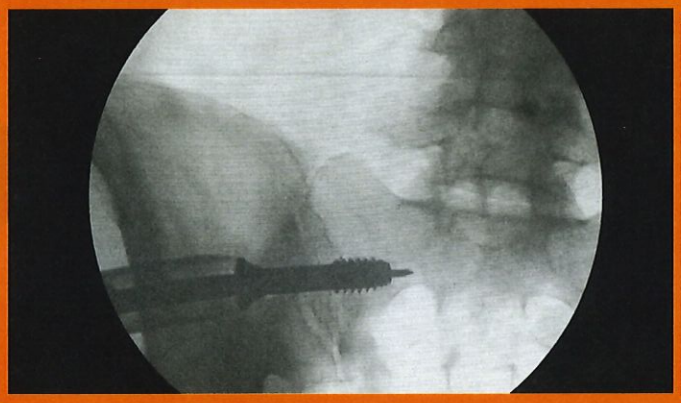
SICONUS™

SI JOINT FIXATION SYSTEM



SURGICAL TECHNIQUE GUIDE

Camber Spine

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IMPORTANT INFORMATION

NON STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The SICONUS™ SI Joint Fixation System is a threaded bone screw used to provide structural stability in skeletally mature individuals. The SICONUS™ SI Joint Fixation System is comprised of implants of various diameters and lengths to fit the needs of individual patient anatomy. The bone screws are designed as a highly compressive screw with a hollow cannulation which are applied to the Sacroiliac Joint to provide long-term fixation and stabilization in order to initiate fusion. Fenestrations on the larger diameter bone screw are designed to allow bone growth through the implant.

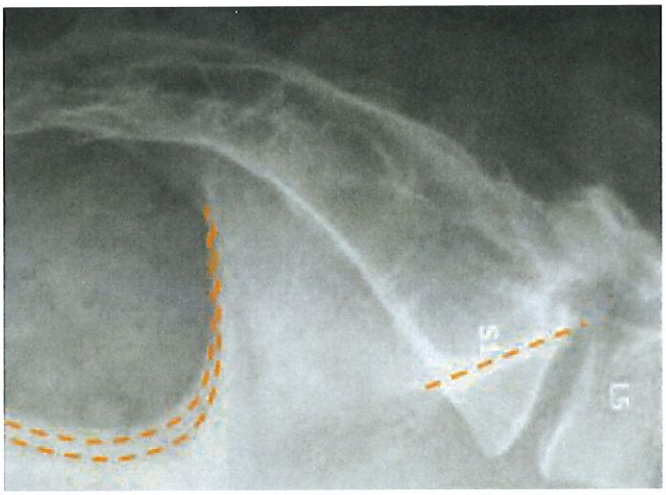
MATERIALS

The Camber Spine Technologies SICONUS™ SI Joint Fixation System are manufactured from a Titanium alloy (Ti-6Al-4V) per ASTM-F136.

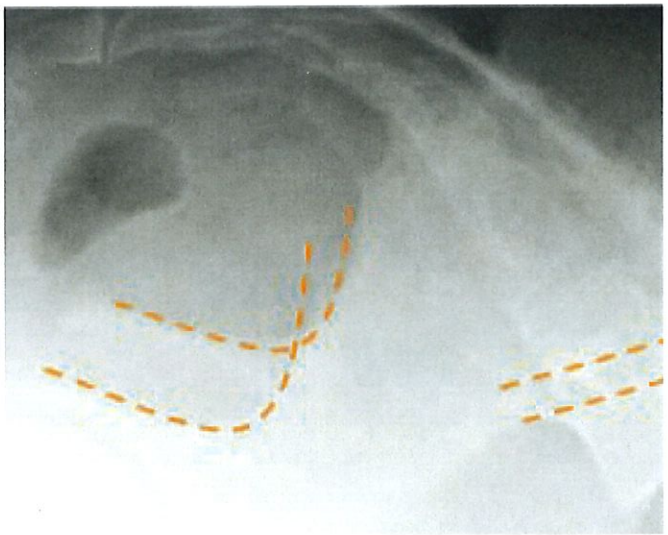
APPROACH

LATERAL ALIGNMENT

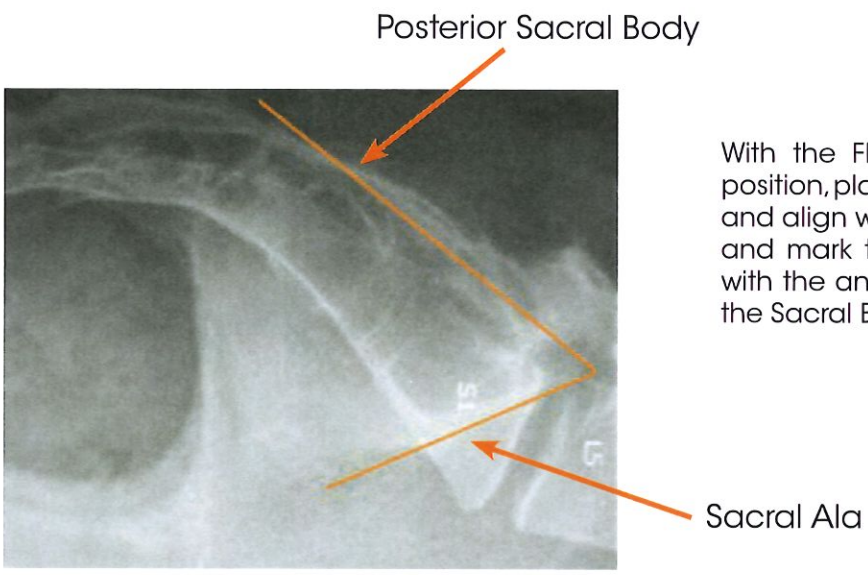
With the patient in the prone position, align the Fluoroscope with the location of Sacroiliac Joint. Ensure the Fluoroscope is directly lateral by aligning the right and left Sciatic Notches and Sacral Ala.



Correct Alignment



Incorrect Alignment



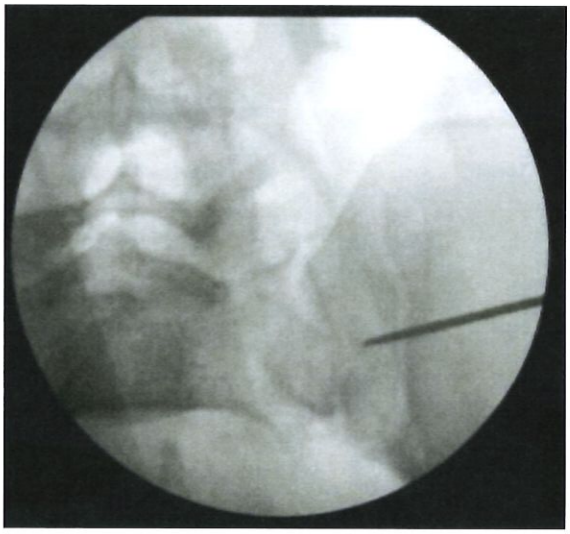
With the Fluoroscope still in the lateral position, place a Guide Wire along the skin and align with the angle of the Sacral Ala and mark the skin. Align the Guide Wire with the angle of the posterior surface of the Sacral Body and mark the skin.

STEINMANN PIN INSERTION

STEINMANN PIN ANGULATION

Make a 35 mm incision along the Posterior Sacral Body line starting approximately 10mm inferior to the Sacral Ala line.

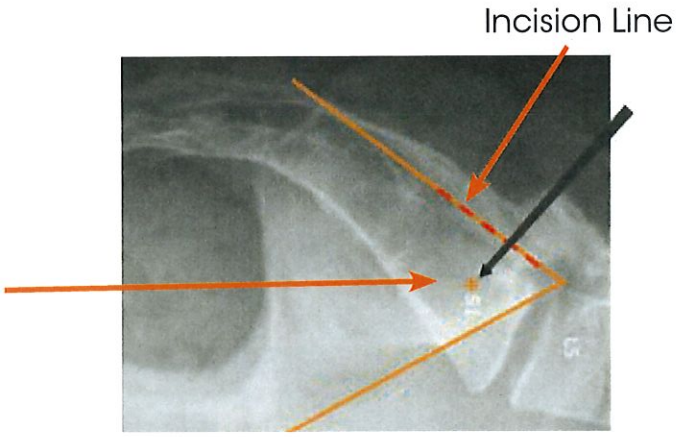
Insert a Ø2.4mm Trocar Tipped Steinmann Pin (SCL-130-101, 400) through the lateral tissue to the surface of the Ilium. The Pin should be angled approximately 10° from the Coronal Plane and perpendicular to the Anterior Sacral wall. The Pin tip shall contact the Ilium 5-10mm anterior of the Posterior Sacral wall.



Correct direction of the Steinmann Pin toward the anterior portion of the Sacral Body

Before driving the Pin, confirm the angle and location of the Pin using Lateral, Inlet, and Outlet fluoroscopic imaging of the Sacroiliac joint. The Pin should be angled toward the anterior portion of the Sacral Body.

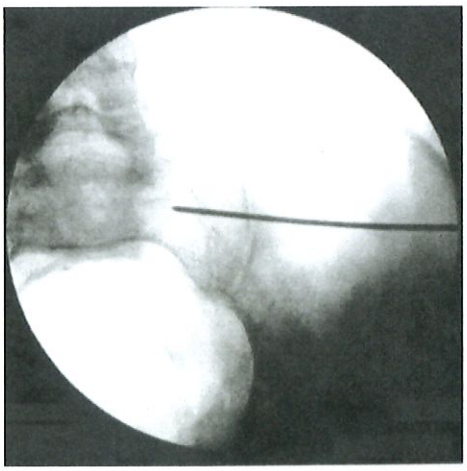
Location of the tip of Ø2.4 mm Steinmann Pin as it contacts the Ilium



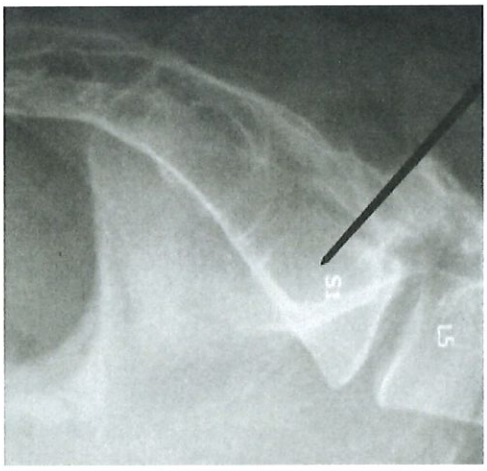
STEINMANN PIN INSERTION

When the location and direction of the Pin are confirmed, drive the Pin through the Ilium into the Sacrum. The Pin can be inserted above or between the Foramen of the Sacrum, but a minimum distance of at least 5mm should be maintained from the Pin to the edge of the nearest Sacral Foramen. During insertion, constantly confirm the location and direction with Lateral, Inlet, and Outlet Views using fluoroscopic imaging.

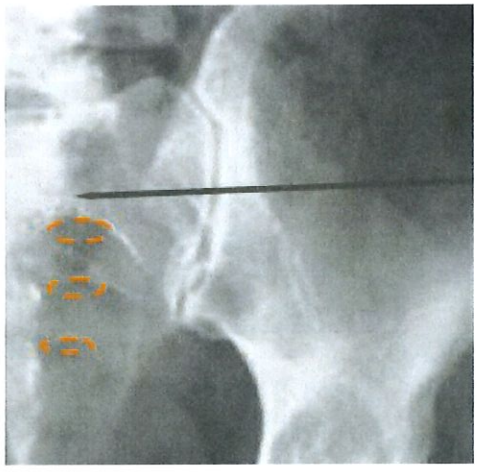
CAUTION: During insertion, maintain the recommended minimum distance of 5mm from the Foramen. If the Pin is approaching a Sacral Foramen remove it and reset the Pin to the correct angle or location.



Inlet View



Lateral View

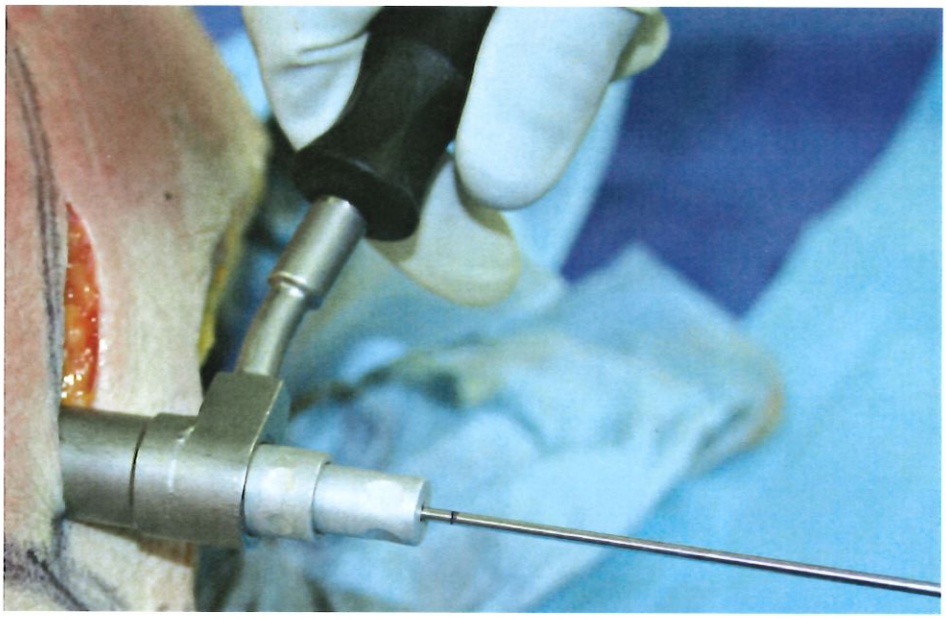


Outlet View

LARGE SCREW INSERTION

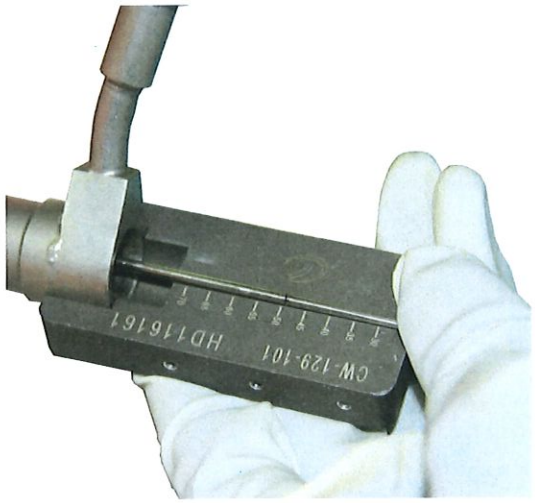
DILATION

Insert the Primary Dilator (SCL-119-101) over the Steinmann Pin and through the periphery tissue until it contacts the Ilium. Insert the Secondary Dilator (SCL-119-102) and the Tertiary Dilator (SCL-119-103) in the same manner. If desired, the Handle Dilator (SCL-119-106) can be used in place of the Tertiary Dilator. After all three Dilators are in place, remove the two inner Dilators leaving the Pin and the Tertiary Dilator or Handle Dilator in place.



LARGE SCREW DEPTH MEASUREMENT

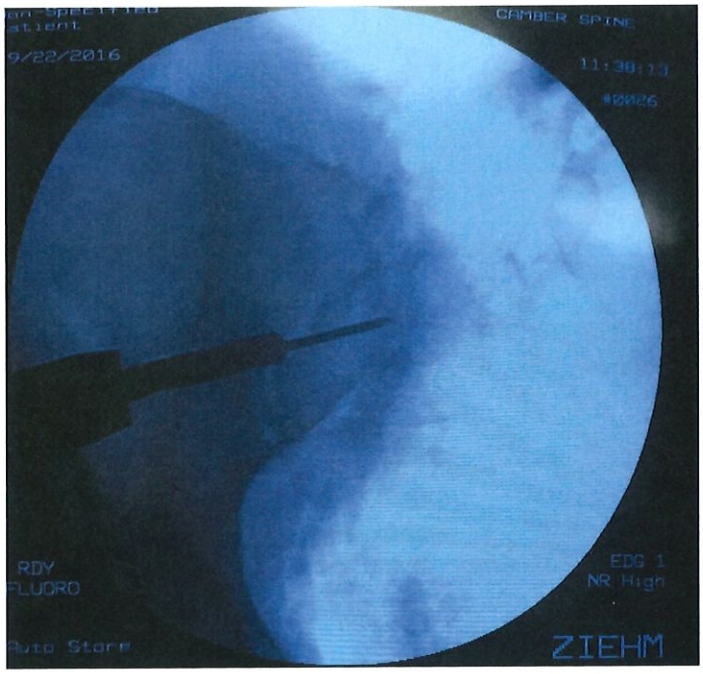
Place the Depth Gauge (SCL-129-101) on the end of the Tertiary Dilator and hold the Dilator against the Ilium. Read the measurement on the Depth Gauge. This reading corresponds to the depth of the Pin tip past the end of the Dilator, and ultimately the depth of the Drill Bit and length of Screw to be used in subsequent steps.



SCREW PREPARATION

Drill through the Ilium and into the Sacrum using the Ø11mm Drill Bit (SCL-125-104). Use the laser markings on the side of the Drill Bit to control the depth relative to the end of the Tertiary Dilator. Use continual A/P fluoroscopic imaging to confirm that Drill Bit is not proceeding into the Sacral Foramen, and that the Pin is not translating axially while drilling. If necessary, hold the proximal end of the Pin where it protrudes from the back of the drill.

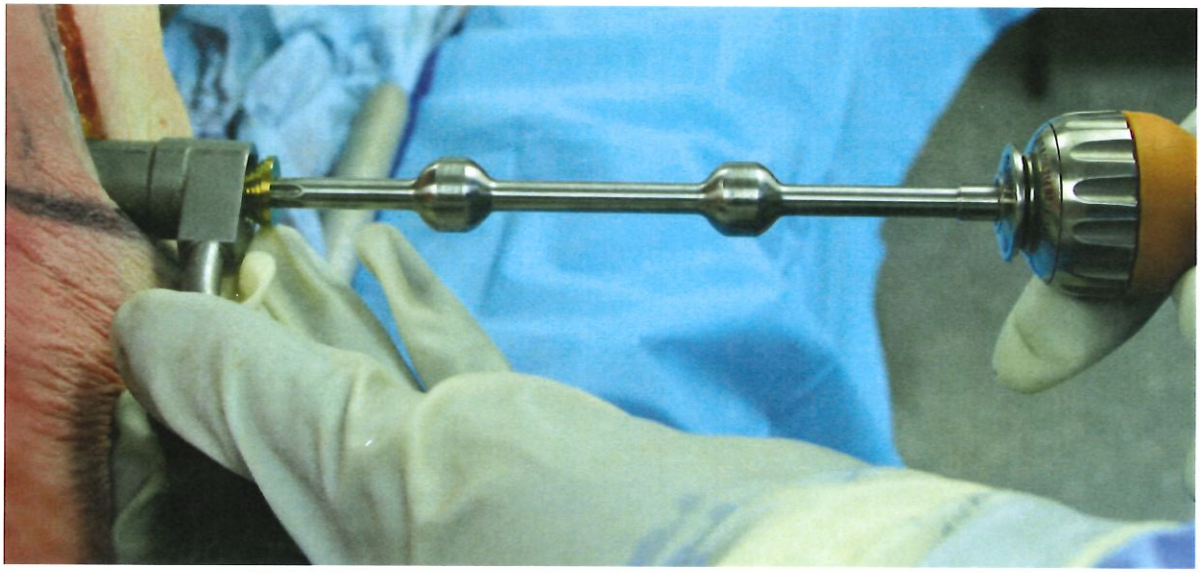
Caution: Constantly review A/P fluoroscopic imaging during this step to prevent axial translation of the Pin and drilling into the Sacral Foramen.



LARGE SCREW INSERTION

Select a large Ø11mm Screw (SCL-11-XXX) based on the length measured previously. If desired, pack the fenestration of the Screw with autograft from the drilling process. Attach the Ø11mm Driver (SCL-103-102) to the Ratcheting T-handle (CP-100-34). Place the selected Screw on the Driver, insert over the Pin and through the Tertiary Dilator.

Engage the Screw in the drilled hole and advance the Screw, rotating it clockwise until the proximal face of the Screw is flush with the Ilium. Confirm with fluoroscopy.



SMALL SCREW INSERTION

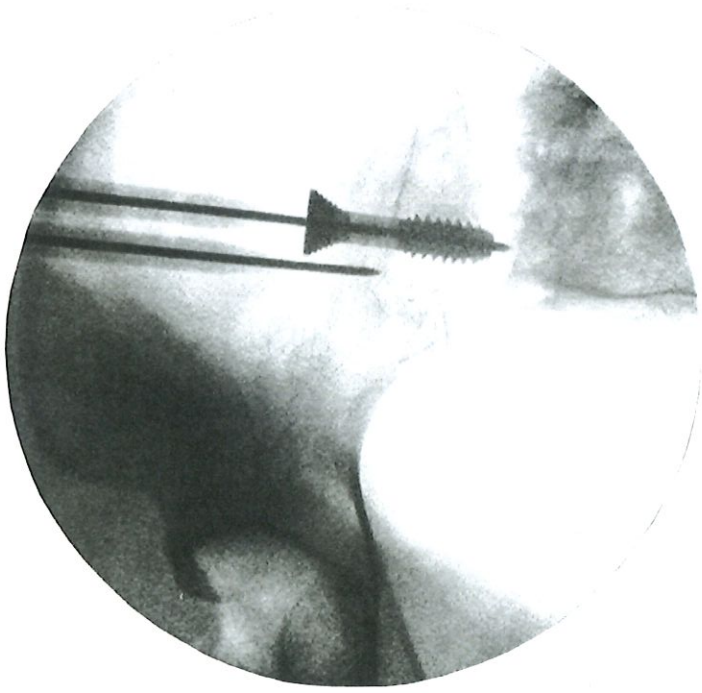
SECOND PIN POSITION

With the first Screw firmly in place, use the Pin Positioner (SCL-131-101) to determine the location of the second Pin. Place the Pin Positioner over the end of the Steinmann Pin in the large Screw.

Align the second hole of the Pin Positioner in line with the Posterior Sacral Body mark on the skin. Insert the Pin Positioner through the tissue so that it contacts the Ilium and verify its location using lateral fluoroscopy. Place a second Steinmann Pin through the second hole of the Pin Positioner.

Drive the Pin through the Ilium and into the Sacrum until firmly in place. Continually confirm the location and direction with Lateral, Inlet, and Outlet fluoroscopic imaging. Use the inlet view to adjust the angle of the second Pin to direct it toward the anterior portion of the Sacral Body.

Remove the Pin Positioner and the first Pin after inserting the second Pin firmly into the Sacrum.

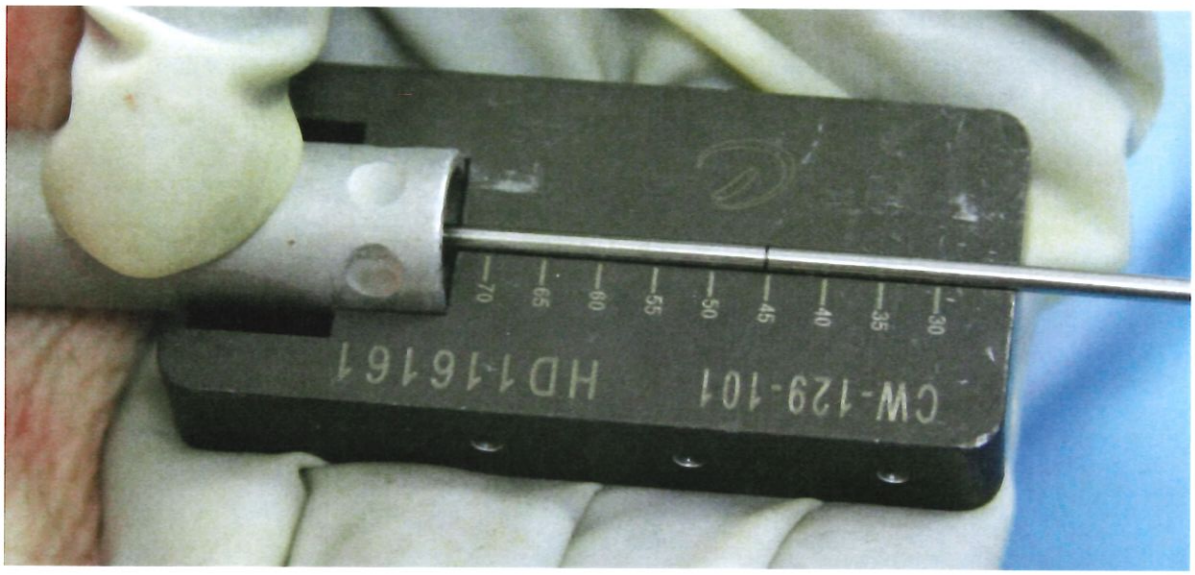


Outlet View

Lateral View

SMALL SCREW DILATORS AND DEPTH

When using a small Ø7mm Screw, insert only the Primary and Secondary Dilators over the Pin. Remove the Primary Dilator and place the Depth Gauge on the end of the Secondary Dilator. Read the measurement on the Depth Gauge. This reading corresponds to the depth of the Steinmann Pin tip past the end of the Secondary Dilator, and ultimately the depth of the Drill Bit and Screw to be used in subsequent steps.



OPTIONAL DRILLING FOR SMALL SCREWS

The Ø7mm Screws have a self-drilling tip but can be inserted in a drilled hole using the Ø7mm Drill Bit (SCL-125-101) .

If the drilling option is chosen, drill through the Ilium and into the Sacrum using the Ø7mm Drill Bit. Use the gauge on the side of the Drill Bit to control the depth relative to the end of the Secondary Dilator. Use continual A/P fluoroscopic imaging to confirm that Drill Bit is not directed toward the Sacral Foramen, and that the Steinmann Pin is not translating axially while drilling. Hold the proximal end of the Pin where it protrudes from the back of the drill.

Caution: Constantly review A/P fluoroscopic imaging during this step to prevent axial translation of the Pin and drilling into the Sacral Foramen.

SMALL SCREW INSERTION

Select a Small Ø7mm Screw (SCL-07-XXX) based on the length measured previously. Attach the Ø7mm Driver (SCL-103-101) to the Ratcheting T-handle (CP-100-34). Place the selected Screw on the Driver, insert over the Pin and through the Secondary Dilator.

Advance the Screw, rotating it clockwise until the proximal face of the Screw is flush with the Ilium. Confirm with fluoroscopy.

ADDITIONAL PIN INSERTION

ADDITIONAL PIN LOCATION

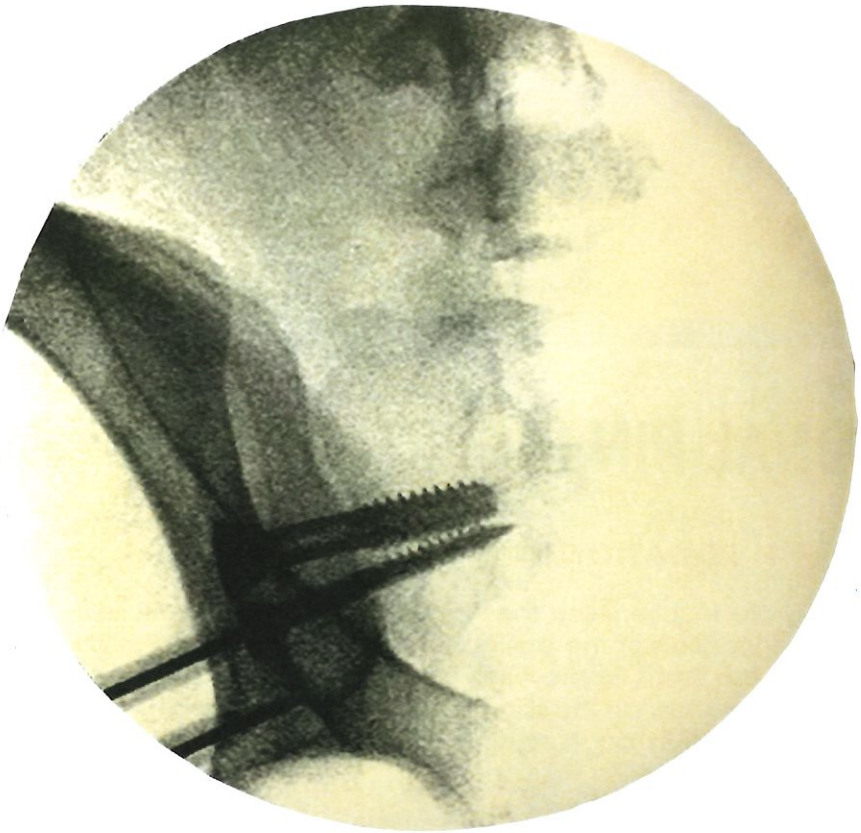
If additional Screws are required, use the Pin Positioner on the previously placed Steinmann Pin to determine the location of the additional Pin. Place the Pin Positioner over the end of the Steinmann Pin in the Small Screw. Align the second hole of the Pin Positioner in line with the Posterior Sacral Body mark on the skin. Insert the Pin Positioner through the tissue so that it contacts the Ilium and verify its location using a lateral view. Place an additional Steinmann Pin through the second hole of the Pin Positioner.

Drive the Pin through the Ilium and into the Sacrum until firmly in place. Continually confirm the location and direction with Lateral, Inlet, and Outlet fluoroscopic imaging. Use the inlet view to adjust the angle of the additional Pin to direct it toward the anterior portion of the Sacral Body.

ADDITIONAL SCREW PREPARATION AND INSERTION

To place additional Small Screws, please repeat the previous steps;

- Second Pin
- Small Screws Dilators and Depth
- Optional Drilling for the Small Screws
- Small Screw Insertion



REMOVAL TECHNIQUE

With the patient in the prone position, align the Fluoroscope using the Lateral Alignment procedure. Determine the location of the Screw that needs to be removed and make a mark on the skin. Make an appropriate incision at the center of the mark to allow for the Ø7mm or Ø11mm Screw to be removed.

Place a Trocar Tipped Steinmann Pin through the tissue and drive into the Screw Cannulation. Drive the Pin into the Screw so that it travels about half the length of the Screw Cannulation.

CAUTION: Do not surpass the tip of the Screw with the Steinmann Pin. Confirm with fluoroscopy.

Use the Primary, Secondary, and Tertiary/Handle Dilator to dilate the tissue to the required Screw diameter.

- For Small Screws, only the Primary and Secondary Dilators are necessary for removal.
- For Large Screws, the Primary, Secondary, and Tertiary/Handle Dilators are necessary for removal.

Select the appropriate Driver for removal and connect to a Ratcheting T-Handle (CP-100-34). Once the hex from the driver mallet matches the hex in the screw, lightly mallet to ensure a tight fit. Set the T-Handle in reverse and rotate counter-clockwise to remove the Screw.

- For Small Screws, select the Ø7mm Screwdriver (SCL-103-101)
- For Large Screws, select the Ø11mm Screwdriver (SCL-103-102)

SET CONTENTS

IMPLANTS

SCL-07-030	ø7.0mm Bone Screw, Cannulated, 30mm
SCL-07-035	ø7.0mm Bone Screw, Cannulated, 35mm
SCL-07-040	ø7.0mm Bone Screw, Cannulated, 40mm
SCL-07-045	ø7.0mm Bone Screw, Cannulated, 45mm
SCL-07-050	ø7.0mm Bone Screw, Cannulated, 50mm
SCL-07-055	ø7.0mm Bone Screw, Cannulated, 55mm
SCL-07-060	ø7.0mm Bone Screw, Cannulated, 60mm
SCL-07-065	ø7.0mm Bone Screw, Cannulated, 65mm
SCL-07-070	ø7.0mm Bone Screw, Cannulated, 70mm
SCL-11-035	ø11.0mm Bone Screw, Cannulated, 35mm
SCL- 11-040	ø11.0mm Bone Screw, Cannulated, 40mm
SCL-11-045	ø11.0mm Bone Screw, Cannulated, 45mm
SCL-11-050	ø11.0mm Bone Screw, Cannulated, 50mm

IMPLANTS

SCL-11-055	ø11.0mm Bone Screw, Cannulated, 55mm
SCL-11-060	ø11.0mm Bone Screw, Cannulated, 60mm
SCL-11-065	ø11.0mm Bone Screw, Cannulated, 65mm

INSTRUMENTS

SCL-103-101	ø7.0mm Screwdriver
SCL-103-102	ø11.0mm Screwdriver
SCL-117-100	Chuck Adaptor
SCL-119-101	Primary Dilator
SCL-119-102	Secondary Dilator
SCL-119-103	Tertiary Dilator
SCL-119-106	Handle Dilator
SCL-125-101	ø7.0mm Drill Bit
SCL-125-104	ø11.0mm Drill Bit
SCL-129-101	Depth Gauge
SCL-130-101	ø2.4mm X 230mm Trocar Steinmann Pin
SCL-130-400	ø2.4mm X 400mm Trocar Steinmann Pin
SCL-130-401	ø2.4mm X 400mm Blunt Steinmann Pin
SCL-131-101	Pin Positioner
CP-100-33	QC Cannulated Handle, Straight Ratchet
CP-100-34	QC Cannulated Handle, T-Handle Ratchet

NOTES

SEE INSTRUCTIONS FOR USE (IFU) FOR INDICATIONS, CONTRAINDICATIONS AND WARNINGS.

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