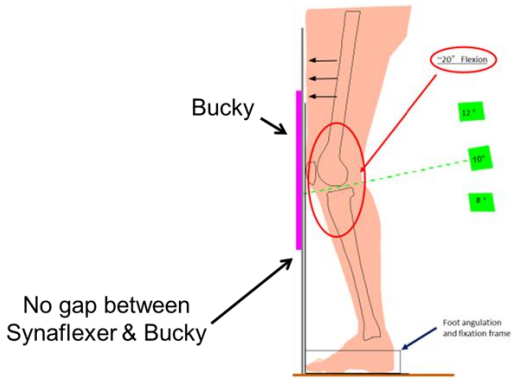
X-Ray Quick Reference Guide
Regeneron Protocol R475-OA-1758

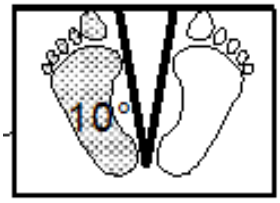
PER BioClinica this is the same protocol as R475-OA-1611

For a full description of devices and procedures, please refer to the study imaging guidelines

POSITIONING – Left and Right PA Knee Radiograph

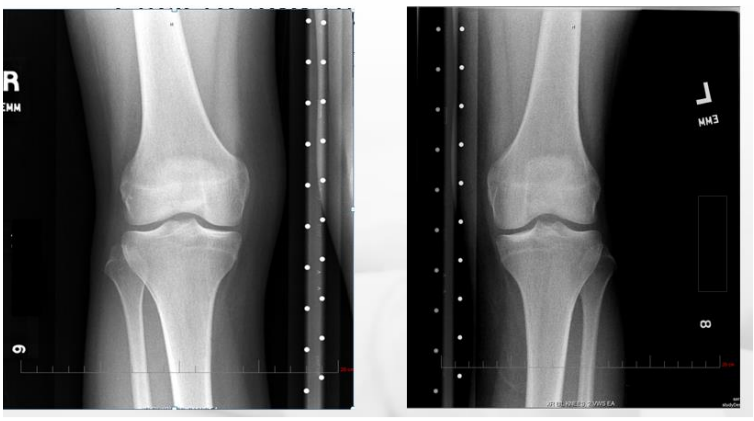
- Use the SynaFlexer™. It ensures consistent and reproducible angulation and alignment.
- The patient is barefoot.
- The great toes (or longest toe) of both feet are placed in contact with the anterior wall (vertical) of the frame.
- The knee of interest is centered on the film.
- The knees and thighs are pressed directly against the wall of the frame and Bucky. Instruct the patient to hold onto the Bucky for stability.
- Ensure that the feet of the subject stay flat on the base of the SynaFlexer™.
- PA Projection.
- X-ray beam is centered on the joint line of the knee. Start with the tube angled at 10° caudal. Review the positioning of the knee and if the IMD is ≥ than 1.5 mm, adjust the tube angle to either 8° or 12° caudal. If IMD is very large the tube may be adjusted more than 2°. Additional angles may be needed. At least one image must have an IMD 0 to 1.5 mm. Do not allow the subject to move between acquisitions



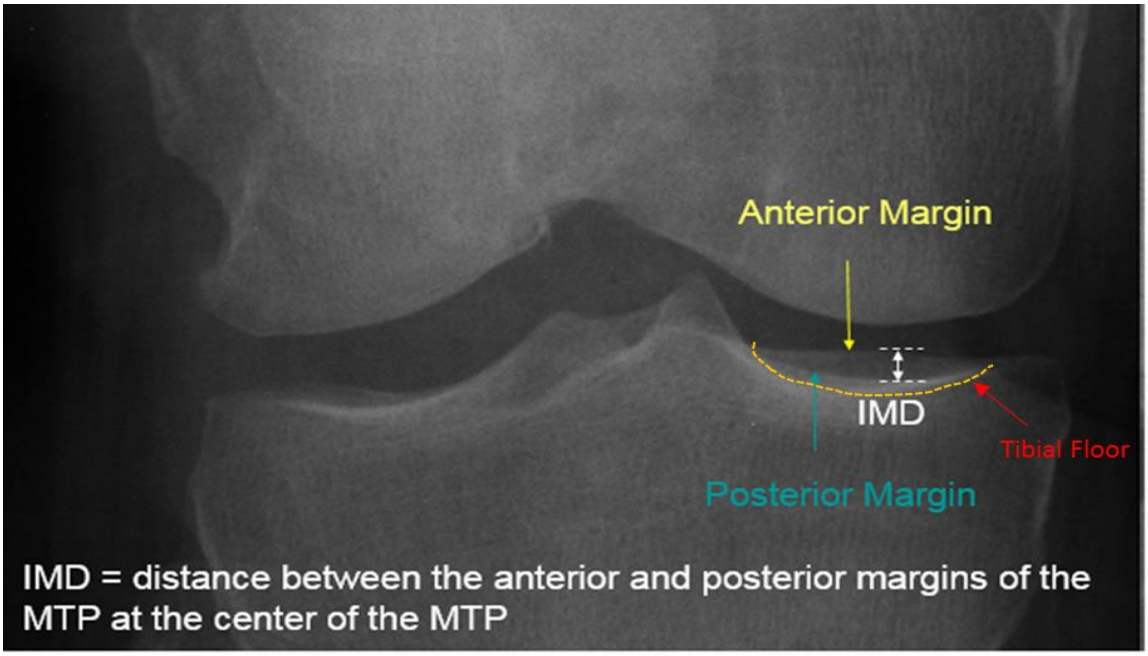


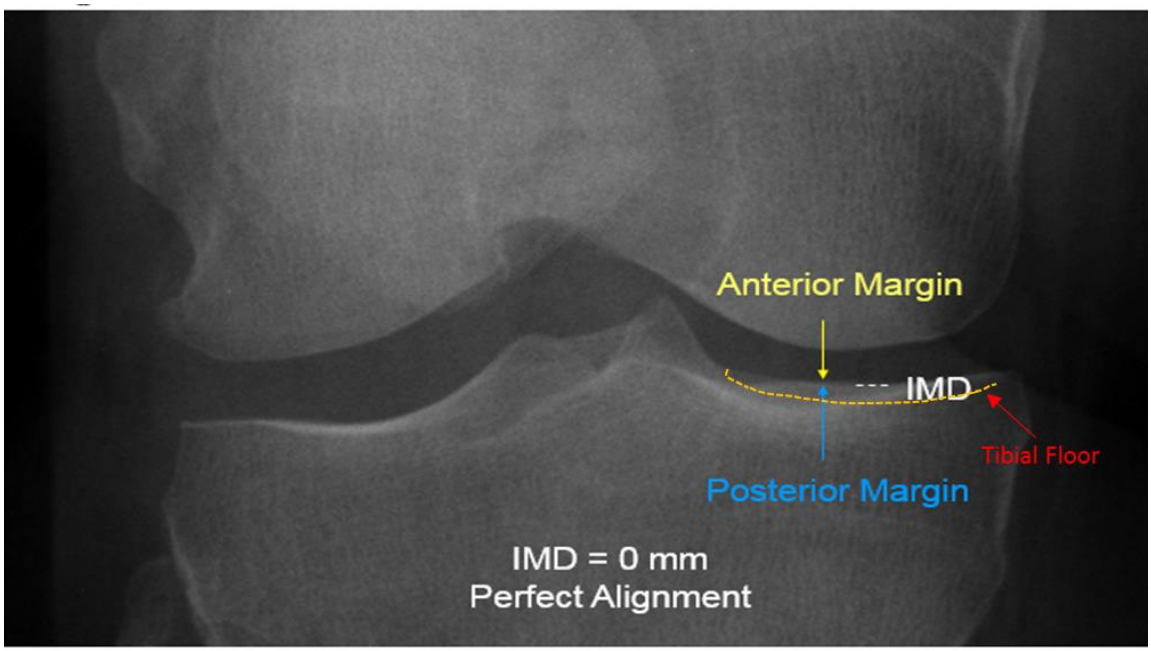
TECHNICAL REQUIREMENTS – Left and Right PA Knee Radiograph

- FFD 40 - 47 inches (100cm - 120cm) - The FFD needs to remain consistent for all subject visits.
- Film size 10” x 12” (24cm x 30cm)
- 10° caudal angle (to start), if it is not the correct angle (tibial plateau not flat) and IMD >1.5 mm use 8°and 12°. Additional angles may be needed
- Use R/L lead markers and lead angle markers if available
- Both columns of beads on Positioning Frame (SynaFlexer™) visible on film with at least 10 cm above and below the knee joint (approximately 5 beads) (see figure below)
- Recommended kVp Range: 70-76 kVp
- In the case of Knee Total Joint Replacement, the following views of the knee are required: Weight Bearing PA – The radiograph will be acquired as a single weight bearing exposure using the Synaflexer with perpendicular beam.
- In the case of Hemi Arthroplasty knee joints Image in Synaflexer following standard Modified Lyon-Schuss imaging technique (the SAME as a normal knee).



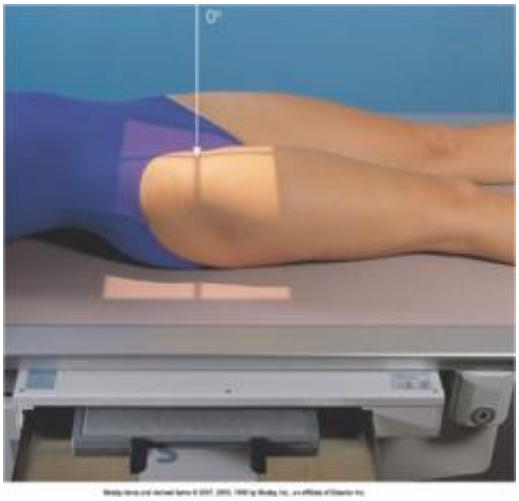
**HOW TO FIND THE INTER MARGIN DISTANCE (IMD)
IN ORDER TO DETERMINE THE ALIGNEMENT OF THE MEDIAL TIBIAL PLATEAU
(Acceptable IMD = 0-1.5 mm)**





POSITIONING – Left and Right AP Hip Radiograph

- Position the subject so that target hip is centered to the midline of the table.
- Ensure that the pelvis is not rotated.
- Separate the legs and feet and internally rotate the thighs and both feet by 15-20°, aligning the femoral neck horizontal and parallel with the table top.
- AP Projection.
- Central ray should enter approximately 1”-2” (2.5cm-5cm) above the mid femoral neck.
- In case of Hip Joint Replacement Surgery, the following views are required: AP Hip and Frog Leg Lateral Hip or Horizontal Shoot Through lateral if unable to acquire Frog Leg due to recent (within 3 weeks) replacement surgery

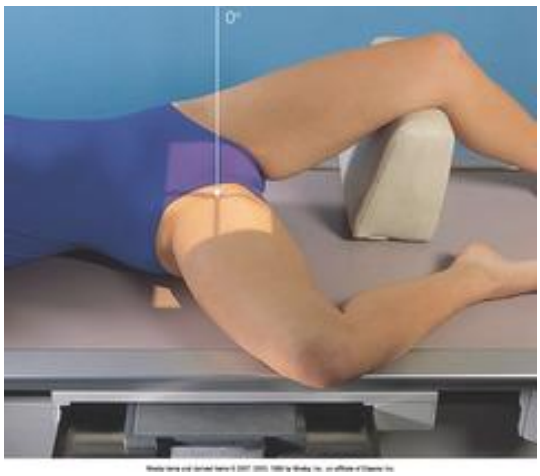


TECHNICAL REQUIREMENTS – Left and Right AP Hip Radiograph

- FFD 40 Inches (100 cm) perpendicular to the table Bucky
- Film size 10” x 12” (24cm x 30cm)
- Use R/L lead marker at the lateral side of the target hip
- Recommended kVp of 75

POSITIONING - Lateral Hip (Frog Leg view)

- Ensure that the subject is lying on the table and the center of the hip to be imaged is midline to the table.
- Flex the knee of the hip to be imaged (approx. 30-40 degrees) and abduct the limb to a near right angle (45 degrees). The affected knee is dropped towards to the table. Use of a sponge or positioning device can be placed under the knee. Extend the other thigh and support at hip level.
- The pelvis is rotated posteriorly to prevent its superimposition on the affected hip.
- Direct the CR through the hip joint. This is located midway between the anterior superior iliac spine and the symphysis pubis.
- In case of Hip Joint Replacement Surgery, the following views are required: AP Hip and Frog Leg Lateral Hip or Horizontal Shoot Through lateral if unable to acquire Frog Leg due to recent (within 3 weeks) replacement surgery

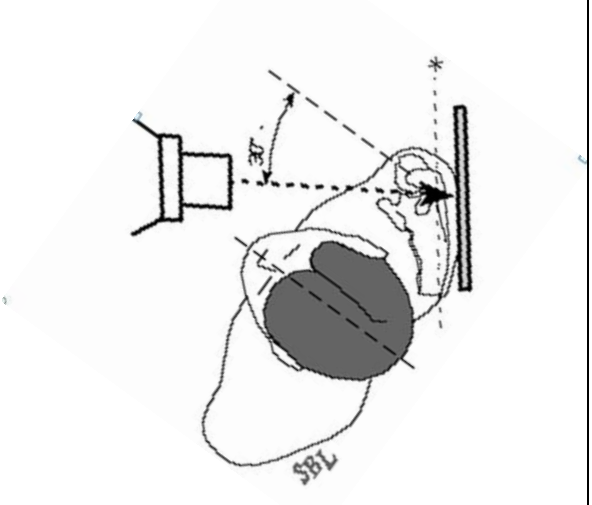


TECHNICAL REQUIREMENTS - Lateral Hip (Frog Leg view)

- FFD 40 Inches (100 cm) perpendicular to the table Bucky
- Film Size 24 x 30 cm (10” x 12”)
- Use R/L lead marker at the lateral side of the target hip
- Recommended kVP of 75

POSITIONING – Left and Right AP Shoulder (Grashey View) Radiograph

- Standing - Rotate the non-target shoulder 35-45 degrees away from the Bucky while keeping the target shoulder centered to the midline of the Bucky.
- The target scapula must be parallel to the plate and the humerus in contact with the Bucky.
- Abduct the target side arm slightly while internally rotating to rest the palm-side down on the abdomen.
- Align the CR to the glenoid joint of the target shoulder.
- X-ray beam crosshair reference point: 2 inches (5cm) medial and 2 inches (5cm) distal from the superolateral border of the shoulder.
- In case of Shoulder Joint Replacement Surgery, the Grashey view is still required for both shoulders



TECHNICAL REQUIREMENTS – Left and Right AP Shoulder (Grashey View)

- FFD 40 Inches (100 cm) perpendicular to the upright Bucky
- Film size 10” x 12” (24cm x 30cm)
- Recommended kVp range 70-80
- Use R/L lead markers on the Bucky outside the anatomy

Entering Subject Data in Electronic Header

In order to ensure patient confidentiality, please enter the following information into the electronic header:

- "**Patient Information**" enter the 3-digit Country Code, 3 Digit Site Number followed by the 3-digit Subject Number

  Example: 123101-001

- "**Date of Birth**" enter **DD-MMM-YYYY***

  Example:

  07-MAY-1945

  Example for countries not allowed to record DOB:

  01-JAN-1945

- "**Patient History**" enter: **Visit Name**

  Example: Screening

The possible entries for Visit identification:
Screening
Week 16
Week 24
Week 72-AA patients only
JR Pre-Operative
Post-OP Week 4
Post-OP Week 20
Event Driven
Unscheduled

Please enter the date of birth as indicated. If regulations prohibit your site from entering the day and month of the date of birth please enter 01 JAN and the correct Year of Birth for the subject. The Year of Birth must be the actual year for the subject.

DATA SHIPMENT TO BIOCLINICA

The data to be sent from the imaging site should include both the imaging study and the transmittal form. Submitting data electronically via the secure FTP website: https://smart.bioclinica.com/ is the required method of submission for this protocol. If your site cannot submit data electronically after attempts have been made to submit a test image, courier services can be utilized.

Electronic Data Transfer Using SMART submit

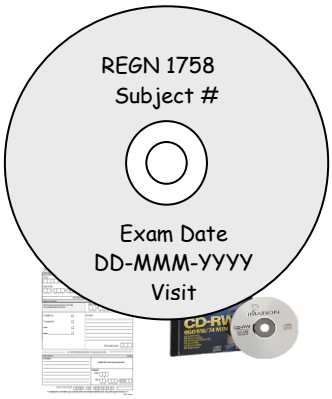
SMART submit is a web-based portal that allows sites to submit images via secure file transfer protocol (FTP). It eliminates delays and expenses associated with shipping images via courier. The Transmittal Form (TF) is completed and submitted electronically as well. Access to SMART submit or technical support may be requested by emailing the study team at Regeneron1602@bioclinica.com

Sending Data Using Courier Service – Digital

The complete package should contain a CD with imaging data and the completed TF.

Export the data to the CD in **uncompressed DICOM** format. Use an indelible marker to label directly on the CD with:

- Study Protocol Number: Regeneron 1758 (5322)
- Subject Identifiers (Site Number and Subject Number)
- Exam Date (DD-MMM-YYYY)
- Visit Name



Sending Data Using Courier Service – Film

Send original radiographic films to BioClinica.

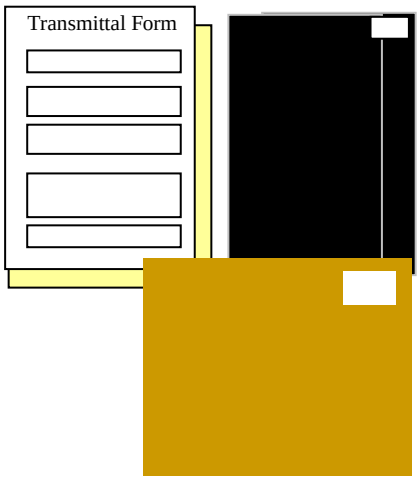
Affix a properly completed radiograph identification label to each radiograph (on front of film, right side – top or bottom) and complete the required information.

Do not wrap the label around the edge of the film.

Do not attach any other labels to the films.

Do not mark on the films. If you must, do not use grease or wax pens.

A Radiograph Transmittal Form must be filled out completely to accompany the radiograph (white and yellow pages).



Sending a Package to BioClinica

1. Complete the sender sections of the air waybill, keeping a copy for tracking purposes.
2. Place the white and yellow copies of the TF and the CD or Film for each patient into a shipping envelope.
   Retain the pink copy of the TF at the imaging center.
3. Call courier to schedule package pick-up.

Ship data to: Regeneron 1758 (5322) Study Team
BioClinica, Inc.
7707 Gateway Blvd., Third Floor
Newark, CA 94560 USA
Regeneron1602@bioclinica.com
Office: +1-415-817-8900