

# SACRIX

LES<sup>®</sup> SIJ Fusion

SacroFuse<sup>®</sup>

Sacroiliac Joint Fusion Technology

Surgical Technique







## About Sacrix®

Sacrix® is a medical device company that provides the highest quality Sacro-Iliac fusion devices, offering solutions for degenerative sacroiliitis and sacroiliac joint disruption. Our sacrix technique is designed for lateral oblique SIJ fusion with outpatient less exposure surgery in mind.

With leading technologies and superior LES® approaches at the forefront, Sacrix® innovates, recognizing the needs of the patients and surgeons.



## About LESspine®

LESspine® was founded by practicing spine surgeons with the belief that, as surgeons, we are best able to identify our own needs as well as those of our patients. Our team of surgeons, engineers, and industry experts collaborate seamlessly on our innovations to develop a company that is driven to be a leader in cutting edge technology.

Our mission is to focus on surgeon needs, allowing us to improve patient care through innovative technologies.



## About the LES® Philosophy

LES, or Less Exposure Surgery, is the philosophy of achieving optimum surgical exposure, maximally preserving the anatomy, minimizing exposure to radiation, and lessening the damaging effects of traditional surgical techniques. It optimizes surgical access, use of radiation, muscle dissection, anatomy removal, and implant selection into one pivotal focus: less exposure with optimal visualization.

LESS, Less Exposure Segmental Spine Surgery, is a component of the LES philosophy. LESS is the practice of applying the LES philosophy to spine surgery securing one segment at a time and repeating procedures segment by segment.

“Each multi-level condition in the spine could be treated and repeated for adjacent segments,” said Kingsley R. Chin, M.D. “The future of spine surgery is dependent upon devices and techniques for less exposure segmental spine surgery.”

## About the LES Society®



The LES Society seeks to advance research, education, and technology for user friendly tissue sparing treatments with improved patient outcome. The LES Society is a non-profit, tax-exempt, educational organization whose purpose is to protect the health of the patient and to optimize surgical procedures for the surgeon by promoting the less exposure surgery philosophy.

The society provides a forum for dialogue amongst spine surgeons to discuss and debate the LES approach, to train, and contribute to educational endeavors. It is also a resource for other physicians and patients to learn the benefits of LES philosophy and technology.

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# About the System



The SacroFuse® System is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

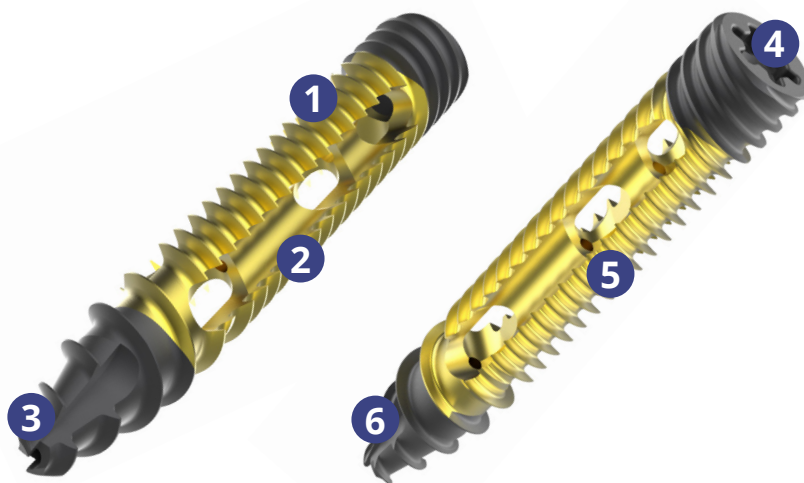
The SacroFuse® System is intended to be used from a lateral oblique approach. Implants are available in varying diameters and lengths, and are fabricated from medical grade titanium alloy (Ti-6Al-4V ELI).

All implants are provided non-sterile, and are intended for single use only.

Implants, instruments, and other components of the SacroFuse® System are not designed to be used in conjunction with any other surgical systems.

## Anatomy of SacroFuse®

- 1 Full Length Dual Cortical and Cancellous Thread Form Optimized for Maximum Bone Purchase
- 2 Fusion Channels for Improved Bony Ingrowth
- 3 Cannulated for Precision Implant Placement
- 4 Robust Inserter Drive and Attachment Features
- 5 Color Coded Implants for Ease of Identification
- 6 Self-cutting Tip Eliminates Subsequent Pilot Hole Preparation




## Features & Benefits

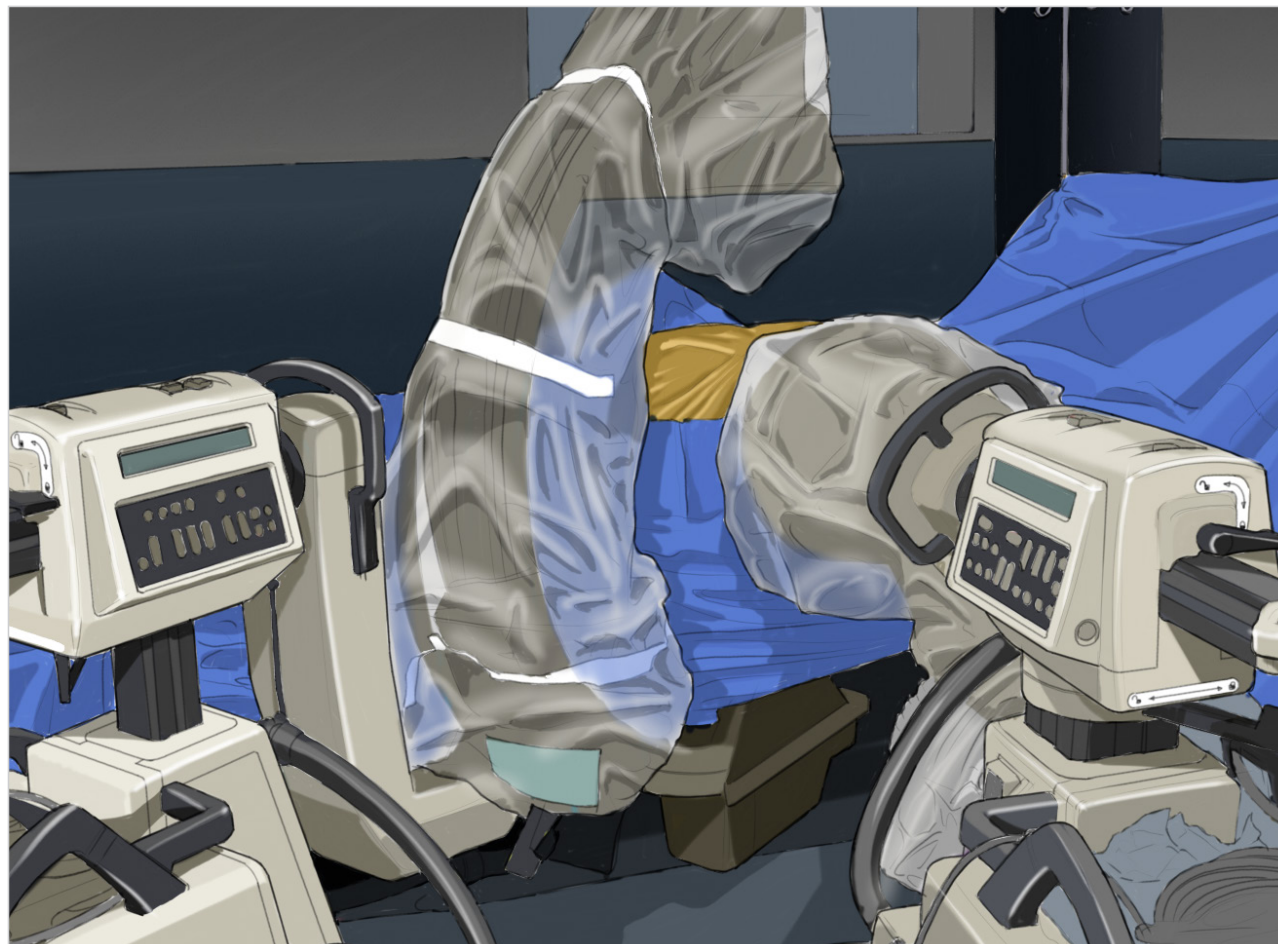
- Self-cutting implant design
- Dual cortical and cancellous threads
- Fully cannulated for percutaneous implant delivery
- Three fusion channels improve bony ingrowth and stabilization
- Wide array of sizes available to accommodate varying patient anatomy
- Fusion channels focus bone product into the SI joint, improving fusion
- Channel network connects fusion channels to threaded engagement feature for focused post packing
- RBM (Resorbable Blast Media) surface treatment at tip & tail for improved bony ongrowth
- Back-taper provides increased compression locking

## Surgical Technique Symbols

 Additional Information

 Warning

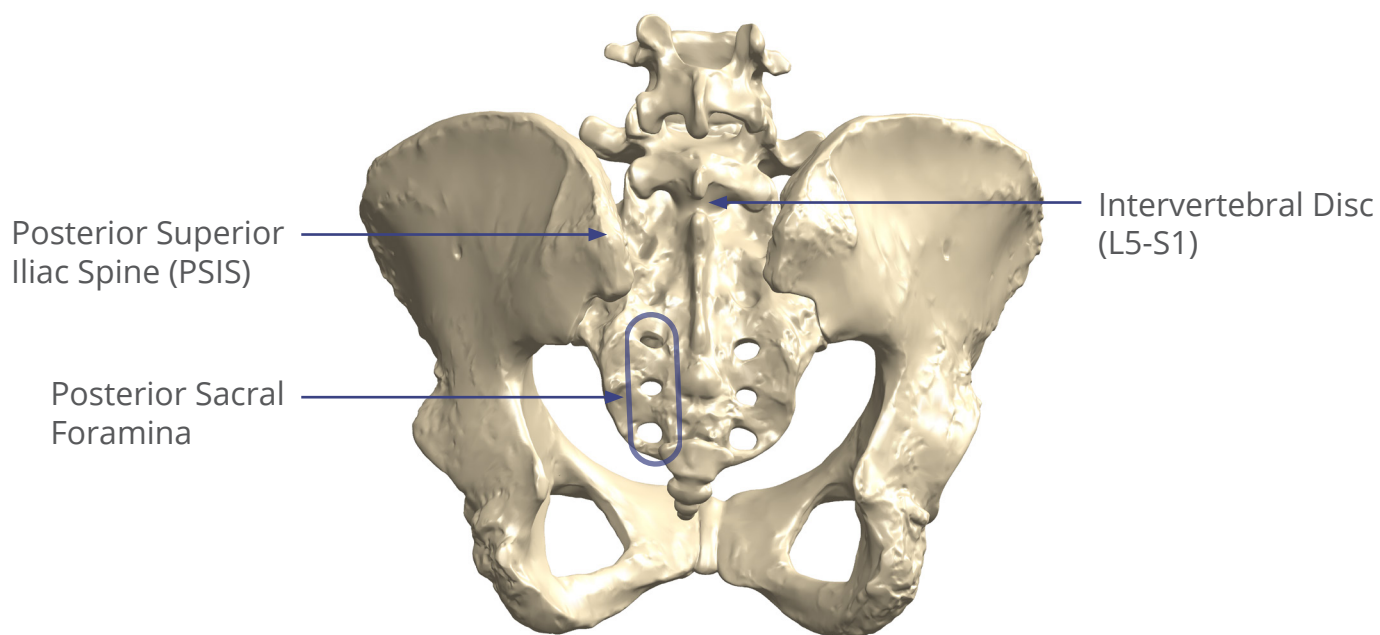
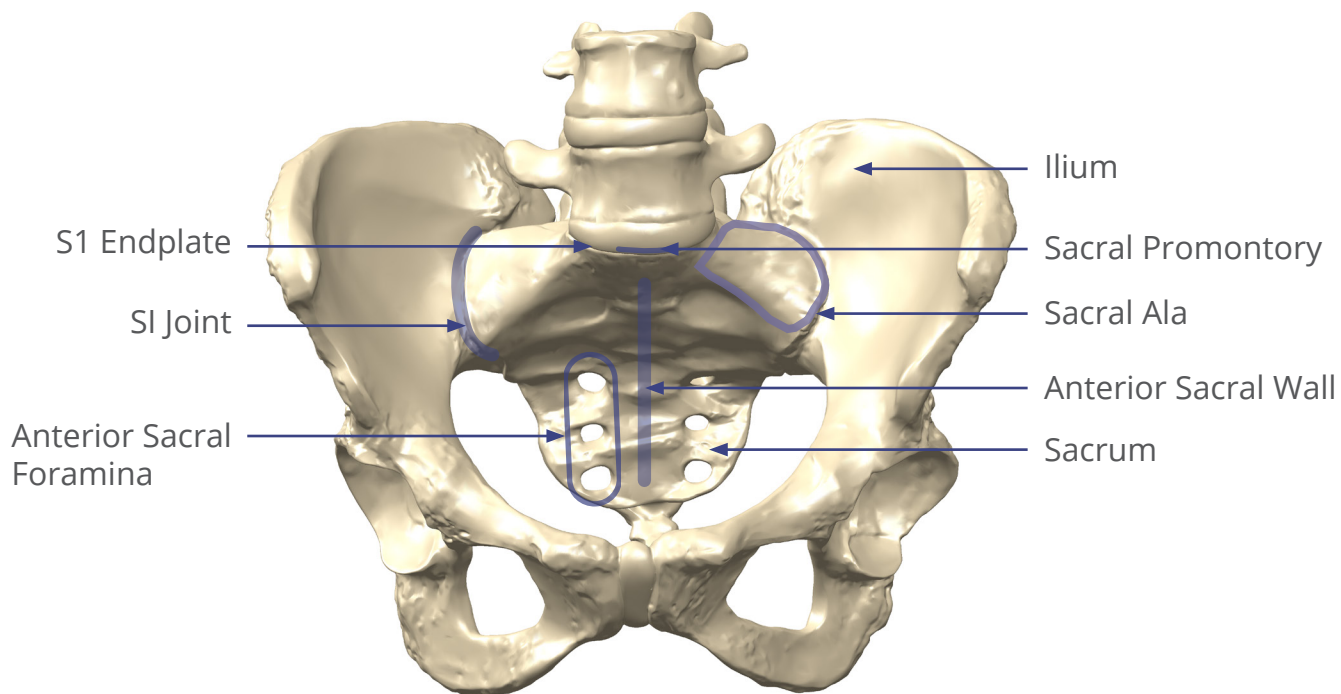
# 1. Pre-Operative Planning



- All necessary imaging studies (CT scans, X-rays, etc.) are recommended to be available to visualize patient anatomy and plan implant placement.
- Prior to surgery, estimate the appropriate size of the SacroFuse® device.



### Anterior View



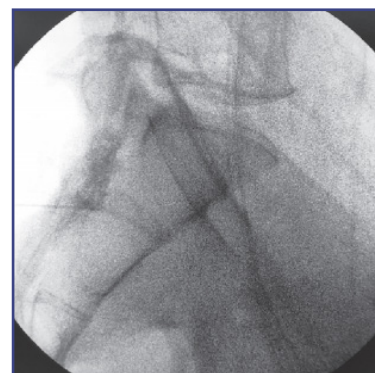
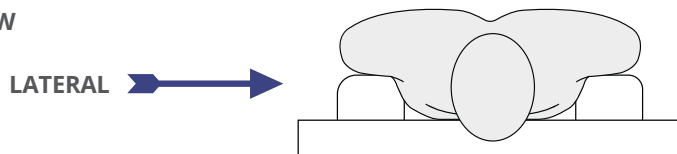
### Posterior View

# 3. Patient Positioning



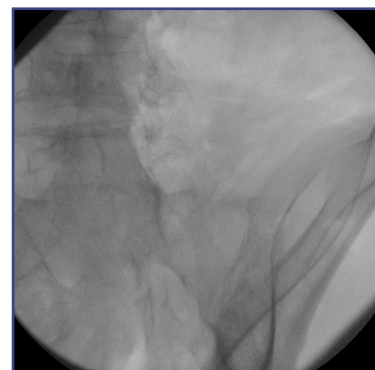
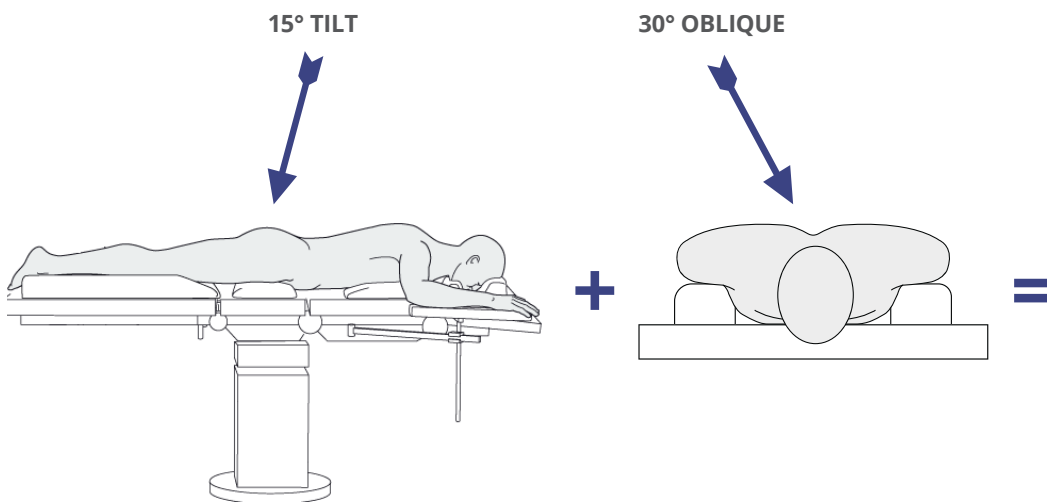
## Fluoroscopic Views

### 1. LATERAL VIEW



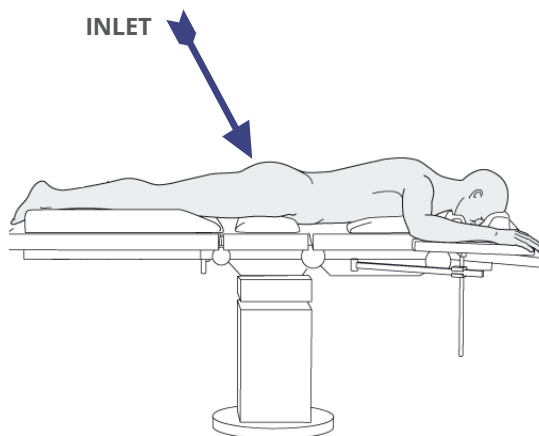
Lateral View

### 2. OUTLET OBLIQUE VIEW: COMBINATION OF 15° TILT AND 30° OBLIQUE



Outlet Oblique View

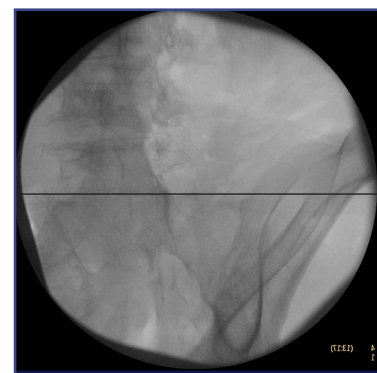
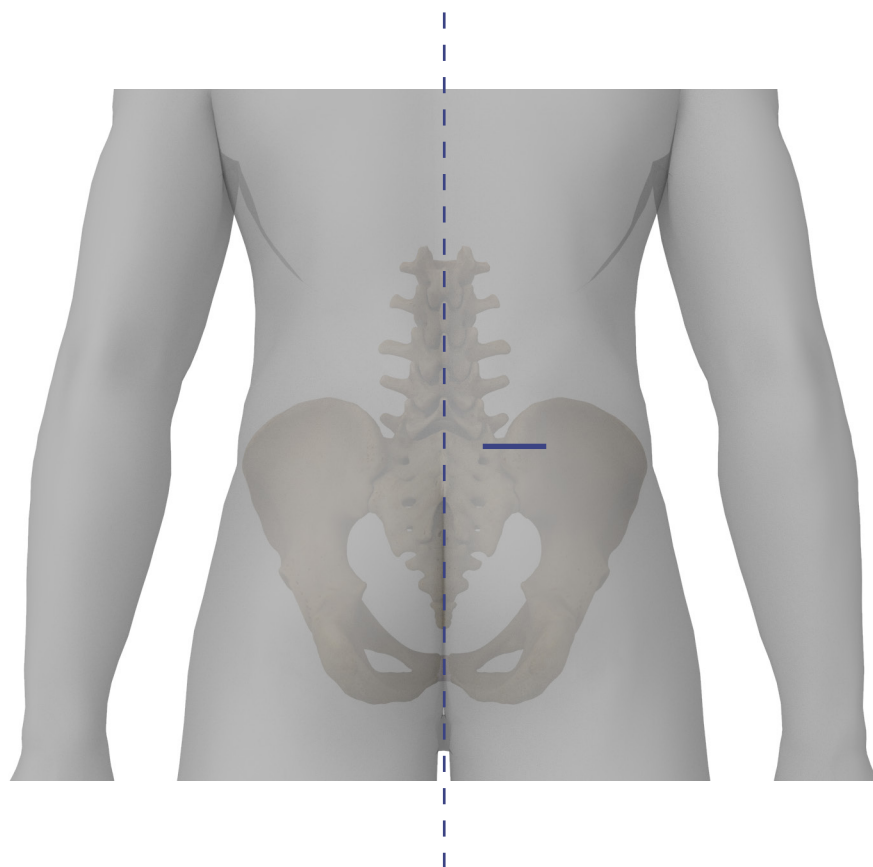
### 3. INLET VIEW



Inlet View

- Place the patient in the prone position, with the waist slightly elevated to flex the patient's hips and relax the sacroiliac joint.

## 4. Pre-Operative Skin Marking



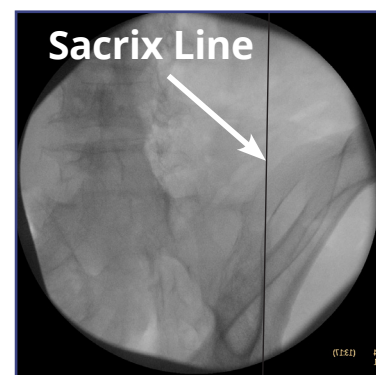
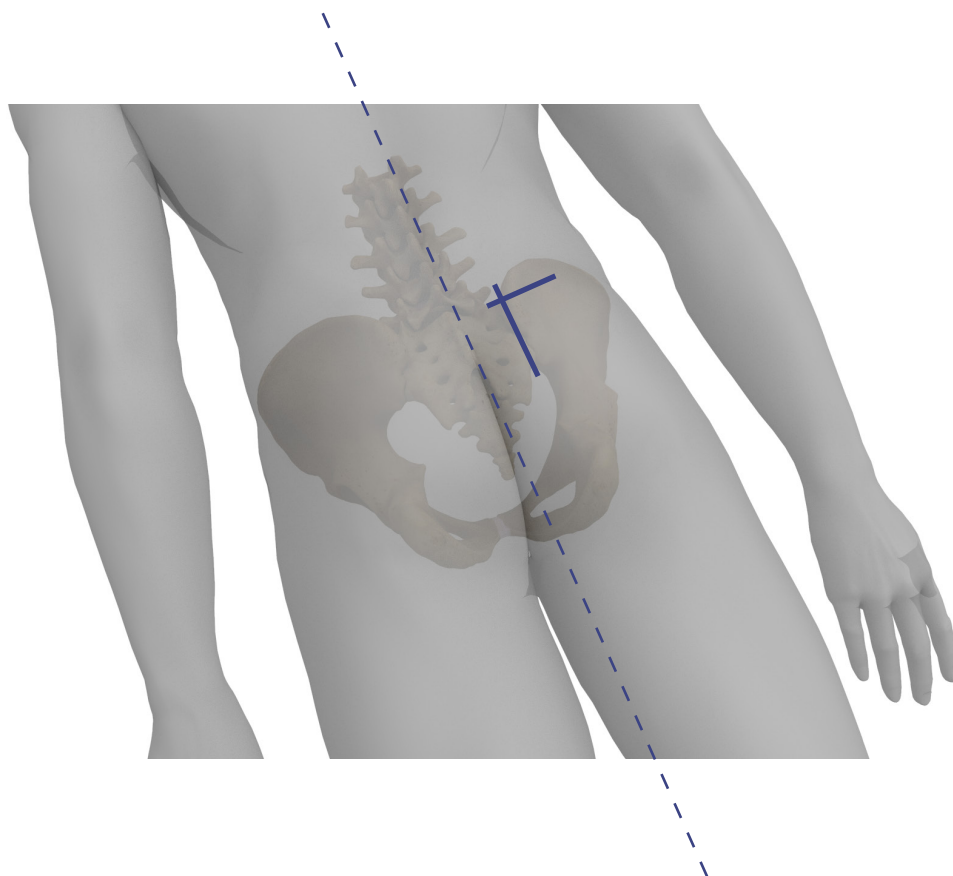
(A)

Position the fluoroscope for a Outlet Oblique View (15° tilt towards cephalad (outlet) and 30° off of the sagittal plane) of the sacroiliac joint and the iliac crest on the operative side. Using fluoroscopy and a Guidewire:

- Mark a line transversely along the superior edge of the sacral ala (A).



## 4. Pre-Operative Skin Marking (Cont.)



(B)

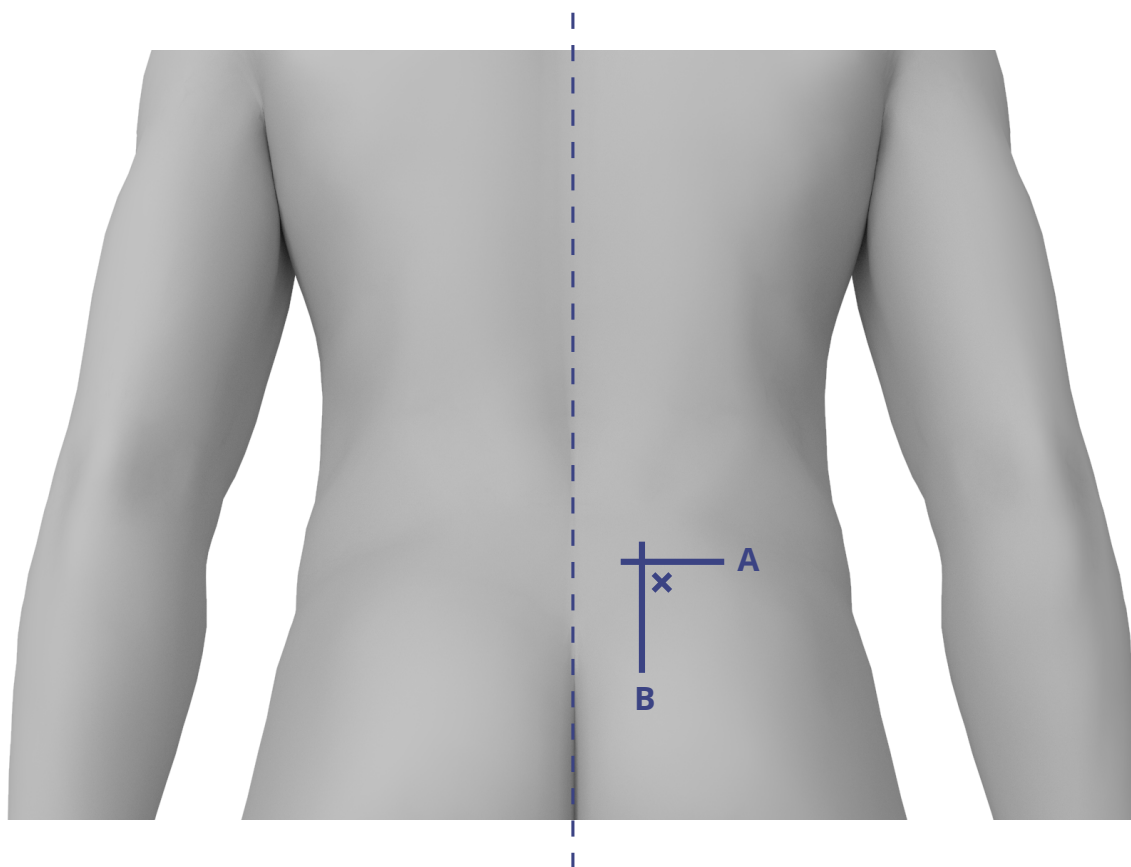
Maintain the same fluoroscopic view.

Using fluoroscopy and a Guidewire:

- Mark a line along the lateral edge of the ilium 'Sacrix Line' (B).

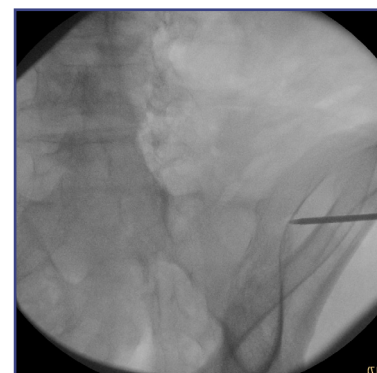
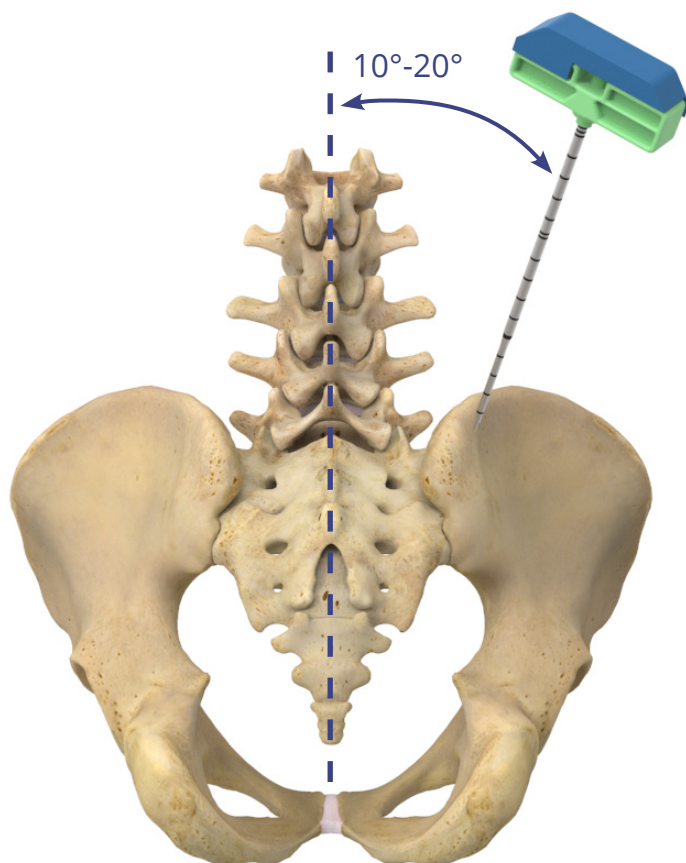


## 5. Starting Position



- Mark the starting position approximately one finger breadth inferior of line (A) and one finger breadth lateral of line (B).

## 6. Trajectory



Outlet Oblique View

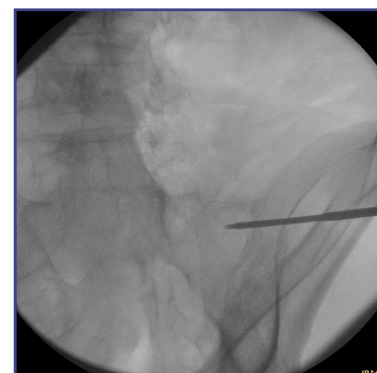
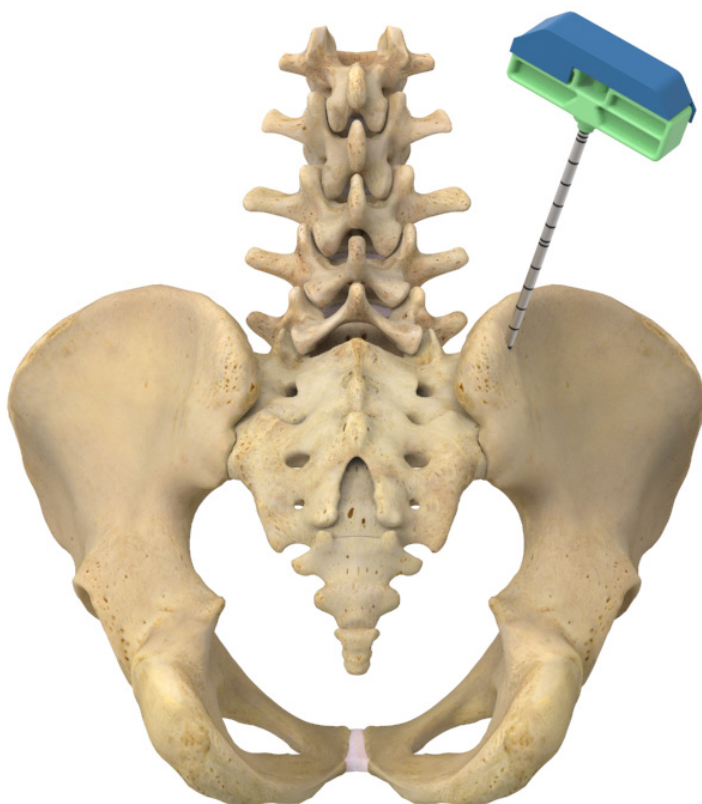


Inlet View

Start the first implant trajectory with the Bone Needle:

- Position the tip of the Bone Needle on the starting point marked in the previous step.
- Seat the Bone Needle into the ilium, just lateral of the iliac crest.
- Under inlet fluoroscopy, angle the Bone Needle approximately  $10^{\circ}$ - $20^{\circ}$  and confirm the trajectory will cross the SI joint and aim towards the sacral ala.
- Maintain the established mediolateral angle and orient the Bone Needle so that it is parallel with the S1 endplate under Outlet Oblique fluoroscopy.

## 7. Advancement



Outlet Oblique View



Inlet View

- Under Outlet Oblique fluoroscopy, confirm that the Bone Needle is inferior of the superior sacral ala and advance through the ilium across the SI joint into the sacrum.
- Switch to Inlet fluoroscopy and continue advancing the Bone Needle, terminating shy of the anterior sacral wall.



Bands laser marked on the Bone Needle shaft are in 10mm increments, with a thicker band at 50mm and a double band at 100mm.

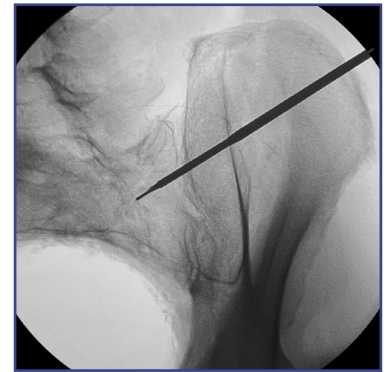
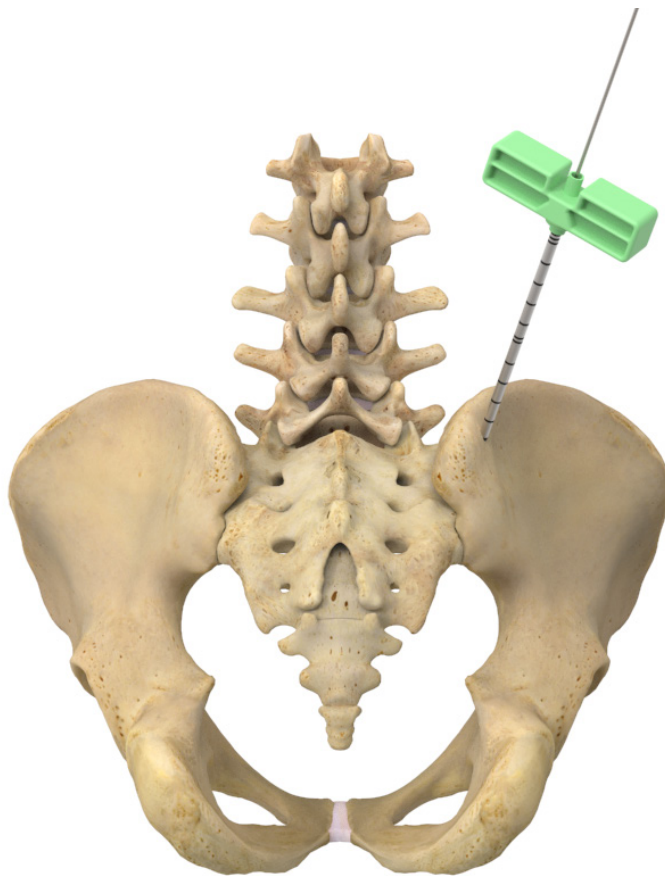
Due to the curvature of the sacrum, the anterior sacral floor may not be accurately represented under fluoroscopy.



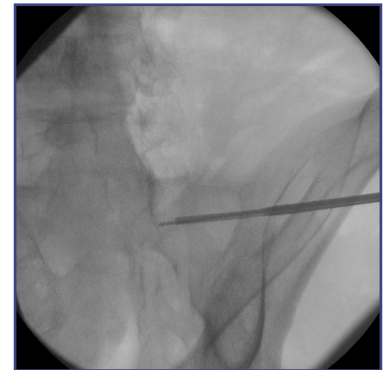
Take care not to over advance the Bone Needle, causing a breach in the anterior sacral wall.

Take care not to breach the superior ala wall and not to enter the sacral foramina.

## 8. Guidewire Placement



Inlet View



Outlet Oblique View

- Remove the inner stylet from the Bone Needle and advance a blunt Guidewire through the outer sleeve of the Bone Needle, until the tip of the Guidewire extends past the tip of the Bone Needle.
- Remove the outer sleeve of the Bone Needle and confirm that the Guidewire depth and trajectory have not changed.
- Make a 1.5cm longitudinal incision inferior to the Guidewire.

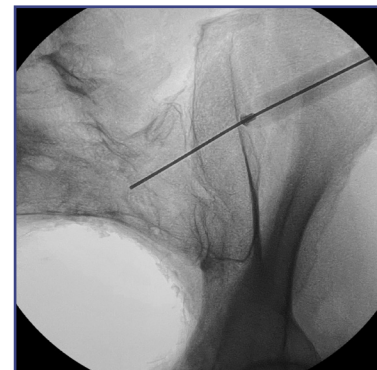
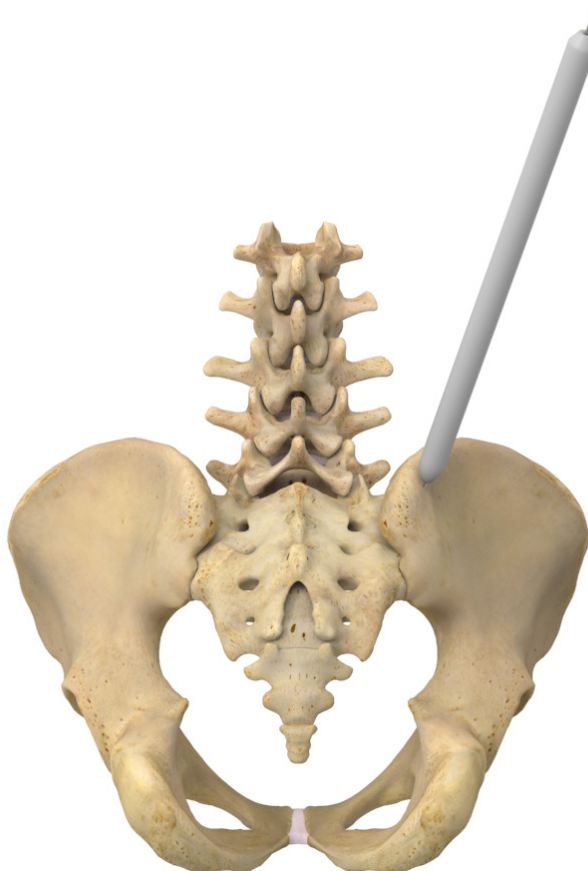


Optional: The Depth Measurement Probe may be used to determine depth.



Take care not to lose trajectory of the Guidewire as the Bone Needle is removed.

## 9. Tissue Dilation



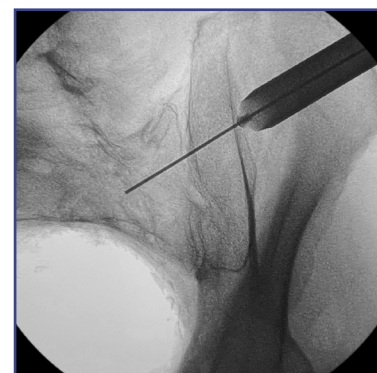
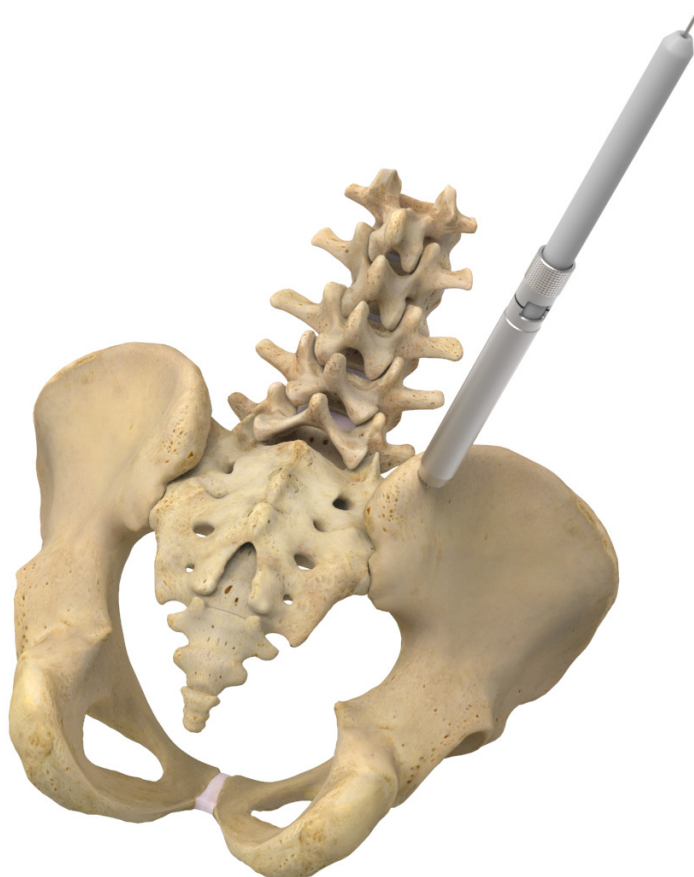
Inlet View

- Advance the Tissue Dilator over the Guidewire.



Increase the incision size as necessary for placement of the Tissue Dilator.

## 9. Tissue Dilation (Cont.)



Inlet View

- Advance the Tissue Protector over the Tissue Dilator until the distal end of the Tissue Protector bottoms out on the ilium.
- Remove the Tissue Dilator.

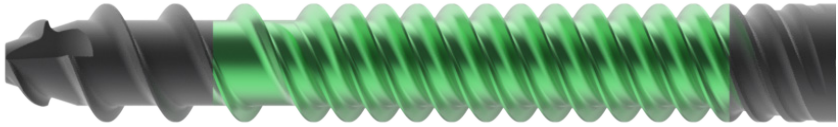
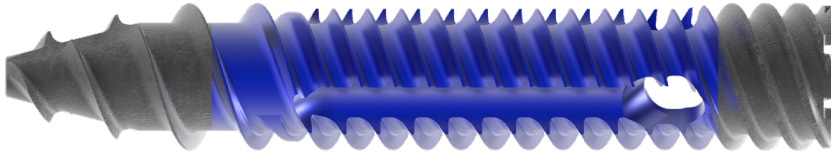
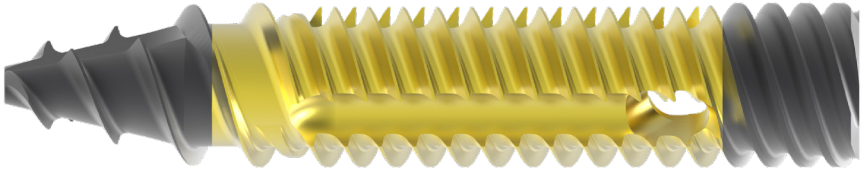
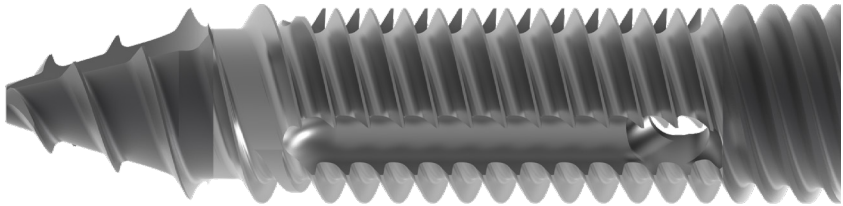


Increase the incision size as necessary for placement of the Tissue Dilator.



# 10. Implant Selection



Diameter	Color	Picture
Ø8mm	<b>GREEN</b>	
Ø10mm	<b>BLUE</b>	
Ø12mm	<b>GOLD</b>	
Ø14mm	<b>GRAY</b>	

- Determine the intended implant diameter and length based on patient anatomy and bone quality.



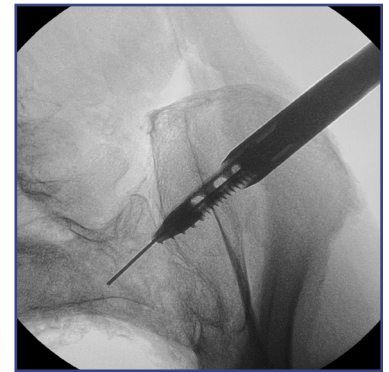
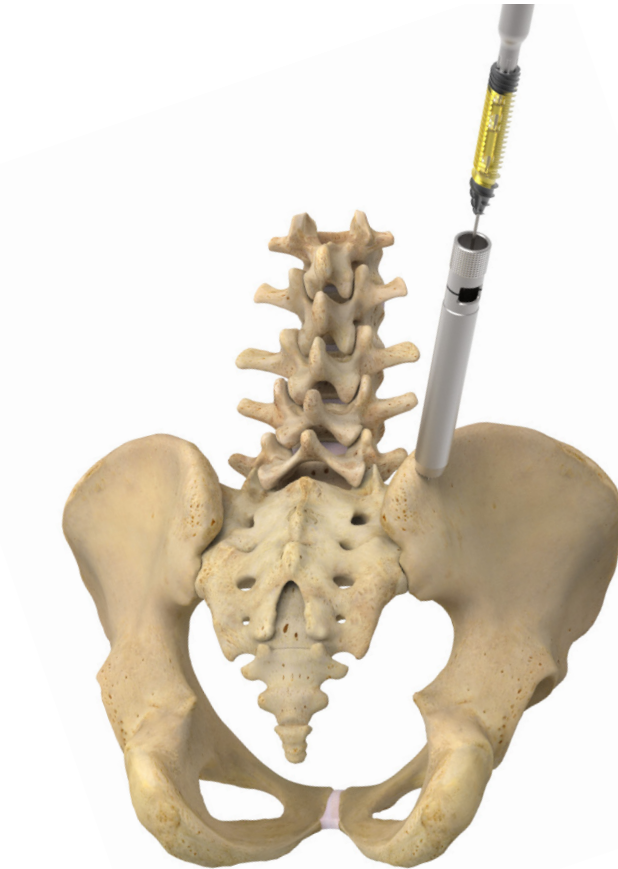
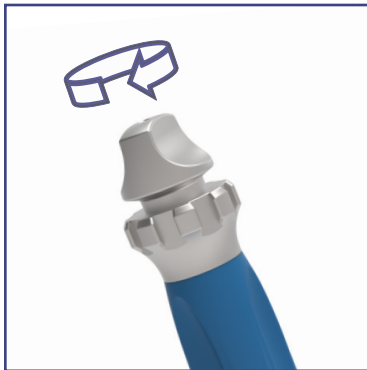
Optional: Implant length may be obtained via the proximal laser markings on the main shaft of the Tap when used in conjunction with the Tissue Protector.

An optional tap may be used to prepare the implant site for patients with hard bone.

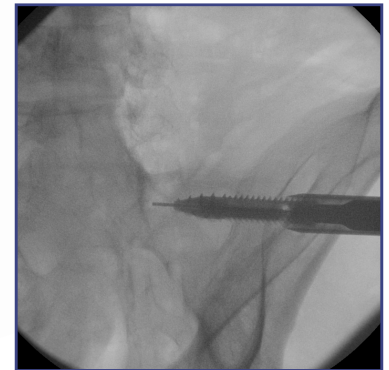


Suboptimal selection of implant length and diameter may cause harm.

# 11. Implant Insertion



Inlet View



Outlet Oblique View

- Place the distal tip of the Inserter into the proximal end of the implant, keying in the crown features.
- Rotate the knob on the proximal end of the Inserter clockwise to thread the implant onto the Inserter's retention shaft. Continue to rotate the knob until the implant bottoms out on the tip of the Inserter.
- Advance the Inserter over the Guidewire with clockwise rotation while using Inlet fluoroscopy.
- After the implant is inserted past the cortical layer of the ilium and the desired depth is achieved, use Inlet and Outlet Oblique fluoroscopy to confirm the position of the implant.
- Detach the Inserter from the implant.



Optional: Fusion channels may be packed with desired Bone Product before insertion.

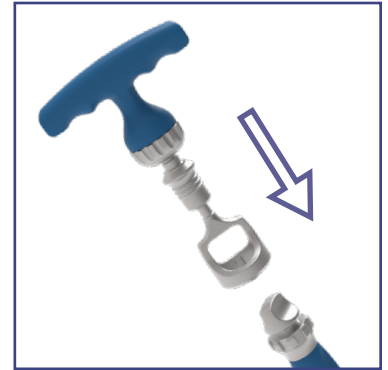
If additional torque is needed, the Handle Adapter and Ratcheting T-Handle may be used with the Inserter to advance the implant (see page 19).

The Guidewire may be left in place to guide the trajectory of the second implant.



Take care to:  
Maintain trajectory while advancing.  
Not to advance the Guidewire while advancing or removing the Inserter.  
Not to breach the anterior sacral wall, superior ala wall, and not to enter the sacral foramina.

## 11. Insertion with Handle Adapter (Optional)



- After the implant is inserted past the cortical layer of the ilium, remove the Guidewire.
- Engage the proximal end of the Handle Adapter to the Ratcheting T-Handle until fully seated.
- Attach the Handle Adapter to the Inserter by aligning the grooves of the Handle Adapter with the mating grooves on the Inserter until fully seated.
- Continue to advance the Inserter with clockwise rotation until the desired depth is achieved.
- Confirm implant position via Inlet and Outlet Oblique fluoroscopy.
- Remove the Handle Adapter from the Inserter and detach the Inserter from the implant.

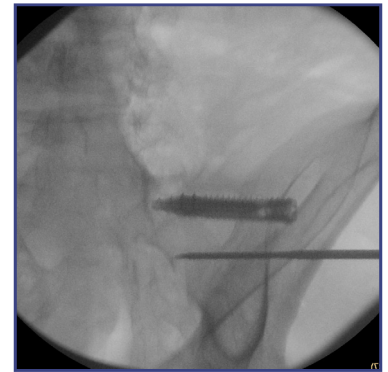
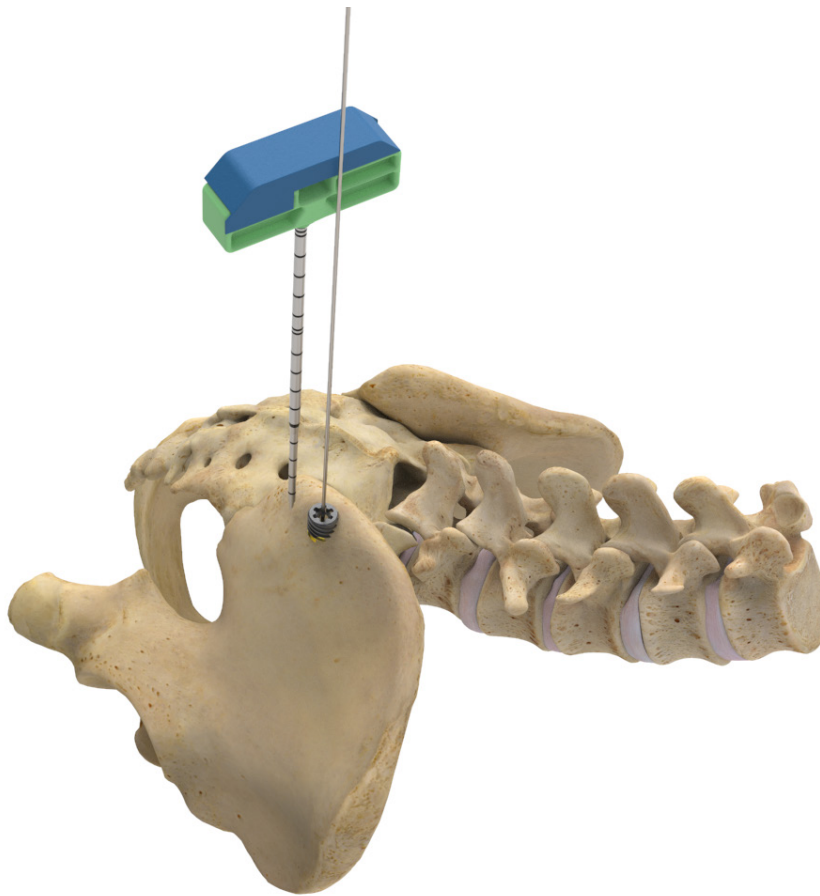


Take care to maintain trajectory while advancing.

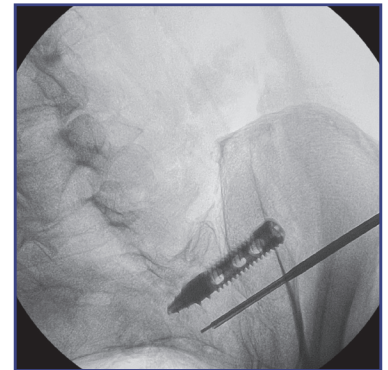
The Guidewire must be removed when using the Handle Adapter in conjunction with the Inserter.

Take care not to breach the anterior sacral wall, superior ala wall, and not to enter the sacral foramina.

## 12. Second Implant Trajectory



Outlet Oblique View



Inlet View

Find the trajectory for the second implant:

- Using the Bone Needle and moving the initial incision, translate 20-30mm inferior of the initial implant, following the curvature of the iliac crest.
- Find the trajectory for the second implant by mimicking the angulation/trajectory of the first implant.
- Advance the Bone Needle towards sacral ala, terminating shy of the anterior sacral wall. Use Outlet Oblique View to confirm.
- Repeat steps 7-11 as necessary.

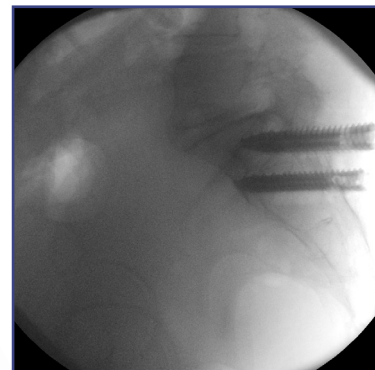


Optional: A Guidewire may be retained within the first implant to guide the trajectory of the second implant.

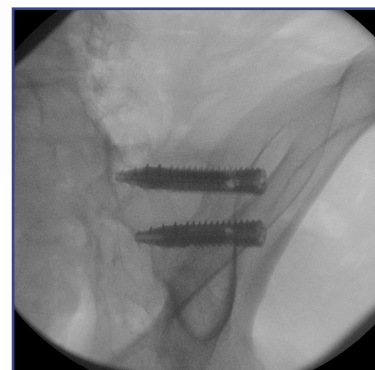


Take care not to breach the anterior sacral wall, superior ala wall, and not to enter the sacral foramina, for all applicable steps.

## 13. Final Implant Placement



Lateral View



Outlet Oblique View

- Once the final implant has been placed, confirm position under Lateral and Outlet Oblique View fluoroscopy.

## 14. Implant Removal (Optional)



If conditions allow, insert a Guidewire into the cannulated hole in the implant to guide the Inserter back to the implant.

Place the Inserter over the Guidewire and slide the Inserter down to the implant.

Rotate the Inserter knob to mate the tip of the Inserter to the mating feature on the implant.

Turn the knob on the proximal end of the Inserter to secure the Inserter to the implant.

Turn the Inserter counterclockwise to back out the implant until it has been fully removed.

The Inserter can be used without connection of the Inserter stylet to the implant, if the situation warrants it.



**Revision could be necessary under the following situations, including, but not limited to:**

- Intraoperative revision
- Larger implant preferred after initial implant inserted
- Misplaced implant - breaches sacral foramen or sacral cortices
- Implant fracture during insertion
- Loss of neurologic function of unknown cause
- Postoperative revision
- Non-union
- Infection
- Implant breakage due to patient postoperative activities
- Psychological patient fear of having a device in forever
- Painful hardware irritating soft tissues or nerves
- Implant migration causing neural compression
- Fracture around implant leading to malposition





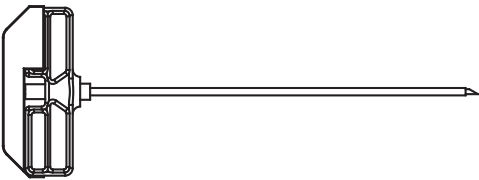
## Implants

Ø8mm to Ø12mm implants are available in 30mm - 70mm lengths, in 5mm increments.

The Ø14mm implant is available in 35mm - 70mm lengths, in 5mm increments.

01-42400-XX	Ø8mm Fusion Implant, Gen II
01-42401-XX	Ø10mm Slotted Fusion Implant, SacroFuse
01-42402-XX	Ø12mm Slotted Fusion Implant, SacroFuse
01-42403-XX	Ø14mm Slotted Fusion Implant, SacroFuse
01-42404-XX	Ø12mm Hybrid Fusion Implant, SacroFuse
01-42405-XX	Ø14mm Hybrid Fusion Implant, SacroFuse

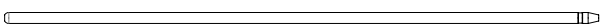
## Instruments



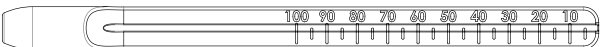
Bone Needle



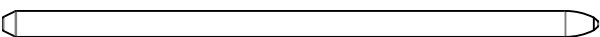
Guidewire



Depth Measurement Probe Shaft (upon request)



Depth Measurement Gauge (upon request)

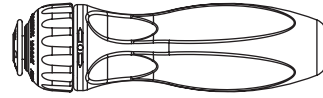


Tissue Dilator

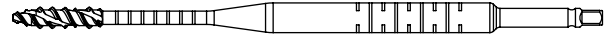


Tissue Protector

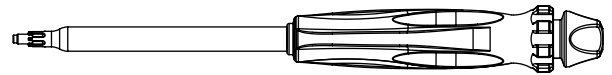
## Instruments (Cont.)



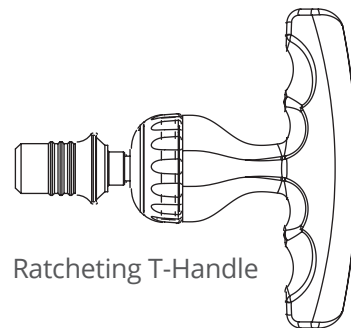
Ratcheting Straight Handle (upon request)



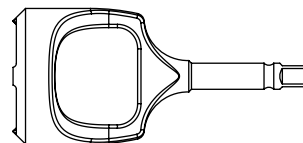
Tap (optional sizes available upon request)



Inserter



Ratcheting T-Handle



Handle Adapter



Graft Funnel (upon request)



Graft Pusher (upon request)



# Outpatient Technologies for Less Exposure Surgery.

ST-42-00002 Rev I SacroFuse® Surgical Technique

Distributed by

**SACRIX**  
LES® SJ Fusion

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Manufactured by

 **LESspine**  
Less Exposure Surgery Technologies

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