WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

MAVEN™ Patient-Specific Guides and Surgical Planning Case Reports were designed to effectively expedite alignment and positioning of the APEX 3D™ Total Ankle Replacement System. The contoured guides are based on individual patient anatomic structures, are aligned to the mechanical axis and utilize a CT based coordinate system to aid in implant placement. Adhering to this CT scan protocol is critical.

All LineUP scans for the MAVEN™ PSI System are weight-bearing. The Paragon 28® MAVEN™ TAR protocol for LineUP requires imaging of the proximal tibia, ankle, and foot for satisfactory results. The positioning for this scan will differ from that of a typical knee/ankle scan. In every case, please follow these guidelines and instructions.

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 (i.e. no ankle chains, toe rings, magnets, socks with copper fiber, etc.).
- The patient must be able to stand still for approximately 3 minutes while being scanned; seated scans for Paragon 28® MAVEN™ are not possible.
- The Knee Positioner 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**. *This is the preferred procedure.*
  - If their foot is longer 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 inset)
- **Reformats: None**
- **Burn: DICOM CD**
- Upload through website: www.apexankle.com
- Mail:

Attn: Paragon 28® MAVEN™ TAR PSI
5381 South Alkire Circle
Littleton, CO 80127

CONTACT FOR ASSISTANCE:

Paragon 28® MAVEN™ TAR Support Team
E-mail: MAVENorders@paragon28.com

CurveBeam Technical Support
Phone: 267-483-8097 (USA)
E-mail: techsupport@curvebeam.com

WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

MAVEN™ PATIENT SPECIFIC SURGERY

Paragon 28®

ADD PATIENT AND PROCEDURE

For **Manual entries**, select Add Patient and type in the patient information as follows:

- The Referring and Requesting Physician fields both should contain the name of the surgeon who will be performing the surgery. This is required by Paragon 28®.
- The Procedure Code is then selected: "**P28 MAVEN TAR Protocol Left**" or "**P28 MAVEN TAR Protocol Right**"
- Once the patient has been added to the worklist, select the patient to scan.

For **RIS worklist entries**, select your patient from the list, verify that both the Referring and Requesting Physician fields contain the name of the surgeon who is performing the surgery. If "**P28 MAVEN TAR Protocol_(L or R)"** does not appear in the Procedure column to the right, then select "Add Procedure for Patient" (at bottom). In the Add Patient Window, select "**P28 MAVEN TAR Protocol_(L or R)**" from the list, then select "Add Patient to Worklist" button. Find the entry for the patient in the worklist that has "**P28 MAVEN TAR Protocol_(L or R)**" in the Procedure column and select it.

Add Patient Window

Protocol Code:

"**P28 MAVEN TAR Protocol Left**" or "**P28 MAVEN TAR Protocol Right**"

Protocol Description:

"**Large Field Standard**" or "**Medium Field Standard**"

On the Protocol Tab:

- If feet measure 11.25" or smaller, select "**Medium Field Standard**".
- If feet measure greater than 11.25", select "**Large Field Standard**".
- MAR should be enabled for scans which have metal present in the ankle, foot, or knee.

Continue to page 3 for Patient Positioning for feet 11.25" or smaller.
Continue to page 4 for Patient Positioning for feet larger than 11.25".

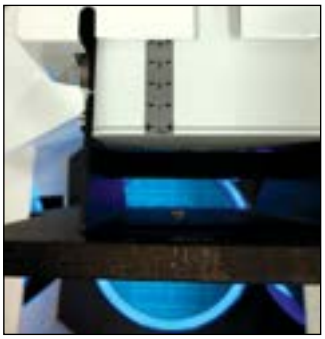
WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

MAVEN™ PATIENT SPECIFIC SURGERY

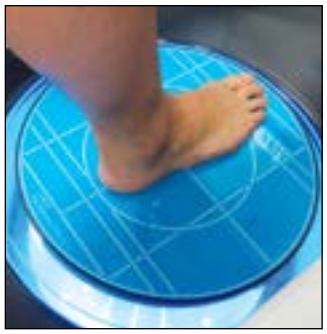
Paragon 28

PREFERRED PATIENT POSITIONING



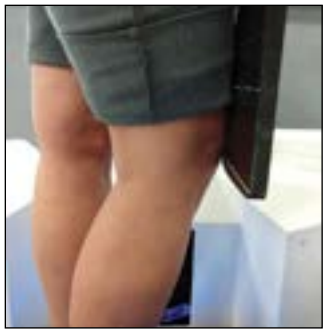
Once instructed in the LineUP Acquisition software to position the patient in the scanner, ensure that the **Knee Positioner** is in place and hanging down. **Set the knee plate position to 4cm.**

Instruct the patient to use the handle bars for support during the entire time they are in the scanner, and while entering or exiting the scanner.



To position the feet,

- Have the patient enter the scanner, placing their leg to be imaged in the center of the scan area first. The heel of the imaged leg should be just inside the center circle.
- Have the patient bring their other foot on to the platform. This foot should be offset from the imaged foot. Ensure that the entire foot is on the patient platform.
- The patient's knee to be imaged should remain within the cylinder that would go upwards from the center circle on the patient platform.



To position the knees,

- The patient should be FACING the Knee Positioner at all times.
- Using the **hand-held controller**, raise the knee positioner until the crease at the back of the knee is at the same height as the bottom edge of the Knee Positioner.
- Adjust the in/out position of the knee plate as needed, maintaining a minimum of 4cm, so that the knee plate has good contact with the patient's thighs and the knee is fully within the center cylinder on the foot platform.

TIP:
If there is a concern about locating the knee joint line while the patient is in the scanner, locate the crease in the skin at the back of the knee, and mark the side of the patients leg with a pen. Then use this line for reference while in the scanner.

Before pressing the **Exposure Button** on the **Operator Control Box**, provide instructions to the patient that the scanner will raise to the knee level, perform a scan around the knee, lower to the shin level, and perform a second scan, lower to the ankle, and perform a final scan. This may require 3-4 passes. **The patient MUST remain still and in the same position for the ENTIRE duration of all scans.** The Operator must continuously press the exposure button during the entire procedure, this allows for the movement of the gantry up, around the knees, down for each subsequent pass, and then back to the start position.

NOTE:
Knee position for the P28 MAVEN TAR protocol is slightly lower on the Knee Positioner compared to the standard knee scan.

Proceed to page 5 for DICOM Export instructions.

WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

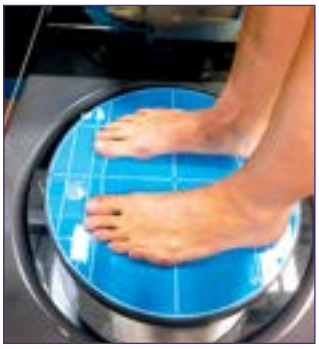
MAVEN™ PATIENT SPECIFIC SURGERY

Paragon 28

PATIENT POSITIONING FOR EXTRA LARGE FEET

Once instructed in the LineUP Acquisition software to position the patient in the scanner, ensure that the **Knee Positioner** is in place and hanging down.

Instruct the patient to use the handle bars for support during the entire time they are in the scanner, and while entering and exiting the scanner.



To position the feet,

- Have the patient enter the scanner, as you would for standard knee, foot, or ankle CT scan.
- They should be in a comfortable, natural stance with both feet completely on the blue platform.

To position the knees,

- The patient should be FACING the Knee Positioner at all times.
- Using the **hand-held controller**, raise the knee positioner until the crease at the back of the knee is at the same height as the bottom edge of the Knee Positioner.
- Adjust the in/out position of the Knee Positioner so that the positioner has good contact with the patient's thighs to eliminate movement during scanning.
- Both knees need to fully fit within the cylinder of the large circle on the foot platform – may need to flex knees slightly to accomplish this.

TIP:
If there is a concern about locating the knee joint line while the patient is in the scanner, locate the crease in the skin at the back of the knee, and mark the side of the patients leg with a pen. Then use this line for reference while in the scanner.

Before pressing the **Exposure Button** on the **Operator Control Box**, provide instructions to the patient that the scanner will raise to the knee level, perform a scan around the knee, lower to the shin level, and perform a second scan, lower to the ankle, and perform a final scan. This may require 3-4 passes. **The patient MUST remain still and in the same position for the ENTIRE duration of all scans.** The Operator must continuously press the exposure button during the entire procedure, this allows for the movement of the gantry up, around the knees, down for each subsequent pass, and then back to the start position.

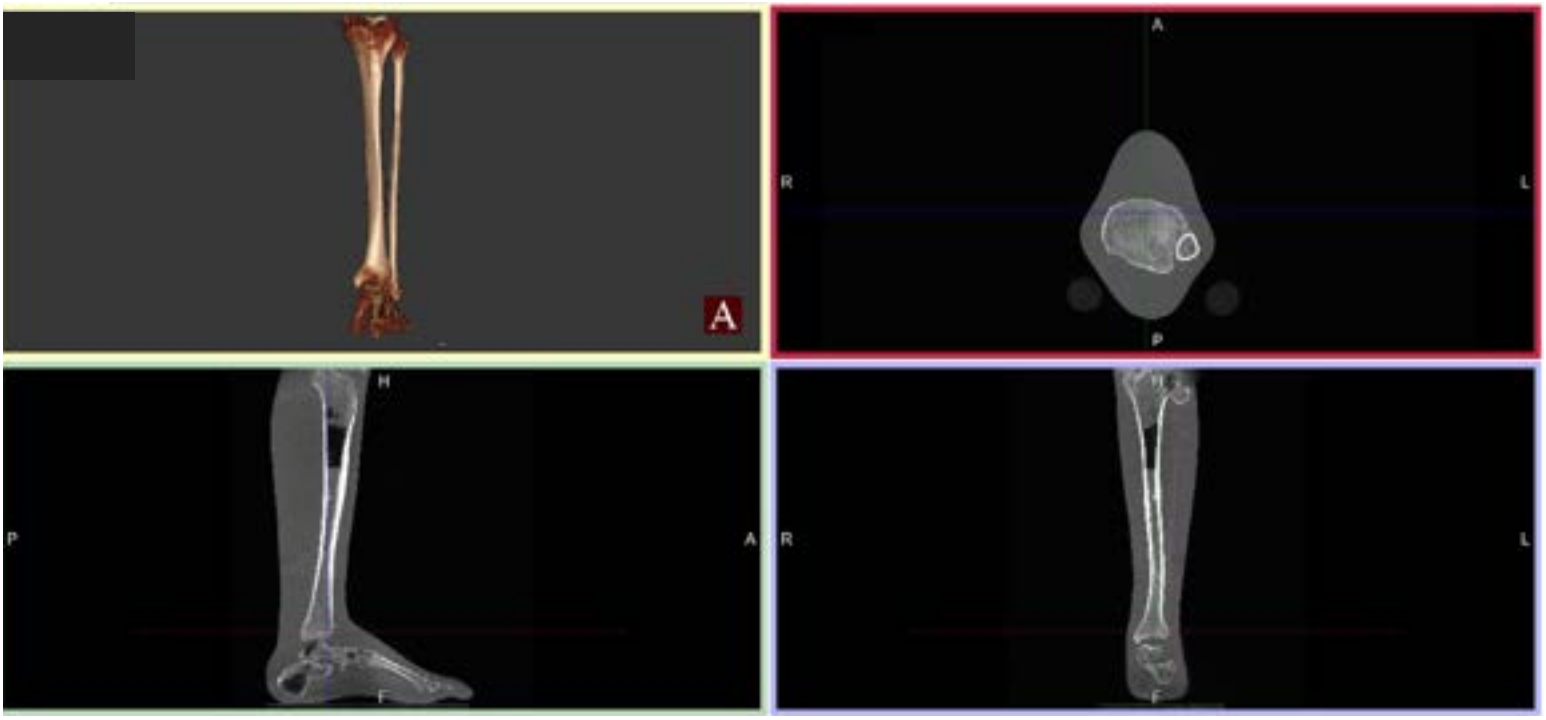
NOTE:
Knee positioning for the P28 MAVEN TAR protocol is slightly lower compared to the standard knee scan.

DICOM EXPORT

Reconstruction begins as soon as the LineUP returns to the home position after the scan. Because multiple large datasets are being created, reconstruction may take up to 10 minutes to be able to view the scan in CubeVue. Both the knee and foot scans are reconstructed separately, and then combined to form a **Super Volume (SV)**. In the CubeVue software, the Operator can assess the **Reconstructed (Recon)** images for movement, image quality, and anatomy covered.

After selecting the patient name, then find, select, and review the Recon images with the Series Description that starts with "SV-" (Super Volume). For Example: SV-CT_P28_LOWER_LEG_L-X-CBCT_TAR_120-ROI_LEFT where the Region of Interest (ROI) is the left ankle.

The SV dataset should include images that look like the picture below. Check for movement and overall image quality.



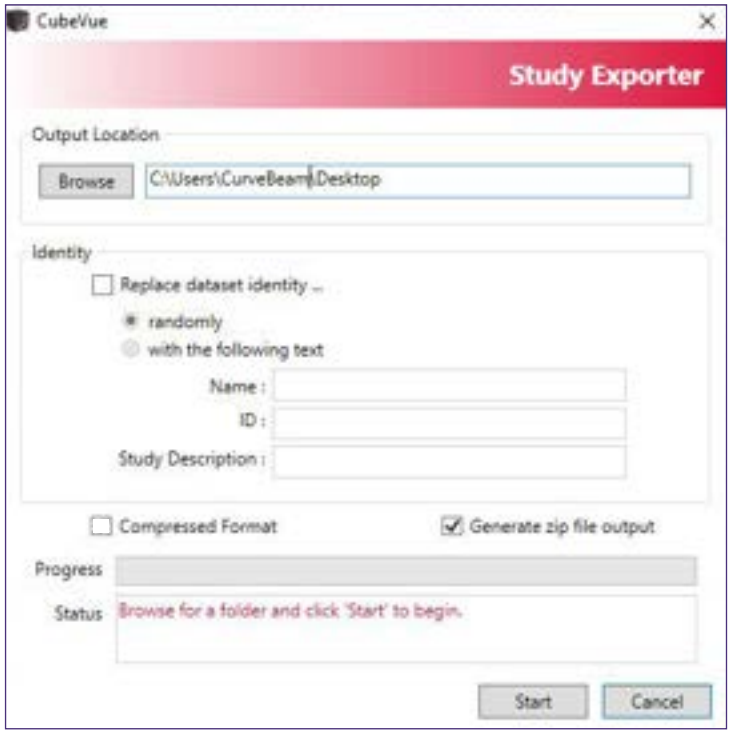
- Verify that you have the entire tibia and distal calcaneous within the scan.

(Continue to page 6)

DICOM EXPORT

Once the scan has been reviewed in CubeVue, the scan will need to be exported and uploaded. Follow these steps:

1. On the Patient List, locate SV-CT_P28_LOWER_LEG_L-X-CBCT_TAR_120-ROI_LEFT (for a left ankle). The Super Volume will have an "**SV**" as the start of the Series Description and be of the type "**Recon**".
2. Right click on the file and select DICOM Export, and the Study Exporter window will open.



Do NOT edit identity. This will eliminate patient information needed by Paragon 28®.

3. Deselect the box for "Compressed Format".
4. Check the box for "Generate zip file output".
5. Export to a temporary location to upload via the Internet, or burn to a disk for submission later.
6. Upload to the MAVEN™ TAR team through the secure, rapid electronic transfer system: www.apexankle.com

WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

WEIGHT-BEARING CT SCAN PARAMETERS – PARAGON 28 MAVEN TAR PROTOCOL

Exam	Scan Mode	Slice Thickness (mm)	kV	mA
Total	Cone Beam CT	0.8 MAX	120	5

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 white region in figure)

If **"P28 MAVEN TAR Protocol"** is not installed on your system, use a generic **CT Bilateral Lower Leg ("knee-shin-foot")** scan.

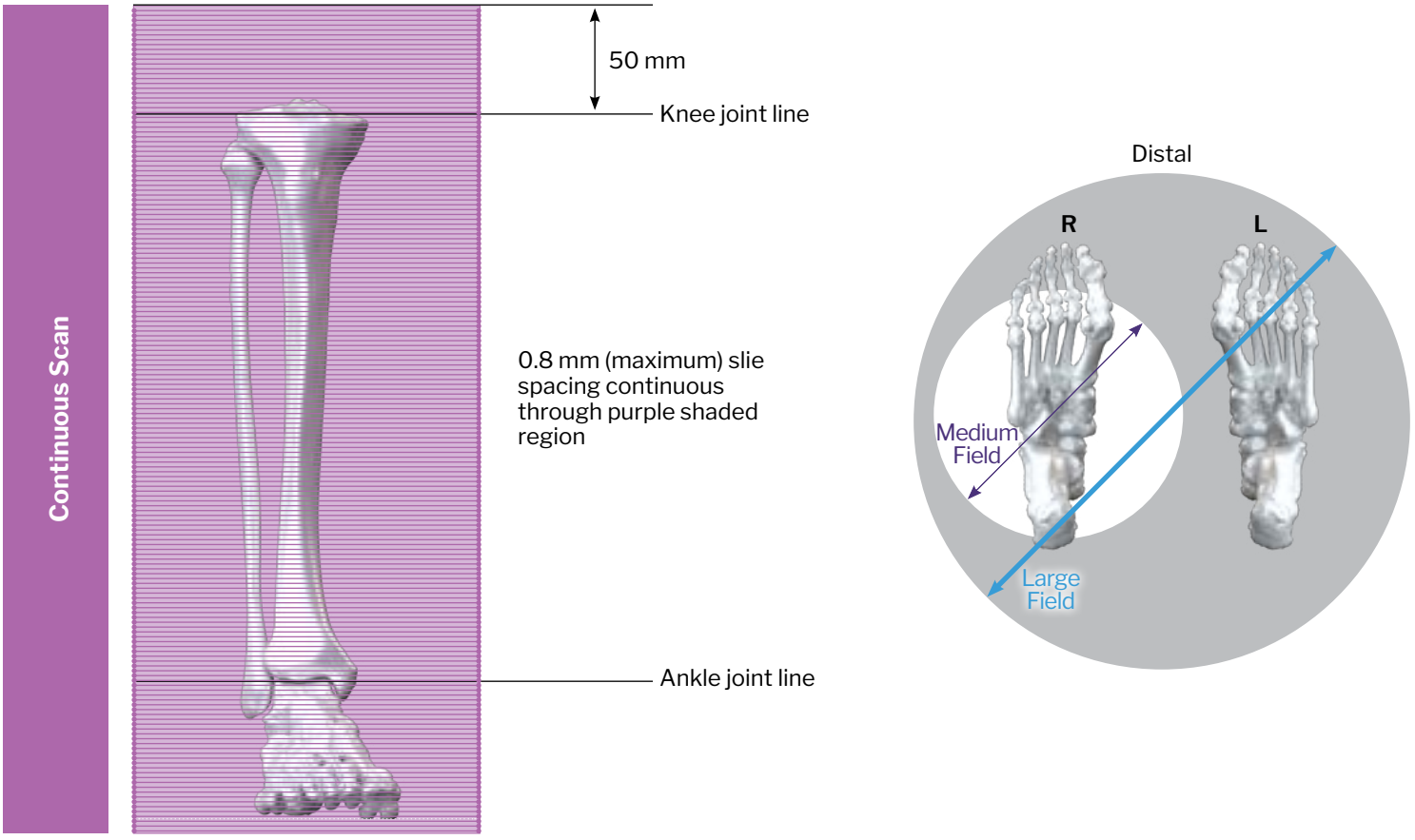


Figure 1. Schematic of scan boundary and slice thickness for continuous knee and ankle scan

WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

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.**

NOTES

NOTES

WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

MAVEN™ PATIENT SPECIFIC SURGERY

Paragon 28®

NOTES

MAVEN™

PATIENT SPECIFIC SURGERY

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P10-CTS-0002 RevB (Revised: 4/2021)

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112 USA
(855) 786-2828