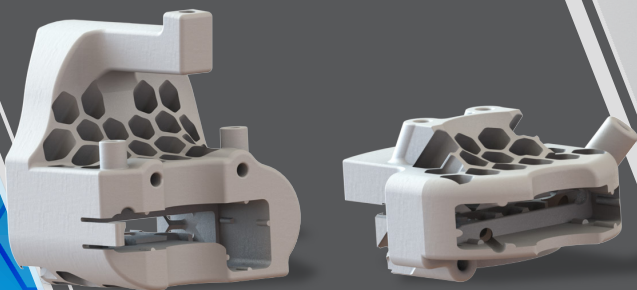


Quantum[®]

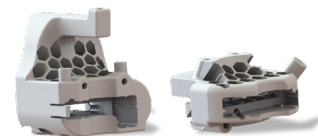
Total Ankle System
with OrthoPlanify[™] PSI



CT SCAN & X-RAY PROTOCOL

OrthoPlanify™ Patient Specific Instrumentation

Detailed Imaging Protocol



To enable use of the OrthoPlanify™ Patient Specific Instrumentation for the Quantum® Total Ankle System, a required set of DICOM images are necessary for reconstruction and case planning.

It is critical to directly follow the protocol for the collection of the necessary CT Scan and Weight-Bearing X-rays to prevent image rejection and potential delays in case planning.

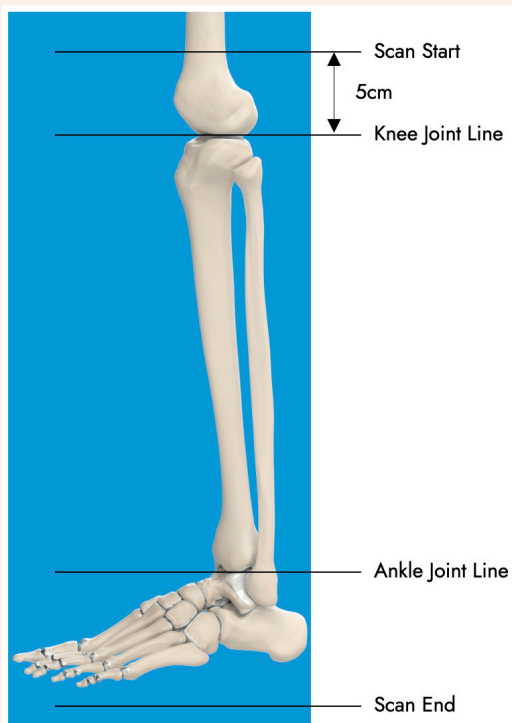
CT Scan

Patient Positioning:

- » Supine with operative leg extended and the patella oriented toward the zenith.
- » Position the operative foot as close to 90° relative to the tibia as possible, taking into consideration any deformity that would preclude this orientation.
- » **Note:** A radiolucent boot or bracket is recommended to maintain a consistent position during the scan acquisition. Movement may generate offsets within the scan that could prevent use for reconstruction.
- » **Note:** In the presence of hardware in the contralateral ankle, flex the contralateral knee to enable positioning of the contralateral foot midway up the scanned extremity to avoid the introduction of artifacts into the scan.

Scan Parameters:

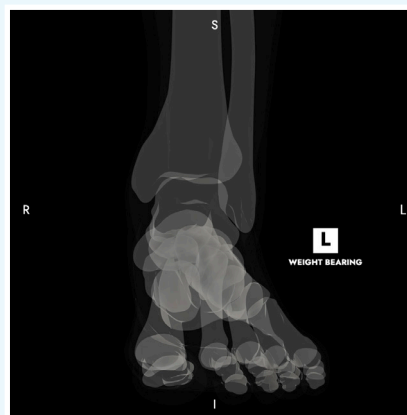
- » Scan Type: Axial, with Slices Perpendicular to the Table Axis
- » Acquisition Method: Continuous
- » Region: 5cm Proximal to Knee Joint Through the Full Foot, with Toes Included
- » Slice Thickness: 1.0mm Maximum
- » Table Feed: ≤ Slice Thickness
- » Resolution: Minimum of 512x512 Pixels
- » Image Processing: None. Raw Images without Filters
- » Image Format: DICOM



Weight-Bearing X-Rays

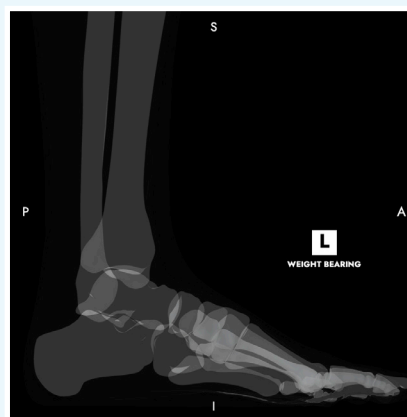
AP View:

- » Patient standing on bipedal support
- » Direct AP or Mortise View
- » Optional: Radiopaque tape may be placed around the hindfoot and ankle to locate the plantar support



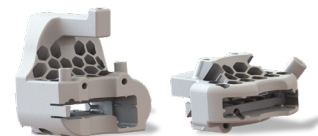
Profile View (Lateral):

- » Patient standing on bipedal support
- » Plate placed on the medial side of the ankle to block contralateral ankle during image acquisition
- » Horizontal incident ray centered on the navicular



OrthoPlanify™ Patient Specific Instrumentation

Image Acquisition Standards and Submission



Important: The CT Scan and Weight-Bearing X-Rays should be saved in **uncompressed DICOM format** prior to upload or shipment for upload.

Acquisition Standards

Scan Type

Axial

Acquisition Method

Continuous

Scan Region

5cm Proximal to Knee Through Full Foot

Slice Thickness

1.0mm Maximum

Table Feed

≤ Slice Thickness

Minimum Resolution

512x512 Pixels

Post-Processing

Raw Images without Filters

Exported Image Format

DICOM Required

Image Submission

All images provided for use in reconstruction and pre-planning associated with the Quantum® Total Ankle System in conjunction with the OrthoPlanify™ Patient Specific Instrumentation are required to be in DICOM format. Alternative formats will not be accepted and will result in image rejection.

To upload case files directly into the OrthoPlanify™ platform:

- 1 Export all files in DICOM format into a single .zip folder, named in the following format:
Quantum_[Patient First & Last Name]_DOB_[Operative Side]_[Surgeon Name]
- 2 Log into the software portal at:
<https://in2bones.digitalsolutions.app>
- 3 Once logged into the system, generate a new case and add the .zip folder prior to upload.

Alternatively, the weight-bearing X-rays and associated CT scan may be exported in DICOM format and saved to a disk for submission. Label the disk with the patient's full name or identification number, date of birth, surgeon's full name, operating facility, and operative side, and mail it to the following address for image review and case generation:

In2Bones - Quantum
6000 Poplar Avenue, Suite 115
Memphis, TN 38119

Quantum[®]

Total Ankle System with OrthoPlanify[™] PSI

Quantum[®] PSI Guides

In2Bones Quantum[®] Patient Specific Instrumentation (PSI) Guides for Total Ankle Replacement (TAR) is indicated as an orthopaedic instrument system to assist in the instrumentation positioning dedicated to In2Bones Quantum[®] Total Ankle Replacement implantation. In2Bones Quantum[®] PSI guides are compatible with Quantum[®] tibial tray, Quantum[®] tibial inlay, as well as standard and Flat-Cut Quantum[®] talar implants. Quantum[®] PSI Guides are intended for single use only. PSI Guides are manufactured in correlation with a pre-operative planning validated by the surgeon on the TAR Planning Software and assist in the positioning of the dedicated Quantum[®] instrumentation with which drillings or bone cuts will be performed. In2Bones Quantum[®] PSI guides are indicated for patient population fulfilling the Quantum[®] Total Ankle Replacement indications and for which X-rays, and CT scan images are available and compliant with imaging protocol provided by In2Bones.

OrthoPlanify[™] Planning Software:

The TAR Planning Software is a preoperative surgical planning software intended to be used with In2Bones Quantum[®] Patient Specific Instrumentation (PSI) Guides and Quantum[®] Total Ankle Replacement. TAR Planning Software allows the surgeon to use advanced display and positioning tools to guide the marking of bone before cutting and preview the total ankle replacement components intraoperatively, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient X-rays and imaging scans. X-rays and CT scan are the accepted imaging modalities for these procedures.

Scope of Protocol:

This protocol describes the various parameters and conditions that must be followed to produce adequate CT-scan images for segmentation into patient-specific 3D bone models. These models are used in the design and manufacturing of Patient-Specific Instrumentation (PSI). The quality and accuracy of the PSI is dependent on the quality of the patient data received. The front and sagittal weight-bearing X-rays enable alignment of the patient-specific 3D bone models in the weight-bearing position for planning.

REGULATORY INFORMATION

In2Bones, as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. The Surgical Technique is furnished for information purposes, as an aid to properly use the device and its dedicated instruments. Instruments composing the Quantum[®] PSI Guides for Total Ankle Replacement are described in the associated implants' Surgical Technique.

RECOMMENDATION

It is recommended to carefully read the Instructions for Use available in the package insert.

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

Scope of Application:

The Scan Protocol is valid for all images of the patient's operative ankle.

Contraindications

The Quantum[®] Total Ankle Prosthesis is contraindicated for the following conditions:

- » Sepsis, active / prior deep infection in ankle joint or adjacent bones, fever and/or local inflammation
- » Avascular necrosis of the talus / tibia
- » Osteoporosis / osteopenia
- » Poor skin coverage / soft-tissue quality around the ankle joint that would make the procedure unjustifiable
- » Inadequate or insufficient quality of bone stock, Important joint laxity or tendon dysfunction
- » Neuromuscular or mental disorders which might jeopardize fixation and post-operative care
- » Neurobiological diseases
- » Non-functional lower limb muscle / weakness
- » Skeletal immaturity
- » Known allergy to one of the materials
- » Pregnancy / breast-feeding woman

The Quantum[®] PSI Guides should not be used if any of the following occur:

- » The patient has an active infection
- » Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained
- » The patient presents one of the contraindications for the Quantum[®] Total Ankle Replacement implantation (refer to the Quantum[®] TAR sterile implant instructions for use)

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