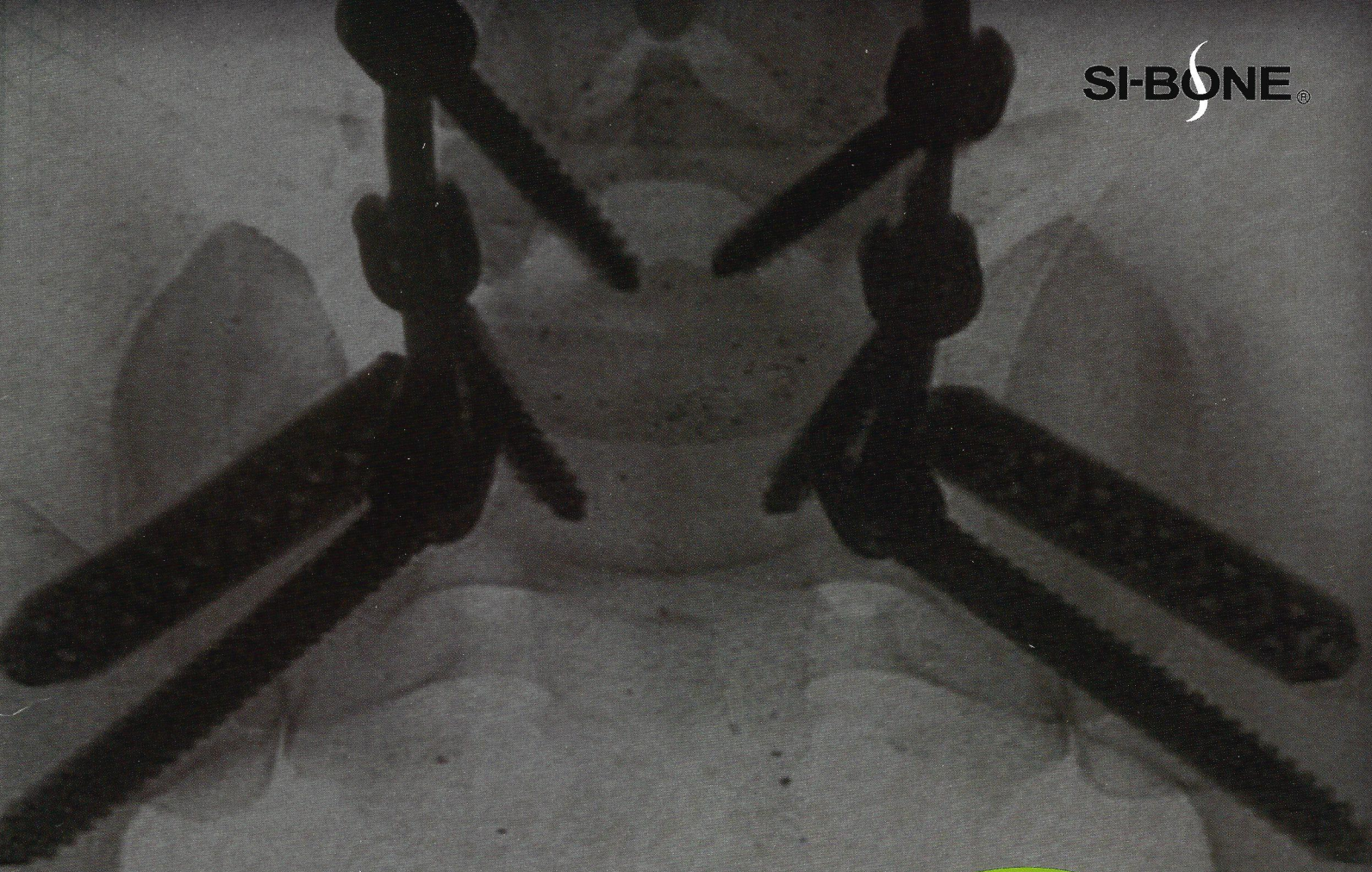
SI-BONE®



Surgical Technique Manual

iFuse Bedrock™ Technique

The Next Step in Pelvic Fixation™

The Bedrock procedure and indications are not yet approved for the EU and the CE mark is pending.

PROCEDURE

PRE-OP PLANNING & SETUP

iFuse implants may be placed via a dorsal, or posterior, approach with either an open or minimally invasive surgical (MIS) technique, per surgeon preference.

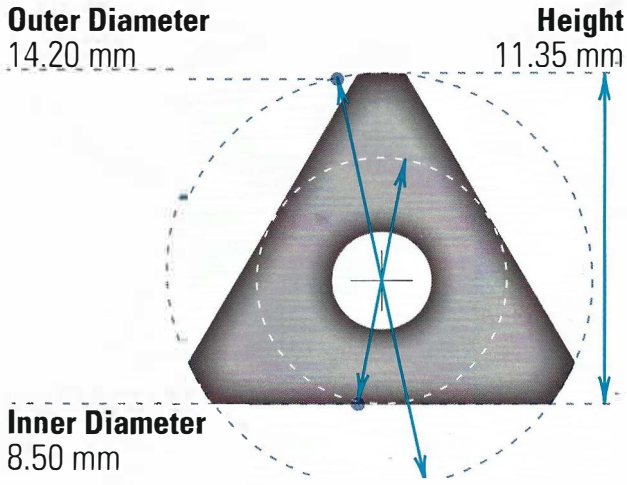
This technique is intended for trained surgeons with experience performing multilevel dorsal constructs and pelvic fixation.

Note: What follows is an example of two iFuse implants being placed across the SI joints from a dorsal approach with a more caudal S2AI screw and a more cephalad iFuse implant. Alternatively, the implants could be positioned with the iFuse implant more caudal and the S2AI screw more cephalad.

iFuse implants should only be placed in conjunction with an S2AI screw that is secured to the rod. Failure to secure the rod to the pelvis could result in failure (i.e. fracture) of the sacral bone.

iFuse-3D™

Implant	Height	Inner Diameter	Outer Diameter
iFuse-3D™	11.35	8.50	14.20



Implant Length	Graft V
35	1.2
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

PRE-OP PLANNING & SETUP

Pre-Op Planning

a. Carefully evaluate sacrum and ilium on cross-sectional imaging study, such as CT scan

b. Special considerations should include defects in ilium secondary to prior iliac crest bone graft (ICBG) harvest and/or any other deficiencies of dorsal sacrum (laminar defects) and/or ilium

c. Modification of standard implant placement may be necessary

d. In cases of sacral dysmorphism, implant placement may be modified

Patient set up

a. Patient positioned prone on either a Jackson or flat imaging table

b. Typically, one C-Arm is used for imaging, although two may be used

c. Ensure the patient is in a "spine neutral" position including a neutral SI joint without extreme extension or flexion of the hips

d. Note: It is recommended to stand on the contralateral side of the patient when placing implants from a dorsal approach

Placement of pedicle screws

a. Surgeon to place pedicle screws using technique of choice

PROCEDURE

8. Create a track for the iFuse implant

a. Position C-Arm in Teardrop View

b. Use rongeur or pedicle awl to open the sacral cortex at starting point described above

c. Use pedicle awl/probe to create the implant track. Note, the starting point is typically medial to the "teardrop" on the Teardrop View **(Figure 7)**

d. Advance the pedicle awl to create channel parallel and cephalad to that of the S2AI screw using both the Lateral and Teardrop Views

e. As the awl is advanced, it should become centered within the "teardrop" and remain parallel to the S2AI screw on the lateral view (Figure 8)

f. Use ball tip probe to palpate planned implant trajectory, confirming circumferential osseous integrity and bony endpoint

g. Avoid lateral breach of ilium. Should breach occur, create new implant path using above technique. Adjust proposed trajectory in cephalo-caudal and/or medial lateral planes and confirm with imaging.

9. Pin Placement

a. Remove pedicle awl and place Blunt Pin down channel until bony resistance is felt. Confirm placement with fluoroscopy.

b. The Radiolucent Clamp can be used to hold the pin while keeping the surgeon's hand away from the radiation source

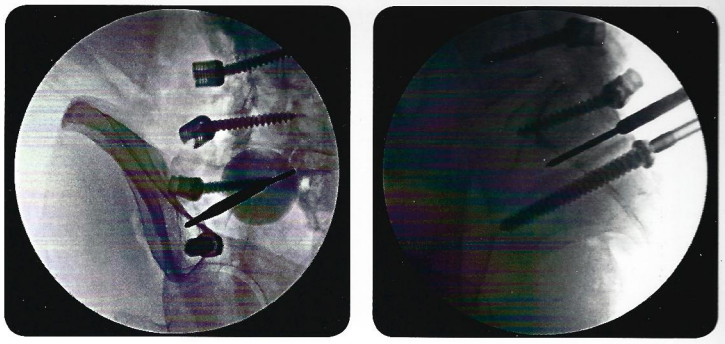


Figure 7: Pedicle awl entering "teardrop" in the Teardrop View (left), and parallel to the S2AI screw in the Lateral View (right).

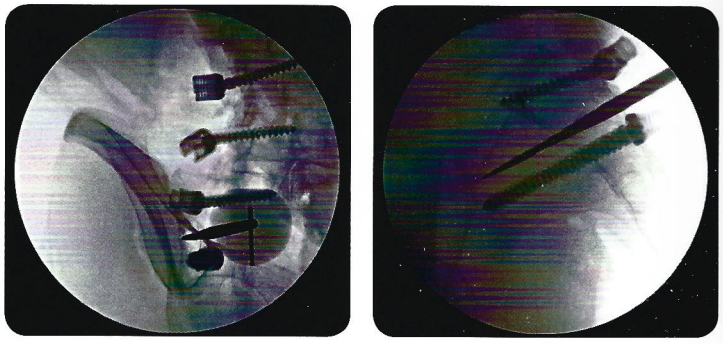


Figure 8: Final placement of the pedicle awl/finder, noting it is now centered within the "teardrop" in the Teardrop View (left), and remains parallel to the S2AI screw in the Lateral View (right).

PROCEDURE

c. Confirm pin placement with imaging, ensuring there is enough room for the iFuse implant with respect to adjacent hardware (e.g. S2AI screw and S1 pedicle screw) **(Figure 9)**

d. An alternative option to using a pedicle awl is to create the channel/trajectory for the pin using a Jamshidi needle that can accommodate the 3.2 mm Pin.

10. Blunt Dissector Insertion (Optional for MIS technique)

a. If performing a MIS technique, the Blunt Dissector may be used to dilate soft tissues

b. Slide Blunt Dissector over pin and advance to dorsum of sacrum, ensuring blade is parallel to muscle fibers

c. Once seated on ilium, gently rotate to spread tissue around pin

11. Soft Tissue Protector Insertion (Optional for MIS technique)

a. If performing a MIS technique, the Soft Tissue Protector can be used to protect soft tissues

b. Snap Pin Sleeve into Soft Tissue Protector, and slide assembly over pin and down to sacrum until bony contact is achieved.

c. For MIS technique, drilling, broaching, and implant impaction steps may be done through Soft Tissue Protector

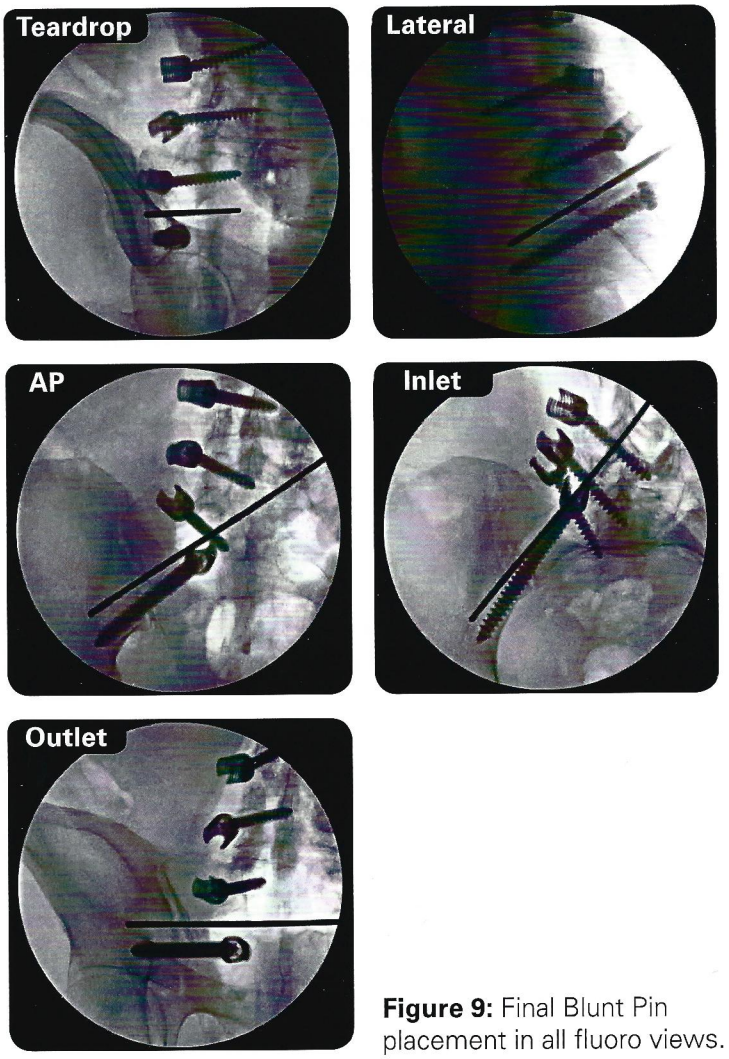


Figure 9: Final Blunt Pin placement in all fluoro views.

PROCEDURE

12. Measure Implant Length

a. For open technique:

» Option 1: Measure appropriate implant length using markings on a ball tip feeler

» Option 2: Using the two pin technique

› **1.** Place a 2nd Blunt Pin seated down to the outer sacral cortex and adjacent against the Pin docked in the patient

› **2.** Line the bent portion of the Length Gage flush with the back end of the 2nd Pin and measure the delta between the two Pins **(Figure 10)**

b. For MIS technique:

» Ensure Pin Sleeve/Soft Tissue Protector Assembly is firmly seated to the outer sacral cortex

» Use Length Gage to select proper implant length by positioning Length Gage under Pin, as shown **(Figure 11)**

» Once implant length is determined, remove Pin Sleeve

› Due to angle of the STP with respect to the sacrum, the STP may contact the sacrum before seating flush – causing the measurement to be long **(Figure 11)**

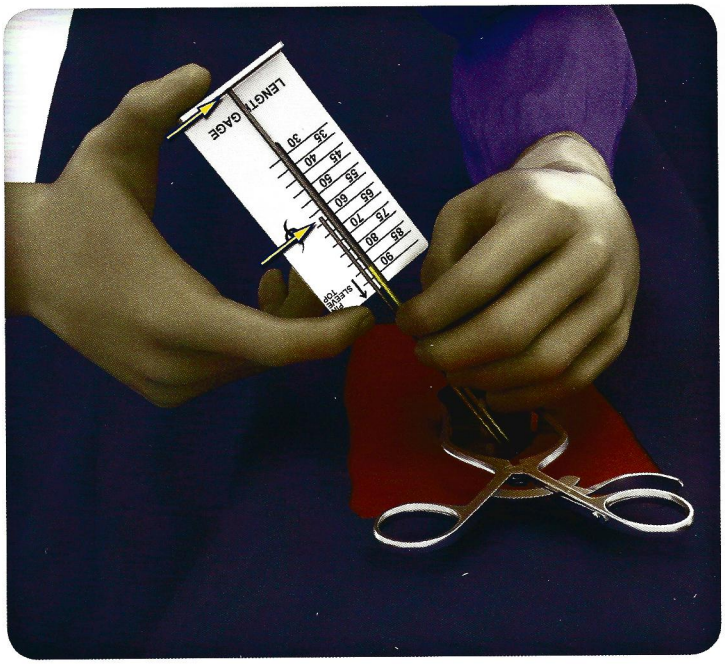


Figure 10: For open technique: Example of the two pin technique for determine implant length.

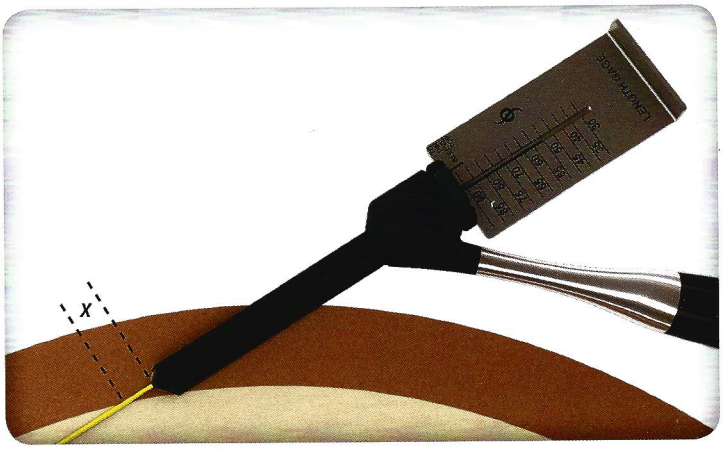


Figure 11: For an MIS technique: Example of using the Length Gage with the Soft Tissue Protector and Pin Sleeve to determine implant length.

PROCEDURE

13. Drilling

a. Position C-Arm in AP View

b. For open technique, insert Drill Bit directly over pin

c. For MIS technique, insert Drill Bit over pin and through Soft Tissue Protector

d. Ensure Drill Bit and pin are colinear to minimize Pin binding

e. Advance Drill Bit under fluoroscopic guidance in AP view until Drill Bit tip is across the SI joint and within 1 – 2 cm of pin tip **(Figure 12)**

f. Watch for unwanted pin advancement

g. Remove Drill Bit while using the Exchange Pin to reduce inadvertent Blunt Pin removal

h. Should Blunt Pin bind and come out, replace it with new Blunt Pin and confirm placement via fluoro

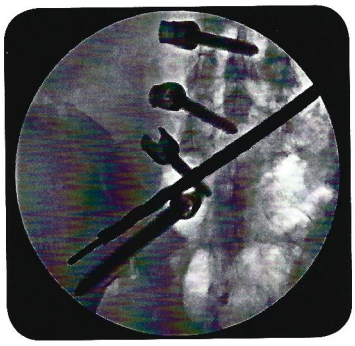


Figure 12: AP view showing Drill Bit across SI joint and within 1 - 2 cm of Blunt Pin tip.

14. Broaching

a. For open technique:

» Place Broach over pin and orient Broach such that 1 flat side is parallel to sacral midline

b. For MIS technique:

» Thread adjustable Broach Stop onto Broach with large end towards patient (this will help prevent over broaching)

» Orient Soft Tissue Protector such that 1 flat side is parallel to the sacral midline

» Insert Broach over pin and through Soft Tissue Protector

c. Ensuring a flat side of the Broach faces the sacral midline will help avoid an apex of the triangle from penetrating a foramen (Figure 13)

Figure 13: Schematic showing orientation of triangular Broach with respect to S1 foramen.

iFuse Implant System®
Minimally Invasive Sacroiliac Joint Surgery

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The iFuse Implant System® is intended for sacroiliac fusion for conditions including 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. The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. Rx only. For information about the risks, visit *si-bone.com/risks*