

Onkos Surgical My3D® Pelvic Reconstruction System – CT Scan Protocol



OVERVIEW:

Onkos Surgical My3D technology uses patient specific CT scans to develop accurate models of a patient's anatomy for analysis and design of personalized implants, instruments, and anatomic models. This CT scanning protocol consists of several requirements for obtaining patient specific images. We understand concerns about keeping the radiation dose to patients as low as reasonably possible, therefore, please apply these guidelines as appropriate to your patients. Please contact Onkos Surgical at +1.844.767.2766 with any questions. For additional information regarding safety concerns of CT scanners, go to <https://www.fda.gov/radiation-emitting-products/medical-imaging/medical-x-ray-imaging>

IMPORTANT:

Good quality images are critical to the successful application of My3D technology. Adherence to this protocol is required for this process. Please read the following instructions carefully. **Images that do not conform to this protocol will NOT be accepted.** Patient matched components designed from the images obtained in this protocol are valid for a period of 6 months from the date of image acquisition. Past this date, changes in patient anatomy may prevent the device(s) from fitting as intended.

RECOMMENDED CT PROTOCOL FOR MEDICAL CT SCANNERS:

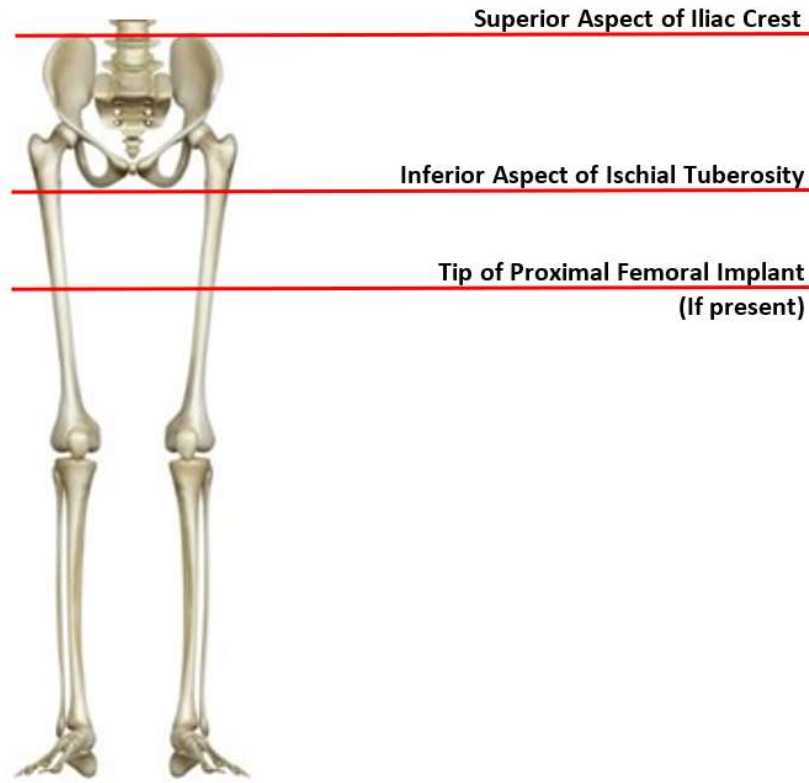
<u>Confirmed</u>	<u>Parameter</u>	<u>Value</u>
<input type="checkbox"/>	Analytical Reconstruction Method	Iterative (preferred) Filtered Back Project (acceptable)
<input type="checkbox"/>	kVP	120kVP 130kVP for cases where pelvic hardware is present
<input type="checkbox"/>	Scan Spacing	Less than or equal to 3.0mm (equal to slice thickness)
<input type="checkbox"/>	Slice Thickness	Less than or equal to 3.0mm (equal to scan spacing)
<input type="checkbox"/>	Field of View	Magnify or zoom image so it fills the entire screen without cutting off any of the anatomy for imaging. The FOV must not be changed during the scan.
<input type="checkbox"/>	Pixel Size	0.6mm or less (If pixel size is not a direct input for your scanner, please be sure to scan with a FOV of 30cm or less)
<input type="checkbox"/>	Reconstruction Kernels (Algorithm/ Filter)	A standard or soft tissue algorithm with no edge enhancement. No bone algorithm. If hardware is present, use of metal artifact reduction algorithms (MAR/OMAR) is required.
<input type="checkbox"/>	Gantry Tilt	0°. Images acquired with gantry tilt then post-processed to reorient images (i.e. "take out" tilt) are not acceptable.
<input type="checkbox"/>	File Type	DICOM (uncompressed)
<input type="checkbox"/>	Series	Original/Primary/Axial (No recon, reformat, or post process data)

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REVISION AND ONCOLOGY PELVIS CT SCAN OVERVIEW:

<u>Confirmed</u>	<u>Parameter</u>	<u>Value</u>
<input type="checkbox"/>	Patient Positioning:	Patients should be supine with both arms elevated and hips fully extended in a neutral position with their feet inverted. Images to be acquired in craniocaudal direction.
<input type="checkbox"/>	Start:	Superior aspect of Iliac Crest
<input type="checkbox"/>	Stop:	Inferior aspect of Ischial tuberosity OR below existing proximal femoral hardware
<input type="checkbox"/>	Field of View:	Needs to include full pelvis or, depending on patient size, as much of the pelvis as possible



PLEASE KEEP IN MIND THE FOLLOWING KEY POINTS:

1. CT Scans may be done with or without contrast.
2. Patients must remain completely still through the entire scan. Please ensure that scans are free from motion artifacts. If patient motion occurs, the scan must be restarted. Image distortion from patient motion can severely compromise the accuracy of the device.
3. Acquire helical scans at high spatial resolutions using a CT scanner with at least 16 detector rows. Series should be acquired with thin, contiguous, or overlapping image slices (equivalent **thickness and spacing of 3.0mm or less**) and as small a field of view (FOV) as possible while still including the patient's anatomy of interest.
4. Please provide images in the original scanning plane. If software post-processing is performed to reorient or reformat the scan volume, then a series of thin slice images in the original acquisition plane **MUST** be included.
5. Archive the entire study in uncompressed DICOM format and upload to the Onkos Digital Portal. Don't have a share code? Contact PatientSolutions@onkossurgical.com to request a login.
6. Please upload any other available imaging including any MRI's or X-Rays.

