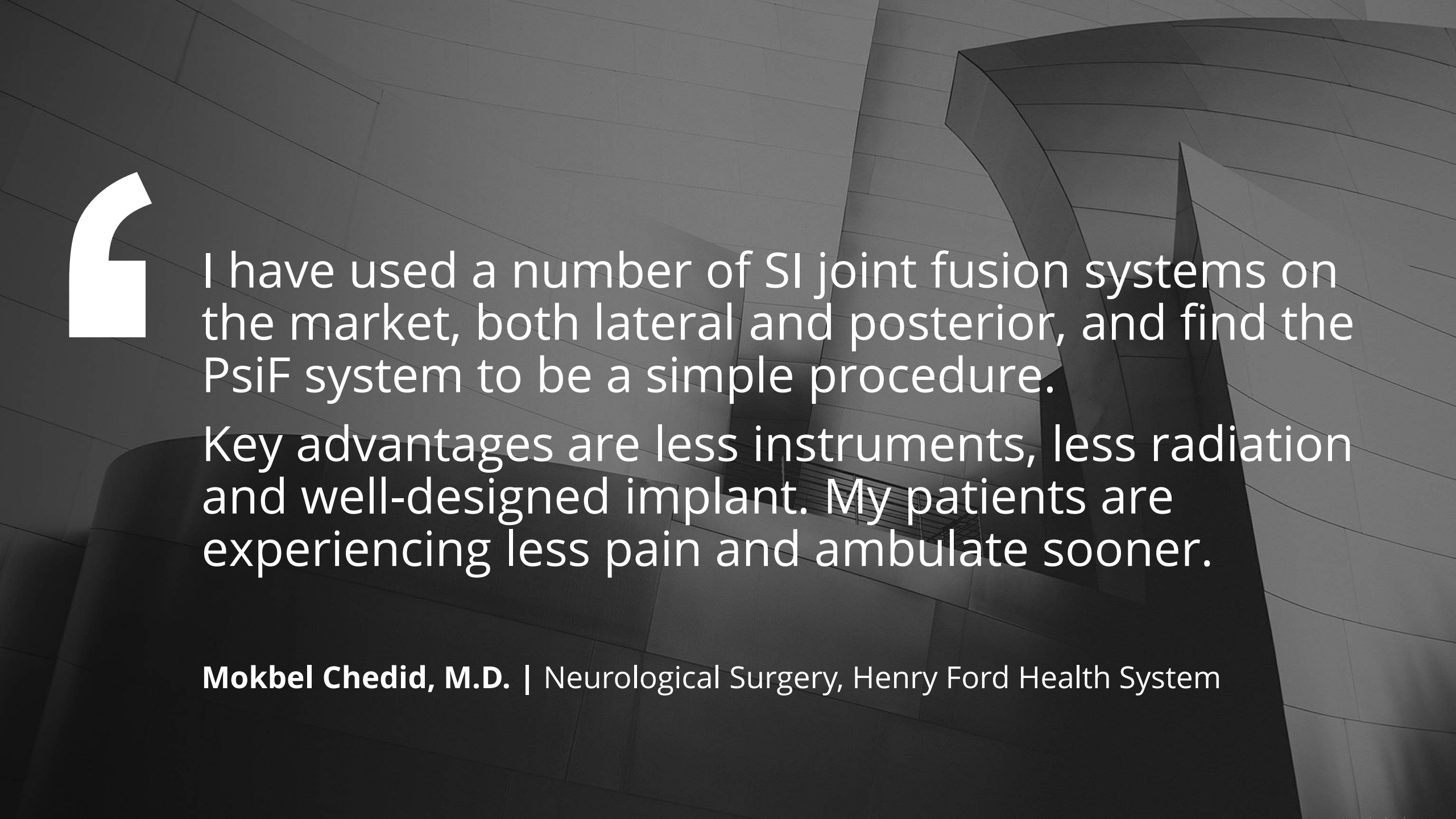
Omnia Medical

Professional Education

PsiF Bioskills Course

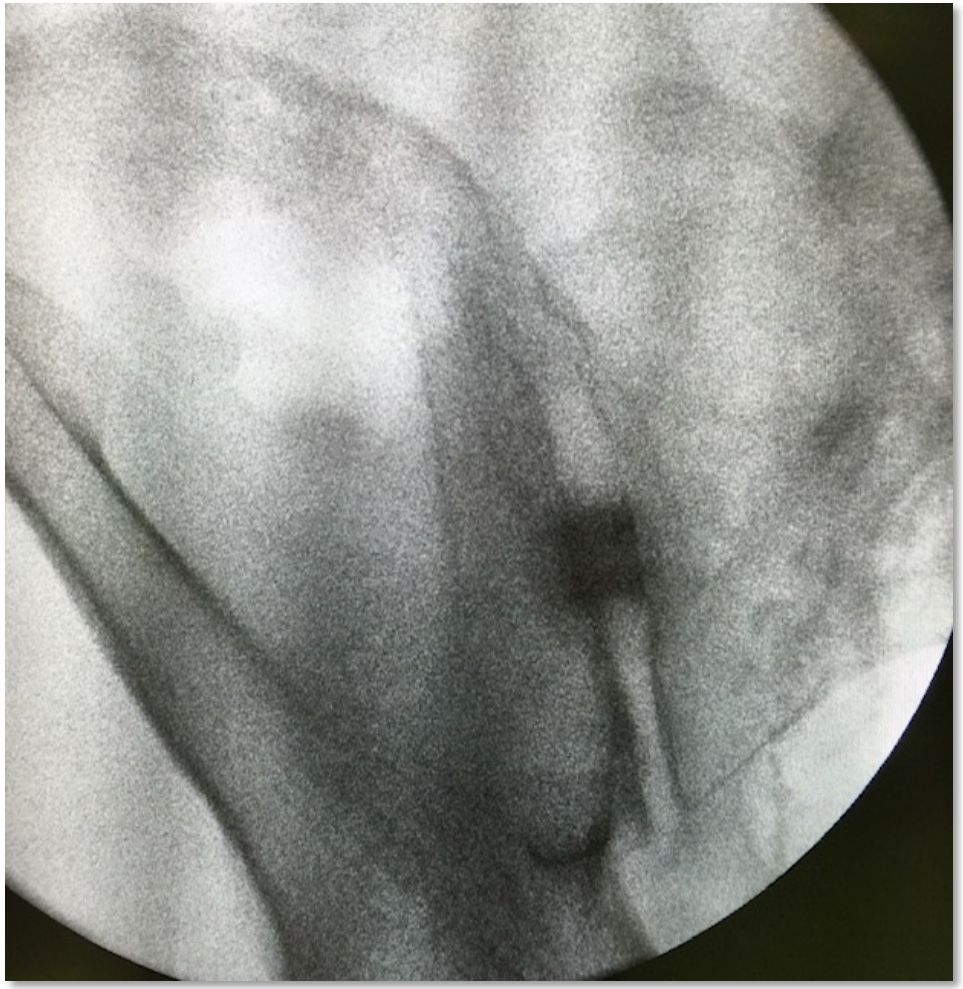


I have used a number of SI joint fusion systems on the market, both lateral and posterior, and find the PsiF system to be a simple procedure.

Key advantages are less instruments, less radiation and well-designed implant. My patients are experiencing less pain and ambulate sooner.

Mokbel Chedid, M.D. | Neurological Surgery, Henry Ford Health System

1st Case March, 2014



Agenda

- The Problem
- Causes
- Symptoms
- Diagnosis
- Treatment Options
- The Posterior Approach
- Coding & Reimbursement
- Insurance Coverage
- Medical Necessity
- SI Joint Studies

Diagnosis

The Problem We Aim to Solve

- Back pain is the leading cause of disability in the world[1]
- 80% of the population will experience low back pain in their lifetime[2]
  - LBP persists > 1 year in 20% of cases[3]
- 15-30% of individuals experience chronic LBP due to SIJ dysfunction[4]
- Conservative management of SIJ dysfunction can be costly and ineffective[5]

Causes

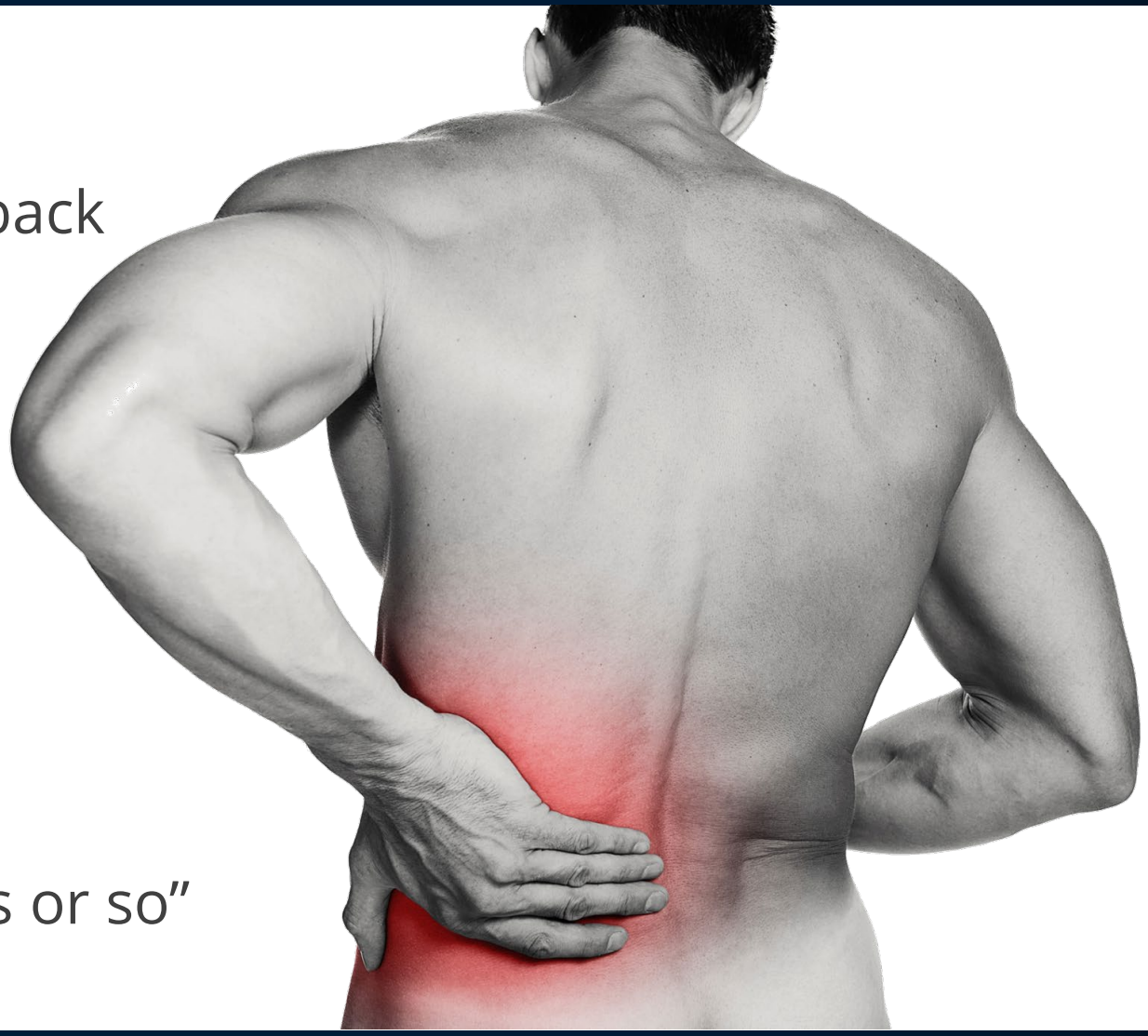
- There are several factors that can predispose someone to SI joint pain, most of which include forces that place a significant amount of stress to the joint, including:
  - Disruption of the lining of the joint
  - Ligament injury
  - Arthritis
  - Spondyloarthropathy
  - Trauma
  - Infection
  - Cystic disease
  - Pregnancy
  - Obesity
  - Spinal deformities
  - **Previous spine surgery***

15-30% of patients presenting with low back pain actually have SI joint dysfunction[6]

Up to **75%** of postoperative lumbar fusion patients will develop significant SI joint degeneration after 5 years[7]

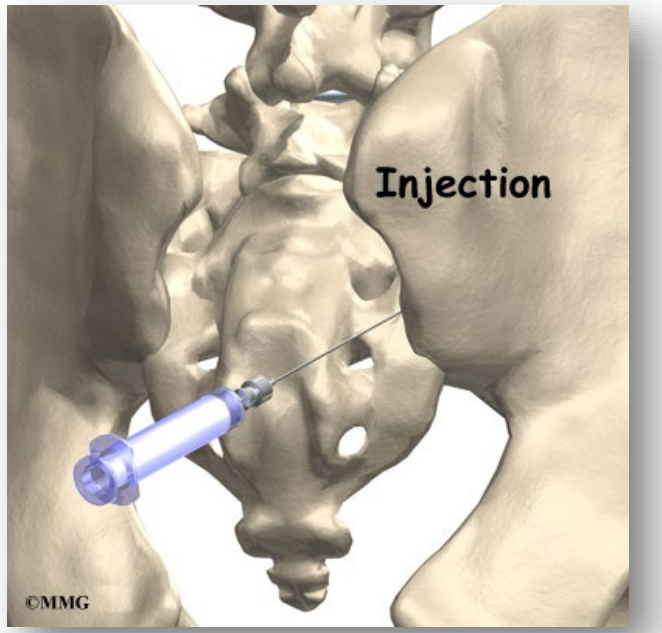
Patient Presentation - SI Joint Pain

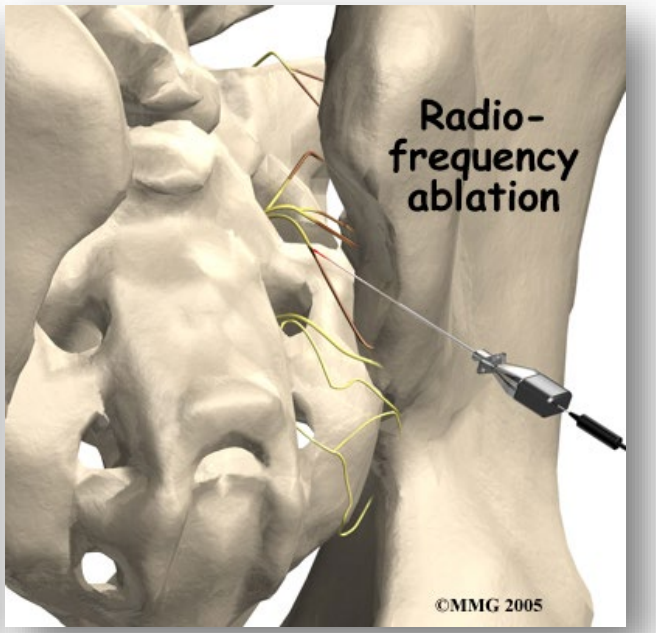
- Sudden Movement
  - "When I get out of my chair my low back hurts"
  - "Walking up stairs aggravates my pain"
  - "Getting out of the car always hurts"
- Prolonged Rest
  - "I can't sleep through the night"
  - "I can't sit for longer than 30 minutes or so"



Conservative Treatment Options

- Conservative care for SI Joint consists of:
  - Brief rest period of 1 to 2 days
  - Applying ice or heat
  - Pain medication
  - Physical therapy
  - Supports or braces
  - SI joint injections
  - Radiofrequency ablation





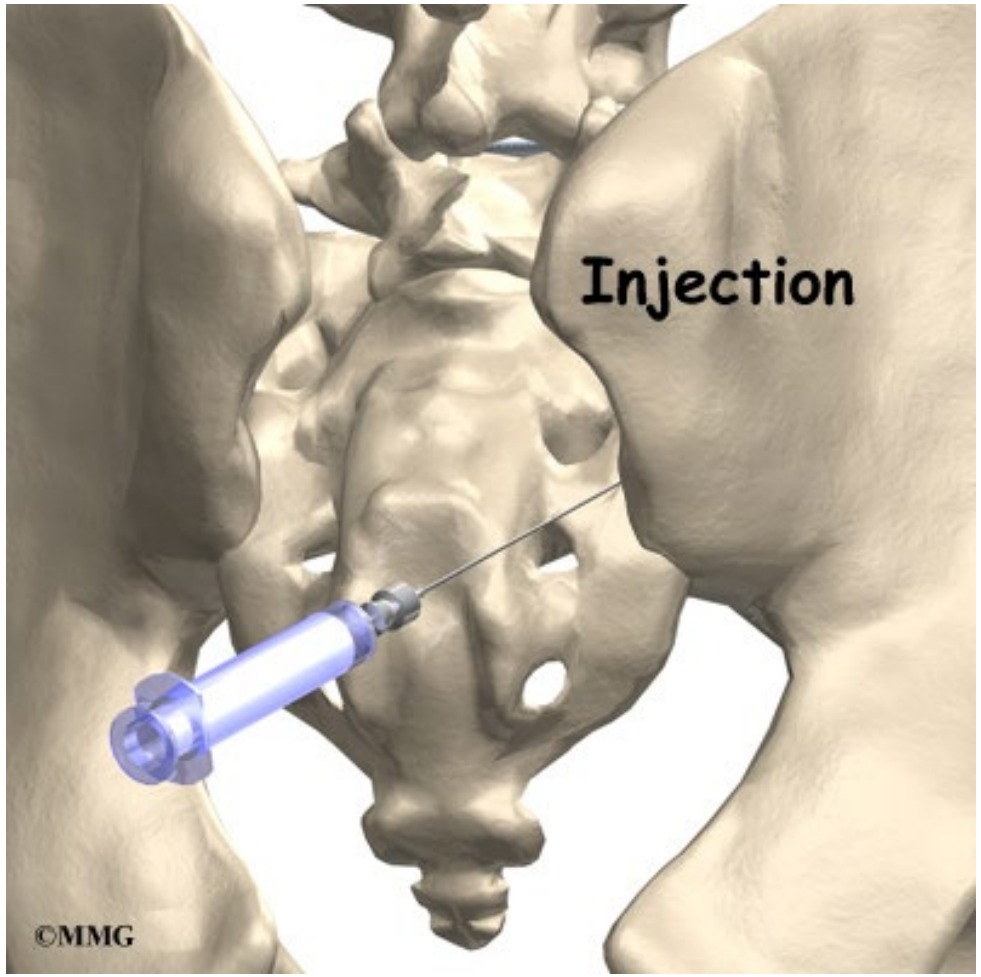
- If pain persists for greater than 6 months, without resolution from conservative care, surgical options may be considered

Patient Selection

Diagnosis Part I: Fortin Finger Test

- "It hurts here"
- Patient must be able to identify the SI Joint as the area where the pain originates
  - PSIS is usually most prominent landmark
- Pain may radiate, but must originate near PSIS

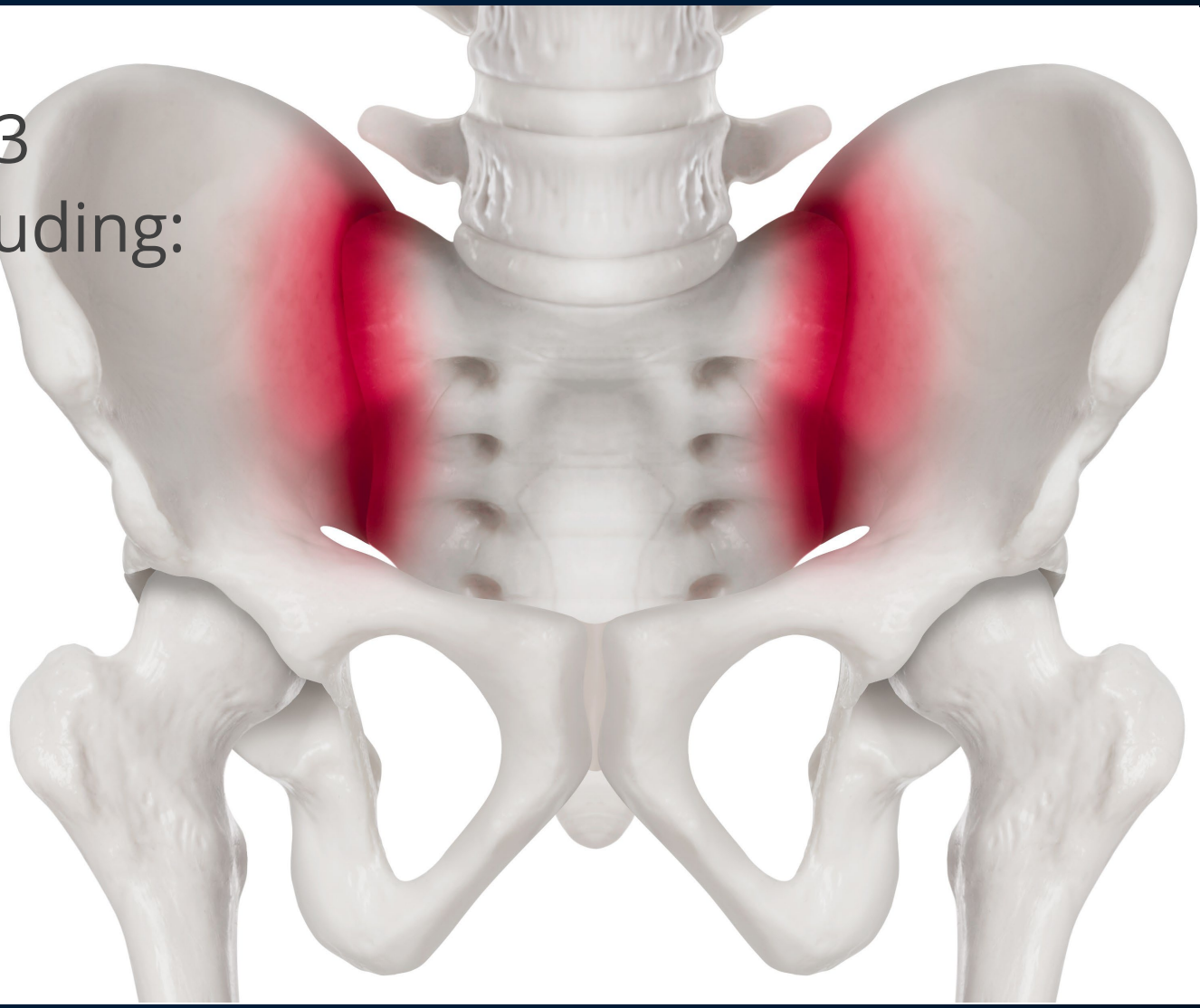
Diagnosis Part II: SI Joint Injection



- Two Positive Diagnostic SI Joint Injections
  - 75% relief, duration not specified
- One Therapeutic SI Joint Injection
  - 75% relief, duration not specified
- Private insurance can vary in requirement for relief
  - 70-80%

Diagnosis Part III: Physical Exam

- A positive response on at least 3 physical examination tests, including:
  - FABER Test
  - Thigh Thrust Test
  - Distraction Test
  - Compression test
  - Gaenslen Test



Diagnosis Part III: Physical Exam

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Distraction

①

Compression

④

Thigh Thrust

②

Gaenslen's

⑤

FABER

③

3 of 5 positive tests

provides discriminative power for diagnosing SI joint pain

Szadek – *J Pain* 2009

Laslett – *J Man Manip Ther* 2008

Provocative Test Descriptions

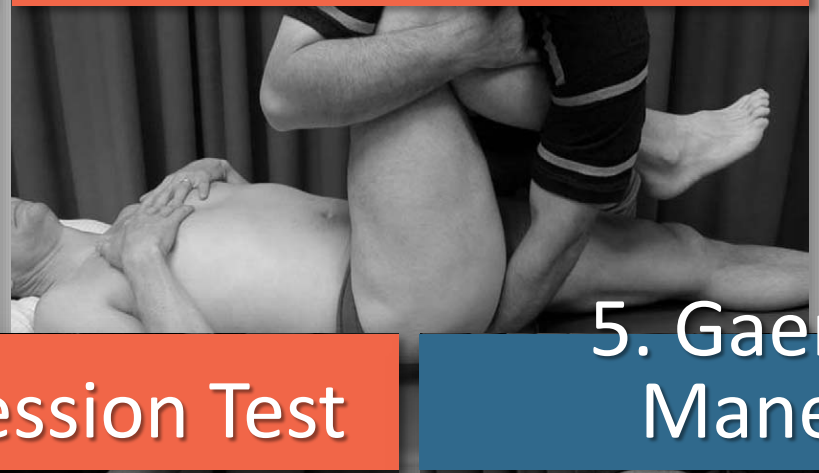
1. The Distraction Test
2. Thigh Thrust Test
3. FABER Test
4. Compression Test
5. Gaenslen's Maneuver

- The five following provocative tests have a high degree of sensitivity and specificity when used in combination.
- Three or more tests must be positive with at least one resulting from the Thigh Trust or Compression Test.
- This diagnostic threshold yields a sensitivity of **85%** and a specificity of **76%**.[2]

Provocative Tests

1. The Distraction Test

2. Thigh Thrust Test



3. FABER Test

4. Compression Test

5. Gaenslen's Maneuver

The Distraction Test

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Thigh Thrust Test

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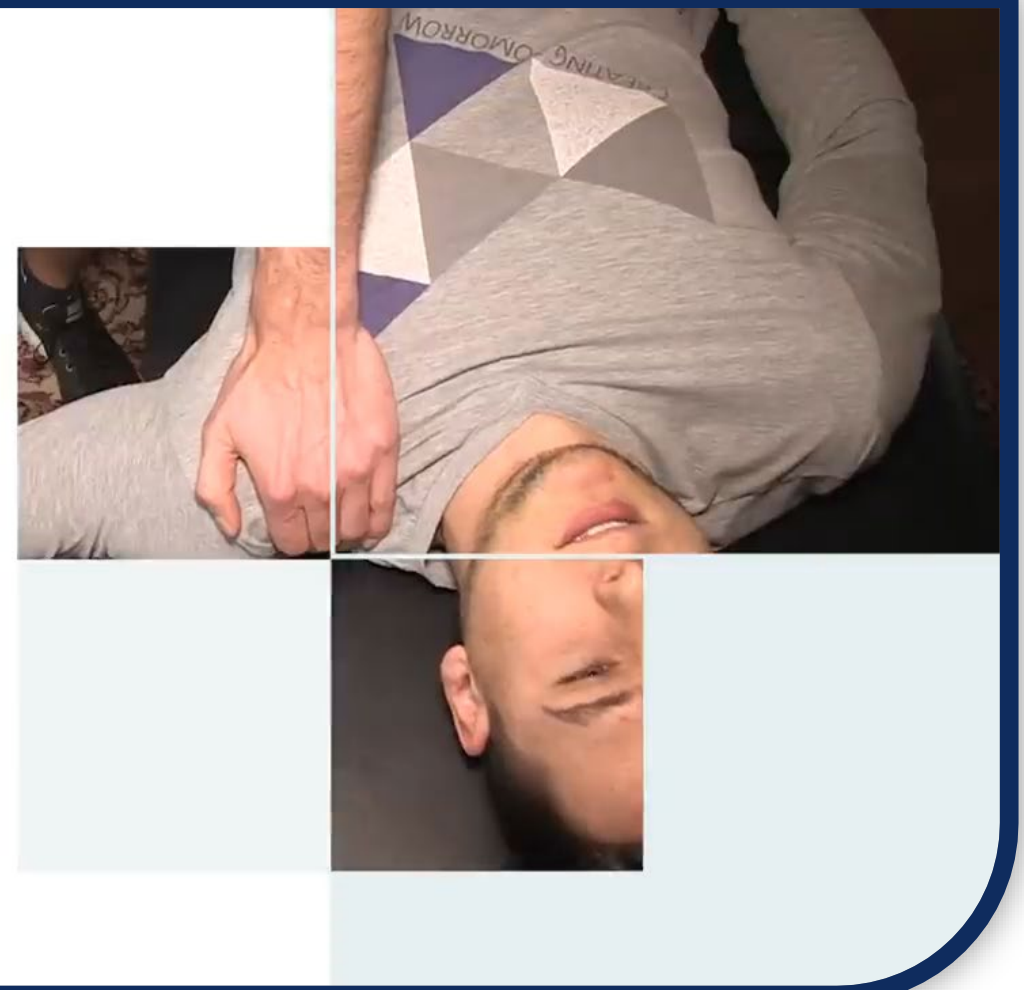
Physiotutors™

Online Physiotherapy Education

FABER Test



Compression Test

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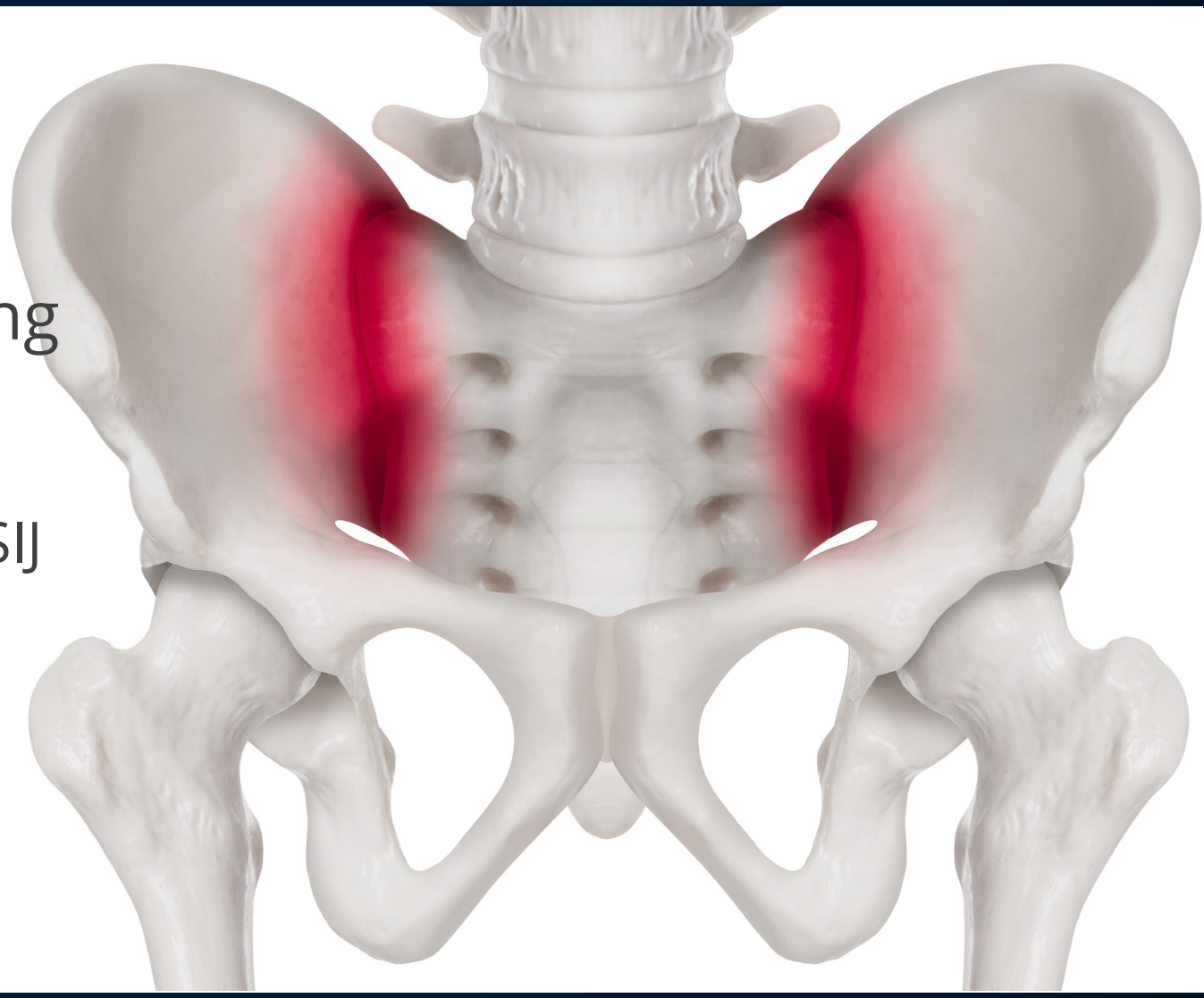
Gaenslen's Maneuver

Diagnosis Part IV: Imaging

- Patient Must Have The Following Imaging
  - CT or MRI of Lumbar Spine and SIJ
  - X-Ray of Pelvis and Hips



PsiF System Rationale

PsiF (Posterior Sacroiliac Fusion) System

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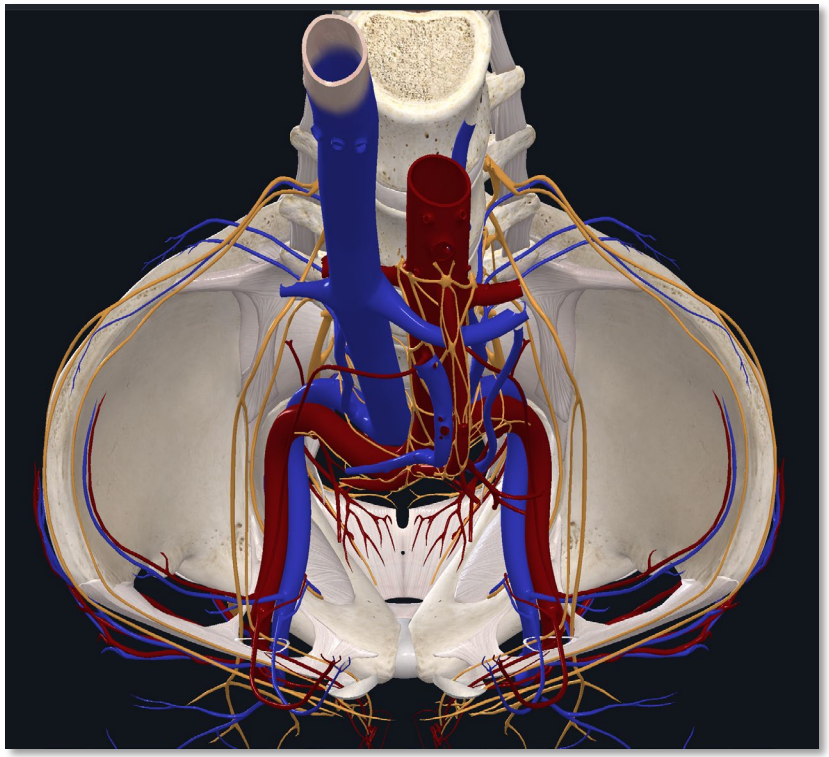
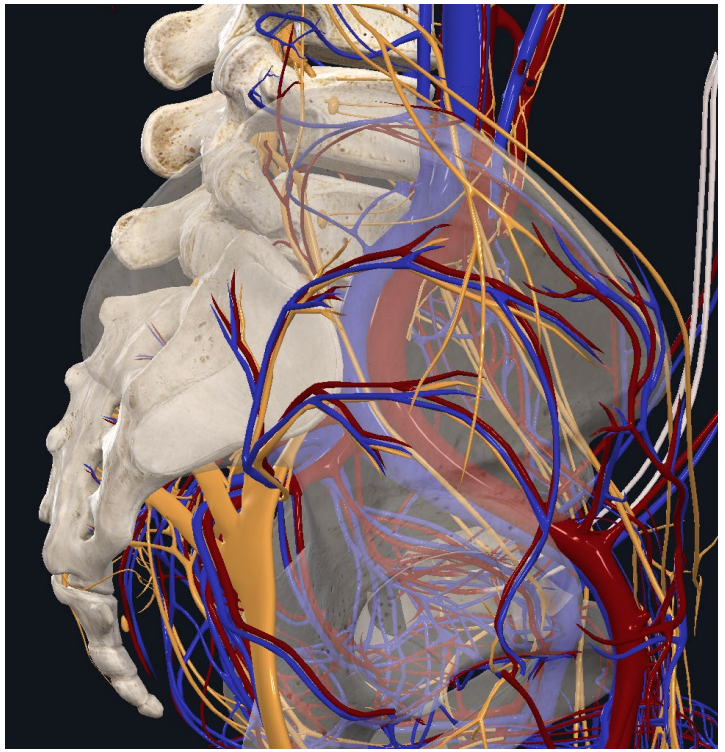
PsiF

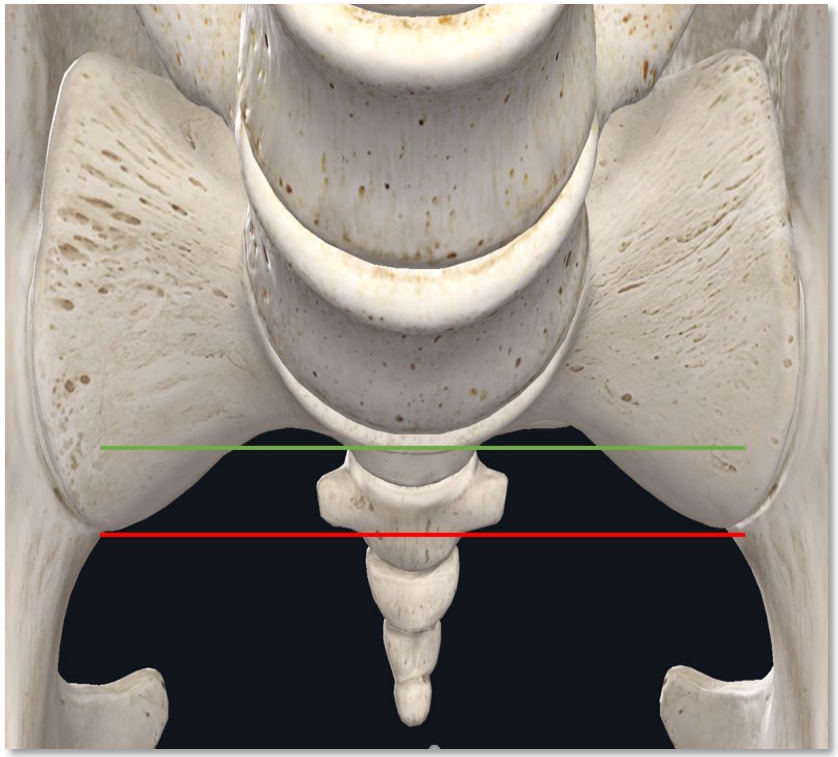
POSTERIOR SI FUSION

- **Simple:** One implant size (8x10x25mm) made of structural allograft bone (cortical femoral shaft)
- **Safe:** Easily identifiable landmarks make placement safe every time
- **Secure:** Placement near sacral axis fixates joint at the pivot point

Why PsiF? - Safety

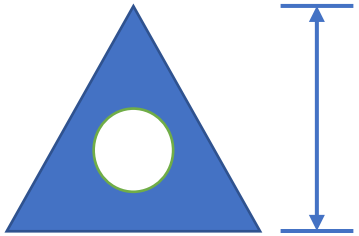




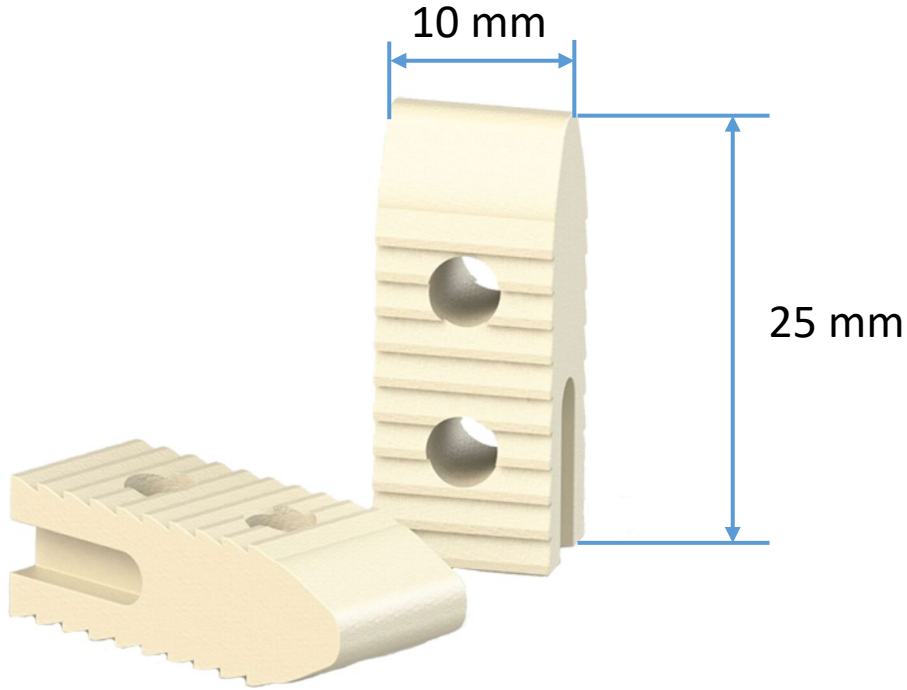


- Lateral techniques advance instruments and devices towards vascular and neural structures
- Posterior techniques advance instruments and devices away from vascular and neural structures
- Posterior techniques use clear landmarks to promote patient safety

PsiF System – Fusion Volume vs Lateral Competitor



149 mm³ Per Implant*

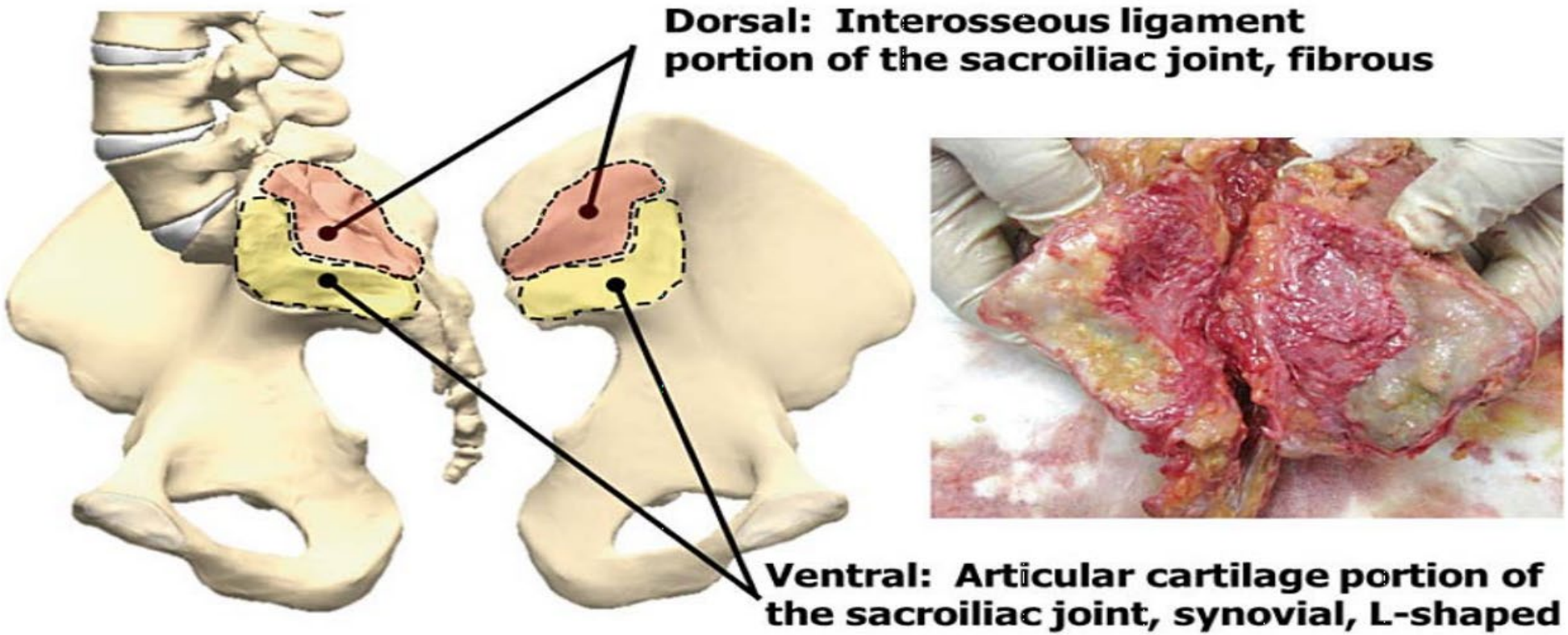


10x25 PsiF Implant

500 mm³ Per Implant*

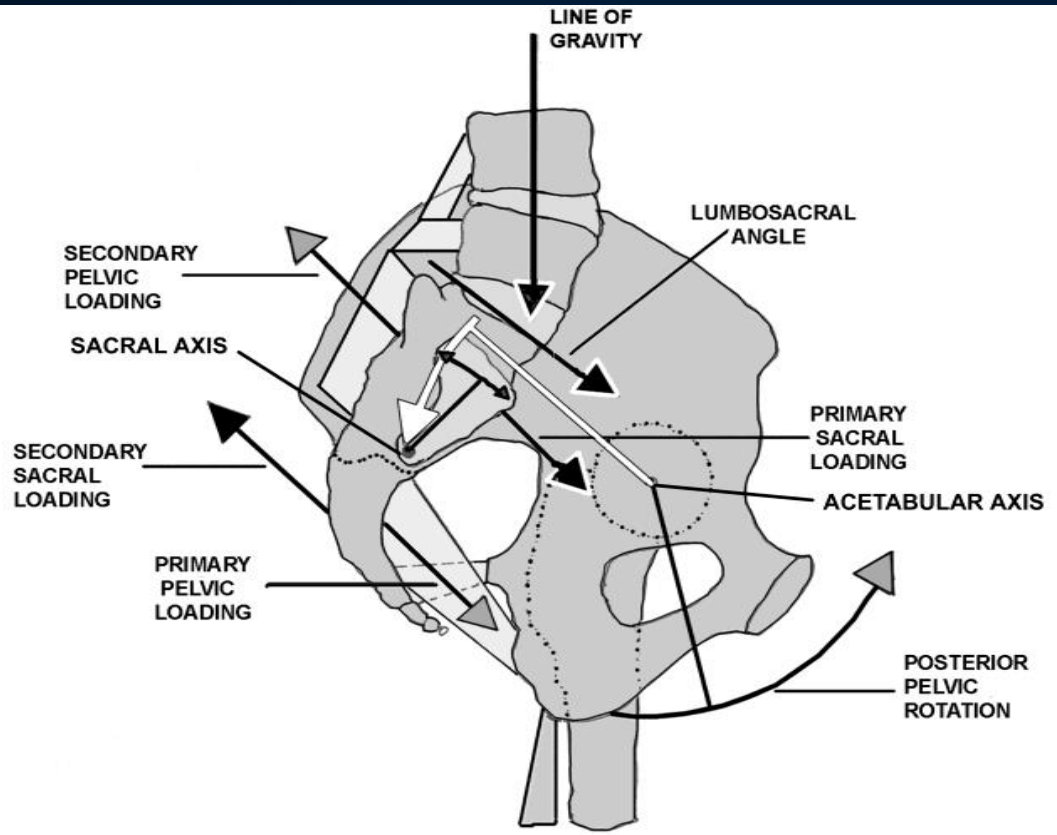
*Assuming 2mm wide joint

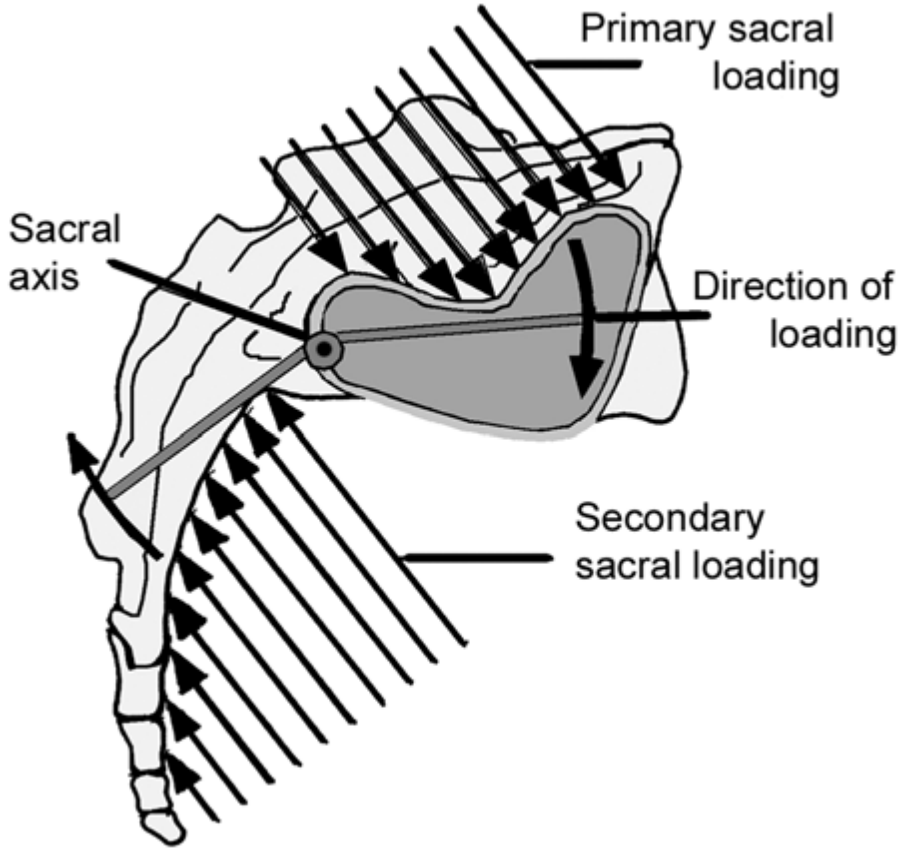
PsiF System – Implant Placement: Anatomy



- Caudal approach allows for direct access to the long, synovial portion of the joint

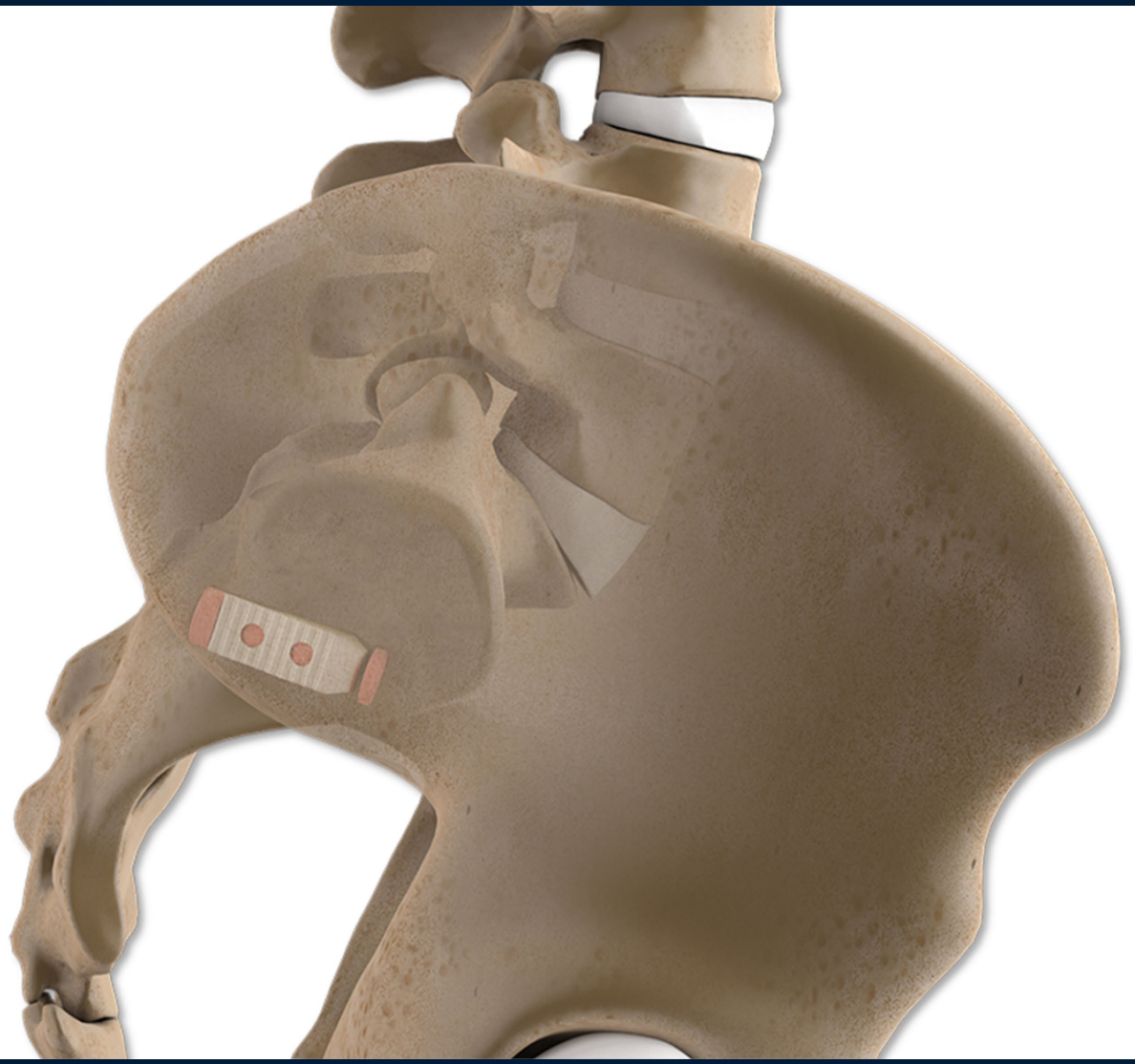
PsiF System – Implant Placement: Biomechanics





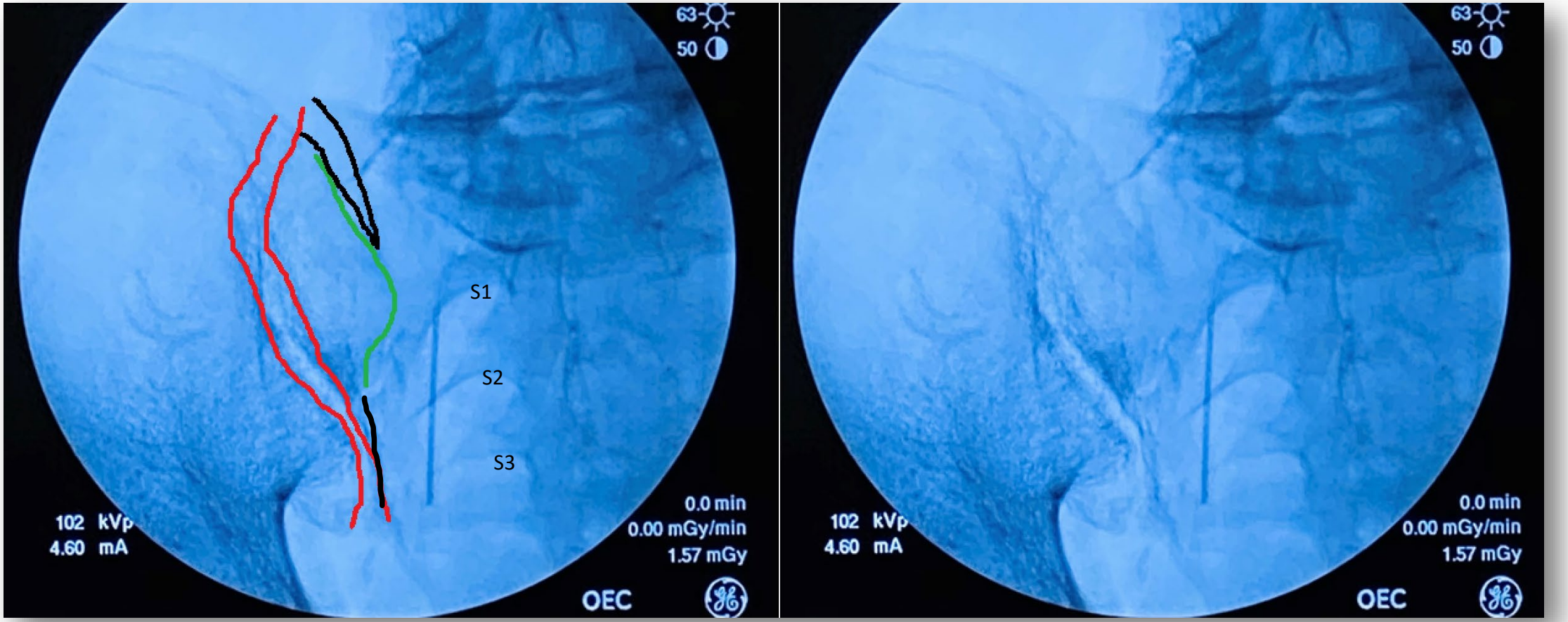
- Placement of the implant closer to the sacral axis creates maximum fixation while minimizing the biomechanical force on the implant
- Angled placement into the joint addresses sacral rotation, sacral translation, and pelvic rotation

PsiF System – Implant Placement



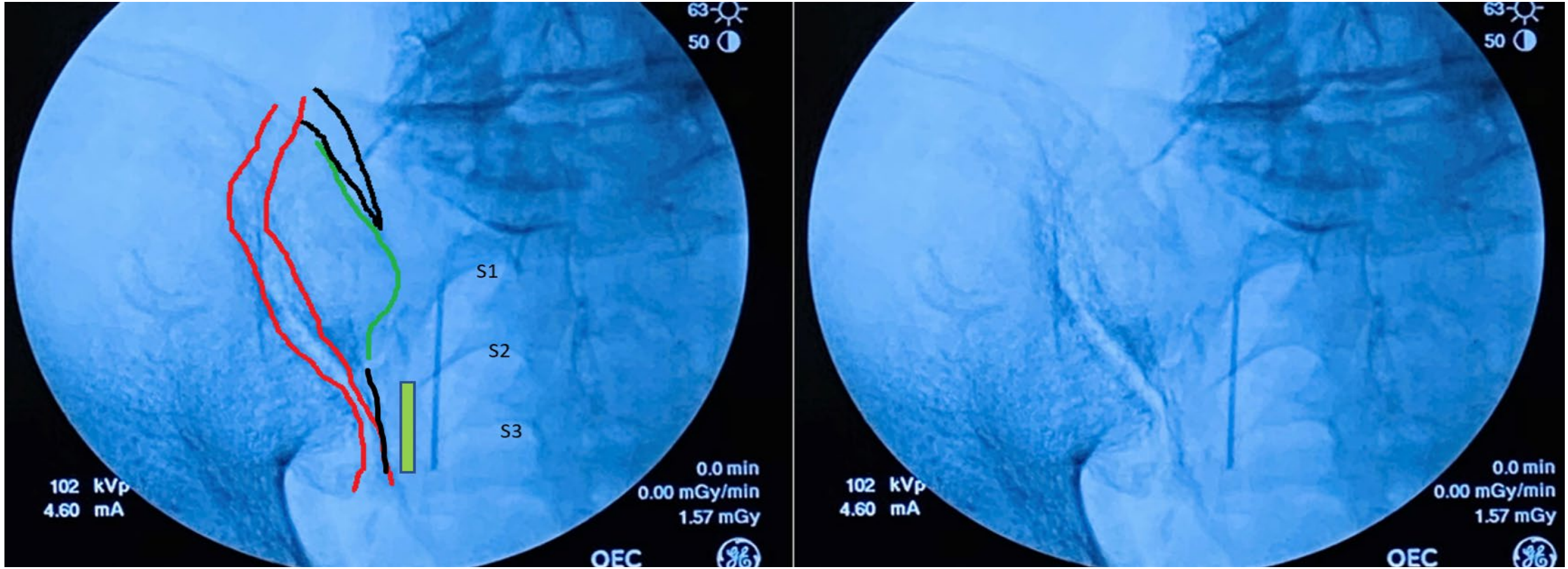
Anatomical Landmarks

Anatomical Landmarks



- In AP view, identify your landmarks
- **RED:** Ventral (Anterior) portion of the joint
- **GREEN:** PSIS
- **BLACK:** Dorsal (Posterior) portion of the joint

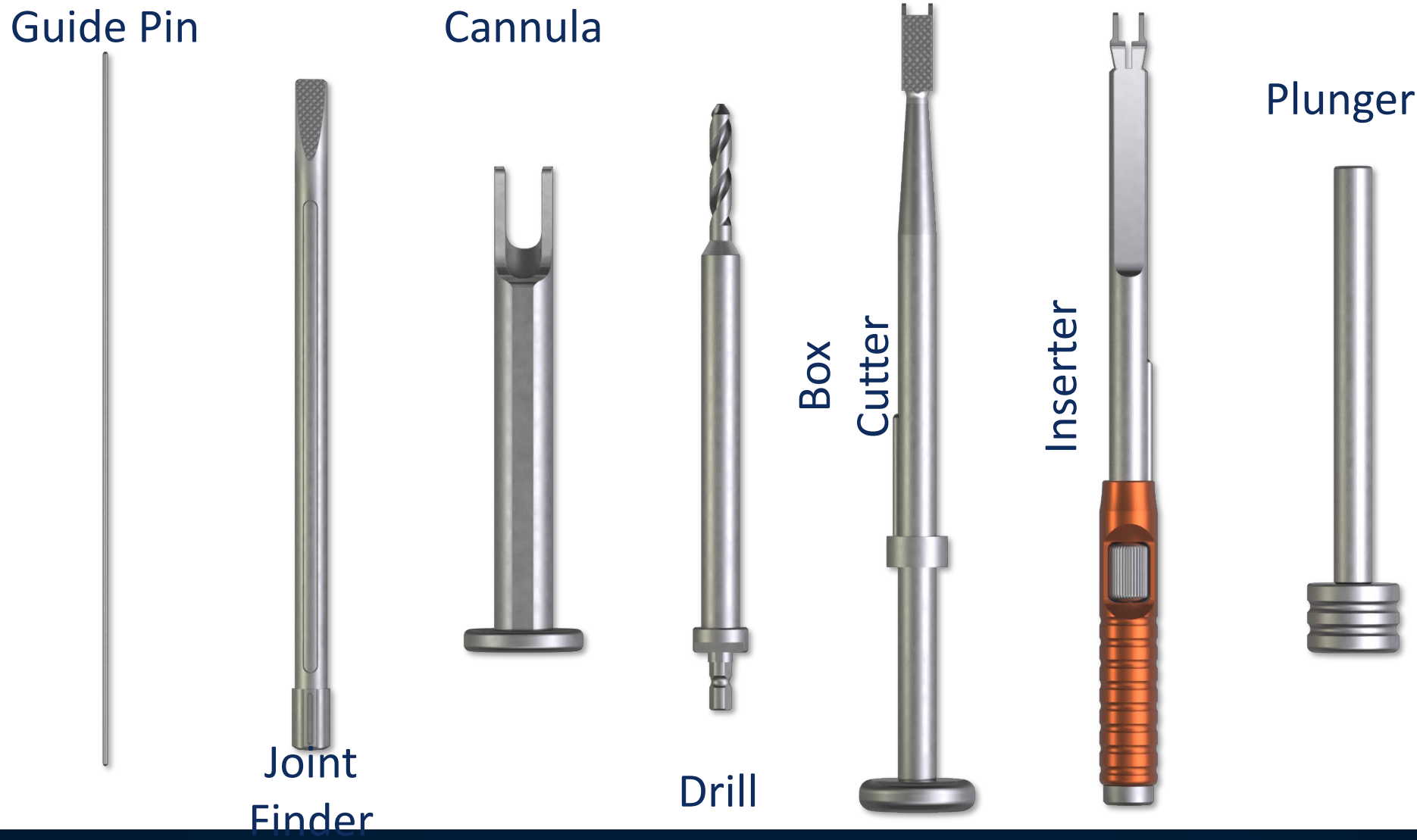
Skin Entry



- Enter Skin lateral to the foramen
- Inferior to PSIS
- Between S2 and S3

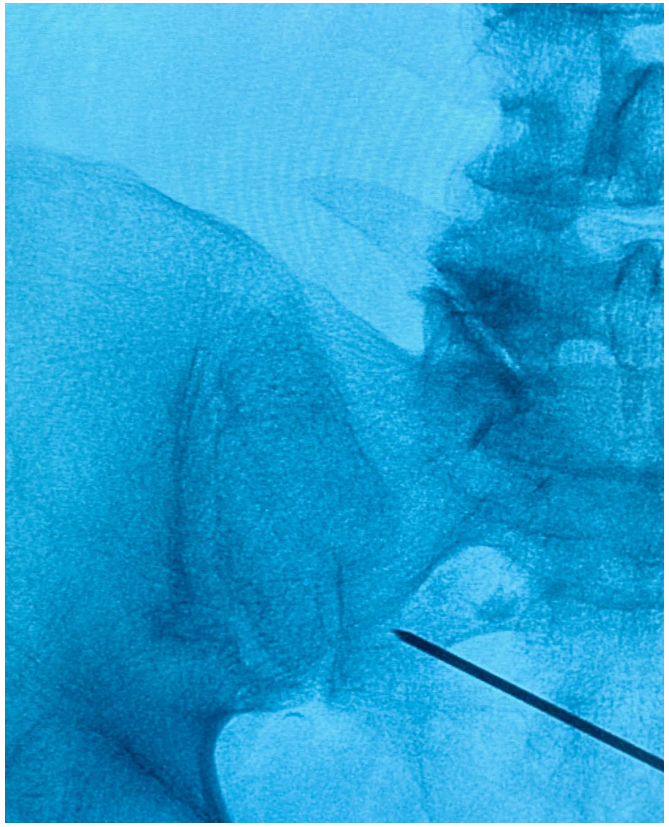
Procedural Technique

PsiF System Instrumentation



Step I: Obtain an AP View and Identify Landmarks

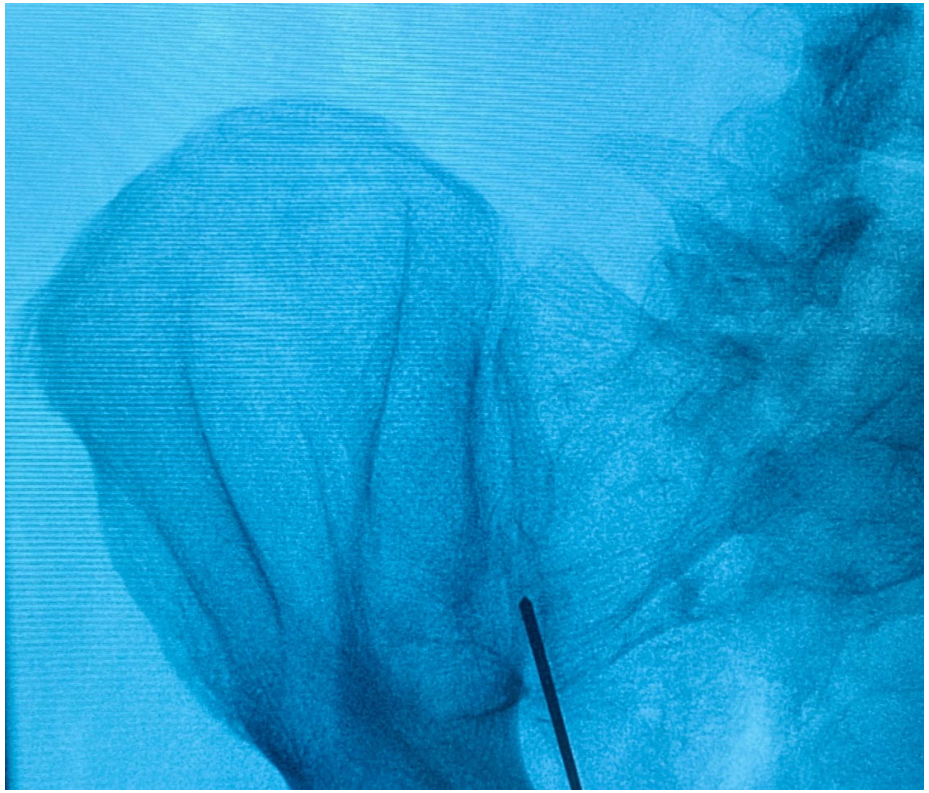
- Identify entry point
  - Inferior and medial to PSIS
  - Inferior to S2
  - Superior to S3
  - Medial to PSIS
  - Lateral to foramen



NOTE: Pin entry location will vary depending on proximity of PSIS, S2, and S3

Step II: Contralateral Oblique Angle

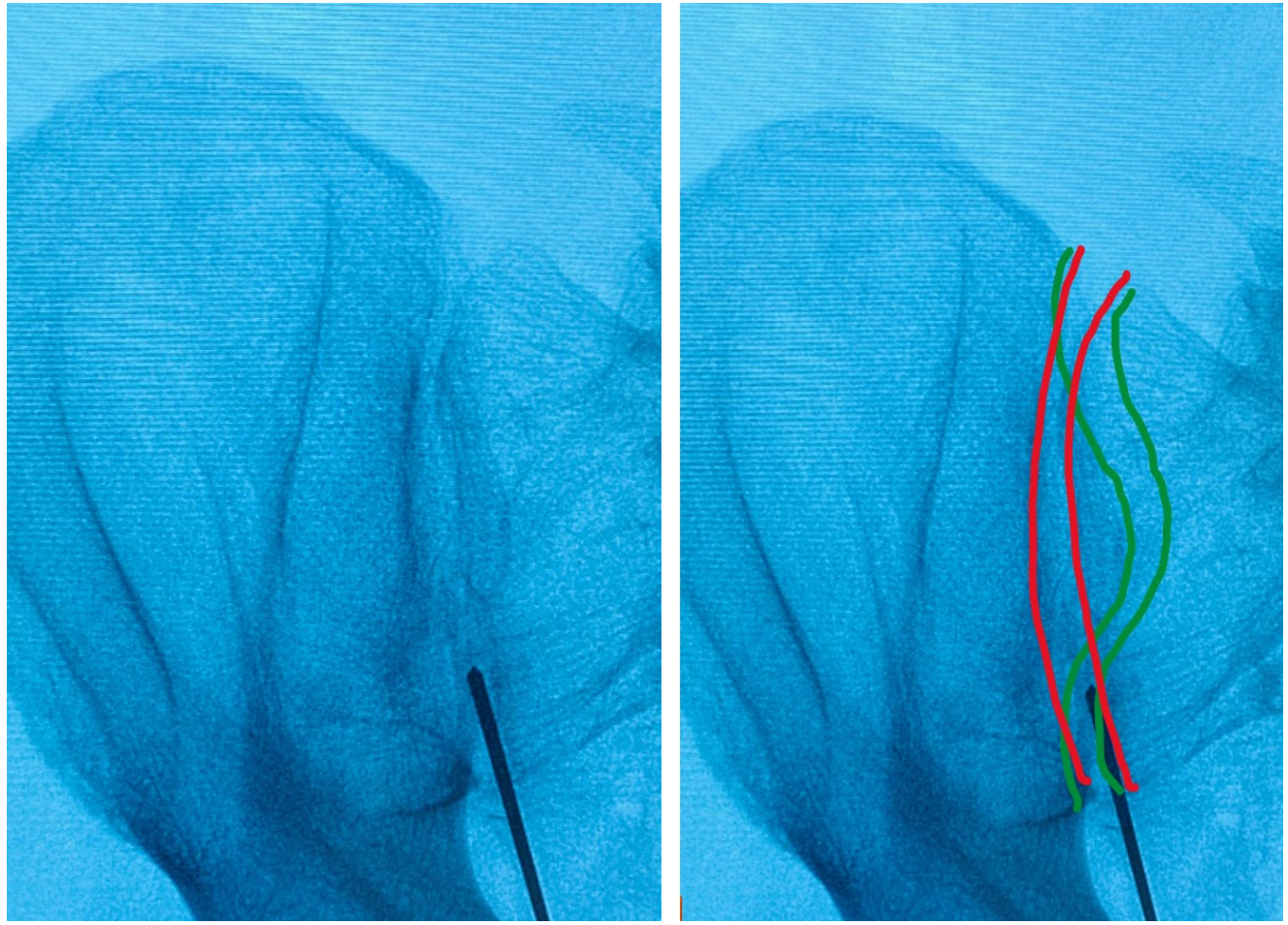
- Find the Contralateral Oblique angle that allows you to best view the posterior aspect of the joint superimposed over the anterior aspect
- Advance the Steinmann Pin toward the inferior aspect of the PSIS



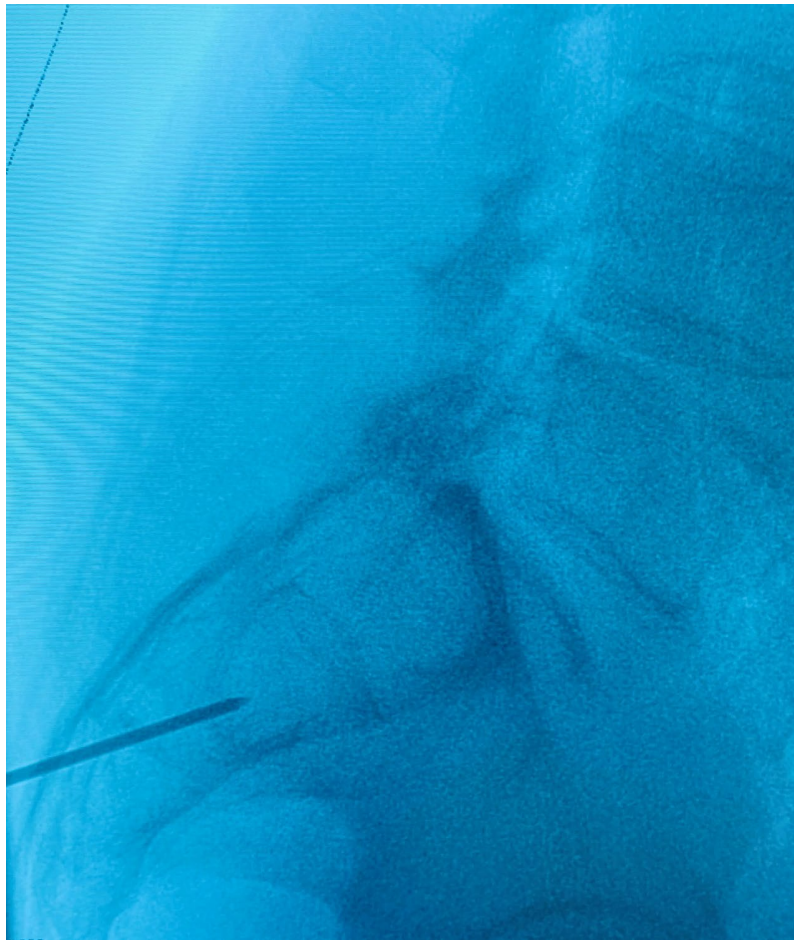
NOTE: The Steinmann Pin will make contact with ilium (PSIS) before advancing into the joint

Step II Note: Contralateral Oblique “Figure 8”

- Anterior and posterior joint lines often form a “figure 8” as you oblique
  - This is often caused by the PSIS protruding medially
- Ideal landing spot for the pin will be where these lines cross



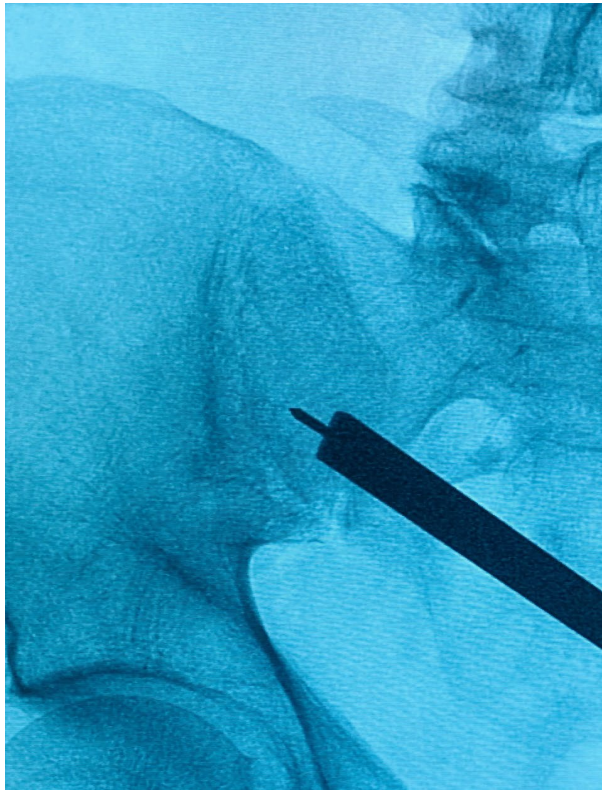
Step III: Advance the Pin

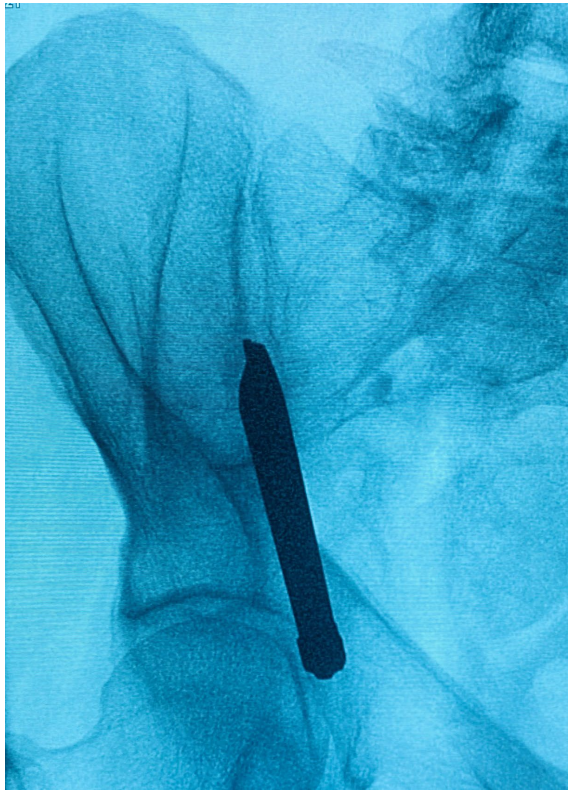


- Once you feel that you have entered the joint, change to lateral view and advance the pin until the tip is stopped by the lateral wall of the sacrum
  - As you advance, do not breach the anterior cortical wall of the sacrum
- Once you have advanced to the desired depth, make an incision on the superior and inferior aspects of the pin
- The incision should measure about 2-3 cm in length and extend down to the ilium.

Step IV: Place the Joint Finder

- Return to AP view and place the joint finder over the pin
- Advance the joint finder with your hands as far as you are able
- Confirm that the angle of the joint finder matches the angle of the posterior aspect of the joint using AP and oblique views





Step V: Advance Joint Finder in Lateral View

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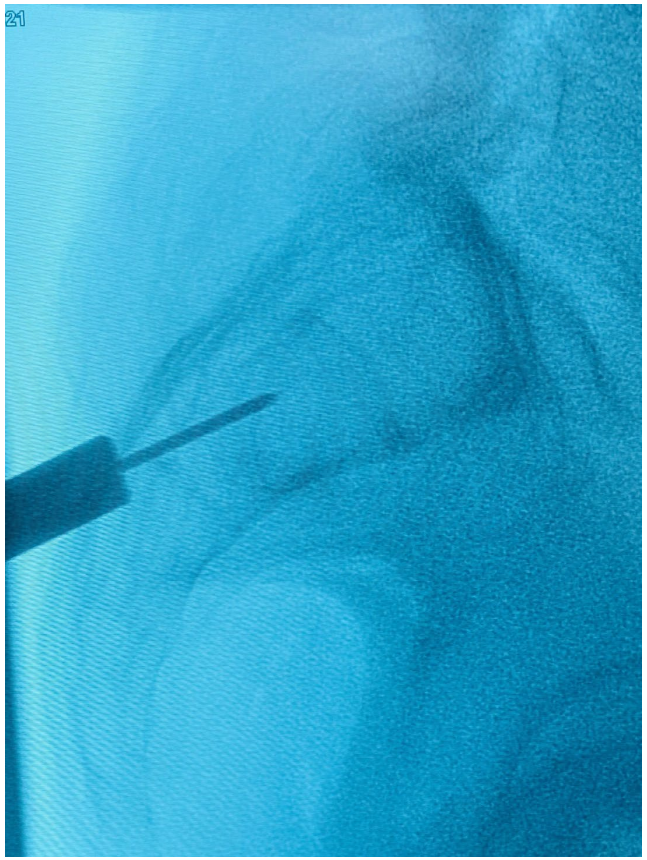
- Advance the joint finder until it enters the joint
- Both corners of the joint finder should pass the posterior cortical outline of the sacrum
- Both corners of the joint finder should pass the inferior aspect of the ilium



NOTE: The joint finder should stand on its own once it has passed the ilium into the joint

Step VI: Place Cannula Over the Joint Finder

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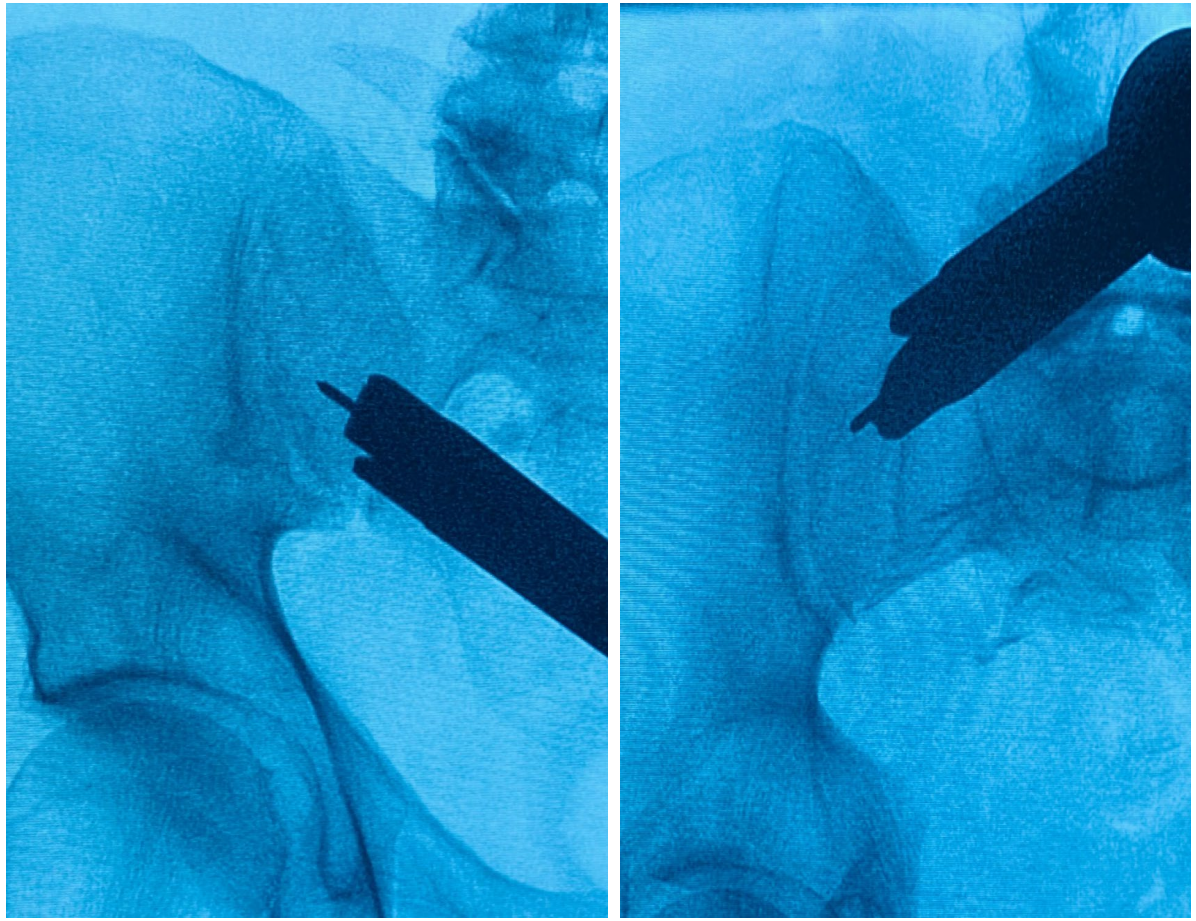
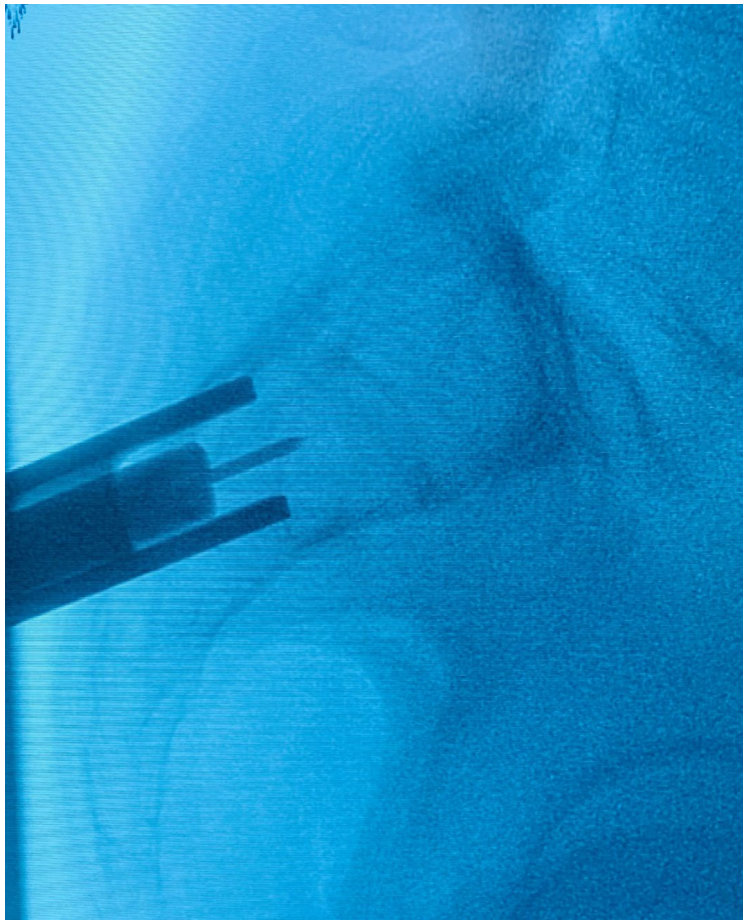
- Return to AP view and slide the cannula over the joint finder
- Take an inlet view (caudal tilt) to make sure the cannula tangs are properly entering the joint



Step VII: Advance the Cannula



- Once the cannula has been properly aligned, return to lateral view to advance the cannula
- Advance the cannula until the cut outs are seated against the ilium and sacrum

NOTE: DO NOT let either of the tangs advance past the ventral (anterior) cortical border of the sacrum.

Step VIII: Remove the Joint Finder and Pin

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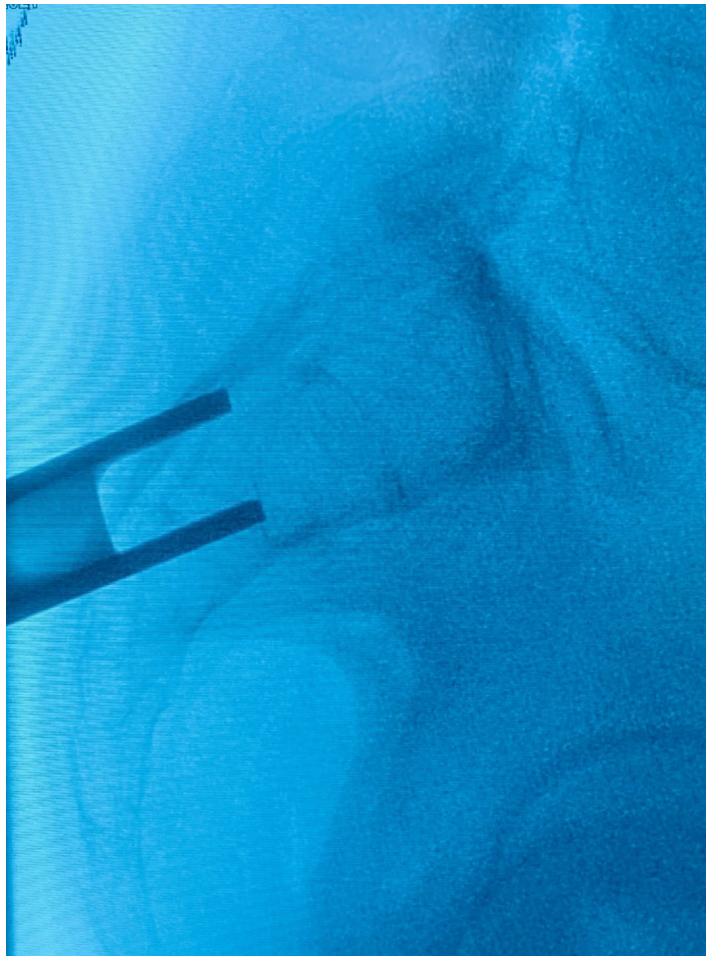
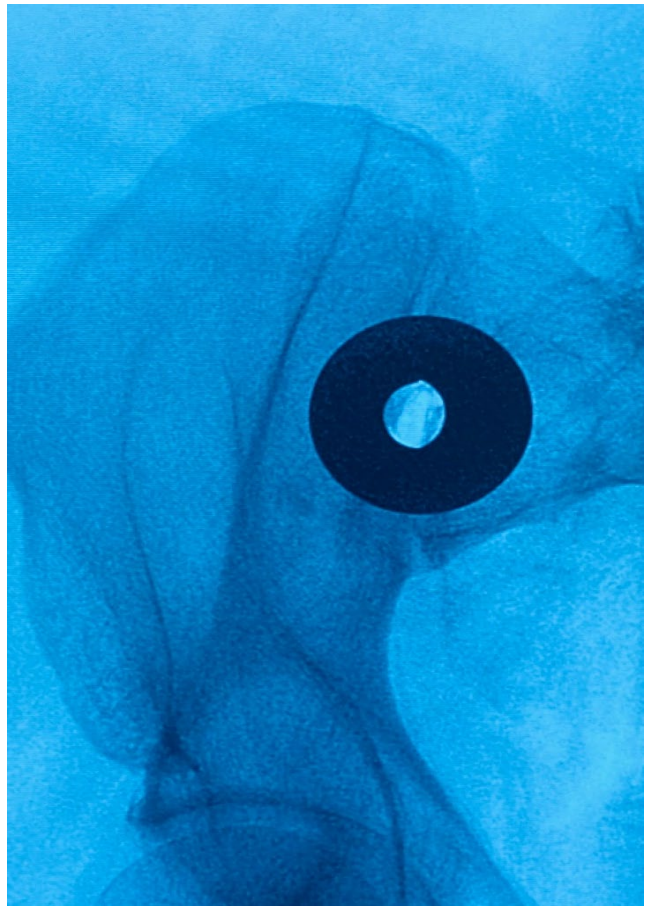
- Remove the joint finder and pin, leaving just the cannula in the joint



Step VIII: Take a “Bull’s Eye” View

- Position the C-Arm to look directly down the channel of the cannula
- You can also use a light source to directly visualize the joint, ensuring proper set up for decortication



Step IX: Advance the Drill

- In lateral view, using the T-Handle or power attachment; advance the drill thru the ilium to the sacrum, until it bottoms out in the cannula.

NOTE: When bottomed out, the drill will extend 15 mm past the anterior (ventral) tangs of the cannula.

DO NOT advance the drill past the anterior (ventral) cortical border of the sacrum.

There may be blood pooling in the cannula, so as you advance the drill use a lap sponge to cover the cannula opening and prevent splatter.

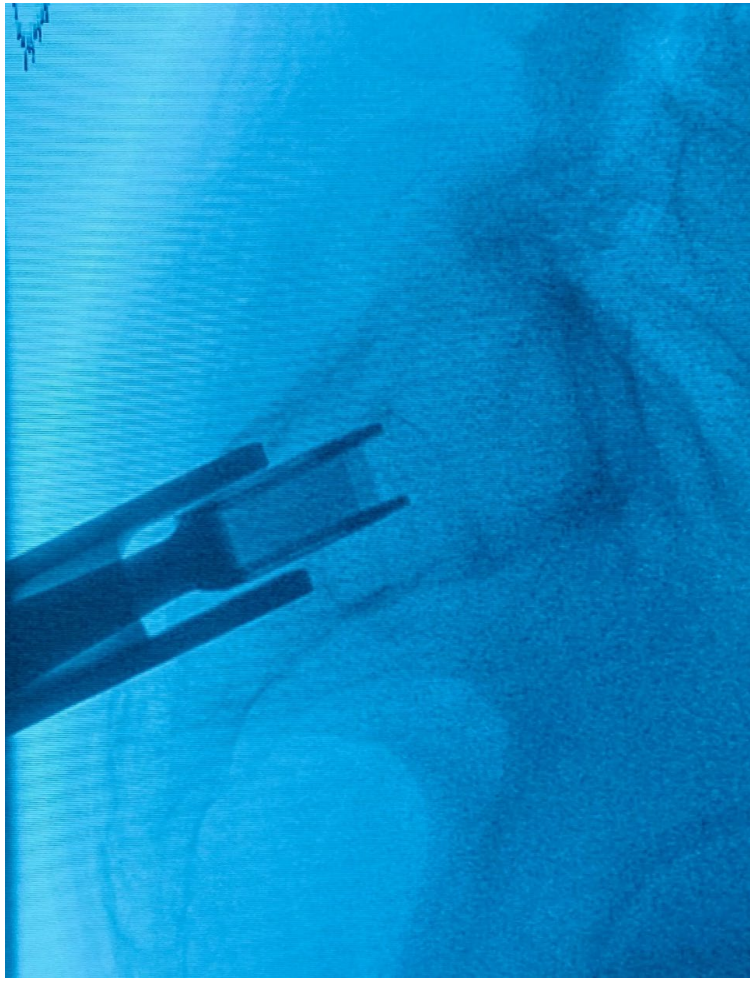
Step IX: Advance the Box Cutter

- In lateral view, advance the box-cutter until it bottoms out in the cannula.

NOTE: When bottomed out, the box-cutter will extend 15 mm past the anterior (ventral) tangs of the cannula.

DO NOT advance the box-cutter past the anterior (ventral) cortical border of the sacrum.

There may be blood pooling in the cannula, so as you advance the box-cutter use a lap sponge to cover the cannula opening and prevent splatter.



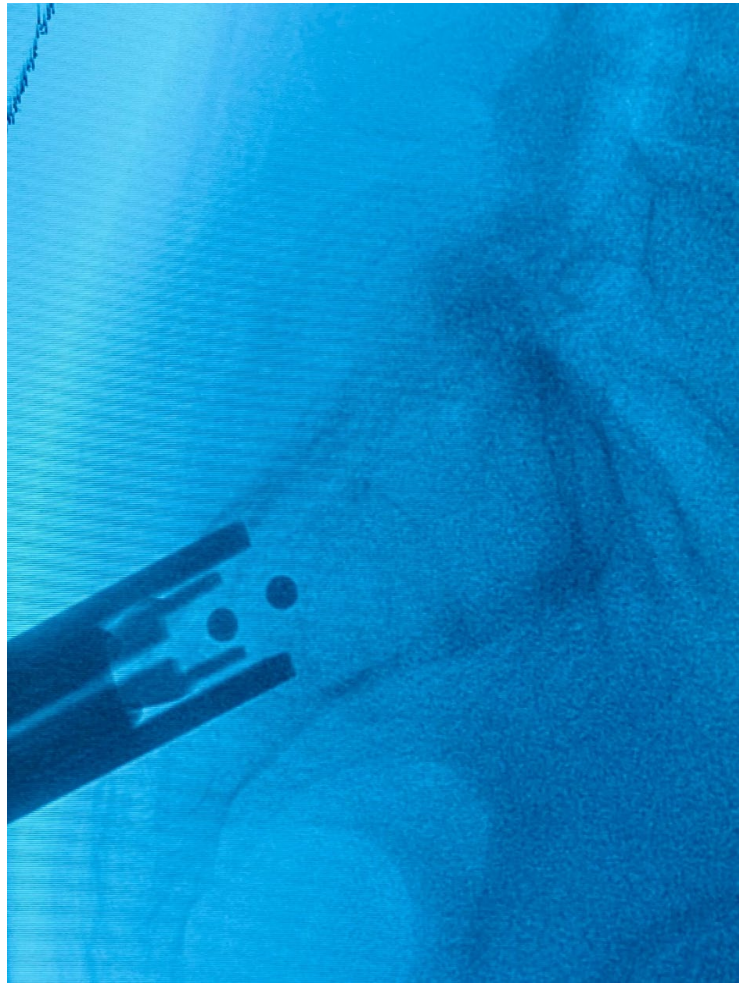
Step X: Place the Implant

- In lateral view, advance the implant until the inserter bottoms out in the cannula.

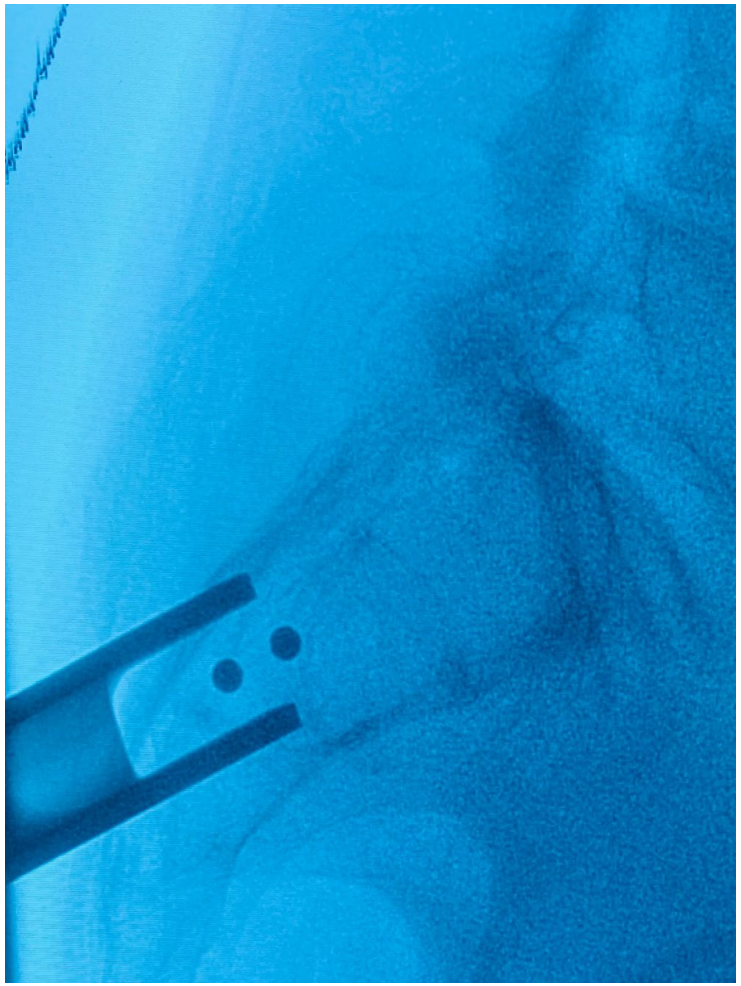
NOTE: When bottomed out, the implant will extend 15 mm past the ventral (anterior) tangs of the cannula.

DO NOT advance the implant past the ventral (anterior) cortical border of the sacrum.

There may be blood pooling in the cannula, so as you advance the implant use a lap sponge to cover the cannula opening and prevent splatter.



Step XI: Remove Inserter

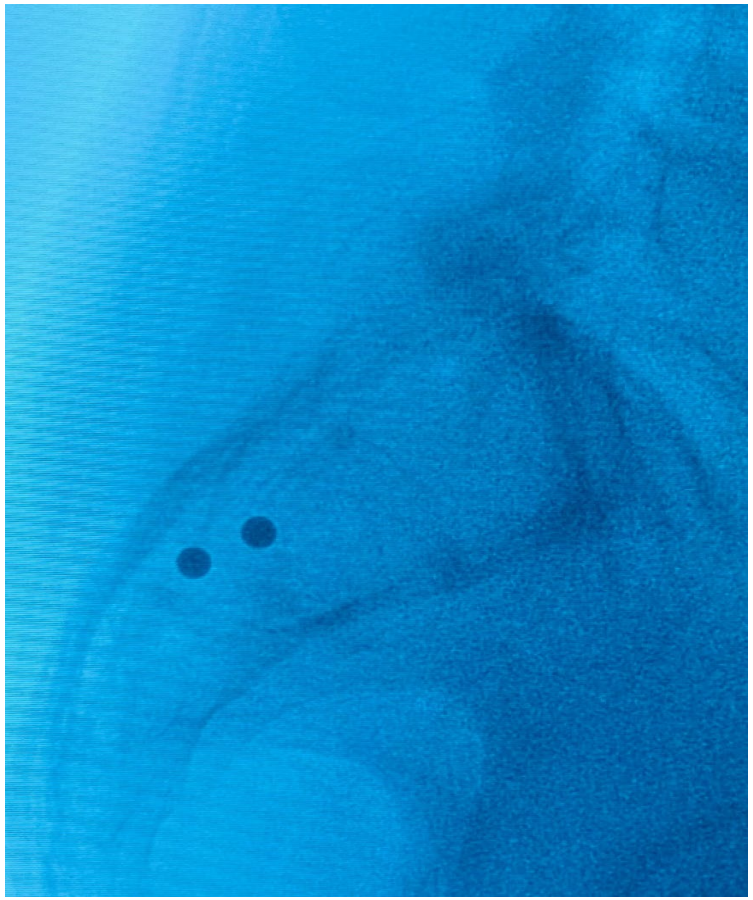


- Turn the knob of the inserter until the implant is no longer attached and remove the inserter.

NOTE: You will need to turn the knob at least 10 times to properly loosen the grip on the implant.

If the inserter is sticking to the implant, making slight cranial and caudal rocks of the inserter as you pull back can loosen its grip on the implant.

Step XII: Final Placement



- Lateral view: between the ventral and dorsal cortical outlines
- AP: Lateral to anterior joint line and medial to posterior joint line

Post-Op Guidelines

Post-Operative Protocol

- Patient may leave ASC/Hospital the same day as the procedure
- Cane, crutches or walker can help reduce stress on the SI joint as it fuses and walk as tolerated within hours after procedure
- First post-operative visit is at 1 week (follow instructions before this first post-op visit)
  - Keep incisions dry and dressing on (sponge baths)
  - No driving
  - During visit, HCP determines if patient can return to work with light activities
- Second post-operative visit is at 2 weeks and no lifting above 10lbs up to this visit
- No running or jumping for 12 weeks
- Regular diet
- Pain medication as prescribed
- Applying ice can reduce inflammation, a common contributor to pain
- Heat therapy can help reduce muscle tension and spasms caused by the surgery
- With proper physical therapy and healing, patient should be able to return to full activities after 12 weeks

Reimbursement

Coding & Reimbursement

- **CPT Code 27279:**
  - Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
  - This CPT code should be considered when an indirectly visualized, minimally invasive, sacroiliac joint fusion procedure is performed
  - Medicare payments (National Average):
    - Physician Payment = **$893.61 (RVUs = 12.13)**
    - Hospital Outpatient = **$15,868.10**
    - Ambulatory Surgery Center = **$12,974.05**

Insurance Coverage

- **Accepting Carriers:**
  - Medicare
  - United Healthcare | Cigna | Aetna (new)
  - Blue Cross Blue Shield
    (State by State)
  - Motor Vehicle/No-Fault
    (Depends on Policy)
  - Worker's Compensation

Marketing

Omnia Support

- Presentation
- Brochure
- Surgical Technique Guide
- Surgical Technique Videos
- Patient Tri-fold Brochure
- Implant Sample
- Sawbones Model w/Implant
- Website
- Patient Room Posters

Questions & Answers

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Thank you

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