Surgical Technique Manual

Lateral Technique - Fluoroscopy

SI Joint Fusion

Pelvic Fracture Fixation

Removal & Revision

SI-BONE®

Sacropelvic Solutions®

CONTENTS

iFuse TORQ® Implant System

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

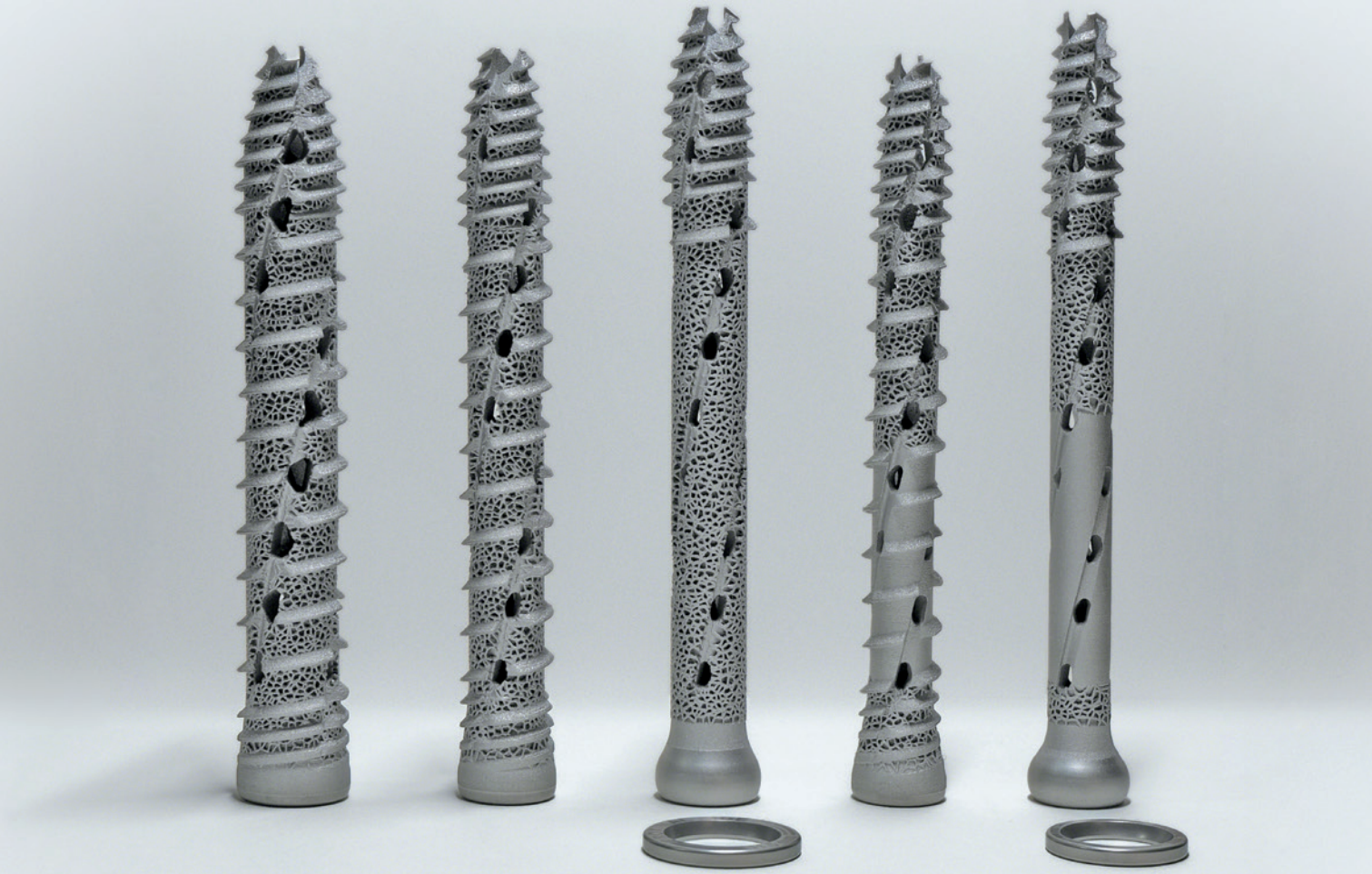
- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

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 Physician 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.

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 informatio on contraindications, warnings, precautions, and potential risks, refer to the iFuse TORQ Implant System Instructions For Use.

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 prevents 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

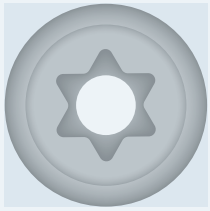
PRECAUTIONS:

- ➤ *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**

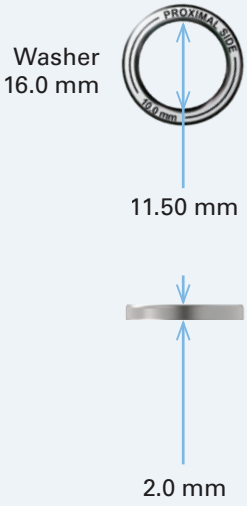
Disposables / Single-Use Only	
Guide Pin – 3.2 mm	500373
Blunt Pin – 3.2 mm	500374
Exchange Pin – 3.2 mm	500375
8 Gauge Bone Access Needle, Bevel Tip	502156

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

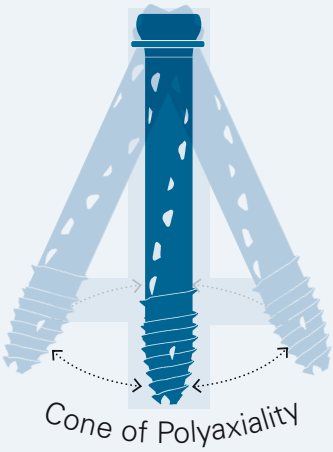


11.5 mm Lag Implant and Washer

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

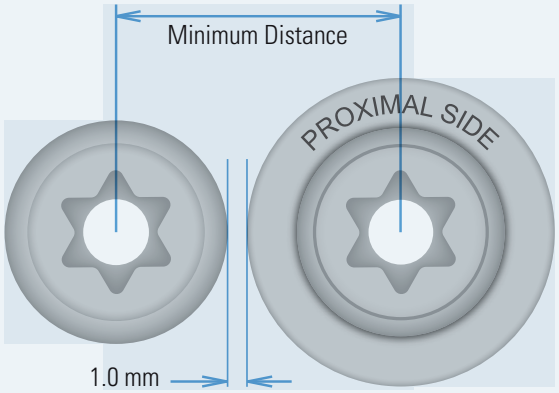
* Values apply for 10.0 mm and 11.5 mm diameter implants

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

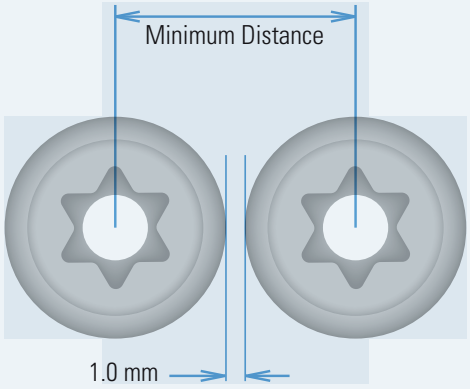


Subsequent Implant Spacing

Fully-Threaded Implant and Lag Implant with Washer



Fully-Threaded Implant and Fully-Threaded Implant



Minimum Implant Distance*

	iFuse TORQ, Fully-Threaded			iFuse TORQ Implant, Lag			
	10.0 mm	11.5 mm	13.5 mm	10.0 mm	11.5 mm	10.0 mm with 16.0 mm Washer	11.5 mm with 18 .0 mm Washer
10.0 mm FT	12.5						
11.5 mm FT	12.75	13.0					
13.5 mm FT	13.65	13.9	14.75				
10.0 mm Lag	13.0	13.25	14.2	13.5			
11.5 mm Lag	13.25	13.5	14.4	13.75	14.0		
10.0 mm Lag with 16.0 mm Washer	14.75	15.0	15.9	15.25	15.5	17.0	
11.5 mm Lag with 18.0 mm Washer	15.75	16.0	16.9	16.25	16.5	18.0	19.0

* All values are in millimeters and represent center to center spacing plus 1.0 mm of additional space between implants.

PRECAUTIONS:

- *Center to center spacing assumes parallel pins. To compensate for any angulation, consider adding additional distance between pins and/or Implant placement in order to prevent Implants from contacting each other during insertion.*
- *Consider adding additional distance between Implants in the unlikely case a Trephine or chisel is needed to remove Implants in the future. iFuse TORQ Trephines have a wall thickness of 1.0 mm.*

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

- Jackson and flat imaging tables are common.
- One or two C-arms may be used – usually one is sufficient.
- If a flat table is used, place towel rolls transversely under the chest and waist, and pillows under the feet to relax hip and knee joints **(Figure 1)**.
- 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.

Patient Positioning

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

- Prone positioning may be beneficial for obese patients, while supine positioning may be favorable in some trauma patients.

Options for Instrumenting with Power

iFuse TORQ Instruments are compatible with a Jacobs Chuck using the Quarter Inch to Tri-Lobe Adapter. iFuse TORQ Instruments are also compatible with the Medtronic POWEREASE® System using the Quarter Inch to POWEREASE Adapter.

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 might minimize the occurrence of binding of instruments and/or Implants. Please refer to 300065, iFuse Family of Instruments – Hospital Cleaning and Sterilization Instructions, USA.

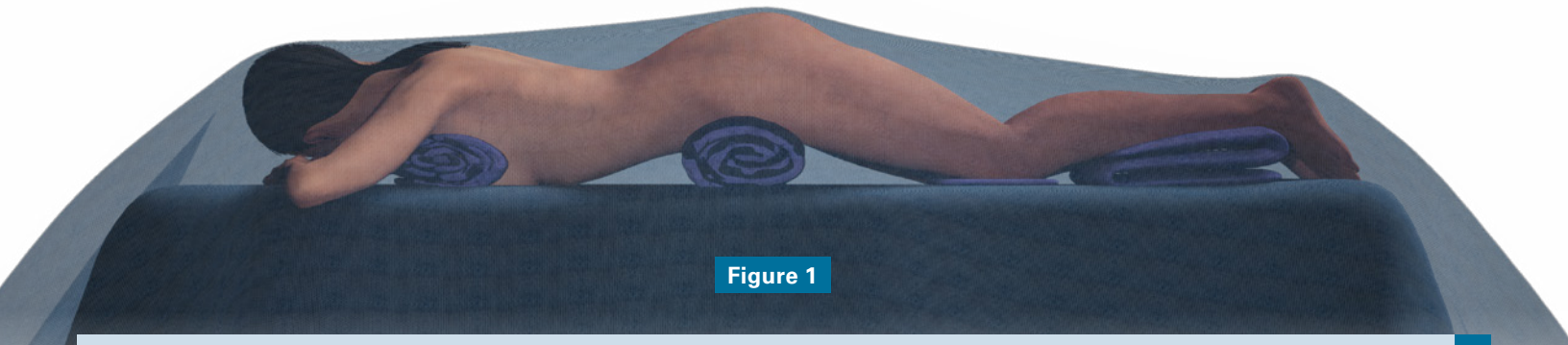


Figure 1

PRECAUTIONS:

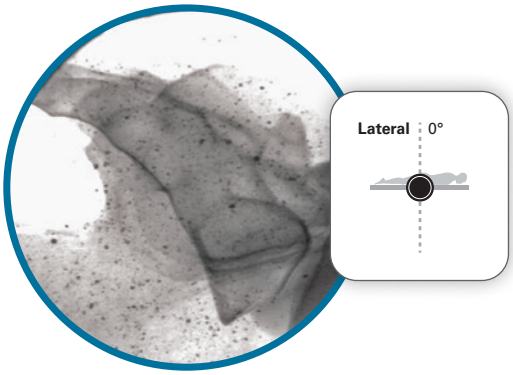
- *This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the physician's judgment. Instruments not shown in this manual may be used at the physician's discretion.*
- *Breakage, slippage or misuse of instruments or Implants may cause injury to 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/instrument interface.*
- *Position C-arm to minimize interference with instruments throughout the procedure.*

Fluoroscopic Guidance

Lateral View

First align the disc space and end plates of L5-S1 to a true lateral view using C-arm swivel or "wig-wag." The sciatic notches should overlap once in correct alignment. Finalize the alignment by superimposing the left and right iliac cortical densities (alar lines).

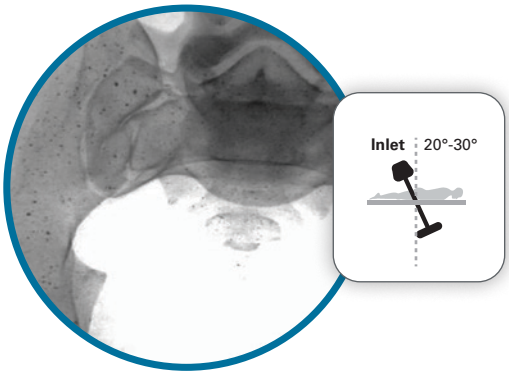
Figure 2



Inlet View

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

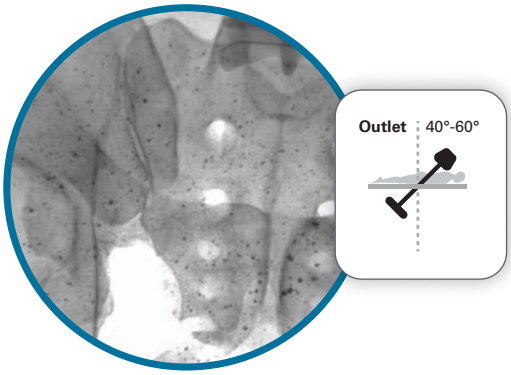
Figure 3



Outlet View

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

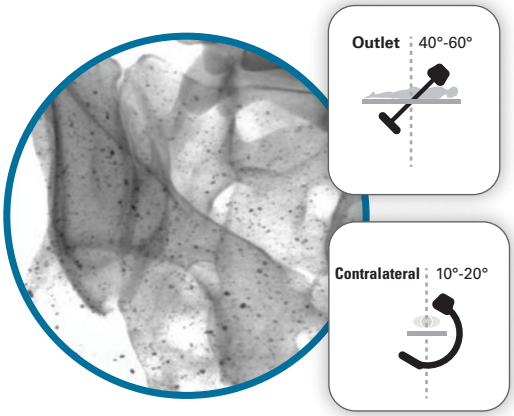
Figure 4



Outlet Oblique View

The outlet oblique view is an anterior-to-posterior view with 10-20 degrees of obliquity used to optimize visualization of the lateral aspect of the S1 neuroforamen and the sacroiliac joint in an open profile.

Figure 5



First Skin Marking

Under fluoroscopy, use a Guide Pin to localize the ala/ICD (Iliac cortical density). Mark the skin overlying the ala/ICD.

Second Skin Marking

Under fluoroscopy use a Guide Pin to localize the mid-sacral body. Mark the skin overlying the mid-sacral body.

Incision

Make a 3 cm skin incision along the mid-sacral body line starting about 1 cm from the first skin marking.

The incision should be made through the skin and subcutaneous tissue.

Do not continue the skin incision through the muscle and fascia to the bone, the muscle fibers run perpendicular to the skin incision. Cutting muscle fibers may result in significant bleeding and/or muscle damage.

Place Pin(s) through the fascia and seat it (them) into the bone.

Figure 6

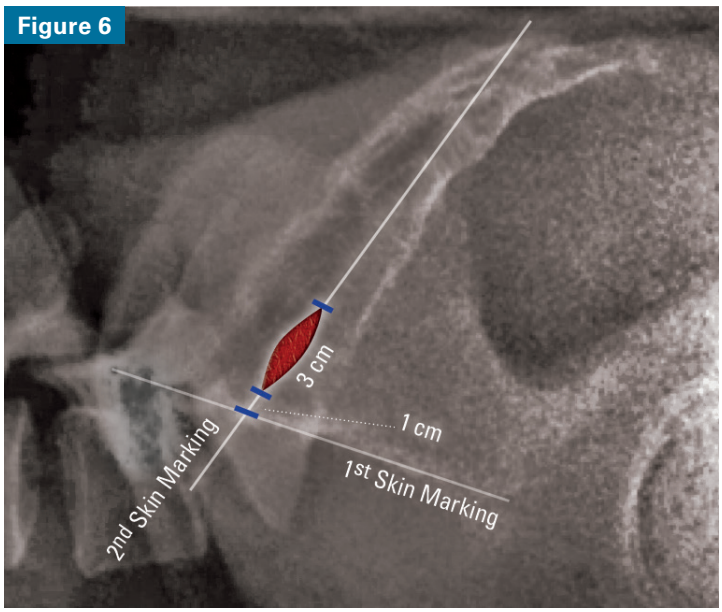
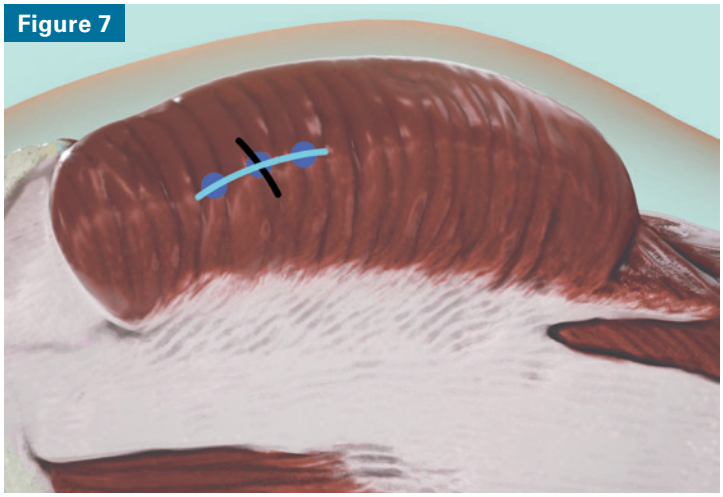


Figure 7



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.*

PROCEDURE: First Pin Placement

The 3.2 mm Guide Pin is a method for obtaining bone access. Another method for creating a channel includes the 8 Gauge Bone Access Needle (Bevel Tip) **(Figure 8).**

- Follow Pin instructions to create a channel with the Bone Access Needle.

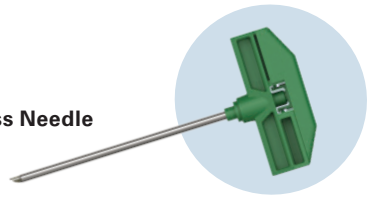


Figure 8
Bone Access Needle

> ***NOTE:***
> *If using an 8 Gauge Bone Access Needle for bone access, remove the stylet and place the 3.2 mm Guide Pin into the cannula. Remove the cannula of the Bone Access Needle and proceed with the procedure.*

Lateral View

Initial Guide Pin position is always started distal to the alar line (iliac cortical density; ICD).

The middle 1/3 of the first sacral body is the typical, but not the universal, starting point.

Once the starting point is identified, dock the Pin into the lateral cortex of the ilium.

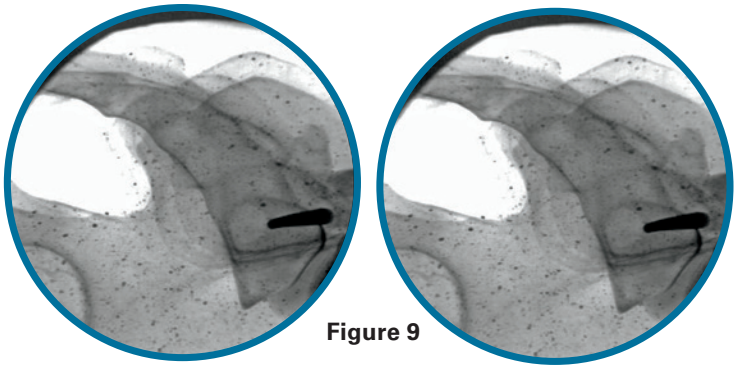


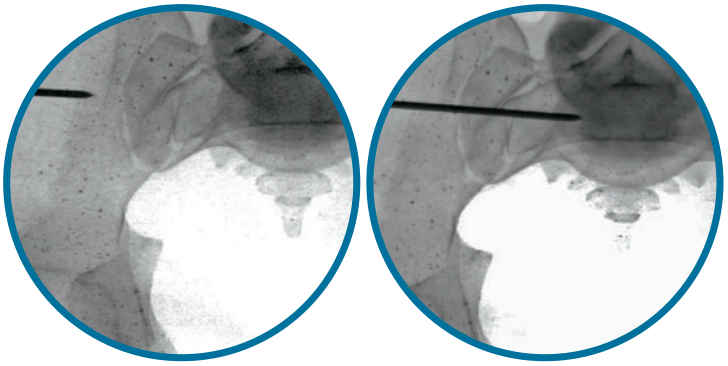
Figure 9

Figure 8

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.



Outlet View

Adjust the trajectory of the Pin on the outlet view such that the Pin is parallel to the S1 endplate.

Advance the Pin under the outlet view.

The Pin may be advanced toward the mid-line if there is a favorable trajectory and adequate bony corridor.

Re-check the Pin position on the inlet view.

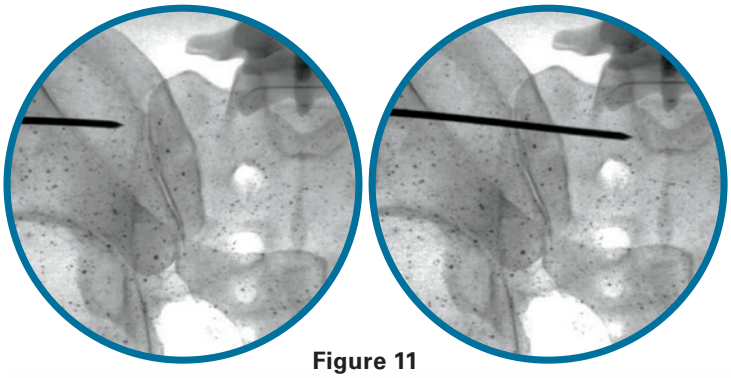


Figure 11

Fracture Repair: Using the necessary fluoroscopic views, confirm fracture reduction and that the Pin has crossed the fracture.

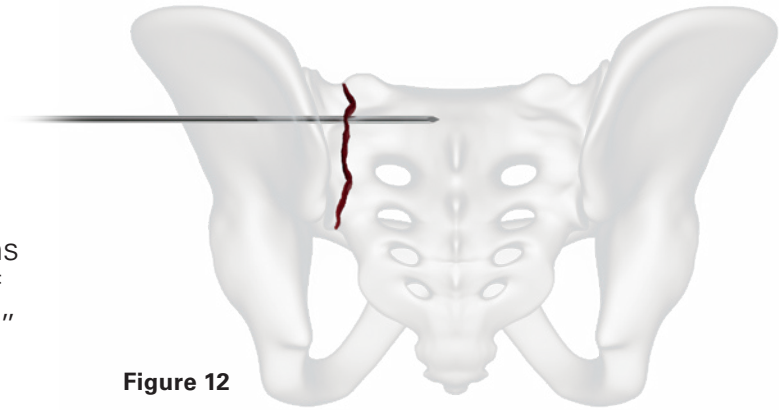


Figure 12

Optional Three Pin Technique:

Follow the steps above for placing three guide pins correlating to final Implant positions at the start of the procedure. See "Subsequent Implant Spacing"

- Optional: See "Parallel Pin Guide" for an optional technique for placing second and third pins.

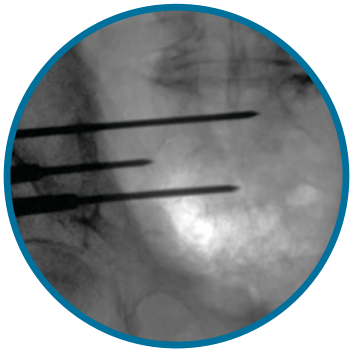


Figure 13

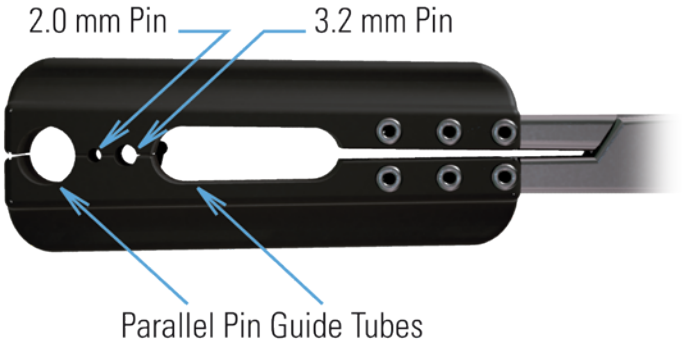
PRECAUTIONS:

- *When advancing Pin or Implant, avoid penetrating the sacral canal and/or foramen.*
- *At all times, extreme caution should be used around the spinal 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. If using a Guide Pin Repositioner to reposition the first Pin, use the Mallet to place the second Pin.*
- *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" (pg. 7). If Implants are placed too close together the heads of the Implants may overlap or the Implants' threads may interdigitate, potentially making removal of Implant(s) more difficult.*
- *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.*
- *If using an 8 Gauge Bone Access Needle for bone access, hold the cannula while removing the stylet. Hold the 3.2 mm Guide Pin while removing the cannula. If the 3.2 mm Guide Pin is removed with cannula, utilize a 3.2 mm Blunt Pin to find trajectory.*

PROCEDURE: Radiolucent Clamp (Optional)

The Radiolucent Clamp is designed to allow the user to hold the Pin and/or the Parallel Pin Guide while keeping their hand away from the radiation source. The tips of the Clamp are radiolucent to allow for visualization of the Pin (and Parallel Pin Guide) under fluoroscopy.

Figure 14



Clamp onto the end of the Pin.

- If using an O-Arm Pin, 3.1 mm Pin, clamp it in the hole for the 3.2 mm Pin.

Ensure the Pin is clamped at a 90-degree angle to firmly grasp onto the Pin.

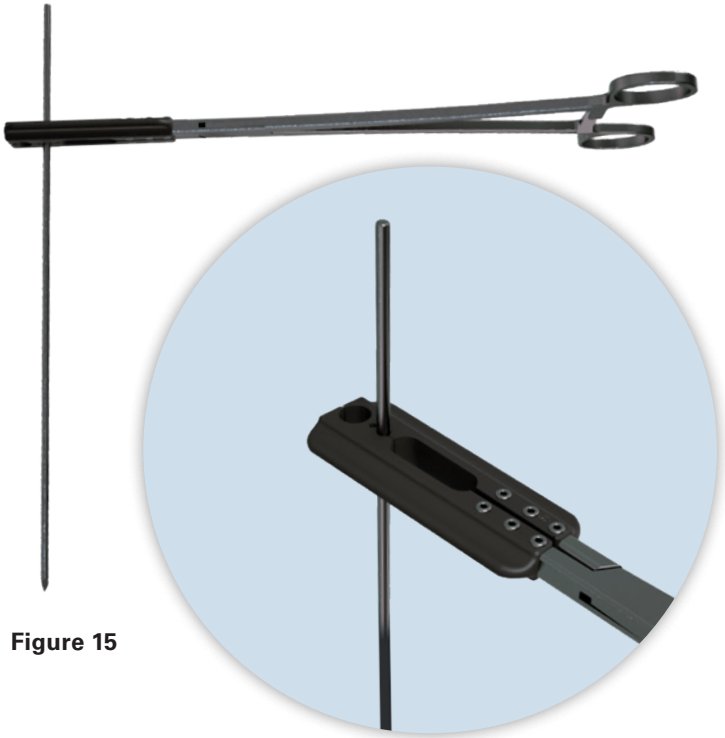


Figure 15

PRECAUTIONS:

- *Please 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.*
- *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.*
- *Apply appropriate force to insert the Pin while utilizing the Pin Guide to prevent any Instrument damage*
- *Do not attempt to use any other instrumentation to drill over the guide Pin*

PROCEDURE: Blunt Dissector Insertion (Optional)

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 tool 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.

Figure 16

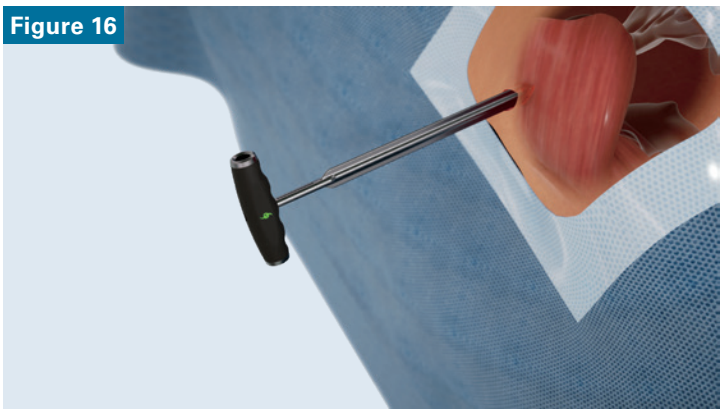
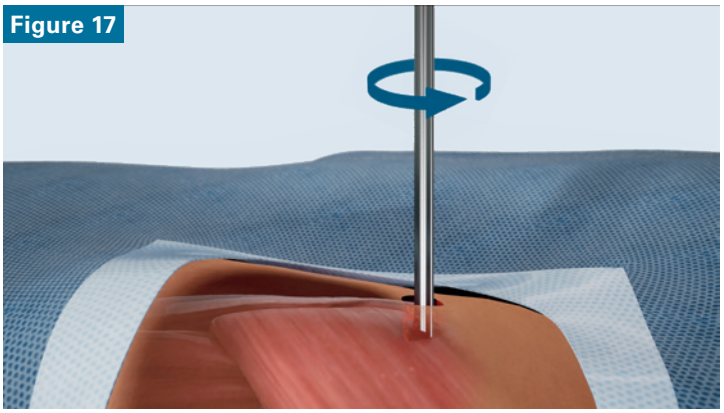


Figure 17



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

Ensure the Long Blunt Dissector is properly seated and collinear with the Pin before dissecting.

PRECAUTIONS:

- *Do not lower hand while twisting the Blunt Dissector to avoid bending the Pin.*
- *When using the Blunt Dissector do not aggressively spread tissue to help avoid injury.*
- *Do not attempt to use any other instrumentation to drill over the Guide Pin.*
- *Take care not to move Soft Tissue Protector during drilling and tapping steps.*

PROCEDURE: Dilator and Determining Implant Length

Dilator 1 is used in preparation for all iFuse TORQ Implants. Dilator 2 is used in addition to Dilator 1 when implanting an iFuse TORQ Lag Implant with Washer.

Slide Dilator 1 over the Pin until the distal tip of the Dilator 1 engages with the ilium and bony contact is achieved **(Figure 18)**.

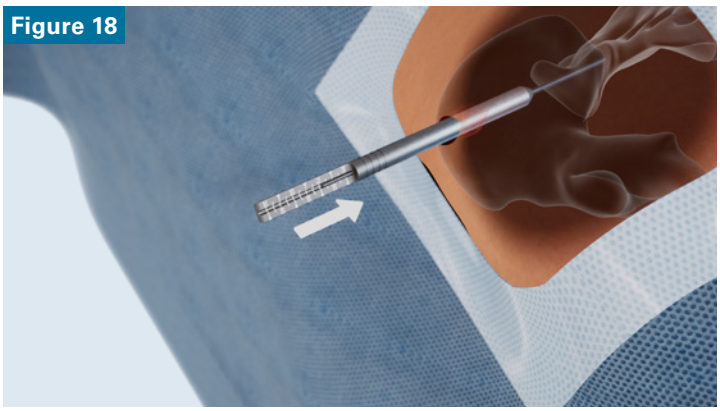


Figure 18

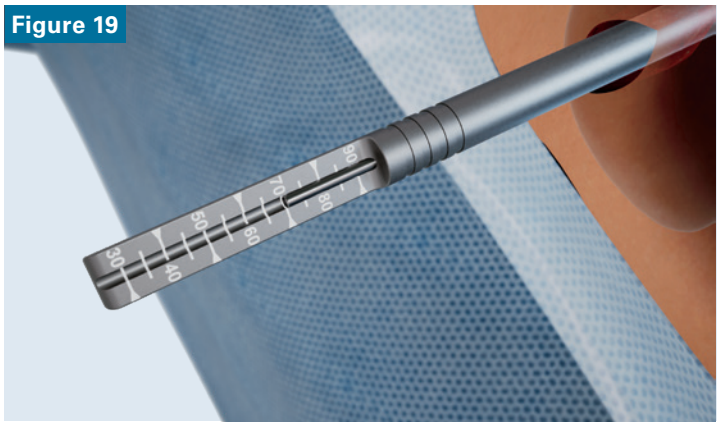


Figure 19

Use Dilator 1 to select the proper Implant length by measuring the Pin length against Dilator 1 **(Figure 19)**.

Dilator 1 measures the depth of the Pin that is beyond the lateral cortex of the ilium, providing a reference for Implant length.

Choose the Implant length indicated in the measurement marking range of where the Pin ends. See "iFuse TORQ Specifications".


Figure 20

Lag Implant with Washer: Once the Implant length is determined from Dilator 1, slide Dilator 2 over Dilator 1 **(Figure 20)**.

PRECAUTIONS:

- *Do not impact the flat surface of the Dilator(s). This may damage the bone and/or Dilator(s).*
- *The physician must choose the available Implant length he/she determines is most appropriate for the situation.*

PROCEDURE: Soft Tissue Protector

The Soft Tissue Protector (STP) contains a moderately radiolucent tube to allow for visualization of the instruments inside the STP under fluoroscopy. STP 1 is used in preparation for all iFuse TORQ Implants. STP 2 is used when implanting an iFuse TORQ Lag Implant with Washer. STPs come with an optional Handle.

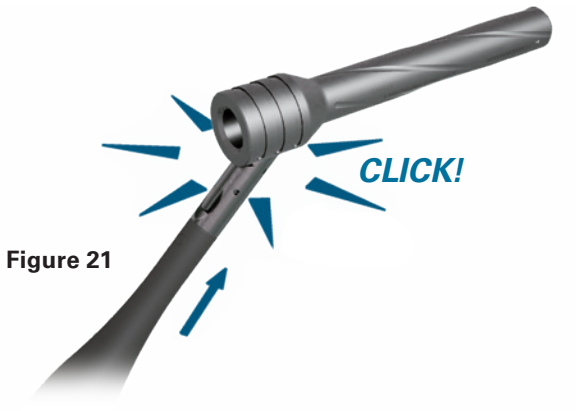
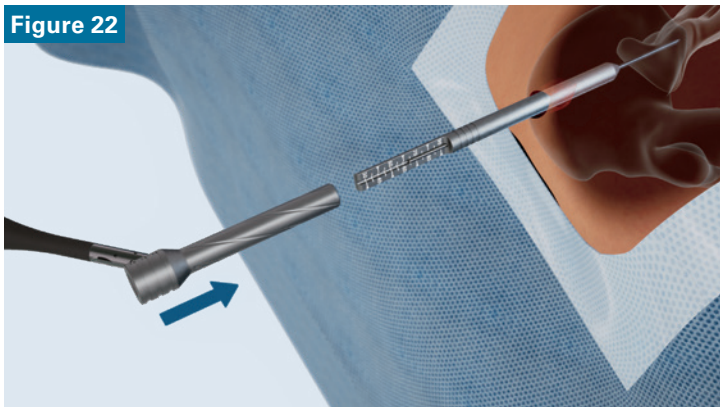


Figure 21

Slide STP 1 over Dilator 1 until the distal tip of the STP achieves bony contact with the ilium **(Figure 22)**.

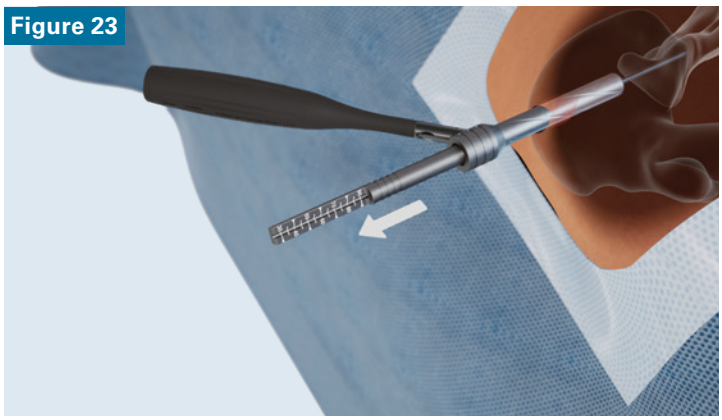
- **Lag Implant with Washer:** Slide STP 2 over Dilator 2 until the distal tip of the STP achieves bony contact with the ilium.

Figure 22



Once STP is in position, remove Dilator(s) from STP **(Figure 23)**.

Figure 23



NOTE:

- *Ensure collinearity of the Dilator(s) over the Pin, before removing the Dilator(s).*
- *Ensure collinearity of the of the drill bit and the STP before and during the use of power*
- *When manually drilling and tapping, the Blunt Pin may be used in place of the Exchange Pin.*

PRECAUTIONS:

- *Do not impact the flat surface of the Soft Tissue Protector. This may damage the bone and/or Soft Tissue Protector.*
- *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 ilium.*
- *The fit of the Drill Bit within STP 2 is not snug. There will be some play between the two instruments, and care must be taken to remain collinear during use to prevent drilling into the lumen walls of STP 2*

PROCEDURE: Drilling (Optional)

Drill bits have measurement markings for estimating drill depth when used through the STP.

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

Insert the appropriate Drill Bit (see iFuse TORQ Specifications) over the Pin, through the STP.

- 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 Bit is against bone.

- A Blunt Pin may be used in place of the Guide Pin if the Guide Pin is close to a foramen.

Commence drilling under fluoroscopy in the outlet view. Drill through the lateral cortex of the sacrum, but no more than 2-3 mm medial to the lateral sacral cortex. Watch for unwanted Pin advancement **(Figure 24)**.

Monitor Drill Bit advancement under fluoroscopy with measurement markings on drill bit relative to the STP **(Figure 25)**.

Fracture Repair: Consider drilling past the fracture to minimize the risk of fracture displacement during Implant insertion **(Figure 26)**.

As the Drill Bit is removed, use the Exchange Pin to prevent the Pin from withdrawing.

Ensure collinearity of the Drill Bit over the Pin, before and during the use of power.

Figure 24

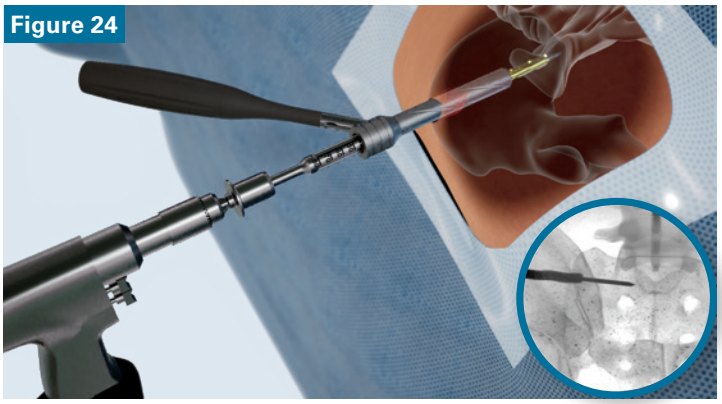


Figure 25

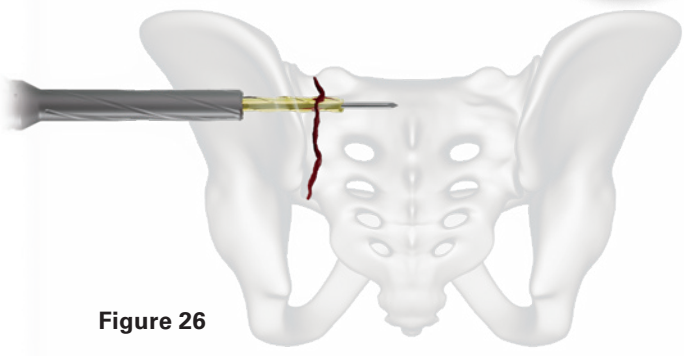


Figure 26

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 preperation is recommended to help avoid fractures to the sacrum or illium.*
- *Use care to avoid advancing the Pin during drilling. Do NOT push on the Pin. Applying a medial force to the Pin or the Exchange 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.*
- *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.*

PROCEDURE: Tapping (Optional)

Taps have measurement markings for estimating tap depth when used through the STP.

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

Connect appropriate size Tap (see iFuse TORQ Specifications) to either the T-Handle or Inline Handle.

Insert the Tap over the Pin, through the STP. To minimize binding ensure the Tap can move easily back and forth over the Pin.

- A Blunt Pin may be used in place of the Guide Pin if the Guide Pin is close to a foramen.

Commence tapping under fluoroscopy in the outlet view. Tap through the lateral cortex of the sacrum, but no more than 2-3 mm medial to the lateral sacral cortex. Watch for unwanted Pin advancement **(Figure 27)**.

Monitor Tap advancement with measurement markings on the Tap relative to the STP **(Figure 28)**.

Fracture Repair: Consider tapping past the fracture to minimize the risk of fracture displacement during Implant insertion **(Figure 29)**.

As the Tap is removed, use the Exchange Pin to prevent the Pin from withdrawing.

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

Figure 27

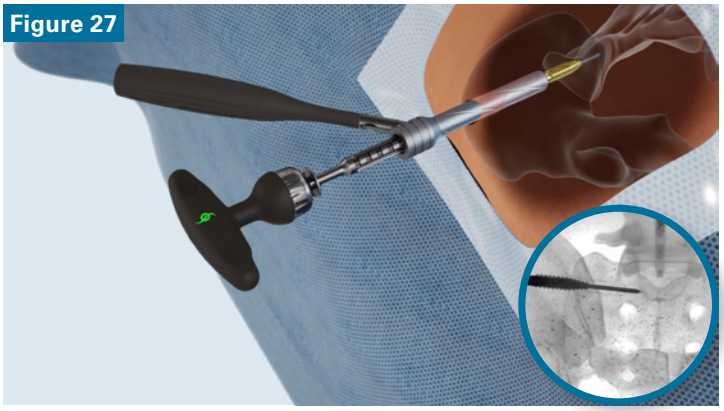


Figure 28

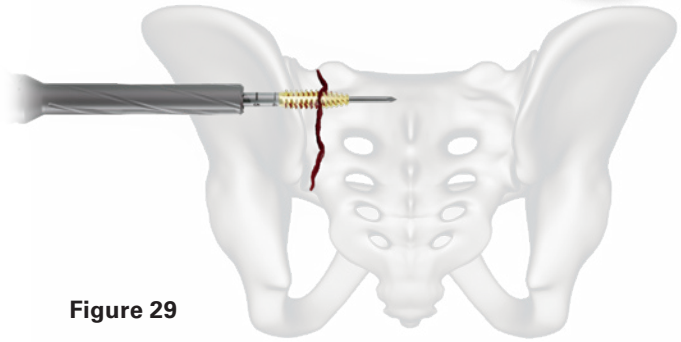


Figure 29

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 or the Exchange Pin may cause them to advance.*
- *Excessive advancement of the Tap may cause nerve damage, hemorrhage, or other possible adverse events listed in the Instructions for Use.*
- *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.*
- *Selecting a Tap larger than the corresponding Implant may result in loss of Implant fixation to bone (e.g., using a 10.75 mm Tap with a 10.0 mm Implant).*
- *Do not use non-compatible taps with the iFuse TORQ Implant System*

PROCEDURE: Washer Assembly with Lag Implant

The Washer comes in a separate pouch in the same package as the iFuse TORQ Lag Implant.

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

Place the washer over the distal end of the Lag Implant and slide the Washer until flush with the head of the Lag Implant **(Figure 30)**.

Figure 30

The 10.0 mm and 11.5 mm Lag Implant Washers have distinct laser markings to distinguish the appropriate Washer with its respective Lag Implant.

- See iFuse TORQ Specifications, for more information on the Washers.

Figure 31

16.0 mm Washer For
10.0 mm Lag Implant

Figure 32

18.0 mm Washer For
11.5 mm Lag Implant

PRECAUTIONS:

If implanting multiple Lag Implants, ensure the appropriate Washer is used with each Lag Implant or Implant may not perform as designed.

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 **(Figure 33)**.

- **Lag Implant with Washer:** Slide Driver Sleeve 2 over the distal end of the Torx Driver and lock into place.

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.

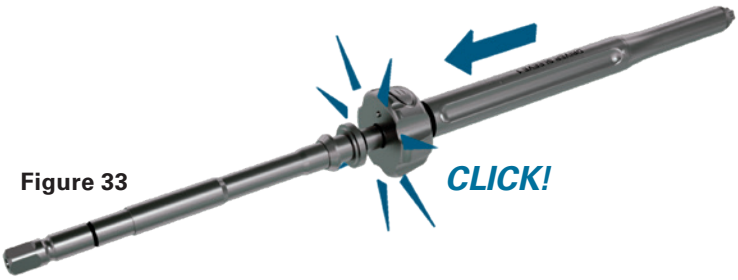


Figure 33

NOTE:

*There is a laser mark on Driver Sleeve 1 & 2. When using the Driver Sleeve 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 **(Figure 34)**.*

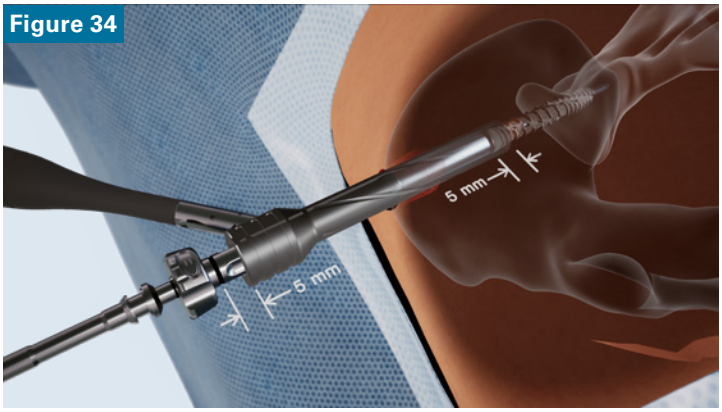


Figure 34

Load the chosen Implant onto the Torx Driver. Thread Driver Sleeve (1 or 2) into the head of the Implant. **(Figure 35)**.

- Consider using the poly bag to hold the Implant while loading onto the Torx Driver.

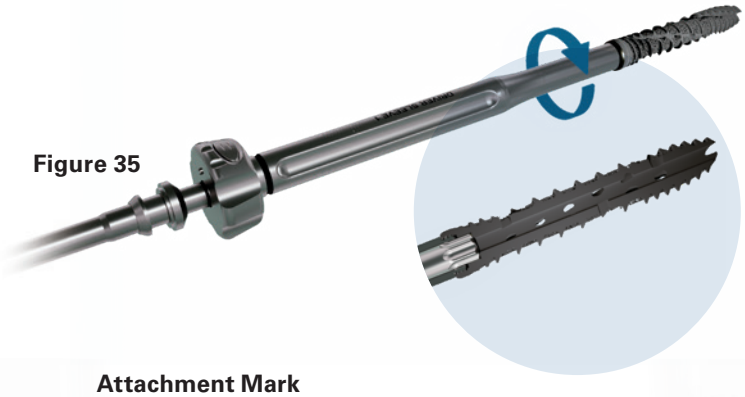


Figure 35

NOTE:

*When Driver Sleeve is fully engaged, "attachment mark" is visible **(Figure 36)**.*

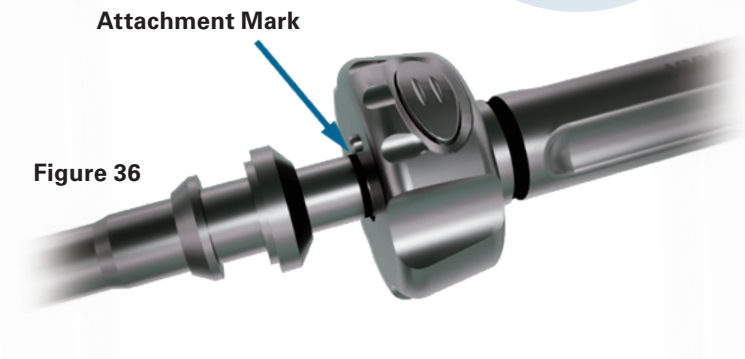


Figure 36

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 **(Figure 37)**.

- Always keep forward pressure on the Driver when advancing the Implant.

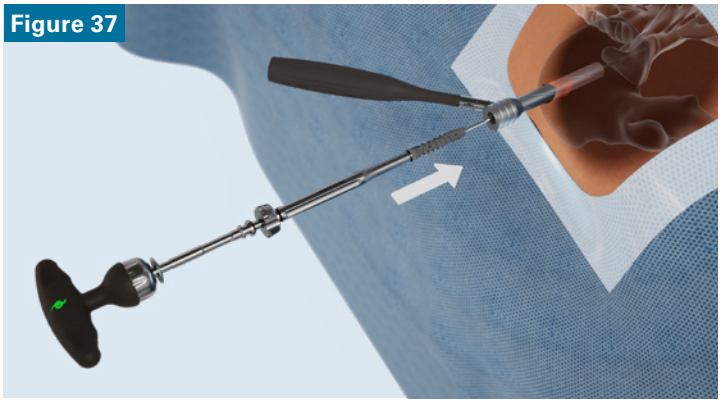


Figure 37

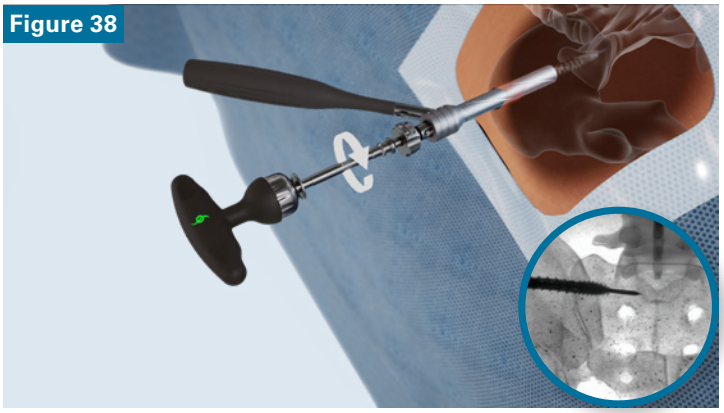
Ensure collinearity of the Driver over the Pin, before and during use.

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 to always use the soft tissue protector, docked against the ilium, to protect surrounding soft tissue from injury that could be caused by the implants' rough surface and sharp edges.*
- *Firmly tighten the Implant to Driver Sleeve, take care not to cross-thread the Implant.*
- *Do not overtighen the Driver sleeve into the Implant head (two finger tightness only) as this may make disengagement and removal of the driver sleeve more difficult.*
- *If implanting an iFuse TORQ Lag Implant with Washer, take care to ensure the Washer does not slide off the Implant while positioning the Implants for insertion.*
- *If placing an iFuse TORQ Implant under power, monitor position of Implant and pin with fluoroscopy. Perform final Implant positioning by hand.*
- *If using the Three Pin Technique, monitor the position of the Driver Sleeve relative to adjacent pins. The Driver Sleeve may impinge adjacent pins during use.*

Always monitor the progress of the Implant and any movement of the Pin under fluoroscopy **(Figure 38)**.

Figure 38



Final Implant seating should always be performed manually, with either the T-Handle or Inline Handle **(Figure 38)**.

While holding the driver handle steady, unthread the Driver Sleeve **(Figure 39)**.

Figure 39

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).

Fracture Repair: Fluoroscopically confirm that the Implant has adequately crossed the fracture site **(Figure 40)**.

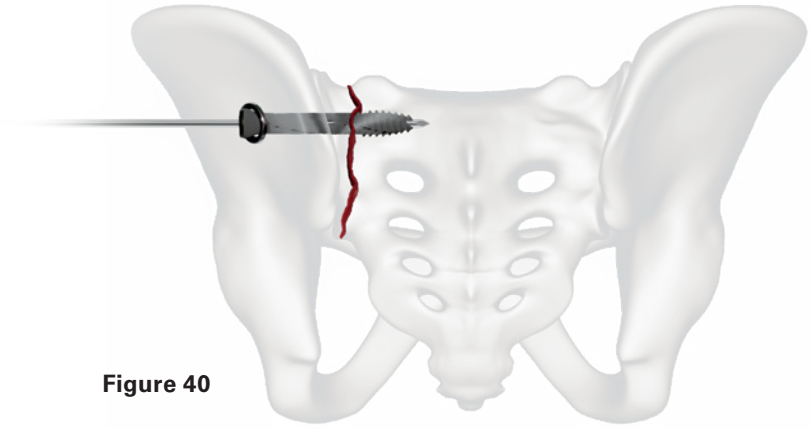


Figure 40

PRECAUTIONS:

- *Do not hold or press the Release Button on Driver Sleeve when inserting an iFuse TORQ Implant. Doing so may cause the Driver to unthread from the Implant.*
- *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 Exchange Pin may cause them to advance.*
- *Take care when inserting an iFuse TORQ Implant. Over-tightening may cause damage to the bone or Implant.*
- *The Implant has been designed to optimize initial fixation with surrounding bone. If 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.*

The Implant may be left slightly proud (2-5 mm) or implanted flush to the cortex.

- A proud Implant provides another cortical wall for load bearing support.

Optional: Monitor the position of the laser mark on the Driver Sleeve relative to the proximal end of the STP **(Figure 41)**.

When the laser mark is in line with the STP, the head of the Implant is flush with the outer bony cortex **(Figure 42)**.

- Due to the curvature of the surface of the lateral ilium, even if the Implant is completely seated in the STP, a portion of the Implant head may still be proud.

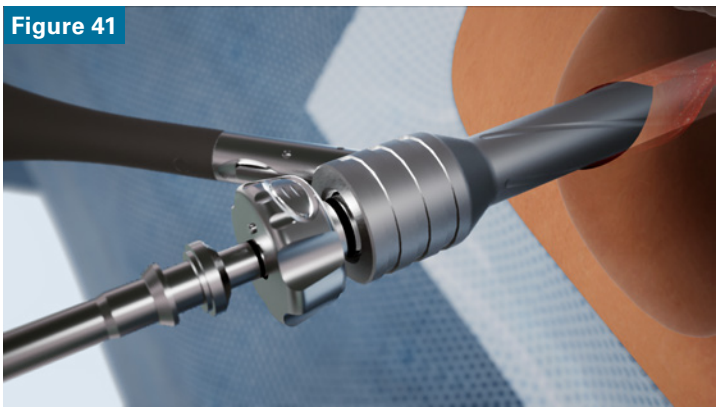
For countersinking the Implant, continue to advance the Implant until the laser mark is no longer visible and is below the top of the STP.

- The Driver Sleeve has a hard stop against the STP. This stop correlates to 5 mm of Implant countersinking depth relative to the outer cortex **(Figure 43)**.

Lag Implant with Washer: Advance the Lag Implant until desired compression is achieved.

- Consider using an outlet oblique view to confirm Washer is seated against iliac cortex.

Figure 41



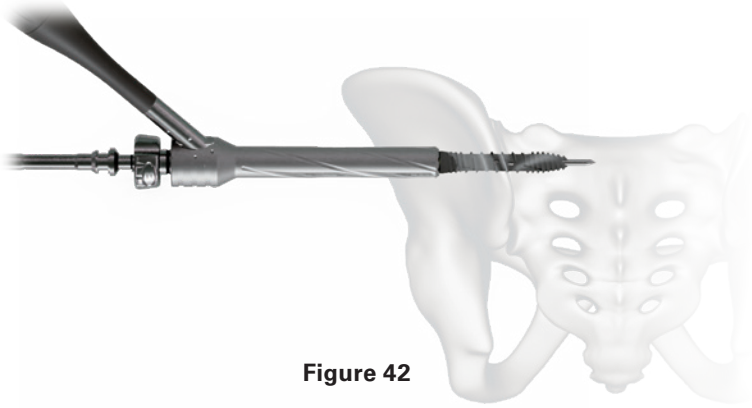
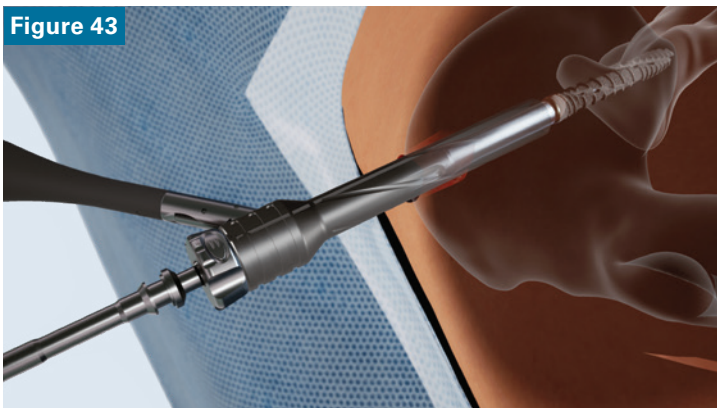


Figure 42

Figure 43



PRECAUTIONS:

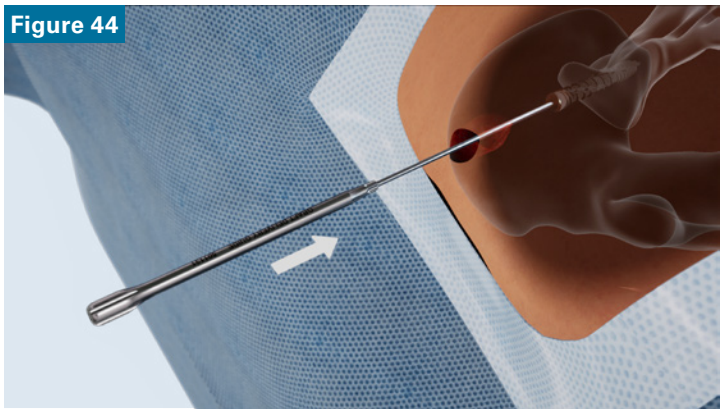
- *iFuse TORQ Lag Implants cannot be countersunk. Do not advance the laser mark past the end of the STP. Use fluoroscopy to monitor Implant insertion depth to prevent driving the Washer through the cortex. Over-inserting may cause damage to the bone or Implant(s).*
- *Take care when inserting an iFuse TORQ Implant. Over-tightening may cause damage to the bone or Implant.*
- *Do not over-insert or use an Implant that is either too long or too large. Using an incorrectly sized Implant,may cause nerve damage, hemorrhage, or other possible adverse events as listed in the Instructions For Use.*
- *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 or impossible.*
- *Take care when inserting the surgical instruments and the iFuse-TORQ Implants to avoid damage to surrounding soft tissue.*

After implantation, the iFuse TORQ Implant may be filled with flowable autograft and/or allograft material of the physician's choice.

Insert the Graft Delivery Guide over the Pin and engage the head of the iFuse TORQ Implant **(Figure 44)**.

NOTE:
The Graft Delivery Guide cannot be used through the STP. Remove the STP prior to using the Graft Delivery Guide.

Figure 44



Ensure collinearity of the Graft Deliver Guide over the Pin, before and during use.

Fill Implant using the 3.3 mm Graft Delivery System, P/N 400214, per instructions in STM 300669-US.

It takes 0.4 to 1.9 cc of graft material to fill each iFuse TORQ Implant, depending on the Implant size (see the table below for details).

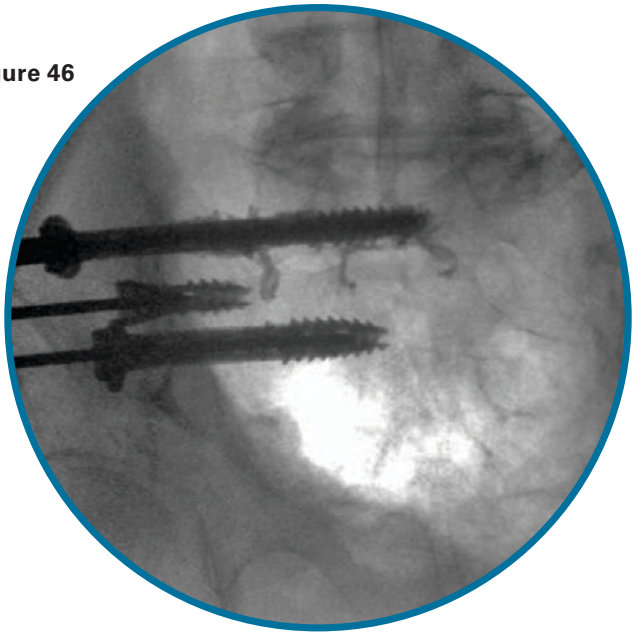
Figure 45

Volume of Graft (cc) Held in Implant*

Length (mm)	Diameter (mm)		
	10.0	11.5	13.5
35	0.4	0.4	0.5
40	0.5	0.5	0.6
45	0.5	0.6	0.8
50	0.6	0.7	0.9
55	0.7	0.8	1.0
60	0.8	0.9	1.2
65	0.9	1.0	1.2
70	0.9	1.0	1.4
75	1.0	1.2	1.5
80	1.1	1.2	1.6
85	1.1	1.3	1.8
90	1.3	1.4	1.9

*Lag Implant volume does not account for graft in head of Implant.

Figure 46



PRECAUTIONS:

- *Ensure Graft Delivery Guide is fully-seated into the head of the Implant in order to prevent extravasation of graft material between Graft Delivery Guide and the head of the Implant.*
- *Do not rotate Graft Delivery Guide once seated in the iFuse TORQ Implant in order to prevent over insertion or backing-out of the Implant.*

Fixed Parallel Pin Guide

There are three Fixed Parallel Pin Guide options and one Variable Parallel Pin Guide. All have radiolucent heads to allow for better visualization under fluoroscopy. All Parallel Pin Guides are to be used for 3.2 mm Guide Pins.

Figure 47

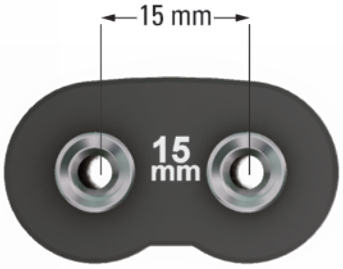


Figure 48

The Fixed Parallel Pin Guides shown **(Figure 49)**, have Pin Guide Tubes that are separated by 15 mm, 17 mm, or 19 mm, center-to-center.

Figure 49

NOTE:

*Ensure that the second Pin is adequately spaced from the first Pin to allow a minimum of 1 mm of distance between side-by-side placement of the Implants (**Figure 50**).*

- *For a complete list of all Implant minimum spacing requirements, see "Subsequent Implant Spacing" (pg. 7).*

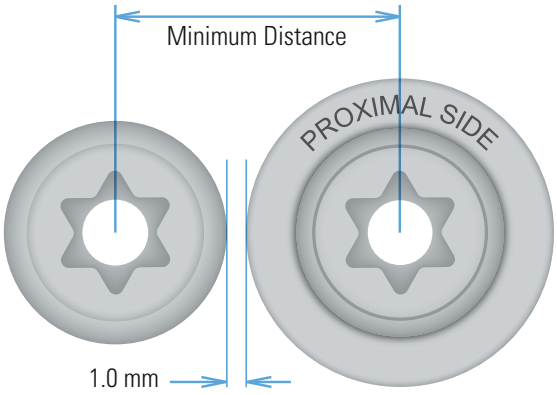


Figure 50

PRECAUTIONS:

- *Center to center spacing assumes parallel pins. Consider adding additional distance between pins and/or Implant placement in order to prevent Implants from contacting each other during insertion.*
- *Consider adding additional distance between Implants in the unlikely case a Trephine or chisel is needed to remove Implants in the future. iFuse TORQ Trephines have a wall thickness of 1.0 mm.*

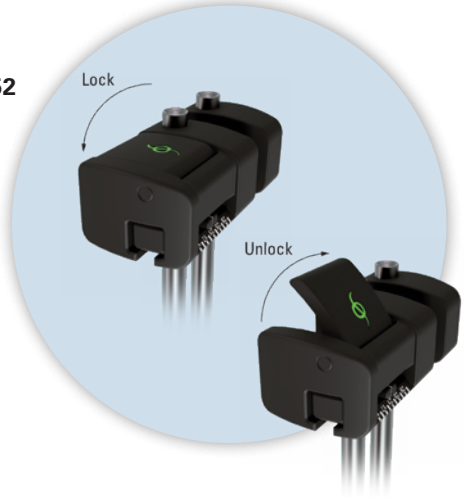
Variable Parallel Pin Guide

The Variable Parallel Pin Guide **(Figure 51)**, allows for the Pin Guide Tubes to be separated anywhere from 13 mm to 31 mm center-to-center in 2 mm increments.

Figure 51

Once the desired distance is determined, the Variable Parallel Pin Guide can be locked into place by closing the cam-lock **(Figure 52)**.

Figure 52



Both Pin Guide options can be held by the Radiolucent Clamp to keep the user's hand away from the radiation source **(Figure 53)**.

Figure 53

PROCEDURE: Second Pin Placement

Depending on the patient's anatomy, placement of the second and third Pins may vary.

Always check the inlet and outlet views to assess Pin/Implant position and trajectory.

Fracture Repair: Fluoroscopically confirm that the Pin has passed across the fracture site.

Figure 54

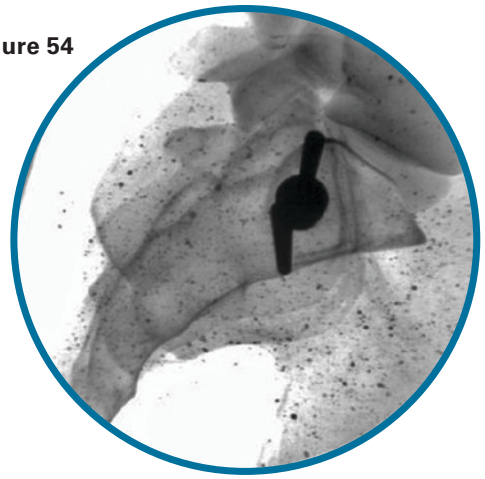


Figure 55

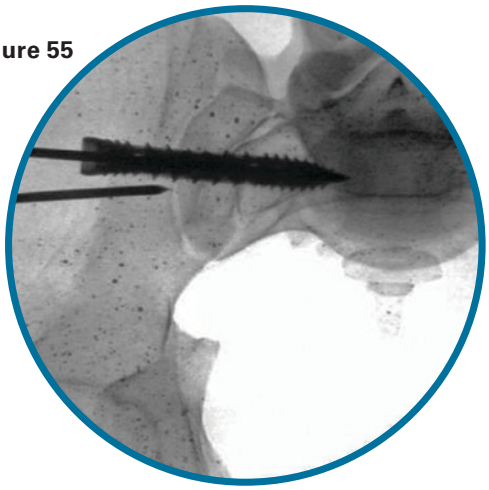
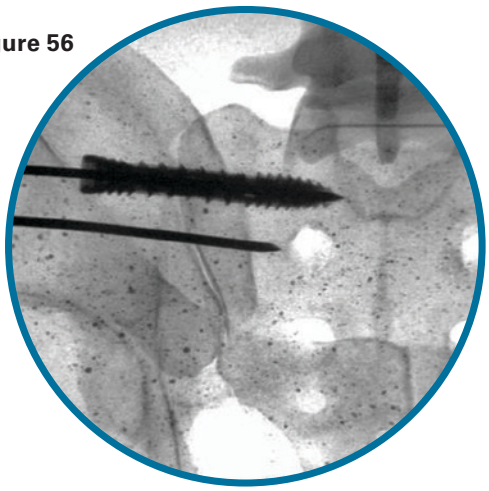


Figure 56



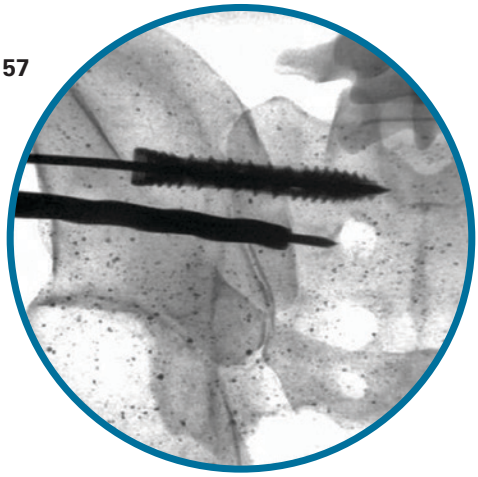
Follow the technique previously described for inserting subsequent Implants.

Drill (Optional)

Monitor the progress of the Drill Bit and any movement of the Pin **(Figure 57)**.

- **Fracture Repair:** Fluoroscopically confirm that the Drill Bit has adequately crossed the fracture site.

Figure 57

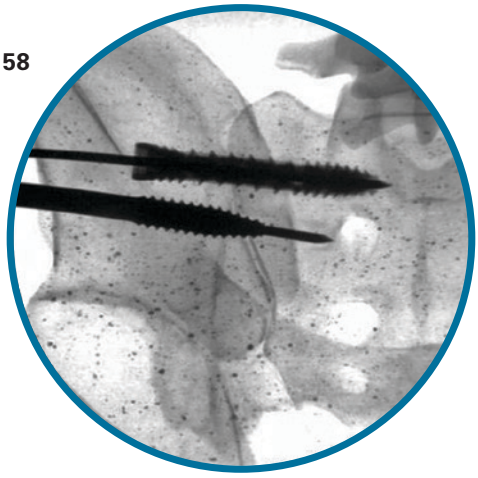


Tap (Optional)

Tap across the joint, but no more than 2-3 mm medial to the sacral cortex, in the outlet view **(Figure 58)**.

- **Fracture Repair:** Fluoroscopically confirm that the Tap has adequately crossed the fracture site.

Figure 58



Implant Insertion

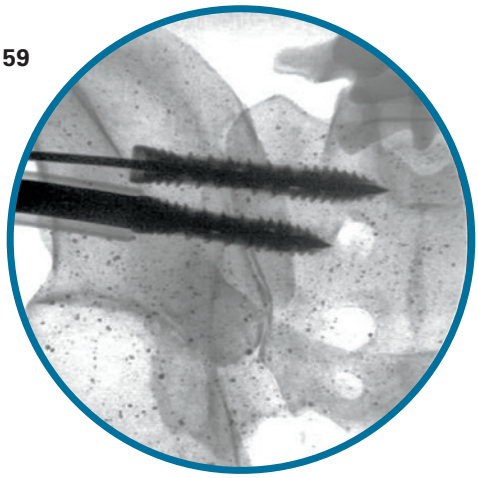
Fully insert the second Implant.

Monitor the progress of the Implant and any movement of the Pin **(Figure 59)**.

Be sure to avoid the foramen.

- **Fracture Repair:** Fluoroscopically confirm that the Implant has adequately crossed the fracture site.

Figure 59



PRECAUTIONS:

Be sure to avoid the foramen and ensure the Drill Bit does not go more than 2-3 mm medial to the sacral cortex.

Depending on the patient's anatomy, the placement of the third Pin may vary. Always check inlet and outlet views to assess Pin/Implant position and trajectory.

Outlet View

Place the chosen Fixed or Variable Parallel Pin Guide over the 2nd Pin.

Adjust the Parallel Pin Guide so that the guide tube is aimed between the S1 and S2 neuroforamina toward the S2 body.

Insert a Guide Pin into the free arm of the Parallel Pin Guide (do not dock pin yet).

Lateral View

Rotate the Parallel Pin Guide so that the starting Pin position is at the anterior sacral cortical body line.

Dock the Pin **(Figure 60)**.

Remove the Parallel Pin Guide.

Inlet View

Adjust the Pin trajectory; aim for the middle to anterior third of the sacral body **(Figure 61)**.

Outlet View

Verify the trajectory of the 3rd Pin; advance.

- **Fracture Repair:** Confirm that the Pin has crossed the fracture site.

Use Dilator 1 to determine the Implant length.

Place and advance the 3rd Implant **(Figure 62)**.

Outlet Oblique View

Confirm that all Implants cross the sacroiliac joint **(Figure 63)**.

- **Fracture Repair:** Fluoroscopically confirm that the Implant has adequately crossed the fracture site.

Figure 60

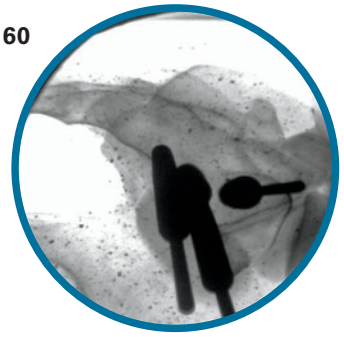


Figure 61

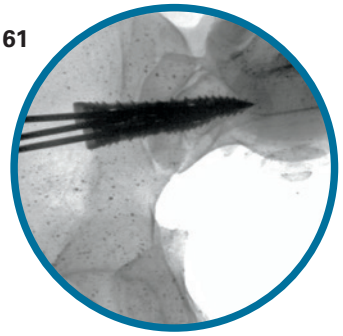


Figure 62

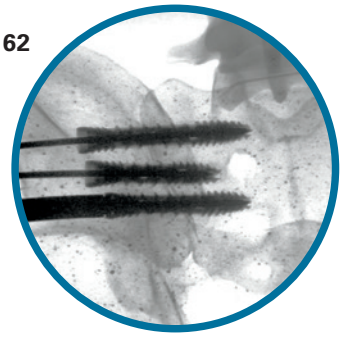
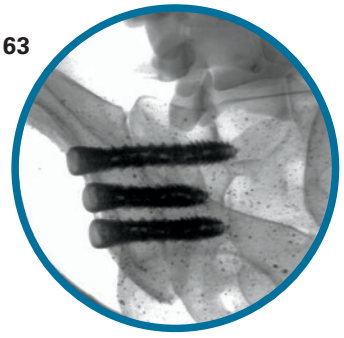


Figure 63



PRECAUTIONS:

- *When advancing Pin, Drill Bit, Tap, and/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.*

Always obtain final fluoroscopic images in the lateral, inlet, outlet, and outlet oblique views to confirm no cortical wall breach, foramen breach, other malposition, and/ or loss of fracture reduction.

Figure 64

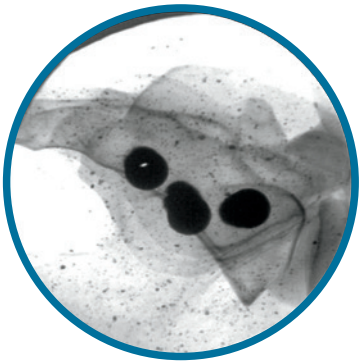


Figure 65

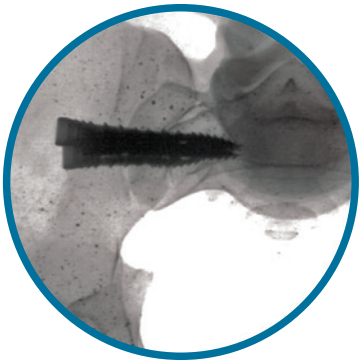


Figure 66

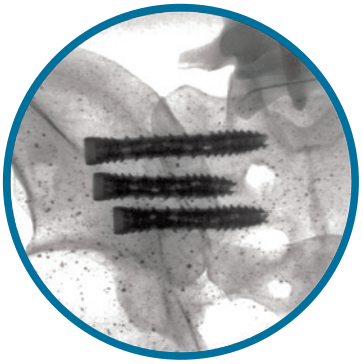
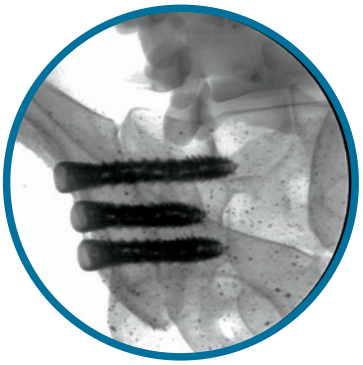


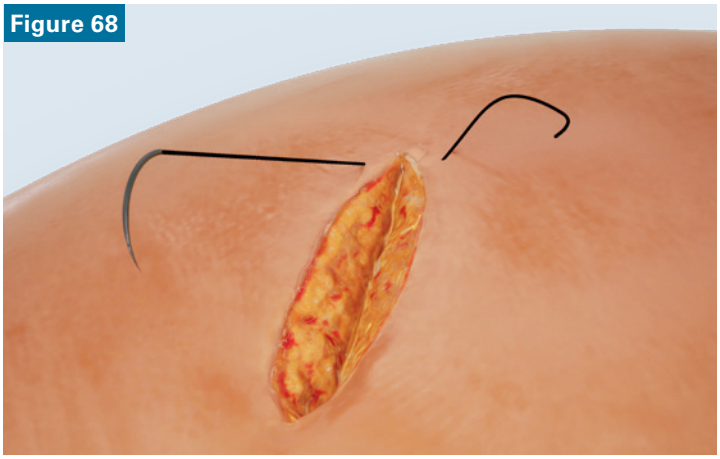
Figure 67



Closure

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

Figure 68



Recommended closure

- Muscle fascia if possible
- Subcutaneous tissue
- Skin

POST-OP CARE

SI Joint Fusion

- Some patients may be able to progress rapidly to full weightbearing. Other patients may require a period of protected weight-bearing 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.

The Revision Instrument Set contains a Torx Driver, Trephines, and Extractor for Implant removal.

Torx Driver

Attach Torx Driver to either the T-Handle or Inline Handle.

- Remove any bone or fibrous tissue from the head of the Implant to seat driver.
- Turn driver counterclockwise to confirm Implant is disengaged from surrounding bone.

Once removal has started, Implant may be removed by power. Attach Torx Driver to power using the Quarter Inch To Tri-Lobe Adapter.

Consider using the Cannulated Torx Driver in combination with Driver Sleeve 1 to capture and remove the Implant when appropriate **(Figure 71)**.

Figure 69

Figure 70

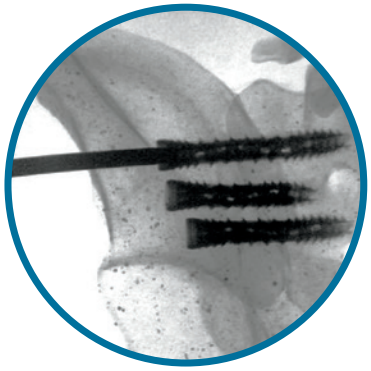


Figure 71

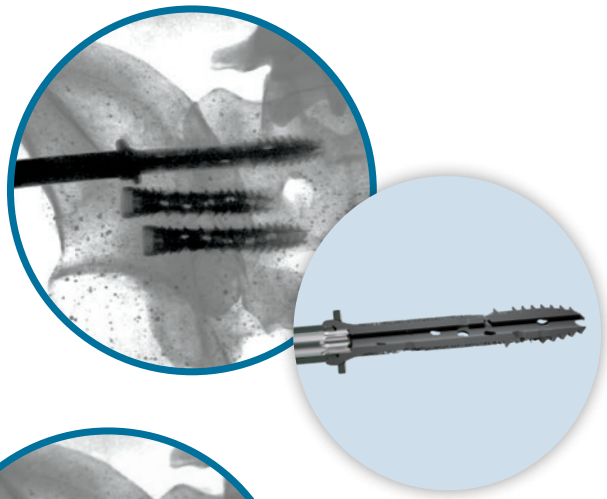
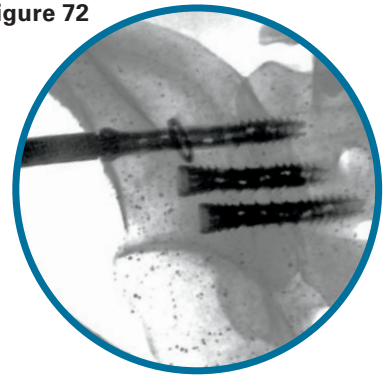


Figure 72



PRECAUTIONS:

- *Once the fusion and/or fracture has healed, the physician and patient should carefully weigh the risks and benefits if considering the removal of the iFuse TORQ Implant.*
- *Implants are designed to optimize long-term integration of the implant with the surrounding bone. During Implant revision/removal the removal torque may exceed the limit of the user/driver.*
- *In revision/removal cases, trephines **(Figure 73)** 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). Pliers or other tools should not be used to grip the head of the Implant, as it could damage the Torx connection, internal threads, or break the Implant.*
- *The Washer is not attached to the Lag Implant. If removing a Lag Implant with Washer, consider the need to remove the Washer, as it may remain in the surgical site during removal **(Figure 72)**.*
- *Fluoroscopy should be used to identify the implant to be removed.*
- *Take care to not strip the implant head by over-torquing the implant.*

Trephines

If one-handed use of the Torx Driver is unsuccessful in removing the iFuse TORQ Implant due to bony incorporation, proceed to Trephine.

Select the appropriate size Trephine to fit over the Implant to be removed **(Figure 73).** See "iFuse TORQ Specifications" (pg. 4) for details on Implant dimensions.

- Small Trephine for Implants with an 11.5 mm or smaller diameter head (e.g., iFuse TORQ 100XXT implants).
- Large Trephine for Implants with an 12.5 mm or smaller diameter head (e.g., iFuse TORQ 100XXT, 115XXT, 100XXLG without Washer, Implants).

Attach the Trephine to power using the Quarter Inch to Tri-Lobe Adapter, or for manual removal use with either the T-Handle or Inline Handle.

Place the Trephine over the end of Implant, while staying colinear to the Implant.

Advance the Trephine counterclockwise while applying forward pressure **(Figure 74)**.

- The Trephine may bind the head of the Implant and back out the Implant during use.

Once it is determined that an adequate amount of bone has been removed to free the Implant, use Torx Driver to remove Implant.

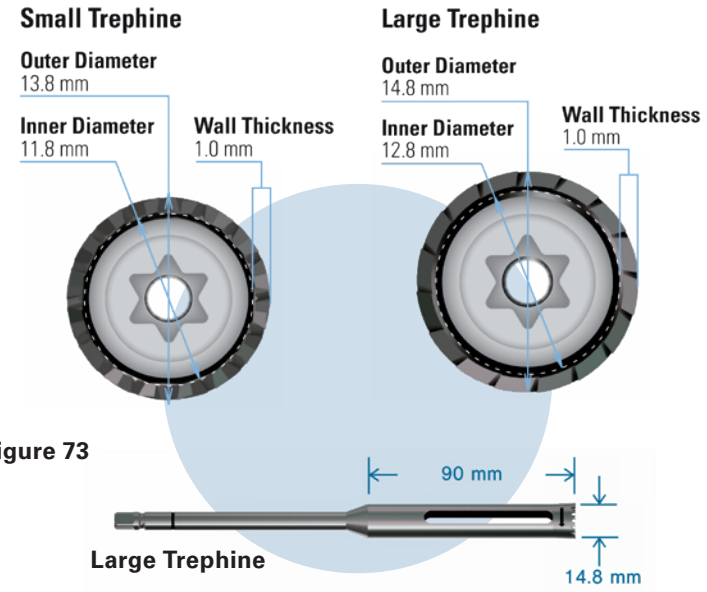


Figure 73

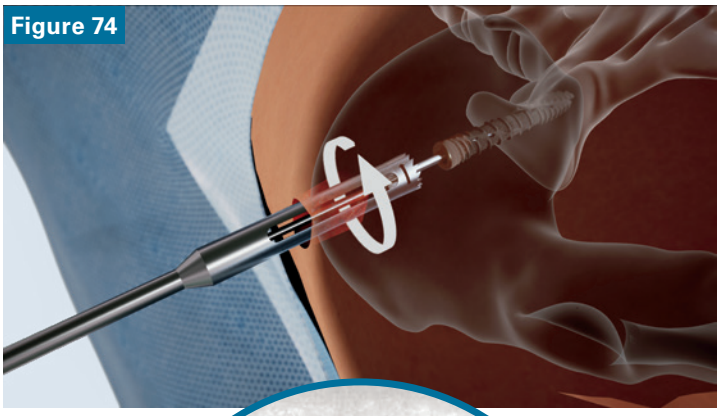


Figure 74

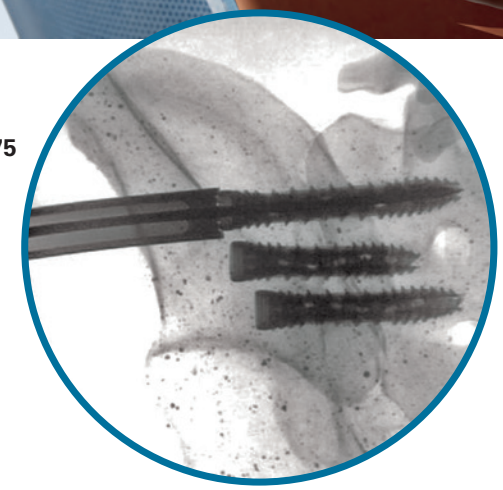


Figure 75

PRECAUTIONS:

- *When using the Trephine, consider using an open or mini open approach to improve visualization of the Implant head.*
- *Use saline irrigation to cool the Trephine during extended use to prevent potential damage to surrounding bone.*
- *Keep trephine collinear to implant and/or trephine over pin to prevent implant advancement.*

Extractor

If the Torx Driver is unable to obtain an adequate connection with the Implant for removal (e.g., Implant head strips), use the Extractor for Implant removal.

Connect Extractor to T-Handle or Inline Handle.

While keeping Extractor collinear,advance Extractor into the head and down the lumen of the cannulated Implant **(Figure 77)**.

Rotate Extractor counterclockwise while applying forward pressure **(Figure 77)**.

Once the Extractor has cut a channel into the lumen of the Implant and become engaged, continue turning the Extractor counterclockwise to remove the Implant.

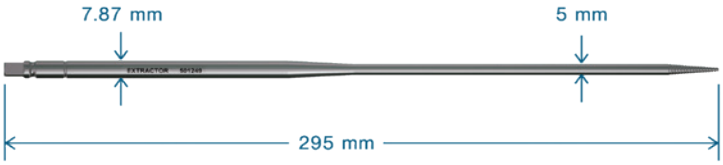


Figure 76

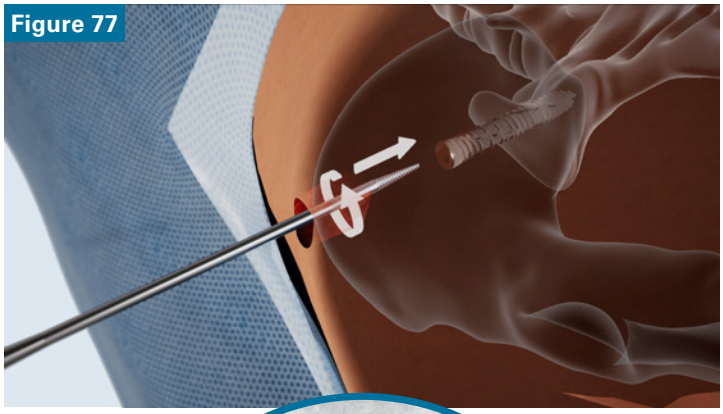


Figure 77

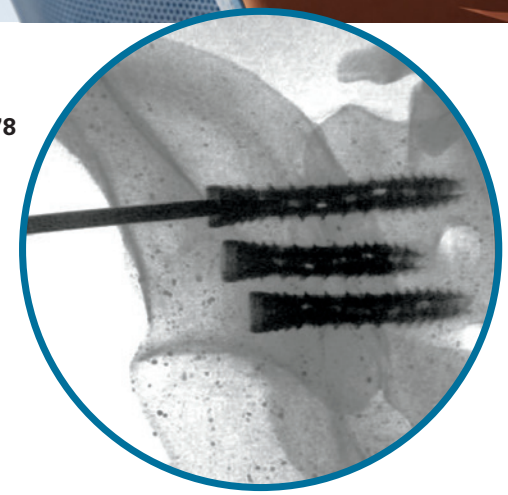


Figure 78

The iFuse TORQ Revision Instrument Set contains instrumentation to prepare for 13.5 mm diameter iFuse TORQ Implants for filling bone voids created from prior implant removal. When implanting a 13.5 mm iFuse TORQ Implant, both the iFuse TORQ Instrument Tray and the iFuse TORQ Revision Tray are needed.

The 13.5 mm iFuse TORQ Implant is designed to fill bone voids left by removal of the 10.0 mm, 11.5 mm iFuse TORQ Implants, and the 7.0 mm iFuse and iFuse 3D Implants **(Figure 79)**.

> ***NOTE:***
> *For removal of iFuse and iFuse 3D Implants, see* ***STM 300333-US***

Identify location of the bone void using fluoroscopy and/or digital palpation.

After removing the previous implant, if the bone void diameter is less than 11.0 mm, the minor diameter of the 13.5 mm Implant, follow the previous steps for inserting a 13.5 mm Implant, see "Implant Driver Assembly".

> ***NOTE:***
> *Dilator 1 may be smaller than the bone void and not able to sit against the cortex. Consider using fluoroscopy to monitor the position of the distal tip of Dilator 1 relative to the cortex in order to more accurately determine Implant length.*

If drilling and/ or tapping, ensure collinearity with Pin in the bone void.

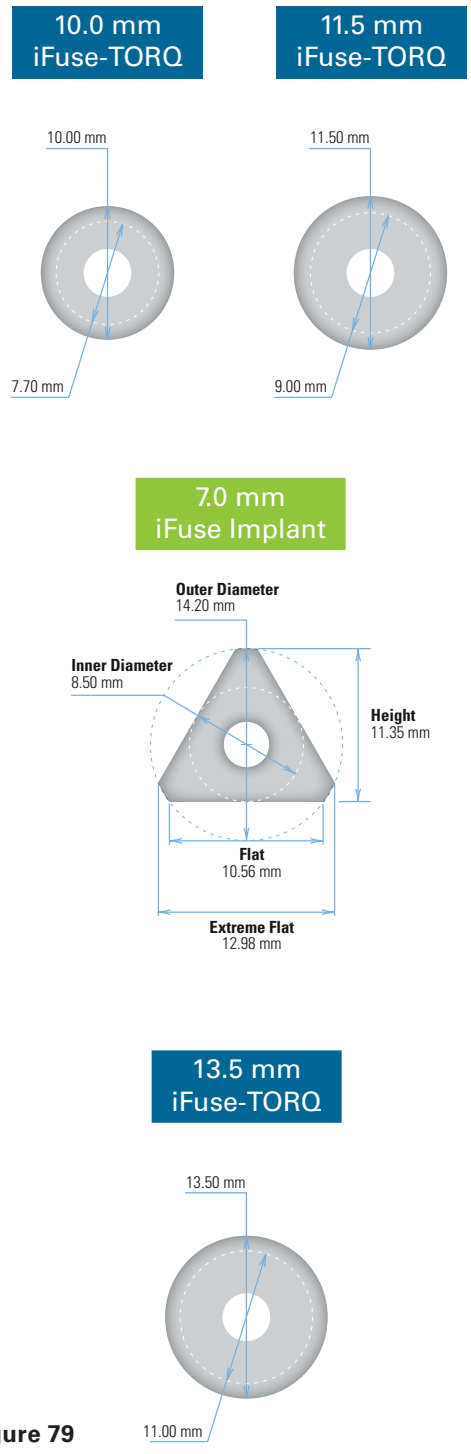
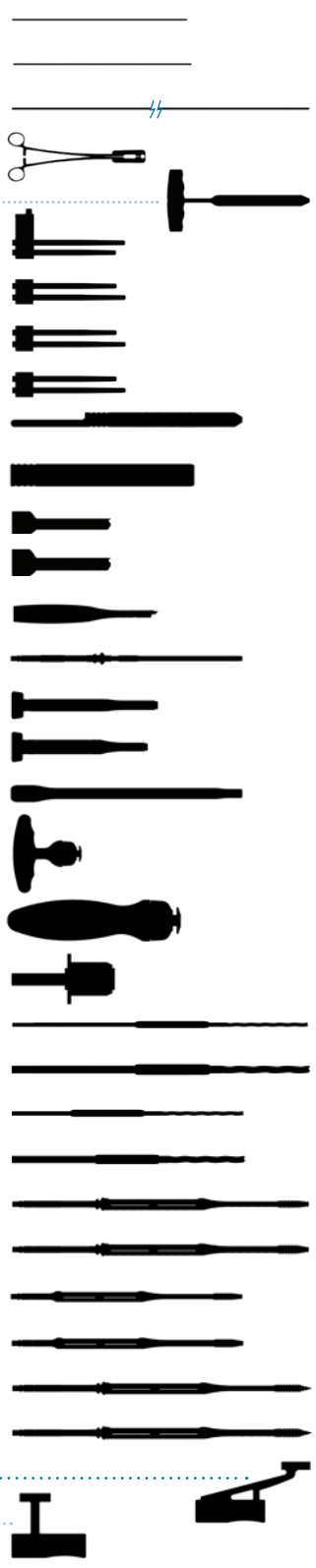


Figure 79

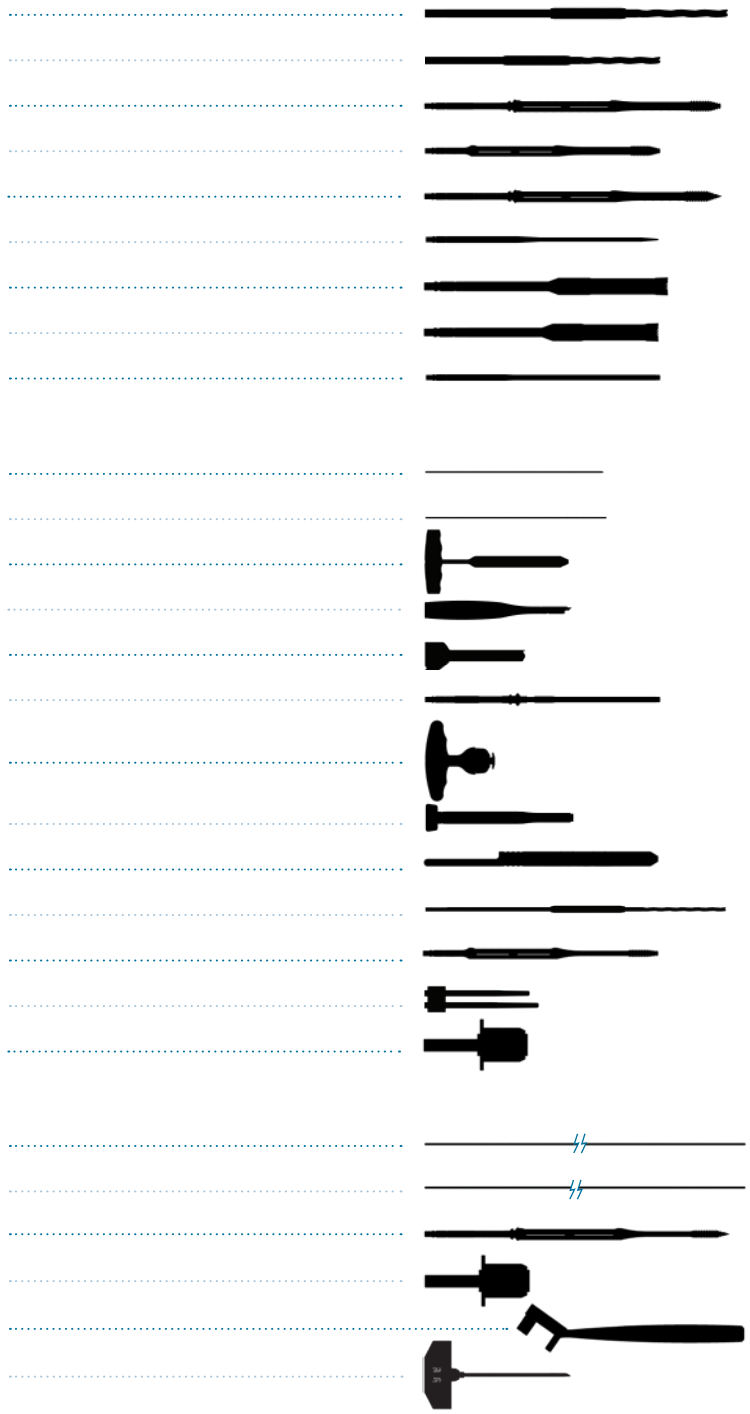
> ***PRECAUTIONS:***
> - *If the bone void is larger than 11.0 mm, the 13.5 mm iFuse TORQ implant should not be used as it may not achieve adequate fixation.*
> - *Use fluoroscopy to monitor advancement of the Pin to desired depth within bone void to reduce the risk of damaging anatomic structures.*

iFuse TORQ Instrument Set	400287
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
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 Instrument Set	400289
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
iFuse TORQ Fluoro Instrument Set	**400451**
Guide Pin – 3.2 mm	500373
Blunt Pin – 3.2 mm	500374
Blunt Dissector – Long	400224
Soft Tissue Protector Handle	400283
Soft Tissue Protector 1	400284
Torx Driver, Cannulated	501129
T-Handle, Ratcheting, Quarter Square, Low Profile, Pinned	501621
Driver Sleeve 1	400248
Dilator 1	501130
7.00 mm Drill Bit, Cannulated	501154-0700
9.25 mm Tap, Cannulated	501157-0925
Fixed Parallel Pin Guide (15 mm)	400050
QC Adapter, Quarter Inch to Tri-Lobe	501417
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
Driver Sleeve Wrench	400430
8 Gauge Bone Access Needle, Bevel Tip	502156



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.

Refer to the Instructions For Use, for contraindications, warnings and precautions. There are potential risks associated with the iFuse TORQ Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *https://si-bone.com/label*

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***

℞ ONLY

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

US | Providers

300867-US Rev. L
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