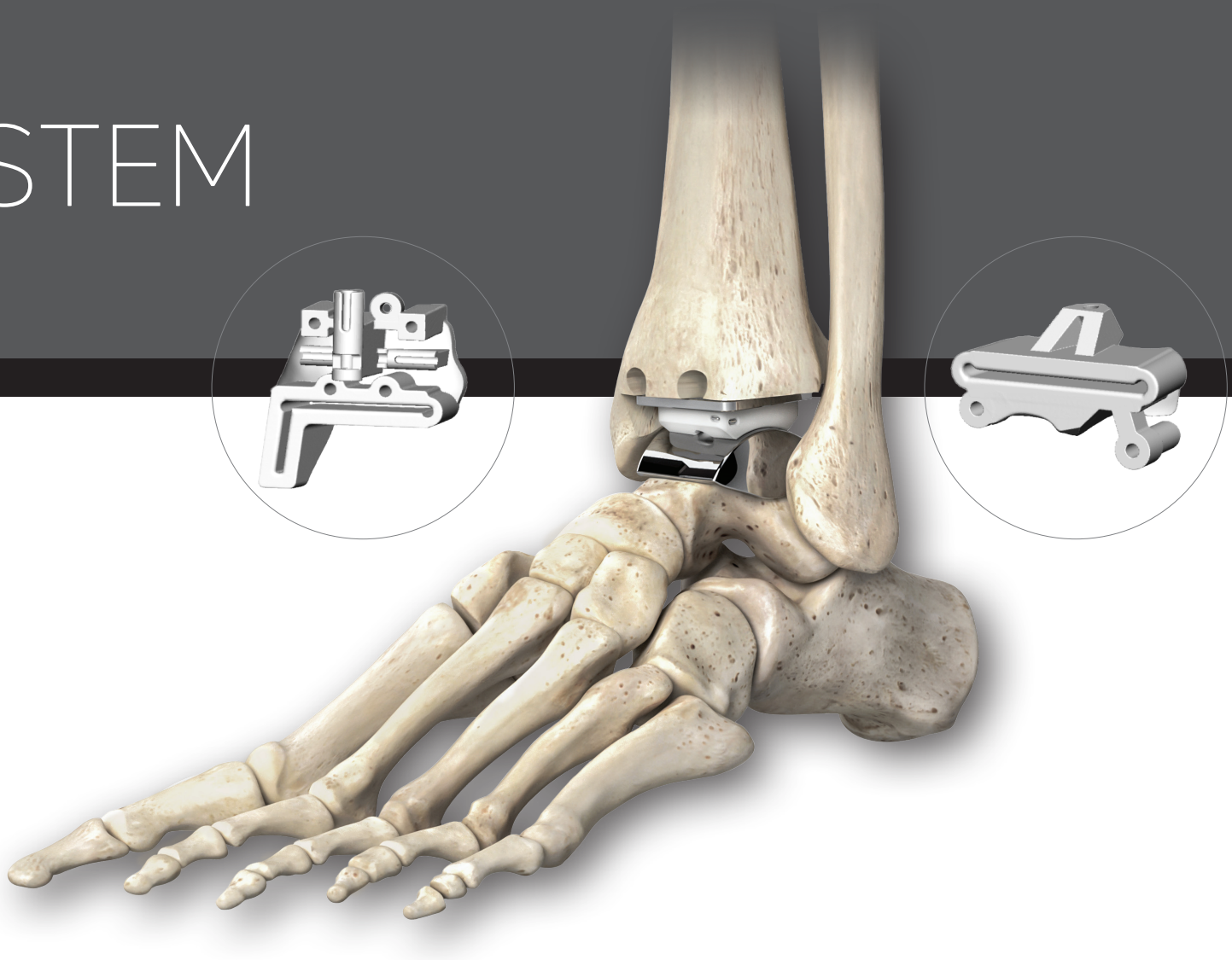
CTP

CT SCAN PROTOCOL

enovis™

STAR™ PSI SYSTEM

TOTAL ANKLE REPLACEMENT



PURPOSE

This computed tomography (CT) scan protocol consists of a localizer and a detailed scan requirement for STAR™ PSI System. The CT scan quality must identify clear bony edges and surface detail critical for the production of accurate patient-specific surgical instruments. Deviations from this protocol may result in unusable images.

For more information or questions about the scan protocol, please contact 3DSystems via email at dataimport@3dsystems.com or by phone at 1-844-643-1001.

PATIENT PREPARATION

- Remove any non-fixed metal prosthesis, jewelry, or zippers that might interfere with the region to be scanned.
- Make the patient comfortable and instruct them not to move during the procedure.
- Position patient supine feet-first with foot secured in an upright position and the ankle in a 90-degree neutral position (FIGURE 1A). A foot holder/brace should be used to ensure foot alignment. If this is not possible due to a patient's condition, such as severe contracture, ensure the CT scan contains slices through the ball of the foot.
- If implant is present in the contra-lateral limb, bend limb out of the field of view (FIGURE 1C). This will prevent artifacts from affecting the scan quality.

FIGURE 1A

CORRECT: ANKLE IN A 90˚ NEUTRAL POSITION

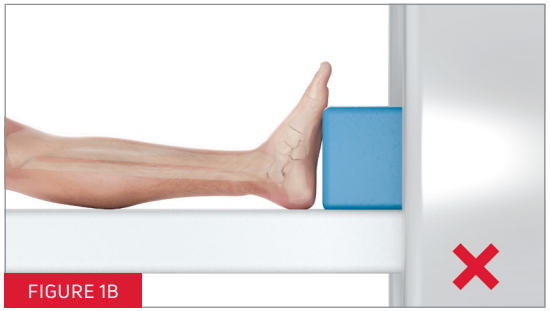


FIGURE 1B

INCORRECT: ANKLE NOT IN A 90˚ NEUTRAL POSITION

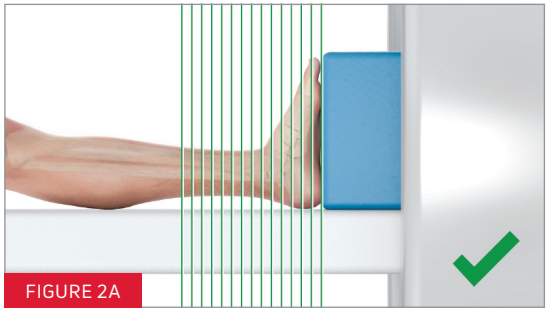
FIGURE 1C

IF THERE IS A METAL IMPLANT PRESENT IN THE CONTRALATERAL LIMB, BEND THE LIMB OUT OF THE FIELD OF VIEW

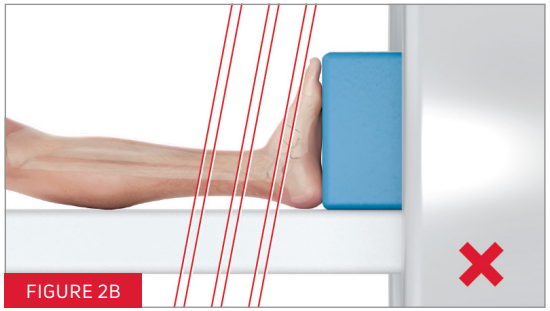
SCAN REQUIREMENTS

CT IMAGE

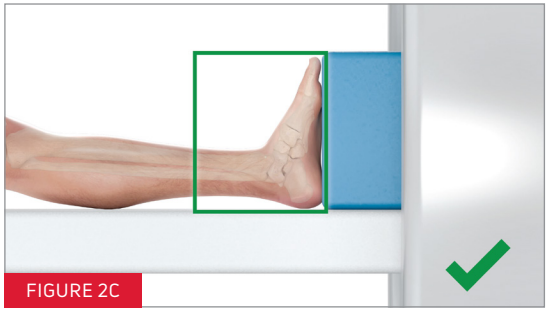
- Use true axial slices (FIGURE 2A). Oblique slices are not accepted (FIGURE 2B).
- **Do not** alter the X or Y centering between scan regions. Center points must be identical.
- **Do not** change the table position between images so that all images create one unified volume.
- Gantry tilt is not accepted.
- **Region of Interest:**
  - Provide full knee-to-foot scout images, both AP (Anterior-to-Posterior) and Lateral.
  - There are 2 scan regions, one for the knee and one for the foot & ankle. Scan the foot completely past the ball, and include the toes (FIGURES 2C & 2D).
- **Scan Range:**
  - Maintain a single coordinate system for both the knee and foot & ankle scan regions.
  - Provide a contiguous scan within regions, with no gaps and no overlapping.
  - Scans should be taken from head-to-foot, not foot-to-head (FIGURES 2E & 2F).



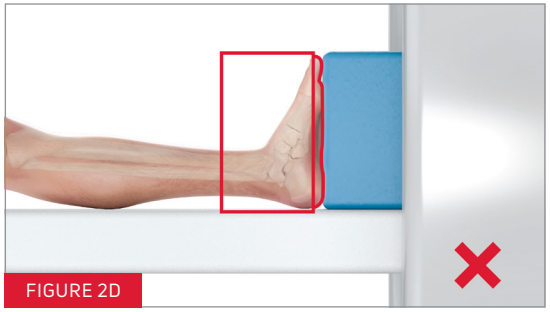
TRUE AXIAL SLICES REQUIRED



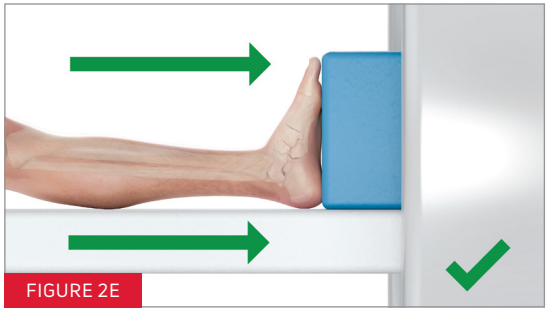
OBLIQUE SLICES NOT ACCFEPTED



FOOT SCANNED PAST THE BALL WITH TOES INCLUDED



ENTIRE FOOT NOT SCANNED



SCANNED CORRECTLY FROM HEAD TO FOOT

SCANNED INCORRECTLY FROM FOOT TO HEAD

SCAN PARAMETERS

SCANNER TYPE	Multi-detector row CT with number of detector rows ≥ 16
SCAN MODE	Helical or Axial
REGION OF INTEREST	**Knee:** Include minimum 5cm proximal and 5cm distal to the knee joint. **Foot & Ankle:** Include minimum 10cm proximal to the ankle joint, and scan past the ball of the foot. Toes must be fully captured.
KVP	120-140 (automatic voltage selection, if available)
mA(S)	As given by the automatic system
PITCH	≤ 1
DETECTOR CONFIGURATION	Single collimation ≤ slice thickness
SLICE THICKNESS	1.25mm or smaller
SLICE SPACING	1.25mm or smaller
MATRIX	512 x 512
FIELD OF VIEW (FOV)	250mm is preferred. Up to 500mm accepted.
RECONSTRUCTION ALGORITHM/KERNEL	Use a **standard or bone algorithm** without edge enhancement. **Always provide this reconstruction.** If metal is present, the metal artifact reducing algorithm should be provided along with the standard CT scan.
HU SCALE	If metal implants are present, use a HU scaled of 16-bit

CT Scan compatibility for the STAR PSI System has been validated using the equipment and parameters listed below.

MAKE	Siemens
MODEL	SOMATOM Perspective
PIXEL MATRIX	512x512
KVP	130
SLICE THICKNESS	1mm
ALGORITHM	B705
GANTRY TILT	0
FIELD OF VIEW	250 mm
EXPOSURE	600msec
TUBE CURRENT	**Knee:** 22mA **Ankle:** 29mA

NOTE: CT scan parameters not explicitly outlined in the CT Protocol are at the discretion of the radiology team and should follow the default CT scanner parameters.

KNEE REGION

- 5mm interval spacing (or smaller)
- Include minimum 5cm proximal and 5cm distal to the knee joint.
- Field of view (FoV): Always verify that the FoV encompasses the region of interest and does not exceed 500mm.

FOOT & ANKLE REGION

- 1.25mm interval spacing (or smaller).
- Include minimum 10cm proximal of the ankle joint and scan past the ball of the foot.
- Toes must be fully captured.
- Field of view (FoV): Always verify that the FoV encompasses the region of interest, and do not exceed 250mm.

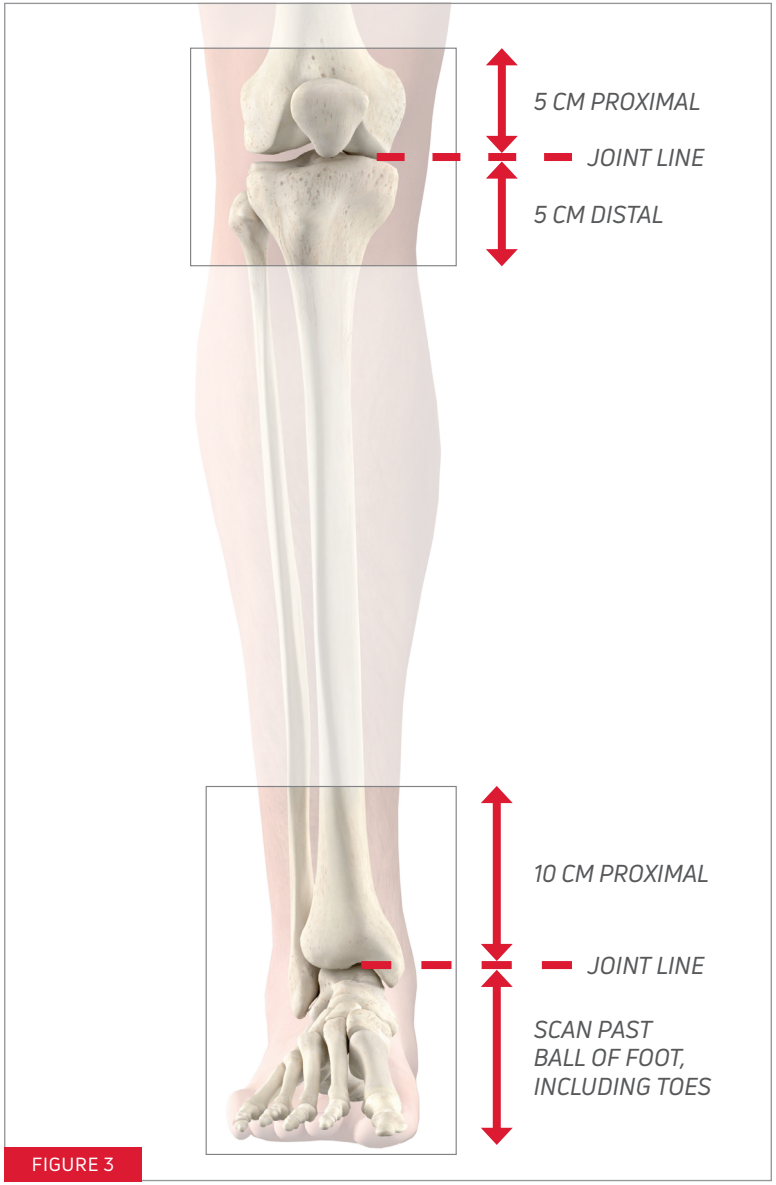


FIGURE 3

REGION OF INTEREST SCHEMATIC FOR CONTINUOUS KNEE AND FOOT & ANKLE SCAN

CONSIDERATIONS

- Scan patient up to 6 months in advance of the procedure to ensure anatomic changes are minimized. If the patient's anatomy changes significantly since the time of the CT scan, the patient specific guides and models should not be used, even if the time period of 6 months has not expired.
- If metallic components are present in the operative leg, it may not be possible to obtain an image of sufficient quality to support the creation of a STAR PSI cut guide. If metal components are present in the non-operative leg, attempt to move the non-operative limb from the scan region. See Page 2, Patient Preparation.

POST-SCAN EXAMINATION

The Physician and CT Technologist should verify the following:

- Patient position and image acquisition orientation/scan direction are correct.
- Scan dataset includes knee and foot & ankle regions.
- Image slice thickness is correct.
- If metal is present, the metal artifact reducing algorithm should be provided along with the standard CT scan.

DATA SET TRANSFER

FROM CT TECHNOLOGIST TO SURGEON/SALES

Archive image data in uncompressed DICOM only on CD, network or USB.

Do not include the DICOM viewer.

FROM SURGEON/SALES REP TO DJO PRODUCT TEAM

1. Go to https://enovis.enhatch.com/.
2. Log in. (If you do not have an account yet, please contact your local sales representative.)
3. Follow steps to initiate a new case.
4. Zip CT scan (uncompressed DICOM images) and X-ray images into one file.
5. Upload zip file to initiated case.

⚠ RADIATION SAFETY RESOURCES

- www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct
- www.imagewisely.org/imaging-modalities/computed-tomography
- For general radiation safety concerns, refer to: www.cdc.gov/nceh/radiation/alara.html

NOTES

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