

SURGICAL TECHNIQUE MANUAL

SacroLoX® *Allograft Implant System*

Posterior inlet articular technique (fluoroscopy guided)

Sacroiliac joint fusion



01 Introduction

This manual describes a minimally invasive, fluoroscopy guided, posterior inlet articular technique for SI joint fusion using the SacroLoX system.

- Access the SI joint through a small incision
- Prepare the joint corridor using hand drill
- Place two cylindrical allograft implants in a parallel configuration
- Stabilize the joint and support long term fusion

This guide is technique support only. Follow the current IFU for full prescribing information.

02 Device Overview

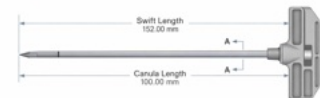
SacroLoX system

- Two cylindrical allograft implants delivered through a cannula based instrumentation set
- Intended for posterior inlet articular placement of bone allografts into the SI joint



Core placement concept

- Two implants placed with parallel orientation (minimum spacing of 5 mm between implants). Implants positioned to stabilize the SI joint.



Main assembly view — dimensions as labelled.

03 Indications

Use according to the SacroLoX IFU. Typical clinical use is for patients with SI joint dysfunction where stabilization and fusion are clinically indicated.

04 Contraindications

Follow the SacroLoX IFU. Common contraindication categories may include:

- Active infection
- Inability to tolerate surgery or anesthesia
- Local anatomy that prevents safe access or stable implant placement
- Conditions that compromise bone healing or fixation stability, as defined in the IFU

05 Warnings

- Use fluoroscopic guidance throughout the procedure.
- Confirm bony landmarks in multiple views before advancing instruments.
- Do not advance instruments without a confirmed trajectory.
- Maintain awareness of pelvic anatomy and neurovascular structures at all times. Confirm final implant position in at least two orthogonal views.

06 Precautions

- Use sterile technique.
- Handle allograft per IFU and facility policy.
- Avoid excessive force during docking and cannula advancement.
- Maintain instrument control. Brace hands on the patient when possible.
- If visualization is suboptimal, stop and re-establish views before proceeding.

07 Required Equipment

Imaging

- Fluoroscopy with the ability to obtain:
 - True lateral view
 - Inlet view with 20 to 30 degrees caudal tilt
 - Inlet oblique view with approximately 0 to 5 degrees obliquity and about 10 degrees cranial adjustment as needed for corridor confirmation

Standard supplies

- Skin prep and drape set
- Local anesthetic per protocol
- Suture and dressing supplies

SacroLoX instrumentation set

- Bone access needle
- Hand drill
- Bone tamp stylet

08 Patient Positioning

- a) Position the patient prone.
- b) Pad bony prominences.
- c) Confirm pelvis is level.
- d) Prep and drape to allow unobstructed fluoroscopic imaging.
- e) Sedation or anesthesia per surgeon and facility protocol.



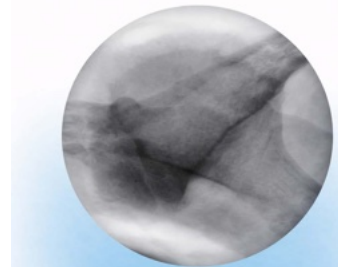
Prone position.

09 Fluoroscopy Setup and Key Views

Establish consistent imaging before incision.

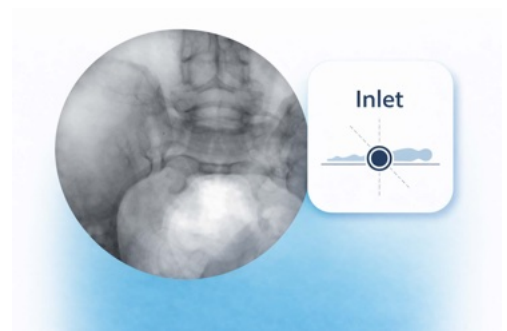
A. True lateral

Goal: define the posterior SI joint corridor and confirm sacral and iliac silhouettes.



B. Inlet view (20 to 30 degrees caudal)

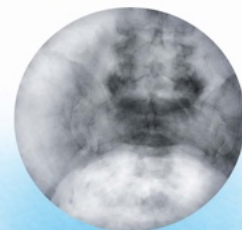
Goal: confirm the inlet corridor and joint orientation.



C. Inlet oblique (0 to 5 degrees)

Goal: refine the trajectory and confirm safe corridor alignment.

Tip: adjust incrementally. Lock in views that you can reproduce.

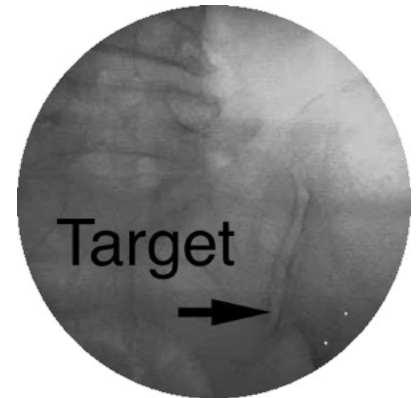


10 Surgical Technique

Step 1. Identify the target corridor

- Use fluoroscopy to identify the inferior third of the SI joint corridor with inlet oblique view.
- Confirm the joint line and planned trajectory in true lateral and inlet views.

Target concept: dock near the inferior third of the SI joint, approximately 10 mm from the anterior pelvic brim, consistent with safe corridor planning and IFU guidance.

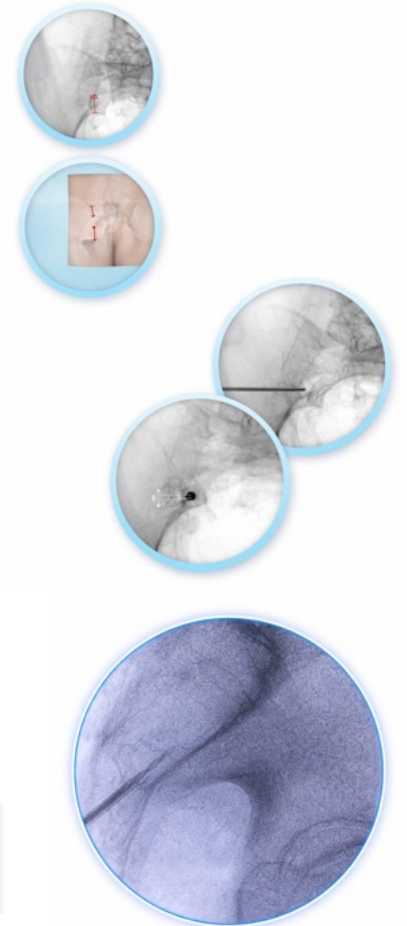


Step 2. Skin mark and incision

- Mark the entry site based on the planned trajectory.
- Make a small skin incision.
- Bluntly dissect to fascia as needed.

Step 3. Bone access needle docking

- Advance the bone access needle to the docking point (inferior 3rd of SI corridor).
- Confirm trajectory in inlet and inlet oblique views.
- Confirm position in true lateral.
- Do not advance if any view is uncertain. Re-image and correct.
- Advance bone access needle 5–10 mm into joint.



Step 4. Hand drill

- Insert the hand drill through the access needle.
- Confirm hand drill location and trajectory in at least two views.
- Remove the hand drill.

GOAL: create a controlled path for implant placement without violating the planned corridor.

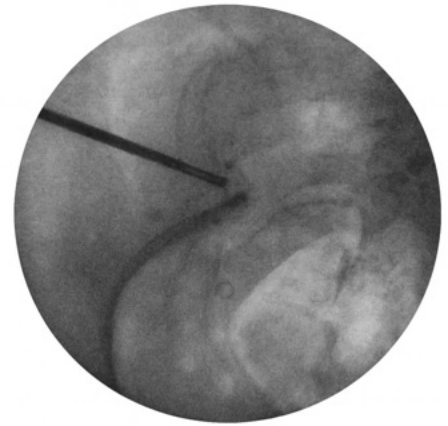
Step 5. Bone allograft placement

- Place the allograft down the access cannula.
- Use bone tamp stylet to progress the allograft out of the cannula and into the inlet articular space.

10 Surgical Technique (continued)

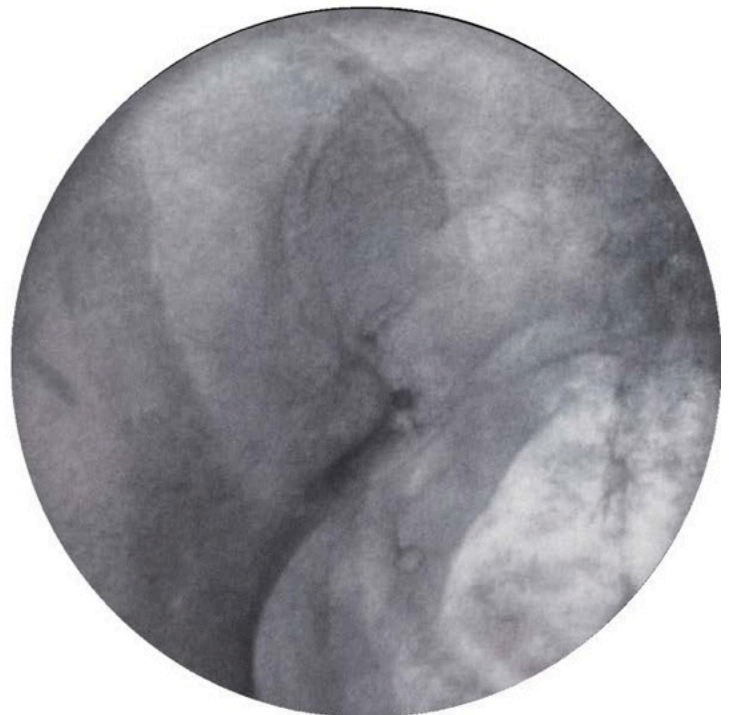
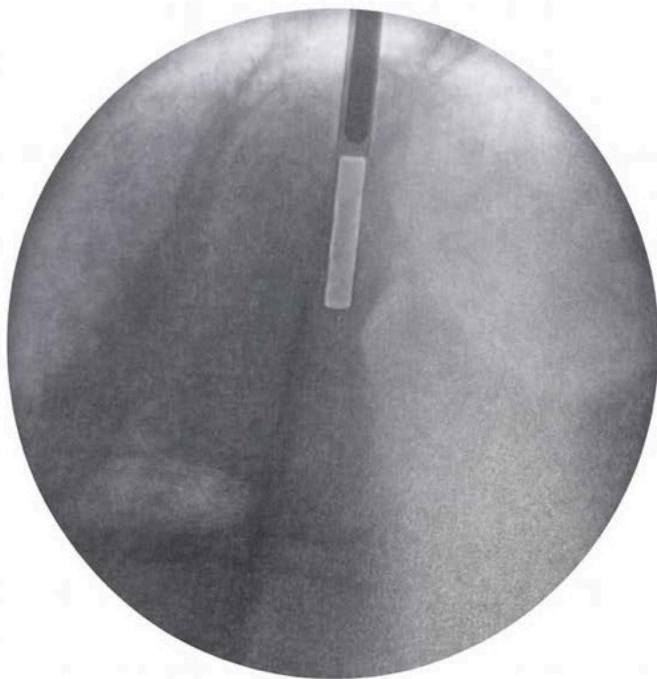
Step 6. Reposition cannula for 2nd graft placement

- Using same incision site, advance the bone access needle to the docking point (inferior 3rd of SI corridor).
- Confirm position in inlet oblique view, 5 mm distance between 1st allograft (above or below).
- Confirm trajectory in lateral view.
- Do not advance if any view is uncertain. Re-image and correct.
- Advance bone access needle 5–10 mm into joint.



Step 7. Implant 2 trajectory planning

- Plan the second implant track parallel to the first.
- Maintain at least 5 mm spacing between implants.
- Confirm the second trajectory in multiple views before preparation.



Confirming the second trajectory in multiple views before preparation.

10 Surgical Technique (continued)

Step 8. Implant 2 placement

- Prepare the second corridor as needed per system steps.
- Deliver the second implant.
- Confirm both implants:
 - ▢ Parallel orientation
 - ▢ Adequate spacing
 - ▢ Final position confirmed in at least two views



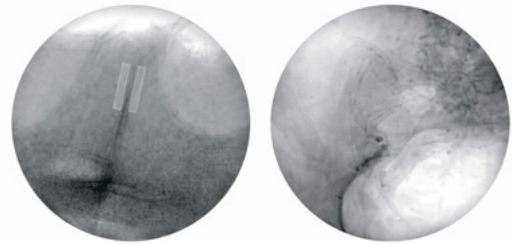
Step 9. Final imaging

- Obtain final fluoroscopic images in:
 - ▢ True lateral
 - ▢ Inlet
 - ▢ Inlet oblique or an additional confirming view

Step 10. Closure

- Remove instruments.
- Irrigate per preference.
- Close in layers as appropriate.
- Apply sterile dressing.

Document final implant position per facility protocol.



11 Postoperative Care

Follow surgeon preference and facility protocol. Typical postoperative expectations include:

- Same day ambulation as tolerated
- Progressive activity advancement
- Return to light work in approximately 2 weeks for many patients, depending on clinical factors
- Ongoing improvement over time
- Provide clear restrictions and follow up schedule.

12 Troubleshooting Tips

Poor fluoroscopic visualization

- Re-level the pelvis.
- Reposition the C-arm.
- Re-establish true lateral first, then inlet.

Cannula instability

- Reduce force.
- Re-seat cannula.
- Confirm depth and alignment.

Trajectory uncertainty

- Stop advancing.
- Re-confirm in at least two views.
- Adjust before continuing.

Implant spacing risk

- Plan the second track early.
- Use fluoroscopy to verify parallel spacing before preparation.

13 Adverse Events

Refer to the SacroLoX IFU for a complete list. Report events per facility policy and applicable regulations.

14 Storage and Handling

Handle allograft per IFU and institutional tissue handling policies. Maintain sterility.

Do not use if packaging is compromised.

15 Reference Information

This manual supports technique education. The IFU is the controlling document for:

- Indications and contraindications
- Warnings and precautions
- Implant specifications and sizing
- Sterility and handling requirements
- Complaint reporting and contact information

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