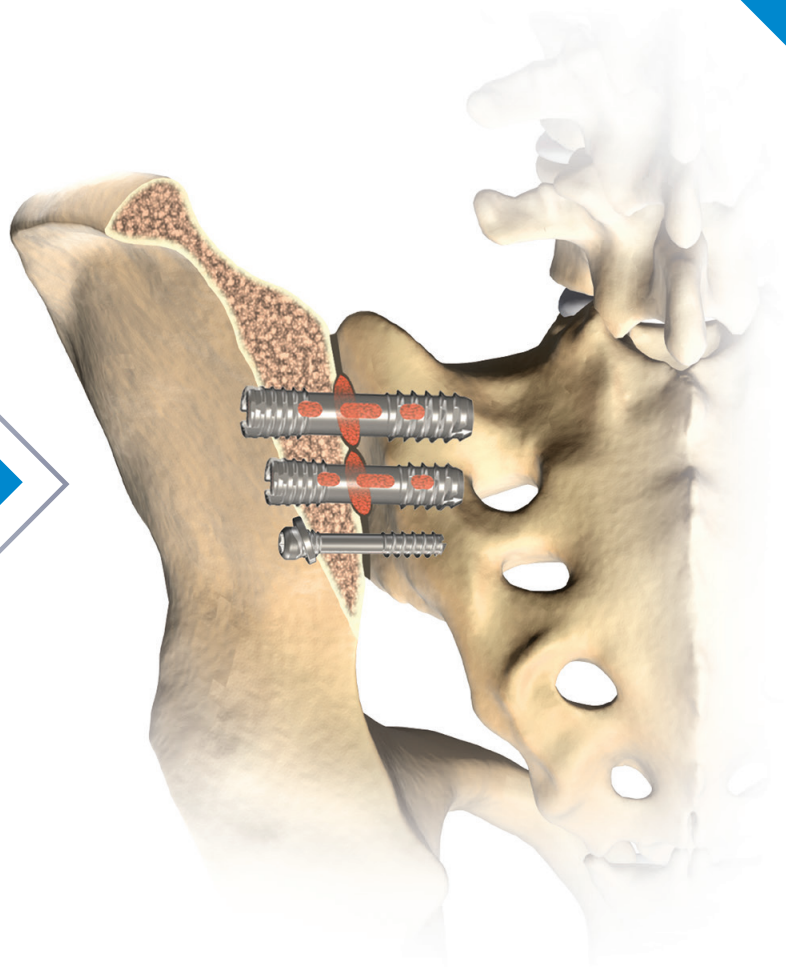
Silex®

Sacroiliac Joint Fusion System



SURGICAL TECHNIQUE

OVERVIEW

SILEX® SACROILIAC JOINT FUSION SYSTEM SURGICAL TECHNIQUE

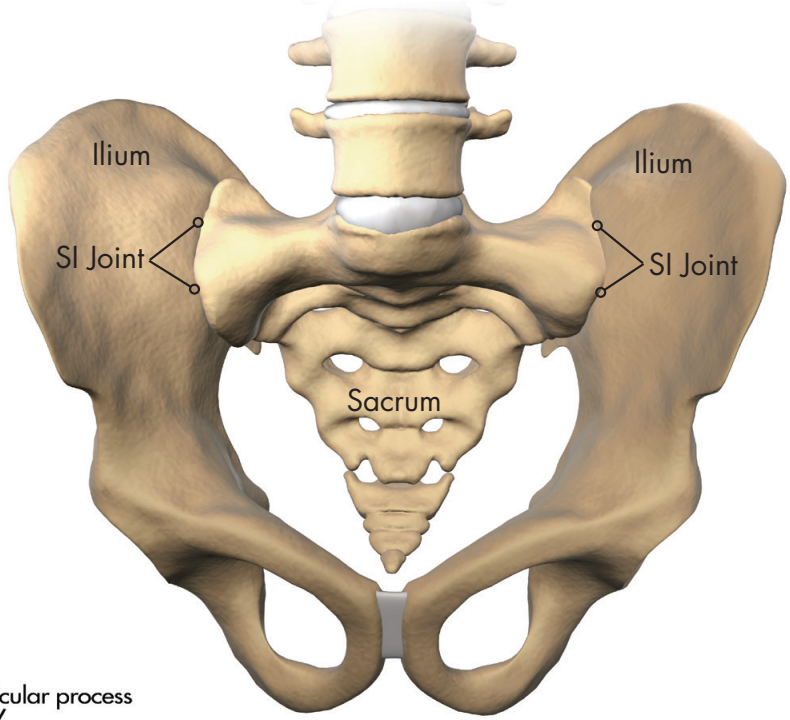
This document is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

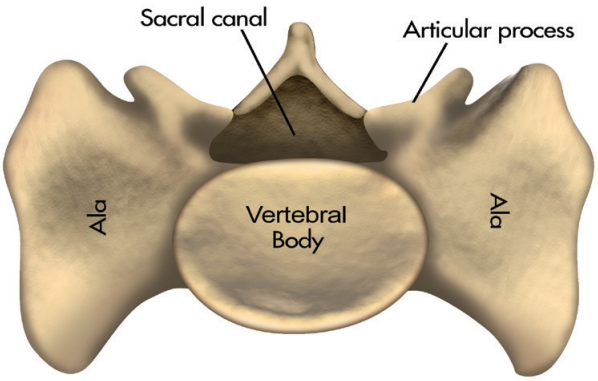
Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

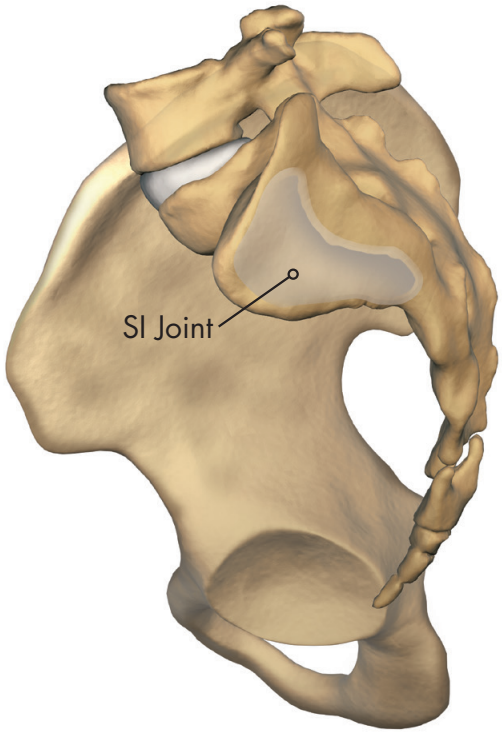
Information contained in this document was gathered and compiled by experts in the field and company employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. The company does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and is not liable for any losses whatsoever of any kind or any nature that may be caused by the use and/or reliance of said information.

Sacroiliac Joint

- Bicondylar synovial joint
- Joins the sacrum to the pelvis
- Weight-bearing, shock absorber
- "Kidney-bean" shape
- Strengthens ligamentous support and irregular articular surfaces help to resist shear forces







CAUSES OF SI JOINT PAIN

- Degenerative sacroilitis
- Sacral disruption
- Ankylosing spondylitis
- Post-traumatic SI Joint disruption
- Leg length discrepancy
- Structural pelvic asymmetry
- Tumor (pituitary or metastatic)
- Infection
- Inflammation
- Degenerative osteoarthritis
- Ligamentous laxity (pregnancy)
- Trauma
- Adjacent segment disease

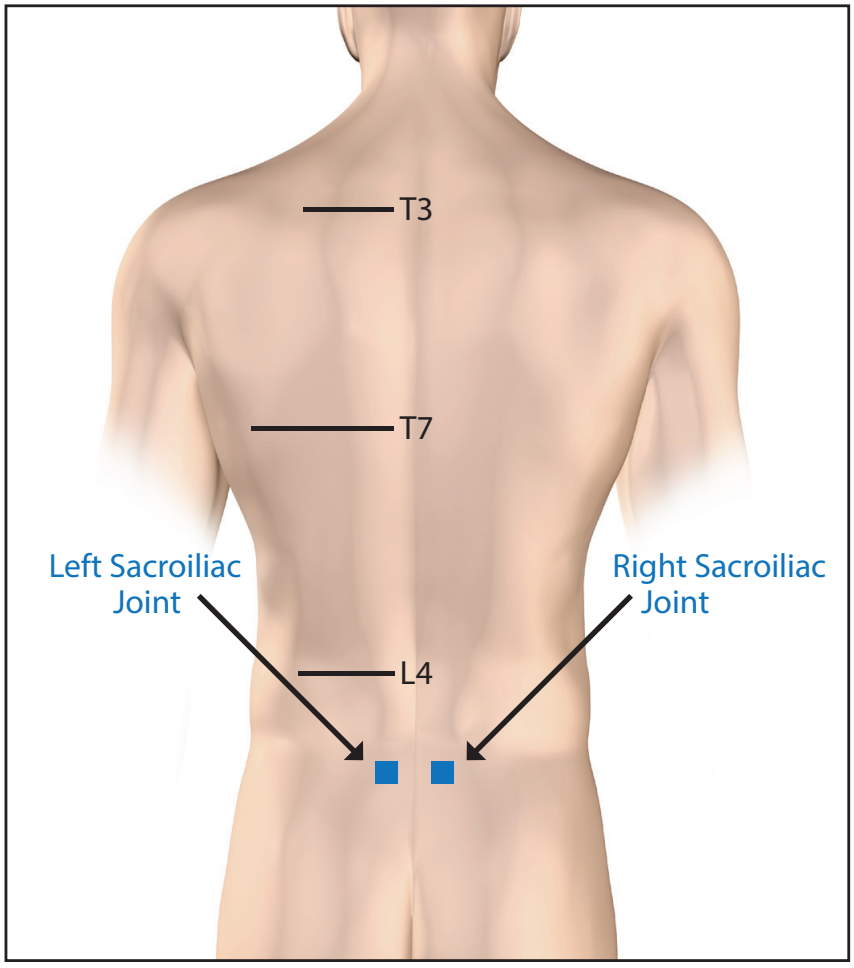
SYMPTOMS OF SI JOINT PAIN

- Pain located on one side of lower back
- Pain radiating into the buttocks, lower back and groin
- Referred pain into the lower limbs (which can be mistaken for sciatica)
- Difficulty turning over in bed, struggling to put on shoes and socks, leg pain while getting in and out of car
- Stiffness in the lower back when getting up after sitting for long periods and when getting up from bed
- Aching on one side of lower back when driving long distances

DIAGNOSIS – Fortin Finger Test

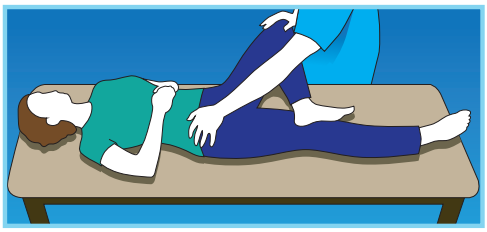
- Ask the patient to place one finger directly on the area of pain two times.
  If patient points to the exact spot where the SI Joint is located (right or left) each time, pain is likely coming from the SI Joint.

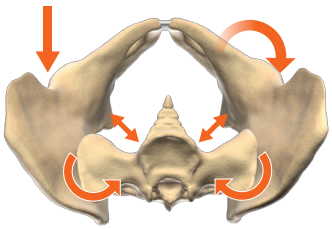
- The SI Joints are located immediately below and to the inside of the posterior superior iliac spine.



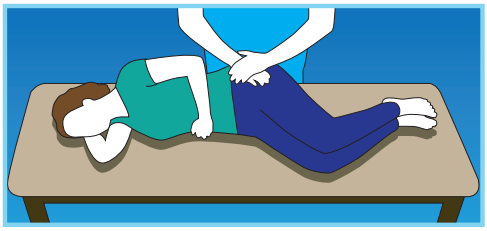
DIAGNOSIS – Provocative Tests

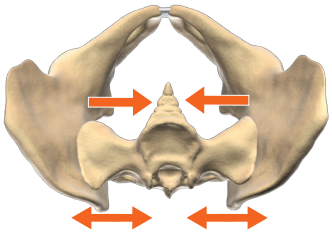
- FABER



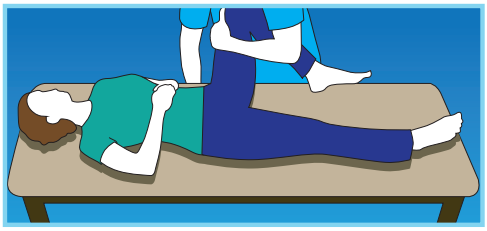


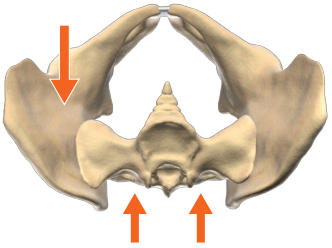
- Compression



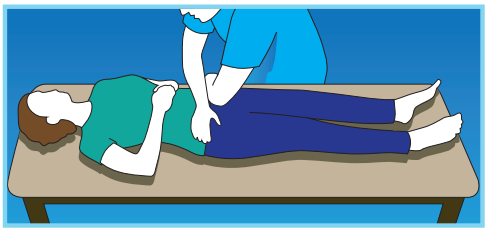


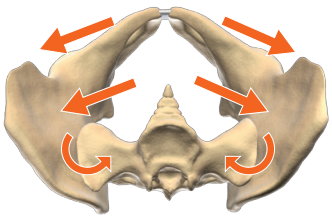
- Thigh Thrust



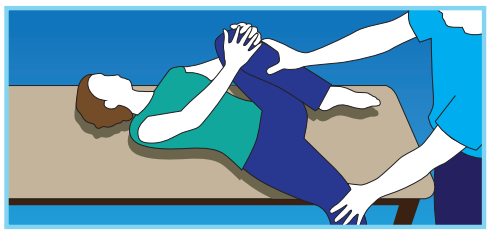


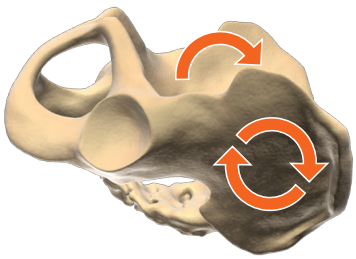
- Distraction





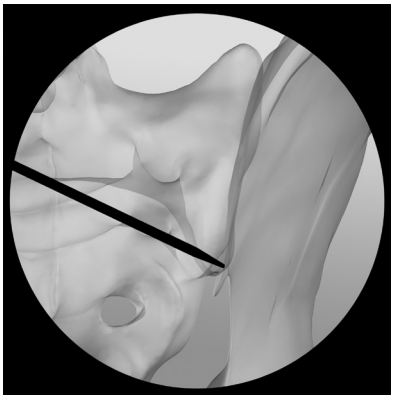
- Gaenslen





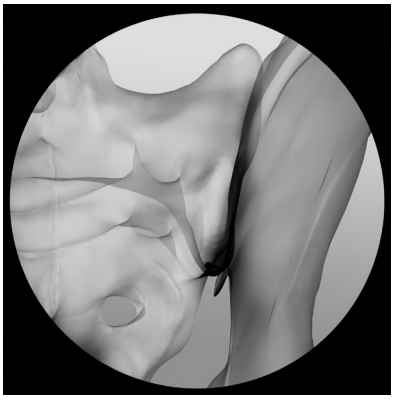
DIAGNOSIS – Fluoroscopic Sacroiliac Joint Injection

- Utilize fluoroscopic guidance to verify accurate placement of SI Joint injection site. Inject the symptomatic SI Joint with Lidocaine to identify if the SI Joint is a pain generator. If patients' symptoms are decreased by at least 75%, the SI Joint may be a source or contributor to pain.



AP inferior SIJ target

AP needle in SIJ pre-contrast



AP needle in SIJ

DIAGNOSIS – SPECT/CT

- **SPECT/CT** is a combination of two studies, **Single Photon Emission Computed Tomography (SPECT)** and **Computer Tomography (CT)**. This is another diagnostic tool that may be used when identifying Sacroiliac Joint pain. The SPECT/CT will be able to identify bone inflammation through blood flow to the joint.

PATIENT SELECTION

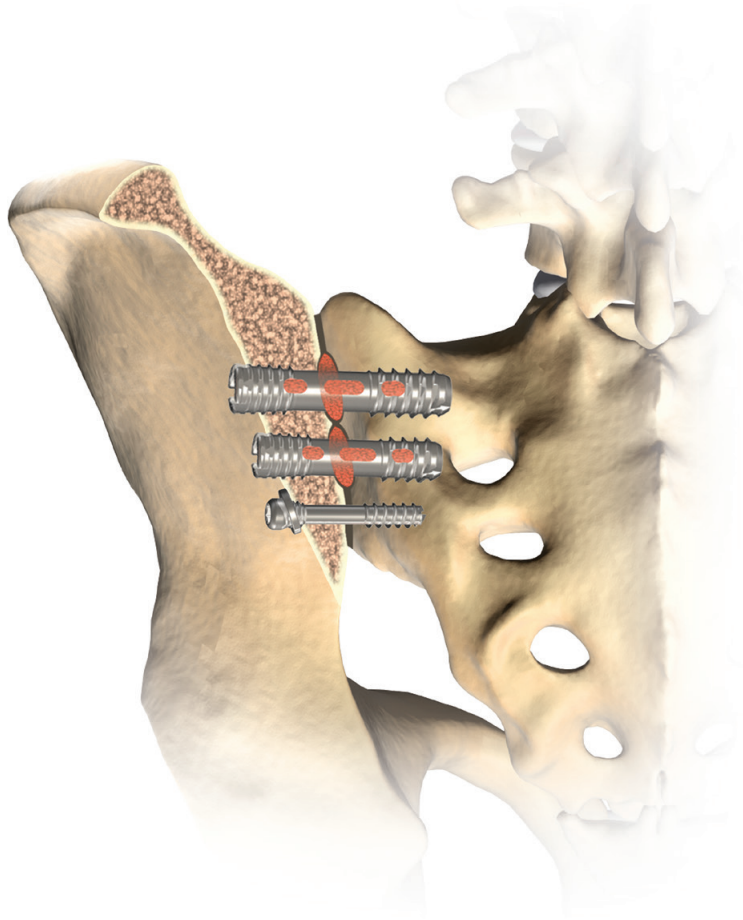
Patients who may be candidates for SI fusion...

- Failed combination of previous treatments
- Extreme chronic pain
- Trauma
- Postpartum
- Adjacent segment disease
- Motivated and capable of reasonable post-surgical expectations
- Failed required diagnostic exams (provocative testing and fluoroscopic SI Joint injection)

SILEX® INTRODUCTION

The Silex® system allows for fusion and stabilization of the SI Joint in eligible patients where appropriate non-surgical treatment has failed. The Silex® Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac-joint disruptions. The device optionally incorporates a proprietary dual-pitch compressionthread-design and titanium plasma coating to stabilize the SI Joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to promote fusion. The Silex® is a true bony fusion and arthrodesis system. The implant and instrumentation suite allows for direct exposure and preparation of the SI Joint surface, placement of bone graft into the SI Joint space under direct visualization, and placement of bone graft directly within the Silex® implant itself.

The Silex® system consists of different diameter implants in various lengths and thread configurations to accommodate variations in patient anatomy. The Silex® Sacroiliac Joint Fusion System is manufactured from titanium alloy in accordance with ASTM F136, as well as an optional version where exterior surfaces are coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. All implants are intended as single use only and should not be reused under any circumstances.



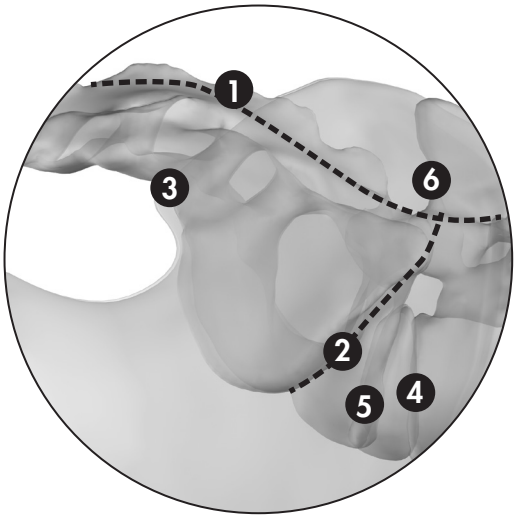
SILEX® CONSIDERATIONS

- Safe, Reproducible Lateral Access
- Minimal Step Technique
- True Arthrodesis of the Sacroiliac Joint (SI Joint)

IMAGING TECHNIQUES

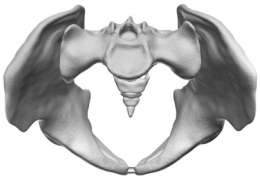
Lateral view:

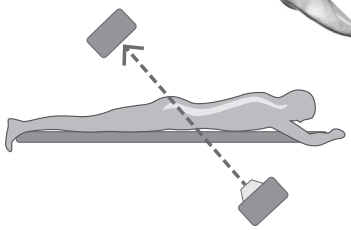
1. Posterior Sacral Wall (PSW)
2. Ala (2 lines superimposed)
3. Anterior Sacral Wall
4. Inferior Endplate L5
5. Superior Endplate S1
6. Greater Sciatic Notch

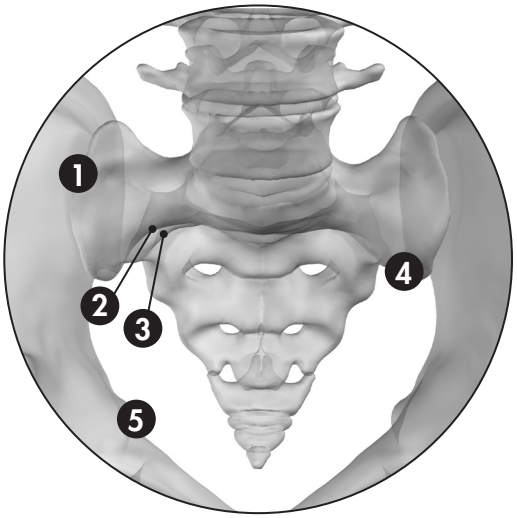


Inlet view: (20-25 Degrees Caudally)

1. SI Joint
2. S1 Foramen
3. S2 Foramen
4. L5 Nerve
5. Pelvic Brim

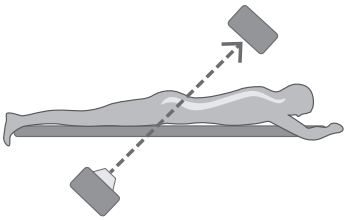


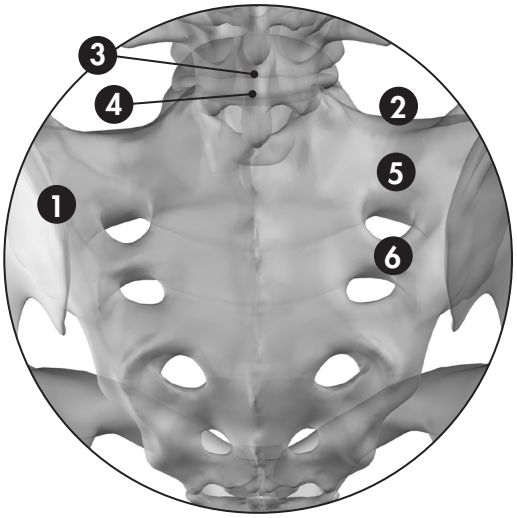




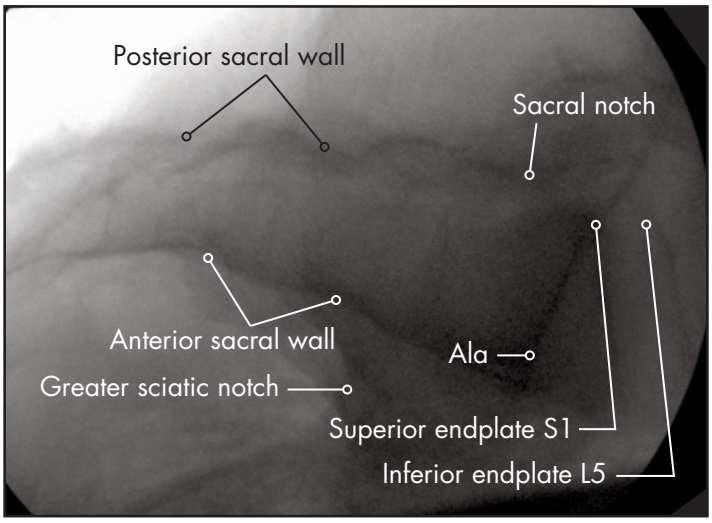
Outlet view: (40-60 Degrees Cephalad)

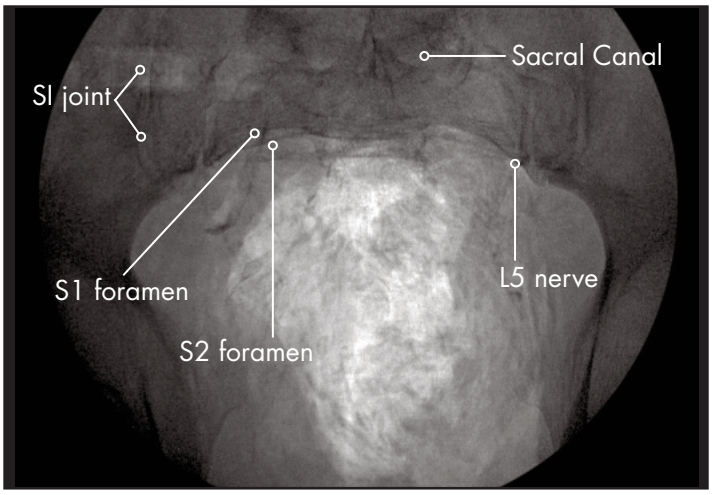
1. SI Joint
2. Superior Alar Surface
3. Inferior Endplate of L5
4. Superior Endplate of S1
5. S1 Foramen
6. S2 Foramen

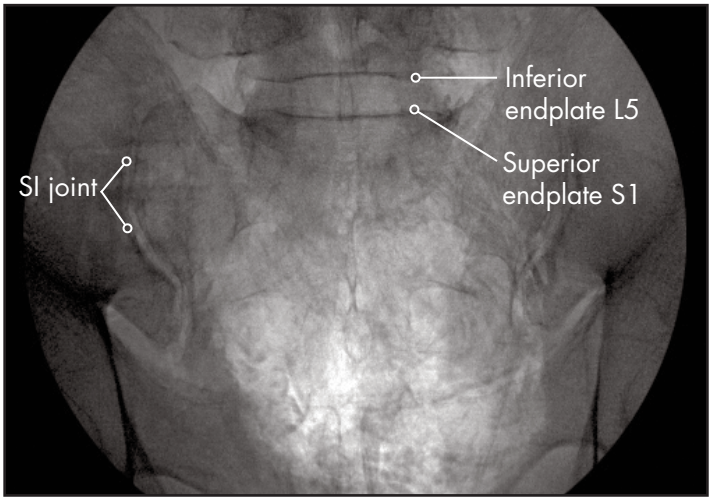




PATIENT PREPARATION



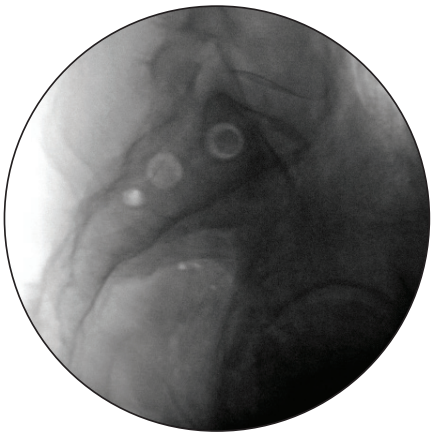




SILEX® INTRAOPERATIVE IMAGING

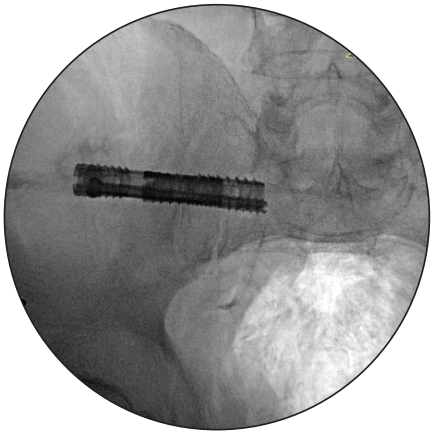
Lateral View

In order to obtain a true lateral view, align the Alae so they are superimposed over one another.



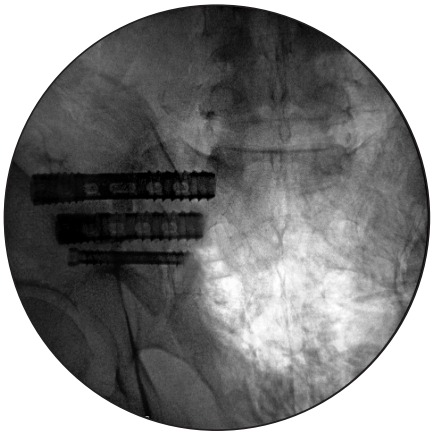
Inlet View

Tilt the C-Arm until a clear, strong pelvic brim is seen, the anterior wall of the Sacrum will appear as one line.



Outlet View

The SI Joint, Ilium, Sacrum and sacral foramen will be visible.



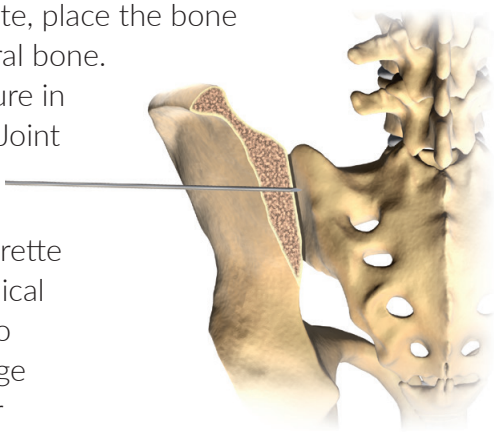
PRE-OP PLANNING – Operating Room Setup

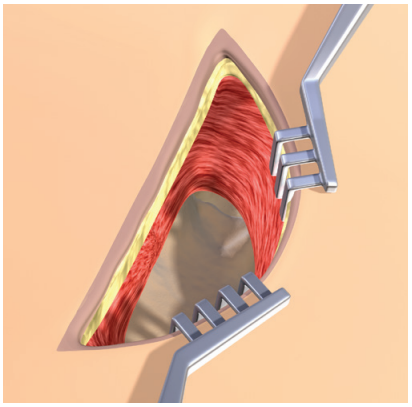
- Patient positioned in a prone position
- Jackson or Flat table preferably
- C-Arm positioned on non-operative side

SILEX® SACROILIAC JOINT FUSION SYSTEM OPEN SURGICAL TECHNIQUE

Step 1: Posterior Skin Incision

- Make an incision along the posterior two-thirds of the iliac crest following the posterior superior iliac spine. Surgeon to use preferred retraction method to access and visualize the symptomatic SI Joint. Cut into the ilium and remove a block of bone as well as any necessary cartilage. Once the cartilage removal is complete, place the bone back so it contacts the sacral bone. Make sure the block is secure in order to prepare for the SI Joint for bony arthrodesis.

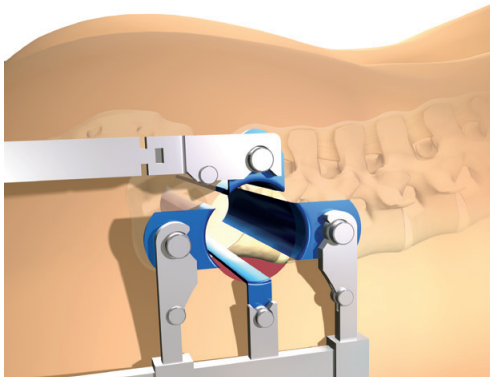




Note: The Right Angled Curette or any other preferred medical instruments may be used to decorticate, remove cartilage and prepare the SI Joint for bony arthrodesis.

Step 2: Lateral Skin Marking

- Use the Exchange Pin to mark the Posterior Sacral Wall (PSW) and Sacral Alar Line with a marking pen.



Step 3: Lateral Skin Incision

- Make skin incision along Posterior Sacral Wall, approx. 3-5mm in length, starting at intersection with Sacral Ala skin marking.

Step 4: Steinmann Pin Placement

Beginning in the Lateral View, take the sharp Steinmann Pin and insert the Steinmann Pin through skin incision approximately 1cm Anterior to the Posterior Sacral Wall and 1cm Inferior to the Ala.

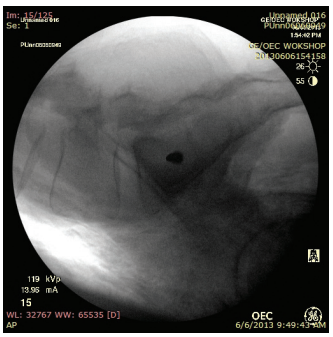
Confirm placement in 3 views:

Lateral View
Place Steinmann Pin approximately 1cm Anterior to PSW and 1cm Inferior to Ala.

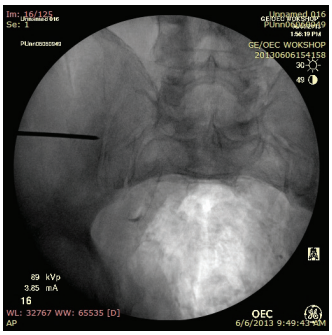
Inlet View
The angle of Steinmann Pin should be heading towards the middle of the Sacrum.

Outlet View
Steinmann Pin should be parallel to S1 endplate. Mallet the Steinman Pin in final desired depth in Outlet view.

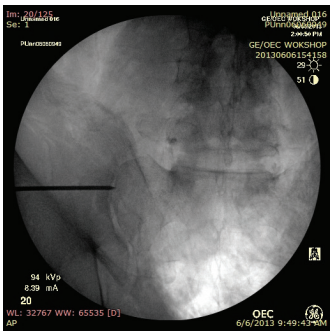
Lateral View



Inlet View



Outlet View



Step 5: Measure

Position #2 or #3 Soft Tissue Shield over Steinmann Pin. While keeping the Soft Tissue Shield in place, use the Steinmann Pin Depth Gage/Guide to select appropriate Silex implant. Insert the Steinmann Pin Depth Gage/Guide underneath the inserted Steinmann Pin and dock onto the proximal end of the Soft Tissue Shield. Measure with #3 Soft Tissue Shield for 12.5mm Implants and measure with #2 Soft Tissue Shield for 7mm implants. Remove the Soft Tissue Shield.

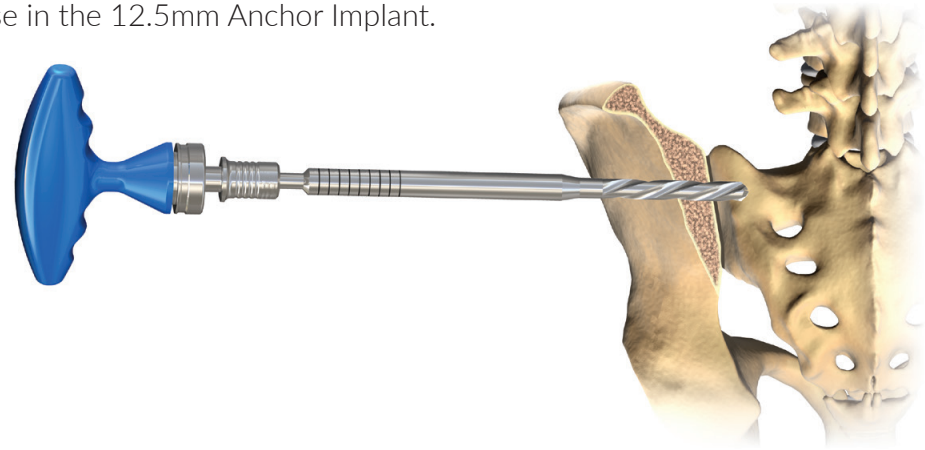
Note: Utilize the correct side of the Steinmann Pin Depth Gage/Guide, it is indicated for #2 and #3 Soft Tissue Shields.

Step 6: Drill Assembly

- Attach the Drill Bit to the Ratcheting T-Handle (or in-line handle) or Cordless Power Drill using the provided Jacobs Chuck.

  Note: Make sure the flat portion of the provided Jacobs Chuck attachment fits flush to the walls if using the Cordless Power Drill.

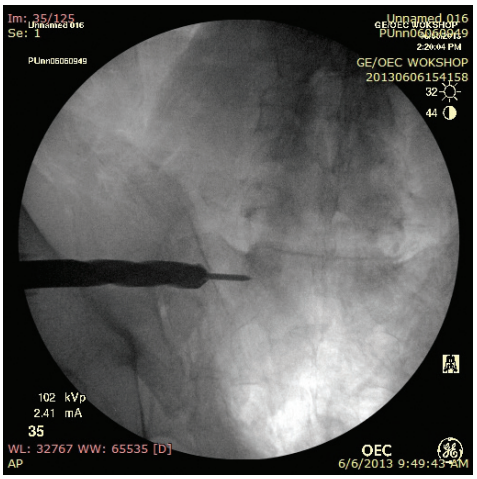
  Note: The drill flutes are designed to capture the autogenous bone graft for reuse in the 12.5mm Anchor Implant.



Step 7: Drill

- Place the Drill Bit over the Steinmann Pin slowly advancing until the Ilium is reached. Make sure the Drill is co-linear with the pin to avoid binding on the pin.

  Using the Outlet view, confirm accurate placement of the Drill Bit over the Steinmann Pin. Under fluoroscopic guidance continue to advance the Drill just across the Sacroiliac Joint, through the sacral cortex. Try to preserve sacral bone for re-packing the implant.



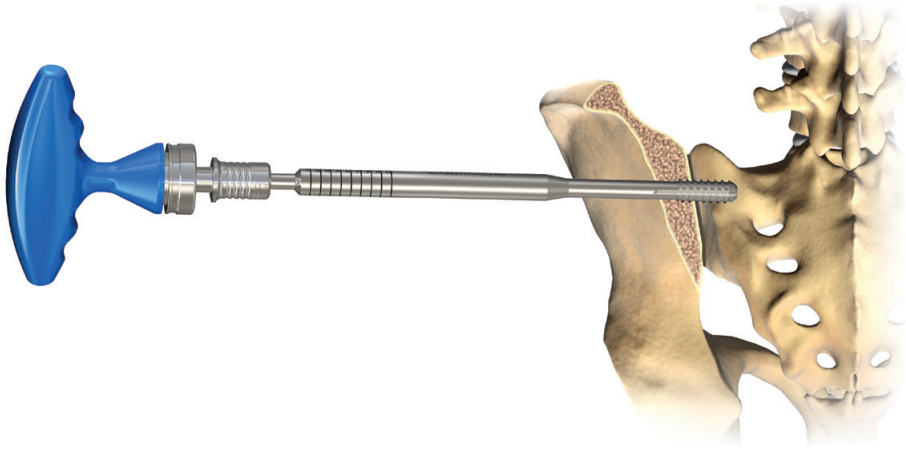
  Note: Once the Drill reaches the SI Joint, exercise caution advancing into the Sacrum.

  Note: Once the Drill Bit has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Drill Bit while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Step 8: Tap Assembly

- Attach the Tap to the Ratcheting T-Handle (or in-line handle).

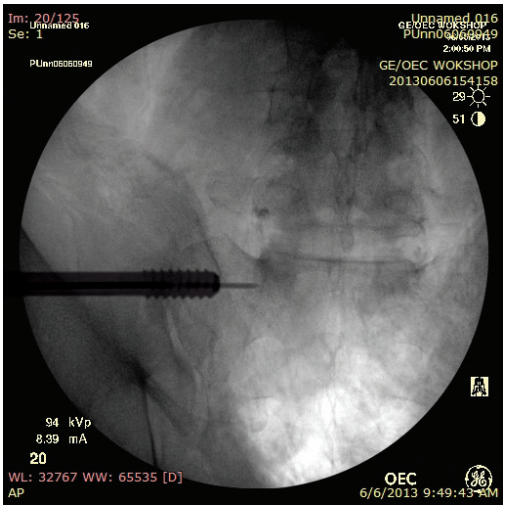
  Note: Do not tap under power.



Step 9: Tap

- Place the Tap over Steinmann Pin slowly advancing until you reach the Ilium. Make sure the Tap is co-linear with the pin to avoid binding on the pin.

  Using Outlet view, confirm placement. Under fluoroscopic guidance continue to advance the Tap across the Sacroiliac Joint, through to the sacral cortex. Try to preserve sacral bone for re-packing into the implant.



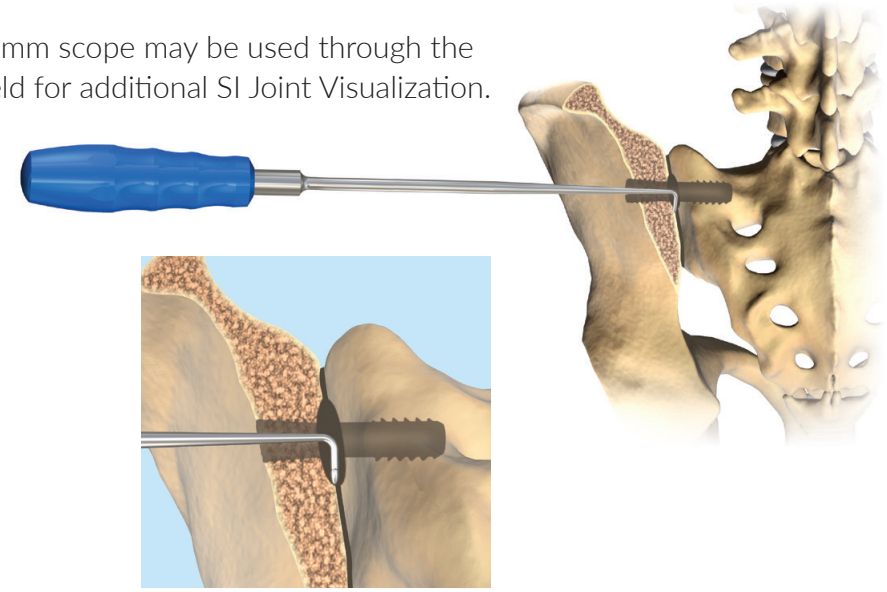
  Note: Once the Tap reaches the SI Joint exercise caution advancing into the Sacrum.

  Note: Once the Tap has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Tap while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Step 10: Decortication and Sacroiliac Joint Visualization

- Take the Right Angle Curette and follow along the Steinmann Pi down to the SI Joint. Once a tactile feel has been achieved, confirm in the Outlet View to verify placement in the joint. Rotate the instrument to prepare the SI Joint space for bony arthrodesis. Remove the instrument once the site has been properly prepared.

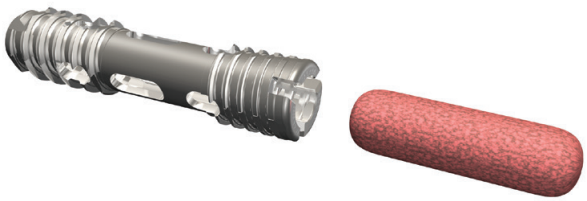
Note: A standard 2mm scope may be used through the #3 Soft Tissue Shield for additional SI Joint Visualization.



Step 11: Bone Graft Pre-Pack (12.5mm Implant only)

- Use the Bone Graft Packing Block to pre-pack selected implant with preferred bone grafting choice. Place the distal tip of the implant on the block and insert the bone graft into the implant through the proximal end.

Caution: Do not over pack as implant will obtain patient autograft during implantation.



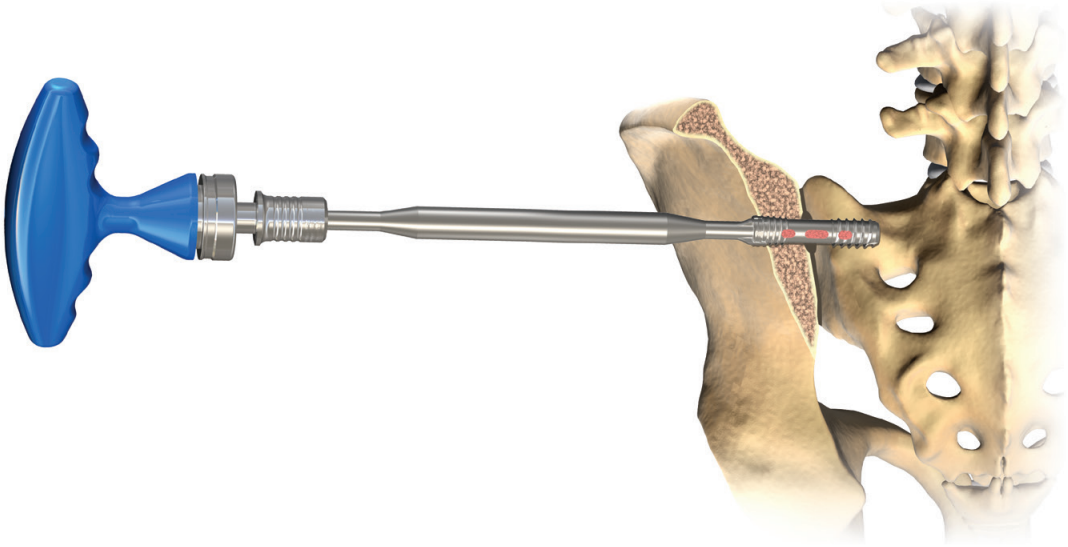
SILEX BONE GRAFT VOLUMES (Approximate)

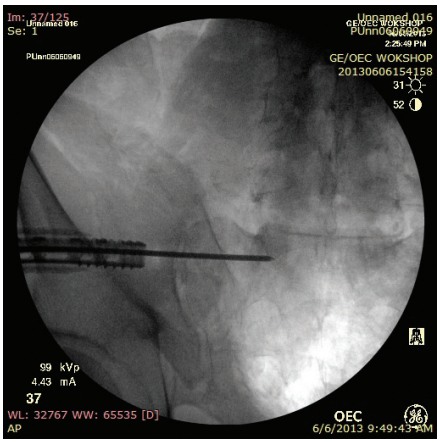
12.5mm dual & single thread implants

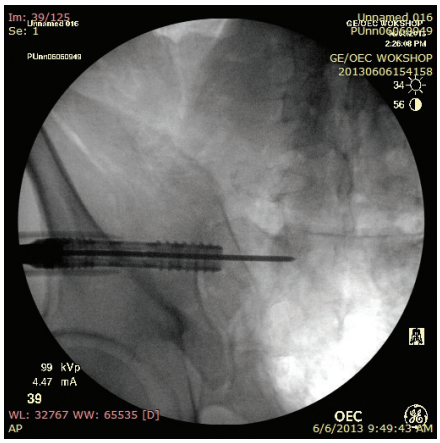
Length	Volume
30mm	1.50cc
35mm	1.70cc
40mm	2.00cc
45mm	2.20cc
50mm	2.50cc
55mm	2.70cc
60mm	3.10cc
65mm	3.30cc
70mm	3.50cc

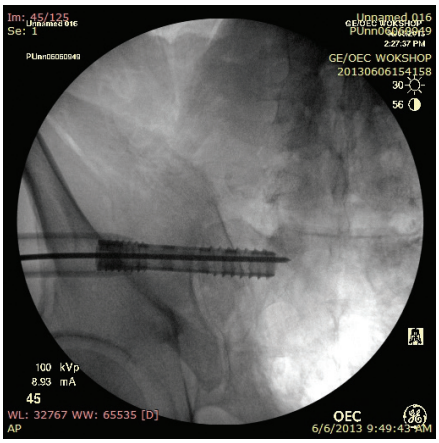
Step 12: Implant Loading and Final Placement

- Select the Implant Driver and place onto the Ratcheting T-Handle (or in-line handle, if desired). Select the corresponding Silex Implant and place onto the distal tip of the driver, make sure the implant is fully seated with the driver shaft. Insert the distal end of the implant over the Steinmann Pin and advance the implant, under fluoroscopy, to desired depth.



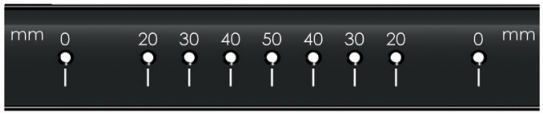






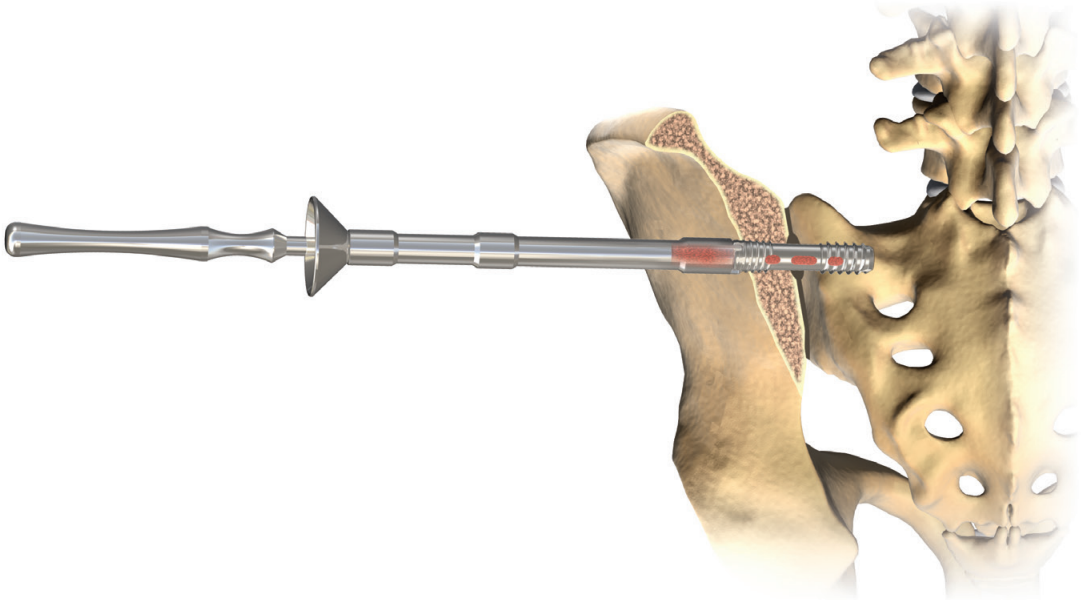
Step 13: Steinmann Pin Depth Gage

- Using the first Steinmann Pin, insert the fixed portion of the guide over the already inserted pin. Under fluoroscopy in the Lateral View, insert the second pin following the curve of the Sacrum. Confirm in the three views (Lateral, Inlet, Outlet) that the second Steinmann Pin placement is accurate. Repeat steps above for implant insertion of the subsequent implants.

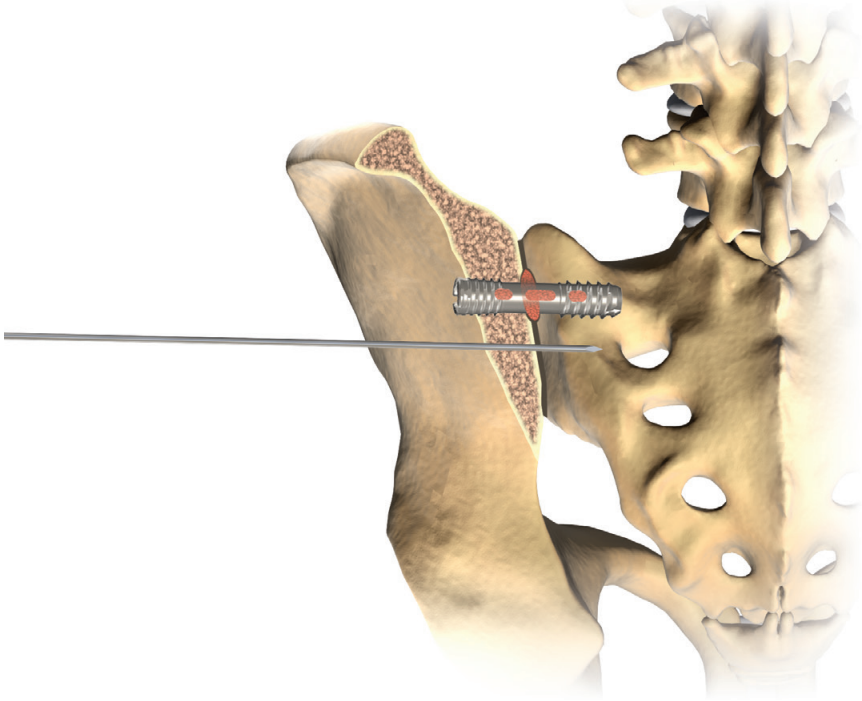


Step 14: Bone Graft Post Fill (12.5mm Implant only)

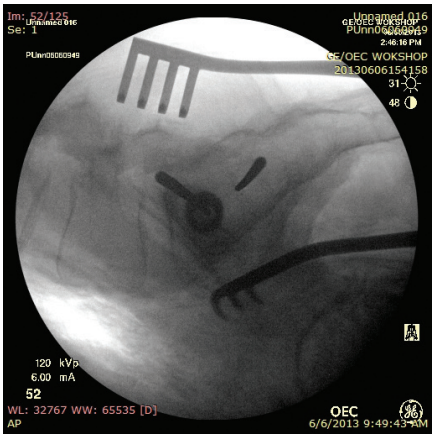
- After the Second Steinmann Pin placement is confirmed, insert the Bone Graft Funnel over the Steinmann Pin from the first implant. Rotate the funnel until fully engaged with the implant. Remove the Steinmann Pin from the first implant once the Bone Graft Funnel is in place. Next, insert the preferred bone graft through the Bone Graft Funnel, follow with the Graft Tamp until fully seated with the implant.



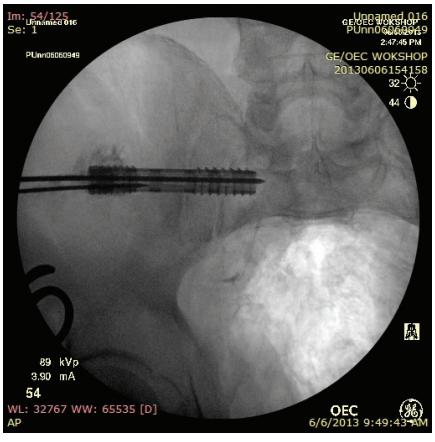
Step 15: Second Implant Targeting



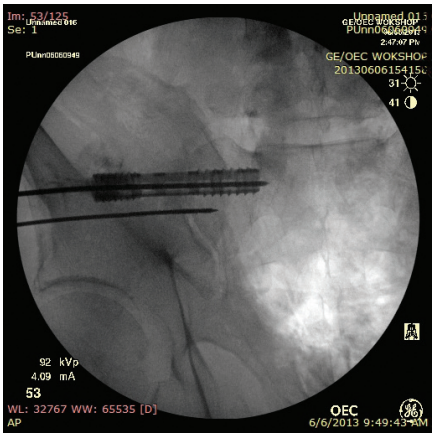
Lateral View



Inlet View

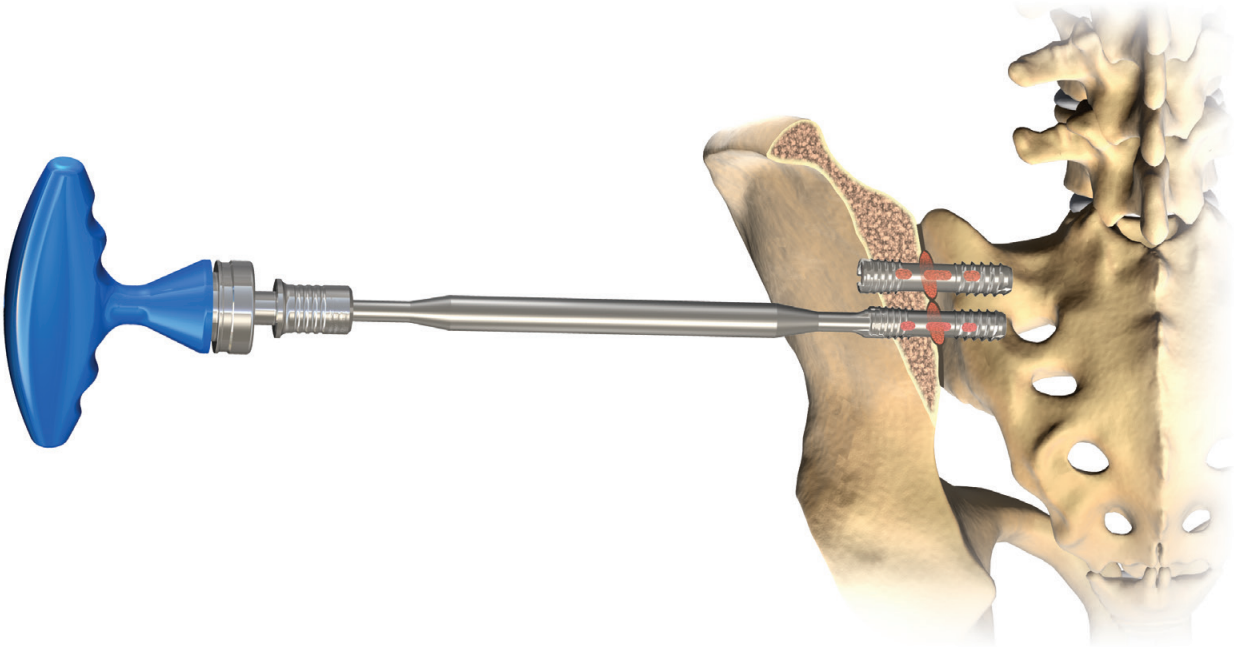


Outlet View

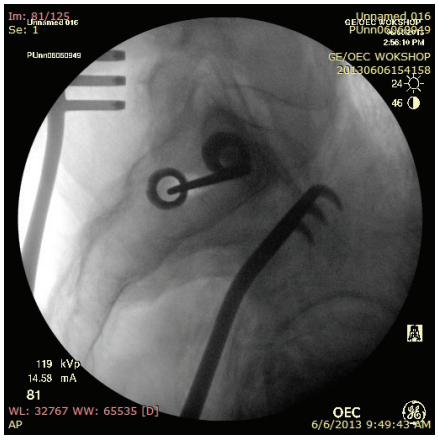


Step 16: Second Implant Insertion

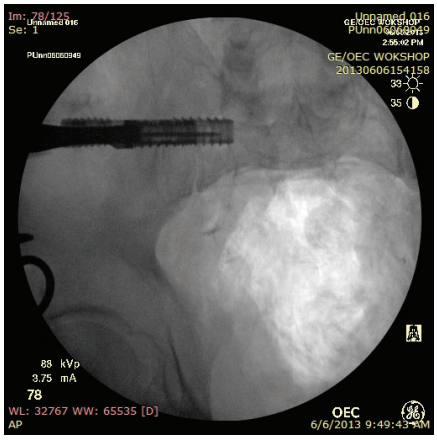
- Repeat steps 4-14



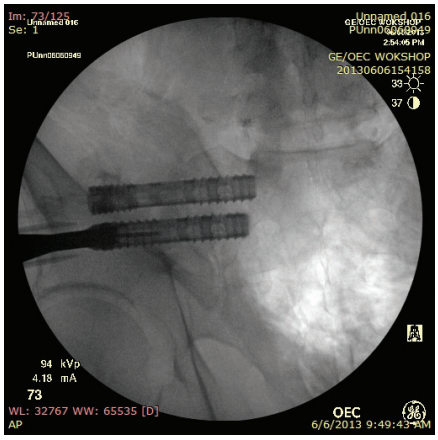
Lateral View



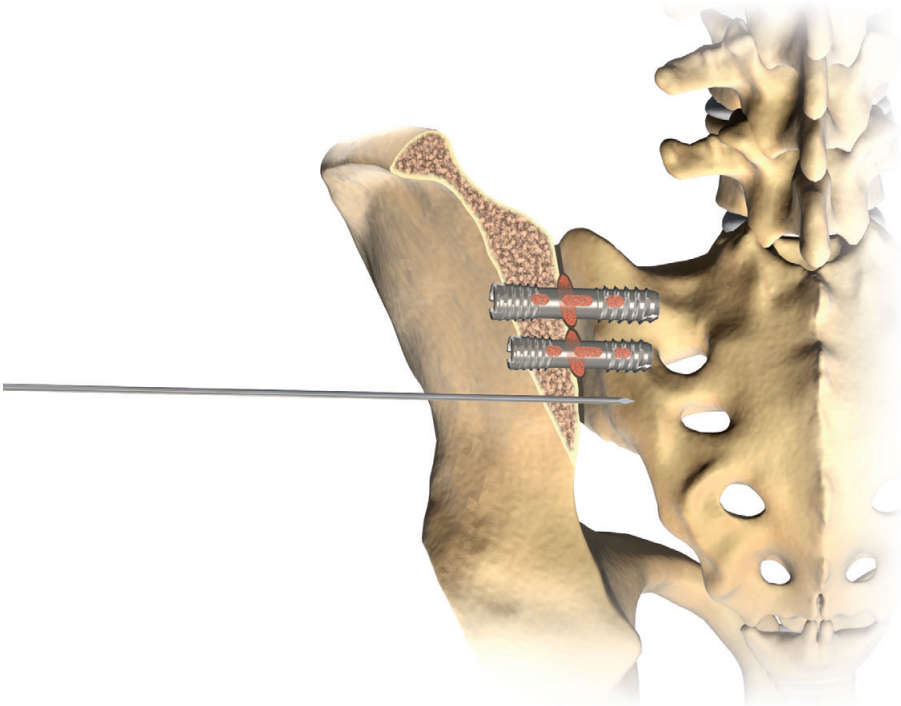
Inlet View



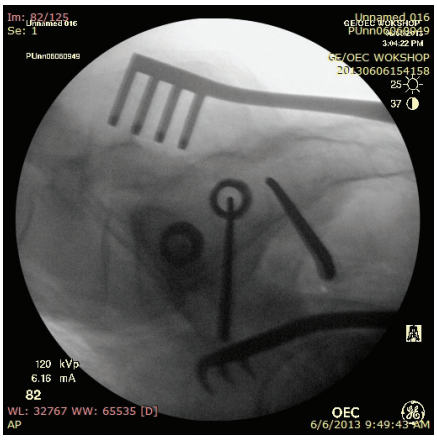
Outlet View



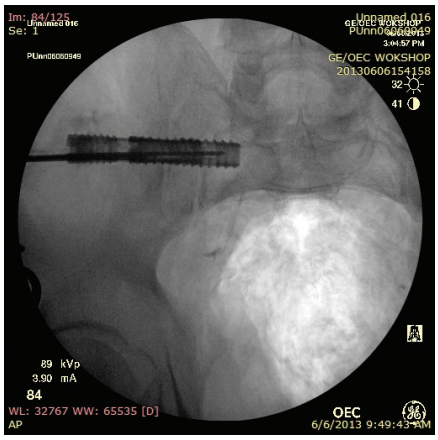
Step 17: Third Implant Targeting



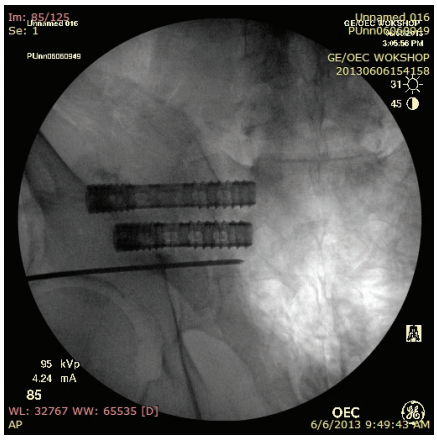
Lateral View



Inlet View

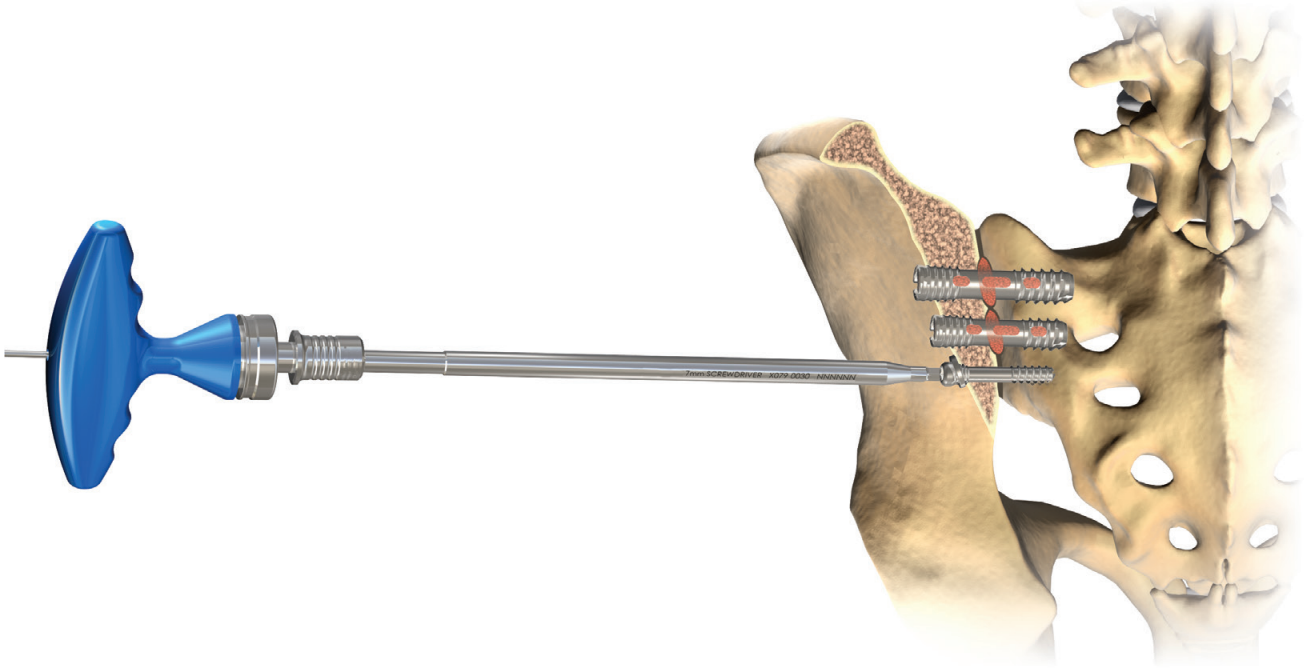


Outlet View

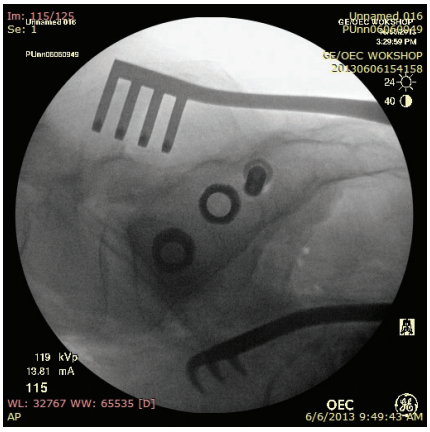


Step 18: Third Implant Insertion

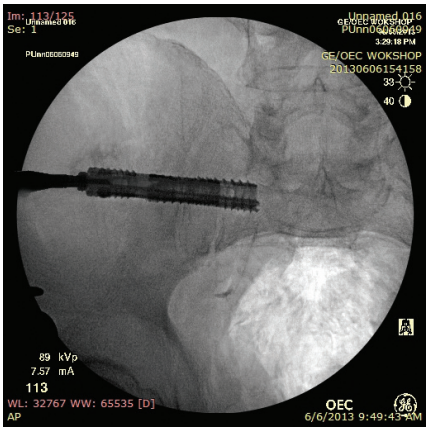
- Repeat steps 4-14



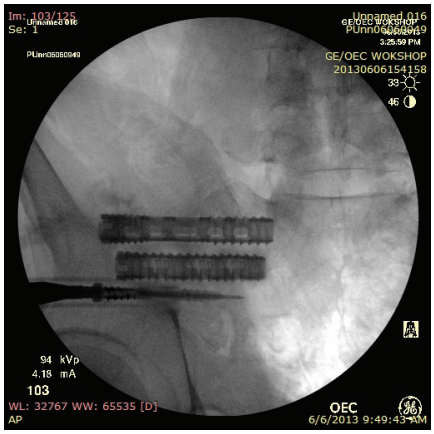
Lateral View



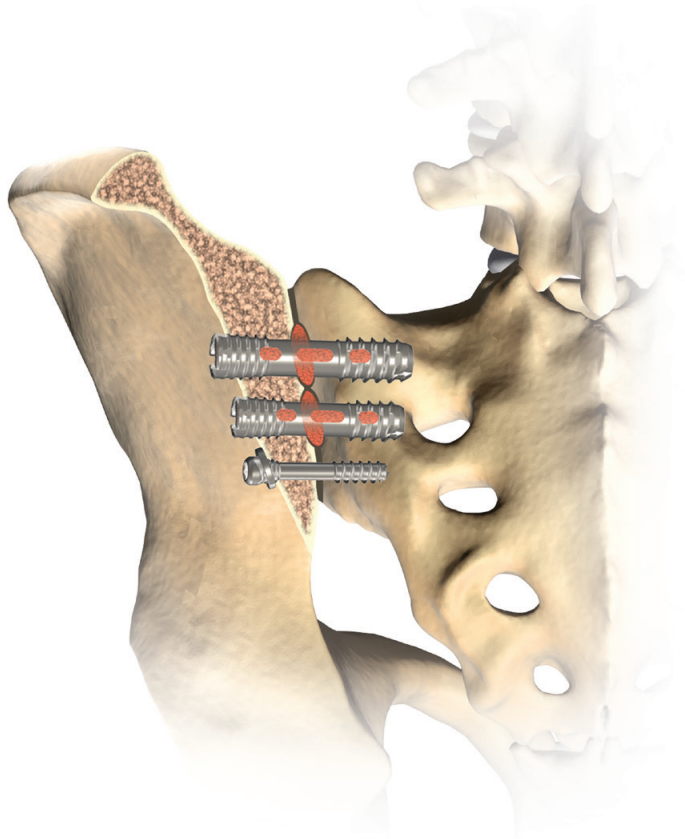
Inlet View



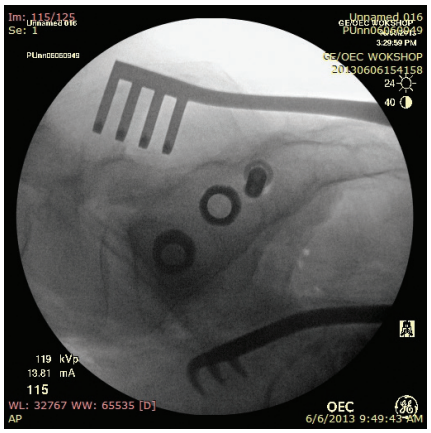
Outlet View



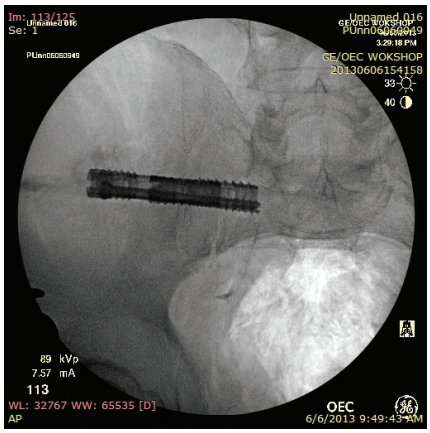
Step 19: Final Implant Construct



Lateral View



Inlet View



Outlet View

Step 20: Implant Removal and Adjustment

Option #1 – 12.5mm Implant

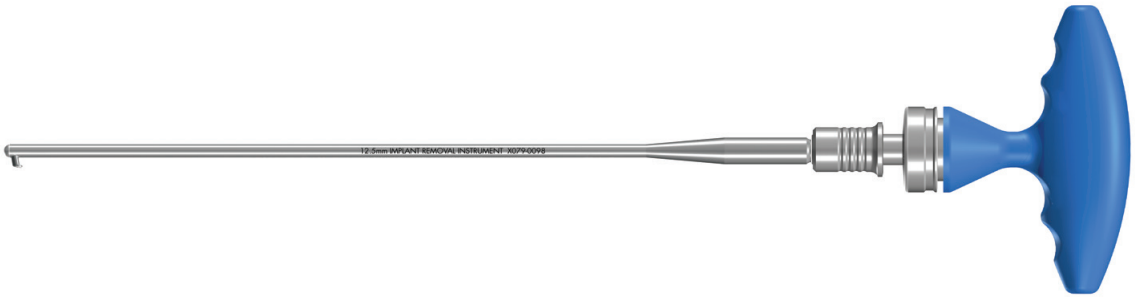
Attach the Ratcheting T-Handle to the 12.5mm Implant Driver, locate the proximal end of the implant that needs adjusting. Fully seat the distal end of the implant driver into the desired implant. With the Ratcheting T-Handle, rotate counterclockwise to adjust or fully remove implant.

Option #2 – 12.5mm Implant

Attach the Ratcheting T-Handle to the 12.5mm Implant Removal Instrument, palpating and under fluoroscopy, locate the proximal end of the implant that needs adjusting Insert the distal end of the 12.5mm Implant Removal Instrument into the desired implant until the initial fenestration is reached. With the Ratcheting T-Handle, rotate counter-clockwise or pull axially to adjust or fully remove implant.

7mm Anchor Implant

Attach the Ratcheting T-Handle to the 7mm Implant Driver, locate the proximal end of the implant that needs adjusting. Fully seat the distal end of the implant driver into the desired implant. With the Ratcheting T-Handle, rotate counterclockwise to adjust or fully remove implant.



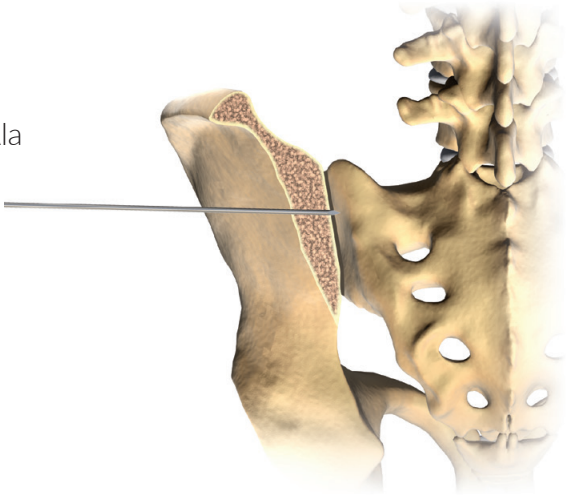
SILEX® SACROILIAC JOINT FUSION SYSTEM
OPTIONAL SOFT TISSUE SHIELD SURGICAL TECHNIQUE

Step 1: Skin Marking

- Use the Exchange Pin to mark the Posterior Sacral Wall (PSW) and Sacral Alar Line with a marking pen.

Step 2: Skin Incision

- Make skin incision along Posterior Sacral Wall, approx. 3-5mm in length, starting at intersection with Sacral Ala skin marking.



Step 3: Steinmann Pin Placement

- Beginning in the Lateral View, take the sharp Steinmann Pin and insert the Steinmann Pin through skin incision approximately 1cm Anterior to the Posterior Sacral Wall and 1cm Inferior to the Ala.

Confirm placement in 3 views:

Lateral View

Place Steinmann Pin approximately 1cm Anterior to PSW and 1cm Inferior to Ala.

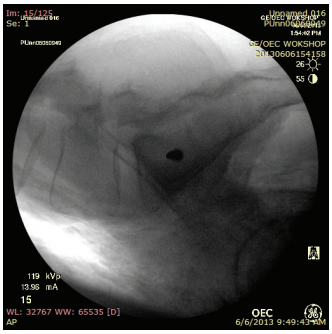
Inlet View

The angle of Steinmann Pin should be heading towards the middle of the Sacrum.

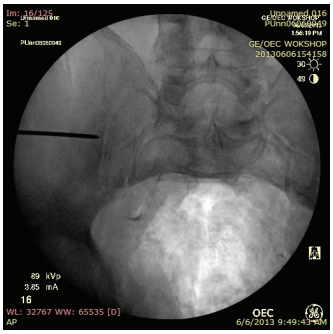
Outlet View

Steinmann Pin should be parallel to S1 endplate. Mallet the Steinman Pin in final desired depth in Outlet view.

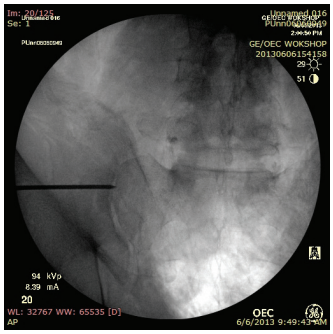
Lateral View



Inlet View



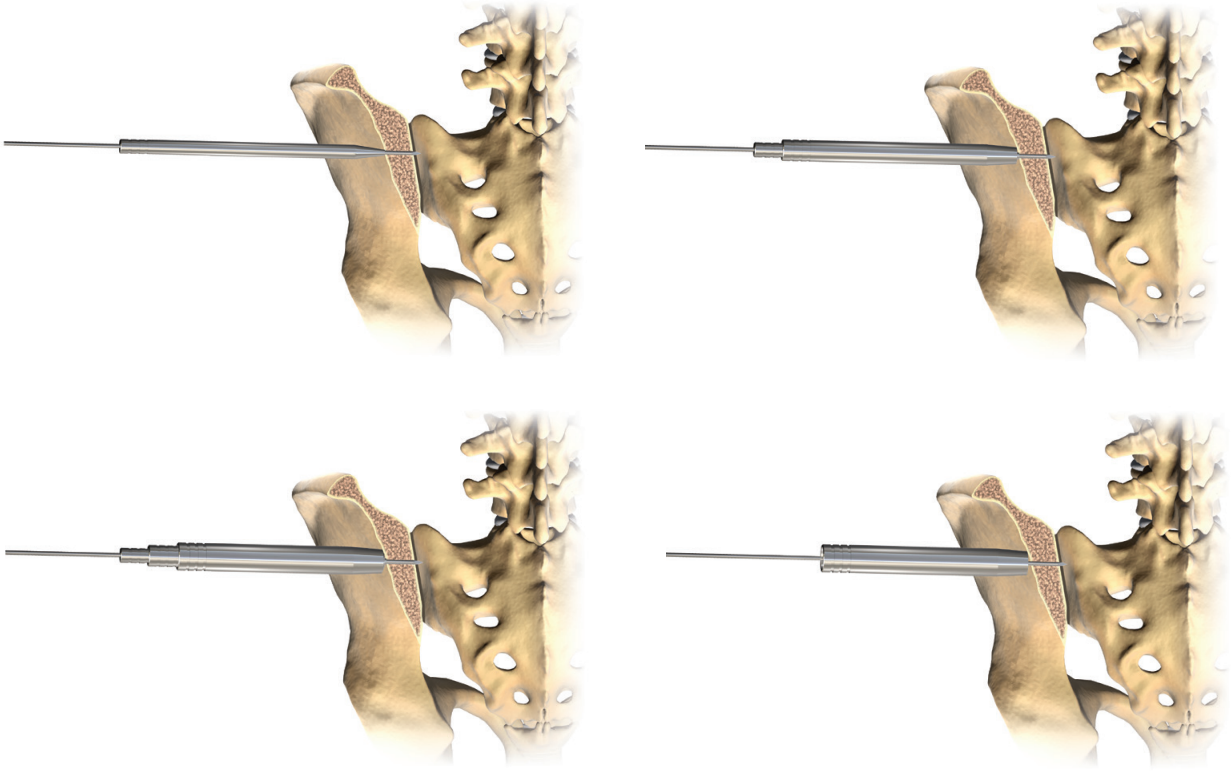
Outlet View



Step 4: Soft Tissue Shield Placement

- Drop #1, 2 and 3 Soft Tissue Shields, in sequence, over the Steinmann Pin. Once the #3 Soft Tissue Shield is in place, remove #1-2 Soft Tissue Shields.

  Note: Optional Guide Handle may be used for added stability.



Step 5: Measuring/Implant Selection

- While keeping the Soft Tissue Shield in place, use the Steinmann Pin Depth Gage/Guide to select appropriate Silex implant. Insert the Steinmann Pin Depth Gage/Guide underneath the inserted Steinmann Pin and dock onto the proximal end of the Soft Tissue Shield. Measure with #3 Soft Tissue Shield for 12.5mm Implants and measure with #2 Soft Tissue Shield for 7mm implants.

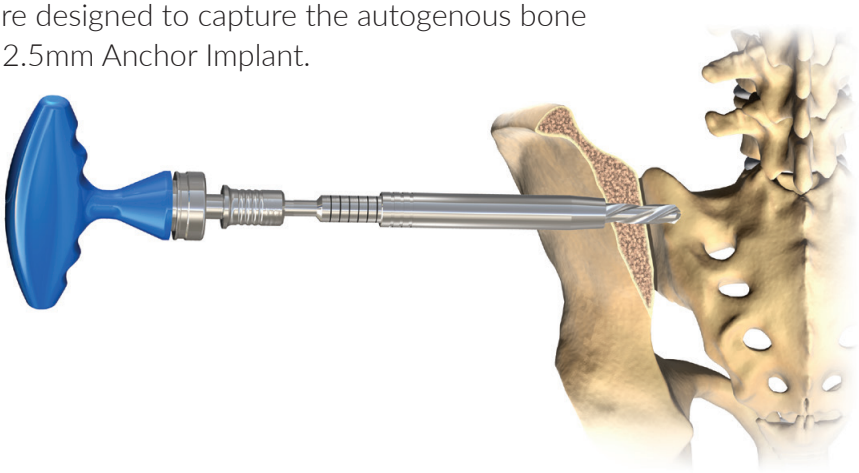
  Note: Utilize the correct side of the Steinmann Pin Depth Gage/Guide, it is indicated for #2 and #3 Soft Tissue Shields.

Step 6: Drill Assembly

- Attach the Drill Bit to the Ratcheting T-Handle (or in-line handle) or Cordless Power Drill using the provided Jacobs Chuck.

  Note: Make sure the flat portion of the provided Jacobs Chuck attachment fits flush to the walls if using the Cordless Power Drill.

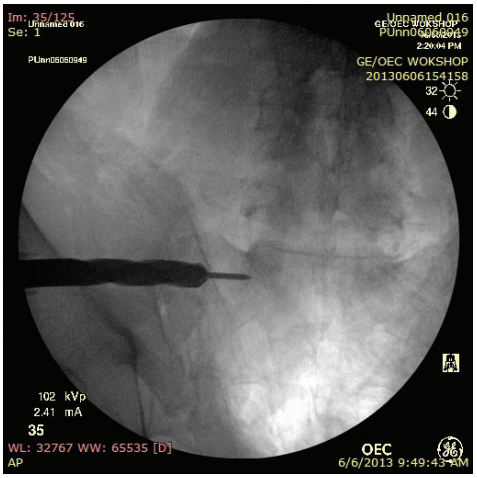
  Note: The drill flutes are designed to capture the autogenous bone graft for reuse in the 12.5mm Anchor Implant.



Step 7: Drill

- Place the Drill Bit over the Steinmann Pin slowly advancing until the Ilium is reached. Make sure the Drill is co-linear with the pin to avoid binding on the pin.

  Using the Outlet view, confirm accurate placement of the Drill Bit over the Steinmann Pin. Under fluoroscopic guidance continue to advance the Drill just across the Sacroiliac Joint, through the sacral cortex. Try to preserve sacral bone for re-packing the implant.



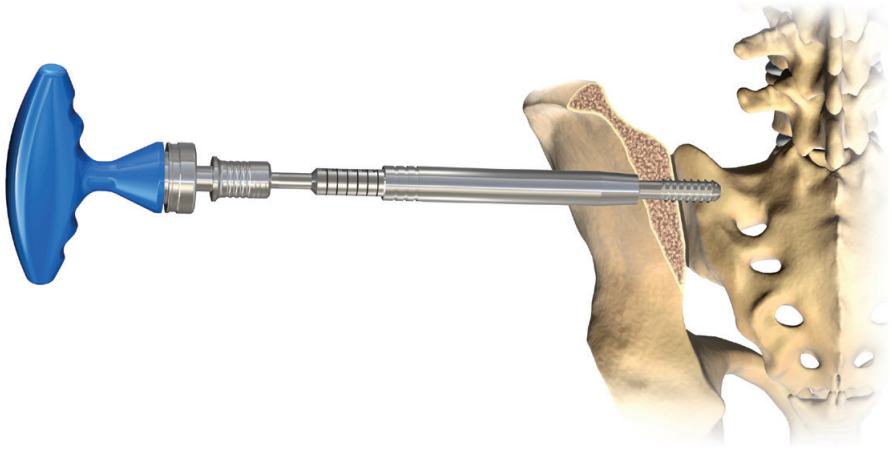
  Note: Once the Drill reaches the SI Joint, exercise caution advancing into the Sacrum.

  Note: Once the Drill Bit has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Drill Bit while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Step 8: Tap Assembly

- Attach the Tap to the Ratcheting T-Handle (or in-line handle).

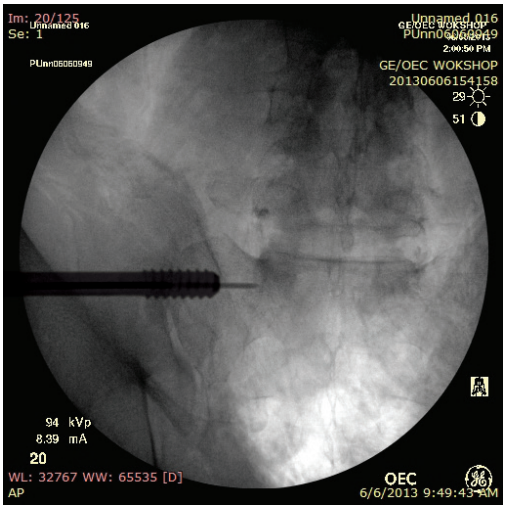
  Note: Do not tap under power.



Step 9: Tap

- Place the Tap over Steinmann Pin slowly advancing until you reach the Ilium. Make sure the Tap is co-linear with the pin to avoid binding on the pin.

  Using Outlet view, confirm placement. Under fluoroscopic guidance continue to advance the Tap across the Sacroiliac Joint, through to the sacral cortex. Try to preserve sacral bone for re-packing into the implant.



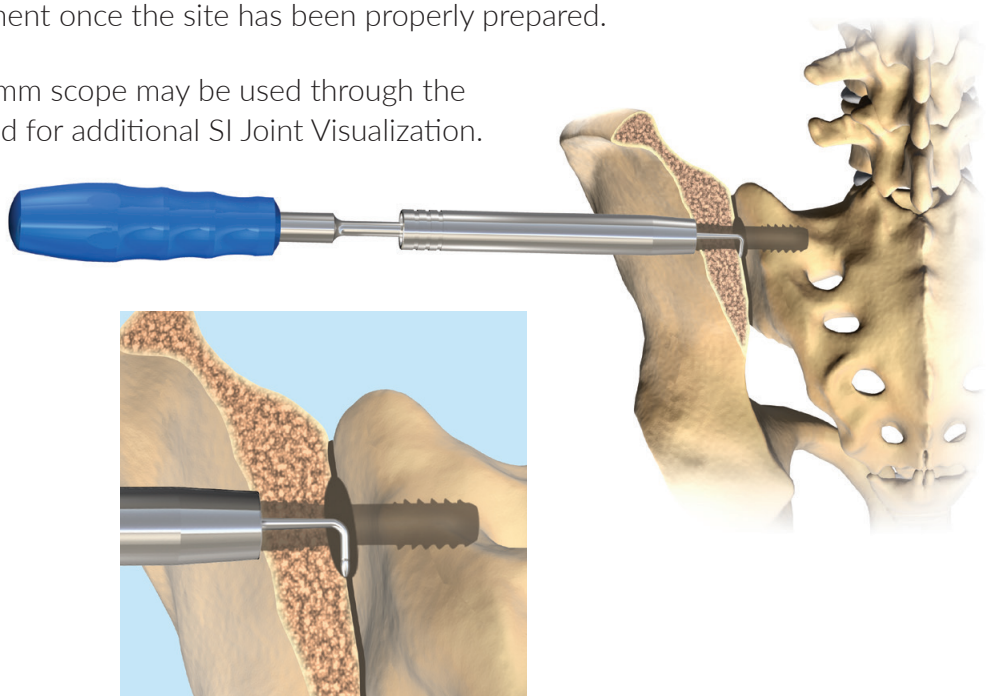
  Note: Once the Tap reaches the SI joint exercise caution advancing into the Sacrum.

  Note: Once the Tap has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Tap while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Step 10: Decortication and Sacroiliac Joint Visualization

- Take the Right Angle Curette and place through the #3 Soft Tissue Shield. Once a tactile feel has been achieved, confirm in the Outlet View to verify placement in the joint. Rotate the instrument to prepare the SI Joint space for bony arthrodesis. Remove the instrument once the site has been properly prepared.

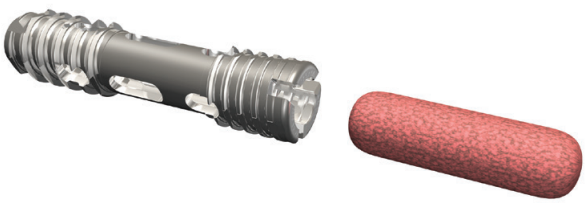
Note: A standard 2mm scope may be used through the #3 Soft Tissue Shield for additional SI Joint Visualization.



Step 11: Bone Graft Pre-Pack (12.5mm Implant only)

- Use the Bone Graft Packing Block to pre-pack selected implant with preferred bone grafting choice. Place the distal tip of the implant on the block and insert the bone graft into the implant through the proximal end.

Caution: Do not over pack as implant will obtain patient autograft during implantation.



SILEX BONE GRAFT VOLUMES (Approximate)

12.5mm dual & single thread implants

Length	Volume
30mm	1.50cc
35mm	1.70cc
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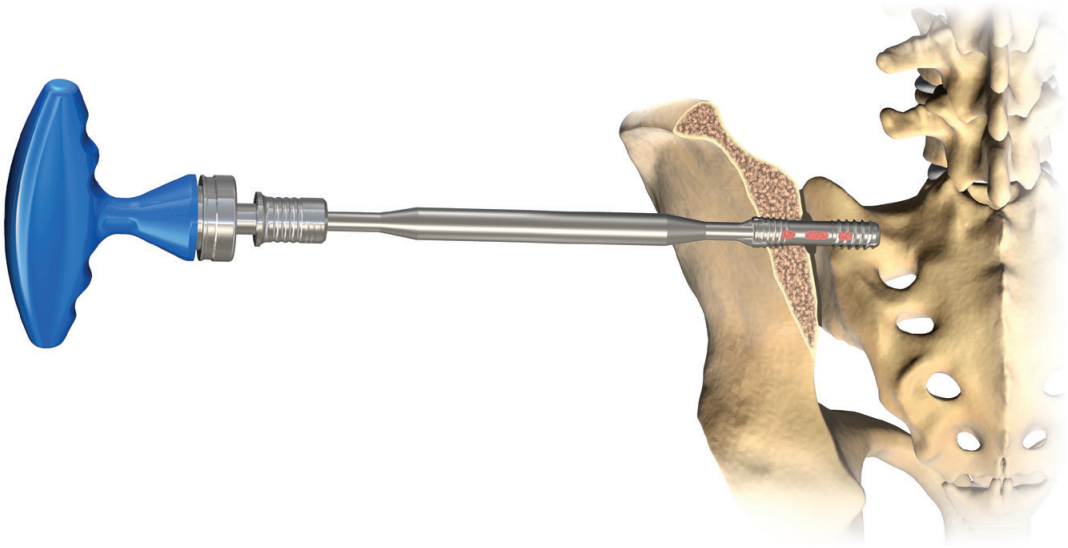
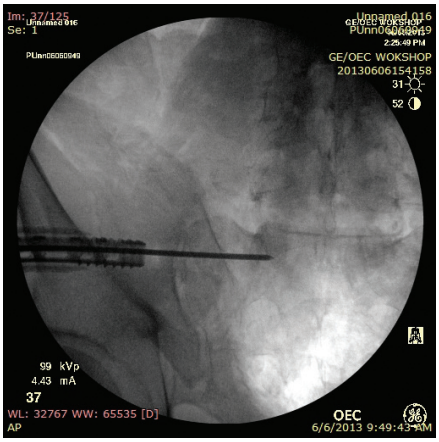
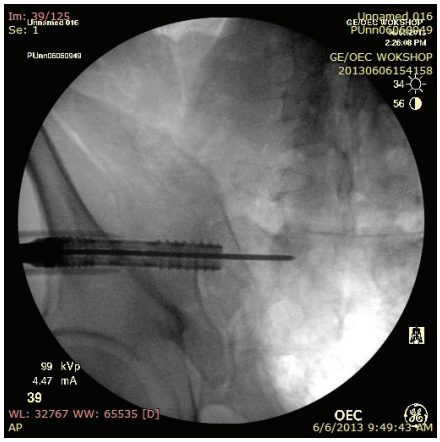
45mm	2.20cc
50mm	2.50cc
55mm	2.70cc
60mm	3.10cc
65mm	3.30cc
70mm	3.50cc

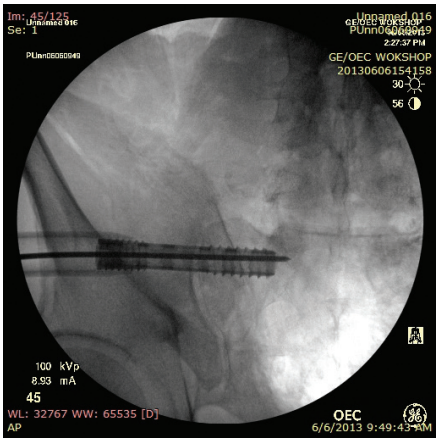
Step 12: Implant Loading and Final Placement

- Select the Implant Driver and place onto the Ratcheting T-Handle (or in-line handle, if desired). Select the corresponding Silex Implant and place onto the distal tip of the driver, make sure the implant is fully seated with the driver shaft. Insert the distal end of the implant over the Steinmann Pin and advance the implant, under fluoroscopy, to desired depth.



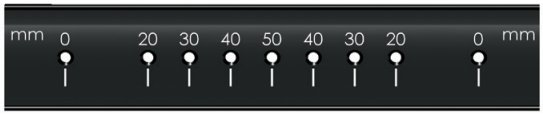






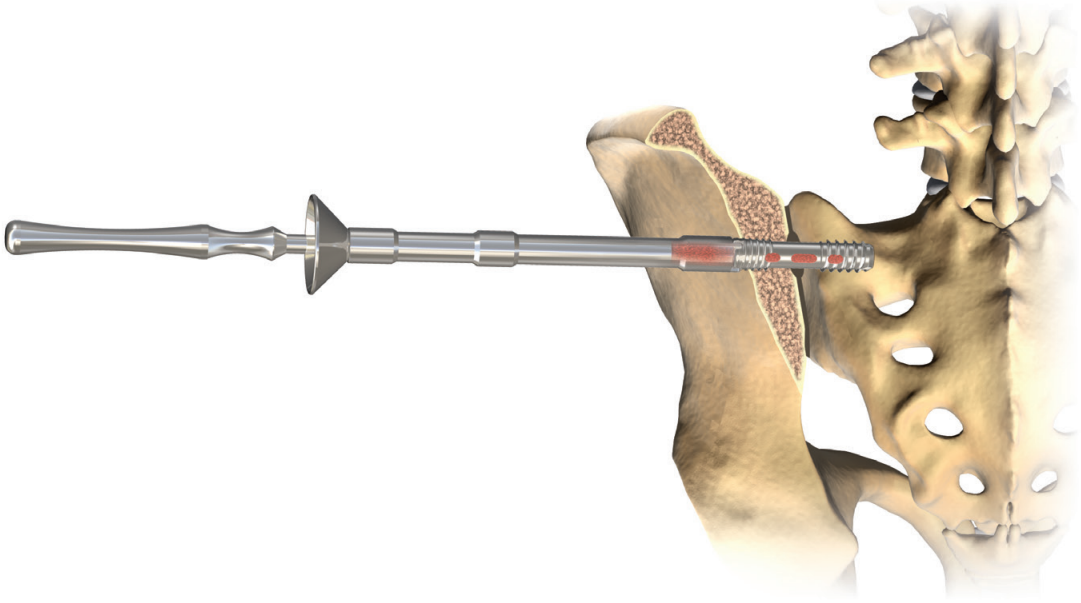
Step 13: Steinmann Pin Depth Gage

- Using the first Steinmann Pin, insert the Steinmann Pin Depth Gage/Guide starting in the 0 degree position over the already inserted pin. Under fluoroscopy in the Lateral View, insert the second pin at the 20 degree marker while following the curve of the Sacrum. Confirm in the three views (Lateral, Inlet, Outlet) that the second Steinmann Pin placement is accurate. Repeat steps above for implant insertion of the subsequent implants.

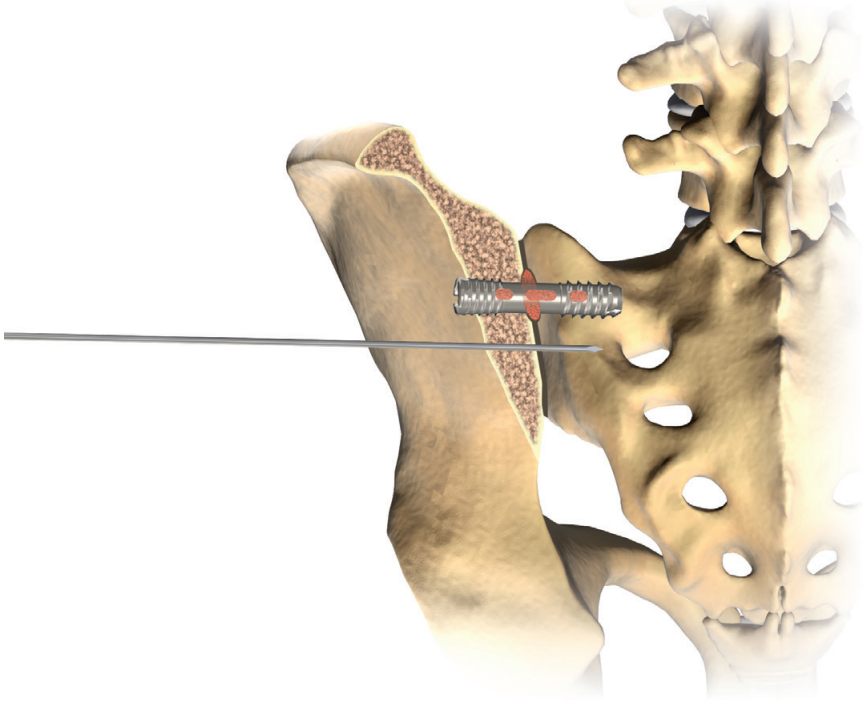


Step 14: Bone Graft Post Fill (12.5mm Implant only)

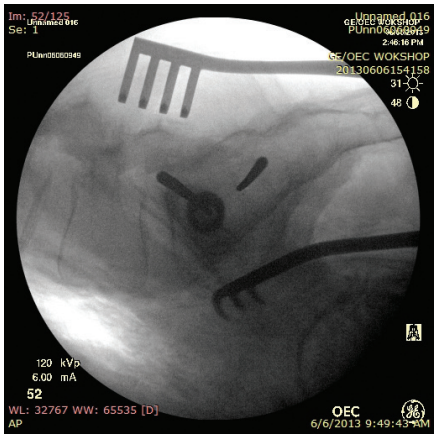
- After the Second Steinmann Pin placement is confirmed, insert the Bone Graft Funnel through the #3 Soft Tissue Shield and over the Steinmann Pin from the first implant. Rotate the funnel until fully engaged with the implant. Remove the Steinmann Pin from the first implant once the Bone Graft Funnel is in place. Next, insert the preferred bone graft through the Bone Graft Funnel, follow with the Graft Tamp until fully seated with the implant.



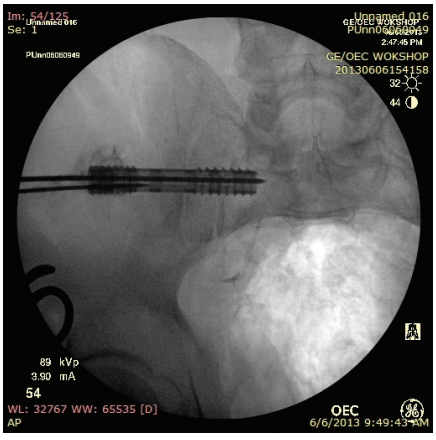
Step 15: Second Implant Targeting



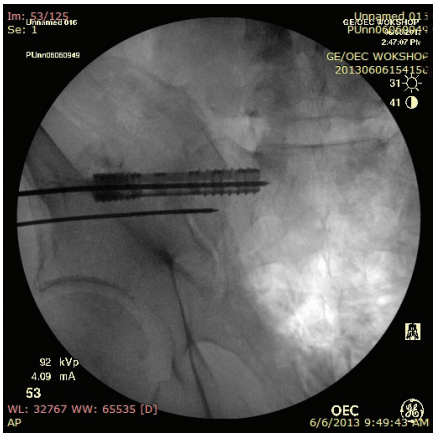
Lateral View



Inlet View

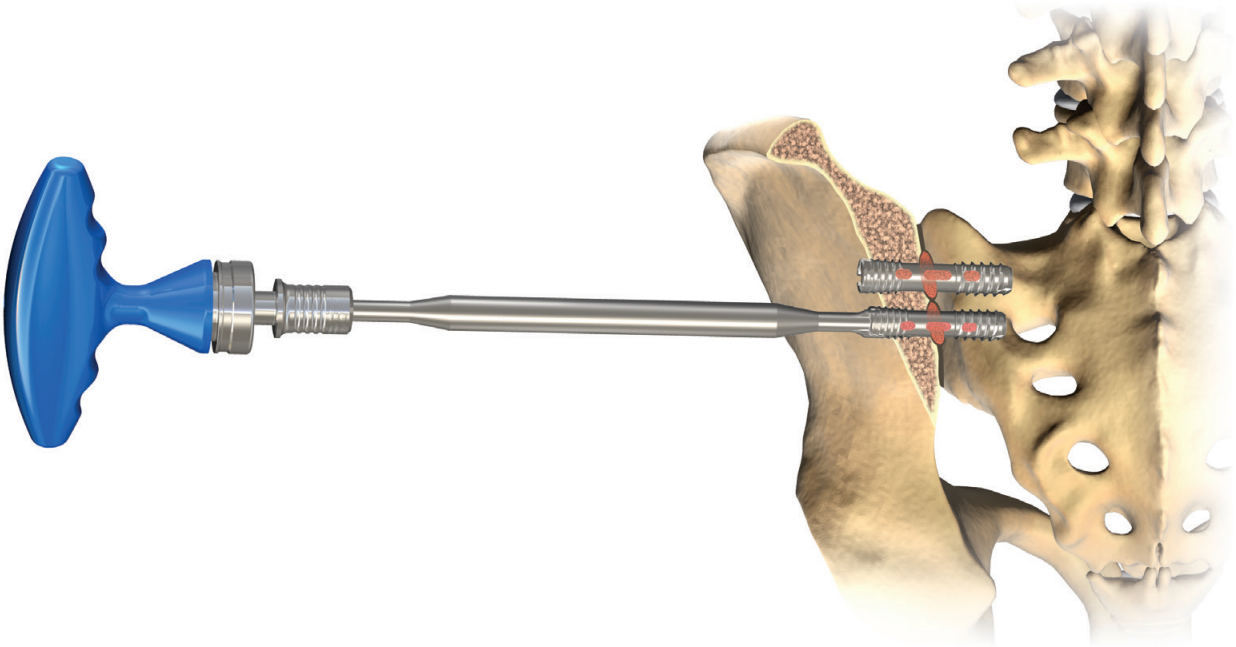


Outlet View

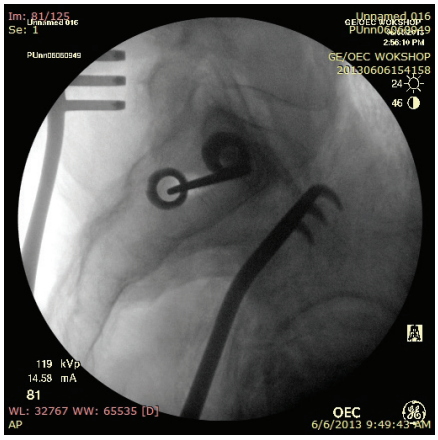


Step 16: Second Implant Insertion

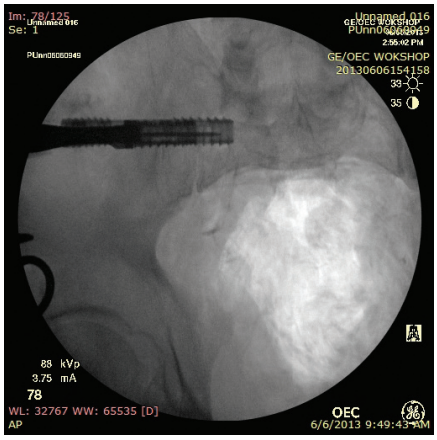
- Repeat steps 4-14



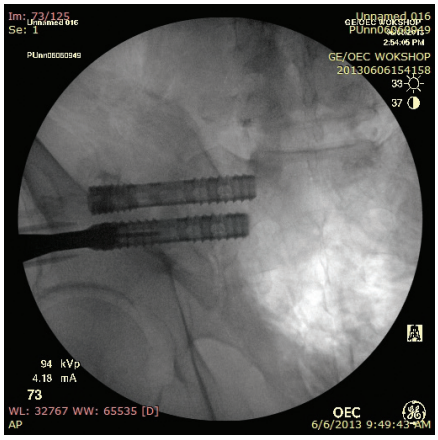
Lateral View



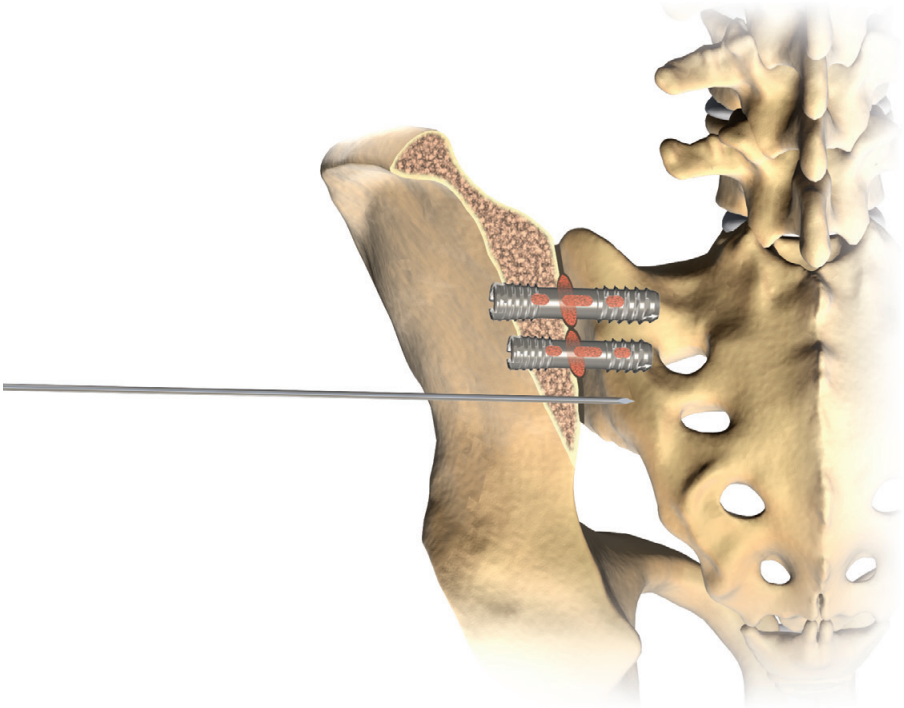
Inlet View



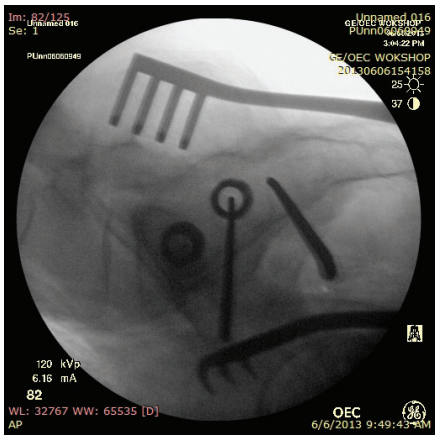
Outlet View



Step 17: Third Implant Targeting



Lateral View



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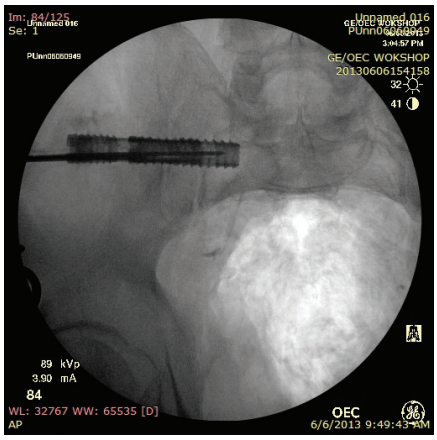
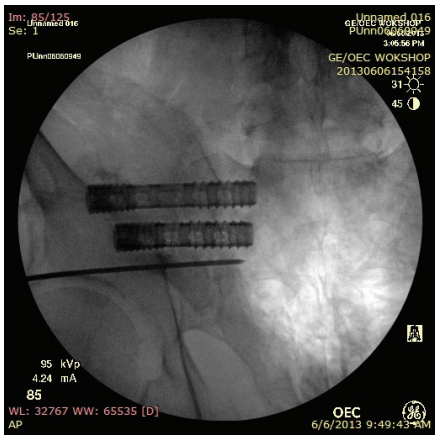
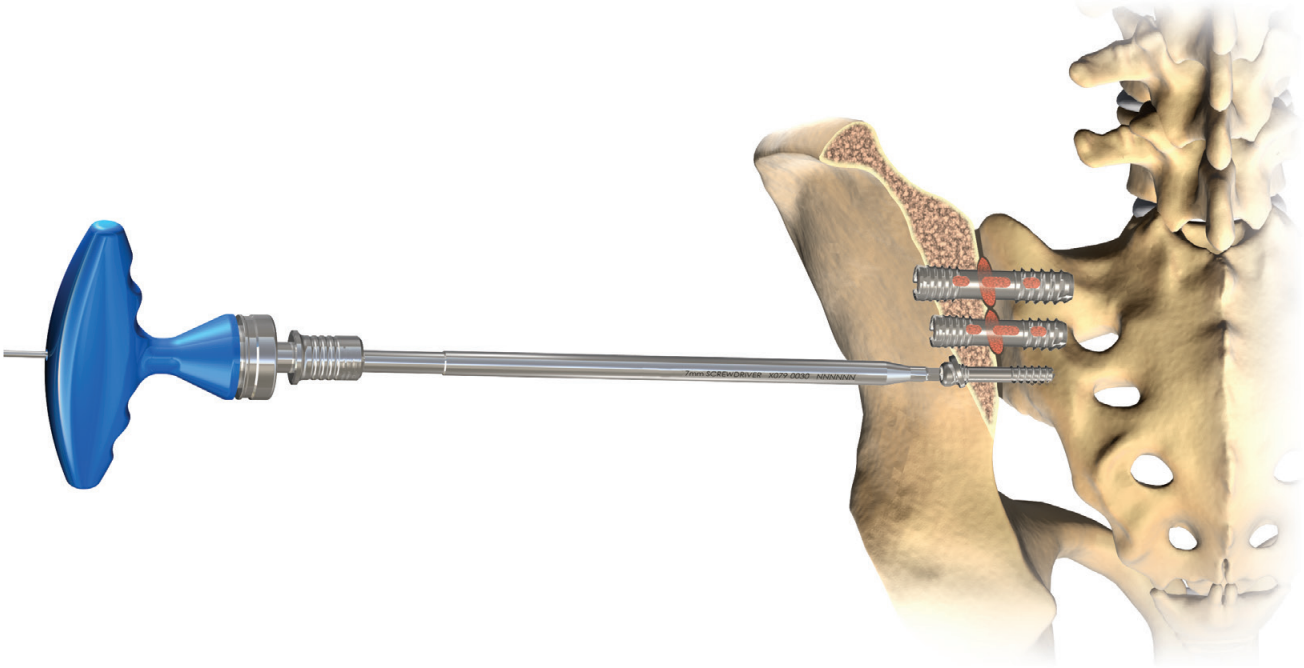


Outlet View

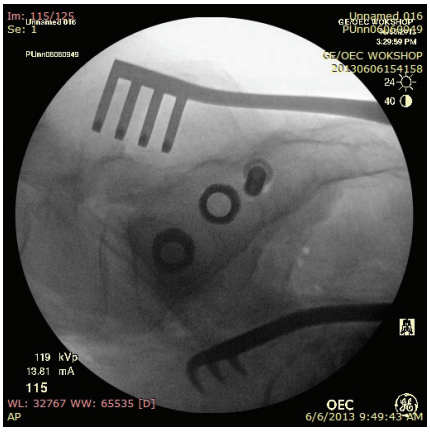


Step 18: Third Implant Insertion

- Repeat steps 4-14



Lateral View



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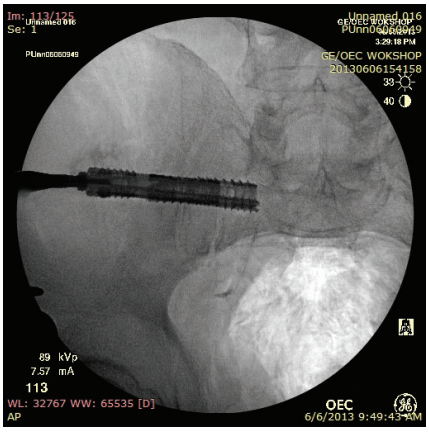
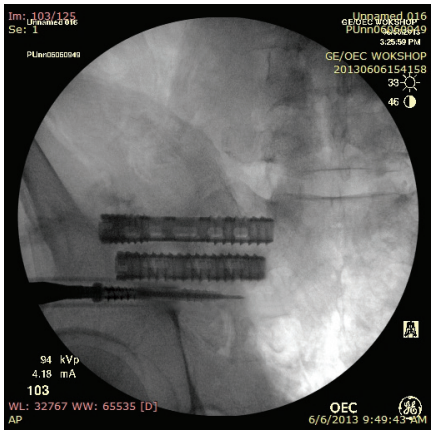
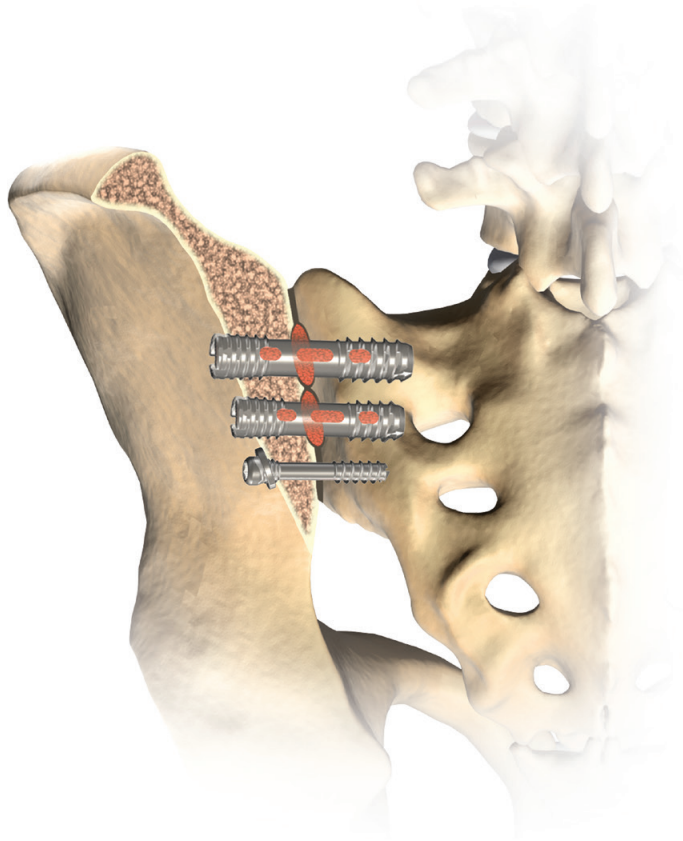


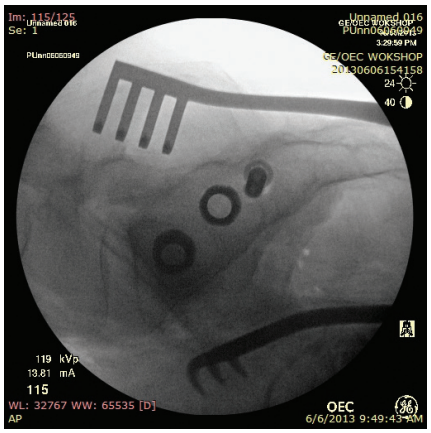
Outlet View



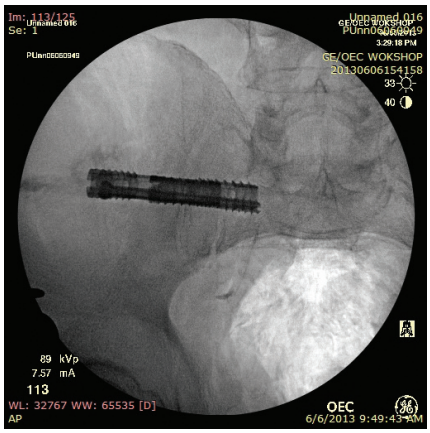
Step 19: Final Implant Construct



Lateral View



Inlet View



Outlet View

Step 20: Implant Removal and Adjustment

Option #1 – 12.5mm Implant

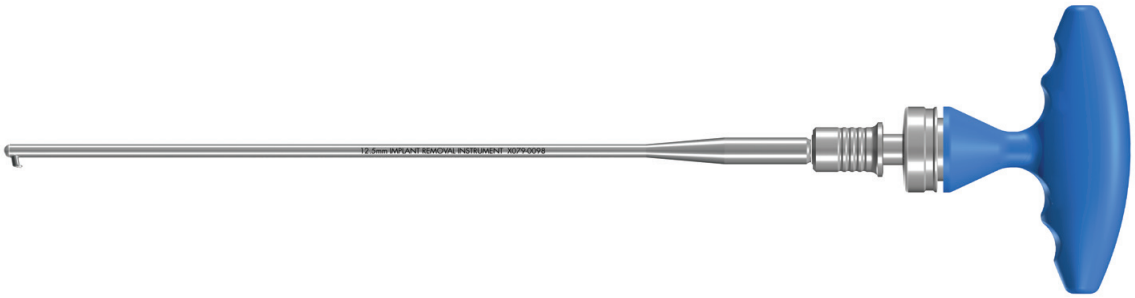
Attach the Ratcheting T-Handle to the 12.5mm Implant Driver, locate the proximal end of the implant that needs adjusting. Fully seat the distal end of the implant driver into the desired implant. With the Ratcheting T-Handle, rotate counterclockwise to adjust or fully remove implant.

Option #2 – 12.5mm Implant

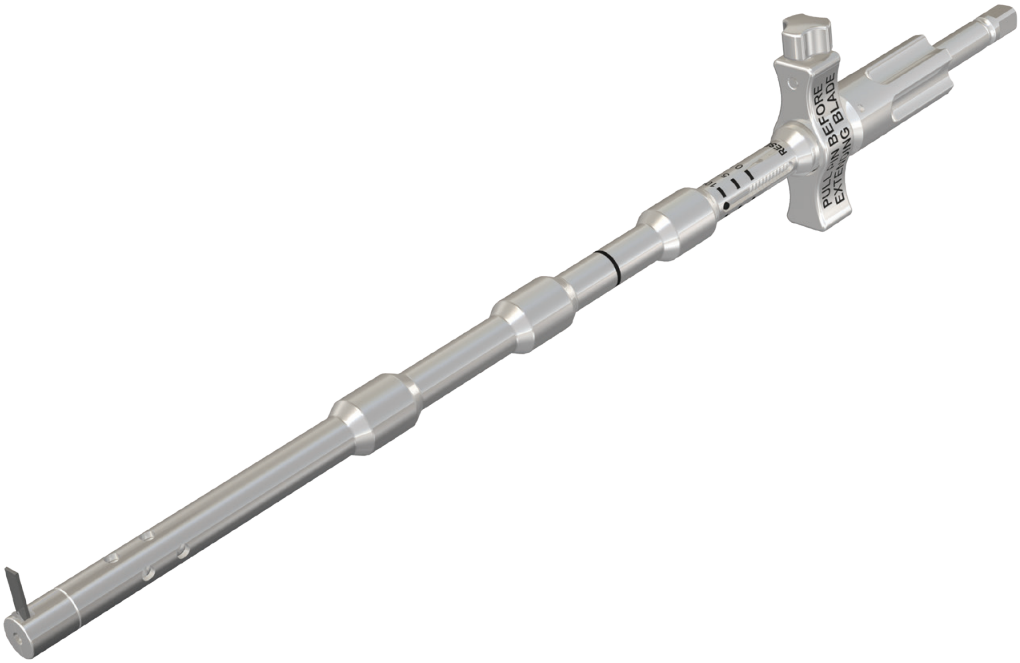
Attach the Ratcheting T-Handle to the 12.5mm Implant Removal Instrument, palpating and under fluoroscopy, locate the proximal end of the implant that needs adjusting Insert the distal end of the 12.5mm Implant Removal Instrument into the desired implant until the initial fenestration is reached. With the Ratcheting T-Handle, rotate counter-clockwise or pull axially to adjust or fully remove implant.

7mm Anchor Implant

Attach the Ratcheting T-Handle to the 7mm Implant Driver, locate the proximal end of the implant that needs adjusting. Fully seat the distal end of the implant driver into the desired implant. With the Ratcheting T-Handle, rotate counterclockwise to adjust or fully remove implant.



SILEX® SACROILIAC JOINT FUSION SYSTEM
SACROILIAC JOINT DECORTICATION INSTRUMENT



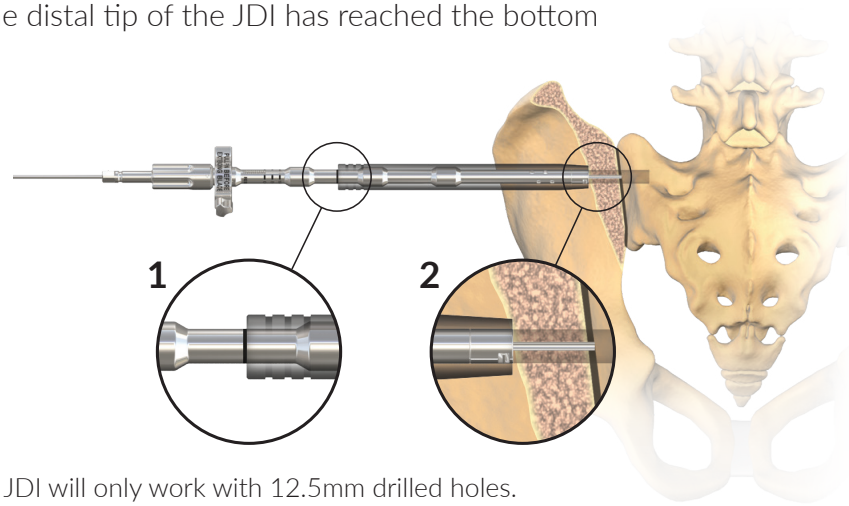
- Joint Decortication Instrument (JDI) can extend up to 10mm in the SI joint
- Cannulation allows for easy insertion and placement of the Joint Decortication Instrument
- Laser marked ring helps with visualization of instrument alignment

Step 1 : Assembly and Initial Insertion

- Before using the Joint Decortication Instrument (JDI), the Steinmann Pin must be replaced by the Exchange Pin.

  Ensure the instrument is set to the 'RESET' position before inserting the JDI over the Exchange Pin and through the #3 Soft Tissue Shield.

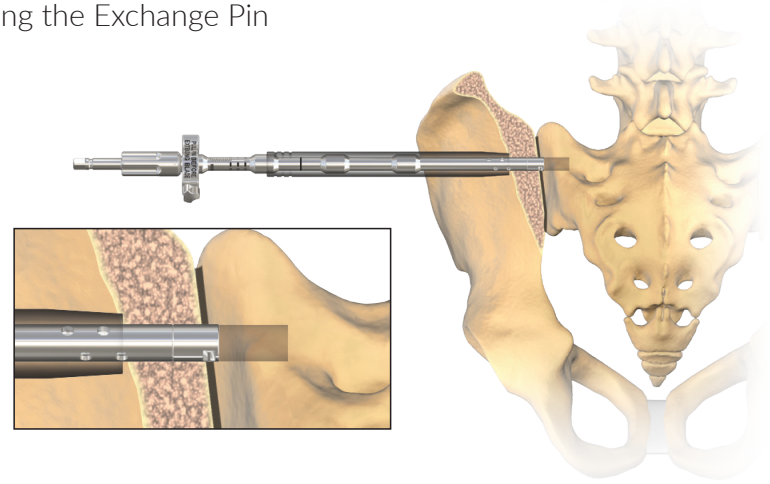
  The laser marked ring(1) on the JDI will be aligned with the top of the #3 Soft Tissue Shield when the distal tip of the JDI has reached the bottom of the Soft Tissue Shield(2).



NOTE : The JDI will only work with 12.5mm drilled holes.

Step 2 : Insertion Continued

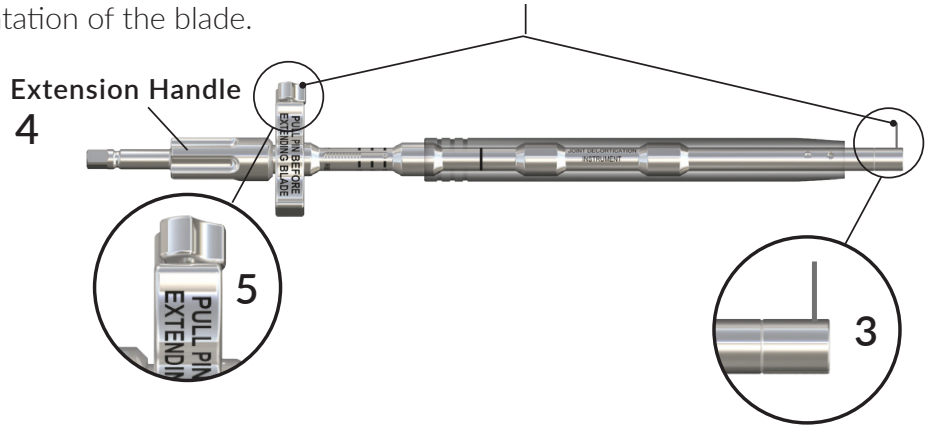
- Continue inserting the JDI until the tip of the instrument has reached the SI joint. Confirm under fluoroscopy the JDI is in the preferred position prior to removing the Exchange Pin and deploying.



Step 3 : Decortication

- Using caution, extend the blade(3) into the SI Joint by rotating the extension handle (4)/clockwise. Ensure the blade has entered the joint by confirming fluoroscopy and tactile feel.

  NOTE: The blade will extend 10mm from the tip of the instrument. The locking set screw(5) indicates the orientation of the blade.

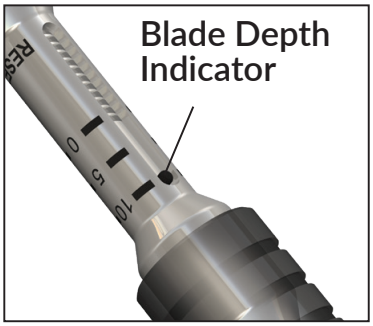


Step 4 : Decortication Continued

- Once the blade has entered the joint, tighten the locking set screw, then rotate the entire instrument to decorticate the SI joint. The blade can be incrementally extended, locked, and rotated to achieve the desired decortication.

  NOTE: Excessive force should not be used when decorticating the joint. If the blade becomes blocked or stopped, reverse direction or retract the blade.

  The blade depth indicator can be used to determine the approximate blade depth.



Step 5 : Removal

- Once the joint has been decorticated, fully retract the blade to 'RESET' position by rotating the locking set screw counter-clockwise/clockwise. The Exchange Pin can now be re-inserted into position through the JDI, and the JDI can be removed.

  NOTE: The procedure can be completed using the Exchange Pin, or the Exchange Pin can be replaced with the Steinmann Pin after tapping.

SILEX® FEATURES

12.5mm Anchor Implants

Available in 30mm - 70mm lengths
(5mm increments)

- Single-thread and dual-thread implants
- All implants are titanium plasma-coated to aid in frictional resistance and to provide bioactive template
- All implants fenestrated to allow for direct bone graft apposition
- Multiple lengths allow for anatomical variation
- Dual-thread to aid in compression across the joint
- Anti-migratory scallop features to prevent implant back out
- Self-tapping implant
- All implants cannulated

7mm Locking Implants

Available in 30mm - 70mm lengths
(5mm increments)

- Dual-thread implant only
- Optional 13mm washer available (see below)
- Multiple lengths allow for anatomical variation
- Fully cannulated for guide wire use
- Anti-migratory scallop features help prevent implant back out
- Self-tapping implant

13mm Washer

- Allows for distribution of load
- For use with 7mm Locking implant

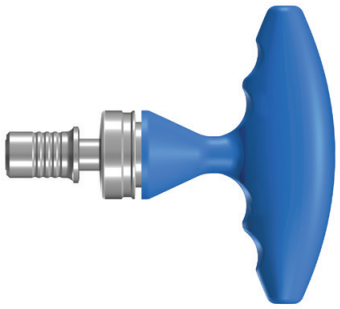
Note: 12 .5mm Anchor Implants are plasma-coated, 7mm Locking Implants are not coated.

SILEX® IMPLANTS AND DISPOSABLE LIST

Item#	Description
X079-0730-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 30mm
X079-0735-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 35mm
X079-0740-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 40mm
X079-0745-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 45mm
X079-0750-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 50mm
X079-0755-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 55mm
X079-0760-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 60mm
X079-0765-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 65mm
X079-0770-DT	Dual-Thread Sacroiliac Locking Implant, 7mm x 70mm
X079-1230PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 30mm
X079-1235PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 35mm
X079-1240PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 40mm
X079-1245PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 45mm
X079-1250PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 50mm
X079-1255PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 55mm
X079-1260PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 60mm
X079-1265PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 65mm
X079-1270PC	Single-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 70mm
X079-1230PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 30mm
X079-1235PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 35mm
X079-1240PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 40mm
X079-1245PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 45mm
X079-1250PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 50mm
X079-1255PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 55mm
X079-1260PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 60mm
X079-1265PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 65mm
X079-1270PC-DT	Dual-Thread Sacroiliac Anchor Implant, Plasma-Coated, 12.5mm x 70mm
X079-0801	Washer, 13mm
X079-0054	Trocar Steinmann Pin, 300mm
X079-0057	Threaded Steinmann Pin, 300mm
X079-0086	Blunt Steinmann Pin, 300mm
X079-0089	Exchange Pin, 500mm
X079-0063	12.5mm Drill Bit
X079-0034	7mm Drill Bit

SILEX® INSTRUMENTS

N60000472 Ratcheting T-Handle

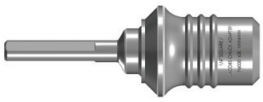


X079-0045 #1 Soft Tissue Shield - 9mm

X079-0106 #2 Soft Tissue Shield - 13mm

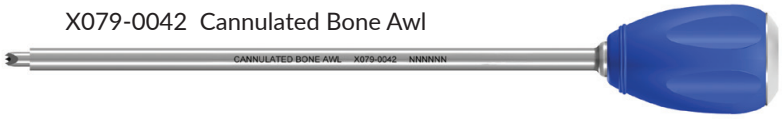
X079-0107 #3 Soft Tissue Shield - 16mm

N60001630 Jacobs Chuck Adaptor



X079-0090 Guide Handle

X079-0042 Cannulated Bone Awl



X079-0034 7mm Drill

X079-0035 7mm Tap

X079-0030 7mm Implant Driver

X079-0063 12.5mm Drill

X079-0064 12.5mm Tap

X079-0060 12.5mm Implant Driver

SILEX® INSTRUMENTS

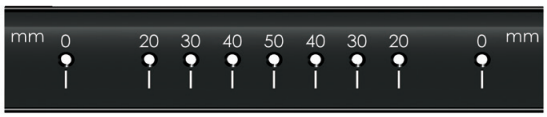
X079-0067 12.5mm Graft Packing Block

X079-0080 12.5mm Graft Funnel

X079-0048 Graft Tamp

X034-0915 Mallet

X079-0084 Steinmann Pin Depth Gage/Guide



X079-0053 Right Angle Curette

X079-0098 12.5mm Implant Removal Instrument

X079-0033 7mm Adjustment Driver

X079-0043 Cannula Cleaner, 300mm

X079-0054 Trocar Steinmann Pin, 300mm

X079-0057 Threaded Steinmann Pin, 300mm

X079-0086 Blunt Steinmann Pin, 300mm

X079-0089 Exchange Pin, 500mm

NOTES

NOTES

XTANT MEDICAL

888-886-9354
cs@xtantmedical.com
xtantmedical.com

INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

FM-C-MRK-79 Rev B 12/21