

CUSTOMIMPLANTS[®]

CT BONE TUMOR

PROTOCOL FOR COMPUTED TOMOGRAPHY

CUSTOMIMPLANTS®

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CONTACT



Telephone
(+34) 900 377 266

Working time
Monday to Friday
08:00 to 20:00



Email
comunicacion@customimplants.es



www.customimplants.es



Calle 16, nave 13. Polígono Industrial San Cibrao das Viñas. 32901 - Ourense



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 bone and the tumor. The resulting scans will be used to prepare a virtual 3D model and surgical plan for the removal of the tumor. This virtual 3D model is intended for the design of custom instrumentation or a custom implant. This document contains CT protocols for scanning the tibia, femur or hip.

Additional images that help locating the tumor are also requested. This includes MR images of the tumor to provide additional soft tissue views. The MR images are only used for the planning of the resection around the tumor, and not for guide and implant design. For these MR images no defined protocol is required; diagnostic MR images are sufficient. Additional information like PET-CT images or radiology reports may also be provided.

Please contact CUSMTOMIMPLANTS@ 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.

FEMUR OR TIBIA

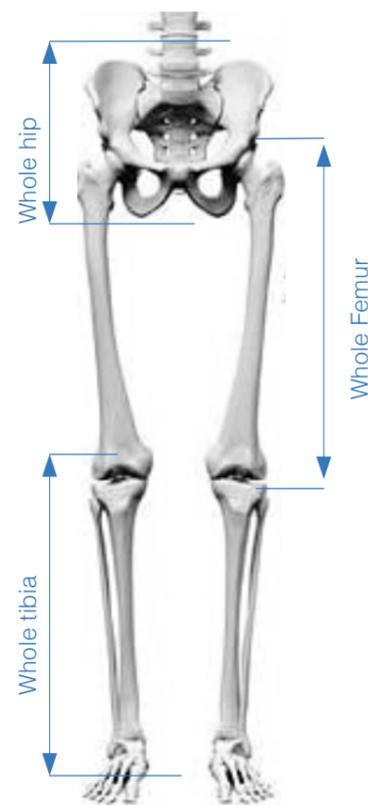
PATIENT POSITION

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 legs are extended. If an implant is present in the contralateral leg, elevate the contralateral knee to prevent the artifact from affecting surgical side.

WHOLE 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.
Los brazos cruzados, fuera de la zona pélvica



Scanning parameters

TABLE POSITION

Set the table so that the región to be scanned is centered in the field of view.

FIELD OF VIEW (FOV)

Use the smallest FOV possible to capture all required bone regions of interest. Scan all slices with the same FOV, reconstruction center and table height (coordinate system). Capture soft tissue is unnecessary, only the bony regions are of interest.

RECONSTRUCCIÓN

No obliqueness, no gantry tilt, no oblique reconstructions.

Scanning parameters

Collimation	Slice thickness: 1.5 mm or smaller Slice increment: 50% overlap
Field of View (FOV)	Use the smallest FOV possible to capture the required bone regions:
Matrix	512x512
Algorithm	Use a standard or soft tissue algorithm with no edge enhancement
Pitch	1 or smaller
kVp	120-140 (higher for obese patients or metal hardware in scan region)
mAs	As given by the automatic system

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).
- ▷ Diagnostic images that help locating the tumor. This may include: MR images, PET-CT images or radiology reports.

- ▷ 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® Bone tumor protocol" in your CT with the appropriate ranges and parameters.

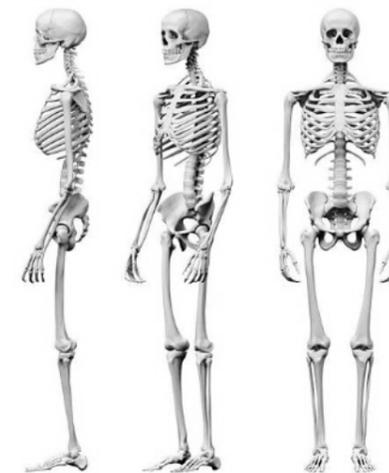
Disclaimer

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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