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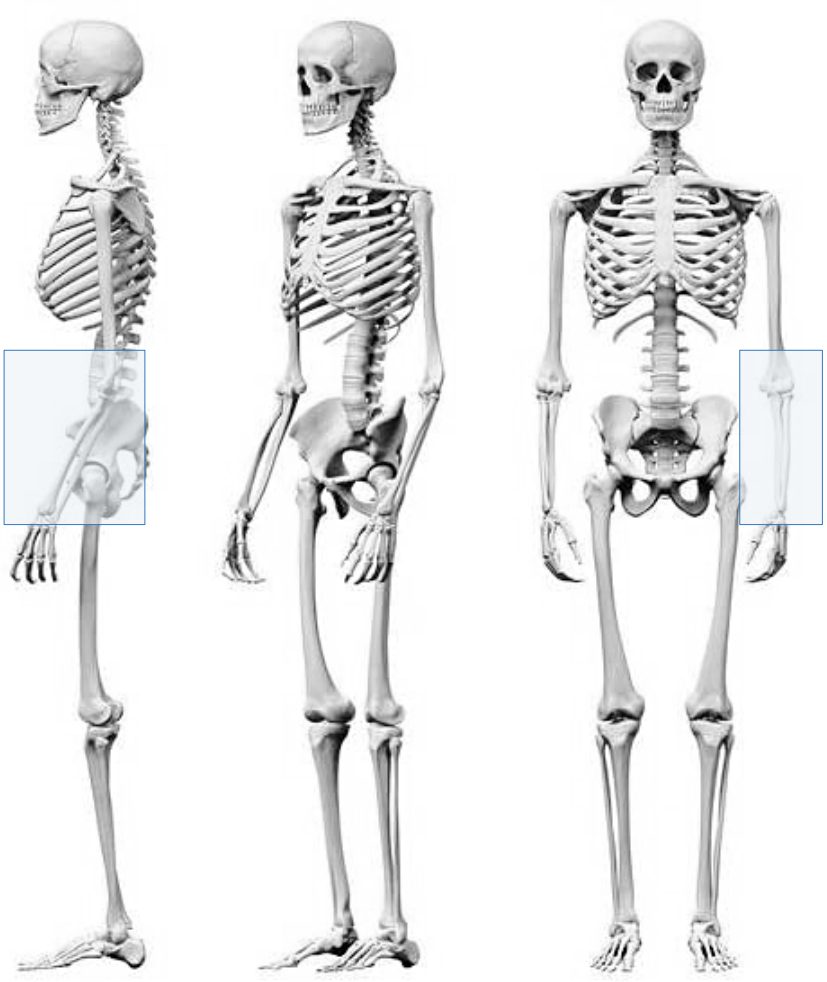

CUSTOMIMPLANTS®

CT FOREAM

PROTOCOL FOR COMPUTED TOMOGRAPHY

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CUSTOMIMPLANTS®

INDEX

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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 of the bilateral forearm. 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 minimize the movement.
- ▷ If possible, scan the forearms in the position of greatest deformity, with both limbs in as close to the same position as possible (ex. Full supination to demonstrate subluxation of the radial head). Otherwise, position the patient prone with arms in front of him/her and with palms facing each other in the neutral position. If this is not possible, position the patient in the supine position.
- ▷ Scan forearms with both arms above the head and the head out of the FOV, if possible. Make sure the patient's elbows are propped up, if needed, to allow for even scanning within the same plane. Place forearms as close together as possible to fit into the designated FOV. Scan each arm separately if both arms do not fit within the required FOV.

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. Do not alter X/Y centering between scans. Center points must be identical. - No reformatting into coronal or sagittal planes. No MRP's or 3D reconstructions.

FIELD OF VIEW (FOV)

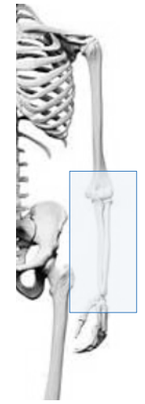
200mmx200mm or smaller. Use the smallest FOV possible to capture the required bone regions.Capturing soft tissue is unnecessary.

RECONSTRUCTION

No secondary reconstructions, images must be scanned at the given parameters or smaller.
No reformatting into coronal or sagittal planes, no MPR's or 3D reconstructions.

Parámetros de referencia radiológica

Region of interest/Axial scan	From the elbow to the carpometacarpal joint.
CollimationSlice thickness: 0.625mm o smaller **Slice increment: Contiguos Slices**	Bilateral: prefer a single acquisition; individual scans area acceptable.
	No gantry tilt or obliqueness or oblique reconstructions.
kVp	90-120 (higher for obese patiento metal hardware in scan region).
mAs	As given by the automatic system.
Pitch	1 or smaller
Field of view (FOV)	200mmx200mm or smaller. Use the smallest FOV possible to capture the required bone regions.Capturing soft tissue is unnecessary.
Matrix	512x512
Kernel/algorithm	Bone/ Details



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

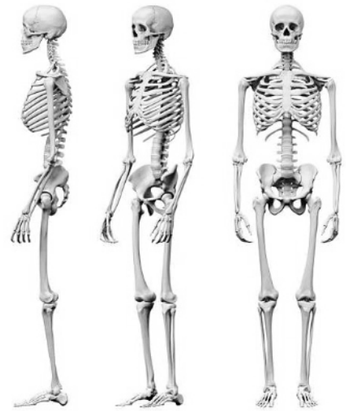
Disclaimer

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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