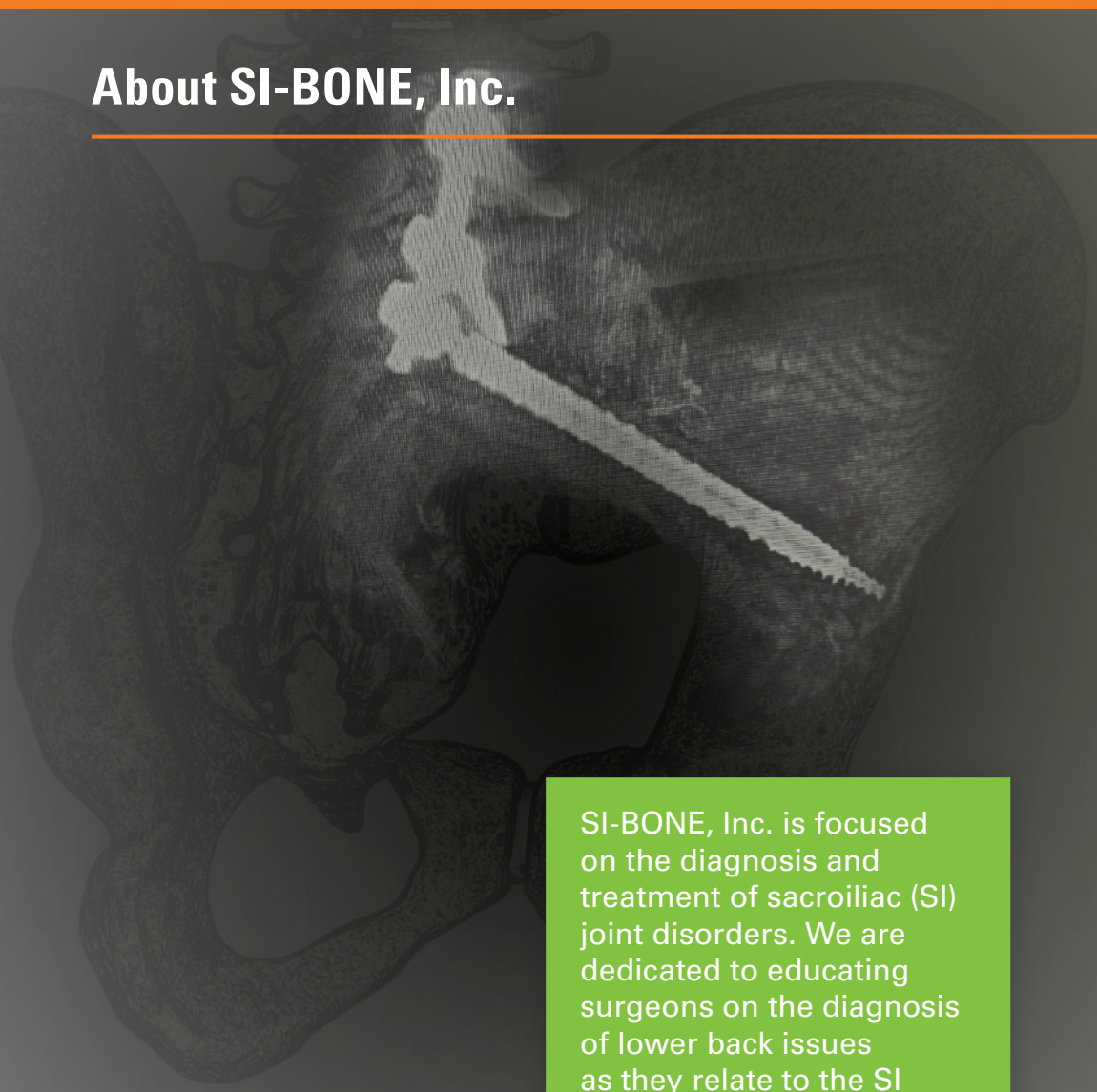
Deformity

iFuse Bedrock Granite®
Surgical Technique Manual

SI-BONE®
Sacropelvic Solutions™

Contents

About SI-BONE, Inc.



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

iFuse Bedrock Granite® System: Introduction

The iFuse Bedrock Granite Implant System is intended to provide fusion of the sacroiliac joint and fixation to the pelvis when used with pedicle screw fixation as a foundational element for segmental spinal fusion. The procedure can be performed through an open surgical technique, or a minimally invasive surgical technique and implants are typically placed in a sacral-alar-iliac or iliac trajectory. Treatment with the iFuse Bedrock Granite Implant System was designed to minimize complications seen in multilevel long constructs (i.e., screw breakage, screw loosening, rod breakage, set screw failures) and address the stresses of the heavily loaded sacroiliac joint.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Bedrock Granite Implant System. Please review the Instructions For Use for a complete discussion of contraindications, warnings, precautions and risks.

iFuse Bedrock Granite® System Advantage

The iFuse Bedrock Granite System is intended for SI joint fusion and pelvic fixation.

ADVANTAGES:

- ***Intelliharvest Fenestrations*** *– Graduated fenestrations designed for optimal bone self-harvesting*
- ***FuSIon 3D Surface*** *– 3D-printed microporous lattice surfaces that mimic native cancellous bone for enhanced bone fixation*
- ***EZDrive Tip*** *– Tapered tip designed to reduce insertion force and offer more controlled Implant placement*
- ***OMNICapture System*** *– Designed to mitigate tulip splay, set screw disassociation, Implant neck fracture, and cross-threading while providing higher locking torque. Larger degree of tulip angulation for improved rod approximation*
- *Designed specifically for foundational fixation of multilevel long constructs and to fuse the heavily loaded SI joint*

Implant Part Numbers

		Diameter (mm)		
		9.5	10.5	11.5
	40	095040BG	—	—
	45	095045BG	—	—
	50	095050BG	105050BG	—
	60	095060BG	105060BG	—
	70	095070BG	105070BG	115070BG
	80	095080BG	105080BG	115080BG
	90	095090BG	105090BG	115090BG
	100	095100BG	105100BG	115100BG
	110	095110BG	105110BG	—
Length (mm) Open Head Tulip	120	095120BG	105120BG	—
	50	095050CH	105050CH	—
	60	095060CH	105060CH	—
	70	095070CH	105070CH	115070CH
	80	095080CH	105080CH	115080CH
	90	095090CH	105090CH	115090CH
	100	095100CH	105100CH	115100CH
	110	095110CH	105110CH	—
Length (mm) Closed Head Tulip	120	095120CH	105120CH	—

Description	Standard Part No.
Set Screw	501117

Pre-Op Planning and Patient Set-Up

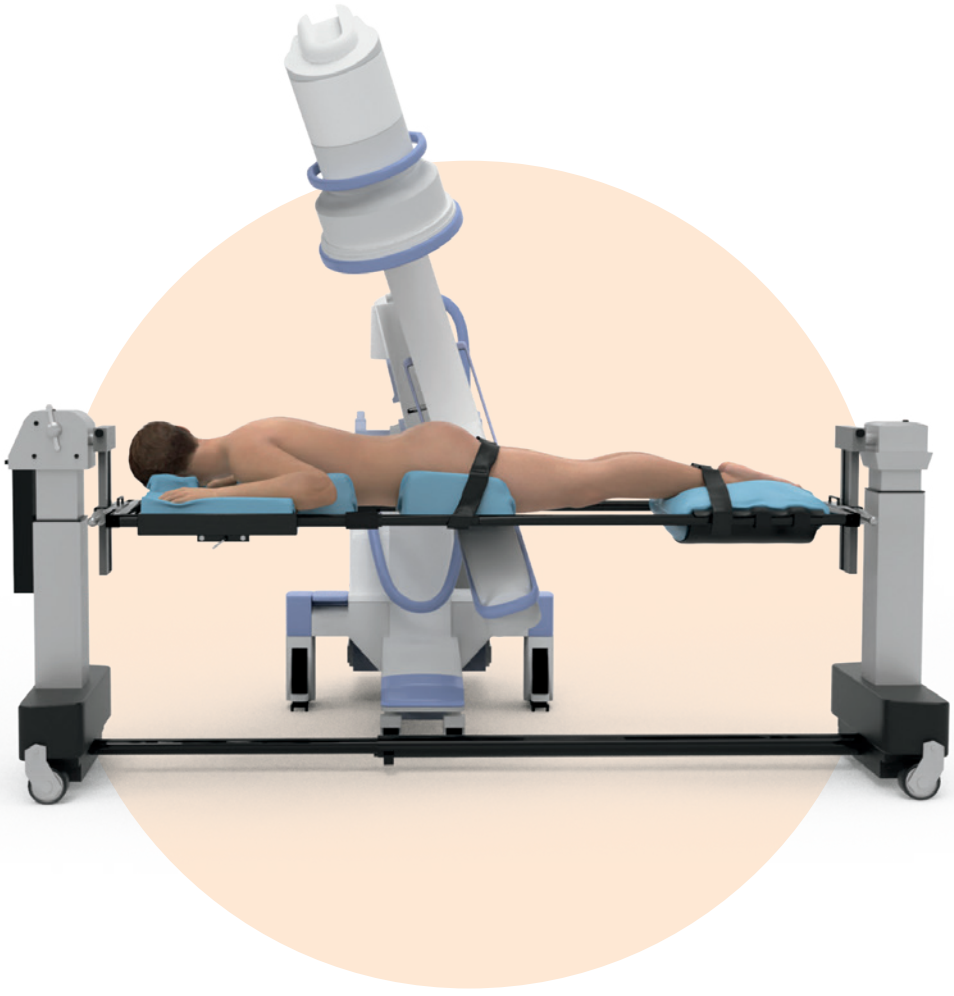
Pre-Op Planning

- A CT is recommended for pre-op planning.
  - » Check for anatomic abnormalities
- Ensure compatibility of all planned implanted components. This may involve contacting your SI-BONE representative or the pedicle screw manufacturer with any questions or concerns to ensure compatibility of all implanted components.

Patient Positioning:

- This procedure may be performed in standard prone positioning for deformity surgery.

***NOTE**: This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the surgeon's judgment. Instruments not shown in this manual may be used at the surgeon's discretion.*



Open Procedure: Fluoroscopic Guidance

- Utilize anterior-posterior (AP) view of the pelvis (or outlet view) for approximation of the sciatic notch. Instrument/Implant path should be just cephalad (within 20 mm) of the sciatic notch when aiming toward the (anterior inferior iliac spine) AIIS.
- Utilize an inlet view to confirm trajectory has not violated the ventral cortex of the pelvis.
- Utilize the teardrop view to confirm the anterior posterior trajectory is within the confines of the iliac tables. Obturator oblique with a 30° caudal and 30° lateral beam. Reference **Figs. 1-4** for C-arm set up and approximate fluoroscopic result.

Figure 1

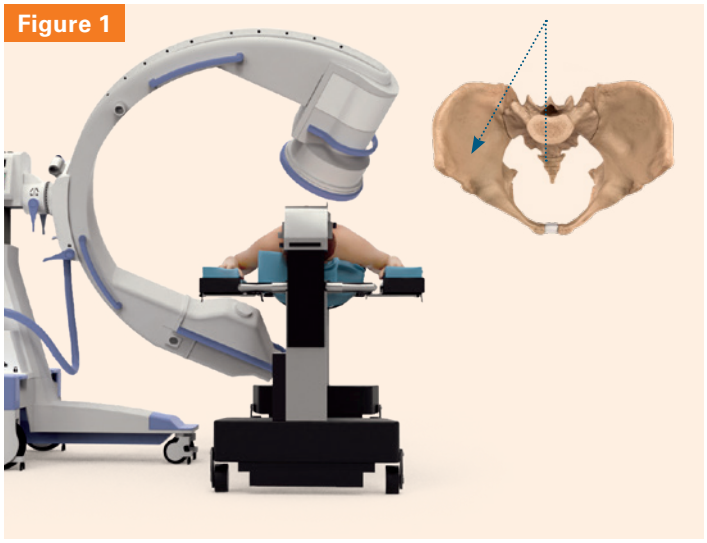


Figure 2

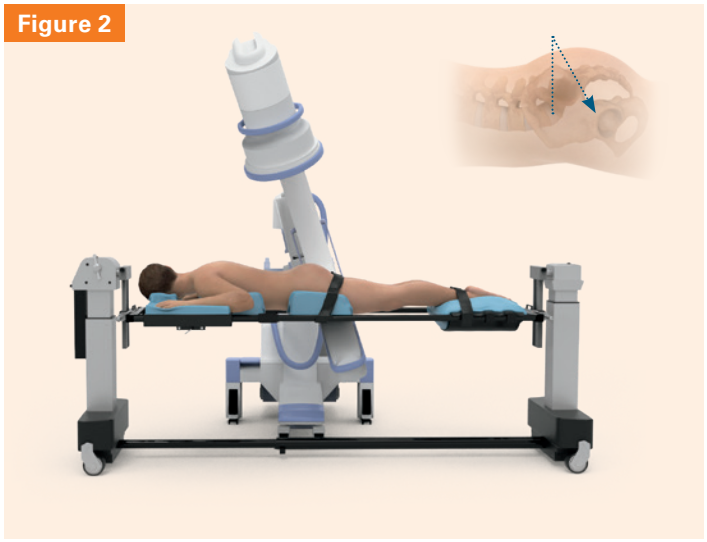


Figure 3

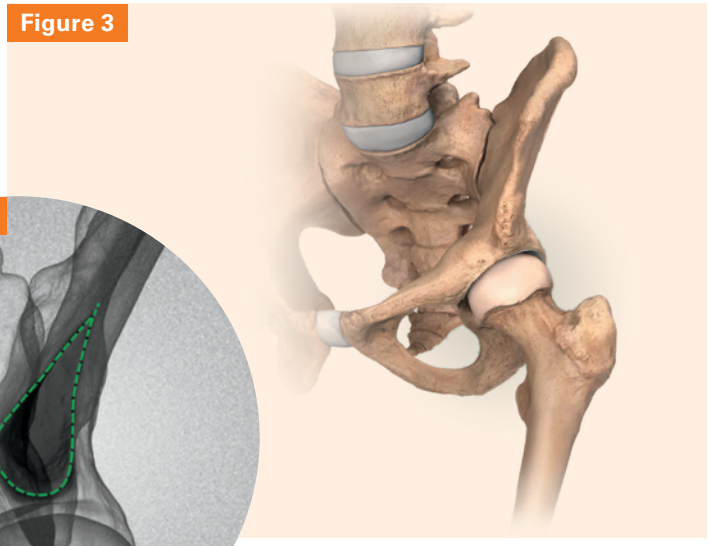
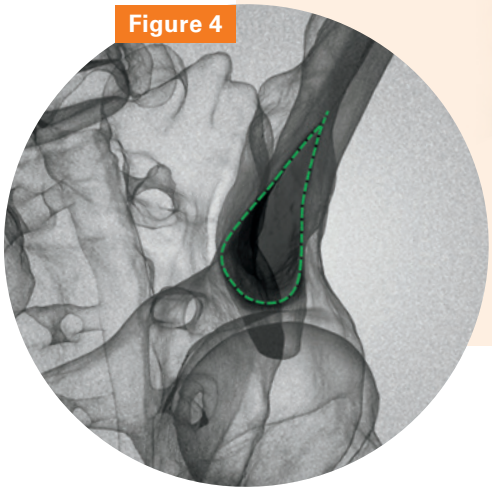


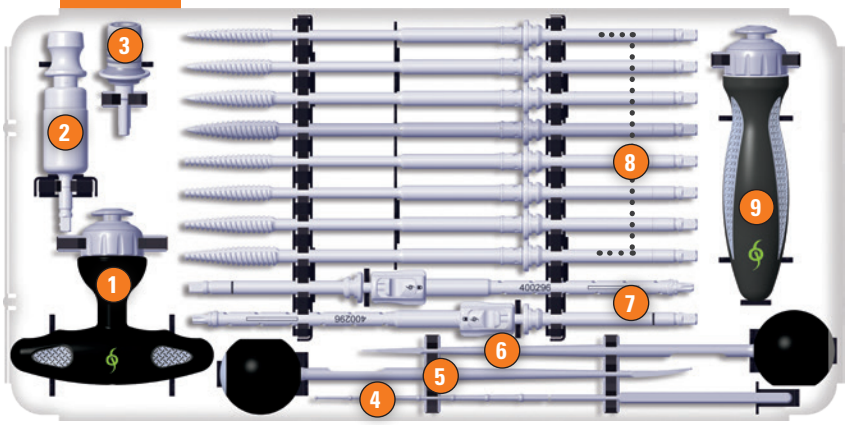
Figure 4



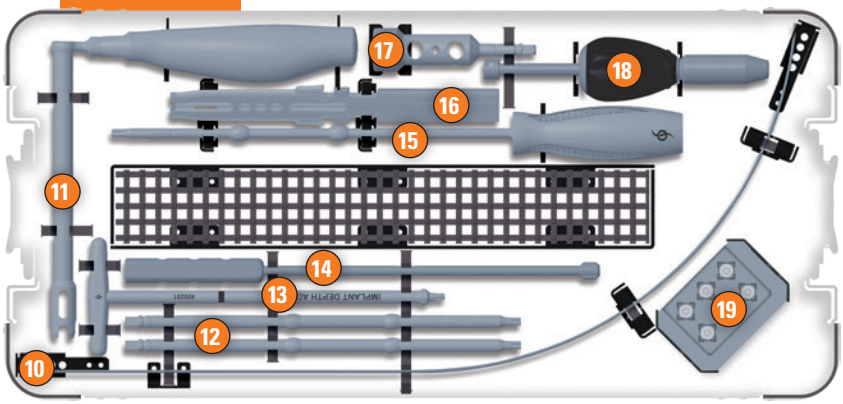
Open Procedure: Instrument Tray Layout

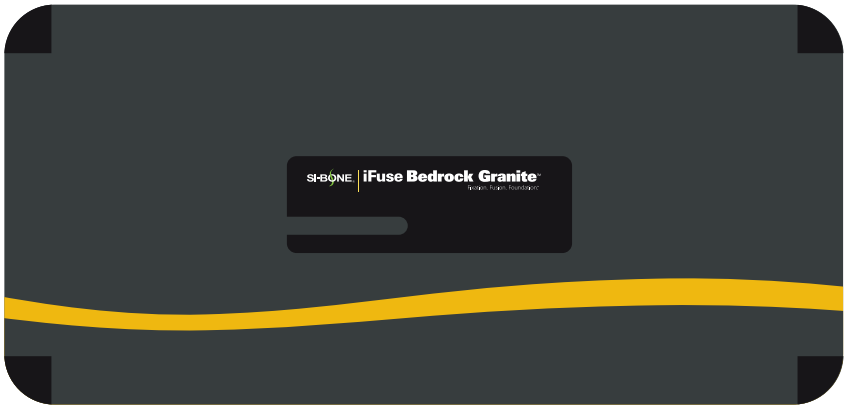
1. T-Handle, Ratcheting, Quarter Square, Low Profile
2. Torque Limiting Adapter 115 in-lb
3. QC Adapter, Quarter Inch to Trilobe
4. iFuse Bedrock Granite Measurement Probe
5. Bone Probe, Curved
6. Bone Probe, Straight
7. Navigation, Locking Driver
8. Taps (Cannulated and Awl Tip)
9. Inline Handle, Ratcheting, Quarter Square, Low Profile
10. iFuse Bedrock Granite Guidewire Sharp (1.4 mm) – Disposable item
11. Counter Torque
12. T30 Final Driver
13. Implant Depth Adjuster
14. Closed Head Turner, Axial Handle
15. Set Screw Starter, Axial
16. Axial Reducer
17. iFuse Bedrock Granite Threaded Reducer Extension
18. Guidewire Driver
19. Set Screw Caddy

Top Shelf



Bottom Shelf





Open Procedure: Pilot Hole Preparation

- Prepare a pilot hole for the Implant using the Bone Probe, typically at the midpoint between the S1 and S2 dorsal foramen and in line with the lateral border of the foramen **(Fig. 5).**
- Advance the Bone Probe toward the patient's anterior inferior iliac spine, which can be found by palpating the top of the greater trochanter **(Fig. 6).**
- Advance the Bone Probe to terminal depth **(Fig 7).** Depth markings are available for Implant measurement.
- Use fluoroscopy to confirm trajectory as the instrument advances.

NOTE: *The gold, box tip length of the Bone Probe is 30 mm, with depth markings from 30 mm to 120 mm, marked in 10 mm increments.*

PRECAUTION: *The Bone Probe tip is sharp and can puncture or tear gloves.*

Bone Probe

Figure 5

Figure 6

Figure 7

Open Procedure: Pilot Hole Verification

- Advance the Measurement Probe into the pilot hole to confirm the integrity of the inner and outer cortical walls of the ilium and measure desired Implant length **(Fig. 8).**
- Determine the desired Implant length by counting the number of nodes on the Measurement Probe **(Fig. 9).**

NOTE:

- *The nodes are spaced apart in 20 mm increments from 20-120 mm.*
- *The depth of Implant engagement within the sacrum and the ilium may be visualized using the Measurement Probe in an outlet oblique view* ***(Fig. 10, 11).***
- *A standard ball-tip feeler probe may also be used to confirm pilot hole integrity.*
- *A surgical clamp may be used on the Measurement Probe or the standard ball-tip feeler probe at the dorsal sacrum to confirm depth measurement by counting the nodes on the Measurement Probe or measuring the ball-tip feeler.*

Measurement Probe

Figure 8

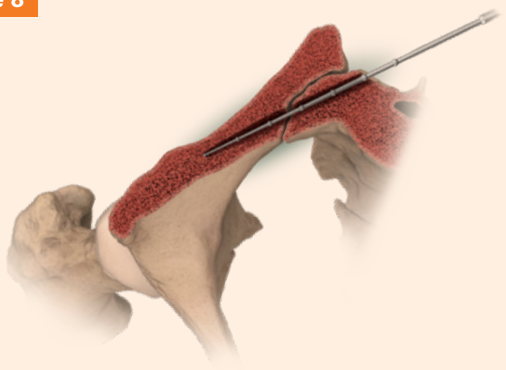


Figure 9

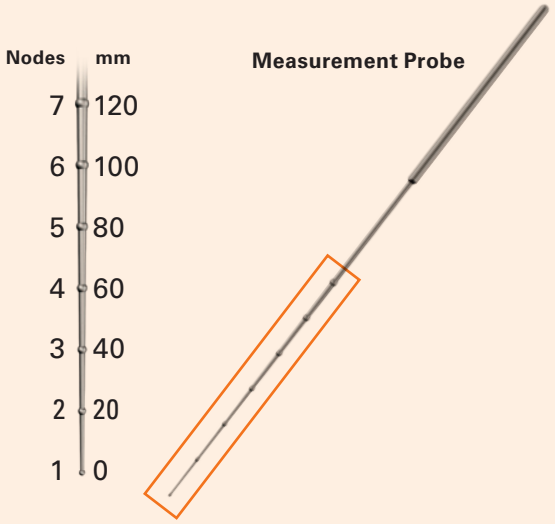
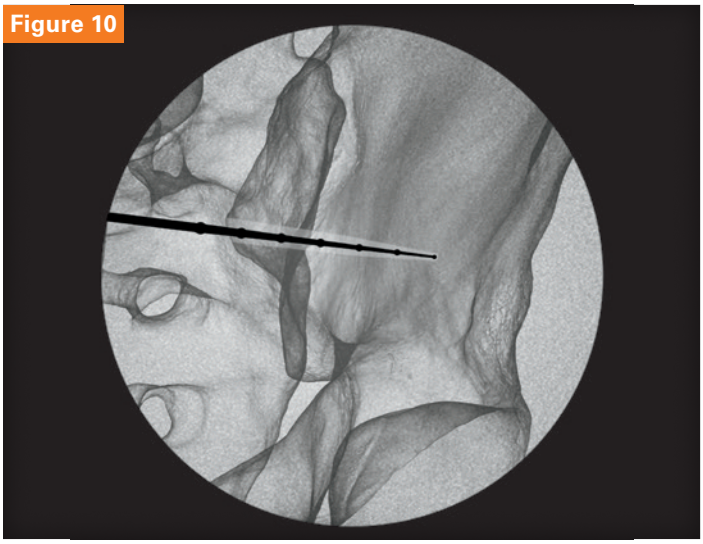


Figure 10



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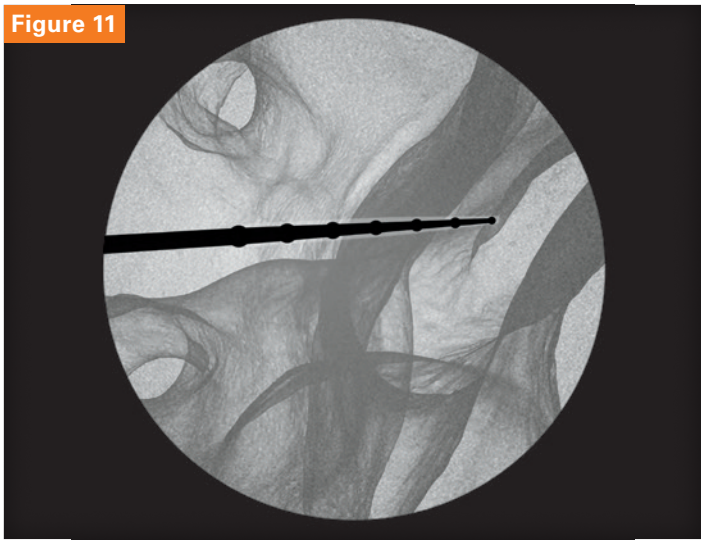


Open Procedure: Tapping

- Solid Awl Tip Taps and Cannulated Taps for use over a Guidewire are provided.
- Sequentially tap to desired Implant length and diameter **(Fig. 12)** using the depth markings for reference (60 mm – 120 mm in 10 mm increments).

NOTE**: Some users may elect to undersize with taps based on bone quality **(Table, Fig. 13).

- Confirm tap depth and placement as the instrument advances under fluoroscopic visualization.

NOTE:

- *Taps are true to size (i.e. the 10.5 mm Tap has a 10.5 mm major diameter).*
- *The black ring on the proximal shaft of the Tap will not be visible when the handles or the optional Quick Connect (QC) Adapter are properly engaged **(Fig. 14).***
- *All Taps have depth markings from 60 mm to 120 mm, in 10 mm increments.*
- *A QC Adapter (1/4" square to Tri-lobe) for use with power is provided.*
- *If utilizing the Standard Cannulated Taps or Standard Awl Tip Taps and terminal depth cannot be reached, utilize the Granite Cannulated and Awl Tip Taps from the Open Instrument Tray.*
- *The iFuse Bedrock Granite 6.5 mm Awl Tip Tap may be used as a starter tap.*

Solid Awl Tip Tap

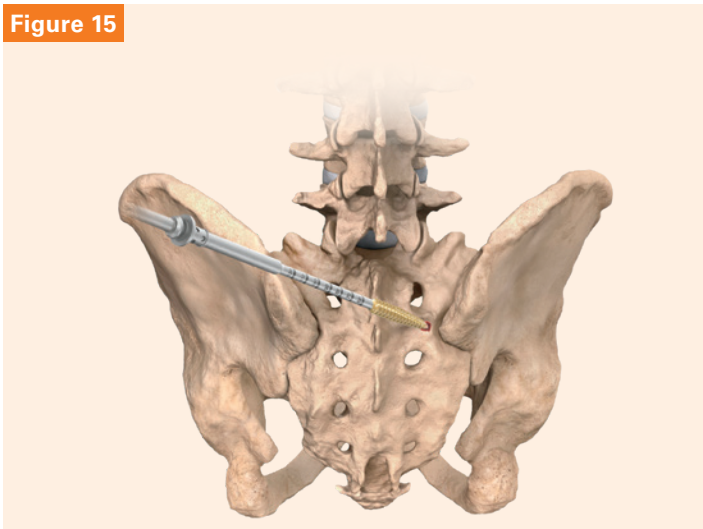
Figure 12

Figure 13

Implant Size (mm)	Undersized	Line-to-Line
9.5	6.5, 8.5	9.5
10.5	6.5, 8.5, 9.5	10.5
11.5	6.5, 8.5, 9.5, 10.5	11.5
Additional tap sizes are available upon request		

Figure 14

Figure 15



Open Procedure: Transferring the Implant to the Sterile Field

Circulator

- Remove the outer polywrap of the Implant tube and remove labels.

> ***NOTE**: Implant sizing may be referenced on both the cap and the tube.*

- Hold the Implant tube vertically in one hand with the cap up. Unscrew and remove the cap counterclockwise, breaking the seal **(Fig. 16).**

> ***NOTE**: Once Implant tube cap is removed, do not touch the sterile threaded portion of the Implant tube or the sterile clamshell **(Fig. 17).***

- Aseptically transfer the contents of tube (clamshell containing Implant) to the sterile field.
  - » OPTION 1: Hand-to-hand transfer
  - » OPTION 2: Drop transfer to sterile basin

Figure 16

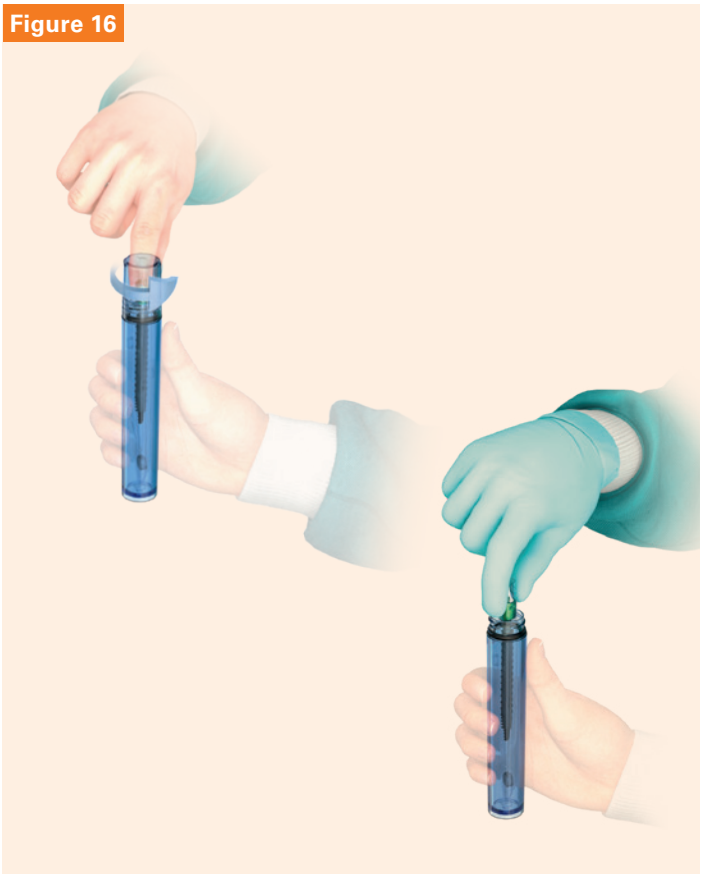
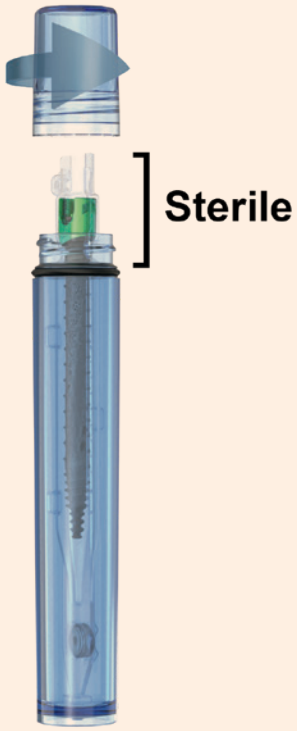


Figure 17



Open Procedure: Implant Loading

Back Table Assist (sterile)

- Hold the sterile clamshell packaging vertically. Pinch the tulip and neck through the clamshell to prevent tulip rotation **(Fig. 18).**
- Insert the hexalobe tip of the Navigated Locking Driver into the hexalobe drive feature of the screw **(Fig. 19).**
- Maintaining the Implant in a vertical position, advance the outer sleeve of driver into tulip. Rotate the outer sleeve clockwise until it is fully engaged into tulip threads **(Fig. 20).**
- Slide the gold locking button distally toward the Implant into the locked position **(Fig. 21).**
- With a secure hold on the sterile clamshell, remove the loaded Implant assembly by pulling up on the Navigated Locking Driver **(Fig. 22)**.
- Keep the sterile clamshell which contains the Implant set screw.

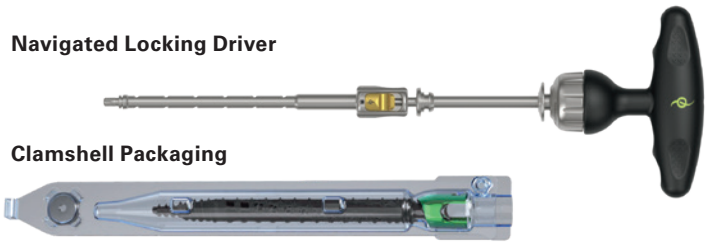


Figure 18

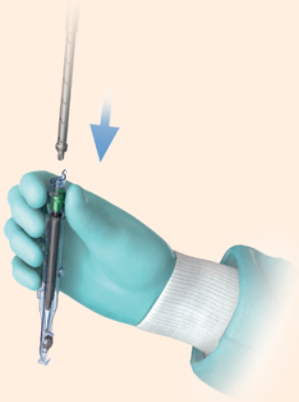


Figure 19

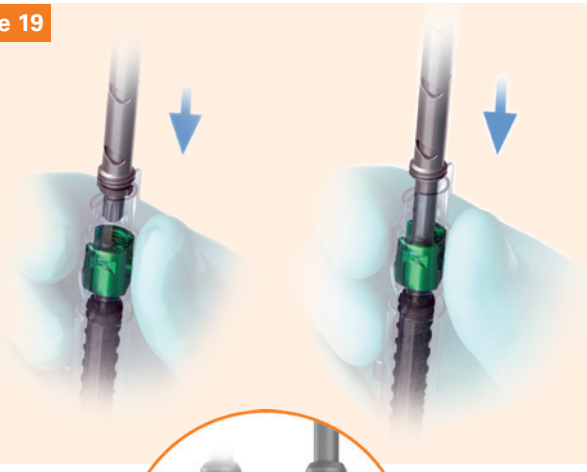


Figure 20

Figure 21

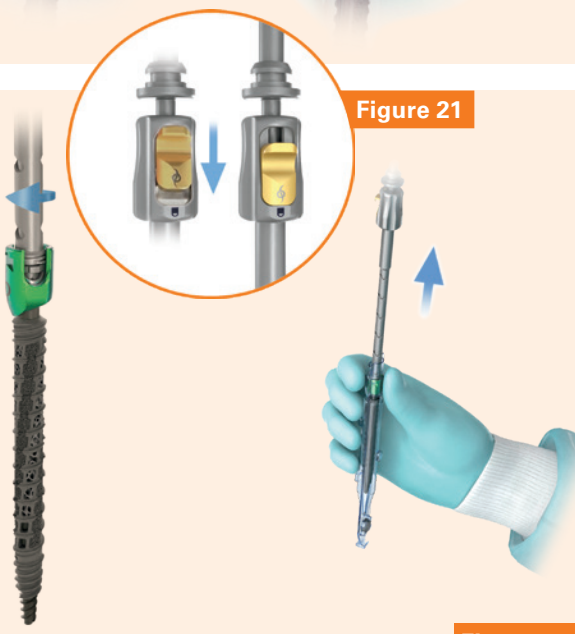


Figure 22

Open Procedure: Implant Placement

- Attach desired handle to the proximal end of the Navigated Locking Driver and advance the Implant assembly to desired depth using fluoroscopy **(Fig. 23).**

***NOTE**: The black ring on the proximal shaft of the Navigated Locking Driver will not be visible when the handles or the optional Quick Connect (QC) Adapter are properly engaged.*

- Slide the gold locking button proximally, away from Implant into the unlocked position.
- Unthread the outer sleeve of the Navigated Locking Driver from the tulip threads by rotating counterclockwise **(Fig. 24).**
- Remove the Navigated Locking Driver from placed Implant.

***NOTE**:*

- *A Closed Head Turner is available to rotate both Open Head and Closed Head Implant tulips clockwise to optimize the favored angle. Do not rotate the tulip counterclockwise. Rotating counterclockwise may unthread the tulip head from the Implant body.*
- *A Depth Adjuster with Wings is available for use with Open Head Implants to make additional adjustment to implant depth.* ***This instrument is not compatible with Closed Head Implants.***
- *If utilizing the Standard Locking Driver and terminal depth cannot be reached, utilize the Navigated Locking Driver from the Open Instrument Tray.*

Figure 23

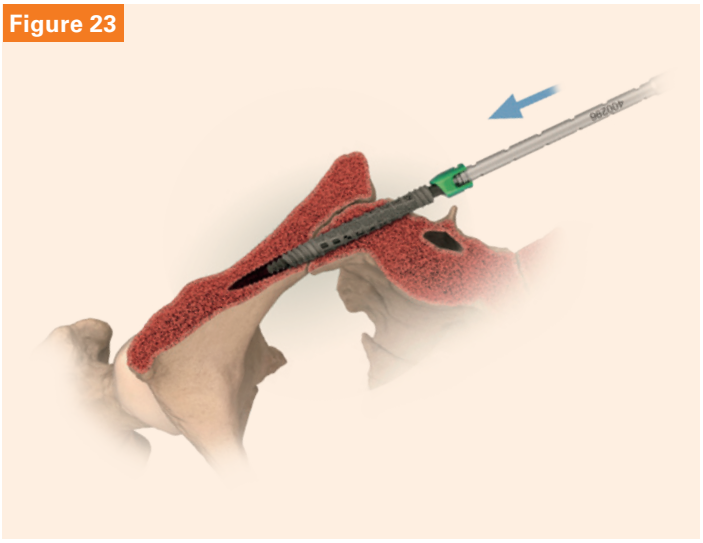
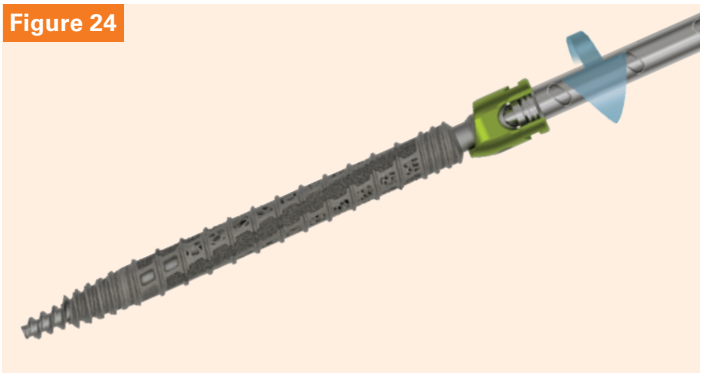


Figure 24



PRECAUTIONS:

- *As the Implant advances, the sacroiliac joint cortices may deflect the Implant anteriorly. Use either inlet or teardrop fluoroscopy to confirm desired trajectory is maintained.*
- *Instrument and Implant tips have potential to puncture or tear gloves.*

Open Procedure: Rod Reduction & Set Screw Placement

- Retract the inner sleeve of the Axial Reducer by rotating the knurled knob counterclockwise. Secure the distal attachment feature of the Axial Reducer onto the tulip head until full engagement can be confirmed.
- Turn the knurled knob of the Axial Reducer clockwise to advance the inner sleeve until the rod is fully reduced and seated into the bottom of the tulip head **(Fig. 25).**
- Alignment of the black and silver laser mark indicates when the rod is fully seated and reduction is complete.
- Retain the set screw onto the Set Screw Starter by aligning the distal star tip of the Set Screw Starter to the set screw and pushing down firmly. The Set Screw Starter will self-retain the set screw. **(Fig. 26)**
- Insert the Set Screw Starter with set screw attached through the center of the Axial Reducer. Orient the set screw perpendicular to the tulip head and tighten until "two-finger tight."
- Remove the Set Screw Starter by pulling up.

NOTE:

- *There are six additional set screws found within the Set Screw Caddy in the instrument tray, should the set screw from the original Implant packaging be compromised.* ***(Fig. 27)***
- *Facilitate the set screw engagement by rotating the Set Screw Starter counter-clockwise, then clockwise to properly engage the threads. This will mitigate cross-threading.*

- To disengage the Axial Reducer, depress both side buttons and detach from the tulip head.

Figure 25

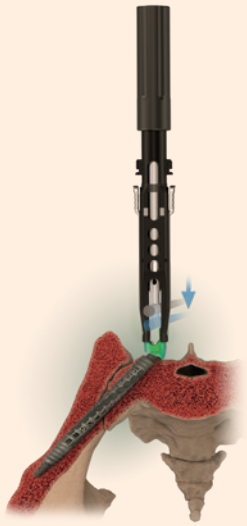


Figure 26

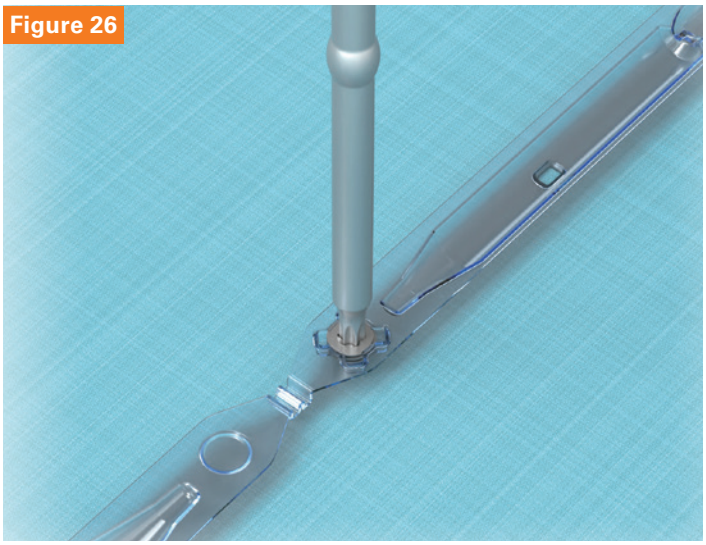


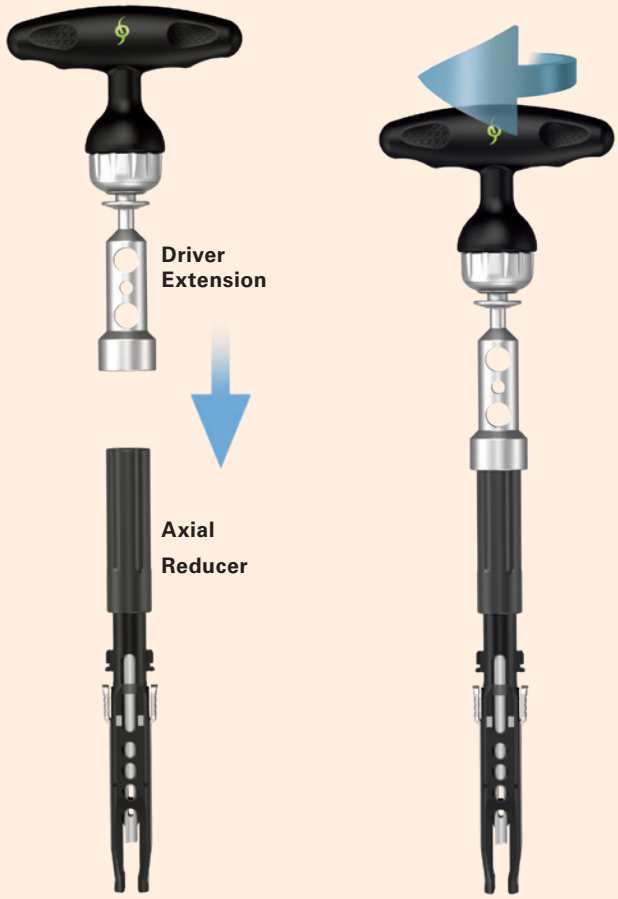
Figure 27

Open Procedure: Rod Reduction & Set Screw Placement

OPTIONAL: Use the Threaded Reducer Extension in conjunction with a modular handle to apply additional torque during rod reduction **(Fig. 28).**

- This assembly requires the preferred modular handle, Reducer Driver Extension, and Axial Reducer.

Figure 28

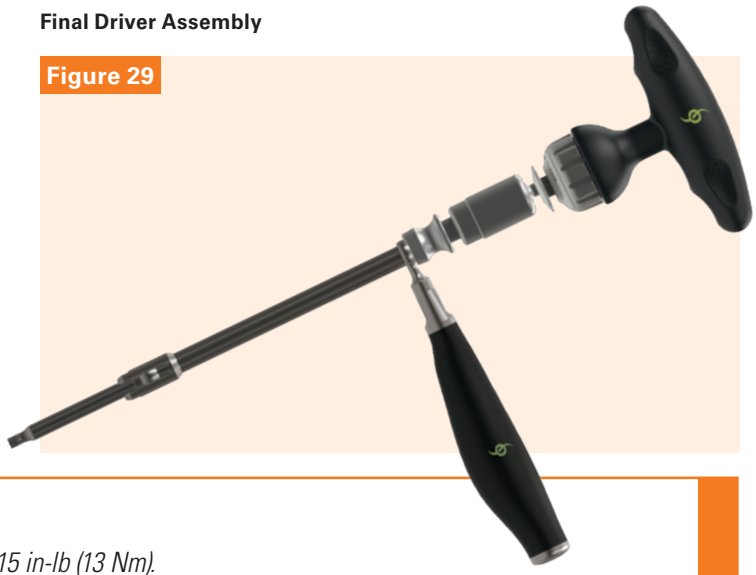


Open Procedure: Final Tightening

- Assemble the T30 Final Driver **(Fig 29 b)** to the Torque Limiting Adapter **(Fig 29 c),** and to the T-Handle **(Fig 29 d).** Slide the distal end of the T30 Final Driver through Counter Torque **(Fig 29 a)** and into the set screw head. Slide the Counter Torque down, perpendicular to the rod and fully seated over the Implant tulip. **(Fig. 30).**
- Final tighten the set screw by slowly turning the T-Handle clockwise until a minimum of two audible clicks are heard or tangibly felt.

Final Driver Assembly

Figure 29



NOTE:

- *The iFuse Bedrock Granite System requires final tightening to 115 in-lb (13 Nm).*
- *During final tightening, when resistance is felt, each rotation should take 1-2 seconds to reach the audible click.*
- *If the Granite Implant is final tightened before the rest of the pedicle screw construct, it is recommended to final tighten the Granite Implant again before closing the incision.*
- *Set screws should not sit proud of the tulip if properly final tightened. The set screw will sit slightly recessed in the tulip head when used with a 5.5 mm rod, and will sit flush with the top of the tulip when used with a 6.0 mm rod.*

ALWAYS use the Torque Limiting Adapter together with the Counter Torque to prevent disruption of the construct.

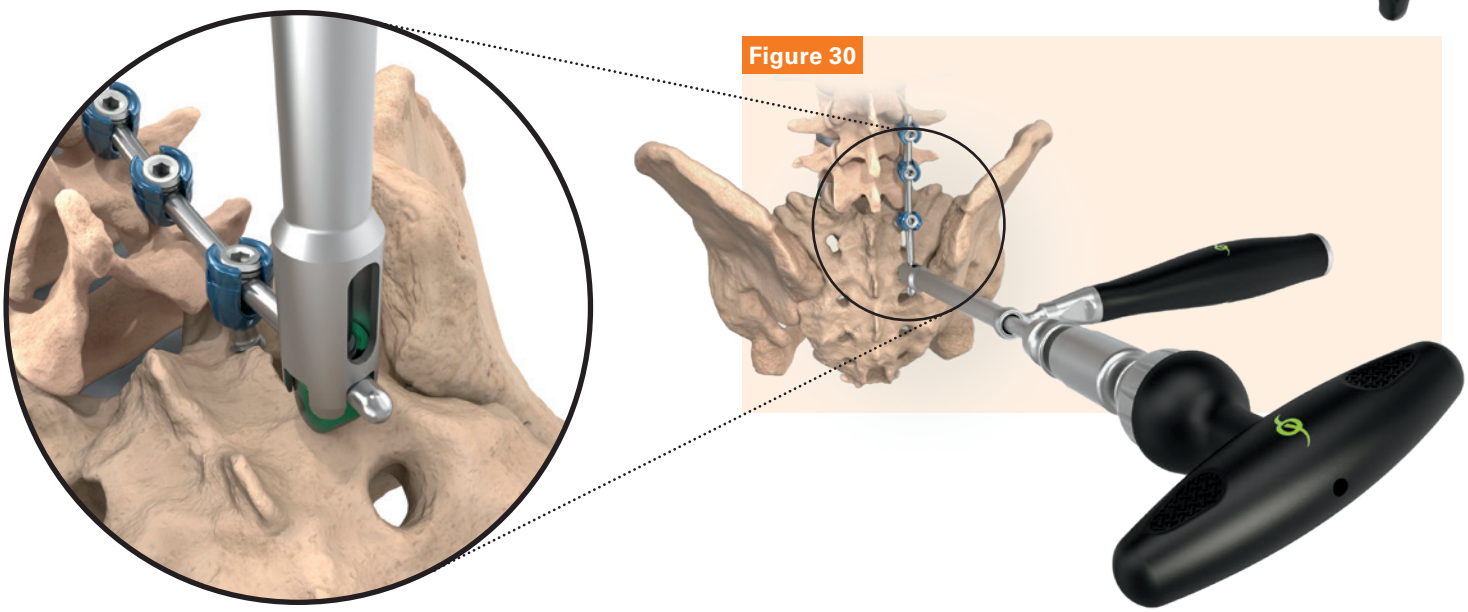
Figure 29 a

Figure 29 b

Figure 29 c

Figure 29 d

Figure 30



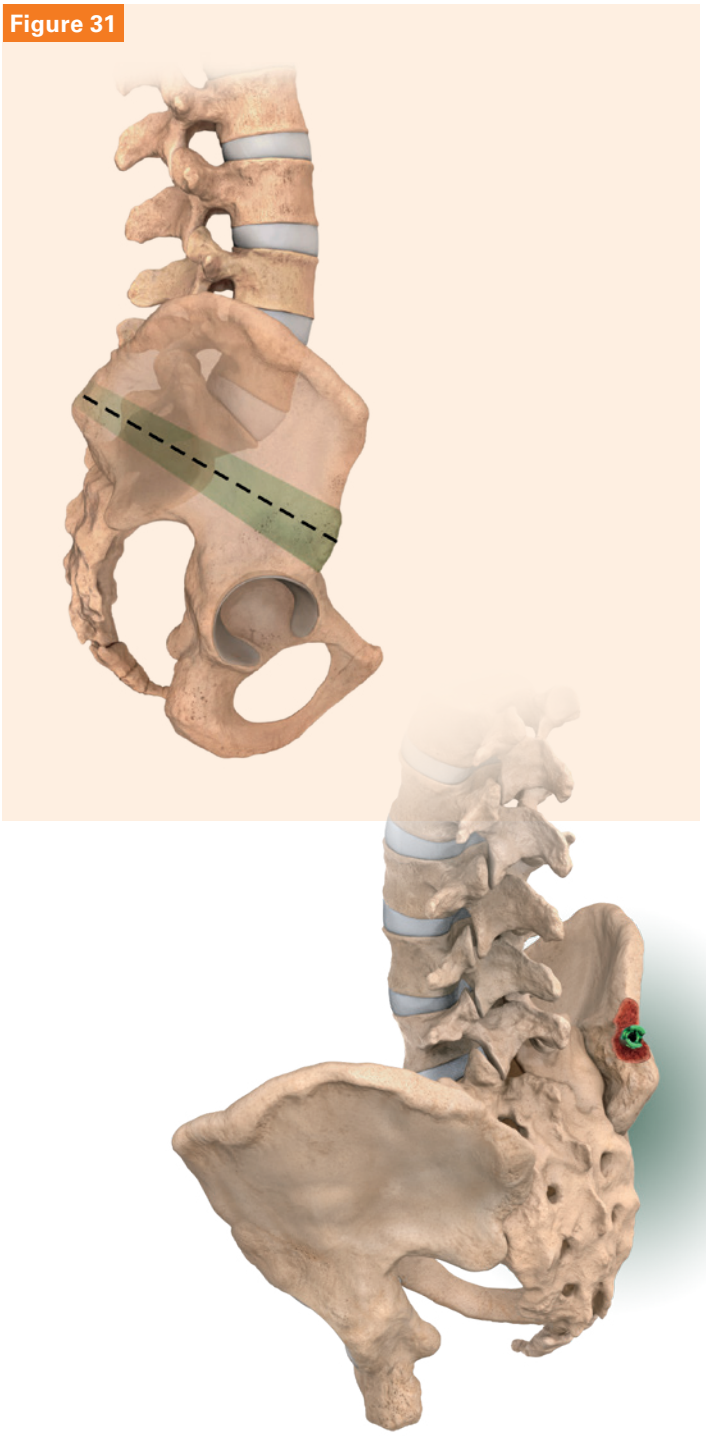
Procedure: Iliac Placement (Optional)

- One or more Granite Implants may be placed in an iliac trajectory using standard techniques and the same instrument sequence as S2AI placement.

> ***NOTE**: The iFuse Bedrock Granite Implant System does not include transverse connectors or rods..*

- The iliac trajectory is highly variable, but typically is angled approximately 20–45 degrees caudal and 30–45 degrees lateral. In selected cases, placement of two Granite Implants per ilium can be performed as well. In these cases, careful planning of the first Implant will make placement of the second Implant easier, as the more caudal Implant should be placed low within the ilium 'tear drop' and immediately above the sciatic notch. This will allow adequate room for the second Implant within the remainder of the cephalad ilium.

Figure 31

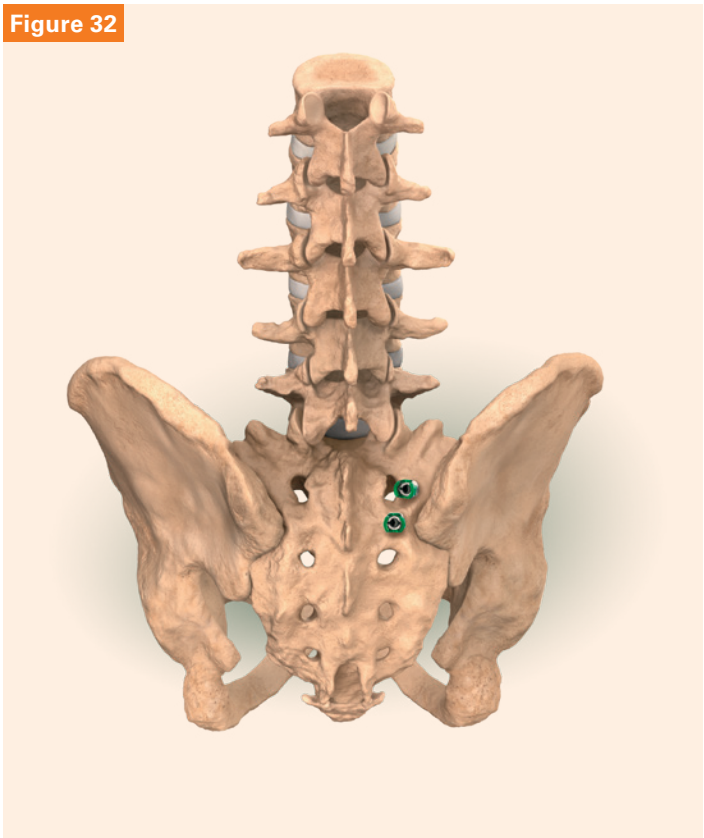


Procedure: Stacked Granite Placement (Optional)

- A second Granite Implant may be placed in conjunction with an S2AI-trajectory Granite Implant. The second, cephalad Implant starting point is typically midway between the S1 pedicle screw and S2AI Implant. Frequently placed at the lateral border of the S1 neuroforamen. In these selected cases, careful planning of the first Implant will make placement of the second Implant easier.
- The trajectory of the Implant path runs in a caudal and lateral direction through the ala and into the ilium, towards the ASIS. The surgeon should direct the Implant 40°–50° laterally in the transverse plane, similar to S2AI screws.

NOTE: *If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI Joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.*

Figure 32

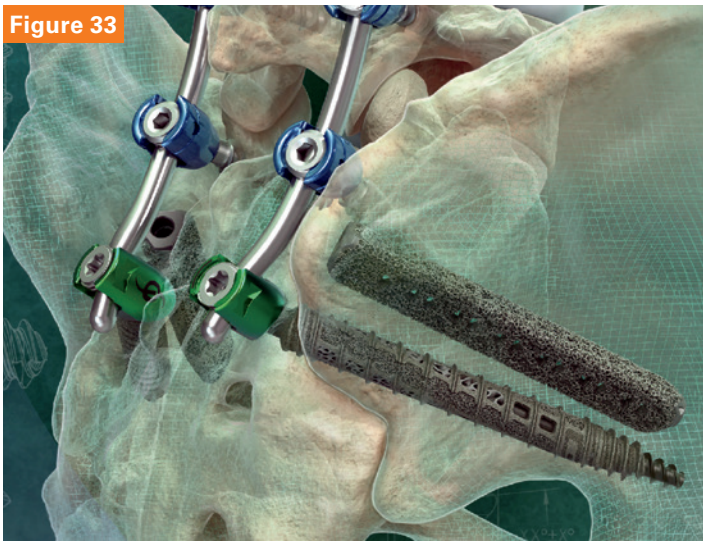


Procedure: iFuse Bedrock + Granite (Optional)

- A secondary iFuse Implant may be used in conjunction with a Granite Implant using standard techniques and the same instrument sequence as S2AI placement.
- The second, cephalad iFuse Implant starting point is typically midway between the S1 pedicle screw and S2AI Implant. Frequently placed at the lateral border of the S1 neuroforamen. In these selected cases, careful planning of the first Implant will make placement of the second Implant easier.

NOTE: *If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI Joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.*

Figure 33

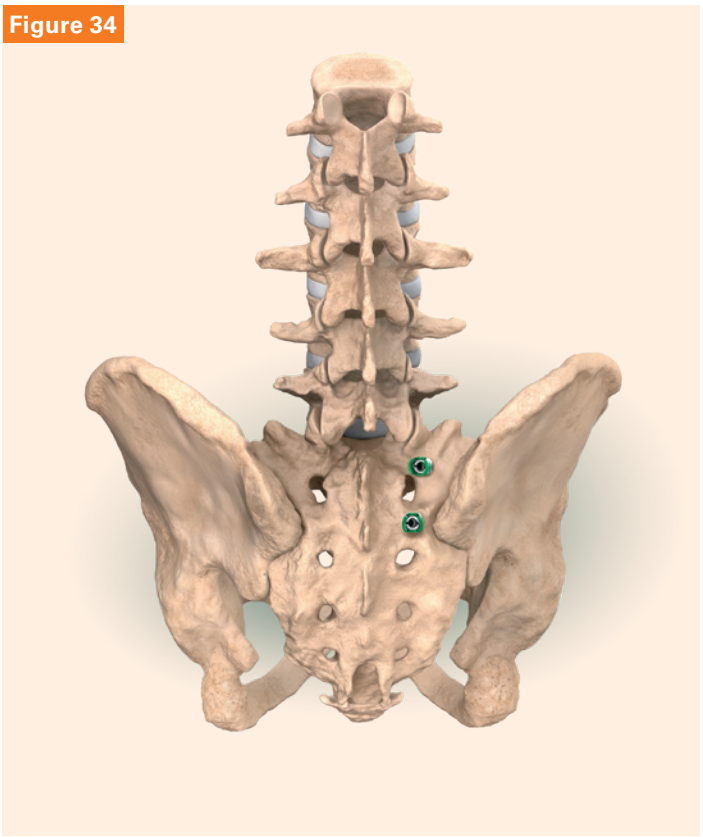


Procedure: S1AI Placement (Optional)

- A second Granite Implant may be placed in conjunction with an S2AI-trajectory Granite Implant, in an S1AI trajectory. Placement will use standard techniques and the same instrument sequence as S2AI placement. The S1AI trajectory is highly variable, but typically starts just lateral to the junction of the S1 superior articular facet and the posterior sacral ala. It is typically 3-5 mm above the superolateral corner of the S1 foramen. In these selected cases, careful planning of the first Implant will make placement of the second Implant easier.
- The trajectory of the Implant path runs in a caudal and lateral direction through the sacral ala and into the ilium. The surgeon should direct the more cephalad Implant 40°–50° laterally in the transverse plane, similar to S2AI screws.

NOTE: *If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI Joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.*

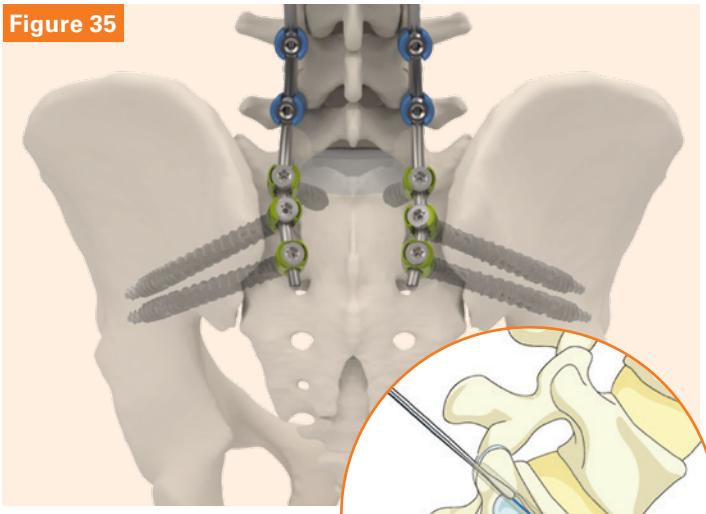
Figure 34



Procedure: S1 Pedicle Placement (Optional)

- The iFuse Bedrock Granite Implant may be placed in the S1 pedicle trajectory. The S1 trajectory is highly variable, but typically starts 5-10 mm caudal and 10 mm lateral to the junction of the S1 superior articular process of S1. Ensure that the starting point for S1 placement does not interfere with the placement of other Implants or preclude attachment of the Implant to the rod.
- Use standard imaging techniques to determine Implant starting position and trajectory. Device implantation should follow the same sequence as described for S2AI placement.

Figure 35



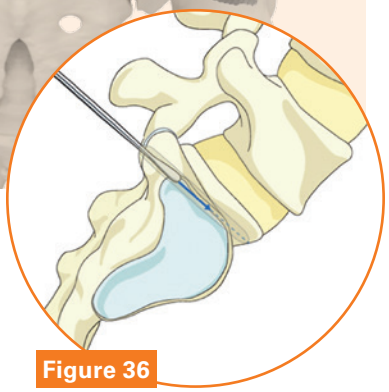


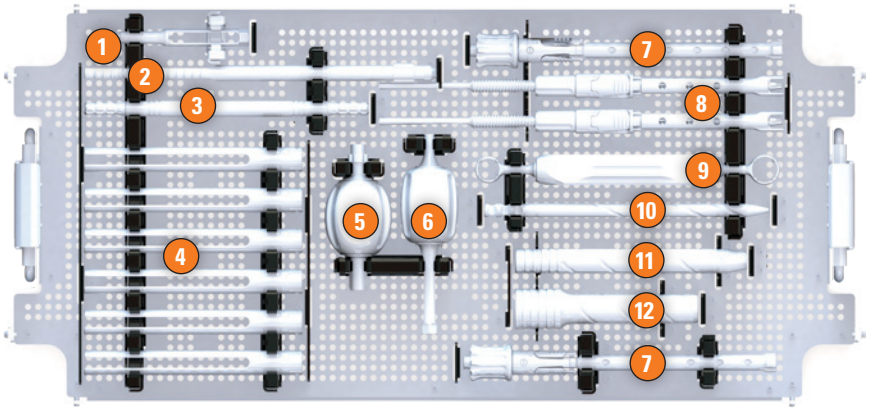
Figure 36

Minimally Invasive Surgery (MIS) Technique

Per surgeon preference or patient requirement, the iFuse Bedrock Granite Implant procedure can be performed under a minimally invasive surgical (MIS) technique. Utilizing the MIS instrumentation, in addition to the Open instrumentation, the subsequent pages outline the surgical steps to perform an MIS procedure.

Procedure: MIS Instrument Tray Layout

1. Reducer Driver MIS Reduction
2. Tower Attachment Tool
3. Rod Confirmation
4. Snap Towers Bedrock Granite MIS
5. Head Wrench
6. Reducer Multi-Driver
7. Manual Tower Remover
8. Tower Reducers
9. Dual End Counter Torque (CT)
10. Dilator 1 (Stainless)
11. Dilator 2 (Black)
12. Dilator 3 (Black)



PRECAUTION: *The MIS technique and instruments are NOT compatible with the Closed Head Tulip Implants (P/N 100000CH) or the Standard (Short Instrument) Accessory Instrument Tray (P/N 400439).*

Procedure: Starting Point & Trajectory

- Make appropriate skin incision. Fluoroscopy may be used to determine the appropriate surgical site.

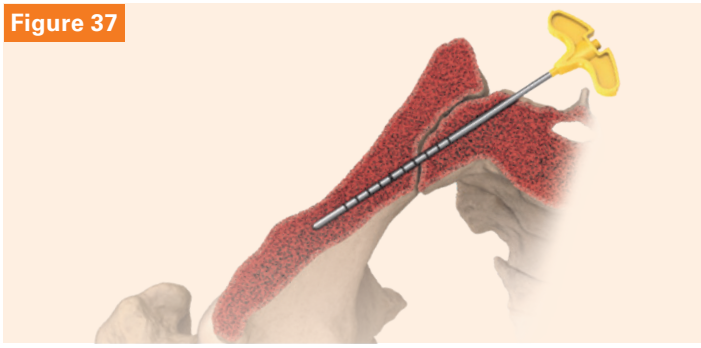
NOTE*: A skin incision of approximately 2 cm is recommended to accommodate sequential dilation.*

- Advance an access needle in the desired trajectory to terminal depth (**Fig. 37).** Remove the access needle stylet and advance the Guidewire through the access needle to terminal depth, using the Guidewire Driver (optional).

NOTE*: Access needle should accommodate a Guidewire maximum diameter of up to 1.45 mm. The Pedicle Awl, Straight with Trocar accommodates the 1.45 mm Guidewire and is available upon request to use for bone access (optional).*

Guidewire Driver

Figure 37



PRECAUTION:

- *Ensure the stylet remains in the Pedicle Awl until reaching terminal depth to prevent debris from entering the cannula. If the Guidewire is unable to pass through the cannula due to debris, remove the Pedicle Awl and place the Guidewire directly in the prepared channel.*
- *Hold the Pedicle Awl cannula while removing the stylet to prevent unwanted advancement.*
- *Hold the Guidewire while removing the cannula. If the Guidewire is prematurely removed, place the Guidewire directly in the prepared channel.*

Procedure: Sequential Dilation

- Advance Dilators 1, 2 and 3 **(Fig. 38)** sequentially over the Guidewire **(Fig. 39).**

NOTE**: Laser markings on Dilator 1 and Dilator 2 will help confirm the distal tip of each sequential Dilator is seated against dorsal sacrum **(Fig. 40).

Figure 38

Instrument	Outer Diameter (mm)
Dilator 1	8.5
Dilator 2	15.4
Dilator 3	18.3

Figure 39

Figure 40

Procedure: Sequential Tapping

- Remove Dilators 1 and 2.
- Sequentially advance the desired Cannulated Taps over the Guidewire through Dilator 3.
- Advance the Cannulated Taps to terminal depth referencing the depth markings (60 mm - 120 mm in 10 mm increments) on the Cannulated Tap as they enter the Dilator.

NOTE:

- *After crossing the sacroiliac joint, monitor tap trajectory via fluoroscopy to mitigate the risk of guidewire kinking. If guidewire kinking appears likely, pull back the guidewire into the tap cannula, and proceed with tapping to full depth.*
- *Taps will allow for up to 110 mm in length through Dilator 3*

- Sequentially tap as desired to full depth and selected Implant diameter **(Fig. 41).**

***NOTE**: Some users may elect to undersize with taps based on bone quality.*

Implant Size (mm)	Undersized	Line-to-Line
9.5	6.5, 8.5	9.5
10.5	6.5, 8.5, 9.5	10.5
11.5	6.5, 8.5, 9.5, 10.5	11.5
Additional tap sizes are available upon request		

- Use fluoroscopy to confirm tap depth as the instrument advances.

Figure 41

Figure 42

NOTE:

- *Taps are true to size (i.e. 10.5 mm Tap is 10.5 mm major diameter).*
- *Black laser mark on proximal tap shaft is not visible when handles and QC Adapter are properly engaged **(Fig. 42).***
- *The Cannulated Taps have depth markings from 60 mm to 120 mm, in 10 mm increments.*
- *A QC Adapter (Quarter Inch to Tri-lobe Adapter) for a Power Drill is provided.*
- *The iFuse Bedrock Granite 6.5 mm Awl Tip Tap may be used as a starter tap.*

Procedure: Implant Assembly to Tower

- Unscrew the tube cap **(Fig. 43).**
- Aseptically transfer the sterile inner clamshell into the sterile field **(Fig. 44).**
- Remove the Implant and set screw from the sterile clamshell **(Fig .45).**
- Attach the Tower to the Implant tulip by aligning the Tower slots with the tulip rod opening, snapping it directly into place with downward pressure onto the tulip **(Fig. 46).**

Figure 43

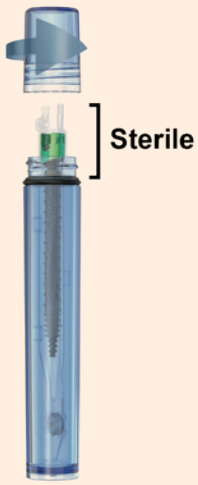
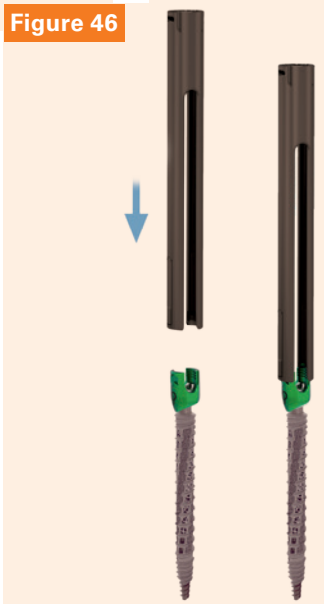


Figure 44

Figure 45

Figure 46



Procedure: Implant Placement

- Insert the Navigated Locking Driver tip through the Tower and engage it into the mating Implant drive feature.
- Secure the Implant onto the Driver by rotating the ribbed knob clockwise until tight.
- Slide the gold button down toward the Implant and into the locked position.
- Place the Implant, Tower, and Driver assembly over the Guidewire and through Dilator 3 **(Fig. 47).**
- Confirm Implant trajectory and placement under fluoroscopic visualization.
- When the Implant is fully seated, disengage the Driver by sliding the gold button towards the handle into the unlocked position.
- Unthread the Driver from the Implant tulip by rotating the ribbed knob counterclockwise.
- Remove the Driver, Dilator 3, and the Guidewire.

NOTE:

- *A Pin Driver may be used to back out the Guidewire.*
- *A Closed Head Turner is available to rotate both Open Head and Closed Head Implant tulips* ***clockwise*** *to optimize favored angle. Do not rotate the tulip counterclockwise. Rotating counterclockwise may unthread the tulip head from the Implant body.*
- *A Depth Adjuster with Wings is available for use with Open Head Implants to make additional adjustment to implant depth.*

PRECAUTION: *Watch for Guidewire advancement or kinking during Implant placement. Guidewire should be removed once the Implant tip crosses the sacroiliac joint.*

Figure 47

Procedure: Set Screw Placement & Optional Rod Reduction

- Upon ensuring that the rod is placed and seated within the Implant tulip and tower slots, set screw insertion may be achieved.
- Remove set screw from Implant clamshell or utilize additional set screw in the set screw caddy.
- Align distal "star" attachment guide with set screw.
- Apply downward pressure to Tower Reducer while pressing on proximal end to retain set screw **(Fig. 49).**
- Preset reduction to desired amount. Default setting should be set at 30 mm.
- Insert the Tower Reducer into the MIS Tower until locked into place **(Fig. 48).**

NOTE:

- *Align silver laser marks on sides of Tower Reducer and Tower attachment **(Fig. 48).***
- *Maximum reduction is 30 mm.*

Figure 48

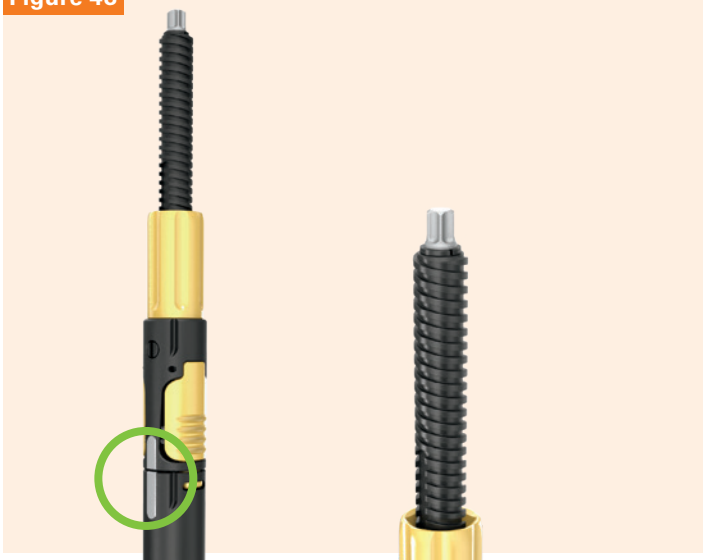
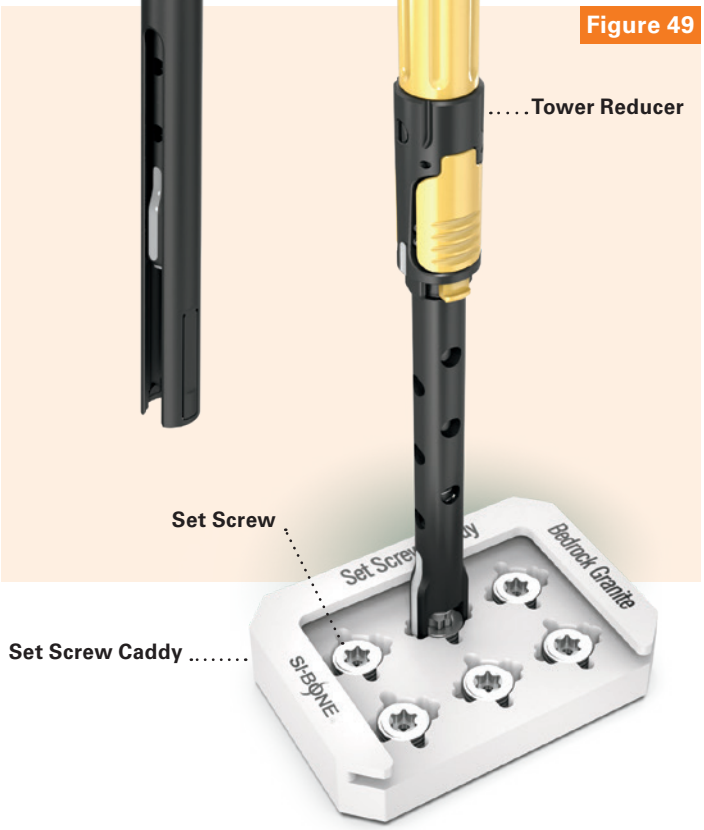


Figure 49



Procedure: Optional Rod Reduction & Provisional Tightening

Engage the Reducer Multi-Driver

- Reduce rod into tulip by rotating gold knurled knob clockwise. Additional torque can be achieved by using Reducer Multi-Driver **(Fig. 50).**

***NOTE**: Reducer Driver MIS Reduction with quarter-inch drive adapter is available for additional torque as needed.*

***PRECAUTION:** Do not over tighten. If torsional resistance is experienced, there may be soft tissue between the tulip and rod. Sufficiently remove tissue before proceeding.*

- Once the green ring on the inner shaft of the Tower Reducer is visible, the rod will be fully seated **(Fig. 51).** Use the silver set screw driver tip of the Reducer Multi-Driver to deliver set screw.
- Rotate set screw inserter shaft ¼ turn counterclockwise to positively engage set screw into tulip.
- User should feel threads skip over and engage. Rotate clockwise to provisionally place set screw.
- Remove the Tower Reducer by depressing the gold clips to release the Reducer from the Tower.

***NOTE**: Excess pressure on the Reducer can make releasing clips more challenging. If so, unthread the Reducer 1 full turn, or until pressure is released and clips can be properly depressed for removal.*

Figure 50

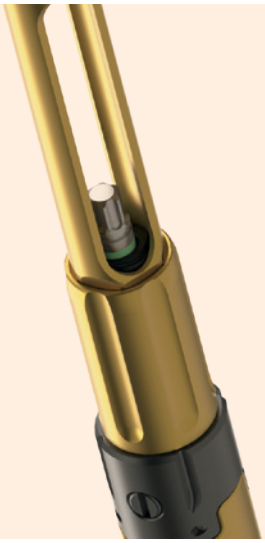
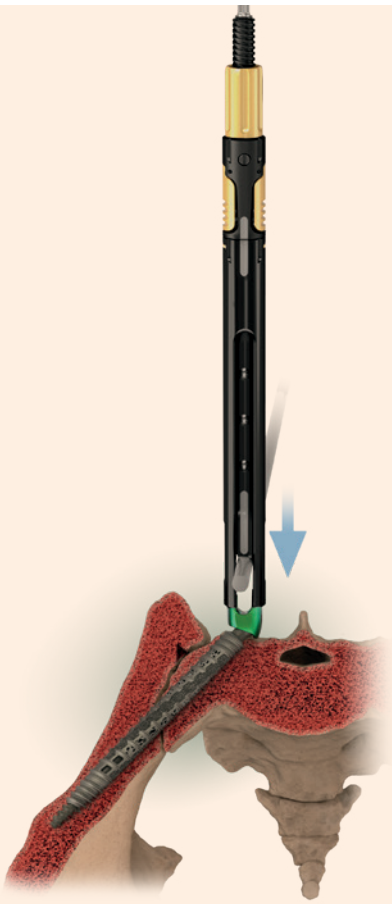


Figure 51



Procedure: Final Tightening

- Assemble the T-handle **(Fig. 52 a)** to the Torque Limiting Adapter **(Fig. 52 b)** and then to the T30 Final Driver **(Fig. 52 c).**
- Securely attach the larger, black aperture of the Dual End Counter Torque **(Fig. 52 d)** to the proximal end of Tower **(Fig. 52 e).**
- Insert final tightening assembly through the Tower and fully seat the distal tip into the set screw.
- Final tighten the set screw by firmly holding the Dual End Counter Torque and slowly rotating the T-Handle clockwise until a minimum of two audible clicks are heard or tangibly felt.

NOTE:

- *During final tightening, when resistance is felt, each rotation should take 1-2 seconds to reach the audible click.*
- *If the Granite Implant is final tightened before the rest of the pedicle screw construct, it is recommended to final tighten the Granite Implant again before closing the incision.*

Figure 52 a

Figure 52 b

Figure 52 c

Figure 52 d

Figure 52 e

Procedure: Tower Re-Engagement Tool (Optional)

- If the Tower becomes detached from the tulip, the Tower Attachment Tool may be used to replace the Tower. Advance the Tower Attachment Tool into the tulip, aligning the flat proximal ends within the tulip slots.
- Advance the Tower over the Tower Attachment Tool until the distal Tower flanges are secured onto the tulip.

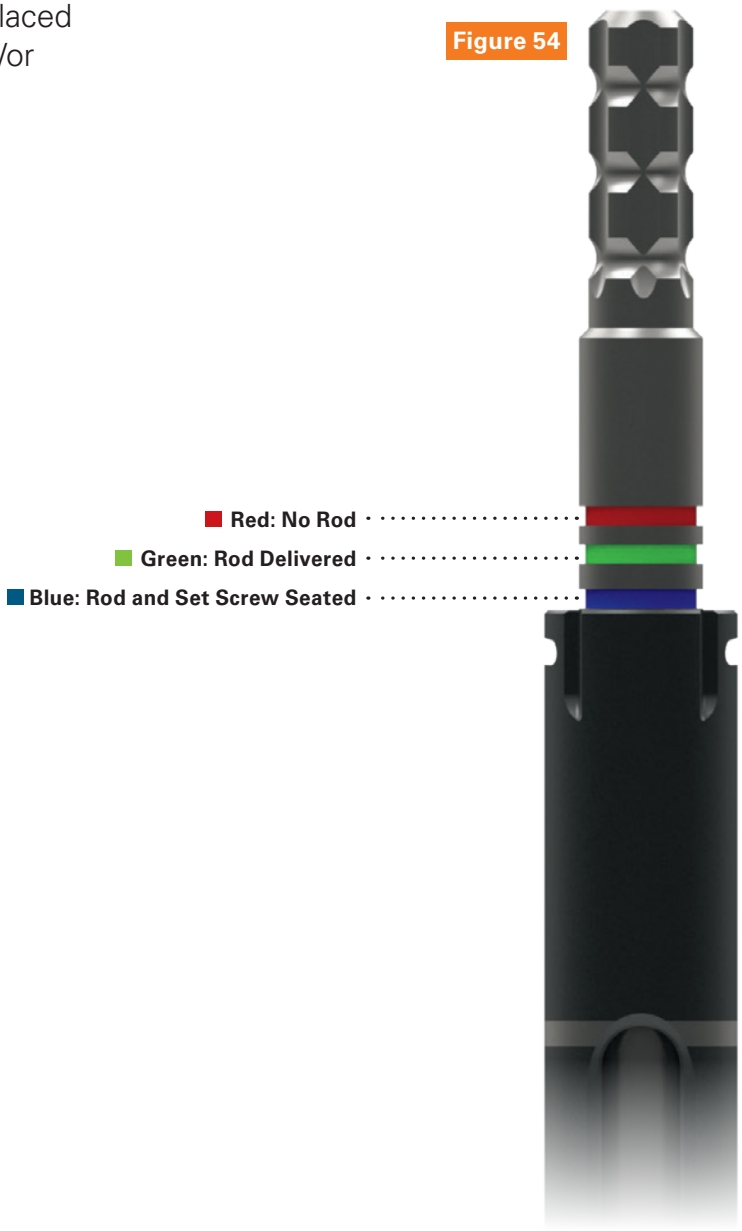
***NOTE**: The Tower Attachment Tool is cannulated and may be advanced over a Guidewire.*

Figure 53

Procedure: Rod Confirmation Tool (Optional)

- The Rod Confirmation Tool may be placed through the Tower to assess rod and/or set screw placement.

Figure 54



Procedure: Tower Removal

- Ensure that the green ring of the Manual Tower Remover inner shaft is visible by rotating the gold barrel counterclockwise **(Fig. 55).**
- Insert the Manual Tower Remover into the Tower by aligning the silver laser marks. Advance the Manual Tower Remover until the gold tabs engage into the Tower slots.
- Rotate the gold barrel clockwise until the green ring is no longer visible. Pull up on the Manual Tower Remover to remove Tower.

Figure 55

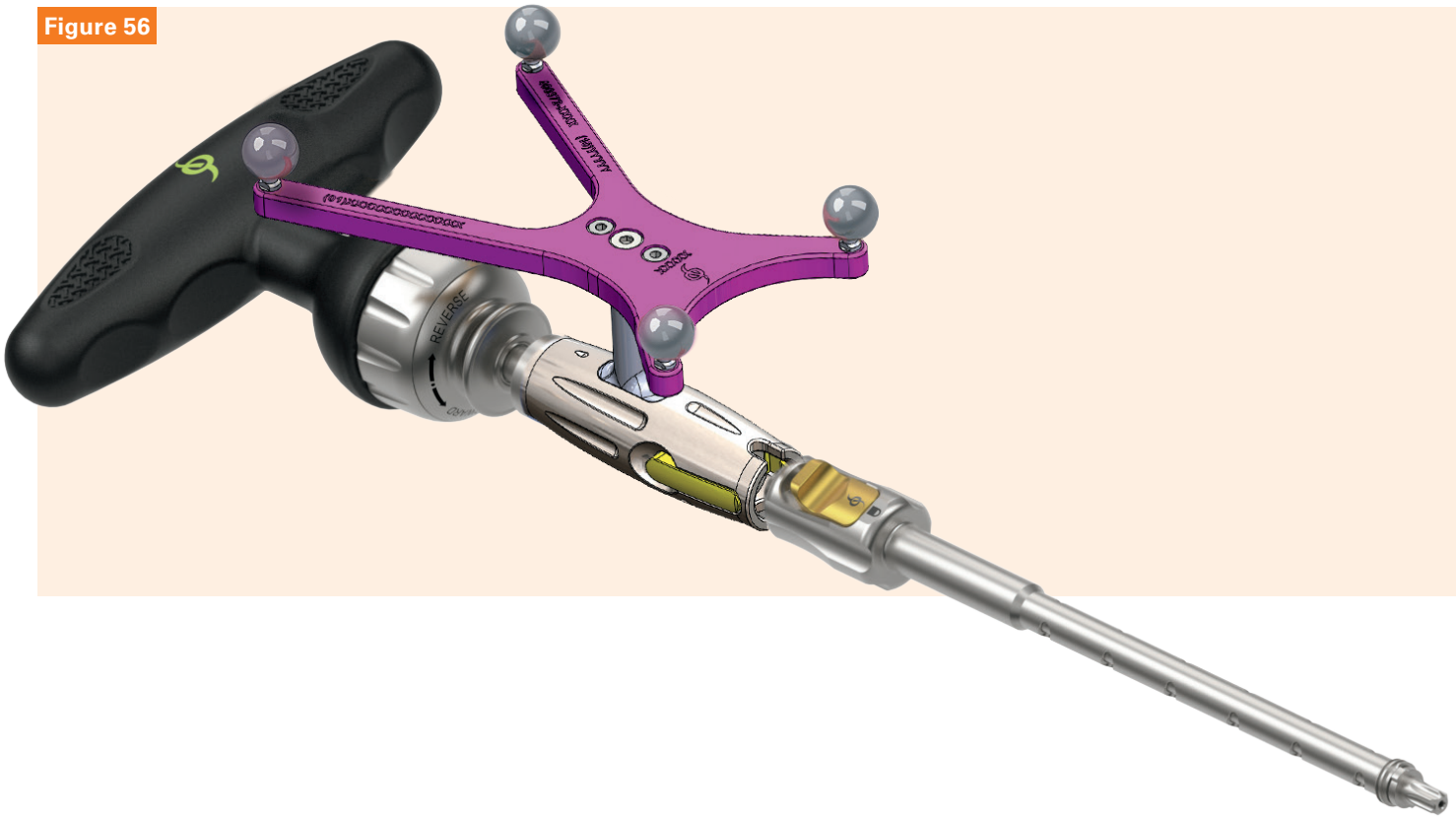
Manual Tower Remover

Navigation Instruments

Background: iFuse Bedrock Granite Instrumentation allows for surgeons to perform the procedure while navigating under Medtronic StealthStation.

- 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.
- The subsequent steps cover only navigation-related instrumentation. All other technique steps may be referenced in the OPEN and MIS sections of this technique manual.

Figure 56

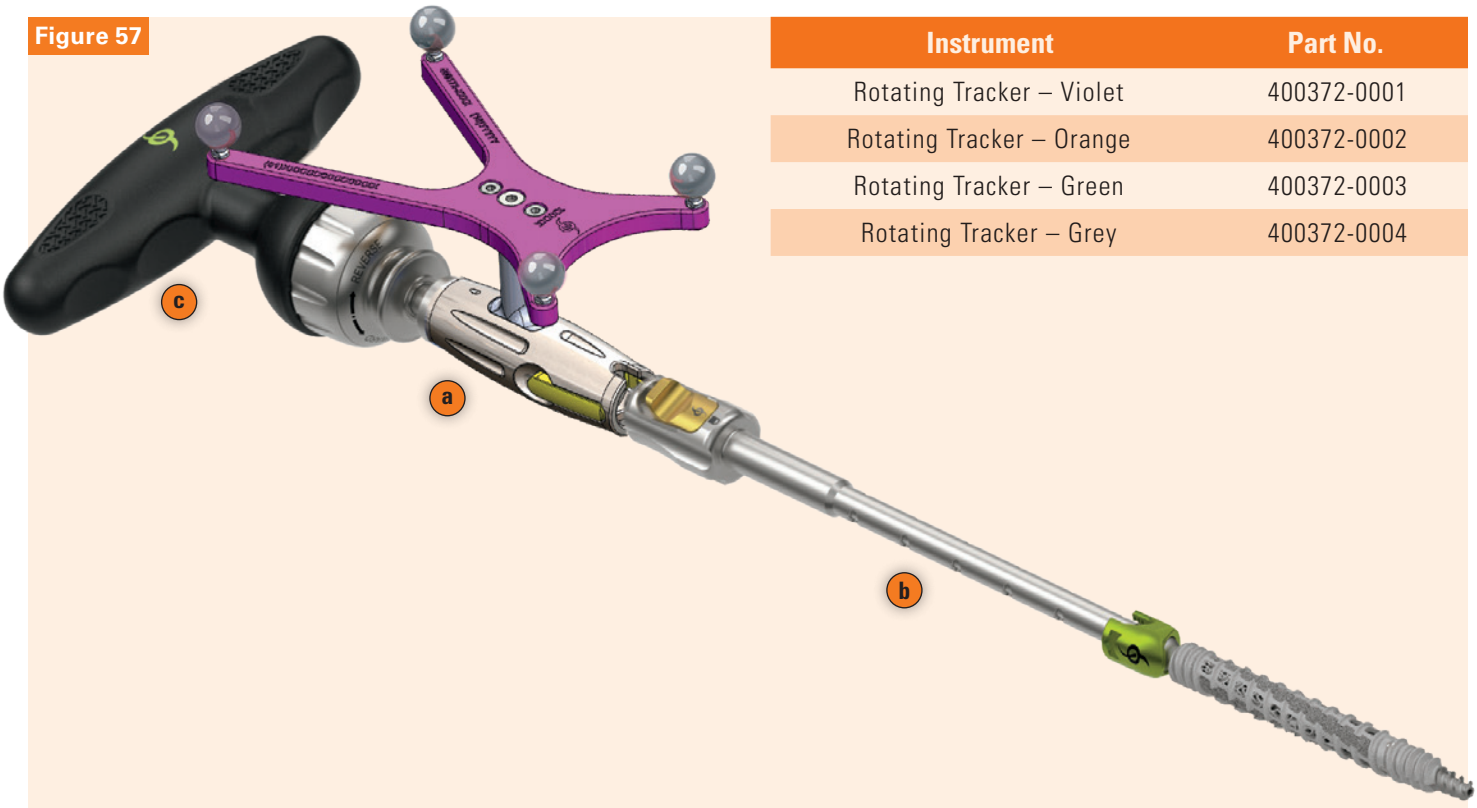


Procedure: Instrument Assembly

- Select desired SI-BONE Rotating Tracker or Medtronic NavLock array **(Fig. 57 a).**
- Select desired iFuse Bedrock Granite Taps and Navigated Locking Driver **(Fig. 57 b).**
- Attach array to proximal instrument engagement feature.
- Connect desired handle **(Fig. 57 c).**

***NOTE**: For Implant assembly to Navigated Locking Driver: See Page 12 of OPEN Technique*

Figure 57



Instrument	Part No.
Rotating Tracker – Violet	400372-0001
Rotating Tracker – Orange	400372-0002
Rotating Tracker – Green	400372-0003
Rotating Tracker – Grey	400372-0004

Procedure: Tool Card Selection

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

Part Number	Granite Instrument	Medtronic Tool Card
400268	iFuse Bedrock Granite Navigation, Locking Driver	NavLock Lumbar Probe **PN 9734679**
400387-XXXX 400298-XXXX 400302-XXXX	iFuse Bedrock Granite Tap	NavLock Lumbar Probe **PN 9734679**

Procedure: Instrument Registration

Taps & Navigated Locking Driver

- A pop-up window will appear with available instruments for pairing. Use the search box to select your desired NavLock array and click "add".
- 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 Navigated Locking Driver similarly, as a Lumbar Probe.

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 **qara@si-bone.com** or **1-855-511-1545.

Figure 58

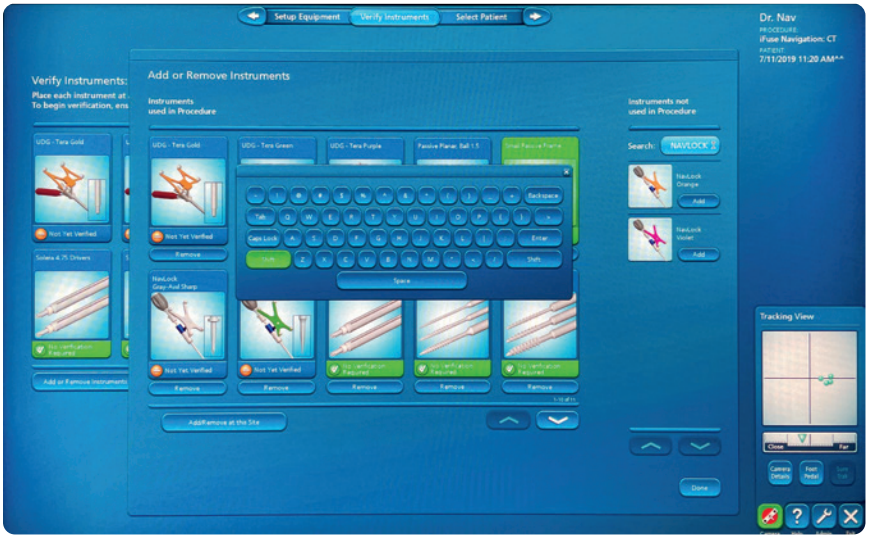


Figure 59

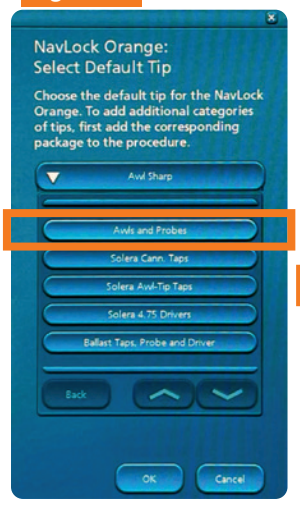


Figure 60

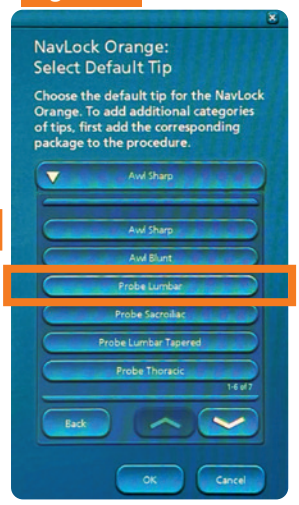
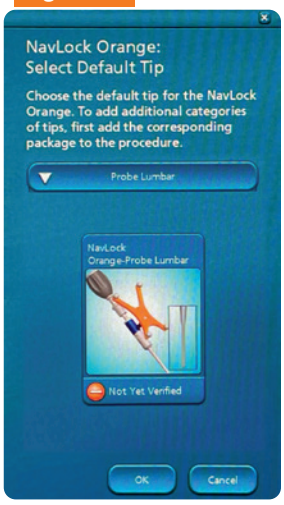


Figure 61

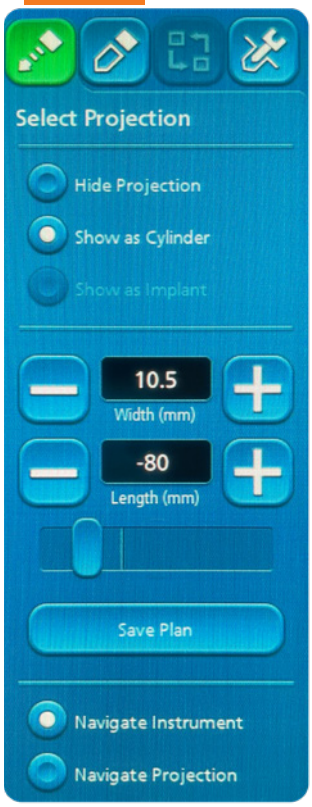


Procedure: Projecting Instruments

Taps

- When projecting for the Taps, utilize a projection of the chosen tap diameter and a negative length **(Fig. 62).**

Figure 62



Navigated Locking Driver

- When projecting for the Navigated Locking Driver, utilize a projection of the chosen Implant diameter and length **(Fig. 63).**

> ***NOTE**: The projection accounts for length and diameter of the Implant, but not the tulip head **(Fig. 64).***

Figure 63

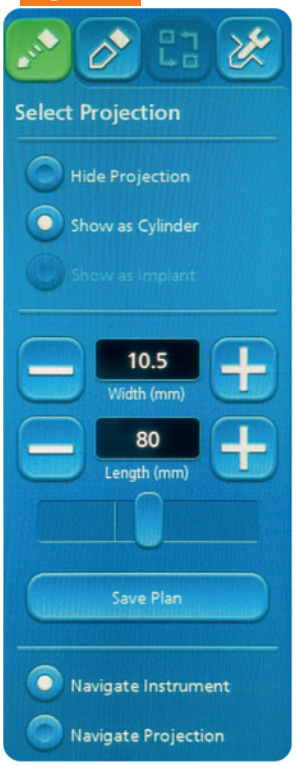
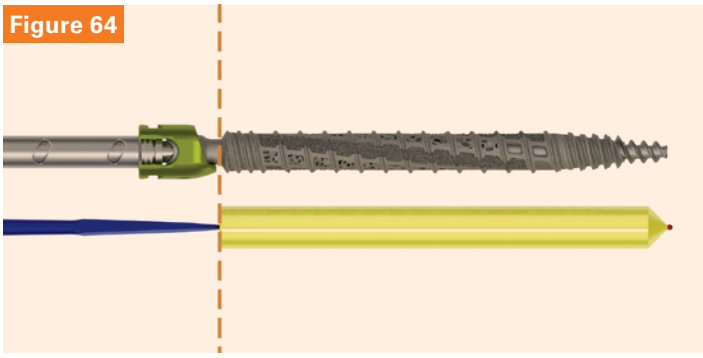


Figure 64



Implant Removal: Scenarios

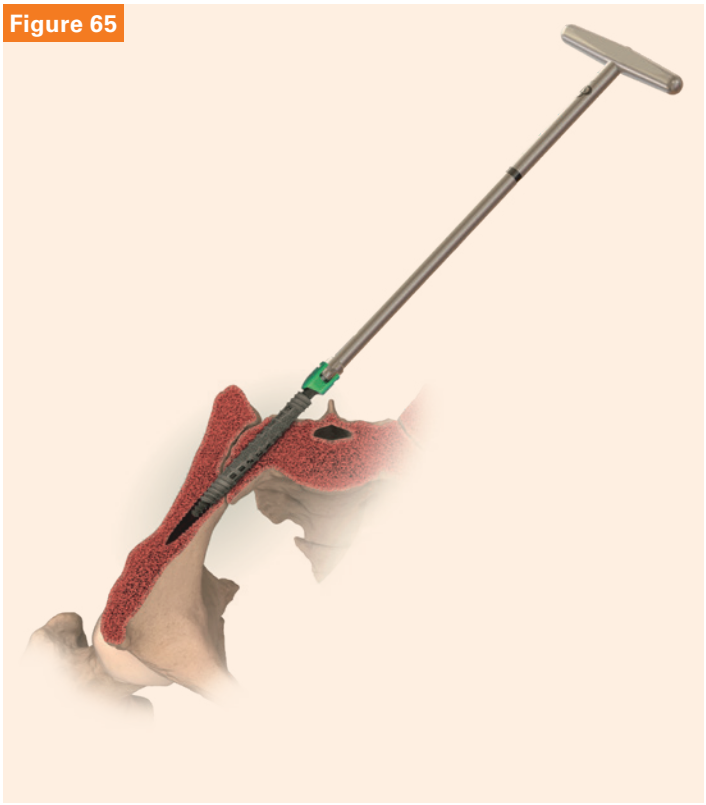
The iFuse Bedrock Granite system includes various removal tools. Upon need for Implant removal, please follow the subsequent steps and methods for removal.

Scenario 1:

- If Implant needs to be removed, remove set screw and rod. Use Cannulated Implant Depth Adjuster with Wings to remove **(Fig. 65).**

Warning: *iFuse Bedrock Granite Implants have porous surfaces that are designed to integrate with bone (i.e., bone ongrowth and ingrowth). Growth of bone onto/ into the Implants may make late removal of Implants challenging. Trephines, chisels or other instruments may be needed to separate the implant from surrounding bone to allow removal.*

Figure 65



Scenario 2

- An iFuse Bedrock Granite Extraction Instrument is available upon request should the inner shank become dislodged from the sleeve **(Fig. 66).**

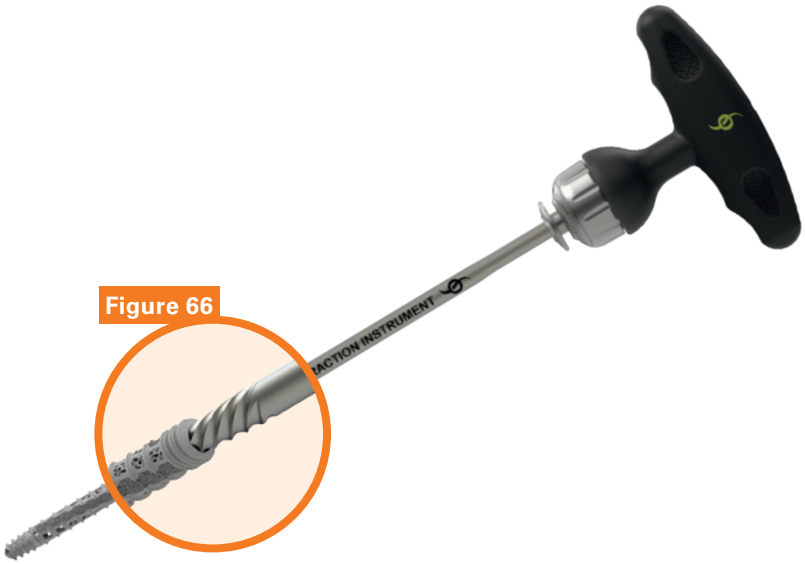


Figure 66

Product Catalog: iFuse Bedrock Granite Instrumentation

Open Instrument Tray	400309
Bone Probe, Curved	400263
Bone Probe, Straight	400264
Navigation, Locking Driver	400268
Closed Head Turner, Axial Handle	400508-02
Set Screw Starter, Axial	400270
Axial Reducer	400338
Counter Torque	400272 -0100
iFuse Bedrock Granite Cannulated Implant Depth Adjuster with Wings	400281
iFuse Bedrock Granite 6.5 mm Awl Tip Tap	400387
iFuse Bedrock Granite 8.5 mm Awl Tip Tap	400298-0850
iFuse Bedrock Granite 9.5 mm Awl Tip Tap	400298-0950
iFuse Bedrock Granite 10.5 mm Awl Tip Tap	400298-1050
iFuse Bedrock Granite 8.5 mm Cannulated Tip Tap	400302-0850
iFuse Bedrock Granite 9.5 mm Cannulated Tip Tap	400302-0950
iFuse Bedrock Granite 10.5 mm Cannulated Tip Tap	400302-1050
T-Handle, Ratcheting, Quarter Square, Low Profile	501621
Inline Handle, Ratcheting, Quarter Square, Low Profile	501622
iFuse Bedrock Granite Guidewire Sharp (1.4 mm) — Disposable Item	501168
Guidewire Driver	501323
QC Adapter, Quarter Inch to Trilobe	501417
iFuse Bedrock Granite Measurement Probe	501167
Torque Limiting Adapter 115 in-lb	501192
T30 Final Driver	501199
Threaded Reducer Extension	501353
Set Screw Caddy	501402

Product Catalog: iFuse Bedrock Granite Instrumentation

MIS Instrument Tray	400310
Head Wrench	400275
Reducer Multi-Driver	400276
Manual Tower Remover	400278
iFuse Bedrock Granite Dilator 2	400279
Dual End CT	400280
Tower Reducer	400294
iFuse Bedrock Granite Dilator 1	501213
Snap Tower Bedrock Granite MIS	501224
iFuse Bedrock Granite Dilator 3	501235
Rod Confirmation	501350
Reducer Driver MIS Reduction	501382
Tower Attachment Tool	501351

Standard Accessory Instrument Tray (Short Instruments)	400439
iFuse Bedrock Granite Standard Locking Driver	400429
iFuse Bedrock Granite Standard 8.5 mm Cannulated Tap	501858-0850
iFuse Bedrock Granite Standard 9.5 mm Cannulated Tap	501858-0950
iFuse Bedrock Granite Standard 10.5 mm Cannulated Tap	501858-1050
iFuse Bedrock Granite Standard 8.5 mm Awl Tip Tap	501859-0850
iFuse Bedrock Granite Standard 9.5 mm Awl Tip Tap	501859-0950
iFuse Bedrock Granite Standard 10.5 mm Awl Tip Tap	501859-1050

Available Upon Request	
Rotating Tracker, Violet	400372-0001
Rotating Tracker, Orange	400372-0002
Rotating Tracker, Green	400372-0003
Rotating Tracker, Grey	400372-0004
iFuse Bedrock Granite Sleeve Extraction Instrument	501349
QC Adapter, Quarter Inch to POWEREASE	501485
iFuse Bedrock Granite 7.5 mm Awl Tip Tap	400298-0750
Threaded Rod Reducer	400271-0100
iFuse Bedrock Granite 11.5 mm Awl Tip Tap	400298-1150
iFuse Bedrock Granite 11.5 mm Cannulated Tip Tap	400302-1150
Bedrock Granite Closed Head Turner, T Handle	400508-01
Head Turner	400269
Pedicle Awl, Straight with Trocar	502206

Indications For Use, Contraindications, Warnings and Precautions

INDICATIONS FOR USE

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite 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, MRI, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

The SI-BONE Trackers and Universal Pin Guide are intended to enable navigation of SI-BONE instrumentation during spinal surgical procedures that utilize Medtronic StealthStation™ Systems and Stealth™ Technology. The SI-BONE Trackers and Universal Pin Guide are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

ADDITIONAL COMPATIBILITY INFORMATION

Compatible pedicle screw system rods include all the conditions listed below:

1. 5.5- or 6.0-mm in diameter
2. Cross section is circular and non-threaded
3. Made of:
   - Titanium alloy (Ti-6Al-4V ELI per ASTM F136),
   - Cobalt chrome (Co-28Cr-6Mo per ASTM F1537 or 35Co-35Ni-20Cr-10Mo per ASTM F562)
4. Not additively manufactured
5. Not coated with additional materials (e.g., Hydroxyapatite)

Note: Anodization (color or type II) does not alter the material

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

Please refer to the Instructions for Use of the connected pedicle screw system and the Navigation Tracking Instruments for a complete list of all warnings, precautions and possible adverse events associated with its use.

CONTRAINDICATIONS

The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon.

- Deformities or anatomic variations that prevent or interfere with iFuse Bedrock Granite Implant placement.
- Tumor of sacral or ilial bones that could adversely affect implant placement.
- Active infection at treatment site.
- Allergy to metal components.
- Use of incompatible materials from other systems.

WARNINGS

1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
2. Inspect implants and instruments for damage prior to use. Do not use any component from an opened or damaged package or use any device that appears damaged or worn; do not attempt to repair damaged devices. Use of damaged devices may result in patient injury.
3. Do not reuse implants under any circumstances. A used implant should be discarded.
4. Do not use implants after the expiration date, as use of expired devices may result in patient harm.
5. Care should be used during surgical procedures to prevent damage to the device(s), and injury to the patient.
6. iFuse Bedrock Granite Implants have porous surfaces that are designed to integrate with bone (i.e., bone ongrowth and ingrowth). Growth of bone onto/into the implants may make late removal of implants challenging. Trephines, chisels or other instruments may be needed to separate the implant from surrounding bone to allow removal.
7. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.

CAUTION: This device has not been tested with all FDA-cleared spinal rods. Performance may vary.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury.

PRECAUTIONS

1. The iFuse Bedrock Granite Implant System should only be used by physicians familiar with pelvic fixation techniques as illustrated in the SI-BONE iFuse Bedrock Granite Surgical Technique Manual.
2. Consult the Pedicle Screw System Surgical Technique Manual for use instructions and warnings, precautions, and recommendations relevant to the pedicle screw system.
3. Pay careful attention to selection of implant size. Pre- operative X-rays and/or CT scan may be helpful in selecting implant size.
4. Select implant size sufficient to ensure adequate fixation within the pelvis given the planned trajectory and pelvic anatomy.
5. Use sterile technique when handling the implant and during the procedure to maintain sterility and minimize risk of infection.
6. Care should be used in the handling and storage of the implants. Instruments should be protected during storage and from corrosive environments.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

iFuse
Bedrock Granite®
Implant System

SI-BONE®

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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