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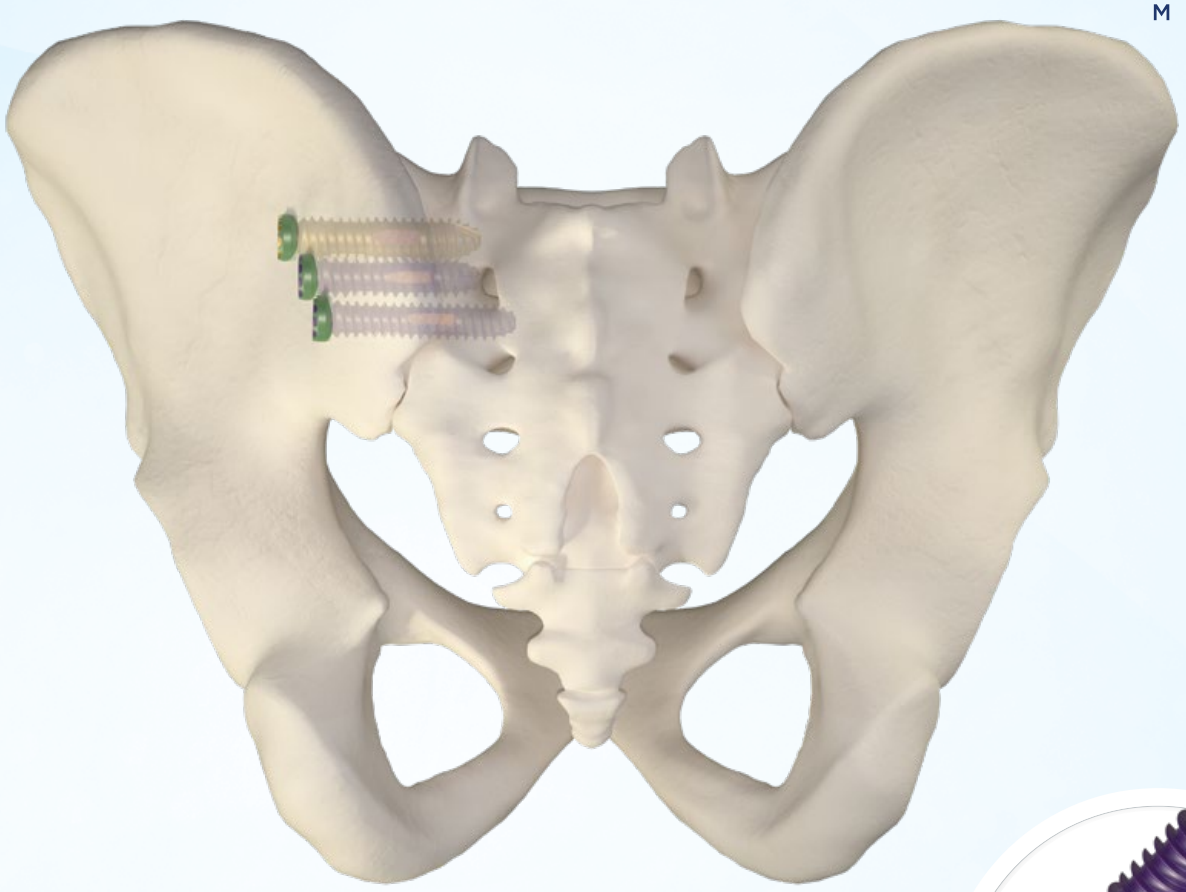

SI-LOK® SELECT

Sacroiliac Joint Fusion System

SURGICAL TECHNIQUE GUIDE

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GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

SURGICAL TECHNIQUE GUIDE

SI-LOK® SELECT

SI-LOK® SELECT

Sacroiliac Joint Fusion System

SI-LOK® SELECT Sacroiliac Joint Fusion System consists of screws and instruments designed for **lateral** and **posterior** approaches to the sacroiliac (SI) joint.

With optimal slot geometry for varying patient anatomy and the new SintrOS™ laser surface treatment, SI-LOK® SELECT is designed for multiple approaches and engineered for fusion.

Versatile Placement

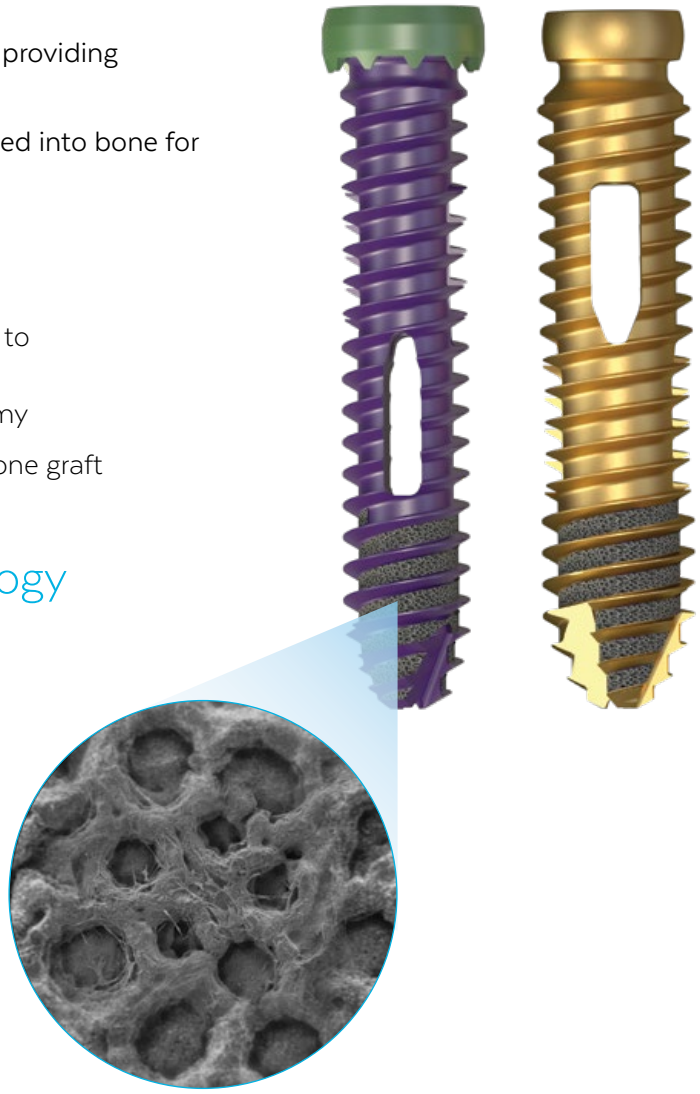
- Polyaxial washer contours to iliac wing providing tactile feedback of secured placement
- Washerless screw option can be recessed into bone for a no profile option

True Fusion

- Overlapping slot geometry engineered to optimize fusion across the SI joint and accommodates varying patient anatomy
- Slots accept allograft or autogenous bone graft

SintrOS™ Surface Technology

- Laser surface treatment is designed to encourage cellular activity at the bone interface



SELECT YOUR APPROACH
SELECT YOUR WORKFLOW

LATERAL APPROACH
Page 7

POSTERIOR APPROACH
Lateral to Medial
Page 18

POSTERIOR APPROACH
Medial to Lateral
Page 26

Compatible with freehand fluoroscopy, ExcelsiusGPS®, and other navigation techniques.
Use your preferred guidance method to perform sacral fusions. Robotic technologies allow advanced screw trajectory planning and accurate placement for multi-planar fixation.

ExcelsiusGPS® User Manual (GMUML01) [page 35]

Guided Instruments (GI1) Surgical Technique Guide (GMTGD158) [page 34]

IMPLANT OVERVIEW

SCREW FEATURES

- Overlapping slots increase surface area up to 290mm^2
- Slots accommodate autogenous bone graft or allograft
- SintrOS™ surface technology along distal tip
- Cannulated for delivery through an MIS approach
- Robust T27 driving feature

SCREW SIZES

- Screw diameters: 10mm and 12mm
- Screw lengths: 25–110mm

LOW PROFILE OPTION

- Washer angulates ±15° to contour to patient anatomy

NO PROFILE OPTION

- Washerless screw may be recessed into bone

Bone Graft Slots & SintrOS™ Laser Surface Treatment												
Screw Length (mm)	25	30	35	40	45	50	55	60	65	70	75-80	85-110
Number of Slots	1	1	1	2	2	2	2	2	2	2	2	2
Overall Slot Length (mm)	16.5	16.5	18	21	25	25	29	33	35	39	39	39
SintrOS™ Length (mm)	3.5	5	7.5	10	9.5	13	13	15	18	18	20	25

SURGICAL TECHNIQUE

SI-LOK® SELECT

Sacroiliac Joint Fusion System

Refer to the product insert located in the back of this manual for a complete description, indications, contraindications, and warnings associated with this system.

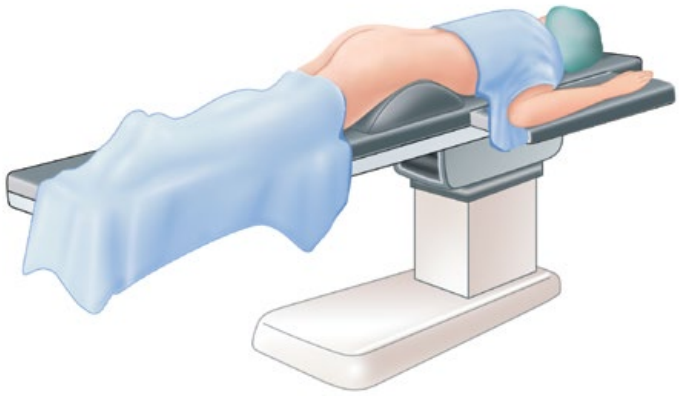
A lateral, a posterior lateral to medial, or a posterior medial to lateral approach may be used to implant SI-LOK® SELECT screws depending on surgeon preference and patient requirements. Each approach is described using fluoroscopy in this technique guide; an MIS approach is shown throughout. For the lateral approach, a minimum of two screws must be used. For posterior approaches, one, two or three screws may be used.

Lateral Approach

A preoperative CT scan is recommended for planning purposes.

STEP 1 PATIENT POSITIONING

The patient is placed under anesthesia and positioned prone on an open Jackson Table and Wilson Frame, or a suitable translucent table. One C-arm fluoroscope is recommended, as shown in this technique.



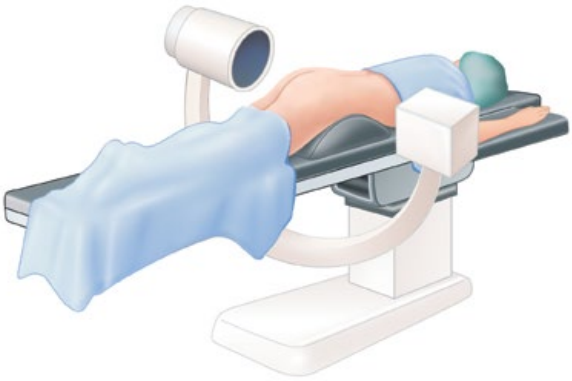
Patient positioned prone

For the purposes of this technique, the term "slope line" is used to define the posterior cortical wall of the sacrum.

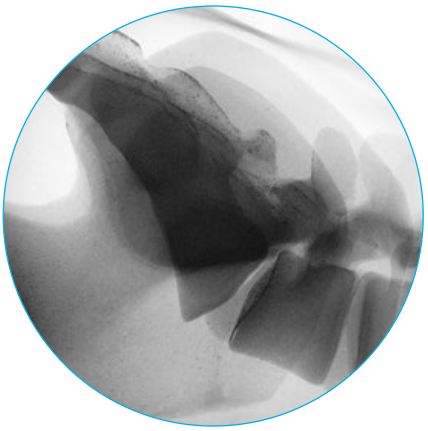
Lateral, outlet, and inlet C-arm fluoroscopy or other radiographic methods should be used during surgery to ensure correct placement. Position the C-arm to a true lateral view so the sacral notches and the ala are aligned. Rotate the C-arm to an outlet view of the sacrum. The S1 pedicle, SI joint, and foramina should be visible. Rotate the C-arm to an inlet view to identify the anterior border of the pelvis.

PATIENT POSITIONING (cont'd)

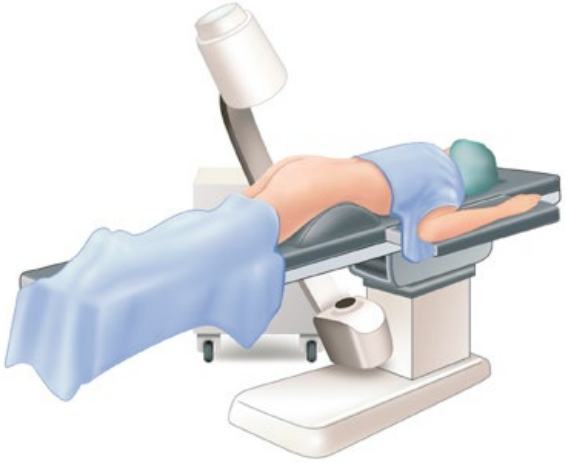
Fluoroscopy Positioning



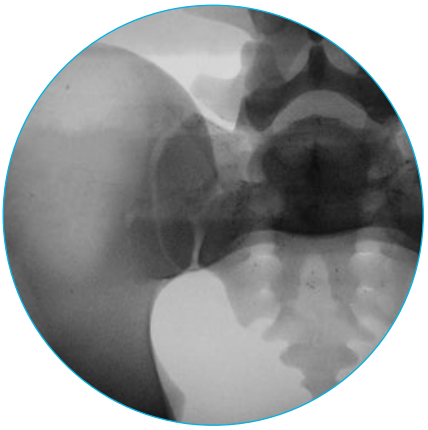
Lateral fluoroscopy – positioned directly to the sacrum



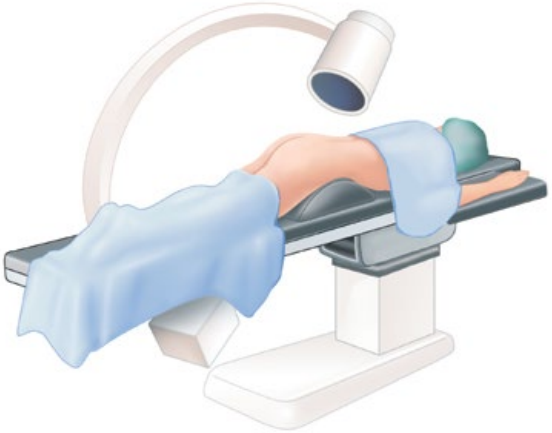
Lateral view



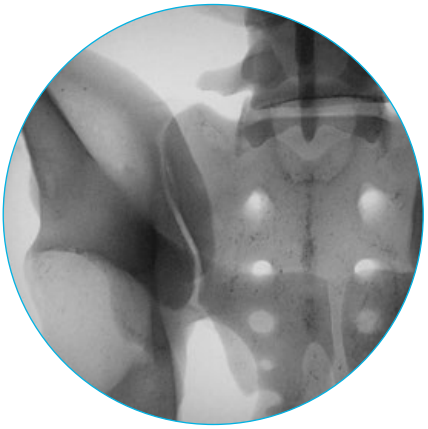
Inlet fluoroscopy – positioned 30-50° to the sacrum



Inlet view



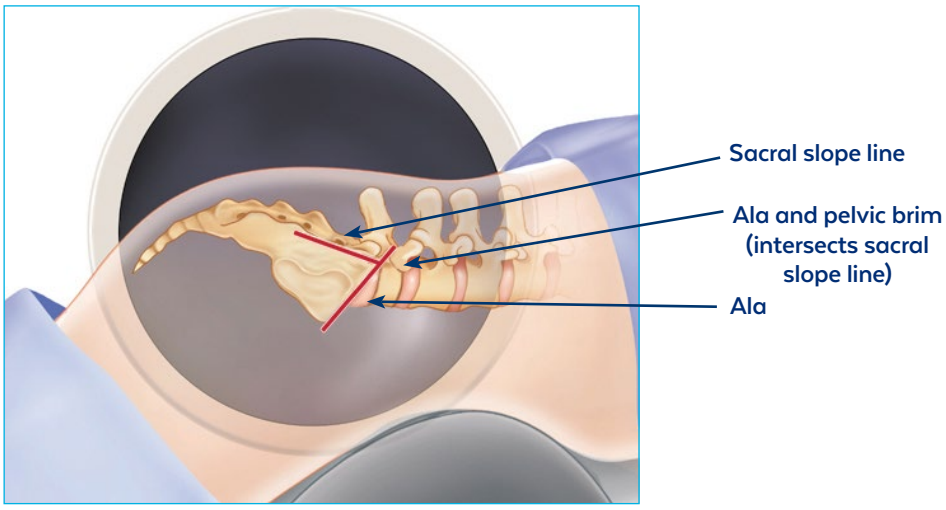
Outlet fluoroscopy – positioned 30-50° to the sacrum



Outlet view

STEP 2 LANDMARK IDENTIFICATION

Identify the posterior cortical wall of the sacrum and the ala on the lateral view. The sacral slope line should be perpendicular to the true AP view. Mark the area of the intersection on the skin with a sterile marker.



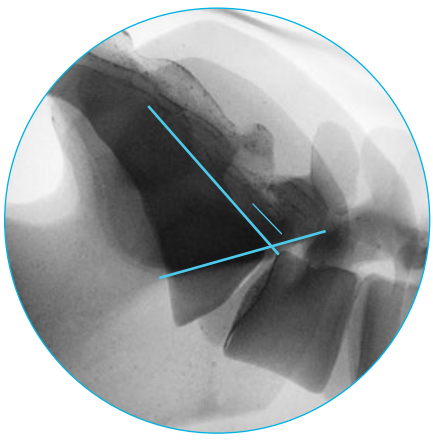
STEP 3 K-WIRE INSERTION

For the placement of K-wires, using a slight downward angle (5-10°) make a 3cm incision 1-3cm above the sacral slope line. The distance above the line is dependent upon the amount of tissue between the entry point and the iliac wing.

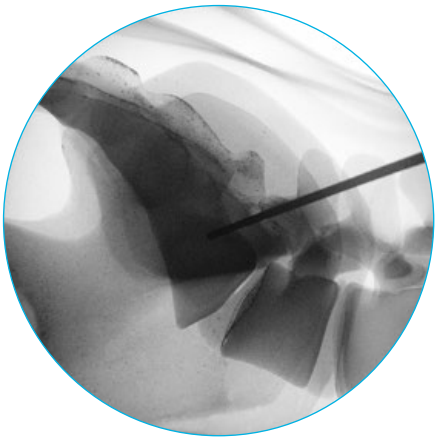
Using a standard orthopedic wire driver or mallet, introduce the **2.4mm K-wire, Sharp** through the incision, aiming slightly downward so the K-wire tip is clear of the wire driver when using fluoroscopy.

The K-wire tip should be visible at the top of the sacrum on a lateral view when against the ilium. The sacral notches and the ala should be aligned.

The incision may be made directly on or below the sacral slope line. The K-wire trajectory is directly lateral with minimal angulation.



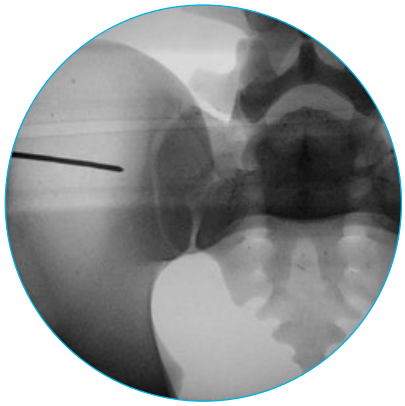
Incision site 1-3cm above sacral slope line and 1.5cm caudal to ala line



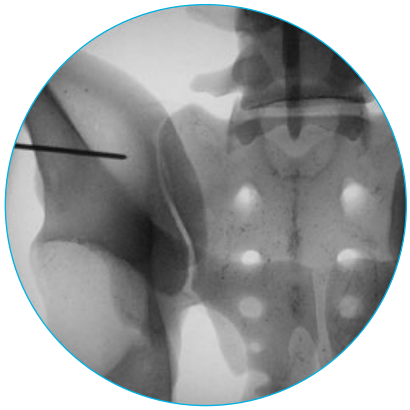
K-wire tip visible at the top of the sacrum against the ilium (lateral view)

K-WIRE INSERTION (Cont'd)

Drive the K-wire through the ilium and sacrum using a slight downward angle (5-10°), targeting the S1 pedicle for the first screw. The **2.4mm K-wire Holder, Radiolucent Tips** may be used to hold the K-wire in place. Monitor the position of the K-wire tip throughout the procedure so that it remains at least 1cm away from the anterior wall. Aim the K-wire toward the point where the anterior wall intersects with the sacral ala.



K-wire tip visible at top of sacrum against ilium (inlet view)



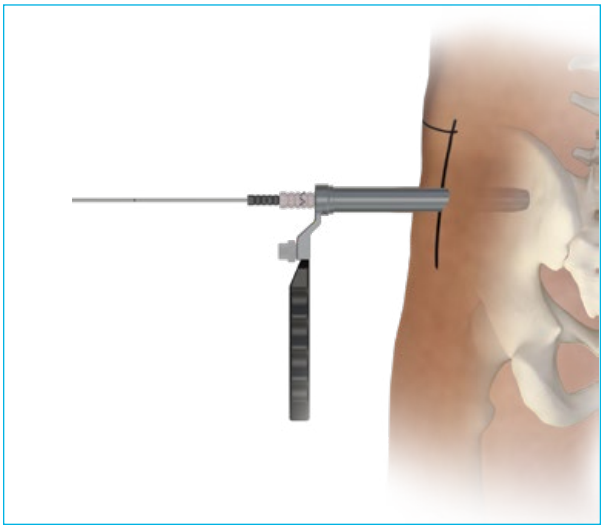
K-wire tip visible at top of sacrum against ilium (outlet view)

STEP 4 TISSUE DILATION

Consecutively dilate the tissue over the K-wire, increasing the cannula diameter up to the **13mm Cannula**. Push the cannula through the skin until the tip is flush against the bone.

Use fluoroscopy to confirm K-wire positioning.

*The **9mm Cannula** used for dilation may remain in place for additional guidance when determining depth and using drill bits 8.5mm in diameter or smaller.*

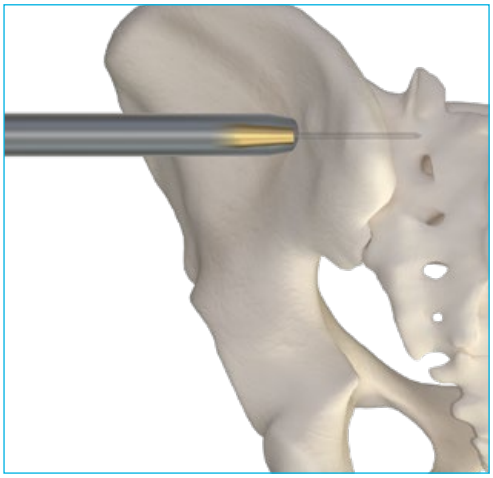


Cannulas in position

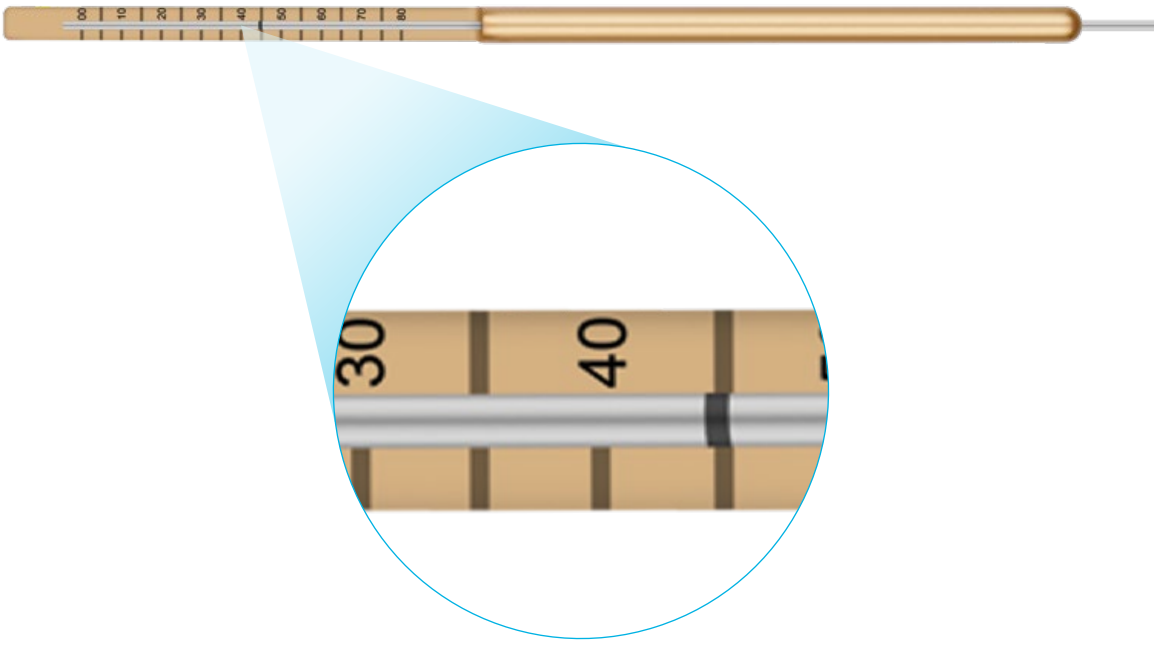
STEP 5 SCREW SIZING

Leaving the outer cannulas in place, determine screw length using the **K-wire Depth Gauge**, taking care not to displace the K-wire. Slide the K-wire Depth Gauge over the K-wire using the demarcation line on the K-wire as a guide to determine the appropriate screw length. Ensure that the depth gauge is placed against the outer iliac wall.

If the measurement is between screw sizes, select the next shortest length. For a washerless screw, subtract 5mm from the length to account for recessing the screw head into bone.



Ensure depth gauge is against cortical wall of ilium



Using location of demarcation line on K-wire to determine screw length (41-44mm measurement indicates use of 40mm screw)

STEP 6 SITE PREPARATION

Select the appropriate size **Cannulated Drill** and attach it to a standard variable speed cannulated power drill (high speed, low pressure). Drill a pilot hole over the K-wire for screw insertion, 10mm shorter than the intended screw length or just past the cortices of the joint, ensuring that the K-wire does not advance.

Use lateral and true AP fluoroscopy to ensure the correct trajectory. Place the **2.4mm K-wire, Blunt 450mm** in the proximal end of the power drill and hold while withdrawing the drill and drill bit to retain the K-wire.

SI LOK® SCREW DIAMETER	DRILL SIZE
10mm	7.5mm
12mm	9.5mm

For hard or sclerotic bone, drill 1.5mm smaller than the screw or tap the screw hole. SI-LOK® SELECT screws are self-tapping; however, the screw hole may be tapped to ease insertion. Drill to the diameter shown in the table at left and tap the screw hole.

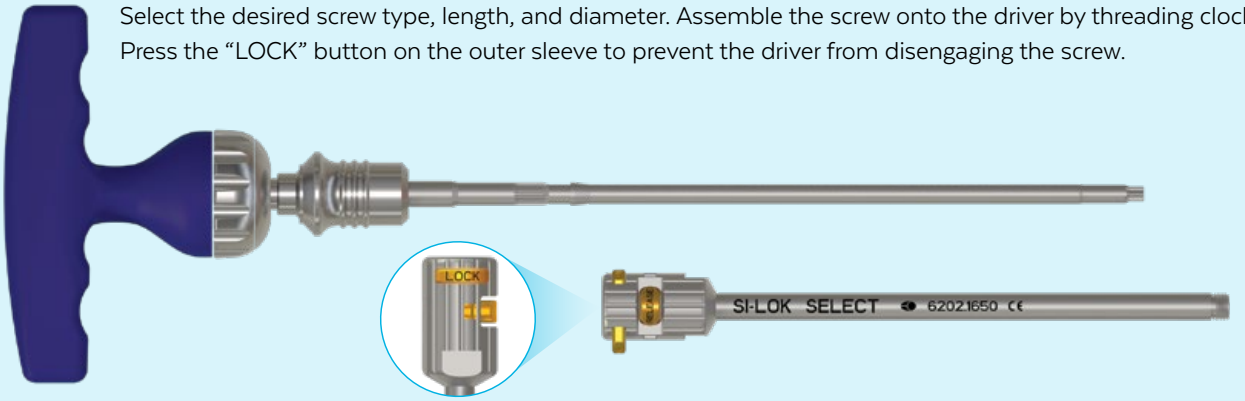
Drilling pilot hole

STEP 7 SCREW INSERTION

SI-LOK® SELECT Driver

To assemble the driver, attach the **Quick-Connect Ratcheting Handle, Cannulated** (straight handle) or the **Quick-Connect Ratcheting T-Handle** to the **T27 Cannulated Shaft** and insert it into the **Outer Sleeve**. An audible click is heard when correctly assembled.

Select the desired screw type, length, and diameter. Assemble the screw onto the driver by threading clockwise. Press the "LOCK" button on the outer sleeve to prevent the driver from disengaging the screw.



To dissassemble, press the "UNLOCK" button on the Outer Sleeve to disengage. Hold down the "RELEASE" button on the Outer Sleeve to remove the inner shaft.

Screw Preparation

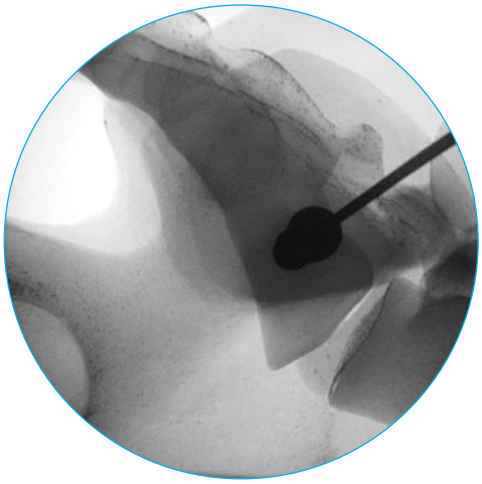
Place a **2.4mm Temporary K-wire, Blunt 150mm** (or similar K-wire) in the distal end of the screw. Pack autogenous bone graft from the drill bit or allograft in the graft slot over the K-wire to avoid displacement of the graft material. Remove the temporary K-wire.

Screw Insertion

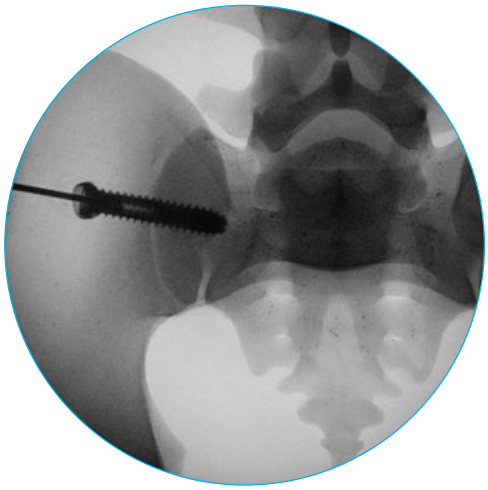
Place the screw and driver over the K-wire. Ensuring that the K-wire does not advance, insert the driver through the cannula and advance the screw until the washer tightens up against the bone. If using a washerless screw, advance until it is flush with the bone. Verify using fluoroscopic views to ensure proper trajectory and placement.

Detach the driver by pressing the "Unlock" button on the Outer Sleeve and rotating the knurled knob counterclockwise until it disengages from the screw. Place the **2.4mm K-wire, Blunt 450mm** in the proximal end of the driver and hold while withdrawing the driver to retain the K-wire position. Remove the cannula, ensuring the K-wire stays in position.

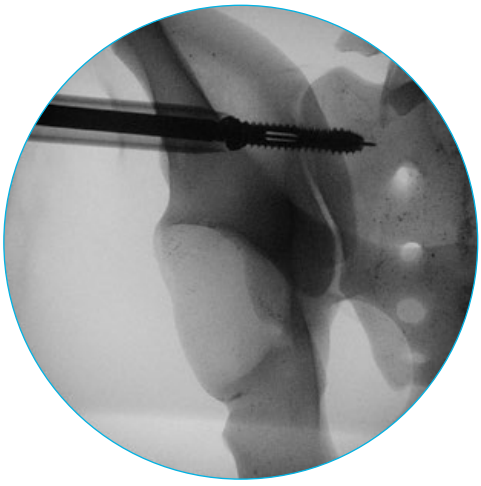
Fluoroscopic Views of First Screw Insertion



Lateral view



Inlet view



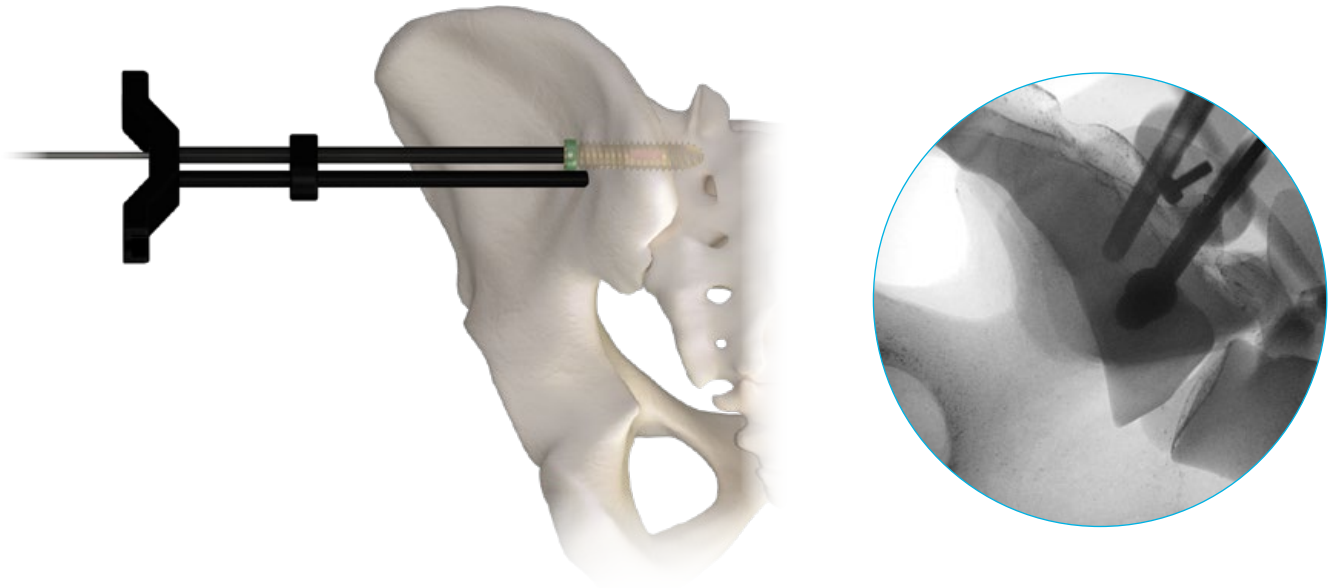
Outlet view

STEP 8 SECOND SCREW INSERTION

Use the **Radiolucent Fixed Alignment Guide** or preferred alignment guide to determine the second K-wire and screw position. The guide aligns the screws parallel to one another and allows sufficient separation of the screws.

Place the shorter tube of the guide over the first K-wire and position the longer cannulated arm of the guide caudal.

Drive the second K-wire and determine if the trajectory is acceptable. Continue to drive the second screw to the desired position. The second screw is typically placed medial to the superior screw without overlap of the screw heads. Remove the guide and the first K-wire. Repeat Steps 4–7 from tissue dilation to screw insertion.



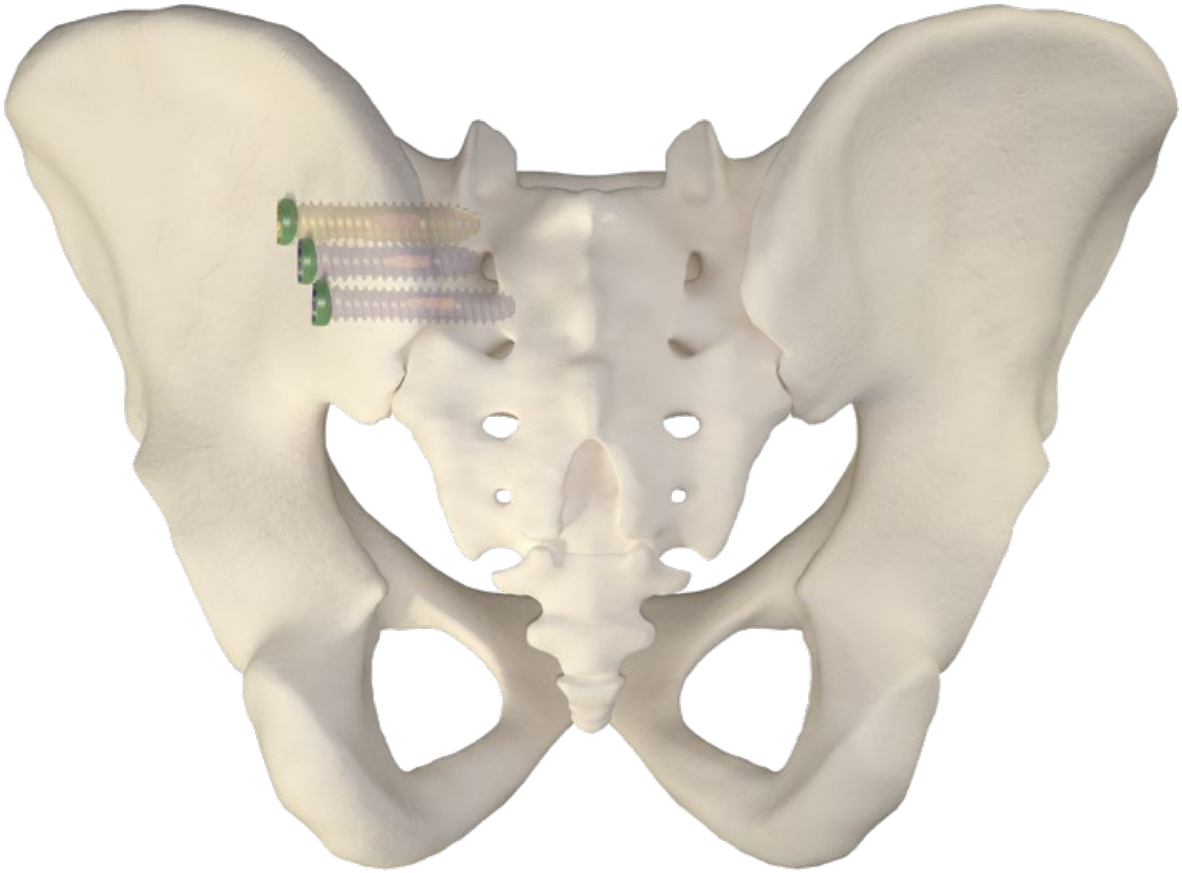
Radiolucent Fixed Alignment Guide in position

OPTIONAL: THIRD SCREW INSERTION

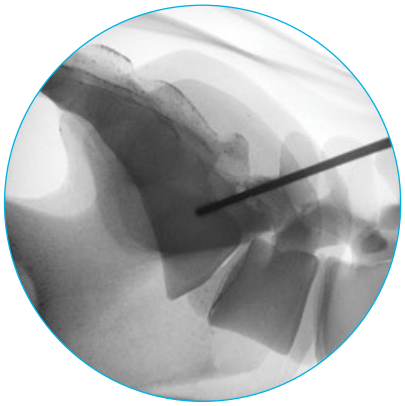
A minimum of two screws bridging the sacroiliac joint are required to achieve stabilization for the lateral approach. Three screws of the largest practical diameter, depending on the patient's anatomy, are recommended for the most rigid stabilization.

Repeat Step 8 to place a third screw.

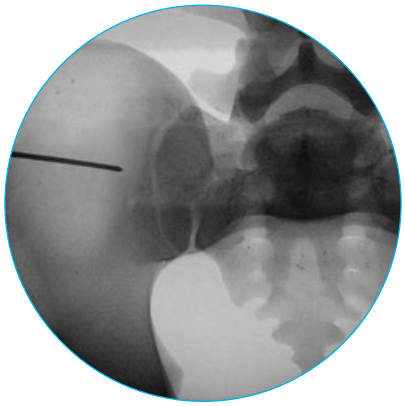
FINAL IMPLANT PLACEMENT



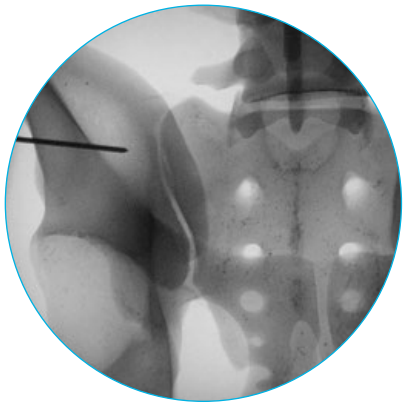
FLUOROSCOPIC OVERVIEW



1 – Lateral view
1st K-wire insertion

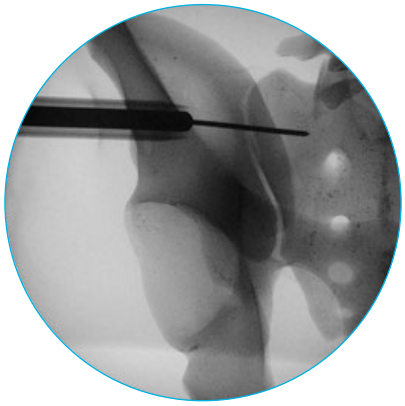


2 – Inlet view
1st K-wire insertion

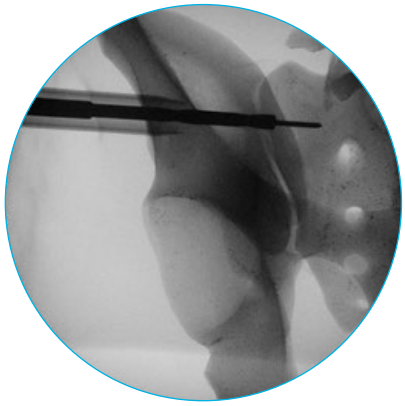


3 – Outlet view
1st K-wire insertion

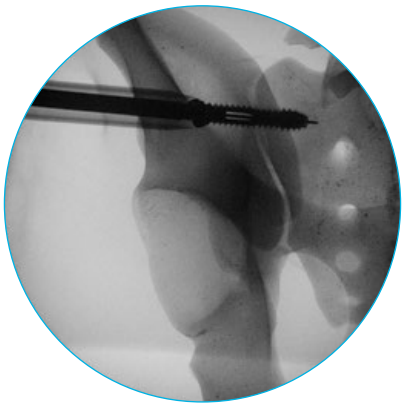
4 – Outlet view
1st K-wire advanced



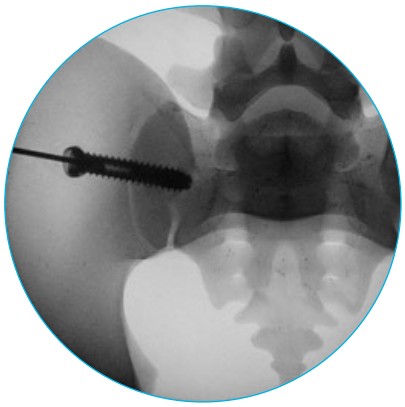
5 – Outlet view
Screw sizing



6 – Outlet view
Drilling

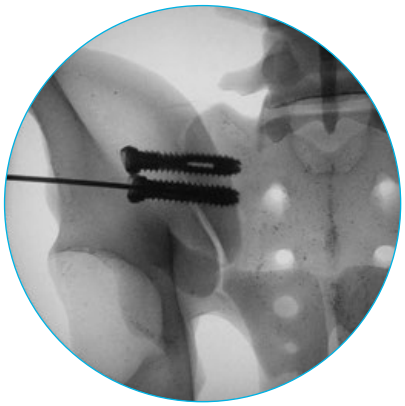


7 – Outlet view
1st screw insertion

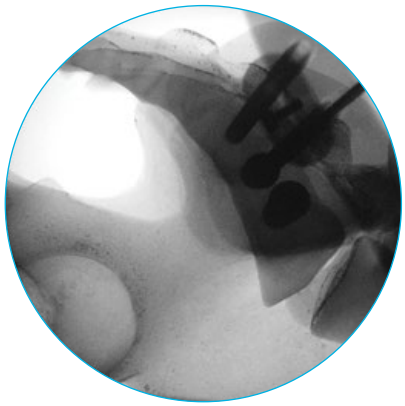


8 – Inlet view
1st screw insertion

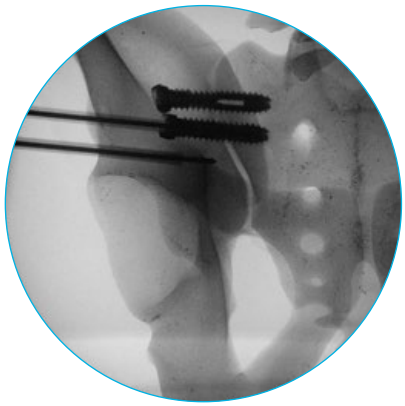
9 – Lateral view
2nd screw alignment



10 – Outlet view
2nd screw insertion

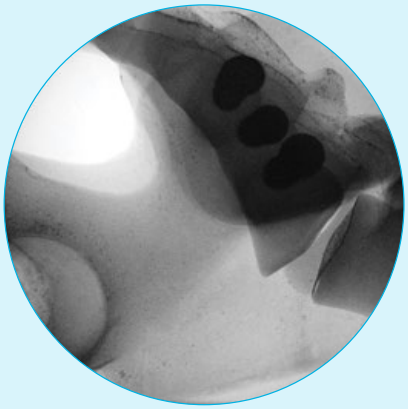


11 – Lateral view
3rd screw alignment

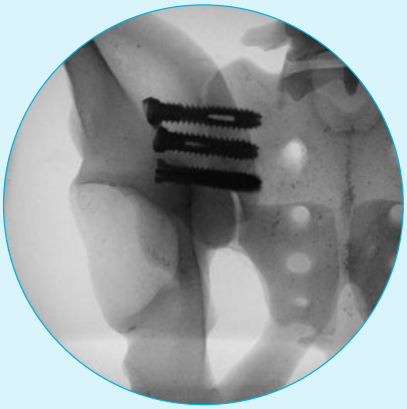


12 – Outlet view
3rd screw alignment

Inlet View
Final Position



Lateral View
Final Position



Outlet View
Final Position

SURGICAL TECHNIQUE

SI-LOK® SELECT

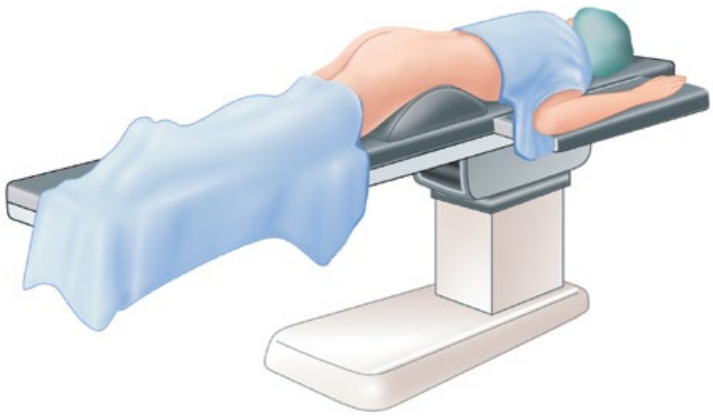
Sacroiliac Joint Fusion System

Posterior Lateral to Medial Approach

A preoperative CT scan is recommended for planning purposes.

STEP 1 PATIENT POSITIONING

The patient is placed under anesthesia and positioned prone on an open Jackson Table and Wilson Frame, or a suitable translucent table. One C-arm fluoroscope is recommended, as shown in this technique.

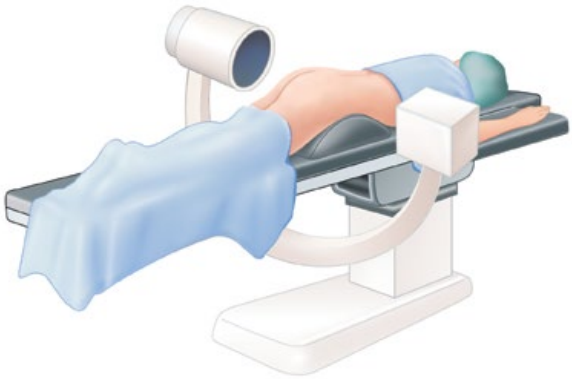


Patient positioned prone

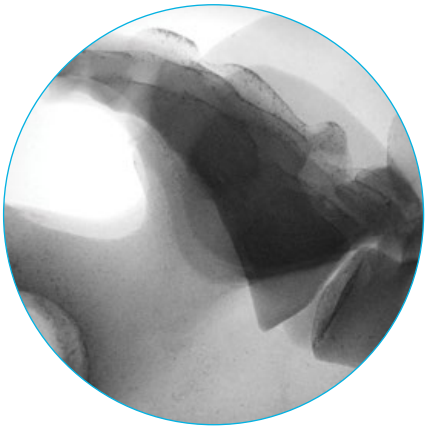
For the purposes of this technique, the term "slope line" is used to define the posterior cortical wall of the sacrum.

Position the C-arm to a true lateral view so the sacral notches and the ala are aligned. Rotate the C-arm to an oblique view of the sacrum. The lateral border of the posterior superior iliac spine (PSIS), SI joint, and foramina should be visible. Rotate the C-arm to an inlet view to identify the anterior border of the pelvis.

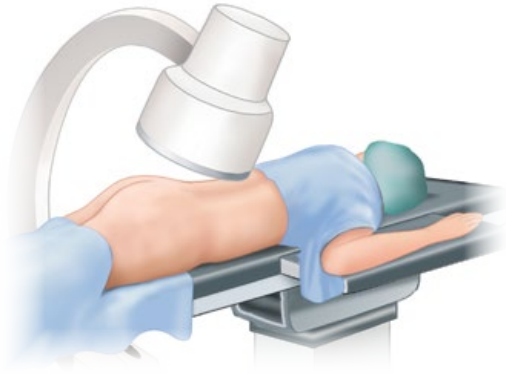
Fluoroscopy Positioning



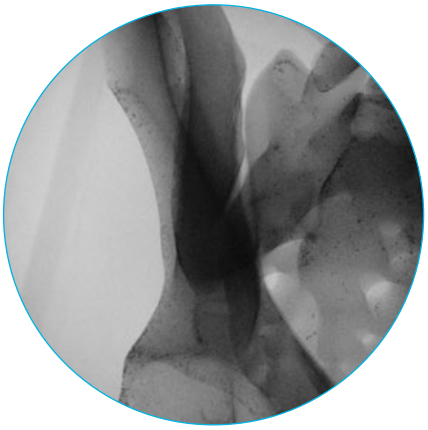
Lateral fluoroscopy – positioned directly to the sacrum



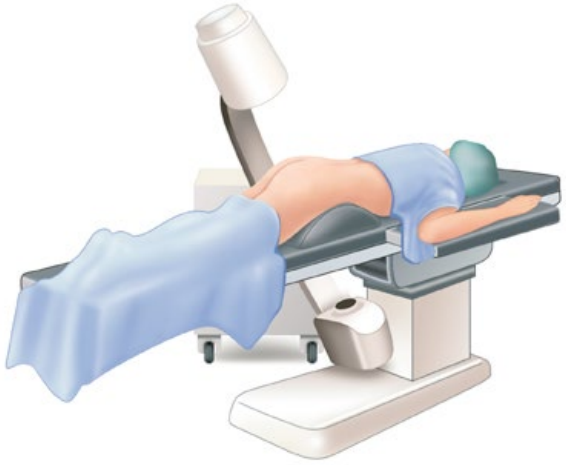
Lateral view



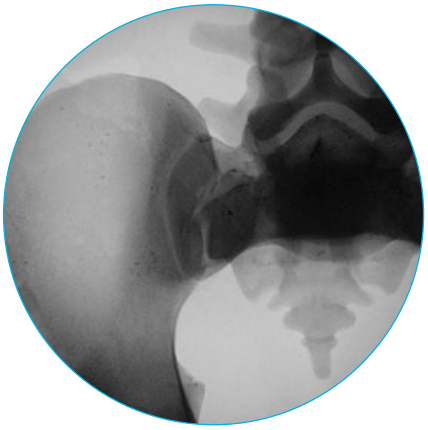
Oblique fluoroscopy – positioned 25-30° to the AP plane



Oblique view



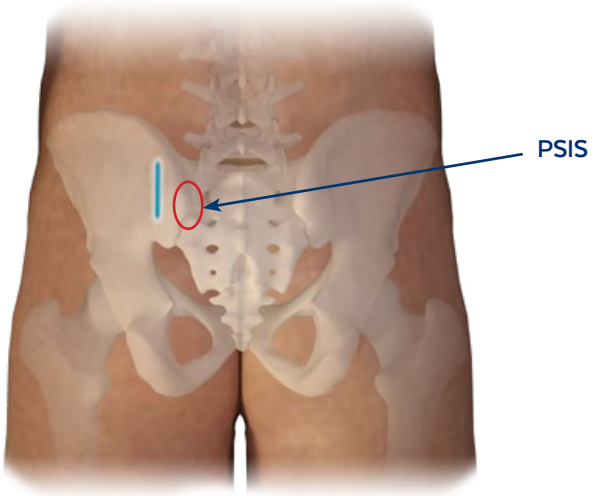
Inlet fluoroscopy – positioned 30-50° to the sacrum



Inlet view

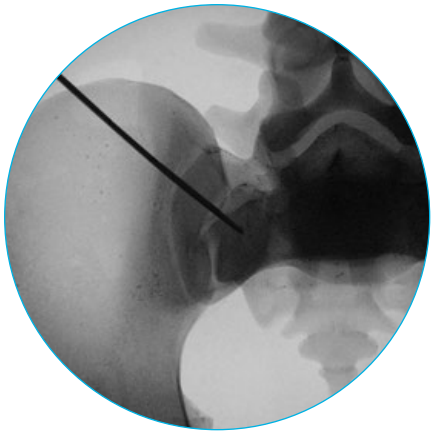
STEP 2 LANDMARK IDENTIFICATION

Palpate the posterior superior iliac spine (PSIS). Make a 3cm longitudinal incision 1cm lateral to the PSIS.

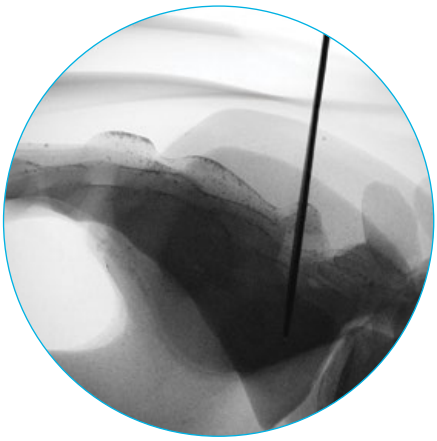


STEP 3 K-WIRE INSERTION

Using a standard orthopedic wire driver or mallet, introduce the 2.4mm K-wire, Sharp, through the incision, aiming downward. The 2.4mm K-wire Holder, Radiolucent Tips, may be used to hold the K-wire in place. Monitor the position of the K-wire tip throughout the procedure, starting 1cm lateral to the PSIS and remaining at least 1cm away from the anterior wall. The K-wire should generally be parallel to the S1 endplate or pointed toward the sacral promontory.



Inlet fluoroscopic view of K-wire tip



Lateral view of K-wire inserted through ilium toward sacral promontory

STEP 4 TISSUE DILATION

Perform tissue dilation, as described in Step 4 (p. 10) of the lateral technique.

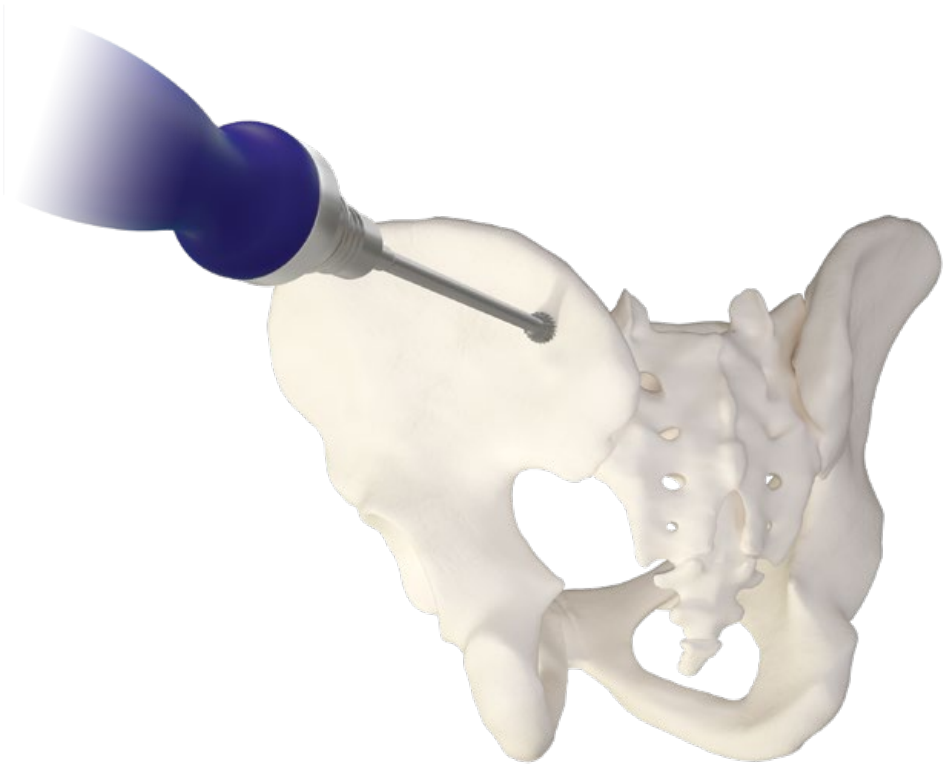
STEP 5 SCREW SIZING

Determine screw sizing, as described in Step 5 (p. 11) of the lateral technique.

STEP 6 SITE PREPARATION

A washerless screw is recommended for this approach to minimize implant prominence. To recess the screw into the ilium, prepare the area using the **Decorticator** to remove any surrounding tissue and bone.

Repeat pilot hole preparation and drilling instructions, as described in Step 6 (p. 12) of the lateral technique.

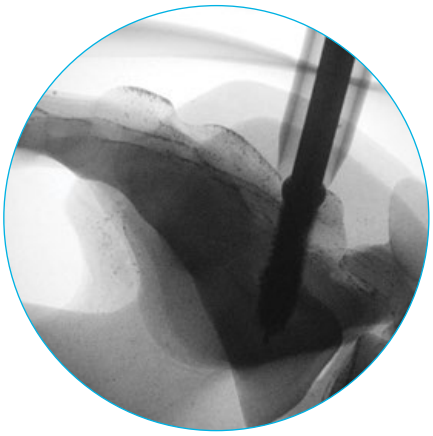


Using the Decorticator

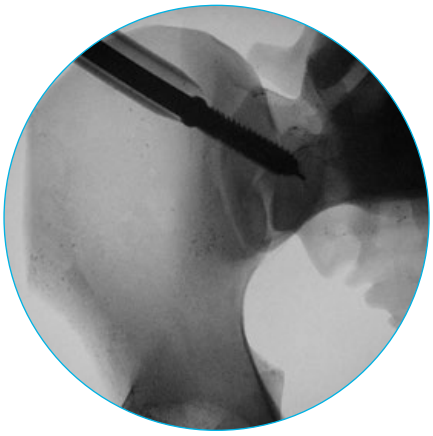
STEP 7 SCREW INSERTION

Perform screw insertion as described in Step 7 (p. 13) of the lateral technique.

Fluoroscopic Views of the First Screw Insertion



Lateral view



Inlet view

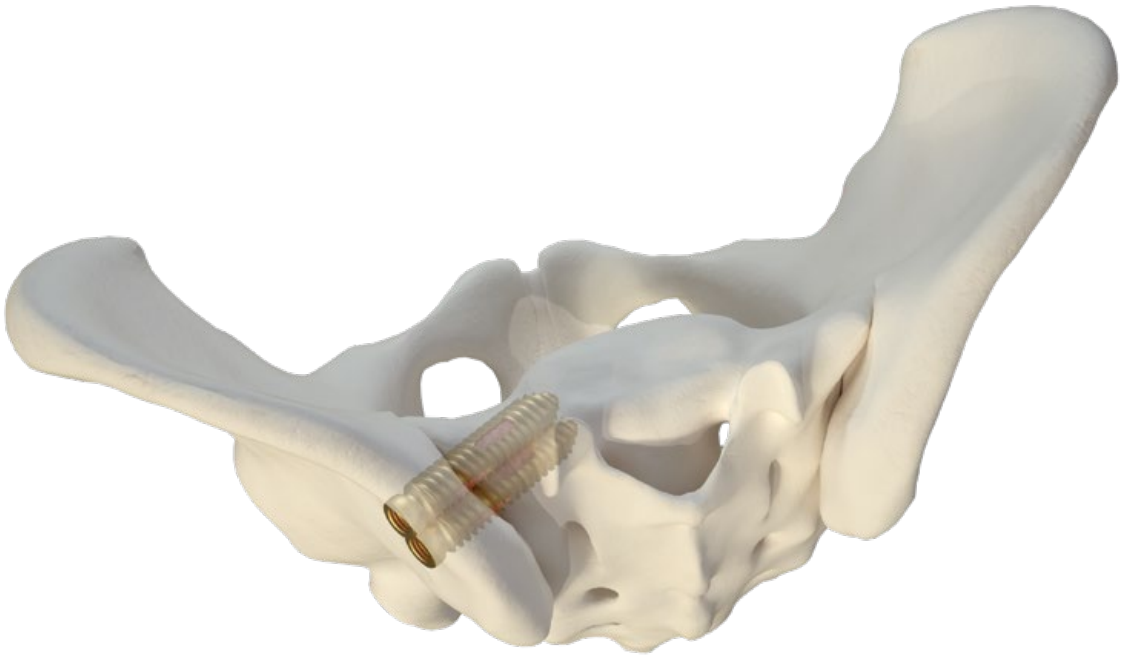
Oblique view

STEP 8 SECOND SCREW INSERTION

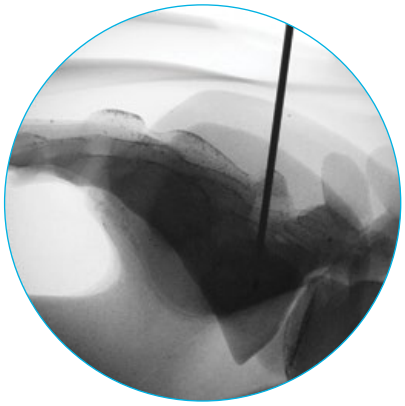
A minimum of one screw bridging the sacroiliac joint is required to achieve stabilization for the posterior approach. Two screws of the largest practical diameter, depending on the patient's anatomy, are recommended for the most rigid stabilization.

Insert the second screw as described in Step 8 (p. 14) of the lateral technique.

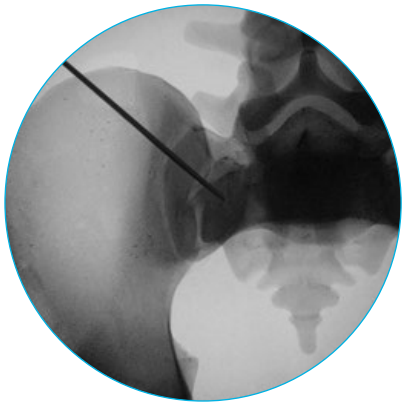
FINAL IMPLANT PLACEMENT



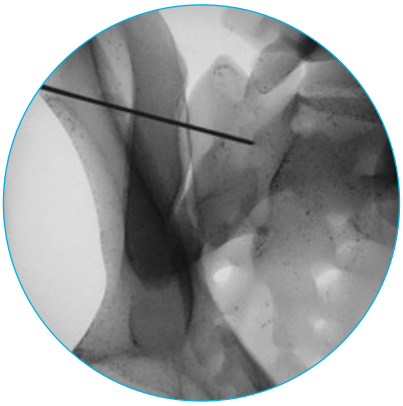
FLUOROSCOPIC OVERVIEW



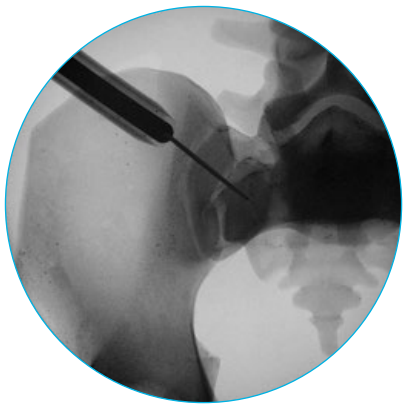
1 – Lateral view
1st K-wire insertion



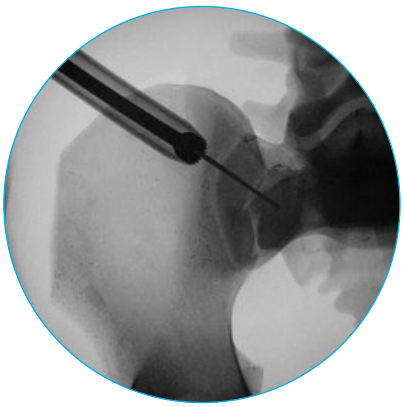
2 – Inlet view
1st K-wire insertion



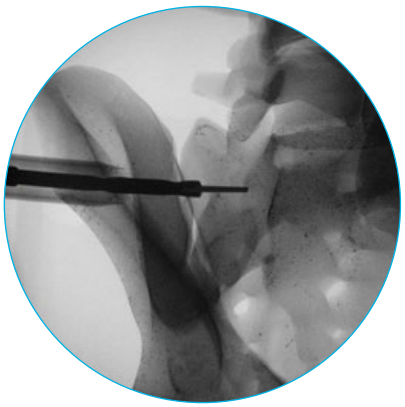
3 – Oblique view
1st K-wire insertion



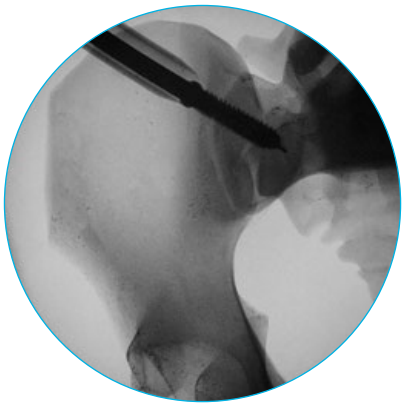
4 – Inlet view
Screw sizing



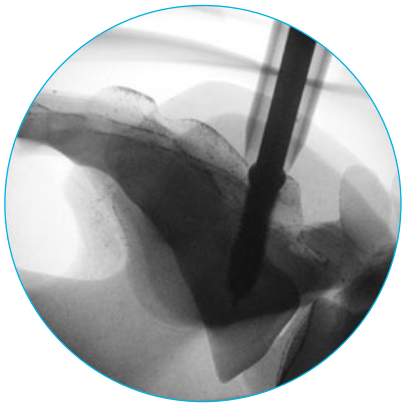
5 – Inlet view
Decortication



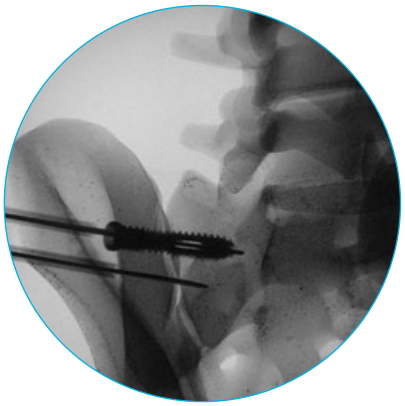
6 – Oblique view
Drilling



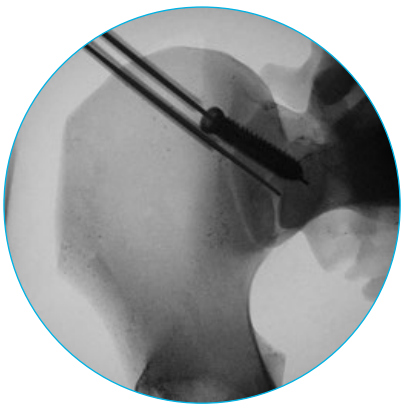
7 – Inlet view
1st screw insertion



8 – Lateral view
1st screw insertion

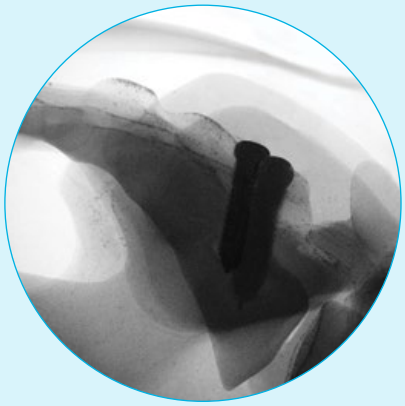


9 – Oblique view
2nd screw alignment

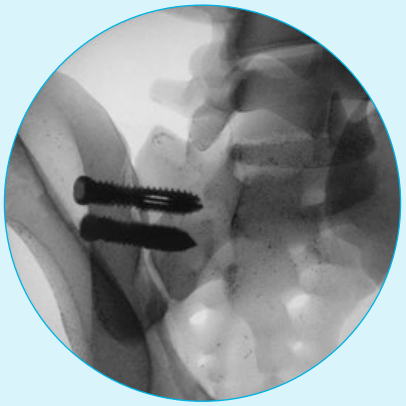


10 – Inlet view of 2nd screw alignment

Inlet View
Final Position



Lateral View
Final Position



Oblique View
Final Position

SURGICAL TECHNIQUE

SI-LOK® SELECT

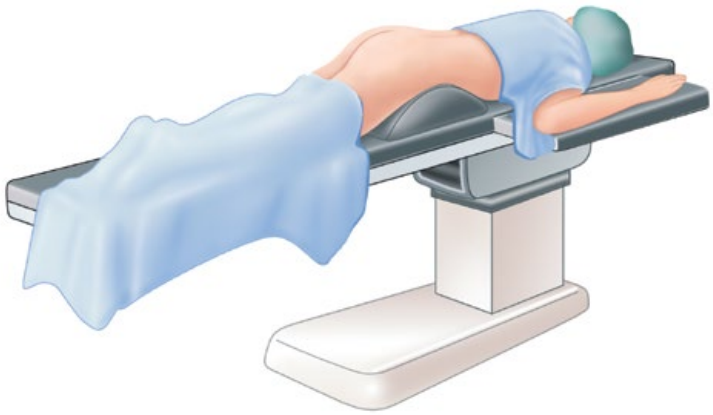
Sacroiliac Joint Fusion System

Posterior Medial to Lateral Approach

A preoperative CT scan is recommended for planning purposes.

STEP 1 PATIENT POSITIONING

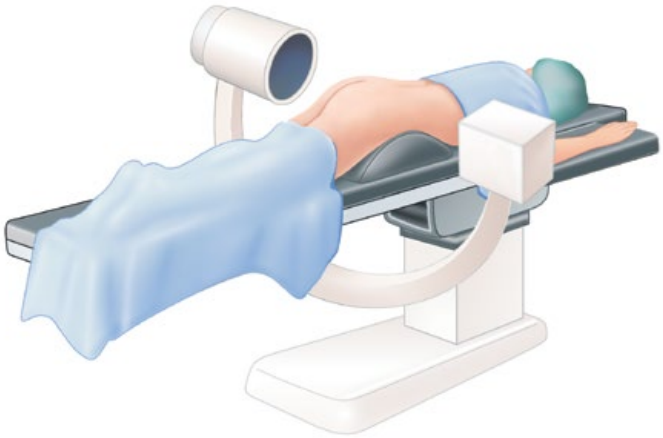
The patient is placed under anesthesia and positioned prone on an open Jackson Table and Wilson Frame, or a suitable translucent table. One C-arm fluoroscope is recommended.



Lateral and teardrop C-arm fluoroscopy or other radiographic methods should be used during surgery to ensure correct placement.

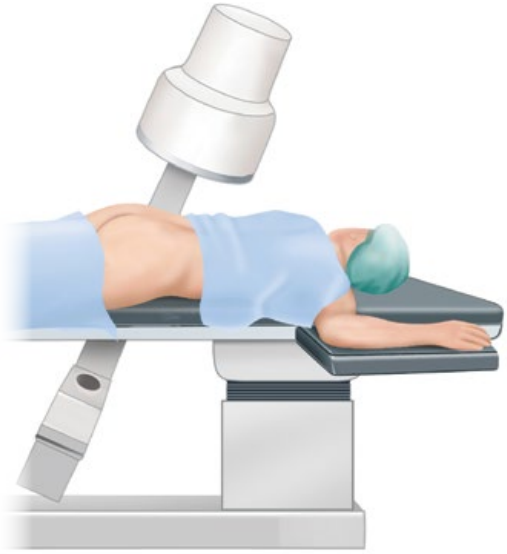
Position the C-arm to a true lateral view so the sacral notches and the ala are aligned. Rotate the C-arm to a teardrop view of the sacrum. The iliac teardrop should be visible.

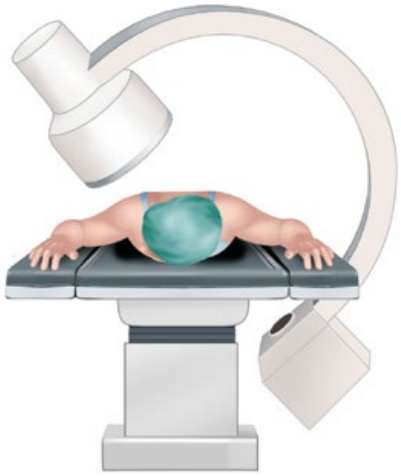
Fluoroscopy Positioning



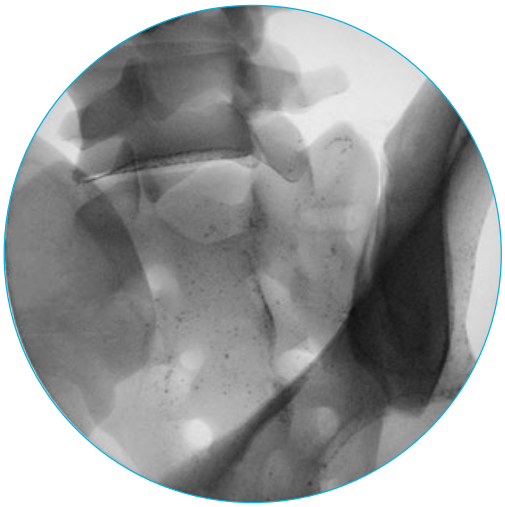
Lateral fluoroscopy – positioned directly to sacrum

Lateral view





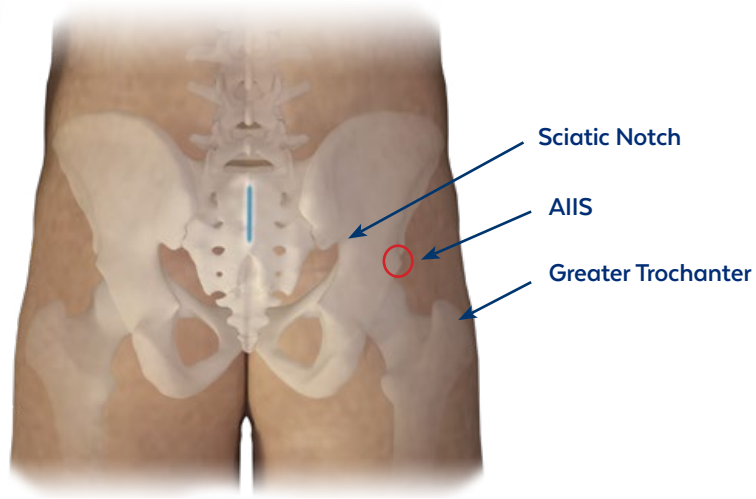
Teardrop fluoroscopy – positioned 20-30° caudal and 40-50° to vertical plane



Teardrop view

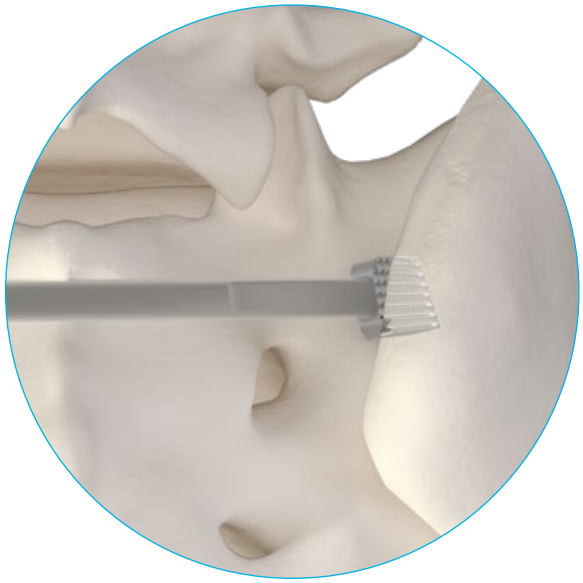
STEP 2 LANDMARK IDENTIFICATION

Palpate the top of the greater trochanter to locate the anterior inferior iliac spine (AIIS). Make a 3cm longitudinal midline incision to expose the dorsal foramina of the sacrum, specifically the S1 and S2 foramina.



OPTIONAL: SI JOINT PREPARATION

Before K-wire insertion, the **Rasp** may be used to clear SI joint cartilage.

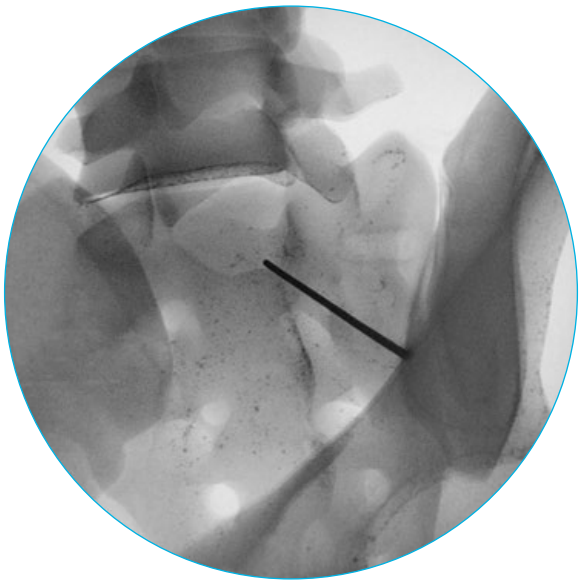


STEP 3 K-WIRE INSERTION

Using a standard orthopedic wire driver or mallet, introduce the 2.4mm K-wire, Sharp, through the incision, aiming above the sciatic notch and toward the AIIS.

Drive the K-wire through the sacrum and ilium and monitor the position of the K-wire tip using a slight downward angle. The 2.4mm K-wire Holder, Radiolucent Tips, may be used to hold the K-wire in place.

Monitor the position of the K-wire tip throughout the procedure, starting between the lateral borders of the S1 and S2 foramina. Remain at least 1cm away from the sciatic notch.



Teardrop fluoroscopic view of K-wire tip

STEP 4 TISSUE DILATION

Perform tissue dilation, as described in Step 4 (p. 10) of the lateral techinque.

STEP 5 SCREW SIZING

Determine screw sizing as described in Step 5 (p. 11) of the lateral technique.

STEP 6 SITE PREPARATION

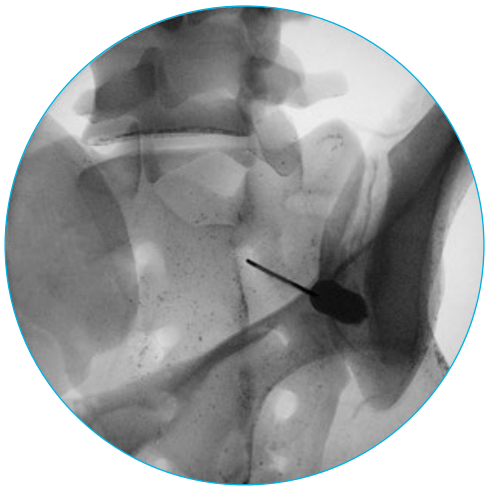
Perform pilot hole preparation and drilling as described in Step 6 (p. 12) of the lateral technique.

After drilling, tapping to size and the intended screw length is recommended for this approach.

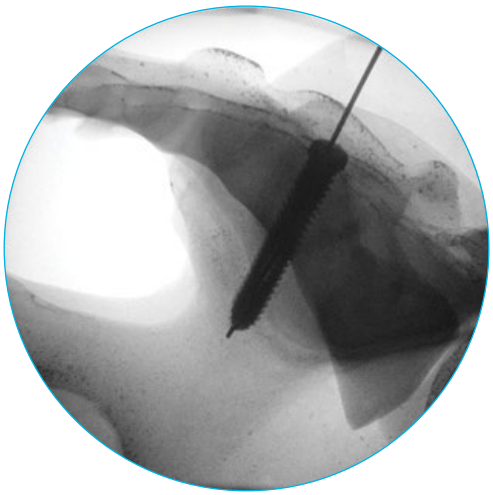
STEP 7 SCREW INSERTION

Insert the screw as described in Step 7 (p. 12-13) of the lateral technique.

Fluoroscopic Views of First Screw Insertion



**Teardrop view–
first screw insertion**



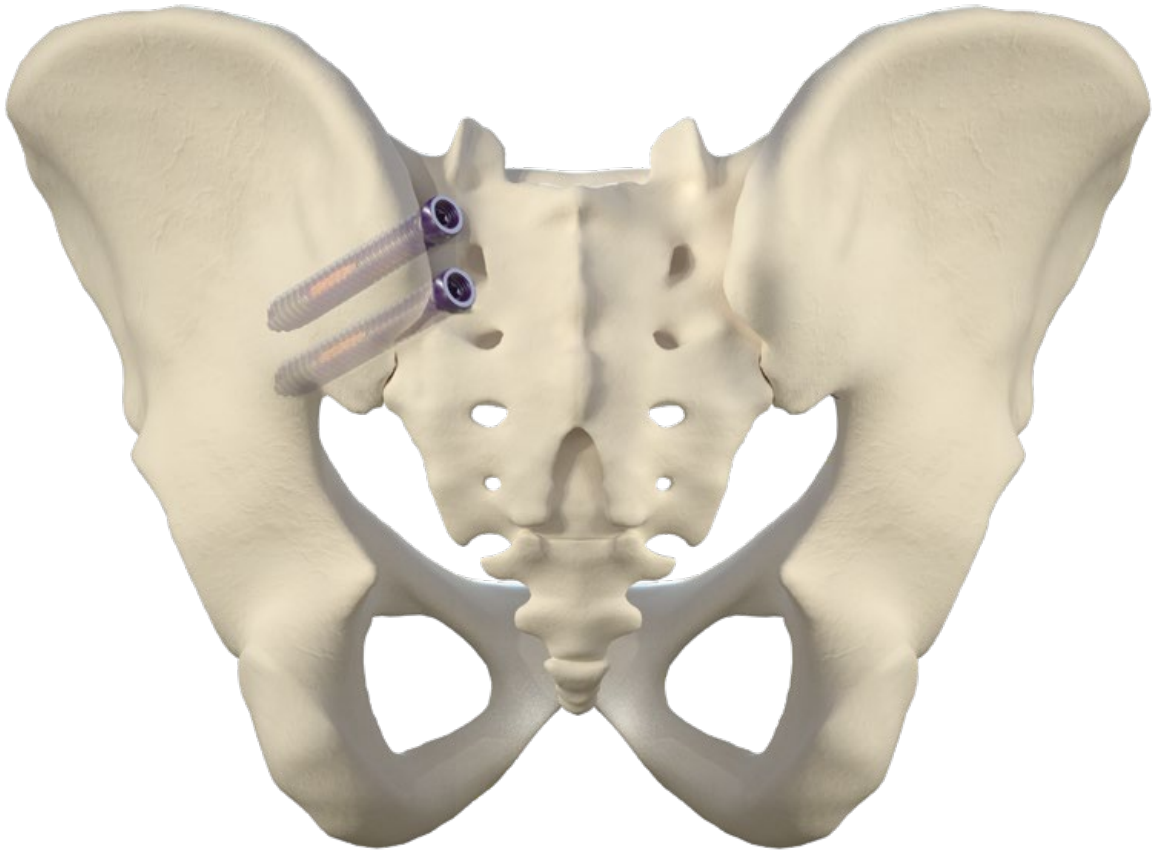
**Lateral view–
first screw insertion**

STEP 8 SECOND SCREW INSERTION

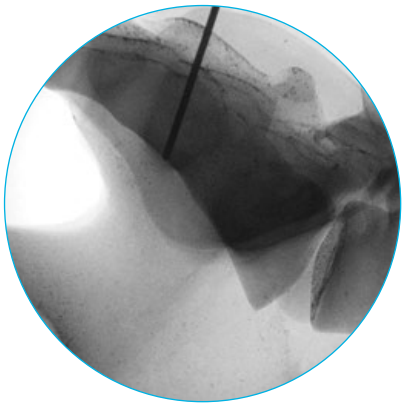
A minimum of one screw bridging the sacroiliac joint is required to achieve stabilization for the posterior approach. Two screws of the largest practical diameter, depending on the patient's anatomy, are recommended for the most rigid stabilization.

Insert the second screw as described in Step 8 (p. 14) of the lateral technique.

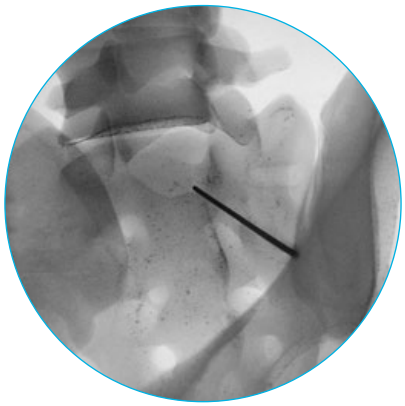
FINAL IMPLANT PLACEMENT



FLUOROSCOPIC OVERVIEW

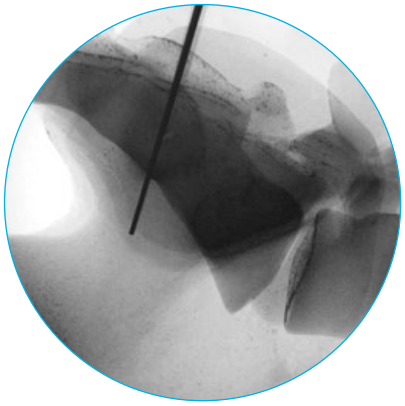


1 – Lateral view
1st K-wire insertion

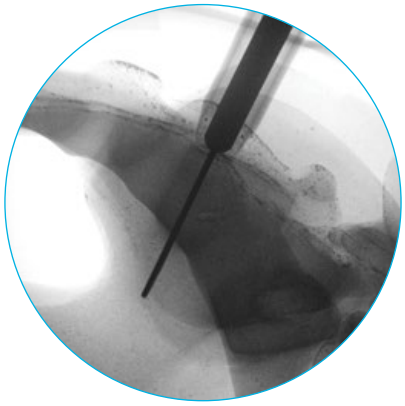


2 – Teardrop view
1st K-wire insertion

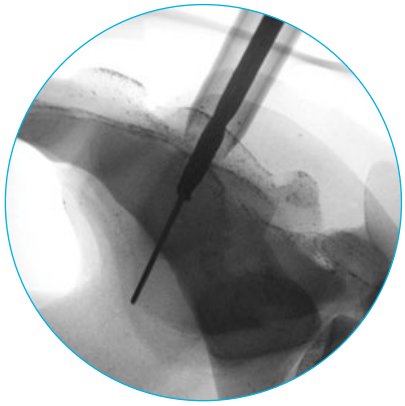
3 – Teardrop view
1st K-wire advanced



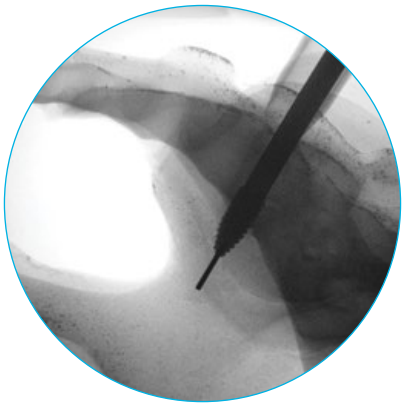
4 – Lateral view
1st K-wire advanced



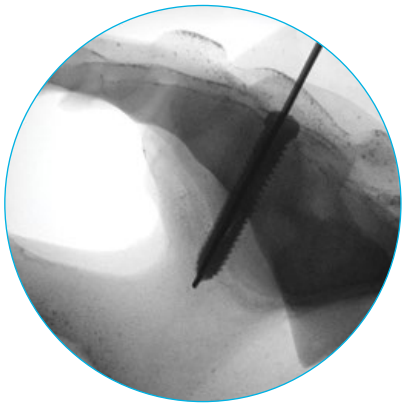
5 – Lateral view
Screw sizing



6 – Lateral view
Drilling

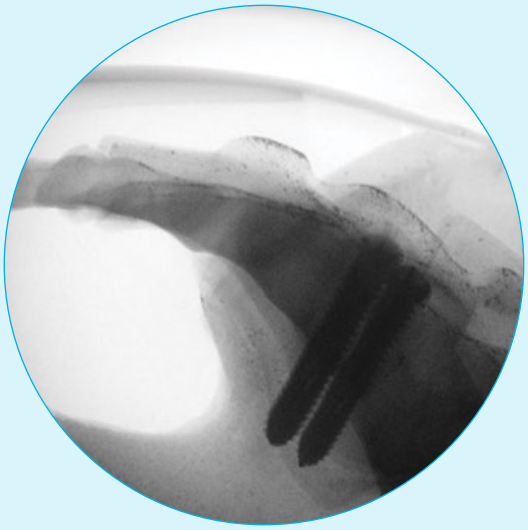


7 – Lateral view
Tapping

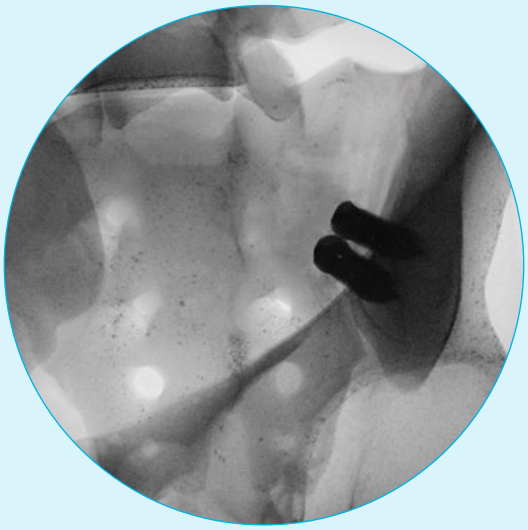


8 – Lateral view
1st screw insertion

9 – Teardrop view
2nd screw alignment



Lateral View
Final Position



Teardrop View
Final Position

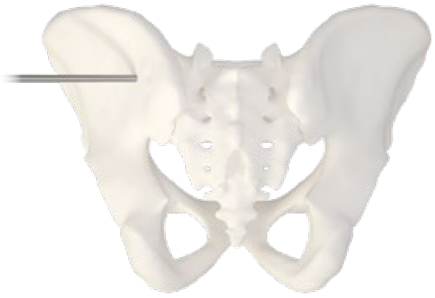
TECHNIQUE

GUIDED INSTRUMENTS (GII)

Guided Instruments may be used manually or under power, with the Medtronic StealthStation® Navigation System. Refer to the Guided Instruments Technique Guide (GMTGD158) for instructions on how to these instruments. Select the "Solera" or "Legacy" screw system on the StealthStation®.

Perform surgery according to instructions for the desired approach, substituting the steps below. A lateral or posterior approach may be used. A lateral approach is shown.

STEP 1 PILOT HOLE PREPARATION

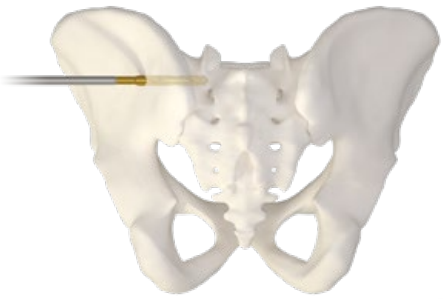


Place a **500mm** or longer K-wire in the Awl and align the K-wire tip with the Awl tip. Rotate the knurled knob clockwise on the Awl to tighten, locking the K-wire.

Insert the Awl into bone at the desired trajectory to create a pilot hole. Rotate the knurled knob counterclockwise to loosen and advance the K-wire. Carefully remove the Awl.

If desired, place cannulas over the K-wire to dilate tissue.

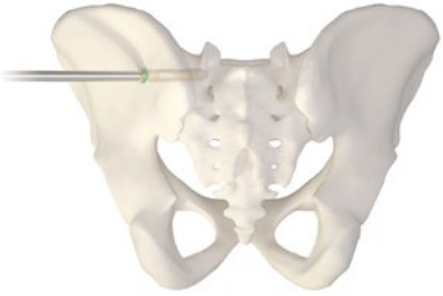
STEP 2 SITE PREPARATION



Perform site preparation and drilling instructions in Step 6 (p. 12) of the lateral technique.

If dilation is performed, the drill stops at the cannula. Therefore the maximum drilling length is 25mm when using the 9mm cannula and 45mm for the 13mm cannula.

STEP 3 SCREW INSERTION



Perform screw insertion instructions as described in Step 7 (p. 13) of the lateral technique, and continue with the remaining technique.

TECHNIQUE

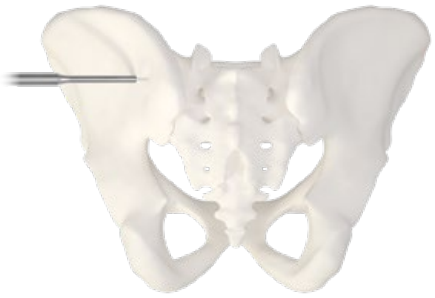
ExcelsiusGPS®

ExcelsiusGPS® instruments may be used manually or under power, in conjunction with the ExcelsiusGPS® system.

Refer to the ExcelsiusGPS® User Manual (GMUML01) for important safety information regarding the use of the system for navigation, planning trajectories, and positioning the robotic arm.

Perform surgery according to instructions for the desired approach, substituting the steps below. A lateral or posterior approach may be used. A lateral approach is shown.

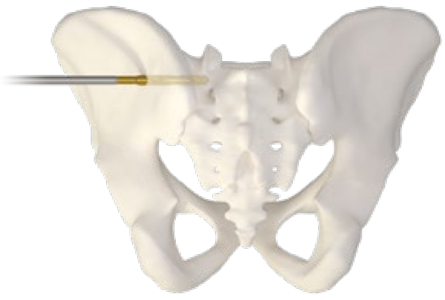
STEP 1 PILOT HOLE PREPARATION



Insert the Awl or the **3.5mm Pilot Drill** into bone at the set trajectory to create a pilot hole. Carefully remove the Awl or drill.

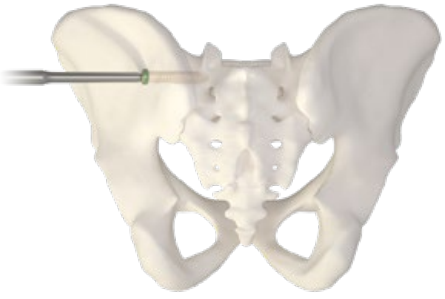
If desired, place cannulas to dilate tissue after the Awl or drill has been removed.

STEP 2 SITE PREPARATION



Select the appropriate size Cannulated Drill. Attach it to a standard variable speed cannulated power drill if desired. Drill a larger pilot hole, 10mm shorter than the intended screw length or just past the cortices of the joint. (Use high speed and low pressure when using the power drill.)

STEP 3 SCREW INSERTION



Perform screw insertion instructions as described in Step 7 (p. 14) of the lateral technique, and continue with the remaining technique.

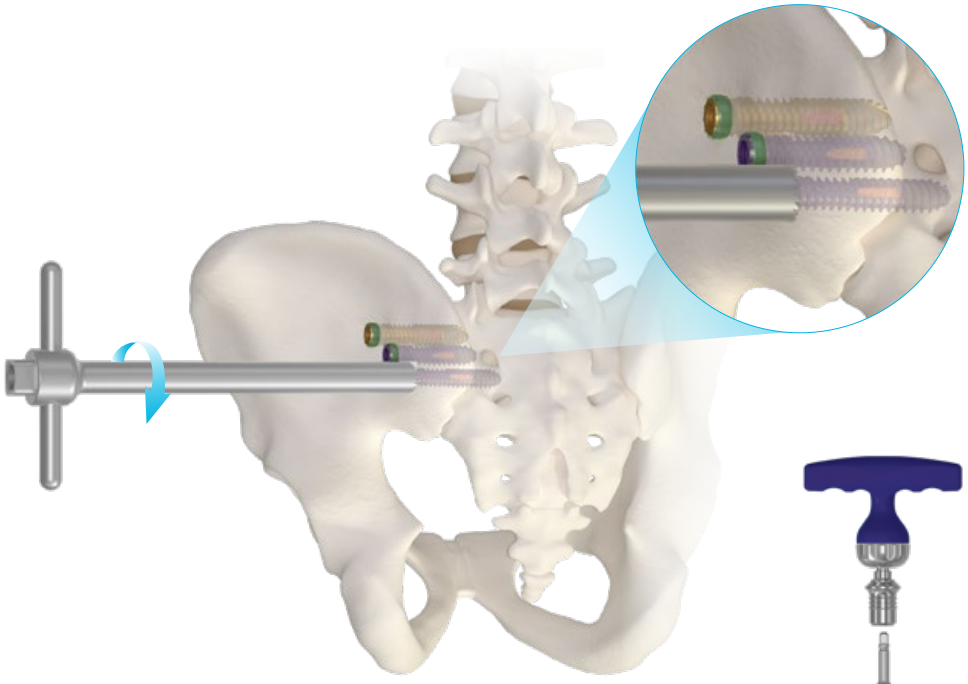
OPTIONAL: SCREW REMOVAL

Locate the desired screw using fluoroscopy. If postoperative screw removal is necessary, bone may have grown onto and/or through the SI-LOK® SELECT implant, which may require greater torque to remove the screw. A small burr may be used to drill the bone around the washer to loosen the implant. The **T27 Non-Cannulated Shaft** may be used to remove the screw.

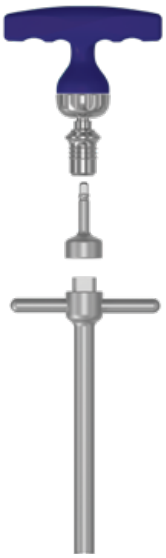
Note: The SI-LOK® SELECT washer may separate from the screw upon removal. Use forceps to extract the washer if necessary.

T27 Non-Cannulated Shaft, SI-LOK® Select Driver

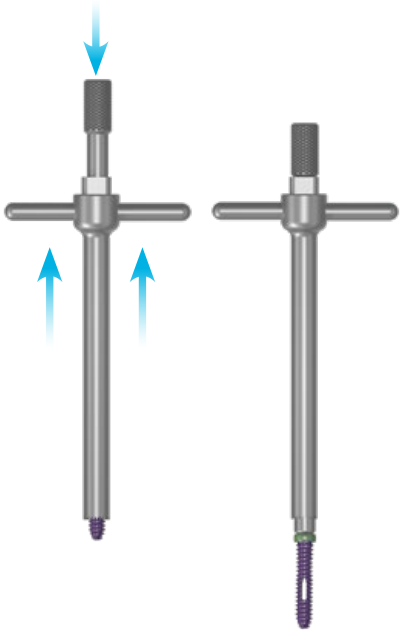
If the T27 Non-Cannulated Shaft does not loosen the screw, use a K-wire to locate the screw. Place the **Trephine** over the washer of the screw, center, and rotate clockwise until the Trephine has partially or fully cored the bone around the screw as shown below. A handle may be connected to the **Trephine Attachment** for easier insertion. Remove the screw. The **Pusher** may be used to remove the Trephine from the bone or to remove the screw from the Trephine.



Coring bone around screw with Trephine



Trephine Attachment



Pusher to remove Trephine from bone or screw

SETS AND PARTS TO ORDER GUIDE

All Cases

SET NUMBER	SET DESCRIPTION
9202.9001	SI-LOK® SELECT Implant Set
9202.9002	SI-LOK® SELECT Instrument Set
939.902	SI-LOK® Instrument Set

Navigated Cases

SET/PART NUMBER	SET/PART DESCRIPTION
9123.9006	Guided Instruments VI Set
6202.6650	Outer Sleeve, SI-LOK® SELECT Driver, GI1
6202.6651 or 6202.6652	T27 Non-Cannulated Shaft, SI-LOK® SELECT Driver, GI1 or T27 Cannulated Shaft, SI-LOK® SELECT Driver, GI1

ExcelsiusGPS® Cases

SET/PART NUMBER	SET/PART DESCRIPTION
9143.9008	SI-LOK®, GPS
6202.2830	Outer Sleeve, SI-LOK® SELECT Driver, GPS
6202.2832	T27 Cannulated Shaft, SI-LOK® SELECT Driver, GPS

SI-LOK® SELECT
IMPLANT SET 9202.9001

10.0mm SI-LOK® SELECT Screws

Length	Part Number	Qty
25mm	1202.5025S	0
30mm	1202.5030S	0
35mm	1202.5035S	0
40mm	1202.5040S	2
45mm	1202.5045S	2
50mm	1202.5050S	2
55mm	1202.5055S	1
60mm	1202.5060S	1
65mm	1202.5065S	2
70mm	1202.5070S	2
75mm	1202.5075S	0
80mm	1202.5080S	0
85mm	1202.5085S	0
90mm	1202.5090S	0
95mm	1202.5095S	0
100mm	1202.5000S	0
105mm	1202.5005S	0
110mm	1202.5010S	0

12.0mm SI-LOK® SELECT Screws

Length	Part Number	Qty
25mm	1202.5225S	0
30mm	1202.5230S	2
35mm	1202.5235S	0
40mm	1202.5240S	2
45mm	1202.5245S	2
50mm	1202.5250S	2
55mm	1202.5255S	0
60mm	1202.5260S	2
65mm	1202.5265S	0
70mm	1202.5270S	0
75mm	1202.5275S	0
80mm	1202.5280S	0
85mm	1202.5285S	0
90mm	1202.5290S	0
95mm	1202.5295S	0
100mm	1202.5200S	0
105mm	1202.5205S	0
110mm	1202.5210S	0

10.0mm SI-LOK® SELECT Screws w/washer

Length	Part Number	Qty
25mm	1202.6025S	0
30mm	1202.6030S	2
35mm	1202.6035S	2
40mm	1202.6040S	3
45mm	1202.6045S	3
50mm	1202.6050S	2
55mm	1202.6055S	1
60mm	1202.6060S	1
65mm	1202.6065S	2
70mm	1202.6070S	2
75mm	1202.6075S	0
80mm	1202.6080S	0
85mm	1202.6085S	0
90mm	1202.6090S	0
95mm	1202.6095S	0
100mm	1202.6000S	0
105mm	1202.6005S	0
110mm	1202.6010S	0

12.0mm SI-LOK® SELECT Screws w/washer

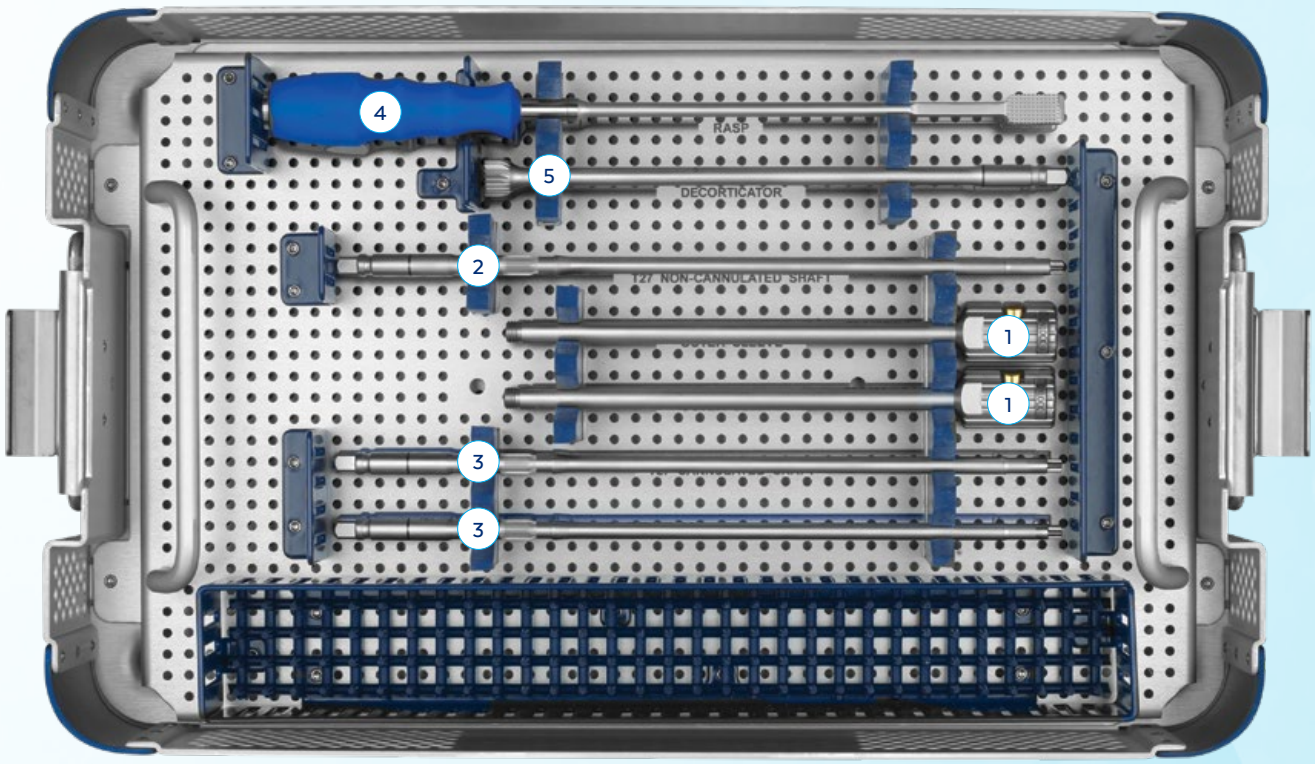
Length	Part Number	Qty
25mm	1202.6225S	0
30mm	1202.6230S	0
35mm	1202.6235S	0
40mm	1202.6240S	1
45mm	1202.6245S	1
50mm	1202.6250S	1
55mm	1202.6255S	1
60mm	1202.6260S	1
65mm	1202.6265S	0
70mm	1202.6270S	0
75mm	1202.6275S	0
80mm	1202.6280S	0
85mm	1202.6285S	0
90mm	1202.6290S	0
95mm	1202.6295S	0
100mm	1202.6200S	0
105mm	1202.6205S	0
110mm	1202.6210S	0

Items highlighted in gray are additionally available


GLOBUS
MEDICAL
SI-LOK® SELECT
SCREWS
Life moves us
Patent www.globusmedical.com/patents

SI-LOK® SELECT
INSTRUMENT SET 9202.9002

	Instruments		QTY
1	6202.1650	Outer Sleeve, SI-LOK® SELECT Driver	2
2	6202.1651	T27 Non-Cannulated Shaft, SI-LOK® SELECT Driver	1
3	6202.1652	T27 Cannulated Shaft, SI-LOK® SELECT Driver	2
4	6202.8000	Rasp	1
5	6202.8001	Decorticator	1
	9202.0002	SI-LOK® SELECT Instrument Graphic Case	1


4
RASP
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DECORTICATOR
2
127 NON-CANNULATED SHAFT
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SI-LOK®
INSTRUMENT SET 939.902

	Preparation Instruments		QTY
1	639.001	2.4mm K-Wire, Sharp, 300mm	6
2	639.002	2.4mm K-Wire, Sharp, 450mm	2
3	639.003	2.4mm Temporary K-Wire, Blunt, 150mm	2
4	639.005	Screw Hole Alignment Guide, Left	1
5	639.006	Screw Hole Alignment Guide, Right	1
6	639.050	Fixed Pin Guide, 10mm	1
7	639.007	2.4mm Wire Holder, Radiolucent Tips	1
8	639.500	Radiolucent Fixed Pin Guide, 10mm	1
	639.008 (not shown)	2.4mm K-Wire, 450mm, Blunt Tip	2

	Drill Bits and Taps		QTY
9	639.011	K-Wire Depth Gauge	1
10	639.208	8.0mm Cannulated Tap	1
11	639.210	10.0mm Cannulated Tap	1
12	639.212	12.0mm Cannulated Tap	1
13	639.215	5.5mm Cannulated Drill	1
14	639.216	6.5mm Cannulated Drill	1
15	639.217	7.5mm Cannulated Drill	1
16	639.218	8.5mm Cannulated Drill	1
17	639.219	9.5mm Cannulated Drill	1
18	639.220	10.5mm Cannulated Drill	1
19	639.407	1/4" Quick-Connect Adaptor	1

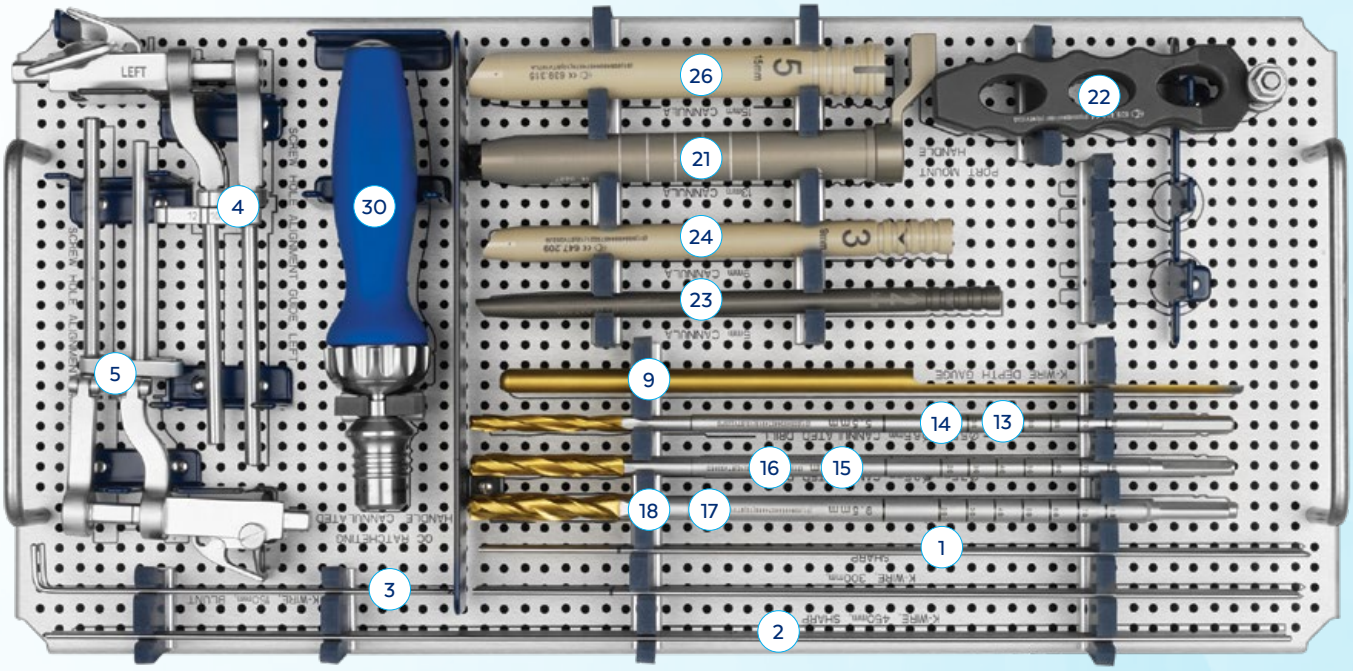
	Cannulas		QTY
20	632.150	10mm Socket Driver	1
21	639.114	Fixed Port Mount Cannula	1
22	639.413	Port Mount Handle	2
23	647.205	Cannula, 5mm	1
24	647.209	Cannula, 9mm	1
25	639.201	Cannula, 2.5mm ID	1
26	639.315	Cannula, MARS, 15mm ID	1

	Implant Instrument		QTY
27	639.650	4.0mm Retaining Hex SIJ Driver	2
28	639.651	SIJ, Non-Cannulated Driver Shaft	1

	Quick-Connect Handles		QTY
29	630.401	Quick-Release Ratcheting T-Handle, Cannulated	1
30	630.407	Quick-Release Ratcheting Handle, Cannulated	1
31	634.611	Torque Limiting T-Handle, Ratcheting, 8Nm, 1/4" Connect, Black	1

	939.002	SI-LOK® Instrument Graphic Case
	639.004	2.4mm K-Wire, 500mm
	639.009	2.4mm K-Wire, 600mm
	639.012	2.4mm K-Wire, 300mm, Blunt Tip
	639.015	Bone Funnel
	639.017	Bone Pusher Rod
	639.020	Up Angle Curette
	639.021	Down Angle Curette
	639.060	Fixed Pin Guide, 12mm
	639.209	9.0mm Cannulated Tap
	639.211	11.0mm Cannulated Tap
	652.220	Wrench
	639.600	Radiolucent Fixed Pin Guide, 12mm
	639.900	Trephine Attachment
	639.903	Pusher, SI-LOK® Removal
	639.904	Trephine, SI-LOK® Removal

Items highlighted in gray are additionally available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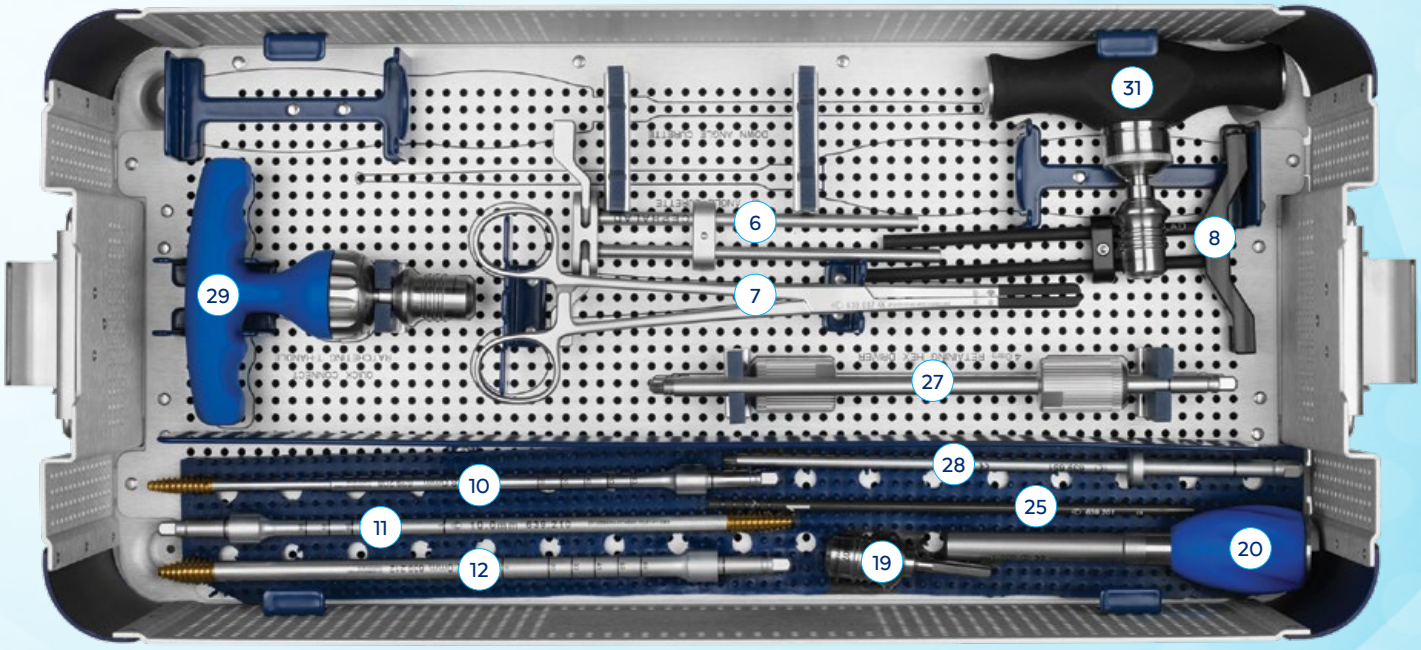
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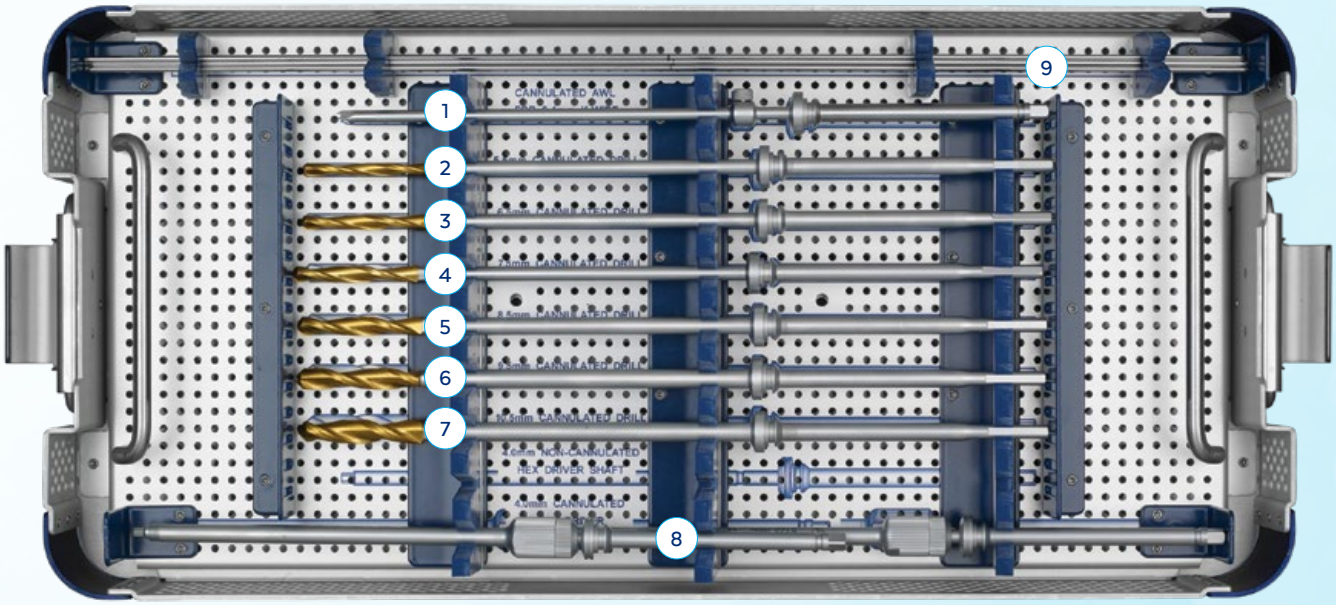
GUIDED INSTRUMENTS
INSTRUMENT VI SET 9123.9006

	Instruments		QTY
1	6123.1600	Cannulated Awl for 2.4mm K-wire, GI1	1
2	6123.1615	5.5mm Cannulated Drill, GI1	1
3	6123.1616	6.5mm Cannulated Drill, GI1	1
4	6123.1617	7.5mm Cannulated Drill, GI1	1
5	6123.1618	8.5mm Cannulated Drill, GI1	1
6	6123.1619	9.5mm Cannulated Drill, GI1	1
7	6123.1620	10.5mm Cannulated Drill, GI1	1
8	6123.1650	4.0mm Cannulated Hex Driver, GI1 (SI-LOK®)	2
9	639.004	2.4mm K-wire, Sharp 500mm	6
	9123.0006	Guided Instruments VI Graphic Case	

	6123.1651	4.0mm Non-Cannulated Hex Driver, GI1
	6202.6650	Outer Sleeve SI-LOK® SELECT Driver, GI1
	6202.6651	Non-Cannulated Shaft SI-LOK® SELECT Driver, GI1
	6202.6652	Cannulated Shaft SI-LOK® SELECT Driver, GI1

Items highlighted in gray are additionally available


CANNULATED AWL
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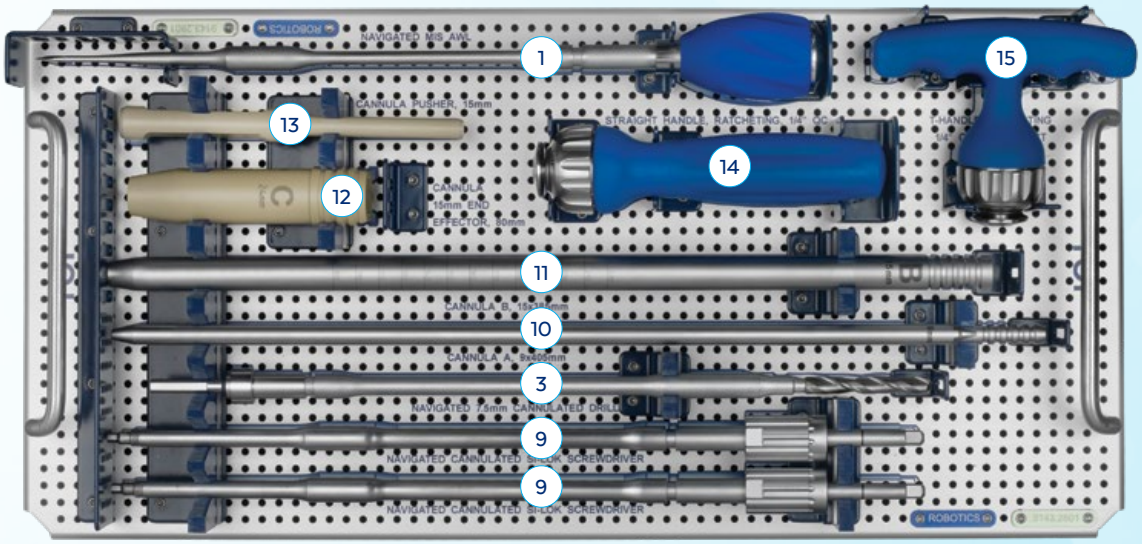
SI-LOK® GPS
INSTRUMENT SET 9143.9008

	Instrument		QTY
1	6143.2701	MIS Awl, GPS	1
	6143.2802	MIS Awl, Cannulated for 2.4mm K-Wire, GPS	
2	6143.2810	SI-LOK® Cannulated Drill, GPS, 6.5mm	1
3	6143.2811	SI-LOK® Cannulated Drill, GPS, 7.5mm	1
4	6143.2812	SI-LOK® Cannulated Drill, GPS, 8.5mm	1
5	6143.2813	SI-LOK® Cannulated Drill, GPS, 9.5mm	1
6	6143.2814	SI-LOK® Cannulated Drill, GPS, 10.5mm	1
7	6143.2820	SI-LOK® Cannulated Tap, GPS, 8.0mm	1
8	6143.2821	SI-LOK® Cannulated Tap, GPS, 10.0mm	1
9	6143.2830	SI-LOK® Cannulated Screwdriver, GPS	2
10	6143.2843	Cannula A, 9mm x 405mm	1
11	6143.2845	Cannula B, 15mm x 385mm	1
12	6143.2686	Cannula, 15mm End Effector, 80mm, GPS	1
13	6143.2690	Cannula Pusher, 15mm	1
14	6067.0010	Straight Handle, Ratcheting, 1/4” Quick Connect	1
15	6067.0020	T-Handle, Ratcheting, 1/4” Quick Connect	1
	9143.2801	SI-LOK® Graphic Case, GPS	

	6143.2802	MIS Awl, Cannulated for 2.4mm K-wire, GPS
	6202.2830	Outer Sleeve, SI-LOK® SELECT Driver, GPS
	6202.2832	T27 Cannulated Shaft, SI-LOK® SELECT Driver, GPS

Items highlighted in gray are additionally available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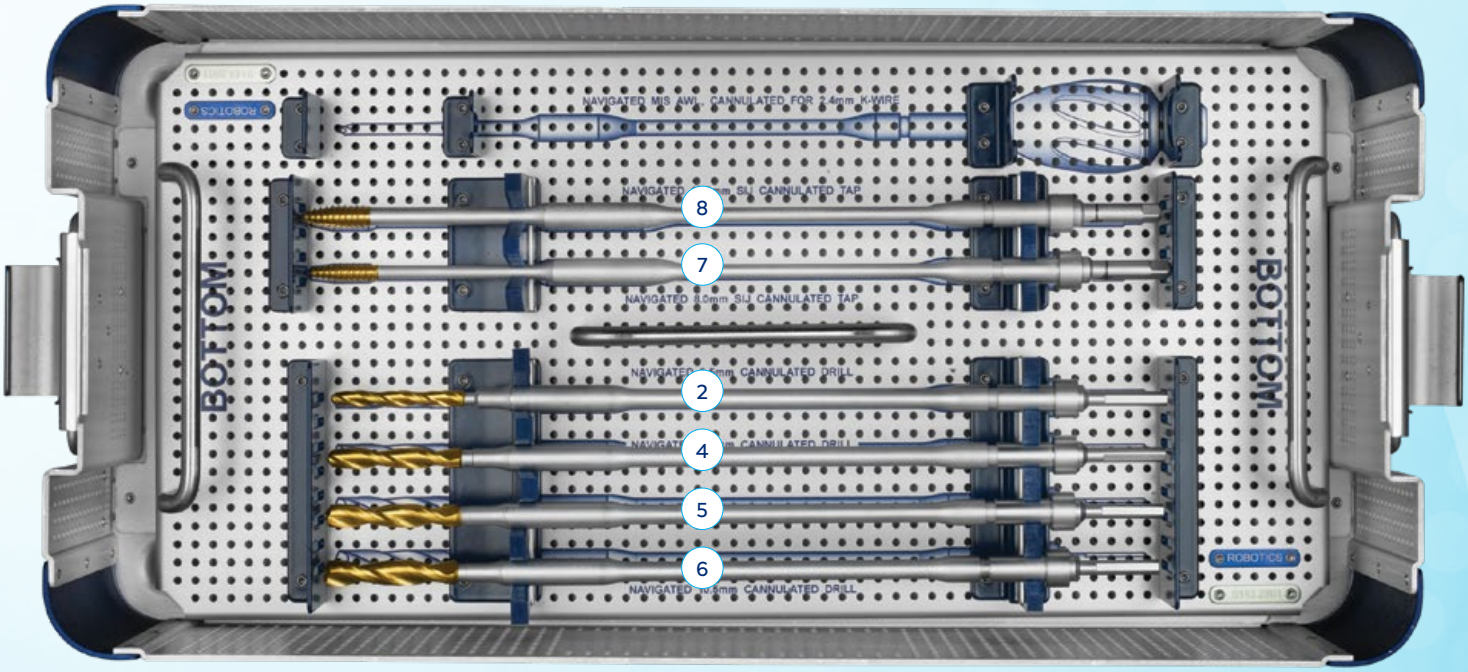
NAVIGATED MIS AWL CANNULATED FOR 2.4mm K-WIRE
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BOTTOM
BOTTOM

IMPORTANT INFORMATION ON SI-LOK® SACROILIAC JOINT FIXATION SYSTEM

DESCRIPTION

The SI-LOK® Sacroiliac Joint Fixation System (including SI-LOK® Select) consists of screws designed to enhance sacroiliac joint fusion and to provide fixation of large bones and large bone fragments of the pelvis. SI-LOK® screws are cannulated, partially threaded or fully threaded screws that contain a pre-assembled contouring washer. SI-LOK® Select screws are cannulated, fully threaded screws that are offered with or without a pre-assembled contouring washer, in various diameters and lengths to accommodate patient anatomy. A minimum of two screws are required for the lateral approach to achieve stabilization. A third screw may be used as needed for additional fixation. One to three screws may be used for the posterior approaches.

The SI-LOK® Sacroiliac Joint Fixation System screws and contouring washers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. SI-LOK® screws are available with or without hydroxyapatite (HA) coated, as specified in ASTM F1185.

The SI-LOK® Sacroiliac Joint Fixation System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, re-usable instruments that can be operated manually or under power using a power drill such as POWEREASE™, that are intended to be used with the Medtronic StealthStation® System.

INDICATIONS

The SI-LOK® Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliiitis.

Globus Navigation Instruments are intended to be used during the preparation and placement of SI-LOK® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery include:

Possible adverse effects which may occur include, but are not limited to: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; infection; device fracture or failure; device migration or loosening; decrease in bone density; loss of spinal mobility or function; inability to perform activities of daily living; graft donor site complications including pain, fracture and wound healing problems; tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, numbness or tingling; cauda equina syndrome; injury to vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional surgery may be necessary to correct some of these effects. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, delivery options should be discussed with her obstetrician.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of fracture fixation of large bones and large bone fragments of the pelvis.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

PRECAUTIONS

Use of the SI-LOK® Sacroiliac Joint Fixation System should be performed only by experienced orthopedic/spinal surgeons with specific training in the use of this system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered prior to performing the sacroiliac joint fusion.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability

to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

For optimal implant performance, when using the SI-LOK® Sacroiliac Joint Fixation System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Extreme caution should be used around the nerve roots. Damage to the nerves will cause loss of neurological functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery. To insert a cannulated screw, a guide wire may be used, followed by a sharp tap. Ensure that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Also ensure that the guide wire does not advance during tapping or screw insertion. Remove the guide wire and confirm that it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Correct handling of the implant is extremely important. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture or has healed or fusion has occurred, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. A higher risk of device loosening, bending, or breaking exists with fractures involving severe comminution, displacement or other difficult fracture management situations.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to constantly changing environment of salts, acids and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn can enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys in conjunction with each other.

MRI SAFETY INFORMATION

These devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CONTRAINDICATIONS

The contraindications include, but are not limited to: active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented metal allergy or intolerance; any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; any patient unwilling to follow post-operative instructions; any case not described in the indications.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

PACKAGING

These implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be

IMPORTANT INFORMATION ON SI-LOK® SACROILIAC JOINT FIXATION SYSTEM

carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants may be available sterile or nonsterile. HA-coated implants are only available sterile. Instruments are available nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat-sealed double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10-6. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	45 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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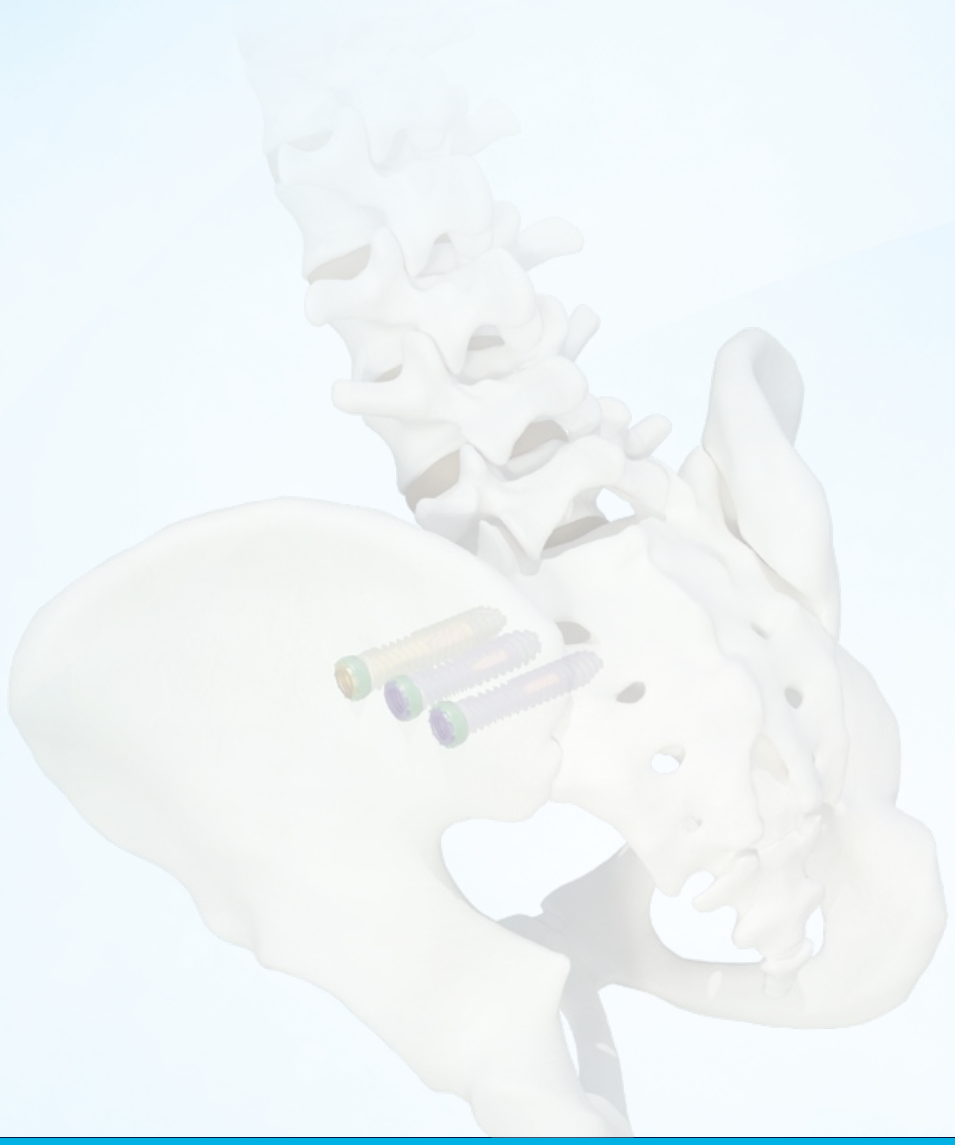

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