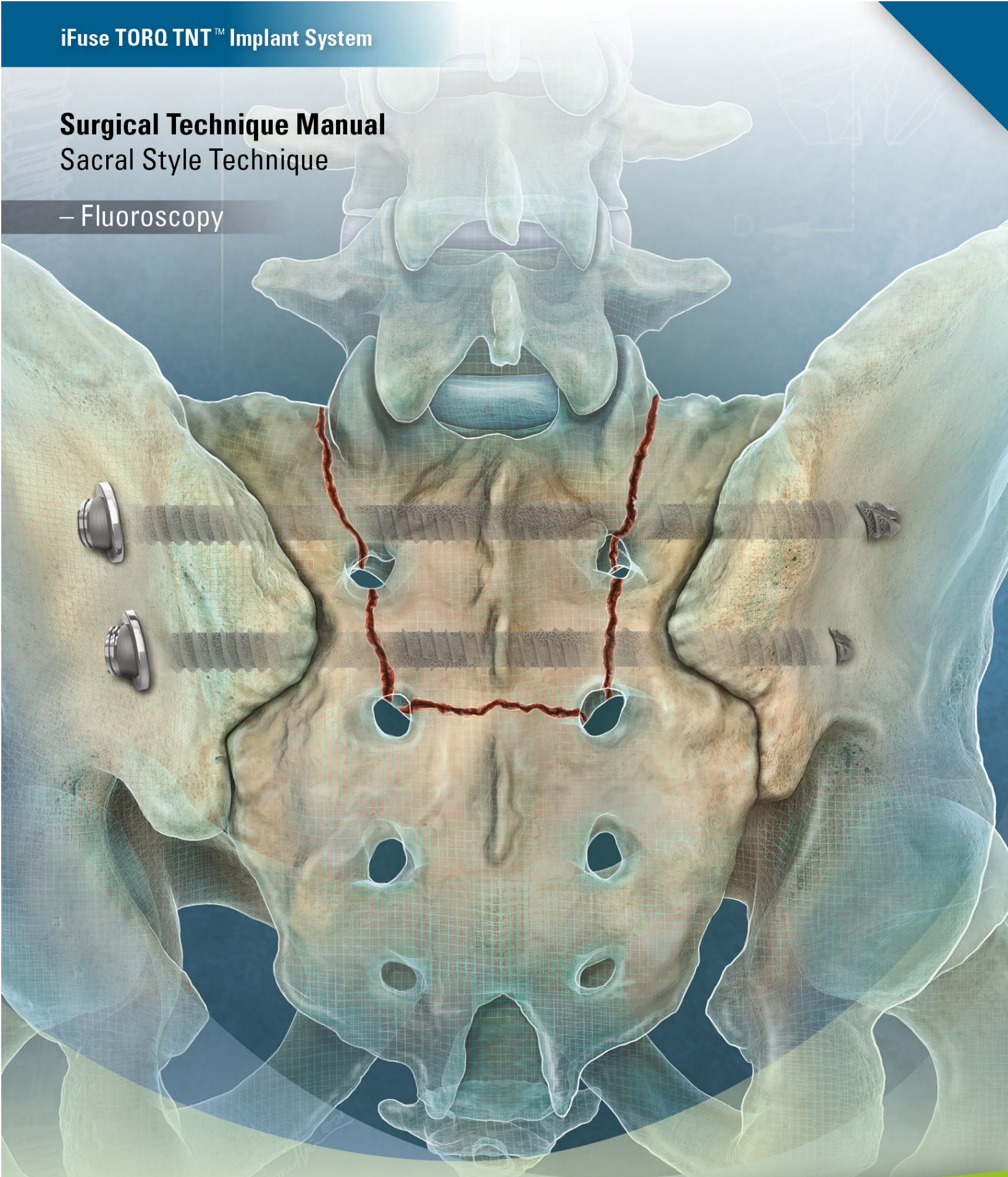
iFuse TORQ TNT™ Implant System

Surgical Technique Manual

Sacral Style Technique

– Fluoroscopy



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Sacropelvic Solutions™

CONTENTS

DISCLAIMER

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The following information is not treatment advice for any particular patient. Physicians should use their clinical judgment and experience when deciding how to treat patients. Please reference the product IFU for full prescribing information. Suggestions offered are based on physician experience. Medical choices for patients are to be based upon their condition and the medical judgment of the treating practitioner. SI-BONE does not recommend or endorse any particular course of treatment or medical choice.

iFuse TORQ TNT™ Implant System

iFuse TORQ TNT™ Implant: A porous threaded Implant with lengths capable of spanning the posterior pelvis, passing through the ipsilateral ilium, sacrum, and through the contralateral ilium (through and through, “TNT”).

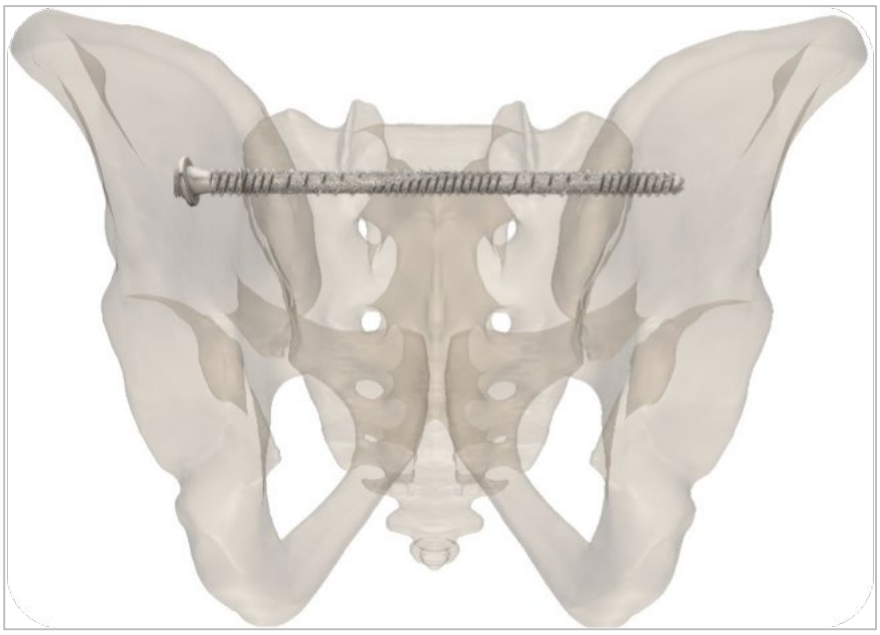


Figure 1

As with all surgical procedures and permanent Implants, there are risks and considerations associated with surgery and use of the iFuse TORQ TNT™ Implant System.

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

iFuse TORQ TNT Implant Specifications

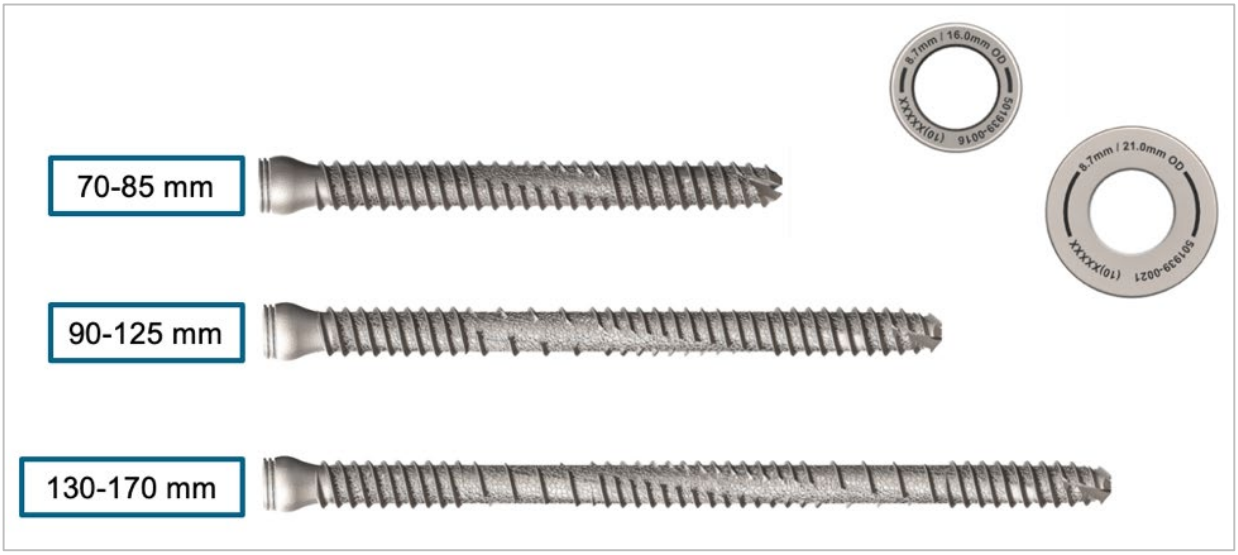


Figure 2

Specification	Size (mm)	Part Number
Major Diameter	8.7	870070 – 870170
Minor Diameter	6.9	
Inner Diameter	2.7	
Head Diameter	10.5	
Lengths	70 – 170	
Washer – Outer Diameter	16.0 or 21.0	501939-0016 or 501939-0021
Washer – Inner Diameter	10.3	
Drill Bit Dimensions	4.5 x 280	501765
	5.5 x 280	501766-0280
	5.5 x 375	501766-0375
Tap Dimensions	8.0 x 275	400418

Disposable Instruments – Fluoroscopy	
Part Number	**Instrument Name**
501769-0250	Trocar Pin, 2.0 mm x 250 mm
501769-0330	Trocar Pin, 2.0 mm x 330 mm
501770-0330	Trocar Pin, 2.5 mm x 330 mm
501771-0330	Reverse Threaded Pin, 2.5 mm x 330 mm
501772-0330	Drill Pin, 2.5 mm x 330 mm
501918-0330	Blunt Pin, 2.5 mm x 330 mm
501770-0450	Trocar Pin, 2.5 mm x 450 mm
501771-0450	Reverse Threaded Pin, 2.5 mm x 450 mm
501772-0450	Drill Pin, 2.5 mm x 450 mm
501918-0450	Blunt Pin, 2.5 mm x 450 mm
501765	4.5 mm Cannulated Drill Bit

Pin Types			
			
Trocar	**Reverse Threaded**	**Drill**	**Blunt**

Subsequent Implant Spacing

When placing multiple Implants, refer to the chart below to allow adequate implant spacing for the subsequent implant. This is necessary to ensure there is no implant interference when placing multiple Implants.

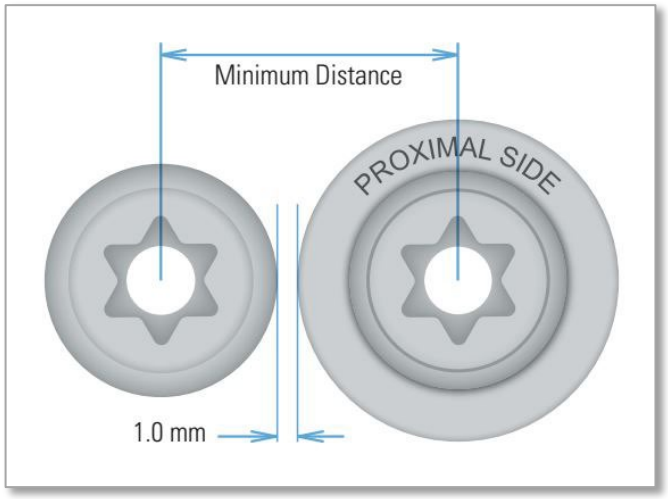


Figure 3

All Implants require a minimum of 1 mm of distance between the edges of implant heads when placing more than one implant. The table below indicates the minimum distance (center-to-center) between the implants.

		First Implant		
		8.7 mm TNT	8.7 mm TNT with 16 mm Washer	8.7 mm TNT with 21 mm Washer
Subsequent Implant	8.7 mm TNT	11.5 mm	15 mm	17 mm
	8.7 mm TNT with 16 mm Washer	15 mm	17 mm	20 mm
	8.7 mm TNT with 21 mm Washer	17 mm	20 mm	22 mm

PRECAUTIONS

Minimum implant spacing assumes parallel pins. To compensate for any angulation, consider adding more distance between pins and/or Implant placement in order to prevent Implants from contacting each other during insertion.

Pre-Op Planning and Patient Set-up

Pre-Op Planning

A CT is recommended for pre-op planning. Check for anatomic abnormalities.

Patient Set-Up

- One or two C-arms may be used – usually one is sufficient.
- If a flat table is used, place towels under the sacrum to allow proper positioning.

Patient Positioning

This procedure may be performed in the supine or prone position. This Surgical Technique Manual illustrates the supine positioning technique.

- 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.
- When utilizing the SI Style Implant (see **Skin Marking**) it is recommended the patient is closer to the edge of the surgical table. This will help ensure the table does not interfere with the instrumentation.

Options for Instrumenting with Power

iFuse TORQ TNT Instruments, not including disposables, are compatible with a Jacobs Chuck using the Quarter Inch to Tri-Lobe Adapter.

Care of Instruments

The iFuse TORQ TNT 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 might minimize the occurrence of binding of Instruments and/or Implants. Please refer to 300065, *iFuse Implant System® Instruments – Hospital Cleaning and Sterilization Instructions, USA.* (si-bone.com/label). The System includes a cleaning stylet as an option for cleaning debris from instrument lumens.

PRECAUTIONS

- This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the physician's judgment. Instruments not shown in this manual may be used at the physician'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 devices can damage the Implant and/or instrument(s).
- Position C-arm to minimize interference with instruments throughout the procedure.
- With any cannulated instrument e.g., (drills, tap, drivers, etc.) ensure collinearity between the instruments and Pins during advancement, use, or removal to prevent damage to the instrument(s), or surrounding tissue.
- The iFuse TORQ TNT system is a pin based, cannulated system. Make sure all lumens are clear of debris before using and that all Pins are straight. If a Pin is bent or becomes bent during the procedure, replace it with a straight Pin.

Pre-Op Imaging (Supine Position)

Inlet View

The inlet view is used to optimize visualization of the anterior cortex of the sacrum. In this view, the fluoroscope is aligned with the anterior cortex of the S1 body.

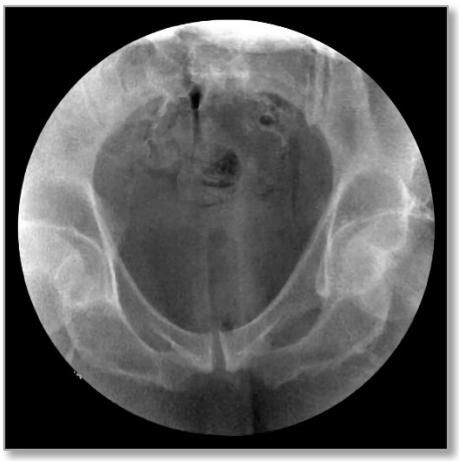


Figure 4

Outlet View

The outlet view is used to optimize visualization of the neuroforamina. The fluoroscope is tilted until the S1 & S2 neuroforamina are clearly visible and the pubic symphysis is at the level of the S2 foramen.

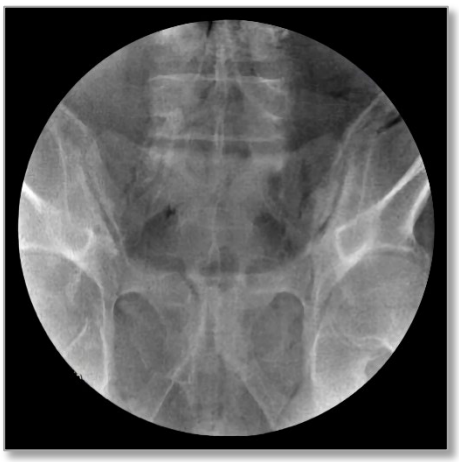


Figure 5

Additional Views

Lateral View

The lateral view can be used to assist with obtaining an ideal start site and/or to determine a safe path for Implant placement. First align the disc space and end plates of L5-S1. The sciatic notches should overlay each other once in correct alignment. Finalize the alignment by superimposing the left and right iliac cortical densities (ICDs or alar lines).

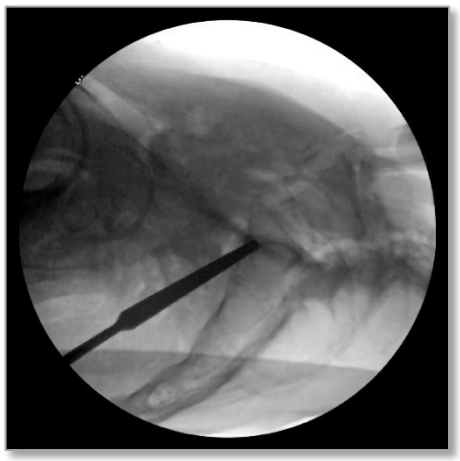


Figure 6

Rollover Inlet View (a.k.a., Obturator Inlet)

The rollover inlet (obturator inlet) is used to optimize visualization of the iliac cortex at the level of the pin. This view is obtained by using an inlet view with 20-30 degrees of C-arm rollover toward the surgeon/operative side. The exact location and amount of rollover can be optimized by placing another pin against the ilium next to the previously placed pin and adjusting the rollover until the lateral iliac cortex becomes a clear line adjacent to the tip of the second pin.

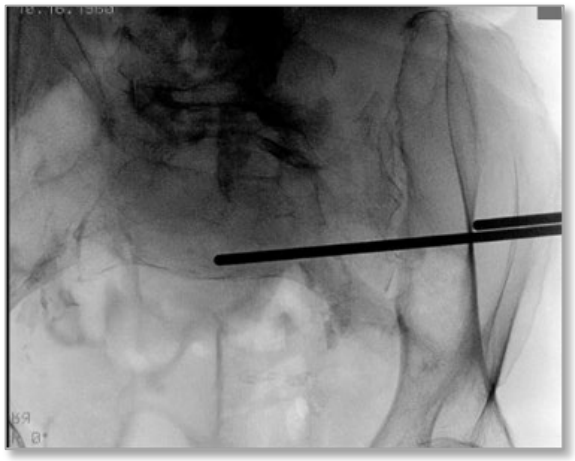


Figure 7

Skin Marking

First Skin Marking

With the patient in supine position, a straight line should be made from the anterior superior iliac spine (ASIS) towards the floor. A second transverse line is made in-line with the center of the femur extending posteriorly and intersecting the previous line.

Sacral and SI trajectories utilize the same instrumentation, but the starting points and trajectories vary slightly.

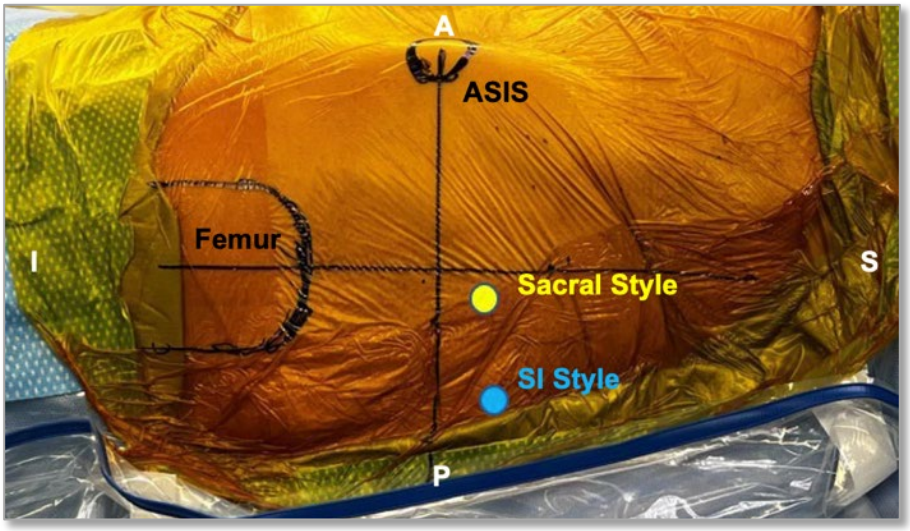


Figure 8

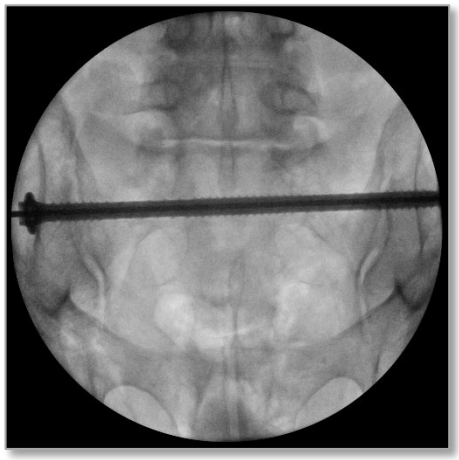


Figure 9

Sacral Style Implant: Placed in a transverse orientation, orthogonal to a vertical sacral fracture.

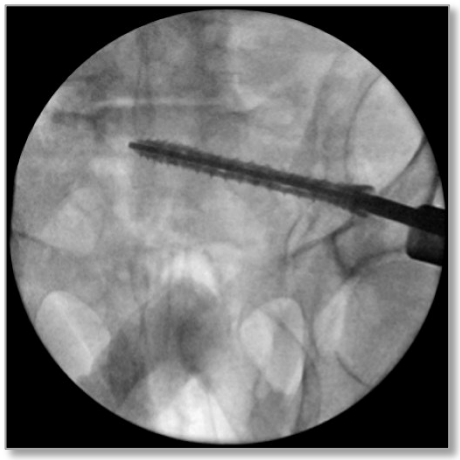


Figure 10

SI Style Implant: Placed orthogonally to the SI joint. Commonly starting posterior-superior on the ilium and terminating in the anterior-inferior sacrum.

PRECAUTIONS

- If placing the Implants in conjunction with an open procedure, the physician should take care not to destabilize the joint prior to placing the Implants.
- When incising and dissecting, take care to avoid the superior gluteal artery and other sensitive neurovascular structures in the surrounding soft tissue.
- Stabilize and reduce any fracture(s) using fluoroscopic guidance prior to Implant placement to help reduce potential delayed union, malunion, non-union, or Implant loosening.
- Reduce the SI joint prior to or in conjunction with implant placement to help minimize potential delayed union, malunion, non-union, or Implant loosening.

First Pin Placement

Inlet View

Adjust the trajectory of the Pin so that the Pin is aiming towards the middle-to-anterior third of the sacral body. If the Pin is in an unfavorable position and cannot be advanced safely, adjust the Pin starting position before advancing.

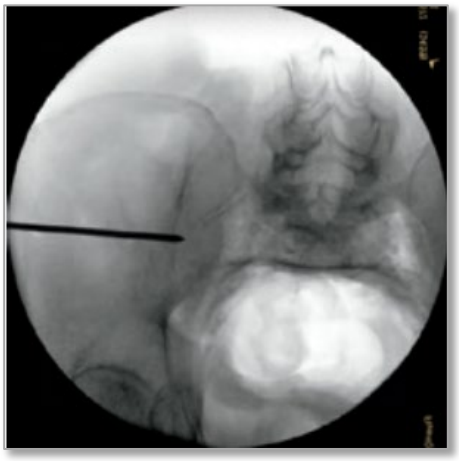


Figure 11

Outlet View

Adjust the trajectory of the Pin on the outlet view such that the Pin is cranial to the S1 foramen. Advance the Pin under alternating inlet and outlet views.

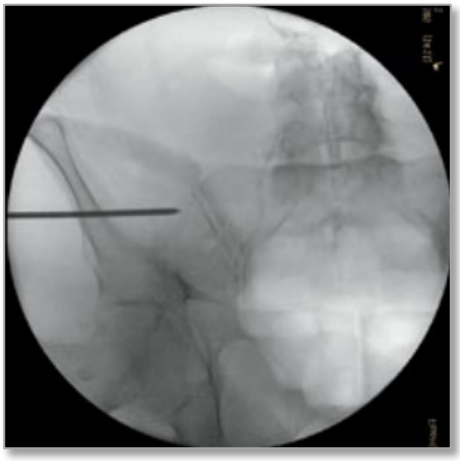


Figure 12

Lateral View (Alternate View)

Initial Pin position is started distal to the alar line (iliac cortical density; ICD). The middle 1/3 of the first sacral body is the typical starting point. Once the starting point is identified, dock the desired Pin into the lateral cortex of the ilium.

NOTE: *Consider using a Kocher clamp to hold the Pin in position when taking lateral images. Monitor pin interference with C-arm when utilizing the lateral view.*

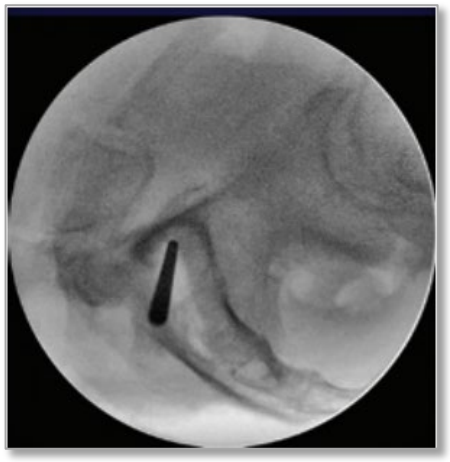


Figure 13

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 nerve roots to avoid damage to the nerves.
- Do not redirect the Pin within bone to help avoid Pin bending.
- 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.
- If placing multiple Pins, take care to avoid inadvertent advancement of an adjacent Pin.
- Take care to ensure adequate spacing between Implants; see **Subsequent Implant Spacing**. If Implants are placed too close together the heads of the Implants may overlap, or the Implants' threads may interdigitate.
- Take care to place additional Implant(s) in a trajectory that does not intersect the previously placed Implant(s). If Implants contact each other there is a chance that the threads could interdigitate making removal of Implant(s) more difficult.

Insert preferred 2.5 mm Pin into the ilium to the desired depth.
(Refer to **iFuse TORQ TNT Implant Specifications, Pin Types**)

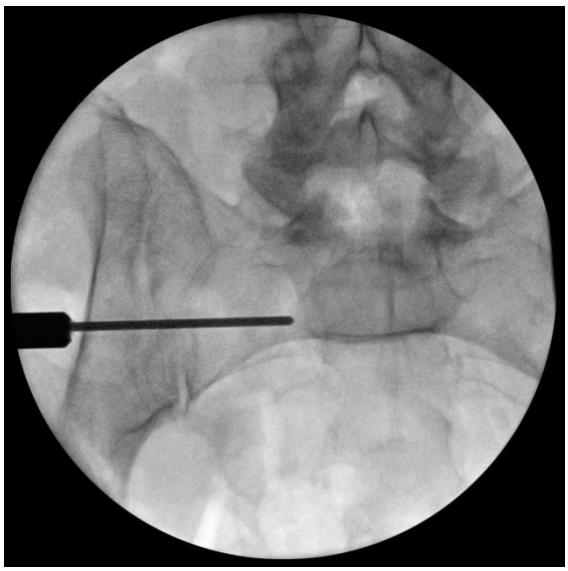


Figure 14

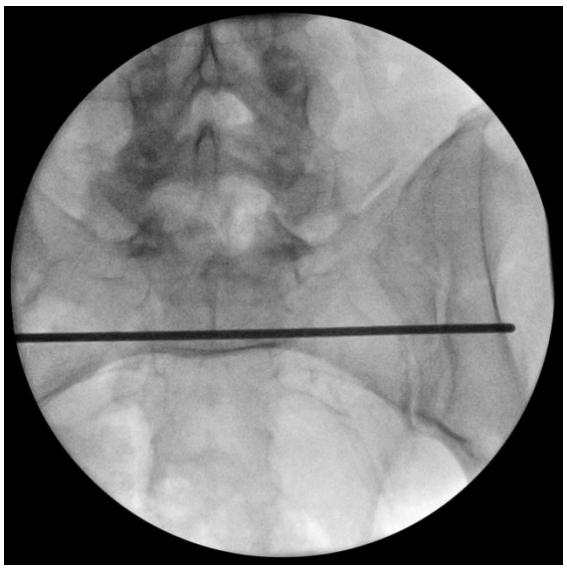


Figure 15

Following Pin placement, create an incision through the skin and subcutaneous tissue extending approximately 1 cm on each side of the Pin, ensuring a symmetrical incision to facilitate subsequent steps of the procedure.

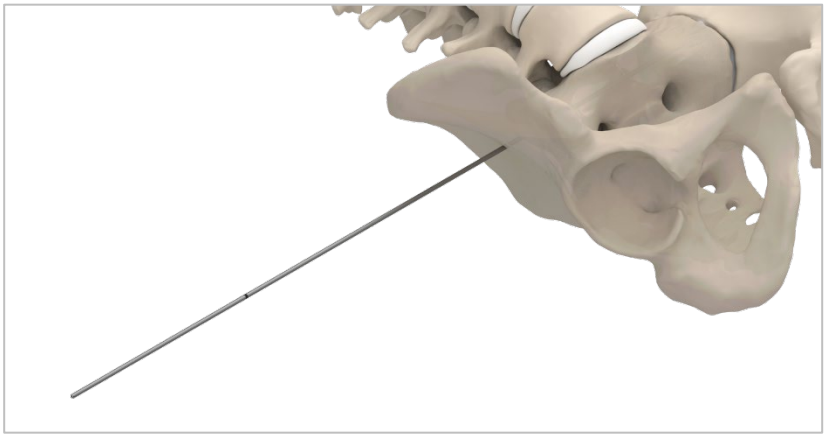


Figure 16

NOTE: *When fixing a fracture, ensure the Pin crosses the fracture site to minimize the risk of fracture displacement during Implant insertion.*

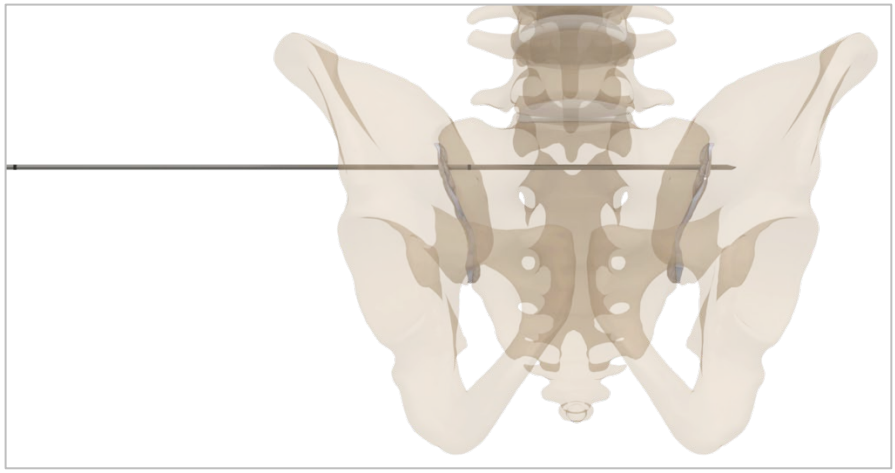


Figure 17

PRECAUTIONS

Be mindful and aware 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.

Pin Insertion Guide (Optional Technique for Pin Placement)

Position the distal tip of the Pin Insertion Guide or a Pin at the desired location on the skin in the lateral view.

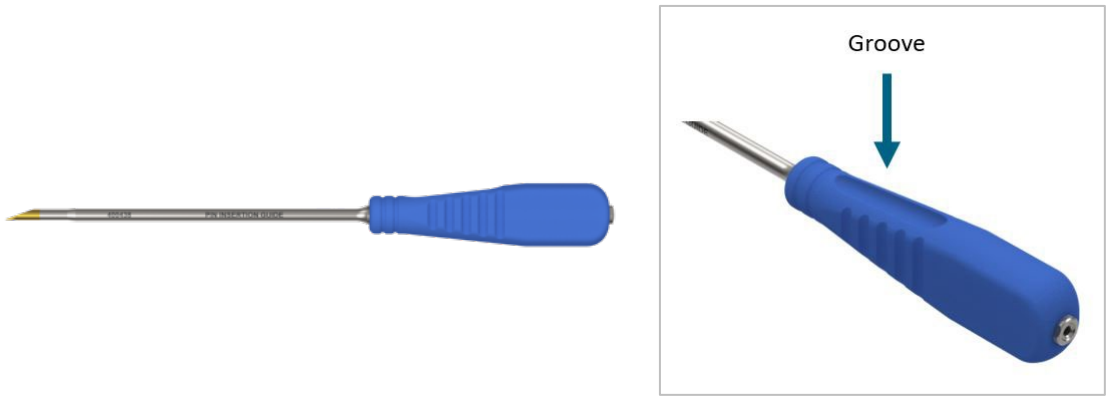


Figure 18

NOTE: *The finger groove on the handle indicates the orientation of the open bevel tip.*

Using prior skin markings, make a stab incision with a scalpel in the desired location. Insert the Pin Insertion Guide, directing it towards the desired location on the cortex of the ilium. Dock the Pin Insertion Guide into ilial cortex by hand. Take fluoroscopic images as needed in the lateral view to confirm the position of Pin Insertion Guide tip.

Figure 19

NOTE: *If using the Pin Insertion Guide, use a 2.5 x 450 mm length Pin to ensure adequate Pin length is available to place the Pin through the Pin Insertion Guide.*

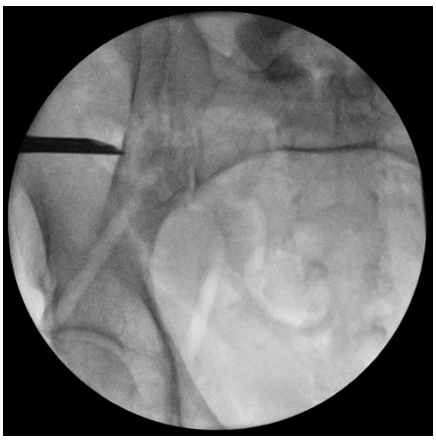


Figure 20

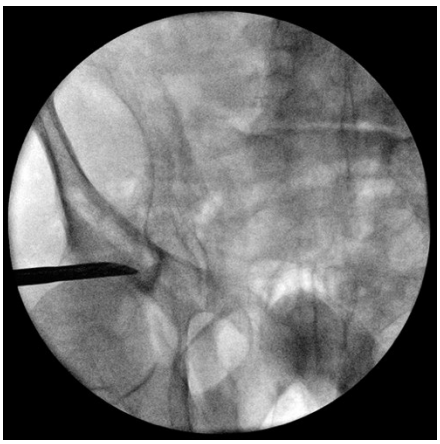


Figure 21

Insert 2.5 x 450 mm Pin to desired depth. Remove Pin Insertion Guide once Pin is securely in bone.

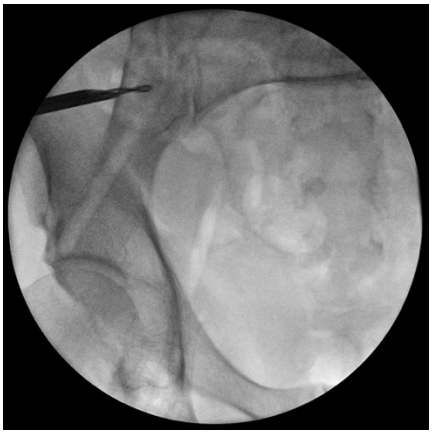


Figure 22

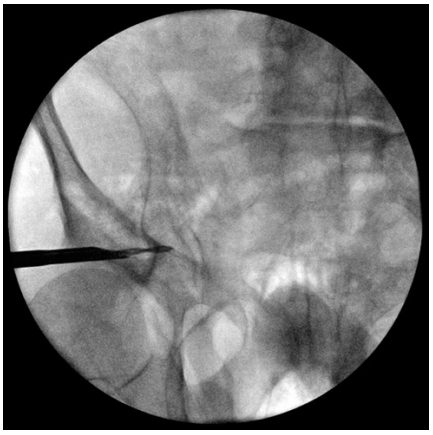


Figure 23

PRECAUTIONS

- Do not use excessive force or mallet when inserting the Pin Insertion Guide to minimize instrument damage to bone.
- Do not dock / advance tip of the Pin Insertion Guide into bone to a depth beyond the instrument's bevel.
- Do not attempt to change the Pin's trajectory with the Pin Insertion Guide once the Pin is in bone to avoid damage to Pin.
- The lumen of the Instrument is 3.4 mm. Take care to ensure collinearity of the Pin and the Pin Insertion Guide.

2.0 mm Pin & 4.5 mm Drill (Optional Technique for Pin Placement)

Insert 2.0 mm Pin through skin to desired start site on ilium. Use fluoroscopic image guidance to find trajectory.

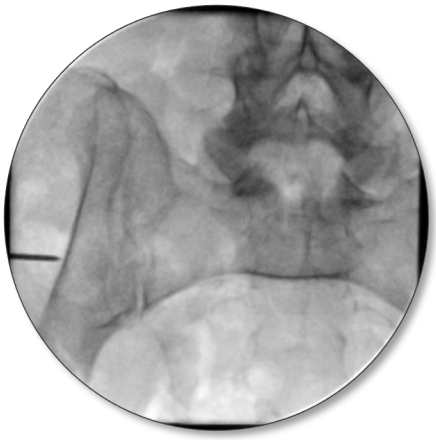


Figure 24

NOTE: *Do not advance Pin across SI joint.*

Position the Exchange Tube directly over the 2.0 mm Pin.

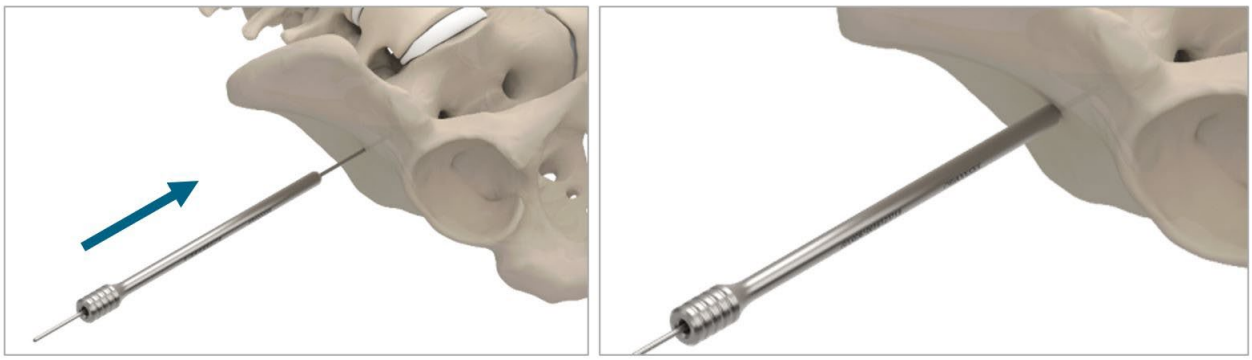


Figure 25

Advance the 4.5 mm Drill Bit over the 2.0 mm Pin. Use the 4.5 mm Drill Bit to adjust and find the desired trajectory for the Implant.

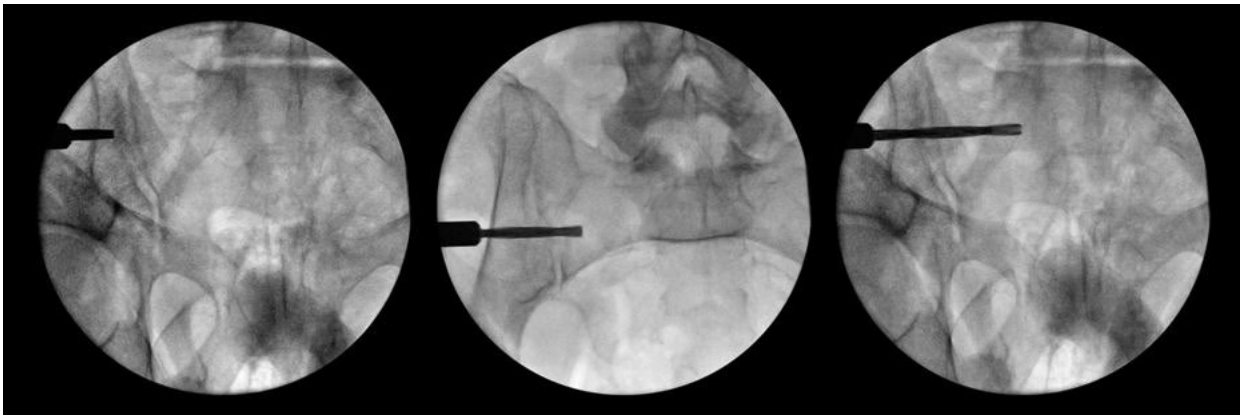
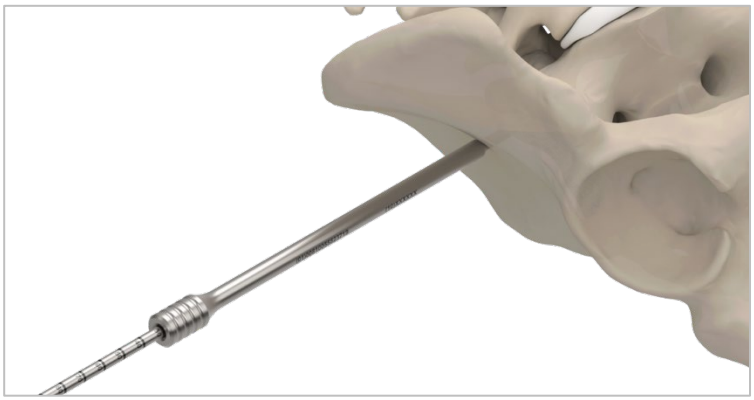


Figure 26

NOTE: *Watch laser mark lines on Drill Bit relative to the back of the Exchange Tube to monitor Drill Bit depth. Maximum Drill Bit depth is 90 mm.*

Drill across the SI joint to desired depth.



NOTE: *Consider using the oscillate mode on Power when advancing the Drill Bit and use Forward when adjusting trajectory.*

Hold the Exchange Tube in place when removing 4.5 mm Drill Bit and 2.0 mm Pin. Maintain position of Exchange Tube and place the 2.5 mm Blunt Pin. Use fluoroscopic guidance, to confirm final Pin position.

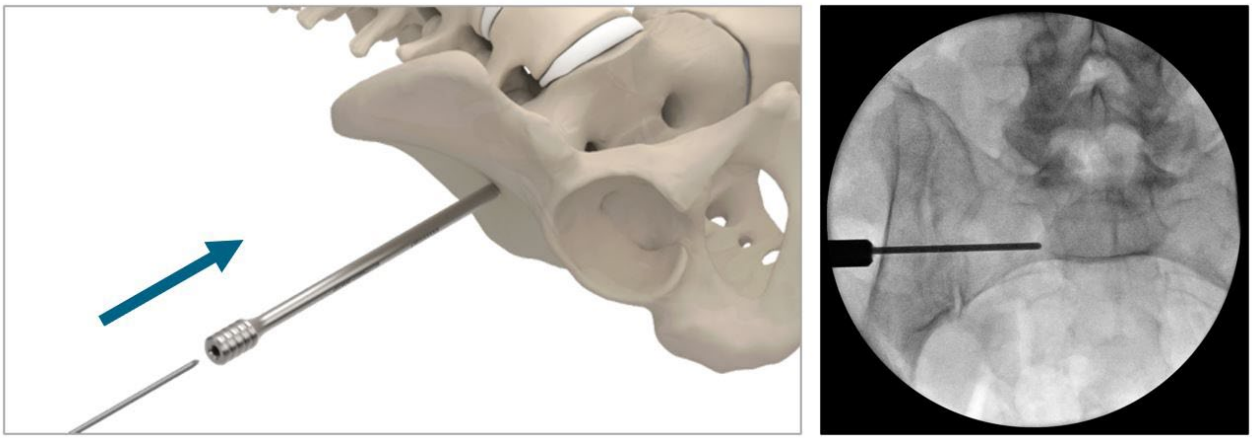


Figure 27

PRECAUTIONS

- Maintain Exchange Tube position on bone when exchanging instruments to reduce risk of losing Pin position.
- Take care when adjusting trajectory with 4.5 mm Drill Bit to not damage 2.0 mm Pin.
- Ensure the sharp end of Pin is oriented toward to patient to ensure User does not damage their glove/hand.
- Do not redirect the pin trajectory with the Exchange Tube.
- Take care not to aggressively place or twist the Exchange Tube.
- When placing exchange cannula over the 2.0 mm pin, take care not to advance the Pin.

Pin Repositioner (Optional)

The Pin Repositioners are available for use with the 2.0 mm or 2.5 mm Pins with both Odd and Even Pin spacing.

Pin Repositioners are available in ODD or EVEN spacing. The ODD Pin Repositioners allow pin position adjustments of 3 mm or 5 mm. The EVEN Pin repositioners allow pin position adjustments of 2 mm or 4 mm.

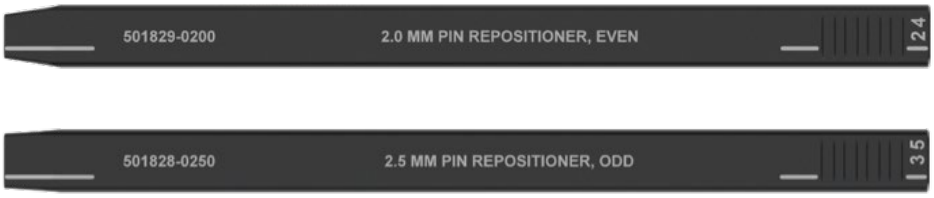


Figure 28

The Pin Repositioners have a laser mark line that designates the hole that fits over the original Pin. Orient the appropriate Repositioner in the desired direction the Pin will be repositioned to.

Pin Repositioner – Odd

Figure 29

Pin Repositioner – Even

Figure 30

Advance the new Pin through the chosen repositioning hole to desired depth. Monitor Pin advancement using fluoroscopic imaging.

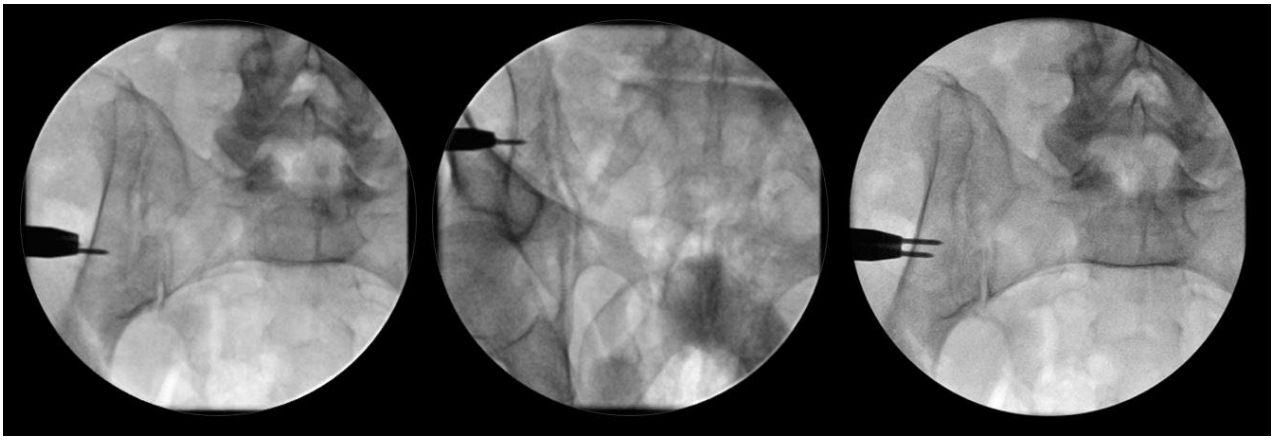


Figure 31

NOTE: *If longer Pin is available, consider using that as the new Pin to avoid inadvertent advancement of the original Pin.*

PRECAUTIONS

Ensure the appropriate Pin Repositioner is selected for Pin diameter in use (e.g., 2.0 mm Repositioner with 2.0 mm Pin).

Blunt Dissector Insertion

The Blunt Dissector-Long is a cannulated paddle that allows for gentle dilation of the soft tissues prior to inserting the Dilator. It is an optional Instrument for this procedure.

Slide the Blunt Dissector over the Pin. Gently advance the Blunt Dissector to the ilium, ensuring the blade is parallel to the muscle fibers.

Ensure the Blunt Dissector is seated on the ilium. Rotate gently to spread out the tissue around the Pin.

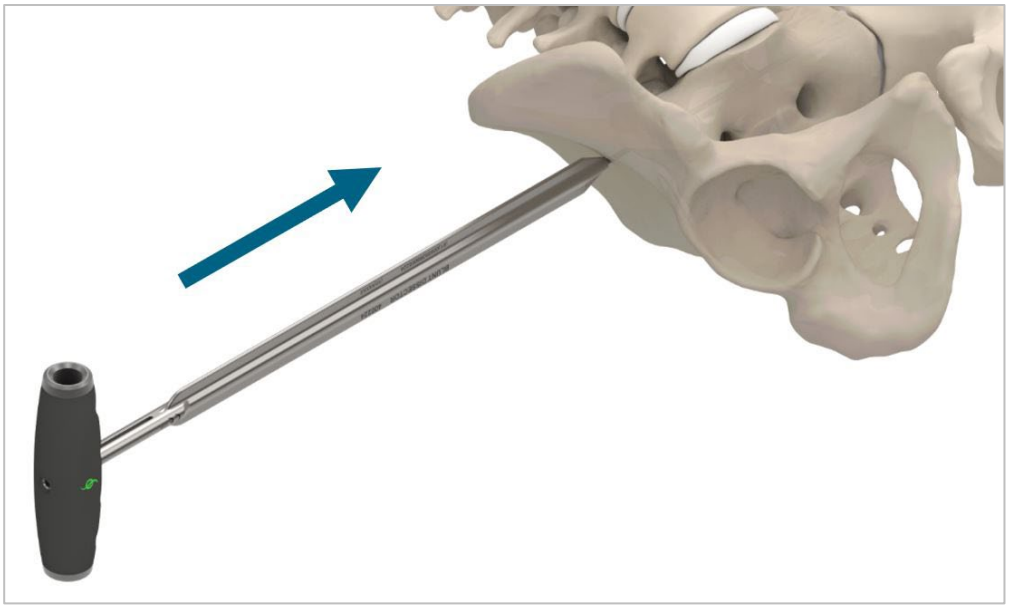


Figure 32

PRECAUTIONS

- Do not lower your hand while twisting the Blunt Dissector to avoid bending the Pin.
- To help avoid injury when using the Blunt Dissector, do not aggressively spread tissue or insert the instrument.
- The lumen of Instrument is 3.4 mm. Maintain collinearity of instrument with 2.5 mm Pin during use.
- Take care not to apply excessive forward pressure when twisting the Blunt Dissector to avoid creating a hole in the cortex.
- Take care when using the Blunt Dissector with the 450 mm Pins as they will extend out of the back of the instrument and could damage the user's glove / hand. Consider using the 330 mm Pin.

Dilator and Determining Implant Length

The Dilator is used to spread tissue and determine Implant length. Slide and rotate the Dilator gently over the Pin until the distal tip of the Dilator contacts the ilium.

Figure 33

If using the 450 mm Pin, use the laser mark on the Pin to determine the Implant length.

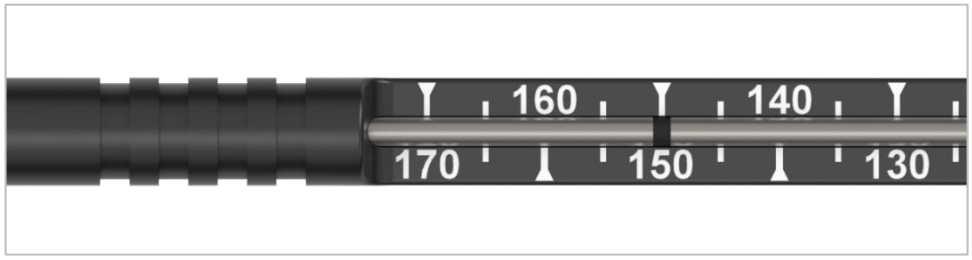


Figure 34

If using the 330 mm Pins, use the back of the Pin to determine the Implant length.

Figure 35

PRECAUTIONS

- Do not impact the flat surface of the Dilator. This may damage the bone and / or Dilator.
- The physician must choose the available Implant length that is most appropriate for the procedure.
- Take care to not aggressively insert Dilator to avoid instrument, bone, or tissue damage.

Soft Tissue Protector & Drill Sleeve

The iFuse TORQ TNT Soft Tissue Protector (STP) can be used in preparation for all iFuse TORQ TNT Implants with a 16 mm Washer. There is an optional handle that can be assembled to the iFuse TORQ TNT STP. The iFuse TORQ TNT STP comes with a Drill Sleeve. The Drill Sleeve is assembled into the lumen of the STP and functions as a centering sleeve when using the Drill Bits and Taps.

Align laser mark arrows on Drill Sleeve and STP. Press the Drill Sleeve into the iFuse TORQ TNT STP to assemble the two Instruments.

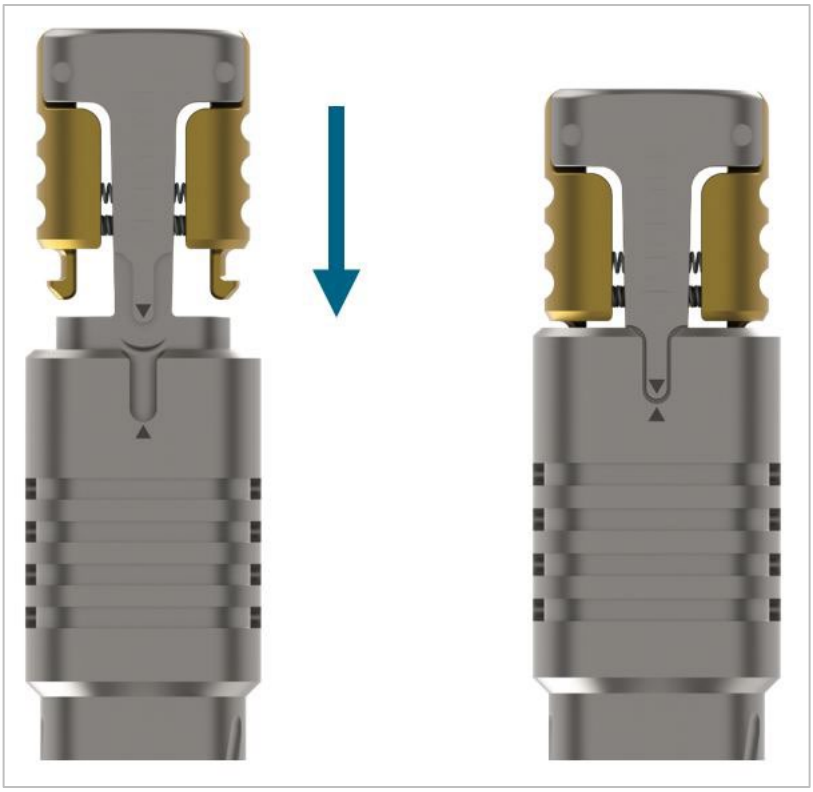


Figure 36

Slide the iFuse TORQ TNT STP with Drill Sleeve over the Dilator until the distal tip of the STP achieves bony contact with the ilium. Once STP is in position, remove Dilator from the Drill Sleeve-STP assembly.

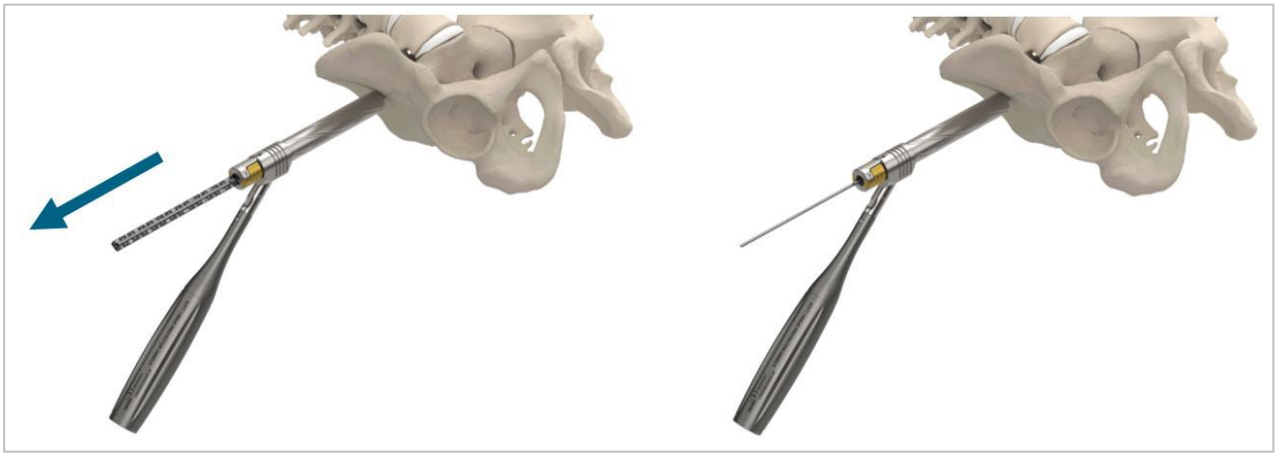


Figure 37

PRECAUTIONS

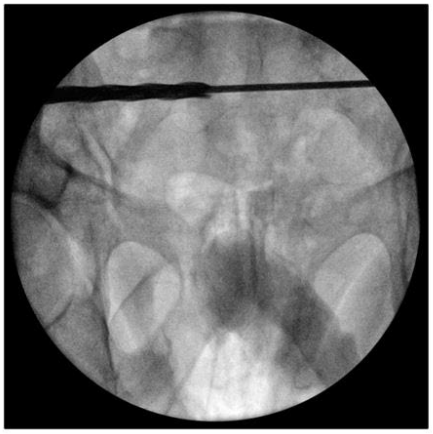
- Do not impact the flat surface of the Soft Tissue Protector. This may damage the bone and/or Soft Tissue Protector.
- Listen for an audible click when the STP Handle is connected to the STP to ensure the two instruments are connected to avoid the Handle falling outside of the sterile field.
- Ensure the STP is flush to the ilium, so the measurement markings on instruments are correct and depth of Implant placement is accurate.
- Ensure Drill Sleeve is fully seated within STP so measurement markings on Drills/Taps are accurate relative to back of Drill Sleeve-STP assembly when drilling/tapping.
- Maintain position of STP through and after Drilling, Tapping, and Implantation steps to ensure proper alignment of instruments and Implant.

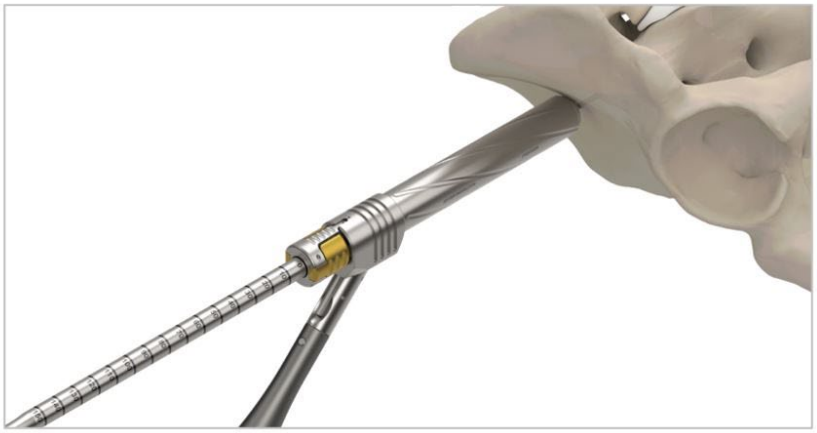
Drilling (Optional)

It is possible to perform this procedure without drilling, as iFuse TORQ TNT Implants are self-drilling and self-tapping in most cases. In hard bone, drilling and tapping may be required. Insert the Drill Bit over the Pin, through the STP.

NOTE: *To connect to power, attach Drill Bit to the Quarter Inch to Tri-Lobe Adapter until laser marking indicates it is fully seated.*

To prevent binding ensure the Drill Bit can move easily back and forth over the Pin. Start applying power only after the Drill tip is against bone. A Blunt Pin may be used in place of the Pin if the Pin is close to a foramen. Commence drilling under fluoroscopy. Drill through the lateral cortex of the ilium to the desired depth.





Monitor Drill Bit advancement under fluoroscopy and with measurement markings on Drill Bit relative to the back of the Drill Sleeve. As the Drill Bit is removed, hold the Pin to ensure the distal tip remains in bone. Insert Blunt Pin as an Exchange Pin to help maintain Pin position.

NOTE: *There are two lengths of 5.5 mm Drill Bits in the set, 280 mm and 375 mm. The 280 mm Drill Bit is designed to drill to a maximum depth of 60 mm. The 375 mm Drill Bit is designed to drill across the posterior pelvis, in most patients, to a maximum depth of 150 mm.*

PRECAUTIONS

- Ensure the lumen of the Drill Bit is free of debris prior to each use. Flushing the Drill Bit lumen with sterile saline prior to each subsequent use during the procedure may also minimize Pin binding.
- Adequate bone preparation is recommended to help avoid fractures to the sacrum or ilium.
- Use care to avoid advancing the Pin during drilling. Do NOT push on the Pin. Applying a medial force to the Pin may cause them to advance medially.
- Over-drilling (excessive advancement) may cause nerve damage, hemorrhage, or the other possible adverse events listed in the Instructions for Use, 503008.
- Take care to monitor Drill Bit advancement if using with power.
- Do not impact the drill handle assembly with mallet to advance the drill.
- 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.
- 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.

NOTE: *When fixing a fracture, consider drilling past the fracture site to minimize the risk of fracture displacement during Implant insertion.*

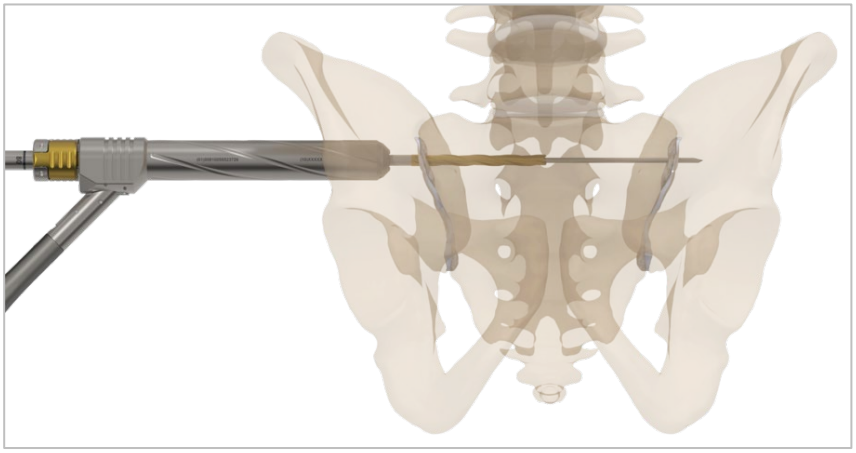


Figure 38

Tapping (Optional)

It is possible to perform this procedure without tapping, as iFuse TORQ TNT Implants are self- drilling and self-tapping in most cases. In hard bone, drilling and tapping may be required.

Connect the Tap to either the T-Handle or Inline Handle. Insert the Tap over the Pin, through the Drill Sleeve-STP assembly.

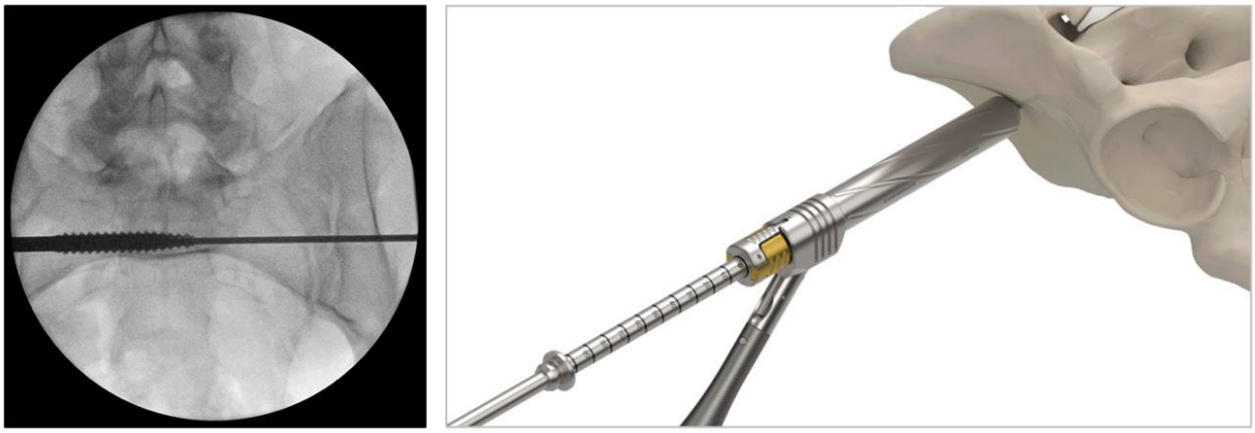


Figure 39

To minimize binding ensure the Tap can move easily back and forth over the Pin. A Blunt Pin may be used to minimize the risk of pin advancement if the Pin is close to a foramen.

Commence tapping under fluoroscopy. Tap through the lateral cortex of the ilium to desired depth, watch for unwanted Pin advancement. The Tap is designed to reach a maximum depth of 100 mm. Monitor Tap advancement with measurement markings on the Tap relative to the Drill Sleeve.

NOTE: *When fixing a fracture, consider tapping past the fracture site to minimize the risk of fracture displacement during Implant insertion.*

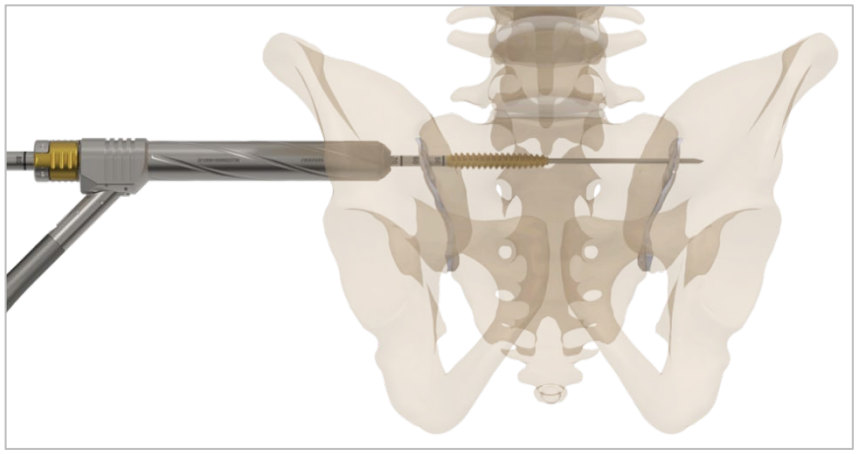


Figure 40

PRECAUTIONS

- Ensure the lumen of the Tap is free of debris prior to each use. Flushing the Tap lumen 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 medially directed force to the Pin may cause it to advance.
- Excessive advancement of the Tap may cause nerve damage, hemorrhage, or other possible adverse events listed in the Instructions for Use, 503008.
- Take care to monitor Tap advancement if using with power.
- 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.
- Continued rotation of the Tap without advancement may result in the stripping of internal threads into the bone.
- Take care when using the T-Handle with the 450 mm Pins as they will extend out of the back of the instrument and could damage the user's glove / hand. Consider using the Inline Handle with the 450 mm Pins.

Drill Sleeve

Remove the Drill Sleeve from the Soft Tissue Protector (STP) prior to Implant insertion.

Press on the gold tabs to release the Drill Sleeve from the STP.

Maintain position of the STP while removing Drill Sleeve.

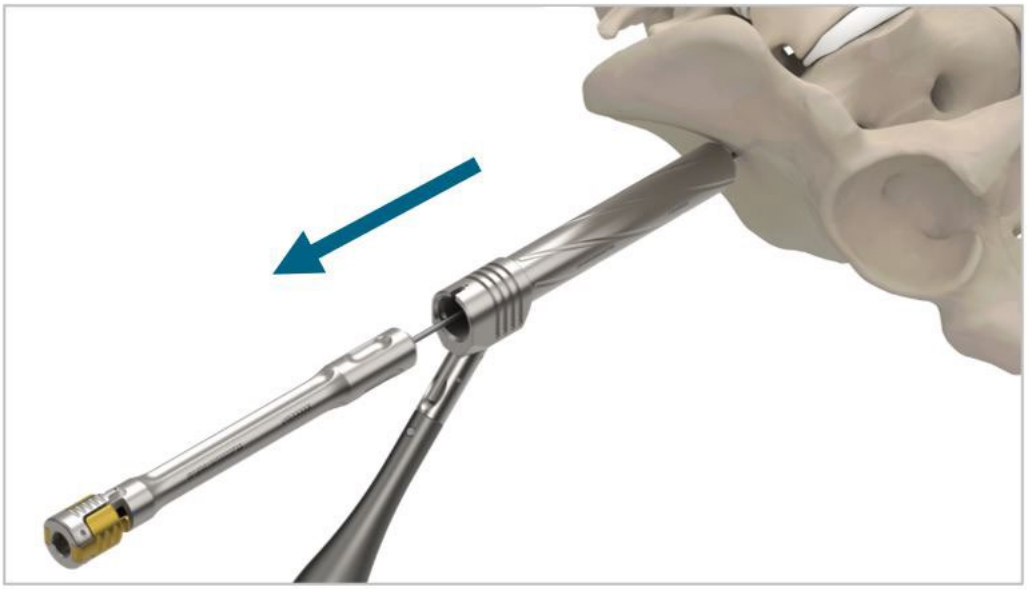


Figure 41

Implant Transfer and Assembly to Driver

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.

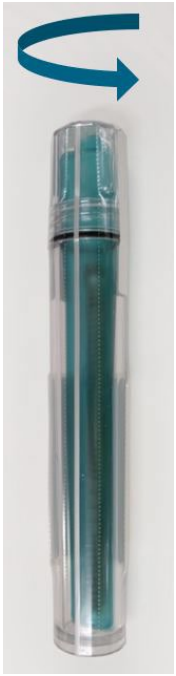


Figure 42

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.

Figure 43

Insert the TNT Locking Driver through the opening in the TPU sleeve into the T40 Torx drive feature of the Implant.

Maintaining the Implant in a vertical position, advance the outer sleeve of the Locking Driver onto the Implant. Rotate the outer sleeve until it is fully engaged onto the Implant (use two finger tightness).

Figure 44

Slide the gold locking button distally toward the Implant into the locked position.

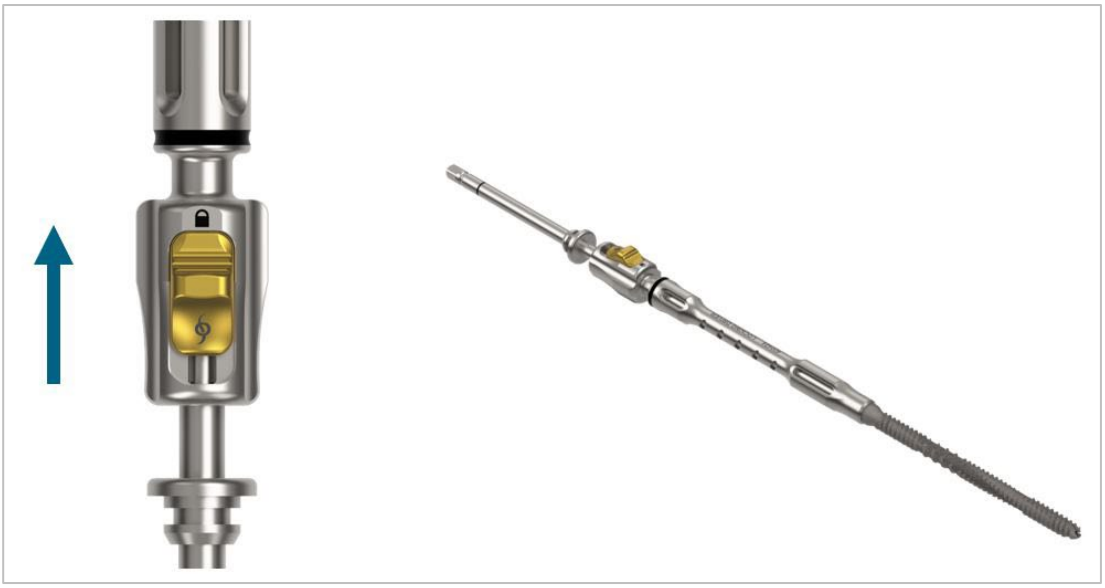


Figure 45

NOTE: *This step may be done prior to Implant assembly.*

Remove the loaded Driver-Implant assembly from the TPU sleeve.

PRECAUTIONS

- Be mindful and aware when handling the Implant to maintain sterility.
- If the implant leaves the sterile field, dispose of the implant per facility policy to avoid potential infection or inflammatory reaction.

Washer Assembly

The Washers come in the Instrument Set, 400463, separate from Implant packaging. There are two washer caddies, one for the 16 mm Washers and one for the 21 mm Washers.

Orient the laser markings on the Washer toward the head of the Implant.

Place the washer over the distal end of the Implant and slide the Washer until flush with the head of the Implant.

See **iFuse TORQ TNT Implant Specifications** for more information on the Washers.

NOTE: *The STP will need to be removed prior to placing an iFuse TORQ TNT Implant with a 21 mm Washer.*

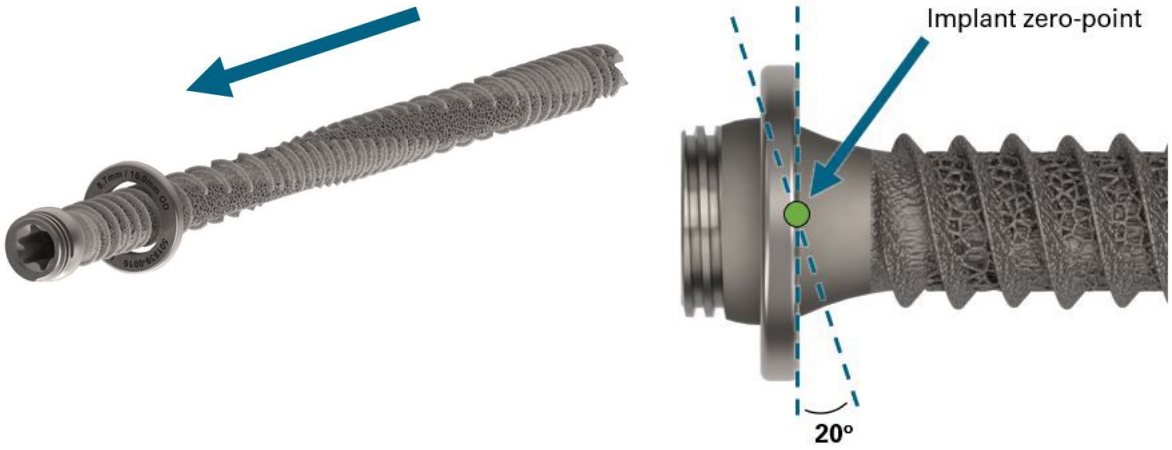


Figure 46

PRECAUTIONS

There are multiple Washers in each caddie. Take care to remove the desired number of Washers during the procedure to prevent Washers from falling outside of sterile field.

Implant Insertion

Advance the Implant on the Locking Driver Assembly with either power, using the Quarter Inch to Tri- Lobe Adapter, or by hand with the ratcheting T-Handle or Inline Handle in Forward position. Ensure Driver is fully seated in Handle or Adapter prior to use.

Figure 47

NOTE:

If using power, consider using the "ream" setting opposed to "drill".

There is a laser mark on the Driver. When using the Driver and the STP together, the relation of this laser mark 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.

Always keep forward pressure on the Driver when advancing the implant.

Optional: A TNT non-locking T40 Torx Driver is also available for Implantation.

Monitor the progress of the Implant and any movement of the Pin under fluoroscopy.

NOTE: *Final Implant seating should always be performed manually, with either the T-Handle or Inline Handle.*

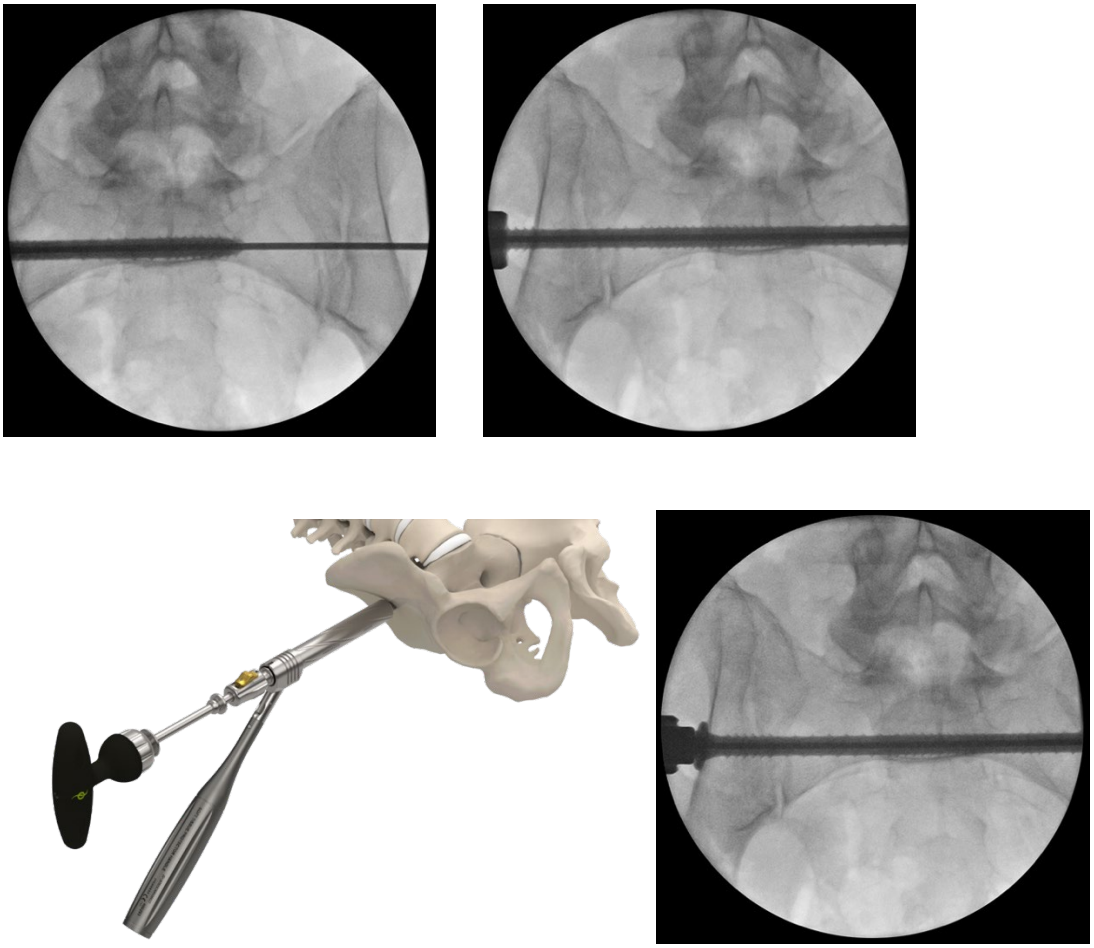


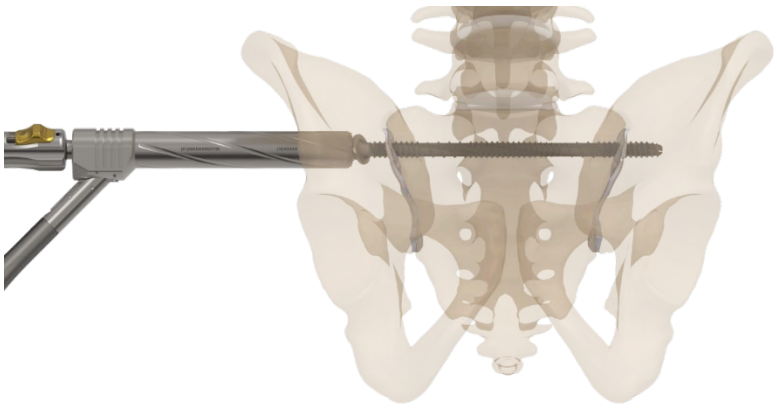
Figure 48

If SI joint fusion is desired, iFuse TORQ TNT should be placed along with one or more additional implants across the SI joint.

NOTE:

If placing multiple Implants, presence of Implant(s) may obscure visualization of the osseous anatomy on the inlet view.

When fixing a fracture, fluoroscopically confirms that the Implant has adequately crossed the fracture site.



PRECAUTIONS

- Please be mindful and aware the Implants have sharp edges and a roughened surface. The Implants can cause injury if handled in an unsafe manner.
- Physicians are advised when using the STP that it should be docked against the ilium to protect surrounding soft tissue from injury that could be caused by the Implants' rough surface and sharp edges.
- Use care to avoid advancing the Pin during Implant insertion. Do NOT push on the Pin. Applying a medially directed force to the Pin or the secondary Blunt Pin may cause them to advance.
- If placing an Implant with a 21 mm Washer, tissue retractors may be used to aid in Implant placement.
- Take care when inserting an iFuse TORQ TNT Implant. Over-tightening may cause damage to the bone or Implant.
- The Implant has been designed to optimize initial fixation with surrounding bone. If the Implant becomes difficult to advance during insertion (e.g., patient has hard bone) do not continue to advance Implant. Insertional torque could exceed limits of the User/Driver. In this situation, remove the Implant, and drill and tap to fully prepare the bone channel to accommodate the Implant.

Monitor the position of the laser mark on the Driver relative to the proximal end of the STP. When the laser mark is in-line with the STP, the Implant is fully seated. Slide the gold button backward to unlock Driver. While applying counter torque to the Driver shaft, rotate Driver knob counterclockwise to unthread Driver from head of Implant and remove Driver.

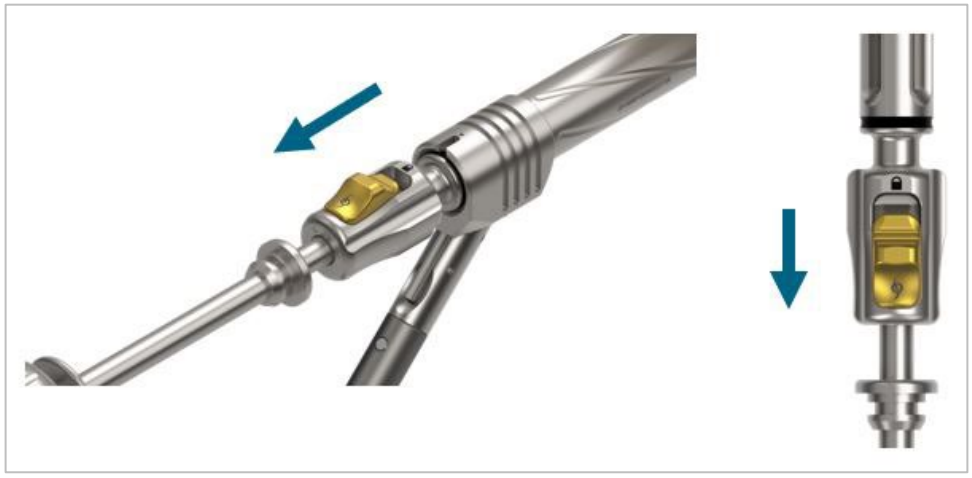


Figure 49

NOTE: *Consider using a rollover Inlet view to confirm the Implant is seated against the iliac cortex (left image below).*

Take final fluoroscopic views to confirm Implant placement.

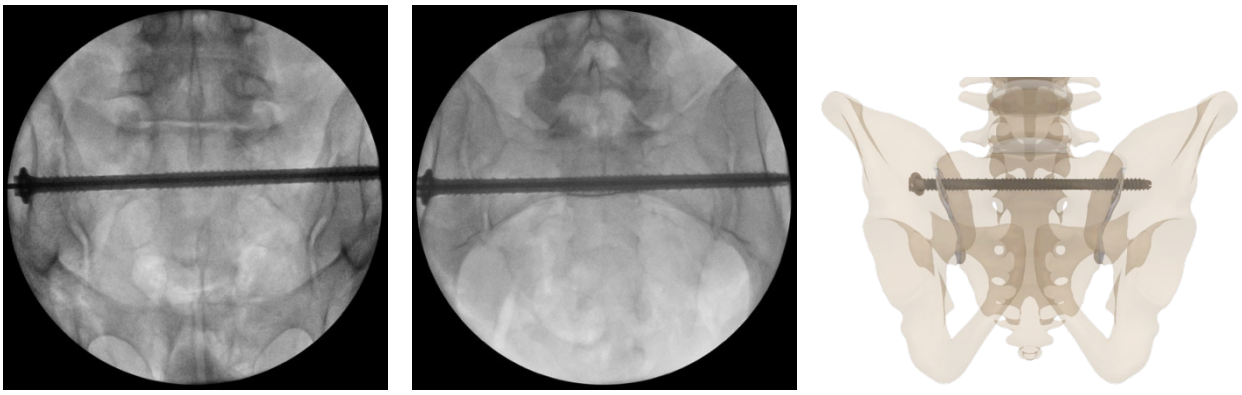


Figure 50

PRECAUTIONS

- Do not over-insert or use an Implant that is too long. Using an incorrectly sized Implant, may cause nerve damage, hemorrhage, or the other possible adverse events listed in the Instructions for Use, 503008.
- Do not reference laser marking on standard cannulated T40 Torx (TNT) driver if using TNT driver to place an iFuse TORQ Implant.
- When placing additional Implants bilaterally, ensure there is no collision of the distal tip of the contralateral implant.
- Take care when inserting the surgical instruments and iFuse TORQ TNT Implants to avoid damage to surrounding soft tissue.

Fixed Parallel Pin Guide (Optional)

The 11.5 mm Fixed Parallel Pin Guide (FPPG) has a radiolucent head to allow for better visualization under fluoroscopy.

When using the FPPG, place the shorter tube over the initial Pin, and use the longer tube to place the second Pin.

NOTE: *The FPPG is designed to be used for placing two iFuse TORQ TNT Implants without Washers in the S1 corridor.*

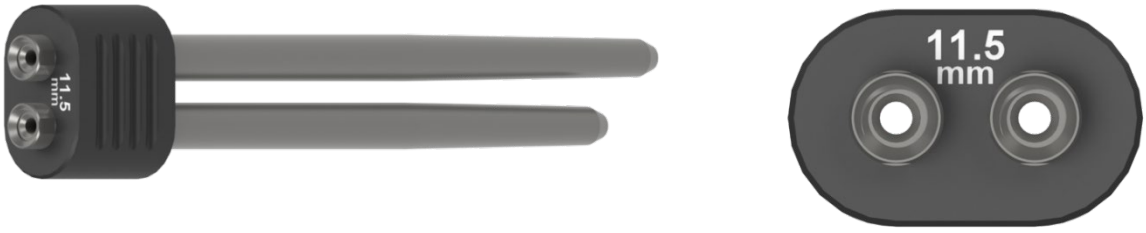


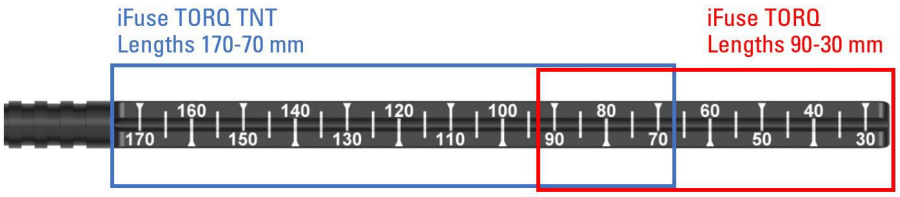
Figure 51

PRECAUTIONS

Center-to-center spacing assumes parallel Pins. Attempt to keep Pins parallel during insertion to help prevent Implants from contacting each other.

iFuse TORQ Implants with iFuse TORQ TNT Instruments

iFuse TORQ Implants can be placed using iFuse TORQ TNT instrumentation. Follow the previously described procedural steps using the applicable Instruments listed below. Note these differences in the instrumentation when implanting iFuse TORQ Implants with the iFuse TORQ TNT instrumentation.

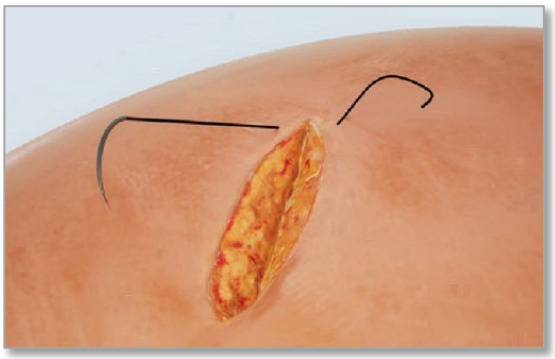
Instruments	Note(s) for Placing iFuse TORQ Implants with iFuse TORQ TNT Instruments
2.0 mm Pins	No additional notes – Refer to **First Pin Placement**.
4.5 mm Drill Bit	4.5mm Drill bit is 90 mm long which accommodates the longest iFuse TORQ implant.
2.5 mm Pins	Lumen of iFuse TORQ Implants and instruments is 3.4 mm diameter. Maintain collinearity of Instruments and Implants during use.
Pin Insertion Guide (optional)	No additional notes – Refer to **Pin Insertion Guide**.
Blunt Dissector (optional)	No additional notes – Refer to **Blunt Dissector Insertion**
Dilator Depth Gauge	
Soft Tissue Protector with Drill Sleeve (optional)	STP can accept the following iFuse TORQ Implants – Fully- Threaded 10, 11.5, 13.5 mm; Lag 10 mm with 16 mm Washer. If placing an 11.5 mm iFuse TORQ Lag with 18 mm Washer, have the iFuse TORQ Instrument tray, 400287, available.
5.5 mm Drill Bit (Optional)	The Drill Bit diameter is smaller than the Drill Bits used with iFuse TORQ Implants. In the case of hard bone, do not use iFuse TORQ Implants without the iFuse TORQ Instrument tray, 400287.
8.0 mm Tap (Optional)	The Tap diameter is smaller than the Taps used with iFuse TORQ Implants. In the case of hard bone, do not use iFuse TORQ Implants without the iFuse TORQ Instrument tray, 400287.
iFuse TORQ TNT Torx Driver	Laser marking does NOT apply when monitoring iFuse TORQ Implant depth. Use a rollover view to confirm Implant depth relative to the cortex.

PRECAUTIONS

- The iFuse TORQ TNT Locking Driver does not engage with iFuse TORQ Implants.
- Ensure collinearity when utilizing iFuse TORQ TNT instrumentation to place iFuse TORQ Implants.
- Consider adding additional distance between Implants in the unlikely case a Trephine or chisel is needed to remove Implants.
- iFuse TORQ implants cannot be placed using the 11.5 mm FPPG.

Closure and Post Op Care

Closure



- Obtain final outlet, inlet, and lateral views.
- Proceed with the standard closing procedure.
- Local anesthetic may be injected after closure.

Recommended Steps

- Muscle fascia if possible
- Subcutaneous tissue
- Skin

Post-Op Care

Some patients may be able to progress rapidly to full weightbearing. Other patients may require a period of protected weightbearing due to associated health conditions such as age, osteoporosis, altered bone health, impaired balance and/or gait, or other musculoskeletal conditions.

Most physicians and therapists recommend a heel toe gait with normal foot progression.

Fracture Repair

Post-op protocol will be patient dependent.

Implant Removal

Upon need for Implant removal, please follow the subsequent steps and methods for removal.

If an Implant needs to be removed, clear all debris that may be obstructing the Implant's Torx head.

Place a Pin through the Implant.

NOTE: *Consider using the STP to manage soft tissue during Implant removal.*

Assemble the T40 Torx driver onto the T-handle. Insert driver over Pin and engage Implant.

Rotate counterclockwise to remove Implant.

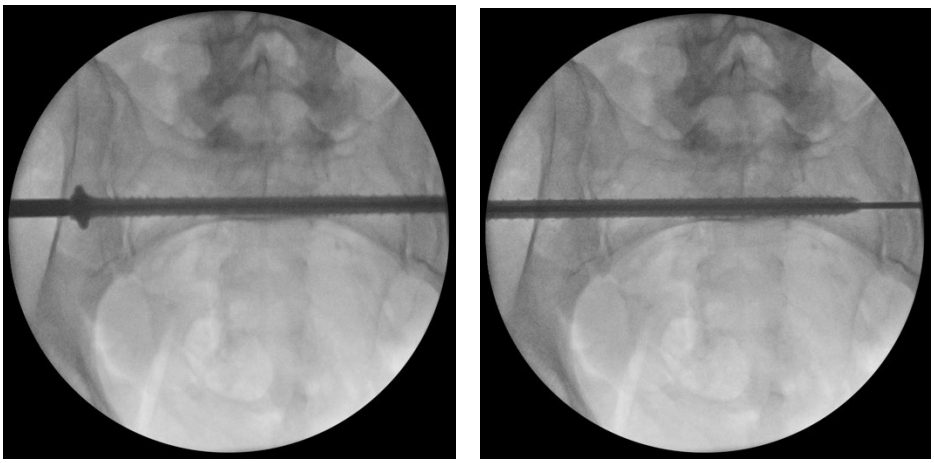


Figure 52

PRECAUTIONS

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 Driver to remove the Implant(s).

Product Catalog: iFuse TORQ TNT Instruments

Part Numbers	Description
400463	iFuse TORQ TNT Instrument Set
501769-0250	Trocar Pin, 2.0 mm x 250 mm, TORQ TNT
501769-0330	Trocar Pin, 2.0 mm x 330 mm, TORQ TNT
501770-0330	Trocar Pin, 2.5 mm x 330 mm
501771-0330	Reverse Threaded Pin, 2.5 mm x 330 mm
501772-0330	Drill Pin, 2.5 mm x 330 mm
501918-0330	Blunt Pin, 2.5 mm x 330 mm
501770-0450	Trocar Pin, 2.5 mm x 450 mm
501771-0450	Reverse Threaded Pin, 2.5 mm x 450 mm
501772-0450	Drill Pin, 2.5 mm x 450 mm
501918-0450	Blunt Pin, 2.5 mm x 450 mm
501773	Cleaning Stylet, TORQ TNT
501767	TORQ TNT Dilator
501765	4.5 mm Cannulated Drill Bit, TORQ TNT
501766-0280	5.5 mm Cannulated Drill Bit, TORQ TNT, 280 mm
501766-0375	5.5 mm Cannulated Drill Bit, TORQ TNT, 375 mm
501829-0200	2.0 mm Pin Repositioner, Even
501828-0200	2.0 mm Pin Repositioner, Odd
501829-0250	2.5 mm Pin Repositioner, Even
501828-0250	2.5 mm Pin Repositioner, Odd
501775	TORQ TNT Exchange Tube
400424	TORQ TNT Locking Driver
501872	TORQ TNT Cannulated Torx Driver
400407	TORQ TNT Fixed Parallel Pin Guide
400224	Blunt Dissector – Long
400409	TORQ TNT Drill Sleeve
501417	QC Adapter, Quarter Inch to Tri-Lobe
400408	TORQ TNT Soft Tissue Protector
400283	Handle, Latching, Assy
501621	T-Handle, Pinned
501622	Inline Handle, Pinned
400438	Pin Insertion Guide
501939-0016	TORQ TNT 16.0 mm Washer
501939-0021	TORQ TNT 21.0 mm Washer
400418	TORQ TNT Tap

About This Manual & Future Changes

This surgical technique manual describes the steps for placing iFuse TORQ TNT implants in sacral style and the SI style trajectories. Other implant trajectories in the pelvis are possible and will be added in the future.

The iFuse TORQ TNT Implant System will include future surgical technique manuals that describe placement of iFuse TORQ TNT implants in the sacroalar iliac (SAI) trajectory under fluoroscopic or navigation guidance. The iFuse TORQ TNT Implant System may expand in the future to include additional implant types.

Users will be notified verbally or by email, by updates to SI-BONE's website (https://si-bone.com/label), and by updated labeling documents.

Indications

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

The iFuse TORQ TNT Implant System is indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.

The iFuse TORQ TNT Navigation Instruments are intended to be used with the iFuse TORQ TNT Implant System to assist the physician in precisely locating anatomical structures in iFuse TORQ TNT 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 TNT Navigation Instruments are intended to be used with the Medtronic StealthStation System.

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

There are potential risks associated 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**.

SI-BONE® | iFuse TORQ TNT™ Implant System

℞ ONLY

US | Providers

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