

CUSTOMIMPLANTS[®]

CT LEG

FULL LEG

PROTOCOL FOR COMPUTED TOMOGRAPHY

CUSTOMIMPLANTS®

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CT scan quality can directly affect the design of guides and implants. Please, ensure that all protocol steps are followed for optimum scan quality.

PRELIMINARY

The CT scan quality –with clear bony edges and details- is critical to the production of accurate patient-specific surgical instruments. Deviations from this protocol may result in an unusable scan and delay of the surgery.

Please contact the CUSTOMIMPLANTS® support team if further clarification is required.

Patient Preparation

- ▷ Remove any non-fixed metal prosthesis, jewelry, zippers and/or any other metal piece that may interfere with the region to be scanned.
- ▷ Inform the patient on the procedure.
- ▷ Make him/her comfortable but always minimizing the movement.
- ▷ Patient positioning: supine, feet first (SFF), patellae pointing forward and the knees in maximal extension, toes pointing straight up.
- ▷ Always place a marker on the contra lateral knee (for indication of left or right). Use a marker that doesn't hinder the quality of the CT 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.

Recommendations for data collection

TABLE POSITION

Set the table height so that the area to be scanned is centered in the scan field. DO NOT raise or lower the CT table between slices. DO NOT alter the X or Y centering between scans. Center points must be identical.

FIELD OF VIEW (FOV)

Use the smallest FOV possible (25x25 max.) to capture the whole of the required bone regions. This will require careful alignment of the leg to capture the femoral head, knee and talus. Scan all slices with the same FOV, reconstruction center and table height (coordinate system). Capturing all of the soft tissue is unnecessary, only the bony regions are of interest.

BILATERAL IMAGES

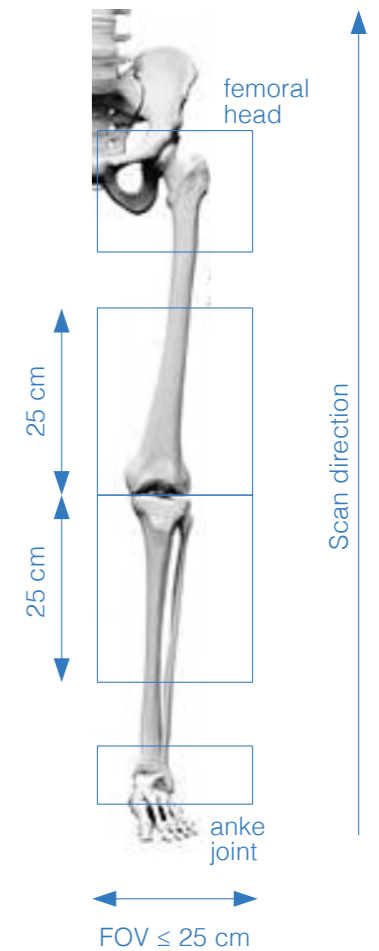
Bilateral imaging can be accomplished with a single acquisition (FOV max. 32 cm).

RECONSTRUCTION

No secondary reconstructions; images must be scanned at the given parameters or smaller. No obliqueness. No gantry tilt.

Scanning parameters

| | |
|---------------------------|---|
| Region of interest | From below the talus to above the femoral head |
| Collimation | Slice thickness: 1.25mm – 1.50 mm Slice increment: 0.625mm-0.75mm (50% overlap) |
| kVp | 120 |
| mAs | As given by the automatic system |
| Pitch | 1 or smaller |
| Field of View | The smallest FOV possible to capture the required bone regions. 25x25cm or smaller (bilateral: max. 32cm) |
| Matrix | 512x512 |
| Kernel/algorithm | Moderate/soft tissue (Do not use bone/detail) |



DATA MANAGEMENT

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



- ▷ Provide 1 localizer + 1 complete data set of images.
- ▷ Only true axial scanning is required.
- ▷ For processing purposes, only uncompressed DICOM is accepted. No .jpg images or other formats are acceptable. Do not submit any other types of reconstructed or reformatted images.
- ▷ Lossy compression is NOT allowed. (ISO_10918_1, ISO_14495_1, ISO_15444_1 or ISO_13818_1).
- ▷ 3D images or similar that may seem beneficial for diagnosis are accepted, if available. Submit them separately.

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



We recommend building a “CUSTOMIMPLANTS® full leg protocol” in your CT with the appropriate ranges and parameters.

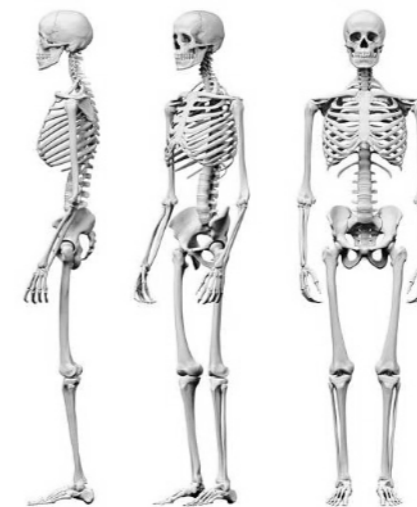
Disclaimer

The information is intended exclusively for healthcare professionals. A healthcare professional should always rely on his or her clinical and professional opinion when deciding which product is most suitable to treat a patient.

Custom Implants SL do not provide medical advice and recommend that healthcare professionals be trained in the use of any particular product before using it in a procedure or in surgery.

Before using any product from Custom Implants SL., the healthcare professional must always read the instructions which are inside the package, the label of the product and/or the instructions for use, included those for cleaning and sterilization, when applicable. The information provided is for the purpose of showing specific products as well as the wide range of Custom Implants products.

It may occur that not every product be available in all markets due to their availability is subject to the medical or regulatory practice.



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innovators you can count on