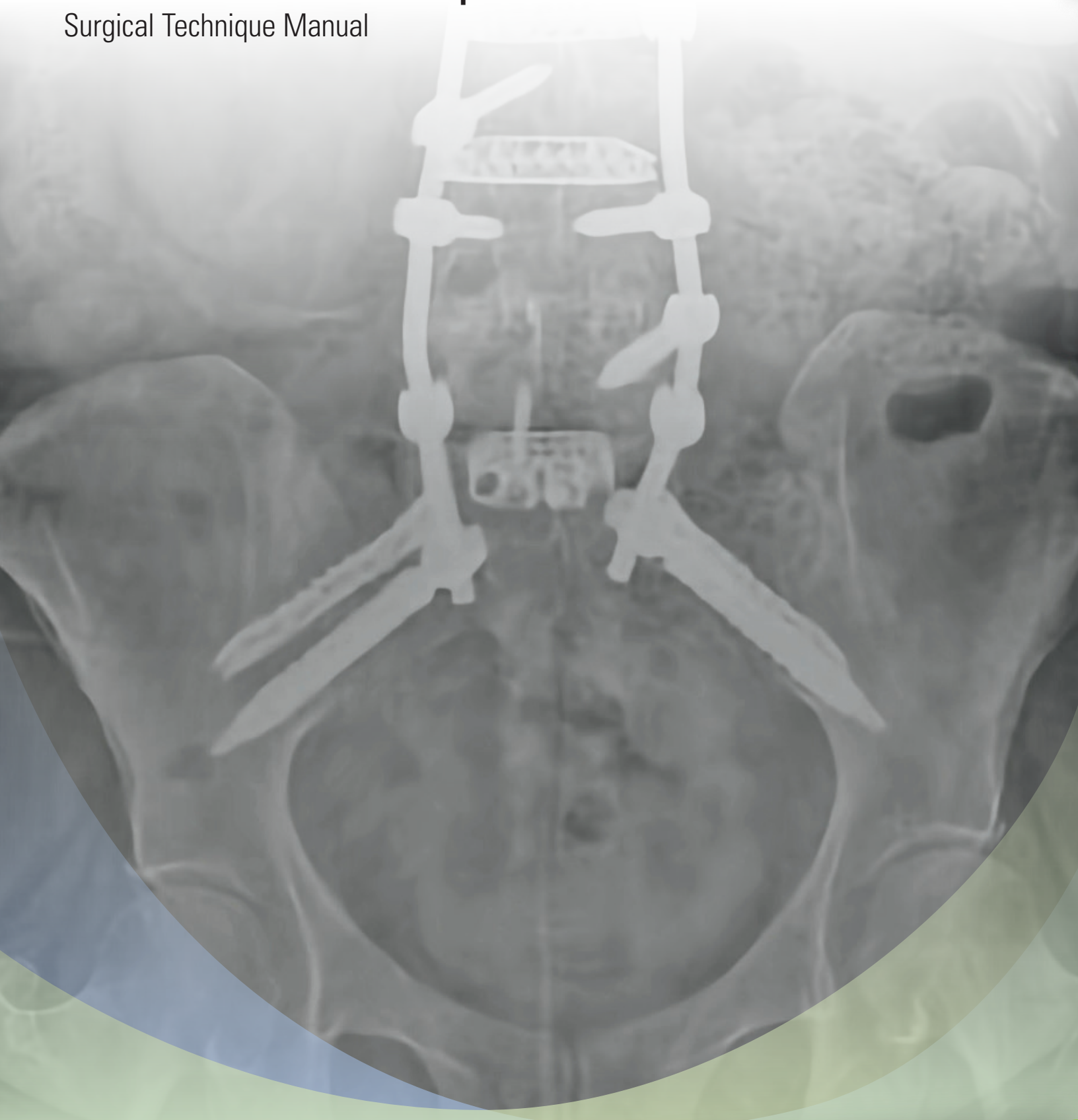
Deformity

iFuse TORQ® Bedrock® Technique

Surgical Technique Manual



SI-BONE®

Sacropelvic Solutions™

Contents

About SI-BONE, Inc.

SI-BONE, Inc. is focused on the diagnosis and treatment of sacroiliac (SI) joint disorders. We are dedicated to educating surgeons on the diagnosis of lower back issues as they relate to the SI joint and training them to effectively perform surgeries with the goal of outstanding patient results every time.

iFuse TORQ® Implant System: Introduction

The iFuse TORQ® Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ Navigation instruments are intended to be used with the Medtronic StealthStation System.

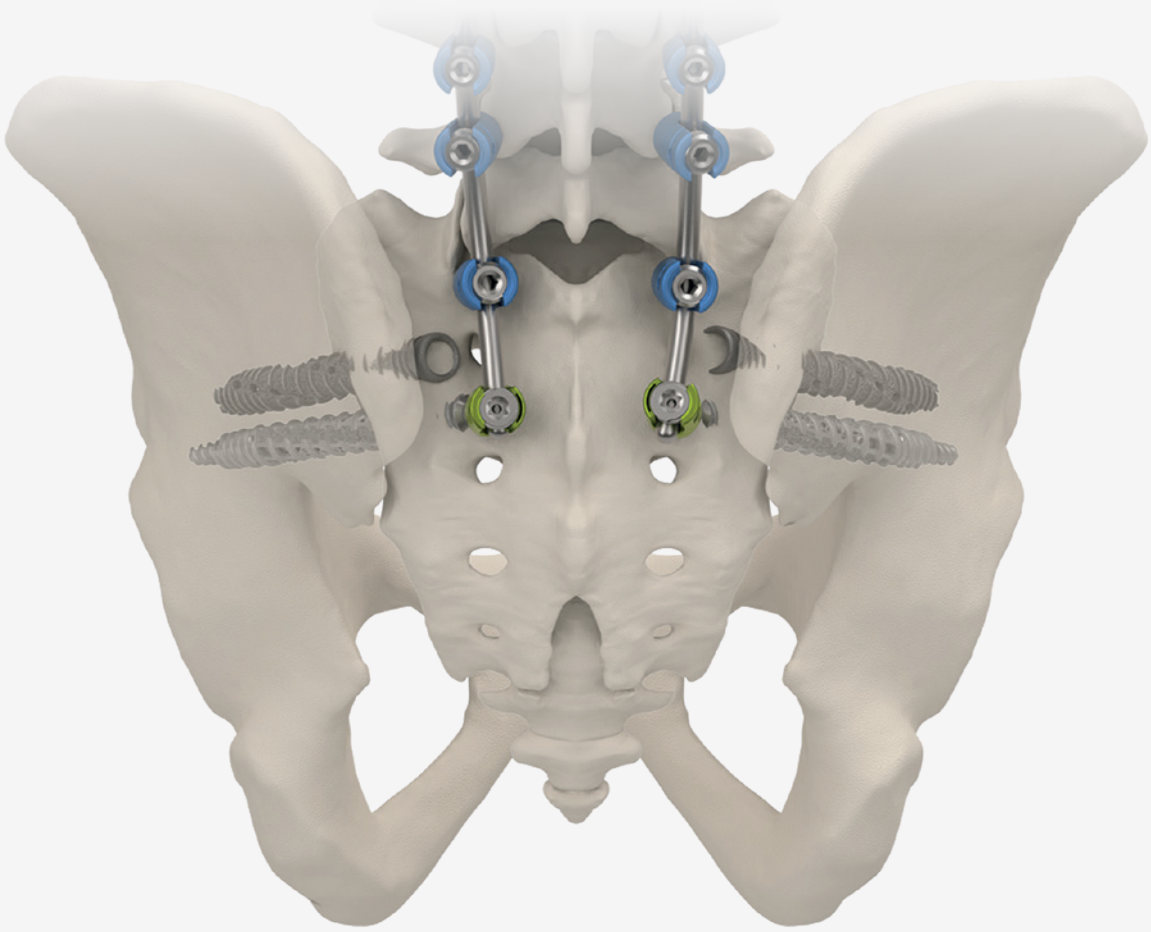
iFuse TORQ® Bedrock® Technique

iFuse TORQ implants may be placed via a sacro-alar-iliac approach to supplement pelvic fixation, with either an open or minimally invasive surgery (MIS) technique, per surgeon preference.

This technique is intended for trained surgeons with experience performing multilevel posterior spinal fusion with instrumentation including pelvic fixation.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse TORQ Implant System. For complete information on contraindications, warnings, precautions, and potential risks, refer to the iFuse TORQ Implant System Instructions For Use, 501381.

***NOTE**: This STM describes placement of iFuse TORQ in the SAI trajectory placed cranially to the S2AI screw using various techniques. Most descriptions refer to instruments found in the full TORQ tray. When placing iFuse TORQ in the context of simultaneous placement of iFuse Granite (see STM 300961), a reduced instrument set, called Granite+, can be used. See Appendix for listing of Granite+ instruments.*



***PRECAUTION:** In this trajectory, always place iFuse TORQ in conjunction with a pelvic fixation device attached to the spinal rod..*

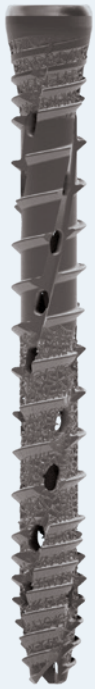
iFuse TORQ® Implant System

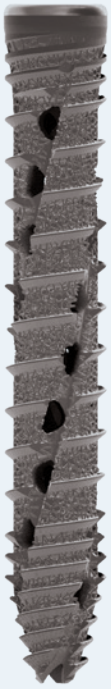
- iFuse TORQ Implants are designed to optimize initial fixation and long-term integration of the implant with the surrounding bone
- 3D printed lattice surface
- Self-drilling and self-tapping, for speed of implantation (in hard bone, drilling and tapping may be required)
- Hooked thread design may prevent screw loosening and toggle, especially in low density bone
- Helical flutes and fenestrations self-harvest bone during implantation
- Torx head design for ease of Implant insertion or removal
- Navigation-compatible instrumentation
- Fully-Threaded design when fixation is desired along entire length of Implant, and Lag version provides compression
- Dual-single-dual thread design allows for greater purchase in sacrum and ilium bone, and more surface area for integration with surrounding bone
- Polyaxial Washer available on the 10.0 mm and 11.5 mm Lag Implants to conform to angled edge of lateral ilium and as such optimize compression

PRECAUTIONS:

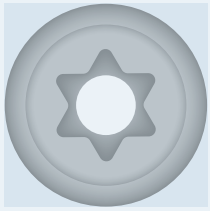
- *In hard bone, users should drill and tap to ensure that the implant can be fully inserted and/or adjusted as necessary during the index procedure.*
- *In revision/removal cases, trephines and/or other instruments such as chisels, may be needed to free the Implant(s) from the surrounding bone prior to using the iFuse TORQ Driver to remove the Implant(s).*

iFuse TORQ Fully-Threaded Implants: Specifications





Specifications (all sizes in mm)			
Major Diameter	10.0	11.5	13.5
Minor Diameter	7.5	9.0	11.0
Inner Diameter	3.4	3.4	3.4
Head Diameter	11.5	12.0	13.75
Length	35-90	35-90	35-90
Drill Bit Diameter	7.0	8.5	10.5
Tap Diameter	9.25	10.75	12.75
Part Numbers			
Implant	100XXT	115XXT	135XXT
Drill Bit: Fluoro	501154-0700	501154-0850	501154-1050
Nav	501122-0700	501122-0850	501122-1050
Tap: Fluoro	501157-0925	501157-1075	501157-1275
Nav	501124-0925	501124-1075	501124-1275
Nav, Awl Tip	501126-0925	501126-1075	501126-1275



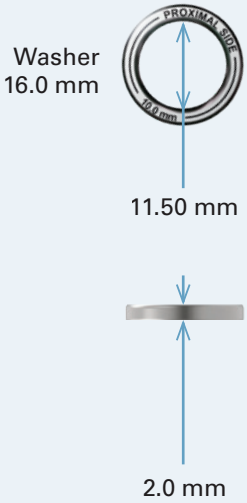
iFuse TORQ implants have a **T40 Torx Head**

iFuse TORQ Lag Implants: Specifications

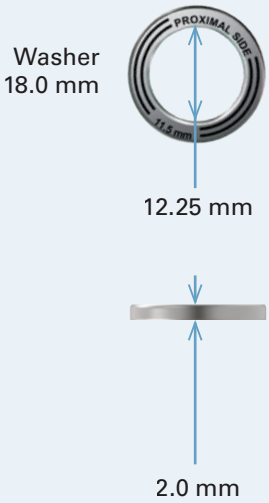
Specifications (all sizes in mm)		
Major Diameter	10.0	11.5
Minor Diameter	7.5	9.0
Inner Diameter	3.4	3.4
Head Diameter	12.5	13.0
Length	40-90	40-90
Drill Bit Diameter	7.0	8.5
Tap Diameter	9.25	10.75
Washer Outer Diameter	16.0	18.0
Washer Inner Diameter	11.5	12.25
Part Numbers		
Implant	100XXLG	115XXLG
Washer	501284	501285
Drill Bit: Fluoro	501154-0700	501154-0850
Nav	501124-0700	501122-0850
Tap: Fluoro	501157-0925	501157-1075
Nav	501124-0925	501124-1075
Nav, Awl Tip	501126-0925	501126-1075

iFuse TORQ Lag Implants: Specifications

10.0 mm Lag Implant and Washer



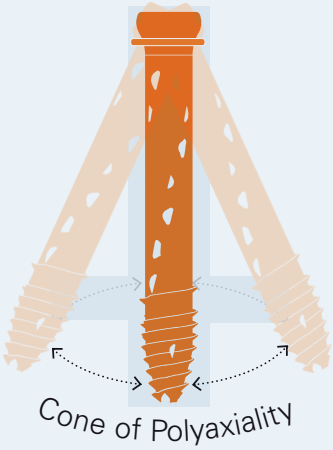
11.5 mm Lag Implant and Washer



Lag Implant Thread Length*	
Implant Length (mm)	Thread Length (mm)
40	22.0
45	25.0
50	28.0
55-90	32.0

* Values apply for 10.0 mm and 11.5 mm diameter implants

Implant-Washer Cone of Polyaxiality
10.0 mm Lag Implant: 24.5°
11.5 mm Lag Implant: 21.5°



Procedure: Pre-Op Planning and Patient Set-Up

Pre-Op Planning

- Carefully evaluate sacrum and ilium on cross-sectional imaging study, such as CT scan
- Special considerations should include defects in ilium secondary to prior iliac crest bone graft (ICBG) harvest and/or any other deficiencies of the dorsal sacrum (laminar defects) and/or ilium
- Modification of the trajectory may be necessary, especially in patients with sacral dysmorphism
- iFuse TORQ Implants are designed both to optimize internal fixation and to integrate in the long term with surrounding bone

Patient Set Up

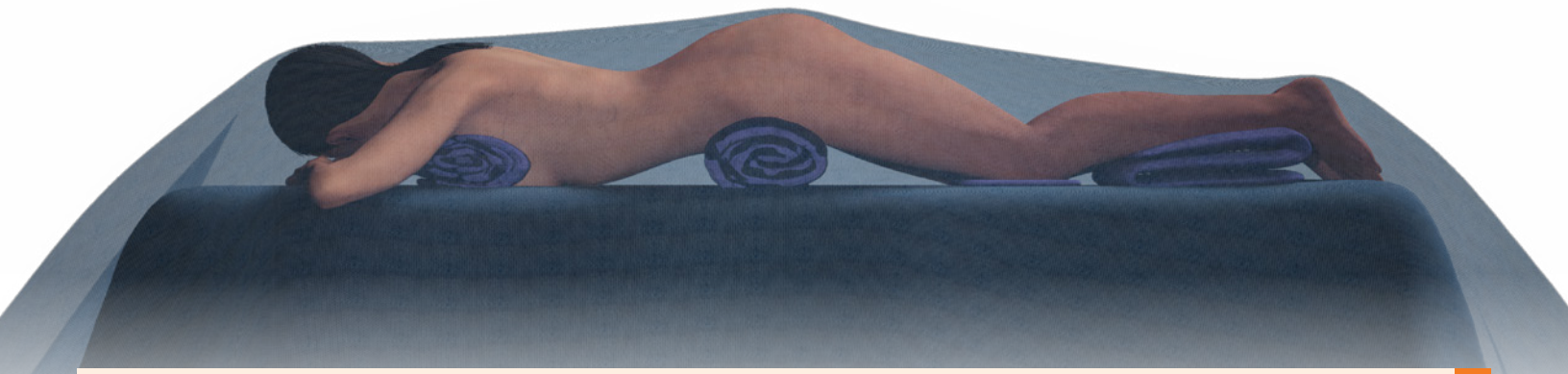
- Position the patient prone on either a Jackson or flat imaging table
- Typically, use one C-Arm for imaging, although two may be used
- Typically, the patient is in a "spine neutral" position including a neutral SI joint without extreme extension or flexion of the hips
- Note: It is recommended to stand on the contralateral side of the patient when placing implants from a sacro-alar-iliac approach

Placement of Pedicle Screws

Surgeon to place pedicle screws using technique of choice

Care of Instruments During Procedure

The iFuse TORQ Implant System is a pin-based system. As is common with standard pin-based systems, bone material may adhere to the Drill Bit, Tap 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 may minimize the occurrence of binding of instruments and/or Implants. Please refer to 300065, iFuse Family of Instruments – Hospital Cleaning and Sterilization Instructions, USA.



PRECAUTIONS:

- *This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the surgeon's judgement. Instruments may be used at the surgeon's discretion.*
- *Breakage, slippage or misuse of instruments or implants may cause injury to the patient or operative personnel.*
- *Excessive loads, such as excessive torque, tensile or compression load applied to long handle insertion tools attached to the implant or direct application of loads to a small area of the device, can damage the Implant/Instrument interface and make implant deliver/removal challenging or impossible.*
- *In revision/removal cases, trephines and/or other instruments such as chisels, may be needed to free the Implant(s) from the surrounding bone prior to using the iFuse TORQ Driver to remove the Implant(s).*
- *Position C-arm to minimize interference with instruments throughout the procedure.*

Procedure: Fluoroscopic Guidance

Lateral View

- Align disc space and end plates of L5-S1 to a true lateral view
- Sciatic notches should overlap, and iliac cortical densities (alar lines) should be superimposed **(Fig. 1)**

Anteroposterior (AP) View

- C-Arm placed vertical and centered over the sacrum **(Fig. 2)**

Teardrop View

- Start from an AP view
- Teardrop view is oblique in two planes
- Tilt C-Arm cranially ~20 - 40°, typically less than an outlet view angle
- Rainbow C-Arm toward the surgeon such that the beam is directed co-axially with the working trajectory toward the ipsilateral greater trochanter (opposite the working side), which will typically be ~20 - 40° relative to the vertical plane, aiming toward the anterior inferior iliac spine (AIIS) **(Fig. 3)**

Inlet View

- Start from an AP view
- Tilt C-Arm caudally until sacral promontory and the vestigial disk of S1 and S2 overlap and appear as one line (~20 - 30°) **(Fig. 4)**

Outlet View

- Start from an AP view
- Tilt C-arm cranially until the S1 and S2 neural foramina are well visualized (~40 - 60°) **(Fig. 5)**

Figure 1: Lateral view

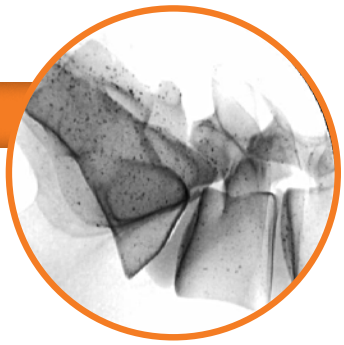
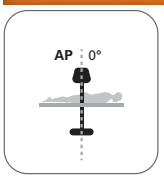


Figure 2: AP view



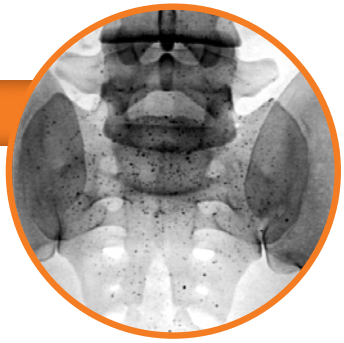


Figure 3: Teardrop view

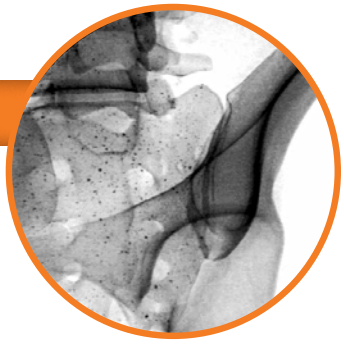
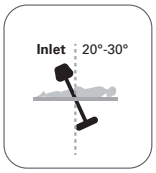


Figure 4: Inlet view



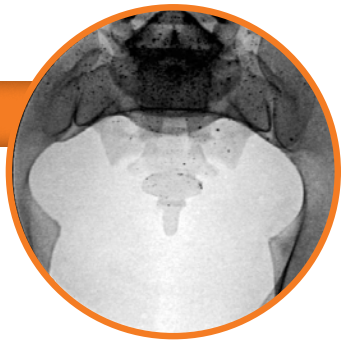
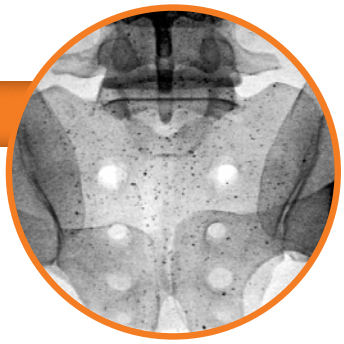


Figure 5: Outlet view



Procedure: Surgical Exposure, S2AI Screw and iFuse TORQ Placement

Open Approach:

- Extend midline lumbar surgical incision caudally
- Expose the dorsal/posterior aspect of the sacrum to a minimum of 1.5 cm lateral to the S1 and S2 neuroforamen
- It is not necessary to dissect to iliac crest for placement of implants

MIS Approach:

- Create a midline 2 - 3 cm skin incision starting at the level of the S1 neural foramen, extending to the level of the inferior aspect of the S2 neuroforamen
- Avoid occult midline sacral laminar defects based on pre-op advanced imaging review

***NOTE**: The MIS approach requires additional instruments that can be found in the product catalog on pages 22 and 23.*

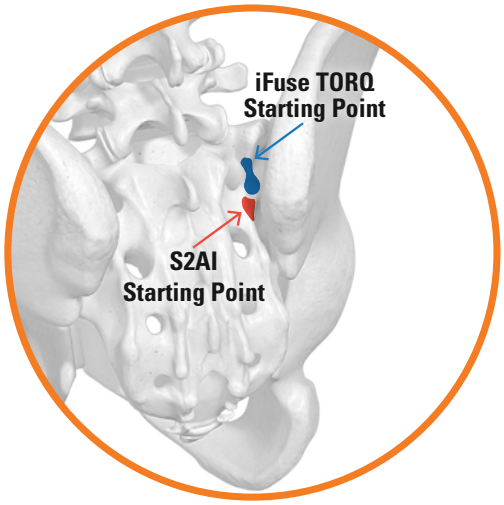


Figure 6: Schematic showing starting point for S2AI screw (red arrow) and iFuse TORQ Implant (blue arrow)

Placement of S2AI Screw

- Place S2AI or other pelvic fixation device (e.g. iFuse Bedrock Granite or other pedicle screw in the iliac trajectory) using technique of choice. Consider a more caudal starting point on the sacrum and trajectory within the teardrop to leave adequate room for an iFuse TORQ implant starting between the S1 pedicle screw and S2AI screw (typically lateral to the S1 neuroforamen)
- **The starting point for the S2AI screw should be at the level of the midpoint between the S1 and S2 dorsal foramina, at the level of the lateral aspect of the foramen, and in line with the S1 pedicle (Fig. 6, red arrow)**
- **Starting point may vary with patient anatomy**

iFuse TORQ Placement

- Starting point will be midway between S1 pedicle screw and S2AI screw, cranial to the S2AI screw.
- Starting point will frequently be at level of the midpoint of the S1 neuroforamen along the lateral border of the foramen **(Fig. 6, blue arrow)**
- **Starting point may vary with patient anatomy.**
- **Leave 1 - 2 mm between iFuse TORQ and any adjacent hardware.**

PRECAUTIONS:

- *If placing the Implants in conjunction with an open SI joint fusion, the surgeon should take care not to destabilize the joint prior to placing the Implants.*
- *Consider adding additional distance between Implants to facilitate potential removal/revision surgery. iFuse TORQ Trephines, used to remove iFuse TORQ (if required), have a wall thickness of 1.0 mm.*
- *Take care to avoid contacting other hardware when performing the iFuse TORQ procedure.*

Procedure: Create a Channel for the iFuse TORQ Implant

- Position C-Arm in Teardrop View.
- Use rongeur or pedicle awl to open the sacral cortex at starting point described above.
- Use pedicle awl/probe to create the implant channel. Note, the starting point is typically medial to the "teardrop" on the Teardrop View.
- Advance the pedicle awl to create channel parallel and cephalad to that of the S2AI screw using both the Lateral and Teardrop Views **(Fig. 7).**
- **As the awl is advanced, it should become centered within the "teardrop" and remain parallel to the S2AI screw on the Lateral View (Fig. 8).**
- Use ball tip probe to palpate planned implant trajectory, confirming circumferential osseous integrity and bony endpoint.
- **If lateral breach of the ilium occurs, create new implant channel using the steps above.**

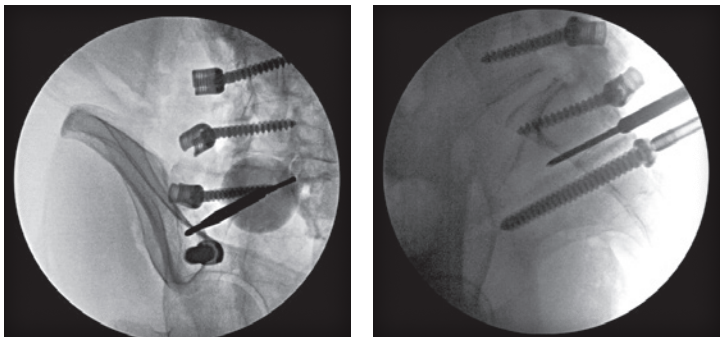


Figure 7

Pedicle awl entering "teardrop" in the Teardrop View (left), and parallel to the S2AI screw in the Lateral View (right).

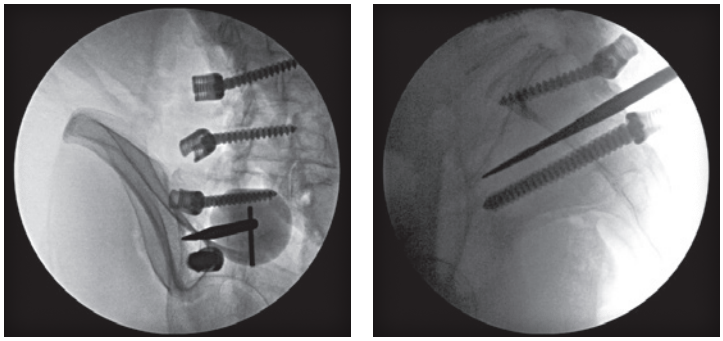


Figure 8

Final placement of the pedicle awl/probe, noting it is now centered within the "teardrop" in the Teardrop View (left), and remains parallel to the S2AI screw in the Lateral View (right).

PRECAUTIONS:

- *Avoid implant trajectory that will intersect previously placed implants as interdigitation of threads from adjacent implants may make implant removal more difficult.*
- *Avoid breach of ilium with instrument or implants to minimize risk of injury to adjacent neurovascular structures and/or muscle.*
- *Use of a guide pin may be helpful to avoid deflection of instruments/implants.*

Procedure: Pin Placement (Optional)

- Remove pedicle awl and advance Blunt Pin down channel until bony resistance is felt. Confirm placement with fluoroscopy.
- The Radiolucent Clamp can be used to hold the pin while keeping the surgeon's hand away from the radiation source (optional step).
- Confirm pin placement with imaging, ensuring there is enough room for the iFuse TORQ implant with respect to adjacent hardware (e.g. iFuse Bedrock Granite, S2AI screw and S1 pedicle screw) **(Fig. 9).**
- **An alternative option to using a pedicle awl is to create the channel/trajectory for the pin using a Jamshidi needle that can accommodate the 3.2 mm Pin.**

***NOTE**: The iFuse TORQ tray does not include a pedicle awl or Jamshidi needle.*

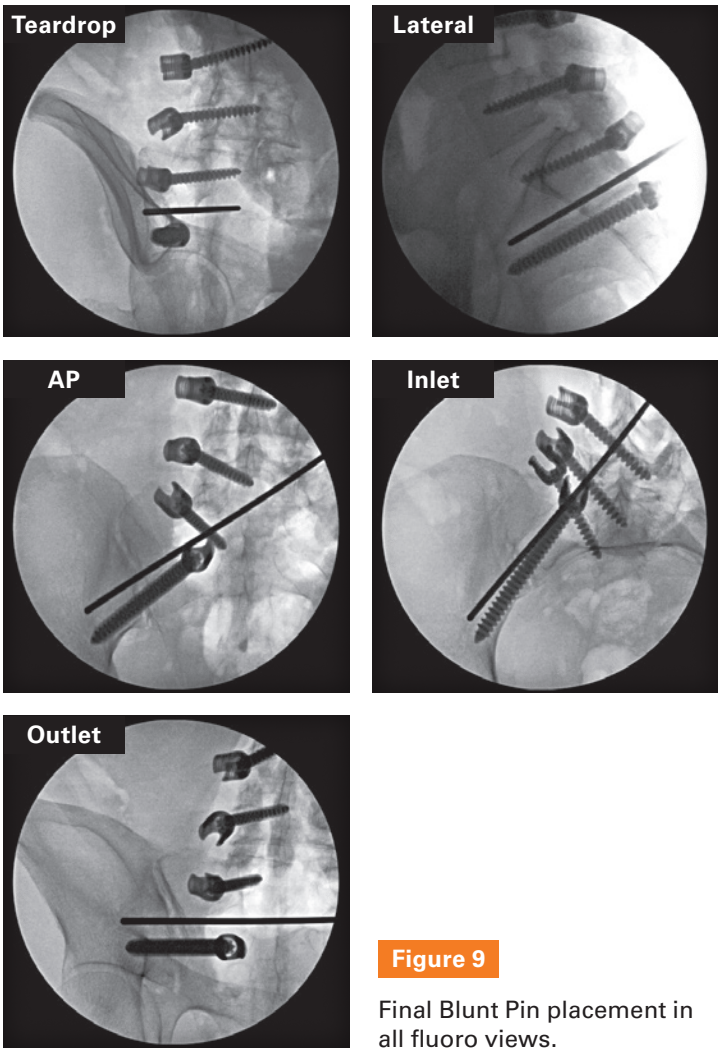


Figure 9

Final Blunt Pin placement in all fluoro views.

PRECAUTIONS:

- *When advancing Pin or Implant, avoid penetrating the sacral canal and/or foramen.*
- *At all times, extreme caution should be used around the spinal canal and nerve roots to avoid damage to the nerves.*
- *Replace any bent Pins with new Pins immediately during the procedure to ensure proper trajectory before drilling. Consider using a pin driver if Pin advancement is difficult due to dense bone.*
- *Please be mindful of the sharp instruments in the set. These instruments may include: the Pins, Drill Bits, and Taps, and can cause injury if handled in an unsafe manner.*
- *Do not attempt to redirect the trajectory of the Pin if the Pin is well-seated in the bone. This may bend the Pin and make it more prone to damage during subsequent steps.*
- *Do not attempt to clamp down on any object that the Radiolucent Clamp is not specifically designed to hold.*

Procedure: MIS technique (Optional)

Blunt Dissector Insertion

- If performing an MIS technique, the Blunt Dissector may be used to dilate soft tissues
- Slide Blunt Dissector over pin and advance to dorsum of sacrum, ensuring blade is parallel to muscle fibers
- Once seated on ilium, gently rotate to spread tissue around pin
- Ensure the Long Blunt Dissector is properly seated and collinear with the Pin before dissecting.

Soft Tissue Protector Insertion

- If performing a MIS technique, the Soft Tissue Protector can be used to protect soft tissues
- Slide Dilator 1 over the pin and down to sacrum until bony contact is achieved
- Slide Soft Tissue Protector 1 over Dilator 1 until both instruments are in contact with the cortex
- For MIS technique, drilling and tapping steps may be done through Soft Tissue Protector

PRECAUTION: *Ensure STP is flush on the bone so the measurement numbers are correct and accurately indicate the head of the implant is flush with the illium.*

Procedure: Measure Implant Length

Open technique:

- Measure appropriate implant length using markings on Bone Probe, Measurement Probe, or equivalent device

MIS technique:

- Slide Dilator 1 over the Pin
- Ensure Dilator 1 is firmly seated to the outer sacral cortex
- Use length markings on Dilator 1 to select proper implant length, as shown **(Fig. 10).**
- Once implant length is determined, remove Dilator 1
  - » Due to angle of the Dilator 1 with respect to the sacrum, Dilator 1 may contact the sacrum before seating flush – causing the measurement to be long **(Fig. 11).**

Ensure collinearity of the Dilator(s) over the Pin, before removing the Dilator(s).

Figure 10

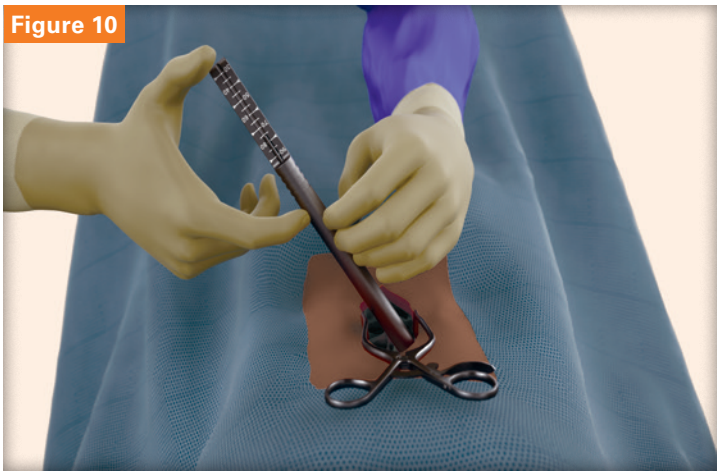


Figure 11

PRECAUTIONS:

- *Do not impact the flat surface of the Dilator(s). This may damage the bone and/or Dilator(s).*
- *Due to the angle of Dilator 1 with respect to the sacrum, Dilator 1 may contact the sacrum before seating flush – causing the measurement to be long. Consider a shorter implant length when using Dilator 1.*

Procedure: Drilling (Optional)

- Position C-Arm in AP View
- To connect to power, attach Drill bit to Quarter Inch to Tri-Lobe Adapter until laser marking indicates it is fully seated.
- **For open technique**
  - Insert Drill Bit directly over pin
- **For MIS technique**
- Insert Drill Bit over pin and through Soft Tissue Protector
  - Ensure Drill Bit and pin are colinear to minimize pin binding
- Advance Drill Bit under fluoroscopic guidance in AP view until Drill Bit tip is across the SI joint and within 1–2 cm of pin tip **(Fig. 12)**
- **Watch for unwanted pin advancement**
- Use Exchange Pin during Drill Bit removal to reduce inadvertent Blunt Pin removal
- **Should Blunt Pin bind and come out, replace it with new Blunt Pin and confirm placement via fluoroscopy**

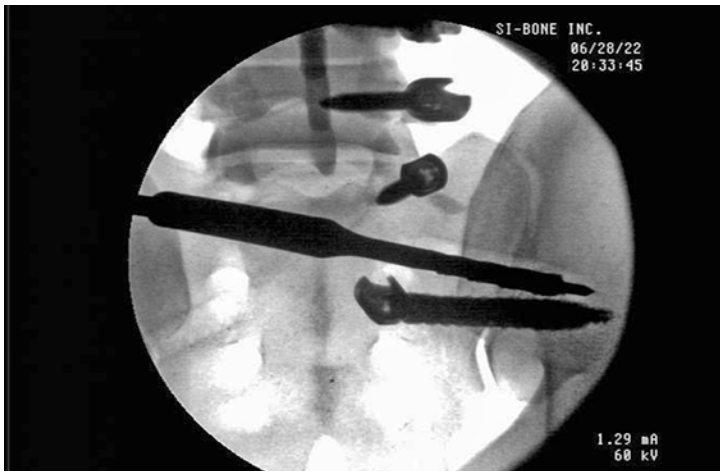


Figure 12

AP view showing Drill Bit across SI joint and within 1 – 2 cm of Blunt Pin tip

NOTE:

- *Ensure colinearity between the Drill Bit and STP.*
- *If manually drilling, the Blunt Pin may be used in place of the Exchange Pin.*

PRECAUTIONS:

- *Ensure the cannula of the Drill Bit is free of debris prior to each use. Flushing the Drill Bit cannula with sterile saline prior to each subsequent use during the procedure may also minimize pin binding.*
- *Use saline irrigation to cool the Drill Bit during extended use.*
- *Use care to avoid advancing the Pin during drilling. Do NOT push on the Pin. Applying a ventrolateral force to the Pin or the Exchange Pin may cause them to advance ventrolaterally.*
- *Ensure the Pin has not backed out of the anatomy prior to drilling.*
- *Over-drilling (excessive advancement) may cause injury to anatomic structures, or the other possible adverse events listed in the Instructions For Use, 501381.*
- *In hard bone, drill and tap to ensure that the implant can be fully inserted and/or adjusted as necessary during the index procedure.*
- *Take care not to move Soft Tissue Protector during drilling and tapping steps.*
- *During extended use of drill, i.e., drilling in hard bone or creation of deep bone channels, irrigate the Drill Bit to minimize overheating of adjacent bone and Pin binding.*
- *In hard bone, users should drill and tap to ensure that the Implant can be fully inserted and/or adjusted as necessary during the index procedure.*
- *When drilling in hard bone, use a "pecking technique" to lower the risk of overheating adjacent bone.*
- *Adequate bone preperation is recommended to help avoid fractures to the sacrum or illium.*
- *Do not attempt to use any other instrumentation to drill over the guide Pin*
- *Do not impact the drill handle assembly with mallet to advance the drill*

Procedure: Tapping (Optional)

- **For open technique:**
  - » Insert Tap directly over pin
- **For MIS technique:**
  - » Insert Tap over pin and through Soft Tissue Protector
- Advance Tap under AP fluoroscopic guidance until the Tap is across the SI joint and is 1–2 cm from the pin tip **(Fig. 13)**
- **Watch for unwanted pin advancement**
- Use Exchange Pin during Tap removal to reduce inadvertent Blunt Pin removal. Replace Blunt Pin, if necessary

Ensure collinearity of the Tap over the Pin, before and during use.

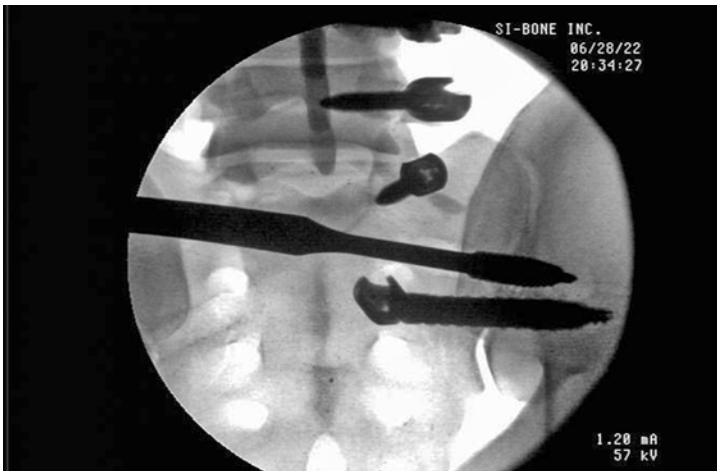


Figure 13

AP view showing Tap across SI joint and within 1 – 2 cm of Blunt Pin tip

NOTE:

- *When placing an implant in hard bone, additional bone preparation (e.g. Drilling/Tapping) may be required.*
- *If manually tapping, the Blunt Pin may be used in place of the Exchange Pin.*

PRECAUTIONS:

- *Ensure the cannula of the Tap is free of debris prior to each use. Flushing the Tap cannula with sterile saline prior to each subsequent use during the procedure may also minimize pin binding.*
- *Use care to avoid advancing the Pin during tapping. Do NOT push on the Pin. Applying a ventrolateral force to the Pin or the Exchange Pin may cause them to advance ventrolaterally.*
- *Over-tapping (excessive advancement) may cause nerve damage, hemorrhage, or the other possible adverse events listed in the instructions for use.*
- *Take extra care to monitor Tap for excessive advancement if tapping under power.*
- *In hard bone, drill and tap to ensure that the implant can be fully inserted and/or adjusted as necessary during the index procedure.*
- *When using the Granite+ instrument set, use a 10 mm iFuse TORQ Implant in patients with hard bone.*
- *Do not use non-compatible taps with the iFuse TORQ Implant System.*
- *Do not impact the tap handle assembly with mallet to advance the tap.*

Procedure: Implant Driver Assembly

iFuse TORQ Implants are designed with an internal thread on the head of the Implant. This thread is designed to mate with the Driver Sleeve in order to provide a stable, self-retaining method of Implant delivery.

- Slide Driver Sleeve 1 over the distal end of the Torx Driver and lock into place **(Fig. 14).**
- Attach the Torx Driver to either the T-Handle or Inline Handle
  - » To connect to power, attach Quarter Inch To Tri-Lobe Adapter to Torx Driver until laser marking indicates it is fully seated.

***NOTE**: There is a laser mark on Driver Sleeve 1. When using the Driver Sleeve and the STP together, the position of this laser mark relative to the proximal end of the STP is used to indicate the position of the head of the Implant relative to the distal end of the STP.*

Figure 14

Procedure: Implant Transfer and Assembly to Driver

Implants may be provided in a carton or in a tube. The following instructions pertain to Implants provided in the tube packaging:

Figure 15

Circulator

Confirm Implant size from the label on the top and the side of the tube.

Remove the outer poly wrap from the Implant tube.

Hold the Implant tube vertically in one hand with the cap up. Unscrew counterclockwise and remove the cap, breaking the seal.

> ***NOTE:***
> *Once Implant tube cap is removed, do not touch the sterile threaded portion of the Implant tube or the sterile thermoplastic polyurethane (TPU) sleeve.*

Aseptically transfer the contents of the tube (TPU Sleeve containing Implant) to the sterile field.

Option 1: Drop transfer to sterile basin.

Option 2: Hand-to-Hand Transfer

Back Table Assist (Sterile)

Hold the sterile TPU Sleeve packaging vertically. Open the end of the sleeve to show the head of the Implant through the sleeve.

Procedure: Implant Transfer and Assembly to Driver

- Load the chosen Implant onto the Torx Driver.
- Thread Driver Sleeve 1 into the head of the Implant **(Fig. 16).**
  - » Consider using the TPU Sleeve or the poly bag to hold the Implant while loading onto the Torx Driver.

NOTE**: When Driver Sleeve is fully engaged in Implant, "attachment mark" is visible **(Fig. 17).

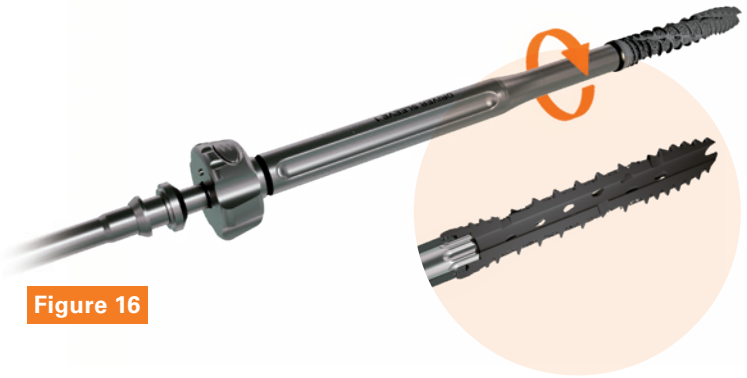


Figure 16

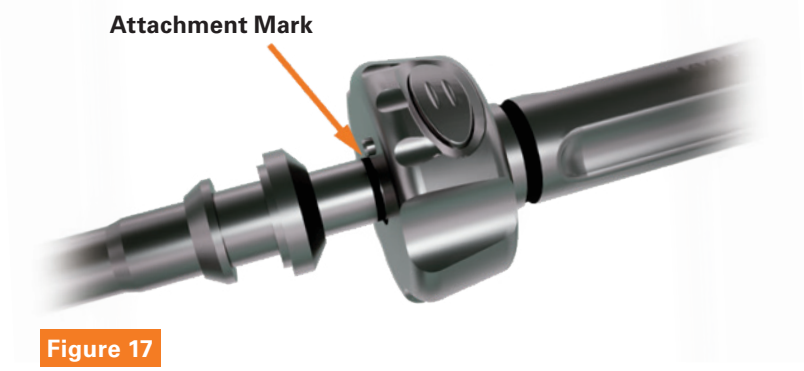


Figure 17

PRECAUTIONS:

- *Implants have sharp edges and a roughened surface. The Implants can cause injury if handled in an unsafe manner.*
- *Firmly tighten the Implant to Driver Sleeve, taking care not to cross-thread the Driver sleeve with the Implant.*
- *Do not overtighten the driver sleeve into the implant head (two finger tightness only) as this may make disengagement and removal of the driver sleeve more difficult.*
- *The T-Handle and Inline Handles are designed for one-handed use only.*
- *If placing an iFuse TORQ Implant under power, monitor position of Implant and pin with fluoroscopy.*
- *Perform final Implant tightening by hand.*

Procedure: Implant Insertion

For open technique:

- Place implant over pin (optional).
- Advance the Implant on the Torx Driver Assembly with either power, using the Quarter Inch To Tri-Lobe Adapter, or by hand with the T-Handle or Inline Handle.
  - » Always keep forward pressure on the Driver when advancing the Implant.
  - » Ensure collinearity of the Driver over the Pin, before and during use.
  - » Final Implant seating should always be performed manually, with either the T-Handle or Inline Handle.
  - » While holding the driver handle steady, unthread the Driver Sleeve from the Implant.

***NOTE**: Driver Sleeve Wrench may be used to remove Driver Sleeve 1 from the Implant. Wrench is attached to the Driver Sleeve from the side in three possible orientations. Apply counter torque to the Driver when using Wrench. Turn Wrench in a counterclockwise direction to loosen Driver Sleeve. Take care to avoid damage to surrounding tissue or adjacent instrumentation (e.g., Pins).*

For MIS technique:

- Place implant over pin and through Soft Tissue Protector.

***NOTE**: The dense medial cortex of the ilium may cause the implant to skive into the joint, instead of across the joint. Monitor implant trajectory during insertion with fluoroscopy.*

- Advance implant under AP fluoroscopic guidance until either the laser mark on the Driver Sleeve is in line with the shoulder of the Soft Tissue Protector for the MIS technique, or until the implant is visibly/palpably 1–2 mm proud via the open technique
- If implant is left too proud, it may be difficult to connect the posterior rod to the S2AI screw. In this case, the Driver may be used to gently advance the implant to the appropriate depth to allow rod placement
- Confirm placement with fluoroscopic views **(Fig. 18)**

***NOTE**: Do not hold or press the Release Button on Driver Sleeve when inserting an iFuse TORQ Implant.*

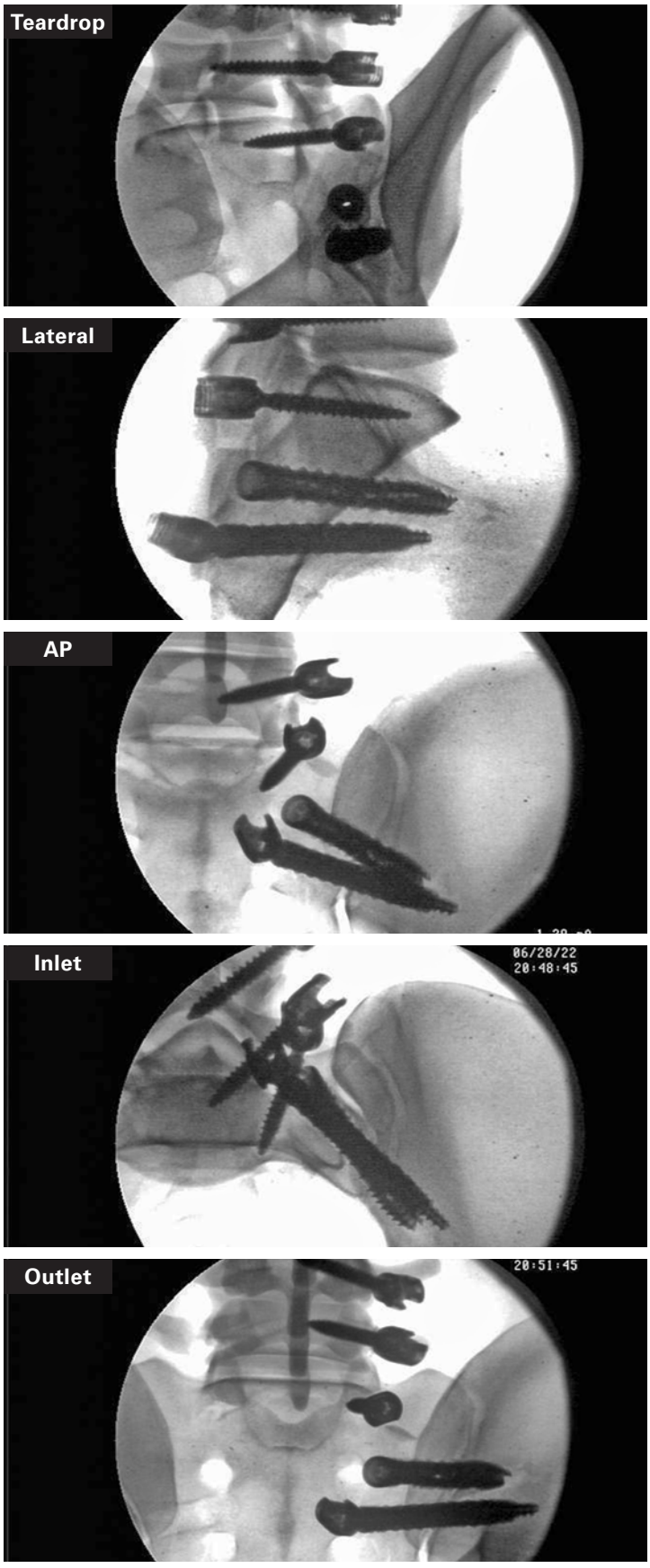


Figure 18 Final implant placement in all fluoro views

Procedure: Intra-op and Post-op

Intra-op Repositioning and Removal Surgery:

- To reposition an Implant, use the Torx Driver to advance or retract as necessary.
- Confirm final placement with fluoro.
- To remove Implant, use the Torx Driver to withdraw the Implant until Implant is removed.

Rod Placement

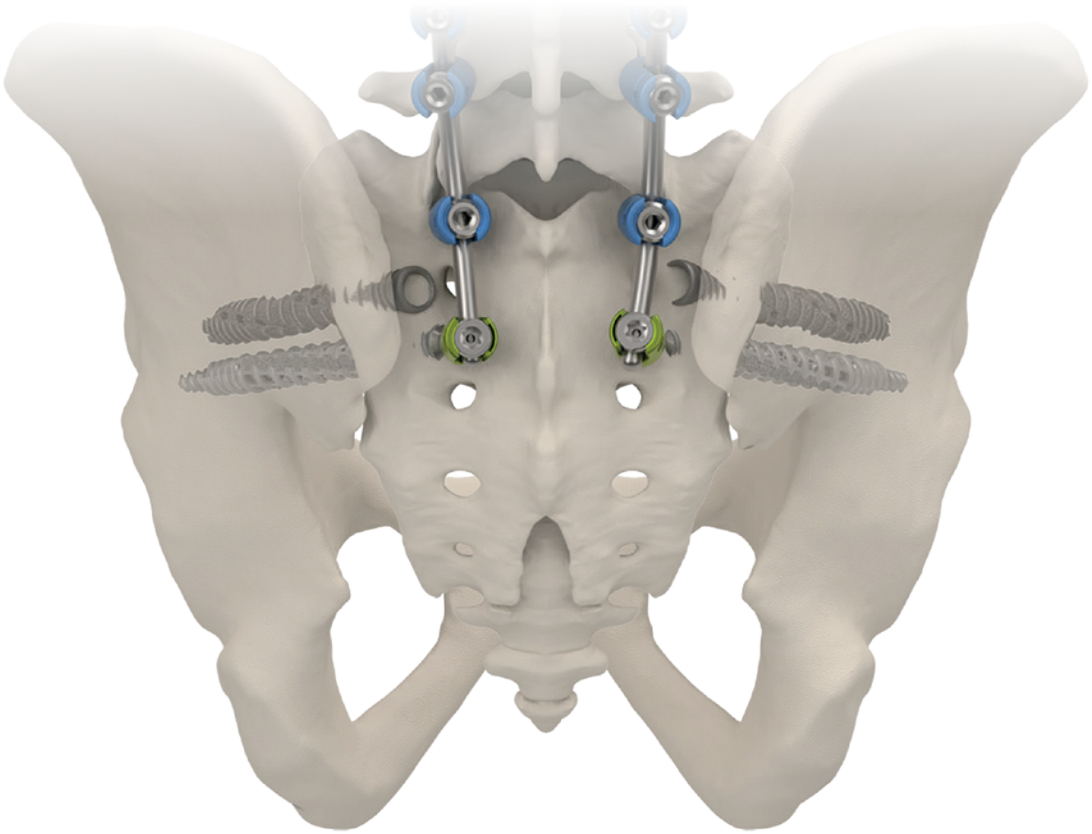
- Once all pedicle screws, pelvic fixation screws, and iFuse TORQ implants are in place, finish procedure by placing the rod and securing it in place via standard techniques.

Closure and Post-Op Care

- Proceed with standard wound closure and post-op care.

***NOTE**: For Navigation Procedure see STM 300891.For Removal & Revision Procedure see STM 300867.*

Figure 19

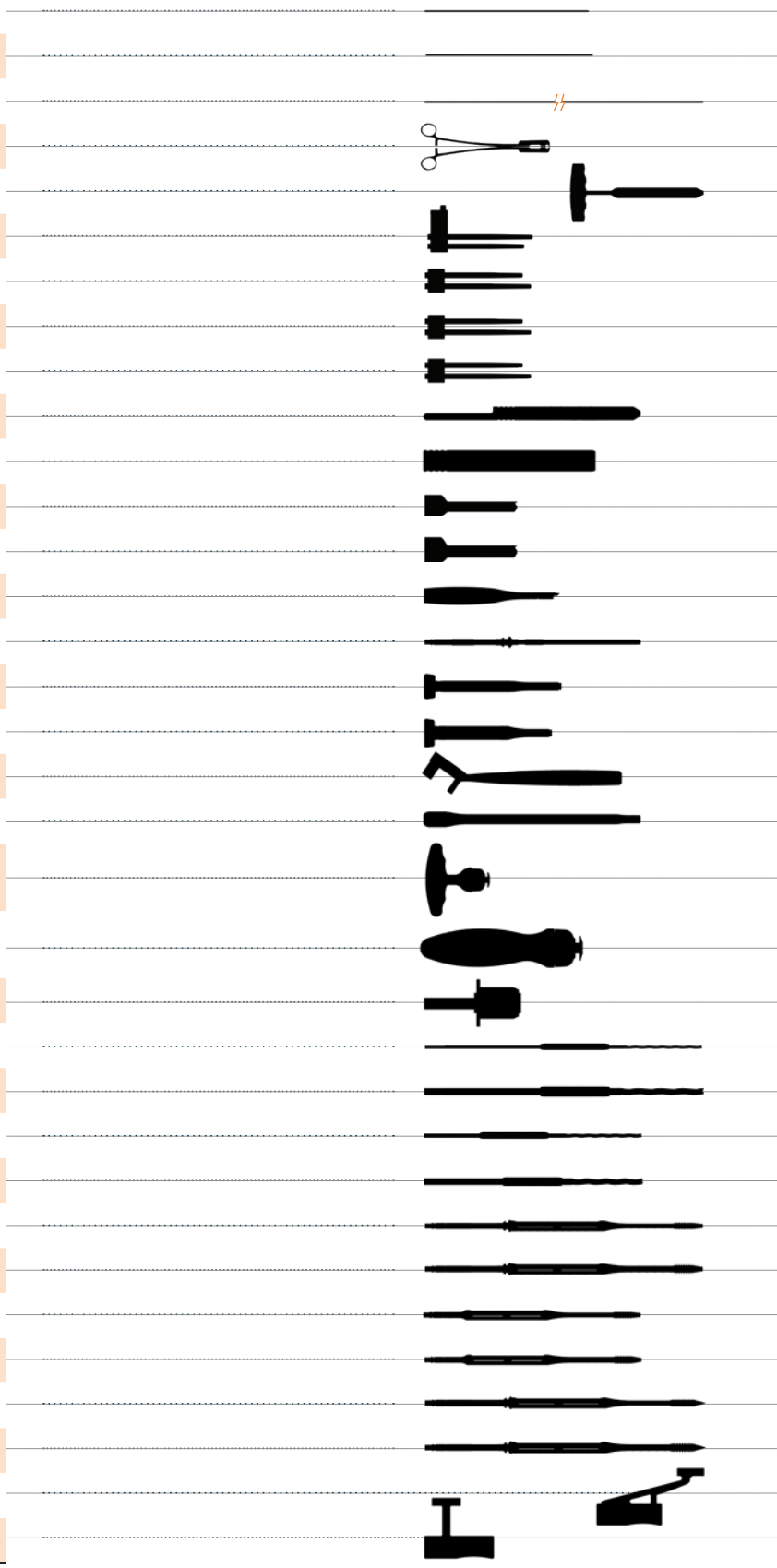


PRECAUTIONS:

- *Take care when inserting an iFuse TORQ Implant. Over-rotation could lead to over-advancement of the implant or stripping the bone channel, diminishing fixation of the Implant in bone, or damage to the bone and/or implant.*
- *Carefully choose implant size and length. Using an incorrectly sized Implant, may cause nerve damage, hemorrhage, or other possible adverse events as listed in the Instructions For Use, 501381.*
- *Seating an Implant flush or countersinking a Fully-Threaded Implant may result in bone growing over the head of the Implant. This may make future removal of the Implant more difficult.*

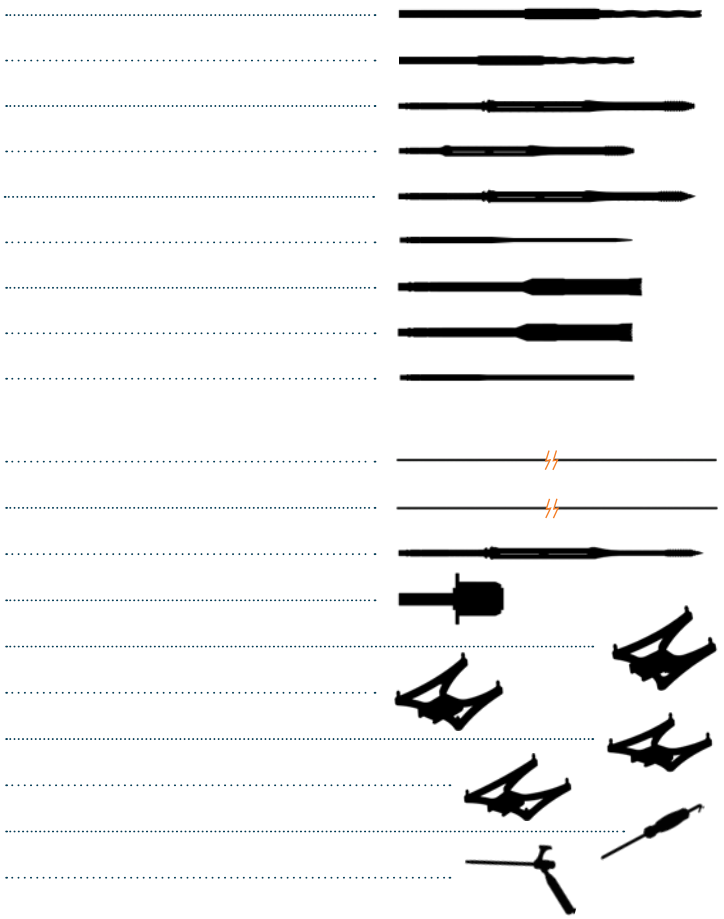
Product Catalog: iFuse TORQ Instruments

iFuse TORQ Instruments	Part No.
Guide Pin – 3.2 mm	500373
Blunt Pin – 3.2 mm	500374
Exchange Pin – 3.2 mm	500375
Radiolucent Clamp	400106
Blunt Dissector – Long	400224
Variable Parallel Pin Guide	400041
Fixed Parallel Pin Guide (15 mm)	400050
Fixed Parallel Pin Guide (17 mm)	400253
Fixed Parallel Pin Guide (19 mm)	400254
Dilator 1	501130
Dilator 2	501161
Soft Tissue Protector 1	400284
Soft Tissue Protector 2	400285
Soft Tissue Protector Handle	400283
Torx Driver, Cannulated	501129
Driver Sleeve 1	400248
Driver Sleeve 2	400262
Driver Sleeve Wrench	400430
Graft Delivery Guide	501131
T-Handle, Ratcheting, Quarter Square, Low Profile, Pinned	501621
Inline Handle, Ratcheting, Quarter Square, Low Profile, Pinned	501622
QC Adapter, Quarter Inch to Tri-Lobe	501417
7.00 mm Navigation Drill Bit, Cannulated	501122-0700
8.50 mm Navigation Drill Bit, Cannulated	501122-0850
7.00 mm Drill Bit, Cannulated	501154-0700
8.50 mm Drill Bit, Cannulated	501154-0850
9.25 mm Navigation Tap, Cannulated	501124-0925
10.75 mm Navigation Tap, Cannulated	501124-1075
9.25 mm Tap, Cannulated	501157-0925
10.75 mm Tap, Cannulated	501157-1075
9.25 mm Navigation Tap, Awl Tip	501126-0925
10.75 mm Navigation Tap, Awl Tip	501126-1075
Nav Adapter - Drill Bit/Tap	400290
Nav Adapter - Driver	400291



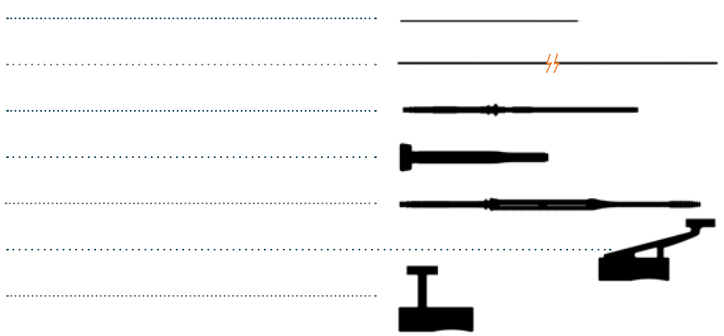
Product Catalog: iFuse TORQ Instruments

iFuse TORQ Revision Instruments	Part No.
10.50 mm Navigation Drill Bit, Cannulated	501122-1050
10.50 mm Drill Bit, Cannulated	501154-1050
12.75 mm Navigation Tap, Cannulated	501124-1275
12.75 mm Tap, Cannulated	501157-1275
12.75 mm Navigation Tap, Awl Tip	501126-1275
Extractor	501249
Trephine, Small	501250
Trephine, Large	501252
Torx Driver	501243
Optional Instruments	
O-arm Pin, 3.1,mm, Threaded, Sharp	500842
O-arm Pin, 3.1 mm, Blunt	500845
6 mm Navigation Pilot Tap	501449
QC Adapter, Quarter Inch to POWEREASE	501485
Fixed Tracker, Blue	400366
Fixed Tracker, Gold	400367
Fixed Tracker, Green	400368
Fixed Tracker, Purle	400369
Fixed Tracker Screwdriver	400380
Universal Pin Guide	400402



To place iFuse TORQ along with iFuse Bedrock Granite, the following instruments are required:

Granite+ Instrument Set	Part No.
Guide Pin – 3.2 mm	500373
Exchange Pin – 3.2 mm	500375
Torx Driver, Cannulated	501129
Driver Sleeve 1	400248
9.25 mm Navigation Tap, Cannulated	501124-0925
Nav Adapter - Drill Bit/Tap	400290
Nav Adapter - Driver	400291



Instrument set configurations may vary. Refer to a local sales representative for tray set part numbers and configurations available.

SI-BONE® | **iFuse** TORQ®
Implant System

Indications
The iFuse TORQ® Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ Navigation instruments are intended to be used with the Medtronic StealthStation System.

Healthcare professionals should refer to the Instructions for Use for indications for use, contraindications, warnings and precautions at *https://si-bone.com/label*

There are potential risks with iFuse Procedures. They may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *https://si-bone.com/risks*

Complaints and adverse events relating to use of the procedure and/or device should be reported to SI-BONE, Inc. Toll Free: *(855) 511-1545* or E-mail *qara@si-bone.com*

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