

Imaging Protocol: Juvenile Tumor System (JTS) and Minimally Invasive Grower (MIG)

OVERVIEW

The purpose of this protocol is to outline the imaging that must be provided to the Onkos Surgical Patient Solutions Team, which will be used to design and manufacture devices specific to individual patients and their bone anatomy.

A complete scan consists of a series of CT scan images or a series of anterior-posterior (A/P) and medial-lateral (M/L) radiographs with magnification markers. The successful design of the device relies on the quality of the information provided. The best results are achieved by adhering to the following instructions.

IMPORTANT

Field of View:

Maximize the magnification for the area of interest. Magnify or zoom the image so it fills the entire screen without cutting off any of the anatomy for imaging. FOV must not be changed during the scan. Choose the appropriate FOV for the area of interest only. For example, if the request is for the left foot, do not include both feet unless otherwise requested. If a bilateral scan is requested, two separate datasets should be provided and labeled appropriately. This can be accomplished during post processing if the initial scan included both sides.

Table Positioning and Centering:

The X and Y center must not be changed during the scan. The CT table should not be raised or lowered between slices.

Scanning Method and Matrix:

The area of interest where the design of the implant is critical should be scanned at the listed spacing for each case to allow for more detail. All slice spacing must be contiguous or overlapping. Slice thickness is dependent on the anatomy. A standard or soft tissue algorithm with no edge enhancement should be used. A bone algorithm is not recommended. Gantry tilt should be set to 0 degrees. Quality images can be obtained from any scan matrix. However, a high resolution (512 x 512) should be used whenever possible. If scanning helically, the pitch should be set at 1:1 or 1:1.5. Slice thickness should be reconstructed to 1 mm before saving the data to a disk.

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Image Age:

Due to constant change in the patient's bone, recent imaging is required to design a suitable device. Imaging older than three months for oncological indications, and six months for non-oncological indications may be subject to refusal based on the designing engineer's judgment. The images should be an accurate representation of the patient's bone condition at the time of the operation. If the patient's bone condition changes between the receipt of images and shipment of the device, the designing engineer must be informed, and if deemed necessary, new imaging supplied.

Metal Artifacts:

It is always best to eliminate any metal from the field of a CT scan. However, if a metal artifact is present, please maximize the X-ray strength (kVp) and the intensity (mA) of the scan to help reduce the scatter effect. The recommended settings are 200 mA and 120 kVp.

Patient Positioning:

Instructions are found on the following pages for patient positioning, with illustrations. Please review them carefully before scanning.

Use of X-ray:

CT images are the preferred image modality for all implant design scenarios. If a CT scan cannot be obtained, X-rays that meet the requirements described in this document may be provided. X-rays may not be suitable for all design applications, and it is left to the discretion of the design engineer if the provided X-rays are suitable for use in a specific case.

Use of MRI:

Onkos Surgical does not use magnetic resonance imaging (MRI) to design and manufacture patient specific devices. However, if all other options are unavailable or unsuitable, please contact patientsolutions@onkossurgical.com.

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SUBMITTING DATA TO ONKOS

Preferred Media:

All imaging should be provided in the native DICOM format wherever possible. Imaging and other case information can be sent through the online Onkos Digital Portal. To enroll in this service, or for support using this service, please contact Onkos Patient Solutions. CDs and other media can also be mailed directly to the design office.

Requesting a PS Device:

Please complete a device request form and send the completed form, along with any supplementary material (CT scan, X-rays, etc.) to the following addresses, emails or fax numbers.

PatientSolutions@onkossurgical.com

Please contact Onkos Patient Solutions for the relevant request form or for additional methods of request submission.

CT Parameters for Femur, Knee, and/or Tibia

Type of Case	Patient Position	Scan Region and Field of View (FOV)	Slice Thickness
Proximal and diaphyseal femur	Patient in AP position with feet inverted Femurs parallel to the horizontal plant of the table	5 mm above the femoral head ending beyond the distal femoral condyles FOV should be adjusted to the affected side only. Include the contralateral anatomy if necessary for comparison or length assessment purposes	1 mm – 2 mm
Revision and oncology total knee Distal and total femur Proximal and total tibia	Patient in AP position with feet inverted Femur parallel to the horizontal plane of the table	5 mm above the femoral head to 2 mm below the heel If the total femur cannot be scanned, follow the guidelines below: Total femur or tibia replacements require the entire bone to be captured in the scan. The scan must extend at least 5 cm beyond any existing implants or defects, whichever is greater. FOV should be adjusted to the affected side only. Include the contralateral anatomy if necessary for comparison or length assessment purposes	1 mm – 3 mm
Distal and diaphyseal tibia	Patient in AP position with feet inverted Femurs parallel to the horizontal plane of the table	From the femoral condyles to 2 mm below the heel FOV should be adjusted to the affected side only. Include the contralateral anatomy if necessary for comparison or length assessment purposes	1 mm – 3 mm

Refer to diagram on the following page

CT Parameters for Femur, Knee, and/or Tibia

Revision and oncology total knee, distal and total femur, proximal and total tibia

Beginning slice 5 mm above femoral head

1 mm – 3 mm
Slice thickness

Ending slice 2 mm below heel

Proximal and diaphyseal femur

Beginning slice 5 mm above femoral head

1 mm – 2 mm
Slice thickness

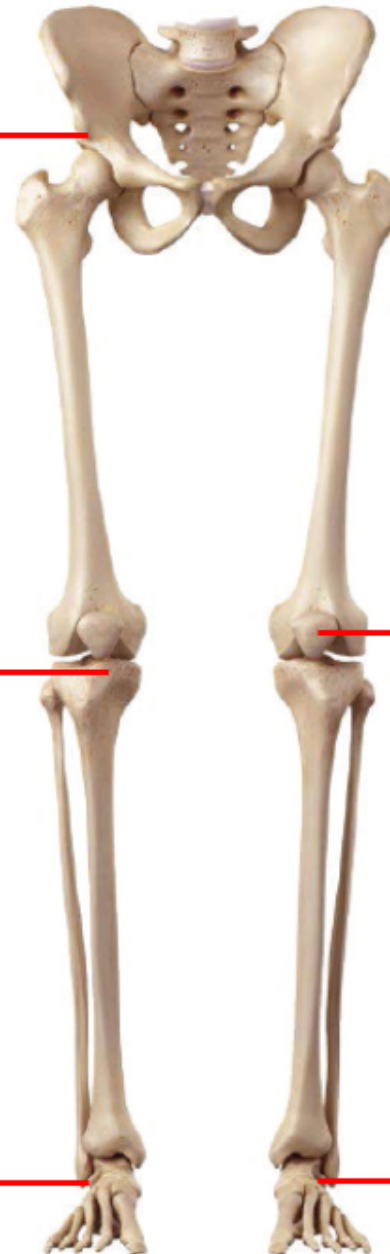
Ending slice beyond distal femoral condyles

Distal and diaphyseal tibia

Beginning slice through distal femoral condyles

1 mm – 3 mm
Slice thickness

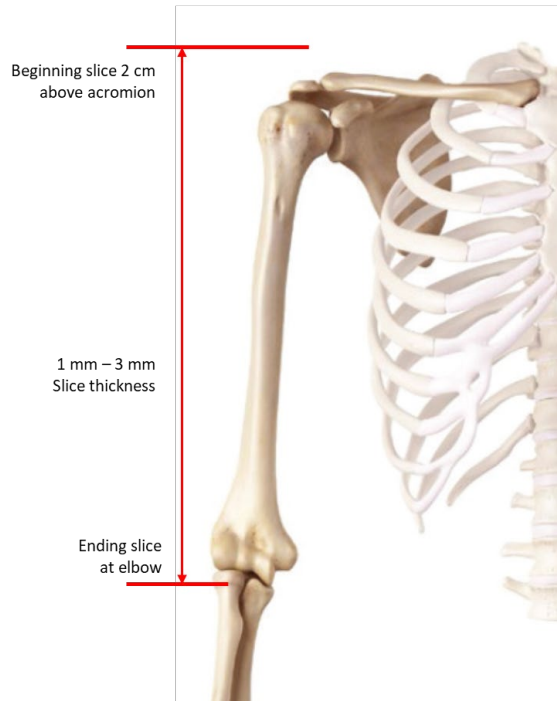
Ending slice 2 mm below heel



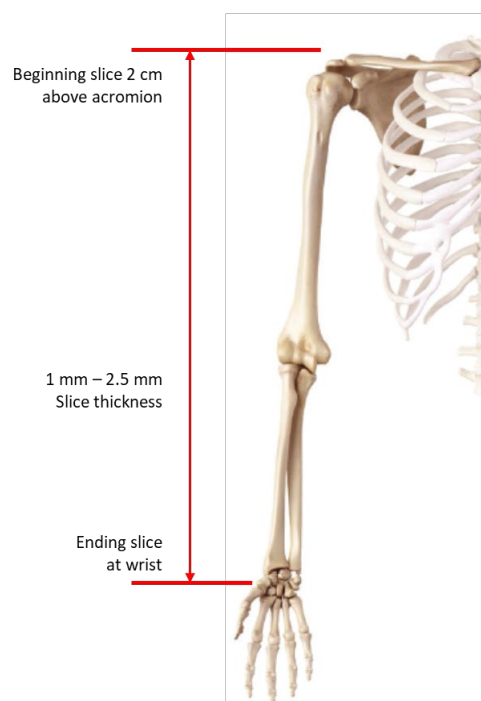
CT Parameters for Humerus and Elbow

Type of Case	Patient Position	Scan Region and Field of View (FOV)	Slice Thickness
Proximal and diaphyseal humerus	Patient in AP position with arm extended and palm inverted • Humerus parallel to the horizontal plane of the table	<p>2 cm above the acromion to the elbow joint</p> <p>If the total humerus cannot be scanned, follow the guidelines below –</p> <p>The scan should extend past the mid-humerus, or 3 cm past any implants or defects, whichever is larger</p> <p>Five additional slices through the distal humeral condyles to establish humeral version. Do not change FOV or centering for the condyle slices</p> <p>FOV should be adjusted to include the affected side only. Include the contralateral anatomy if necessary for comparison or length assessment purposes</p>	1 mm – 3 mm
Total elbow Distal and total humerus	<p>Patient in AP position with arm extended and palm inverted</p> <p>Humerus and ulna parallel to the horizontal plane of the table</p>	<p>2 cm above the acromion to the wrist</p> <p>FOV should be adjusted to the affected side only. Include the contralateral anatomy if necessary for comparison or length assessment purposes</p>	1 mm – 2.5 mm

Proximal and diaphyseal humerus



Total elbow, distal and total humerus



X-Ray Parameters for the Femur, Tibia, and/or Humerus

Required imaging range:

Images are required for certain femoral, tibial and humeral devices.

X-rays may not be suitable for all design applications, and it is left to the discretion of the design engineer if the provided X-rays are suitable for use in a specific case.

X-rays alone are not suitable for the design of certain uncemented devices.

Orientation:

A/P and M/L radiographs are needed for all cases.

Implant Type	Top of Image	Bottom of Image
Femur (proximal and diaphyseal)	Above femoral head	Below femoral condyles
Femur (distal), tibia (proximal and diaphyseal)	Above femoral head	Below ankle
Humerus (proximal)	Above acromion	Below elbow

Magnification, scaling and calibration:

A radiopaque graduated scale should be used in each radiograph, with the scale placed alongside and parallel to the shaft of the long bone. The scale should be raised off the plate so that it lies in the same plane as the bone, ensuring that the magnification scale corresponds to that of the bone. Multiple images can be stitched together to ensure the full length of bone and ruler are shown. See the reference image for approximate scale placement.

If a full scale cannot be shown, a calibrated magnification marker may be used so long as the exact size of the marker is provided with the radiographs.

Contralateral limb:

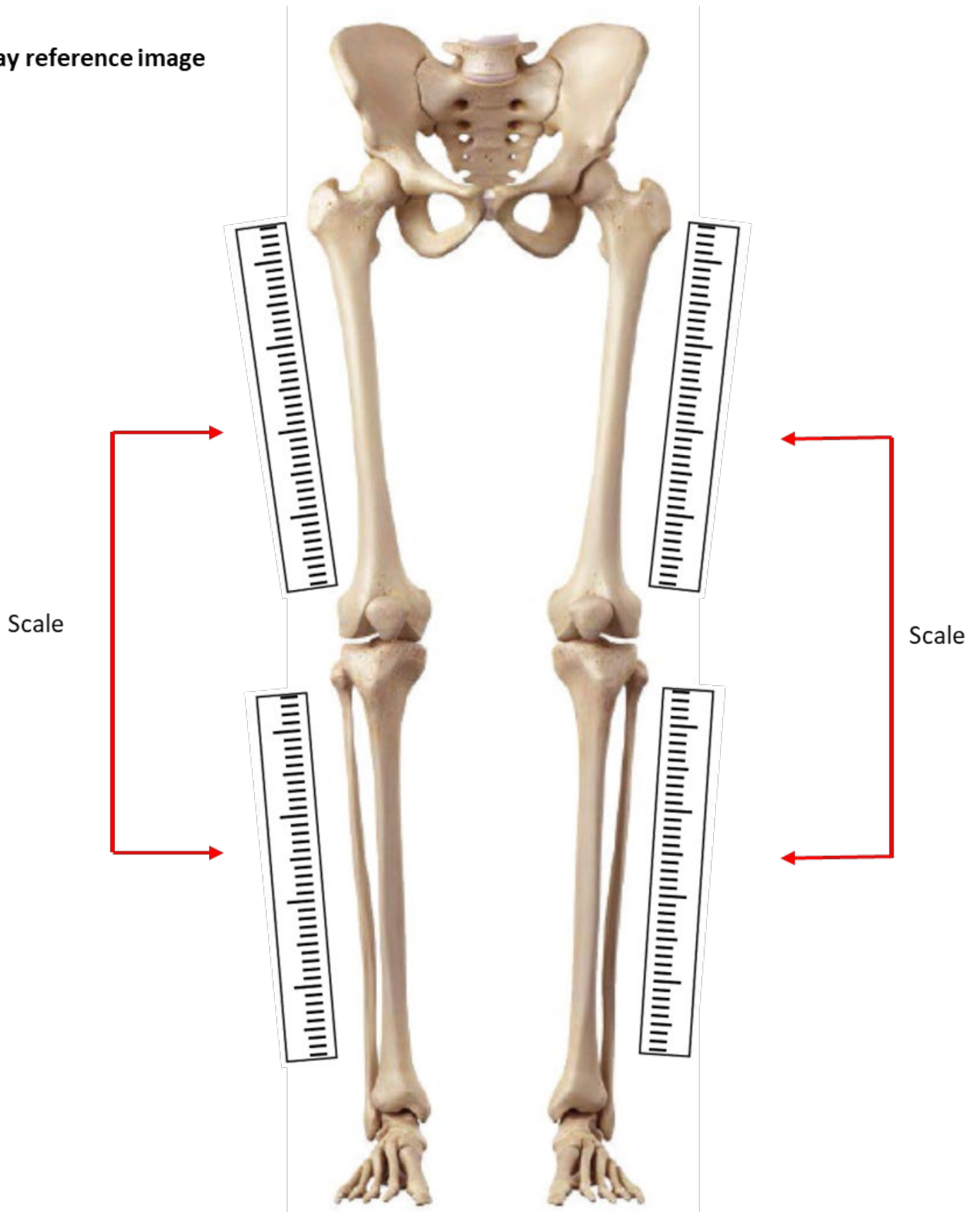
An anterior X-ray of the contralateral limb must be included to determine leg length equality.

Fixed flexion:

If a patient has a fixed flexion contracture, CT scans of the flexed limb are requested.

X-Ray Parameters for the Femur and Tibia

X-ray reference image



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