

To: Value Analysis Committee
From: Paragon 28® and Product Development Team
Subject: APEX 3D™ Total Ankle Replacement System
Date: July 13, 2020
CC: Field Training Managers, Product Management, Customer Service, Quality

Paragon 28® is pleased to announce the release of the APEX 3D™ Total Ankle Replacement System (APEX 3D™ System), the newest addition to the Paragon 28® Precision Ankle Solutions portfolio of products. The release of the APEX 3D™ System complements the Gorilla® Ankle Fracture Plating System, Silverback® Fusion Plating System, Phantom™ Hindfoot TCC and ActivCore™ Nail Systems.

The APEX 3D™ System consists of cemented, fixed bearing, anatomically contoured implant components, intuitive instrumentation and precision bone resection guides intended for use in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery is also indicated when sufficient bone stock is present. Components are intended for cemented use only. For additional information regarding Indications for Use, Contraindications, Warnings, Precautions, etc. please visit: Paragon28.com/ifus/.

The APEX 3D™ System has been efficiently streamlined to accommodate surgeon preference and is equipped to address a wide range of arthritic ankle conditions. The APEX 3D™ System is based on over a century of combined clinical experience, cutting-edge biomechanical research, and designed to address inherent challenges associated with total ankle joint replacement clinical outcomes including:

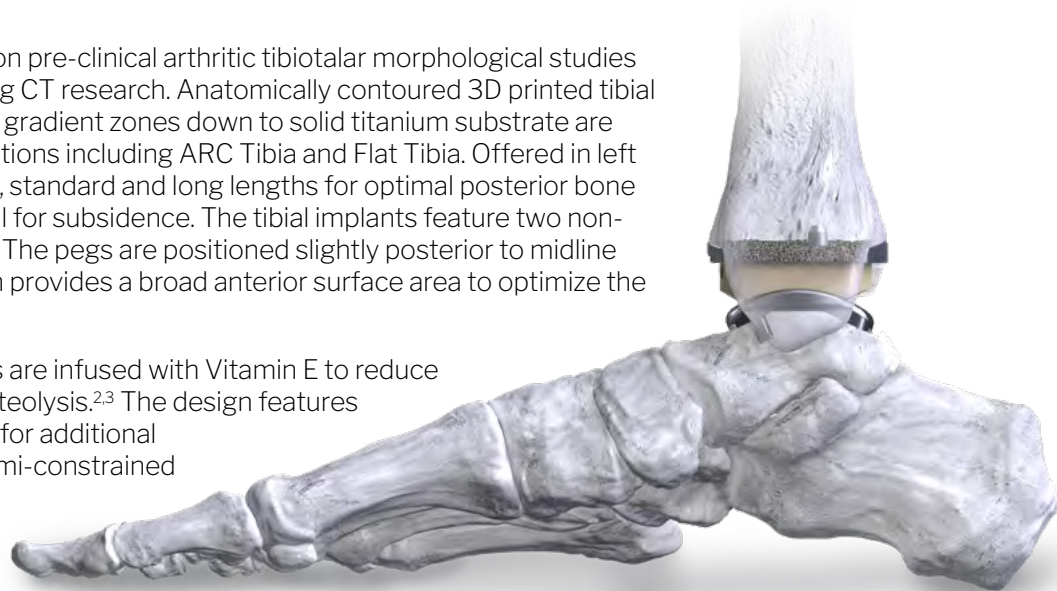
- Implant loosening
- Pathological wear
- Instability
- Persistent pain

The APEX 3D™ System offers surgeons: four targeted bone preparation options, including interchangeable configurations such as ARC Tibia™ or Flat Tibia with either Chamfer or Flat Talus preparation options and provides coupled or decoupled bone resection options to accommodate individual patient condition types.

Tibial and talar implant designs are based on pre-clinical arthritic tibiotalar morphological studies and guided by healthy ankle weight-bearing CT research. Anatomically contoured 3D printed tibial tray implants with porous architecture and gradient zones down to solid titanium substrate are available in two distinct geometric style options including ARC Tibia and Flat Tibia. Offered in left and right configurations, available in short*, standard and long lengths for optimal posterior bone coverage and AP fit to reduce the potential for subsidence. The tibial implants feature two non-coated vertical pegs for initial stabilization. The pegs are positioned slightly posterior to midline where peak bone density is located¹, which provides a broad anterior surface area to optimize the contact interface.

The cross-linked polyethylene tibial inserts are infused with Vitamin E to reduce oxidation, wear debris, and potential for osteolysis.^{2,3} The design features a universal locking mechanism that allows for additional intraoperative implant optionality and a semi-constrained bicondylar design that allows for anatomic conformity. Vitamin E polyethylene components are available in primary and revision thicknesses.

Two distinct Talar Dome style options are offered (Chamfer and Flat) in left and right configurations, featuring tapered shoulders designed to reduce potential for painful gutter impingement, a gentle sulcus and multi-axial articulation that helps to mimic natural motion.



*available in size 1 only

TIBIAL TRAY - 3D PRINTED ADDITIVE METAL TECHNOLOGY

- **Material:** 3D Printed (Titanium Alloy) -Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial)
- **Sizing:** 52 Anatomically contoured low-profile options available in sizes 1 - 6 (Lengths: Short*, Standard & Long)
- **Anatomic Fit:** Left & right specific components featuring:
 - Anterior/posterior curvatures based on both arthritic and healthy pre-clinical tibiotalar morphology studies.
 - Anterior/posterior lengths and medial/lateral widths based on both arthritic and healthy pre-clinical tibiotalar morphology studies.
 - Anterior/posterior lengths with fixed 3mm increments between sizes.
 - Medial/lateral widths with fixed 2.4mm increments between sizes
 - 5 mm overall height consistent across all sizes and style options
- **Style Options:** ARC Tibia™ & Flat Tibia geometric configurations
- **Sterile Packaged Shelf Life:** 5 years



POLYETHYLENE INSERT - CROSS-LINKED VITAMIN E INFUSION

- **Material:** UHMWPE + Medical Grade Vitamin E Formula (100 kGy)
- **Sizing:** 35 Sizing options with universal locking mechanism available in sizes 1 - 5:
 - Seven primary and revision thicknesses options including 6 - 12mm (in 1mm increments)
- **Anatomic Fit:** Components feature semi-constrained bicondylar bearing surface to allow for anatomic conformity.
 - Anterior/posterior lengths have fixed 3mm increments between sizes (except Size 1 - 2)
 - Medial/lateral widths have fixed 2.4mm increments between sizes
- **Style Options:** Neutral
- **Sterile Packaged Shelf Life:** 5 years



TALAR DOME - ANATOMICALLY CONTOURED FOOTPRINT

- **Material:** Cobalt-chromium-molybdenum alloy (CoCr) with Titanium Plasma Spray (TPS) undercoating
- **Sizing:** 12 Anatomically contoured options available in sizes 1 narrow (1N) & 1 - 5.
- **Anatomic Fit:** Left & right specific components featuring anterior/posterior curvatures based on arthritic & non-arthritic tibiotalar morphology studies.
 - Anterior/posterior lengths and medial/lateral widths based on Tibia & Talar Sizing & Morphology Study (TR-19021117: Internal test report, data available for review at Paragon 28)
 - Medial/lateral widths have 2.25mm increments between sizes (except for size 1N - 1)
- **Style Options:** Chamfer & Flat-cut
- **Sterile Packaged Shelf Life:** 5 years



KEY SYSTEM FEATURES & BENEFITS

COMPONENT	UNIQUE FEATURES	BENEFITS
Tibial Tray	Anatomic design based on arthritic ankle preclinical morphology studies intended to more accurately describe the curvature of the distal tibia.	Implant designed to overcome shortcomings seen in competitive implants, as reported in both literature and MAUDE database and match the anatomic fit to the disease-shaped tibias allowing for better surface contact, with the intent to reduce the potential for subsidence.
	Additive metal 3D printed porous architecture with gradient zones down to solid titanium substrate.	Porous surface area introduced to optimize pore structure.
	Geometrically shaped ARC Tibia™ & Flat Tibia style options.	Designed to decrease rotational forces and provide additional stability.
	Broad anterior surface area	Optimize congruent distal tibia contact interface. ⁴
	ARC Tibia option allows for less bone removal.	vs. traditional Flat-cut tibial components.
	ARC Tibia & Flat Tibia style options available in anatomically contoured left & right configurations.	Designed to provide optimal distal tibia coverage.
	Equipped with two non-coated vertical pegs positioned slightly posterior to midline where peak bone density is located ¹	Provides initial stabilization. Designed to reduce posterior translation during implantation compared to designs with anterior peg placement and mitigate potential for posterior gapping.
	During bone preparation steps, corners are drilled rather than cut avoiding two intersecting saw cuts.	Results in rounded edges of (both the flat-cut design and ARC Tibia design) intended to help mitigate the risk of tibial stress fracture ^{5, 6} and malleolar fracture seen in existing tibial implant designs, ^{7, 6} as well as post-operative malleolar fracture seen in other total ankle replacement designs. ^{8, 9, 10, 11, 12}
Vitamin E Tibial Poly Insert	Medical Grade Vitamin E Infusion	Incorporated to help reduce oxidation, wear debris and potential for osteolysis that can lead to implant failure. ^{2,3} Material composition allows for enhanced wear characteristics compared to conventional polyethylene.
	Semi-constrained bicondylar bearing surface	Allows for more natural anatomic conformity.
	Universal locking mechanism	Allows for additional implant optionality and provides the ability to downsize without restriction** & upsize by one to accommodate patient needs. **Largest Tibial implant option (Size 6) can be paired with smallest Polyethylene Insert and Talar implant option. (Size 1 Polyethylene Insert & Size 1 Narrow Talar Implant)

COMPONENT	UNIQUE FEATURES	BENEFITS
Talar Dome	Anatomic Talar "footprint" based on arthritic ankle pre-clinical studies.	Designed to optimize talar bone coverage.
	Design considers tibiotalar kinematic motion during simulated gait using modern weight-bearing CT technology research.	Allows for multi-axial articulation, reducing the potential of bony and component impingement.
	Chamfer & Flat-cut options available in left & right configurations with sizing for anterior / posterior length and medial / lateral width based on Tibia & Talar Sizing & Morphological Study (TR-19021117: Internal test report, data available for review at Paragon 28).	Accommodates surgeon bone preparation preferences, various arthritic conditions and allows for a more anatomic fit.
	Designed with gentle sulcus.	Mimics natural motion, resist medial/lateral translation and subluxation.
	Chamfer Style Option - 15° tapers on medial and lateral shoulders Flat Style Option - 20° tapers on medial and lateral shoulders	Helps to reduce potential for painful gutter impingement.
	Chamfer Style Option - Designed with singular non-coated central fin	For ease of insertion, featuring bone preparation trajectory that allows the implant to be properly impacted posteriorly, overcoming issues of posterior gapping and potential for component loosening, as noted in current designs. ^{13, 7, 14, 15}
	Flat Style Option - Equipped with dual non-coated anterior pegs	Designed to provide initial fixation and rotational stability.

PART NUMBERS AND DESCRIPTIONS



ARC Tibia™ Implants

PART #	DESCRIPTION
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P10-100-BL10-S	APEX 3D™ ARC Tibia, Left, Size 1, Short, 3DP
P10-100-BL1L-S	APEX 3D™ ARC Tibia, Left, Size 1, Long, 3DP
P10-100-BL1S-S	APEX 3D™ ARC Tibia, Left, Size 1, Standard, 3DP
P10-100-BL2L-S	APEX 3D™ ARC Tibia, Left, Size 2, Long, 3DP
P10-100-BL2S-S	APEX 3D™ ARC Tibia, Left, Size 2, Standard, 3DP
P10-100-BL3L-S	APEX 3D™ ARC Tibia, Left, Size 3, Long, 3DP
P10-100-BL3S-S	APEX 3D™ ARC Tibia, Left, Size 3, Standard, 3DP
P10-100-BL4L-S	APEX 3D™ ARC Tibia, Left, Size 4, Long, 3DP
P10-100-BL4S-S	APEX 3D™ ARC Tibia, Left, Size 4, Standard, 3DP
P10-100-BL5L-S	APEX 3D™ ARC Tibia, Left, Size 5, Long, 3DP
P10-100-BL5S-S	APEX 3D™ ARC Tibia, Left, Size 5, Standard, 3DP
P10-100-BL6L-S	APEX 3D™ ARC Tibia, Left, Size 6, Long, 3DP
P10-100-BL6S-S	APEX 3D™ ARC Tibia, Left, Size 6, Standard, 3DP
P10-100-BR10-S	APEX 3D™ ARC Tibia, Right, Size 1, Short, 3DP
P10-100-BR1L-S	APEX 3D™ ARC Tibia, Right, Size 1, Long, 3DP
P10-100-BR1S-S	APEX 3D™ ARC Tibia, Right, Size 1, Standard, 3DP
P10-100-BR2L-S	APEX 3D™ ARC Tibia, Right, Size 2, Long, 3DP
P10-100-BR2S-S	APEX 3D™ ARC Tibia, Right, Size 2, Standard, 3DP
P10-100-BR3L-S	APEX 3D™ ARC Tibia, Right, Size 3, Long, 3DP
P10-100-BR3S-S	APEX 3D™ ARC Tibia, Right, Size 3, Standard, 3DP
P10-100-BR4L-S	APEX 3D™ ARC Tibia, Right, Size 4, Long, 3DP
P10-100-BR4S-S	APEX 3D™ ARC Tibia, Right, Size 4, Standard, 3DP
P10-100-BR5L-S	APEX 3D™ ARC Tibia, Right, Size 5, Long, 3DP
P10-100-BR5S-S	APEX 3D™ ARC Tibia, Right, Size 5, Standard, 3DP
P10-100-BR6L-S	APEX 3D™ ARC Tibia, Right, Size 6, Long, 3DP
P10-100-BR6S-S	APEX 3D™ ARC Tibia, Right, Size 6, Standard, 3DP



FLAT Tibia Implants

PART #	DESCRIPTION
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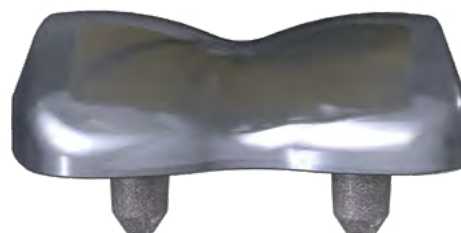
P10-101-BL10-S	APEX 3D™ Tibia, Flat, Left, Size 1, Short, 3DP
P10-101-BL1L-S	APEX 3D™ Tibia, Flat, Left, Size 1, Long, 3DP
P10-101-BL1S-S	APEX 3D™ Tibia, Flat, Left, Size 1, Standard, 3DP
P10-101-BL2L-S	APEX 3D™ Tibia, Flat, Left, Size 2, Long, 3DP
P10-101-BL2S-S	APEX 3D™ Tibia, Flat, Left, Size 2, Standard, 3DP
P10-101-BL3L-S	APEX 3D™ Tibia, Flat, Left, Size 3, Long, 3DP
P10-101-BL3S-S	APEX 3D™ Tibia, Flat, Left, Size 3, Standard, 3DP
P10-101-BL4L-S	APEX 3D™ Tibia, Flat, Left, Size 4, Long, 3DP
P10-101-BL4S-S	APEX 3D™ Tibia, Flat, Left, Size 4, Standard, 3DP
P10-101-BL5L-S	APEX 3D™ Tibia, Flat, Left, Size 5, Long, 3DP
P10-101-BL5S-S	APEX 3D™ Tibia, Flat, Left, Size 5, Standard, 3DP
P10-101-BL6L-S	APEX 3D™ Tibia, Flat, Left, Size 6, Long, 3DP
P10-101-BL6S-S	APEX 3D™ Tibia, Flat, Left, Size 6, Standard, 3DP
P10-101-BR10-S	APEX 3D™ Tibia, Flat, Right, Size 1, Short, 3DP
P10-101-BR1L-S	APEX 3D™ Tibia, Flat, Right, Size 1, Long, 3DP
P10-101-BR1S-S	APEX 3D™ Tibia, Flat, Right, Size 1, Standard, 3DP
P10-101-BR2L-S	APEX 3D™ Tibia, Flat, Right, Size 2, Long, 3DP
P10-101-BR2S-S	APEX 3D™ Tibia, Flat, Right, Size 2, Standard, 3DP
P10-101-BR3L-S	APEX 3D™ Tibia, Flat, Right, Size 3, Long, 3DP
P10-101-BR3S-S	APEX 3D™ Tibia, Flat, Right, Size 3, Standard, 3DP
P10-101-BR4L-S	APEX 3D™ Tibia, Flat, Right, Size 4, Long, 3DP
P10-101-BR4S-S	APEX 3D™ Tibia, Flat, Right, Size 4, Standard, 3DP
P10-101-BR5L-S	APEX 3D™ Tibia, Flat, Right, Size 5, Long, 3DP
P10-101-BR5S-S	APEX 3D™ Tibia, Flat, Right, Size 5, Standard, 3DP
P10-101-BR6L-S	APEX 3D™ Tibia, Flat, Right, Size 6, Long, 3DP
P10-101-BR6S-S	APEX 3D™ Tibia, Flat, Right, Size 6, Standard, 3DP



Chamfer Talus Implants

PART #	DESCRIPTION
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P10-250-TLL0-S	APEX 3D™ Talus, Chamfer, Left, Size 1 Narrow, TPS
P10-250-TLL1-S	APEX 3D™ Talus, Chamfer, Left, Size 1, TPS
P10-250-TLL2-S	APEX 3D™ Talus, Chamfer, Left, Size 2, TPS
P10-250-TLL3-S	APEX 3D™ Talus, Chamfer, Left, Size 3, TPS
P10-250-TLL4-S	APEX 3D™ Talus, Chamfer, Left, Size 4, TPS
P10-250-TLL5-S	APEX 3D™ Talus, Chamfer, Left, Size 5, TPS
P10-250-TLR0-S	APEX 3D™ Talus, Chamfer, Right, Size 1 Narrow, TPS
P10-250-TLR1-S	APEX 3D™ Talus, Chamfer, Right, Size 1, TPS
P10-250-TLR2-S	APEX 3D™ Talus, Chamfer, Right, Size 2, TPS
P10-250-TLR3-S	APEX 3D™ Talus, Chamfer, Right, Size 3, TPS
P10-250-TLR4-S	APEX 3D™ Talus, Chamfer, Right, Size 4, TPS
P10-250-TLR5-S	APEX 3D™ Talus, Chamfer, Right, Size 5, TPS



Flat Talus Implants

PART #	DESCRIPTION
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P10-251-TLL0-S	APEX 3D™ Talus, Flat, Left, Size 1 Narrow, TPS
P10-251-TLL1-S	APEX 3D™ Talus, Flat, Left, Size 1, TPS
P10-251-TLL2-S	APEX 3D™ Talus, Flat, Left, Size 2, TPS
P10-251-TLL3-S	APEX 3D™ Talus, Flat, Left, Size 3, TPS
P10-251-TLL4-S	APEX 3D™ Talus, Flat, Left, Size 4, TPS
P10-251-TLL5-S	APEX 3D™ Talus, Flat, Left, Size 5, TPS
P10-251-TLR0-S	APEX 3D™ Talus, Flat, Right, Size 1 Narrow, TPS
P10-251-TLR1-S	APEX 3D™ Talus, Flat, Right, Size 1, TPS
P10-251-TLR2-S	APEX 3D™ Talus, Flat, Right, Size 2, TPS
P10-251-TLR3-S	APEX 3D™ Talus, Flat, Right, Size 3, TPS
P10-251-TLR4-S	APEX 3D™ Talus, Flat, Right, Size 4, TPS
P10-251-TLR5-S	APEX 3D™ Talus, Flat, Right, Size 5, TPS



PART #	DESCRIPTION
P10-310-I106-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 6MM, NEUTRAL
P10-310-I107-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 7MM, NEUTRAL
P10-310-I108-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 8MM, NEUTRAL
P10-310-I109-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 9MM, NEUTRAL
P10-310-I110-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 10MM, NEUTRAL
P10-310-I111-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 11MM, NEUTRAL
P10-310-I112-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 12MM, NEUTRAL
P10-310-I206-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 6MM, NEUTRAL
P10-310-I207-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 7MM, NEUTRAL
P10-310-I208-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 8MM, NEUTRAL
P10-310-I209-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 9MM, NEUTRAL
P10-310-I210-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 10MM, NEUTRAL
P10-310-I211-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 11MM, NEUTRAL
P10-310-I212-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 12MM, NEUTRAL
P10-310-I306-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 6MM, NEUTRAL
P10-310-I307-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 7MM, NEUTRAL
P10-310-I308-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 8MM, NEUTRAL
P10-310-I309-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 9MM, NEUTRAL
P10-310-I310-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 10MM, NEUTRAL
P10-310-I311-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 11MM, NEUTRAL
P10-310-I312-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 12MM, NEUTRAL
P10-310-I406-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 6MM, NEUTRAL
P10-310-I407-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 7MM, NEUTRAL
P10-310-I408-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 8MM, NEUTRAL
P10-310-I409-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 9MM, NEUTRAL
P10-310-I410-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 10MM, NEUTRAL
P10-310-I411-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 11MM, NEUTRAL
P10-310-I412-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 12MM, NEUTRAL
P10-310-I506-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 6MM, NEUTRAL
P10-310-I507-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 7MM, NEUTRAL
P10-310-I508-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 8MM, NEUTRAL
P10-310-I509-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 9MM, NEUTRAL
P10-310-I510-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 10MM, NEUTRAL
P10-310-I511-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 11MM, NEUTRAL
P10-310-I512-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 12MM, NEUTRAL

PART NUMBER	ALIGNMENT CASE INSTRUMENT DESCRIPTIONS	QTY PER SET
Case and Tray Components		
P10-900-0001	APEX 3D-PS Total Ankle Replacement System, Alignment, Tray	1
P10-900-0002	APEX 3D-PS Total Ankle Replacement System, Resection, Tray	1
P10-900-0007	APEX 3D-PS Total Ankle Replacement System, Small Tray	1
P10-900-CASB	APEX 3D-PS Total Ankle Replacement System, Case Base	1
P10-900-CASL	APEX 3D-PS Total Ankle Replacement System, Case Lid	1
P10-901-24TH	APEX 3D-PS Total Ankle Replacement System, T-Handle	1
P10-901-OS01	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Osteotome,	1
P10-901-RGA1	APEX 3D-PS Total Ankle Replacement System, Resection Gap Checker, ARC Tibia/Chamfer Talus	1
P10-901-RGA2	APEX 3D-PS Total Ankle Replacement System, Resection Gap Checker, ARC Tibia/Flat Talus	1
P10-901-RGF1	APEX 3D-PS Total Ankle Replacement System, Resection Gap Checker, FLAT/Chamfer Talus	1
P10-901-RGF2	APEX 3D-PS Total Ankle Replacement System, Resection Gap Checker, FLAT/Flat Talus	1
P10-901-RSP1	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Rasp, Size 1	1
P10-901-RSP2	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Rasp, Size 2	1
P10-901-RSP3	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Rasp, Size 3	1
P10-901-RSP4	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Rasp, Size 4	1
P10-901-RSP5	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Rasp, Size 5	1
P10-901-RSP6	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Rasp, Size 6	1
P10-902-2425	APEX 3D-PS Total Ankle Replacement System, 2.4 Shoulder-Thread Pin, 25mm Thread length	6
P10-902-2450	APEX 3D-PS Total Ankle Replacement System, 2.4 Shoulder-Thread Pin, 50mm Thread length	4
P10-902-3010	APEX 3D-PS Total Ankle Replacement System, 3.0 Pin, 316LVM, Fluted, 100mm	3
P10-902-3016	APEX 3D-PS Total Ankle Replacement System, 3.0 Pin, 316LVM, Fluted, 160mm	3
P10-910-SCKT	APEX 3D-PS Total Ankle Replacement System, Socket Driver	1
P10-940-JL01	APEX 3D-PS Total Ankle Replacement System, Joint-Line, Pin-Guide	1
P10-940-JL10	APEX 3D-PS Total Ankle Replacement System, Joint-Line, Pin Tube	2
P10-941-AL01	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment Guide, Telescoping Rod	1
P10-941-AL02	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment Guide, Telescoping Base	1
P10-941-AL03	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment Guide, Distal Body	1
P10-941-AL04	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment Guide, Lateral Rod	1
P10-941-AL05	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment Guide, Fast-Track	1
P10-941-AL06	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment, Gutter Tool	1
P10-941-AL07	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment Guide, Joint Line Pointer ("JLP")	1
P10-941-AW01	APEX 3D-PS Total Ankle Replacement System, Tibial Alignment, Joint Line Reference Wing	1
P10-942-3513	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Resection Drill, SS, Ø3.5MM	2
P10-942-35TH	APEX 3D-PS Total Ankle Replacement System, Top Hat, SS, Ø3.5MM	2
P10-942-DT01	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 1mm	1
P10-942-DT02	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 2mm	1
P10-942-DT03	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 3mm	1
P10-942-DT04	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 4mm	1

P10-942-DT05	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 5mm	1
P10-942-DT06	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 6mm	1
P10-942-DT07	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Shim, 7mm	1
P10-942-DT11	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 1mm	1
P10-942-DT12	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 2mm	1
P10-942-DT13	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 3mm	1
P10-942-DT14	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 4mm	1
P10-942-DT15	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 5mm	1
P10-942-DT16	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 6mm	1
P10-942-DT17	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Split Shim, 7mm	1
P10-942-DTSM	APEX 3D-PS Total Ankle Replacement System, Decoupled Talar Resection, Body, Small	1
P10-942-FL01	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Chamfer-Cut, Size 1	1
P10-942-FL02	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Chamfer-Cut, Size 2	1
P10-942-FL03	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Chamfer-Cut, Size 3	1
P10-942-FL04	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Chamfer-Cut, Size 4	1
P10-942-FL05	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Chamfer-Cut, Size 5	1
P10-942-FL06	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Chamfer-Cut, Size 6	1
P10-942-FL11	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Flat-Cut, Size 1	1
P10-942-FL12	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Flat-Cut, Size 2	1
P10-942-FL13	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Flat-Cut, Size 3	1
P10-942-FL14	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Flat-Cut, Size 4	1
P10-942-FL15	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Flat-Cut, Size 5	1
P10-942-FL16	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, FLAT/Flat-Cut, Size 6	1
P10-942-RS01	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Chamfer-Cut, Size 1	1
P10-942-RS02	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Chamfer-Cut, Size 2	1
P10-942-RS03	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Chamfer-Cut, Size 3	1
P10-942-RS04	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Chamfer-Cut, Size 4	1
P10-942-RS05	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Chamfer-Cut, Size 5	1
P10-942-RS06	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Chamfer-Cut, Size 6	1
P10-942-RS11	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Flat-Cut, Size 1	1
P10-942-RS12	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Flat-Cut, Size 2	1
P10-942-RS13	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Flat-Cut, Size 3	1
P10-942-RS14	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Flat-Cut, Size 4	1
P10-942-RS15	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Flat-Cut, Size 5	1
P10-942-RS16	APEX 3D-PS Total Ankle Replacement System, Coupled Resection Block, ARC Tibia/Flat-Cut, Size 6	1
P10-942-SZ01	APEX 3D-PS Total Ankle Replacement System, Sizing Resection Block, Size 1	1
P10-942-SZ02	APEX 3D-PS Total Ankle Replacement System, Sizing Resection Block, Size 2	1
P10-942-SZ03	APEX 3D-PS Total Ankle Replacement System, Sizing Resection Block, Size 3	1
P10-942-SZ04	APEX 3D-PS Total Ankle Replacement System, Sizing Resection Block, Size 4	1
P10-942-SZ05	APEX 3D-PS Total Ankle Replacement System, Sizing Resection Block, Size 5	1

P10-942-SZ06	APEX 3D-PS Total Ankle Replacement System, Sizing Resection Block, Size 6	1
P99-150-0040	Osteotome, Straight, 6mm	1
P99-150-0041	Osteotome, Straight, 12mm	1
P99-150-0042	Osteotome, Straight, 19mm	1
P99-150-HX35	3.5MM Hex Screw Driver, 225mm Length	1
P99-160-2411	Steinmann Pin, 316LVM, Smooth, Ø2.4x110mm	30

PART NUMBER	ALIGNMENT CASE INSTRUMENT DESCRIPTIONS	QTY PER SET
Total Ankle Case and Tray Components		
P10-900-0003	APEX 3D-PS Total Ankle Replacement System, Tibia Trialing, Tray	1
P10-900-0004	APEX 3D-PS Total Ankle Replacement System, Talus Trialing, Tray	1
P10-900-CASB	APEX 3D-PS Total Ankle Replacement System, Case Base	1
P10-900-CASL	APEX 3D-PS Total Ankle Replacement System, Case Lid	1
P10-910-TB1L	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 1, Left	1
P10-910-TB1R	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 1, Right	1
P10-910-TB2L	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 2, Left	1
P10-910-TB2R	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 2, Right	1
P10-910-TB3L	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 3, Left	1
P10-910-TB3R	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 3, Right	1
P10-910-TB4L	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 4, Left	1
P10-910-TB4R	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 4, Right	1
P10-910-TB5L	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 5, Left	1
P10-910-TB5R	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 5, Right	1
P10-910-TB6L	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 6, Left	1
P10-910-TB6R	APEX 3D-PS Total Ankle Replacement System, ARC Tibia Trial, Size 6, Right	1
P10-911-TB1L	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 1, Left	1
P10-911-TB1R	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 1, Right	1
P10-911-TB2L	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 2, Left	1
P10-911-TB2R	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 2, Right	1
P10-911-TB3L	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 3, Left	1
P10-911-TB3R	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 3, Right	1
P10-911-TB4L	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 4, Left	1
P10-911-TB4R	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 4, Right	1
P10-911-TB5L	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 5, Left	1
P10-911-TB5R	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 5, Right	1
P10-911-TB6L	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 6, Left	1
P10-911-TB6R	APEX 3D-PS Total Ankle Replacement System, FLAT Trial Tibia, Size 6, Right	1

P10-920-TFT0	APEX 3D-PS Total Ankle Replacement System, Talar Fin Tower, Size 1 Narrow & 1	1
P10-920-TFT2	APEX 3D-PS Total Ankle Replacement System, Talar Fin Tower, Size 2-5	1
P10-920-TLL0	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 1 Narrow, Left	1
P10-920-TLL1	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 1, Left	1
P10-920-TLL2	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 2, Left	1
P10-920-TLL3	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 3, Left	1
P10-920-TLL4	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 4, Left	1
P10-920-TLL5	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 5, Left	1
P10-920-TLR0	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 1 Narrow, Right	1
P10-920-TLR1	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 1, Right	1
P10-920-TLR2	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 2, Right	1
P10-920-TLR3	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 3, Right	1
P10-920-TLR4	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 4, Right	1
P10-920-TLR5	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Chamfer, Size 5, Right	1
P10-920-TLRM	APEX 3D-PS Total Ankle Replacement System, Talar Fin Sweeper	2
P10-921-TLL0	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 1 Narrow, Left	1
P10-921-TLL1	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 1, Left	1
P10-921-TLL2	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 2, Left	1
P10-921-TLL3	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 3, Left	1
P10-921-TLL4	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 4, Left	1
P10-921-TLL5	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 5, Right	1
P10-921-TLR0	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 5, Left	1
P10-921-TLR1	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 1 Narrow, Right	1
P10-921-TLR2	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 1, Right	1
P10-921-TLR3	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 2, Right	1
P10-921-TLR4	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 3, Right	1
P10-921-TLR5	APEX 3D-PS Total Ankle Replacement System, Trial Talus, Flat, Size 4, Right	1
P10-930-I106	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 6mm	1
P10-930-I107	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 7mm	1
P10-930-I108	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 8mm	1
P10-930-I109	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 9mm	1
P10-930-I110	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 10mm	1
P10-930-I111	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 11mm	1
P10-930-I112	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 1, 12mm	1
P10-930-I206	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 6mm	1
P10-930-I207	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 7mm	1
P10-930-I208	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 8mm	1
P10-930-I209	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 9mm	1
P10-930-I210	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 10mm	1
P10-930-I211	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 11mm	1
P10-930-I212	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 2, 12mm	1

P10-930-I306	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 6mm	1
P10-930-I307	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 7mm	1
P10-930-I308	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 8mm	1
P10-930-I309	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 9mm	1
P10-930-I310	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 10mm	1
P10-930-I311	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 11mm	1
P10-930-I312	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 3, 12mm	1
P10-930-I406	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 6mm	1
P10-930-I407	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 7mm	1
P10-930-I408	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 8mm	1
P10-930-I409	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 9mm	1
P10-930-I410	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 10mm	1
P10-930-I411	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 11mm	1
P10-930-I412	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 4, 12mm	1
P10-930-I506	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 6mm	1
P10-930-I507	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 7mm	1
P10-930-I508	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 8mm	1
P10-930-I509	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 9mm	1
P10-930-I510	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 10mm	1
P10-930-I511	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 11mm	1
P10-930-I512	APEX 3D-PS Total Ankle Replacement System, Poly Trial Insert, Size 5, 12mm	1
P10-944-0975	APEX 3D-PS Total Ankle Replacement System, Talar Chamfer Resection Router, Ø9mm	2
P10-944-1175	APEX 3D-PS Total Ankle Replacement System, Talar Chamfer Resection Router, Ø11mm	2
P10-944-1375	APEX 3D-PS Total Ankle Replacement System, Talar Chamfer Resection Router, Ø13mm	2
P10-944-4013	APEX 3D-PS Total Ankle Replacement System, Talar Peg Router	2
P10-944-LL00	APEX 3D-PS Total Ankle Replacement System, Talar Sizing Resection Guide, Chamfer, Size 1 Narrow	1
P10-944-LL01	APEX 3D-PS Total Ankle Replacement System, Talar Sizing Resection Guide, Chamfer, Size 1	1
P10-944-LL02	APEX 3D-PS Total Ankle Replacement System, Talar Sizing Resection Guide, Chamfer, Size 2	1
P10-944-LL03	APEX 3D-PS Total Ankle Replacement System, Talar Sizing Resection Guide, Chamfer, Size 3	1
P10-944-LL04	APEX 3D-PS Total Ankle Replacement System, Talar Sizing Resection Guide, Chamfer, Size 4	1
P10-944-LL05	APEX 3D-PS Total Ankle Replacement System, Talar Sizing Resection Guide, Chamfer, Size 5	1
P10-944-LL10	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, Single-Slotted, Size 1 Narrow	1
P10-944-LL11	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, Single-Slotted, Size 1	1
P10-944-LL12	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, Single-Slotted, Size 2	1
P10-944-LL13	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, Single-Slotted, Size 3	1
P10-944-LL14	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, Single-Slotted, Size 4	1
P10-944-LL15	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, Single-Slotted, Size 5	1
P10-944-LL20	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, 2-Holed, Size 1 Narrow	1
P10-944-LL21	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, 2-Holed, Size 1	1

P10-944-LL22	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, 2-Holed, Size 2	1
P10-944-LL23	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, 2-Holed, Size 3	1
P10-944-LL24	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, 2-Holed, Size 4	1
P10-944-LL25	APEX 3D-PS Total Ankle Replacement System, Anterior Chamfer Resection Insert, 2-Holed, Size 5	1
P10-944-TCC1	APEX 3D-PS Total Ankle Replacement System, Chamfer Checker, All-in-one, SS	1
P10-944-TCC2	APEX 3D-PS Total Ankle Replacement System, Chamfer Checker, AP Double-Ended, SS	1
P10-951-P001	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Tibia Paddle, Constrained	1
P10-951-P002	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Tibia Paddle, A-P Translation	1
P10-951-P011	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Talus Paddle, Size 1 Narrow & 1	1
P10-951-P012	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Talus Paddle, Size 2 & 3	1
P10-951-P013	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Talus Paddle, Size 4 & 5	1
P10-951-P021	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Tibia Implantation Paddle	1
P10-951-TBL1	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Dimple, Left	1
P10-951-TBL2	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Coin, Left	1
P10-951-TBR1	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Dimple, Right	1
P10-951-TBR2	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Coin, Right	1
P10-951-TBV1	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Viper Tip, Size 1, SS	1
P10-951-TBV2	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Viper Tip, Size 2, SS	1
P10-951-TBV3	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Viper Tip, Size 3, SS	1
P10-951-TBV4	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Viper Tip, Size 4, SS	1
P10-951-TBV5	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Viper Tip, Size 5, SS	1
P10-951-TBV6	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor, Viper Tip, Size 6, SS	1
P10-951-TPL1	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Left, Size 1	1
P10-951-TPL2	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Left, Size 2	1
P10-951-TPL3	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Left, Size 3	1
P10-951-TPL4	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Left, Size 4	1
P10-951-TPL5	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Left, Size 5	1
P10-951-TPL6	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Left, Size 6	1
P10-951-TPR1	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Right, Size 1	1
P10-951-TPR2	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Right, Size 2	1
P10-951-TPR3	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Right, Size 3	1
P10-951-TPR4	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Right, Size 4	1
P10-951-TPR5	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Right, Size 5	1
P10-951-TPR6	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Peg Punch, Right, Size 6	1
P10-953-IN01	APEX 3D-PS Total Ankle Replacement System, Poly Trial Handling Tool	1
P10-953-TL01	APEX 3D-PS Total Ankle Replacement System, Talus Trial Handling Tool	1

PART NUMBER	ALIGNMENT CASE INSTRUMENT DESCRIPTIONS	QTY PER SET
Case and Tray Components		
P10-900-0005	APEX 3D-PS Total Ankle Replacement System, Impaction, Tray	1
P10-900-0006	APEX 3D-PS Total Ankle Replacement System, Large Instrumentation, Tray	1
P10-900-CASB	APEX 3D-PS Total Ankle Replacement System, Case Base	1
P10-900-CASL	APEX 3D-PS Total Ankle Replacement System, Case Lid	1
P10-901-PP24	APEX 3D-PS Total Ankle Replacement System, Pin Puller	1
P10-944-STR0	APEX 3D-PS Total Ankle Replacement System, Square Tip Ronguer	1
P10-944-TCR1	APEX 3D-PS Total Ankle Replacement System, 2mm Dorsal, Recut Guide	1
P10-944-TCR2	APEX 3D-PS Total Ankle Replacement System, Posterior, Recut Guide	1
P10-951-4BAR	APEX 3D-PS Total Ankle Replacement System, 4-Bar Distractor	1
P10-951-IN02	APEX 3D-PS Total Ankle Replacement System, Poly Insertion Tool	1
P10-951-TB00	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Handle	1
P10-951-TP01	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Protector, Size 1	2
P10-951-TP02	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Protector, Size 2	2
P10-951-TP03	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Protector, Size 3	2
P10-951-TP04	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Protector, Size 4	2
P10-951-TP05	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Protector, Size 5	2
P10-951-TP06	APEX 3D-PS Total Ankle Replacement System, Tibia Impaction Protector, Size 6	2
P10-952-TL00	APEX 3D-PS Total Ankle Replacement System, Talus Impaction Handle	1
P10-952-TL00-04	APEX 3D-PS Total Ankle Replacement System, Talus Impaction Handle, Pad	2
P99-150-0016	Pin Cutter	1
P99-150-0105	Rasp, General	1
P99-150-1340	Osteotome, Solid, Handled, Curved, 6mm	1



July 10, 2020

Paragon 28, Inc.
% Hollace Rhodes
Vice President, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K192994

Trade/Device Name: Paragon 28 APEX 3D Total Ankle Replacement System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: June 19, 2020
Received: June 19, 2020

Dear Hollace Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G.
Allen -S

Digitally signed by Peter
G. Allen -S
Date: 2020.07.10 11:20:50
-04'00'

for
Ting Song, Ph.D., R.A.C.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure



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