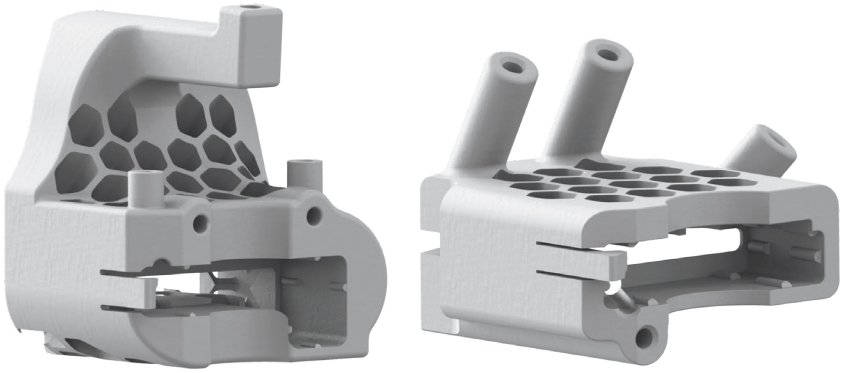
QUANTUM®

Total Ankle System

OrthoPlanify™

Patient Specific Instrumentation



In2Bones

A GLOBAL EXTREMITY COMPANY

ORTHOPLANIFY

The TAR Planning Software is a preoperative surgical planning software intended to be used with In2Bones QUANTUM Patient Specific Instrumentation (PSI) Guides for QUANTUM Total Ankle Replacement procedures. 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. Patient X-rays and scan images should be performed according to the In2Bones imaging ankle CT-scan and weight-bearing X-rays protocol supplied to the user.

QUANTUM

The QUANTUM Total Ankle prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.
***Note**: In the United States, the ankle prosthesis is intended for cemented use only.*

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 Inserts, as well as Standard and Flat-Cut QUANTUM Talar Implants. PSI Guides are intended for single use only. PSI Guides are manufactured in correlation with a preoperative planning validated by the surgeon on the TAR Planning Software and assist in the positioning of the dedicated QUANTUM instrumentation with which drilling or bone cuts will be performed. In2Bones QUANTUM PSI Guides are indicated for the patient population fulfilling the QUANTUM Total Ankle Replacement indications and for which X-rays and scan images are available and compliant with imaging protocol provided by In2Bones.

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.

SCOPE OF APPLICATION

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

CT SCAN PROTOCOL

1. General Guidelines and Instructions

Take care **to**:

- Save each scan separately in the DICOM format, with the file name structured as:
  - IN2BONES QUANTUM_PATIENT NAME_DOB
- Record tag (0008,0022) with the date and time of the exam in the file
- Segment the scan to move from proximal to distal along the patient's operative leg
- Use a constant pixel size in the scans, with a minimum overall slice resolution of 512 x 512 pixels
- Submit raw unprocessed images for 3D reconstruction
  - No filters are required

Take care **not to**:

- Reset the coordinate system between sequences
- Change the X and Y position between different slices
- Change the image parameters during the scans
- Change the table position during each scan

2. Patient Positioning Guidelines

- Secure the patient's leg in a boot and position the operative foot 90° to the leg, perpendicular to the table, and with the patella facing the zenith.
  ***Note**: If the patient has a severe contracture, or other condition that prevents orientation in this manner, take care to ensure that the completed CT scans contain sections of the foot to enable the full reconstruction of the anatomy based on the weight-bearing x-rays.*
- Take care to prevent movement of the patient between or during the necessary scans.
  ***Note**: If a contralateral implant is present, it is necessary to flex the contralateral knee and locate the corresponding foot midway up the scanned tibia.*

3. Scan Regions

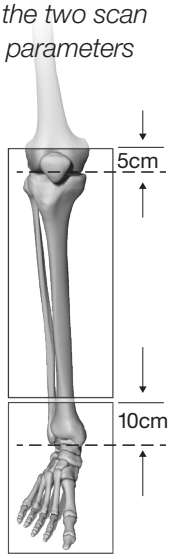
***Note**: Different parameters are required in the two scan regions. Take care to follow the prescribed parameters based on the area being scanned.*

Tibia

- Anatomic Landmarks: Patella at the zenith, tibial tuberosity, tibial diaphysis
- Slice Thickness: 2.5mm maximum
- Scan Boundaries: 5cm above the knee joint line, 10cm above the ankle joint line

Ankle

- Anatomic Landmarks: Foot 90° to leg
- Slice Thickness: 0.6mm to 1.0mm
- Table Feed: Less than or equal to slice thickness
- Scan Boundaries: 10cm above the joint line, full foot



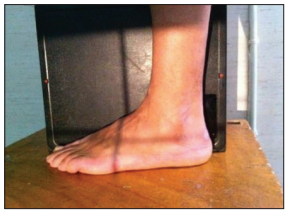
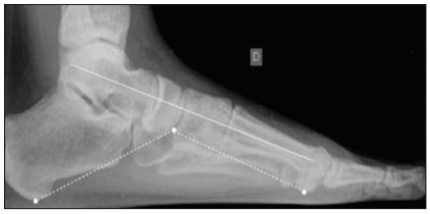
WEIGHT-BEARING X-RAY PROTOCOL

***Note**: A graduated ruler should be used when capturing both weight-bearing X-rays.*

- Save each image separately in the DICOM format, with the file name structured as:
  - IN2BONES QUANTUM_PATIENT NAME_DOB

1. Profile View X-Ray

Place the patient in a standing bipedal support plate, with the plate placed on the medial side of the operative ankle, and the horizontal incident ray centered on the navicular.

2. AP View X-Ray

Place the patient's feet in slight medial rotation with radio-opaque tape around the hindfoot and ankle (metallic wire vertical to both malleoli) to locate the plantar support.

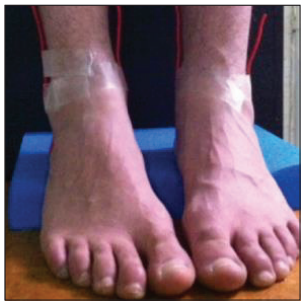
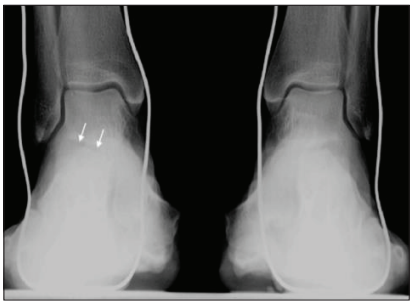



IMAGE SUBMISSION

The DICOM CT scans and weight-bearing X-rays should be compressed into a single ZIP folder and uploaded by the prescribing surgeon to the OrthoPlanify™ online platform at:

https://in2bones.digitalsolutions.app/

As an alternate submission route, the DICOM CT scans and weight-bearing X-rays may be saved to a CD-ROM. The disc should be labeled with the patient's last name, first name, and DOB and mailed to the following address:

In2Bones QUANTUM
28 Chemin du Petit Bois
69130 Écully, France

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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.

DEVICES

- EC Classification (EC Directive MDD 93/42/EC):
- Implant: CE Class IIb-CE2797
- Instruments Connected to a Power Driver: Class IIa – CE2797
- PSI Guides: Class IIa – CE2797
- Trial Implants: Class IIa – CE2797
- Other Instruments: Class I – CE

REIMBURSEMENT

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

MANUFACTURER

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