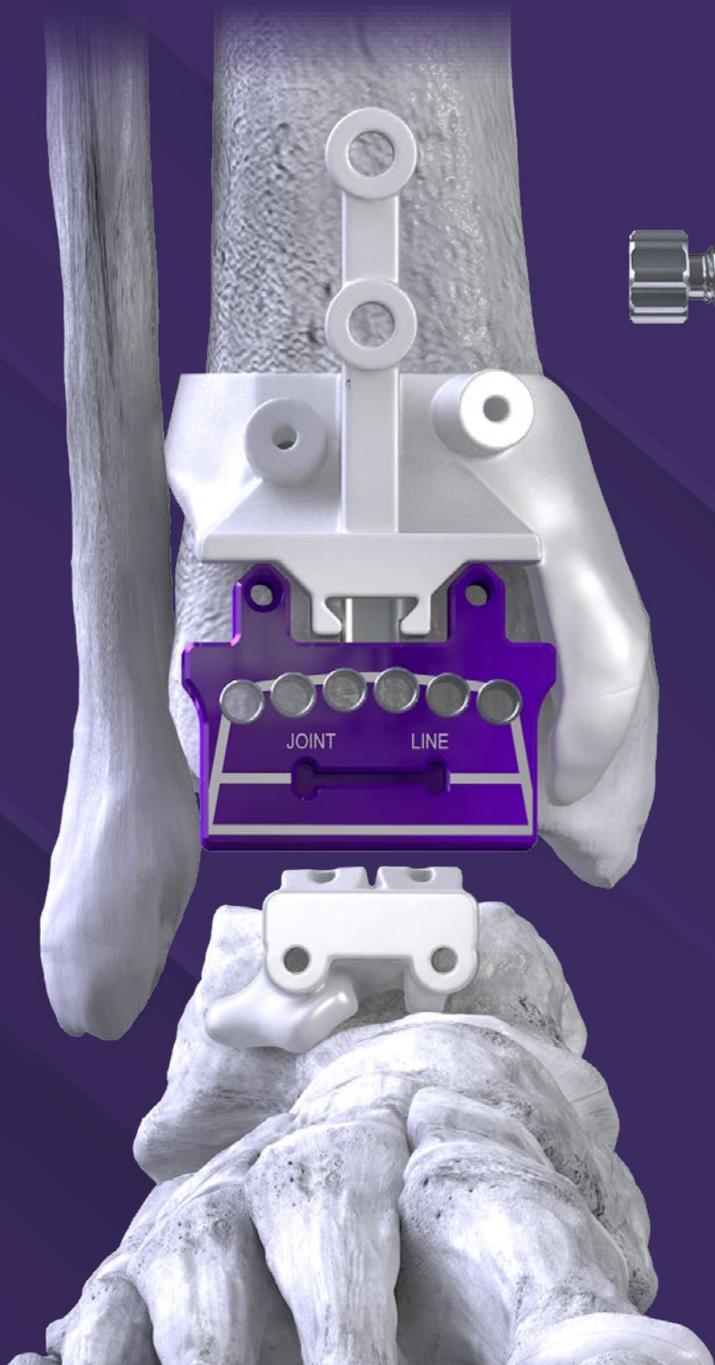




PATIENT SPECIFIC SURGERY

FEATURING NEW TO MARKET
AP Positioning Technology



Paragon²⁰

**PATIENT-SPECIFIC
INSTRUMENTATION**
& SURGICAL PLANNING
CASE REPORTS



Powered by MAVEN™

MAVEN™ Patient-Specific Guides and Surgical Planning Case Reports were developed to:

- Simplify and expedite alignment
- Accurately determine both implant size selection and placement critical for long-term survivorship¹



PATIENT-SPECIFIC TECHNOLOGY BASED ON CT RESEARCH.

Convenient Varus/Valgus Verification Points

Streamlined FasTrac™ Conversion Points for Refined Positioning & Micro Adjustments

Provides Secure & Stable Tactile Feedback During Initial Positioning

True Contour to Patient's Bone Geometry not Osteophytes

Provides Precise Component Alignment & Clearly Defined Bone Resection Planes

JOINT LINE

Equipped with a Medially Contoured Wrap to Reinforce Guide Stability

Identifies Anatomic Landmarks & Establishes Accurate Guide Positioning

ALIGNMENT. ORIENTATION. POSITIONING.

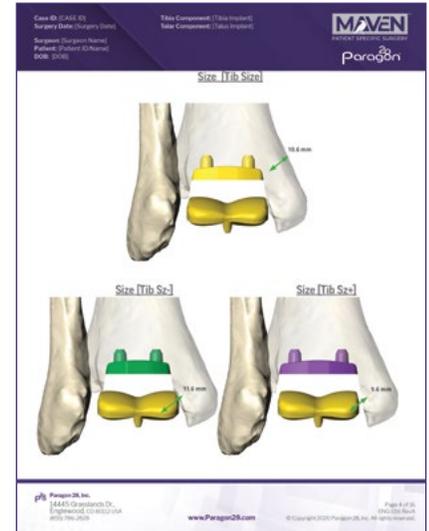
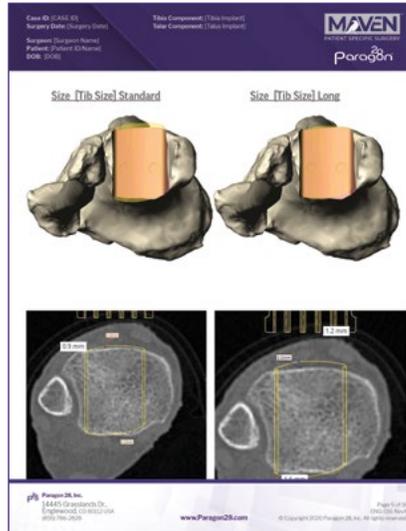
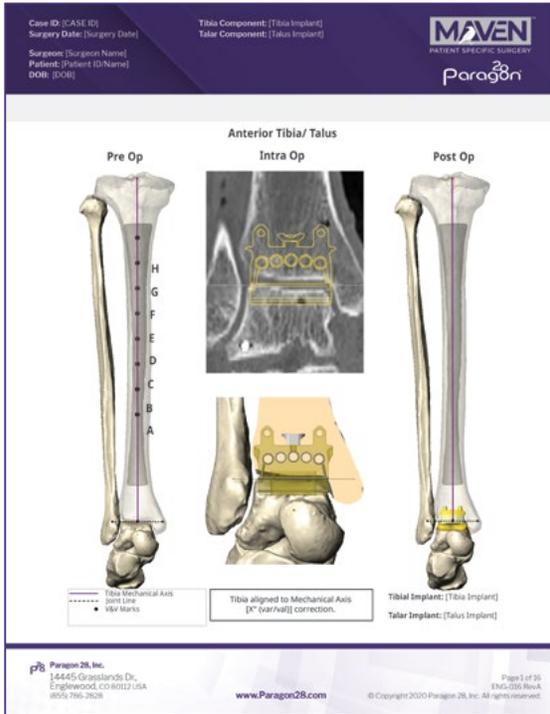
The MAVEN PSI System utilizes surgeon inputs and computer assisted processing technology to achieve accurate tibiotalar alignment and implant placement to reduce potential for eccentric loads, wear debris and osteolysis.^{2,3}

MINIMAL JOINT PREPARATION REQUIRED.

Preserves Periosteum Due to Minimal Guide / Bone Contact Surface

Preserves Anterior Talar Cartilage

SURGICAL PLANNING CASE REPORTS.



- Are generated based on surgeon inputs and segments of the patient's CT scanned anatomy
- Address all 6 degrees of rotational and translational orientation
- Allow for enhanced pre-operative visualization of anatomic structures, bone resection levels and help to identify anatomic abnormalities
- Depict APEX 3D™ System Tibia & Talus Implant sizes in simulated implantation

CT SCANNING PROTOCOLS.

- CT protocols are available in both weight-bearing and simulated weight-bearing scanning options
- Feature a comprehensive continuous knee scan, 5 cm proximal to the knee joint through the bottom of the foot for optimal visualization
- Incorporates 1.25 mm maximum slice spacing for optimal resolution

WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP
MAVEN™ PSI System - APEX 3D™ Total Ankle Replacement

PREPARATION:

- Where possible, the patient should be instructed to wear or bring shorts before they arrive for the scan, and not to wear any items from the knees down that might contain metal (ie, no ankle chains, toe rings, magnets, socks with copper fibers, etc.)
- The patient must be able to stand still for approximately 3 minutes while being scanned, seated scans for Paragon 28P MAVEN™ are not possible.
- The knee brace/booster will be required for this protocol.
- **Measure patient's foot with a ruler.**
 - If their foot is 11.25" or smaller, select the "P28 MAVEN TAR Protocol LEFT" or "P28 MAVEN TAR Protocol Right" procedure. Then select "Medium Field Standard" slice as the preferred procedure.
 - If their foot is larger than 11.25", select the "P28 MAVEN TAR Protocol LEFT" or "P28 MAVEN TAR Protocol Right" procedure. Then select "Large Field Standard". This is an exception and should only be used when necessary.

SCAN REQUIREMENTS:

- **Scan**
 - Range: See tables and figures below
 - Scan mode: Cone Beam CT
 - File format: Uncompressed DICOM
 - Pixel size: 0.8mm or smaller in axial view
 - Include full knee to ankle. Ensure complete foot is in view. MUST include MT bases, can cut distal toes, see figure insert)
- **Reformats: None**
- **Beam: DICOM GD**
 - Located through website: www.apexankle.com
- **Mail**
 - Attn: Paragon 28P MAVEN™ TAR PSI
 - 5381 South Alkire Circle
 - Littleton, CO 80127

CONTACT FOR ASSISTANCE:
Paragon 28P MAVEN™ TAR Support Team
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Curvebeam Technical Support
Phone: 267-483-8097 (USA)
E-mail: techsupport@curvebeam.com

SIMULATED WEIGHT-BEARING CT SCANNING PROTOCOL
MAVEN™ PSI System - APEX 3D™ Total Ankle Replacement

CT SCAN PARAMETERS - PARAGON 28 MAVEN TAR PROTOCOL

Exam	Scan Mode	Pitch	Slice Thickness (mm)	Slice Spacing (mm)	kV	mAs/Auto mAs Noise Index Over Range	DFOV (mm)	Recon Type
Lower Extremity	Initial	Var to 1	1.25	1.25	120	105	25 (extended 8.0 to 40.0 projected)	Bone 2000/800

Continuous Scan

- 5 cm proximal to knee joint through bottom of foot (MUST include metatarsals without off, can cut off posterior heel and distal toes; see gray shaded region in figure)

Figure 1. Schematic of scan boundary and slice spacing for continuous knee and ankle scan

FOR MORE INFORMATION VISIT:
APEXANKLE.COM

Paragon 28® APEX 3D™ Total Ankle Replacement System was designed to address end-stage ankle arthritis and current challenges within the total ankle market including: implant loosening, pathological wear, instability and persistent pain.

RESEARCH BASED. SOLUTION FOCUSED.

Low-profile 3D Printed Tibial Tray

designed for rotational stability and features a porous architecture with gradient zones down to solid substrate, available in Flat and ARC Tibia™ options

Anatomically Constrained Gentle Sulcus

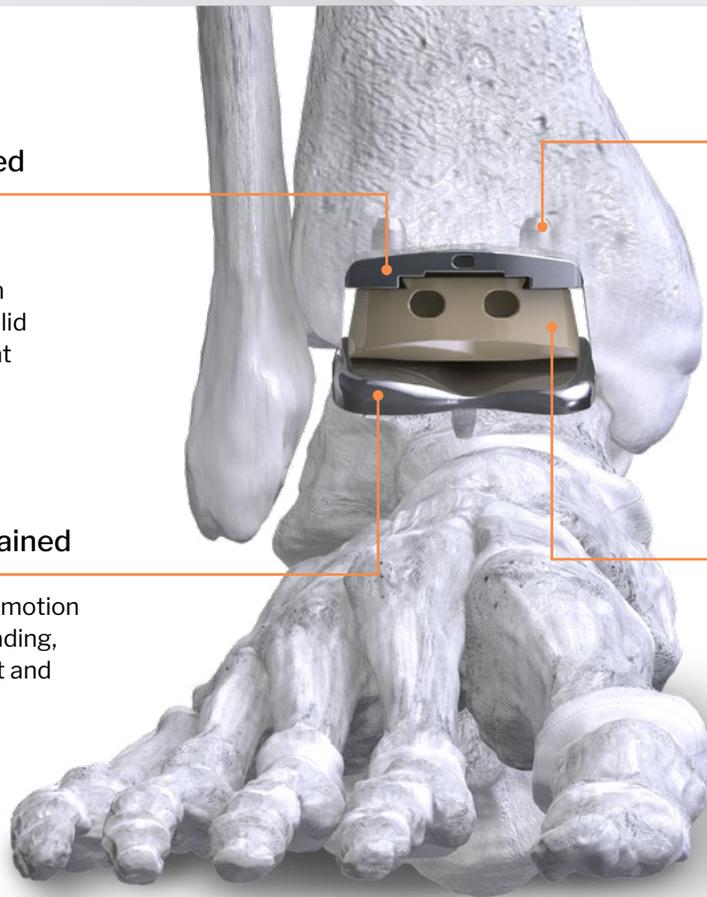
designed to mimic natural motion and reduce eccentric loading, available in Chamfer-cut and Flat-cut options

Non-Coated Vertical Pegs

positioned slightly posterior to mid-line where peak bone density is located⁴ for initial stability

Vitamin E Highly Cross-linked Poly

to reduce oxidation, wear debris, and potential for osteolysis^{2,3}



Powered by MAVEN™

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Exclusively foot & ankle **28**
Paragon®
www.Paragon28.com

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2. Kurtz, S.M., Bracco, P., Costa, L., Oral, E., Muratoglu, O.K. (2016) Vitamin E-Blended UHMWPE Biomaterials. UHMWPE Biomaterials Handbook, 293-325.
3. G. Rochcongar, MD, G. Buia, MD, E. Bourroux, J. Dunet, MD, V. Chapus, MD, and C. Hulet, MD, PhD. (2018) Creep and Wear in Vitamin E-Infused Highly Cross-Linked Polyethylene Cups for Total Hip Arthroplasty A Prospective Randomized Controlled Trial. Journal of Bone and Joint Surgery, Incorporated.
4. Hvid, I. et al. (1985) Trabecular Bone Strength Profiles at the Ankle Joint. Clinical Orthopaedics and Related Research, 306-312.

For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this device, please refer to the device specific instructions for use at <http://www.paragon28.com/ifus>