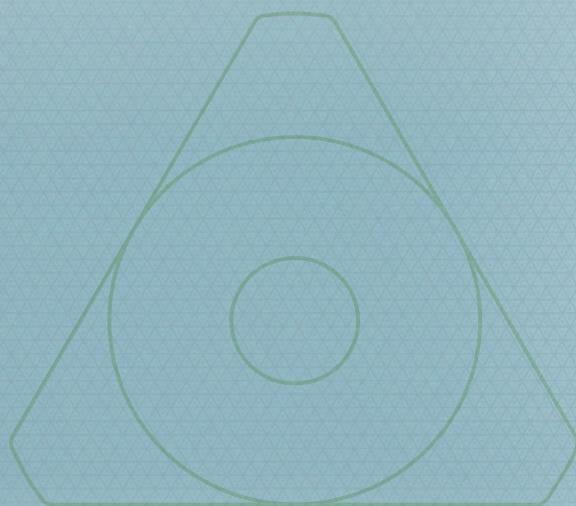


C-arm

Surgical Technique Manual



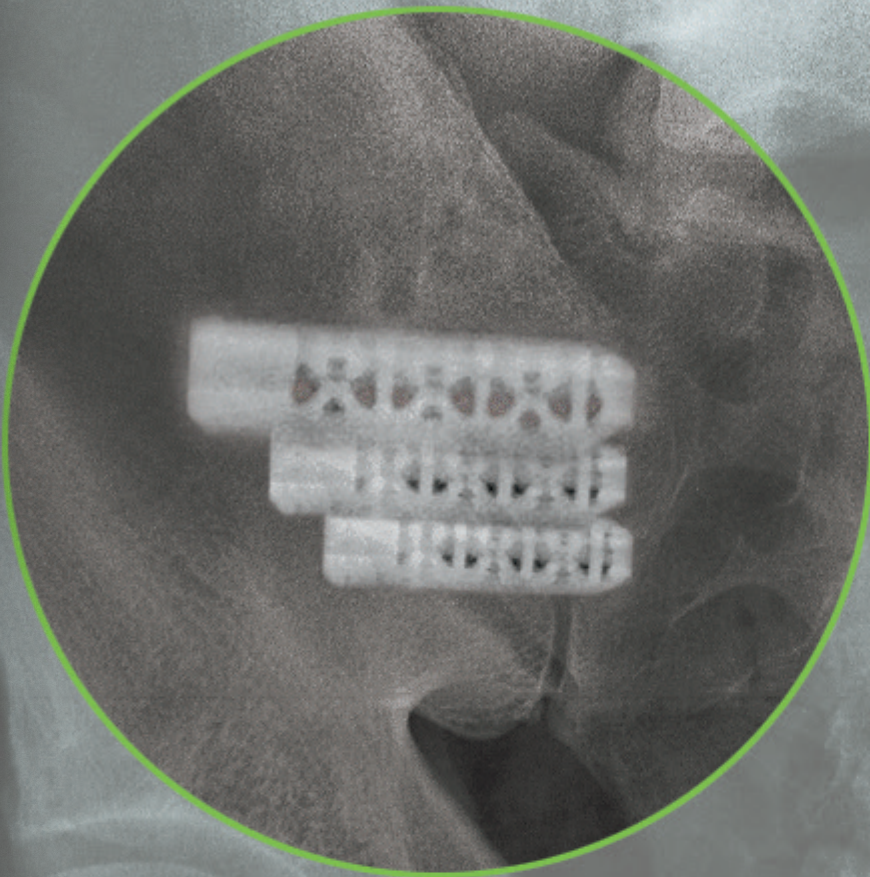
Radiolucent
Efficient
Simple



Contents

About SI-BONE, Inc.	2
iFuse Implant System®: Introduction	3
The iFuse Implant System Advantage	4
iFuse Implant System: Features and Benefits	6
Procedure: Pre-Op Planning and Patient Set-Up	7
Fluoroscopic Guidance	8
Understanding Fluoroscopic Images	9
Skin Marking and Incision	10
First Pin Placement	11
Neuromonitoring for Guide Pin (Optional)	12
Radiolucent Clamp (Optional)	13
Blunt Dissector (Optional)	14
Soft Tissue Protector	15
Implant Length Determination	16
Orientation Guide (if using a 4.0 mm Implant)	17
Drilling	18
Broach Orientation	19
Broaching with an Adjustable Broach Stop	20
Implant Transfer	22
Implant Insertion	23
Three-Pin Fixed Parallel Pin Guide Technique	25
Neuromonitoring for Implant (Optional).....	27
Parallel Pin Guide (Subsequent Pin Placement)	28
Second Pin Placement	30
Subsequent Pin Placement	31
Final Implant Placement	32
Intraoperative Repositioning and Removal Strategy	34
Closure and Post-Op Care	35
Product Catalog	36
Supplemental: Graft and iFuse TPS Options	37

About SI-BONE, Inc.



SI-BONE, Inc. is a global Sacropelvic Solutions™ medical device company with technology for surgical treatment of musculoskeletal disorders of the sacropelvic anatomy. SI-BONE utilizes its iFuse Technology® to develop products to treat degenerative conditions, adult spinal deformity, and pelvic trauma.

iFuse Implant System®: Introduction

The iFuse Implant System® is intended for SI joint fusion. The procedure typically involves the insertion of three small titanium Implants across the SI joint, and is designed to stabilize and fuse the SI joint. This minimally invasive procedure is performed through a small incision and requires about one hour of surgical time. Treatment with the iFuse Implant System may potentially minimize complications often seen with open surgery, such as blood loss and average length of hospital stay.



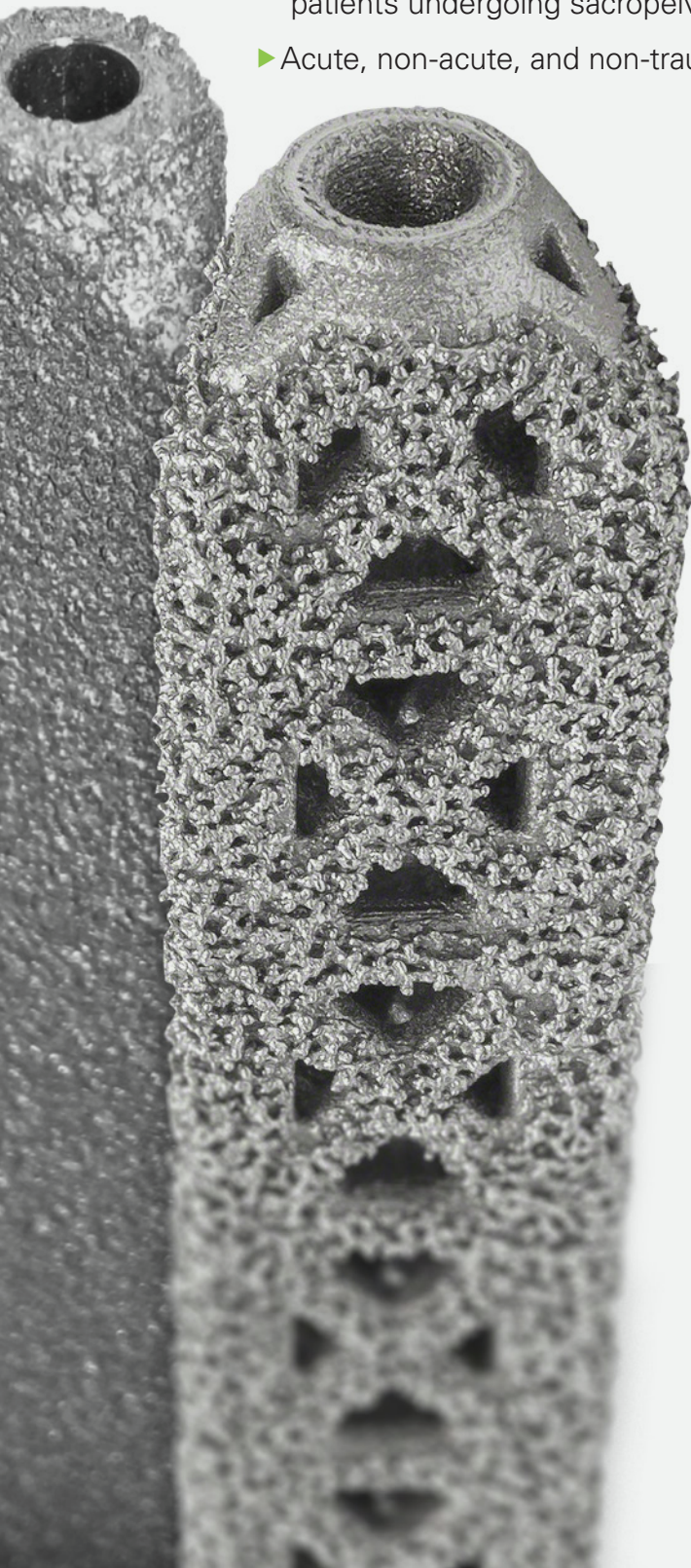
As with all surgical procedures and permanent Implants, there are risks and considerations associated with surgery and use of the iFuse Implant System. Please review the iFuse Implant System Instructions For Use for contraindications, warnings, precautions, and risks.



The iFuse Advantage

The **iFuse Implant System**® is intended for sacroiliac joint fusion for the following conditions:

- ▶ Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- ▶ To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- ▶ Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.



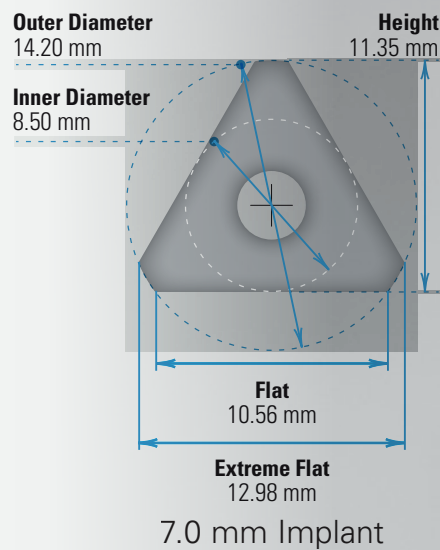
ADVANTAGES:

- ▶ *Triangular Implant profile minimizes rotation*
- ▶ *Porous surface*
- ▶ *An interference fit between the Implant and the adjacent osseous walls minimizes micromotion*
- ▶ *Well suited for sacral bone*
- ▶ *Designed specifically to stabilize and fuse the heavily loaded SI joint*

The iFuse Implant System Advantage

Implant Part Numbers

		Diameter (mm)		
		4.0	7.0	7.0 iFuse 3D™
Length (mm)	30	—	7030-90	—
	35	4035-90	7035-90	7035M-90
	40	—	7040-90	7040M-90
	45	4045-90	7045-90	7045M-90
	50	—	7050-90	7050M-90
	55	4055-90	7055-90	7055M-90
	60	—	7060-90	7060M-90
	65	—	7065-90	7065M-90
	70	—	7070-90	7070M-90
	75	—	—	7075M-90
	80	—	—	7080M-90
	85	—	—	7085M-90
	90	—	—	7090M-90



Disposables

Description	Part No.
Cannulated Drill Bit - 4.0 mm	400074
Cannulated Drill Bit - 7.0 mm	400146
Guide Pin - 3.2 mm	500373
Blunt Pin - 3.2 mm	500374
Exchange Pin - 3.2 mm	500375
Guide Pin - 2.0 mm	500376
Blunt Pin - 2.0 mm	500377
Exchange Pin - 2.0 mm	500378
Guide Pin, 3.2 mm, Threaded*	501385

*Ordered separately

iFuse Implant System: Features and Benefits

The iFuse Implant System consists of titanium Implants and radiolucent surgical instruments provided to facilitate optimal Implant placement. Typically, patients receive three triangular-shaped titanium Implants. Available Implant lengths range from 30 mm to 90 mm. These Implants are delivered to the sacroiliac (SI) joint using a cannulated delivery system designed to protect the soft tissues. The procedure is performed through a minimally invasive 30 mm lateral incision.

Instrumentation Advantages

- ▶ Radiolucent instruments improve intraoperative visualization
- ▶ Snap-lock features allow for easy instrumentation engagement and release
- ▶ Silicone-overmold handles provide ergonomic grip

Instrumentation Benefits

Possible benefits versus traditional surgical SI joint fixation:

- ▶ Facilitates minimally invasive approach
- ▶ Smaller incision size
- ▶ Less trauma to soft tissues
- ▶ Less blood loss

Implant Benefits

- ▶ Triangular Implant profile minimizes rotation
- ▶ Porous surface
- ▶ An interference fit between the Implant and the adjacent osseous walls minimizes micromotion
- ▶ Well suited for sacral bone
- ▶ Designed specifically to stabilize and fuse the heavily loaded SI joint

NOTE: Standard instruments are used through an STP that is 4.65 inches from the distal tip to the handle. If the depth of the soft tissue from the incision site to the ilium is greater than 4.65 inches, it is recommended to use the XL Instrument Set which includes instruments that are 3 inches longer. The depth of the soft tissue lateral to the ilium may be measured on a preoperative CT scan. Refer to Surgical Technique Manual 300279-0US for complete instructions.

Procedure: Pre-Op Planning and Patient Set-Up

Pre-Op Planning

- ▶ A CT is recommended for pre-op planning
 - » Check for anatomic anomalies

Patient Set-Up

- ▶ Jackson and flat imaging tables are common.
- ▶ One or two C-arms may be used – usually one is sufficient.
- ▶ If a flat table is used, place towel rolls transversely under the chest and waist, and pillows under the feet to relax hip and knee joints (**figure below**).
- ▶ The patient should be in a “spine neutral” position as well as having the SI joint in a neutral position without extreme flexion or extension of hips.

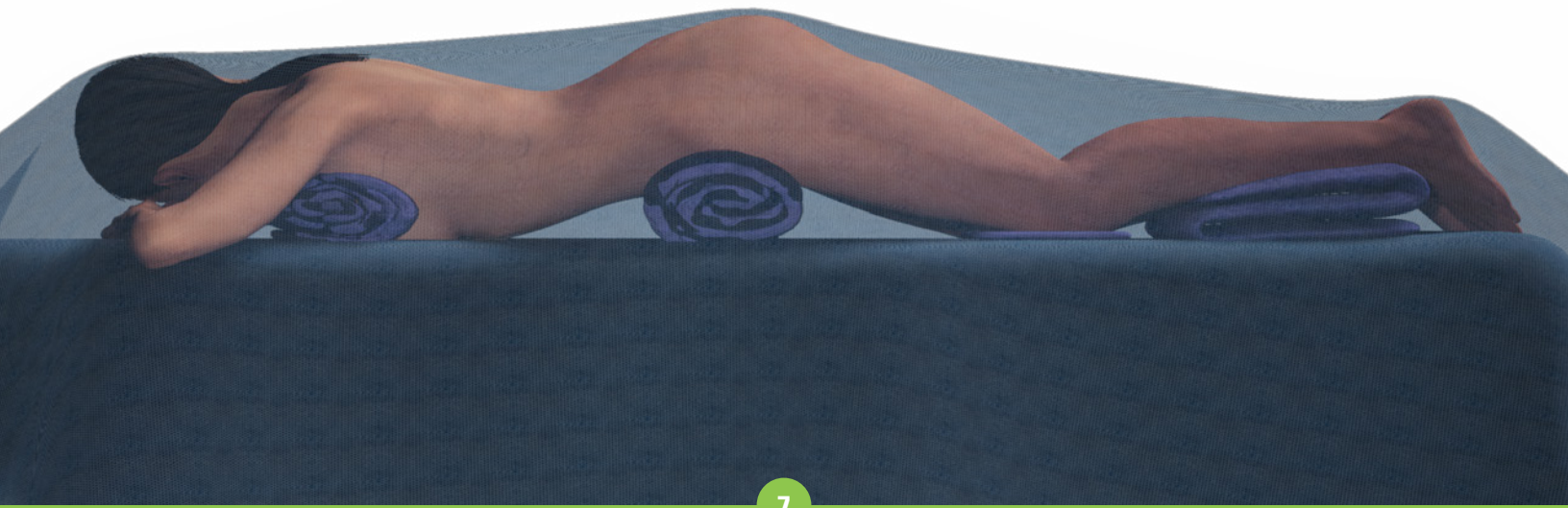
Patient Positioning

- ▶ This procedure may be performed in the prone or supine position. This Surgical Technique Manual illustrates the procedure in the prone position (**figure below**).

Care of Instruments During Procedure

- ▶ The iFuse Implant System is a pin-based system. As is common with pin-based systems, bone material may adhere to the Broach, Soft Tissue Protector, or other instruments, which may result in pin binding or adherence of instruments to each other or to implants. Irrigation of the instruments between uses might minimize the occurrence of binding of instruments and/or implants.

NOTE: This manual is provided for reference only. The procedure should be modified based on patient characteristics and the surgeon's judgment. Instruments not shown in this manual may be used at the surgeon's discretion.

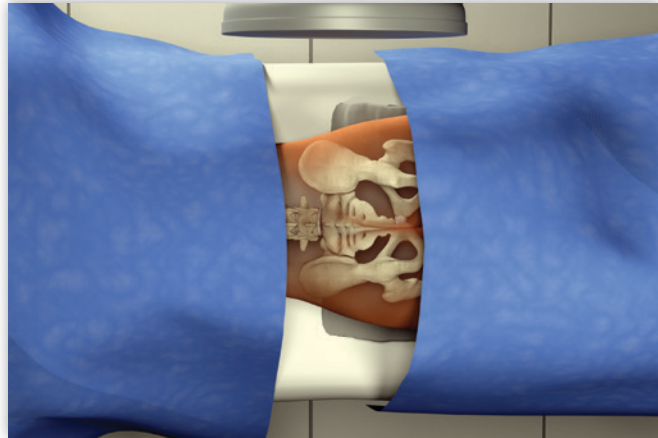


Procedure: Fluoroscopic Guidance

Lateral View

First, align the disc space and end plates of L5-S1 to a true lateral view using C-arm swivel or "wig-wag." The sciatic notches should overlap once in correct alignment.

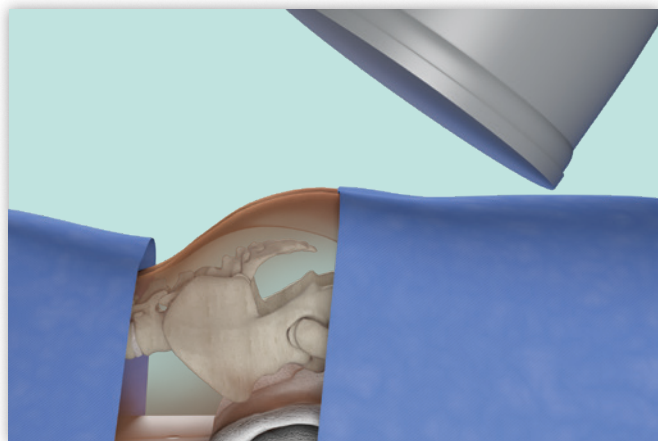
Finalize the alignment by superimposing the left and right iliac cortical densities (alar lines).



Inlet View

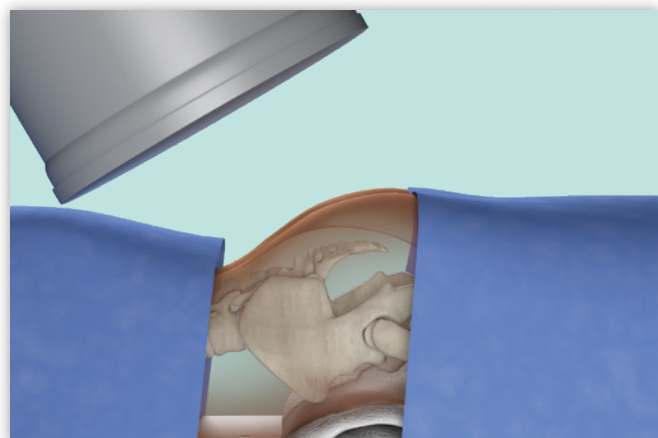
The inlet view is an anterior-to-posterior view to optimize visualization of the ventral cortex of the sacrum.

The fluoroscope is tilted toward the feet until the dense cortical line of the S1-S2 vestigial disc directly overlies the dense cortical line of the sacral promontory. The beam in this view should line up with the anterior cortex of the S1 sacral body.

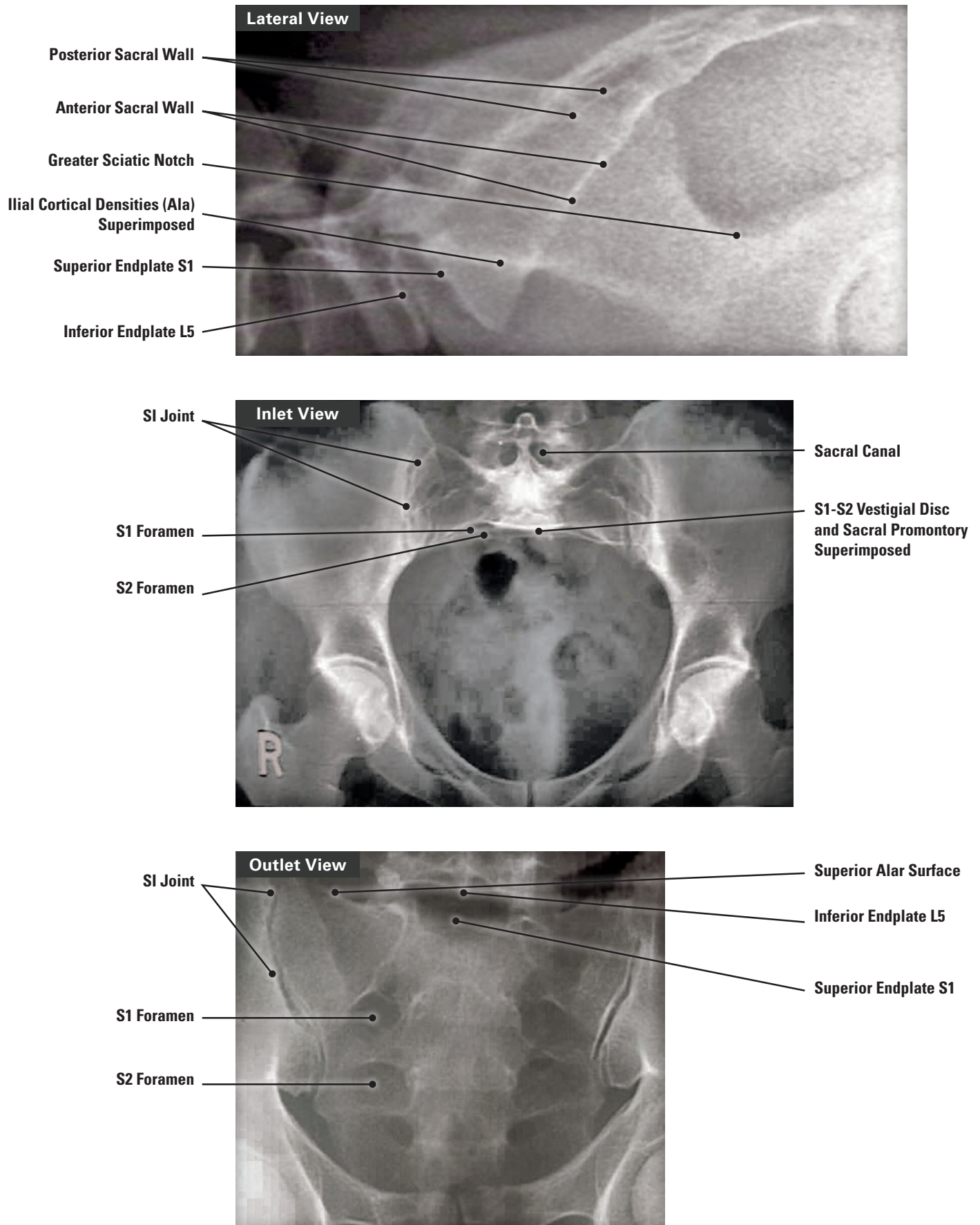


Outlet View

The outlet view is an anterior-to-posterior view to optimize visualization of the sacral neuroforamen.



Procedure: Understanding Fluoroscopic Images



Procedure: Skin Marking and Incision

First Skin Marking

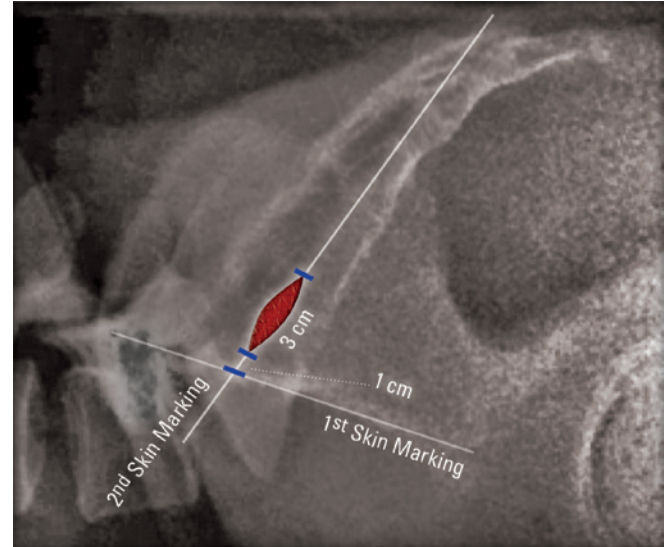
Under fluoroscopy, use a Guide Pin to localize the ala/ICD (Iliac cortical density). Mark the skin overlying the ala/ICD (first skin marking).

Second Skin Marking

Under fluoroscopy, use a Guide Pin to localize the mid-sacral body. Mark the skin overlying the mid-sacral body (second skin marking).

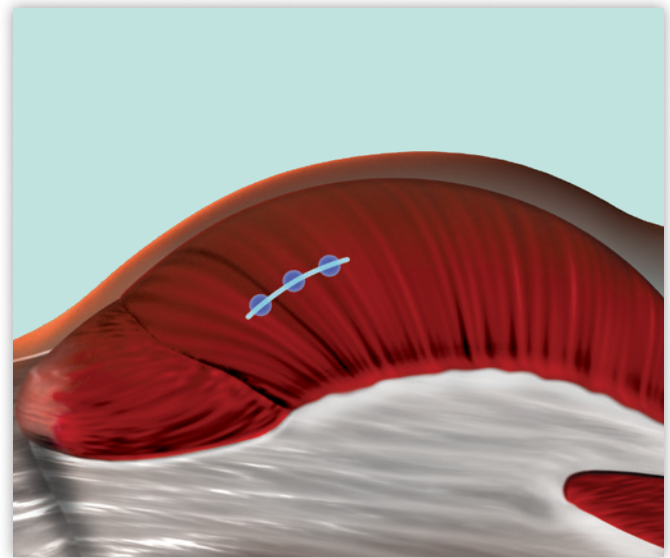
Incision

- ▶ Make a 3 cm skin incision along the mid-sacral body line starting about 1 cm from the first skin marking.
- ▶ The incision should be made through the skin and subcutaneous tissue.



Incision Technique

- ▶ Cut through the skin along the sacral body line.
- ▶ The muscle fibers run perpendicular to the skin incision.
- ▶ Do not continue the skin incision through the muscle and fascia to the bone. Cutting muscle fibers may result in significant bleeding and/or muscle damage.
- ▶ Place Pin(s) through the fascia and seat them into the bone. The muscle may gently be spread in line with the muscle fibers to open the fascia and muscle tissue.



PRECAUTION: If placing the Implants in conjunction with an open procedure, the surgeon should take care not to destabilize the joint prior to placing the Implants.

Procedure: First Pin Placement

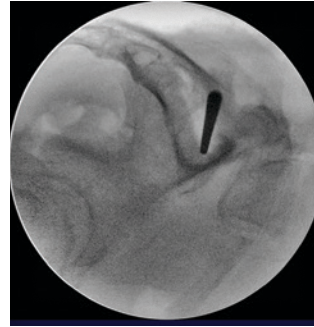
If a 4.0 mm Implant is to be placed, use a 2.0 mm Pin (use pin driver).

If a 7.0 mm Implant is to be placed, use a 3.2 mm Pin.

Lateral view

- ▶ Initial Pin position is always started distal to the alar line (iliac cortical density; ICD).
- ▶ The middle 1/3 of the first sacral body is the typical, but not the universal starting point.
- ▶ Once the starting point is identified, dock the Pin into the lateral cortex of the ilium.

Initial Placement

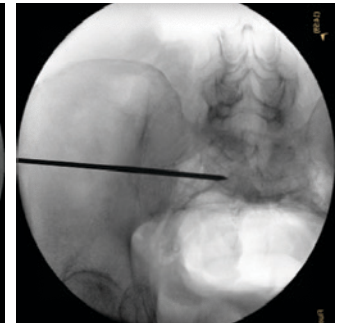
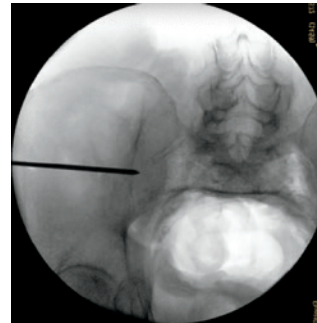


Final Placement



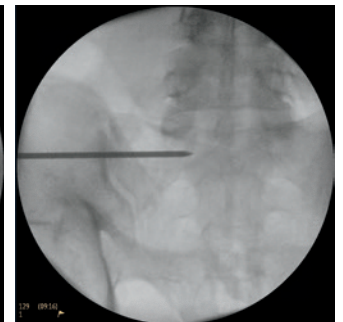
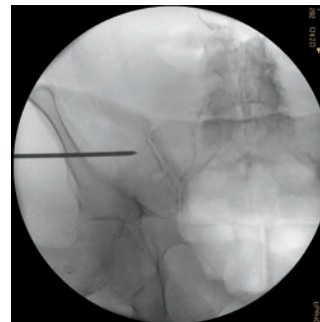
Inlet View

- ▶ Adjust the trajectory of the Pin so that the Pin is aiming towards the middle-to-anterior third of the sacral body.
- ▶ If the Pin is in an unfavorable position and cannot be advanced safely, adjust the Pin starting position before advancing.



Outlet View

- ▶ Adjust the trajectory of the Pin on the outlet view such that the Pin is parallel to the S1 endplate.
- ▶ Advance the Pin under the outlet view.
- ▶ The Pin may be advanced toward the mid-line if there is a favorable trajectory and adequate bony corridor.
- ▶ Re-check the Pin position on the inlet view.



PRECAUTION: Replace any bent Pins with new Pins immediately during the procedure to ensure proper trajectory before drilling. Consider using a pin driver if Pin advancement is difficult due to dense bone quality. If using a Guide Pin Repositioner to reposition the first Pin, use the Mallet to place the second Pin.

Procedure: Neuromonitoring for Guide Pin (Optional)

NOTE: Neuro-tech/operator should review the generator manual and the Neuromonitoring Kit Instructions for Use before using the system.

Using the Guide Pin Sleeve

With the Pin engaged in the bone, slide the Guide Pin Sleeve over the Pin until the distal tip is touching the ilium.

Stimulating the Pin

The SI-BONE Neuromonitoring Kit provides two methods to stimulate the Pin; use only one at a time.

1. Using the Guide Pin Clip

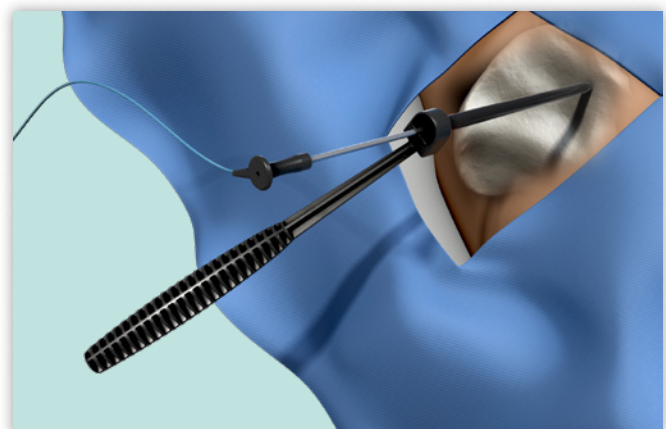
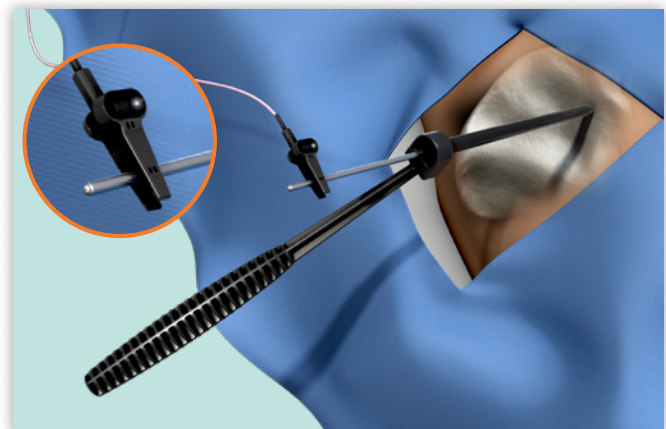
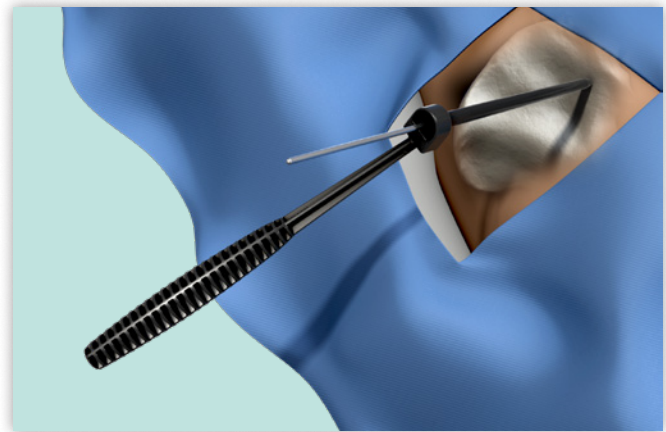
The Clip may be used with the 3.2 mm Pins, or 2.0 mm Pins.

- ▶ Insert the connector end of the Clip into the neuromonitoring system.
- ▶ Place the Clip about 1 cm from the proximal end of the Pin, ensuring that the Clip is attached securely to the Pin (attach Clip at the joint, not at the tip of the jaws).
- ▶ Stimulate the Clip to the desired level.
- ▶ Advance the Pin by tapping on the proximal end of the Pin.

2. Using the Guide Pin Cap

The Cap may only be used with 3.2 mm Pins.

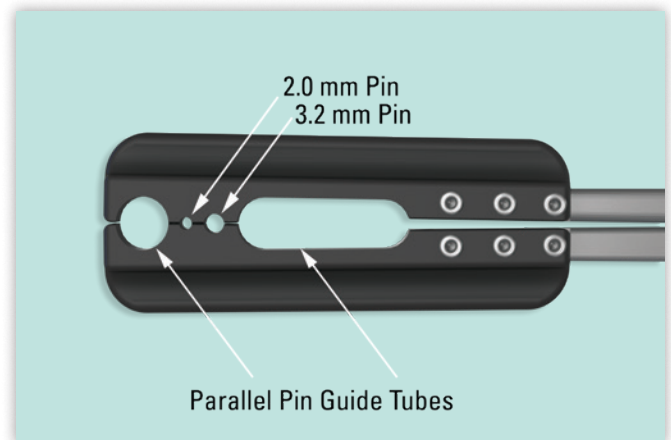
- ▶ Insert the connector end of the Cap into the neuromonitoring system.
- ▶ Place the Cap on the proximal end of the Pin, ensuring that the Cap is securely on the Pin.
- ▶ Stimulate the Cap to the desired level.
- ▶ The Pin may be advanced by tapping directly on the Cap without removing the Cap from the Pin.



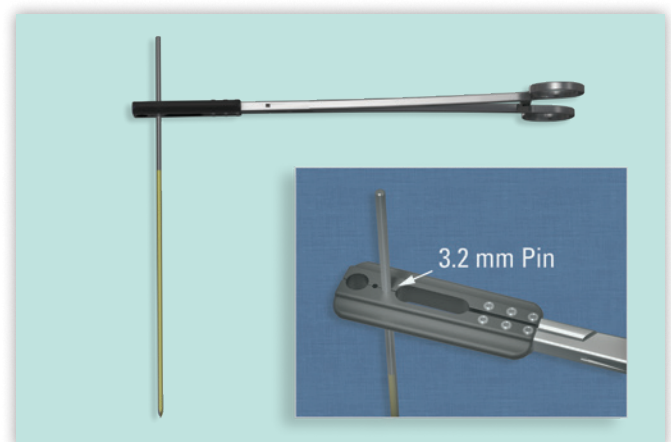
Procedure: Radiolucent Clamp (Optional)

The Radiolucent Clamp is designed to allow the user to hold the Pin and/or the Parallel Pin Guide (see pg. 27) while keeping their hand away from the radiation source. The tips of the Clamp are radiolucent to allow for visualization of the Pin (and Parallel Pin Guide) under fluoroscopy.

Clamp onto the Pin using the appropriate sized hole in the Clamp (3.2 mm or 2.0 mm).



Ensure the Pin is clamped at a 90 degree angle to firmly grasp onto the Pin.



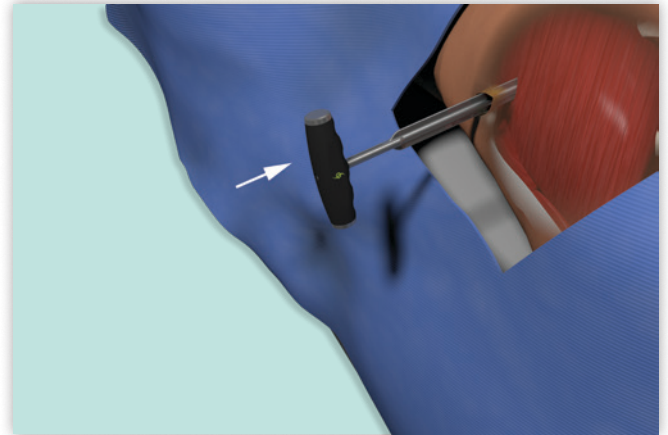
PRECAUTION:

- Please be mindful and aware of the sharp instruments in the set. These instruments may include: the Pins, Drill Bits, and Broaches. The instruments can cause injury if handled in an unsafe manner.
- Do not attempt to redirect the trajectory of the Pin if the Pin is well-seated in the bone. This may bend the Pin and make it more prone to damage during subsequent steps.
- Do not attempt to clamp down on any object that the Radiolucent Clamp is not specifically designed to hold.

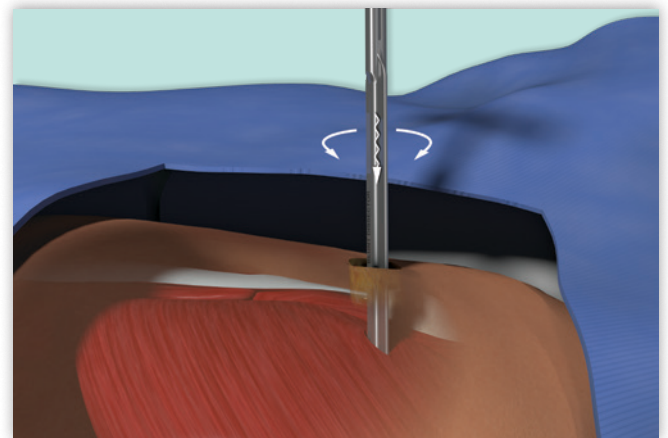
Procedure: Blunt Dissector (Optional)

The Blunt Dissector is a cannulated paddle that allows for gentle dilation of the soft tissues prior to inserting the Soft Tissue Protector. It is an optional tool for this procedure.

Slide the Blunt Dissector over the Pin and gently advance the Blunt Dissector to the ilium, ensuring the blade is parallel to the muscle fibers.



Ensure the Blunt Dissector is seated on the ilium. Rotate gently to spread out the tissue around the Pin.



PRECAUTION: Do not lower hand while twisting the Blunt Dissector to avoid bending the Pin. Ensure the Pin is fully seated into the sacrum prior to using the Blunt Dissector to prevent the proximal end of the Pin from injury to the user's hand.

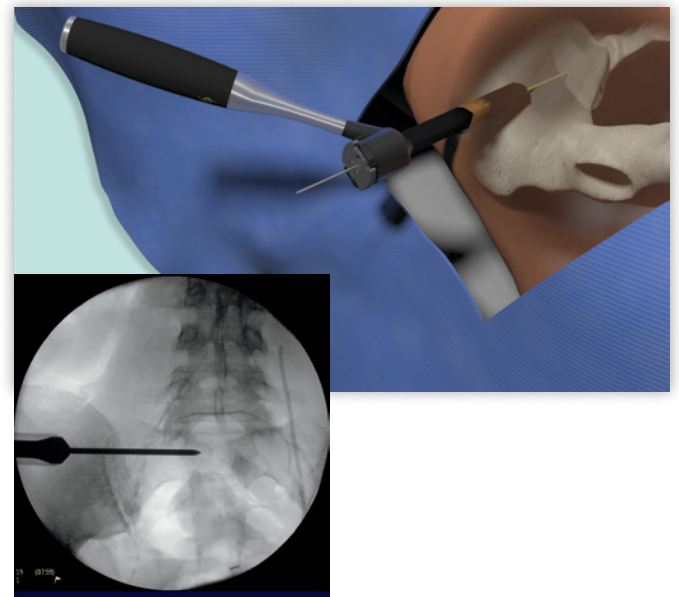
Procedure: Soft Tissue Protector

The Soft Tissue Protector contains a moderately radiolucent tube to allow for visualization of the instruments inside the Soft Tissue Protector under fluoroscopy.

Snap the Pin Sleeve into the Soft Tissue Protector.



Slide the Soft Tissue Protector and Pin Sleeve assembly over the Pin until the distal tip of the Soft Tissue Protector engages with the ilium and bony contact is achieved.



PRECAUTION: Do not impact the flat surface of the Pin Sleeve. This may damage the bone and/or Pin Sleeve.

Procedure: Implant Length Determination

Use the Length Gage to select the proper Implant length by positioning the Length Gage under the Pin as shown in the top right figure.

The Length Gage measures the depth of the Pin that is beyond the lateral cortex of the ilium, providing an easy reference of which length of Implant to use.

Use the Implant length indicated in the range of where the Pin ends.

- ▶ If the end of the Pin is located in between the lines, then read the number on the left column of the Length Gage to determine the Implant length.
- ▶ If the Pin falls on a line, then read the number below the line to determine the appropriate Implant length.

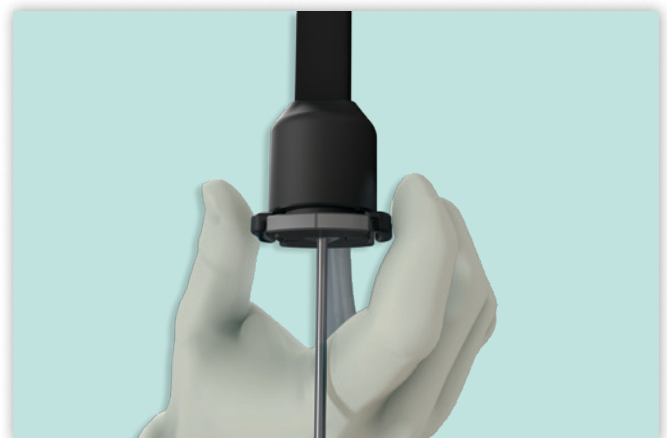
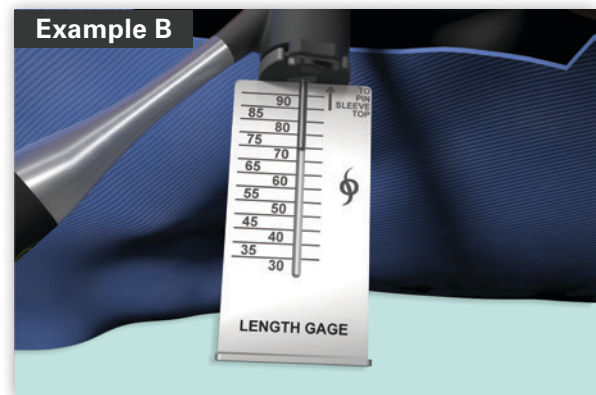
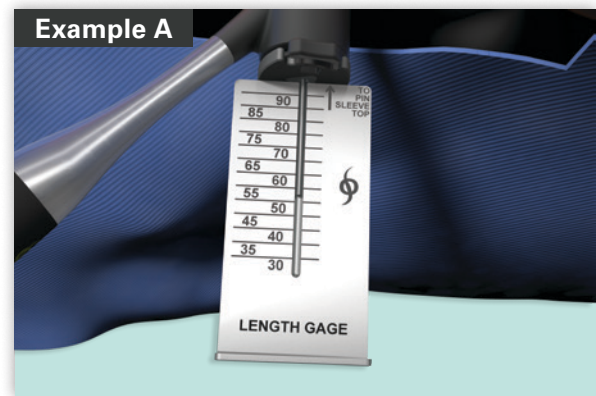
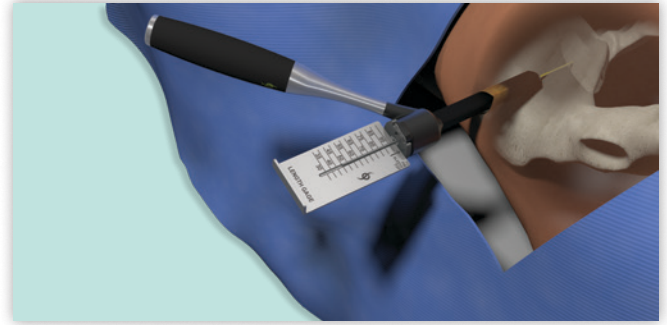
In **Example A**, a 55 mm Implant should be used.

In **Example B**, a 70 mm Implant should be used.

NOTE:

- ▶ 4.0 mm Implants are available in 35 mm, 45 mm, and 55 mm lengths. If the Length Gage measures a length between or above those sizes, the surgeon must choose the available Implant length for the particular situation
- ▶ For accuracy, measurement of Implant length with Length Gage must be made with Pin Sleeve in place.

Once the Implant length is determined, compress the Pin Sleeve tabs and remove the Pin Sleeve from the Soft Tissue Protector.



Procedure: Orientation Guide (if using a 4.0 mm Implant)

From this step onwards, always use an Orientation Guide if planning on inserting a 4.0 mm Implant. The Orientation Guide is designed for more precise placement of the 4.0 mm Implant.

Do not use the Orientation Guide if a 7.0 mm Implant placement is planned.

The Orientation Guide is designed to ensure proper guidance and orientation of the 4.0 mm instruments and Implant.



Snap the Orientation Guide into the Soft Tissue Protector.



All 4.0 mm instruments have been made longer for use with the Orientation Guide.



PRECAUTION: If the Orientation Guide is not used, the longer instruments may lead to patient injury.

Procedure: Drilling

The Drill Bit has a PEEK barrel that is designed to keep the Drill Bit collinear inside the Soft Tissue Protector to minimize the chances of pin binding or shearing.

It is possible to perform this procedure without drilling, as this instrumentation set is equipped with a sharp-tip Broach (see “Broaching with an Adjustable Broach Stop” on pg. 22-23). The decision to skip the drilling step is at the surgeon’s discretion. If the surgeon decides not to drill, skip to the next step “Preparing to Broach” (see pg. 23).

For a 7.0 mm Implant, drilling takes place through the Soft Tissue Protector. For a 4.0 mm Implant, drilling takes place through the Orientation Guide.

Insert the Drill Bit over the Pin. To minimize binding ensure the Drill Bit can move easily back and forth over the Pin. Start applying power only after the PEEK bulb is completely engaged inside the Soft Tissue Protector. A Blunt Pin may be used in place of the Guide Pin if the Guide Pin is close to a foramen.

For 7.0 mm Implant

Drill over Pin with just the Soft Tissue Protector.

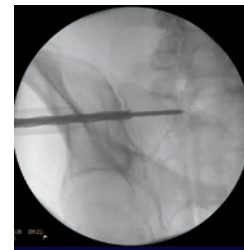


For 4.0 mm Implant

Drill over Pin with Soft Tissue Protector and Orientation Guide.

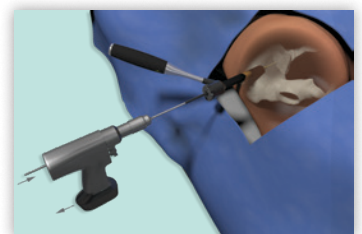


Commence drilling under fluoroscopy in the outlet view. Drill through the lateral cortex of the sacrum, but no more than 2-3 mm medial to the lateral sacral cortex. Watch for Pin advancement.



As the Drill Bit is removed, use the Exchange Pin to prevent the Pin from withdrawing.

Ensure collinearity of the Drill Bit over the Pin, before and during the use of power.



PRECAUTION:

- Ensure the cannula of the Drill Bit is free of debris prior to each use. Flushing the Drill Bit cannula with sterile saline prior to each subsequent use during the procedure may help minimize pin binding.
- Use care to avoid advancing the Guide Pin. Do NOT push on the Guide Pin. Applying a medial force to the Guide Pin or the Exchange Pin may cause them to advance medially.

Procedure: Broach Orientation

The orientation of the Soft Tissue Protector dictates the orientation of the Broach and Implant.

For the first Implant, align the Soft Tissue Protector so that one flat side is parallel to the ala.

For 7.0 mm Implant

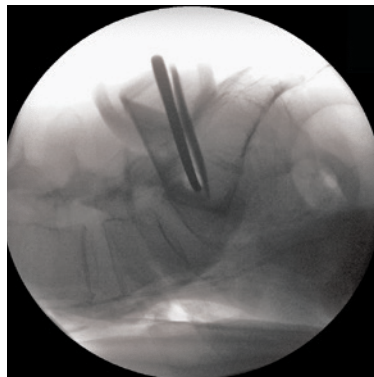


**For 4.0 mm Implant
with Orientation Guide**



Verify under fluoroscopy (lateral view) that the alignment is correct.

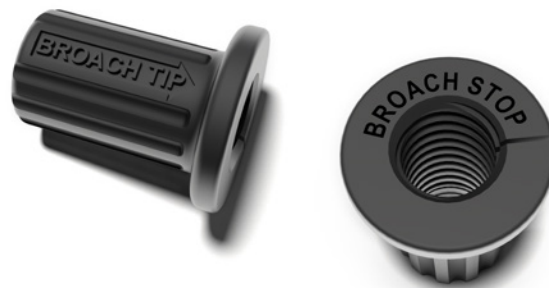
The flat side of the Soft Tissue Protector should be parallel to the ala.



Procedure: Broaching with an Adjustable Broach Stop

An adjustable Broach Stop is provided to prevent over-broaching.

The Broach has a sharp tip, coated with Titanium Nitride, which is an extremely hard ceramic material. The surgeon may elect to proceed directly to broaching without drilling at his/her discretion.



For a 7.0 mm Implant, broaching takes place through the Soft Tissue Protector. For a 4.0 mm Implant, broaching takes place through the Orientation Guide.

If the adjustable Broach Stop is used, thread the Broach Stop onto the Broach with the large end towards the patient. The Broach Stop may be used for both the 7.0 mm and 4.0 mm Broach.



The Broach contains depth measurements. Adjust the Broach Stop on the Broach to the desired broaching depth. In the example on the right, the user has adjusted the Broach Stop to a broaching depth of 30 mm.



PRECAUTION: If the adjustable Broach Stop is assembled with the large end furthest from the patient, the Broach Stop will not stop the Broach at the intended length. It may also bind in the Soft Tissue Protector if using the instrumentation for the 7.0 mm Implant.

Procedure: Broaching with an Adjustable Broach Stop

Insert the Broach into the Soft Tissue Protector.

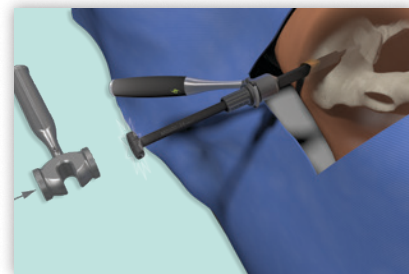
Advance the Broach using the Slotted Mallet.

Ensure collinearity of the Broach over the Pin.

For 7.0 mm Implant

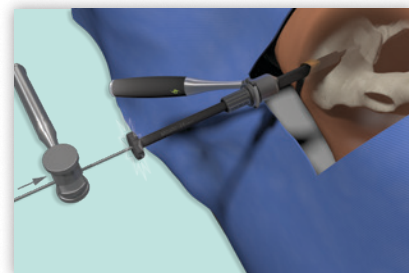
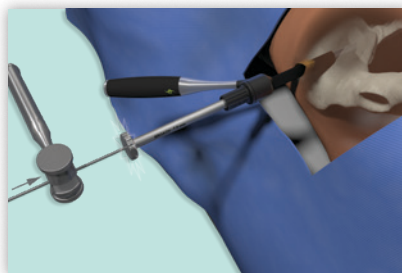


For 4.0 mm Implant



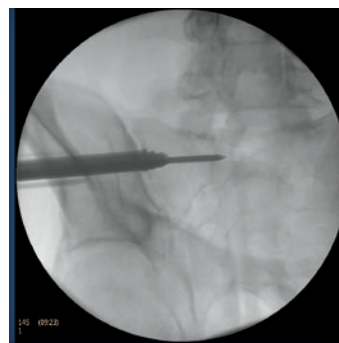
PRECAUTION: Take caution when advancing the Broach to ensure the Broach is not catching on and advancing the Guide Pin.

The slot of the Slotted Mallet may be used over the Exchange Pin if an Exchange Pin is used.

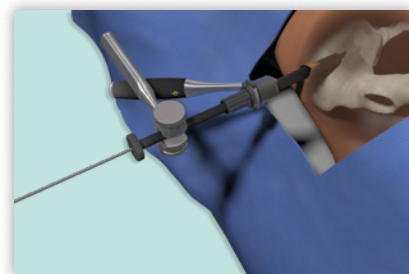
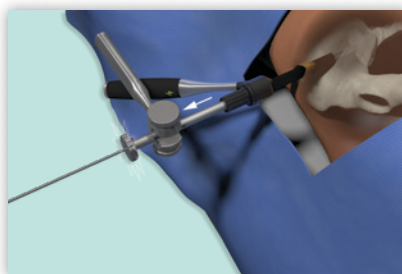


Advance the Broach across the joint until the last tooth of the Broach is past the SI Joint, but no more than 2-3 mm medial to the sacral cortex, in the outlet view.

Avoid penetrating the sacral canal, foramen, or beyond the cortical envelope of the sacrum.



When removing the Broach, use the Exchange Pin to prevent the Guide Pin from withdrawing as the Broach is removed.



PRECAUTION: Use care to avoid advancing the Guide Pin. Do NOT push on the Guide Pin. Applying a medial force to the Guide Pin or the Exchange Guide Pin may cause them to advance medially.

Procedure: Implant Transfer

Implants may be provided in a carton or in a tube. The following instructions pertain to Implants provided in the tube packaging:

Circulator

Confirm Implant size from the label on the top and the side of the tube. Remove the outer poly wrap from the Implant tube. Hold the Implant tube vertically in one hand with the cap up. Unscrew counterclockwise and remove the cap, breaking the seal.

NOTE:

Once Implant tube cap is removed, do not touch the sterile threaded portion of the Implant tube or the sterile thermoplastic polyurethane (TPU) sleeve.

Aseptically transfer the contents of the tube (TPU Sleeve containing Implant) to the sterile field.

Option 1: Drop transfer to sterile basin.

Option 2: Hand-to-Hand Transfer

Back Table Assist (Sterile)

Hold the sterile TPU Sleeve packaging vertically. Open the end of the sleeve to show the head of the Implant through the sleeve.

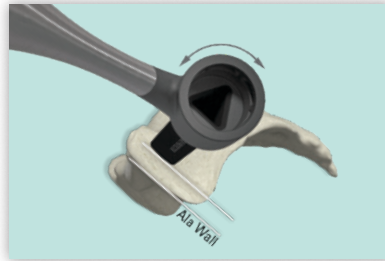


Procedure: Implant Insertion

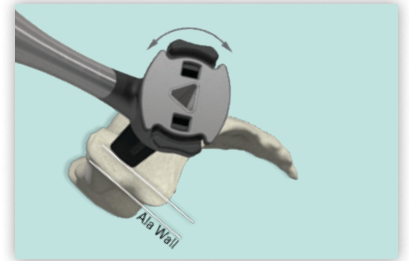
For a 7.0 mm Implant, insertion takes place through the Soft Tissue Protector.
For a 4.0 mm Implant, insertion takes place through the Orientation Guide.

Confirm for alignment of the Soft Tissue Protector and broached channel.

For 7.0 mm Implant

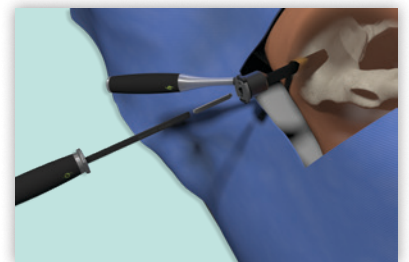
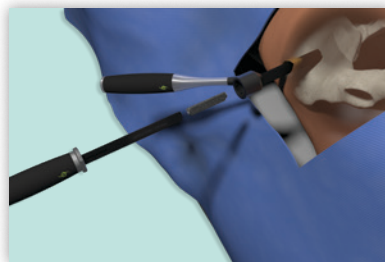


For 4.0 mm Implant

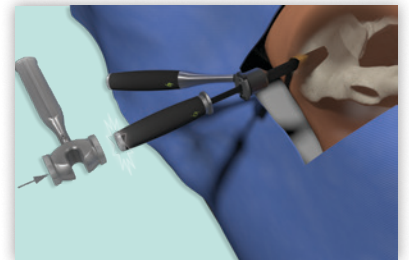
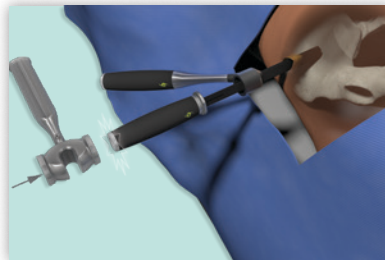


Place Implant over Guide Pin, oriented with tapered end toward patient.

Advance the Implant using the Impactor.



Always monitor the progress of the Implant and any movement of the Guide Pin with fluoroscopy.



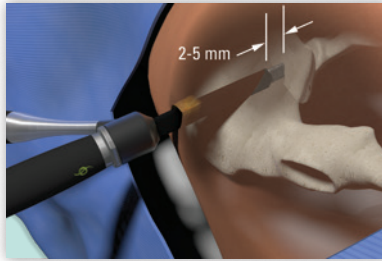
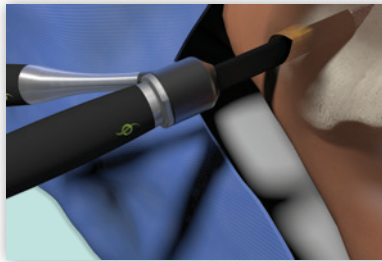
Continue until the Impactor contacts the shoulder of the Soft Tissue Protector.



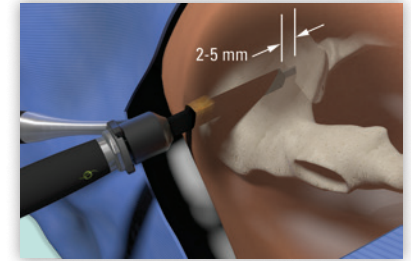
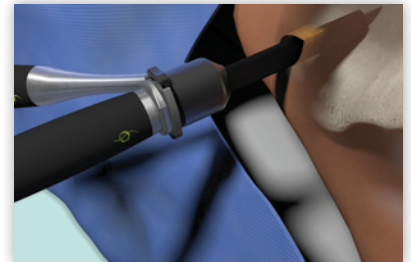
Procedure: Implant Insertion

The Impactor is designed such that when it contacts the shoulder of the Soft Tissue Protector, the Implant is seated 2-5 mm proud of the ilium. Stop impaction when the Impactor contacts the shoulder of the Soft Tissue Protector.

For 7.0 mm Implant

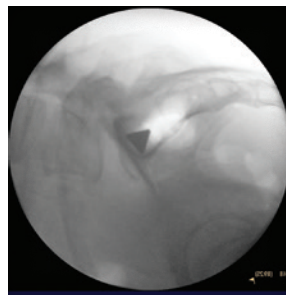


For 4.0 mm Implant

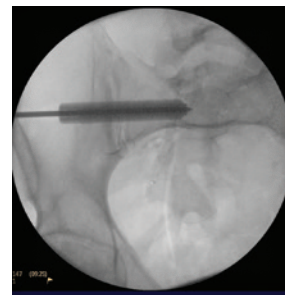


Final first Implant placement:

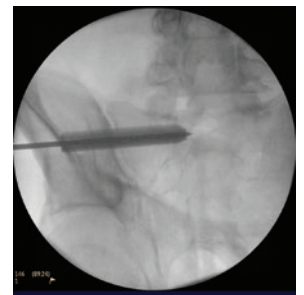
Palpate the end of the Implant to confirm final Implant placement.



Lateral

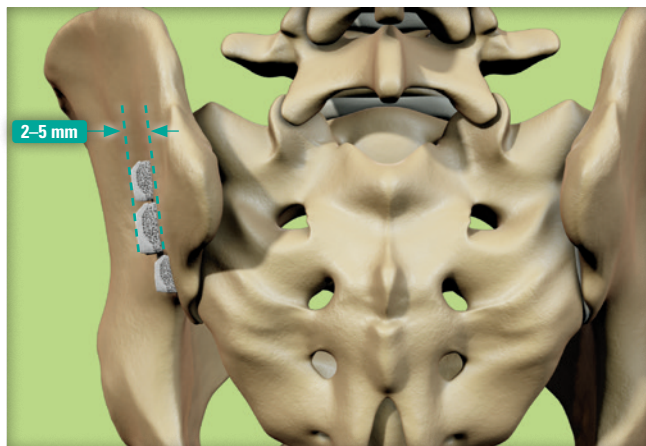


Inlet



Outlet

The Implants should be slightly proud (2-5 mm), with all three sides of the Implant in contact with the lateral iliac cortex. Proud Implants provide another cortical wall for load bearing support.



Final Implant placement

Procedure: Three-Pin Fixed Parallel Pin Guide Technique

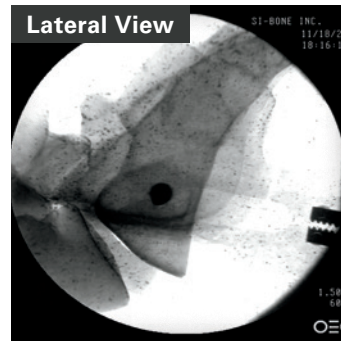
Lateral View

- ▶ Initial Pin position is always started distal to the alar line or iliac cortical density.
- ▶ The middle 1/3 of the first sacral body is the typical, but not the universal starting point.
- ▶ Ensure the first pin is in line with the C-arm, appears as a pinpoint, in the **lateral view**.
- ▶ Once the starting point is identified, dock the Pin into the lateral cortex of the ilium and advance 10-15 mm, ensuring that the pin does not cross the SI joint.
- ▶ Identify the appropriate 3-Pin Fixed Parallel Pin Guide (3 FPPG, P/N 400376 and 400377), Left or Right corresponding to the patient's side being treated.
- ▶ Place the first tube of the 3 FPPG over the pin and advance until the Tube contacts the lateral ilium.
- ▶ Take a lateral image with the 3 FPPG in place to confirm the patient anatomy can accommodate the pin spacing in the selected orientation.
- ▶ Adjust position of 3 FPPG by rotating the guide clockwise or counterclockwise until the tube for the third pin is positioned at the level of the ventral sacral cortex or just dorsal to this –**see Lateral View image on right**.
- ▶ Place the 2nd and 3rd pins into the remaining tubes of the 3 FPPG and advance one at a time into the lateral ilium cortex ensuring not to cross the SI joint.

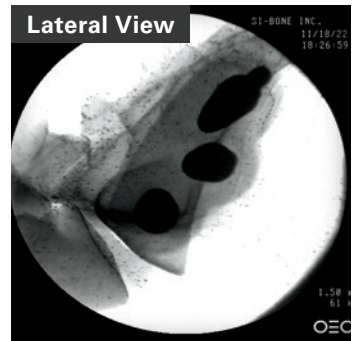
NOTE: The Pin Extender Cap (P/N 501672) may be inserted over the proximal end of the guide pin to raise the impaction surface above adjacent guide pins and mitigate the risk of impacting adjacent pins.

- ▶ Move to Inlet View to confirm Guide Pin trajectories

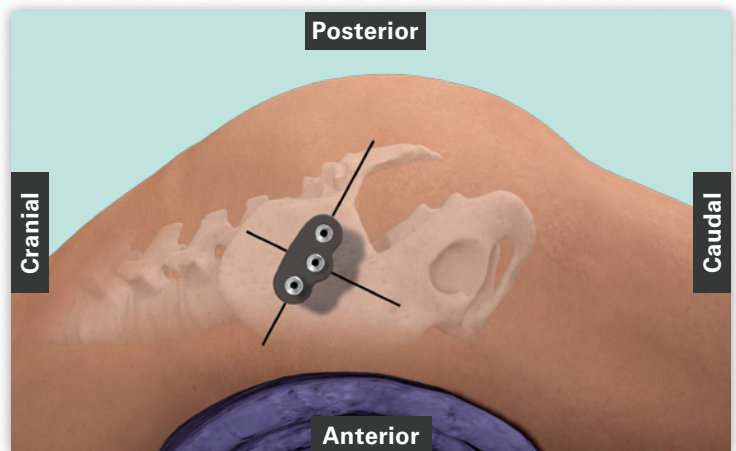
Initial Pin Placement



Verify acceptable anatomy to accommodate 3-Pin FPPG



Ensure correct orientation of 3-Pin FPPG such that the second pin is offset caudal to the first pin and anterior to the third pin. The middle offset pin is ventral to both the first and third pins.



PRECAUTION: The 3-Pin FPPG instruments are unique to the patient side being treated. Ensure P/N 400376 labeled "LEFT" is used on the patient's left side, and P/N 400377 labeled "RIGHT" is used on the patient's right side.

Procedure: Three-Pin Fixed Parallel Pin Guide Technique

Inlet View

- ▶ In the inlet view, verify trajectory of each pin is as desired (aiming towards the middle-to-anterior third of the sacral body).
- ▶ Adjust trajectory by moving pin along line perpendicular to the mid body sacral line, see **inlet view**. 3 FPPG will need to be removed to allow adjustment of pin trajectory.
- ▶ If the Pin has an unfavorable starting position and cannot be advanced safely, adjust the Pin starting position before advancing.
- ▶ When pin trajectories are as desired, advance the pins just across the joint to dock the pins in their existing trajectories.

NOTE: Do not advance the pins more than 5 mm across the joint in the Inlet View.

- ▶ Confirm Guide Pin trajectories

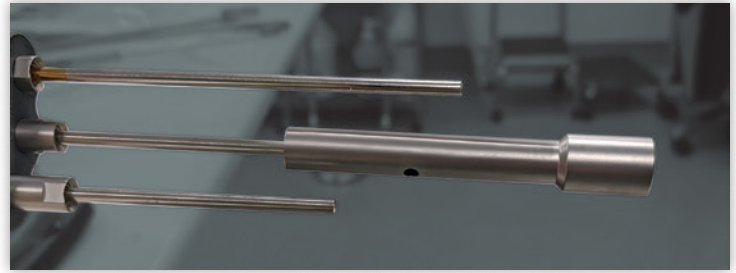
Outlet View

- ▶ If necessary, adjust the trajectory of the Pin on the outlet view such that the Pin is parallel to the S1 endplate.
- ▶ Advance one Pin at a time under the **outlet view**.

NOTE: The Pin Extender Cap (P/N 501672) can be inserted over the proximal end of the guide pin to raise the impaction surface above adjacent guide pins and mitigate the risk of impacting adjacent pins.

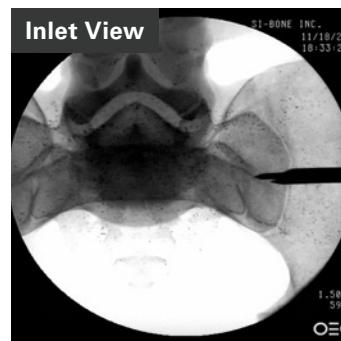
- ▶ The Pins may be advanced toward the midline if there is a favorable trajectory and adequate bony corridor –**see outlet view**.
- ▶ Re-check the Pin position on the inlet view.

PRECAUTION: If patient has a dysmorphic sacrum, the second (middle) pin will be advanced more medially than the first and third pins.

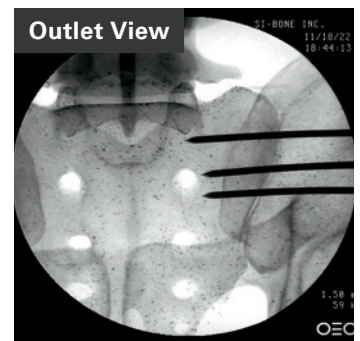


Utilize Pin Extender Cap (P/N 501672) to mitigate risk of impacting adjacent pins during pin advancement

Inlet view of all 3 pins advanced to the SI joint



Outlet view of all 3 pins at terminal depth



Procedure: Neuromonitoring for Implant (Optional)

Implant Probe

An Implant Probe is provided in the SI-BONE Neuromonitoring Kit to stimulate the Implant.

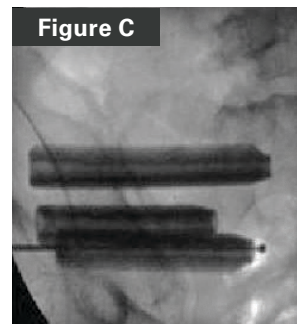
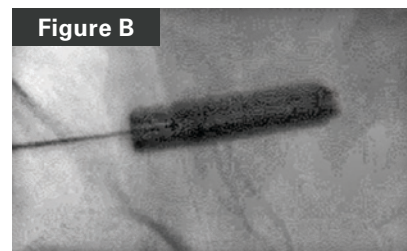
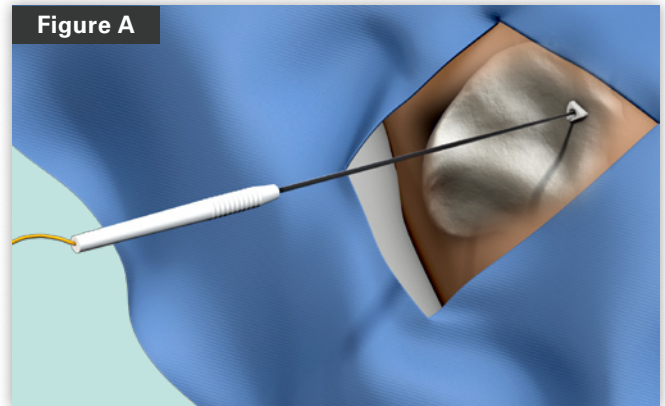
Stimulating the Implant

- ▶ Once the Implant has been placed to the desired depth as confirmed fluoroscopically, remove the Pin from the Implant.
- ▶ Insert the connector end of the Probe into the neuromonitoring system.
- ▶ Advance the Probe through the Soft Tissue Protector and touch the Probe's ball-tip to the inner lumen of the Implant (**Fig. A-B**).
- ▶ Stimulate the Probe to the desired level.
- ▶ Remove the Probe and Soft Tissue Protector if the neuromonitoring reading is determined to be at an acceptable level.
- ▶ **Optional:** To assess Implant proximity to the adjacent nerve structures, the Probe is inserted through the Implant's lumen and advanced past the distal end using a constant current; the Probe is slowly advanced under fluoroscopic guidance (**Fig. C**) until a response is noted, but no farther than 5-10 mm. Use care to avoid impinging on the nerve or lodging the Probe's ball-tip in the bone.

Repositioning the Implant (if necessary)

- ▶ If signal changes indicate neural structures at the tip of the Implant, the Implant can easily be retracted.
- ▶ The Implant may be laterally retracted a few millimeters using the Removal Adapter (see "Intraoperative Repositioning" on pg. 33).
- ▶ Once the Implant is repositioned, repeat the stimulation steps above.
- ▶ Always confirm final Implant placement under fluoroscopic imaging.

NOTE: Neuro-tech/operator should review the generator manual and Neuromonitoring Kit Instructions for Use before using the system.



Note:
The optional step does not apply to the 4.0 mm Implant, as the probe does not fit through the lumen of the 4.0 mm Implant.

Procedure: Parallel Pin Guide (Subsequent Pin Placement)

There is one Fixed Parallel Pin Guide and one Variable Parallel Pin Guide that comes in the instrument tray. Both have radiolucent heads to allow for better visualization under fluoroscopy. Both Parallel Pin Guides can be used for 3.2 mm Pins and 2.0 mm Pins.

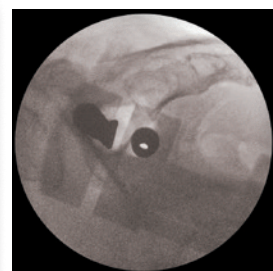
The Fixed Parallel Pin Guide, shown on the right, has Pin Guide Tubes that are separated by 15 mm, center-to-center.



The Variable Parallel Pin Guide, shown on the right, allows for the Pin Guide Tubes to be separated anywhere from 13 mm to 31 mm center-to-center in 2 mm increments.



Once the desired distance is determined, the Variable Parallel Pin Guide can be locked into place by closing the cam-lock.



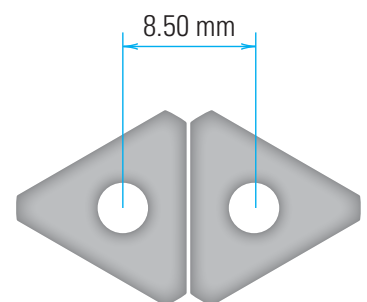
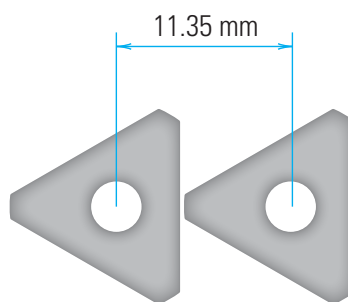
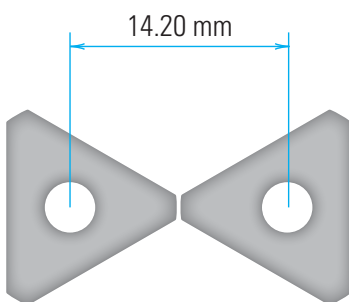
Variable Parallel Pin Guide radiolucent head

Procedure: Parallel Pin Guide (Subsequent Pin Placement)

The Parallel Pin Guide can be held by the Radiolucent Clamp to keep the user's hand away from the radiation source.



PRECAUTION: When placing subsequent Implants, avoid orienting Implants point-to-point. Implant-to-Implant contact may occur in any orientation. If there is Implant-to-Implant contact, the existing Implant may be inadvertently advanced during insertion of the current Implant. The minimum distances, measured center-to-center, before Implant contact in the various orientations are:



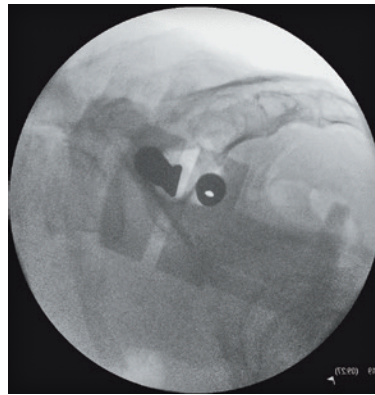
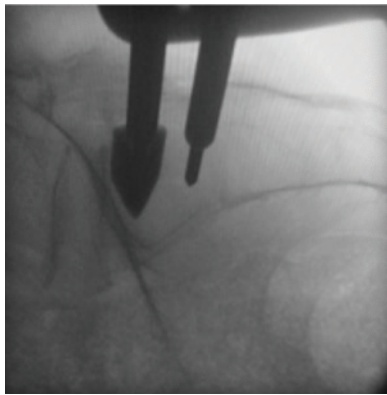
Procedure: Second Pin Placement

- ▶ Depending on the patient's anatomy, placement of the 2nd and 3rd Pins may vary.
- ▶ Always check the inlet and outlet views to assess Pin/Implant trajectory and position.
- ▶ If using the Neuromonitoring Kit: Stimulate subsequent Pins in the same manner as the first Pin (*see pg. 16*).

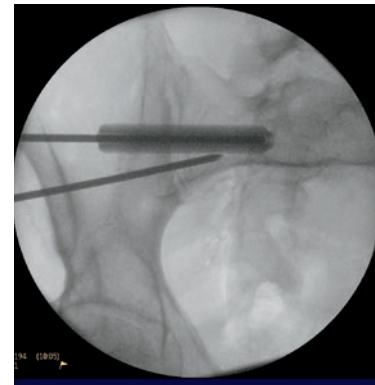
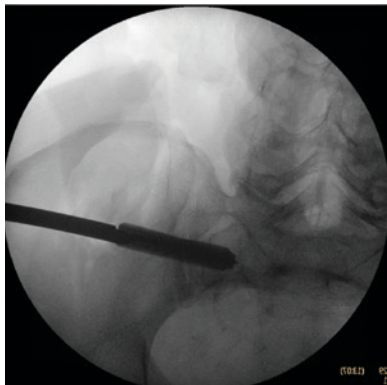
Example A*

Example B

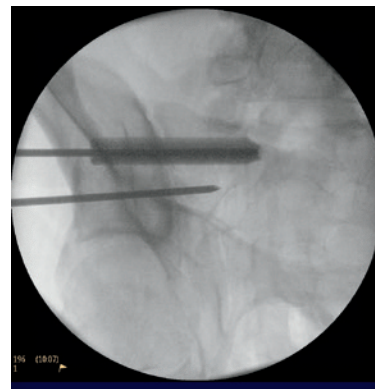
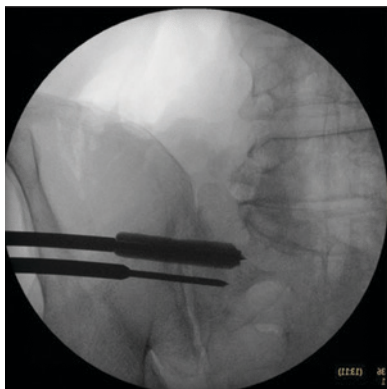
Lateral



Inlet



Outlet



* A different SI-BONE instrument set was used in "Example A."

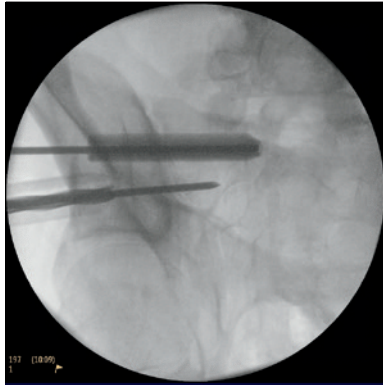
Procedure: Subsequent Pin Placement

The broaching and drilling steps are the same for subsequent Implants.

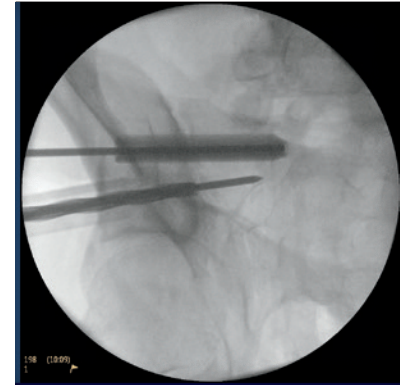
Drill

- ▶ Monitor the progress of the Drill Bit and any movement of the Pin.
- ▶ Be sure to avoid the foramen and ensure the Drill Bit does not go more than 2-3 mm medial to the sacral cortex.

Example A*
(Outlet view)

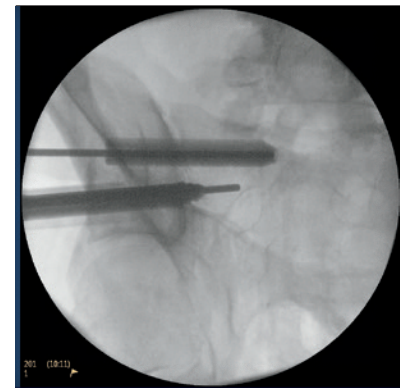
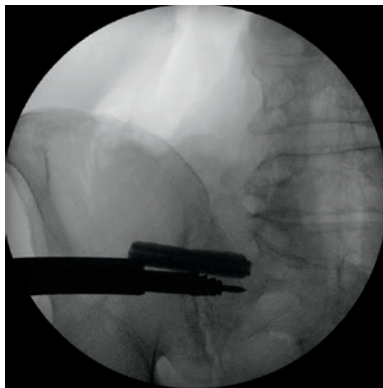


Example B
(Outlet view)



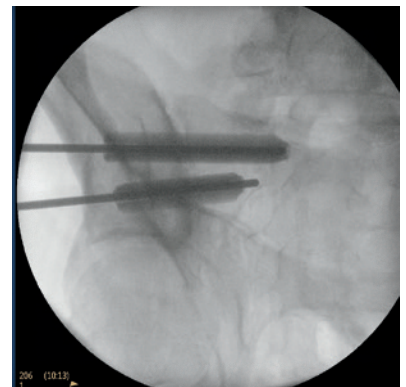
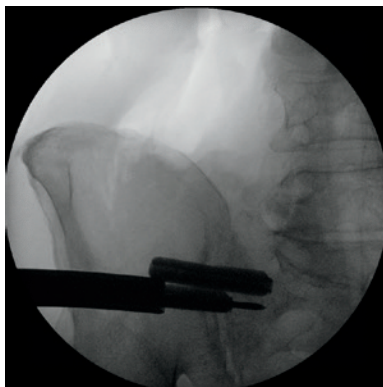
Broach

- ▶ Advance the Broach across the joint until the last tooth of the Broach is past the joint, but no more than 2-3 mm medial to the sacral cortex, in the outlet view.



Implant Insertion

- ▶ Fully insert the second Implant.
- ▶ Monitor the progress of the Implant and any movement of the Pin.
- ▶ Be sure to avoid the foramen.
- ▶ If using the Neuromonitoring Kit: Stimulate the second Implant in the same manner as the first Implant (*see pg. 26*).



* A different SI-BONE instrument set was used in "Example A."

Procedure: Final Implant Placement

Depending on the patient's anatomy, the placement of the third Pin may vary. Always check inlet and outlet views to assess Pin/Implant trajectory and position.

Outlet View

- ▶ Place the Variable Parallel Pin Guide (VPPG) over the 2nd Pin.
- ▶ Adjust the Variable Parallel Pin Guide so that the guide tube is aimed between the S1 and S2 neuroforamina toward the S2 body (**Figure A**).
- ▶ Lock the VPPG.
- ▶ Insert a Guide Pin into the free sleeve of the VPPG (*do not dock Pin yet*).

Lateral View

- ▶ Rotate the Variable Parallel Pin Guide so that the starting Pin position is at the anterior sacral cortical body line (**Figure B**).
- ▶ Dock the Pin.
- ▶ Remove the VPPG.

Inlet View

- ▶ Adjust the Pin trajectory; aim for the middle to anterior third of the sacral body.

Outlet View

- ▶ Verify the trajectory of the 3rd Pin; advance Pin to desired depth (**Figure C**).
- ▶ Use the Length Gage to determine the Implant size.
- ▶ Place and advance the 3rd Implant.

Outlet Oblique View

- ▶ Confirm that all Implants cross the sacroiliac joint (**Figure D**).

Outlet Oblique View:

- ▶ Obtain standard Outlet view and add approximately 15 degrees of rainbow angulation to approximate the dorsal and ventral aspects of the SI joint.

Figure A

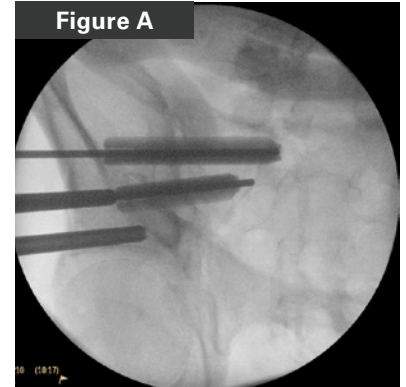


Figure B

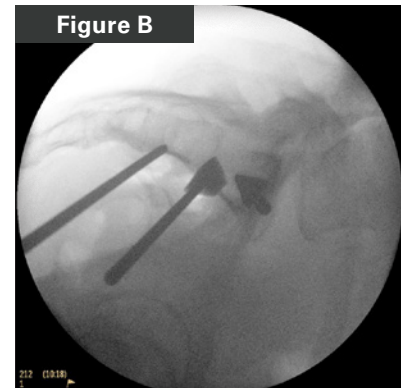


Figure C

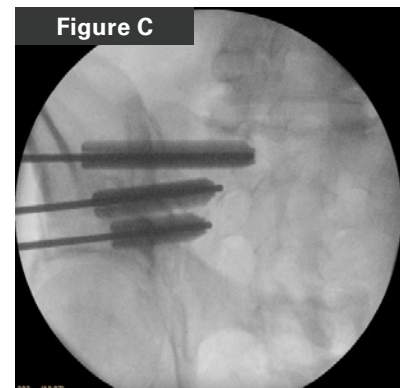
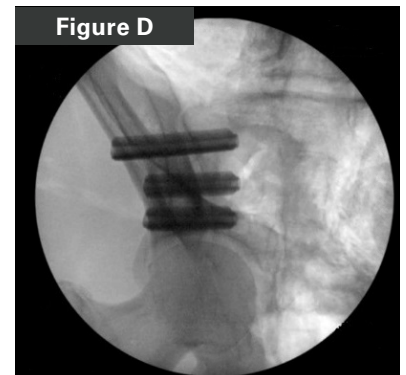


Figure D



PRECAUTION: When advancing Pin or Implant, avoid penetrating the sacral canal, foramen, and cortices. If visualization is difficult, do not advance Pin beyond lateral walls of foramen.

Procedure: Final Implant Placement

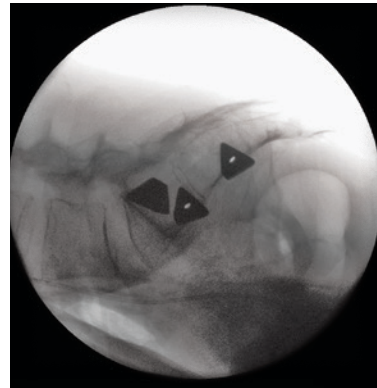
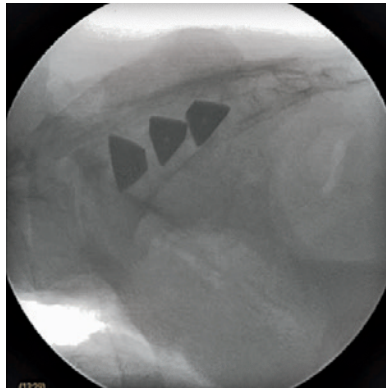
Prior to closure, always obtain final fluoroscopic images in the lateral, inlet, and outlet views to confirm no cortical wall breach, foramen breach, or other malposition.

If using the Neuromonitoring Kit: Stimulate subsequent Pins and Implants in the same manner as the first Pin and Implant (see pg. 14 and 26).

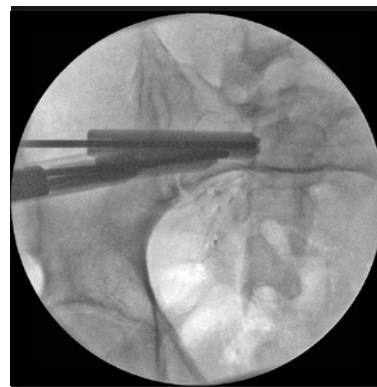
Example A

Example B

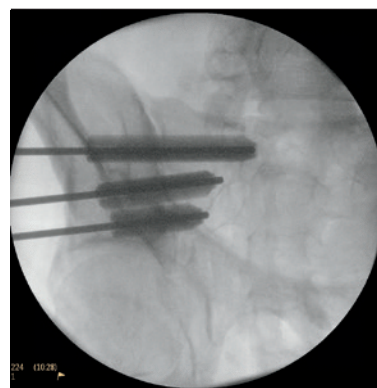
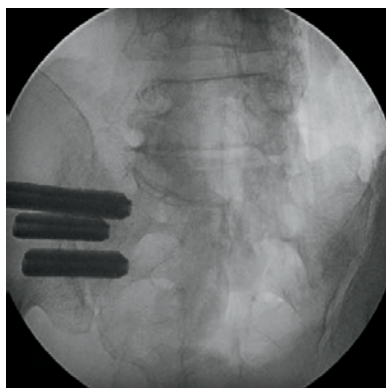
Lateral



Inlet



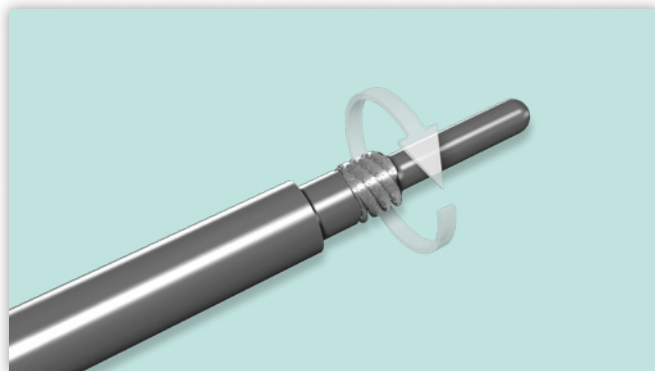
Outlet



Procedure: Intraoperative Repositioning and Removal Surgery

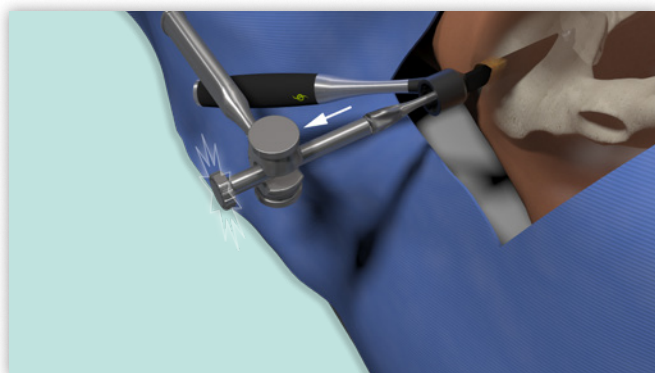
The instrument set includes a Removal Adapter that has a blunt tip to engage the lumen of the Implant with a threaded portion that fastens to the proximal end of the Implant.

- ▶ A fluoro image may be needed to facilitate positioning the Removal Adapter onto the Implant.
- ▶ Fully advance the blunt tip of the Removal Adapter into the Implant lumen. Rotate the Removal Adapter clockwise (while holding Implant until engaged).



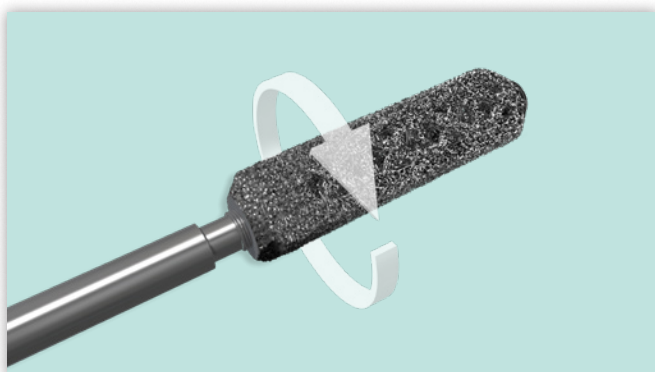
For repositioning or revising an Implant:

- ▶ Once the Removal Adapter is engaged with the Implant, the Implant can be lateralized or removed by impacting the Removal Adapter handle with the Slotted Mallet. Confirm final Implant placement using fluoroscopy.



For removing an Implant:

- ▶ The Slotted Mallet may be used to gently tap and completely back out the Implant.
- ▶ The Implant can be unthreaded from the Removal Adapter by placing the Implant in the Soft Tissue Protector and rotating the Removal Adapter counter-clockwise by hand or with the flattened surface on the shoulder of the Slotted Mallet.



PRECAUTION:

- ▶ *Do not over-tighten the Removal Adapter into the Implant, as the tip of the adapter may break off. Use the "two-finger" technique to tighten the 4.0 mm Removal Adapter into a 4.0 mm Implant.*
- ▶ *Avoid exerting excessive force in any direction, other than straight back, when using the Removal Adapter.*

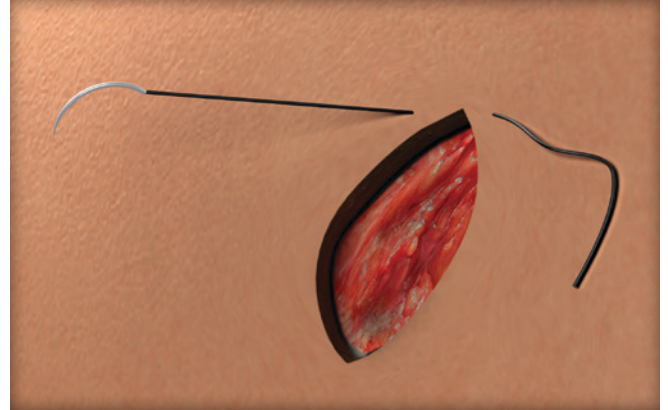
Procedure: Closure and Post-Op Care

Closure

- ▶ Obtain final outlet, inlet, and lateral views.
- ▶ Proceed with the standard closing procedure.
- ▶ Local anesthetic may be injected after closure.

Recommended closure

- ▶ Muscle fascia if desired
- ▶ Subcutaneous tissue
- ▶ Skin

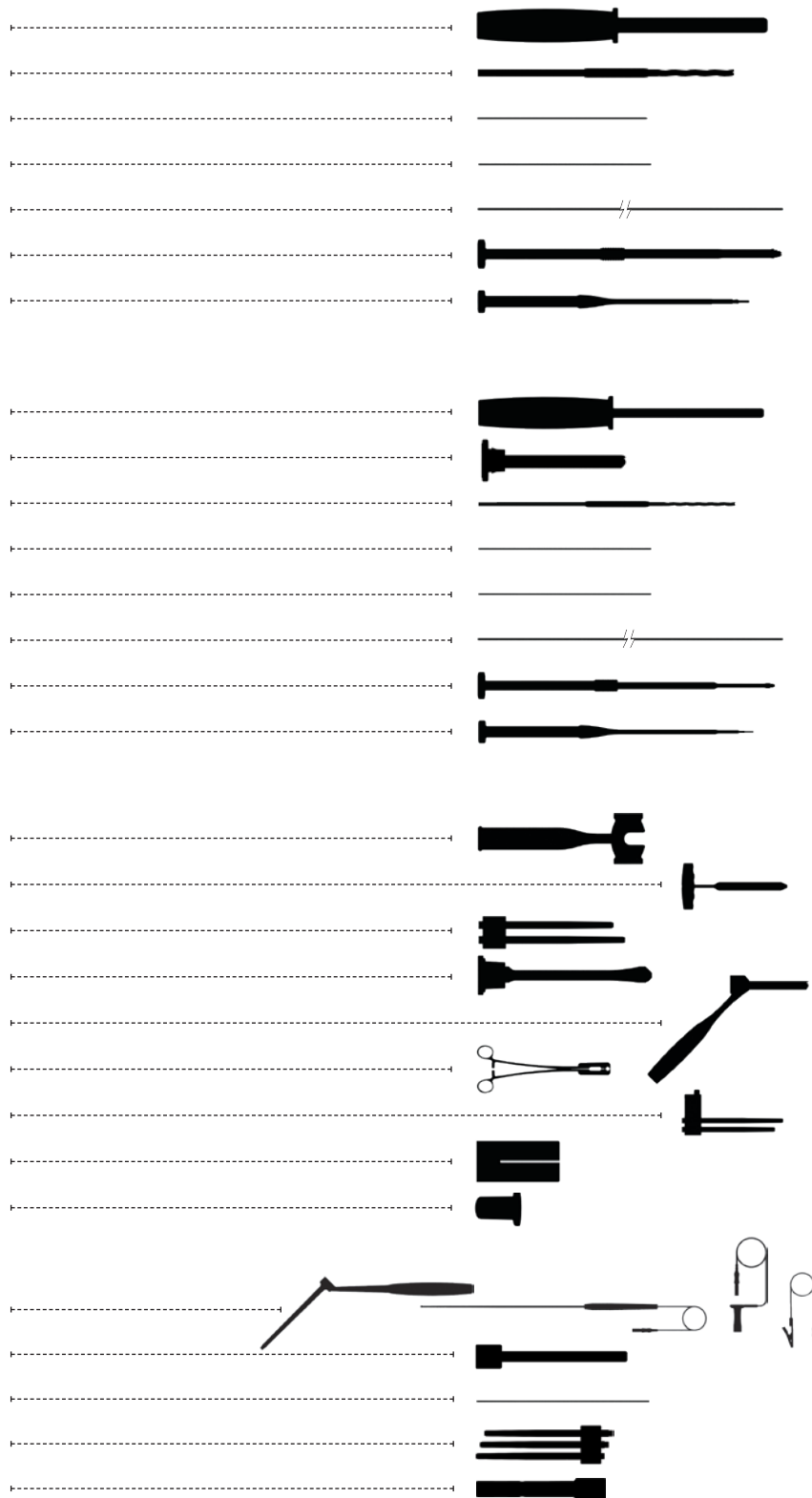


Recommended Post-Op Care

- ▶ Some patients may be able to progress rapidly to full weight bearing. Other patients may require a period of protected weight bearing due to associated health conditions such as age, osteoporosis, altered bone health, impaired balance and/or gait, or other musculoskeletal conditions.
- ▶ Most surgeons and therapists recommend a heel toe gait with normal foot progression.

Product Catalog

Radiolucent Instruments	Part No.
For 7.0 mm Implants	
Impactor – 7.0 mm	400069
Cannulated Drill Bit – 7.0 mm	400146
Guide Pin – 3.2 mm	500373
Blunt Pin – 3.2 mm	500374
Exchange Pin – 3.2 mm	500375
Broach – 7.0 mm	500394
Removal Adapter – 7.0 mm	500402
For 4.0 mm Implants	
Impactor – 4.0 mm	400070
Orientation Guide – 4.0 mm	400071
Cannulated Drill Bit – 4.0 mm	400074
Guide Pin – 2.0 mm	500376
Blunt Pin – 2.0 mm	500377
Exchange Pin – 2.0 mm	500378
Broach – 4.0 mm	500396
Removal Adapter – 4.0 mm	500403
Universal for Implants	
Slotted Mallet	400030
Blunt Dissector	400064
Fixed Parallel Pin Guide	400050
Pin Sleeve	400065
Soft Tissue Protector	400066
Radiolucent Clamp	400106
Variable Parallel Pin Guide	400076/41
Length Gage	500392
Adjustable Broach Stop	500395
Upon Request (Order Separately)	
Neuromonitoring Kit	400170
Guide Pin Repositioner	400112/13/14
Guide Pin, 3.2 mm, Threaded	501385
3-Pin Parallel Pin Guide (L&R)	400376/400377
Guide Pin Extension Cap	501672



Instrument set configurations may vary. Refer to a local sales representative for tray set part numbers and configurations available.

Supplemental: Graft and iFuse TPS options

Prior to implantation, the iFuse 3D Implant may be packed with autograft and/or allograft material of the surgeon's choice.

- ▶ **Insert a Blunt Pin into the lumen of the iFuse 3D Implant prior to packing the Implant with graft material.**
 - » **This will limit the graft material from obstructing the Implant's lumen, which could result in Pin advancement during Implant insertion.**
- ▶ It takes 1.1 to 2.6 cc of graft material to pack each iFuse 3D Implant, depending on the Implant (see the table on right for details).

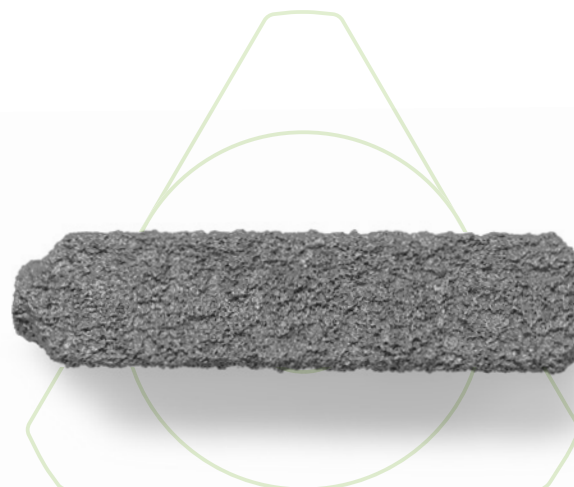
Implant Length	Graft Vol (cc)
35	1.1
40	1.4
45	1.6
50	1.8
55	2.0
60	2.2
65	2.4
70	2.6
75	2.8
80	3.0
85	3.2
90	3.4



- ▶ When packing the Implant with autograft or allograft, a bone mill may be used to crush the graft material into a fine paste.
 - » A small amount of sterile blood may be added to the graft material to achieve a putty-like consistency.
- ▶ Use a surgical spatula to spread and pack the graft material into the Implant, one side at a time, firmly pressing the graft material into the Implant fenestrations.
 - » Avoid using fingers to pack bone material into/onto the Implant.
The rough surface of the Implant could tear surgical gloves.
- ▶ Use a surgical spatula to remove excess material from the sides of the Implant prior to insertion.
 - » Excess graft material may cause the Implant to become lodged in the Soft Tissue Protector, or could get scraped off during Implant insertion and remain in the soft tissues lateral to the ilium.
- ▶ Remove the Blunt Pin from the Implant's lumen.

iFuse TPS option also available

The iFuse Implant, available since 2009, is made of titanium and has a porous, titanium plasma spray (TPS) coating. TPS technology has been used for decades in other medical applications such as orthopedics and dentistry. More than 30 published, peer-reviewed articles demonstrate safety and effectiveness of the iFuse Implant.





SI-BONE® | iFuse Implant System®

Indications

The iFuse Implant System® is intended for sacroiliac fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

The Neurmonitoring Kit™ is indicated for stimulation of peripheral motor nerves, including spinal nerve roots, for localization and identification during surgery.

Healthcare professionals should refer to the Instructions for Use for indications for use, contraindications, warnings and precautions at <https://si-bone.com/label>

There are potential risks with iFuse Procedures. They may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit <https://si-bone.com/risks>

Complaints and adverse events relating to use of the procedure and/or device should be reported to SI-BONE, Inc. Toll Free: (855) 511-1545 or E-mail qara@si-bone.com

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PROVIDERS

300223-US Rev D

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