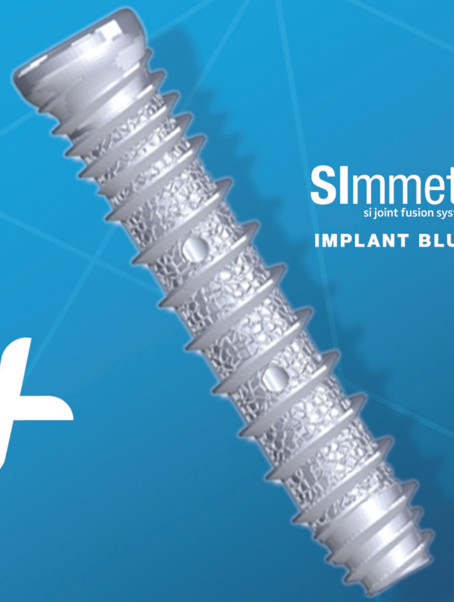
SImmetry®+
si joint fusion system

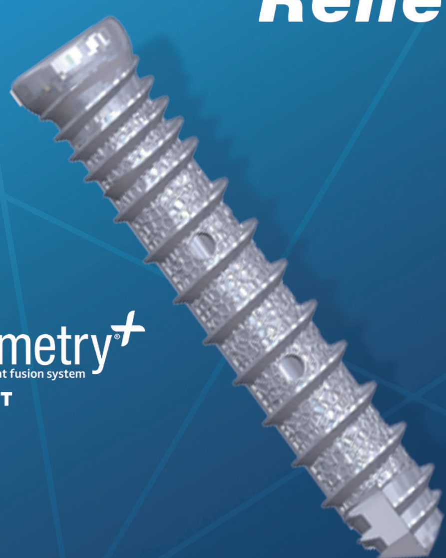


SImmetry®+
si joint fusion system
IMPLANT BLUNT

*Authentic **FUSION**, compelling **SAFETY** profile and **CLINICAL OUTCOMES***

Relieving Pain, *Restoring Life.*

SImmetry®+
Surgical Technique Manual



SImmetry+
si joint fusion system
IMPLANT

TENON MEDICAL®

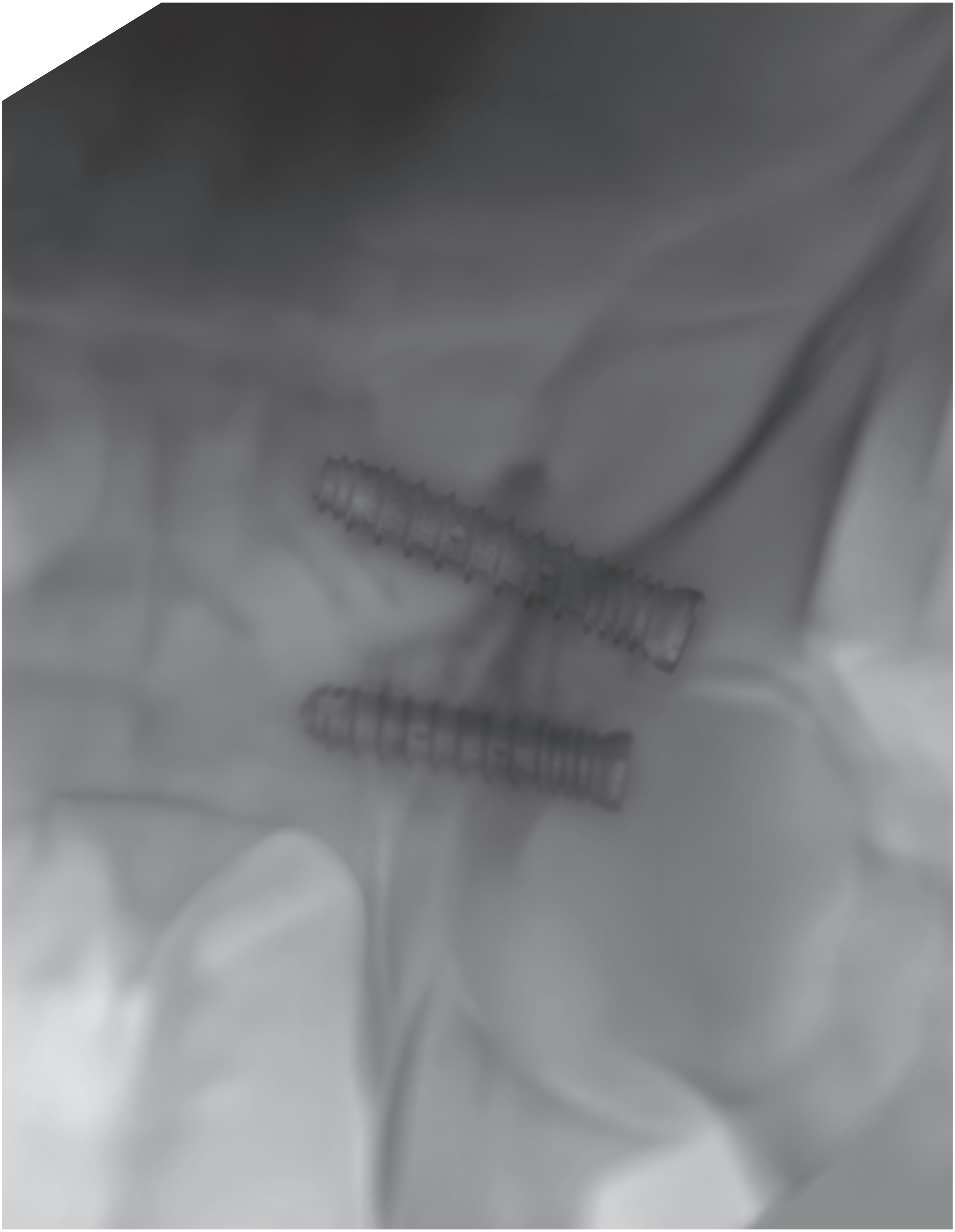


Table of Contents

CONTENTS

Introduction

ABOUT THE SImmetry+ SI Joint Fusion System

The SImmetry+ SI Joint Fusion System provides a minimally invasive, efficient, and effective technique designed to treat the sacroiliac joint and achieve a true arthrodesis by:

1. Minimally invasive lateral access for safety and control.
2. **Optional Joint Preparation**: Cartilage removal and decortication of the opposing joint surfaces may be performed using the proprietary SImmetry+ Quick Step Decorticator instrument.
3. **Optional Graft Delivery:** Bone graft may be optionally delivered by the implant into the prepared joint space to facilitate arthrodesis.
4. Joint fixation with 3D printed threaded titanium implant and optional supplemental fixation.

SAFETY INFORMATION

- This intervention is intended to be used with fluoroscopic guidance.
- The surgeon must completely read this guide and receive training prior to performing any surgical procedure with the SImmetry+ SI Joint Fusion System.
- SImmetry+ instruments and implants must be used as described in this guide. Failure to do so may result in instrument damage or injury.
- The technique employed in each case always depends on the medical judgement of the surgeon before and during surgery as to the best mode of treatment for each patient.
- Do not use the product if any of the instruments appear damaged, or if the sterile implant packaging is damaged or open.

INDICATIONS FOR USE

The SImmetry+ SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

EQUIPMENT REQUIREMENTS

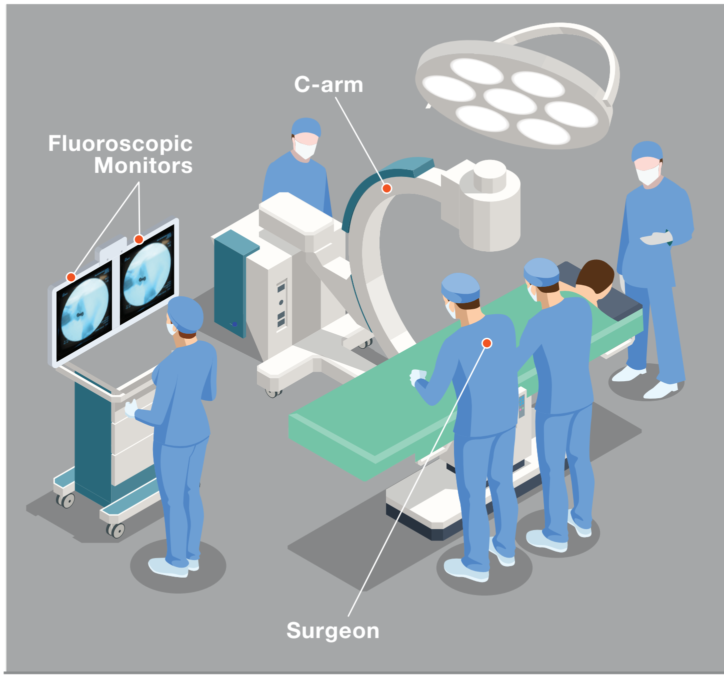
The following equipment and materials are required for the procedure:

- Radiolucent table for unrestricted positioning of Lateral, Inlet and Outlet Views
- Jackson Table, flat top or open recommended
- High-quality C-arm fluoroscope
- Power drill with 3.2mm pin driver and Jacobs Chuck
- ~5-10cc of a suitable void filler medium
- Skin marking pen
- Suction and irrigation equipment
- Mallet
- Optional power instrumentation
- SImmetry+ Instrument Set
- SImmetry+ Implant Set

PATIENT PREPARATION

Due to the anatomic variability of each patient, preoperative X-rays including A-P, Lateral, Inlet and Outlet pelvic images are recommended to plan the operation appropriately. A preoperative MRI should be considered where anatomic variability could affect the determination of proper implant sizing or placement. Anatomic variables include the patient's bone size, morphology, and density, as well as overall physical build.

Introduction *(cont.)*



OR SETUP

- Patient prone
- C-arm on non-operative side
- Monitors on foot-side of C-arm
- Confirm fluoroscopy views and incisions prior to draping

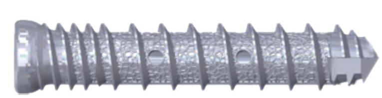
General draping guidelines:

- **Posterior:** Midline
- **Anterior:** Greater Trochanter
- **Cephalad:** Iliac Crest
- **Caudad:** Greater Trochanter

IMPLANTS

SImmetry+ implants are 3D printed titanium devices designed to transfix the ilium and sacrum. These implants feature a unique design that is self-drilling, self-tapping, and self-harvesting.

The system permits the use of one to three implants per joint. Implant size is selected by its diameter at the surgeon's discretion. The decision to use one, two, or three implants is based on the surgeon's judgment and a thorough consideration of the patient's individual SI joint anatomy (e.g., size, dysmorphism).

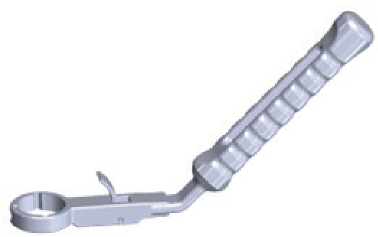
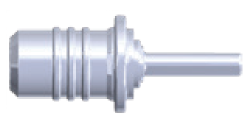
IMPLANT	DIAMETER (mm)	LENGTH (mm)	DEVICE
The SImmetry+ Fusion Implant Blunt	9.5, 10.5, 11.5 12.5, 13.5, 14.5	30-110 in 5 Increments	
The SImmetry+ Fusion Implant	9.5, 10.5, 11.5, 12.5, 13.5, 14.5	30-110 in 5 Increments	

TENON MEDICAL

Instrument Guide

PART NO.	DESCRIPTION	
SV02-0941	3.2mm Blunt Pin (2x)	
SV02-0943	3.2mm Trocar Pin Short (2x)	
SV02-0942	3.2mm Trocar Pin (2x)	
SV02-0945	Pin Guide	
SV02-0946	Pin Guide Inserter	
SV02-0939	Dilator 1	
SV02-0938	Dilator 2	
SV02-0926	6.6mm Drill For 9.5mm Screw	
SV02-0929	9mm Drill For 12.5mm Screw	
SV02-0931	11mm Drill For 14.5mm Screw	
SV02-0961	Quick Step Working Cannula	
SV02-0947	Impactor	
SV02-0963	Quick Step Decorticator Shaft	
SV02-0924	Suction Tube	

Instrument Guide *(cont.)*

PART NO.	DESCRIPTION	
SV02-0917	**Graft Tubes (2)**	
SV02-0925	**Graft Press**	
SV02-0900	**Final Dilator**	
SV02-0908	**Implant Driver**	
SV02-0901	**Implant Tower**	
SV02-0951	**Final Dilator Handle**	
SV02-0949	**T-Handle**	
SV02-0960	**Quick Step Drill**	
SV02-0952	**Jacobs Chuck**	
SV02-0527	**Quick Step Decorticator Blade** (Sterile Packed)	

Surgical Technique

IMAGING TECHNIQUE

For implantation of the SImmetry⁺ SI Joint Fusion System, three main radiographic pelvic views are used: Lateral, Inlet and Outlet Oblique.

CAUTION:

A preoperative MRI is highly recommended to determine the anatomical location of the common iliac vein to aid in the preoperative planning and avoid severe injury.

LATERAL VIEW

Superimpose the dorsal margins of the greater sciatic notches (black arrows) and the alae/iliac cortical densities (white arrows) (Figure 1), with the S1-S2 segments centered in the view. The Lateral view is used to determine the Bony Entry Point.

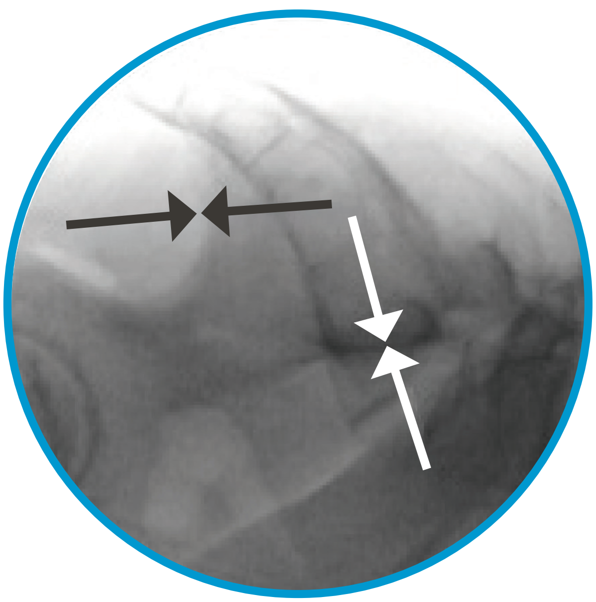
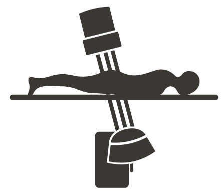


Figure 1
Lateral view

INLET VIEW

Tilt the C-arm 20°-35° caudal from A-P until the ventral surfaces of the first and second sacral segments are superimposed at the midline. The Inlet view assists with implant placement (Figure 2).



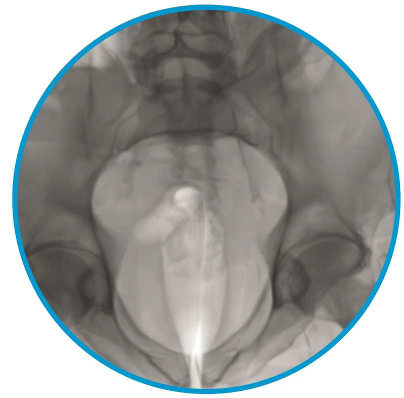
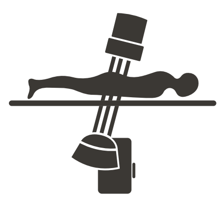


Figure 2
Inlet view

OUTLET-OBLIQUE VIEW

Tilt the C-arm 30°-50° cephalad from A-P until the top of the pubic symphysis superimposes at the second sacral segment. Then roll the C-arm 5°-15° oblique away from the surgeon until the joint can be seen clearly. The Outlet Oblique view assists joint visualization for perpendicular decortication and implant placement (Figure 3).



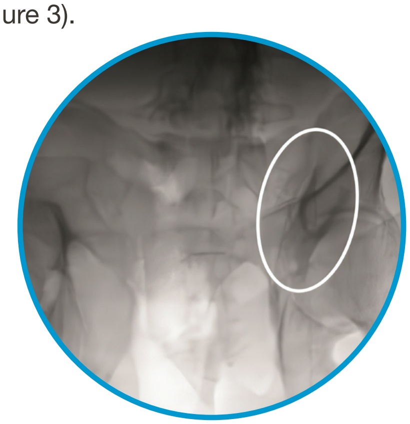


Figure 3
Outlet Oblique View

SKIN MARKING, INCISION, PRIMARY BONY ENTRY POINT AND TRAJECTORY

The SImmetry⁺ SI Joint Fusion System is targeted perpendicular to the articular region of the SI Joint to facilitate optimal joint preparation with the optional SImmetry⁺ Decorticator prior to implant delivery. The resulting angled approach puts the primary incision distinctly caudal to its Bony Entry Point.

Surgical Technique *(cont.)*

NOTE:

When targeting for the SImmetry⁺ SI Joint Fusion System, leave additional space for the optional supplemental fixation Implant.

LATERAL VIEW

Skin Marking

Place a 3.2mm Trocar Pin over the ventral margin of the first and second sacral segments. Mark this “Ventral Line” on the skin (Figure 4).

Incision (2cm)

Establish a targeting line, which passes from the center of the greater sciatic notch to the intersection of the dorsal S1 margin and the alae/ICDs. Mark skin incision on the targeting line, approximately 3cm caudal to the ventral line. Start an incision at the targeting line and move in a posterior direction keeping parallel to the ventral line. (Figure 4).

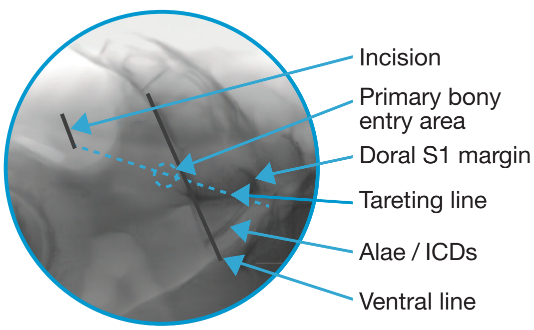


Figure 4
INLET VIEW
Mark the ventral line on the skin

BONY ENTRY POINT

Enter the bone slightly caudal to the ventral sacral margin, along the Targeting Line (Figure 5).

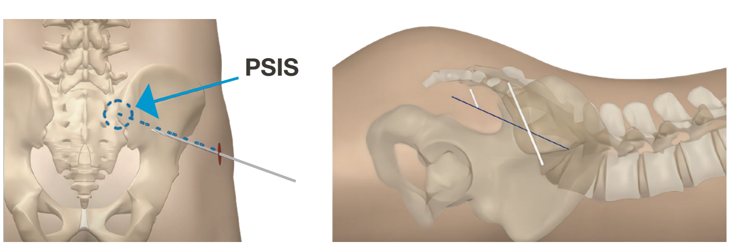


Figure 5
From the incision, insert a 3.2mm Trocar Pin cephalad toward the PSIS, 5°-10° anterior

With your 3.2mm Trocar Pin, target the center of the sacrum (Figure 6). Confirm the perpendicular trajectory of the 3.2mm Trocar Pin and the location of the neuroforamina (Figure 7).

SECONDARY, BONY ENTRY POINT AND TRAJECTORY

Two implants across the joint are recommended but not required.

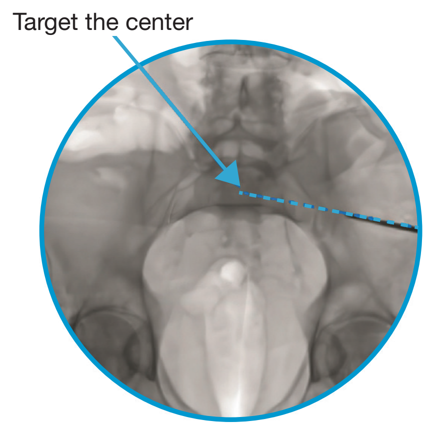


Figure 6
INLET VIEW
Target the center of the sacrum

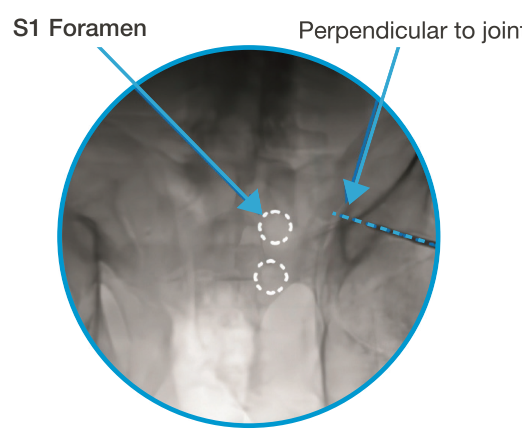


Figure 7
OUTLET OBLIQUE VIEW
Confirm the perpendicular trajectory of the 3.2mm Trocar Pin and location of the neuroforamina

Surgical Technique *(cont.)*

SURGICAL TECHNIQUE

This system features three primary steps in procedural order.

1. Targeting and Access
2. Drilling and Optional Decortication
3. Positioning of the implant

TARGETING AND ACCESS

Step 1

Place a 3.2mm Trocar Pin Short over the ventral margin of first two sacral segments (Figure 8). Mark this "Ventral Line"on the skin. Use the 3.2mm Trocar Pin Short to determine a "Targeting Line" which passes from the center of the greater sciatic notch (*) to the posterior corner of the first sacral segment (o) (Figure 9).

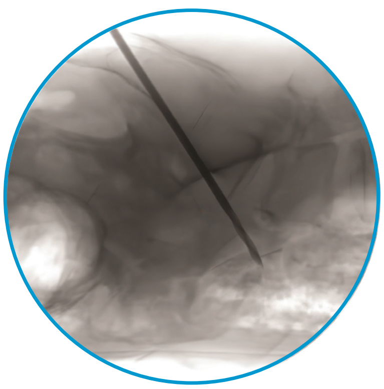


Figure 8
LATERAL VIEW
Place 3.2mm Trocar Pin Short over theventral margin

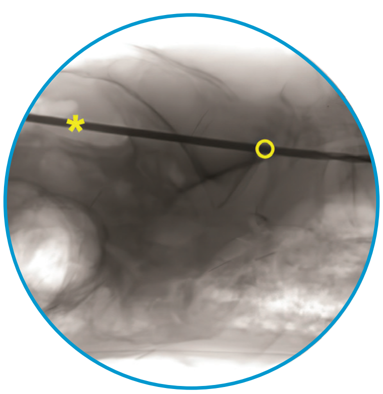


Figure 9
LATERAL VIEW
Determination of target line

NOTE:

The incision is typically near the projection of the center of the greater sciatic notch.

Mark the skin incision point on the Targeting Line ~3cm caudal to the Ventral Line.

Beginning at the mark (Figure 10) and moving upward from the targeting line, make an incision parallel to the ventral line (Figure 11).

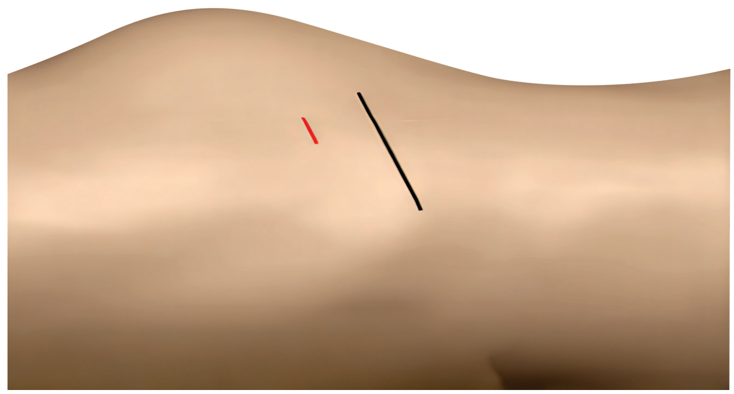


Figure 10
Mark and incision

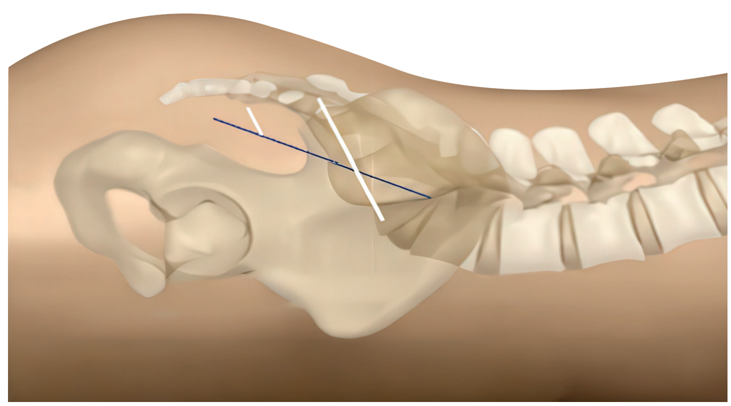


Figure 11
Anatomy reference

Surgical Technique *(cont.)*

Step 1 *Con't*

NOTE:

The Bony Entry Point should be up to halfway between the notch and ventral sacral margin, and just caudal to the S1 foramen in "normal" anatomy.

Insert the 3.2mm Trocar Pin Short through the incision and advance toward the PSIS with a 5°-10° anterior tilt until reaching bone (Fiure 12).

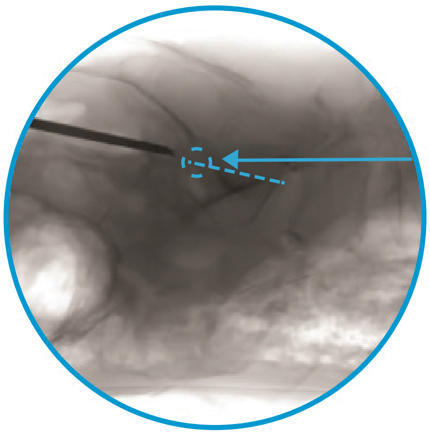


Figure 12
Insert 3.2mm Trocar Pin Short through the incision

Adjust the tip of the 3.2mm Trocar Pin Short to be just caudal to the ventral sacral margin and tap with a mallet until slightly through the outer iliac cortex (Figure 13).

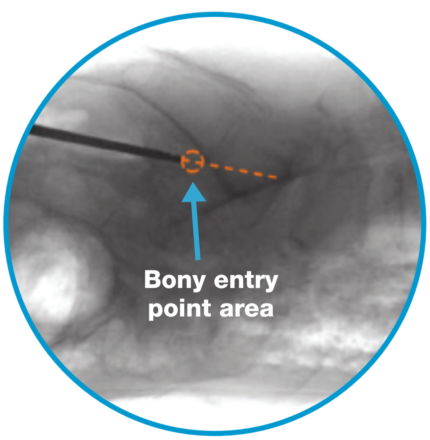


Figure 13
Adjust the tip of teh 3.2mm Trocar Pin Short to be just caudal to the ventral sacral margin

Step 2

Confirm the 3.2mm Trocar Pin Short trajectory is targeting the center of the sacrum in the Inlet view (Figure 14) and perpendicular to the joint in the Outlet Oblique view (Figure 15).

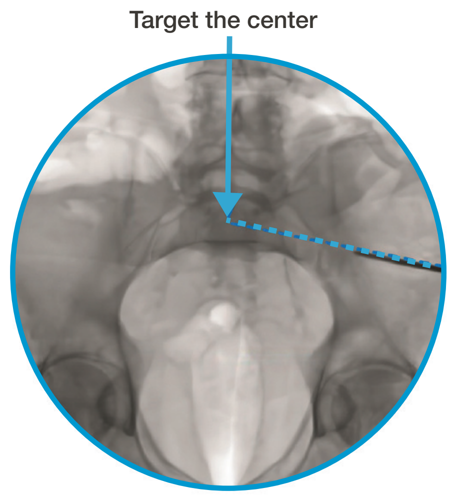


Figure 14
Confirm the 3.2mm Trocar Pin Short trajectory is targeting the center of the sacrum in an **Inlet view**

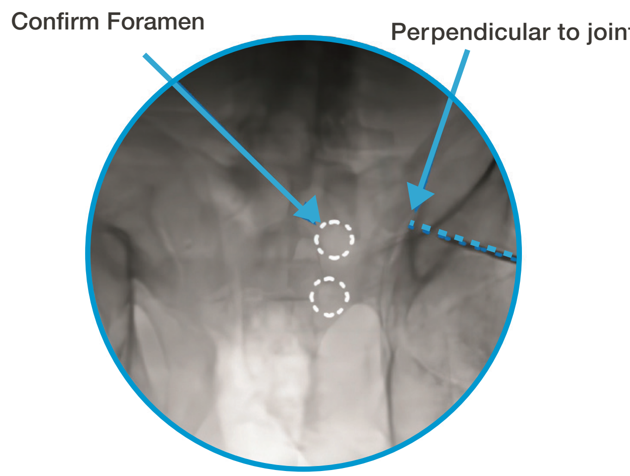


Figure 15
Confirm the 3.2mm Trocar Pin Short trajectory is targeting the center of the sacrum in an **Outlet view**

Once confirmed, advance the 3.2mm Trocar Pin Short to the joint, confirm through fluoroscopy for optimal 3.2mm Trocar Pin Short placement, and continue to advance the 3.2mm Trocar Pin Short to the intended depth of the implant.

Surgical Technique *(cont.)*

Step 3

Insert Dilator 1 (Figure 16) over the 3.2mm Trocar Pin Short, take note of the length of the implant from the laser marking on the 3.2mm Trocar Pin Short (Figure 17). Insert Dilator #2 then insert the Final Dilator over the 3.2mm Trocar Pin Short, and through the soft tissue until contacting bone (Figure 18). At this time, the Final Dilator Handle can attach in one of four positions to aid in holding the Final Dilator in place.

Dialator 1

Figure 16
Insert Dilator 1

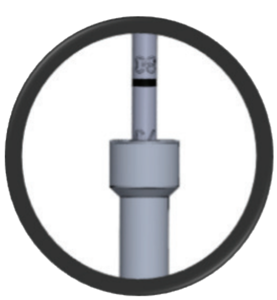


Figure 17
Take note of the length of the implant form the laser marking on the 3.2mm Trocar Pin Short

Dilator 2

Final Dilator

Final Dilator Handle

Figure 18
Insert Dilator 2 then insert the Final Dilator over 3.2mm Trocar Pin Short. The Final Dilator Handle can attach in one of four positions .

Outlet Oblique view
Fluoroscopy confirmation of Final Dilator contacting bone

OPTIONAL:* *The Pin Guide Assembly may be used to place additional 3.2mm Trocar Pins for sequential implants *(Figure 19).*

Figure 19
Optional Pin Guide assembly

There are now two choices available. Either the optional Quick Step Decorticator or simply placing the implant.

Surgical Technique *(cont.)*

NOTE:

If performing decortication, this will require the use of 12.5mm diameter implant or larger. The Quick Step Decorticator steps are below. If electing **NOT** to Decorticate, please skip to standard implant insertion step (Pg. 17).

QUICK STEP ASSEMBLY

Assemble the Quick Step Decorticator on the back table by aligning the laser markings and placing the Quick Step Drill down the shaft of the Quick Step Working Cannula until there is an audible click (Figure 20). The drill length can be adjusted to match the desired depth in reference to the distal end of the Quick Step Working Cannula.

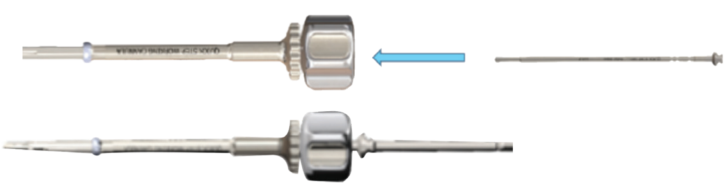


Figure 20
Assemble Quick Step Decorticator Shaft to the Decorticator Blade

QUICK STEP DRILLING

Place the assembled Quick Step Drill over the 3.2mm Trocar Pin Short and through the Final Dilator (Figure 21). Advance the drill until the side windows of the Quick Step Decorticator are within the SI Joint and the drill has pierced the lateral cortex of the sacrum (Figure 22). Confirm placement with an Outlet Oblique view (Figure 23).

CAUTION:

Confirm with fluoroscopy that the 3.2mm Trocar Pin Short does not advance while drilling. Do not drill past the Sacroiliac joint with the Quick Step Working Cannula windows.

OPTIONAL:* *Adjust the outer depth stop to ensure a tight fit on the lateral wall of the Ilium.

Figure 21
Assemble Quick Step Drill over the 3.2mm Trocar Pin Short

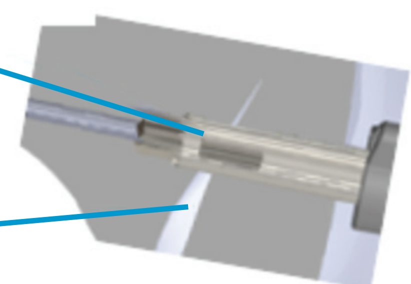


Figure 22
Confirm side windows of the Quick Step Decorticator are within the sacroilic joint

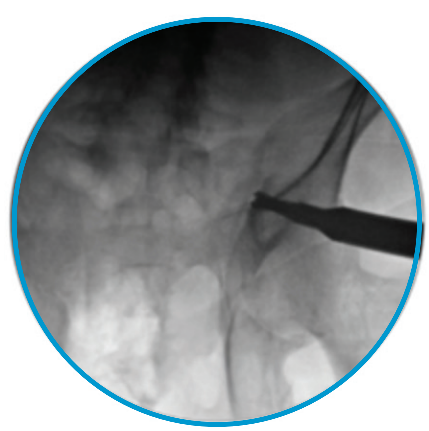


Figure 23
Confirm placement with Outlet Oblique view

Surgical Technique *(cont.)*

NOTE:

A procedure for decortication utilizing an alternative method is detailed in STM004 SImmetry+ Addendum.

QUICK STEP-DECORTICATOR CUTTING ELEMENT INSERTION

Remove the Quick Step Drill and the 3.2mm Trocar Pin Short while keeping the Quick Step Working Cannula in place (Figure 24).

Figure 24
Quick Step Working Cannula in place

Assemble the Decorticating Cutting Blade and Quick Step Decorticator Shaft together on the back table by aligning laser markings (Figure 25).

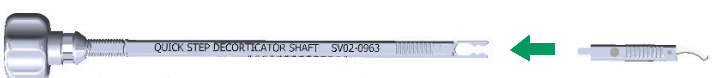


Figure 25
Assemble Quick Step Decorticator Shaft to the Decorticator Blade

Insert the assembled Quick Step Decorticator with the Decorticator Blade into the back of the proximal end of the Quick Step Working Cannula until you hear an audible **click** (Figure 26).

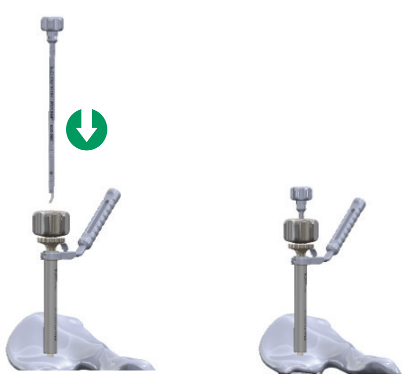


Figure 26
Insert the assembled Quick Decorticator with Blade into the Quick Step Working Cannula.

DECORTICATING STEP

To deploy the cutting element, rotate the proximal Quick Step Decorticator Shaft knob clockwise by two clicks. To decorticate, begin by rotating the proximal handle of the Quick Step Working Cannula (either direction) two or more complete rotations or until resistance drops (Figure 27). Two audible click of the Quick Step Decorticator Shaft knob is equal to approximately 1mm of deployment of the cutting element. Repeat the deployment and decortication steps while confirming progress with fluoroscopic imaging to ensure proper cutter deployment and that the cutting element is within the margins of the sacroiliac joint and not destroying the cortex of the lateral sacral wall or the medial ilial wall.

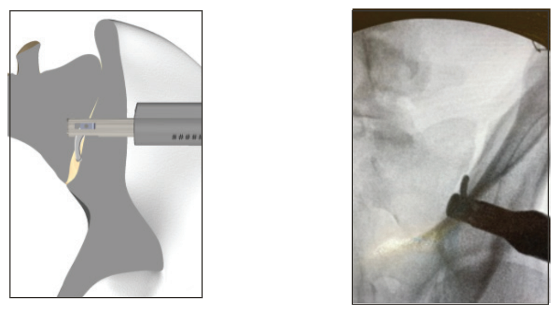


FIgure 27
Decortication of the sacroiliac joint

CAUTION:

Extending the Cutting Element outside the joint margins may damage surrounding anatomical structures. It is suggested to take an Inlet View to confirm that there is not an anterior breach of the cutting element.

NOTE:

If an obstruction is met during the decortication step, attempt the following until full rotations can resume.

1. **Rotate the Handle the opposite direction and continue in that direction.**
2. **Retract the Knob counterclockwise, click-by-click, until full Handle rotations can resume.**

The Decorticator is fully deployed when the Knob reaches the Stop Position.

Surgical Technique *(cont.)*

QUICK STEP CUTTING ELEMENT REMOVAL

Fully retract the Decorticator by rotating the Knob counterclockwise until the Knob reaches the Retracted/ Start Position.

Remove the Decorticator Shaft and cutting element from the Quick Step Working Cannula by pressing the release button that is recessed into the Quick Step Working Cannula handle (Figure 28).

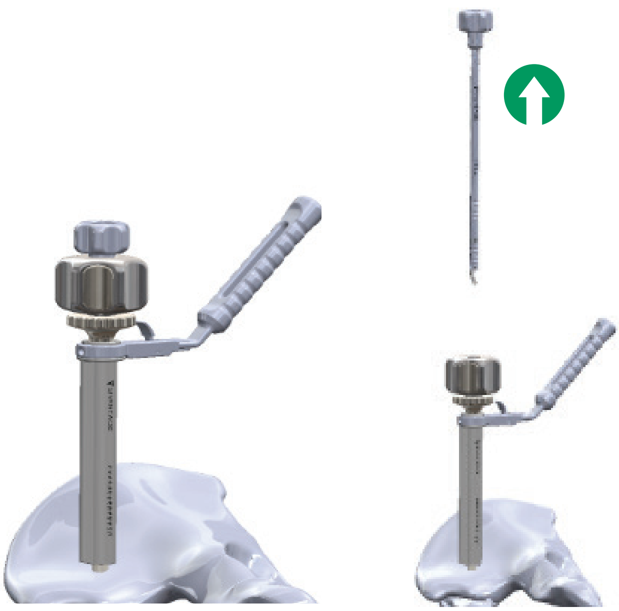


Figure 28
Remove the Decorticator Shaft and cutting element from the Quick Step Working Cannula

> **NOTE:**
>
> **If the cutting element cannot be fully retracted, remove the Quick Step Decorticator with the Cutting Element.**

QUICK STEP-GRAFT INSERTION

Prepare 5-10cc of a suitable void filler medium in the Graft Tube on the back table (Figure 29). This will be used to fill the void created by the decorticators cutting element.

Figure 29
Graft Tube

Use the Suction Tube instrument to lavage the decorticated space that has been created in the sacroiliac joint (Figure 30).

Suction Tube

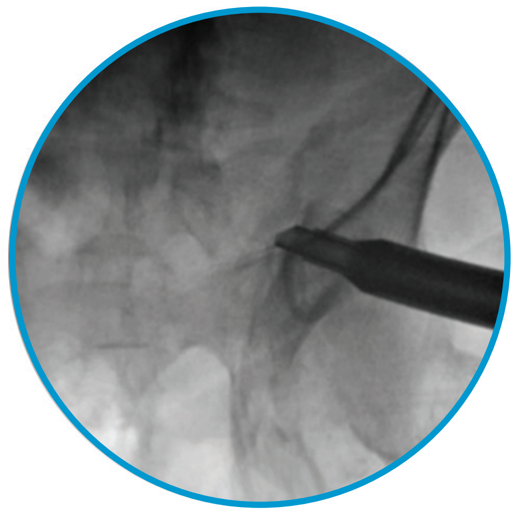


Figure 30
Use Suction Tube instrument to lavage decorticated space

> **CAUTION:**
>
> **Graft tube is required for graft deployment. Failure to use graft tubes will result in inability to remove single step instrument from patient.**
>
> **Do not overfill the joint space.**

Surgical Technique *(cont.)*

Insert the Graft Tube into the Quick Step Working Cannula until it is fully seated. Insert the Graft Press down the Graft Tube to deploy void filler (Figure 31).

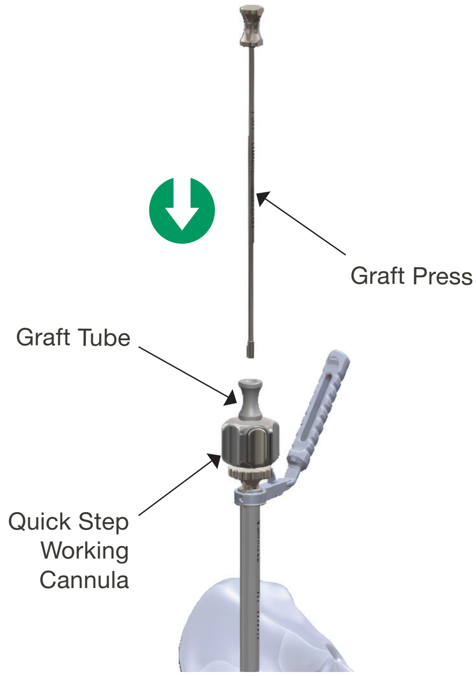
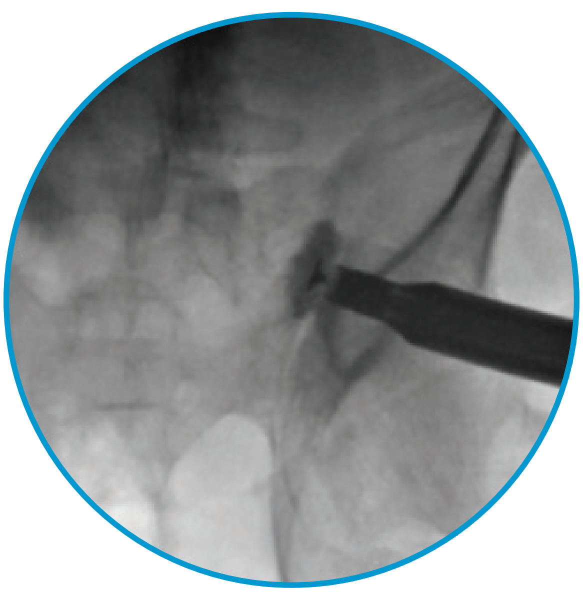


Figure 31
Insert Graft Press down into Graft Tube



X-Ray of deployed graft sacroiliac joint

Once graft is deployed remove the Graft Press and Graft Tube. Repeat as necessary.

Once the joint space is thoroughly grafted, remove the Graft Tube from the Quick Step Working Cannula.

Next, replace the 3.2mm Trocar Pin Short utilizing the 3.2mm Blunt Pin, by re-inserting the Quick Step Drill into the Quick Step Working Cannula. This will ensure accurate placement of the new 3.2mm Blunt Pin in the previous pin trajectory. It is advised to confirm the 3.2mm Blunt Pin placement with Posterior Oblique, Inlet, and Outlet views.

Next, Remove the Quick Step Drill and the Quick Step Working Cannula, leaving behind the 3.2mm Blunt Pin and the Final Dilator (Figure 32).

Figure 32
3.2mm Blunt Pin and the Final Dilator

Surgical Technique *(cont.)*

IMPLANT AND ASSEMBLY AND INSERTION

Step 1: Drill

If you did not decorticate and are using larger than a 9.5mm SImmetry+ implant you must drill into the sacral cortex with the corresponding drill.

Step 2: Assemble

Assemble the Implant Tower and SImmetry+ implant on the back table by inserting the distal tangs on the tower into the implant head and rotating the Implant Tower 90 degrees until an audible click is heard and it cannot continue to turn. The SImmetry+ implant should now be attached to the Implant Tower (Figure 33).

Insert the Implant Driver down the tower by ensuring the driver tip aligns with the implant. (Figure 34). Once the Implant Driver is fully seated on the implant, thread on the proximal end of the Implant Driver knob to the tower in a clockwise direction.

Then attach the T-Handle handle to the proximal end of the Implant Driver (Figure 35).

Step 3: Insertion

When inserting the Implant Tower and Implant Driver down the Final Dilator, face the driver indication marking the same orientation as the v-slot of the Final Dilator.

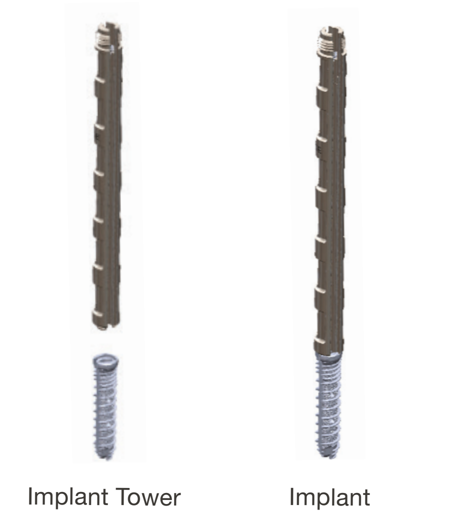


Figure 33
Assembly of Implant Tower and Implant

Figure 34
Assembly of the Implant Tower with Implant and Implant Driver

Figure 35
Attach the T-Handle to the Implant Driver

Surgical Technique *(cont.)*

Begin to insert the implant by rotating the Ratchet T-Handle to the desired depth while monitoring with fluoroscopy. (Figure 36).

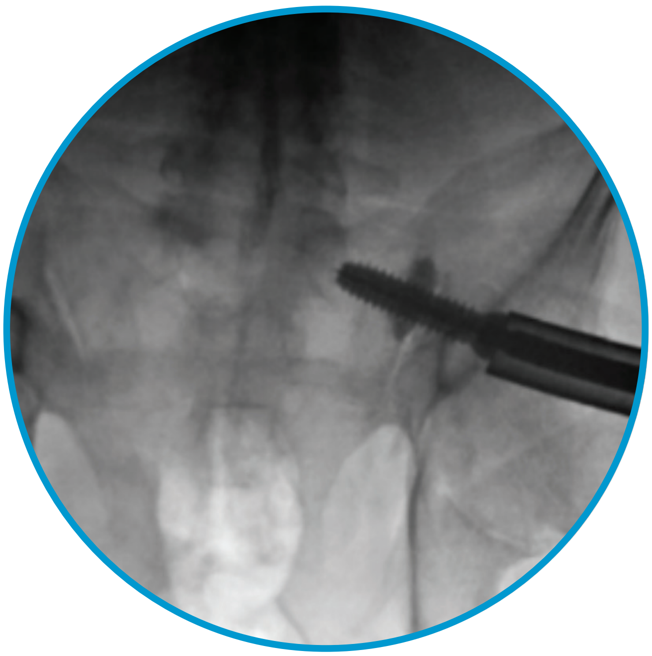


Figure 36
Implant at the desired depth

Once SImmetry+ is implanted to the desired depth, turn the proximal driver knob counterclockwise until not engaged and remove the Implant Driver out of the Implant Tower.

Step 4: Implant Tower Removal

To remove the Implant Tower press and hold the proximal tower button while rotating the tower 90 degrees counterclockwise. At this point you may remove the Implant Tower from the patient (Figure 37).

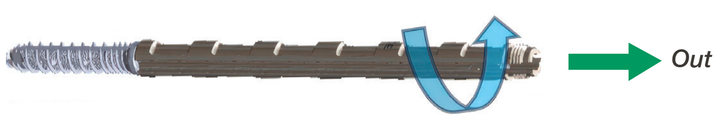


Figure 37

Step 5: Additional Implant Placement

When using additional implants for fixation of the sacroiliac joint and performing additional decortication, repeat the steps of Targeting, Decortication, Implant Assembly and Insertion for all planned implants, while taking into consideration the specific anatomy of that patient's sacroiliac joint, as well as the size and orientation of the first implant.

For additional implant placement without decortication, see Implant delivery of SImmetry+ Without Decortication below.

IMPLANT REMOVAL

Start of Removal Process

To remove the implant, insert the 3.2mm Blunt Pin into the patient and onto the top of the implant. Insert Dilator 1 followed by Dilator 2 and the Final Dilator. You can now remove Dilator 1, Dilator 2 and the 3.2mm Blunt Pin.

SImmetry+ IMPLANT REMOVAL

Insert the Implant Tower tangs down the Final Dilator into the head of the implant and rotate the Implant Tower 90 degrees clockwise. The surgeon should hear an audible click to confirm the tower is locked on to the implant. With the Implant Tower attached, insert the SImmetry+ Implant Driver down the tower until engaged with the head of the SImmetry+ implant.

Attach the quarter square T-handle and turn it counterclockwise to reverse the implant.

CAUTION:

Carefully watch the implant removal under fluoroscopy

Once the implant is fully unthreaded from the bone, it, along with the Implant Tower, can be removed from the patient.

Surgical Technique *(cont.)*

IMPLANT DELIVERY OF SImmetry+ WITHOUT DECORTICATION.

Multiple SImmetry+ implants may be utilized to attain increased fixation. At the surgeons' discretion, the SImmetry+ implants may be placed without the decortication step.

Step 1

Follow the same steps for surgical setup, initial targeting and continue through the surgical technique through Step 3, which includes: 3.2mm Trocar Pin placement, dilation of soft tissue, measurement of screw length, and continued soft tissue dilation to the Final Dilator.

Step 2: Implant Tower Removal

The drills in the SImmetry+ SI Joint Fusion system correlate to specific implant sizes.

There is a Drill for the 9.5mm SImmetry+ implant, the 12.5mm SImmetry+ implant, and the 14.5mm SImmetry+ implant. Choose the appropriate Drill for the desired SImmetry+ implant diameter.

Once the implant diameter is selected, drill to a minimum depth that perforates the lateral cortex of the sacral wall by at least 5mm. The SImmetry+ implants are self-drilling, self-tapping and self-harvesting.

NOTE:

3.2mm pin exchange from 3.2mm Trocar Pin Short to 3.2 Blunt Pin can be performed as a safety precaution.

Once the desired depth has been reached with the drill, remove the drill from the patient and follow the surgical procedure as outlined above for implant assembly and insertion.

Trademarks
Tenon Medical and SImmetry are trademarks or registered trademarks of Tenon Medical. **Rx Only**

Contact Information
For Customer Service and Reporting of Complaints or Adverse Events:

Use the following for information for customer service, including ordering, reporting complaints, or adverse events, and general information regarding Tenon Medical or products and services:

TENON MEDICAL®

Tenon Medical
104 Cooper Court
Los Gatos, CA 95032
Direct: 408.649.5760
Fax: 408.649.5756

Manufactured for:
Tenon Medical
104 Cooper Court
Los Gatos, CA 95032
Direct: 408.649.5760
Fax: 408.649.5756