

PROPHECY[®]

Preoperative Navigation Guides

ANKLE CT SCAN PROTOCOL





FIGURE 1 | Examples of neutral ankle positioning.

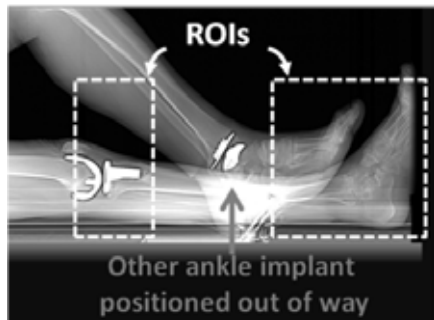


FIGURE 2 | Bending the other limb to position the other ankle implant away from the ankle of interest. This minimizes image artifact in the ankle Region Of Interest.

PROPHECY® Ankle CT Scan Protocol

PROPHECY® INBONE® and PROPHECY® INFINITY® Preoperative Navigation Guides are patient-specific instruments designed for total ankle replacement surgery. One significant requirement for a successful case is adhering to the CT scan protocol. Engineers at Wright Medical Technology have determined the necessary scanning parameters which are described in this document. In every case, please follow these general instructions:

Patient Position

- Patient in supine position.
- The foot of interest should be positioned in neutral (90°) to the leg. | **FIGURE 1**
- Note: If this is not possible due to a patient's condition, such as severe contracture, ensure the CT scan contains slices through the ball of the foot (see bottom of next page).
- If a contra-lateral implant is present, bend the contra-lateral limb out of the field of view of the ankle to be scanned. | **FIGURE 2**
- Do not allow patient movement between or during scans.

Scanning Instructions

Helical and Axial CT modes are acceptable.

Bone or Standard algorithms are acceptable.

- All scan groups' edges should stay aligned. See dashed lines, next page.
 - Maintain a single coordinate system for both the knee and foot scan.
 - Maintain a consistent field of view and pixel size for both the knee and foot scan.
 - Adjusting the width of both knee and foot groups together to span the required anatomy of both groups is appropriate.
- In-plane pixel size (resolution) must be less than 0.8mm.
 - Example: For a 512x512 matrix the field-of-view must be less than 40 cm.
- Include full knee-to-foot scout images (coronal and sagittal) when submitting CT files to Wright.

Other:

- Do not scan at higher slice spacing and reconstruct to smaller increments.
- Only the raw axial images are needed; coronal and sagittal reconstructions are not necessary.
- Images must be provided in uncompressed DICOM format.

Note: It is highly recommended that additional x-ray studies be submitted to Wright for analysis for PROPHECY® pre-op navigation. Useful additional studies include:

- Weight-bearing lateral x-ray
- Stress x-rays/Talar tilt x-rays of the medial deltoid and/or lateral ligaments.

PROPHECY® Ankle CT Scan Protocol

This "ankle" protocol involves a section at the knee.

REQUIRED:

- Provide full Knee-to-Foot CT "scout" images (coronal & sagittal).
- Scan both the Foot-&Ankle AND Knee sections at the same time.

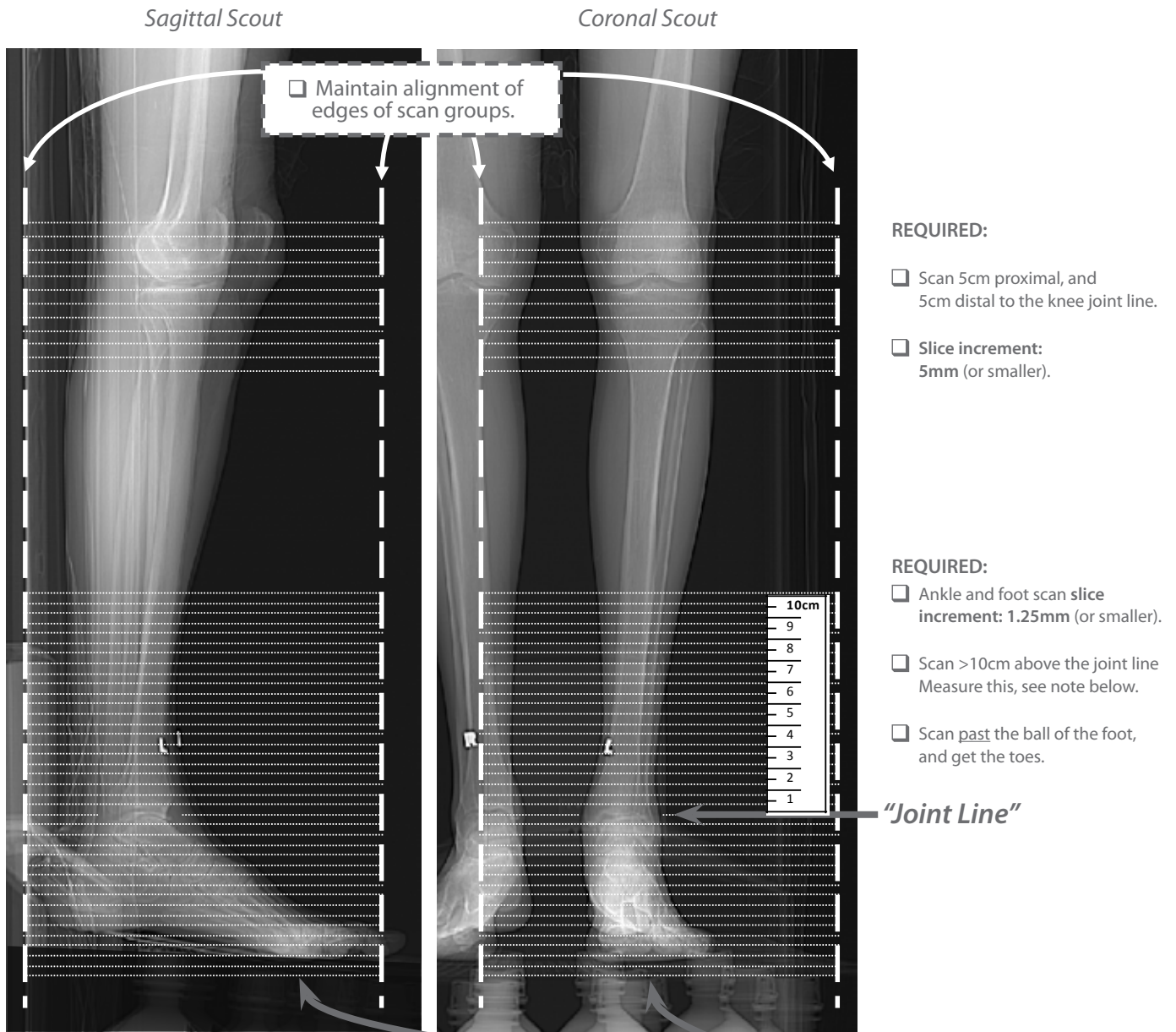


FIGURE 3 |

Note:


- Measure (or calculate) to get >10cm above the joint line.
Examples: 80 slices @ 1.25mm or 100 slices @ 1.0mm or 160 slices @ 0.625mm above the joint line.

Note:

- It's better to "airball" the last slices than to not get enough.

Common Scan Protocol Errors

The most common protocol errors resulting in failed scans are shown below:

 Region missing from scan.

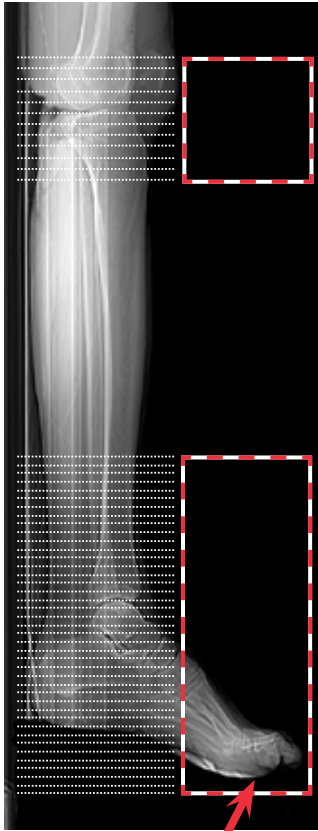


FIGURE 4 |
 Failure to scan the entire foot.

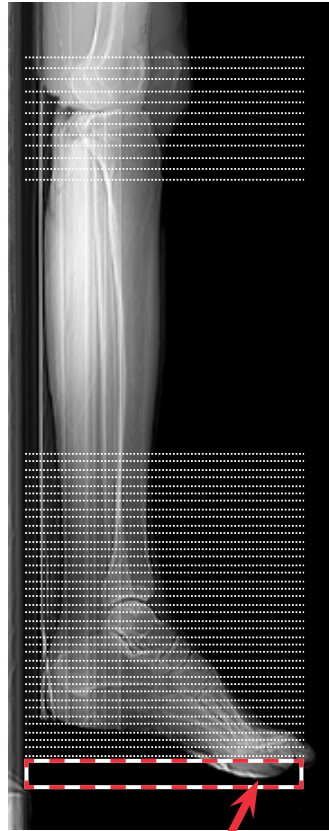


FIGURE 5 |
 Failure to scan the entire foot.

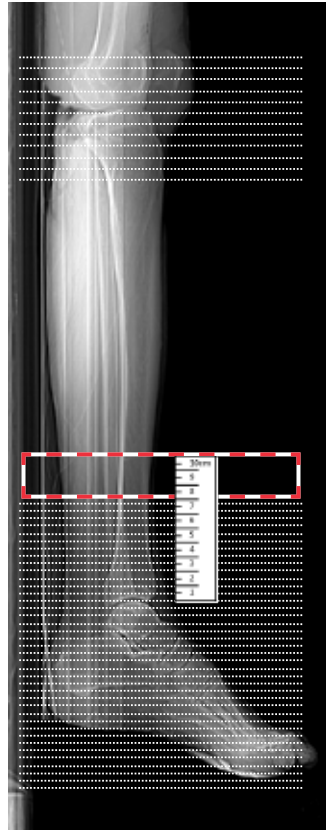


FIGURE 6 |
 Failure to scan at least 10cm above the ankle joint.

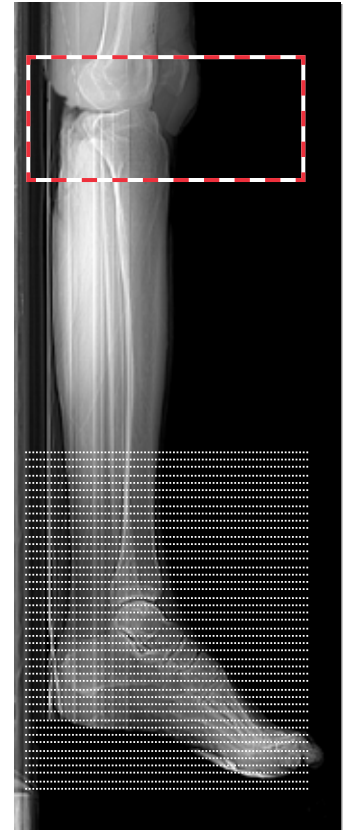
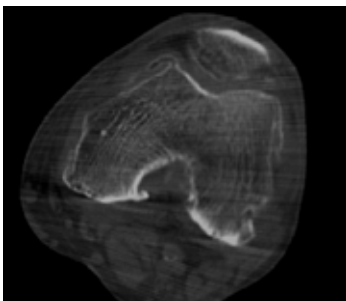
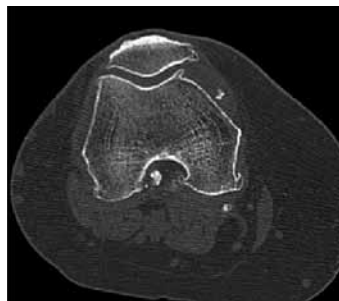


FIGURE 7 |
 Scan of the knee was not performed simultaneously with the ankle.

CT Imaging Examples



Unacceptable CT imaging
 Blurry, poor contrast.



Satisfactory CT Imaging
 Clear, sharp, distinct boundaries between bone & soft tissue.

Frequently Asked Questions

Q. "I can't put in a 1.25mm slice. I can only do a 1mm increment. Is that ok?"

A. *Slices thinner than our specified slice thickness are acceptable; however, using larger slices will result in the scan being rejected for PROPHECY® processing.*

Q. "Do we use axial or helical reconstruction?"

A. *Either is acceptable.*

Q. "Is it really necessary to scan 10cm above the ankle joint?"

A. *Yes. At least 10cm of the tibia shaft, measured from the ankle joint line, is required.*

Q. "Do I need to scan the knee for an ankle surgery?"

A. *Yes. The knee scan is required to obtain the complete axis of the lower extremity. Information based on the entire tibia is used to plan the ankle procedure.*

Submitting the Scan

Rapid Electronic Scan Transfer

Preoperative CT may be sent to the PROPHECY® engineering team through our secure, rapid electronic transfer system.

<https://prophecyscans.wmt.com>

Please follow these steps to request an account and transfer scans:

1. E-mail prophecyscans@wmt.com with the e-mail address of the person who needs access to the system (No other information is needed)
2. Within a few hours, an invitation message will be sent to that address with instructions to complete registration on the scan transfer site.

*** upload times may vary based on connection speed.*

This is typically done by first putting the DICOM files from the CT Scanner computer onto a CD, then putting the CD into a typical office computer for uploading. Therefore, ensure the CD contains the Axial CT slices and full-length scout images.

FAQ: Can I mail the CD of the CT scan?

A. *This method is not preferred.*

If uploading the scans directly from the scanning facility is not possible, please contact the local Wright Medical sales rep to do so. If the sales rep contact information is not known, call the number below.

Contact for Assistance

PROPHECY® Operations at Wright Medical Technology

Phone: 901.290.5884 Fax: 901.867.4791

email: prophecy@wmt.com

The Centers for Medicare & Medicaid Services (CMS) established a National Coverage Determination (NCD) for CT Scans. It states, in part, the following, "Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient." CTs performed prior to total joint replacement procedures for diagnostic purposes may be considered medically necessary. In which case, the procedure should be billed using the CPT codes that accurately describe the imaging procedure furnished to the patient. These same images from the diagnostic CT scan may, in turn, be further utilized for developing the personalized cutting or navigation guides that are used in orthopaedic procedures. However, if providers perform CT scans solely for the purpose of developing personalized cutting instruments or guides, providers should contact the payer for billing and coverage guidance and/or the American College of Radiology with billing questions.



Wright Medical Technology, Inc.

1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971
www.wmt.com

Wright Medical EMEA

Atlas Arena, Australia Building
Hoogoorddreef 7
1101 BA Amsterdam
the Netherlands
011 31 20 565 9060