SIMULATED WEIGHT-BEARING CT SCANNING PROTOCOL

MAVEN® PSI System — APEX 3D™ Total Ankle Replacement

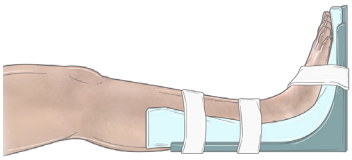
MAVEN PATIENT SPECIFIC SURGERY

PURPOSE:

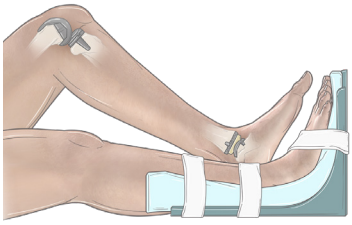
Conduct simulated weight-bearing CT scan for MAVEN® Patient-Specific Guide and Surgical Planning Case Report creation for the Paragon 28® APEX 3D™ Total Ankle Replacement System. Adhering to this CT scan protocol is critical.

PATIENT POSITION ON CT TABLE:

- **Patient: Supine position**
  - No cushions/wedges under legs or feet; may push metatarsal bases out of the field of view, causing scans to be rejected.



- **Affected leg: Foot in neutral position (mimic weight bearing position)**
  - Foot MUST be perpendicular to table with toes pointed up
  - Use any non-metallic holder/brace/object to ensure the foot is in a neutral position



- **Unaffected leg: Flat on table next to affected leg, UNLESS:**
  - If there is a knee (TKR) or ankle (TAR) implant in the unaffected leg, flex leg to get implant out of plane from affected leg and FOV. Positioned in neutral/90° to the leg. (Use of box or positioning box if necessary).

- **INSTRUCT: Patient CANNOT move during scan OR between scan(s).**

SCAN REQUIREMENTS:

- **Scout**
  - Above knee contiguous – down through extents of foot.
- **Scan**
  - Range: Include full knee to ankle. Ensure complete foot is in view (MUST include metatarsals without cut off; can cut off posterior heel and distal toes). See following page.
  - Scan mode: Helical
  - Gantry tilt: 0°
  - File format: Uncompressed DICOM
  - Pixel size: 0.8mm or smaller in axial view (25cm DFOV preferred, up to 40cm accepted)
- **Reformats: None**
- **Burn: DICOM CD**
  - Upload through website: www.apexankle.com
  - If unable to upload, include ordering physician & sender's contact information and send to:

Attn: MAVEN® PSI
14445 Grasslands Dr.
Englewood, CO 80112

Paragon 28®

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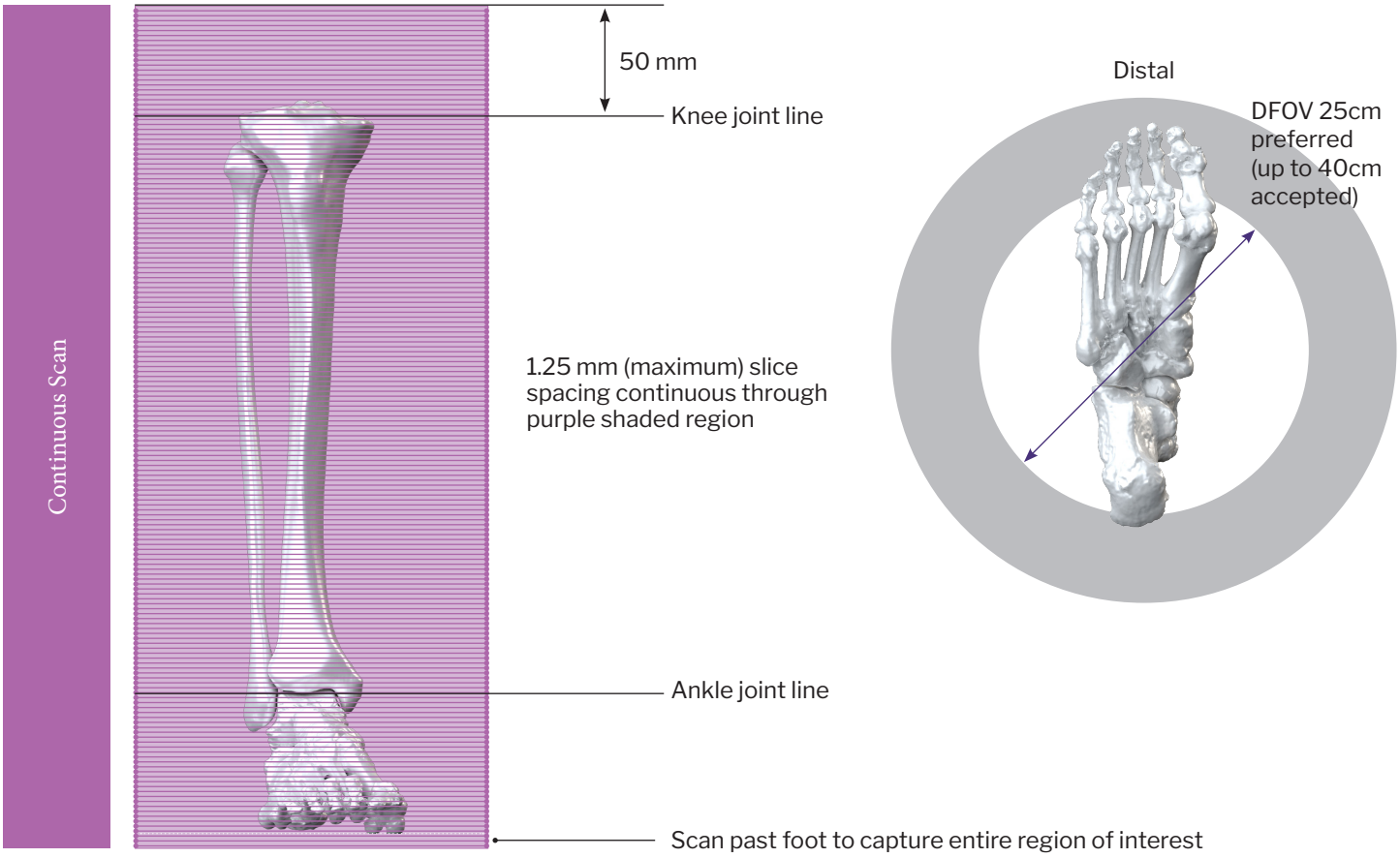
CT SCAN PARAMETERS — PARAGON 28 MAVEN® TAR PROTOCOL

Exam	Scan Mode	Pitch	Slice Thickness (mm)	Slice Spacing (mm)	kV	mA/Auto mA Noise Index Dose Range	DFOV (cm)	Recon Type
Lower Extremity	Helical	Up to 1	1.25	1.25	120	115	25 preferred (Up to 40 accepted)	Bone 2000/400

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



Schematic of scan boundary and slice spacing for continuous knee and ankle scan

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

PRODUCT INFORMATION & INSTRUCTIONS FOR USE

CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

INDICATIONS FOR USE

The MAVEN® Patient-Specific Instrumentation System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The MAVEN® Patient-Specific Instrumentation System is intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans. The MAVEN® Patient-Specific Instrumentation System is intended for single use only. The Paragon 28® Surgical Planning Case Reports are intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans.

CONTRAINDICATIONS

All applications of the MAVEN® Patient-Specific Instrumentation System that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

Patients with significant changes to anatomy occurring after the medical scan used for product definition was obtained. Surgery should occur no later than one year after the patient scans.

WARNINGS AND PRECAUTIONS

- To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides prior to use.
- To avoid serious injury, patient identification on guides and reports must be verified and confirmed against patient identification prior to use.
- Device(s) are single use only and designed for use with a specific patient only. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.
- Guides are designed for a specific patient. To avoid the potential for serious injury, guides should not be modified in any way.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or case reports. Inspect all components preoperatively to assure utility. Inspect holes to ensure no debris is present.
- MAVEN® PSI guides are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
- These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device.
- The surgeon is held liable for complications associated with incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.
- Do not to drop or contaminate the device during surgery.
- Improper placement, positioning, and fixation of the instruments may result in unusual stress conditions and a subsequent reduction in service life of the total ankle replacement components.
- **Do not use other manufacturer's instruments or implants in conjunction with the MAVEN® PSI System.**

MAVEN™

PATIENT SPECIFIC SURGERY

P10-CTS-0001 Rev. F
2023-06-15

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