SI-LOK®

Sacroiliac Joint Fusion System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

SI-LOK®

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Sacroiliac Joint Fusion System

The SI-LOK® Sacroiliac Joint Fusion System is a comprehensive set of hydroxyapatite (HA)-coated screws and cannulated instruments specifically designed for a lateral approach to the sacroiliac (SI) joint. It is intended for SI joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

The SI-LOK® Sacroiliac Joint Fusion System offers lag, fixation, and slotted screw options with HA-coating in a variety of lengths to provide the:

- **Security** of a fully threaded connection
- **Strength** of a large diameter bolt
- Option of a graft slot designed to promote **fusion**
- Cinching effect of a lag screw

Fusion

Graft Slot Options: Accept autogenous bone graft to optimize SI joint fusion

Security

Polyaxial Washer: Contours to ilium

Teeth: Help prevent implant backout

HA-Coating: Designed to promote bony ongrowth to aid in anchoring the screw

Dual Lead Threads: Allow faster insertion

Fluted Tips: Help provide better insertion in cortical bone

Strength

Lag Feature: Allows compression of SI joint

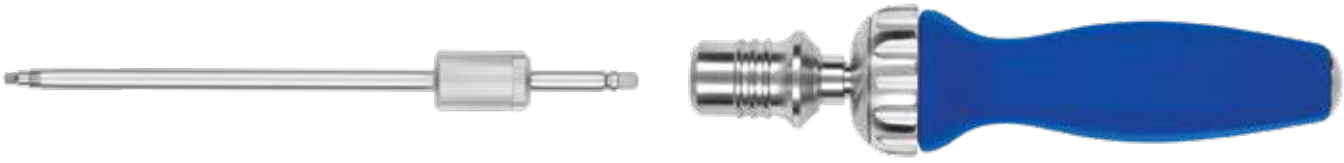
KEY INSTRUMENTS

Screw Hole Alignment Guide

- Simplifies alignment of second and third screws
- Provides a convenient guide for ease of insertion

SI Joint 4.0mm Hex Driver

- Provides solid capture of the screw
- Cannulated for MIS approach



MARS™ Compatible Working Ports

- Radiolucent PEEK material
- Beveled edge to match iliac contour
- Slot for table arm attachment

OPTIMAL SOLUTIONS

HIGH LOAD

Maximize fixation with three screws.
A lag screw may be used for added strength and/or to compress the joint together.

HIGH FUSION

Maximize fusion mass using two HA-coated slotted screws to reinforce a cleared and filled area, sealed with a 25mm plug screw.

HYBRID

Combination of strength and fusion. Use of three screws for tricortical fixation, with the option of two slotted screws to enhance fusion.

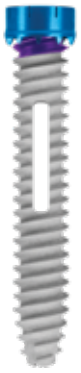
IMPLANT OVERVIEW

Screw Options

- All screws are HA-coated to help promote bonding and fusion
- Cannulated for delivery through an MIS approach
- Dual lead threads for faster insertion
- Screw diameters: 8mm, 10mm, and 12mm
- Up to 60mm in length

Slotted Screws

- Slotted screw accommodates autogenous bone graft to optimize fusion
- Only in larger screw diameters (10mm and 12mm)



Slotted Screws

Slotted Lag Screws

Slotted Lag Screws

- Slotted lag screw accepts autogenous bone graft to optimize fusion
- Only in larger screw diameters (10mm and 12mm)

Fixation Screws

- Fully threaded, self-tapping screw to maximize holding

Fixation Screws

Lag Screws

- Lag portion allows compression of SI joint

Lag Screws

SI-LOK® Screws		Diameter (mm)	Length (mm)
Fully threaded	Standard	8, 10, 12	30-60
	Slotted	10, 12	25-60
Lag	Standard	8, 10, 12	40-60
	Slotted	10, 12	45-60

INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

2.4mm K-Wire, Sharp 300mm 639.001

2.4mm K-Wire, Sharp 450mm 639.002

2.4mm Temporary K-Wire, Blunt 150mm 639.003

2.4mm K-Wire, Blunt Tip 450mm 639.008

Screw Hole Alignment Guide, Left 639.005

Screw Hole Alignment Guide, Right 639.006

Fixed Pin Guide, 10mm 639.050

2.4mm Wire Holder, Radiolucent Tips 639.007

DEPTH GAUGE

K-Wire Depth Gauge 639.011

CANNULATED TAPS

8.0mm Cannulated Tap 639.208

10.0mm Cannulated Tap 639.210

12.0mm Cannulated Tap 639.212

1/4” Quick-Connect Adaptor 639.407

CANNULATED DRILLS

5.5mm Cannulated Drill 639.215

6.5mm Cannulated Drill 639.216

7.5mm Cannulated Drill 639.217

8.5mm Cannulated Drill 639.218

9.5mm Cannulated Drill 639.219

10.5mm Cannulated Drill 639.220

CANNULAS

Cannula, 5mm 647.205

Cannula, 9mm 647.209

Cannula, MARS™, 13mm ID 647.313

Cannula, MARS™, 15mm ID 639.315

Fixed Port Mount Cannula 639.114

Port Lock, 13mm 647.513

Port Lock, 15mm 647.515

Port Mount, 13mm 647.413

Port Mount, 15mm 639.415

CANNULAS (CONT'D)

Port Mount Handle Assembly 639.413

IMPLANT INSTRUMENT

4.0mm SI Joint Hex Driver 639.650

SIJ, Non-Cannulated Driver Shaft 639.651

SI JOINT PREP INSTRUMENTS

Up Angle Curette 639.020

Down Angle Curette 639.021

QUICK-CONNECT HANDLES

Quick-Connect Ratcheting Handle, Cannulated 630.407

Quick-Connect Ratcheting T-Handle 630.401

Torque Limiting T-Handle, Ratcheting, 8Nm, 1/4” Connect, Black 634.611

10mm Socket Driver 632.150

ADDITIONALLY AVAILABLE INSTRUMENTS

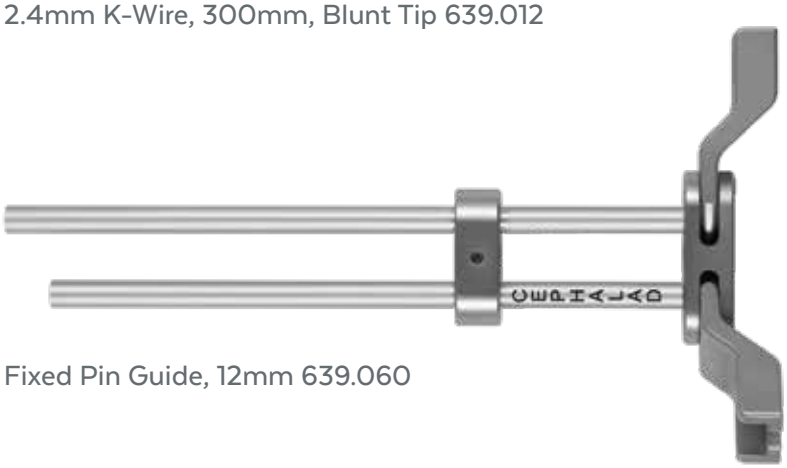
Bone Funnel 639.015

Bone Pusher Rod 639.017

2.4mm K-Wire, 500mm 639.004

2.4mm K-Wire, 600mm 639.009

2.4mm K-Wire, 300mm, Blunt Tip 639.012



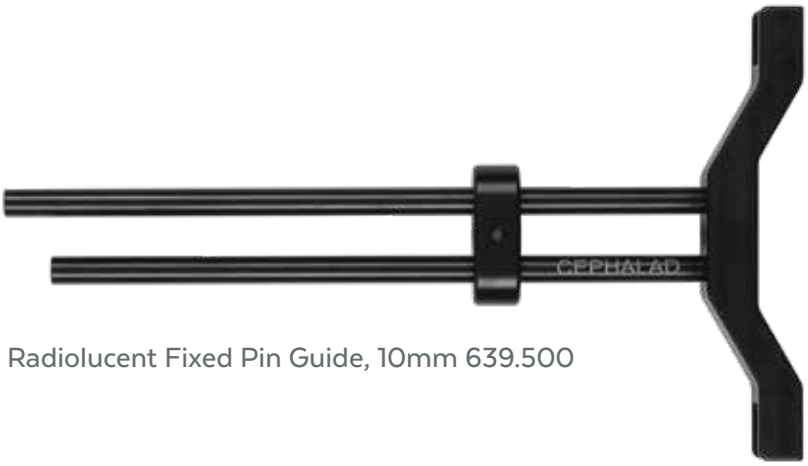
Fixed Pin Guide, 12mm 639.060

Cannula 2.5mm, ID 639.201

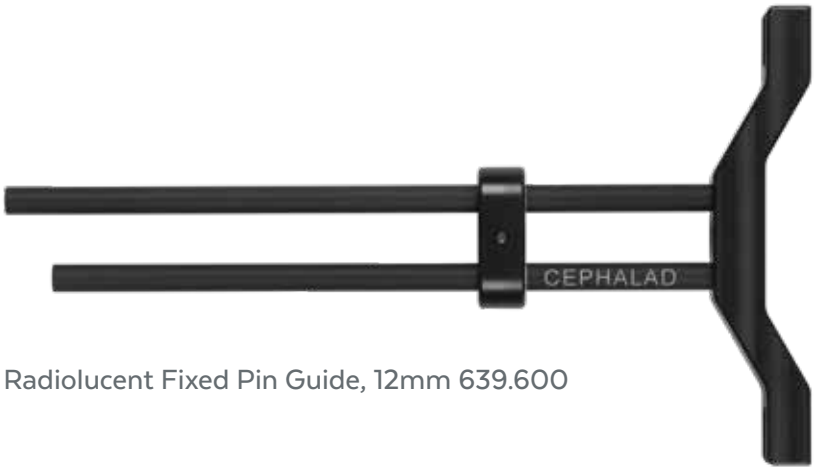
9.0mm Cannulated Tap 639.209

11.0mm Cannulated Tap 639.211

ADDITIONALLY AVAILABLE INSTRUMENTS (CONT'D)

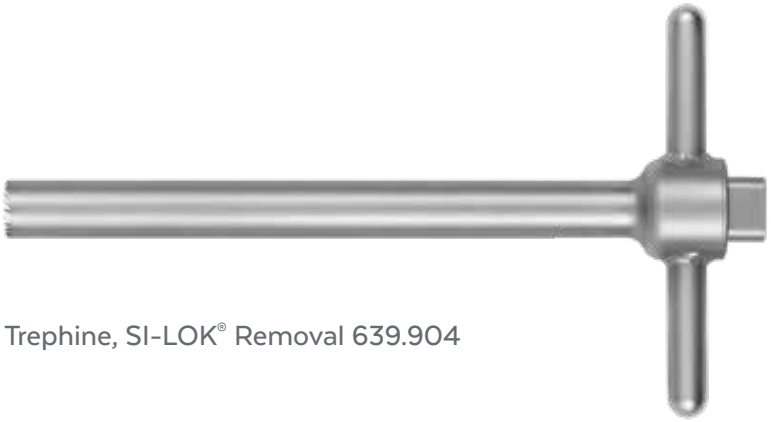


Radiolucent Fixed Pin Guide, 10mm 639.500



Radiolucent Fixed Pin Guide, 12mm 639.600

Pusher, SI-LOK® Removal 639.903



Trephine, SI-LOK® Removal 639.904

Trephine Attachment 639.900

SURGICAL TECHNIQUE

SI-LOK®

A preoperative CT scan is recommended for planning purposes.

STEP 1 PATIENT PREPARATION

Patient Positioning

Caution: If the patient has a lumbosacral transitional vertebrae, refer to the Anatomical Variations section on page 39.

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.

Attach the **Table Clamp** to the end of the surgical table closest to the patient's head. Place the clamp on the side of the surgery, particularly for patients requiring longer arm extensions.

Patient positioned prone

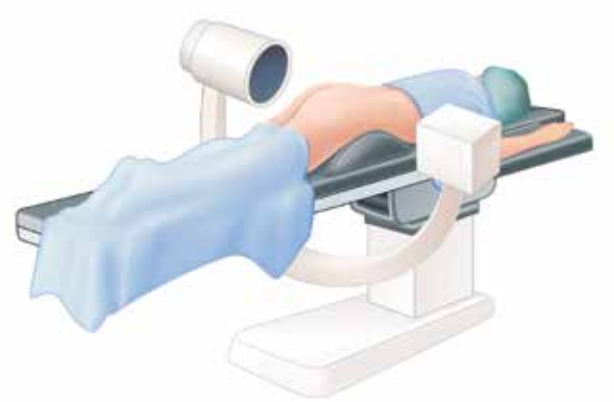
Optional Table Clamp

Radiographic Confirmation

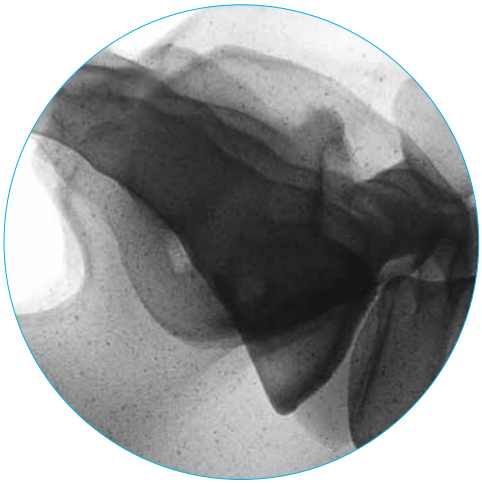
Note: For the purposes of this technique, the term "slope line" will be used to define the posterior cortical wall of the sacrum.

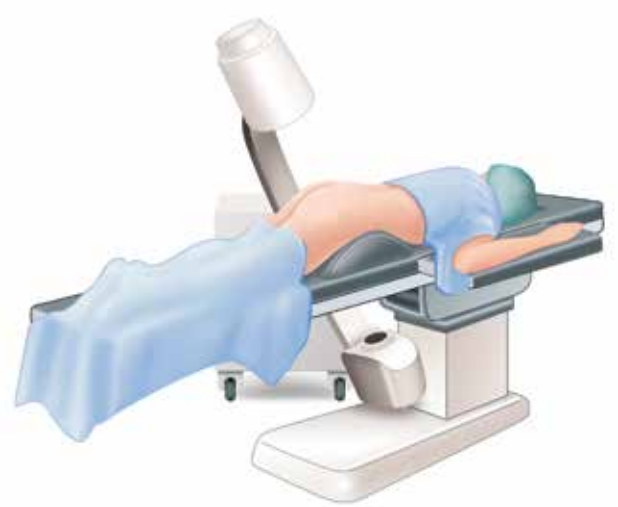
Position the C-arm to a true lateral view, as shown on the following page, such that the sacral notches and the ala are aligned. Next rotate the C-arm to an outlet view of the sacrum as displayed on the following page. The S1 pedicle, SI joint, and foramina should be visible. Rotate the C-arm to an inlet view to identify the anterior border of the pelvis.

Fluoroscopy Positioning

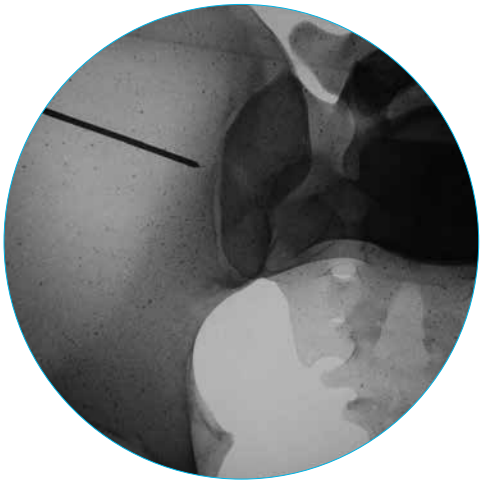


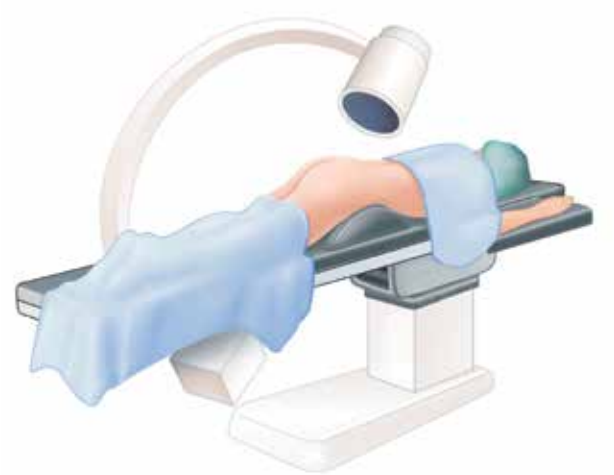
Lateral fluoroscopy is positioned directly to the sacrum



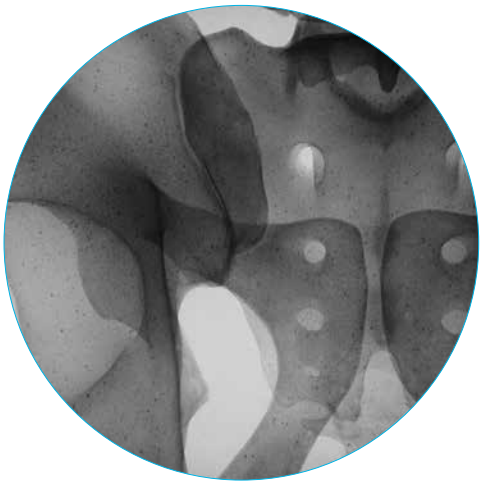


Inlet fluoroscopy is positioned 30–50° to the sacrum



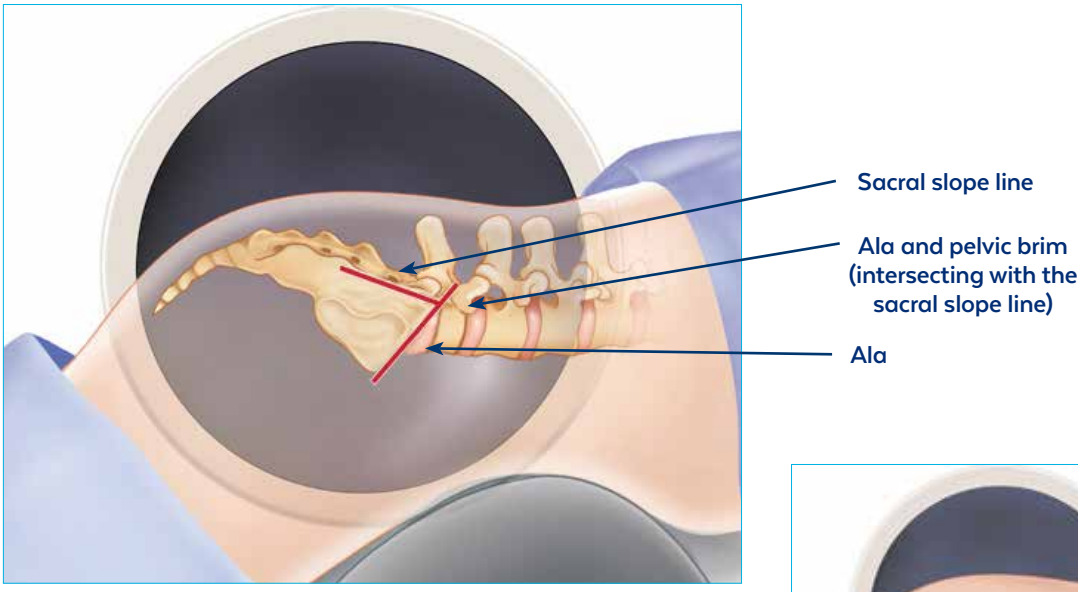


Outlet fluoroscopy is positioned 30–50° to the sacrum



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 angle. Mark the area of the intersection on the skin with a sterile marker as shown.



Identification of the slope of the sacrum and the ala

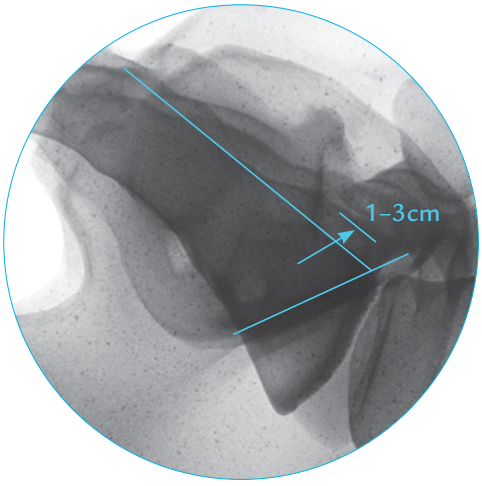
STEP 3 K-WIRE INSERTION

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.

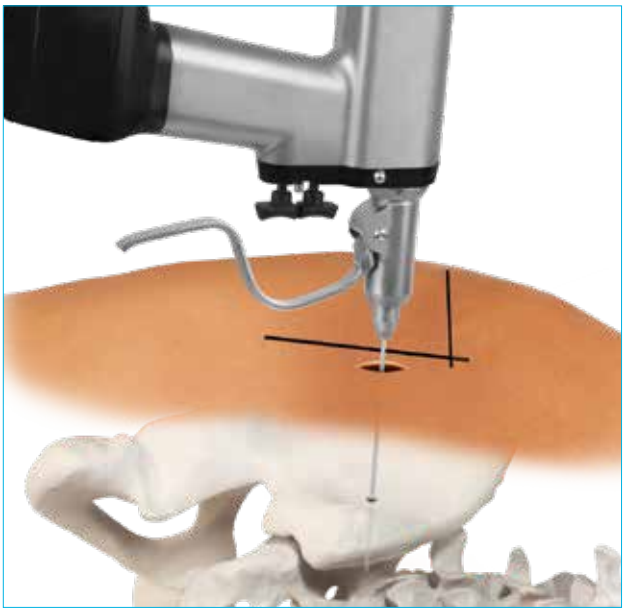
Using a standard orthopedic wire driver or mallet, introduce the **2.4mm K-Wire, Sharp** through the incision, aiming slightly downward to keep the K-wire tip clear of the wire driver when using fluoroscopy.

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

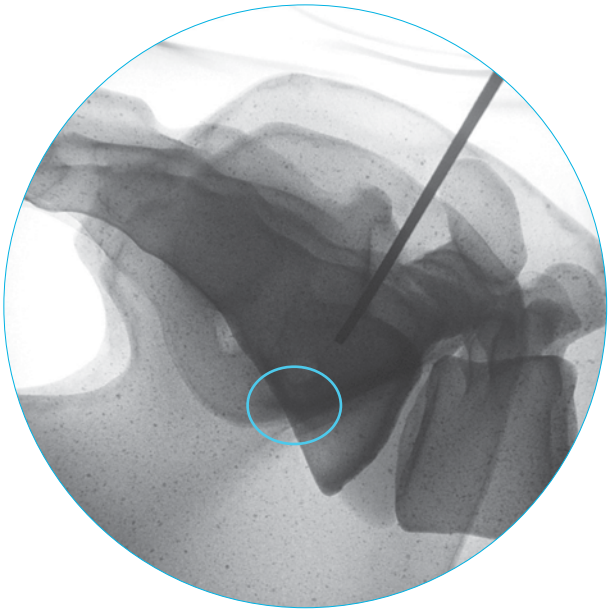
Note: The incision may be made directly on or below the sacral slope line. The K-wire trajectory is directly lateral with minimal angulation.



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

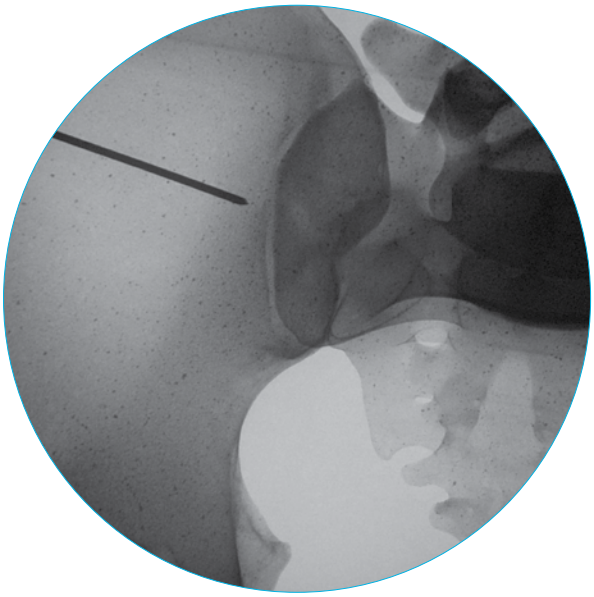


Initial K-wire placement

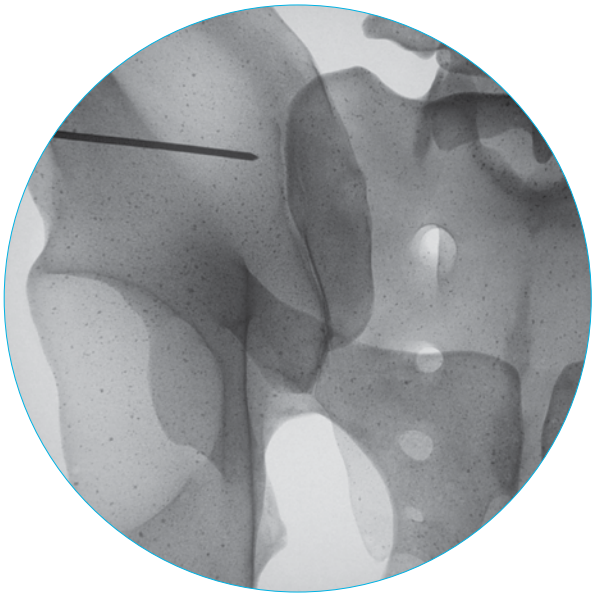


K-wire tip visible at the top of the sacrum against the ilium (lateral view)

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, remaining 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 the top of the sacrum against the ilium (inlet view)

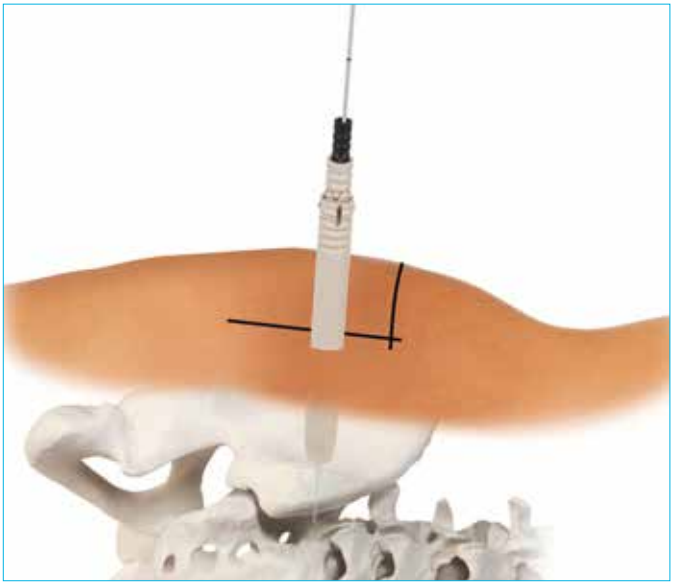


K-wire tip visible at the top of the sacrum against the ilium (outlet view)

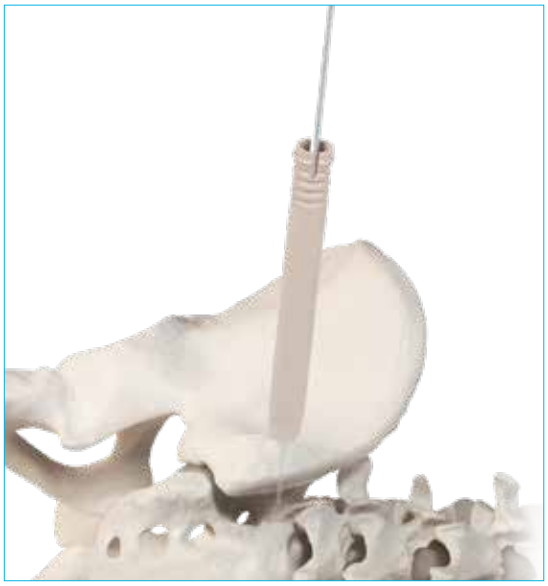
STEP 4 TISSUE DILATION

Consecutively dilate the tissue over the K-wire, increasing the cannula diameter up to a **13mm Cannula**.

Push the cannula through the skin until the angled tip is flush against the ilium. For a 12mm screw, it is necessary to dilate up to a **15mm Cannula** (directly from the initial 9mm dilation). Align the beveled edge of the final cannula with the bony anatomy as desired.

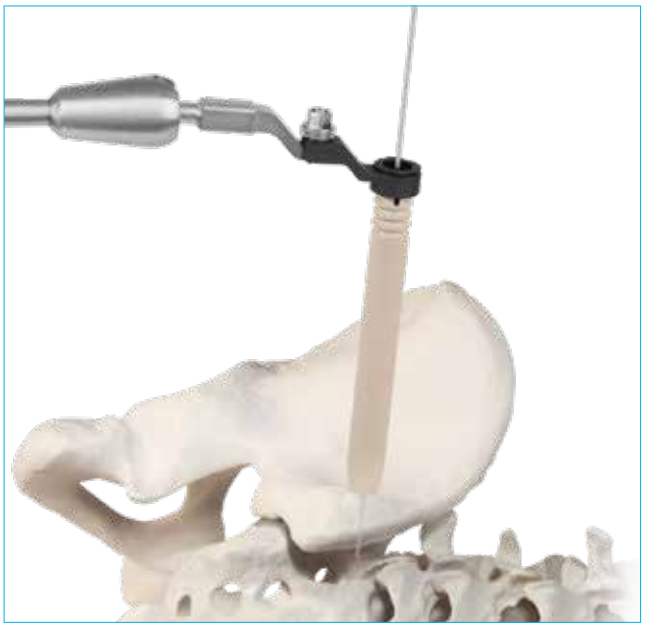


Cannulas in place



Internal cannulas removed

Insert the **Articulating Arm Assembly** into the Table Clamp and secure the knob. The opposite end of the arm is then attached to the **Port Mount** to stabilize the screw insertion site. The **Port Mount Handle** may be used instead of the Articulating Arm Assembly, if desired. Lock the assembly by securing the **Port Lock**. Tighten the thumb screw using the **10mm Socket Driver**. Position the arm and lock in place by tightening the T-handle.



Cannula up against the ilium

Note: AP and lateral images should be taken at this time to ensure the K-wire is in place.

Alternative Port Mount Handle Attachment

The cannula can be positioned with the etched line pointing cephalad.

Note: Minimal torque is required to tighten the thumb screw with the 10mm Socket Driver.

Port Mount Handle attached to the Port Mount and cannula

STEP 5 SCREW SIZING

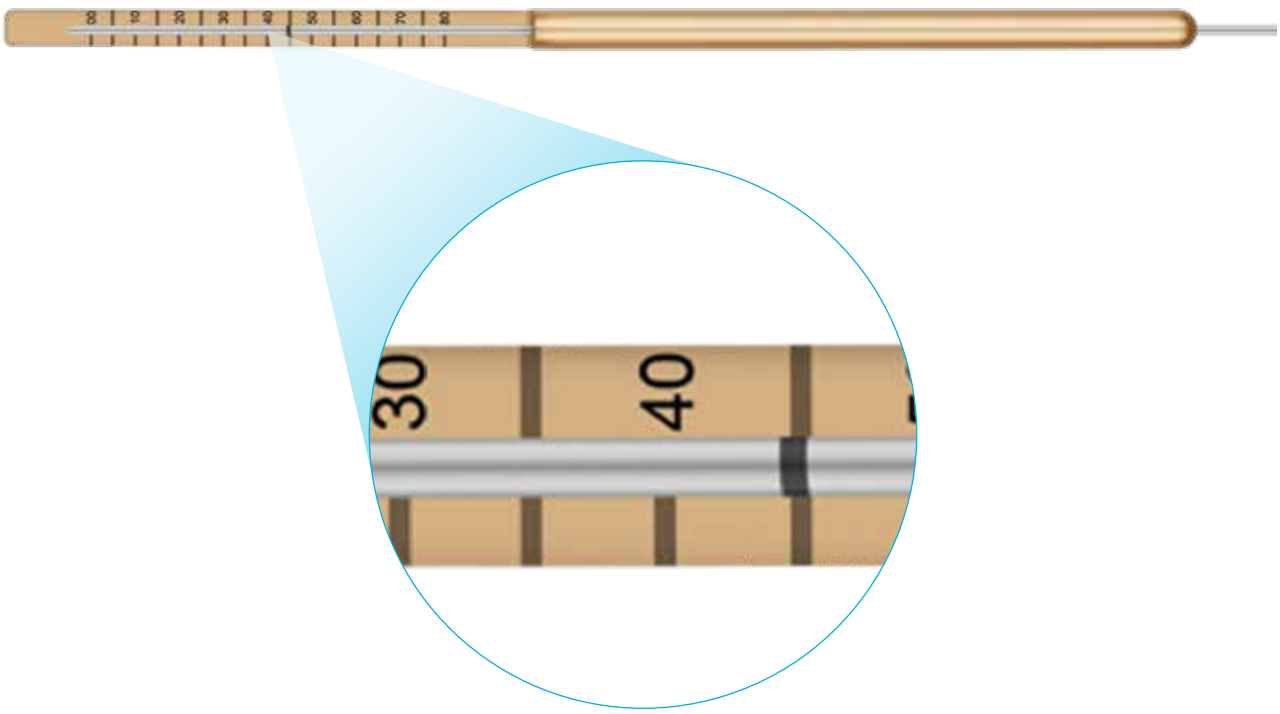
Leaving the cannula in place, determine the screw length using the **K-Wire Depth Gauge**, taking care not to displace the K-wire. Slide the K-Wire Depth Gauge over the K-wire using the demarcation line on the K-wire as a guide to determine the appropriate screw length. Ensure that the depth gauge is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

Using the K-Wire Depth Gauge to determine screw size

Ensure depth gauge is against cortical wall of ilium

Note: The 9mm Cannula used for dilation may be kept in place for extra guidance when determining depth and using drill bits that are 8.5mm in diameter or smaller.

SCREW SIZING (CONT'D)



Using location of demarcation line on K-wire to determine screw length (47mm measurement indicates use of 45mm screw)

Available Screws

With a minimum of two screws for stabilization, it is recommended that a 10 or 12mm screw be used for the first screw. Also, 12mm screws may be used for revision surgery.

SI-LOK® Screws		Diameter (mm)	Length (mm)
Fully threaded	Standard	8, 10, 12	30-60
	Slotted	10, 12	25-60
Lag	Standard	8, 10, 12	40-60
	Slotted	10, 12	45-60

STEP 6 PILOT HOLE PREPARATION

Drilling is required to facilitate proper advancement of the screw in cortical bone.

After determining the screw diameter and length, 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 that the trajectory is correct.

Place the **2.4mm K-Wire, Blunt 450mm** in the proximal end of the power drill and hold while withdrawing the power drill and drill bit to retain the K-wire in place.

SI-LOK® Screw Diameter	Drill Size
8mm	5.5mm
10mm	7.5mm
12mm	9.5mm

Note: For harder cortical bone it is recommended to drill 1.5mm smaller than the screw or to tap the screw hole instead. For a lag screw, drill only through the three cortical walls and no further. SI-LOK® screws are self-tapping; however, in cases of hard or sclerotic bone the screw hole may be tapped to ease insertion. Drill to the diameter shown in the table above and tap the screw hole. 8, 10, and 12mm taps are available.

Drilling 10mm shorter than the intended screw length or just past the cortices of the joint

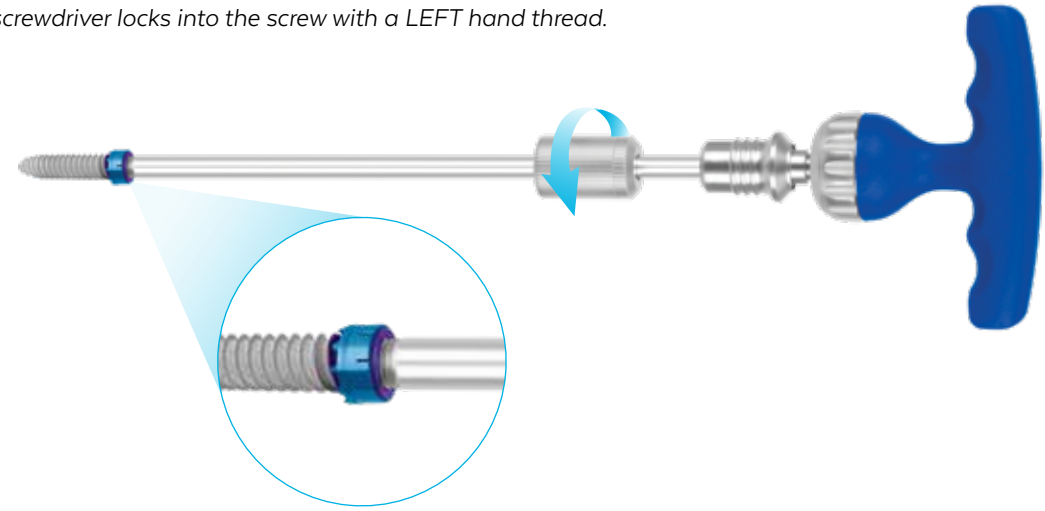
STEP 7 SCREW INSERTION

Screwdriver Assembly

Assemble the **4.0mm Retaining Hex SIJ Driver** to either the **Quick-Connect Ratcheting Handle, Cannulated** (straight handle) or the **Quick-Connect Ratcheting T-Handle**.

Select the appropriate screw type, length, and diameter and assemble it onto the SIJ driver.

Note: The screwdriver locks into the screw with a LEFT hand thread.



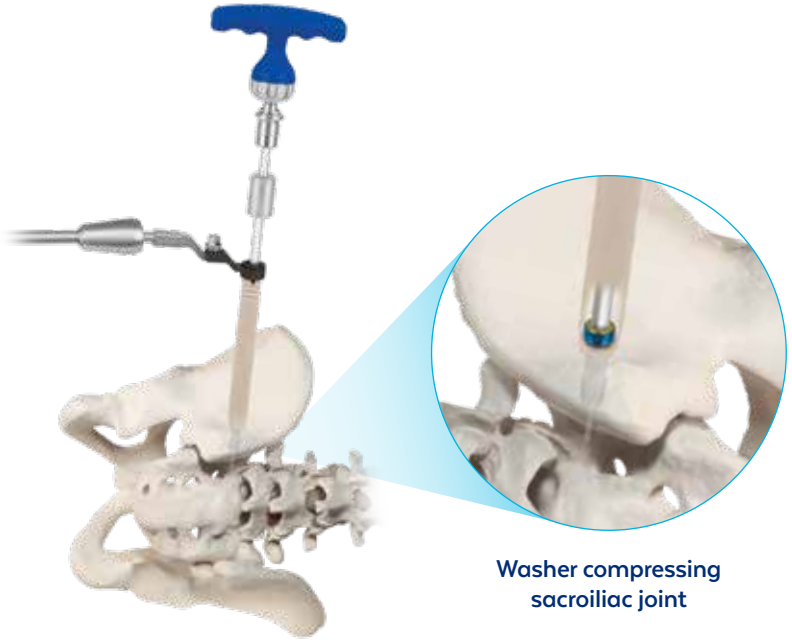
Slotted Screw Graft Preparation

If a slotted screw is used, the **2.4mm Temporary K-Wire, Blunt 150mm** (or similar K-wire) may be placed in the distal end of the screw. Autogenous bone graft from the drill bit or other source is then packed in the graft slot over the K-wire. This will 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 ilium. Verify with straight AP and lateral fluoroscopic views to ensure proper trajectory and placement.

Note: If a slotted screw with autogenous bone graft is used, it is recommended that the screw be placed over the K-wire on the back table or prior to driving the screw through the cannula to avoid displacement of graft material.

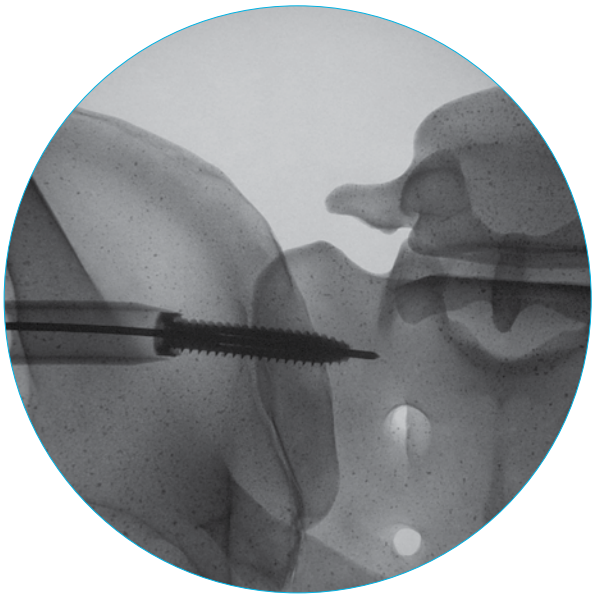


Washer compressing sacroiliac joint

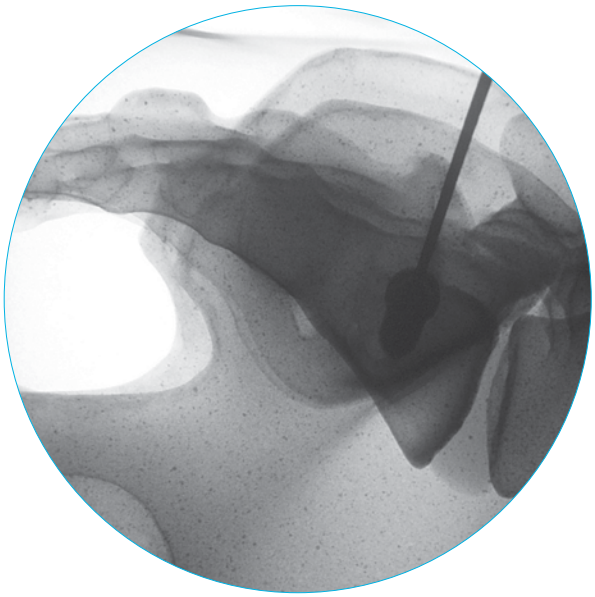
Screw insertion

Detach the driver by placing the ratchet in the neutral or reverse position and rotating the knurled knob clockwise 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.

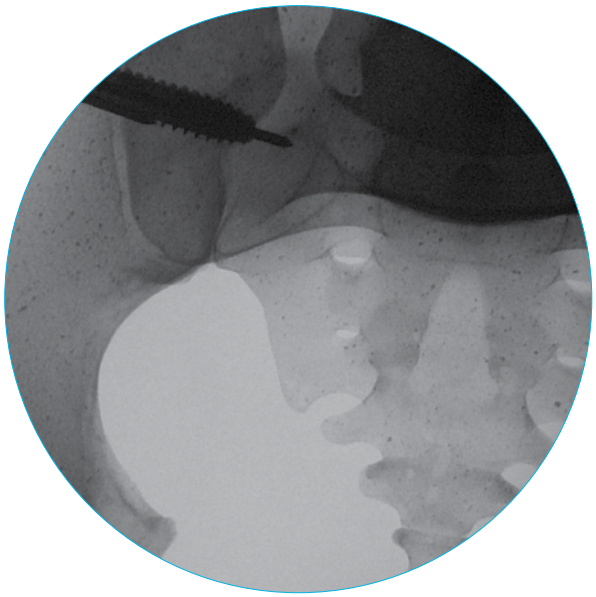
Fluoroscopic Views of First Screw



Outlet view of first screw insertion



Lateral view of first screw insertion



Inlet view of first screw insertion

There are three options: High Load, Hybrid, and High Fusion. The High Load and Hybrid options are described below and the High Fusion option is described on page 31.

High Load Option

Maximize fixation and strength with three solid screws. A lag screw may be used for added strength and/or to compress the joint.

Hybrid Option

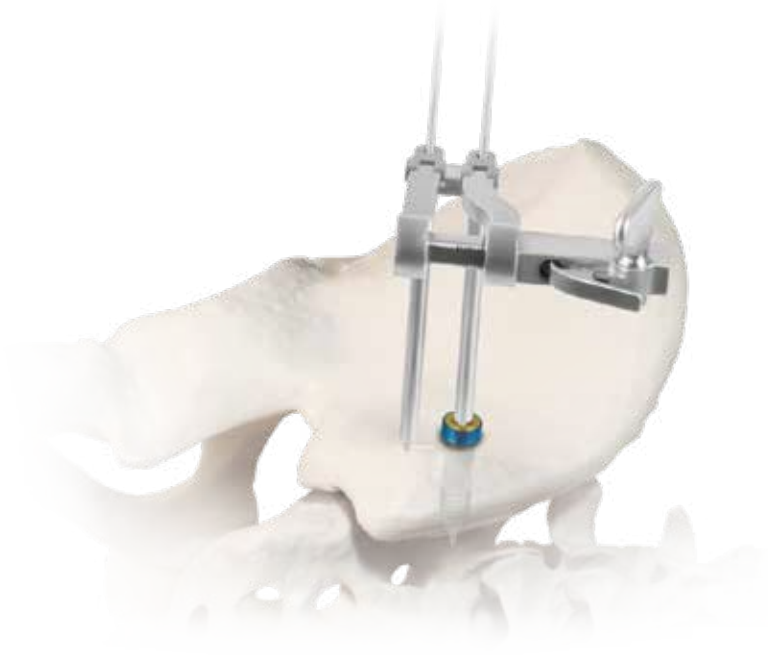
Creates strong fixation while using the fusion capabilities of the slotted screws.

STEP 8 SECOND SCREW INSERTION

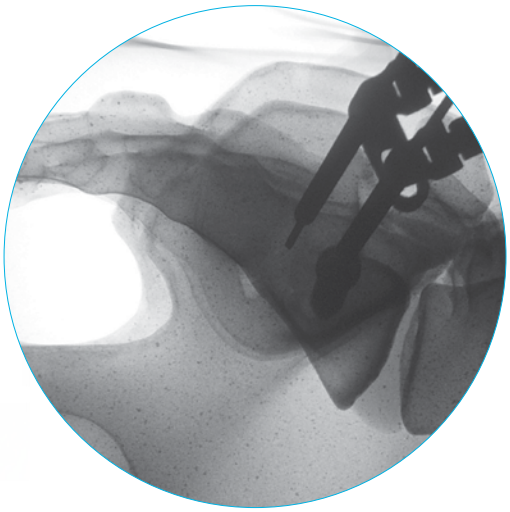
Note: For the High Fusion Option, proceed with Step 8 on page 31.

Choose the **Right** or **Left Screw Hole Alignment Guide** such that it allows the distracting arm to remain up and clear of the fluoroscopic image. The longer cannulated arm of the guide will then be caudal.

It is recommended to adjust the guide separation so that the movable arm is aligned to the demarcation line on the guide to determine the location for the second K-wire. This allows sufficient separation for the larger heads of the 12mm screws. The guide aligns the screws parallel to one another. Place the shorter tube of the guide over the first K-wire to determine the positioning of the second K-wire and screw.



Screw Hole Alignment Guide aligning first and second screws



Lateral view of second K-wire placement

*Note: **Fixed Pin Guide, 10mm/12mm** or **Radiolucent Fixed Pin Guide, 10mm/12mm** may be used instead of the Right or Left Screw Hole Alignment Guide. A **2.5mm Hex Driver** is required to adjust the Fixed Pin Guide.*

Drive the second K-wire and determine if the trajectory is acceptable. Continue to drive to approximately 5mm from the lateral line from the sacral foramen. Remove the guide and first K-wire. Consecutively dilate over the K-wire to a 13mm Cannula. Push the cannula through the skin until the angled tip is flush against the ilium. For a 12mm screw, it is necessary to dilate up to a 15mm Cannula.

Drilling

After determining the screw diameter and length as per Step 5, select the appropriate size Cannulated Drill and attach it to a standard variable speed cannulated power drill. 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 to the sacrum fluoroscopy to ensure correct trajectory.

Place the 2.4mm K-Wire, Blunt 450mm, in the proximal end of the power drill and hold while withdrawing the power drill and drill bit to retain the K-wire in place (from the initial 9mm dilation).

Determine the appropriate length and diameter for the second screw. Pack autogenous bone graft, when applicable, as described in Step 7. With the desired screw loaded onto the hex driver, insert the driver through the cannula, positioning the screw laterally and as posterior as possible, taking care not to enter or encroach upon the S1 foramina.

K-wire aligned for insertion of the second screw

SECOND SCREW INSERTION (CONT'D)

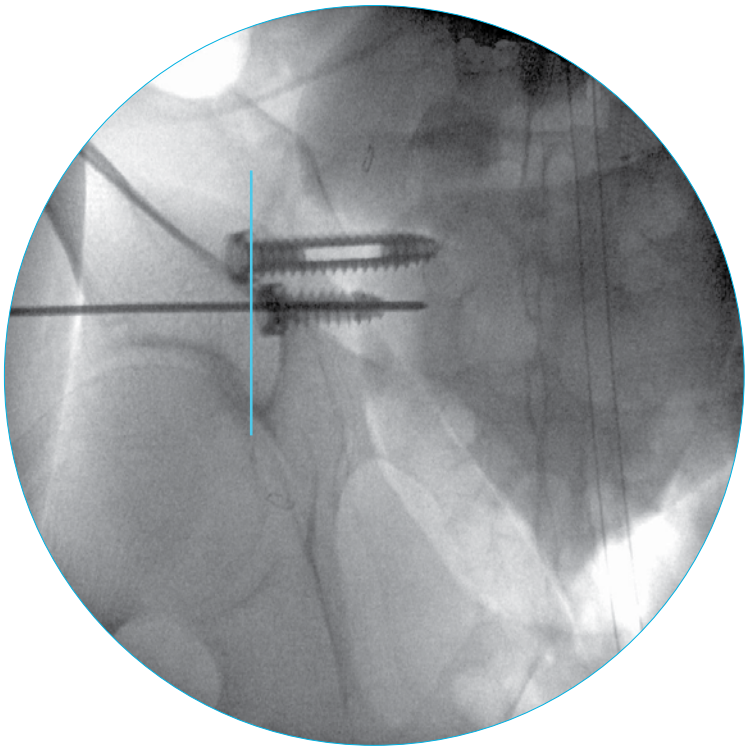
Radiograph

Drive the screw into the SI joint, monitoring its trajectory until the washer engages the ilium. Note the distal tip of the wire as the screw is inserted to ensure it does not advance. Note that the final postion is usually medial to the superior screw without screw head overlap. A snug fit with a slight increase in resistance is expected.

Caution: Do not force the screw through the ilium.

Place the 2.4mm K-Wire, Blunt 450mm in the proximal end of the driver and hold while detaching and withdrawing the driver to retain the K-Wire position.

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



True AP fluoroscopic view showing the second screw positioned laterally. The screw is positioned lateral to the S1 foramina. The screw heads typically trend medially to match the ilium.

STEP 9 THIRD SCREW INSERTION

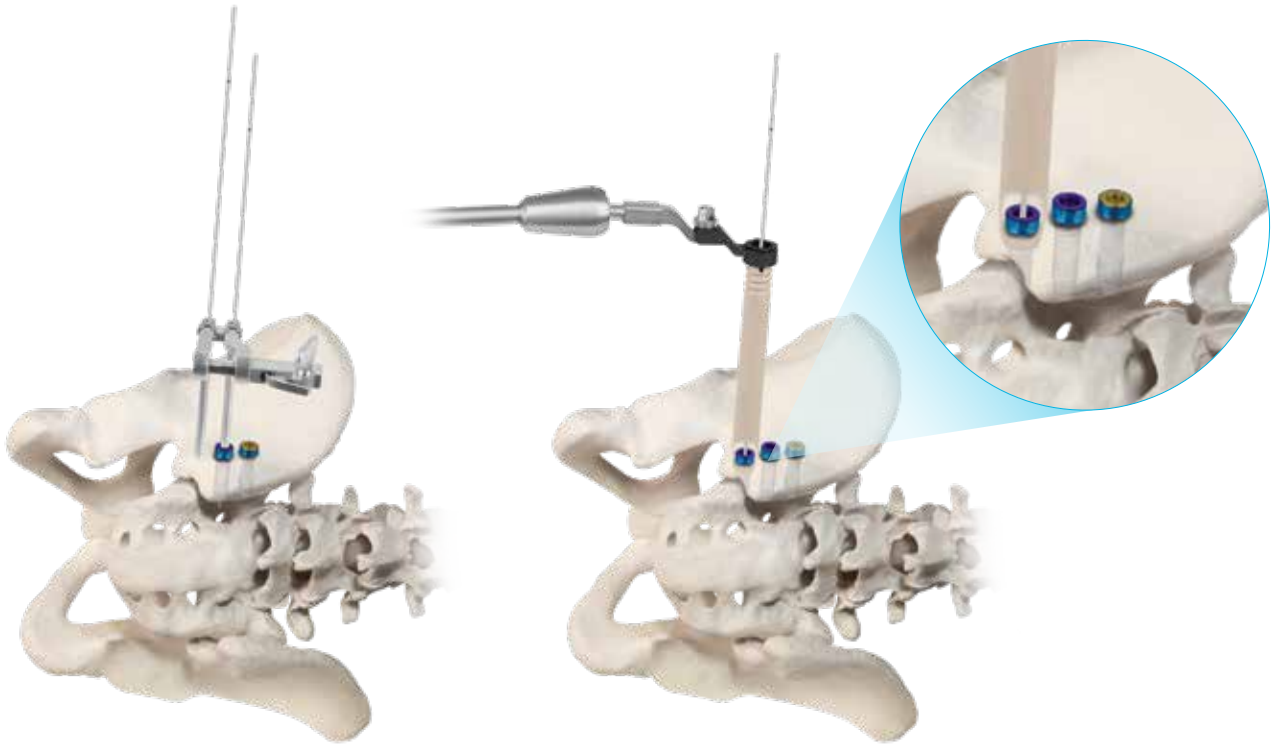
Remove the cannula. Insert the Screw Hole Alignment Guide (shorter cannulated arm) over the second K-wire and into the incision to determine the position of the third screw.

Insert the third K-wire as specified in Step 8. Remove the guide and second K-wire. Dilate and attach the Port Mount as described in Step 4. Measure depth and select the implant diameter and length. Drill a pilot hole over the K-wire, 10mm shorter than the selected screw length or just past the cortices of the joint, per Step 6.*

With the screw attached to the hex driver, insert the driver through the cannula, positioning the screw lateral and inferior to the S1 foramina, with the washer against the ilium, as shown below.

Before detaching the driver, use true AP fluoroscopy of the sacrum and lateral fluoroscopy to ensure proper screw placement.

Detach the driver by rotating the knurled knob clockwise until it disengages from the screw. Remove the cannula and K-wire.

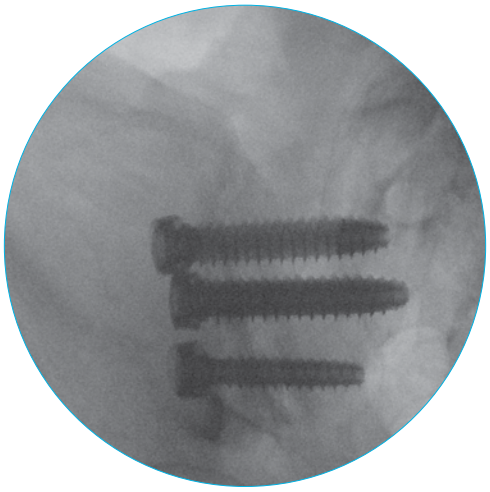


Screw Hole Alignment Guide indicating third screw position

Tissue dilated with the third screw inserted

** When using lag screws, minimize the drill depth to just perforate the sacral cortical wall.*

THIRD SCREW INSERTION (CONT'D)



True AP to the sacrum fluoroscopic view showing the third screw positioned short and below the S1 foramina

It is recommended that a final true AP to the sacrum, lateral, and inlet fluoroscopic views be obtained to confirm the screw positions and the integrity of the sacral boundaries (anterior/posterior notch). If a screw is not properly placed, remove the screw and reinsert a larger diameter and/or different length screw within the sacral boundaries.

FINAL CONSTRUCT

High Fusion Option

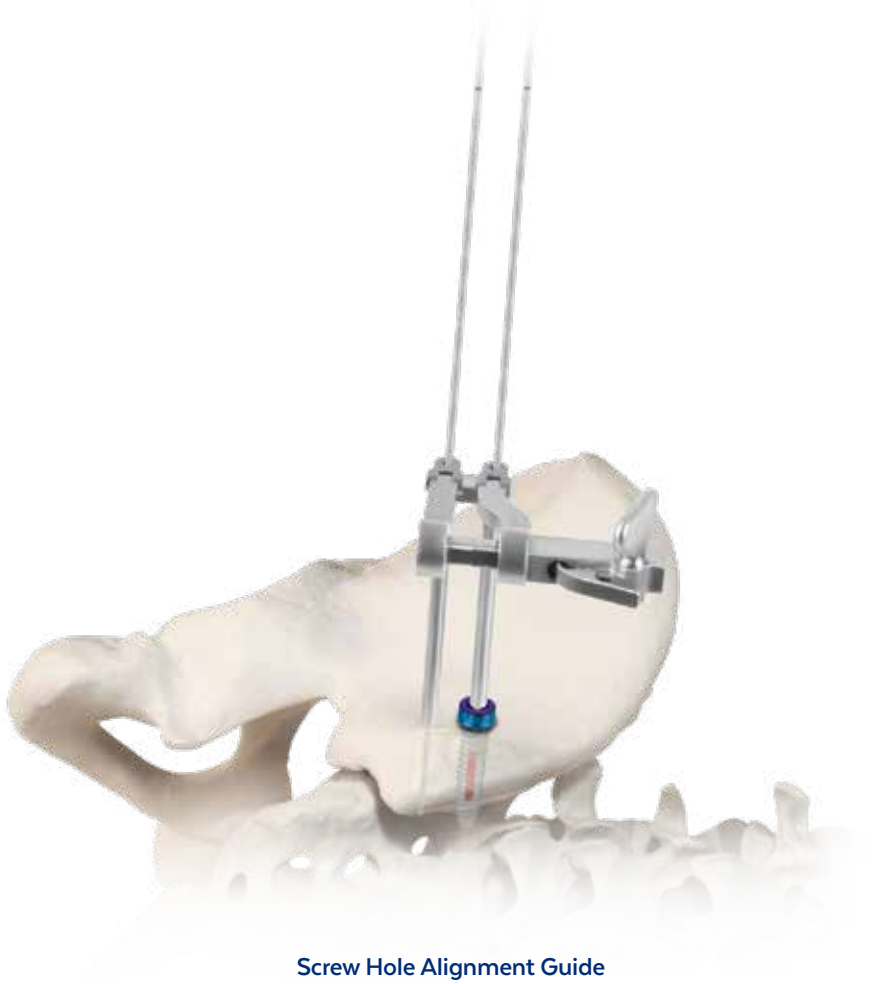
Maximize fusion mass using two HA-coated slotted screws on either end to reinforce a cleared and filled area, sealed with a plug screw.

STEP 8 SECOND K-WIRE INSERTION

Note: Follow steps 1–7 prior to this section.

Remove the cannula, ensuring the K-wire does not advance. Select the Right or Left Screw Hole Alignment Guide so that it remains clear of the fluoroscopic image. The shortest cannulated arm of the guide is placed over the current K-wire. Adjust the guide separation so that the movable arm is aligned to the demarcation line on the guide to determine the location of the second K-wire. The guide aligns the screws parallel to one another.

Drive the K-wire through the cortical wall of the sacrum, until approximately 10mm lateral to the foramen. While holding the second K-wire in place, remove the guide and the first K-wire.



Screw Hole Alignment Guide aligning the first and second screws

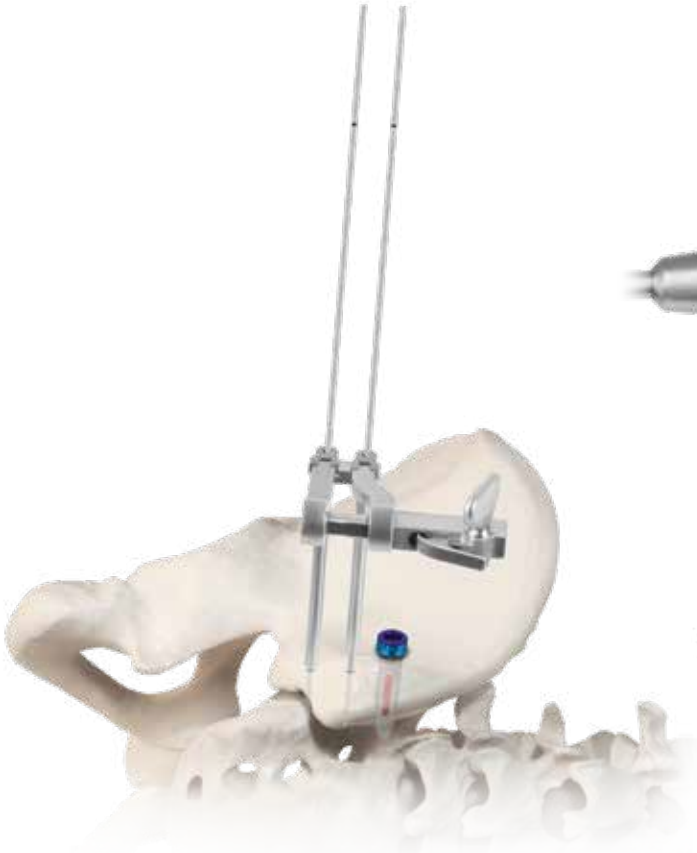
STEP 9 THIRD K-WIRE AND SCREW INSERTION

Noting the intended diameter for the third screw per Step 5, adjust the shorter cannulated arm of the Screw Hole Alignment Guide for the appropriate separation distance according to the screw size. Place the guide over the second K-wire to determine the position of the third screw. Insert the third K-wire and cannula as described in Step 7.

Remove the guide, while ***ensuring the K-wire does not advance***, dilate up to the appropriate cannula and measure the K-wire depth.

Drill over the third K-wire (usually between the S1-S2 foramina upper portion of piriformis), stopping 5-10mm lateral to a line between the two foramina. For a 12mm screw, it is necessary to dilate up to a 15mm Cannula (from the original 9mm dilation).

Attach the appropriate screw to the hex driver and pack the slot as described in Step 7. With the screw mounted, insert the driver over the K-wire and through the cannula, positioning the screw laterally, taking care not to enter or encroach upon the foramina.



Third K-Wire in postion

K-Wire dilated for the third screw

STEP 10 FUSION PREPARATION AND PLUG

Remove the cannula and the third K-wire. Dilate over the second K-wire. Use a **Curette** if necessary to clear cartilage in the sacroiliac joint as desired (see below). Drill to the tip of the K-wire. Pack autogenous bone graft into the joint and drill hole, and into the slots of a 25mm length slotted screw, as described in Step 7. Secure the screw to the hex driver and slide it over the K-wire.

Drive the plug screw while monitoring its trajectory until the washer engages the ilium. Note the distal tip location using lateral fluoroscopy and the screw head position on the AP fluoroscopic view. A snug fit with a slight increase in resistance is expected.

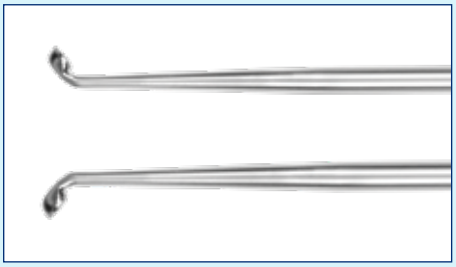
Caution: Do not force the screw through the ilium.

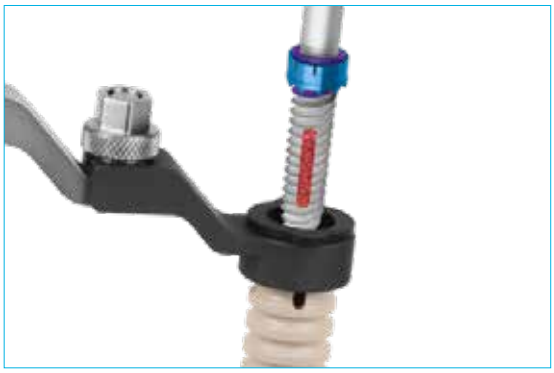
It is recommended that a final true AP to the sacrum, lateral, and inlet fluoroscopic view be obtained to confirm the screw positions and the integrity of the sacral boundaries (anterior/posterior notch). If a screw is not properly placed, remove the screw and reinsert a larger diameter and/or different length screw within the sacral boundaries.

CLEARING CARTILAGE

After final cannula placement, remove the second K-wire. Angled Curettes may be used to clear the SI joint cartilage to enhance fusion.

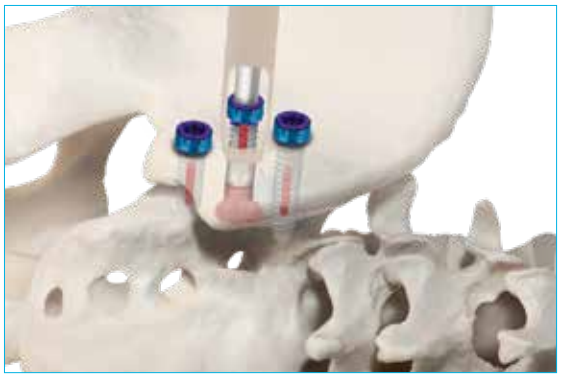
The second K-wire should be inserted across the joint and replaced following this preparation.





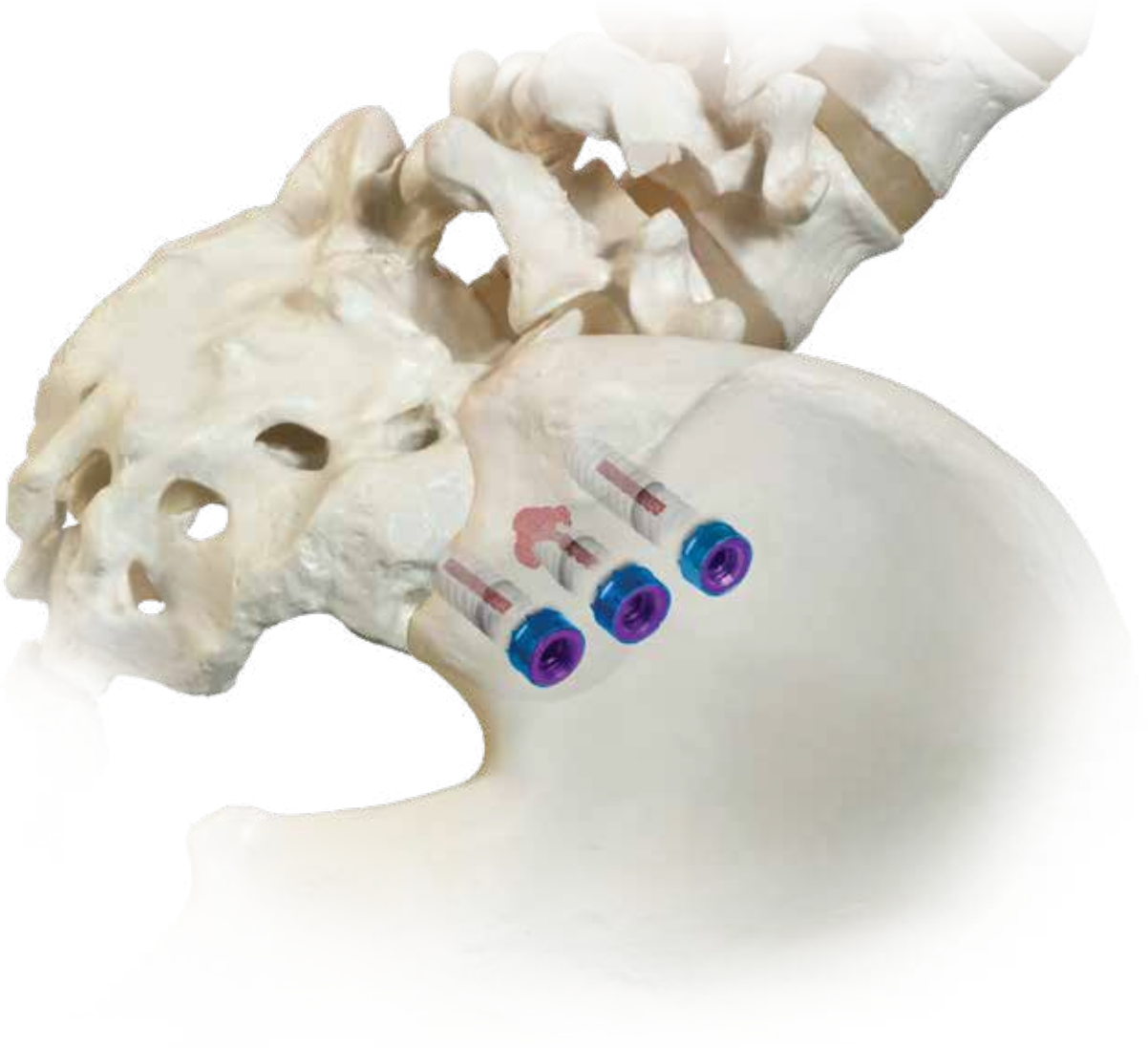
Slotted screw packed with autogenous bone graft

Clearance hole packed with K-Wire in place



Plug screw inserted

FINAL CONSTRUCT



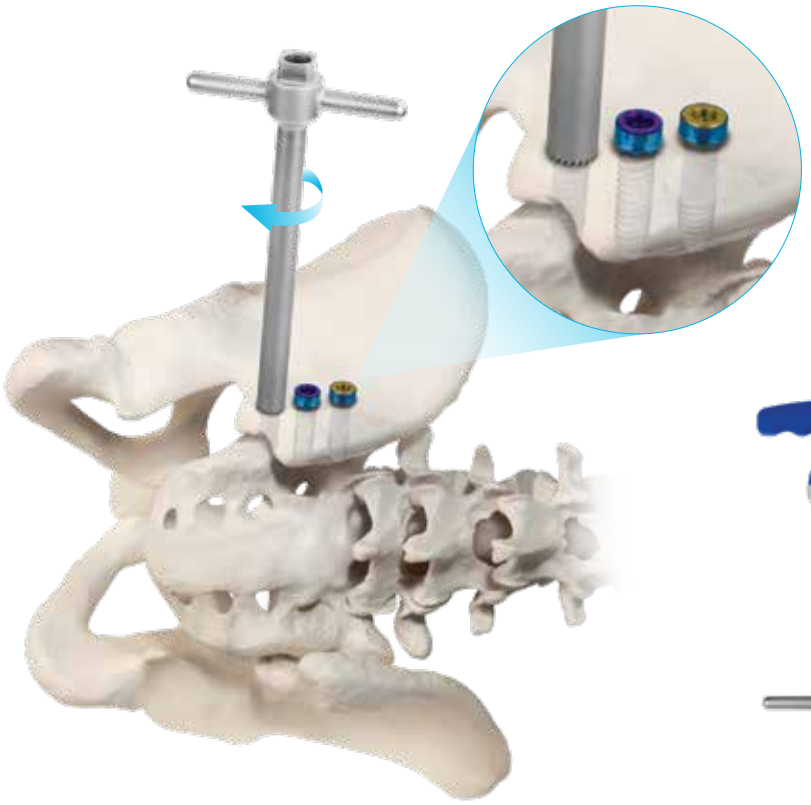
OPTIONAL: SCREW REMOVAL

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

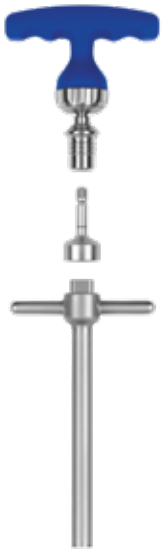
Note: The SI-LOK® washer may separate from the screw upon removal. Use forceps to extract the washer if necessary.

SIJ, Non-Cannulated Driver Shaft

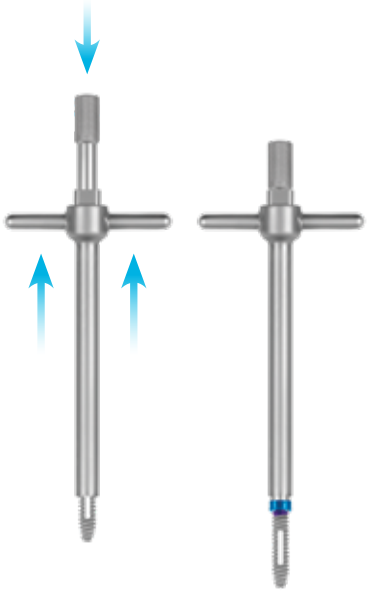
If the Non-Cannulated Hex Driver does not loosen the screw, use a K-wire to locate the screw. Place the **Trephine** over the washer of the screw, center, and rotate clockwise until the Trephine has partially or fully cored the bone around the screw as shown below. A handle may be connected to the **Trephine 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



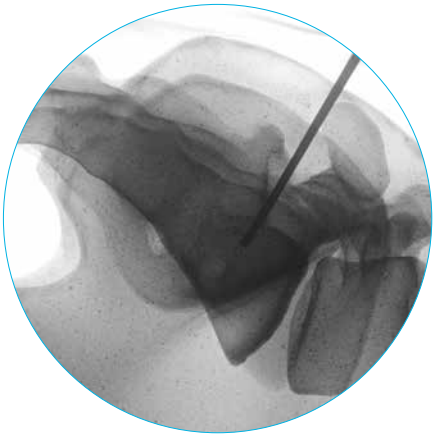
Trephine Attachment



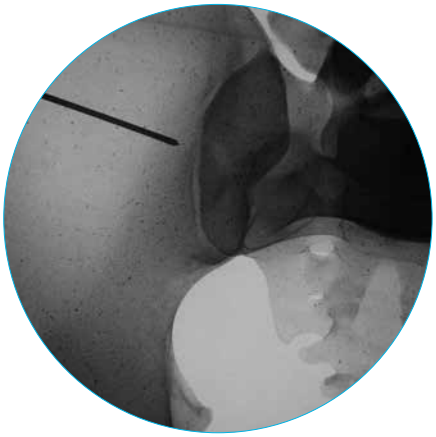
Pusher to remove the Trephine from bone or to remove screw from the Trephine

SI-LOK® SACROILIAC JOINT FUSION SYSTEM

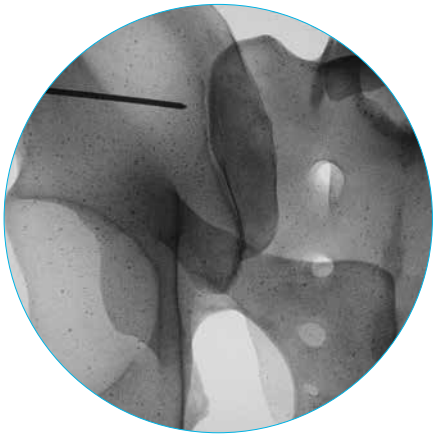
SINGLE C-ARM FLUOROSCOPIC IMAGES



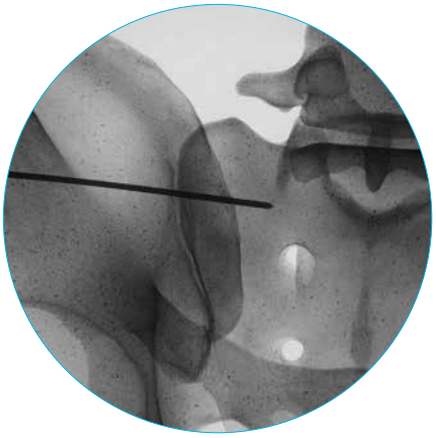
1 - Lateral view of 1st K-wire insertion



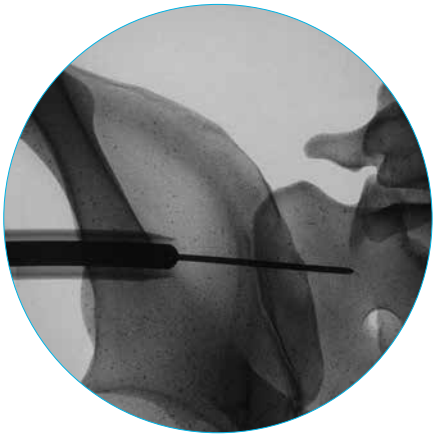
2 - Inlet view of 1st K-wire insertion



3 - Outlet view of 1st K-wire insertion

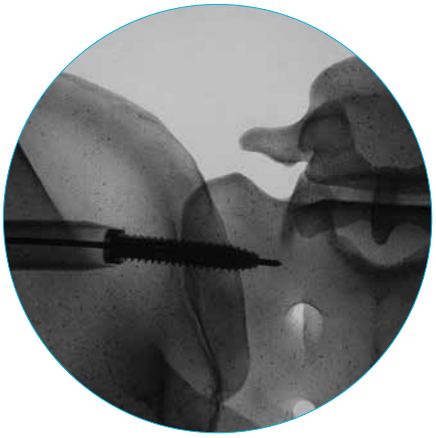


4 - Outlet view of 1st K-wire advanced

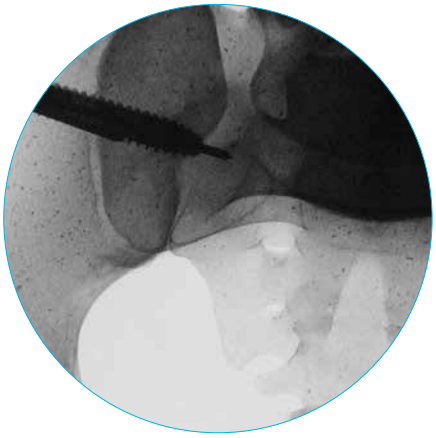


5 - Outlet view of screw sizing

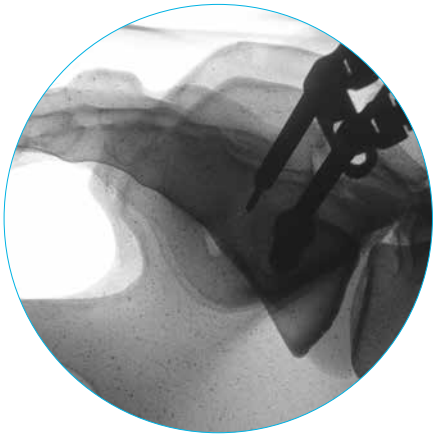
6 - Outlet view of drilling



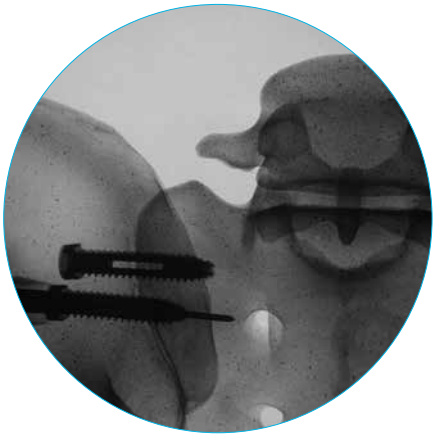
7 - Outlet view of 1st screw insertion



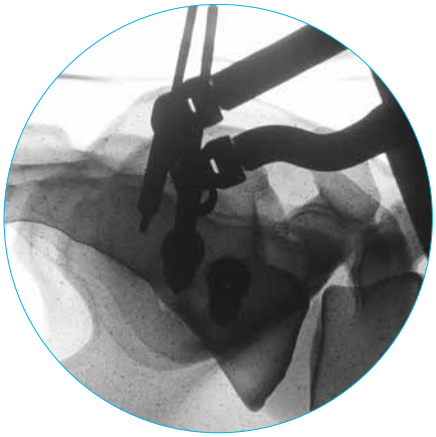
8 - Inlet view of 1st screw insertion



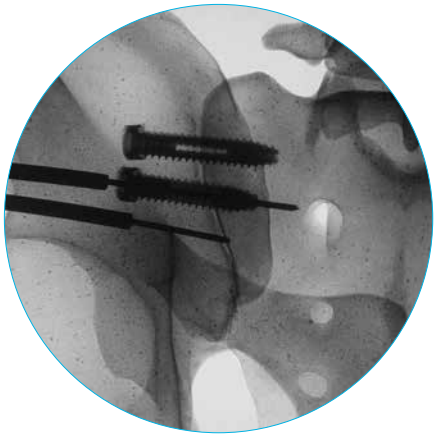
9 - Lateral view of 2nd screw alignment



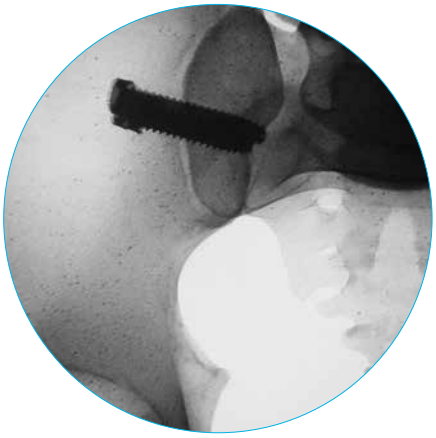
10 - Outlet view of 2nd screw insertion



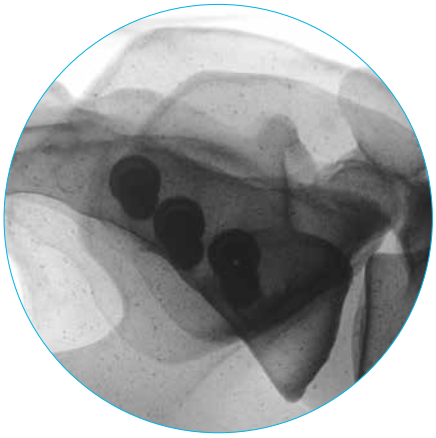
11 - Lateral view of 3rd screw alignment



12 - Outlet view of 3rd screw alignment



Final Inlet



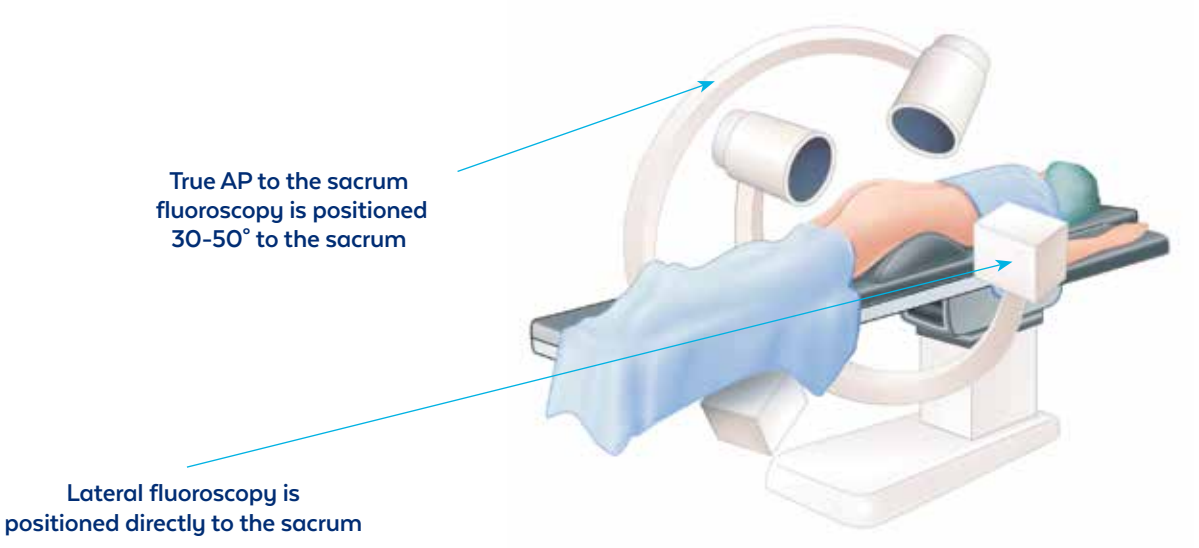
Final Lateral

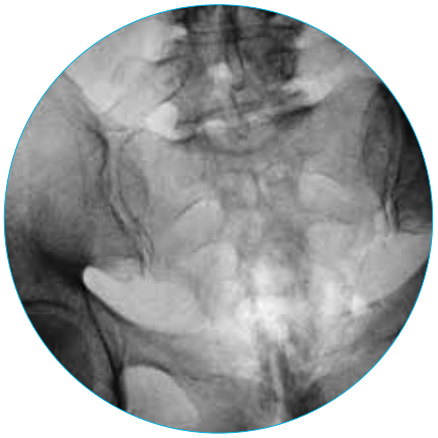
Final Outlet

SI-LOK® SACROILIAC JOINT FUSION SYSTEM

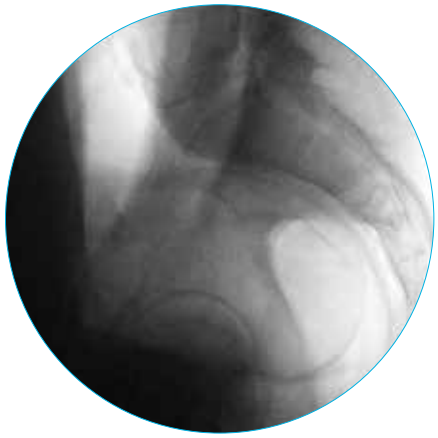
TWO C-ARM SURGICAL TECHNIQUE OPTION

Two C-arms may be used for the SI-LOK® procedure. The surgical steps remain the same as the single C-arm technique.

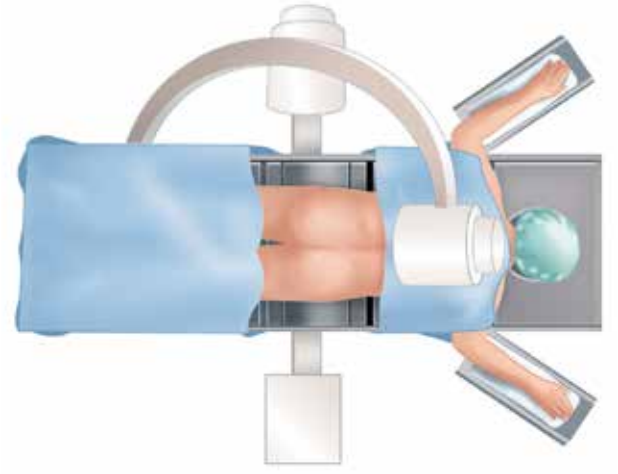




True AP view of the sacrum



Lateral view of the SI joint



Alignment of fluoroscopy on sacral anatomy

ANATOMICAL VARIATIONS

It is important to recognize special anatomical situations that may be present which could affect screw placement in the sacroiliac joint.

LUMBOSACRAL TRANSITIONAL VERTEBRAE

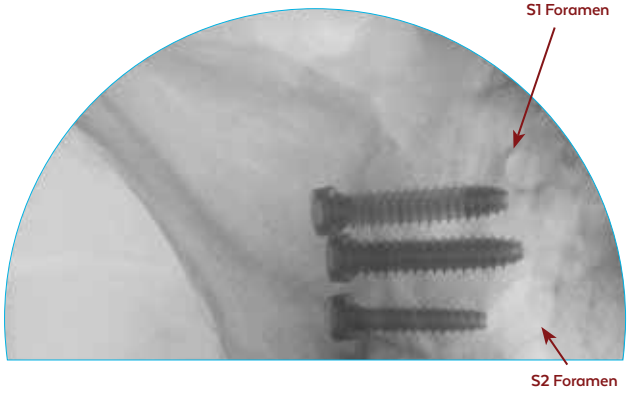
When there is a lumbosacral transitional vertebrae, the source of pain may be external to the SI joint, especially in asymmetrical anatomy. If so, fusion may not be the solution.

There are various types of transitional vertebrae, two of which are described below. In these situations, with SI joints of equal size, SI joint fusion may be useful by making allowances for the anatomical variation. Estimates of the occurrence of lumbosacral transitional vertebrae has been reported to range from 4–24%.[1,2]

Lumbarized Sacrum – S1 vertebra that has failed to fuse with S2

- Implants in the lumbarized S1 or transitional disc are not recommended
- Note presence of S1-2 disc and "squaring" of S1 vertebra
- The ala is targeted more caudally
- The first implant is placed just short of the S1 foramen since the trajectory is at, or caudal to, the foramen

Lumbarized sacrum



Due to transitional S1 vertebra, note the caudal location of first and follow-on screws (relative to S1 foramen)

Sacralized L5

Sacralized L5 – L5 vertebrae fused to sacrum

- Do not estimate the ala location based on L5 or target L5 with the first implant

1. T Kanchan, RG Menezes, KR Nagesh, M Shetty. Lumbosacral transitional vertebrae: clinical and forensic implications. *Singapore Med J* 2009; 50(2): e85-87.
2. R. Hughes, A Sai-fuddin. Numbering of lumbosacral transitional vertebrae on MRI: role of the iliolumbar ligaments. *American Journal of Roentgenology (AJR)* 2006; 187(1): W59-65.

SI-LOK®
IMPLANT SET 939.901

8.0mm SI-LOK® HA Screws

Length	Part Number	Qty
30mm	139.682S	1
35mm	139.683S	1
40mm	139.684S	1
45mm	139.685S	1
50mm	139.686S	0
55mm	139.687S	0
60mm	139.688S	0

10.0mm SI-LOK® HA Screws

Length	Part Number	Qty
30mm	139.702S	1
35mm	139.703S	1
40mm	139.704S	2
45mm	139.705S	2
50mm	139.706S	1
55mm	139.707S	1
60mm	139.708S	1

12mm SI-LOK® HA Screws

Length	Part Number	Qty
30mm	139.722S	1
35mm	139.723S	1
40mm	139.724S	1
45mm	139.725S	1
50mm	139.726S	1
55mm	139.727S	0
60mm	139.728S	0

10.0mm SI-LOK® HA SL Screws

Length	Part Number	Qty
25mm	139.501S	1
30mm	139.502S	2
35mm	139.503S	2
40mm	139.504S	3
45mm	139.505S	3
50mm	139.506S	2
55mm	139.507S	1
60mm	139.508S	1

12.0mm SI-LOK® HA SL Screws

Length	Part Number	Qty
25mm	139.521S	1
30mm	139.522S	1
35mm	139.523S	1
40mm	139.524S	2
45mm	139.525S	2
50mm	139.526S	1
55mm	139.527S	0
60mm	139.528S	0

8.0mm SI-LOK® HA Lag Screws

Length	Part Number	Qty
40mm	139.784S	0
45mm	139.785S	0
50mm	139.786S	0
55mm	139.787S	0
60mm	139.788S	0

10.0mm SI-LOK® HA Lag Screws

Length	Part Number	Qty
40mm	139.804S	1
45mm	139.805S	1
50mm	139.806S	1
55mm	139.807S	1
60mm	139.808S	1

12.0mm SI-LOK® HA Lag Screws

Length	Part Number	Qty
40mm	139.824S	1
45mm	139.825S	1
50mm	139.826S	1
55mm	139.827S	0
60mm	139.828S	0

10.0mm SI-LOK® HA SL Lag Screws

Length	Part Number	Qty
45mm	139.605S	1
50mm	139.606S	1
55mm	139.607S	1
60mm	139.608S	1

12.0mm SI-LOK® HA SL Lag Screws

Length	Part Number	Qty
45mm	139.625S	1
50mm	139.626S	1
55mm	139.627S	0
60mm	139.628S	0

939.001 SI-LOK® Implant Soft Case

Items highlighted in gray are additionally available


GLOBUS
MEDICAL
SI-LOK™ IMPLANT SET
Life moves us


SI-LOK™

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
	639.008 (not shown)	2.4mm K-Wire, 450mm, Blunt Tip	2

	Drill Bits and Taps		QTY
8	639.011	K-Wire Depth Gauge	1
9	639.208	8.0mm Cannulated Tap	1
10	639.210	10.0mm Cannulated Tap	1
11	639.212	12.0mm Cannulated Tap	1
12	639.215	5.5mm Cannulated Drill	1
13	639.216	6.5mm Cannulated Drill	1
14	639.217	7.5mm Cannulated Drill	1
15	639.218	8.5mm Cannulated Drill	1
16	639.219	9.5mm Cannulated Drill	1
17	639.220	10.5mm Cannulated Drill	1
18	639.407	Quick-Connect Adaptor	1

	Cannulas		QTY
19	632.150	10mm Socket Driver	1
20	639.114	Fixed Port Mount Cannula	1
21	639.315	Cannula, MARS™, 15mm ID	1
22	639.413	Port Mount Handle	2
23	639.415	Port Mount, 15mm	1
24	647.205	Cannula, 5mm	1
25	647.209	Cannula, 9mm	1
26	647.313	Cannula, MARS™, 13mm ID	1
27	647.413	Port Mount, 13mm	1
28	647.513	Port Lock, 13mm	1
29	647.515	Port Lock, 15mm	1

	Implant Instrument		QTY
30	639.650	4.0mm Retaining Hex SIJ Driver	2
31	639.651	SIJ, Non-Cannulated Driver Shaft	1

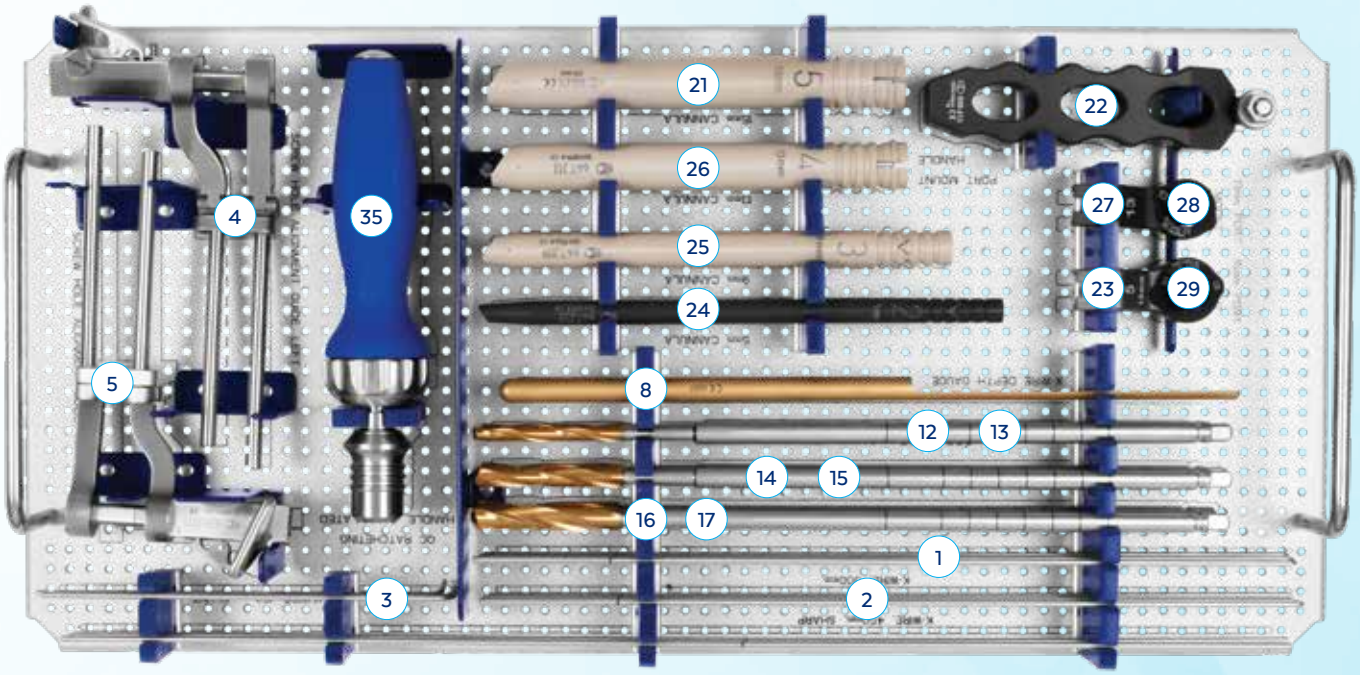
	SI Joint Prep Instruments		QTY
32	639.020	Up Angle Curette	1
33	639.021	Down Angle Curette	1

	Quick-Connect Handles		QTY
34	630.401	Quick-Connect Ratcheting T-Handle	1
35	630.407	Quick-Connect Ratcheting Handle, Cannulated	1
36	634.611	Torque Limiting T-Handle, Ratcheting, 8Nm, 1/4" Connect, Black	1

939.002 SI-LOK® Instrument Graphic Case

ADDITIONALLY AVAILABLE INSTRUMENTS

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
639.060	Fixed Pin Guide, 12mm
639.201	Cannula, 2.5mm ID
639.209	9.0mm Cannulated Tap
639.211	11.0mm Cannulated Tap
652.220	Wrench
639.500	Radiolucent Fixed Pin Guide, 10mm
639.600	Radiolucent Fixed Pin Guide, 12mm
639.900	Trephine Attachment
639.903	Pusher, SI-LOK® Removal
639.904	Trephine, SI-LOK® Removal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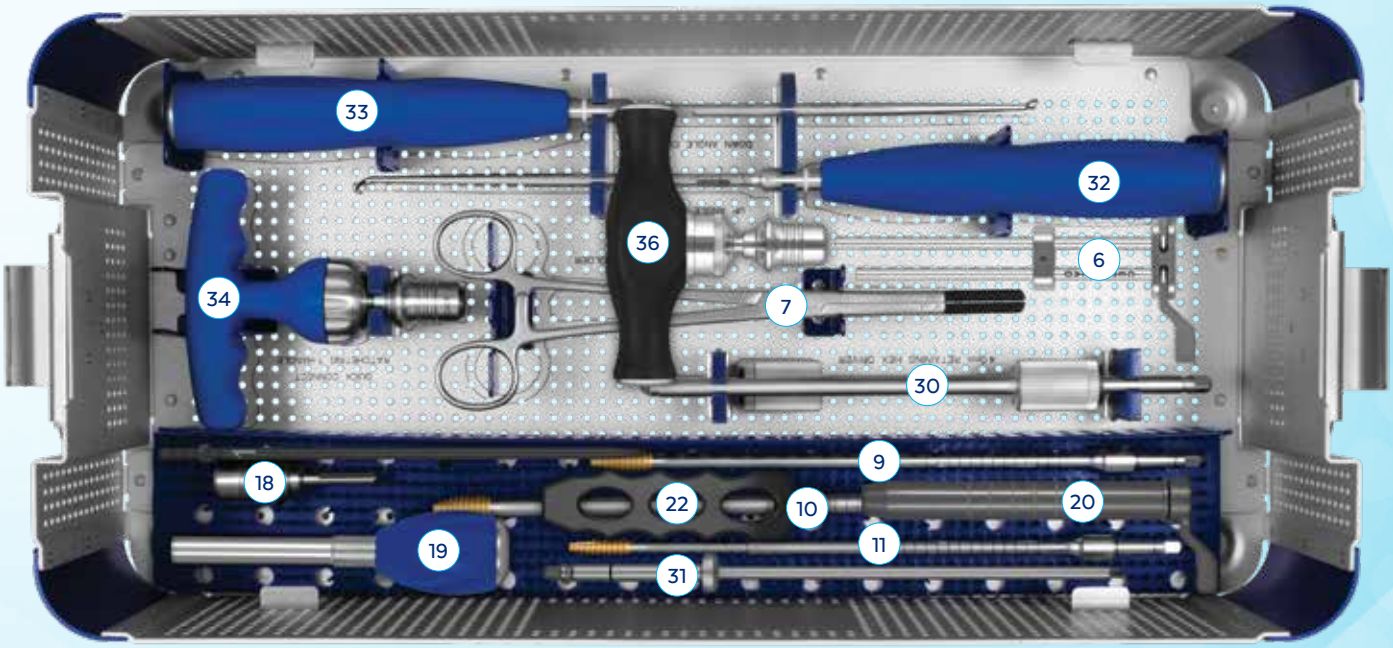
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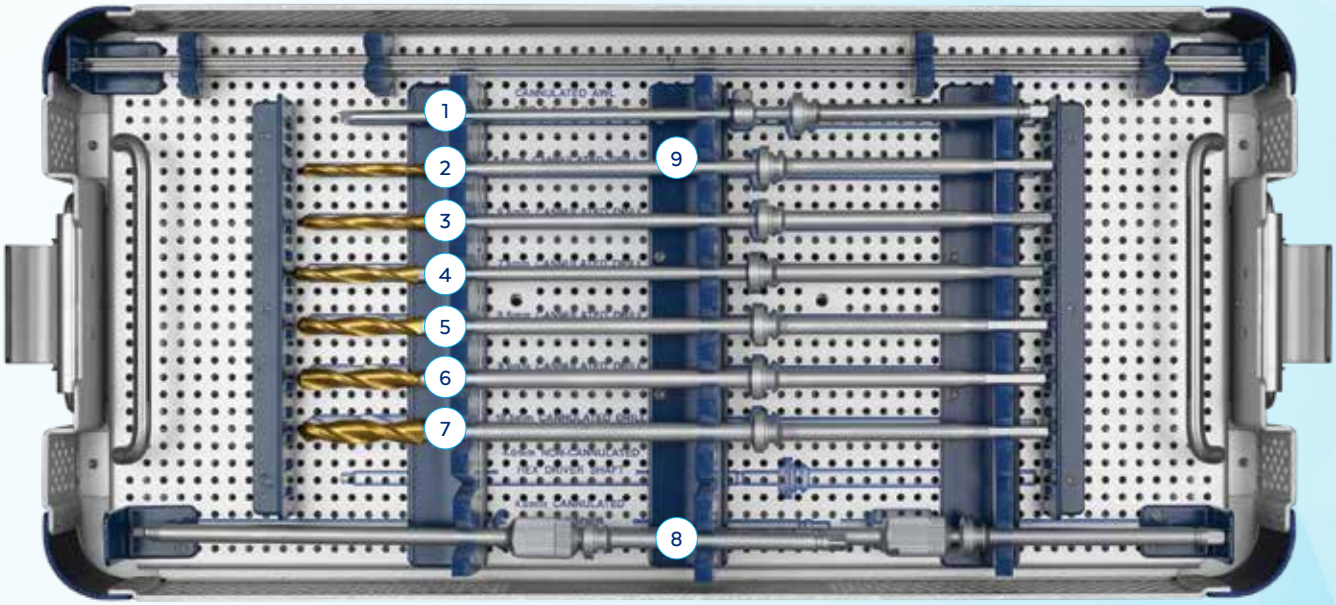
GUIDED INSTRUMENTS
INSTRUMENT VI SET 9123.9006

	Instruments		QTY
1	6123.1600	Cannulated Awl for 2.4mm K-wire, GI 1	1
2	6123.1615	5.5mm Cannulated Drill, GI 1	1
3	6123.1616	6.5mm Cannulated Drill, GI 1	1
4	6123.1617	7.5mm Cannulated Drill, GI 1	1
5	6123.1618	8.5mm Cannulated Drill, GI 1	1
6	6123.1619	9.5mm Cannulated Drill, GI 1	1
7	6123.1620	10.5mm Cannulated Drill, GI 1	1
8	6123.1650	4.0 Cannulated Hex Driver, GI 1 (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, GI 1 (SI-LOK)	

Refer to the Guided Instruments (GI1) Technique Guide for more information and instructions for use (GMTGD158).

Items highlighted in gray are additionally available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IMPORTANT INFORMATION ON SI-LOK® SACROILIAC JOINT FIXATION SYSTEM

DESCRIPTION

The SI-LOK® Sacroiliac Joint Fixation System consists of screws designed to enhance sacroiliac joint fusion and to provide fixation of large bones and large bone fragments of the pelvis. The cannulated partially threaded or fully threaded screws contain a pre-assembled contouring washer, and are offered in various diameters and lengths to accommodate patient anatomy. Optional screws may be used for supplemental screw fixation.

The SI-LOK® Sacroiliac Joint Fixation System screws and pre-assembled contouring washers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The screws in the SI-LOK® system 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 sacroiliitis.

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.

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

MR Unsafe

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 and instruments 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 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.

IMPORTANT INFORMATION ON SI-LOK® SACROILIAC JOINT FIXATION SYSTEM

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 and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments 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 foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

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		PRESCRIPTION USE ONLY

DI158 REV E

NOTES

NOTES

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Audubon, PA 19403
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28 Trinity Road, Nailsea, Somerset, BS48 4NU England

CE 0297

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