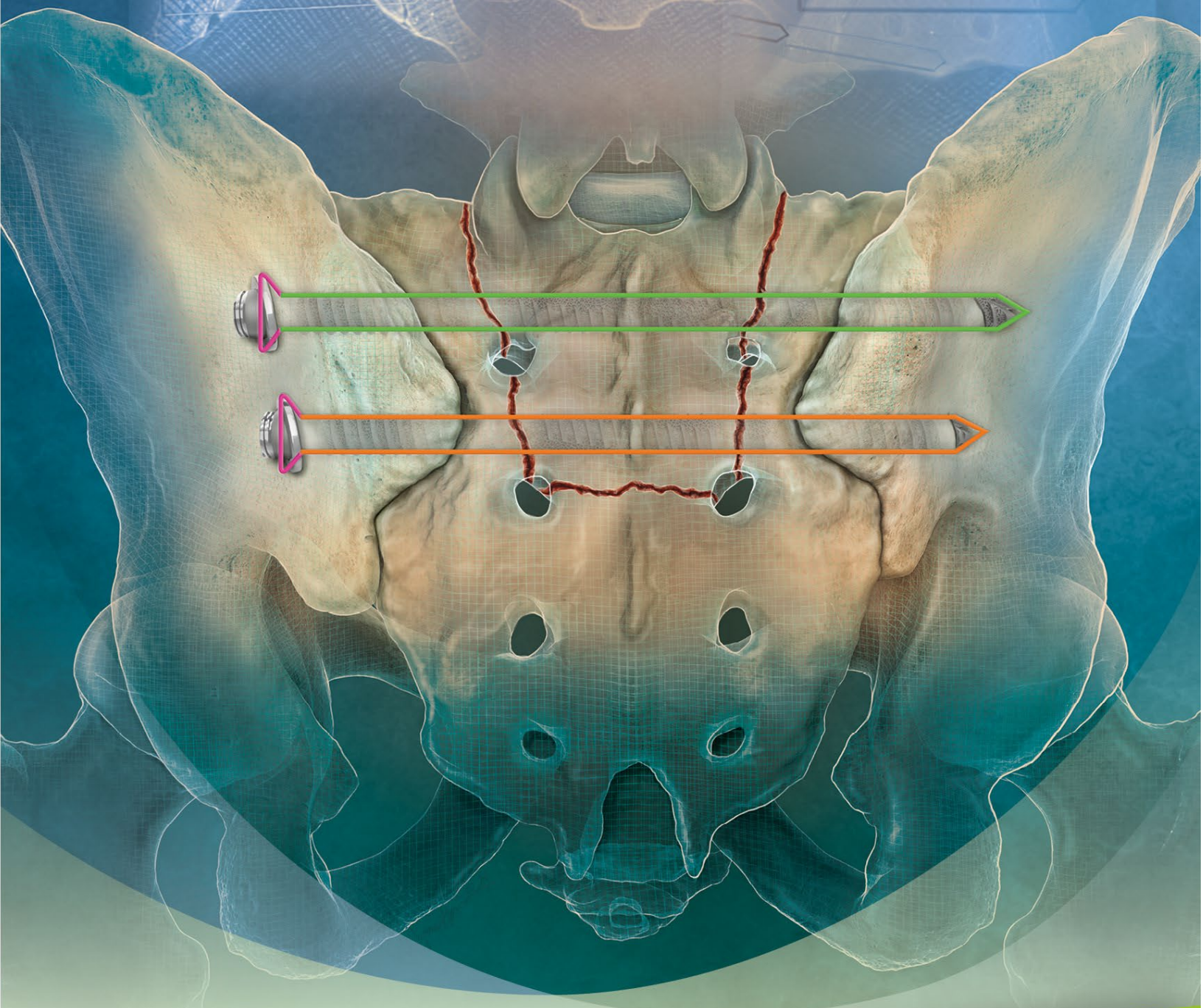


Surgical Technique Manual

Sacral Style Technique

– Navigation



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DISCLAIMER

Reimbursement information is provided for convenience only. It is neither legal advice nor official payor guidance. SI-BONE does not warrant or guarantee that the use of the information will result in coverage or payment. Providers are solely responsible for determining medical necessity and for being in compliance with Medicare and other payor rules and requirements, as well as for the information they submit with claims and appeals. Before any claims or appeals are submitted, providers should review official payor instructions and requirements, confirm the accuracy of their coding or billing practices with these payors, and use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient.

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”).

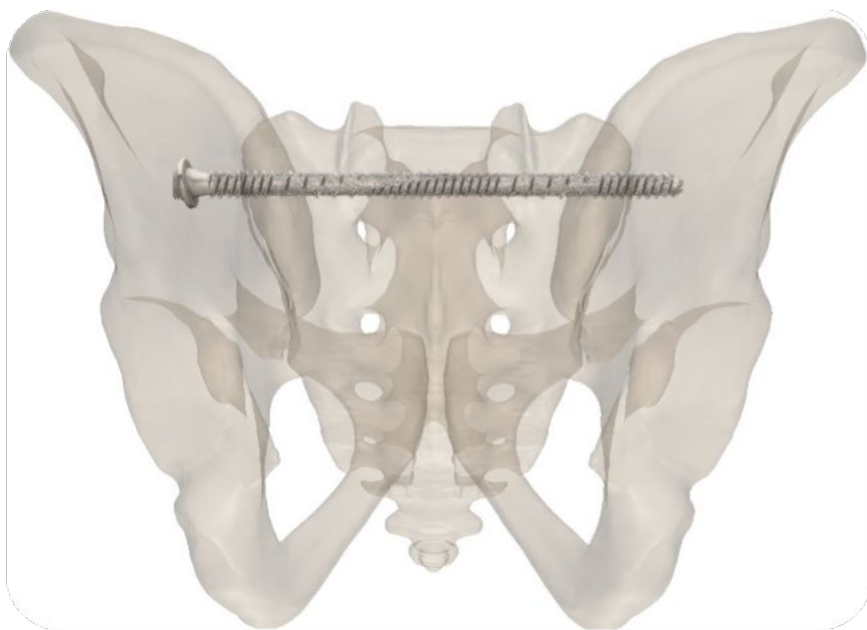


Figure 1

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>.

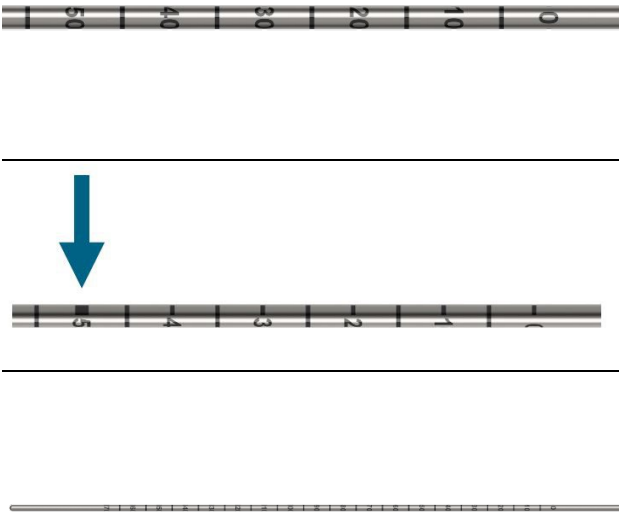
iFuse TORQ TNT Implant Specifications



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 – Navigation

Part Number	Instrument Name
501917	Navigated Pin, 2.5 mm, TORQ TNT
 Navigated Pin Measurement Markings Large Line at 50 mm marks on Pin	 Reverse Threaded Pin Design

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.

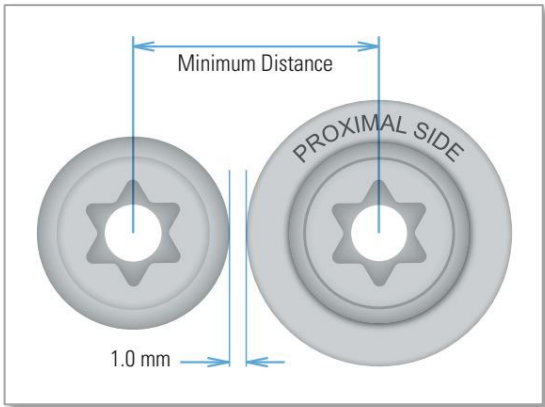


Figure 3

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

- 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 towels under the sacrum to allow proper positioning.
- 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 position technique.

- When utilizing the SI Style Implant (see [303015-US, Skin Marketing](#)) 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*. (<https://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.

iFuse TORQ TNT Navigation Instruments

iFuse TORQ TNT instruments are designed to allow physicians using Medtronic® O-arm™ imaging system and StealthStation® navigation system to perform sacroiliac joint fusion and pelvic fracture fixation procedures with SI-BONE's iFuse TORQ TNT Implant System.

Instruments Needed

- Medtronic StealthStation Spine Referencing Set
- SI-BONE Rotating Trackers or Medtronic NavLock Trackers
- SI-BONE Fixed Trackers or Medtronic TeraTrackers
- Medtronic Disposable Perc Pin (100 mm or 150 mm)
- SI-BONE iFuse TORQ TNT Instrument Set
- SI-BONE iFuse TORQ TNT Navigation Instrument Set

Precautions

- Refer to the instruction manuals for the Medtronic instruments listed above for proper guidance.
- The user should be proficient in the use of the Medtronic O-arm and StealthStation navigation system (Stealth) before performing navigated surgery.
- Please be mindful and aware of the sharp instruments in the set. These instruments may include pins, drill bits, and taps. The instruments can cause injury if handled in an unsafe manner.
- This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the physician's judgment.

iFuse TORQ TNT Navigation Instrument Assembly

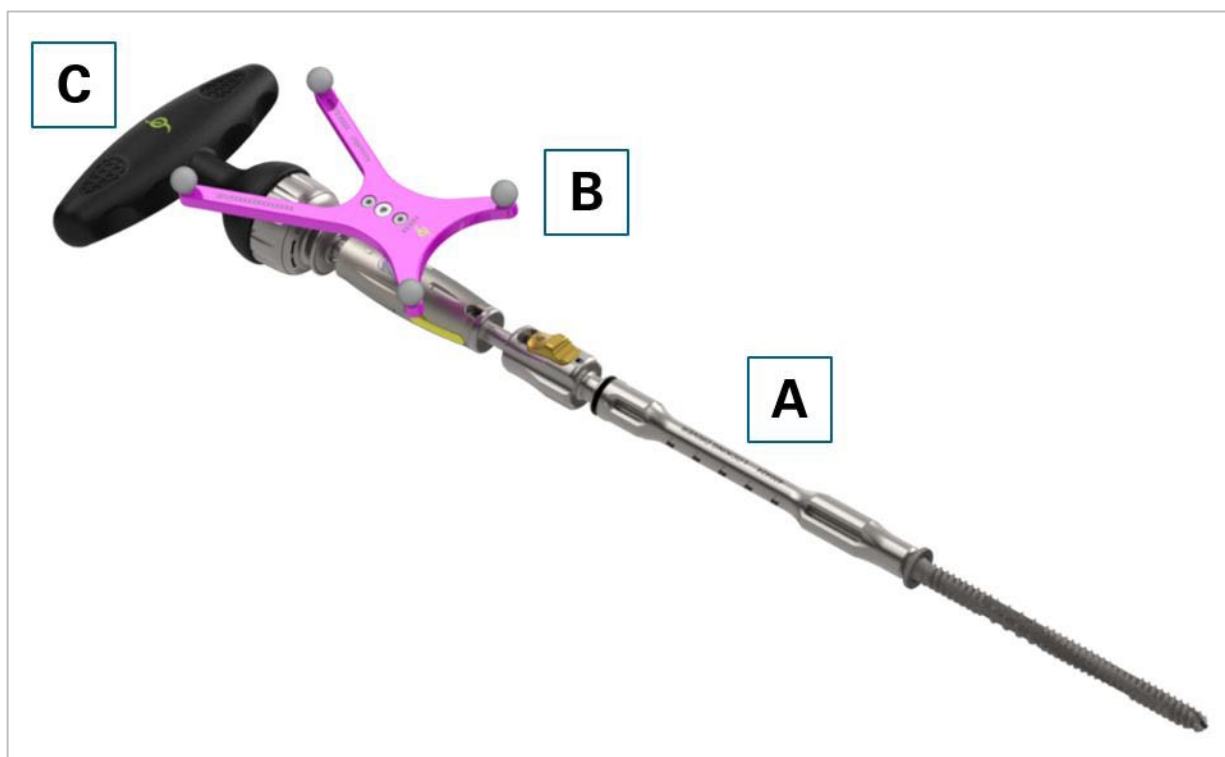


Figure 4

- Select desired SI-BONE Rotating Tracker or Medtronic NavLock array.
- Select desired iFuse TORQ TNT Drill Bit, TNT Tap, or TNT Locking Driver (A).
- Attach array to proximal instrument engagement feature (B).
- Connect desired handle (C).

Note: For Implant assembly to the TNT Locking Driver
(see [Implant Transfer and Assembly to Driver](#))

Attach Trackers to iFuse TORQ TNT Instrumentation

This document describes the use of SI-BONE trackers. Medtronic trackers can also be used for this procedure. The full instructions for use of TeraTrackers and NavLock Trackers can be found in Medtronic's user manuals/technique guides. Below are specific instructions for use with the iFuse TORQ TNT instruments.

Attach reflective spheres to the SI-BONE Fixed and Rotating Trackers. Attach Fixed Tracker with reflective spheres onto the TNT Navigated Pin Guide (TNT-NPG) and tighten using Screwdriver until fully secured. Attach Rotating Trackers to the respective TNT Drill Bit, TNT Tap, and TNT Locking Driver.

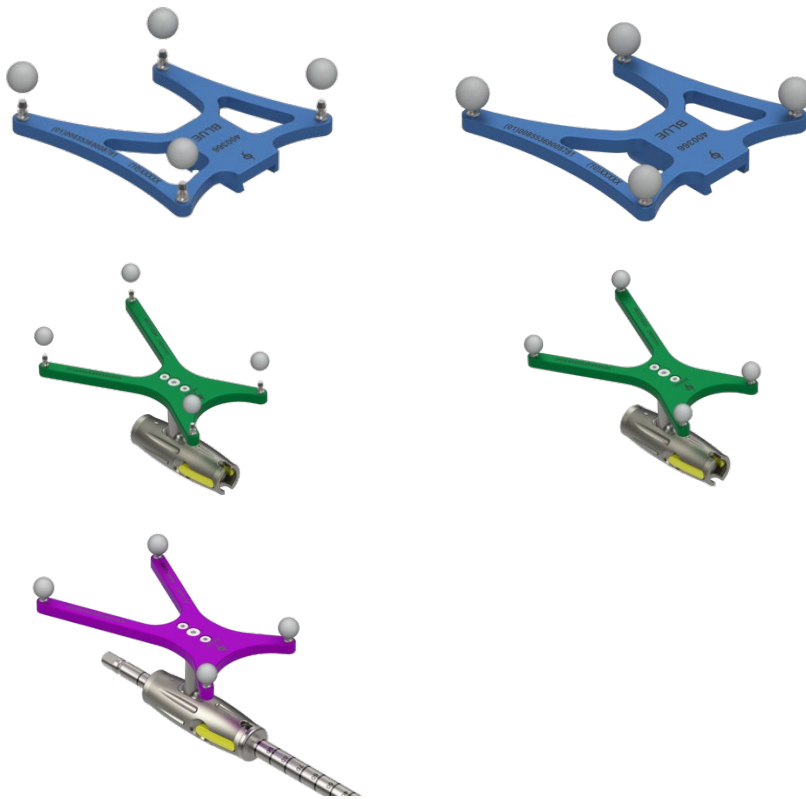


Figure 5

Using the Stealth Software, choose the appropriate instrument tool card (refer to [Tool Card Selection](#)).

Precautions

- Each time a tracker is changed or removed from an iFuse TORQ TNT instrument, the instrument must be reregistered.
- Ensure the trackers are fastened to the iFuse TORQ TNT instruments in the absence of tissue and/or fluid to ensure rigid fixation.
- Replace unclean or damaged spheres and/or trackers prior to or during the procedure.
- If using Medtronic TeraTrackers or NavLock Trackers, the full instructions for use can be found in Medtronic's user manual/technique guide.

Tool Card Selection

Select and register the following instruments according to the displayed Medtronic Tool Card instrument.

Navigation Instruments			
SI-BONE iFuse TORQ TNT Part Number	SI-BONE iFuse TORQ TNT Name	Medtronic Tool Card Part No.	Medtronic Tool Card Name
400434	TORQ TNT Navigated Pin Guide	9735193	UDG
400424	TORQ TNT Locking Driver	9734679	Lumbar Probe
400417	TORQ TNT 5.5 mm Navigated Drill		
400418	TORQ TNT 8.0 mm Tap		

Instrument Registration

Once the system arrives at the “Verify Instruments” screen, confirm that the appropriate colored TeraTracker coupled with the Universal Drill Guide (UDG) and the appropriate pairing of a colored NavLock Tracker coupled with the Lumbar Probe instrument are available to be selected as a Tool Card in the system.

SI-BONE Fixed Trackers* are equivalent to Medtronic TeraTrackers and SI-BONE Rotating Trackers are equivalent to Medtronic NavLock Trackers.

The SI-BONE Trackers are listed in the chart below with their corresponding Medtronic NavLock Trackers or TeraTrackers.

Trackers			
SI-BONE Tracker Part Number	SI-BONE Tracker Instrument	Medtronic Instrument	Medtronic Part Number
400372-001	Rotating Tracker – Orange	NavLock Orange	9734683
400372-002	Rotating Tracker – Violet	NavLock Violet	9734682
400372-003	Rotating Tracker – Green	NavLock Green	9734734
400372-004	Rotating Tracker – Grey	NavLock Grey	9734590

*Fixed Tracker – Blue can be replaced with alternative Fixed Trackers Gold (P/N 400367), Green (P/N 400368), Purple (P/N 400369); TeraTrackers Blue (P/N 9730489), Green (P/N 9730490), Gold, (P/N 9730491), Purple (P/N 9730492).

If the Tool Cards for the instruments shown are not displayed, add the instruments through the “Add or Remove Instruments” feature.

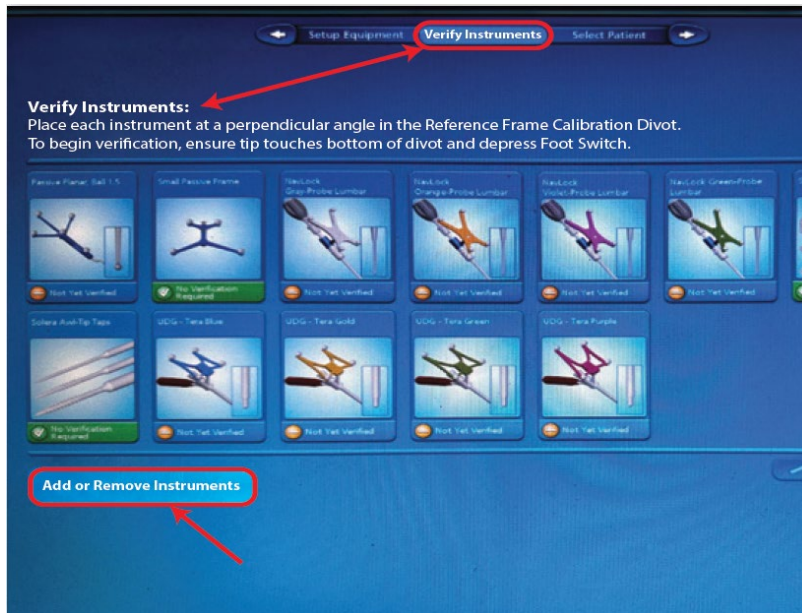


Figure 6

Note: Refer to the Medtronic StealthStation S7 or S8 System Manual and/or Navigation Operative Technique for additional details regarding system use. Changes to the StealthStation system software that result in removal of an instrument tool card or difficulty registering trackers should be reported to gara@si-bone.com or 1-855-511-1545.

A pop-up window will appear with available instruments for pairing. Use the search box to select your desired NavLock array and click “add”.

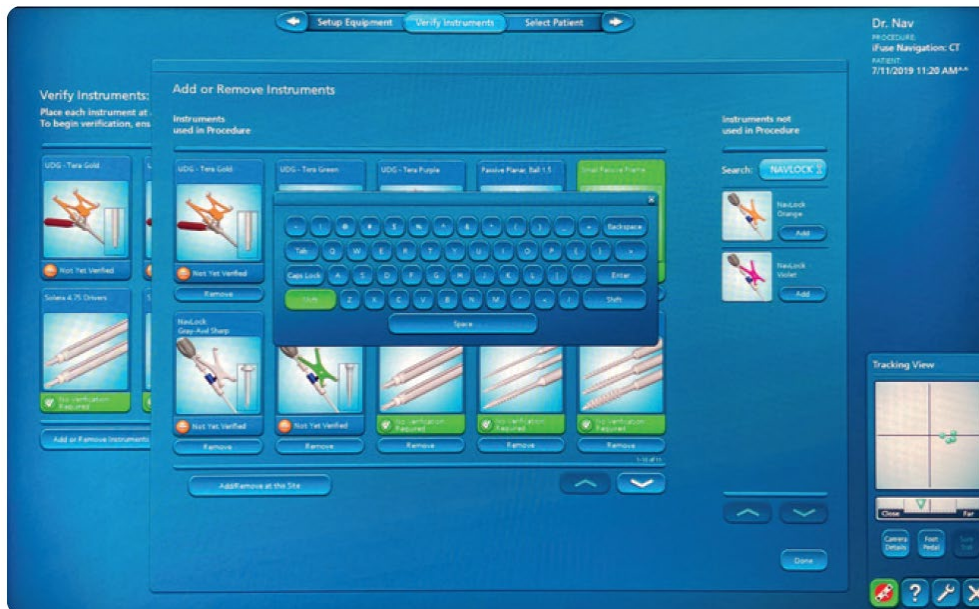


Figure 7

A pop-up window will appear prompting default tip selection. Click on the drop down and select “Awls and Probes”. Then select “Probe Lumbar”.

With another array of your choice, follow the same steps and selections to register the TNT Locking Driver similarly, as a Lumbar Probe.

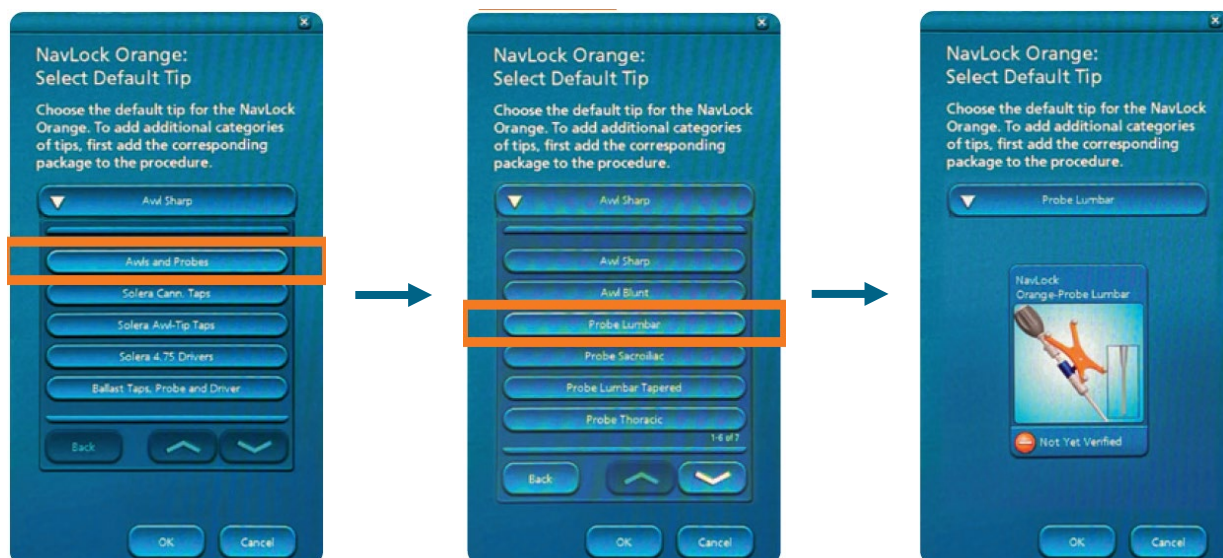


Figure 8

Register the TORQ TNT Navigated Pin Guide (TNT-NPG).

Use the Blunt Pin (450 mm) through the instrument lumen to centralize the tip within the registration divot on the Reference Frame.

Follow the technique above to complete registration of the Drill Bit, Tap, and TNT Locking Driver.

If the optical tracker does not register the instrument, adjust it to create a longer line of site.

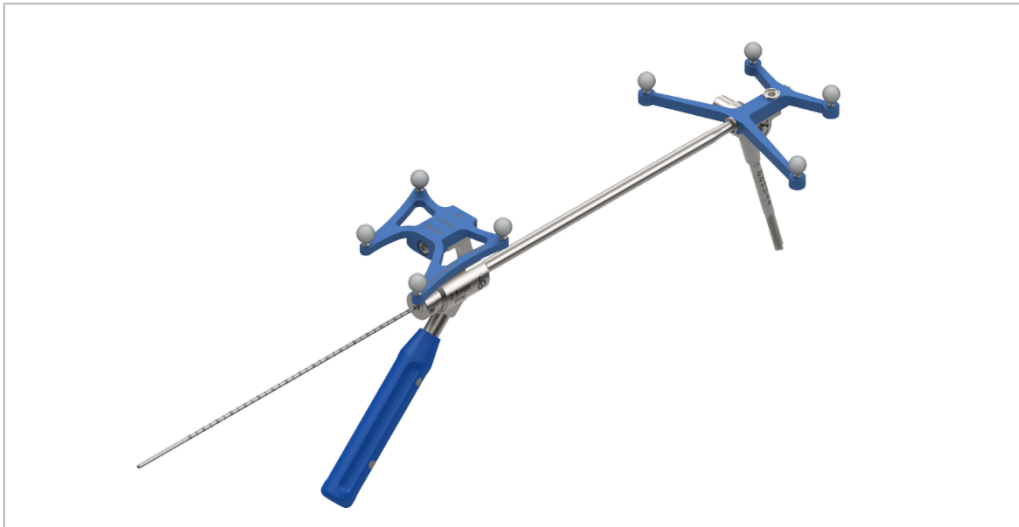


Figure 9

Navigation Accuracy Check

Throughout the procedure, assess instrument navigational accuracy repeatedly. Reconfirm accuracy by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.

If the stereotactic navigation system does not appear to be accurate despite troubleshooting, do not rely on the navigation system.

Precautions

- Ensure that the Rotating Tracker or NavLock Tracker is clicked into place to accurately register the instrument.
- Ensure that the Perc Pin and/or Reference Frame are not disrupted during the procedure. If so, reregistration may be necessary.

Instrument Projections

TNT Locking Driver

When setting a projection for the TNT Locking Driver and iFuse TORQ TNT Implant, use a projection width of 9.0 mm and projection length that matches the chosen Implant size. No additional projection adjustments are needed for instrument length.

Drill Bit & Tap

When setting a projection for the Drill Bit and/or Tap, use a projection width of 5.5 mm for the Drill Bit and 8.0 mm for the Tap. After registering the Drill Bit and/or Tap, an additional 75 mm projection must be added to the Lumbar Probe on the StealthStation to accurately represent the Drill Bit/Tap overall length on the StealthStation monitor.

Projection Length Adjustment

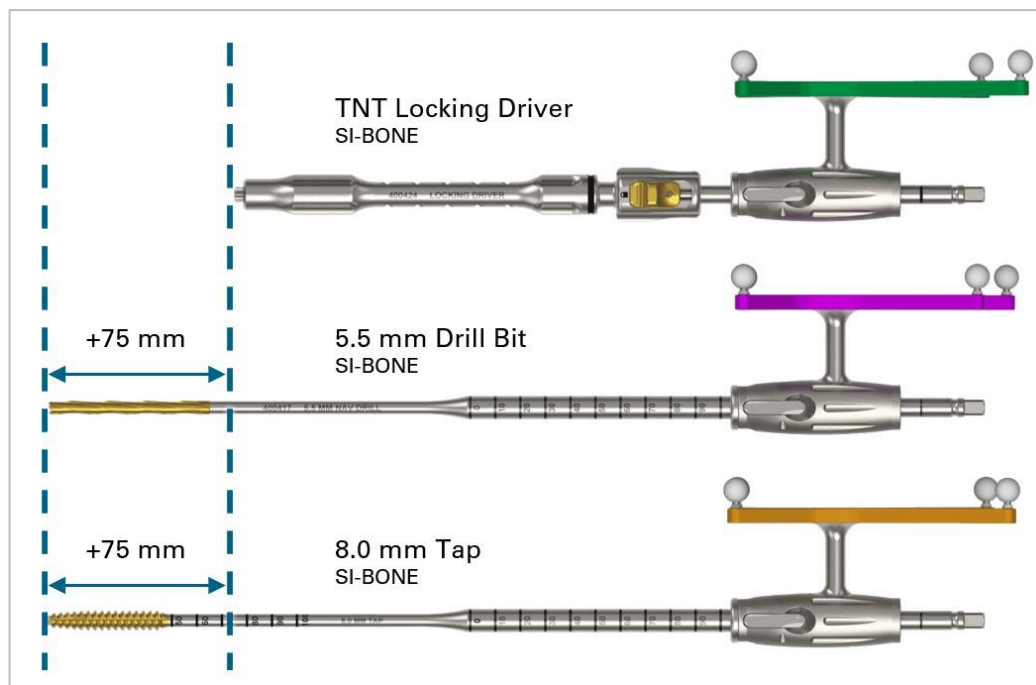


Figure 10

Implant Projections

When setting a projection for the iFuse TORQ TNT Implant, use 9.0 mm width and a length equivalent to desired Implant length for the procedure. If using a Washer, recommended projection settings are 16 mm or 21 mm width (depending on chosen diameter) and 5 mm in length.

iFuse TORQ TNT Implant Projections			
Part Number	SI-BONE Tracker Instrument	Projection Width	Projections Length
870070 - 870170	iFuse TORQ TNT Implant	9.0 mm	70 – 170 mm
501939-0016	iFuse TORQ TNT 16 mm Washer	16.0 mm	5 mm
501939-0021	iFuse TORQ TNT 21 mm Washer	21.0 mm	5 mm

Attach Reference Frame, Capture Images, and Obtain 3D Imaging Views

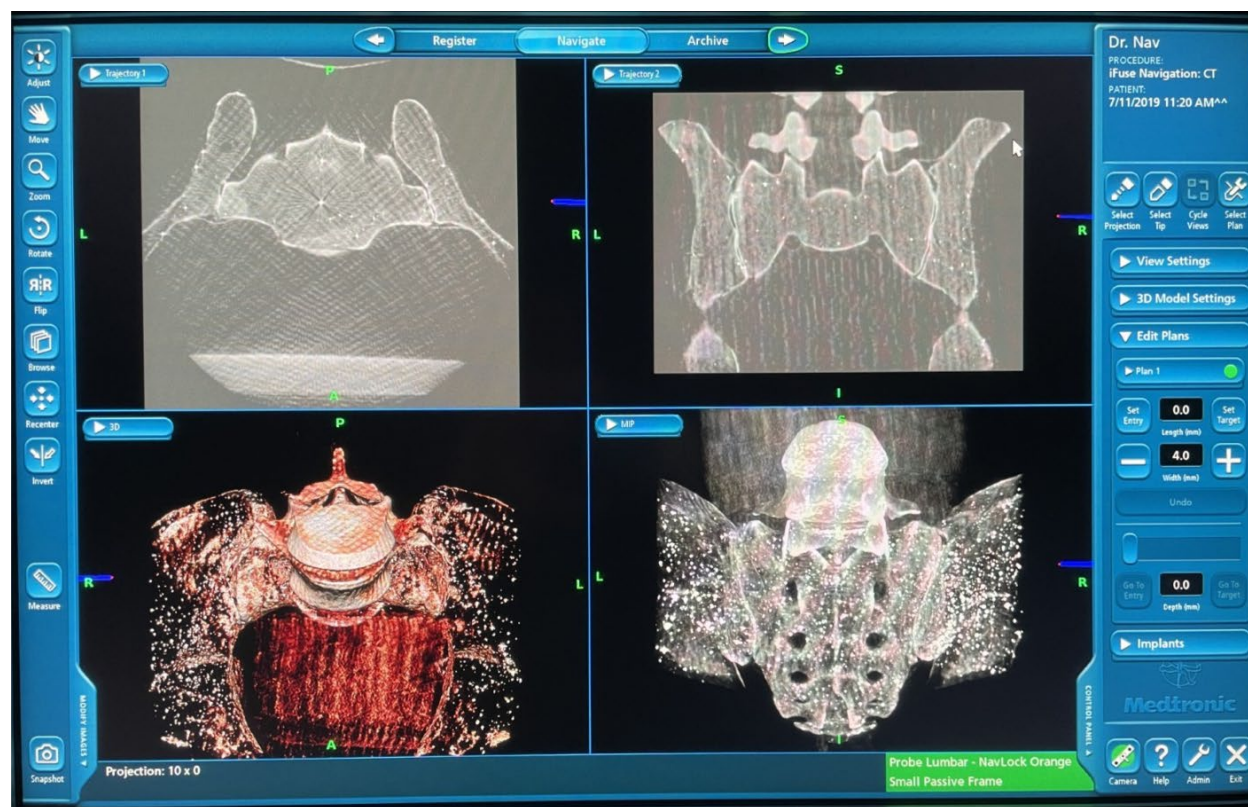
Using the Medtronic Perc Pin Set, attach the Reference Frame to the posterior superior iliac spine per typical set up when using navigation. Ensure the Reference Frame is in proper view of the camera and does not impede the expected working area.

Note: If performing the procedure with the patient in the supine position, attach the Reference Frame to the contralateral anterior superior iliac spine.

Bring the O-arm into position. Take lateral and AP scout images. Following Medtronic's instruction manuals, take an O-arm spin.

Typical views used for the iFuse TORQ TNT navigation procedure are as follows:

- Trajectory 1 – axial (upper left)
- Trajectory 2 – coronal (upper right)
- 3D – Inlet/Lateral (lower left)
- Maximum Intensity Projection (MIP) – Outlet/Lateral (lower right)



Skin Marking and Incision

Place the tip of the TNT-NPG on the skin directly overlying the alar line / iliac cortical density (ICD). The TNT-NPG has a rotating head and self-locking handle, which can be turned to keep the Tracker oriented toward camera line of sight during use.

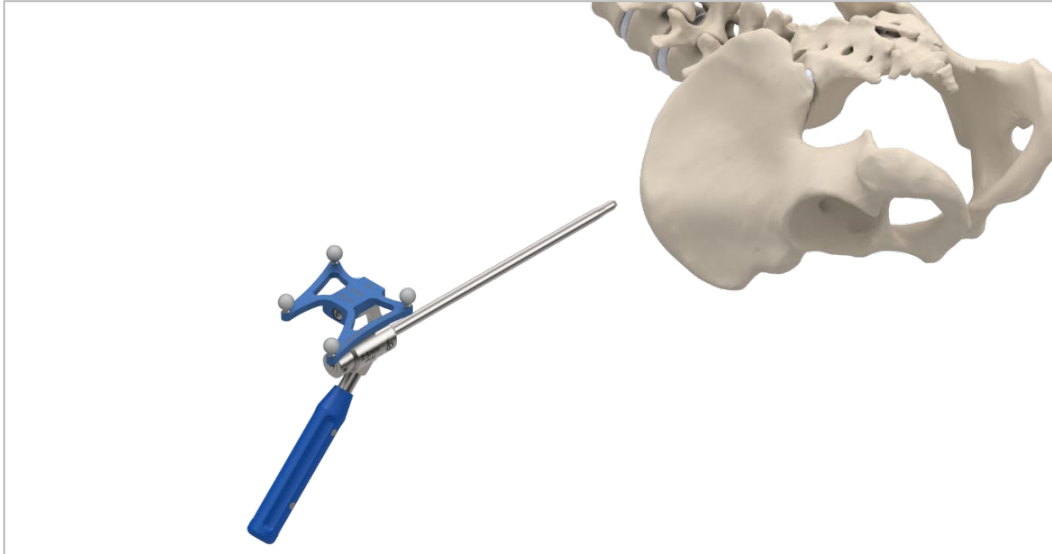
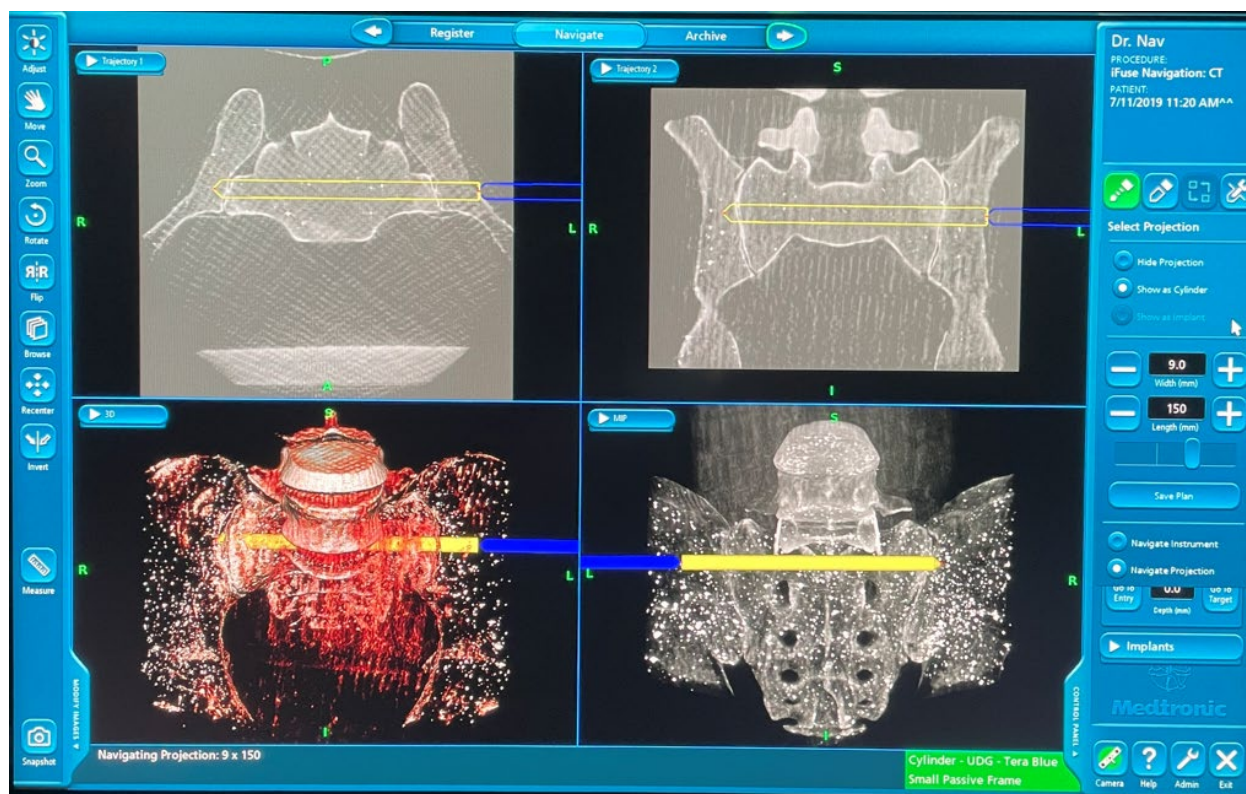


Figure 11

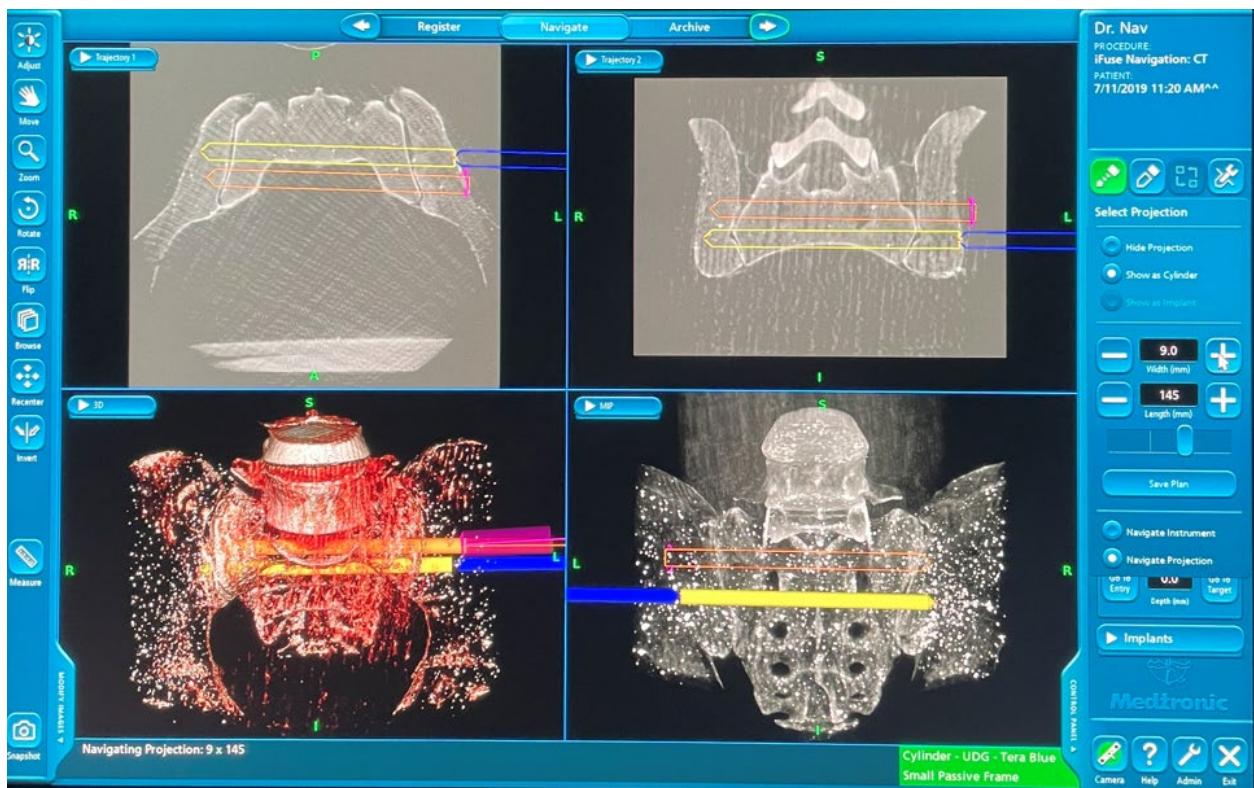


Figure 12

Extend Implant projection to desired depth and position within the bony anatomy. Save this plan and mark the skin at tip of the TNT-NPG.



If desired, plan and save a trajectory for all Implant locations prior to making any incisions. Each trajectory can be visualized on the typical views used in the procedure to confirm that trajectories do not cross or impinge. If using a Washer, 16 mm or 21 mm, take care to account for that diameter (yellow plan in Figure below) when spacing multiple Implants in surgical plan.



Make an approximately 2 cm incision at the skin marking. Incise through the skin and subcutaneous tissue.

Precautions

When incising and dissecting, take care to avoid the superior gluteal artery and other surrounding neuro-vascular structures.

Projecting Implant Position

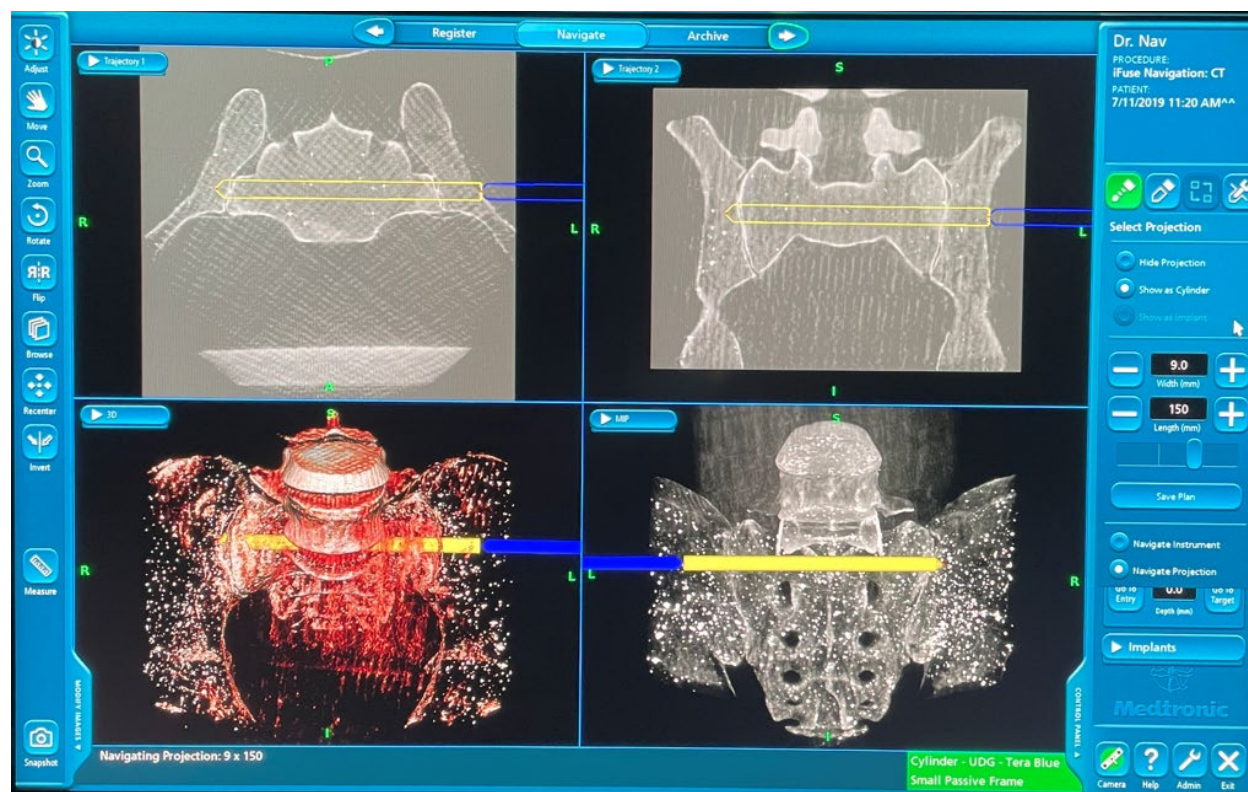
Insert the TNT-NPG into the incision and advance through the soft tissues until it has contacted the lateral wall of the ilium.

To create the Implant trajectory, set the projection length to desired Implant length and then set the diameter to 9.0 mm.

Once the desired Implant position is determined, save the trajectory/plan on the StealthStation.

Note:

Save the Implant length for future use to help determine depth of the TNT Navigated Pin.



Precautions

Review both Trajectory 1 and Trajectory 2 views to verify the projection is safely within bone.

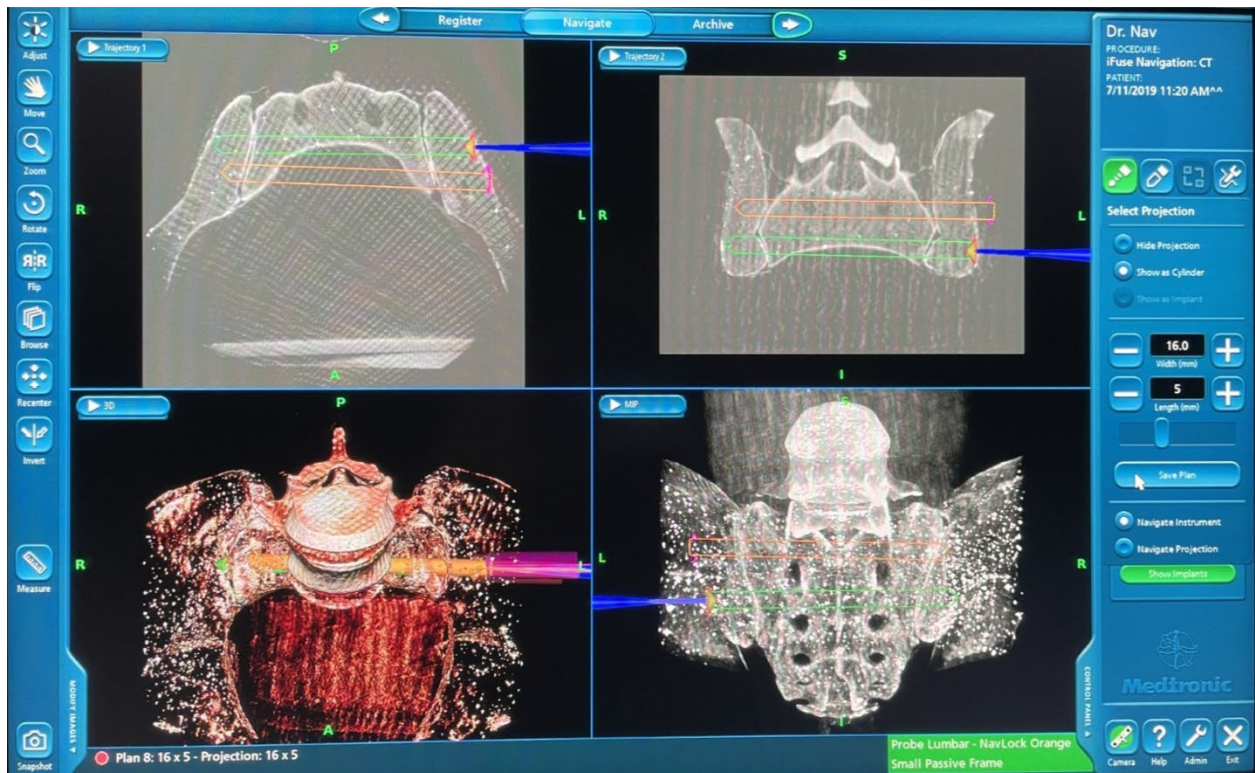
Projecting Multiple Implant Positions and Washers

If placing a Washer on the first Implant, create and save a second plan to have a 9 mm width and 5 mm length; ensure collinearity of this plan with Implant plan. Once confirmed, expand projection width to Washer diameter. This will display the Washer position on the Implant plan.

If placing a second Implant, create and save another plan with projection width of 9 mm and length set to the desired Implant length.

If placing a Washer on the second Implant, create and save another plan with projection width equal to the Washer diameter and a projection length of 5 mm to understand if there will be Washer interference.

Note: When placing multiple Implants with Washers, ensure spacing allows for safe Implant placement. Reference [Subsequent Implant Spacing](#) table to avoid Implant-to-Implant contact.



Precautions

- Minimum implant spacing assumes parallel Pins. Consider adding additional distance between Pins and/or Implant placement 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.

First Pin Placement

Return the TNT-NPG to the position of the first Implant plan. Advance the TNT-NPG through the soft tissue to the lateral ilium. Insert a 2.5 mm Reverse Threaded Tip TNT Navigated Pin through the TNT-NPG until contact is made with the ilium.

Using a pin driver, advance the TNT Navigated Pin, with counterclockwise rotation, to planned Implant depth. Use the markings on the Pin relative to the back of the TNT-NPG to determine Pin depth during insertion.

Optional: Use fluoroscopy to confirm Pin advancement and final position.

Once the Pin has been advanced to the desired depth, check for any variations in placement compared to the original plan. If variations are noted but the new plan for Implant placement is in a good location, re-save the new plan.

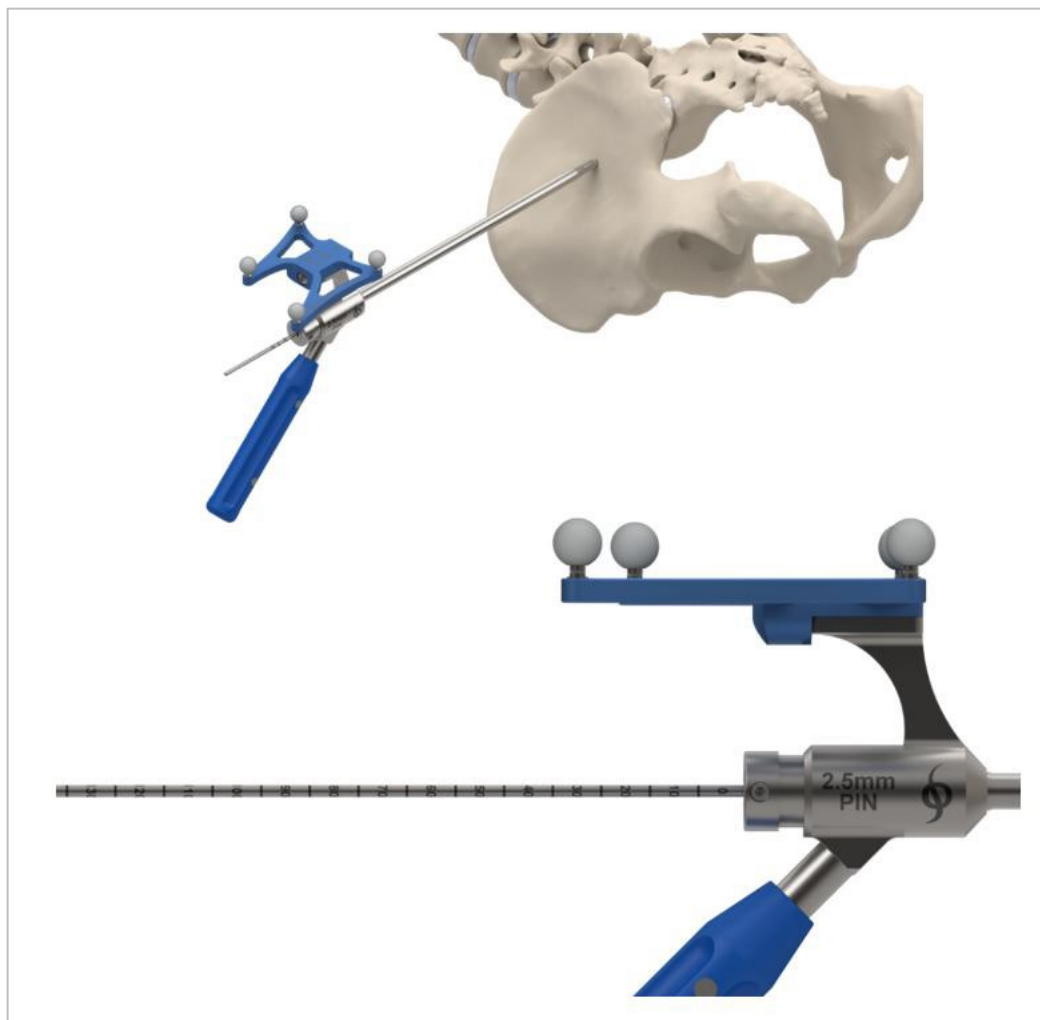


Figure 13

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

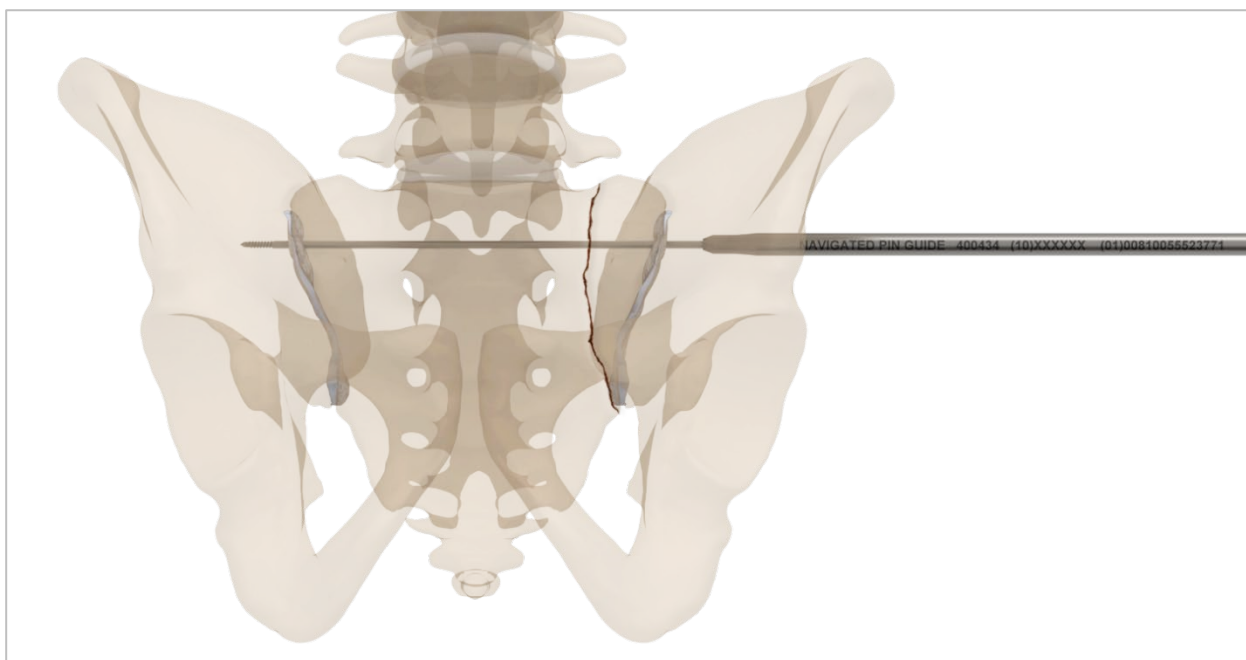


Figure 14

Precautions

- The 2.5 mm Reverse Threaded Tip Pin has left-handed threads. Use counterclockwise rotation to advance and clockwise rotation to remove the Pin.
- Depth markings on the 2.5 mm Reverse Threaded Tip Pin are designed for use with the TNT Navigated Pin Guide.
- Replace any bent Pins with new Pins immediately during the procedure to ensure proper trajectory before drilling.
- 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. Should a Pin trajectory need to be revised, remove the Pin using clockwise rotation and re-insert with the desired trajectory. The 2.5 mm Reverse Threaded Tip Pin is not a navigated instrument. Ensure the Pin remains securely in position throughout the entire duration of the procedure. This can be verified by the markings on the Pin.
- Do NOT push on the Pin or use a mallet to advance it. Applying a medially directed force to the Pin may cause unwanted advancement, or Pin damage.
- When advancing Pin or Implant, avoid penetrating the sacral canal and/or foramen.
- At all times, caution should be used around the spinal canal and nerve roots to avoid damage to the nerves.
- 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.
- 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.

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.

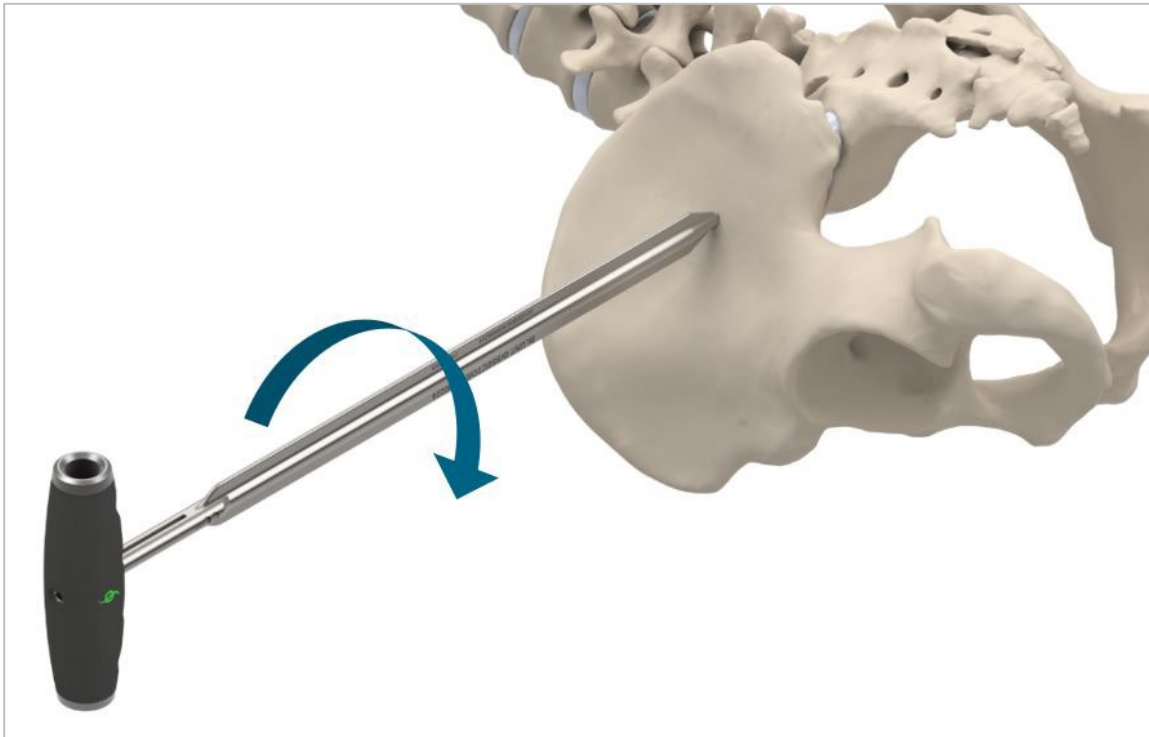


Figure 15

Precautions

- Maintain collinearity 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 the instrument is 3.4 mm. Maintain collinearity of the Blunt Dissector with 2.5 mm Pin during use.
- Take care not to apply excessive forward pressure when twisting the Blunt Dissector to avoid instrument, bone, or tissue damage.
- Take care when using the Blunt Dissector with the 450 mm Pins as they will extend out of the proximal end of the instrument and could damage the user's glove/ hand.

Dilator

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.

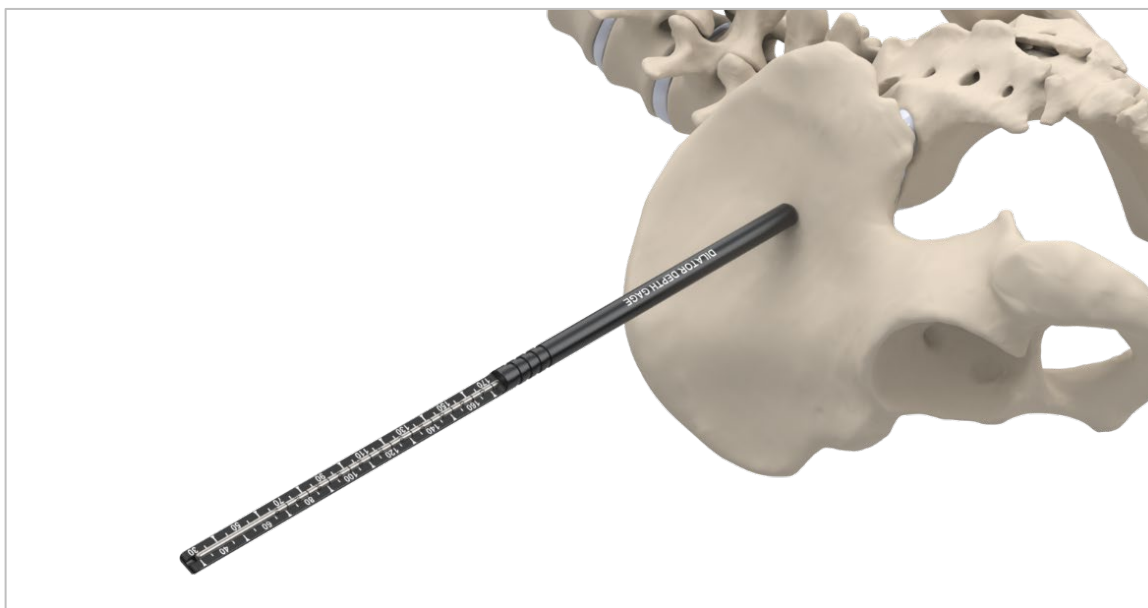


Figure 16

Precautions

- Do not impact the flat surface of the Dilator. This may damage the bone and/or Dilator.
- The Dilator has depth markings designed to be used with the 2.5 mm Pin in a non-navigated procedure. The depth markings on the Dilator are not designed to determine Implant length with 2.5 mm iFuse TORQ TNT Navigated Pin.
- Take care not to 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 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 STP to assemble the two instruments.

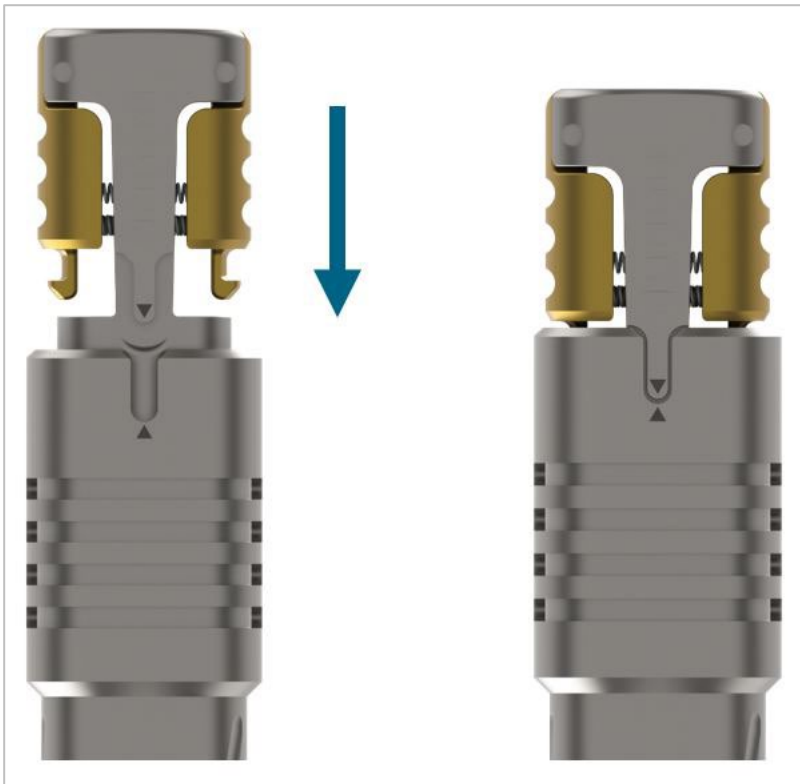


Figure 17

Slide the 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 18

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 Drill Sleeve is fully seated within STP so measurement markings on Drill Bits/Taps are accurate relative to back of Drill Sleeve + STP assembly when drilling/tapping.
- Ensure the STP is flush to the ilium.
- Maintain position of STP through Drilling, Tapping, and Implantation steps to ensure proper alignment of instruments and Implant.

Drilling (Optional)

The Drill Bit has measurement markings for estimating drill depth when used through the STP. It is possible to perform this procedure without drilling, as iFuse TORQ TNT Implants are self-drilling and self-tapping. In hard bone, drilling and tapping may be required.

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

Note: After Drill Bit is registered, set the projection length to 75 mm for the Drill Bit to accurately project the position of the Drill Bit tip.

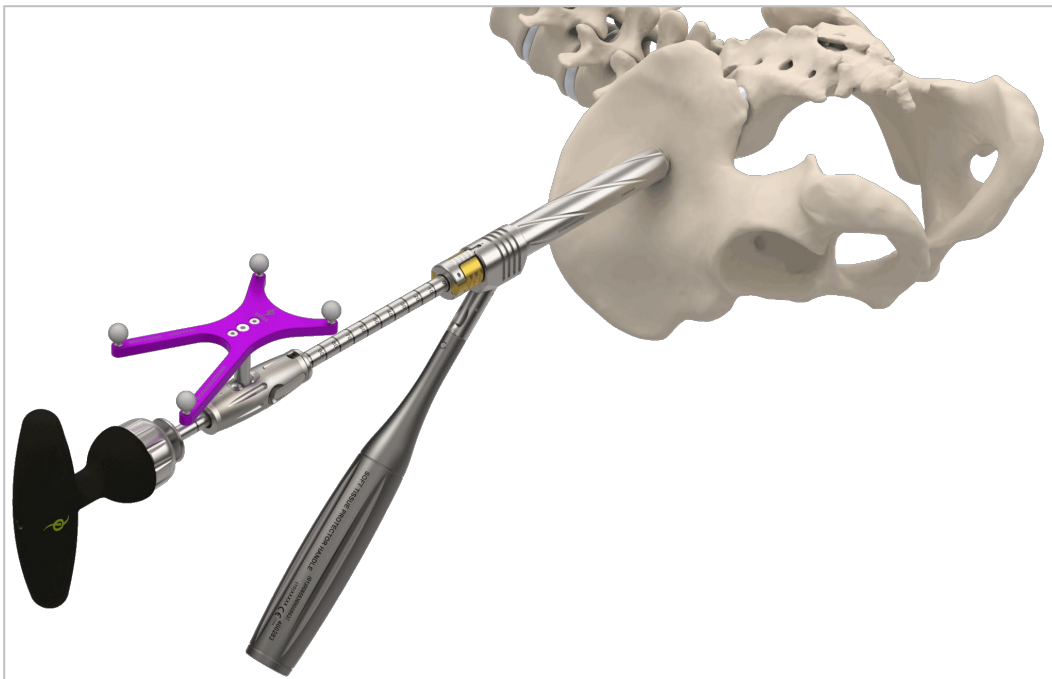
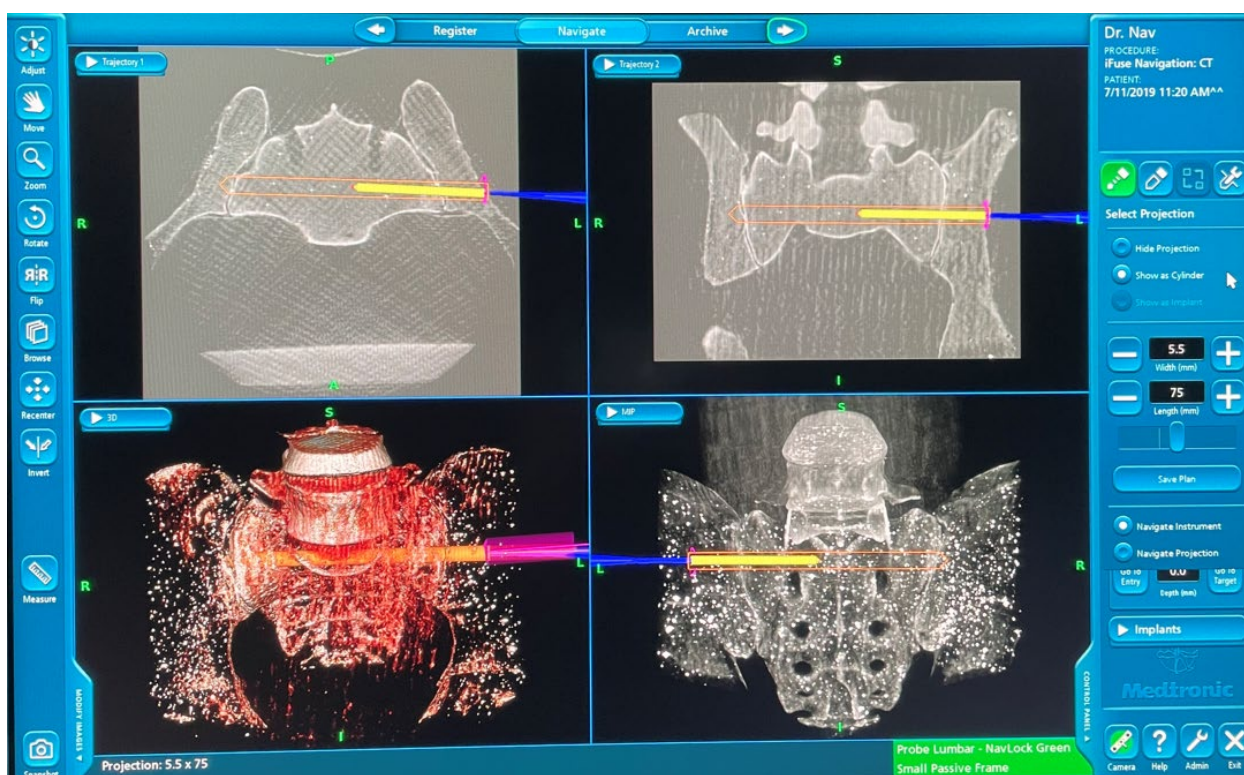


Figure 19



Insert the registered 5.5 mm TNT Drill Bit (with additional 75 mm projection length applied on StealthStation) over the TNT Navigated Pin, through the STP.

Start applying power only after the Drill Bit is against bone. Advance Drill Bit to desired depth, but no deeper than 100 mm. Watch for unwanted Pin advancement.

Optional: Use fluoroscopy to confirm Pin position while drilling.

Drilling (Optional)

Note: If placing a transsacral length iFuse TORQ TNT Implant, the Navigated Drill Bit is only designed to reach the mid-body of the sacrum in most patients (up to 100 mm). If drilling to a deeper depth is desired, use the 5.5 mm non-navigated Drill Bit (up to 150 mm) along with fluoroscopic guidance to complete this step.

To prevent binding, ensure the Drill Bit can easily move back and forth over the pin. A Blunt Pin may be used in place of the Pin if the Pin is close to a foramen.

A surgical clamp (e.g. Kocher) may be used to hold the proximal end of the TNT Navigated Pin to help avoid unwanted Pin advancement. Monitor Drill Bit advancement on the StealthStation and with measurement markings on Drill Bit relative to the back of the Drill Sleeve.

As the Drill Bit is removed, hold the TNT Navigated Pin to ensure the distal tip remains in bone. Insert Blunt Pin as an Exchange Pin to help maintain TNT Navigated Pin position.

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

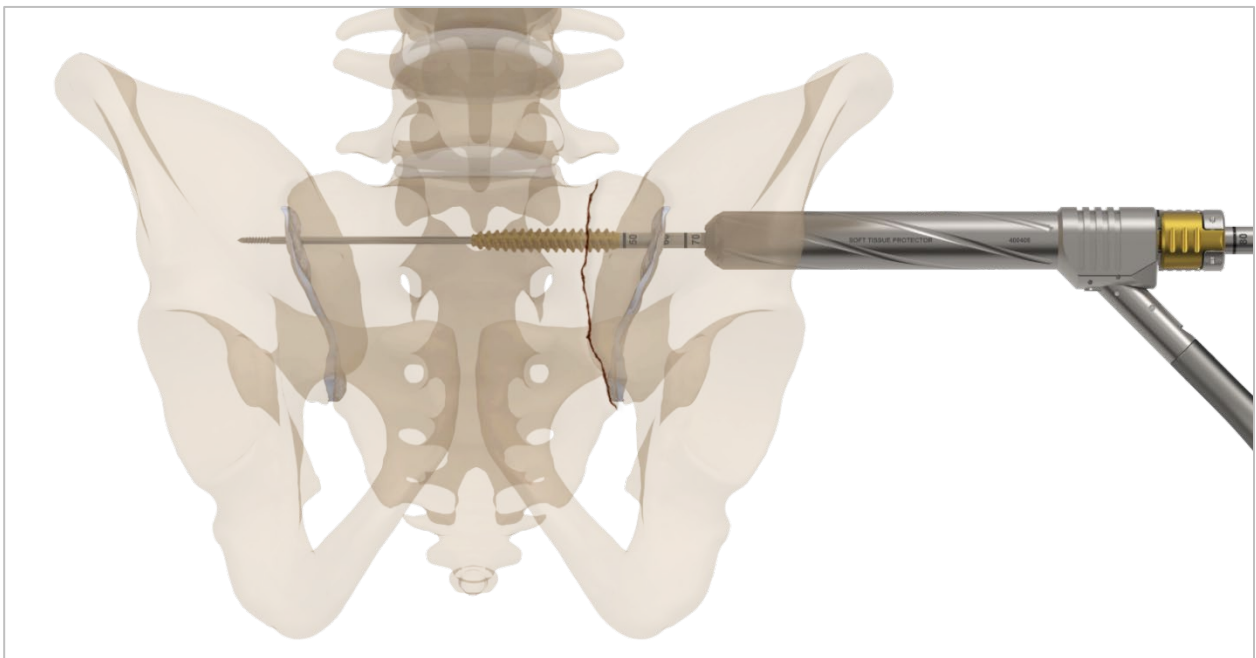


Figure 20

Precautions

- Ensure collinearity of the Drill Bit over the Pin, before and during the use of power. 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 reduce the likelihood of pin binding.
- Take care to monitor Drill advancement if using with power.
- Use care to avoid advancing the Pin. Do NOT push on the Pin. Applying a medially directed force to the Pin may cause it to advance.
- Inadvertent/excessive Drill Bit advancement may cause nerve damage, hemorrhage, or the other possible adverse events listed in the Instructions for Use, 503008.
- During extended use of Drill Bit, e.g., drilling in hard bone or creation of deep bone channels, irrigate the Drill Bit to minimize overheating of adjacent bone and pin binding.
- In hard bone, users should drill and tap to ensure that the Implant can be fully inserted and/or adjusted as necessary during the index procedure.
- When drilling in hard bone, use a “pecking technique” to lower the risk of overheating adjacent bone.
- Take care not to move Soft Tissue Protector during drilling and tapping steps.
- Adequate bone preparation is recommended to help avoid fractures of the sacrum or ilium.
- Do not attempt to use any other Instrumentation to drill over the Pin.
- Do not impact the drill handle assembly with mallet to advance the Drill Bit.

Tapping (Optional)

The Tap has measurement markings for estimating Tap depth when used through the STP. It is possible to perform this procedure without tapping, as iFuse TORQ TNT Implants are self-drilling and self-tapping. In hard bone, drilling and tapping may be required.

To prevent binding, ensure the Tap can move easily back and forth over the Pin.

Note: After the Tap is registered, set the projection length to 75 mm for the Tap to accurately project the position of the Tap tip.

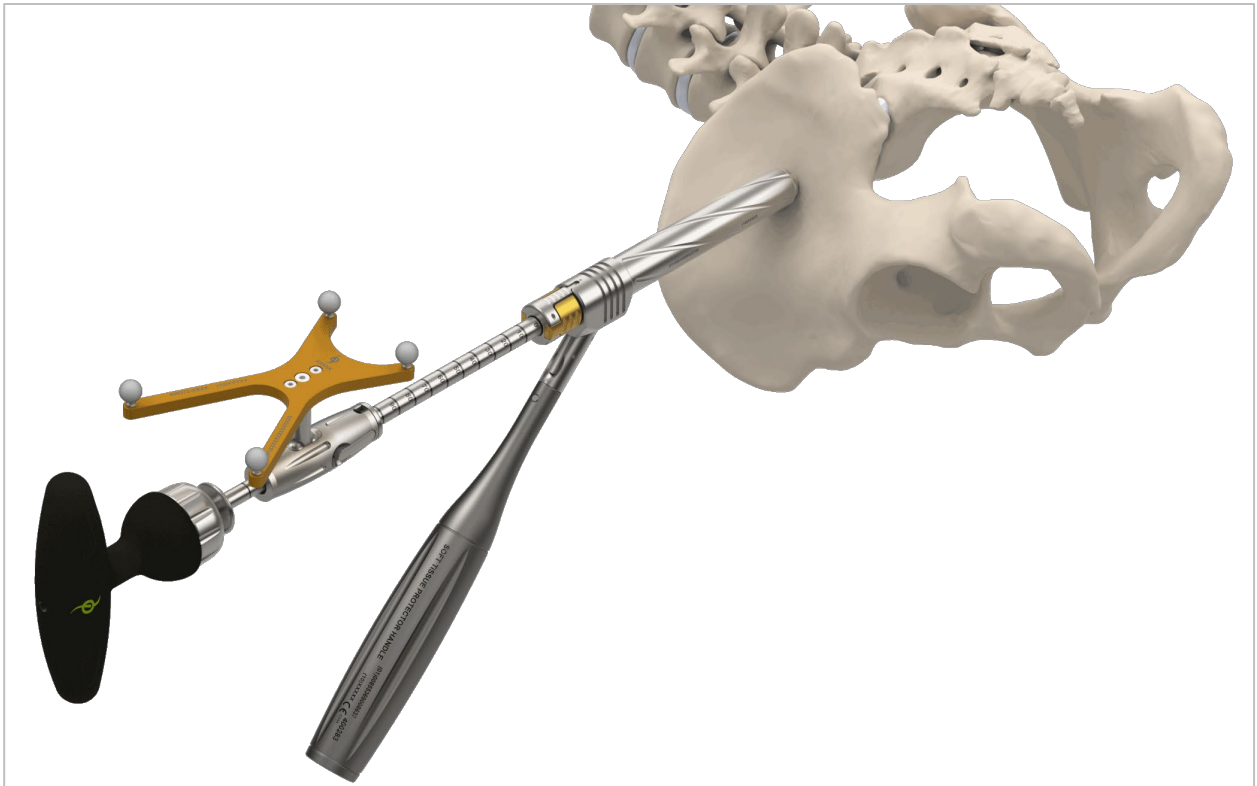


Figure 21

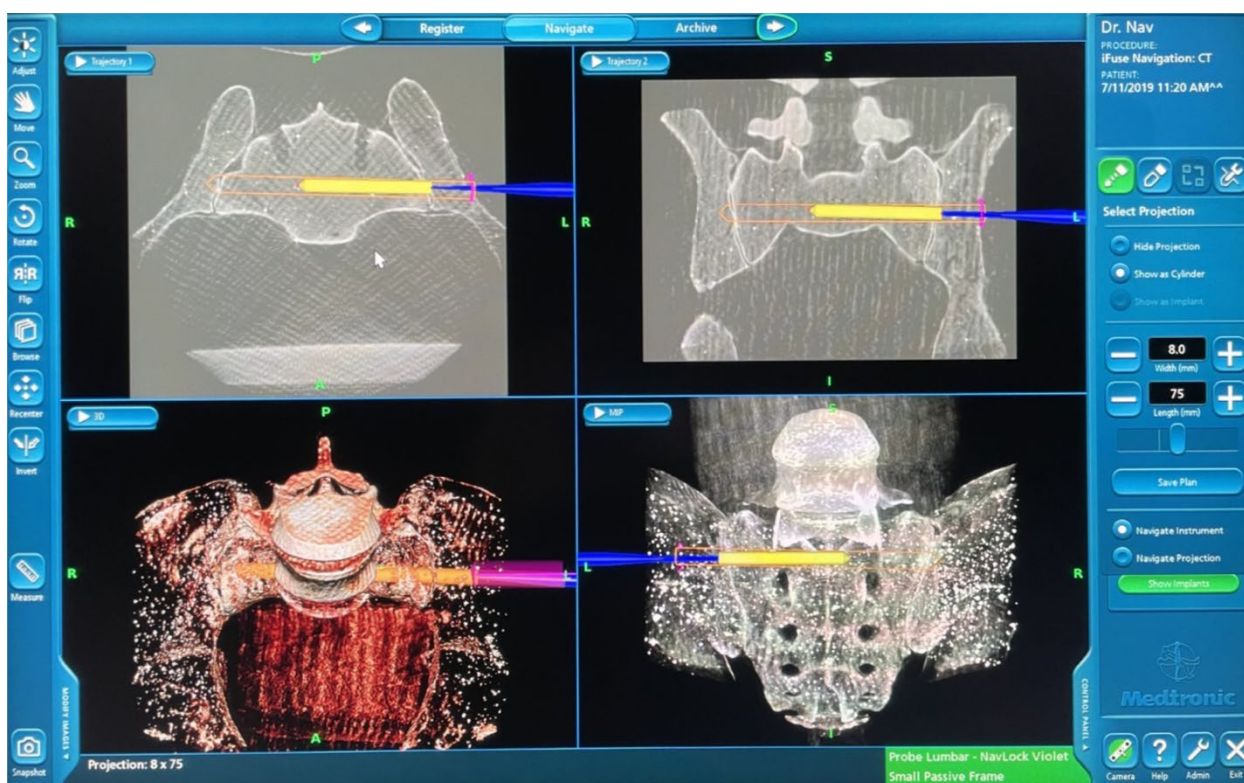


Figure 22

Insert the registered Tap (with additional 75 mm projection length applied on StealthStation) over the TNT Navigated Pin, through the Drill Sleeve-STP assembly.

Monitor tapping to desired depth on the StealthStation. The Tap is designed to reach a maximum depth of 100 mm.

As the Tap is removed, hold the TNT Navigated Pin to ensure the distal tip remains in bone.

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

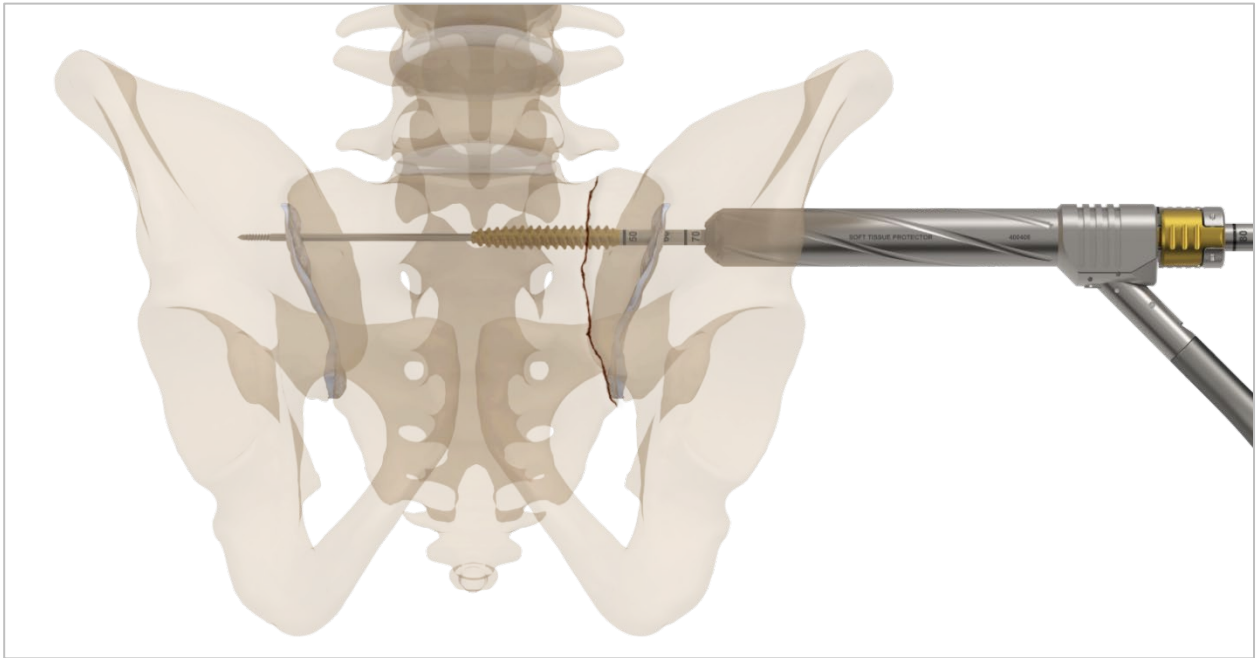


Figure 23

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 help minimize pin binding. Also, the Cleaning Stylet can be utilized for this step to ensure the lumen is free of debris.
- 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.

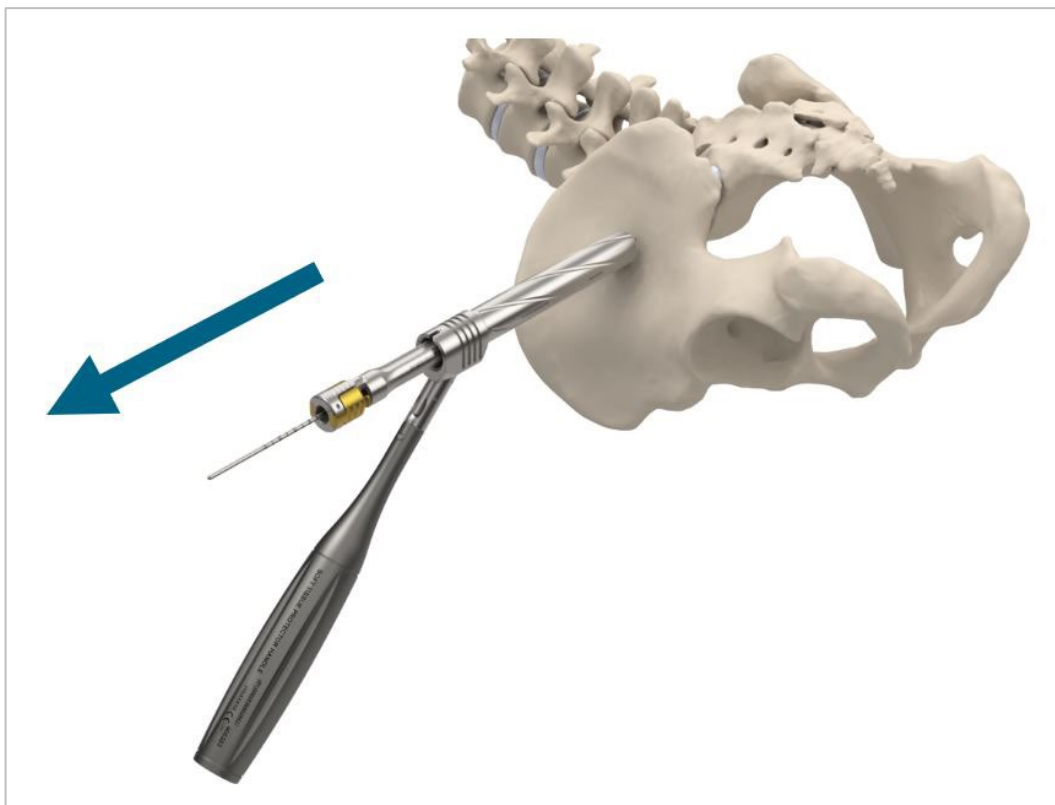


Figure 24

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 25

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 26

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 27

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

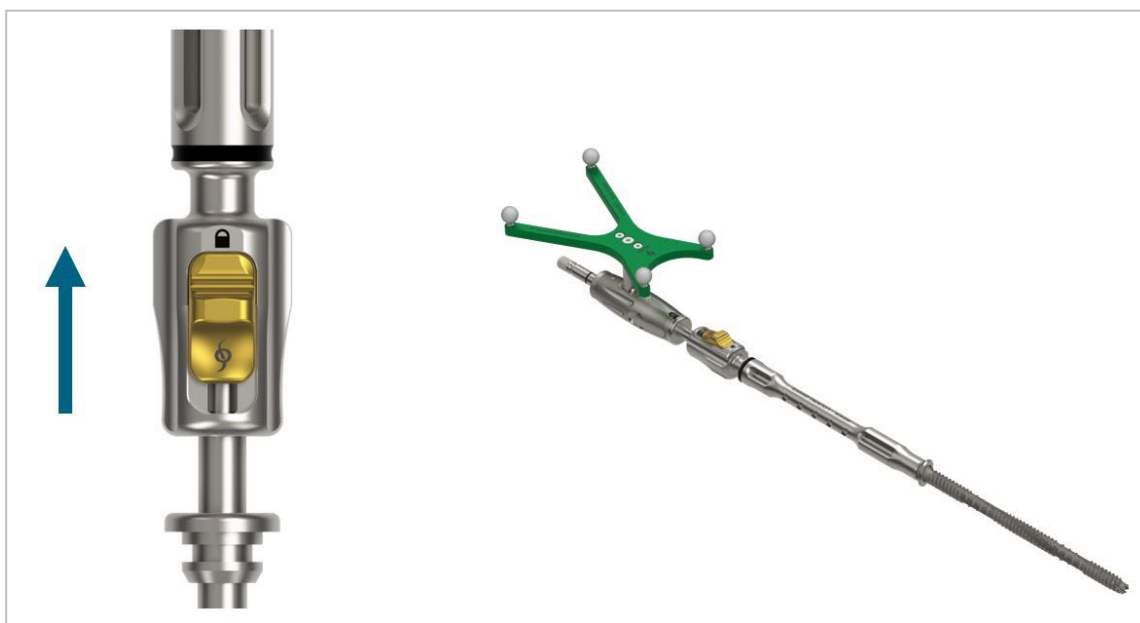


Figure 28

Note: This step may be done prior to Implant assembly.

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

Project the appropriate Implant dimensions on the StealthStation.

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.

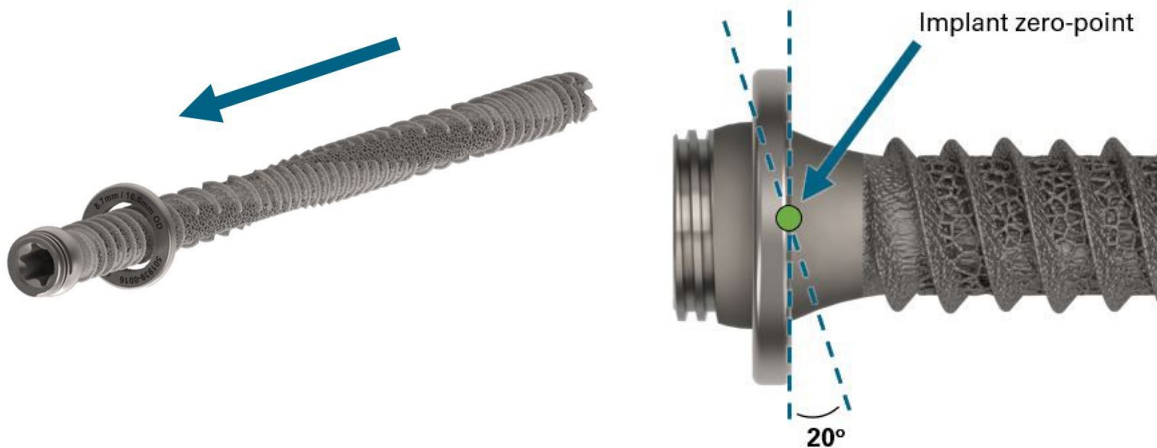


Figure 29

Precautions

There are multiple Washers in each caddy. 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 Driver assembly with the ratcheting TNT T-Handle or Inline Handle in Forward position, or by power using the Quarter Inch to Tri-Lobe Adapter. Ensure Driver is fully seated in Handle or Adapter prior to use.



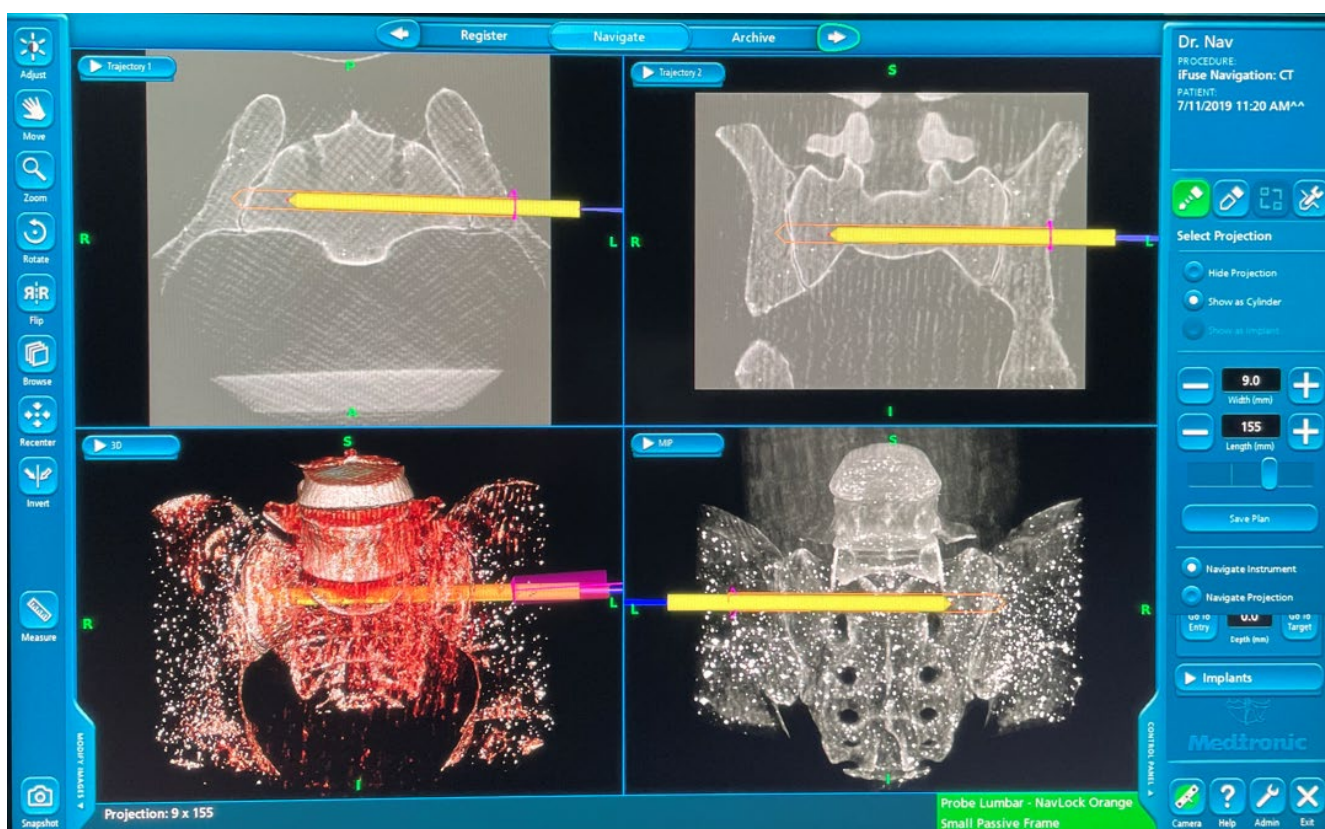
Figure 30

Note:

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

A surgical clamp (e.g. Kocher) may be used to hold the proximal end of the TNT Navigated Pin to aid in limiting unwanted Pin advancement. This technique may not be possible for longer Implant lengths.

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



Monitor the progress of the Implant on the StealthStation, and the position of the laser mark on the Driver relative to the proximal end of the STP. When the center of the laser mark is in-line with the proximal end of the STP, the Implant is fully seated.

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

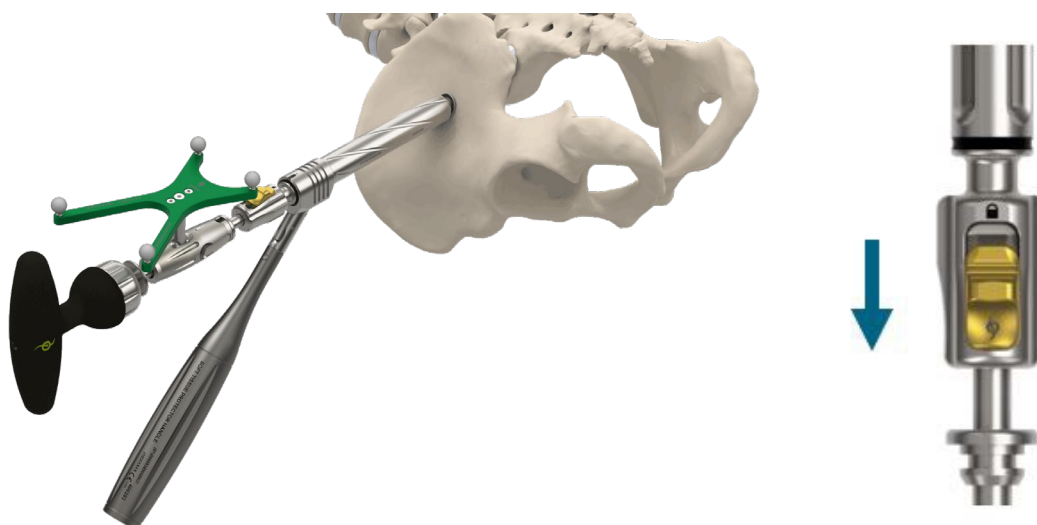
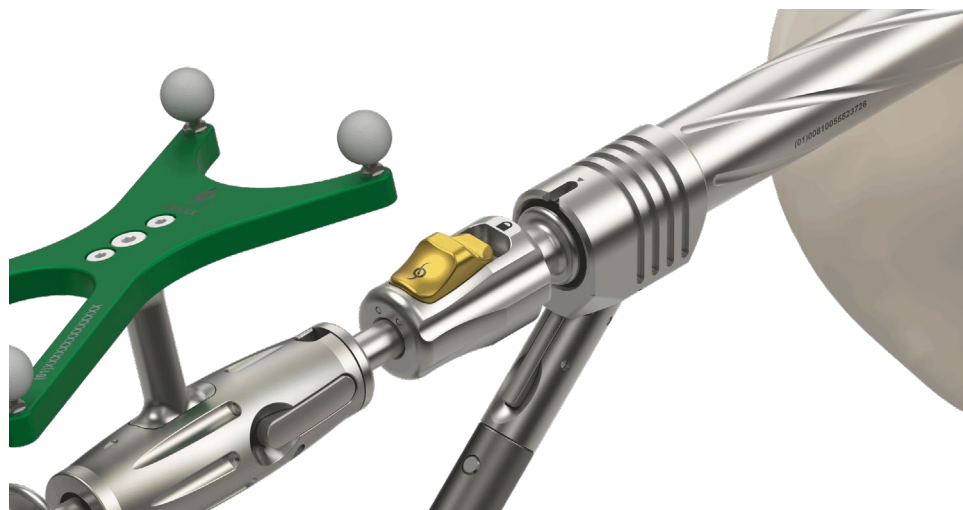


Figure 31

Note: 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.



Implant Insertion

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

Note: When fixing a fracture, fluoroscopically confirm that the Implant has adequately crossed the fracture site.

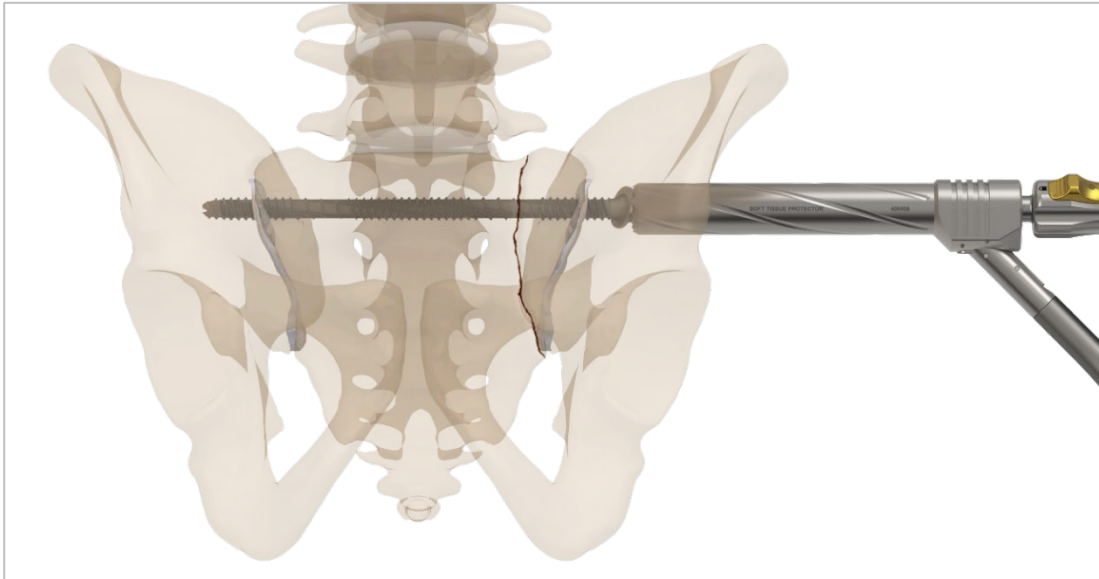


Figure 32

Precautions

- Do not over-insert an Implant. Over-insertion may result in nerve damage, hemorrhage, or the other possible adverse events listed in the Instructions for Use, 503008.
- 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.
- If placing an iFuse TORQ TNT Implant under power, monitor position of Implant and Pin. Perform final Implant positioning by hand.
- When placing additional Implants bilaterally, ensure there is no contact of the distal tip of the contralateral Implant.
- Take care when inserting the surgical instruments and the iFuse TORQ TNT Implants to avoid damage to surrounding soft tissue.
- If placing an Implant with a 21 mm Washer, tissue retractors may be used to aid in Implant placement.
- Monitor Implant projection in relation to anatomic structures (e.g., neuroforamina) during insertion.

Second Pin Placement

Depending on the patient's anatomy, placement of additional Pins may vary.

Use the TNT-NPG to determine trajectory and position for the second Implant. If the trajectory for the second Implant was previously saved, refer to that plan.

Using a second 2.5 mm Reverse Threaded TNT Navigated Pin with a pin driver, place the second Pin through the TNT-NPG and advance it into bone following the trajectory and depth saved for the second Implant.

Once the Pin has been advanced to the desired depth, check for any variations in placement compared to the original plan. If variations are noted but the Implant is in an acceptable location, re-save a new plan.

Second Implant Placement

Save the final plan of the first Implant.

Note: When placing multiple Implants with Washers make sure proper Implant spacing is planned for. Reference [Implant Spacing Table](#).

To create the Implant trajectory, set the projection length to desired Implant length and then set the diameter to 9.0 mm.

If placing a Washer on the second Implant, create and save a second plan to have a 9 mm width and 5 mm length; ensure collinearity of this plan with Implant plan. Once confirmed, expand plan width to match the desired Washer diameter (16 mm or 21 mm). This will display the Washer position on the Implant plan.

Once the desired Implant position is determined, save the trajectory/plan on the StealthStation.

Return to "Planned Implant Position" and insert the second Implant following the previously described steps.

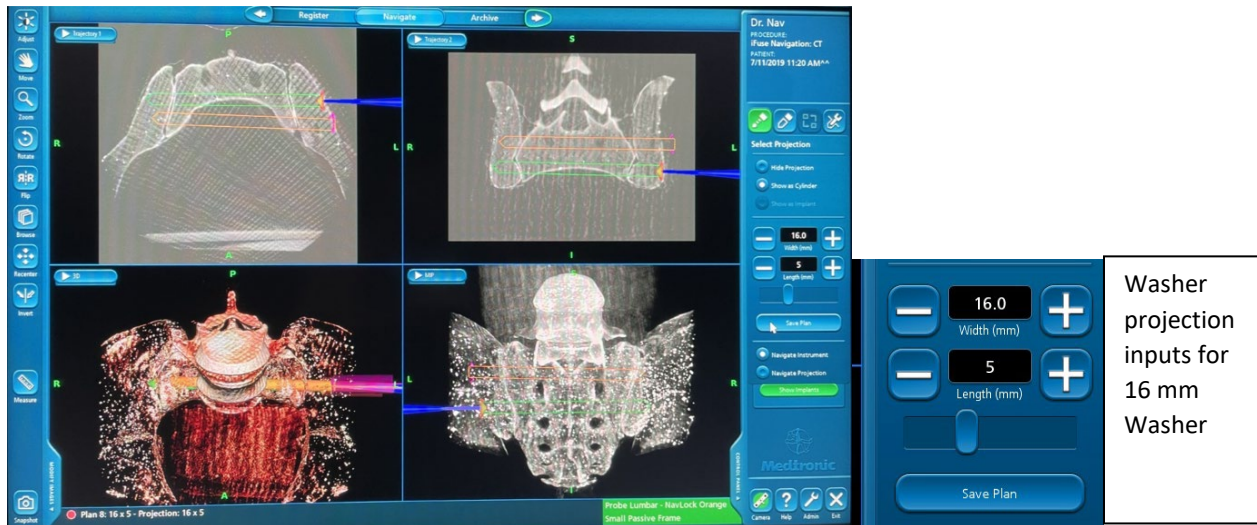


Figure 33

Note: If placement of an iFuse TORQ Implant is also desired, please refer to STM 300891-US for the iFuse TORQ Implant surgical steps.

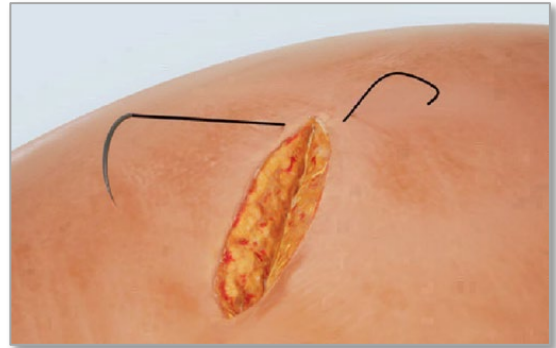
Precautions

- Minimum Implant spacing assumes parallel Pins. Consider adding additional distance between Pins and/or Implant placement 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.
- When placing additional Implants bilaterally, ensure there is no contact with the distal tip of the contralateral Implant.

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

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

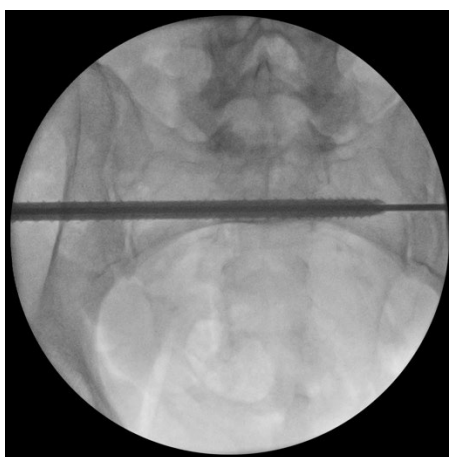
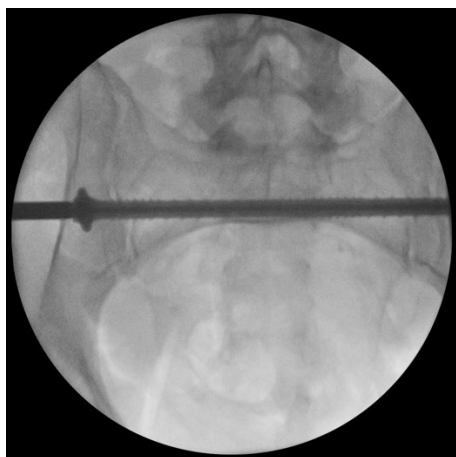
Place a Pin through the Implant.

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

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

Rotate counterclockwise to remove the Implant.

Consider using fluoroscopy to aid in Implant removal.



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 Navigation Instruments

Part Numbers	Description
400464	iFuse TORQ TNT Navigation Instrument Tray Set
400417	iFuse TORQ TNT 5.5 mm Navigated Bit
400424	iFuse TORQ TNT Locking Driver
400434	iFuse TORQ TNT Navigated Pin Guide
400380	Fixed Tracker Screwdriver
501917	Reverse Threaded Navigated Pin, 2.5 mm, iFuse TORQ TNT
400366*	Fixed Tracker – Blue

*Fixed Tracker - Blue can be replaced with alternatives Fixed Trackers Gold (P/N 400367), Green (P/N 400368), Purple (P/N 400369); TeraTrackers Blue (P/N 9730489), Green (P/N 9730490), Gold, (P/N 9730491), Purple (P/N 9730492).

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**



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