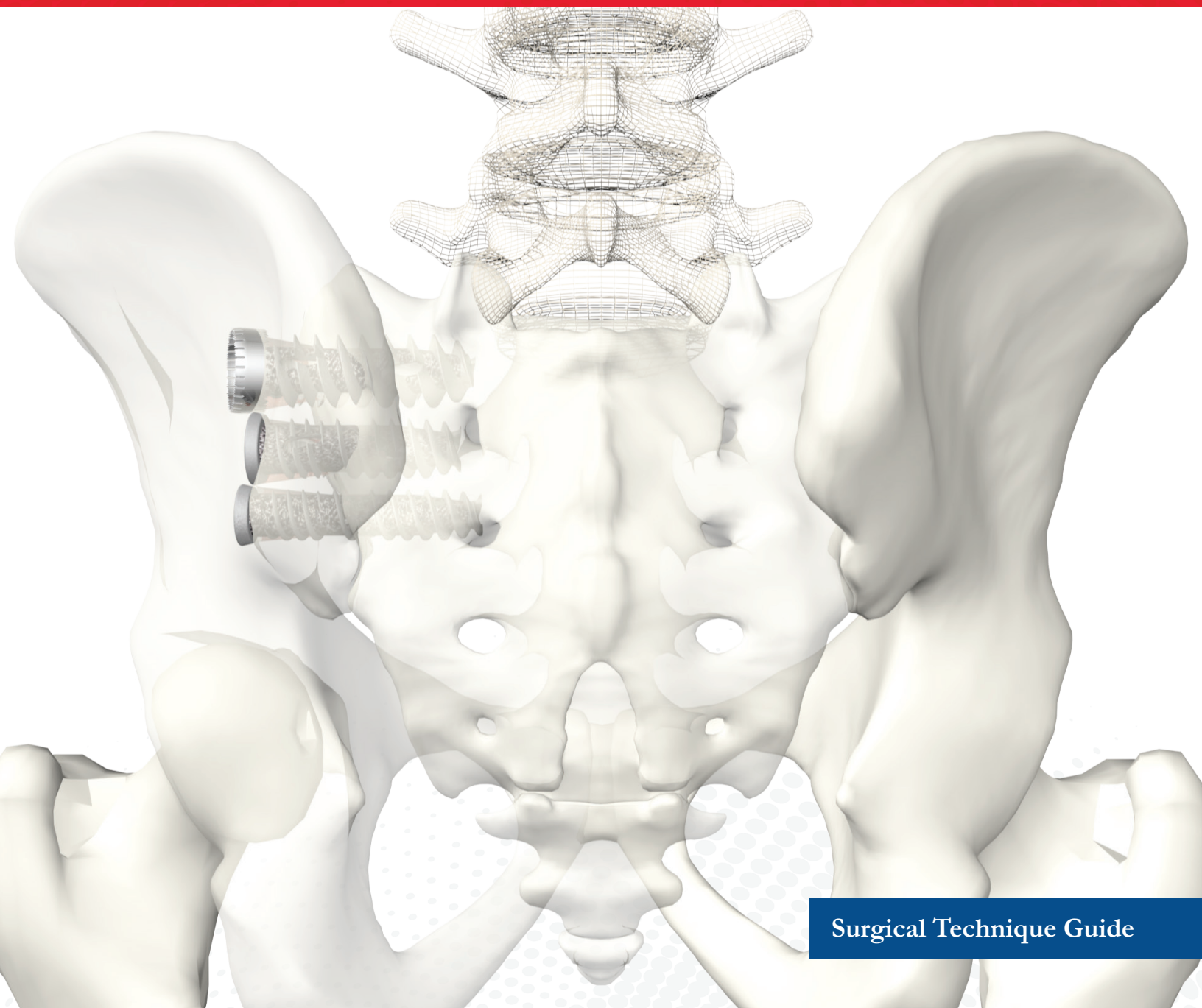
ZAVATION®

SIBER® TI

Sacroiliac Joint Fusion System with Swift Tip Technology®



Surgical Technique Guide

NEW!

THE SWIFT TIP DIFFERENCE

Siber® Ti now features Zavation's patented Swift Tip Technology® with cutting edges that lead directly to the threads, allowing for precise engagement even in the toughest bone.

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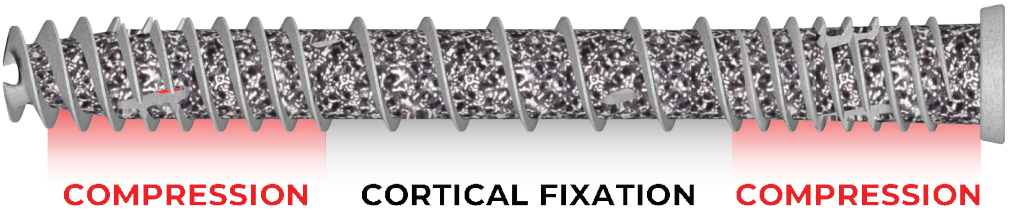
SYSTEM OVERVIEW

The Siber Ti Sacroiliac Joint Fusion System featuring Swift Tip Technology was designed to provide real joint compression the surgeon can feel. Siber Ti has surgical versatility for use in lateral, oblique, and S1AI* implantation approaches.



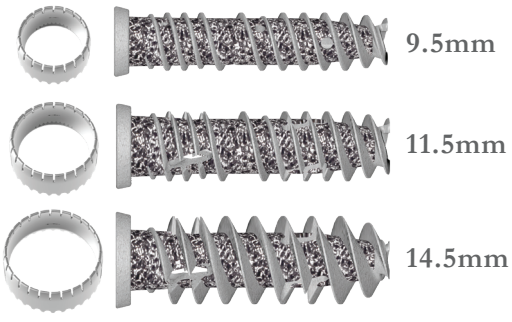
Features & Benefits

- Patented Mimetic Metal® technology creates textures at the macro, micro, and nano (MNM) levels†
- Self-harvesting threads and fenestrated shank allow for bony ingrowth postoperatively
- Swift Tip Technology® self-drilling, patented tip creates easier introduction into cortical bone
- 3D-printed and porous surface architecture
- Varied pitch and dual-lead threads provide a lag effect and tactile strong purchase
- Compression and non-compression thread styles

Implant Specifications

3D-Printed Implants

- **Diameters:** 9.5mm, 11.5mm, 14.5mm
- **Lengths:** 30mm-110mm‡ (5mm increments)



Machined Titanium Implants (Special Order)

- **Diameter:** 7.0mm
- **Lengths:** 30mm-70mm (5mm increments)

Washers (Optional)

The washers complement each screw diameter. They are intended to contour to the angle of the ilium and create tactile feel when the teeth grind into the cortical bone.

The 9.5mm, 11.5mm, and 14.5mm washers are 3D-printed.

*Supplemental fixation required. †Data on file. ‡75mm-110mm lengths Special Order only.

SYSTEM TECHNOLOGY

Mimetic Metal® Technology

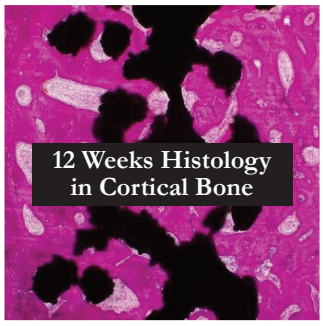
3D-Printed

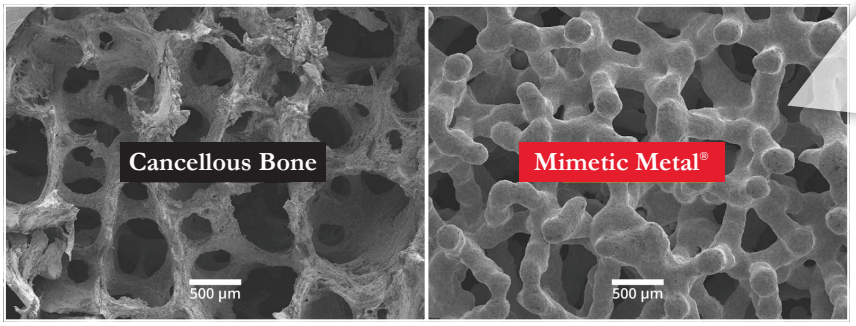
Mimetic Metal is a proprietary 3D-printed technology designed to emulate bone and provide optimal structure for healing.

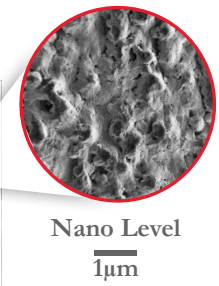
Mimetic Metal allows for greater bony on-growth and in-growth compared to machined titanium, shown in an in-vivo sheep model*.

Nano Properties

Siber Ti is engineered to have textured features at a nanometer level†, which has demonstrated the ability to elicit an endogenous cellular and biochemical response in-vitro.





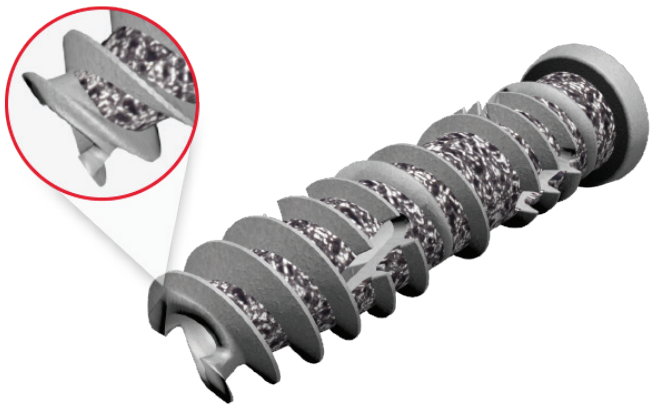


Swift Tip Technology®

New for Siber Ti

Siber Ti now features Zavation's patented Swift Tip Technology with cutting edges that lead directly to the threads, allowing for precise engagement even in the toughest bone.

Siber Ti's self-tapping and self-drilling capabilities, paired with its unique thread pitch, offer an ideal solution for placement and optimal compression of the sacroiliac joint.



*Data on file, pre-clinical data may not be representative of clinical results. †Data on file.

SACROILIAC JOINT OVERVIEW

SI Junction

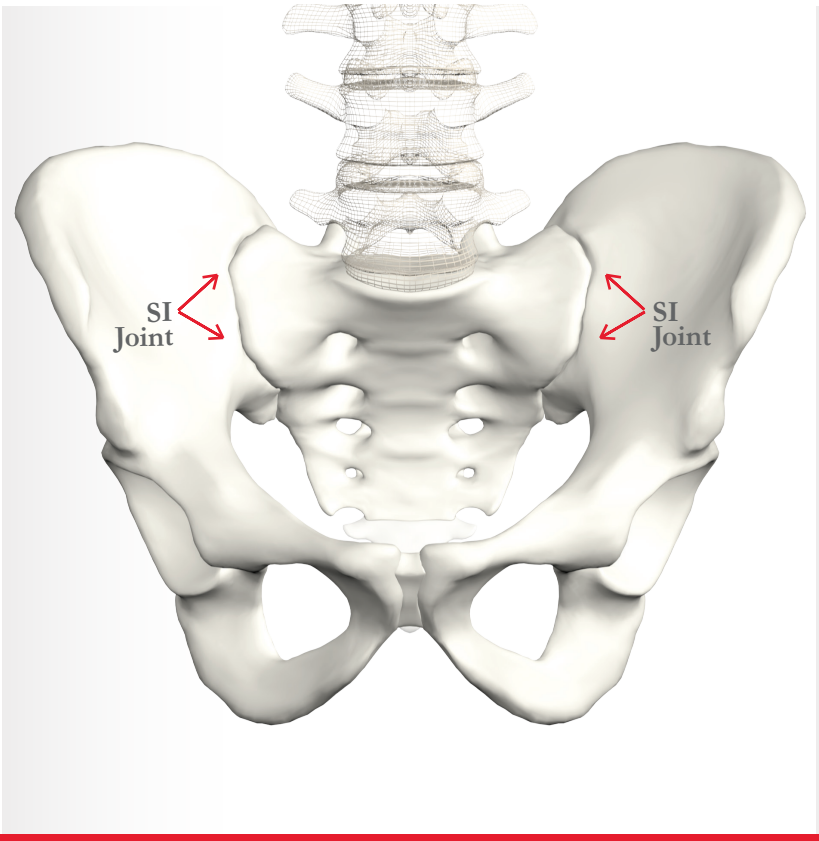
The sacroiliac (SI) joint is a bicondylar synovial joint which joins the sacrum into the ilium.

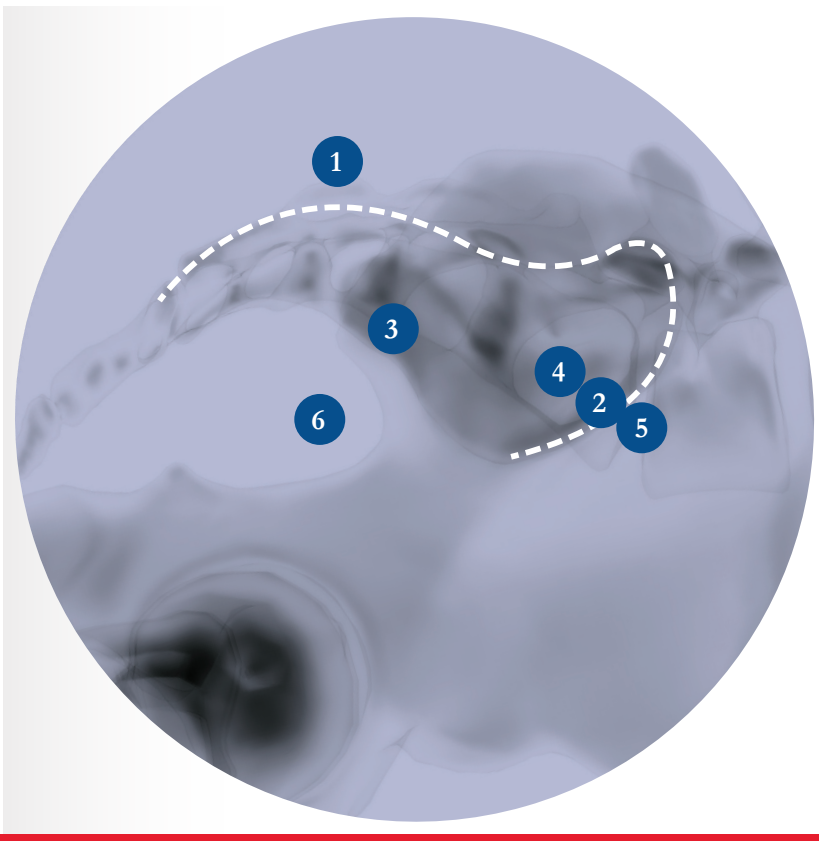
Siber Ti is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

In addition, it is designed to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar thoracolumbar fusion and non-traumatic fractures involving the SI joint.

SI Fluoroscopy (Lateral View)

1. Posterior Sacral Wall
2. Sacral Ala
3. Anterior Sacral Wall
4. Sacroiliac Joint (SI Joint)
5. L5-S1 Disc Space
6. Sciatic Notch





PATIENT POSITIONING & APPROACH

Patient Prep

The patient is put under anesthesia and positioned prone. The operative area is prepared and draped in the standard fashion. Radiographic guidance, such as C-arm fluoroscopy, should be considered throughout the procedure to ensure correct placement of the implant(s).

The initial guide wire targeting and positioning steps for the lateral SI, oblique SI, and Sacral-alar-iliac fusion techniques are different.

The subsequent steps of dilation, drilling, decortication, graft insertion, and removal are consistent between the techniques.

Targeting is shown for various approaches, however, instrumentation steps are only shown via the lateral approach.

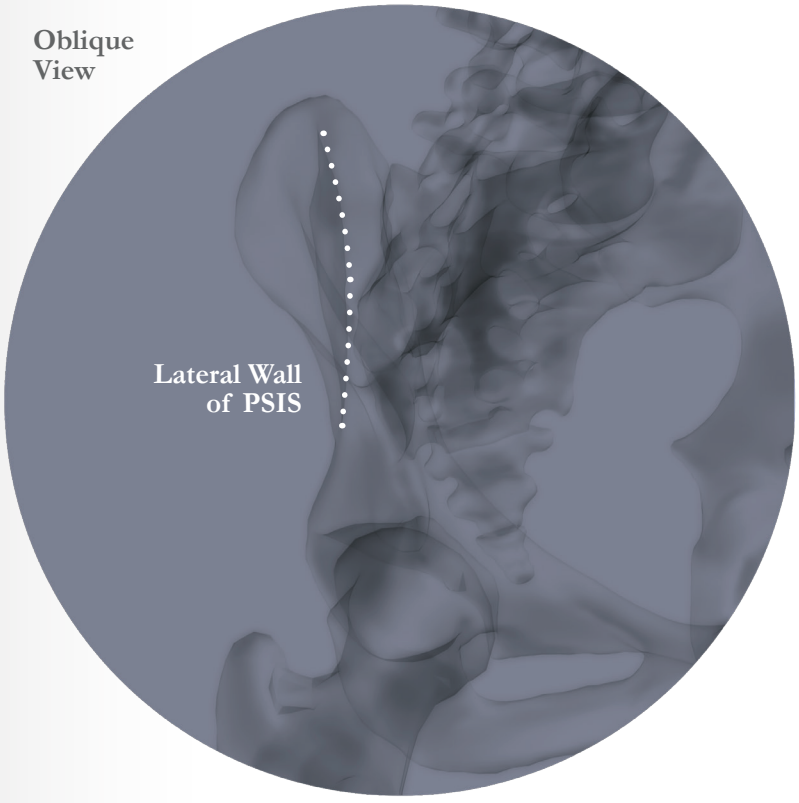
OBLIQUE APPROACH POSITIONING

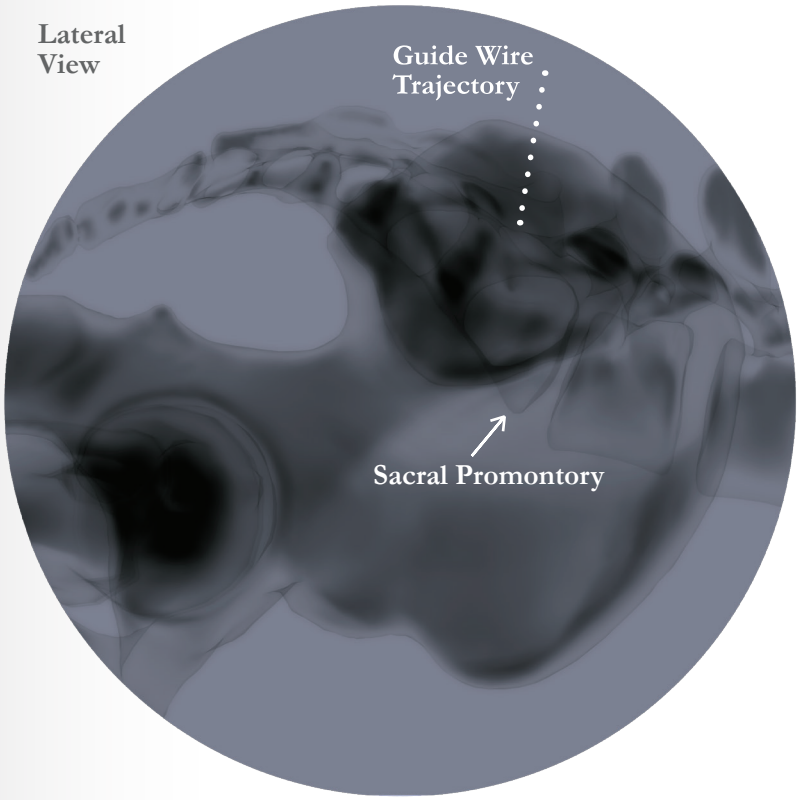
Targeting the Surgical Site

Palpate to locate the posterior superior iliac spine (PSIS). Using the posterior oblique view, confirm location and mark the lateral wall of the posterior superior iliac spine (PSIS).

Using the lateral view, confirm the desired entry point for the guide wire.

Make a 20-50mm incision at the PSIS (in the Posterior Oblique view) about the desired entry point. In the lateral view, this entry point is about 30mm inferior to the L5/S1 joint.





OBLIQUE APPROACH POSITIONING (Continued)

Confirming Trajectory

Confirm target positioning with fluoroscopy images in the lateral, outlet, and inlet views.

Lateral view: Trajectory should be directed at or inferior to the sacral promontory.

Outlet view: Trajectory should be in between marked lines identifying the superior aspect of the S1 foramen and the inferior aspect of the S2 foramen.

Inlet view: Trajectory should not breach the anterior pelvic brim.

Incise and elevate the fascia away from the PSIS. Use a retractor (or weitlander) to expose the PSIS and retract the tissue.

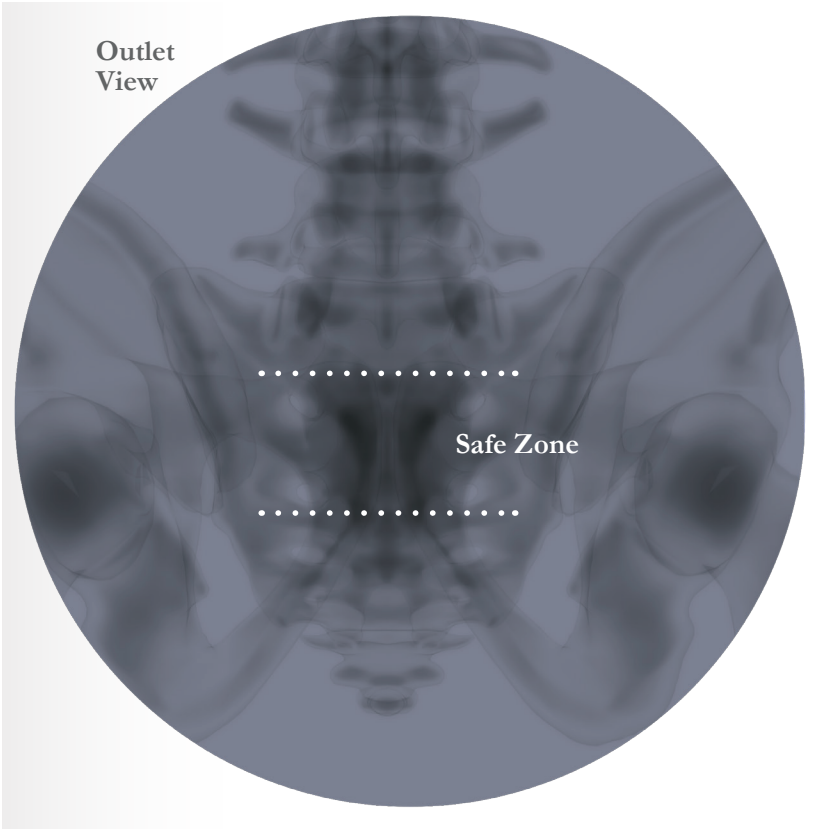
Guide Wire Placement

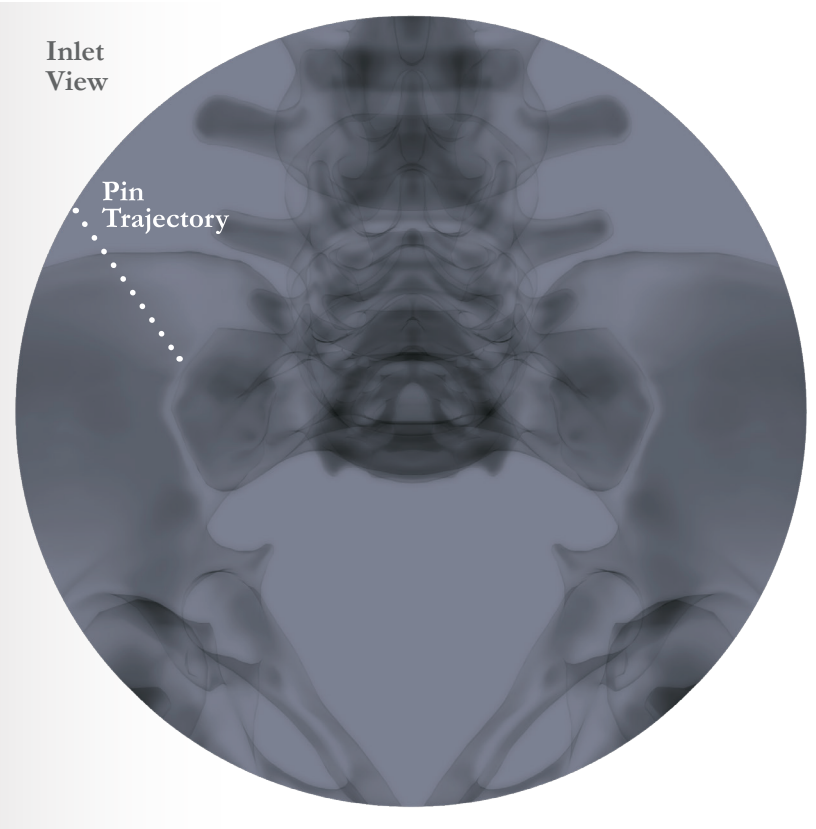
Starting from the lateral aspect of the PSIS, advance the guide wire through the ilium across the joint and into the sacrum to a depth of approximately 4cm-5cm.

The general trajectory of the guide wire should be approximately 10°-15° lateral to medial and 0°-10° cranial to caudal toward the sacral promontory. These angles may vary with patient anatomy and positioning.

Using radiographic imaging, confirm that the guide wire is approximately 1cm in the anterior sacral cortex. In the inlet view, the guide wire should not breach the anterior pelvic brim.

Proceed with screw preparation steps starting on page 10.





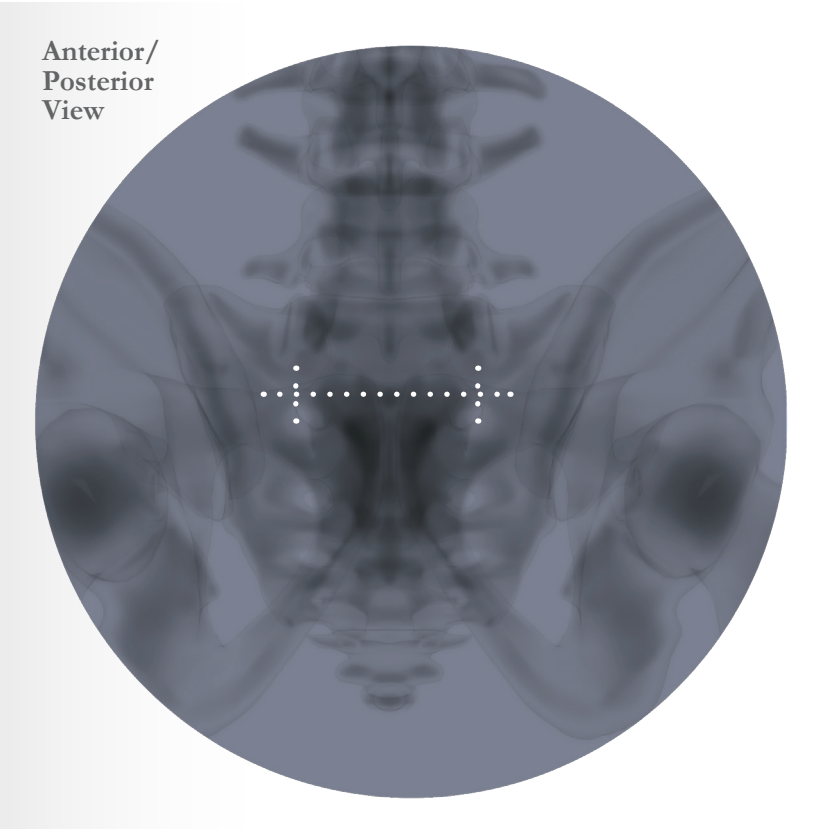
SACRAL-ALAR-ILIAC FIXATION TECHNIQUE (S1AI IMPLANT ALONG S2AI CONSTRUCT)

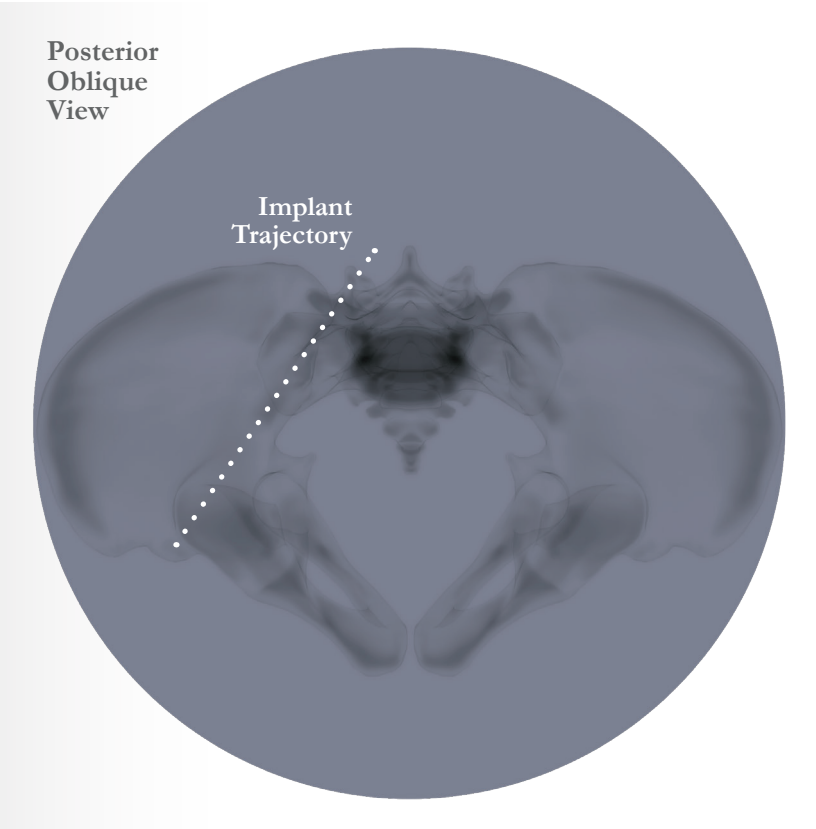
Targeting the Surgical Site

The S1AI technique can be used alongside the existing S2AI construct to stabilize the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. The device should be used in conjunction with additional fixation.

Make a 2cm midline incision to approach both sides for sacral-alar-iliac screw placement.

Locate the S1 and S2 dorsal foramina in the sacrum in an anterior-posterior fluoroscopic view. These points will serve as a starting point for the Jamshidi needle. The starting point is midway between the S1 and S2 foramina on the lateral border of the fluoroscopic view.





SACRAL-ALAR-ILIAC FIXATION TECHNIQUE (S1AI IMPLANT ALONG S2AI CONSTRUCT) (Continued)

Guide Wire Placement

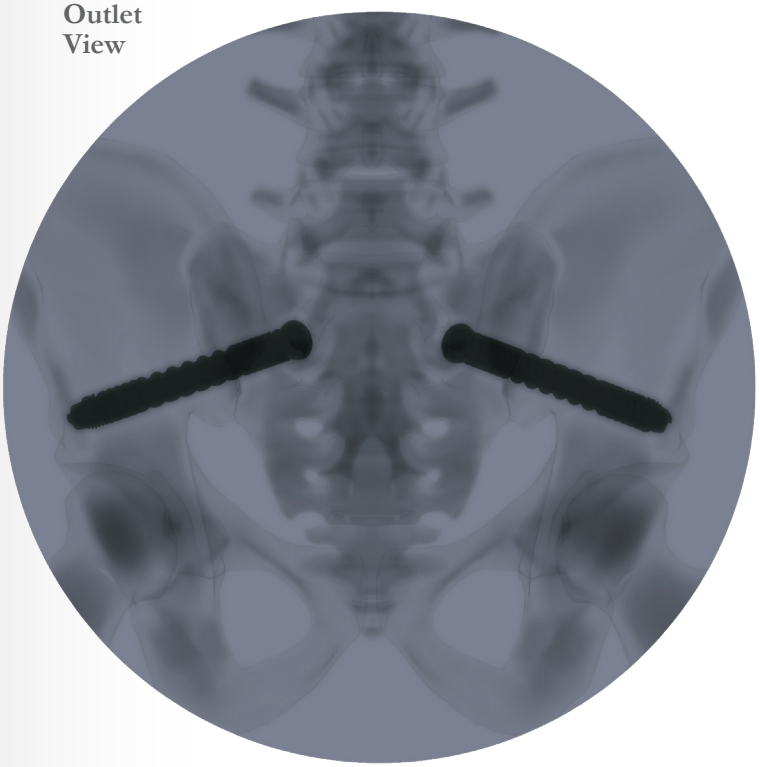
Angle the needle toward the anterior inferior iliac spine. Advance it into the sacral alar. Using the posterior oblique view, verify that the needle is in through the joint into the ilium.

Place the guide wire into the Jamshidi needle under A/P fluoro.

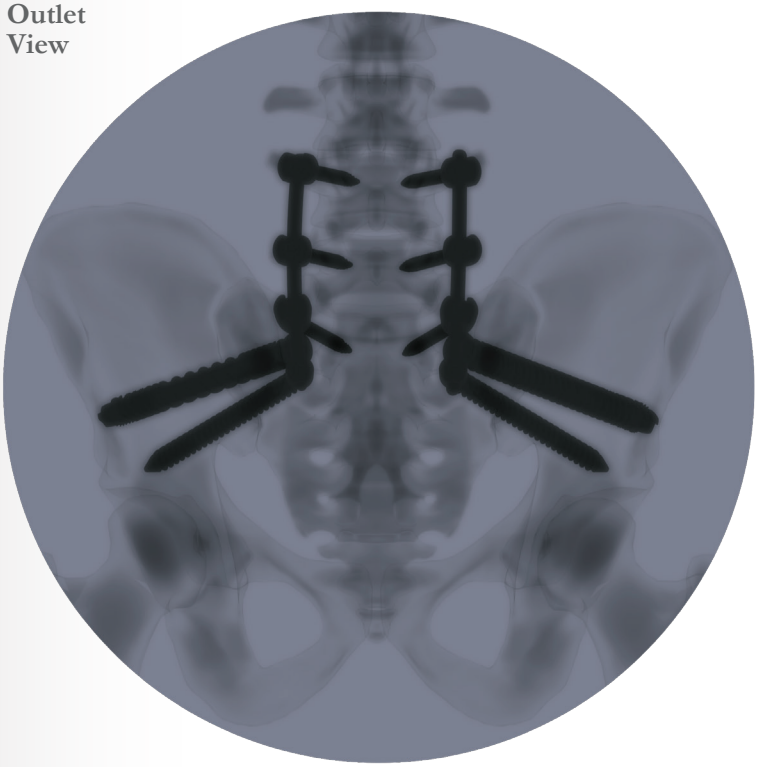
One to two points of fixation, in addition to an S2AI screw, are recommended.

Proceed with screw prep on page 10.

Outlet View

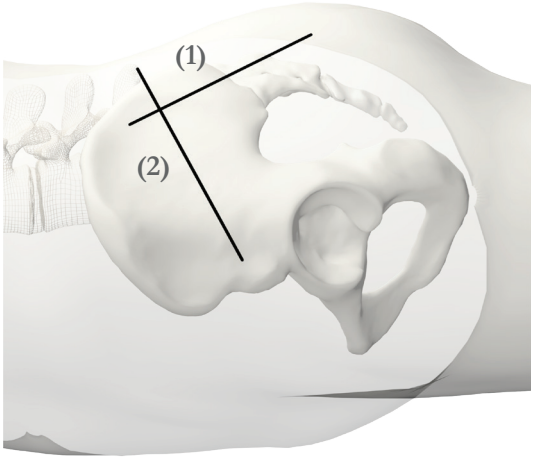


Outlet View



LATERAL APPROACH INITIAL TARGETING

Using the exchange flat pin (5040-103) locate the posterior sacral wall (1) and the sacral alar line (2) via lateral fluoroscopy and demarcate on patient.

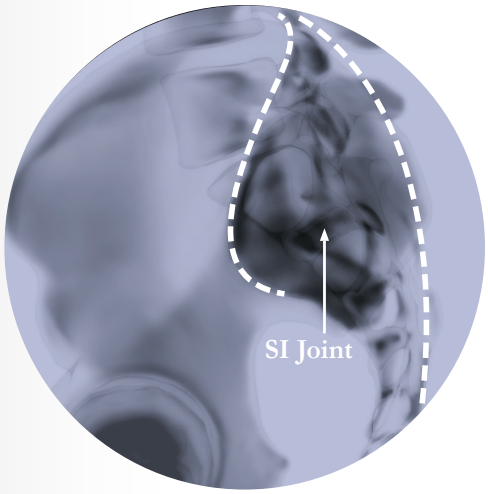


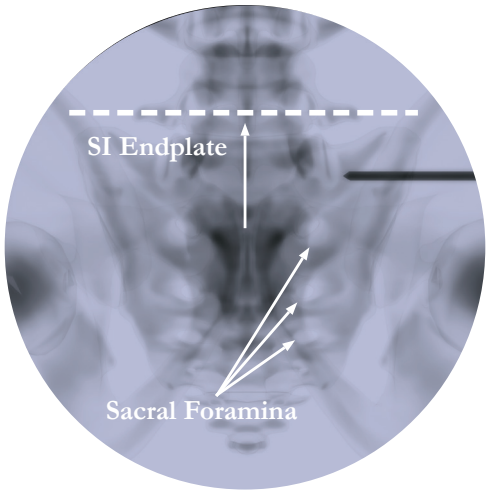
Make an incision along the posterior sacral wall of at least 3cm in length starting at the intersection with sacral alar skin marking.

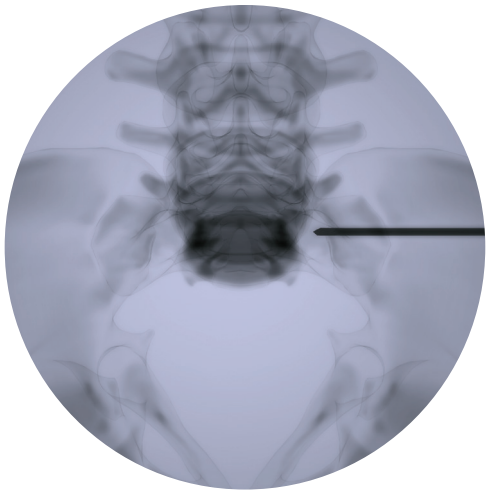
Using the trocar tip guide wire (5040-100), create an initial target vector by inserting through the incision approximately 1cm anterior to the posterior sacral wall and 1cm inferior to the ala.

Place the guide wire using the guide wire holder (5000-164) to protect the surgeon's hands from direct path of fluoroscopy.

Using lateral, outlet, and inlet fluoroscopy, confirm that the guide wire is pointing to the middle of the sacrum. Return the fluoroscopic view to an outlet position. Confirm that the guide wire is parallel to the S1 endplate.





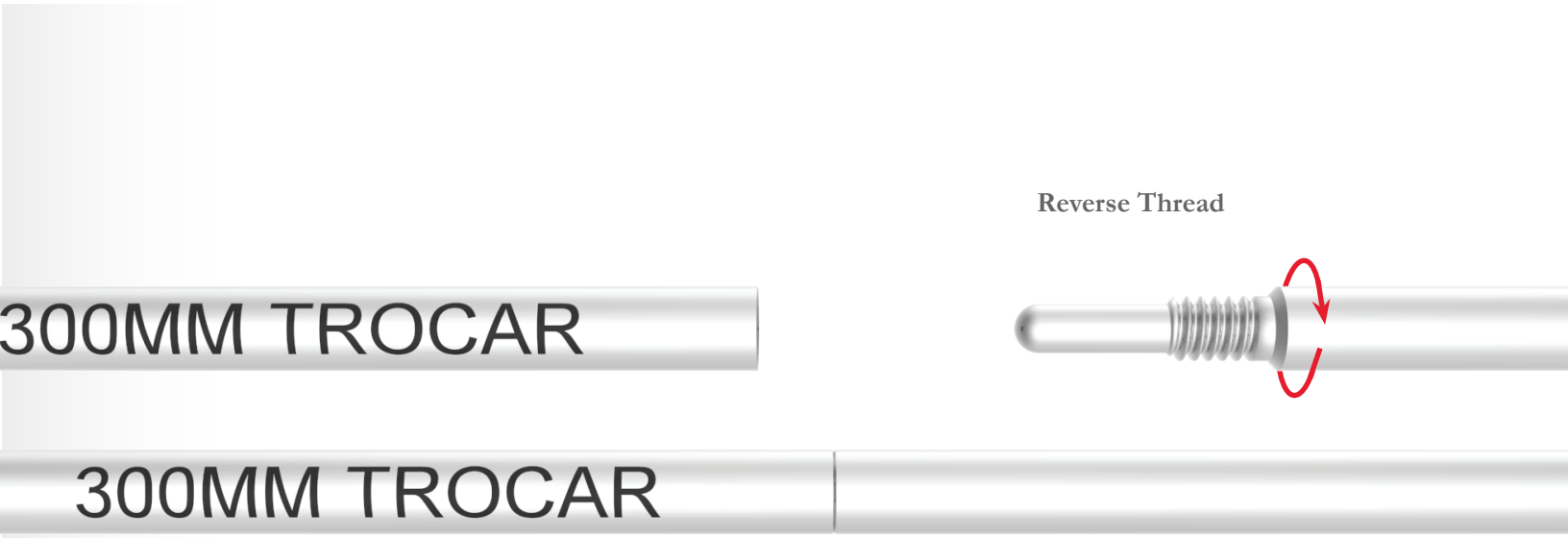


LATERAL GUIDE WIRE APPROACH POSITIONING

Impact the guide wire using the mallet (2042-220) provided in the set to advance the guide wire. Be sure to use the radiolucent guide wire impactor (8040-102). This will help retain the proximal end of the guide wire and prevent warping. Remove the impactor and take fluoroscopy images to confirm placement. Proceed with screw prep on page 10.

WARNING: The distal end of the guide wire must be monitored at all times during surgery to ensure patient safety. This is critically important to monitor during drilling, tapping, and implantation.

Stackable wires (5040-112 and -113) are available in the set to extend construct during the screw hole preparation and screw insertion. A 500mm wire (5040-103) is also available. See page 12.

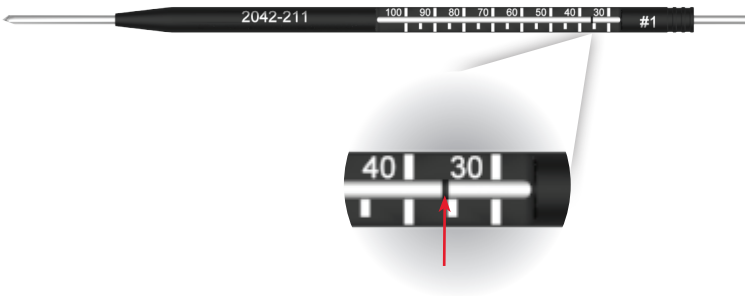


SCREW PLACEMENT PREPARATION

Exposing the Working Channel

Begin creating the working channel by sliding Dilator #1 (2042-211) over the guide wire until it is against the iliac crest. Measure the implant length using the laser mark on the middle of the guide wire and the measurement marks on the dilator. Ensure the dilator is firmly against bone for an accurate reading.

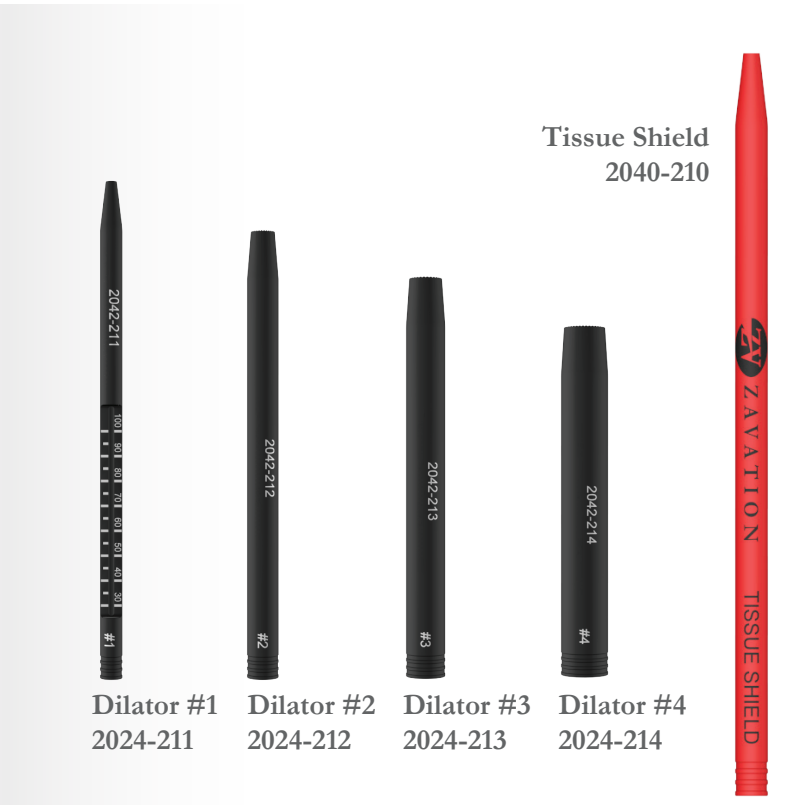
Sequentially slide the remaining dilators #2 through #5 (where applicable).



As shown in the table below, not all dilators are needed for each implant diameter. To test for impedance, replace dilator 1 with the tissue shield (2040-210).

Implant Size	Without Washer	With Washer
7.0mm	#2 Dilator	#3 Dilator
9.5mm	#3 Dilator	#3 Dilator
11.5mm	#4 Dilator	#4 Dilator
14.5mm	#4 Dilator	#5 Dilator

Remove all dilators except the working channel, the largest dilator. The dilator handle can be attached for a better field view and additional leverage. **NOTE:** Dilators #2-5 are radiolucent.

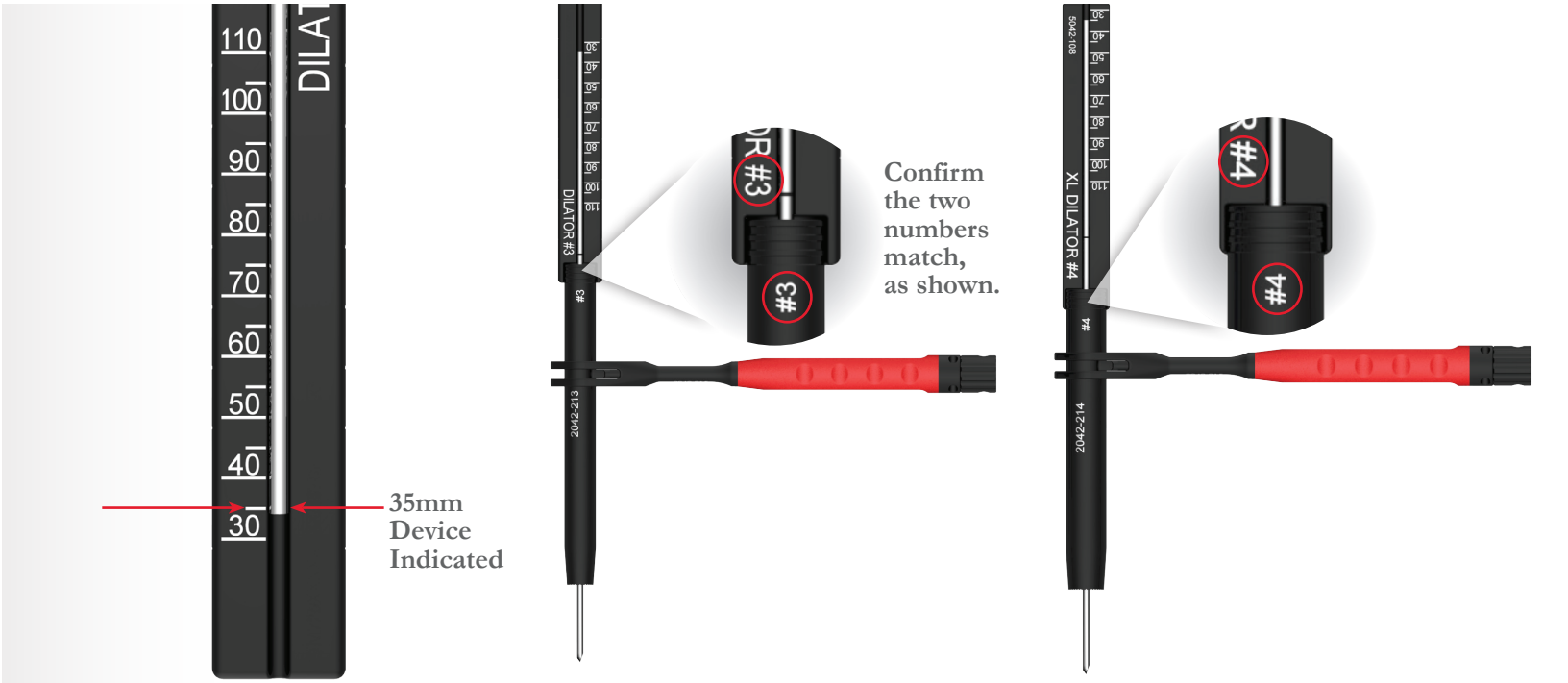


SCREW PLACEMENT PREPARATION (Continued)

Implant Length Gauge

The implant length gauge (5042-108) is a secondary measurement option for the #3 and #4 dilators. The gauge has two sides, one for each dilator.

Fit the corresponding dilator into the appropriate side. The guide wire will lay in the central channel of the gauge and the end of the wire indicates the measured length.



STACKABLE GUIDE WIRE

The blunt stackable wire (5040-113) can be threaded into the proximal end of the trocar guide wire prior to drilling. Take note of the reverse thread connection point to prevent unthreading while drilling, tapping, and inserting screws.
This stackable feature allows constant proximal control of the guide wire.

When using power, a third stacked blunt guide wire can provide additional length, making the passing of the power drill down the guide wire easier.

The 500mm exchange pin (5040-103) is available for surgeons who do not want to stack wires.

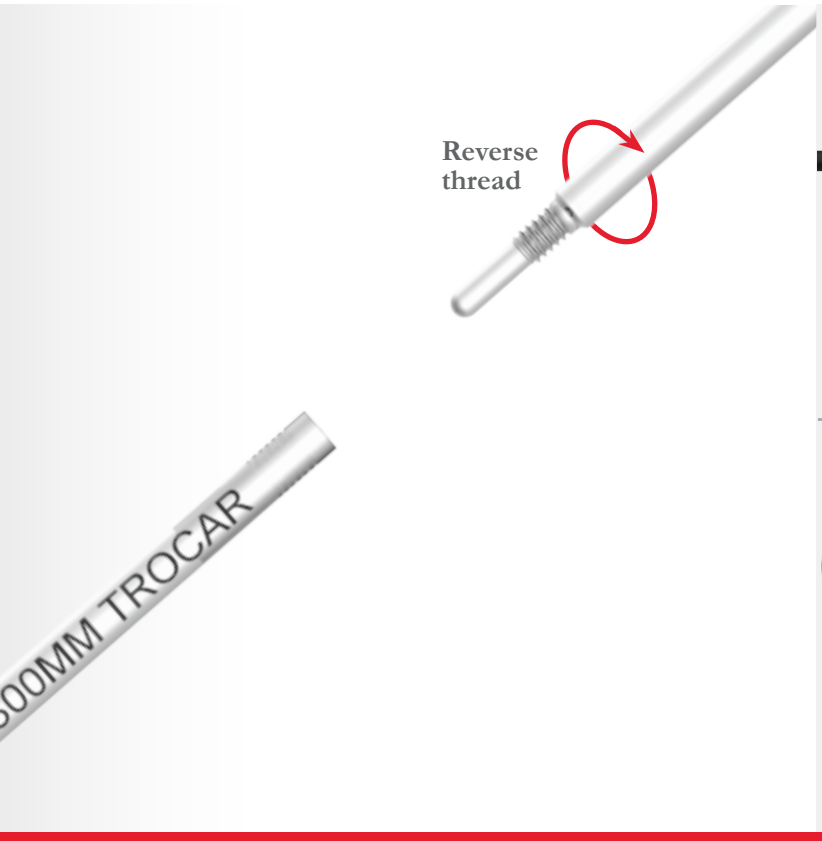
CAUTION: Guide wires should not be stacked when:
1. the first wire is being advanced into the patient,
2. using the implant length gauge, **or**
3. when a lateral fluoroscopy image is being taken (due to the close nature of the fluoroscopy machine during a lateral image).

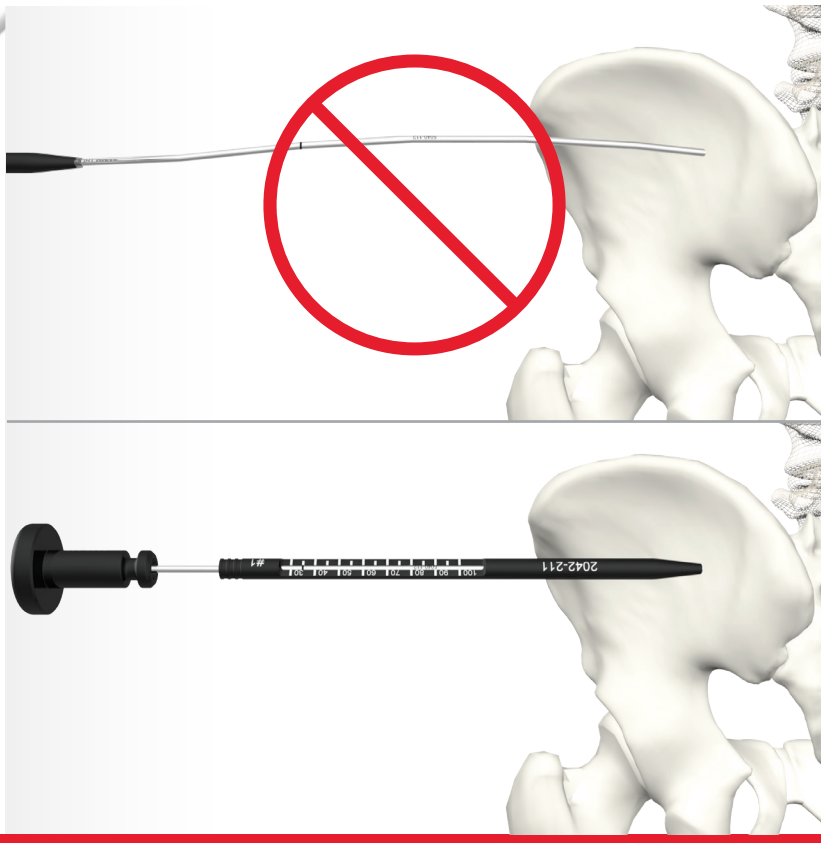
Guide Wire Placement

Do not redirect guide wire during placement. This could cause bending and difficulty with instruments passing over.

Do not mallet directly onto the proximal end of the guide wire. This will cause damage the threads for stacking guide wires. Always use the radiolucent guide wire impactor when using the mallet.

NOTE: For additional stability when placing the wire into hard bone, slide the #1 dilator down the wire to the bone to support the wire and prevent bending while impacting.



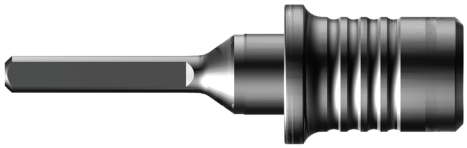


PILOT HOLE PREPARATION

Attach the appropriate drill (7.0mm, 9.5mm, or 11.5mm/14.5mm) to a ratcheting handle.

If desired, the Jacob's Chuck Adapter (8100-105) enables use of a cordless power drill.

At this point, the wires can be stacked.

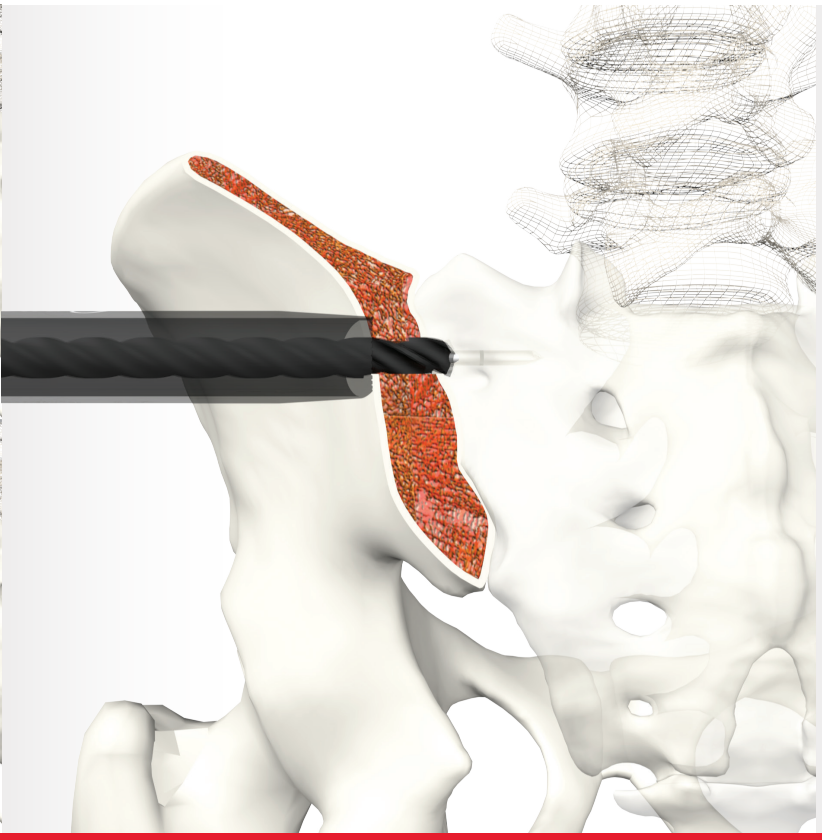


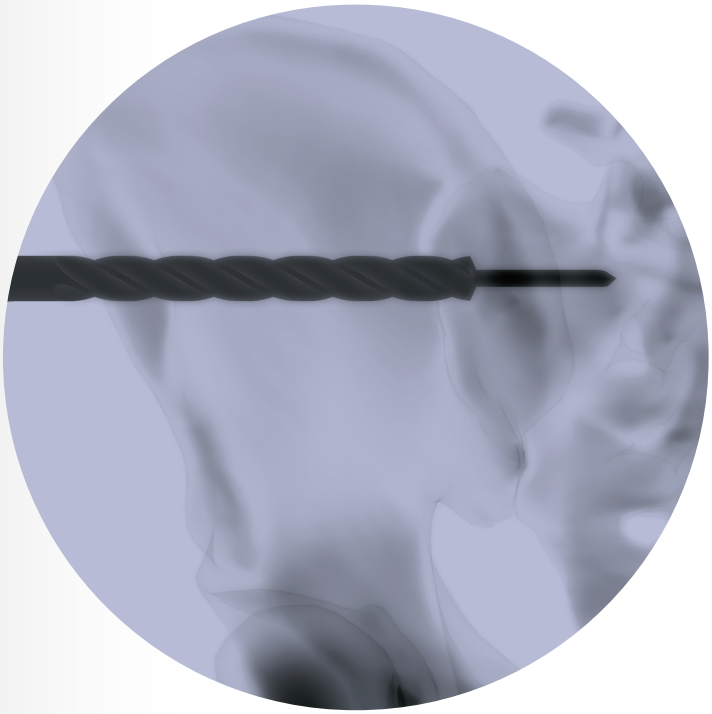
Jacob's Chuck Adapter
8100-105

Place the drill over the guide wire and advance until the ilium is reached. Drill and tap depth markings are only relevant to the #3 and #4 dilators and their appropriate to use cases.

See chart on page 10 for implant and dilator pairing.

Continue advancing until the drill crosses the sacroiliac joint. Periodic images via fluoroscope are encouraged to confirm trajectory. If desired, the drill depth can match the desired implant length.





PILOT HOLE PREPARATION (Continued)

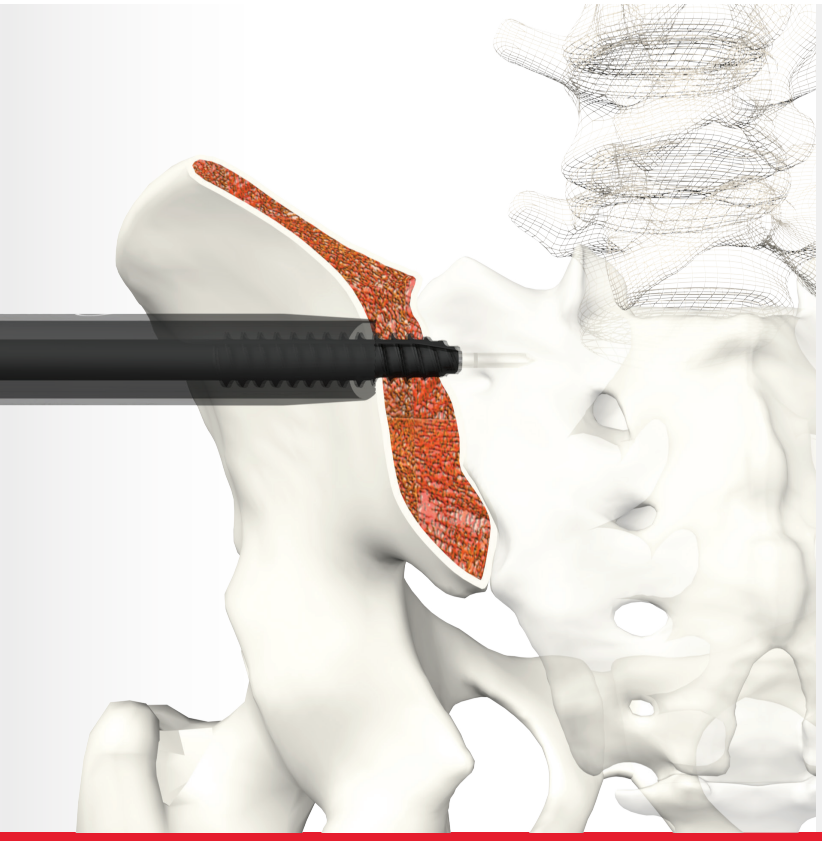
If using stackable wires, keep downward pressure and slide drill toward proximal end of the wires when finished drilling.

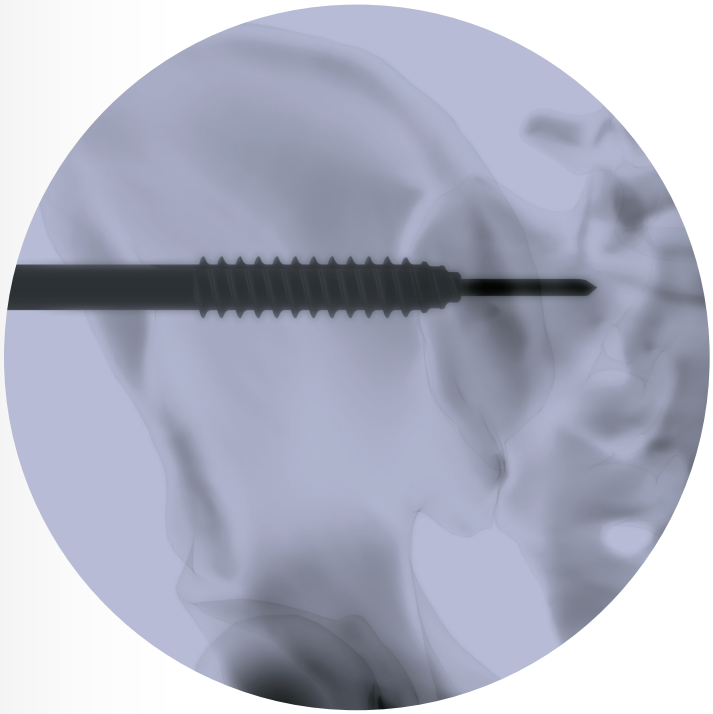
If using non-stackable wires, place the exchange pin (5040-103) down the cannulated portion of the handle-drill interface until it presses on the proximal tip of the guide wire.

Keep downward pressure on the exchange pin while removing the drill to ensure the guide wire stays in place. Forward drilling while removing will prevent guide wire from detaching and allow for autologous bone harvesting in drill threads.

Place the appropriate tap (7.0mm, 9.5mm, 11.5mm, and 14.5mm) on the ratcheting T-handle. Advance the tap over the guide wire in the same manner as the drill.

Pay close attention to the wire, assuring it keeps the guide wire in place during reverse rotation and removal of the tap.

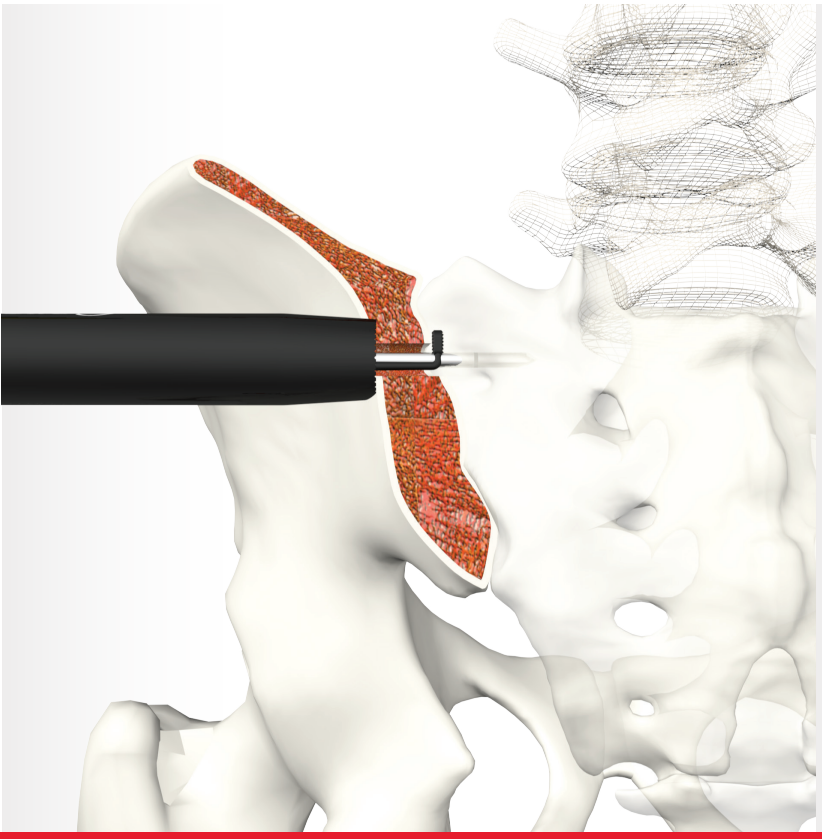




OPTIONAL: PREPARING THE JOINT FOR FUSION

Use the decortication tool (5042-105) through the dilator to remove ligamentous tissue and prepare the joint for bony fusion. Verify joint locator is in joint with pelvic inlet view.

Once the decortication tool is inside the joint, rotate the instrument circumferentially around the guide wire to decorticate the joint.



HOW TO TRANSFER THE IMPLANT TO THE STERILE FIELD

Shrink Sleeve

1. Remove the shrink sleeve of the implant tube using the tear strip as shown.

NOTE: Implant sizes are listed on the patient labels and tamper seals.

Patient Labels

2. Remove the patient labels from outer tube.

HOW TO TRANSFER THE IMPLANT TO THE STERILE FIELD (Continued)

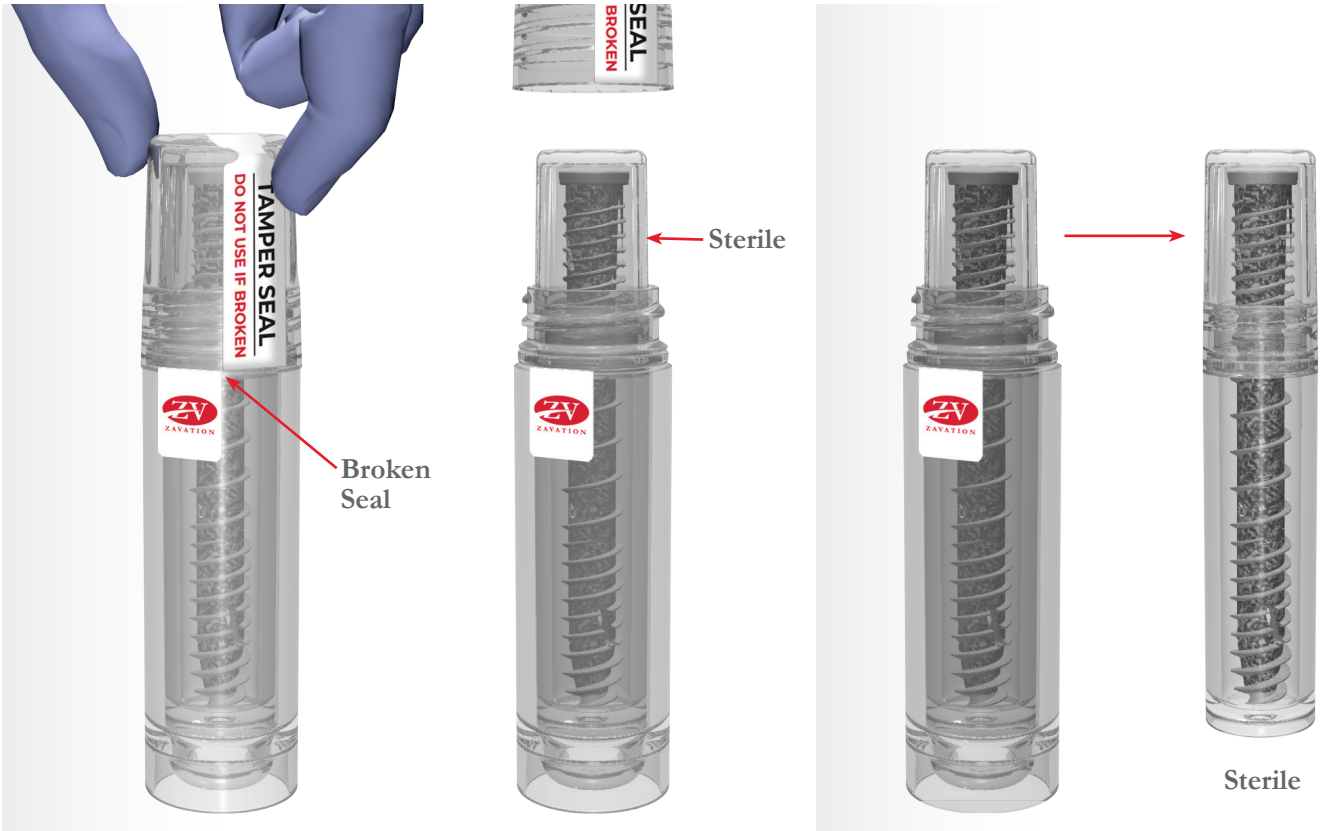
Tamper Seal

3. Unscrew the outer tube cap clockwise, breaking the tamper seal.

WARNING: Do not touch the sterile inner tube that holds the implant. All contents inside the outer tube are sterile.

Sterile Inner Tube

4. Transfer the inner tube containing the implant into the field. The sterile inner tube can be removed by sterile personnel or dropped from the outer tuber into the sterile field.



IMPLANT INSERTION (Continued)

Prepping the Implant

At the back table, slide desired implant with distal tip downward on graft block's post (5042-110). Pack harvested bone into fenestrations on implant. Place a ratcheting T-handle (8125-201/Z-1061) onto the inserter corresponding to the diameter of the prepared hole. Implant can be retrieved from graft block with inserter's stab and grab tip.

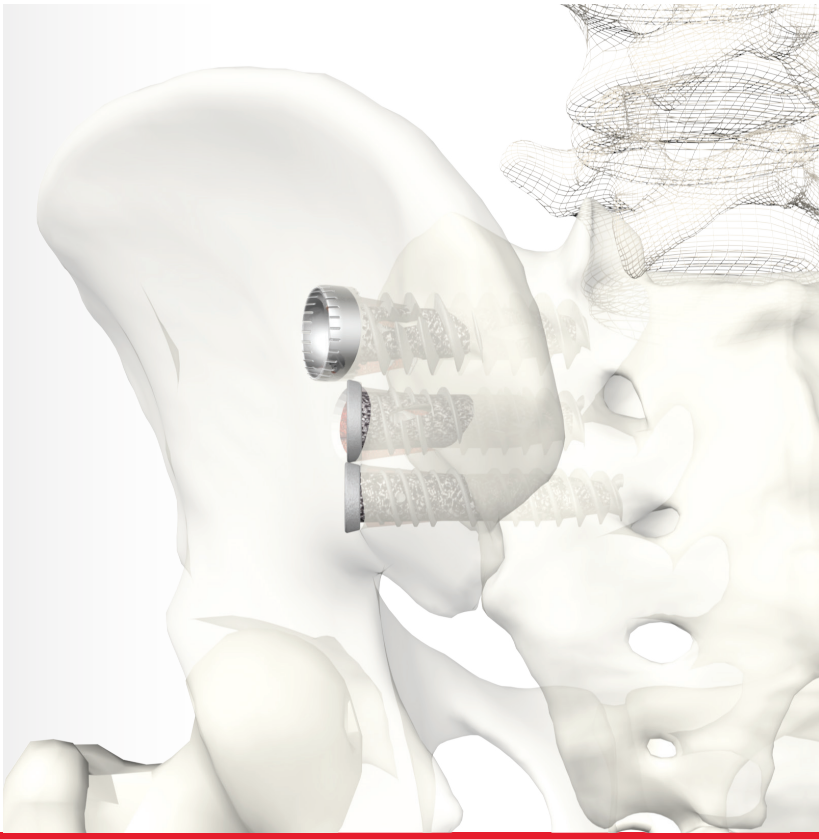
Implants can also be inserted with the T-handle or under power using the Jacob's Chuck Adapter per surgeon choice.

Inserters	
Catalog No.	Respective Implant Diameter
2042-200	7.0mm
2042-201	9.5mm
2042-202	11.5mm / 14.5mm

If using the optional washer, place it over the distal end of the cage and slide toward proximal portion of the implant. The flat teeth on the washer should be positioned toward the screw head and the teeth toward the bone.

If using a washer, surgeons will have tactile feel of the washer grinding against the iliac crest, creating a natural stopping point.

If not using a washer, users will feel significant lag as the head of the screw approaches the ilium. The screw does not allow for countersinking into the bone.



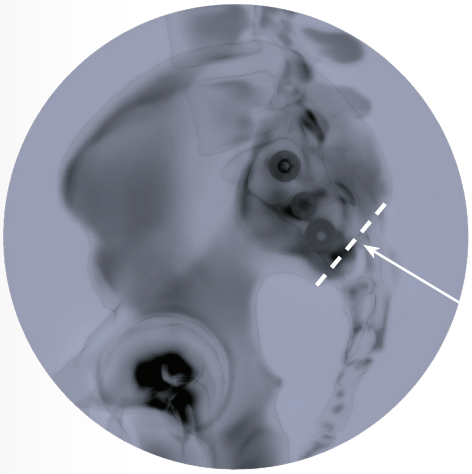
IMPLANT INSERTION (Continued)

Take note of varying patient bone quality and anatomy. Fluoroscopy is encouraged during screw placement.

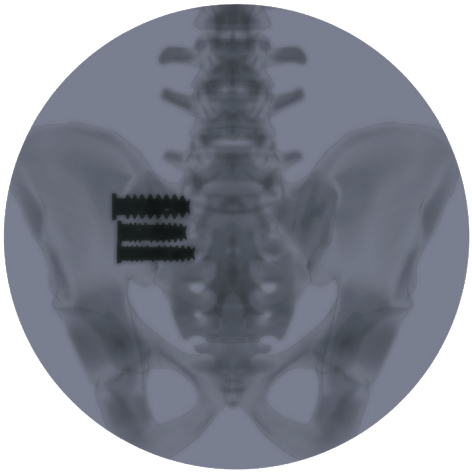
NOTE: The bone funnel (5042-106) and bone tamp (5042-107) can be utilized to post-fill the 11.5mm and 14.5mm implants.

Implant Spacing

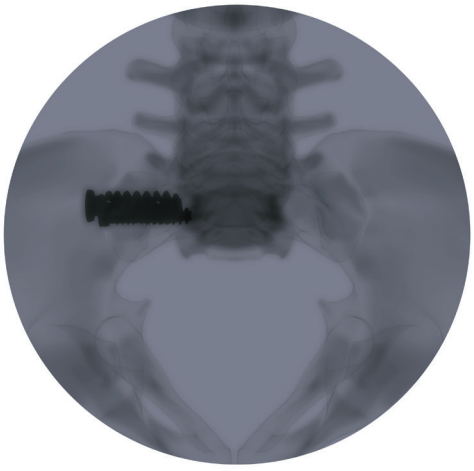
Pay close attention to the relationship between the location of the devices and the sacral foramen, making sure the screws do not cross into the foramen, especially when inserting the second and third screws.



Lateral View
Do not place implant inferior of dotted line



Outlet View



Inlet View

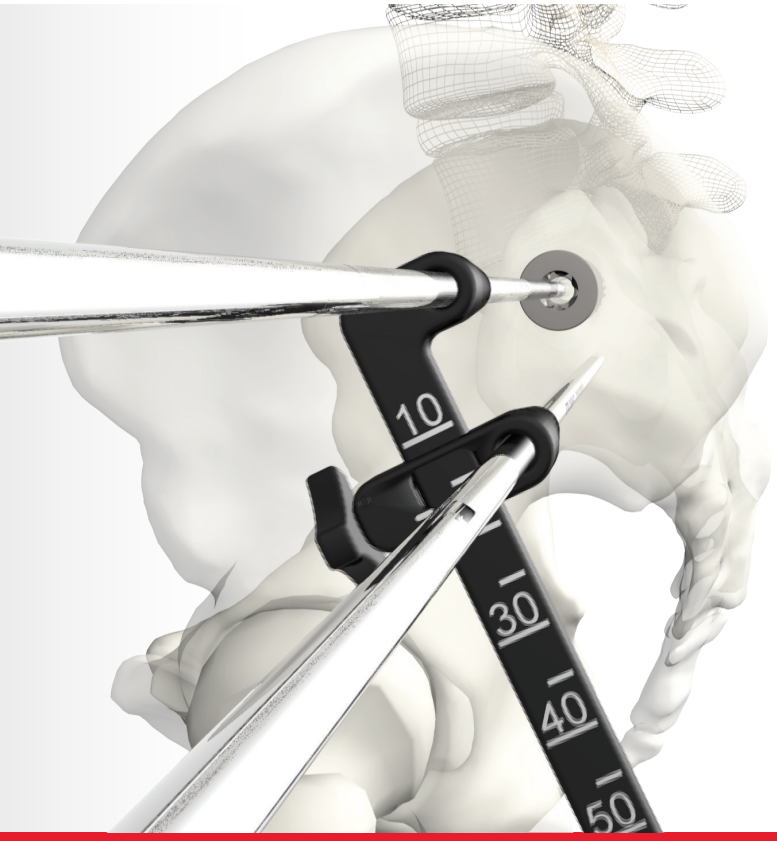
IMPLANT INSERTION (Continued)

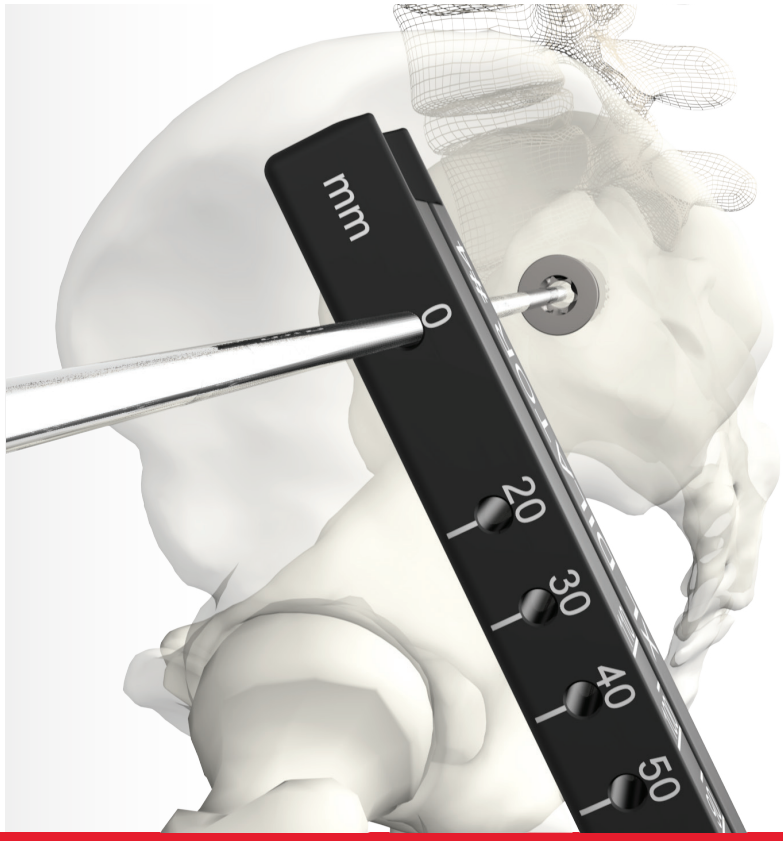
Slide the variable pin guide (5040-109) or implant length gauge (5042-108) over the guide wire at the appropriate marker. Following the sacral curve, place the second guide wire in the variable pinhole set at the appropriate marker (see chart below).

Implant #1 Size	Implant #2 Size	Recommended Spacing
14.5mm	14.5mm	19mm
11.5mm	11.5mm	16mm
9.5mm	9.5mm	14mm
7.0mm	7.0mm	12mm
14.5mm	11.5mm	18mm
11.5mm	9.5mm	15mm
9.5mm	7.0mm	13mm

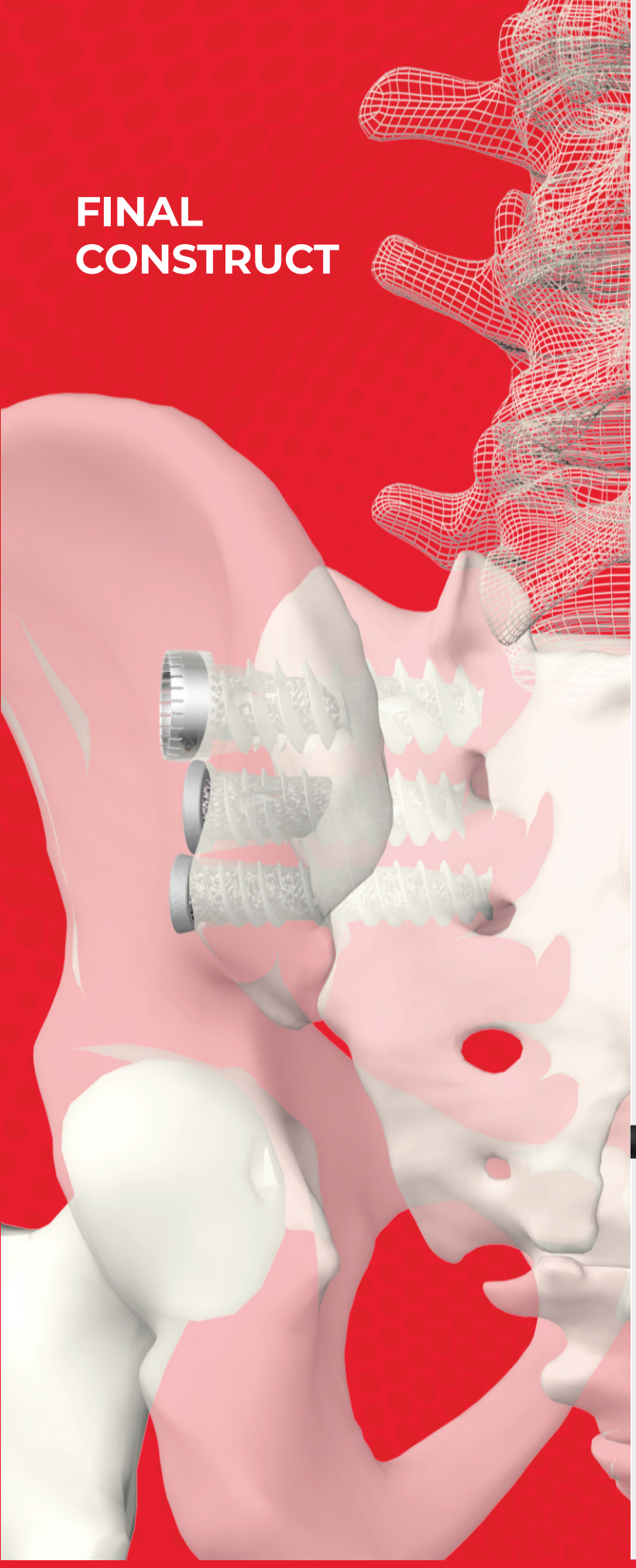
This is the starting point for the next guide wire placement.

Repeat steps “Screw Placement Preparation” (pg 10) through “Implant Insertion” (pg 17) for the remaining implants.





FINAL CONSTRUCT



IMPLANT REMOVAL

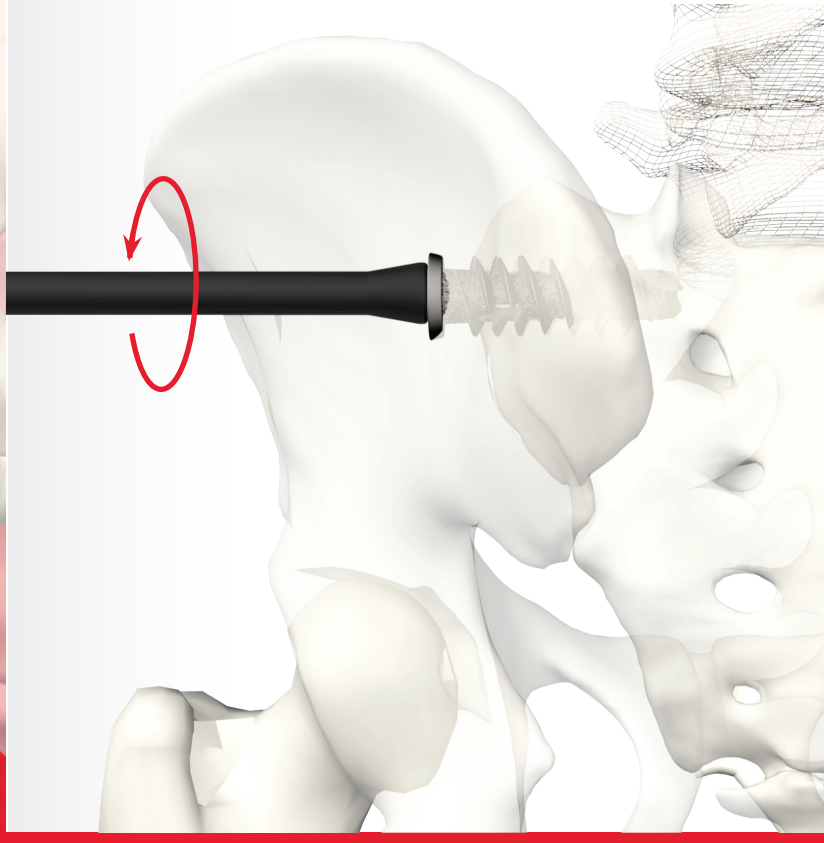
To remove, use the sacroiliac implant extractor that corresponds with the implant diameter:

- 7.0mm extractor (2042-217)
- 9.5mm extractor (2042-218)
- 11.5mm/14.5mm extractor (2042-219, cannulated)

The proximal end of the 9.5mm, 11.5mm and 14.5mm implants have counterclockwise thread. Attach the extractor to the preferred handle. Thread the extractor into the implant by turning counterclockwise until fully seated. Remove from the surgical site.

Non-cannulated off-axis inserter/extractor options are available if needed:

- 9.5mm screws: #40 hexalobe (2042-207)
- 11.5mm screws: #45 hexalobe (2042-208)
- 14.5mm screws: #45 hexalobe (2042-208)



STANDARD SIBER® TI PRODUCT LISTING

Swift Tip Technology® Implant Set—Compression

Kit #K5000652

Swift Tip

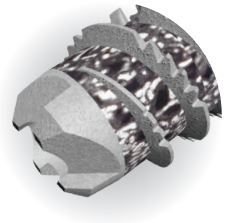
9.5mm SI Implants		
Catalog No.	**Description**	**Qty**
44095-30-ST	9.5mm x 30mm, Compression, Swift Tip Technology	2
44095-35-ST	9.5mm x 35mm, Compression, Swift Tip Technology	2
44095-40-ST	9.5mm x 40mm, Compression, Swift Tip Technology	4
44095-45-ST	9.5mm x 45mm, Compression, Swift Tip Technology	4
44095-50-ST	9.5mm x 50mm, Compression, Swift Tip Technology	6
44095-55-ST	9.5mm x 55mm, Compression, Swift Tip Technology	2
44095-60-ST	9.5mm x 60mm, Compression, Swift Tip Technology	2
44095-65-ST	9.5mm x 65mm, Compression, Swift Tip Technology	2
44095-70-ST	9.5mm x 70mm, Compression, Swift Tip Technology	2
11.5mm SI Implants		
Catalog No.	**Description**	**Qty**
44115-30-ST	11.5mm x 30mm, Compression, Swift Tip Technology	2
44115-35-ST	11.5mm x 35mm, Compression, Swift Tip Technology	4
44115-40-ST	11.5mm x 40mm, Compression, Swift Tip Technology	6
44115-45-ST	11.5mm x 45mm, Compression, Swift Tip Technology	6
44115-50-ST	11.5mm x 50mm, Compression, Swift Tip Technology	6
44115-55-ST	11.5mm x 55mm, Compression, Swift Tip Technology	4
44115-60-ST	11.5mm x 60mm, Compression, Swift Tip Technology	2
44115-65-ST	11.5mm x 65mm, Compression, Swift Tip Technology	2
44115-70-ST	11.5mm x 70mm, Compression, Swift Tip Technology	2
Container		
14Z00848	Soft Case, Size 3	1

NOTE: Siber Ti implants are sterile packaged.

STANDARD SIBER® TI PRODUCT LISTING (Continued)

Implant Set—Compression

Kit #K5000503



Original Tip

9.5mm		
Catalog No.	Description	Qty
44095-30	9.5mm x 30mm, Compression, SI Implant	2
44095-35	9.5mm x 35mm, Compression, SI Implant	4
44095-40	9.5mm x 40mm, Compression, SI Implant	6
44095-45	9.5mm x 45mm, Compression, SI Implant	6
44095-50	9.5mm x 50mm, Compression, SI Implant	4
44095-55	9.5mm x 55mm, Compression, SI Implant	2
44095-60	9.5mm x 60mm, Compression, SI Implant	2
44095-65	9.5mm x 65mm, Compression, SI Implant	2
44095-70	9.5mm x 70mm, Compression, SI Implant	2
11.5mm		
Catalog No.	Description	Qty
44115-30	11.5mm x 30mm, Compression, SI Implant	2
44115-35	11.5mm x 35mm, Compression, SI Implant	4
44115-40	11.5mm x 40mm, Compression, SI Implant	6
44115-45	11.5mm x 45mm, Compression, SI Implant	6
44115-50	11.5mm x 50mm, Compression, SI Implant	4
44115-55	11.5mm x 55mm, Compression, SI Implant	4
44115-60	11.5mm x 60mm, Compression, SI Implant	2
44115-65	11.5mm x 65mm, Compression, SI Implant	2
44115-70	11.5mm x 70mm, Compression, SI Implant	2
14.5mm		
Catalog No.	Description	Qty
44145-30	14.5mm x 30mm, Compression, SI Implant	2
44145-35	14.5mm x 35mm, Compression, SI Implant	2
44145-40	14.5mm x 40mm, Compression, SI Implant	2
44145-45	14.5mm x 45mm, Compression, SI Implant	2
44145-50	14.5mm x 50mm, Compression, SI Implant	2
44145-55	14.5mm x 55mm, Compression, SI Implant	2
44145-60	14.5mm x 60mm, Compression, SI Implant	2
44145-65	14.5mm x 65mm, Compression, SI Implant	2
44145-70	14.5mm x 70mm, Compression, SI Implant	2
Container		
14G00721	Implant Tote	1

NOTE: Siber Ti implants are sterile packaged.

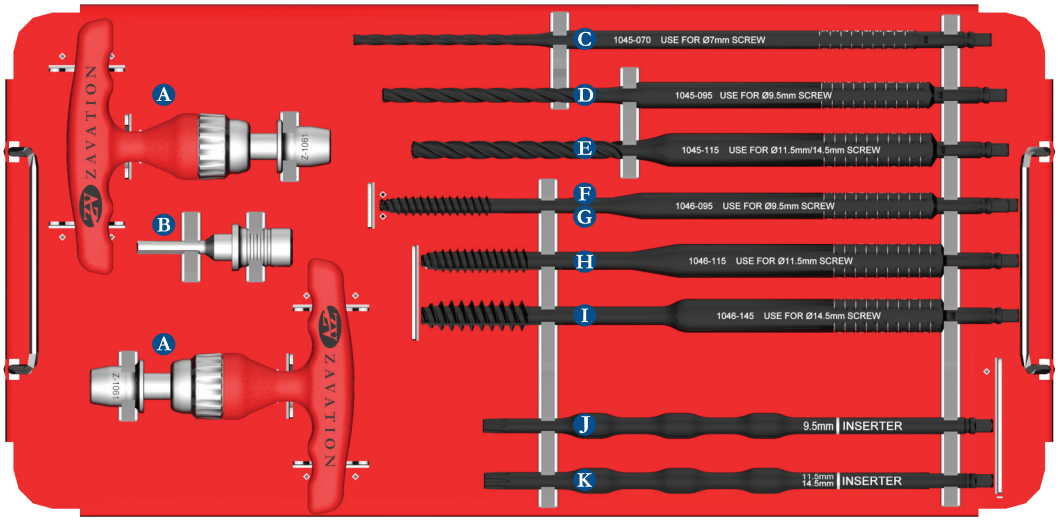
STANDARD SIBER® TI PRODUCT LISTING & TRAY LAYOUT (Continued)

Instrument Set—Top Tray

Kit #K5000504

Top Tray		
Catalog No.	**Description**	**Qty**
8125-201/ Z-1061	Ratcheting T-Handle, 1/4" Drive	2
8100-105	Jacobs Chuck to 1/4" Sq. Power Adapter	1
1045-070	Drill, Sacroiliac, 7.0mm	2
1045-095	Drill, Sacroiliac, 9.5mm	2
1045-115	Drill, Sacroiliac, 11.5mm/14.5mm	2
1046-070	Tap, Sacroiliac, 7.0mm	1
1046-095	Tap, Sacroiliac, 9.5mm	1
1046-115	Tap, Sacroiliac, 11.5mm	1
1046-145	**Special Order:** Tap, Sacroiliac, 14.5mm	1
2042-201	Inserter, Sacroiliac, 9.5mm, #40 Hexalobe	2
2042-202	Inserter, Sacroiliac, 11.5mm/14.5mm, #45 Hexalobe	2

Instrument Set		
Catalog No.	**Description**	**Qty**
14G00705/ 14G00841	Inner Tray 1	1
14G00706/ 14G00842	Inner Tray 2	1
14G00707/ 14G00843	Inner Tray 3	1
14G00704/ 14G00839	Base	1
14G00500/ 14Z00836	Generic Base Lid	1



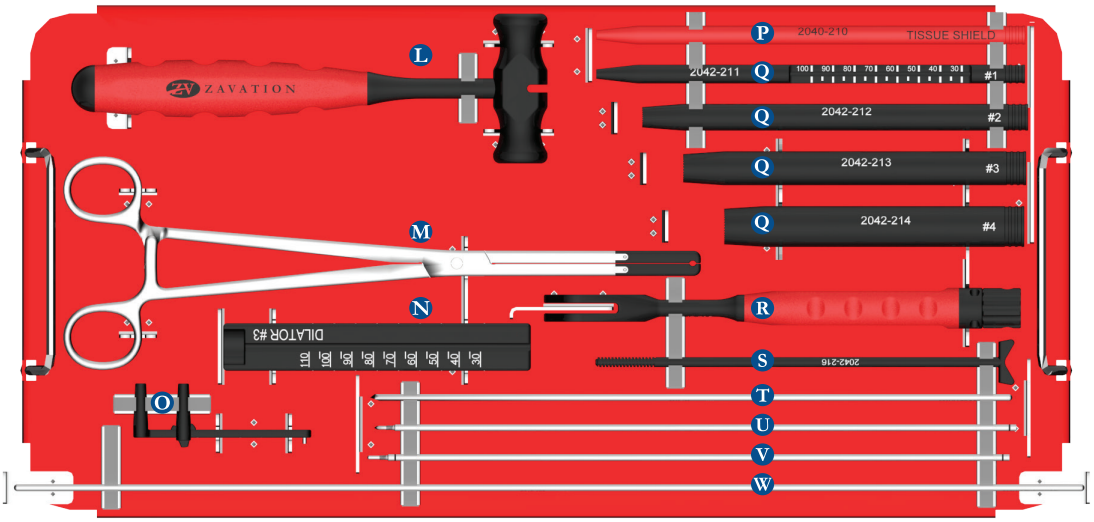
- **A.** Ratcheting T-Handles (qty 2)
- **B.** Jacobs Chuck Adapter
- **C.** Drill, 7.0mm (qty 2)
- **D.** Drill, 9.5mm (qty 2)
- **E.** Drill, 11.5mm/14.5mm (qty 2)
- **F.** Tap, 7.0mm
- **G.** Tap, 9.5mm
- **H.** Tap, 11.5mm
- **I.** Tap, 14.5mm
- **J.** Inserter, 9.5mm (qty 2)
- **K.** Inserter, 11.5mm/14.5mm (qty 2)

STANDARD SIBER® TI PRODUCT LISTING & TRAY LAYOUT (Continued)

Instrument Set—Middle Tray

Kit #K5000504

Middle Tray		
Catalog No.	**Description**	**Qty**
2042-220	Mallet, Sacroiliac	1
5000-164	Radiolucent Guide Wire Holder	1
5042-108	Length Gauge / Pin Guide	1
5040-109	Variable Pin Guide, Sacroiliac	1
2040-210	Tissue Shield, Sacroiliac	1
2042-211	#1 Dilator, Sacroiliac	1
2042-212	#2 Dilator, Sacroiliac	1
2042-213	#3 Dilator, Sacroiliac	1
2042-214	#4 Dilator, Sacroiliac	1
2042-215	Dilator Handle, Sacroiliac	1
2042-216	Dilator Handle Inner Shaft, Sacroiliac	1
5040-100	Trocar Guide Wire, 300mm, 3.2mm	2
5040-112	Stackable Trocar Guide Wire, 300mm, 3.2mm	4
5040-113	Stackable Blunt Guide Wire, 300mm, 3.2mm	2
5040-103	Exchange Pin, 500mm, 3.2mm	2



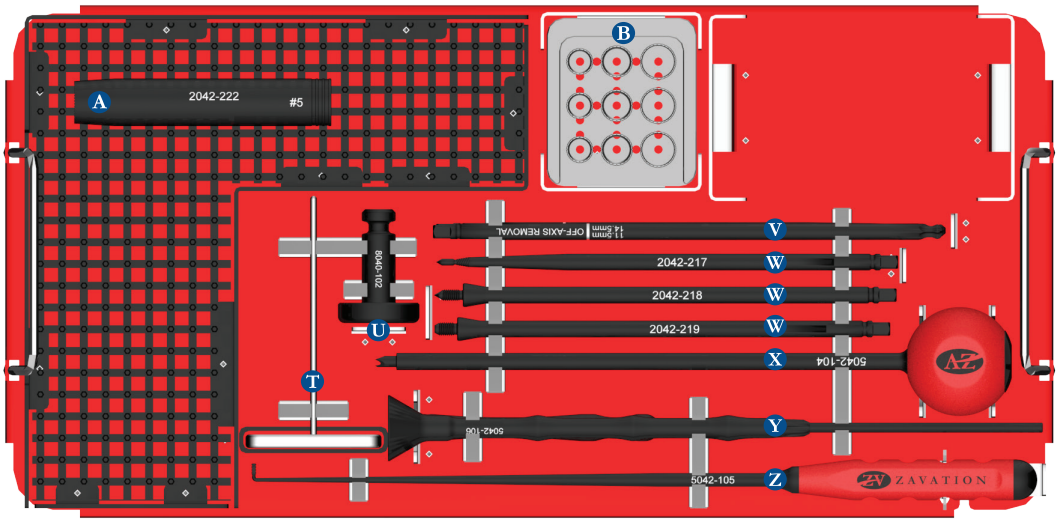
L. Mallet
M. Radiolucent Guide Wire Holder
N. Length Gauge / Pin Guide
O. Variable Pin Guide
P. Tissue Shield
Q. Dilators #1, #2, #3, #4
R. Dilator Handle
S. Dilator Handle Inner Shaft
T. Trocar Guide Wire (qty 2)
U. Stackable Trocar Guide Wire (qty 4)
V. Stackable Blunt Guide Wire (qty 2)
W. Exchange Pin (qty 2)

STANDARD SIBER® TI PRODUCT LISTING & TRAY LAYOUT (Continued)

Instrument Set—Bottom Tray

Kit #K5000504

Bottom Tray		
Catalog No.	**Description**	**Qty**
5042-110	Graft Block, Sacroiliac	1
8040-102	Guide Wire Impactor, 3.2mm	1
2042-207	Off-Axis Inserter/Extractor, #40 Hexalobe	1
2042-208	Off-Axis Inserter/Extractor, #45 Hexalobe	1
2042-217	Implant Extractor, 7.0mm, Sacroiliac	1
2042-218	Implant Extractor, 9.5mm, Sacroiliac	1
2042-219	Implant Extractor, 11.5mm/14.5mm, Sacroiliac	1
5042-104	Cannulated Awl, Sacroiliac	1
5042-106	Graft Funnel, 11.5mm, Sacroiliac	1
5042-107	Graft Tamp, Sacroiliac	1
5042-105	Decorticator Tool, Sacroiliac	1
2042-222	**Special Order:** #5 Dilator, Sacroiliac	1
14G00720/ 14G00840	Caddy, 9.5mm and 11.5mm Washers	1
44095-000	9.5mm Washers (come standard in the caddy)	3
44115-000	11.5mm Washers (come standard in the caddy)	3
44145-000	**Special Order:** 14.5mm Washers (not included standard in the caddy)	3



T. Graft Packing Block
U. Guide Wire Impactor
V. Off-Axis Extractors
W. Implant Extractors
X. Cannulated Awl
Y. Graft Funnel, 11.5mm and Tamp
Z. Decorticator Tool
A. Dilator #5
B. **Washer Caddy:** 9.5mm (qty 3), 11.5mm (qty 3) **Special Order:** 14.5mm

SPECIAL ORDER SIBER® TI PRODUCT LISTING

Implant Set—Non-Compression

Kit #K5000528

9.5mm SI Implants		
Catalog No.	Description	Qty
45095-30	9.5mm x 30mm, Non-Compression	4
45095-35	9.5mm x 35mm, Non-Compression	4
45095-40	9.5mm x 40mm, Non-Compression	4
45095-45	9.5mm x 45mm, Non-Compression	4
45095-50	9.5mm x 50mm, Non-Compression	4
45095-55	9.5mm x 55mm, Non-Compression	2
45095-60	9.5mm x 60mm, Non-Compression	2
45095-65	9.5mm x 65mm, Non-Compression	2
45095-70	9.5mm x 70mm, Non-Compression	2
11.5mm SI Implants		
Catalog No.	Description	Qty
45115-30	11.5mm x 30mm, Non-Compression	4
45115-35	11.5mm x 35mm, Non-Compression	4
45115-40	11.5mm x 40mm, Non-Compression	4
45115-45	11.5mm x 45mm, Non-Compression	4
45115-50	11.5mm x 50mm, Non-Compression	4
45115-55	11.5mm x 55mm, Non-Compression	4
45115-60	11.5mm x 60mm, Non-Compression	4
45115-65	11.5mm x 65mm, Non-Compression	2
45115-70	11.5mm x 70mm, Non-Compression	2
14.5mm SI Implants		
Catalog No.	Description	Qty
45145-30	14.5mm x 30mm, Non-Compression	2
45145-35	14.5mm x 35mm, Non-Compression	2
45145-40	14.5mm x 40mm, Non-Compression	2
45145-45	14.5mm x 45mm, Non-Compression	2
45145-50	14.5mm x 50mm, Non-Compression	2
45145-55	14.5mm x 55mm, Non-Compression	2
45145-60	14.5mm x 60mm, Non-Compression	2
45145-65	14.5mm x 65mm, Non-Compression	2
45145-70	14.5mm x 70mm, Non-Compression	2
Container		
14G00721	Implant Tote	1

Implant Set—Entasis® 7.0mm

Kit #K5000505

7.0mm SI Implants		
Catalog No.	Description	Qty
40070-30	7.0mm x 30mm	2
40070-35	7.0mm x 35mm	2
40070-40	7.0mm x 40mm	2
40070-45	7.0mm x 45mm	2
40070-50	7.0mm x 50mm	2
40070-55	7.0mm x 55mm	2
40070-60	7.0mm x 60mm	2
40070-65	7.0mm x 65mm	2
40070-70	7.0mm x 70mm	2
Instrument		
2042-200	7.0mm Inserter, #30 Hexalobe, Sacroiliac	2
Caddy		
14G00845	7.0mm Implant Caddy, Sacroiliac	1

7.0mm Entasis Screw

SPECIAL ORDER SIBER® TI PRODUCT LISTING (Continued)

Swift Tip Technology® Implant Set—Trauma, Compression

Kit #K5000547

Swift Tip

9.5mm SI Implants		
Catalog No.	**Description**	**Qty**
44095-75-ST	9.5mm x 75mm, Trauma, Compression, Swift Tip Technology	2
44095-80-ST	9.5mm x 80mm, Trauma, Compression, Swift Tip Technology	2
44095-85-ST	9.5mm x 85mm, Trauma, Compression, Swift Tip Technology	2
44095-90-ST	9.5mm x 90mm, Trauma, Compression, Swift Tip Technology	2
44095-95-ST	9.5mm x 95mm, Trauma, Compression, Swift Tip Technology	2
44095-100-ST	9.5mm x 100mm, Trauma, Compression, Swift Tip Technology	2
44095-105-ST	9.5mm x 105mm, Trauma, Compression, Swift Tip Technology	2
44095-110-ST	9.5mm x 110mm, Trauma, Compression, Swift Tip Technology	1
11.5mm SI Implants		
Catalog No.	**Description**	**Qty**
44115-75-ST	11.5mm x 75mm, Trauma, Compression, Swift Tip Technology	2
44115-80-ST	11.5mm x 80mm, Trauma, Compression, Swift Tip Technology	2
44115-85-ST	11.5mm x 85mm, Trauma, Compression, Swift Tip Technology	2
44115-90-ST	11.5mm x 90mm, Trauma, Compression, Swift Tip Technology	2
44115-95-ST	11.5mm x 95mm, Trauma, Compression, Swift Tip Technology	1
44115-100-ST	11.5mm x 100mm, Trauma, Compression, Swift Tip Technology	2
44115-105-ST	11.5mm x 105mm, Trauma, Compression, Swift Tip Technology	2
44115-110-ST	11.5mm x 110mm, Trauma, Compression, Swift Tip Technology	1
Container		
14Z00848	Soft Case, Size 3	1

NOTES

INDICATIONS FOR USE

Siber® Ti Sacroiliac Joint Fusion System

IMPORTANT NOTE: The user of this system must read and acknowledge the conditions of this insert prior to use.

Consult the product electronic instructions for use for all current languages and latest document revision at www.zavation.com/ifu or by scanning the barcode on the product labeling.

Device Description

The Siber Ti Sacroiliac Joint Fusion System is an implant system used for temporary immobilization of the sacroiliac spine while fusion occurs. The Siber Ti system includes additively manufactured titanium alloy screw-type implants in various sizes and configurations to accommodate patient anatomy and surgeon preference. Zavation 3D Mimetic Metal® presents a macro-, a micro, and a nano-surface structure. The implants are provided with general and implant specific reusable manual surgical instruments for surgical site access, preparation, and implantation.

Implants in the Siber Ti Sacroiliac Joint Fusion System are manufactured from medical grade titanium alloy (Ti6AL4V ELI as per ASTM F-136 and ASTM F-3001).

Do not use any of the Siber Ti Sacroiliac Joint Fusion System components with components from any other manufacturer or system unless specifically allowed to do so in this or other Zavation document. Implants in this system must never be reused under any circumstance.

The Siber Ti Sacroiliac Joint Fusion System includes a variety of manual surgical instruments manufactured from surgical grade stainless steel as per ASTM F899. The Siber Ti Sacroiliac Joint Fusion System Navigation Instruments are nonsterile manual surgical instruments that are intended to be used with the Medtronic® StealthStation™ Surgical Navigation System to assist surgeons in precisely locating anatomical structures in either open or minimally invasive procedures for preparation and placement of sacroiliac fusion implants. This surgical imaging technology provides surgeons visualization for procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

The Siber Ti Sacroiliac Joint Fusion System Navigation Instruments are comprised of Drills, Taps, and Screw Drivers. The Siber Ti Navigation Instruments were tested for compatibility utilizing the Medtronic® StealthStation™ S7 with software version 2.1.0 and StealthStation S8 Surgical Navigation System with software version 1.2.0 (1.2.0-20), Violet, Orange, Green, and Gray Navlock Trackers (Part Numbers 9734682, 9734683, 9734734, and 9734590), Medtronic Navigation Instrument Drivers (Part Number NAV7426001), Drill (Part Number NAV7426002), and Tap (Part Number NAV7426002) and the Navlock Small Passive Reference Frame (Part Number (9731478).

Use of the Siber Ti Sacroiliac Joint Fusion System with Navigation Instruments are limited to certain implant sizes. The Siber Ti Sacroiliac Implants are limited to 11.5mm diameter with lengths ranging from 40mm to 60mm. The Siber Ti Navigation Driver is limited to the implant sizes 11.5mm in diameter.

Indications for Use

The Siber Ti Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar thoracolumbar fusion and acute, non-acute, and non-traumatic fractures involving the sacroiliac joint. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

Zavation Navigation Instruments are intended for use during the preparation and placement of Siber Ti Sacroiliac Joint Fusion System implants and Entasis Dual-Lead Sacroiliac Implant System implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

INDICATIONS FOR USE (Continued)

These instruments are designed for use with the Medtronic StealthStation S8 System (V1.2.0), 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 of the anatomy.

Contraindications

Do not use the Siber Ti Sacroiliac Joint Fusion System in the presence of an active or suspected latent systemic infection or infections localized to the site of the proposed implantation. Other relative contraindications include:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices.
- Severe osteoporosis as it may prevent adequate fixation of bone screws and thus preclude the use of this or any other sacroiliac instrumentation system.
- Tumor of sacral or iliac bone as it may present challenges in placement of implants due to size and location.
- Unstable fracture of sacrum and/or ilium involving the sacroiliac joint as they may reduce the effectiveness of the implants to temporarily stabilize the affected region for assistance in bony fusion.
- Any entity or condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis, osteopenia).
- Obesity, certain degenerative diseases, and foreign body sensitivity.
- Patient occupation, activity level, or mental capacity. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.
- Allergy or foreign body sensitivity to any of the implant materials.

Use of the Siber Ti Sacroiliac Joint Fusion System Navigation Instruments and associated implants are contraindicated in any scenario that is contraindicated in the Medtronic StealthStation Instructions for Use. Use of the Siber Ti Sacroiliac Joint Fusion System Navigation Instruments with implant systems other than those indicated in this document must not be performed.

Complications and Adverse Effects

Use and/or misuse of this system may result in the following list of complications and potential adverse effects:

- Loosening of any or all components including screw back requiring surgical intervention.
- Disassembly, bending and/or breakage of any or all components.
- Inadequate fixation.
- Non-union, delayed union or mal-union.
- Allergic reaction to implant material, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Infection.
- Wound healing disorders or hematomas.
- Pain, skin penetration, bruising, swelling, irritation, and fibrosis caused by skin pressure by implant components.
- Bursitis.

INDICATIONS FOR USE (Continued)

- Fracture, microfracture, resorption, damage, impingement, or penetration of any spinal bone at and above the level of surgery.
- Injury to intra-pelvic structures
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological and/or gastrointestinal systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, consumption, etc.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, Phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. Pulmonary embolism, bronchitis, pneumonia, etc.
- Difficulty in delivering fetus vaginally due to device-related restrictions of sacroiliac joint stretching.
- Death.

Additional surgery may be required to correct these potential adverse events and/or outcomes.

Use of Implant Components

WARNING: The safety and effectiveness of sacroiliac fixation and fusion systems has only been established for degenerative sacroiliitis and sacroiliac joint disruptions. This system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. The safety and effectiveness of these devices for any other conditions are unknown.

Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following sacroiliac joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.

Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while fusion about the implant is developing. This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by sufficient fusion mass, the implants will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used or if a pseudarthrosis develops.

INDICATIONS FOR USE (Continued)

Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implants and the development of the fusion mass about the implants. Instruct the patient that implants may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.

Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

Spinal implants of this type may be removed after sufficient bone fusion develops. However, please inform the patient that a second surgical procedure may be necessary and that there are risks associated with a second surgical procedure. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.

Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested.

This device must not be reused. Reuse may result in patient injury or other complications including but not limited to component fracture and/or deformation, breakage, difficulty with implantation, incompatibility with mating components and infection. It is the physician's responsibility to discard all damaged or mishandled implants.

In addition to the warnings and precautions discussed above, the patient must be informed about general surgical risks prior to surgery.

Refer to the Surgical Technique Manual for additional important information about this system, in addition to the information described herein.

PRECAUTIONS: The implantation of sacroiliac fusion systems is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this sacroiliac fusion system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant components. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique Manual can be requested from Zavation by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting from erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the Siber Ti Sacroiliac Joint Fusion System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

Use of the system off-label is forbidden by Zavation.

The Siber Ti Sacroiliac Joint Fusion System has not been evaluated for safety and compatibility in the MR environment. The Siber Ti Sacroiliac Joint Fusion System has not been tested for heating migration, or image artifact in the MR environment. The safety of the Siber Ti Sacroiliac Joint Fusion System is unknown. Scanning a patient who has this device may result in patient injury.

INDICATIONS FOR USE (Continued)

Use of Navigation Instruments

CAUTION: Zavation is not a navigation provider. The navigation system must be set up per the manufacturer's instructions. The Siber Ti Sacroiliac Joint Fusion System Navigation Instruments have been validated for use with the third-party Medtronic® StealthStation™ S7 with software version 2.1.0 and StealthStation S8 Surgical Navigation System with software version 1.2.0 (1.2.0-20). Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company's software and user guides for calibration and navigation guidance. Compatible third-party navigation clamps, reference frames, and arrays are listed in the Surgical Technique Guide. Ensure the hospital has the appropriate third-party navigation equipment prior to the surgical case. It is recommended to setup the operating room and instrument arrays such that camera view of all arrays remain uninterrupted at all times. A field assessment should be performed by positioning the navigation instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. If the inputs result in the correct and anticipated outputs, functional verification is confirmed.

WARNING: Navigation instruments are highly accurate and sensitive medical devices that must be handled with extreme care. If you drop or otherwise damage it, do not use it in a surgical case. Any instrument that is suspected of being damaged, inaccurate, or cannot be registered or verified must not be used in a surgical case and must be returned to Zavation immediately. Failure to do so may lead to serious injury to the patient. Additionally, all navigation instruments and StealthStation tracking instruments must be continuously verified for correct registration with the StealthStation software. Positional accuracy must be continuously monitored intraoperatively. Immediately discontinue use of the navigation instruments if an inaccuracy is detected. Inaccuracy may also occur if bending or other alteration of the instruments occurs.

Only surgeons and medical personnel trained in the use of StealthStation navigation are to use the Siber Ti Navigated Instruments when used with the StealthStation System.

Only the identified tool card is to be selected for each instrument to prevent patient injury from inaccurate navigation.

Only use the Siber Ti Navigated Instruments with the software version of StealthStation System for which the instrument accuracy was validated to prevent patient injury from inaccurate navigation.

Note: For information on use of disposable reflective marker spheres, refer to navigation manufacturers' user guide.

Preparation at the Point of Use

The screws of the Siber Ti Sacroiliac Joint Fusion System are supplied sterile. Additionally, the 7.0mm Siber Ti screws and washers may be alternatively provided non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using the following validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual devices may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments in the Siber Ti Sacroiliac Joint Fusion System must be disassembled to facilitate cleaning. Failure to disassemble a soiled device may lead to inadequate reprocessing. All instruments should be reassembled following cleaning, prior to sterilization.

INDICATIONS FOR USE (Continued)

Prior to use, instruments must be inspected for signs of wear, damage and proper function. Drills and Taps must be inspected for wear and cutting flute damage. Drivers must be inspected to ensure correct and full engagement of implants. Dilators must allow for free passage of any instrument or implant. All navigation instruments must allow for free connection and rotation of any Navlock tracker. If you suspect an instrument is damaged, please contact Zavation for a replacement.

Follow the Cleaning and Sterilization procedures below.

Cleaning and Sterilization

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments should not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

All instruments must be fully disassembled prior to cleaning (e.g. handles must be detached from shafts, driver shafts removed from drivers, and implants disconnected from mating instruments.)

Manual Cleaning Instructions

1. Completely submerge the instruments in a lukewarm neutral pH enzyme solution and allow soaking for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
3. Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices.
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated. **NOTE:** Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

INDICATIONS FOR USE (Continued)

Automated Cleaning Instructions

1. Rinse devices under running tap to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard-to-clean areas. Use a syringe or jetted water to flush difficult to reach areas.
2. Place instruments in a suitable washer basket and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection. Typical Automated Washer Cycle for Surgical Instruments:

Step:	Description:
1.	2-minute prewash with cold tap water
2.	1-minute enzyme spray with hot tap water
3.	2-minute detergent wash with hot tap water (64-66°C / 146-150°F)
4.	1-minute hot tap water rinse
5.	2-minute thermal rinse (80-93°C / 176-200°F)
6.	10-second purified water rinse (64-66°C / 146-150°F)
7.	7 to 30-minute heated air dry (116°C / 240°F)

Notes:

- The washer manufacturer's instructions should be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the implant surface or configuration.
- Pay attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

Sterilization Instructions

Sterile Implants: Implants (screws) of the Siber Ti system are provided "STERILE" via gamma irradiation and intended for single patient use only. **DO NOT RESTERILIZE THIS PRODUCT.** Sterility can only be assured if packaging is intact.

Implants and instruments of the Siber Ti Sacroiliac Joint Fusion System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Sterilization: In a properly functioning calibrated steam sterilizer, independent testing has shown that effective sterilization to a 10-6 sterility assurance level (SAL) may be achieved as follows:

Sterilizer Type:	**Pre-vacuum**
Temperature:	132°C (270°F)
Full Cycle Time:	4 minutes
Minimum Dry Time:	30 minutes (allow for cool down)

Instruments and implants must be sterilized in the steam sterilization cases provided by Zavation. Instrument and implant sets must be wrapped in in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or similar wrap) using sequential envelope techniques. Only wraps validated to maintain sterility after processing are to be used. Saturated steam with a quality of 97-100% must be used. Do not stack instrument cases during sterilization.

Reusable Rigid Sterilization Containers

The Siber Ti Sacroiliac Joint Fusion System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™.

INDICATIONS FOR USE (Continued)

Testing has demonstrated the system, when processed in Aesculap SterilContainer systems JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10-6 sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

Sterilizer Type:	**Pre-vacuum**
Temperature:	132°C (270°F)
Exposure Time:	4 minutes
Minimum Dry Time:	30 minutes (allow for cool down)

Zavation does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the Siber Ti Sacroiliac System is not recommended.

Important Considerations and Warnings

Corrosion from Mixed Metals. Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. The Siber Ti System implants are available in titanium alloy. It is imperative that the Siber Ti implants do not come into contact in-vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment. Corrosion may accelerate failure of implants. Corrosion also causes metal compounds to be released into the body.

1. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain alignment until normal healing occurs and bone fusion mass is developed. If healing is delayed, or does not occur, the implant may fail over time due to metal fatigue. The useful life of the implant will be in part affected by the degree or success of implant to bone union, loads produced by weight bearing, and activity levels. The useful life of the implant will be also in part affected by notches, scratches or bending of the implant which may occur during the surgical procedure. Please inform patients of the risks of implant failure.
2. **Implant Selection.** The selection of the proper size, shape, and design of the implant greatly contribute to the potential of satisfactory fixation. However, the size and shape, and condition of the patient's bones present limitations on the size, shape and strength of implants. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing.

INDICATIONS FOR USE (Continued)

3. **Patient Considerations.** The following must be considered when evaluating whether a patient is a candidate for such a procedure:
   - **Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even after the bone is fully healed, the patient may not be able to resume these activities.
   - **Alcoholism, drug abuse or mental conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
   - **Degenerative diseases.** In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.
   - **Implant sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

Additional Precautions

1. **Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Inform the patient that improper activities may cause the implants to become displaced or damaged and cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
2. **Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (1) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (2) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
3. **Implant Removal.** Spinal implants of this type may require removal if the desired clinical and surgical outcomes are not obtained. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon should provide postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery. Although uncommon, permanent implantation of this device may result in the following: (1) Corrosion, with localized tissue reaction or pain; (2) Possible increased risk of infection; (3) Bone loss due to stress shielding (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Migration of implant position resulting in injury; and (7) Risk of additional injury from postoperative trauma.
4. **Do Not Reuse Implants.** An implant previously implanted must never be reused. An implant previously implanted may have small defects that are not readily visible that may lead to early breakage, and compromise device performance and patient safety. Reuse may also lead to cross contamination and patient infection.

INDICATIONS FOR USE (Continued)

Postoperative Immobilization

Until X-rays confirm the development of a fusion mass, external immobilization (such as bracing or casting) is recommended. Please inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure.

CAUTION: Under federal law, this device may only be sold by or on the order of a physician.

LIMITED WARRANTY AND DISCLAIMER

ZAVATION PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT ZAVATION CUSTOMER SERVICE FOR CURRENT INFORMATION AT 888-349-7808.

The Aesculap SterilContainer System is FDA 510(k) cleared under K792558, K053389, K040865, K093493, K093649, K041623, and K073168. All third-party trademarks used herein are the trademarks of their respective owners. Aesculap and SterilContainer are trademarks of Aesculap, Inc., a B. Braun Company. StealthStation is a registered trademark of Medtronic Navigation, Inc.

For further information contact:

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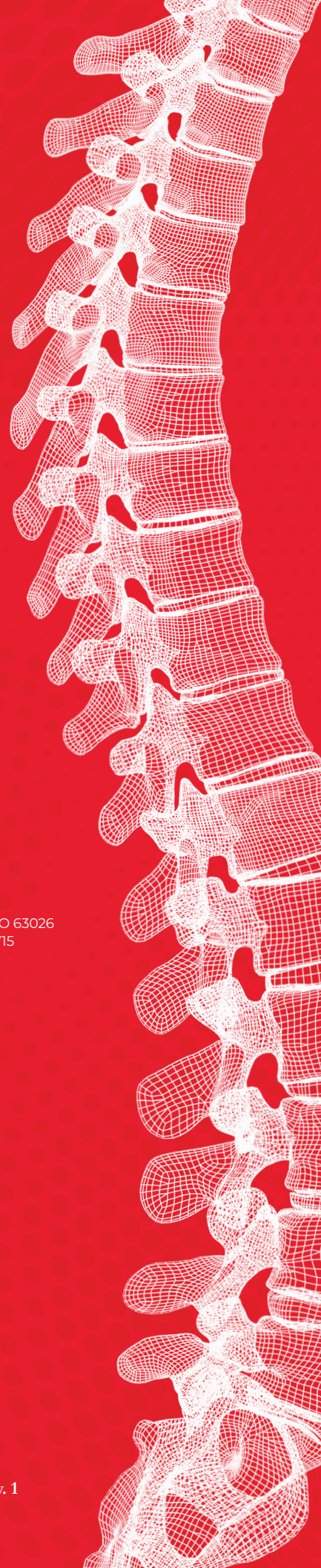
INDICATIONS FOR USE (Continued)

Symbols Glossary

Symbol	Description	ISO 15223 Reference
	**Prescription Required:** Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	**Manufacturer:** Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	**Use-by-Date:** Indicates the date after which the medical device is not to be used.	5.1.1
	**Lot Number:** Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	**Reference Number:** Indicates manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	**Sterilized via Irradiation:** Indicates a medical device has been sterilized using irradiation.	5.2.4
	**Non-Sterile:** Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	**Do Not Re-use:** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	**Consult Instructions For Use:** Indicates the need for the user to consult the instructions for use.	5.4.3
	**Caution:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4



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