm	Single-use
P10-942-35TH	Top Hat, SS, Ø3.5 mm	Reusable
P10-942-DT0[1-3, 7]	Decoupled Talar Resection, Shim, 1, 2, 3, 7 mm	Reusable
P10-942-DT1[1-3]	Decoupled Talar Resection, Split Shim, 1-3 mm	Reusable
P10-942-DTSM	Decoupled Talar Resection, Body, Small	Reusable
P10-942-FL0[1-6]	Coupled Resection Block, FLAT/Chamfer-Cut, Size 1-6	Reusable
P10-942-FL1[1-6]	Coupled Resection Block, FLAT/Flat-Cut, Size 1-6	Reusable
P10-942-RS0[1-6]	Coupled Resection Block, ARC/Chamfer-Cut, Size 1-6	Reusable
P10-942-RS1[1-6]	Coupled Resection Block, ARC/Flat-Cut, Size 1-6	Reusable
P10-942-SZ0[1-6]	Sizing Resection Block, Size 1-6	Reusable
P10-944-PSI0	Talar PSI Resection Block, Size 1N	Reusable
P10-944-PSI[1-6]	Talar PSI Resection Block, Size 1-5	Reusable
P99-150-0040	Osteotome, Straight, 6 mm	Reusable
P99-150-0041	Osteotome, Straight, 12 mm	Reusable
P99-150-0042	Osteotome, Straight, 19 mm	Reusable
P99-150-HB35	3.5 mm Ball Nose Hex Screw Driver, 225 mm Length	Reusable
P99-150-HB35-SHORT	3.5 mm Ball Nose Hex Screw Driver, Short	Reusable
P99-158-0638	Malleable Ribbon Retractor, 6" x 3/8"	Reusable
P99-158-0650	Malleable Ribbon Retractor, 6" x 1/2"	Reusable
P99-160-2411	Steinmann Pin, 316LVM, Smooth, Ø2.4x110 mm	Single-use
P10-842-35SQ	Ø3.5 mm Square Tip, 13CM, Total Ankle Drill	Single-use




P10-STG-0005 Rev. B [2024-12-16]

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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.