

SURGICAL TECHNIQUE GUIDE

SI JOINT TRUSS SYSTEM POSTERIOR APPROACH

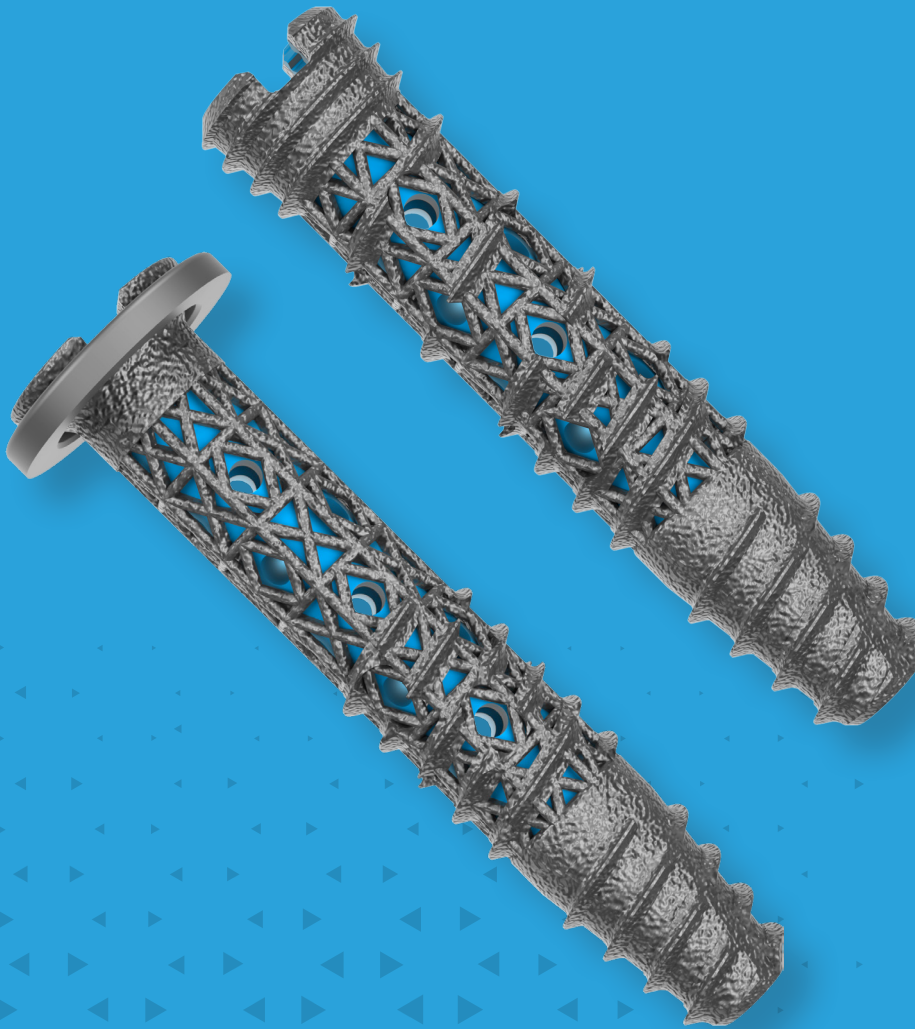




TABLE OF CONTENTS

SJTS OVERVIEW _____	3
SURGICAL PROCEDURE _____	6
INSTRUMENT CATALOG _____	29
IMPLANT CATALOG _____	35

Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, the surgeon should refer to the product's Instructions For Use (IFU) for complete warnings, precautions, indications, contraindications and adverse effects. IFUs are available by contacting 4WEB® at +1(800) 285-7090.

SJTS OVERVIEW



The 4WEB SI Joint Truss System (SJTS) is a comprehensive surgical solution for sacroiliac joint fusion procedures. The system consists of an instrument set and a wide range of threaded implants. The implants come in two distinct sterile implant offerings: a fully threaded implant with compression threads on the proximal head and a partially threaded lag implant with an accompanying washer. All implants in the 4WEB SJTS are cannulated, fenestrated, and made of medical grade Ti6Al4V alloy. The implant offering includes a choice of three different diameters with a variety of lengths to accommodate the patient's anatomy.

INDICATIONS

The SJTS is indicated for sacroiliac joint fusion for:

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

The SI Joint Truss System is also indicated for fracture fixation of the pelvis, including acute, non-acute, and nontraumatic fractures.

CONTRAINDICATIONS

The SJTS devices should not be implanted in patients with:

- An active infection at the operative site or other active systemic infection
- Deformities or anatomic variations that impede or interfere with implant placement
- Tumor of sacral or iliac bone

- Unstable fracture involving sacroiliac joint
- Known sensitivity to the material
- Compromised vascularity that would inhibit adequate blood supply to the operative site.
- Patients having inadequate soft tissue coverage in the operative site or inadequate bone stock or bone quality that cannot provide adequate support and/or fixation of the devices.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS AND PRECAUTIONS

See package insert for warnings, precautions, adverse effects, and other essential product information. Before using the SJTS Instrumentation, verify:

- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-SJTS-05.



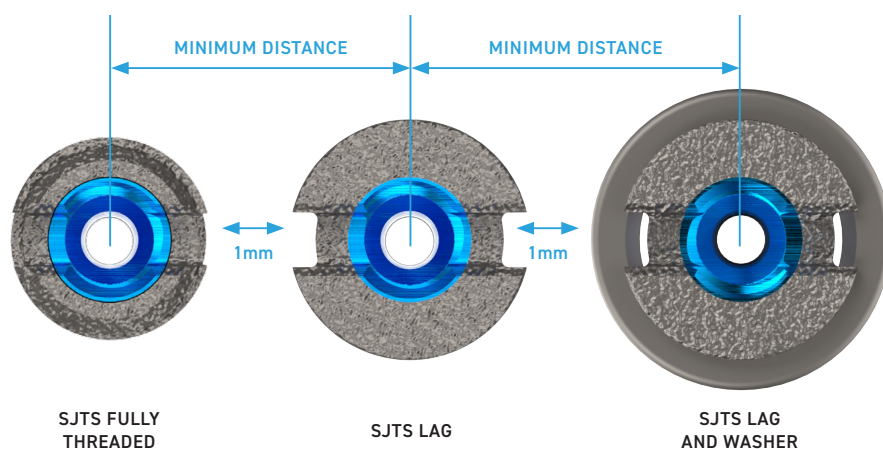
► IMPLANT SPECIFICATIONS



	FULLY THREADED (MM)			LAG (MM)		
PART #	SJTS-S-1035	SJTS-S-1235	SJTS-S-1335	SJTS-L-1035	SJTS-L-1235	SJTS-L-1335
Major Ø	10.5	12.0	13.5	10.5	12.0	13.5
Minor Ø	9.1	10.6	12.1	9.1	10.6	12.1
Inner Ø	3.4	3.4	3.4	3.4	3.4	3.4
Head Ø	11.8	13.2	14.7	13.5	15.0	16.5
Lengths	35-90	35-90	35-90	35-90	35-90	35-90
Drill Ø	9.0	10.5	12.0	9.0	10.5	12.0
Tap Ø	9.5	11.0	12.5	9.5	11.0	12.5
Drive Feature	Inserter - SJTS-100014 Flat Head 2.9mm thick with central M6 threads for engagement					
Washer Major Ø	—	—	—	17.0	18.5	20.0
Washer Minor Ø	—	—	—	11.5	13.0	14.5
Washer Thickness	—	—	—	2.0	2.0	2.0
Washer Angulation	—	—	—	27° Cone	22° Cone	22° Cone
Thread Length	Full-length			Implant Lengths 35-45: 26mm Implant Lengths 50-90: 31mm		



▶ IMPLANT SPACING



MINIMUM IMPLANT DISTANCE (MM)	FULLY THREADED (S)			LAG (L)			LAG (L) & WASHER (W)		
	Ø10.5	Ø12.0	Ø13.5	Ø10.5	Ø12.0	Ø13.5	Ø10.5	Ø12.0	Ø13.5
Ø10.5 S	12.8	13.5	14.2	13.6	14.4	15.1	15.4	16.1	16.9
Ø12.0 S	13.5	14.2	15.0	14.4	15.1	15.9	16.1	16.9	17.6
Ø13.5 S	14.2	15.0	15.7	15.1	15.9	16.6	16.9	17.6	18.4
Ø10.5 L	13.6	14.4	15.1	14.5	15.3	16.0	16.3	17.0	17.8
Ø12.0 L	14.4	15.1	15.9	15.3	16.0	16.8	17.0	17.8	18.5
Ø13.5 L	15.1	15.9	16.6	16.0	16.8	17.5	17.8	18.5	19.3
Ø10.5 LW	15.4	16.1	16.9	16.3	17.0	17.8	18.0	18.8	19.5
Ø12.0 LW	16.1	16.9	17.6	17.0	17.8	18.5	18.8	19.5	20.3
Ø13.5 LW	16.9	17.6	18.4	17.8	18.5	19.3	19.5	20.3	21.0

Notes:

1. Minimum implant distance assumes parallel pins. To compensate for any angulation, consider adding additional distance between pins and/or implant placement to prevent implants from contacting each other during insertion.
2. Consider adding additional distance between implants in the unlikely case a chisel is needed to remove implants in the future.



► PRE-OPERATIVE PLANNING

Pre-operative planning with radiographs and other advanced imaging modalities can be helpful in estimating the appropriately sized implants with the goal of stabilizing, fixating, and fusing the sacroiliac joint.

Determine the surgical approach based on the surgeon's preference (lateral or posterior).

The surgeon should be thoroughly familiar with the SJTS devices, method of application, instruments, and surgical technique. Correct positioning and location of the SJTS device should be checked intraoperatively with x-ray. The size (especially the length) of the SJTS device must be chosen based on the patient's anatomy and desired correction.

► PATIENT POSITIONING

Place the patient in the prone position on the operating table. The patient should be in spine neutral position without excessive flexion or extension of the hips.

Fluoroscopy can be utilized to aid in patient positioning.



► IMAGING AND TARGETING

Lateral View

Align view to visualize crisp endplates of the L5-S1 disc space. C-Arm may be required to swivel to achieve the view. Surgeon should confirm that sciatic notches overlap, are in correct alignment, and alar lines (iliac cortical densities) are superimposed (Fig. 1).



Figure 1

Inlet View

C-Arm is tilted toward the feet until the dense cortical line of the S1-S2 vestigial disc directly overlies the dense cortical line of the sacral promontory. The orientation of the fluoro should line up with the anterior cortex of the S1 body (Fig. 2).

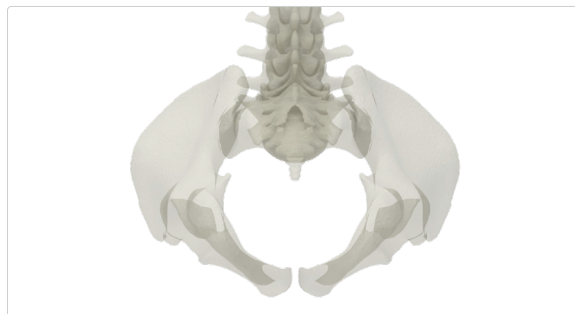


Figure 2

Outlet View

C-Arm is tilted toward the head until the S1 and S2 neuroforamina are clearly visible, and the pubic symphysis is at a level of the S2 foramen (Fig. 3).

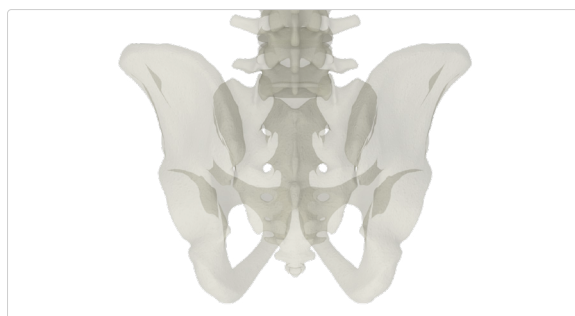


Figure 3

Outlet Oblique View

C-Arm is positioned in an anterior-to-posterior view with a cephalad tilt, and obliquely from the operative side. This view is utilized for the visualization of the lateral aspect of the S1 neuroforamen and the SI joint in an open view (Fig. 4).



Figure 4



► ACCESS AND EXPOSURE

Palpate the posterior superior iliac spine (PSIS), which can be located 3cm inferior and lateral to the L5/S1 joints. A K-Wire (*not provided*) may be placed perpendicular through the tissue until contact with the PSIS as reference.

Utilizing the Outlet view, use a Blunt Steinmann Pin as a guide to mark the skin, draw a line perpendicular to midline connecting the midpoint of the two S1 neuroforamina. Repeat the procedure for the two S2 neuroforamina (Fig. 5).

Notes:

1. Both S1 and S2 skin markings should extend 8-10cm lateral to the PSIS on the operative side (Fig. 6).
2. If placing the implants in conjunction with an open procedure, the physician should take care not to destabilize the joint prior to placing the implants.
3. When incising and dissecting, take care to avoid the superior gluteal artery and other sensitive neurovascular structures in the surrounding soft tissue.

Utilizing the Outlet Oblique view, use the Blunt Steinmann Pin as a guide to mark the skin parallel to midline on the lateral edge of the teardrop.

Depending on patient anatomy noted from pre-operative planning images, create a longitudinal incision from the S1 line to the S2 line located 5-7cm lateral to the vertical skin marking from the lateral edge of the teardrop (Fig. 7).

Incision should be limited to the skin and subcutaneous tissue and not progress to the muscle and bony fascia. Incising muscle fibers (running perpendicular to the incision) may result in significant bleeding or muscle damage.

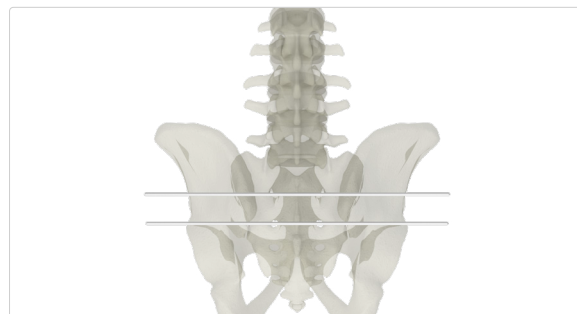


Figure 5



Figure 6

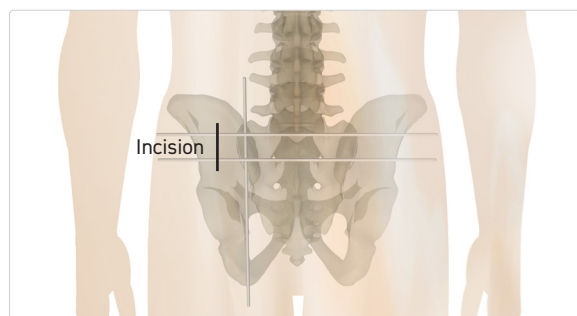


Figure 7



► SINGLE PIN PLACEMENT

Placement of the first pin should be 3-5cm lateral to the crest of the posterior superior iliac spine (PSIS).

Utilizing the S1 skin marking, start the entry of the Steinmann Pin at a 45-degree angle to the lateral ilium. Advance and dock in the lateral cortex of the ilium. Then, transition the Steinmann Pin angulation as needed for the patient's anatomy (Fig. 8).

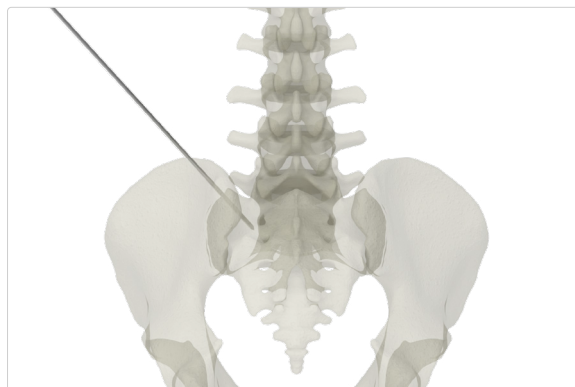


Figure 8

Lateral Fluoro View

Position the distal end of the Steinmann Pin so that it is targeted cranial to the intersection of the ala and anterior sacral cortex. Steinmann Pin should be placed to prevent skiving when making contact (Fig. 9).



Figure 9

Outlet Oblique View

Surgeon should verify the Steinmann Pin trajectory to ensure that it appears parallel to the S1 endplate (Fig. 10).



Figure 10



Inlet View

Surgeon should verify the Steinmann Pin trajectory to ensure that it will traverse the SI joint and remain lateral to the neuroforamen. Advance the Steinmann Pin, stopping short of the anterior sacral cortex (Fig. 11).

The Radiolucent Clamp (SJTS-100003) may be utilized to limit C-Arm exposure and assist with stabilizing the Steinmann Pin (Fig. 12).

Notes:

1. When placing the Steinmann Pin, do not advance past the SI joint. Final positioning of the Steinmann Pin should be accomplished in the outlet oblique and inlet fluoro views.
2. When advancing pin or implant, avoid penetrating the sacral canal and/or foramen.
3. Do not breach the ala or anterior cortex of the sacrum in the lateral view.
4. Steinmann Pin should be targeted inferior to the superior margin of the sacral ala and superior to the S1 neuroforamen.
5. At all times use caution around the spinal canal and nerve roots to avoid damage to the nerves.
6. Replace any bent pins with new pins immediately during the procedure to ensure proper trajectory before moving to the next step.
7. If placing multiple pins, take care to avoid inadvertent advancement of an adjacent pin.
8. Take care to ensure adequate spacing and trajectory between implants, including previously placed implants. See implant spacing on page 5. If implants are placed too close together, the heads of the implants may overlap or the implant threads may interdigitate, potentially making removal of implants more difficult.
9. Be mindful and aware of the sharp instruments in the set. These may include pins, drills, taps and can cause injury if handled in an unsafe manner.
10. For fracture repair, confirm the Steinmann Pin has crossed the fracture line.
11. If placing the second Steinmann Pin before the first implant insertion, refer to the Multiple Pin Placement section on page 24.

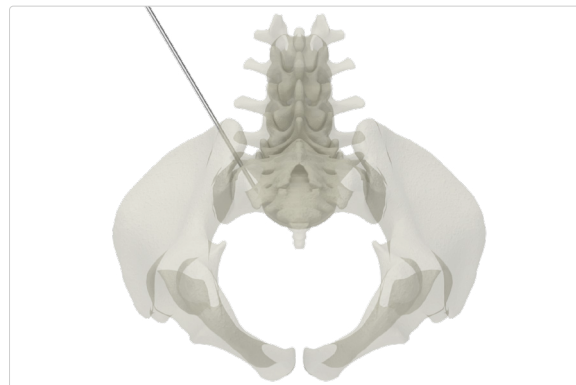


Figure 11



Figure 12



▶ TISSUE DISSECTION (OPTIONAL)

Insert the Tissue Dissector (SJTS-100025) and assembled T-handle (SJTS-100007) over the Steinmann Pin until it reaches the ilium. Rotate the Tissue Dissector to release any soft tissue. Remove the Dissector being mindful of Steinmann Pin position (Fig. 13).

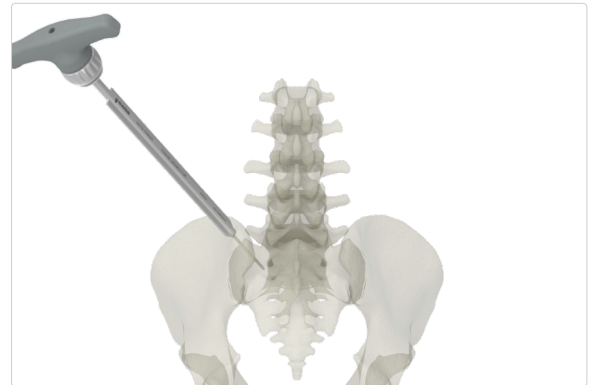


Figure 13

▶ TISSUE DILATION

Insert the Dilator (SJTS-100005) over the Steinmann Pin until it reaches the ilium (Fig. 14). Next, insert the Tissue Protector (SJTS-100006) over the Dilator until it reaches the ilium (Fig. 15). Remove the Dilator.

Note: Do not impact the flat surface of the Dilator or Tissue Protector. This may damage the bone and/or Dilator.

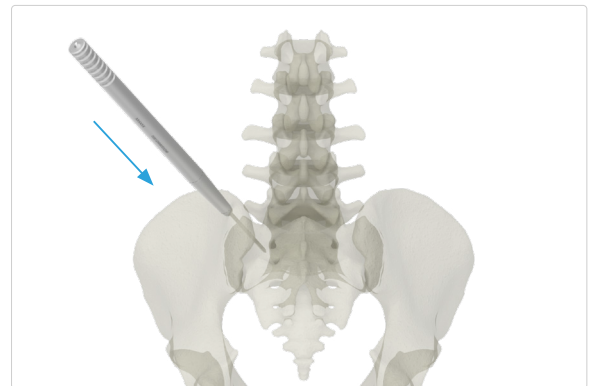


Figure 14

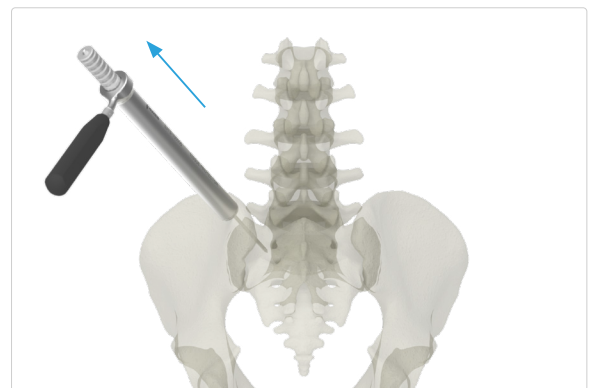


Figure 15



► IMPLANT MEASUREMENT

Insert the Measurement Tool (SJTS-100004) over the Steinmann Pin and flush with the Tissue Protector (Fig. 16). If the short Steinmann Pin is used, select the implant length that corresponds to the proximal end of the pin (Fig. 17). If using the long Steinmann Pin, the laser mark indicates the implant length on the measurement tool (Fig. 18).

Notes:

1. Markings on Measurement Tool are in 5mm increments.
2. The physician must choose the available implant length they determine is most appropriate for the situation.

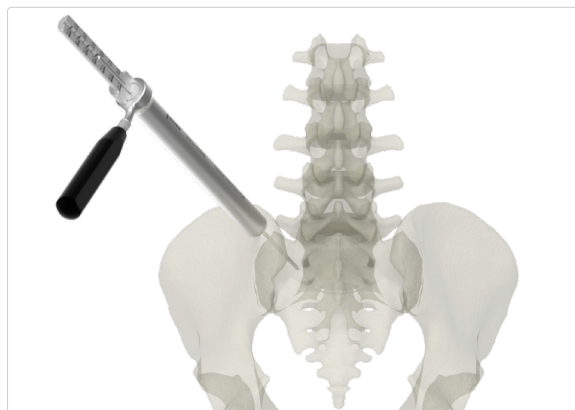


Figure 16

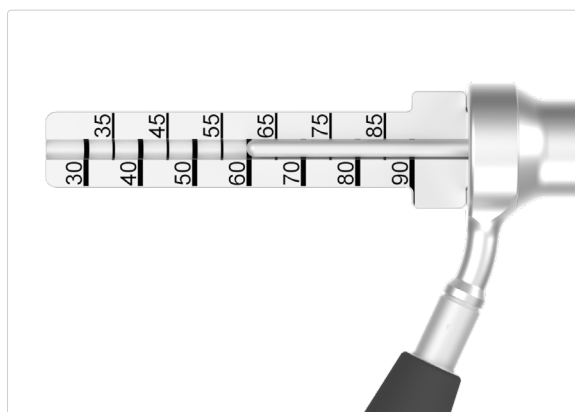


Figure 17

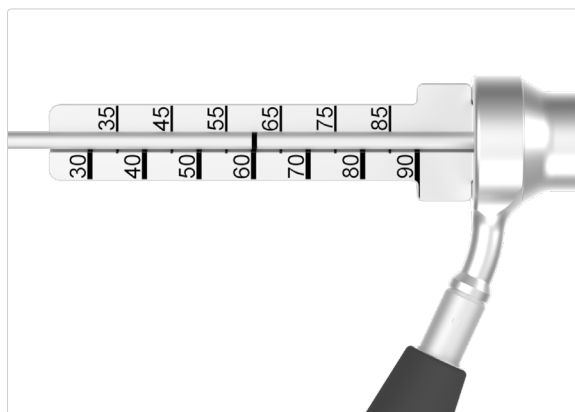


Figure 18



► DRILLING

Attach the optional Depth Stop (SJTS-100026) to the Drill (SJTS-10001X). With the Drill depth markings facing up, insert the Depth Stop with the arrow facing down over the proximal end (Fig. 19). The arrow should point to the distal (patient) end. At the desired depth (Fig. 20a), rotate the depth stop until the arrow faces up (Fig. 20b). Turn the wing nut clockwise until finger tight to lock the Depth Stop. The Drill depth is shown with 60mm in the cut out (Fig. 21).



Figure 19

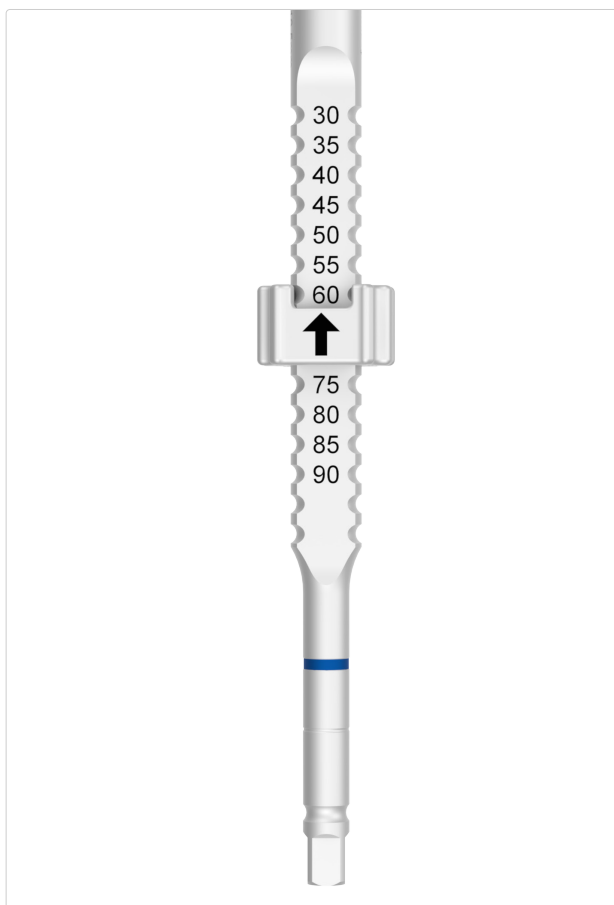


Figure 21

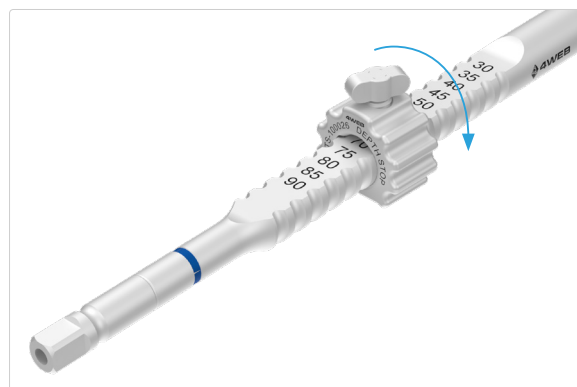


Figure 20a

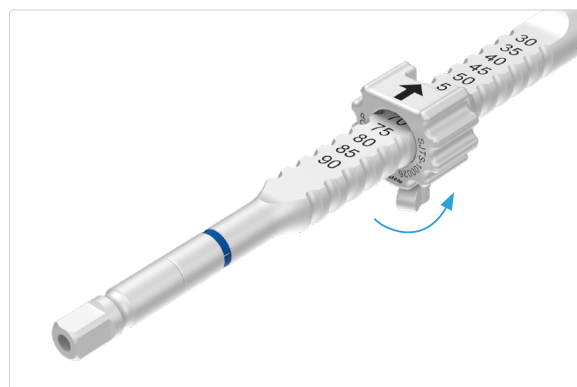


Figure 20b



Attach the assembled Drill to the T-handle or Adapter 1/4" Square to Hudson (SJTS-100023) if necessary (Fig. 22). Under fluoroscopy in the inlet view, drill through the ilium. The Drill should pass across the SI joint and the cortex of the sacrum (Fig. 23). Do not drill more than 2-3mm medial to the sacral cortex.

Drilling should be accomplished under fluoroscopy, ensuring there is no unwanted Steinmann Pin advancement.

Notes:

1. In hard bone, users should drill and tap to ensure that the implant can be fully inserted and/or adjusted as necessary during the index procedure.
2. Use care to avoid advancing the pin during drilling. Do not push on the pin.
3. If the drill appears to be advancing the Steinmann Pin while drilling the pilot hole, the surgeon can replace the Steinmann Pin with the blunt option.
4. The Steinmann Pin has the potential to be inadvertently withdrawn while removing the drill.
5. Ensure the lumen of the drill bit is free of debris prior to each use. Flushing the drill bit lumen with sterile saline prior to each subsequent use during the procedure may also minimize pin binding.
6. Over-drilling (excessive advancement) may cause nerve damage, hemorrhage, or other possible adverse events listed in the instructions for use.
7. When drilling in hard bone, use a 'pecking technique' to lower the risk of overheating adjacent bone.
8. During extended use of drill, i.e., drilling in hard bone or creation of deep bone channels, irrigate the drill bit to minimize overheating of adjacent bone.
9. The fit of the drill bit within the Tissue Protector is not snug. There will be some play between the two instruments, and care must be taken to remain colinear during use to prevent drilling into the lumen walls of the Tissue Protector.

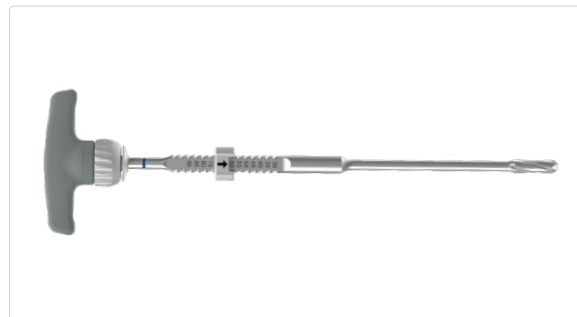


Figure 22



Figure 23

IMPLANT Ø	DRILL Ø	COLOR BAND
10.5mm	9.0mm	BLUE
12.0mm	10.5mm	GREEN
13.5mm	12.0mm	GOLD



► TAPPING (OPTIONAL)

Taps may be used with the T-handle if the patient's bone density or anatomy requires it. The SI Joint Truss System implants are designed with a self-tapping feature, therefore tapping is not required.

Attach the optional Depth Stop (SJTS-100026) to the Tap (SJTS-10101X). With the Tap depth markings facing up, insert the Depth Stop with the flat surface facing down over the proximal end (Fig. 25). The arrow should point to the distal (patient) end. At the desired depth (Fig. 26a), rotate the Depth Stop until the cut out faces up (Fig. 26b). Turn the wing nut clockwise until finger tight to lock the Depth Stop. The Tap depth is shown with 60mm in the cut out (Fig. 27).

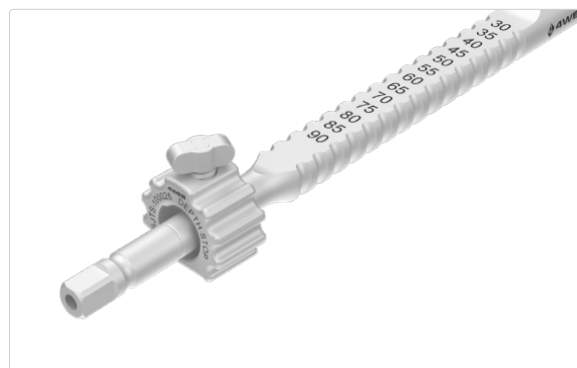


Figure 25

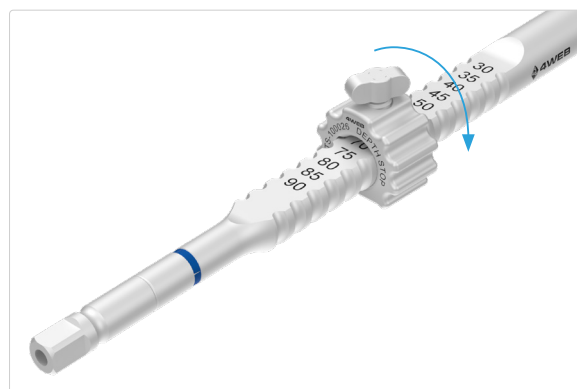


Figure 26a

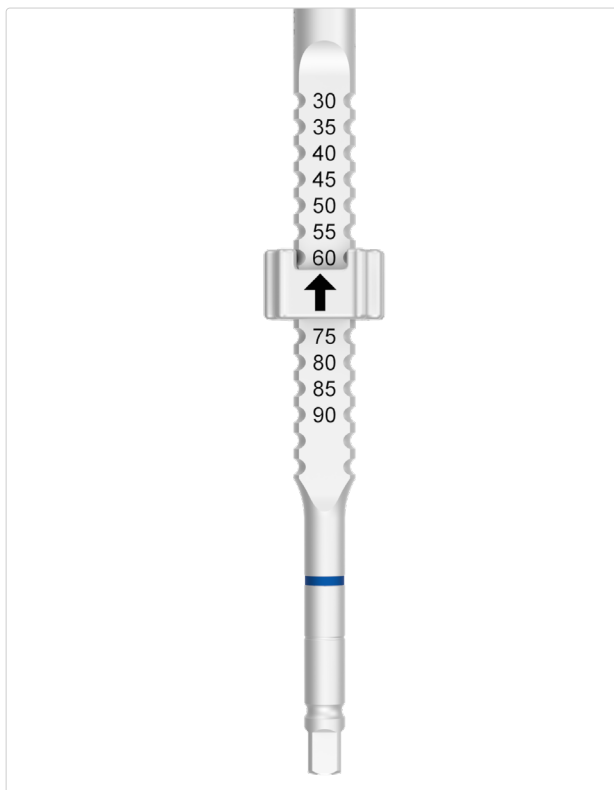


Figure 27

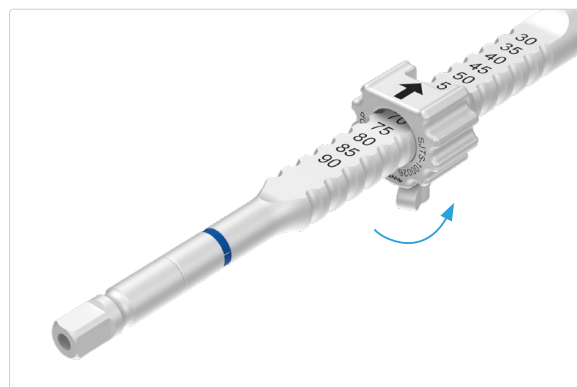


Figure 26b



Assemble the appropriate Tap (SJTS-10101X) to the T-handle (Fig. 28). Insert the tap over the Steinmann Pin and into the Tissue Protector (Fig. 29).

Notes:

1. Ensure that the tap moves easily down the length of the Steinmann Pin to avoid pin advancement. The blunt Steinmann Pin may be used if the pin is close to a foramen or if advancement of the pin is noted. Monitor tap depth with fluoroscopy in the inlet view and measurement markings on the proximal end of the tap. Tap the placement hole to full depth through the lateral cortex of the sacrum.
2. Do not penetrate the anterior sacral cortex.
3. Ensure the lumen of the tap is free of debris prior to each use. Flushing the tap lumen with sterile saline prior to each subsequent use during the procedure may also minimize pin binding.
4. Use care to avoid advancing the pin during tapping. Do not push on the pin. Applying medial force to the pin may cause it to advance medially.
5. Excessive advancement of the tap may cause nerve damage, hemorrhage, or other possible adverse events listed in the instructions for use.
6. Take care to monitor tap advancement if using with power.
7. In hard bone, users should drill and tap to ensure that the implant can be fully inserted and/or adjusted as necessary during the index procedure.
8. Continued rotation of the tap without advancement may result in the stripping of internal threads into the bone.
9. Selecting a tap larger than the corresponding implant may result in loss of implant fixation to bone (e.g., using a 12.0mm Tap with a 10.5mm implant).
10. Do not use non-compatible taps with the SJTS.



Figure 28

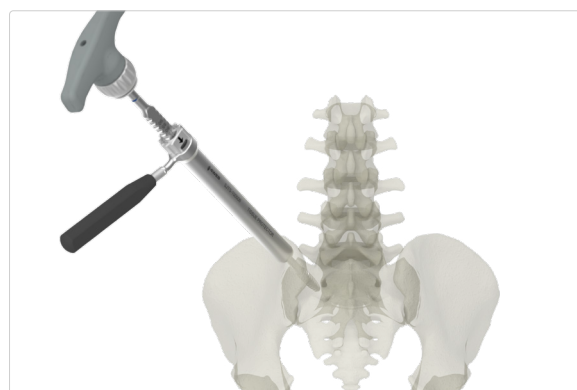


Figure 29

IMPLANT ϕ	TAP ϕ	COLOR BAND
10.5mm	9.5mm	BLUE
12.0mm	11.0mm	GREEN
13.5mm	12.5mm	GOLD



► IMPLANT PREPARATION

The Threaded SIJ Fusion Devices are provided in two distinct sterile implant offerings:

1. Fully threaded
2. Lag with accompanying washer

Pack autograft or allograft bone around the implant as appropriate. The implant is now ready for use.

Note: Be aware the implants have sharp edges and a roughened surface. The implants can cause injury if handled in an unsafe manner.

► IMPLANT INSERTION

Fully Threaded Implant Insertion

Attach the Inserter (SJTS-100014) to the T-handle (Fig. 30). Select the implant that corresponds to the depth indicated on the Measurement Tool. Turn the Inserter knob clockwise and align notches in the Inserter with notches on the implant to attach the implant. Ensure the implant is securely attached to the Inserter. The implant should be flush to the Inserter, and no threads should be seen (Fig. 31).

Note: Do not cross-thread or overtighten (two finger tightness only) as this may make disengagement and removal of the Inserter more difficult.



Figure 30



Figure 31



Depending on surgical preference and tissue coverage, the surgeon may want to countersink the implant. The Inserter has a laser mark to indicate when the implant is flush with the ilium (0mm) that can be read from the Tissue Protector (Fig. 32).

Under fluoroscopic guidance in the inlet view, advance the implant into position (Fig. 33). It is recommended to maintain the threads (where present) of the proximal end of the implant within the cortical layer of the ilium to aid in fixation and stability.

Once fully inserted, unthread the Inserter and remove both the Inserter and Tissue Protector from the incision, retaining the Steinmann Pin.

If post packing is desired, refer to instructions on page 22.



Figure 32



Figure 33



Notes:

1. Take care when inserting an implant. Over-tightening may cause damage to the bone or implant.
2. The implant has been designed to optimize initial fixation with surrounding bone. If implant becomes difficult to advance during insertion (e.g., patient has hard bone) do not continue to advance implant. Insertional torque could exceed limits of the user/inserters. In this situation, remove the implant and drill and tap to fully prepare the bone channel to accommodate the implant.
3. Anatomic curvature of the ilium may cause a portion of the implant proximal head to appear proud even when the Tissue Protector is fully seated. The oblique outlet view can be used to verify seating depth and position.
4. Ensure the Steinmann Pin does not advance when inserting the implant.
5. Physicians are advised to always use the Tissue Protector to protect surrounding soft tissue from injury that may be caused by the implants rough surface and sharp edges.
6. If using the multiple pin technique, monitor the position of the Inserter relative to the adjacent pins. The Inserter may impinge adjacent pins during use.
7. Use care to avoid advancing the pin during implant insertion. Do not push on the pin.
8. Take care not to loosen the Inserter knob during implant insertion. This may cause the Inserter to unthread from the implant.
9. Do not over-insert or use an implant that is either too long or too large. Using an incorrectly sized implant may cause nerve damage, hemorrhage, or other possible adverse events as listed in the instructions for use.
10. Seating an implant flush or countersinking a fully threaded implant may result in bone growing over the head of the implant. This may make future removal of the implant more difficult or impossible.
11. Take care when inserting the surgical instruments and the SJTS implants to avoid damage to surrounding soft tissue.
12. Breakage, slippage or misuse of instruments or implants may cause injury to the patient or operative personnel.
13. Excessive loads, such as excessive torque, tensile, or compression load applied to long handle insertion tools attached to the implant, or direct application of loads to a small area of the devices can damage the implant/instrument interface.



Lag Implant and Washer Insertion

Placement of the Steinmann Pin and assembly of the lag implant to the Inserter should follow the same surgical steps as before.

Notes:

1. Only the 10.5mm lag implant without washer will advance through the Tissue Protector.
2. All diameters of washers will NOT advance through the Tissue Protector.
3. Do not cross-thread or overtighten (two finger tightness only) as this may make disengagement and removal of the Inserter more difficult.

Attach the Inserter (SJTS-100014) to the T-handle (Fig. 34). Select the implant that corresponds to the depth indicated on the Measurement Tool. Turn the Inserter knob clockwise and align notches in the Inserter with notches on the implant to attach the implant. Ensure the implant is securely attached to the Inserter. The implant should be flush to the Inserter, and no threads should be seen.

Assemble the washer onto the lag implant prior to insertion, if the washer will be used (Fig. 35). When transferring the Inserter with implants, take care to hold distal end up so washer does not inadvertently fall from the implant. Under fluoroscopic guidance in the inlet view, advance the implant into position over the Steinmann Pin (Fig. 36). It is recommended to maintain the threads (where present) of the proximal end of the implant within the cortical layer of the ilium to aid in fixation and stability.

The surgeon should visualize final placement in the oblique outlet view to ensure that the polyaxial washer of the lag implant is sitting flush on the ilium and that compression has been achieved (Fig. 37).



Figure 34



Figure 35

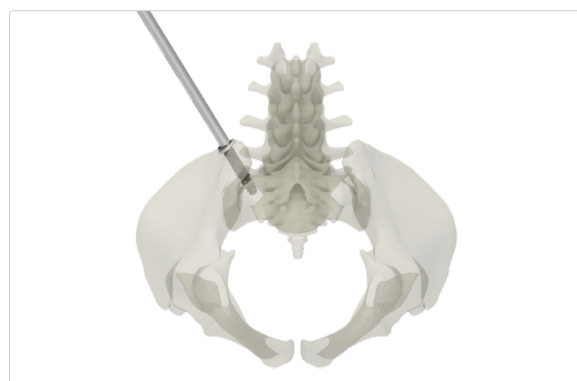


Figure 36

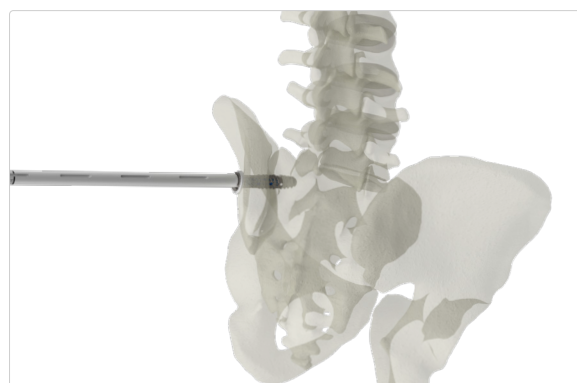


Figure 37



Notes:

1. The markings on the washer should be facing toward the proximal end of the lag implant to ensure polyaxial angulation.
2. Take care when inserting an implant. Over-tightening may cause damage to the bone or implant.
3. The lag implants should not be countersunk either with or without the washer. Over insertion may cause damage to the proximal cortex or limit ability to lag the joint space. Do not advance the laser mark past the Tissue Dissector. Use fluoroscopy to monitor implant insertion depth to prevent driving the washer through the cortex. Over-inserting may cause damage to the bone or implants.
4. If the implant becomes difficult to advance during insertion (e.g., patient has hard bone) do not continue to advance the implant. Insertional torque could exceed limits of the user/Inserter. In this situation, remove the implant and drill and tap to fully prepare the bone channel to accommodate the implant.
5. If implanting the lag with washer, take care to ensure the washer does not slide off the implant before it is placed over the Steinmann Pin.
6. If placing an implant under power, monitor position of the implant and pin with fluoroscopy. Perform final implant positioning by hand.
7. If using the multiple pin technique, monitor the position of the Inserter relative to the adjacent pins. The Inserter may impinge adjacent pins during use.
8. Use care to avoid advancing the pin during implant insertion. Do not push on the pin.
9. Take care not to loosen the Inserter knob during implant insertion. This may cause the Inserter to unthread from the implant.
10. Do not over-insert or use an implant that is either too long or too large. Using an incorrectly sized implant may cause nerve damage, hemorrhage, or other possible adverse events as listed in the instructions for use.
11. Take care when inserting the surgical instruments and the SJTS implants to avoid damage to surrounding soft tissue.



► POST PACKING

For post packing, there are two options for delivery:

1. Funnel (SJTS-100015), Funnel Shaft (SJTS-100016), and Plunger (SJTS-100017)
2. Direct with a syringe attached to the Funnel Shaft

Graft volumes for the implant cannulation and funnel volumes are:

	DESCRIPTION	VOLUME (CCs)
IMPLANT LENGTH (MM)	35	0.24
	40	0.29
	45	0.33
	50	0.38
	55	0.42
	60	0.47
	65	0.51
	70	0.56
	75	0.60
	80	0.65
	85	0.69
	90	0.74
FUNNEL	SJTS-1000015	21.31
FUNNEL SHAFT	SJTS-1000016	1.42



Option 1

Assemble the Funnel onto the Funnel Shaft via the standard luer fitting. Insert the funnel assembly over the Steinmann Pin and secure to the implant by turning clockwise to engage threads. Remove the Steinmann Pin. Use the Plunger to complete packing (Fig. 38).

Option 2

Insert the Funnel Shaft over the Steinmann Pin and secure to the implant by turning clockwise to engage threads (Fig. 39). Remove the Steinmann Pin. Attach the syringe to the Funnel Shaft standard luer fitting and pack the implant (Fig. 40). Remove the syringe and use the Plunger to complete packing. The Plunger is designed to extend to the tip of the Funnel Shaft (Fig. 41).

Repeat for additional implants.

Notes:

1. Ensure Funnel Shaft is fully seated into the head of the implant to prevent extravasation of graft material between the Funnel Shaft and the head of the implant.
2. Do not over rotate Funnel Shaft once seated in the implant to prevent over insertion or backing out of implant.
3. Syringe is not provided.

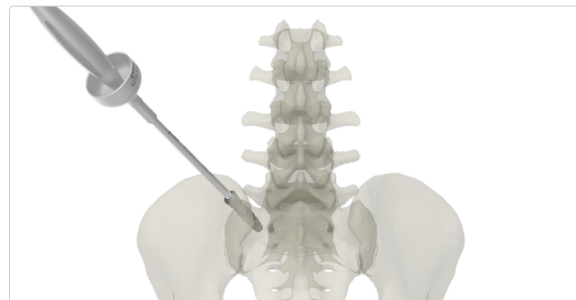


Figure 38

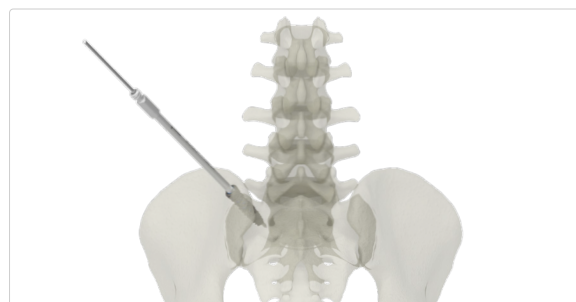


Figure 39

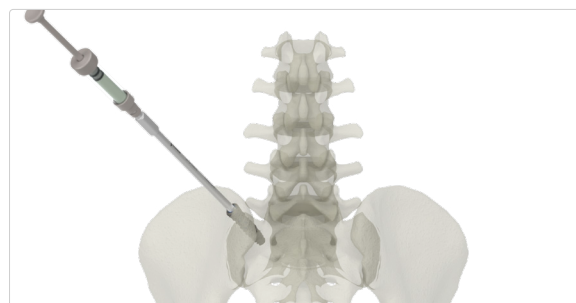


Figure 40

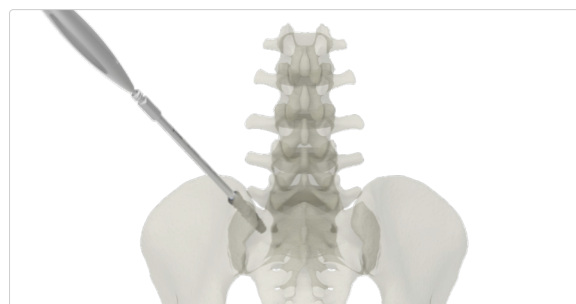


Figure 41



► MULTIPLE PIN PLACEMENT

After placing the first Steinmann Pin, determine the appropriate spacing required for placing the additional implants.

Notes:

1. Minimum spacing should be 12.8mm for \varnothing 10.5mm implants, 14.2mm for the \varnothing 12.0mm implants, and 15.7mm for the \varnothing 13.5mm implants. Lag implants and washer require additional spacing. Ensure the second pin is adequately spaced from the first pin to allow a minimum of 1mm distance between side-by-side placement of the implants. See Implant Spacing on page 5 for minimum spacing requirements.
2. Steinmann Pin should be in line or slightly caudal to the PSIS. Do not advance beyond the SI joint. Adjustments to the trajectory will be made in the outlet oblique and inlet views.
3. When advancing the pin, avoid penetrating the sacral canal and/or foramen.
4. Minimum implant distance assumes parallel pins. Consider adding additional distance between pins and/or implant placement to prevent implants from contacting each other during insertion.
5. Consider adding additional distance between implants in the unlikely case a chisel is needed to remove implants in the future.

An Adjustable Pin Guide (SJTS-100018) (Fig. 42) and three Fixed Pin Guides with spacing of 14mm, 16mm, and 19mm (SJTS-1000XX) (Fig. 43) are available.

If using the Adjustable Pin Guide, set the proper spacing by loosening the wingnut and slide the tube to the correct spacing. Tighten the wingnut to secure the Adjustable Pin Guide. A numerical gage is provided on the proximal surface of the Adjustable Pin Guide for reference. The Radiolucent Clamp may be utilized with the pin guides during imaging.

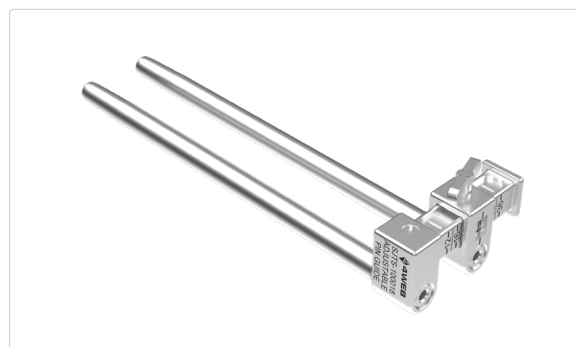


Figure 42

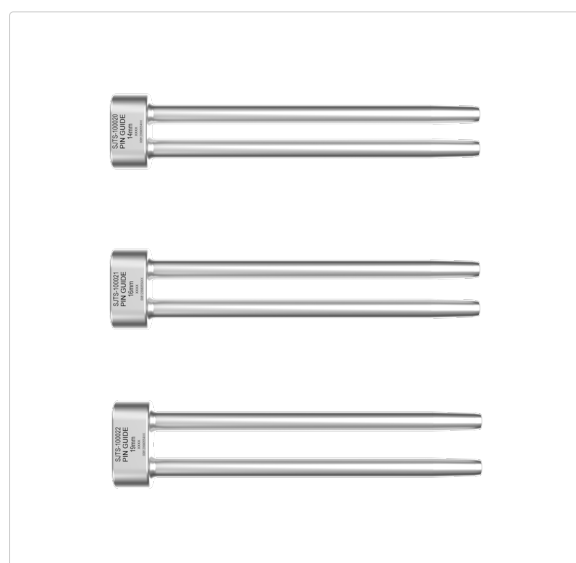


Figure 43



Slide the guide over the first Steinmann Pin. Adjust the guide to position the second tube to the next Steinmann Pin location. Verify location and available space via lateral fluoroscopy.

Position the second Steinmann Pin 3-5cm lateral to the crest of the PSIS (Fig. 44).

In line with the S2 marking, introduce the Steinmann Pin to the lateral ilium and dock on the lateral cortex of the ilium.

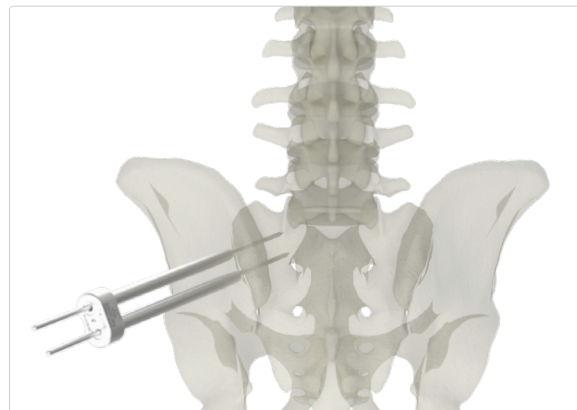


Figure 44

Lateral View

While docked with the ilium, target Steinmann Pin so that the distal tip is aimed just caudal to the intersection of the anterior cortex of the sacrum and the sacral ala (Fig. 45). Verify fluoroscopically in the lateral view. Do not breach the ala or the anterior cortex of the sacrum.



Figure 45

Outlet Oblique View

Confirm the Steinmann Pin or Adjustable Pin Guide trajectory in the outlet oblique view is parallel to the S1 endplate (Fig. 46). Final placement of the Steinmann Pin should be inferior to the first implant so that the second implant has adequate space.

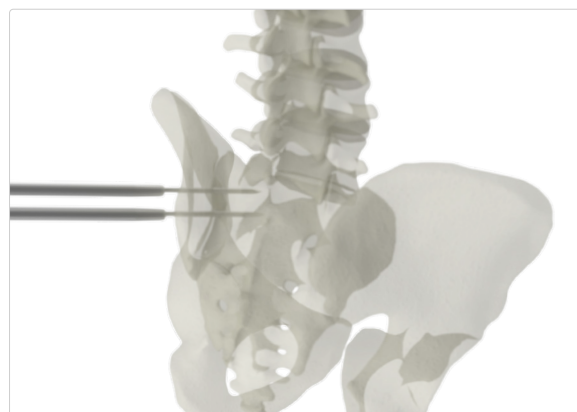


Figure 46



Inlet View

Confirm Steinmann Pin or Adjustable Pin Guide trajectory will traverse the SI joint and remain lateral to the neuroforamen. Advance the Steinmann Pin if a freehand technique is being used or introduce the Steinmann Pin into the Adjustable Pin Guide and advance until the distal trocar tip can be seen under fluoroscopy.

Advance the Steinmann Pin until the distal tip is 1.5cm short of the anterior sacral cortex (Fig. 47).

Repeat the previous steps for inserting SJTS implants.

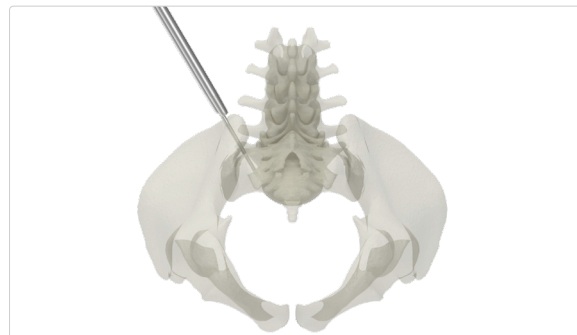


Figure 47



► FINAL FLUOROSCOPIC VIEWS

Verify lateral (Fig. 48a), inlet (Fig. 48b), outlet (Fig. 48c), and outlet oblique (Fig. 48d) views to verify correct implant positioning, wall and foramen integrity, and maintenance of fracture reduction. Proceed with standard closing procedure of muscle fascia (if possible), subcutaneous tissue, and skin.



Figure 48a

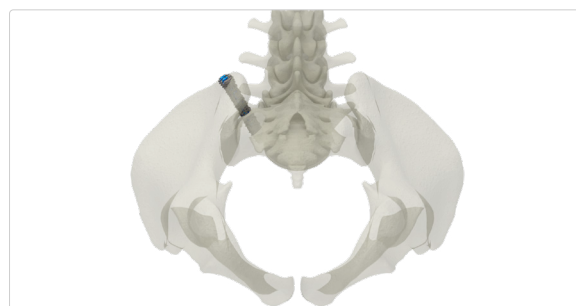


Figure 48b

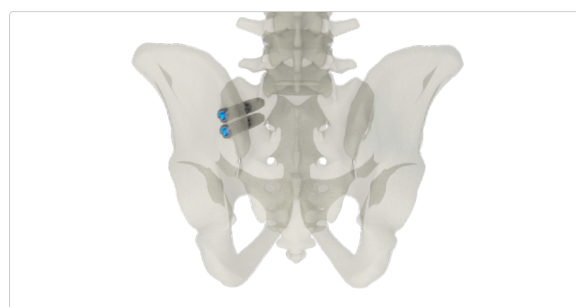


Figure 48c

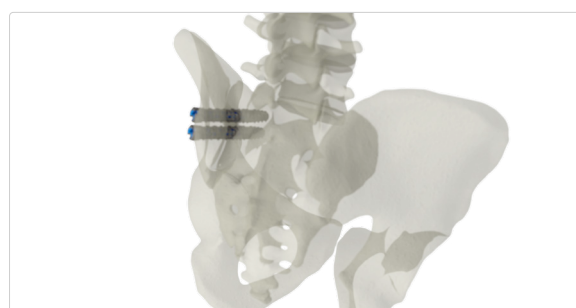


Figure 48d



► REMOVAL

Reattachment of the Inserter should be the primary method of Implant removal.

Clear tissue as necessary to access the implant head and drive feature. If necessary, introduce the Steinmann Pin (SJTS-100X0X) into the cannulation of the implant under fluoroscopic guidance and place the Dilator (SJTS-100005) and the Tissue Protector (SJTS-100006) over the Steinmann Pin to create a working channel and to protect the soft tissue (Fig. 49). Remove the Dilator, leaving the Tissue Protector and Steinmann Pin.

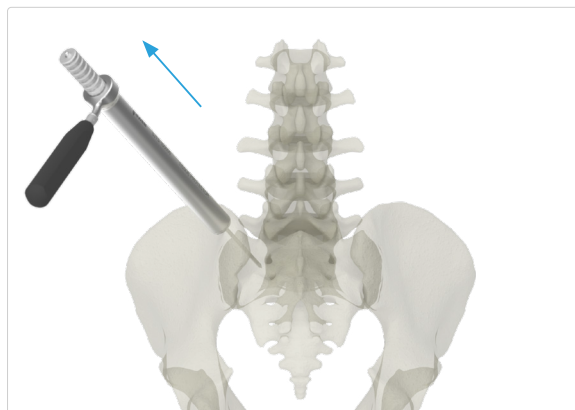


Figure 49

Attach the Inserter (SJTS-100014) to the T-handle (SJTS-100007). Guide the Inserter over the Steinmann Pin and seat the Inserter into the implant. Rotate the Inserter knob clockwise to attach the Inserter into the threads of the implant. Rotate the Inserter counterclockwise to remove the implant from the surgical site. Fill the implant site with bone graft to help with hemostasis. Repeat as necessary (Fig. 50).

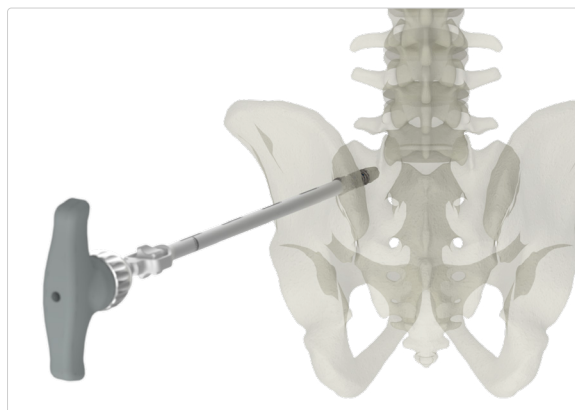


Figure 50

Notes:

1. Once the fusion and/or fracture has healed, the physician and patient should carefully weigh the risks and benefits if considering the removal of the implant.
2. Implants are designed to optimize long-term integration of the implant with the surrounding bone. During implant revision/removal, the removal torque may exceed the limit of the user/Inserter.
3. In revision/removal cases, instruments such as chisels may be needed to free the implant from the surrounding bone prior to using the Inserter to remove the implants. Pliers or other tools should not be used to grip the head of the SJTS implant, as it could damage the drive feature, internal threads, or break the implant.
4. The washer is not attached to the lag implant. If removing a lag implant with washer, consider the need to remove the washer as it may remain in the surgical site during removal.

INSTRUMENT CATALOG



PART NUMBER	DESCRIPTION
SJTS-100201	SJTS STEINMANN PIN SHARP 270MM



SJTS-100202	SJTS STEINMANN PIN BLUNT 270MM
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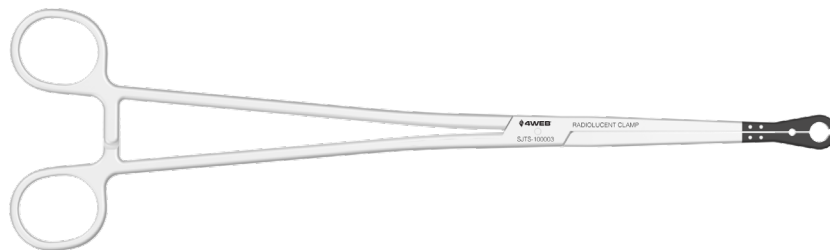
SJTS-100301	SJTS STEINMANN PIN SHARP 350MM
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SJTS-100302	SJTS STEINMANN PIN BLUNT 350MM
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SJTS-100003	SJTS RADIOLUCENT CLAMP
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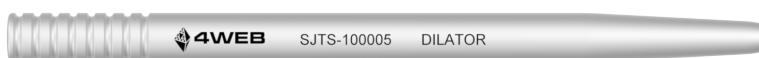




PART NUMBER	DESCRIPTION
SJTS-100004	SJTS MEASUREMENT TOOL



SJTS-100005	SJTS DILATOR
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SJTS-100006	SJTS TISSUE PROTECTOR
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SJTS-100025	SJTS TISSUE DISSECTOR
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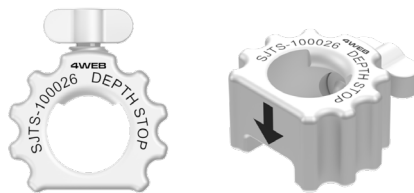
PART NUMBER	DESCRIPTION
SJTS-100007	SJTS T-HANDLE 1/4" SQUARE (CANNULATED)



SJTS-100008	SJTS INLINE HANDLE 1/4" SQUARE (CANNULATED)
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SJTS-100026	SJTS DEPTH STOP
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SJTS-100010	SJTS CANNULATED DRILL 10.5MM
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SJTS-100012	SJTS CANNULATED DRILL 12.0MM
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PART NUMBER	DESCRIPTION
SJTS-100013	SJTS CANNULATED DRILL 13.5MM



SJTS-100014	SJTS INSERTER
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SJTS-100015	SJTS FUNNEL
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SJTS-100016	SJTS FUNNEL SHAFT
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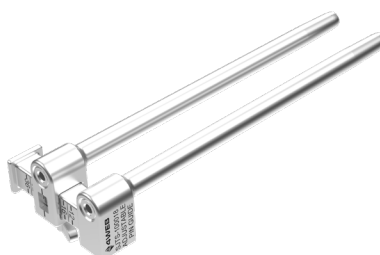


SJTS-100017	SJTS PLUNGER
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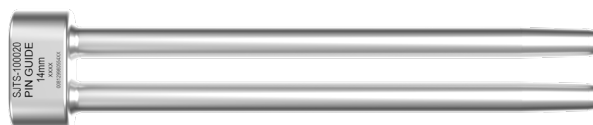




PART NUMBER	DESCRIPTION
SJTS-100018	SJTS ADJUSTABLE PIN GUIDE



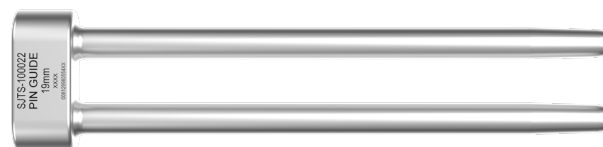
SJTS-100020	SJTS PIN GUIDE 14MM
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SJTS-100021	SJTS PIN GUIDE 16MM
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SJTS-100022	SJTS PIN GUIDE 19MM
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SJTS-100023	ADAPTER 1/4" SQUARE TO HUDSON
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PART NUMBER	DESCRIPTION
SJTS-101010	SJTS CANNULATED TAP 10.5MM



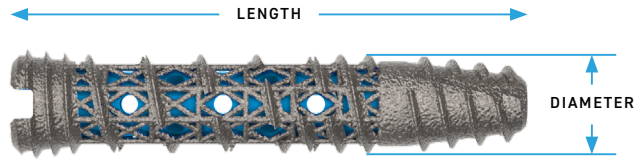
SJTS-101012	SJTS CANNULATED TAP 12.0MM
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SJTS-101013	SJTS CANNULATED TAP 13.5MM
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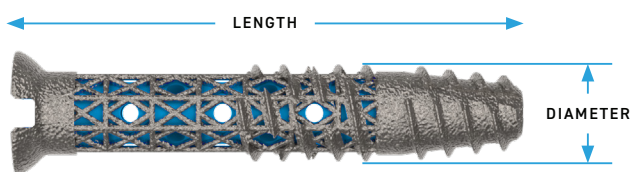
IMPLANT CATALOG



THREADED SIJ FUSION DEVICES

CATALOG NUMBER	DIAMETER, LENGTH
SJTS-S-1035-SP	10.5mm x 35mm
SJTS-S-1040-SP	10.5mm x 40mm
SJTS-S-1045-SP	10.5mm x 45mm
SJTS-S-1050-SP	10.5mm x 50mm
SJTS-S-1055-SP	10.5mm x 55mm
SJTS-S-1060-SP	10.5mm x 60mm
SJTS-S-1065-SP	10.5mm x 65mm
* SJTS-S-1070-SP	10.5mm x 70mm
* SJTS-S-1075-SP	10.5mm x 75mm
* SJTS-S-1080-SP	10.5mm x 80mm
* SJTS-S-1085-SP	10.5mm x 85mm
* SJTS-S-1090-SP	10.5mm x 90mm
SJTS-S-1235-SP	12.0mm x 35mm
SJTS-S-1240-SP	12.0mm x 40mm
SJTS-S-1245-SP	12.0mm x 45mm
SJTS-S-1250-SP	12.0mm x 50mm
SJTS-S-1255-SP	12.0mm x 55mm
SJTS-S-1260-SP	12.0mm x 60mm

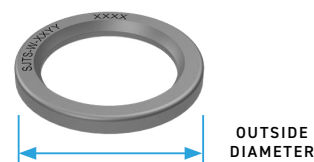
CATALOG NUMBER	DIAMETER, LENGTH
SJTS-S-1265-SP	12.0mm x 65mm
* SJTS-S-1270-SP	12.0mm x 70mm
* SJTS-S-1275-SP	12.0mm x 75mm
* SJTS-S-1280-SP	12.0mm x 80mm
* SJTS-S-1285-SP	12.0mm x 85mm
* SJTS-S-1290-SP	12.0mm x 90mm
SJTS-S-1335-SP	13.5mm x 35mm
SJTS-S-1340-SP	13.5mm x 40mm
SJTS-S-1345-SP	13.5mm x 45mm
SJTS-S-1350-SP	13.5mm x 50mm
SJTS-S-1355-SP	13.5mm x 55mm
SJTS-S-1360-SP	13.5mm x 60mm
SJTS-S-1365-SP	13.5mm x 65mm
* SJTS-S-1370-SP	13.5mm x 70mm
* SJTS-S-1375-SP	13.5mm x 75mm
* SJTS-S-1380-SP	13.5mm x 80mm
* SJTS-S-1385-SP	13.5mm x 85mm
* SJTS-S-1390-SP	13.5mm x 90mm



THREADED SIJ FUSION DEVICES - LAG*

CATALOG NUMBER	DIAMETER, LENGTH
* SJTS-L-1035-SP	10.5mm x 35mm
* SJTS-L-1040-SP	10.5mm x 40mm
* SJTS-L-1045-SP	10.5mm x 45mm
* SJTS-L-1050-SP	10.5mm x 50mm
* SJTS-L-1055-SP	10.5mm x 55mm
* SJTS-L-1060-SP	10.5mm x 60mm
* SJTS-L-1065-SP	10.5mm x 65mm
* SJTS-L-1070-SP	10.5mm x 70mm
* SJTS-L-1075-SP	10.5mm x 75mm
* SJTS-L-1080-SP	10.5mm x 80mm
* SJTS-L-1085-SP	10.5mm x 85mm
* SJTS-L-1090-SP	10.5mm x 90mm
* SJTS-L-1235-SP	12.0mm x 35mm
* SJTS-L-1240-SP	12.0mm x 40mm
* SJTS-L-1245-SP	12.0mm x 45mm
* SJTS-L-1250-SP	12.0mm x 50mm
* SJTS-L-1255-SP	12.0mm x 55mm
* SJTS-L-1260-SP	12.0mm x 60mm
* SJTS-L-1265-SP	12.0mm x 65mm
* SJTS-L-1270-SP	12.0mm x 70mm
* SJTS-L-1275-SP	12.0mm x 75mm
* SJTS-L-1280-SP	12.0mm x 80mm

CATALOG NUMBER	DIAMETER, LENGTH
* SJTS-L-1285-SP	12.0mm x 85mm
* SJTS-L-1290-SP	12.0mm x 90mm
* SJTS-L-1335-SP	13.5mm x 35mm
* SJTS-L-1340-SP	13.5mm x 40mm
* SJTS-L-1345-SP	13.5mm x 45mm
* SJTS-L-1350-SP	13.5mm x 50mm
* SJTS-L-1355-SP	13.5mm x 55mm
* SJTS-L-1360-SP	13.5mm x 60mm
* SJTS-L-1365-SP	13.5mm x 65mm
* SJTS-L-1370-SP	13.5mm x 70mm
* SJTS-L-1375-SP	13.5mm x 75mm
* SJTS-L-1380-SP	13.5mm x 80mm
* SJTS-L-1385-SP	13.5mm x 85mm
* SJTS-L-1390-SP	13.5mm x 90mm



WASHERS*

CATALOG NUMBER	IMPLANT SIZE	OUTSIDE DIAMETER
* SJTS-W-1017	10.5mm	17.0mm
* SJTS-W-1218	12.0mm	18.5mm
* SJTS-W-1320	13.5mm	20.0mm

* Lag implants and Washers are available upon request. Washer is sterile packaged with Lag implant.



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