

CUSTOMIMPLANTS[®]

CT HIT

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 purpose of this CT protocol is to obtain detailed data regarding the 3-dimensional characteristics of the hip joint. The resulting scans will be used to prepare a virtual 3D model. This virtual 3D model is intended for the design of patient-specific instrumentation or implant.

The following instructions are important. Please, read them carefully before scanning.

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: Patient lying supine with legs extended. Legs in natural alignment with neutral rotation. No un-natural tilt of the pelvis. Arms folded upward away from the pelvis.

Recommendations for data collection

TABLE POSITION

The CT table must not be raised or lowered between slices.
The FOV or X and Y centering must not be altered between slices during scanning.

FIELD OF VIEW (FOV)

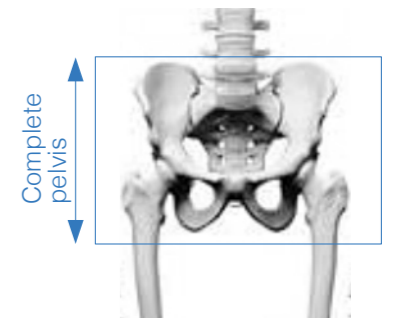
≤50
Adjust the image so that it fills the entire screen without cutting off any of the anatomy of interest. Make sure to include both hemi-pelves. Only bony regions are of interest. Capturing soft tissues is unnecessary. X and Y centering must not be altered between slices during scanning.
The complete pelvis needs to be scanned from above the most superior point of the ilium down to below the most inferior point at the ischium.

RECONSTRUCTION

No secondary reconstructions. Slices to be scanned with the given parameters or more precise. No obliqueness. No gantry tilt. No reformatting into coronal or sagittal planes. No MRP. No 3D reconstructions.

Parámetros de referencia radiológica

Imaging modality	CT
Scan Type	A conventional CT machine can be used. Please make sure that images taken with your scanner fulfill the minimum requirements stated below.
Collimation	Slice thickness: 1.5mm (preferred value). A fixed value between 1 and 3 mm is acceptable. Slice increment: all slices must be contiguous and overlapping. Slice increment should NOT be greater than the chosen slice thickness. Table increment will depend on patient anatomy.
Matrix	512 x 512
Algoritmo de reconstrucción	A standard or soft tissue algorithm without edge enhancement should be used. If additional algorithms can be applied and seem beneficial to facilitate diagnostics (eg.: scatter or artefact reduction), these DICOM sets can be added but separately. Axial images must be provided. No obliqueness; no gantry tilt; no oblique reconstructions; no MPR's 3D reconstructions can be added, but separately.



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 o 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® hit protocol" in you CT scan with the appropriate ranges and parameters.

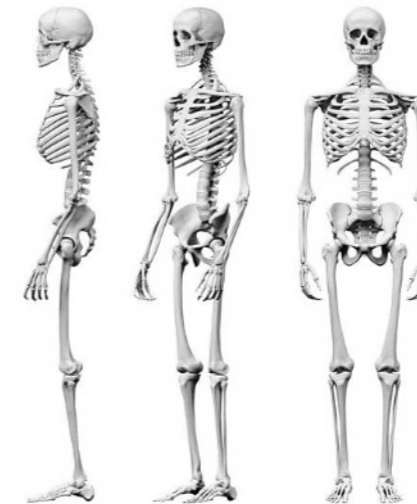
Disclaimer

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