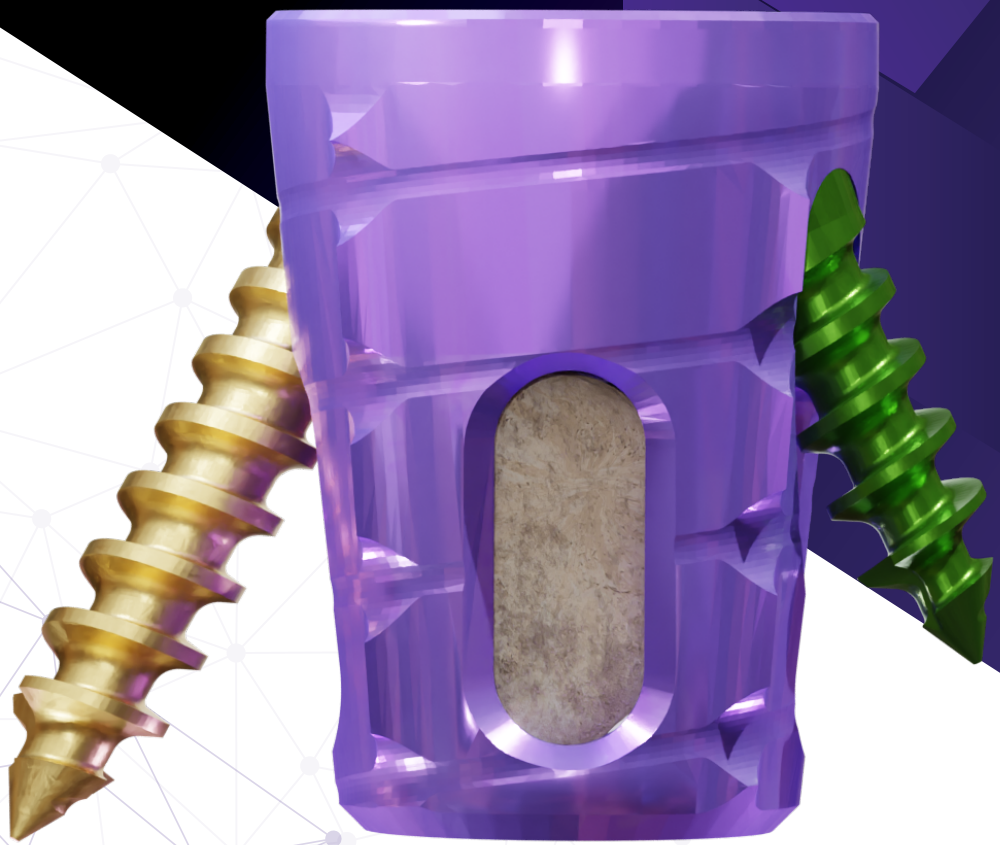
SURGICAL TECHNIQUE GUIDE

SiLO TFX™

THE TRANSFIXING SI JOINT FUSION SYSTEM

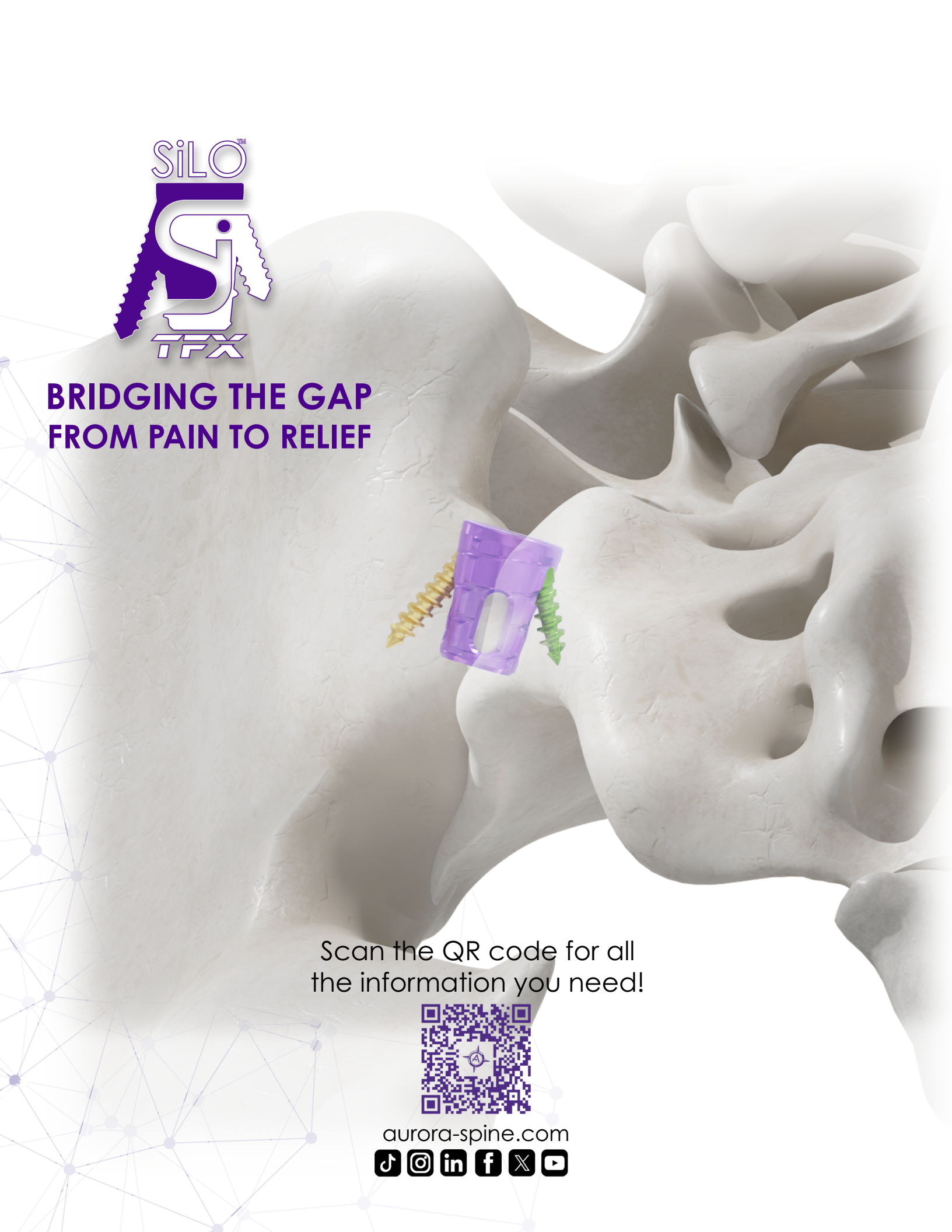


AURORA™

SIMPLIFYING THE COMPLEX

SiLO™ TFX

BRIDGING THE GAP
FROM PAIN TO RELIEF



Scan the QR code for all
the information you need!

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Description

The Aurora Spine SiLO TFX™ Sacroiliac Joint Fixation System includes the SiLO TFX™ Transfixing Bridge, SiLO TFX™ Sacrum Screw, SiLO TFX™ Ilium Screw and associated manual surgical instruments.

The SiLO TFX™ Transfixing Bridge is comprised of a titanium alloy and incorporates a hollow conical shaped barrel with four lateral openings for bone graft material to promote fusion. Two holes span the Bridge, through which screws transfix the Bridge to the Sacrum and to the Ilium.

During the procedure, the implant is inserted in line with the SI Joint via a posterior surgical approach, and bone graft material is placed in the barrel of the implant to facilitate additional bone incorporation after surgery.

Indications for Use

The Aurora Spine SiLO TFX™ MIS Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Instruments

Product Information

SiLO TFX™ SI Joint Fusion System Implant & Screws

Part Number	Description
114-001-24	SiLO TFX™ Transfixing Bridge 24mm
114-004-4520	SiLO TFX™ Sacrum Screw Ø4.5mm x 20mm
114-005-4526	SiLO TFX™ Ilium Screw Ø4.5mm x 26mm

SiLO TFX™ SI Joint Fusion System Instruments

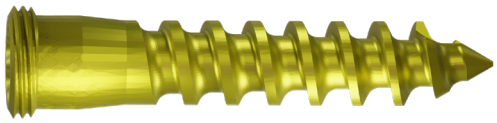
Part Number	Description
110-361-1	Mallet 1lb 2oz
110-364-2	Guidepin Ø2.4mm x 280mm Smooth Sharp
110-712	Removable Handle
114-300-01	SiLO TFX™ Joint Finder
114-301-01	SiLO TFX™ Inserter
114-303-0124	SiLO TFX™ Decorticating Reamer
114-309	SiLO TFX™ Ghost Tube
114-310-01	SiLO TFX™ Striking Adapter
114-310-02	SiLO TFX™ Square Adapter
114-310-03	SiLO TFX™ Hexalobular Adapter
114-311-02	SiLO TFX™ Ghost Tube All Metal
114-315	SiLO TFX™ Flex Retaining Driver
114-320-01	SiLO TFX™ Straight Retaining Driver

SiLO TFX™ Transfixing Bridge

24mm (114-001-24)

SiLO TFX™ Sacrum Screw

Ø4.5mm x 20mm (114-004-4520)



SiLO TFX™ Ilium Screw

Ø4.5mm x 26mm (114-005-4526)

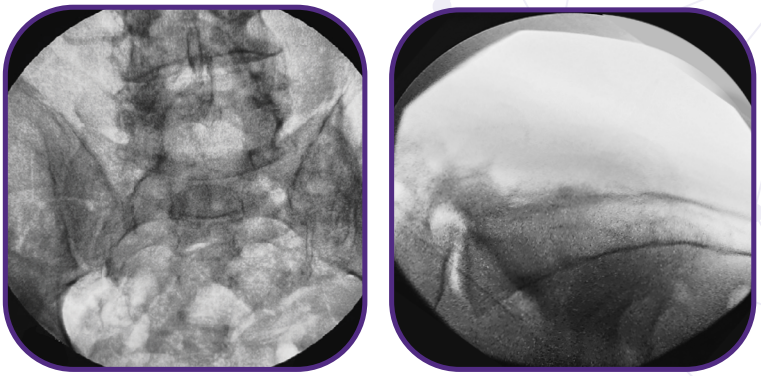
Patient Positioning

The patient should be placed in a prone position in order to facilitate a posterior approach into the SI Joint.

Fluoroscopic Anatomy of the Sacroiliac Joint

Ensure a true lateral and a true AP view of the S1 and S2 vertebra can be visualized.
In the AP view align the pedicles and center the spinous process of the L4 and L5 vertebral bodies. It is advisable to adjust the bed to remove any rotation.

In the lateral view, visualize the sacral base at S1 and the crisp cortical margins of the sacral vertebrae.

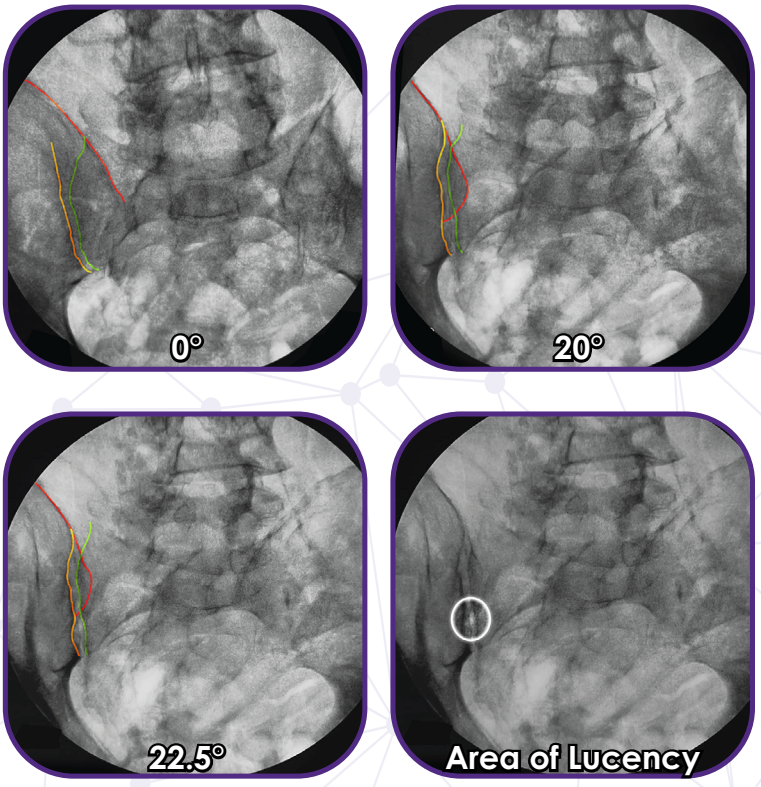


Fluoroscopic Guidepin Placement

In true AP identify the Iliac crest, the Sacral Anterior edge of the SI joint, and the Ilium Anterior Edge of the SI joint.

Rotate the C-Arm to 20 degrees contralaterally to the operative Joint and identify the Iliac crest, the Sacral Anterior edge of the SI joint, and the Ilium Anterior Edge of the SI joint.

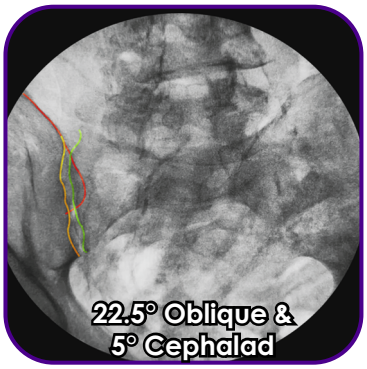
An area of lucency should begin to appear. Its superior border being the PSIS as it traverses the SI joint. Its lateral and medial borders are formed by the Ilium and Sacral joint lines. Use small adjustments of the C-Arm to enlarge or brighten the area of lucency.

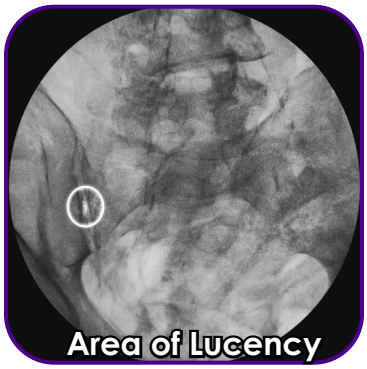


Iliac Crest
Ilium Anterior Edge of SI Joint
Sacral Anterior Edge of SI Joint

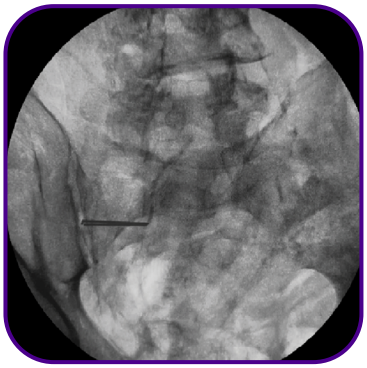
A 5 degrees cephalad tilt of the C-Arm typically establishes the area of lucency more superiorly in the joint.

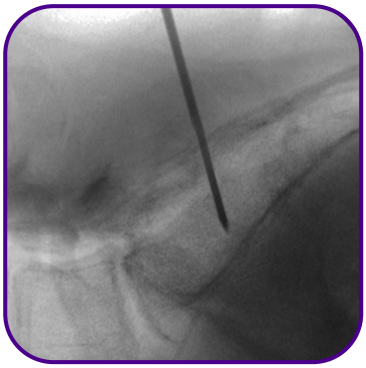
The area of lucency is the target for guidepin entry into the joint.



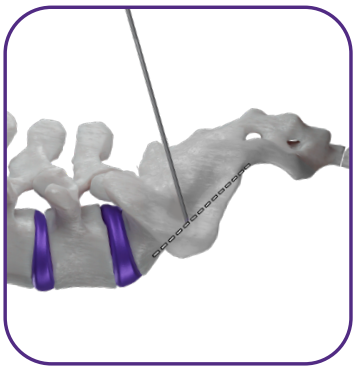


Position the C-Arm for a lateral image and confirm the Guidepin is advanced past the posterior cortical line of the Sacrum. Advance the Guidepin towards the apex of the sacral ala until stable.



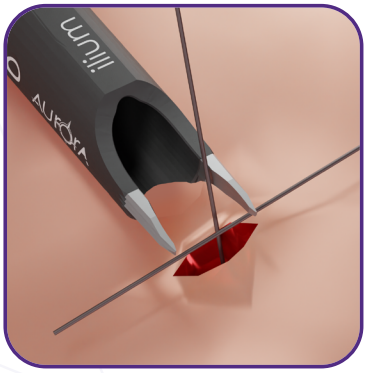


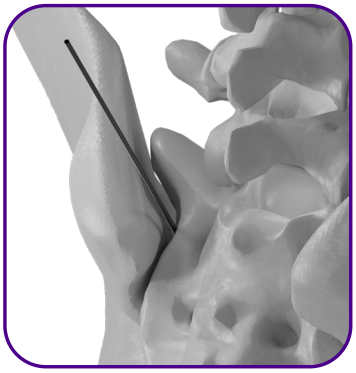
Note: In the lateral view, remember to never advance instrumentation beyond the Anterior cortical line of the Sacrum.



Incision

Make the incision by placing the Ghost Tube against the skin, using it as a template for the incision. Dissect down to the posterior border of the Sacroiliac Joint.

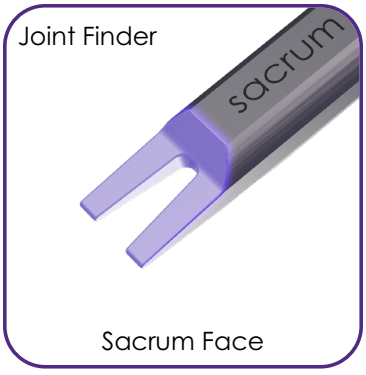




Sacroiliac Joint Finding

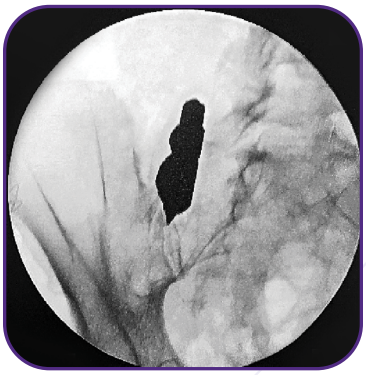
Attach the Joint Finder to the Handle by aligning the arrows on both the button and the Joint Finder, and sliding the Joint Finder into the Handle until they lock together. The button will click and pop out to indicate engagement.

Pass the Joint Finder over the Guidepin and down into the incision. Align the laser-marked words "sacrum" and "ilium" to their respective bones.



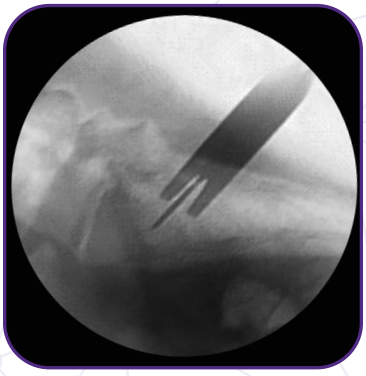
Using fluoruscopy, ensure that the tips of the Joint Finder are parallel with the SI Joint.

AP oblique shot, then tilt cephalad and caudal.



Align the Joint Finder to the SI Joint by visualizing the square profile of the tip. (Removal of the handle may aid in visualizing the tip of the Joint Finder).

Switch to a lateral fluoroscopic view and advance the Joint Finder into the SI Joint by striking the Handle with the Mallet. Pay attention to the Guidepin in the lateral view to ensure it does not continue to advance anteriorly.



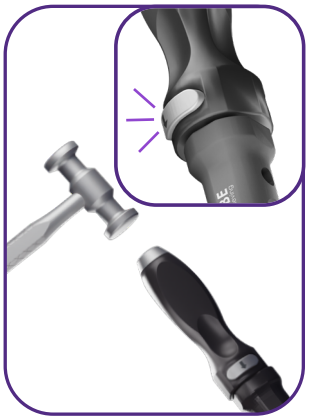
Advance the Joint Finder until the "REF" edge is at the desired depth but tines are no deeper than the anterior margin of the Sacrum.

Placement of Ghost Tube

Remove the Handle from the Joint Finder by pressing the button to disengage the lock and pulling the Handle away, while maintaining control of the Joint Finder in the joint. Advance the Ghost Tube by hand before malleting into final position over the Joint Finder and place the Handle back onto the Joint Finder. Mallet the Handle in order to drive the Ghost Tube into position.

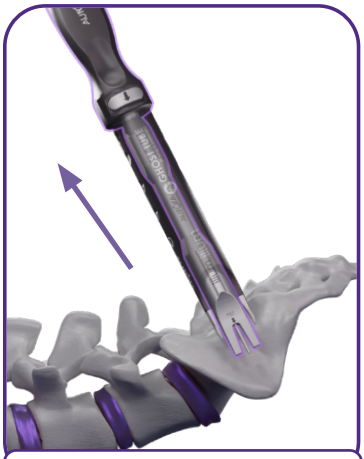

Removing Handle


Inserting Ghost Tube



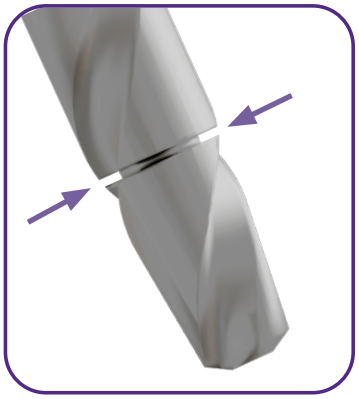
The Ghost Tube is seated when its tines are aligned to those of the Joint Finder and the Handle button locks back onto the Joint Finder. The Handle button will click and pop out to indicate engagement.

Maintain control of the Ghost Tube and remove the Handle and Joint Finder together. The Guidepin will typically be held by the Joint Finder and removed with it.

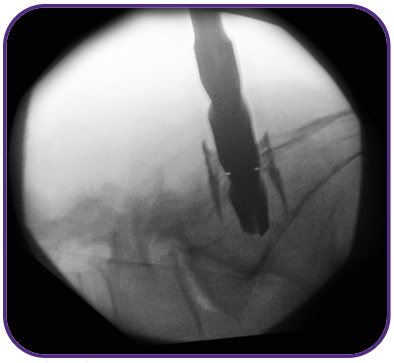

Removing all instruments inside Ghost Tube

Affix the Reamer to the Handle by aligning the arrows on both until they lock. The button will click and pop out to indicate engagement.

Pass the Reamer into the Ghost Tube. Utilize lateral fluoroscopy to assess depth and position of the Reamer. Turn the Reamer Clockwise while pushing in order to advance to the desired depth.



The notch in the Reamer indicates the final position of the Implant's proximal end.



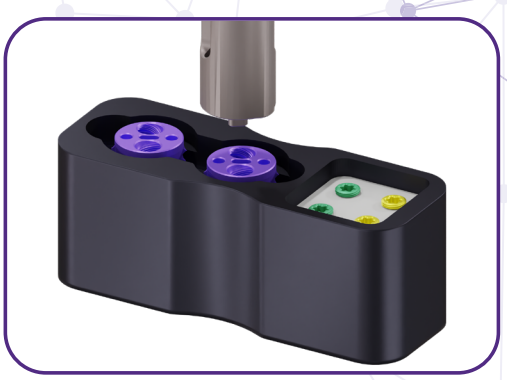
Note: The Reamer will extend a maximum of 6mm beyond the blades of the Ghost Tube once seated.

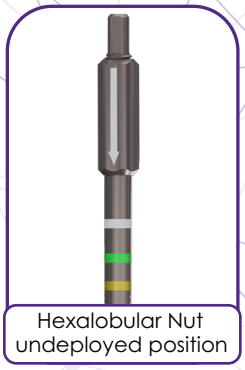
Maintain control of the Ghost Tube and remove the Reamer from the Ghost Tube in a clockwise motion to ensure removal of reamed tissue so implant depth is not compromised.

Implant Preparation

Leave the Transfixing Bridge in the tray and lower the Inserter onto it, making sure the tab and posts of the Inserter align with the respective bores on the Transfixing Bridge.

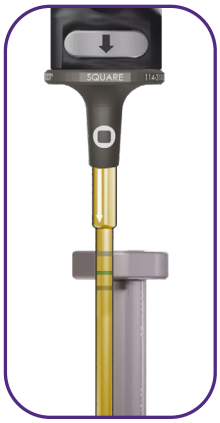
Ensure the Hexalobular Nut on the Flex Retaining Driver is in its undeployed position, covering the threads.

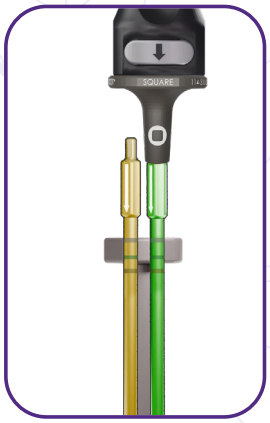




Hexalobular Nut undeployed position

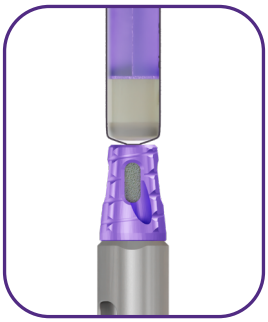
Insert the Flex Driver into Inserter and utilize the Square Adapter to thread the Driver tip into the Transfixing Bridge to secure the Implant to the Inserter, using a slow, pushing and turning motion.
Insert the second Flex Retaining Driver and secure it in the same way.





Remove the Square Adapter and finger tighten the Hexalobular Nuts until both Flex Drivers are pulled into the Inserter and there is no movement between the Transfixing Bridge and the Inserter.

Load the SiLO TFX™ Transfixing Bridge with bone graft from the bottom cavity until it spreads out the side windows.



The "s" and "i" laser markings on both Inserter and Ghost Tube align.

Insertion of the SiLO TFX™ Transfixing Bridge

Place the Inserter with the attached Implant into the Ghost Tube, then place the Striking Adapter over the Drivers and onto the top of the Inserter.

Utilizing lateral fluoroscopy to confirm depth together with positive stop between Inserter and Ghost Tube, use the Mallet to drive the Transfixing Bridge into its final position.

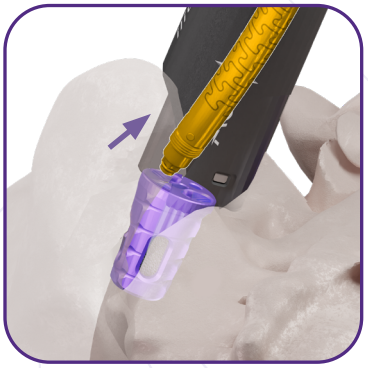
Remove Striking Adapter.

Ilium Screw Insertion/Deployment

Sacrum and Ilium Ports are identified by “s” and “i” laser markings on the Inserter.

Loosen the Hexalobular Nut on the Ilium Port Flex Driver using the Hexalobular Adapter, until the Hexalobular Nut is visibly separated from the Inserter.

Remove the Ilium Flex Driver by attaching the Square Adapter and turning counter-clockwise to release the Flex Driver from the Transfixing Bridge.



Remove the Square Adapter from the Flex Driver and pull out the Flex Driver from the Inserter Ilium Port by hand.

Clean the Flex Driver Tip by rinsing it. The use of gauze is not recommended as gauze strands can get caught on the Flex Driver tip.

Secure the Ilium Screw to the distal Tip of the Flex Driver. Holding the Flex Driver close to the distal tip when inserting into the Screw aids secure attachment. Insert the Flex Driver with the attached Ilium Screw into the Ilium Port on the Inserter. Ensure that the Hexalobular Nut on the Ilium Screw Port Flex Driver is in its undeployed position.

Thread the Ilium Screw into the bone by using the Square Adapter attached to a Handle and turning it clockwise applying a steady, slow, pushing and turning motion.

When the distal part of the yellow-colored band on the Flex Driver aligns with the top of the Inserter, the Ilium Screw is about to pierce into the Ilium.

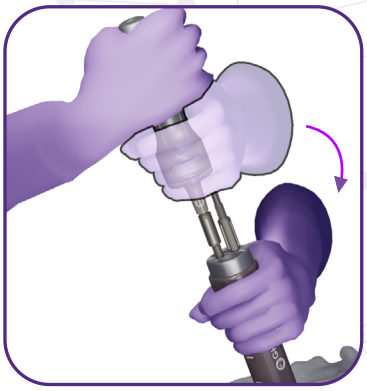
The Flex Driver will begin to recoil once the Screw threads engage with the Transfixing Bridge. The white-colored band on the Flex Driver will start to align with the top of the Inserter.

Final Tightening (Ilium)

When this happens, hold the Handle position with primary hand to prevent the Flex Driver from recoiling. Use the secondary hand to maintain the Handle position with consistent downward force.

Reposition the primary hand on the Handle so that additional clockwise rotation of the Flex Driver can be achieved.

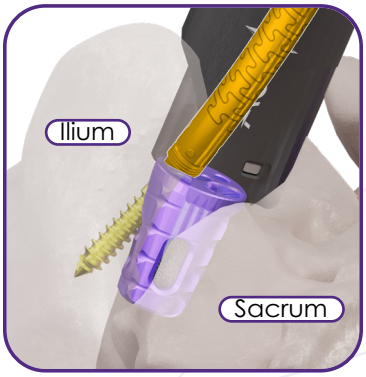
Return secondary hand to Ghost Tube.



Turn the Handle clockwise with steady, slow downward force. Repeat as necessary until a complete stop is reached.

A positive stop is reached once the Screw is locked into the Transfixing Bridge.

We encourage you to Scan QR code to see the explaning video about this section of the procedure.



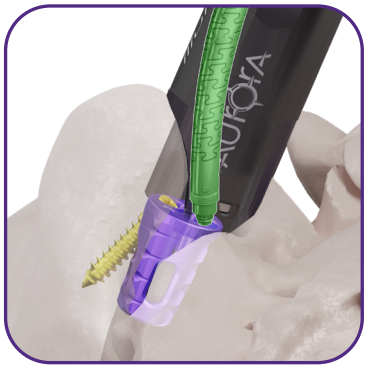
Remove the Handle with the attached Square Adapter.

Sacrum Screw Insertion/Deployment

Loosen the Hexalobular Nut on the Sacrum Port Flex Driver using the Hexalobular Adapter until the Hexalobular Nut is visibly separated from the Inserter.

Note: It is important to maintain control of the Ghost Tube and Inserter while the Sacrum Screw is attached and deployed.

Remove the Sacrum Flex Driver by attaching the Square Adapter and turning counter-clockwise to release the Flex Driver from the Transfixing Bridge.



Remove the Square Adapter from the Flex Driver and pull out the Flex Driver from the Inserter Sacrum port by hand.

Clean the Flex Driver tip by rinsing it.
The use of gauze is not recommended as gauze strands can get caught on the Flex Driver tip.

Secure the Sacrum Screw to the distal Tip of the Flex Driver. Holding the Flex Driver close to the distal tip when inserting it into the screw aids secure attachment. Making sure that it is fully seated into the Screw Socket. Insert the Flex Driver with the attached Sacrum Screw into the Sacrum Port on the Inserter. Ensure that the Hexalobular Nut on the Sacrum Port Flex Driver is in its undeployed position.

Thread the Sacrum Screw into the bone by using the Square Adapter attached to the Handle and turning it clockwise while applying a steady, slow, pushing and turning motion.

When the distal part of the green-colored band on the Flex Driver aligns with the top of the Inserter, the Sacrum Screw is about to pierce the Sacrum.

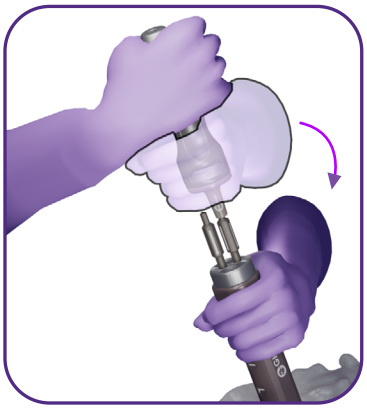
The Flex Driver will begin to recoil once the Screw threads engage with the Transfixing Bridge. The white-colored band on the Flex Driver will start to align with the Top of the Inserter.

Final Tightening (Sacrum)

When this happens, hold the Handle position to prevent the Flex Driver from recoiling. Use the secondary hand to maintain the Handle position with consistent downward force.

Reposition the primary hand on the Handle so that additional clockwise rotation of the Flex Drive can be achieved.

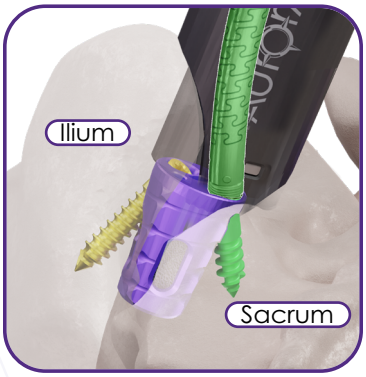
Return secondary hand to Ghost Tube.



Proceed to turn the Handle clockwise with steady, slow, pushing and turning motion. Repeat as necessary, until a complete stop is reached.

If you missed the explanation video on how to correctly tighten the Screws, scan the QR code:

A positive stop is reached once the Sacrum Screw is threaded into the Sacrum and to the Transfixing Bridge.



Remove the Handle with the attached Square Adapter.

Confirm that both Screws are fully deployed by utilizing an oblique cephalad or caudal tilt on the C-Arm.

Instruments Removal

Once confirmation of full deployment for both screws is attained, tighten the Hexalobular Nut on either Flex Driver using the Hexalobular Adapter and turning it clockwise to release the retention between the Flex Driver's tip and the Screw's socket.

Once the Flex Driver is no longer retained in the Screw, remove the Flex Driver by hand.

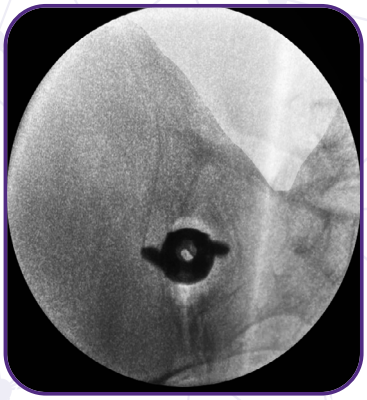
To remove the remaining Flex Driver repeat the two previous steps.

Carefully remove the Inserter and Ghost Tube together. Final Fluoroscopic shots should be taken to confirm screws placement.

Lateral fluoroscopic shots confirm that the Screws are seated in the Transfixing Bridge. Oblique AP shots with Cephalad and Caudal tilt confirms that screws are in the Ilium and Sacrum.

Irrigate and close.

To remove the implant, use the straight Retaining Driver to loosen and remove the Screws to then proceed by retracing the steps in reverse order.



Instructions for Use

Description:
The Aurora Spine SiLO TFX™ Sacroiliac Joint Fixation System includes the SiLO TFX™ Transfixing Bridge, SiLO TFX™ Sacrum Screw, SiLO TFX™ Ilium Screw and associated manual surgical instruments.
The SiLO TFX™ Transfixing Bridge is comprised of a titanium alloy and incorporates a hollow conical shaped barrel with four lateral openings for bone graft material to promote fusion. Two holes span the Bridge, through which screws transfix the Bridge to the Sacrum and to the Ilium. During the procedure, the implant is inserted in line with the SI Joint via a posterior surgical approach, and bone graft material is placed in the barrel of the implant to facilitate additional bone incorporation after surgery.

Material:
All Aurora Spine SiLO TFX™ Implants are manufactured from titanium alloy (Ti-6AL-4V ELI) as described by ASTM F136 or equivalent. The instrumentation is made from various grades of stainless steel, anodized titanium, and/or medical grade plastic.

Please contact Aurora Spine to obtain a Surgical Technique Guide

Indications for Use:
The Aurora Spine SILO TFX™ MIS Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Contraindications:
Contraindications may be relative or absolute, and may include:
- Infection or inflammation, local to the operative site
- Allergy or sensitivity to titanium
- Patients who are immune compromised
- Fever or leukocytosis
- Pregnancy
- Deformities or anatomic variations that prevent or interfere with SiLO TFX™ placement.
- Tumor of sacral or iliac bone.
- Active infection at treatment site.
- Unstable fracture of Sacrum and or ilium Involving the sacroiliac joint.
- Any condition that may affect the process of normal bone remodeling, including, but not limited to, rapid joint disease, poor bone quality, osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis
- Any medical or surgical condition that would preclude the potential benefit of spinal implant surgery (i.e. elevation of white blood count (WBC) or marked left shift in the WBC differential count)
- Grossly distorted anatomy due to congenital abnormalities
- Morbid obesity
- Alcoholism or heavy smoking
- Inadequate tissue coverage over surgical site
- A case not needing bone graft, fusion, or fracture healing
- A patient unwilling or unable to comply with postoperative instructions
- Any instance in which the implant would interfere with anatomical structures or expected physiological performances
- Reuse or multiple use
- Any case not described in the indications for use
- Prior fusion at the area to be treated

Possible Complications:
- Implant breakage, failure, loosening, or migration
- Sacral or iliac bone fracture
- Allergic reaction to the implant material

Other general complications associated with any spinal surgery may include:
- Pseudoarthrosis
- Pain
- Revision surgery
- Bleeding
- Infection, early or late
- Tissue or nerve damage
- Spinal fluid leakage
- Scar formation
- Complications due to the use of bone grafting, including donor site complications

Cleaning:
The following recommendations are for the manual cleaning and decontamination of the Aurora Spine surgical instruments. These recommendations are considered guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user.

Automated cleaning systems may differ between hospitals and therefore must be qualified by the hospital.

Remove all labels and packaging materials before cleaning and sterilization. Submerge products in a standard hospital grade surgical instrument enzymatic detergent (e.g., Miltex®) for a minimum of one hour prior to cleaning with a soft bristle brush, lint free cloth or sponge for a minimum of 8 minutes to remove any visible soil.
Follow the manufacturer's instructions for solution concentration. During cleaning, special attention should be applied to hard-to-reach areas and tight lumens. Lumens should be flushed several times. Rinse each product in a brisk stream of clean, room temperature tap water for a minimum of 2 minutes then soak again for a minimum of 30 minutes in a freshly prepared solution of the cleaning detergent followed by sonication for a minimum of 30 minutes.
Once all visible soil has been removed, rinse immediately and thoroughly with running tap water for a minimum of 3 minutes to remove detergent residues.
Use de-ionized water as a final rinse. Immediately dry product with a lint-free towel and allow to air dry. Sterile compressed air may be used to dry product. Inspect all products prior to sterilization or storage for evidence of wear or damage.

NOTE: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

Sterility:
Implants, instruments, and carrier trays/caddies are supplied **"NON-STERILE"** and must be cleaned and sterilized before use.
The recommended sterilization process for the implants, instruments, and carrier trays/caddies is a high temperature steam autoclave sterilization. It is recommended that the loaded trays/caddies be double wrapped using two standard FDA cleared sterilization wraps. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}.

All implants are single use only. Reuse of this single use device that has come in contact with blood, bone, tissue, or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include but are not limited to mechanical failure and transmission of infectious agents.

Recommended Sterilization Cycle:
Method: Steam (Dynamic-Air-Removal)
Cycle: Pre-vacuum
Minimum Temperature and Exposure Time: 270°F (132°C) for 4 minutes
Drying Time: 60 minutes

All packages containing implants should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned. The product must be handled and stored in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following the cleaning, sterilization, and accepted surgical technique.

Note – It is the responsibility of the user to ensure the sterilization process used is validated.

Instructions for Use:
The physician implanting the Aurora Spine SiLO TFX™ is expected to be fully educated in the techniques and methods of placement of the system. A successful result may not occur in every event in which the Aurora Spine SiLO TFX™ is implanted. Failure rates in the sacroiliac fusion procedures are published and sacroiliac fusion failure is an accepted risk of the procedure. This is particularly true for the patient who chooses to smoke tobacco products, patients in malnourished or obese states, or who abuse alcohol products. Proper selection of patients and good compliance of patients with pre-surgical instructions are an integral part of realization of a successful surgical procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations regarding activities that the patient will face following surgery. Use of the Aurora Spine SiLO TFX™ Scroiliac Joint Fixation System should only be considered when the following preoperative, intraoperative and postoperative conditions exist.

Preoperative:
Patients should be in the previously described diagnostic categories described under 'Indications for Use'.
Patients should not be in the contraindication groups listed under 'Contraindications'.
Sterilization and handling procedures conforming to accepted standards are mandatory.
The techniques for implanting this system should be reviewed by the physician prior to use of the system.
The physician should inspect the available components of Aurora Spine SiLO TFX™ prior to surgery to assure that all necessary components are present.
The physician is expected to follow the instructions made available in surgical technique guides and literature relative to implantation of the Aurora Spine SiLO TFX™.
The Aurora Spine SiLO TFX™ components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage and corrosion, and where applicable, a loss of sterility.

Intraoperative:
The physician is expected to follow the instructions made available in training manuals and literature relative to implantation of the Aurora Spine SiLO TFX™. The physician is expected to exercise extreme care in the placement of implants, particularly in regard to neural elements. Radiographs should be made if there is any question as to the location of the intended or the actual placement of the implants.
Bone graft material must be used in conjunction with the Aurora Spine SiLO TFX™ to augment stability. The bone graft material should be packed inside the device prior to insertion.

Postoperative:
The patient is expected to follow the detailed instructions, limitations, and warnings from the operating physician. The risk of bending, loosening or breakage of the implants during postoperative rehabilitation may be increased if the patient is active.
The physician is expected to supply detailed instructions to the patient regarding postoperative activities. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as ibuprofen during the bone healing process.
Failure to immobilize, a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important to follow preoperative instructions to insure a successful union.
If a state of nonunion persists or if the components loosen, bend and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately educated of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
The potential for multiple complications exists. These are not necessarily due to deficiencies of the implants and may include fracture of the implants due to fatigue, late infection or sensitivity due to fretting-corrosion, prominence of the implants, and displacement of the implants due to failure of the supporting spinal structure.
Retrieved implants should be properly disposed of, or where applicable, returned to Aurora Spine for complaint investigation and are not to be reused under any circumstance.
The patient must be told that the device can affect the results of compute tomography (CT) or magnetic resonance imaging (MRI) scans. Possible risks associated with these types of imaging scanners include, but are not limited to, heating and/or migration.
The Aurora Spine SiLO TFX™ Sacroiliac Joint Fixation System has not been evaluated for safety and compatibility in the MR environment. The Aurora Spine SiLO TFX™ has not been tested for heating or migration in the MR environment.

Complications and Adverse Reactions:
The complications and adverse effects of this system are similar to other systems of similar design.
Complications and adverse reactions include, but are not limited to, the following:
- Loosening, bending, dislocation, and/or breakage of the components, possibly requiring further surgery
- Cessation of growth of the fused portion of the sacroiliac joint
- Nonunion or pseudoarthrosis, possibly requiring further surgery
- Infection and/or wound complications
- Physiological reaction to implant devices due to foreign body intolerance including inflammation local tissue reaction, and possible tumor formation
- Loss of neurological function by several mechanisms, including direct compression by component parts, stretching of the spinal cord by component parts, vascular spinal cord compromise, or other mechanisms
- Malalignment of anatomical structures (i.e. loss of normal spinal contours or change in height)
- Pain or discomfort
- Scar tissue formation possibly causing neurological and/or vascular compromise
- Bone loss and/or decrease in density due to stress shielding
- Subsidence of the device into the vertebral body
- Revision surgery

Warnings:
The Aurora Spine SiLO TFX™ is an implant device used only to provide internal transfixation during the bone fusion process with the assistance of bone graft or other materials. A successful result may not be achieved in every instance of use with this device. This fact is especially true in spinal surgery where other patient conditions may compromise the result.
Surgical outcomes with this device are significantly affected by the physician's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants, and complete compliance of the patient.
All implants are provided non-sterile and instruments are provided non-sterile and must be cleaned and sterilized prior to use.
Based on the fatigue testing results, the physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc., which may impact the performance of the system. This device must not be reused. Reuse may result in patient injury or other complications including, but not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.
Patients with previous spinal surgery at the sacroiliac joint to be treated may have different clinical outcomes compared to those without a previous surgery.

A successful result will not be achieved in every instance of use of this device. Strict adherence by the patient to the instructions of the physician is necessary to insure the optimal result. Known conditions associated with poor or less than optimal results include malnutrition, cigarette smoking, obesity, and alcohol abuse.

Precaution:
Implantation of the Aurora Spine SiLO TFX™ should be performed only by experienced physicians with specific training in the use of this system as this is a technically demanding procedure presenting a risk of serious injury to the patient.

Customer Service

For further information regarding the Aurora Spine SiLO TFX™ Sacroiliac Joint Fixation System or Surgical Technique Guide, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

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