ZIMMER BIOMET

ROSA® Knee X-Atlas™ Training Guide

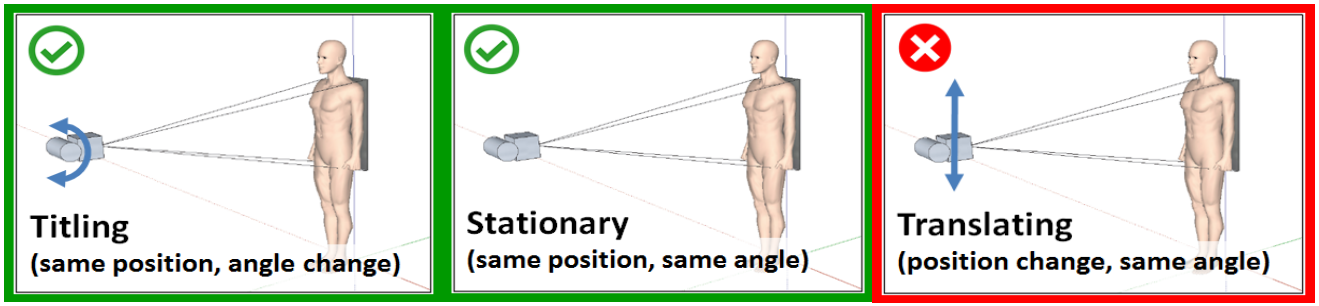
Personalized Solutions

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Check for country product clearances and reference product specific instructions for use. Not for distribution in France.

Requirements for Image Acquisition

- Long Length Board or Upright Bucky with source-tilting (no movement of tube up and down)
- Note: U-Arm and EOS X-ray Machines are currently not compatible with the ROSA X-Atlas Protocol
- Velcro bands and calibration puck marker
- Weight Bearing Positioning Platform
- Patient MUST be weight bearing
- AP and Lateral full leg length images (Hip to Ankle)



Requirements for Image Acquisition

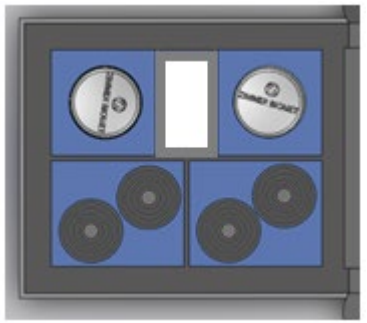
- Reusable X-Ray “Puck” Marker
  - Puck marker provided by Zimmer Biomet
  - Marker can be used multiple times
    - See expiration date on box
  - Clean Puck Marker after each use
    - Refer to IFU in X-PSI™ calibration kit for cleaning instructions

Puck Marker

X-Ray Marker 3D X-PSI
(Part number: 20-8017-020-00)
Quantity: 2

Velcro Bands
(2 sizes)

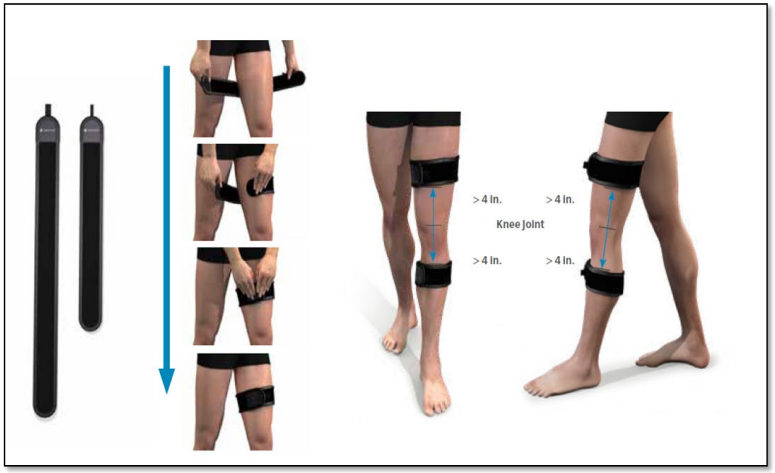
X-Ray Calibration Strap
(Two lengths available)
(Part number: 20-8017-022-00 and 20-8017-023-00)
Quantity: 2



X-PSI Calibration Kit
PN: **20-8085-020-00**

Step 1: Placement of Velcro Bands and Puck Marker

- Place Velcro bands firmly around upper thigh and calf:
  - Ensure bands are snug to avoid movement during imaging
  - Repositioning of the markers is not permitted during the procedure.
  - **If puck marker moves at any time, the exam will need to start over.**
  - **If a patient has to come back for repeat images you have to complete the ENTIRE study again (AP and Lateral images)**



- Puck marker should be placed:
  - Mid-way between AP and Lateral plane of leg (45° angle)
    - Allows good visualization of lead bb's in Puck Marker

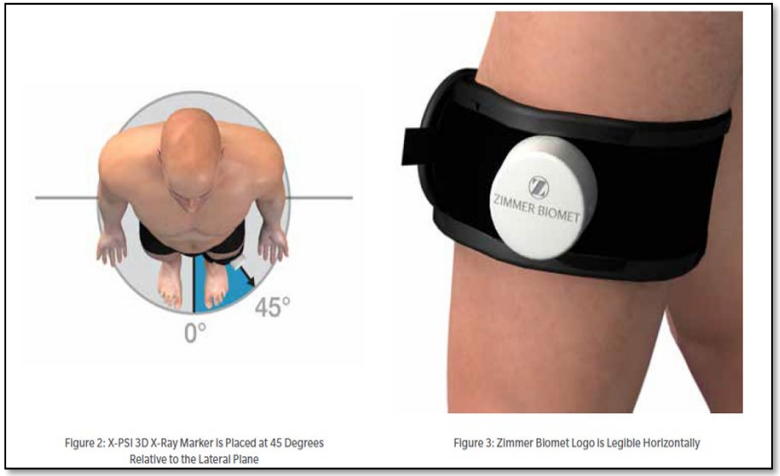


Figure 2: X-PSI 3D X-Ray Marker is Placed at 45 Degrees Relative to the Lateral Plane

Figure 3: Zimmer Biomet Logo is Legible Horizontally

Step 3: Patient Positioning and Image Acquisition

- SID: 72” – 90” is recommended
  - **Use same SID for both views**
  - **Must annotate SID on images**
- Unilateral
  - AP Standing
  - Lateral Standing

Image Acquisition- Long Length Board Method

Long Length X-ray Board

- AP Image
  - Position the patient to adequately cover the hip joint through ankle joint
  - Acquire image at the required SID ensuring there is no patient movement or movement of the puck markers

- Lateral Image
  - Position the patient to adequately cover the hip joint through the ankle joint
  - Acquire the image at the same SID (as AP image) ensuring there is no patient movement or movement of the puck markers

Image Acquisition- Upright Bucky Method

3 Separate AP X-ray Exposures

AP images: Direct central ray at knee joint

1. Exposure 1: Hip
   - Angle tube up (cephalic) and center at hip joint.
   - Take first exposure.
   - *Tube angle will vary depending on patient position*
2. Exposure 2: Knee
   - Return x-ray tube to 90°, align bucky tray and center at knee joint
   - Take 2nd exposure
3. Exposure 3
   - Angle the tube down (caudad), align bucky tray and center at ankle joint
   - Take 3rd exposure

- Acquire image at the required SID ensuring there is no patient movement or movement of the puck markers

Image Acquisition- Upright Bucky Method

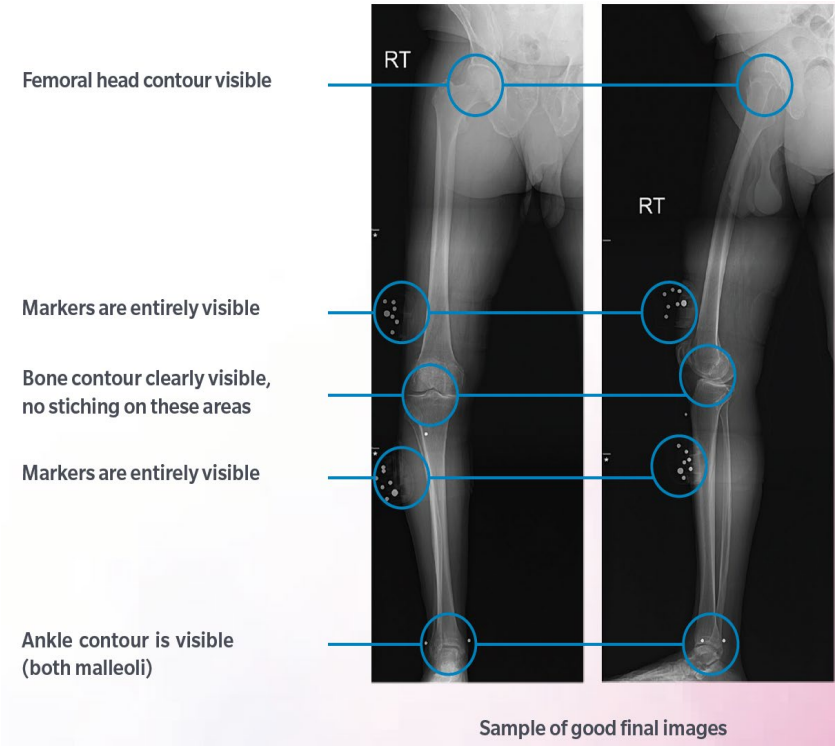
3 Separate Lateral X-ray Exposures

Lateral images: Direct central ray at knee joint

1. Exposure 1: Hip
   - Angle tube up (cephalic) and center at hip joint.
   - Take first exposure.
   - *Tube angle will vary depending on patient position*
2. Exposure 2: Knee
   - Return x-ray tube to 90°, align bucky tray and center at knee joint
   - Take 2nd exposure
3. Exposure 3
   - Angle the tube down (caudad), align bucky tray and center at ankle joint
   - Take 3rd exposure

- Acquire image at the required SID ensuring there is no patient movement or movement of the puck markers

Step 4: Image Acquisition & Stitching



Sample of good final images

Annotate all images with:

- SID
- Laterality (Left/Right)

Visibility of all required anatomy:

- Femoral head contour
- Ankle including both malleoli
- Entire knee joint
- Tibia Tuberosity visible on lateral knee
- Images should not stich or overlap in these areas
- Entire puck marker on both the AP and Lateral images

Machine parameters must be recorded in DICOM Tags:

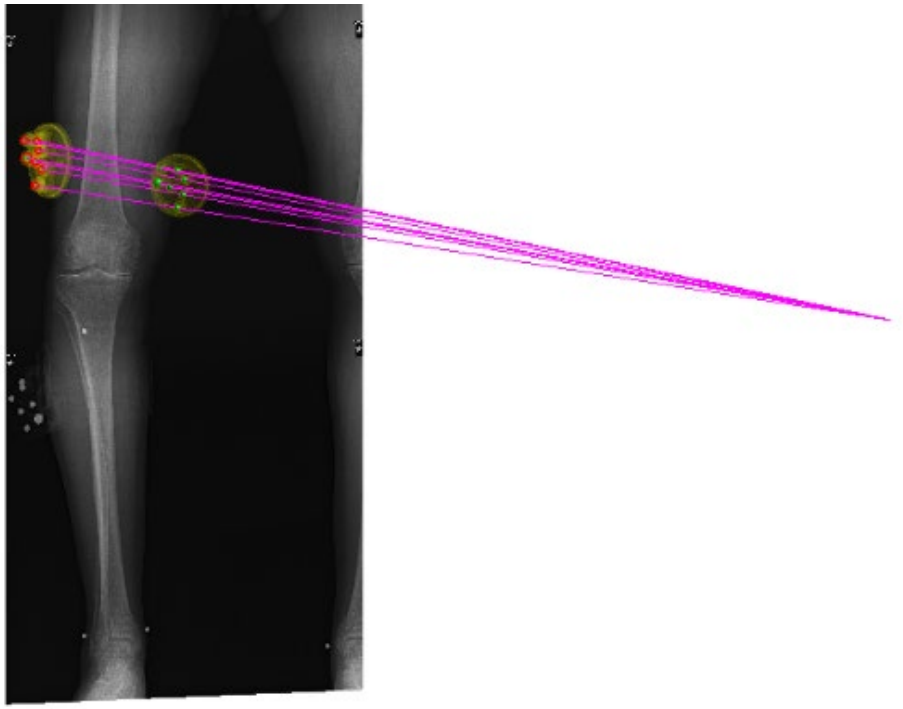
- Pixel Spacing
- Patient Gender (Male/Female)
- Laterality (Left/Right)
- Surgeon's name
- Patient's Name

- Do not engrave this on images, only needs to be present in DICOM tags
  - If images come across engraved then we cannot anonymize images. We see this if the DICOM tag Burned In Annotation (0028, 0301) is present and says "YES"

How Calibration Works

Puck Markers

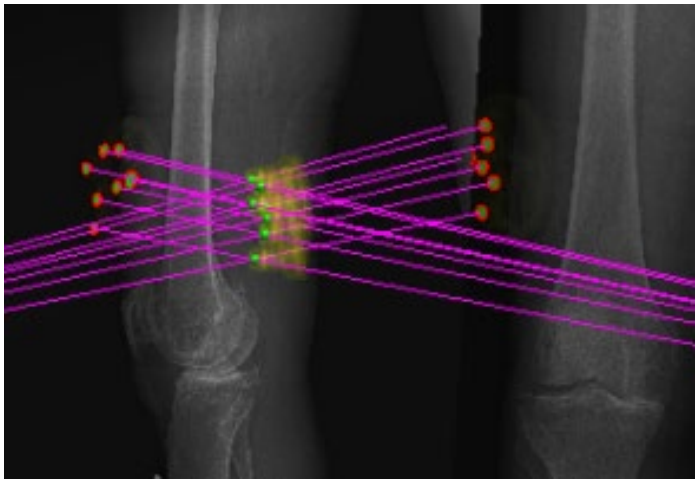
- Step 1: Detect the 3D markers in the X-rays

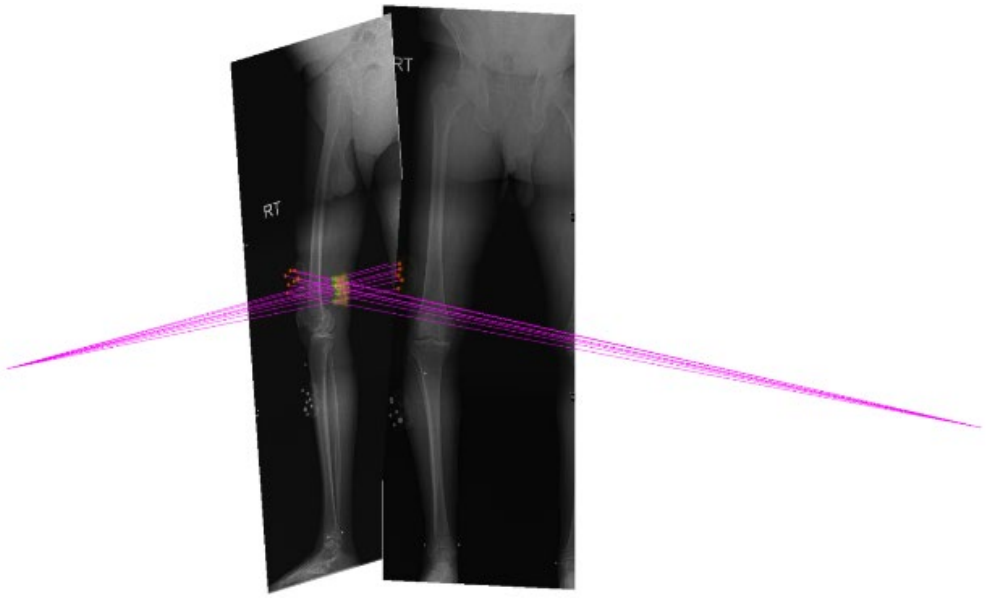


How Calibration Works

Puck Markers

- Step 2: Recreate the acquisition scene

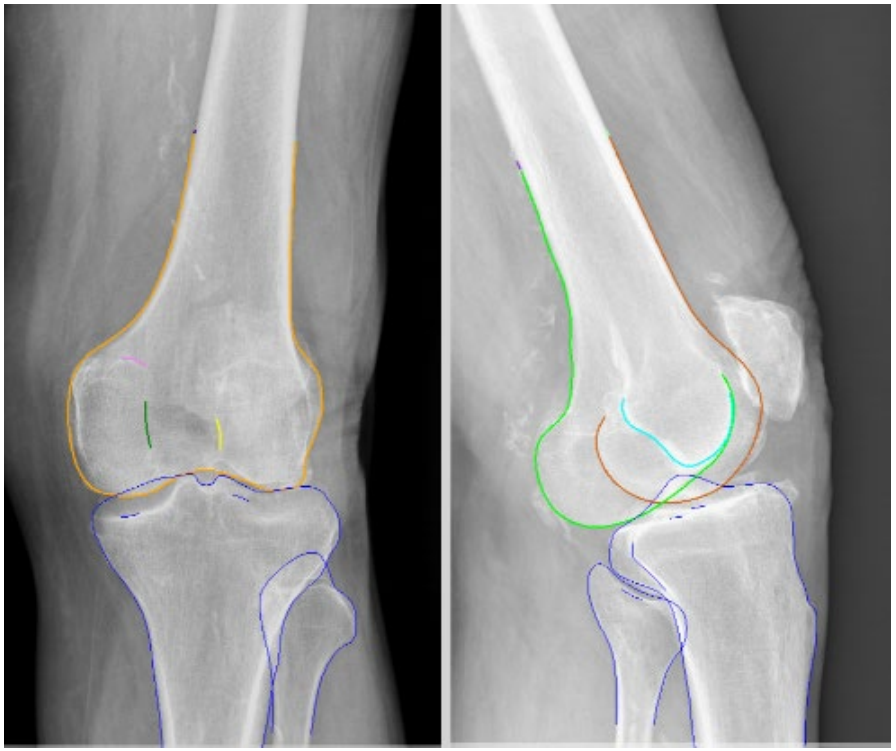


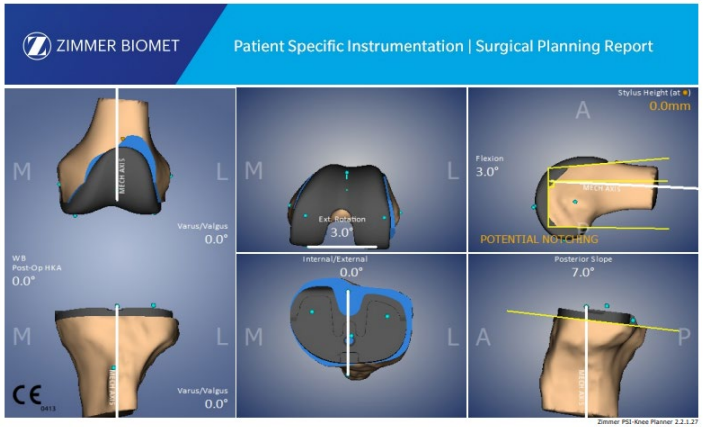


How Calibration Works

3D Bone Model

- Step 3: Segment the bone contours; define landmarks; create 3D surgical plan





Step 5: Image Transfer

- Zimmer Biomet will assist with set-up of image transfer via:
  1. Laurel Bridge
  2. VPN connection
  3. Nuance PowerShare

For questions or assistance, please contact:

personalizedsolutions@zimmerbiomet.com
574-371-3710

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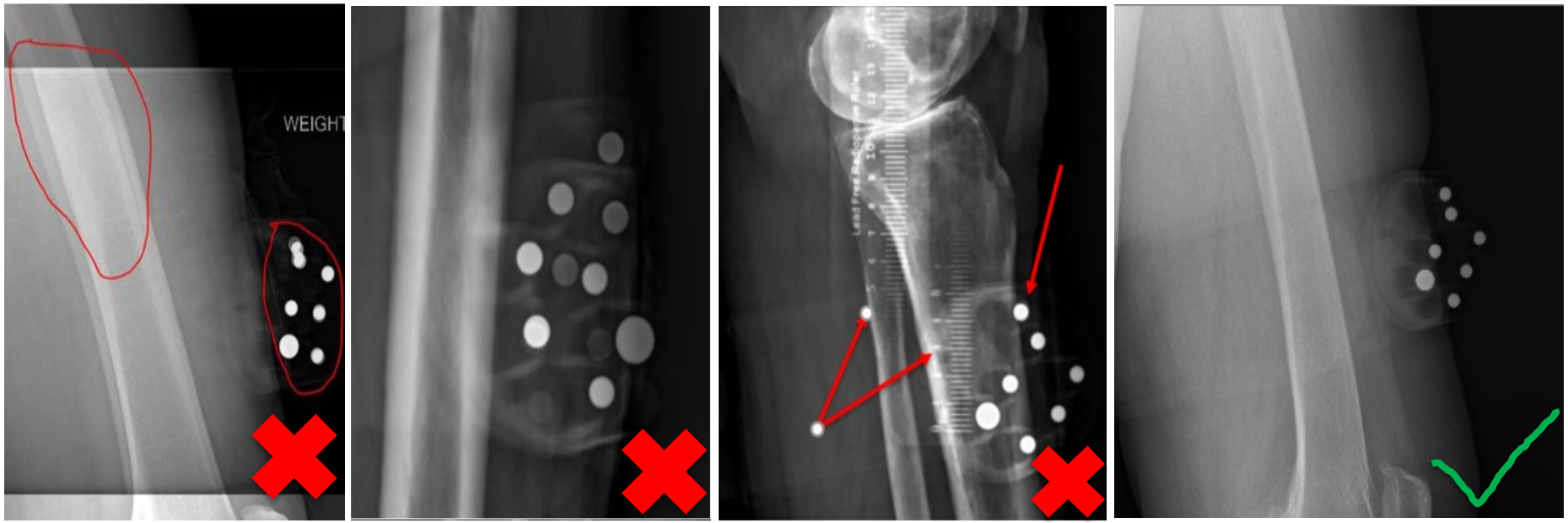
ROSA Knee Image Quality Review

Personalized Solutions

Patient Movement

- On stitched images look for steps in bone contour, mismatch in ruler alignment or burry/additional marker beads.
- Educate your patient on the process of obtaining the images, how the bucky feels moving behind them, and how important it is that they do not move.
- Consider a robust step stool with hand rails and backboard to prevent them from hitting the bucky.

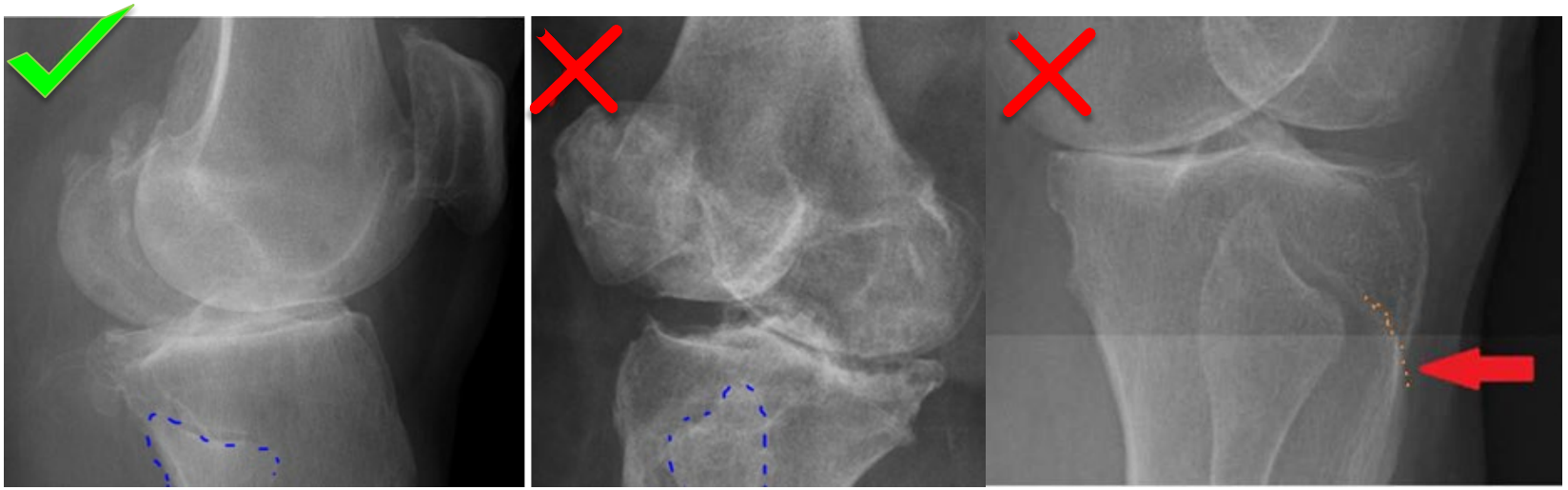


Lateral Knee

Anatomy affected by rotation on the lateral image

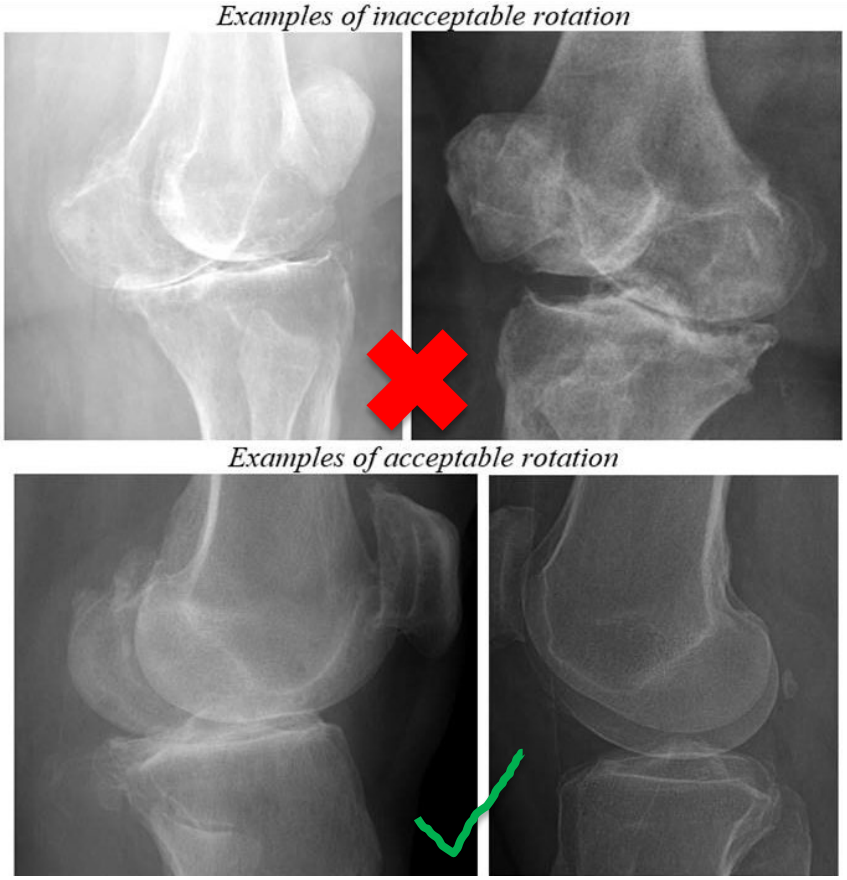
a) Tibial tuberosity
b) Fibula head
c) Tibial spine

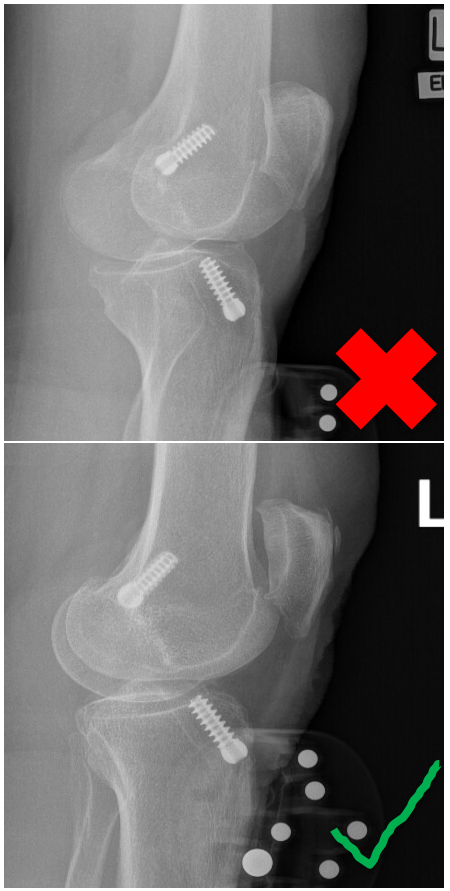
- Good rotation – ***fibula head sitting posterior to tibial spine*** and tibial tuberosity sitting "outside" bone.
- Bad rotation – fibula head sitting anterior to tibial spine and tibial tuberosity sitting "inside" bone.
- Strive for a true lateral that is less than 10 degrees rotated. If epicondyles are slightly offset it is OKAY (as seen in image below with green check mark)



Lateral Knee

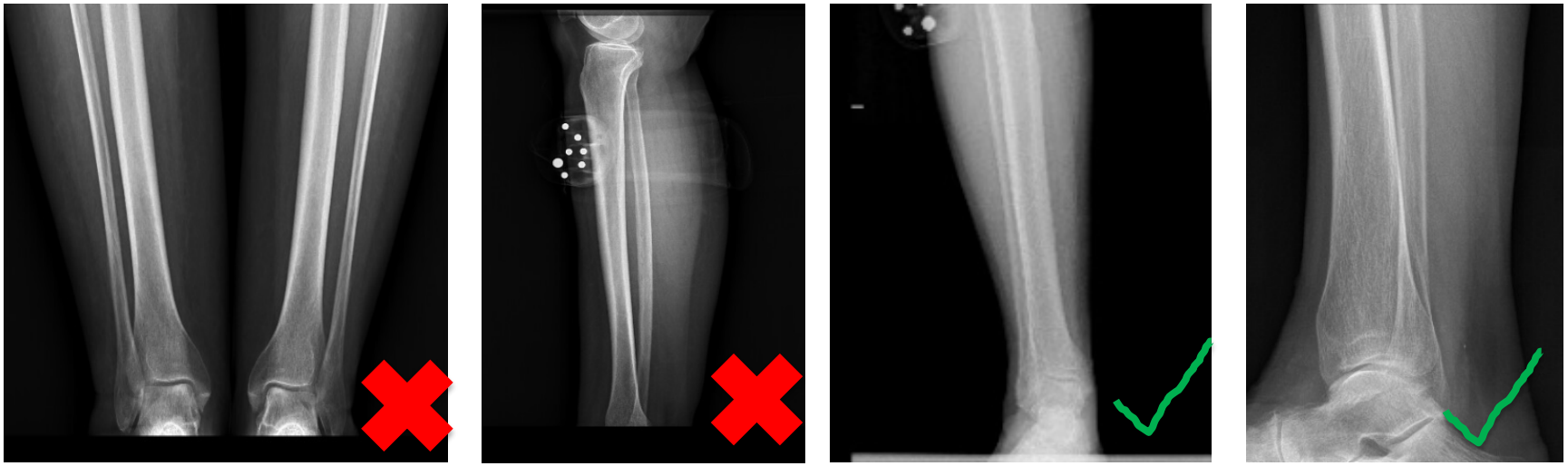
More examples of knee rotation





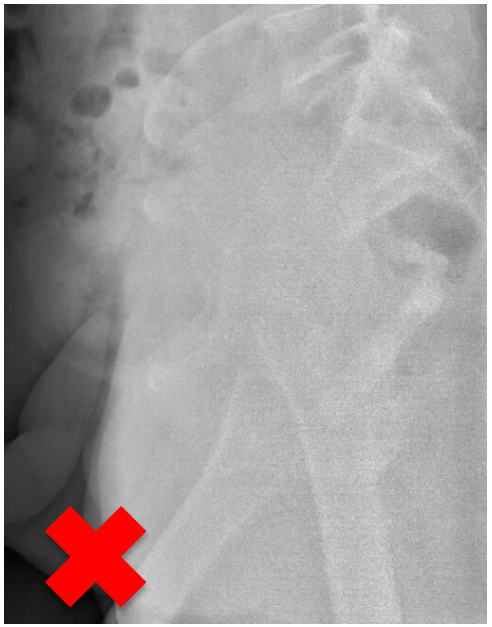
Ankle Joint Visibility

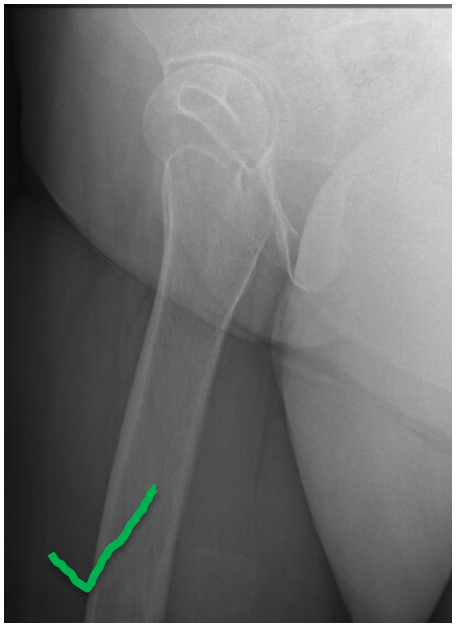
- Entire ankle joint must be visible including both malleoli



Hip Joint Visibility

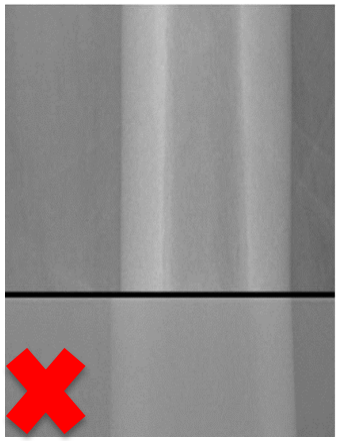
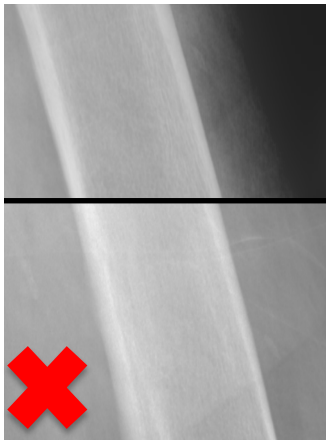
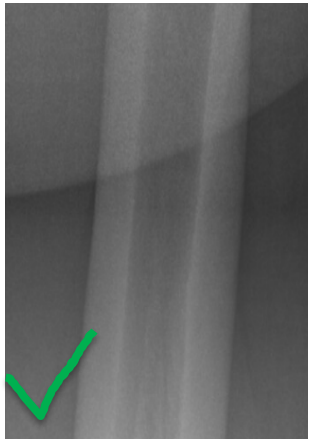
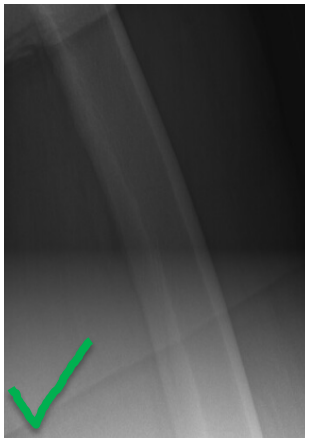
- The knee image is the most important, DO NOT compromise the knee image for hip visibility.
- Ensure the femoral head contour is visible.
- Use appropriate exposure settings and/or position the hip over the central chamber if using AEC.
- We can window and level on our end, but only so much.



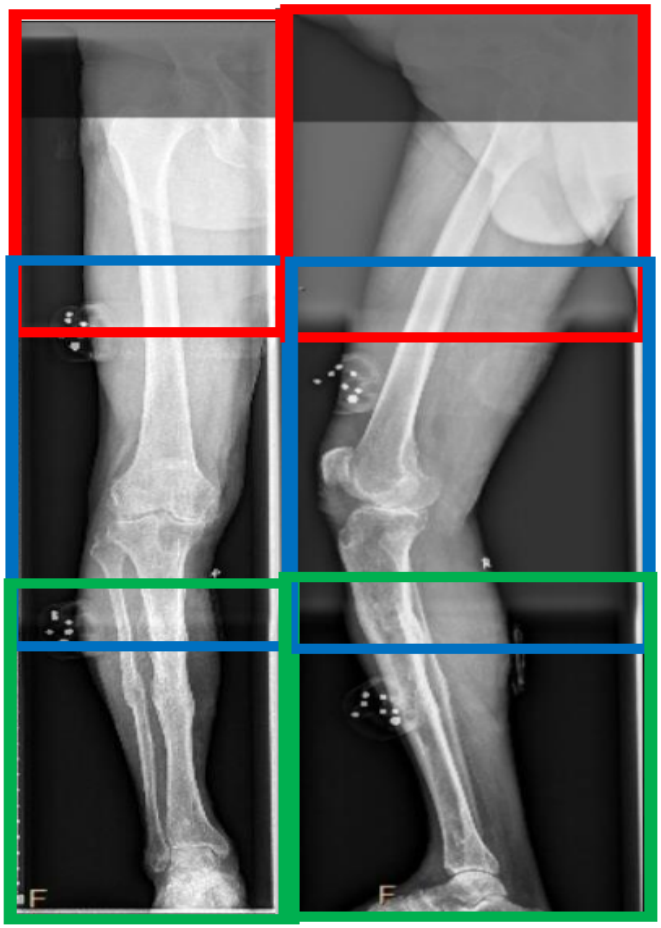


Not enough overlap of anatomy

- Ensure you have enough overlap of anatomy that when the images are stitched all anatomy is included from hip to ankle.
- Use a ruler or marker to ensure you are overlapping on each image.
  - Rule of thumb is 2 fingers of overlap

Adequate Overlap of Anatomy



Red- Cephalic angle of Hip Image ensuring you have entire hip joint and it is seen clearly

Blue- straight on shot of your knee; overlap at least 2 inches of anatomy from hip image; ensure you have a good lateral knee

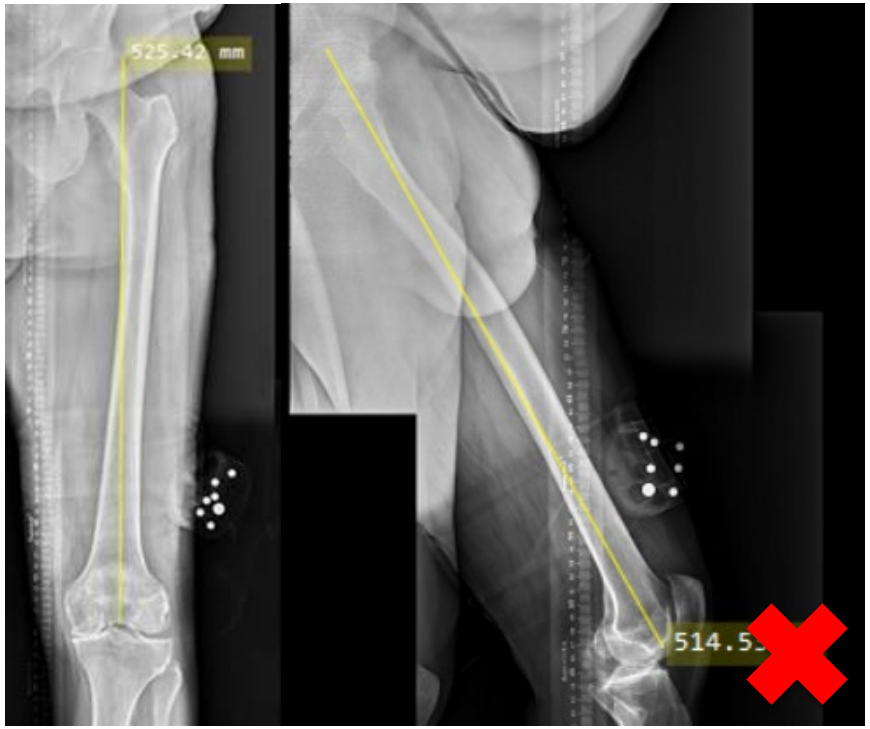
Green-caudle angle of ankle image; overlap at least 2 inches of anatomy from knee image ensuring you have entire ankle joint including both malleoli

Tibial Tuberosity Visibility

- Tibial Tuberosity is a critical landmark in the surgical planning for ROSA. If it is burnt out from technique then we will not be able to utilize the images.
- Ensure you have light enough technique that tibial tuberosity is visible on knee images.

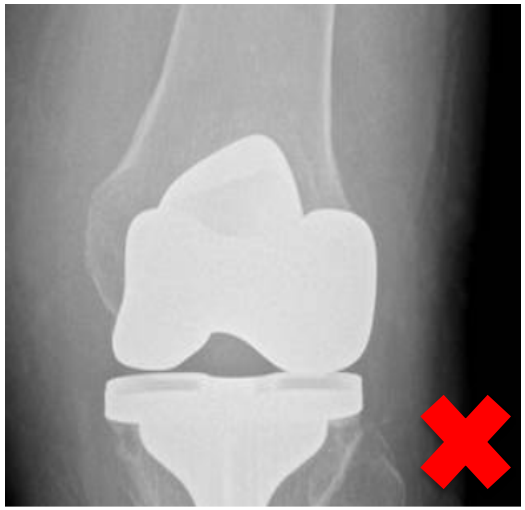
Cropping Images

- Turn off auto-cropping (in software application) and DO NOT apply manual cropping (post-processing)



Contraindication to ROSA Protocol

- If patient has a partial or primary implant then we are unable to create a ROSA plan and these patients should not be imaged with the ROSA Protocol as the images will get rejected.
- If there are screws or rods then this is a case by case scenario and the patients should be imaged and the Zimmer Biomet team will triage the images to decide if they can create a ROSA plan for the patient.



Tips and Tricks

- Explain to the patient exactly what you will be doing step by step so they know how many images are to be taken and that it is imperative that they do not move.
- Look closely at stitched images before letting patient go for shadow of calibration beads or anatomy (patient movement).
- After obtaining AP images, a trick for lateral is to frog the leg out FIRST, then position the knee and foot into your lateral position. Then rotate the patients hips last if it is uncomfortable for them. This helps open the hip joint to visualize the femoral head better.
- Ensure you have enough overlap of the anatomy by using a ruler, bead, or lead marker and overlapping them.

Reminders

- Annotate SID on images so Zimmer Biomet is aware of SID used.
- Once calibration markers are on patient they do not move the entire study. If they move, the entire study will need to be repeated.
- Ensure your knee is as lateral as you can achieve. If condyles are rotated more than 10 degrees than it should be repeated.
- **If you review the images and you would not send them to a Radiologist you do not want to send them to Zimmer Biomet for surgical planning.**
- If you have any questions please feel free to reach us at personalizedsolutions@zimmerbiomet.com or by calling 574-371-3710 and one of our team members will assist you.

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