OptumSI

TIGA™ Technology

Surgical Technique Guide

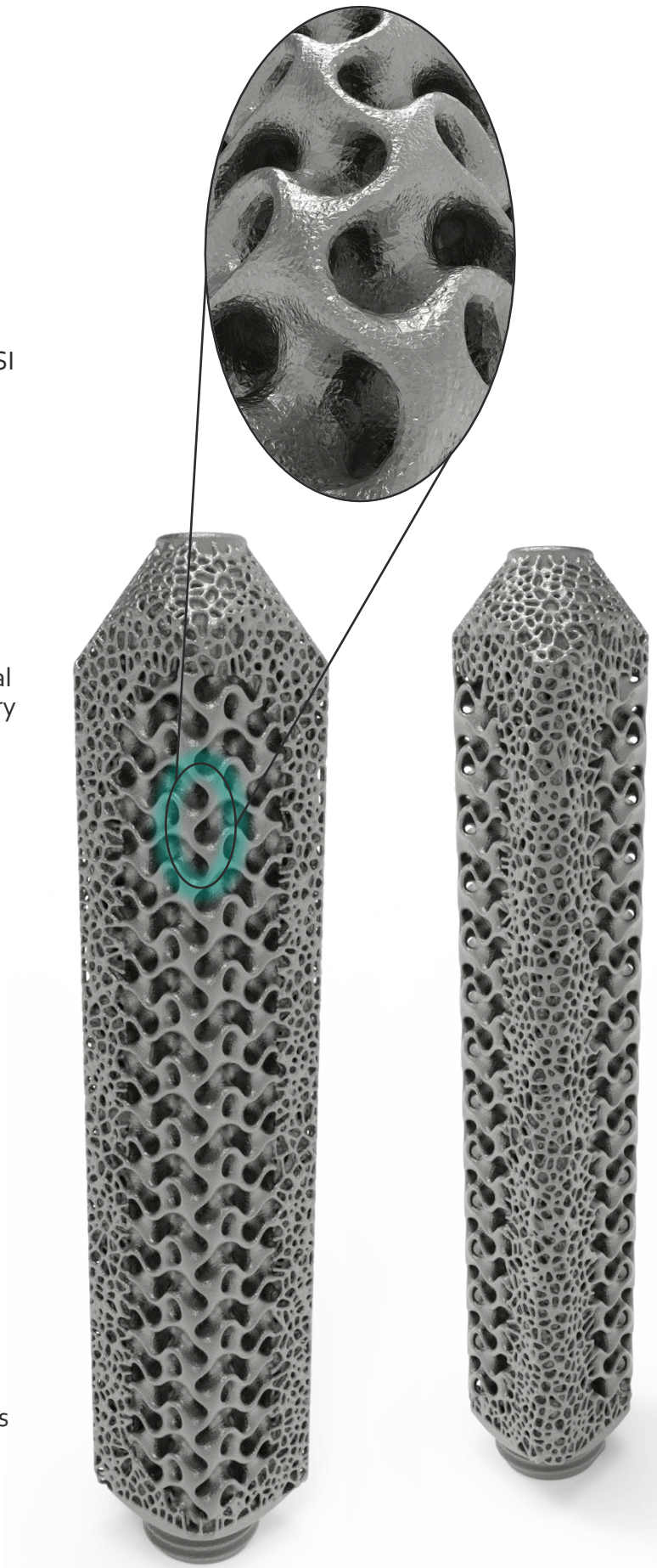
SI Solutions

Contents

OptumSI Implant System

System Overview

- The OptumSI Implant System is composed of specially designed sacroiliac (SI) joint implants and associated instrumentation for a sacroiliac joint fusion procedure.
- Typically, three implants are inserted across the SI joint by a minimally invasive approach through a small portal.
- All OptumSI implants are additively manufactured titanium, diamond-shaped, and optimally designed to stabilize and fuse the SI joint.
- Implant lengths range from 30mm to 70mm.
- OptumSI implants feature TIGA™ (Topographical In-Growth Architecture) technology, a proprietary composition of a porous, dual micro-lattice structure specifically formulated to promote fusion.
- Includes a complete reuseable specialty instrument set for a streamlined minimally invasive surgery.
- The OptumSI Implant System is intended for sacroiliac fusion for the following conditions:
  - Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
  - To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
  - Acute, non-acute and non-traumatic fractures involving the sacroiliac joint.

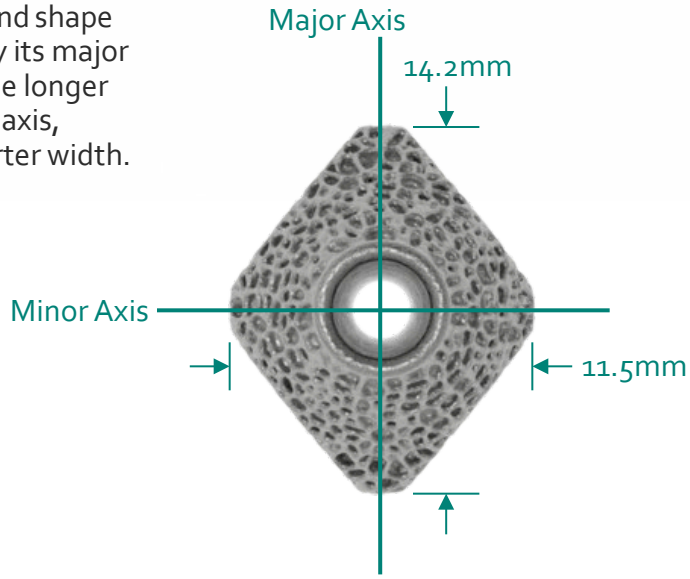


OptumSI Implant System

Implant Overview

Part Number	Description
11-11530	Sacroiliac Joint Fusion Implant, 11.5 x 30
11-11535	Sacroiliac Joint Fusion Implant, 11.5 x 35
11-11540	Sacroiliac Joint Fusion Implant, 11.5 x 40
11-11545	Sacroiliac Joint Fusion Implant, 11.5 x 45
11-11550	Sacroiliac Joint Fusion Implant, 11.5 x 50
11-11555	Sacroiliac Joint Fusion Implant, 11.5 x 55
11-11560	Sacroiliac Joint Fusion Implant, 11.5 x 60
11-11565	Sacroiliac Joint Fusion Implant, 11.5 x 65
11-11570	Sacroiliac Joint Fusion Implant, 11.5 x 70

- The OptumSI diamond shape implant is defined by its major axis, representing the longer width, and its minor axis, representing its shorter width.

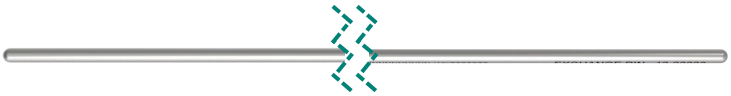


- The optimal shape of the implant allows for bicortical fixation within the SI joint while preventing rotation.

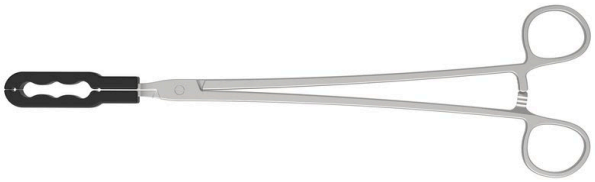
OptumSI Implant System

Instrument Overview

12-00001 Trocar Guide Pin



12-00003 Exchange Pin



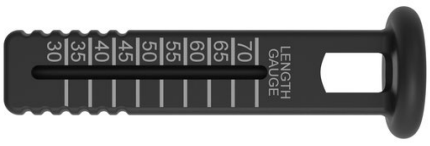
12-00011 Pin Holder

12-00005 Slotted Mallet

12-00017 Blunt Dissector

12-00010 Dilator

12-00021 Access Portal



12-00040 Length Gauge

OptumSI Implant System

Instrument Overview

12-00026	Drill Bit

12-00004	Broach

12-00030	Adjustable Stop

12-00027	Impactor

12-00035	Fixed 2 Pin Guide

12-00037	Fixed 3 Pin Guide*

12-00009	Removal Tool

12-00041	Trocar Guide Pin Dispenser

*Available by Request Only

Surgical Procedure

Preoperative Planning & Patient Set-Up

Pre-Op Planning

- A CT Scan is recommended to check for any anatomic anomalies.

Patient Setup

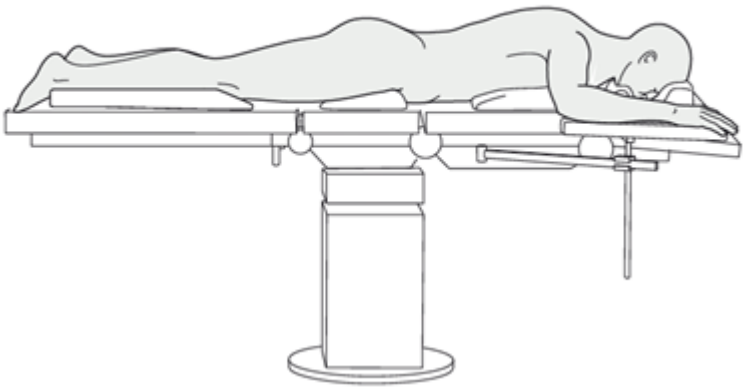
- Jackson and flat imaging tables are commonly used.
- One or Two C-arms may be used, usually one is sufficient.
- If a flat table is used, place towel rolls transversely under the chest and waist, and pillows under the feet to relax hip and knee joints.
- The patient should be in a "spine neutral" position as well as having the SI joint in a neutral position without extreme flexion or extension of hips. (figure below)

Patient Positioning

- This procedure may be performed in the prone or supine position. The Surgical Technique Guide illustrates the procedure in the prone position. (figure below)

Care of Instruments During Procedure

- The OptumSI Implant System is a pin-based system. As is common with pin-based systems, bone material may adhere to the Broach, Access Portal, or other instruments, which may result in pin binding or adherence of instruments to each other or to implants. Irrigation of the instruments between uses might minimize the occurrence of binding of instrument and/or implants.



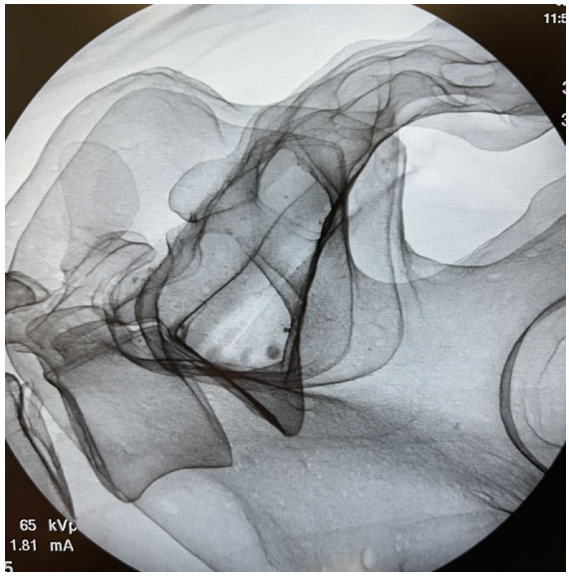
NOTE: *The procedure should be modified based on patient characteristics and the surgeon's judgement. Instruments not shown in this guide may be used at the surgeon's discretion.*

Surgical Procedure

Preparation and Incision

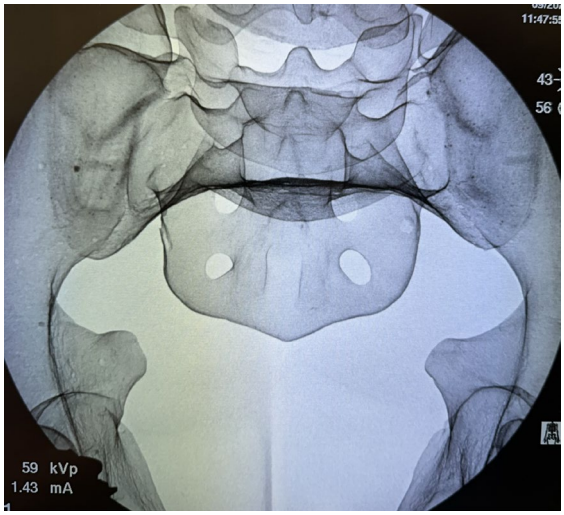
Lateral View

- Align the disc space and endplates of L5-S1 to a true lateral view, then adjust the alignment as necessary until the left and right iliac cortical densities are superimposed.



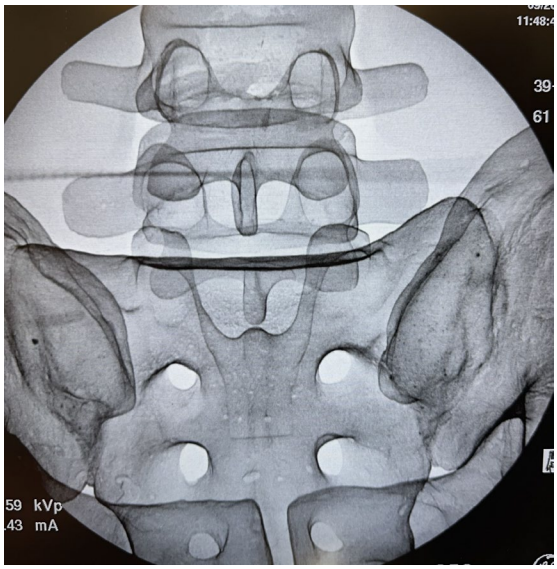
Inlet View

- The inlet view is anterior-to-posterior to optimize visualization of the ventral cortex of the sacrum.
- The fluoroscope is tilted toward the feet until the dense cortical line of the S1-S2 vestigial disc directly overlies the dense cortical line of sacral promontory.



Outlet View

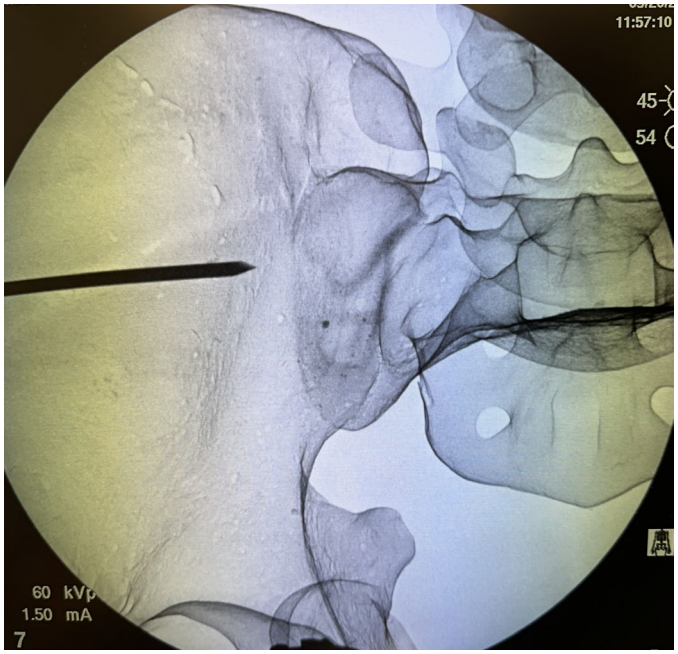
- The outlet view is anterior-to-posterior to optimize visualization of the sacral neuroforamen.

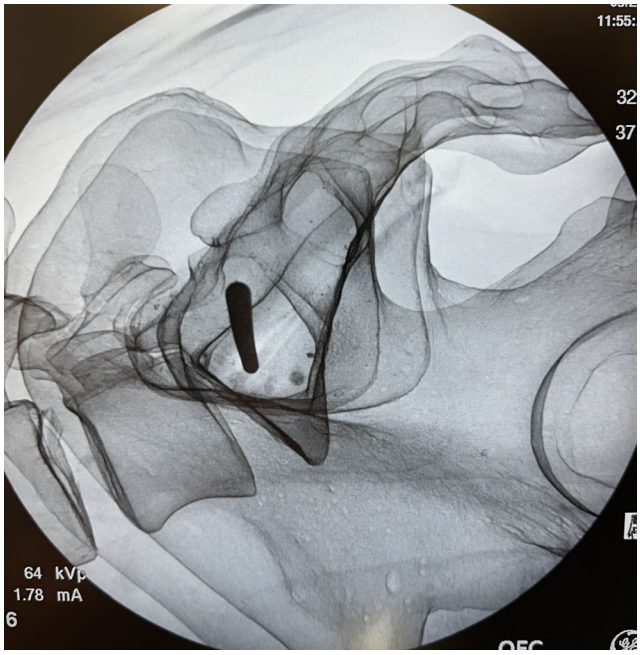


Surgical Procedure

Preparation and Incision

- Mark the skin and make an incision as to target the middle of the S1 sacral body.
- Do not continue the incision through the muscle and fascia. Pins are used to guide the instruments and implants to the bone, including instruments specifically for muscle dilation.
- With the patient in the prone position, use fluoroscopy to identify the S1 sacral body and left and right iliac cortical densities.

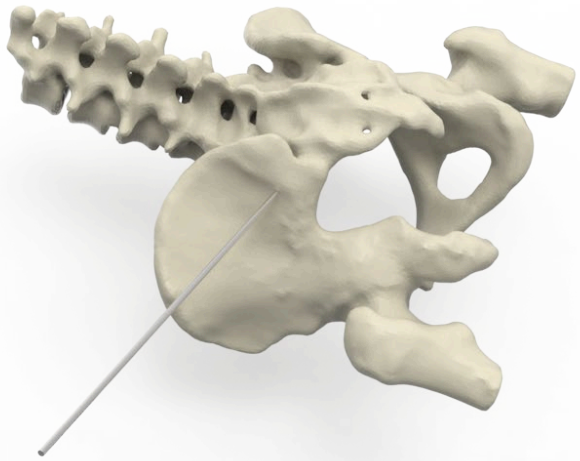




Surgical Procedure

Pin Placement

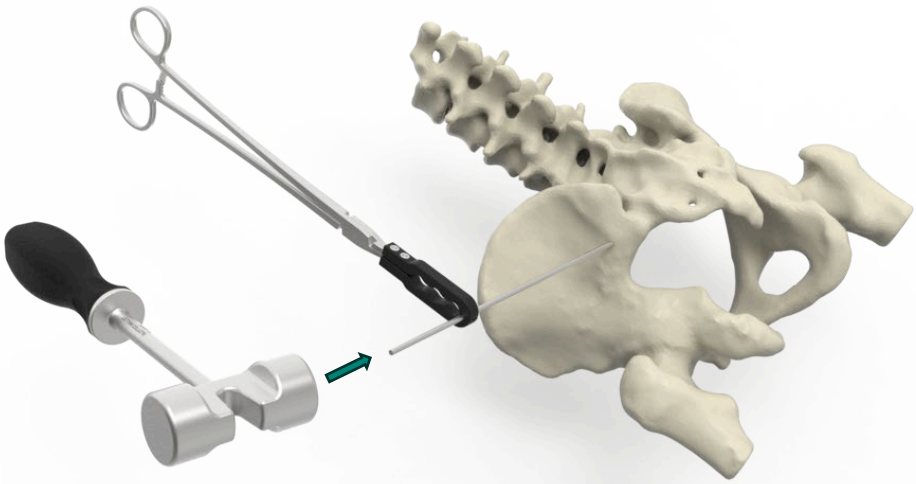
- Identify the starting point along the lateral cortex of the ilium and insert a Trocar Guide Pin through the fascia until it contacts the ilium.



- The Pin Holder may be used to grasp and manipulate the Guide Pin while keeping hands outside of the x-ray.

- Using fluoroscopy, adjust the pin trajectory so that once inserted across the sacroiliac joint and into the sacrum it will be positioned below the sacral alae and above or in line with the S1 foramen.

- When a safe trajectory for the guide pin is confirmed, use the Slotted Mallet to advance it across the sacroiliac joint to the desired depth.

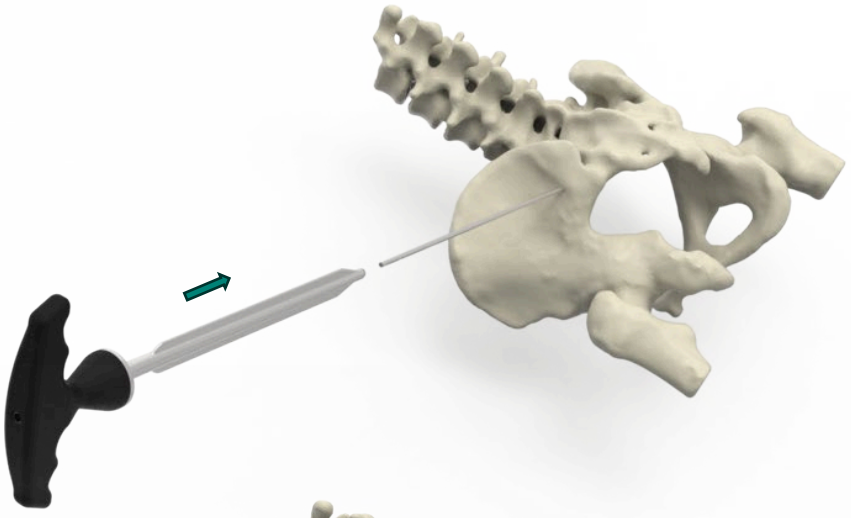


IMPORTANT: *When advancing guide pin, avoid penetrating sacral canal, foramen, or cortices. If visualization is difficult, do not advance beyond lateral walls of foramen.*

Surgical Procedure

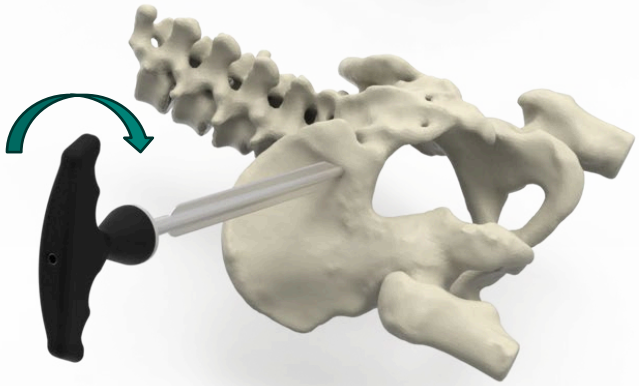
Soft Tissue Preparation

- If desired, a Blunt Dissector is available to gradually loosen the muscle fibers along the pin trajectory.



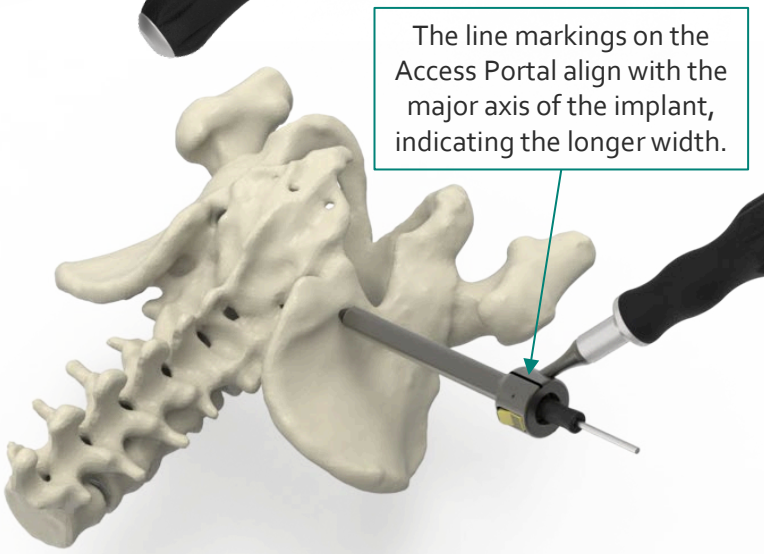
- Pass the Blunt Dissector over the Guide Pin and down to the cortex of the ilium with the blades parallel to the muscle fibers.

- Lightly rotate to loosen the tissue in preparation for the Dilator.



- Assemble the Dilator to the Access Portal by sliding it through the portal's proximal end until it snaps into position and is fixed.
  - › Take care to align the outer profile of the Dilator with the inner profile of the Access Portal for proper fitment.

- Pass the assembled Dilator and Access Portal over the Guide pin until seated on the ilium.



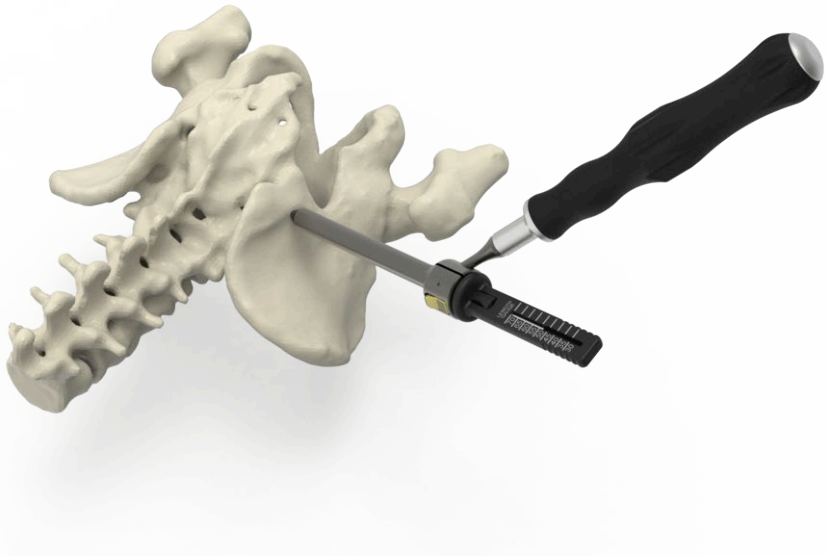
- The Dilator is radiolucent and can serve as an insulator to allow for EMG neuromonitoring by stimulating the pin if desired. The Access Portal tube is partially radiolucent to allow x-ray visualization of passing instruments and implants.

Surgical Procedure

Site Access and Length Measurement

- A Length Gauge is available to use with the Guide Pin and assembled Access Portal + Dilator to determine the appropriate implant length.
  - › The Length Gauge assesses the extent of the pin beyond the lateral cortex of the ilium, offering a convenient reference for determining the appropriate implant length.

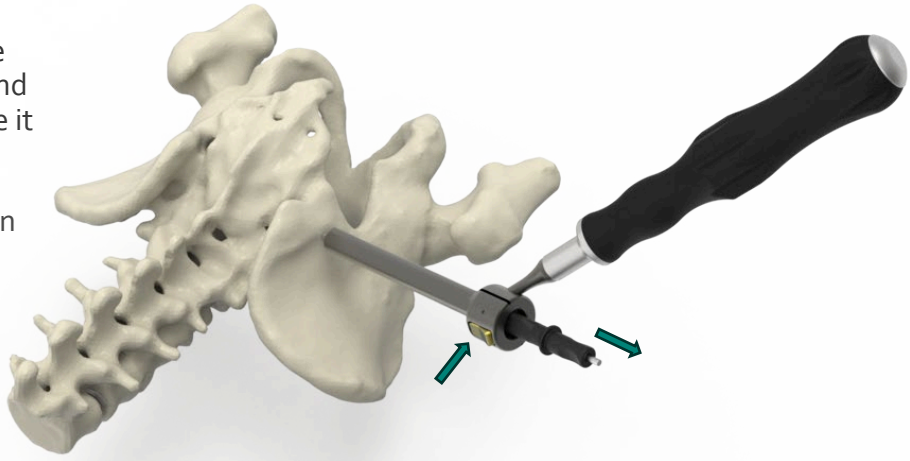
IMPORTANT: *The Dilator must be in place when using the Length Gauge.*



- Slide the Length Gauge over the Guide Pin and Dilator until fully seated against the top of the Access Portal.
  - › Read the implant length on the Length Gauge which aligns with the end of the Guide Pin.

    EX: In the figure shown, a 50mm implant length should be used.
    - › *If the reading falls on a line, then read the number below the line for the appropriate implant length.*
    - › *If the reading falls between two lines, then the shorter length should be used.*

- Keeping the Guide Pin in place, press the button on the side of the Access Portal and pull the Dilator out to detach and remove it from the Access Portal.
- Advance the Access Portal until seated on the ilium.



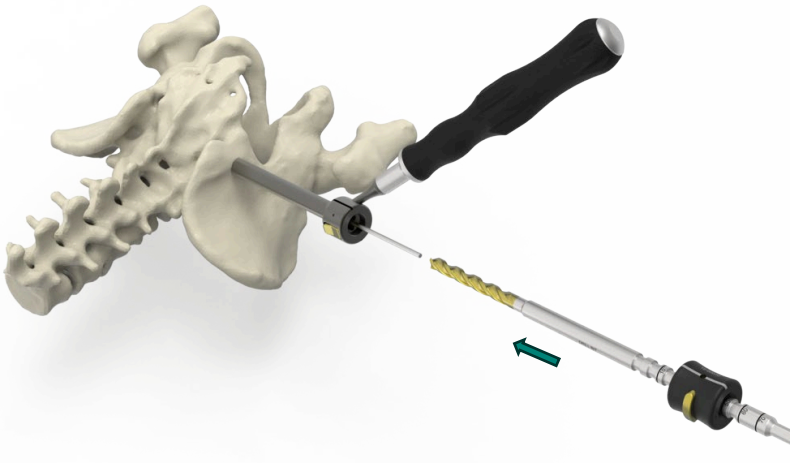
Surgical Procedure

Drilling

- **Optional:** An Adjustable Stop is available for use with the Drill Bit to preset the drilling depth.
  - › Pressing the button, slide the Adjustable Stop over the distal end of the Drill Bit. Adjust the position until the end of the Adjustable Stop aligns with the desired drilling depth marked on the Drill Bit.

    EX: In the figure shown, the Adjustable Stop is set to allow a drilling depth of 50mm.

- Securely attach the Drill Bit to a power drill and slowly pass the Drill Bit over the Guide Pin and through the Access Portal until contact is made with the ilium.

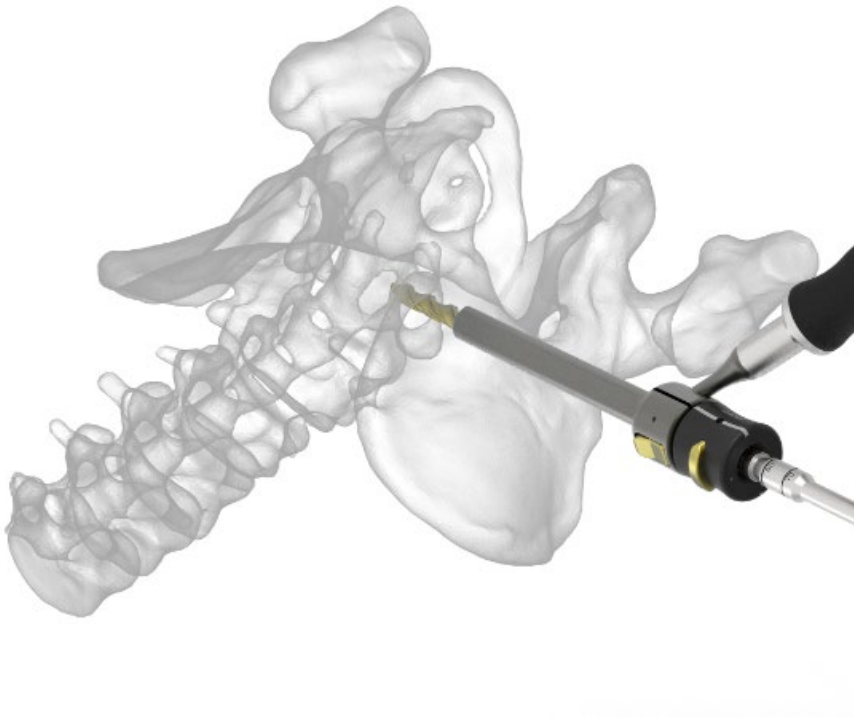


Surgical Procedure

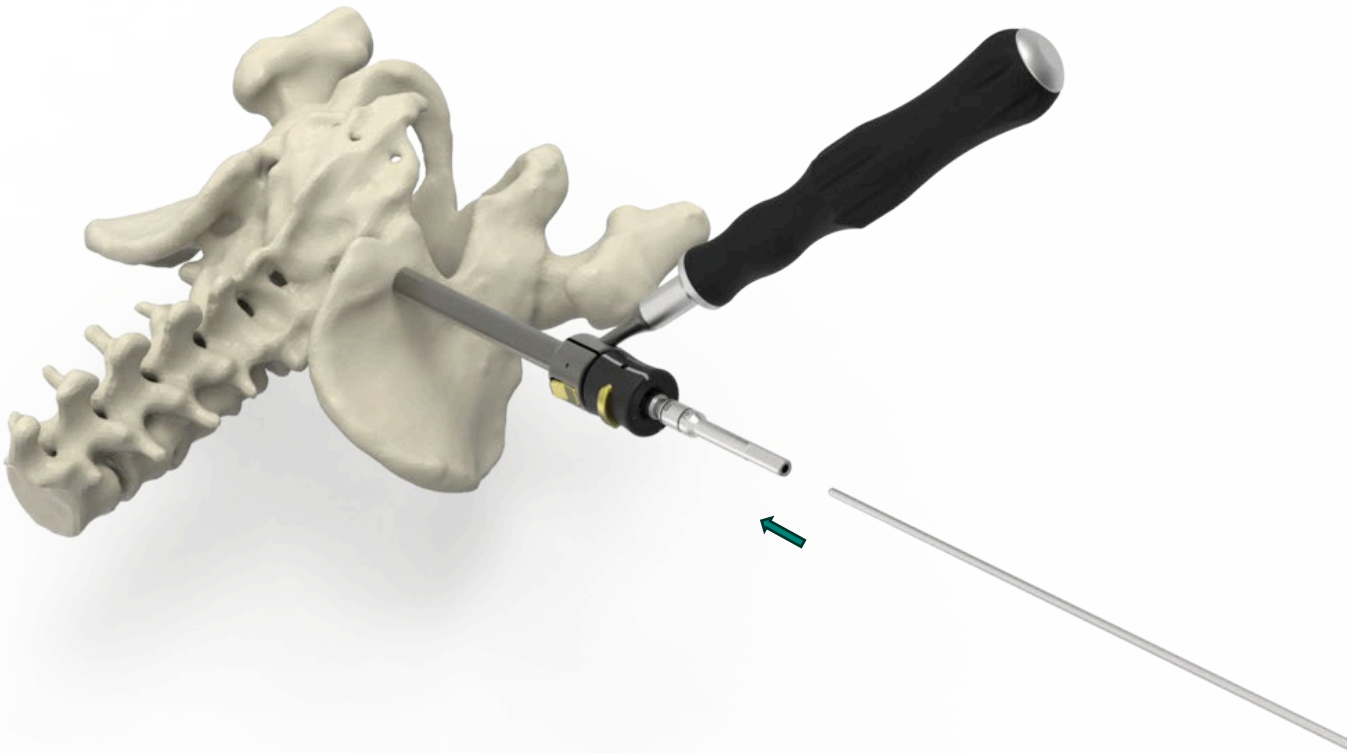
Drilling

- Use fluoroscopy to confirm the position of the Drill Bit before drilling.
- Under fluoroscopic guidance, drill through the ilium, across the SI Joint, and into the sacrum. Exercise caution when advancing into the sacrum, drilling no more than 2-3mm medial to the lateral sacral cortex in the outlet view.

> ***IMPORTANT:*** *Ensure the Guide Pin does not advance during drilling.*
>
> ***IMPORTANT:*** *Take care to maintain axial alignment between the Drill Bit and Guide pin while drilling.*



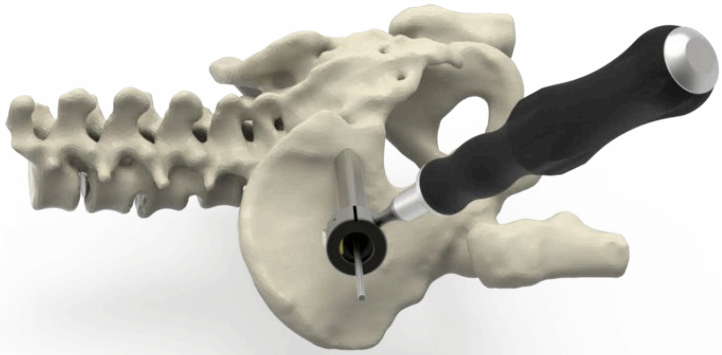
- Insert an Exchange Pin through the Drill Bit before removing to ensure the Guide Pin maintains its position.



Surgical Procedure

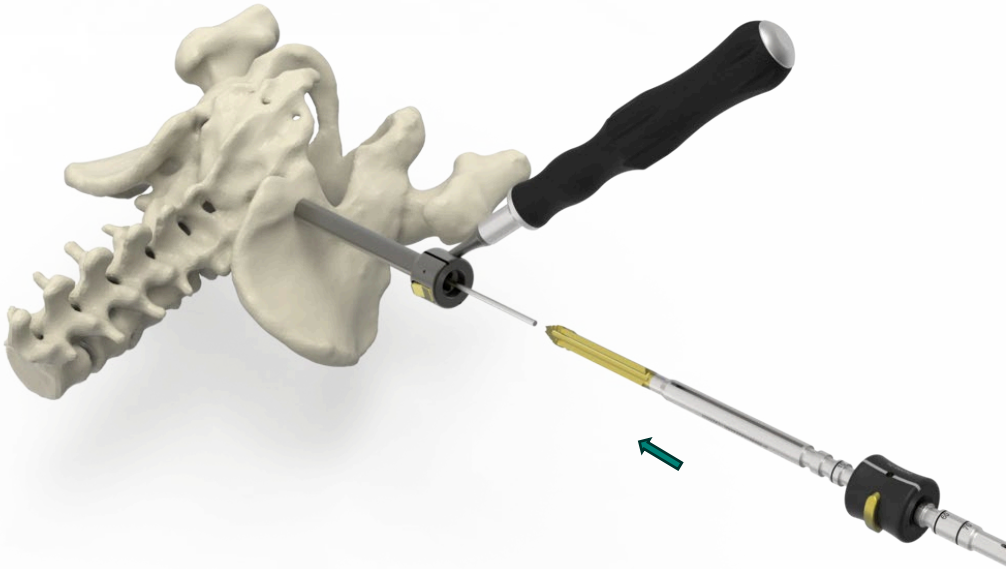
Broaching

- Orient the Access Portal so that the line markings run anterior to posterior.



- **Optional:** The Adjustable Stop can also be used with the Broach to preset the broaching depth.
  - › Pressing the button, slide the Adjustable Stop over the distal end of the Broach. Adjust the position until the end of the Adjustable Stop aligns with the desired broaching depth marked on the Broach.

- Slowly pass the Broach over the Guide Pin and through the Access Portal until contact is made with the ilium. Take care to align the outer profile of the Access Portal for proper fitment.



Surgical Procedure

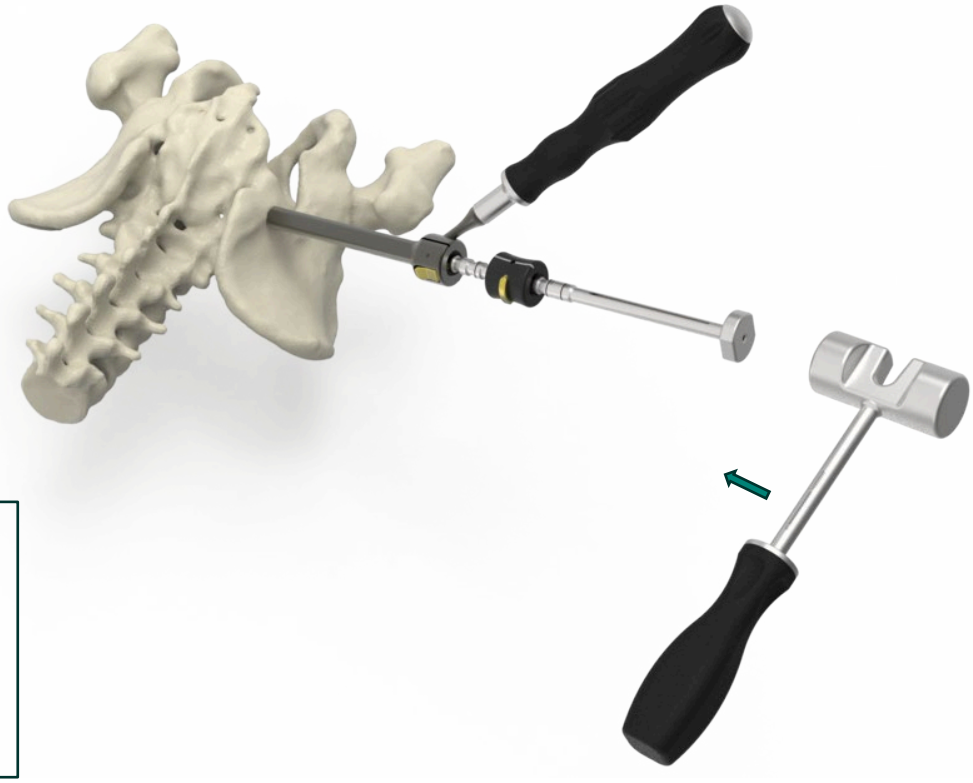
Broaching

- Use fluoroscopy to confirm the position of the Broach before broaching.

- Under fluoroscopic guidance, advance the Broach using the Slotted Mallet. Exercise caution when advancing into the sacrum, broaching no more than 2-3mm medial to the lateral sacral cortex in the outlet view.

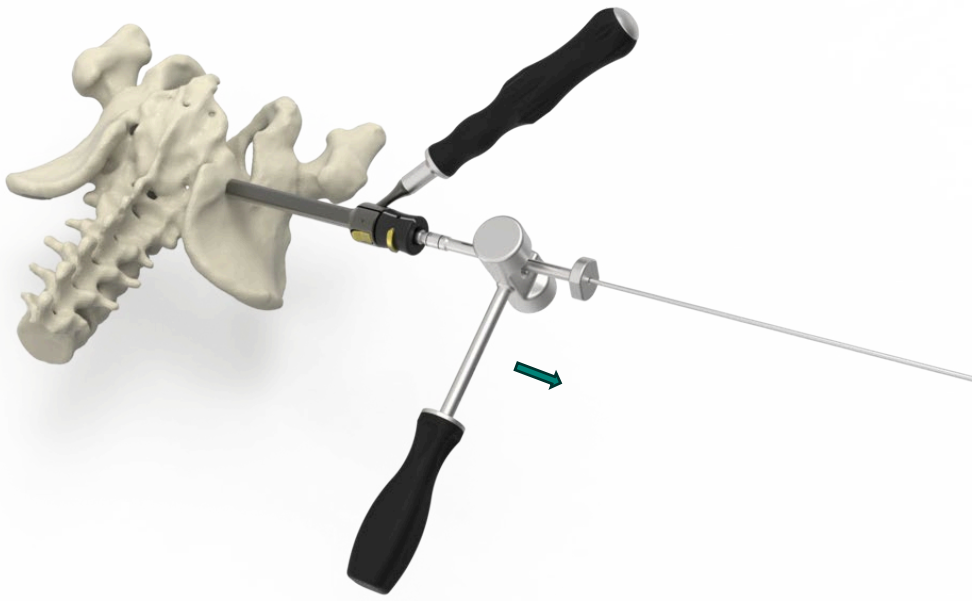
IMPORTANT: *Ensure the Guide Pin does not advance during broaching.*

IMPORTANT: *Take care to maintain axial alignment between the Broach and Guide pin while broaching.*



- Insert an Exchange Pin through the Broach before removing to ensure the Guide Pin maintains its position.

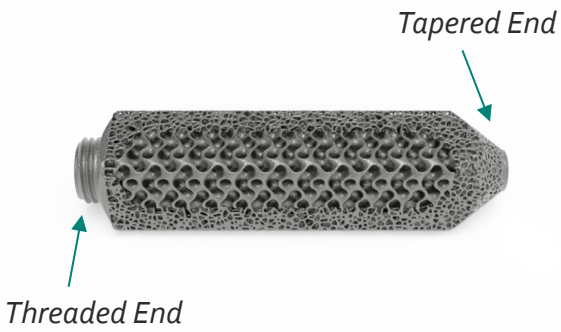
- Use the Slotted Mallet to remove the Broach by striking the cap on the back of the Broach.

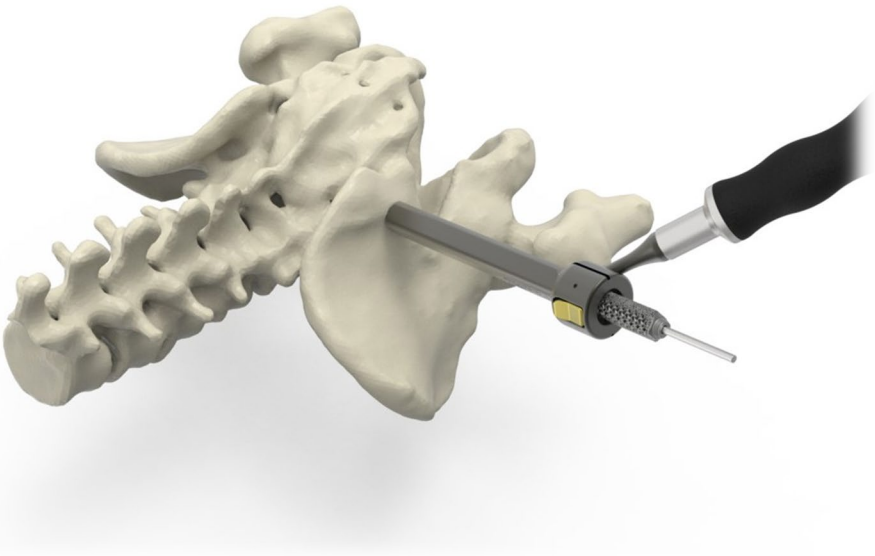


Surgical Procedure

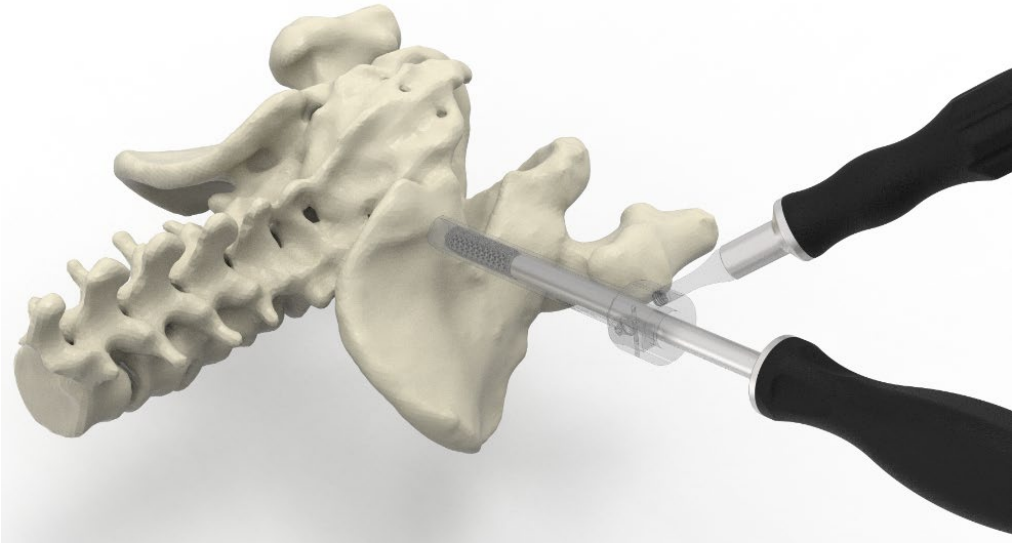
Implant Insertion

- While keeping the Access Portal oriented with the pathway created by the Broach (line markings running anterior to posterior), insert the implant tapered end first over the Guide Pin and into the Access Portal with the threaded end facing away from the patient.



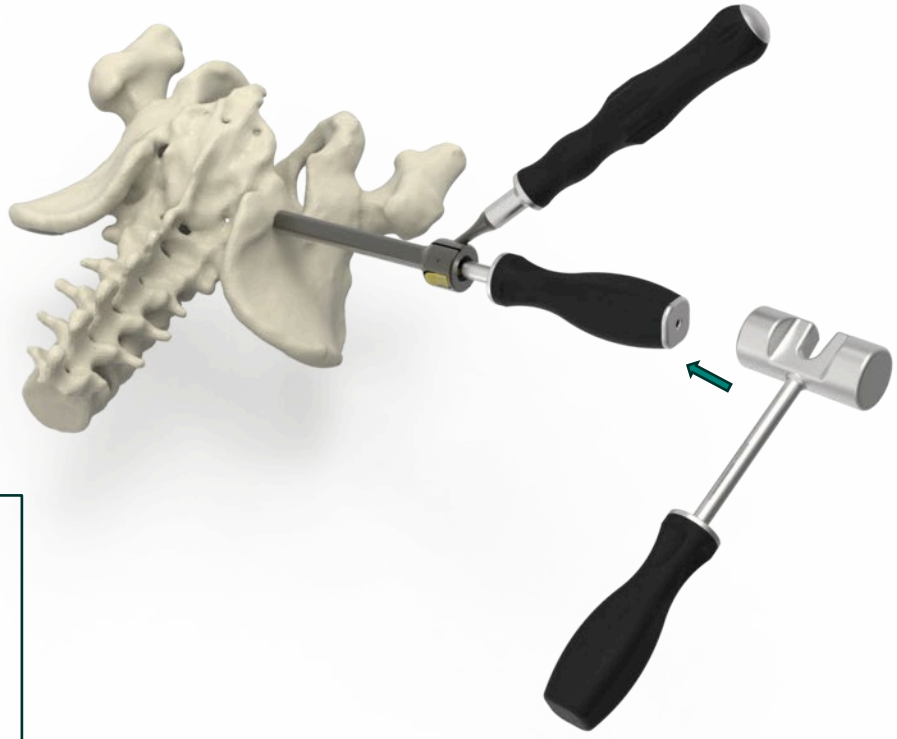


- Advance the implant through the Access Portal using the Impactor, taking care to align the outer profile of the implant with the inner profile of the Access Portal for proper fitment.



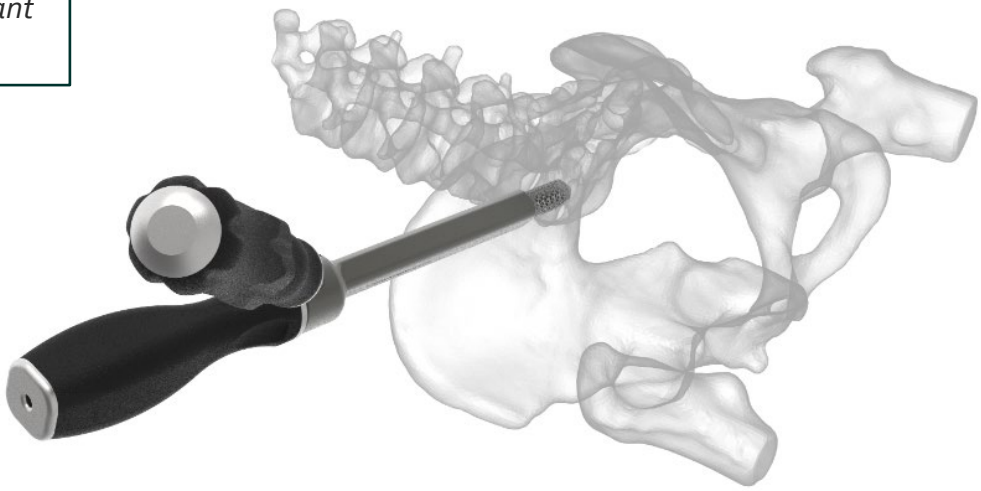
Surgical Procedure

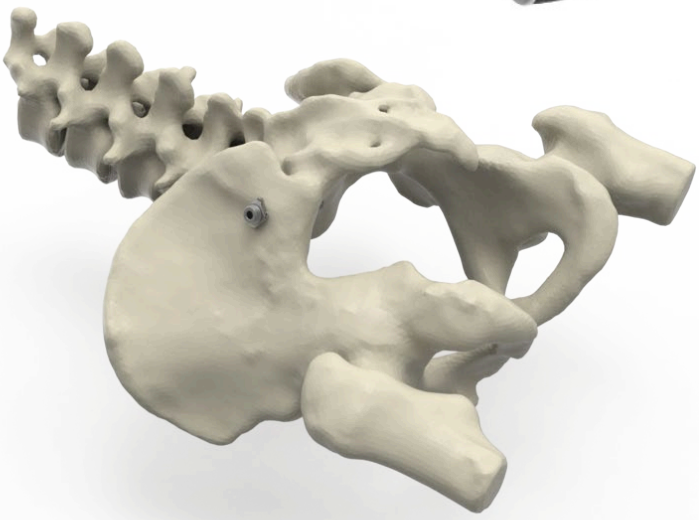
Implant Insertion



- Under fluoroscopic guidance, advance the implant into the pathway by striking the Impactor with the Slotted Mallet until the Impactor bottoms out on the Access Portal.

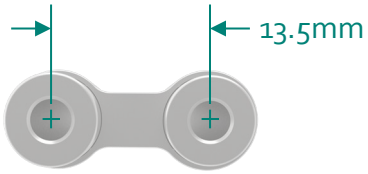
> ***IMPORTANT:*** *Using the Impactor ensures that the proximal end of the implant sits proud of the iliac cortex for adequate cortical stability.*
>
> ***IMPORTANT:*** *Check the inlet and outlet views to assess Pin/Implant trajectory and position*





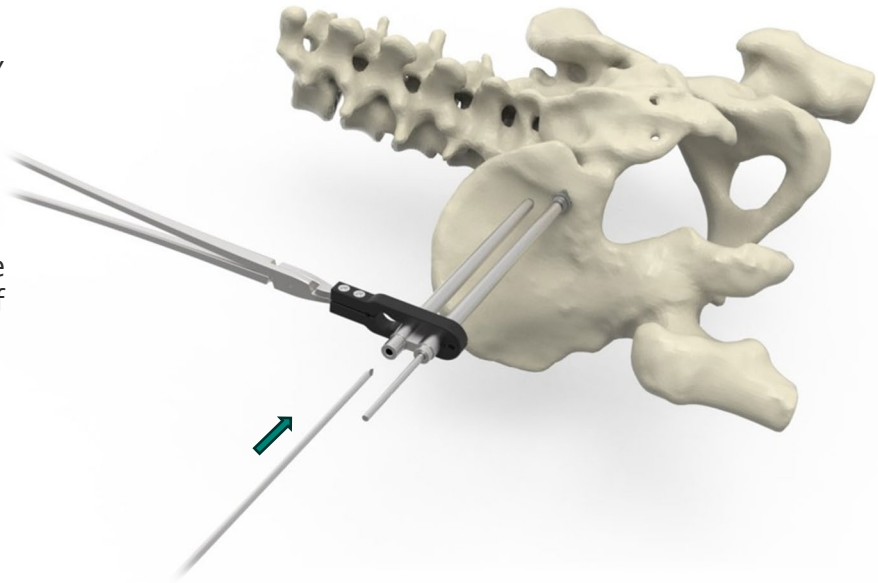
Surgical Procedure

Adjacent Implant Insertion



- To facilitate placement of an adjacent implant, the Fixed 2 Pin Guide is recommended to be used.
  - › The pin guide results in a Guide Pin separation distance of 13.5mm.

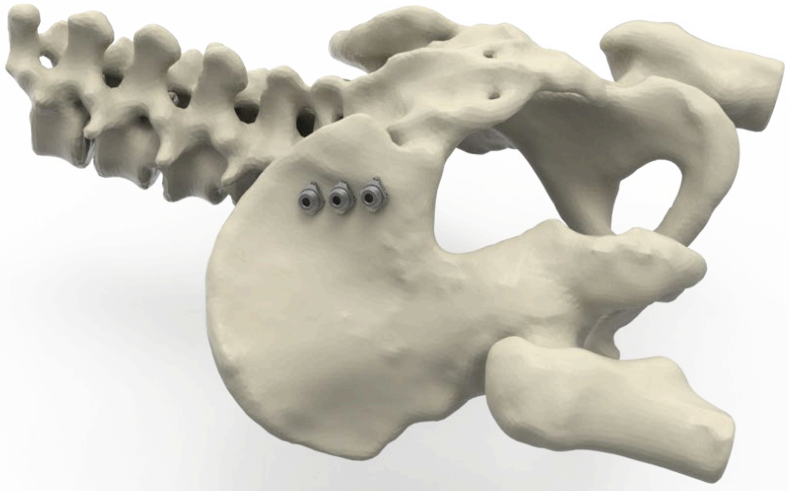
NOTE: *A Fixed 3 Pin Guide is available by request.*

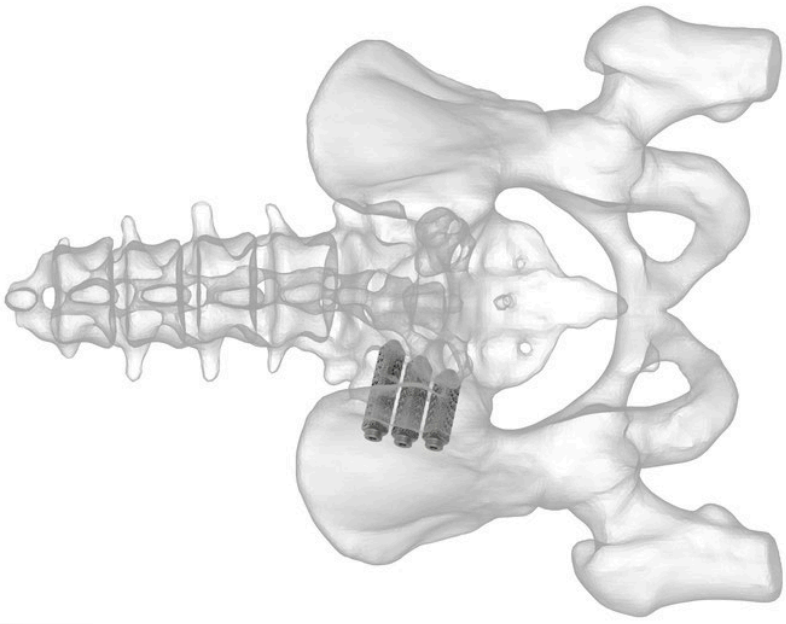


- The Pin Holder may be used to grasp the pin guide while keeping hands outside of the x-ray.

- Placement of the 2nd and 3rd pins and subsequent implants may vary depending on patient anatomy.

- Follow the same procedure as the first implant for placing the 2nd and 3rd implant.



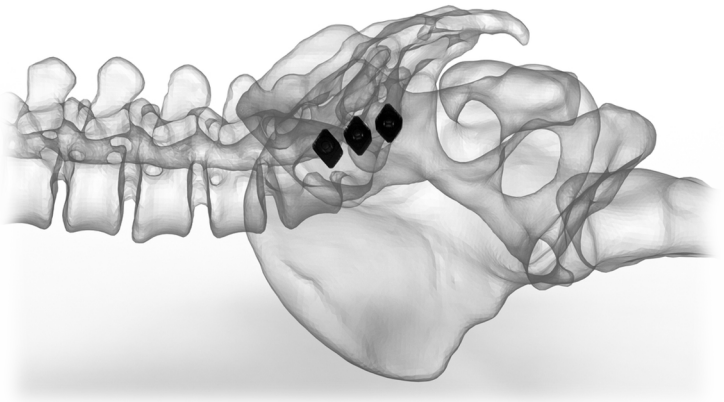


Surgical Procedure

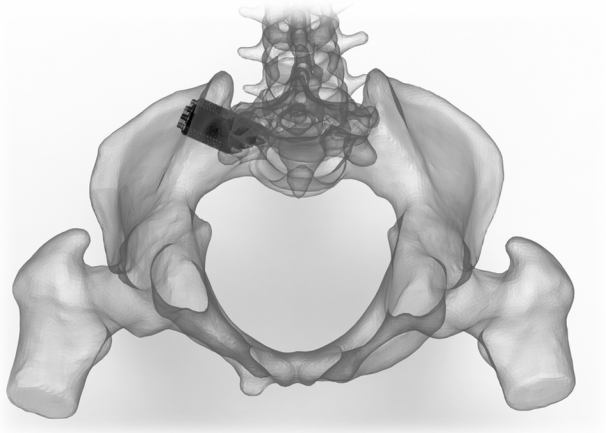
Final Implant Placement

IMPORTANT: *Prior to closure, always obtain final fluoroscopic images in the lateral, inlet, and outlet views to confirm no cortical wall breach, foramen breach, or other malposition.*

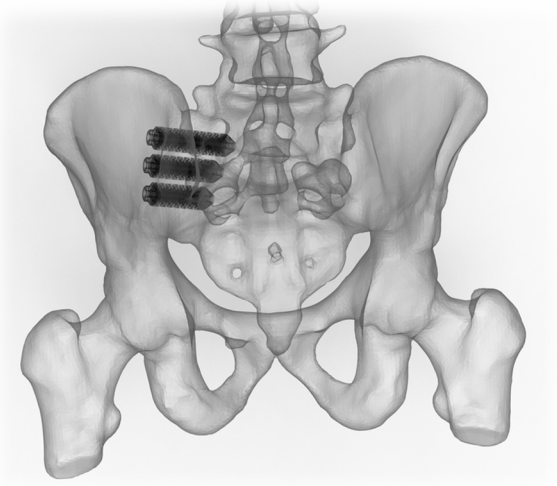
Lateral View



Inlet View



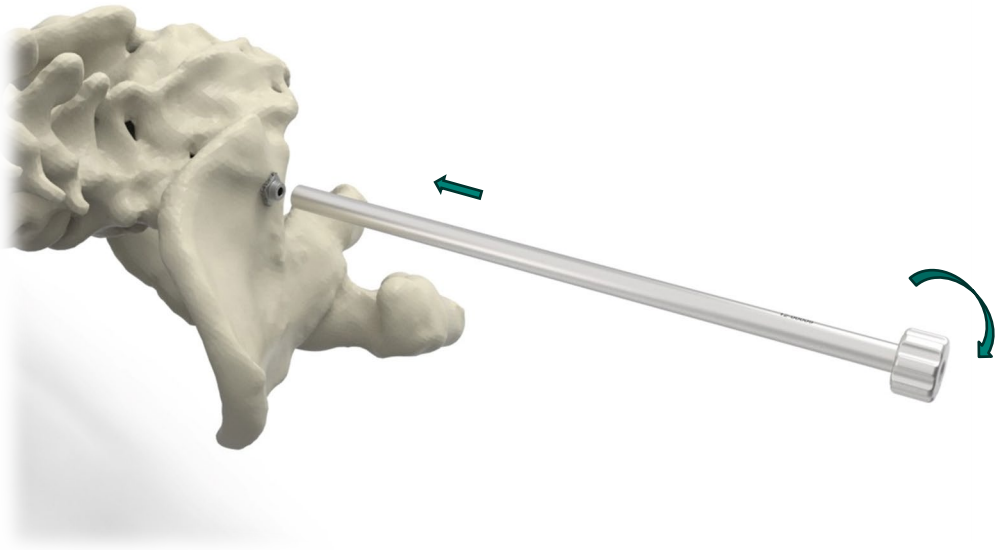
Outlet View



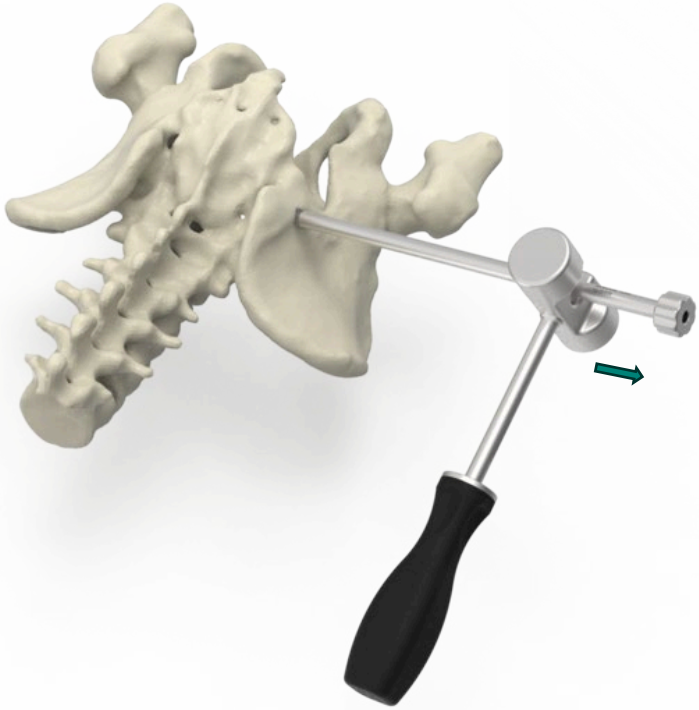
Surgical Procedure

Implant Repositioning or Removal (optional)

- If implant repositioning or removal is necessary, the Removal Tool may be used.



- Thread the Removal Tool onto the back of the implant until tightly secure. If removing, use the Slotted Mallet to strike the back knob of the Removal Tool until the implant is fully removed from the ilium.



OptumSI Implant System

Indication For Use

DEVICE DESCRIPTION:
The OptumSI Implant System is a collection of additively manufactured sacroiliac joint (SI) implants and associated instrumentation. The SI implants are diamond-shaped, cannulated devices and are offered in an assortment of sizes to accommodate the individual anatomic and clinical circumstances of each patient. The system utilizes a transverse approach with a lateral or lateral-to-medial trajectory from the ilium to the sacrum. Each implant device comprises of a solid core, surrounded by a dual micro-lattice structure. The intervening lattice structures are characterized by >40% porosity. The system implants are manufactured from Ti-6Al-4V ELI per ASTM F3001.
The OptumSI instruments are reusable; implants are provided as single-use and sterile. Manual surgical instruments are provided **non-sterile** in an instrument set as a part of the OptumSI to facilitate placement, implantation and removal of the system implants.

INDICATIONS FOR USE:
The OptumSI Implant System is intended for sacroiliac fusion for the following conditions:
- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute and non-traumatic fractures involving the sacroiliac joint.

CONTRAINDICATIONS:
1. Deformities or anatomic variations that prevent or interfere with OptumSI placement
2. Tumor of sacral or iliac bones
3. Active infection at treatment site
4. Unstable fracture of sacrum and/or ilium involving the sacroiliac joint
5. Allergy to metal components

WARNINGS:
1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
2. Single-use devices (e.g. implant.) must not be reused as they are not designed to perform as intended after their initial use.
3. Caution should be exercised when handling instruments and implants, as they are sharp and can puncture or tear gloves, or cause injury.
4. Follow the instructions and warnings issued by the suppliers of any cleaning solutions and equipment used.
5. Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.
6. Cleaning agents with pH of 7-9 are recommended.
7. Highly alkaline conditions (pH > 11) can damage aluminum components.
8. Manual pre-cleaning must be performed prior to Automated Cleaning for all instruments.
9. Soiled or used devices should not be loaded into instrument trays for cleaning in a mechanical washer. Soiled instruments must be processed separate from trays and cases. The instrument trays are designed to be an organization tool for the steam sterilization process, a storage tool for all medical devices and an organizational tool for surgery.
10. The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.

PRECAUTIONS:
1. Carefully read and follow all instructions prior to use.
2. Patient Adherence to post-operative physical activity instructions is important to support long-term service life of the implant.
3. Pay careful attention to selection of implant size. Pre-operative X-rays and/or CT scan may be helpful in selecting optimal implant size.
4. Appropriate patient selection is necessary as patient factors such as size and weight may be helpful in selecting optimal implant size.
5. Inspect implants and instruments for damage prior to use. Do not use if damaged or worn. Do not attempt to repair.
6. Do not use any component from an opened or damaged package.
7. Do not use implants after the expiration date.
8. If placing the implants in conjunction with an open procedure, the surgeon should take care not to destabilize the joint prior to placing the implants.

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Indication For Use

MRI SAFETY INFORMATION:
The OptumSI Implant System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the OptumSI Implant System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

RISKS:
As with other surgical procedures used to treat SI Joint conditions, including acute, non-acute, and non-traumatic fractures involving the SI Joint, the risks associated with the OptumSI Implant System surgical procedure include, but are not limited to the following:

1. Adverse reactions to anesthesia
2. Hemorrhage
3. Muscle damage
4. Hematoma or seroma
5. Neurological deficit, nerve root or peripheral nerve injury, irritation or damage
6. Vascular injury or damage that may result in catastrophic or fatal bleeding
7. Neurovascular injury
8. Injury to inter-pelvic structures
9. Infection of the wound, deep infection, peritonitis
10. Wound dehiscence
11. Thrombosis, thrombophlebitis
12. Death
13. Bruising
14. Local swelling
15. Radiation exposure
16. Loss of fracture fixation

Potential risks specifically associated with the OptumSI Implant System include, but are not limited to the following:

1. Infection
2. Pain, discomfort, or abnormal sensations to the presence of the implant
3. Instrument failure resulting in a complication
4. Migration, loosening, or fracture of the implant
5. Pain in muscle(s) due to altered biomechanics
6. Nerve root or peripheral nerve irritation due to local swelling or altered biomechanics
7. Loss of fixation/stabilization
8. Metal sensitivity or allergic reaction
9. Failure to improve symptoms and/or fracture
10. Increased pain at treated or adjacent levels
11. Implant rejection
12. Decrease in bone density due to stress shielding
13. Failure to achieve SI joint fusion
14. Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint motion
15. Fracture of the sacrum and/or ilium

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