CT SCAN & X-RAY PROTOCOL

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 this 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 comprising 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

In2Bones SAS
28, chemin du Petit Bois
69130 Ecully, FRANCE
Tel: +33 (0)4 72 29 26 26
Fax: +33 (0)4 72 29 28 29

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.
In2Bones QUANTUM PSI Guides are indicated as an orthopaedic instrument system to assist in the instrumentation of Patient Specific Instrumentation (PSI) inserts for Total Ankle Replacement (TAR) 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.

**WEIGHT-BEARING X-RAY PROTOCOL**

- **Note**: A graduated ruler should be used when capturing both weight-bearing X-rays.
- **Note**: Each image should be saved separately in the DICOM format.

**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 NAMEDOB
     - 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 stabilize the anatomy based on the weight-bearing x-rays.

3. **Scan Regions**
   - **Note**: Different parameters are required in the two scan regions. Take care to follow the prescribed parameters based on the areas 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, 1mm foot
**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 post-traumatic, or degenerative arthritis patients with ankle joints damaged by severe rheumatoid, total ankle replacement in primary or revision surgery for QUANTUM supplied to the user.

**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 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**

   - Anatomic Landmarks: Patella at the zenith, tibial tuberosity, tibial diaphysis
   - Slice Thickness: 2.5mm maximum
   - Scan Boundaries: 10cm above the joint line, 10cm above the ankle joint line
   - Note: Different parameters are required in the two scan regions. Take care to follow the prescribed parameters based on the area being scanned.

**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 Ecully, France

**Weight-Bearing X-Ray Protocol**

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

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

SESSION 1: CT Scan

1. CT Scan Planning
   - Imaging Protocol
   - Imaging Parameters
   - Image Quality

2. CT Scan Execution
   - Patient Positioning
   - Scan Parameters
   - Image Acquisition

3. CT Scan Post-processing
   - Image Analysis
   - Image Reconstruction
   - Image Interpretation

SESSION 2: X-Ray

1. X-Ray Planning
   - Imaging Protocol
   - Imaging Parameters
   - Image Quality

2. X-Ray Execution
   - Patient Positioning
   - Scan Parameters
   - Image Acquisition

3. X-Ray Post-processing
   - Image Analysis
   - Image Reconstruction
   - Image Interpretation

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