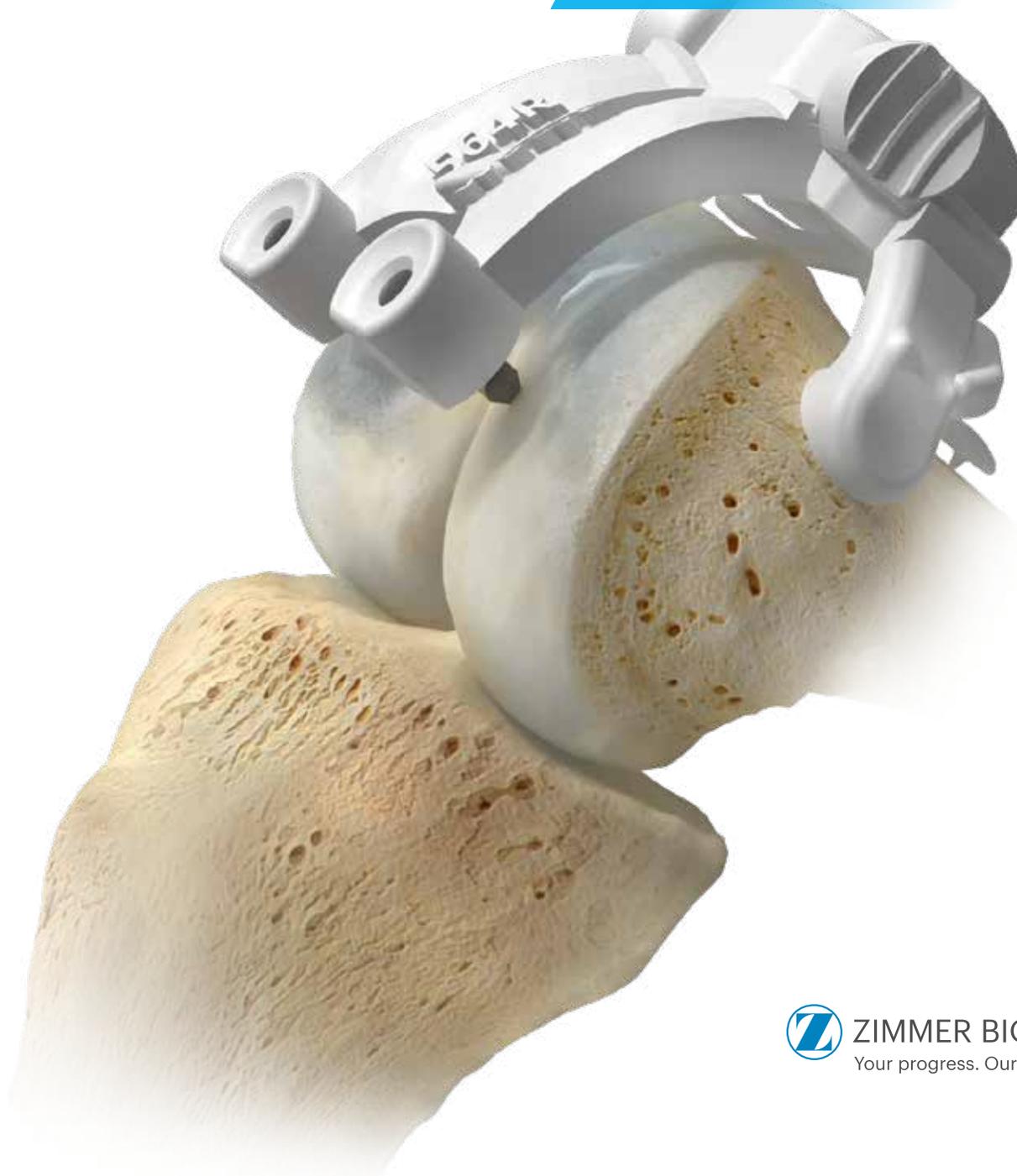


# Image Acquisition Protocol for X-PSI™ Knee System





# Table of Contents

**Overview** ..... 2

**Materials** ..... 5

**Patient Preparation**..... 6

**Machine Parameters**..... 7

**Imaging Procedure** ..... 8

**Image Transfer** ..... 11

**Contact Information** ..... Back Cover

## Overview

### Image Acquisition Protocol for the X-PSI Knee System

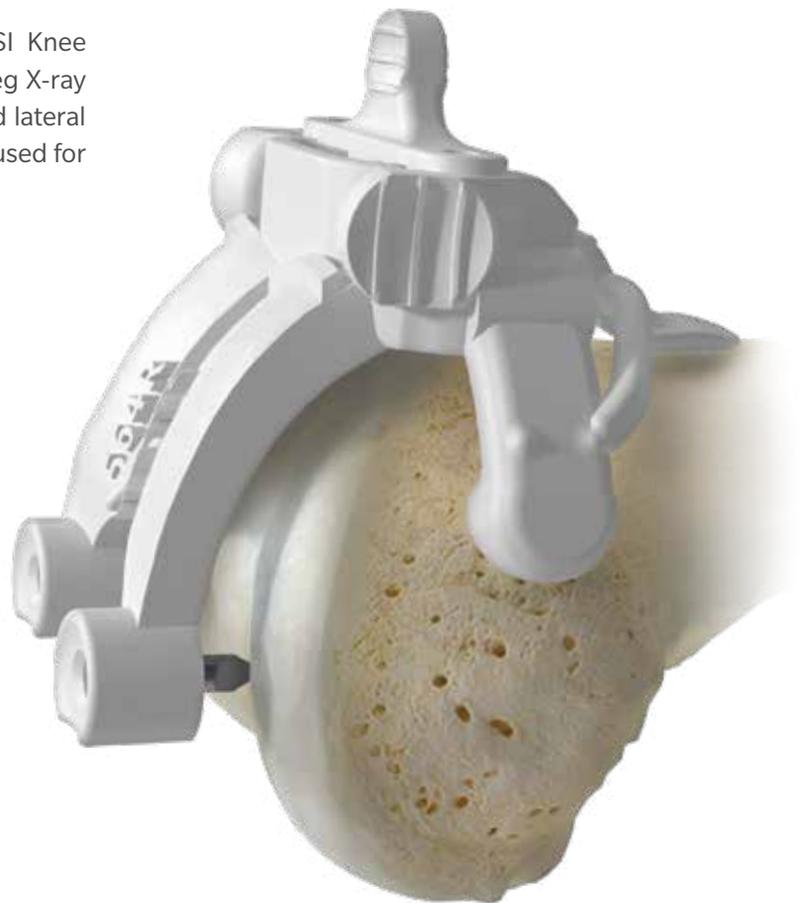
The X-PSI Knee System is comprised of surgical planning software used preoperatively, and surgical instrument components that include Patient Specific Guides to precisely align and position the implant components intraoperatively relative to patient's anatomical features per the surgical plan.

In the X-PSI Knee workflow, the patient X-ray imaging is used to construct 3D models of patient's bony structures and articular surfaces. The constructed model is then used to plan the location and orientation of the knee replacement implant components. The surgical planning software allows the surgeon to review, edit and approve the surgical placement of the implant components relative to the anatomical landmarks. Lastly, the Patient Specific Guides are fabricated to fit each patient's anatomy with features that set the relative placement of the implant components per the approved plan.

This protocol has to be used with the X-PSI Knee System. It describes the procedure for a full leg X-ray image acquisition in anteroposterior (A/P) and lateral (LAT) views. These two full leg image sets are used for creation of the Patient Specific Guides.

This protocol is intended for systems with source-tilting. If the full leg images acquisition is done by acquiring several separated images, an adequate overlap between the images is required for an accurate stitching. The stitching of the acquired images (in AP and LAT) by the scan center is optional but it is only acceptable with automatic image stitching. The separated acquired images can be sent to Zimmer Biomet for stitching and image processing. This protocol is not intended for acquisition with source translation and/or manual stitching method.

Consult the PSI Knee Planner User Guide for instructions on utilizing the Zimmer PSI Knee Planner Software for the X-PSI Knee System. For more information on how the system is used in the OR, refer to the X-PSI Knee System Surgical Technique.



## Overview (cont.)

### X-PSI Knee 3D Bone Reconstruction Flow



#### 1 Recreate Acquisition Scene

A 3D scene representing the position of the patient relative to the source and image detector during X-ray scanning is created.



#### 2 Define Patient Specific Landmarks

The patient's specific bony landmarks are defined on the A/P (anteroposterior) and lateral images.



#### 3 Define Patient Specific Bone Contours

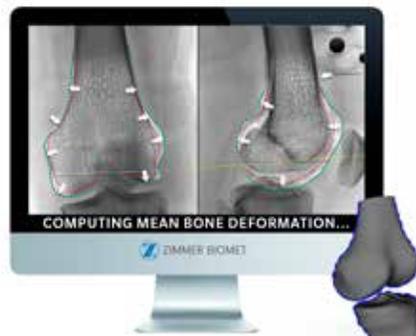
The patient's femoral and tibial bone contours are outlined on the A/P and lateral images, which capture unique features of the patient's bony anatomy.



— Projected Mean Bone contour  
— Patient's bone contour

#### 4 Mean Bone Positioning

A mean bone model for the femur and tibia is positioned and scaled in the 3D scene inside the patient specific contours.



--- Deformed Bone Contour  
— Projected Mean Bone contour  
— Patient's bone contour

#### 5 Mean Bone Deformation

An automatic bone deformation is performed to match the 3D mean bone model to the patient specific contours to fit the patient's anatomy.



--- Deformed Bone Contour  
— Added Cartilage

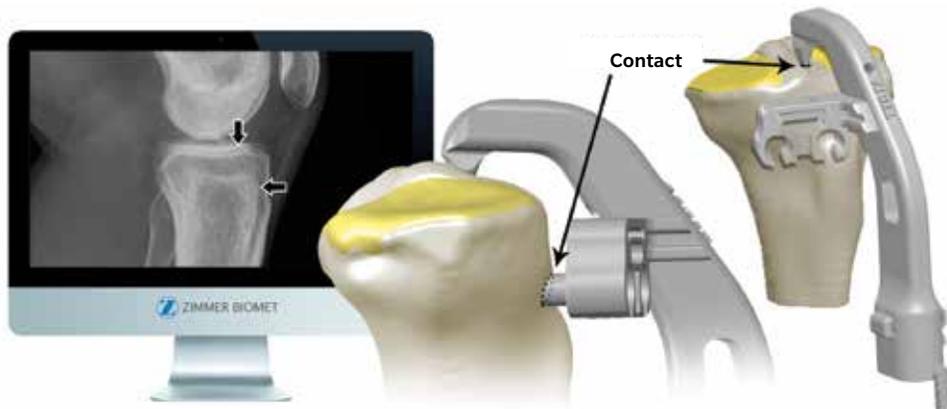
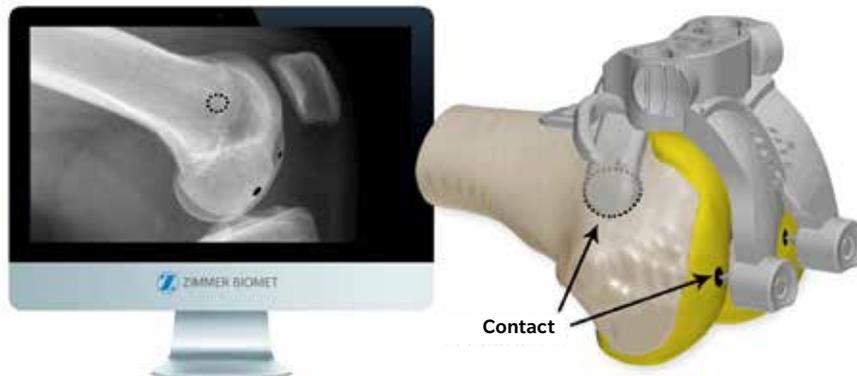
#### 6 Adding Cartilage

Finally, an estimated cartilage thickness is calculated and applied to the femoral and tibial bones.

## Overview (cont.)

### X-PSI Knee Patient Specific Guides

The X-PSI Knee Instrument Guides (jigs) are designed to have a unique fit to the patient's bones using cortical bone contact points and surfaces. The X-PSI Knee Guide's contact surfaces are restricted to the areas that are accurately reconstructed from the A/P and lateral X-ray images. Details on use of X-PSI Knee Guides are described in the "Intraoperative Guide" section in X-PSI System Surgical Technique.



**X-Ray Marker 3D X-PSI**

(Part number: 20-8017-020-00)

Quantity: 2

**X-Ray Calibration Strap**

(Two lengths available)

(Part number: 20-8017-022-00 and 20-8017-023-00)

Quantity: 2

## Materials

The X-Ray Marker 3D X-PSI includes seven radio-opaque spheres of different dimensions in a solid plastic housing. It is used to define the distance between the knee and X-ray source. The marker has a curvature on one side with the hook component for a hook-and-loop fibrous connection (i.e. Velcro®). This curvature imitates the curvature on the leg. This device needs to be positioned correctly on the X-ray calibration strap before X-ray acquisition. The X-ray calibration straps are available in two different lengths (short and long).

The X-Ray Marker 3D X-PSI and the X-ray calibration straps are cleanable and reusable. Refer to the X-PSI Knee System Instructions for Use for more details on cleaning method.

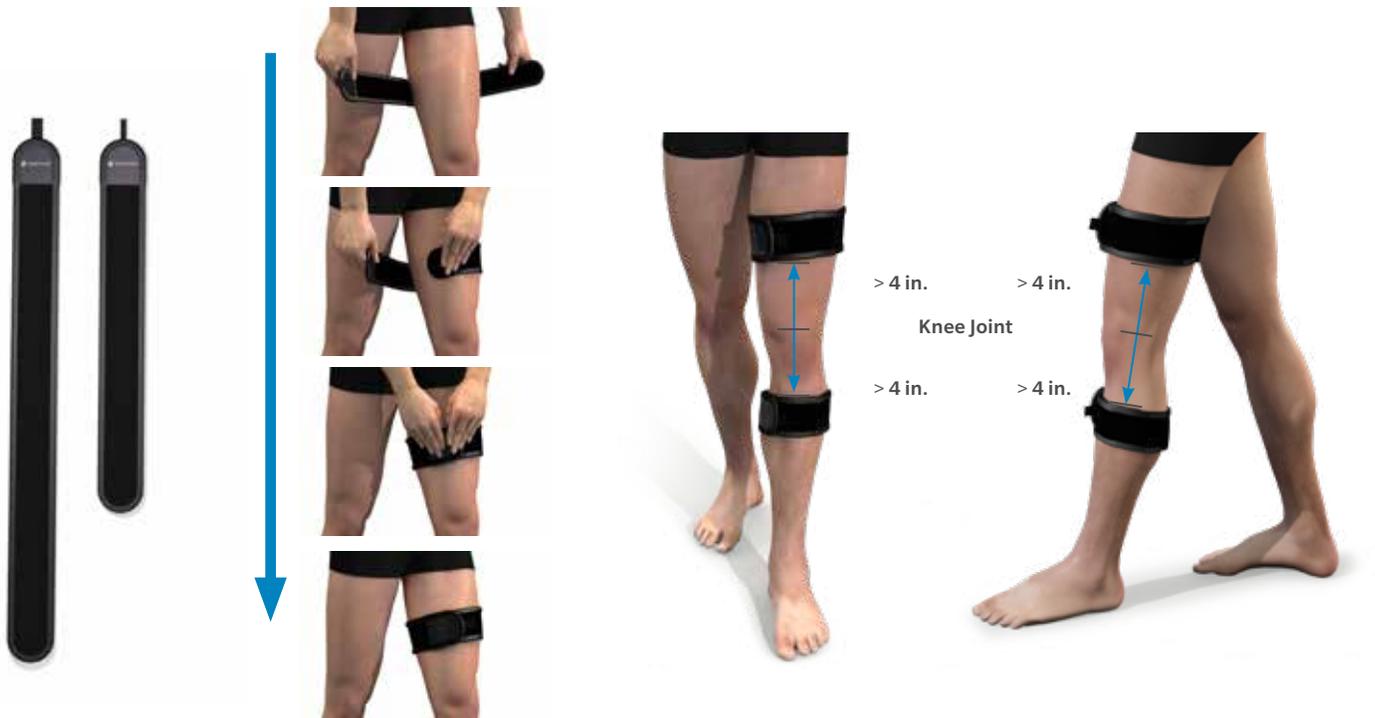


Figure 1: Positioning of X-ray Calibration Straps

## Patient Preparation

### Positioning of the X-Ray Calibration Strap

The X-ray calibration strap can be placed by the patient or the scan technician:

- Wrap one band firmly around the thigh and attach it with the hook end. The band should be at least four inches (10 cm) from the knee joint line.
- Wrap one band firmly around the calf and attach it with the hook end. The band should be at least four inches (10 cm) from the knee joint line.

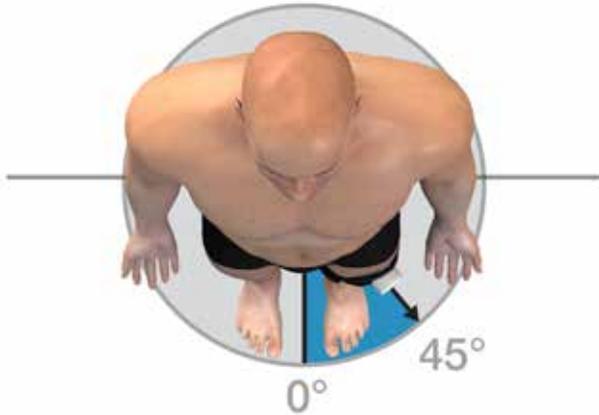


Figure 2: X-PSI 3D X-Ray Marker is Placed at 45 Degrees Relative to the Lateral Plane



Figure 3: Zimmer Biomet Logo is Legible Horizontally

## Patient Preparation (cont.)

### Positioning of the X-Ray Marker 3D X-PSI by the Scan Technician

The X-Ray Marker 3D X-PSI should be positioned by the scan technician per the following instructions:

- Before positioning the X-Ray Marker 3D X-PSI, make sure both of the X-ray calibration straps are stable on the patient's leg.
- Install each X-Ray Marker 3D X-PSI, by sticking the curved side of the marker (with the hook face) to the strap. Press the marker firmly onto the strap. Both of the X-Ray Marker 3D X-PSI should be placed at about 45 degrees relative to the patient's lateral plane (Figure 2). The following visual reference cues must be respected:
  - The Zimmer Biomet Logo must be legible horizontally
  - The curvature of the device must match that of the leg

Make sure that each X-Ray Marker 3D X-PSI is stable on both X-ray calibration straps. The markers need to stay in place during the imaging process and while changing the patient's position from frontal to lateral.

## Machine Parameters

### SID (Source to Image Distance)

- A distance of 72 inches, or 180 cm, is recommended. Set to the fixed value to capture the full leg with automatic source-tilting. It is recommended to use the same standard fixed value for every patient.
- Make sure this value is included correctly in the image information or engraved on the images.

### Imaging Spacing

- A value less than 0.25 mm is recommended.
- Make sure this value is included correctly in the image information.

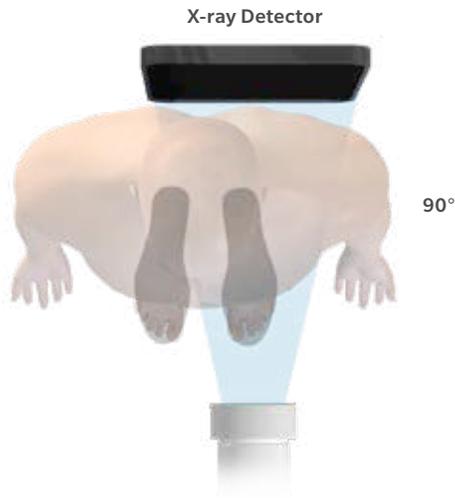


Figure 5: Patient Position for A/P Exposure

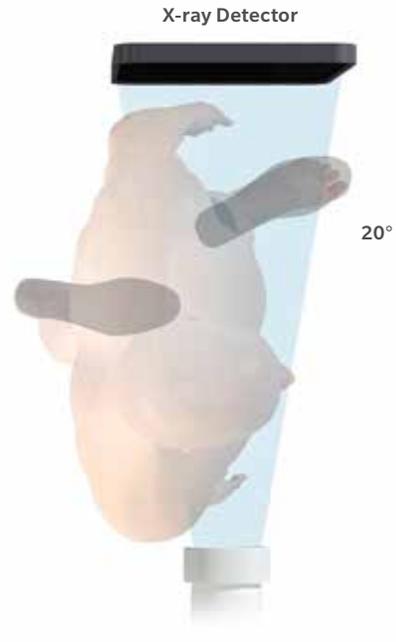


Figure 6: Patient Position for LAT Exposure

## Imaging Procedure

Position the patient in standing position with the leg in extension. The imaging needs to be done only in stable standing position, weight bearing on both legs.

Minimize the distance between the patient and the X-ray detector.

Select an adequate SID value to cover the entire leg from above the femoral head to below the ankle joint. The knee joint and all bony landmarks (femoral head contour and ankle) should be visible on the final A/P and lateral stitched images. The SID value should be fixed during the entire study. **Do not** alter this distance between different images.

### A/P Exposure

Place the patient in the frontal position with both legs towards X-ray source. The imaging needs to cover the entire leg from above the femoral head to below the ankle joint.

### LAT Exposure

Place the patient in lateral position and offset the leg as recommended. The surgical leg should be towards the X-ray detector. The imaging needs to cover the entire leg from above the femoral head to below the ankle joint.

#### ⓘ Note:

- No patient movement between any of the sequential images in A/P or LAT exposure is allowed.
- The femoral head contour and ankle must be clearly discernable on both images.
- The entire X-Ray Marker 3D X-PSI should be visible on the final A/P and lateral stitched images.
- The X-Ray Marker 3D X-PSI should stay in place during the image process and while changing from the frontal to lateral position. Repositioning of any of the markers is not permitted during the procedure.



Figure 7: Example of Stitched images A/P and LAT

## Imaging Procedure (cont.)

### Stitching Requirement

The stitching can be done automatically on A/P and LAT images by available software at the scan center if possible. All acquired images (full leg image (if any) and separate leg regions image acquisition in AP and Lateral) should be sent to Zimmer Biomet.

An adequate overlap between images should exist to make an accurate stitching possible. It is recommended that images are not stitched/overlapped in the knee joint area.

The scan technician should check the following on full A/P and LAT images, before the image transfer:

#### **Visibility of all required anatomy:**

- Femoral head contour
- Ankle
- Entire knee joint
- Ideally images should not stitch/overlap in these areas

#### **Images should not stitch/overlap at these areas:**

- Visibility of entire X-Ray Marker 3D X-PSI on both the A/P and LAT images

#### **Following machine parameters, as well as patient parameters, are recorded correctly and are the same for all images:**

- SID
- Pixel spacing
- Patient gender (male/female)
- Laterality (left/right)
- Surgeon's name
- First letter of the patient's first name and first two letters of the patient's last name, OR/PSI case ID



Figure 8: Example of Good Image Quality and Stitching in A/P and LAT

## Imaging procedure (cont.)

### Stitching Requirement (cont.)

The femorotibial junctions and bone contours are clearly visible. The X-Ray Marker 3D X-PSI are entirely visible on images and stitching points are outside of the knee joint region. For an example of acceptable images, please refer to Figure 8.

**To:** personalizedsolutions@zimmerbiomet.com

**Subject:** X-PSI Patient Acquisition Details

This email is to send the image acquisition details for the patient, uniquely recognized according to the following reduced information:

- Surgeon name
- Image center name
- Patient operating side (left/right)
- Patient gender (male/female)
- First letter of patient first name
- Two first letters of patient last name
- Source to image distance (SID) in millimeters
- Image pixel spacing in millimeters
- Sender name and contact information

### Image Acquisition Requirements in the DICOM Header

Make sure that the following patient reduced information and image acquisition details are included in the DICOM images. If not, create and send an email using the above template.

# Image Transfer

## Image Transfer through SMS

**Note:** Reduced identification is not required.

- 1 All acquired images (full leg image (if any) and/or separate leg regions image acquisition in AP and Lateral) should be sent to Zimmer Biomet.

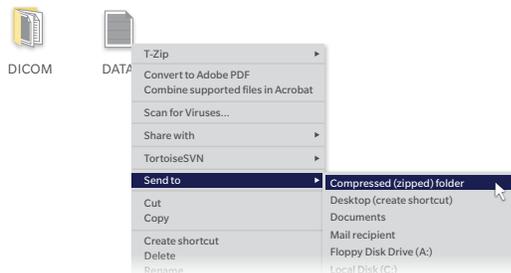
**Note:** There should now be more than two images sent to Zimmer Biomet.

- 2 Save the scan in the DICOM file format.

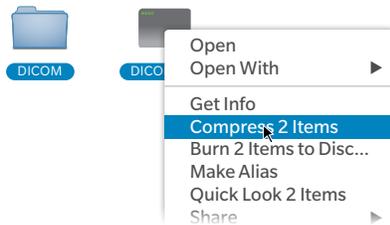
**Note:** There should now be more than two images sent to Zimmer Biomet.

- 3 Compress the DICOM folder using a zip (compressed) file format. First, copy the folder containing all DICOM images on your desktop. Then, right click the folder and select compress.

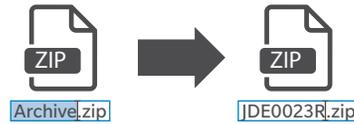
### Compressing the DICOM files on a PC:



### Compressing the DICOM files on a Mac:



- 4 Rename the ZIP (compressed) file with X-PSI Case ID provided by Zimmer Biomet corresponding to the patient.



- 5 Upload the images on Zimmer SMS: [www.zimmersms.com](http://www.zimmersms.com).

Transfer the images by clicking “Upload Scans” in the corresponding case which will bring you to the upload page.

Case #1571550	PENDING
<b>Details</b>	
Site: 01 T0000 LOS ANGELES, CA	
Sales Associate / Team: CAS SALES REP	
Account: GENERAL SURGERY CENTER (00004)	
Surgeon: JANE DOE	
Patient: JOHN SMITH (Male / Age 89, 01-01-1925)	
Coverage:	
Surgery: Sep 11, 2014 7:00 AM (Sep 11, 2014 4:00 AM)	
Pickup: Sep 11, 2014	
<b>Surgery Information (Show All)</b>	
Description:	
Procedure: Knee - Total (2002)	
Body Side: LEFT	
<b>Zimmer PSI (Show All)</b>	
CAS PSI Case: Yes	
Warnings: Left: Delay Approval, Delay Scan (View)	
Scan Center: GENERAL SCAN CTR (0003)	
Scan Date: Aug 26, 2014	
Left Body Side	
Case ID: TNO411L25JS14US	
Scan images:	<a href="#">UPLOAD SCANS</a> <b>Click</b>
Status: Case Created/Awaiting Images	

## Image Transfer (cont.)

### Image Transfer Through Other Transfer Methods

(CD, DVD, USB, FTP, other transfer methods such as [www.wetransfer.com](http://www.wetransfer.com), [www.hightail.com](http://www.hightail.com))

**Note:** Reduced identification is always required.

Do not use “ALTE” (DICOM export via PACS) to save the images. “AGFA” or preferably, a CD should be used. If you are located in Europe Middle-East & Africa (EMEA), refer to the EMEA PSI Logistics Guide.

The imaging center will be responsible to reduce the patient identification of the DICOM image set. The reduced identification shall remove any element permitting to identify the patient. This includes but is not be limited to:

- Patient name
- Date of birth
- Social security/insurance number
- Phone number(s)

Follow the steps below for the transfer of images:

1 All acquired images (full leg image (if any) and/or separate leg regions image acquisition in AP and Lateral) should be sent to Zimmer Biomet.

**Note:** There should now be more than two images sent to Zimmer Biomet.

2 Save the scan in the DICOM file format.

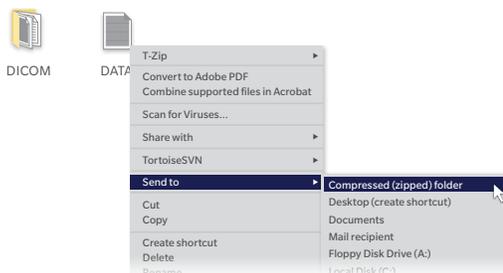
3 Reduced identification the DICOM images as shown in Table 1:

Table 1 Reduced Identification Parameters

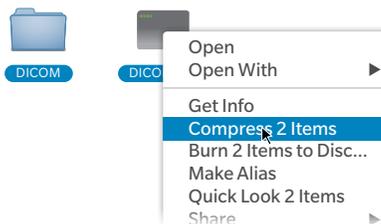
DICOM Field	Patient Different values for every case; provided by the Zimmer Biomet Sales Associate.  Value
PatientName	XXX1111R (Zimmer Biomet Case ID provided by Zimmer CAS) Can be 8 or 15 characters
PatientID (optional)	XXXX11111 (Hospital Patient ID)
PatientBirthDate	1900/01/01 (If date can't be deleted, put this actual value)

4 Compress the DICOM using a zip (compressed) file format. First, copy the folder containing all DICOM images on your desktop. Then, right click on the folder and select “Compress”.

Compressing the DICOM files on a PC:



Compressing the DICOM files on a Mac:



5 Rename the ZIP (compressed) file according to the first row of Table 1:



6 Transfer the zip file to Zimmer Biomet per chosen method (CD, DVD, USB, FTP, or other web transfer service).\*

**Note:** When using [www.wetransfer.com](http://www.wetransfer.com), [www.hightail.com](http://www.hightail.com) or any other web transfer service, send images to [psi-xray@zimmercas.com](mailto:psi-xray@zimmercas.com).

\* Zimmer Biomet does not endorse or recommend any particular transfer method. It is the responsibility of the transferring party to ensure that the transfer method complies with applicable privacy and security laws and regulations.



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