CT Scan Protocols

Purpose and Summary

The purpose of this CT protocol is to obtain detailed data regarding the 3-dimensional characteristics of the bone, joint, or bone and tumor. This document contains CT protocols for scanning the tibia, femur, hip, shoulder and clavicle. The resulting scans will be used to prepare a virtual 3D model and surgical plan. The 3D model is intended also for the design of a custom implant and/or custom instrumentation. The CT scan quality (with clear bony edges and surface detail) is critical for the production of accurate patient-specific implants and instruments. Deviations from this protocol may result in an unusable scan.

Please note that this document should be referred to prior to submitting the "Custom Device Initiation Form" 141-02-0300".

CT Scan Protocols

Patient Preparation

- Remove non-fixed metal prosthesis, jewelry or zippers that might interfere with the region being scanned.

- Make the patient comfortable and instruct him/her not to move during the procedure. If any movement is detected, the patient will need to be rescanned as this will prevent the accurate development of a patient-specific model.

- Position the patient to maximise comfort and minimise rotation.

- For leg scans, position the patient supine feet first with the patellae pointing forward and the knees in maximal extension, toes pointing straight up.

- Always place a marker on the contra lateral knee (for left/right indication), that doesn't hinder the quality of the scan.

- If an implant is present in the contra lateral knee, elevate the contra lateral knee to prevent artifacts appearing in the joint of interest.

- For shoulder and clavicle scans, position the patient supine, head first, arms at sides of the body and with the shoulder in neutral position. Cervical spine in neutral position.

General Scan Requirements

- Only true axial slices are allowed: no oblique or reformatted images and no gantry tilt.
- If additional algorithms can be applied and seem beneficial to facilitate diagnostics (e.g. scatter or artefact reduction), these DICOM sets can be added, but separately from the required images.
- Set the table height so that the area to be scanned is centred in the screening field.
- Do not raise/lower the CT couch between slices.

Data Transmission

File Format:

- Provide the image data in standard DICOM format (axial).
- Uncompressed DICOM data is necessary for processing. Lossy and other forms of compression are NOT allowed (ISO 10918-1, ISO 14495-1, ISO 15444-1 or ISO 13818-1).
- No .jpg images or other formats are acceptable. Do not submit other types of reconstructed or reformatted images. Only the true axial scans are required.
- The scanner should be set to DICOM format "raw image", with no compression. If loading from PACs, import and export the scan as DICOM files with the uncompressed option.

Data Anonymisation:

- Do not erase patient name and ID. Ensure necessary rights are obtained for transfer of data to Signature Orthopaedics.
- Data will be anonymized by Signature Orthopaedics on receipt of the data, after cross-check with prescription of the surgeon to ensure the images of the right patient are provided.

Scan Data:

Send the following images:
- The requested CT images at the given parameters
- The accompanying scout view - An accompanying 3D reconstruction (if available)
- Recent diagnostic X-ray images of the hip (if available)

Note: Your site should keep an archive (PACS) copy of the CT exams, in uncompressed DICOM format and the original scanning parameters.

Transfer scan data to Signature Orthopaedics

By DVD or CD-ROM, labeled at Shipped to:

Signature Orthopaedics
7 Sirius Rd, Lane Cove West
NSW 2066, Australia

OR

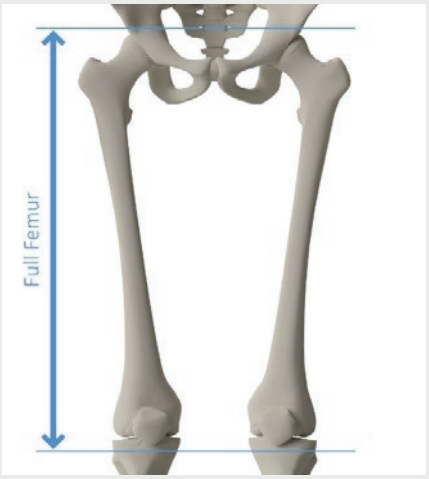
Unit A, IDA Business and Technology Park
Garrycastle, Athlone
N37 DY26 Ireland

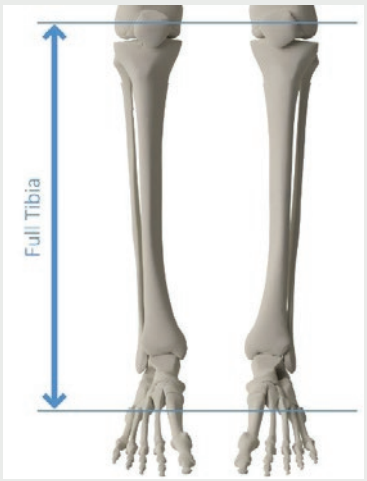
Notification

Please notify Signature Orthopaedics of your shipment via email.
Please mention the name of the surgeon, patient ID, and name of the file.

Area of interest: Femur or Tibia

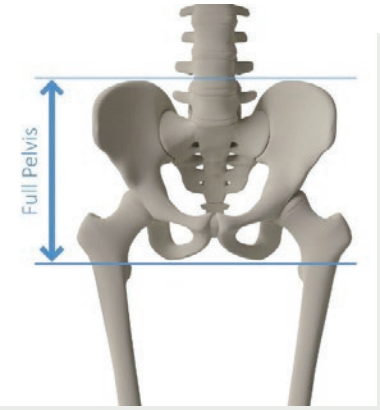
Patient position	Position the patient supine, feet first. Patellae pointing forward and the knee in extension, toes should be pointing up.
	Ankle support is recommended to restrict external rotation of the knee and stabilize the leg.
	Lumbar support is recommended to relieve back pain while the legs are extended.
	If an implant is present in the contra-lateral leg, elevate the contra-lateral knee to prevent the artifact from affecting the surgical side.
Region of interest	Capture the full femur or tibia, from joint to joint.





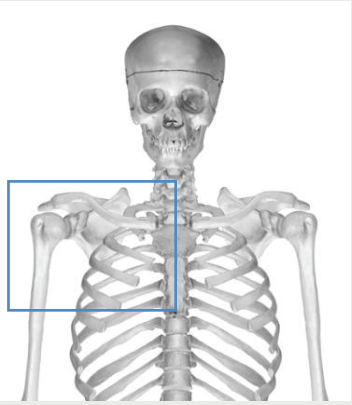
Area of interest: Hip

Patient position	Patient lying on the back, legs extended.
	A small pillow under the legs is allowed for support.
	No tilt or lift of the pelvis.
	Arms folded upward, away from the pelvis.
Region of interest of Helical Scan	All bony regions of the complete pelvis: from just above the most superior point of the ilium down to just below the most inferior point at the ischium.



Region of Interest: Shoulder

Patient position	Position the patient as follows: Supine, arms at sides of the body and with the shoulder in neutral rotation. Position the shoulder as good as possible in the centre of the gantry.
	If a hemi-implant is present, please scan the patient with the arm above their head in order to mitigate the scatter artefact on the glenoid.
	Always place a marker on the arm indicating if it is the right or left arm. Use a marker that does not hinder the quality of the CT scan.
Region of interest	The complete scapula and the proximal part of the upper arm need to be scanned, being from just above the acromioclavicular joint down to just below the inferior angle of the scapula.



Region of Interest: Clavicle

Region of interest	Full clavicle, acrmioclavicular and sternoclavicular joints. Scan the patient bilateral with two FOVs. Reconstruct the scan seperately for the left and right clavicle.