

CUSTOMIMPLANTS[®]

CT CLAVICLE

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

This CT protocol consists of a localizer and a detailed axial scan: one of the left and one of the right clavicle. 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: head first, supine, arms at sides of the body and with the shoulder in neutral rotation. Cervical spine is in neutral position.

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 table between the CT slices.

FIELD OF VIEW (FOV)

Use a FOV for the left and a second FOV for the right clavicle in the same bilateral scan. For reconstruction, the left and right clavicle should be reconstructed separately.
Capture the clavicle, the acromioclavicular joint and sternoclavicular joint using a reconstruction FOV of 25 cm. For large patients, use the smaller FOV possible.
Capturing all soft tissue is not necessary, only the bony regions are of interest.
Scan all slices with the same FOV, reconstruction center and table height (coordinate system).

BILATERAL IMAGES

Although scanning the patient once, two high resolution datasets are obtained.

RECONSTRUCTION

Only true axial scanning is required.
Two original reconstructions are required: left and right clavicle separately.
No reformatting into coronal or sagittal planes. No MRP's. No 3D reconstructions.
No obliqueness; no gantry tilt. No oblique reconstructions.
No secondary reconstructions; images must be scanned at the given parameters or more precise.
3D images which may seem beneficial are accepted, if available. Submit them separately.

Scanning parameters

Region of interest	Full acromioclavicular and sternoclavicular joints.
Collimation	Slice thickness: 1 mm or smaller Slice increment: 1mm or smaller. Contiguous or overlapping slices.NO gap allowed!
kVp	120
mAs	As given by the automatic system
Pitch	1 or smaller
Field of view (FOV)	Place two separate FOVs, one for each clavicle. ≤25cmx25cm.For large patients, use the smallest FOV possible.
Matrix	512x512
Kernel / Algorithm	Standard soft tissue algorithm with no edge enhancement



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® clavicle protocol” in your CT with the appropriate ranges and parameters.

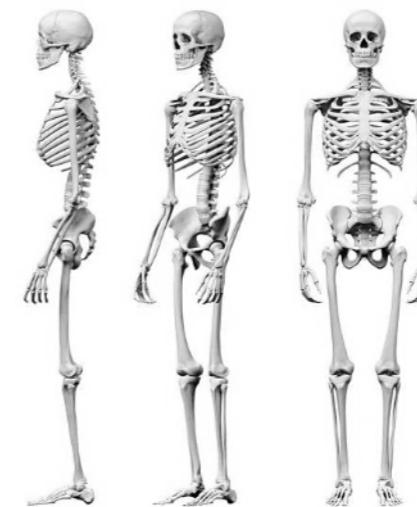
Disclaimer

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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