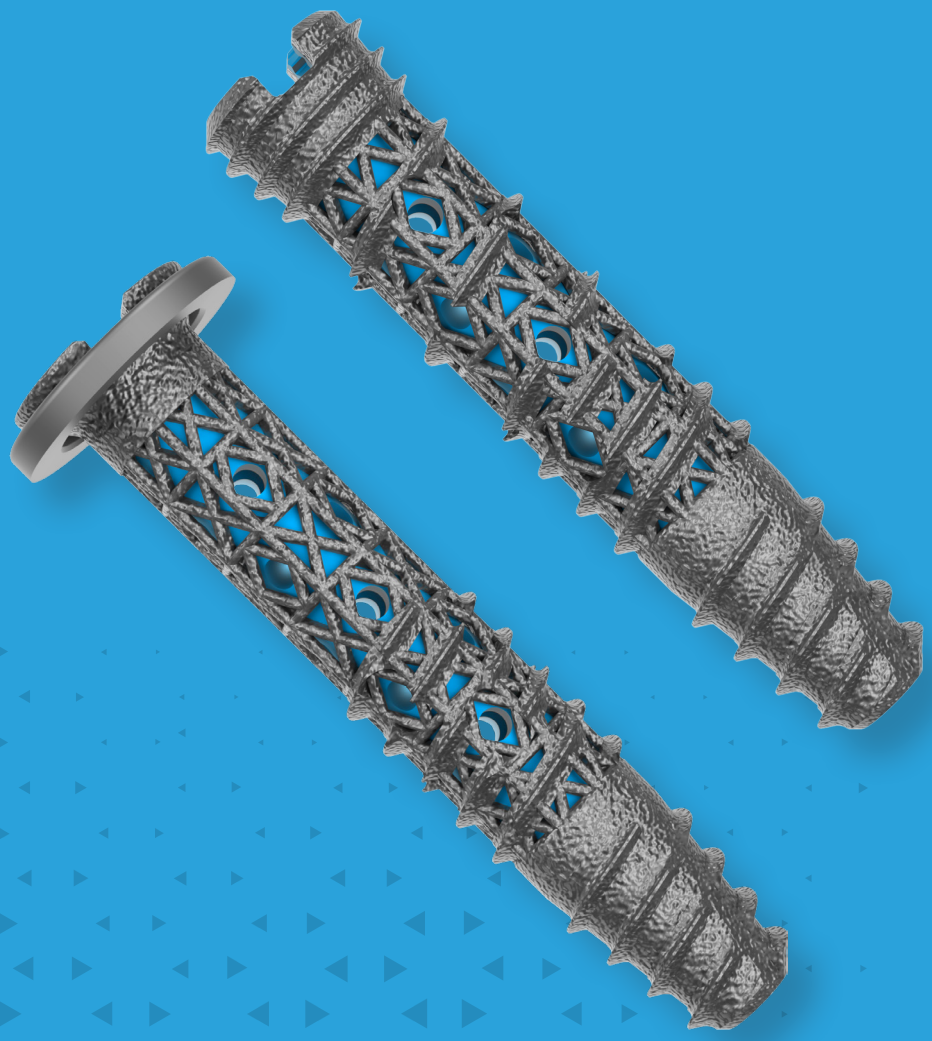
SURGICAL TECHNIQUE GUIDE

SI JOINT TRUSS SYSTEM LATERAL APPROACH



4WEB®

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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.

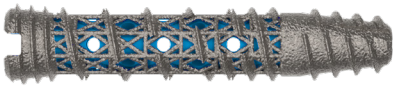
WARNINGS AND PRECAUTIONS

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.

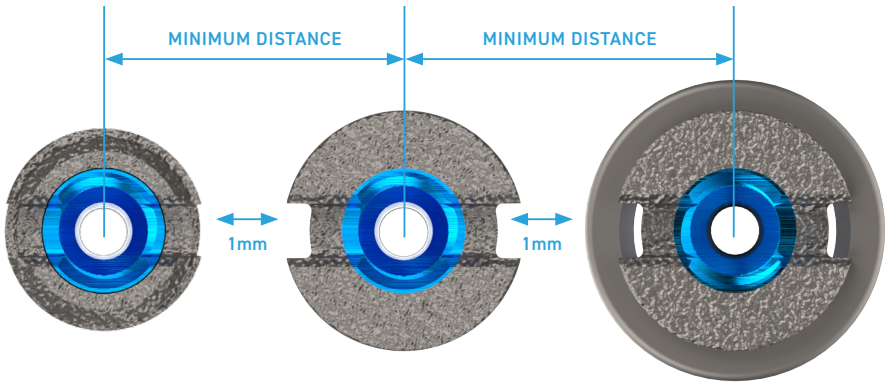
For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-SJTS-05.

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.

SURGICAL PROCEDURE

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).

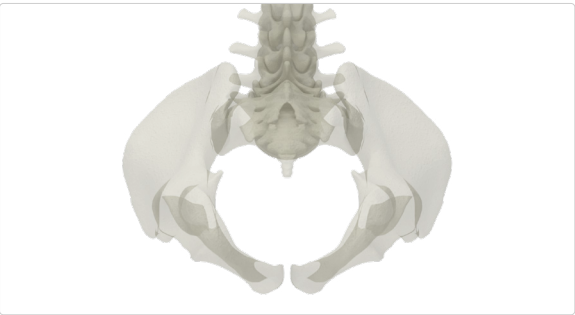


Figure 2

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).

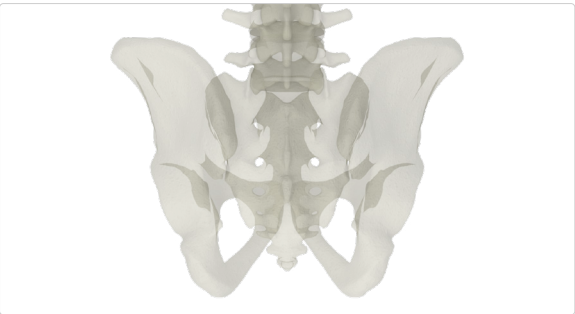


Figure 3

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

Create a 2 to 3cm incision approximately 2cm anterior to the posterior sacral wall and 1cm inferior to the alar skin marks.

Notes:

1. 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.
2. When incising and dissecting, take care to avoid the superior gluteal artery and other sensitive neurovascular structures in the surrounding soft tissue.

SINGLE PIN PLACEMENT

First, under lateral view imaging, position the first Steinmann Pin (SJTS-100X0X) approximately 2cm anterior to the posterior sacral wall and 1cm inferior to the alar line (Fig. 5). Maintain the Steinmann Pin parallel to the floor to prevent misplacement or breaching of the sacrum or ilium.

Next, under inlet view imaging, the Steinmann Pin should be directed toward the middle of the sacrum (Fig. 6).

Figure 5

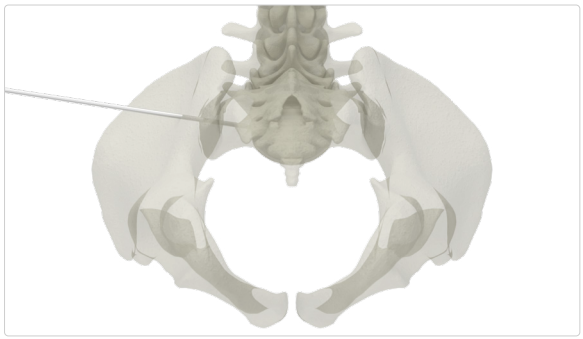


Figure 6

Then, under outlet imaging, ensure that the Steinmann Pin is pointed just above the S1 nerve root foramen (Fig. 7).

At this point, under outlet view imaging, impact the Steinmann Pin through the ilium and into the sacrum at the desired trajectory to the desired depth *(mallet is not provided with the instrumentation).*

The Radiolucent Clamp (SJTS-100003) may be utilized to limit C-Arm exposure and assist with stabilizing the Steinmann Pin (Fig. 8).

Notes:

1. When advancing pin or implant, avoid penetrating the sacral canal and/or foramen.
2. At all times use caution around the spinal canal and nerve roots to avoid damage to the nerves.
3. Replace any bent pins with new pins immediately during the procedure to ensure proper trajectory before moving to the next step.
4. If placing multiple pins, take care to avoid inadvertent advancement of an adjacent pin.
5. 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.
6. 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.
7. For fracture repair, confirm the Steinmann Pin has crossed the fracture line.
8. If placing the second and third Steinmann Pin before the first implant insertion, refer to the Multiple Pin Placement section on page 23.

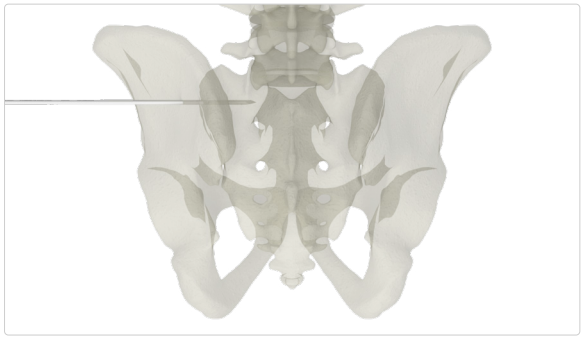


Figure 7

Figure 8

TISSUE DISSECTION *(OPTIONAL)*

Insert the Tissue Dissector (SJTS-100025) and assembled T-handle (SJTS-100007) over the Steinmann Pin until it reaches the ilium (Fig. 9). Rotate the Tissue Dissector to release any soft tissue. Remove the Dissector, being mindful of Steinmann Pin position.

Note: Do not lower hand while rotating the Tissue Dissector to avoid bending the pin.

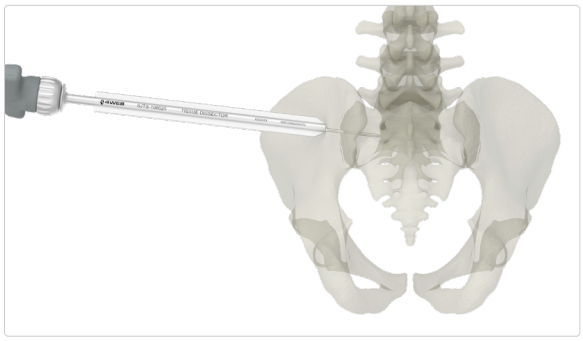


Figure 9

TISSUE DILATION

Insert the Dilator (SJTS-100005) over the Steinmann Pin until it reaches the ilium (Fig. 10). Next, insert the Tissue Protector (SJTS-100006) over the Dilator until it reaches the ilium (Fig. 11). Remove the Dilator.

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

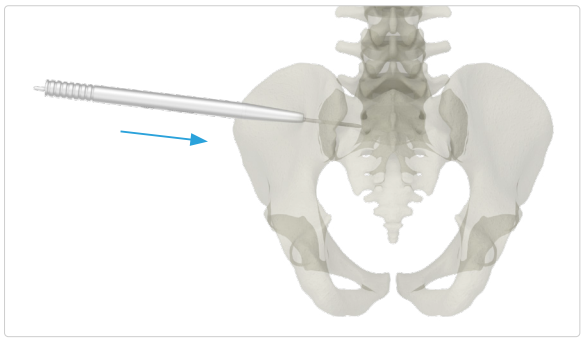


Figure 10

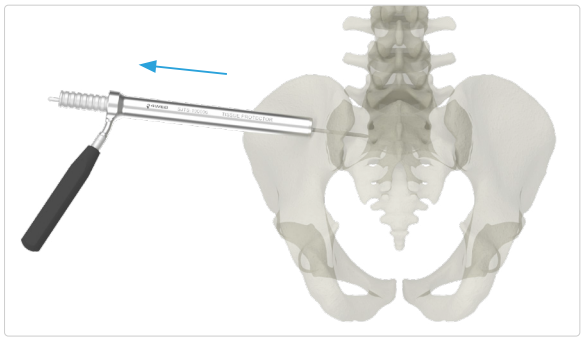


Figure 11

IMPLANT MEASUREMENT

Insert the Measurement Tool (SJTS-100004) over the Steinmann Pin and flush with the Tissue Protector (Fig. 12). If the short Steinmann Pin is used, select the implant length that corresponds to the proximal end of the pin (Fig. 13a). If using the long Steinmann Pin, the laser mark indicates the implant length on the Measurement Tool (Fig. 13b).

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.

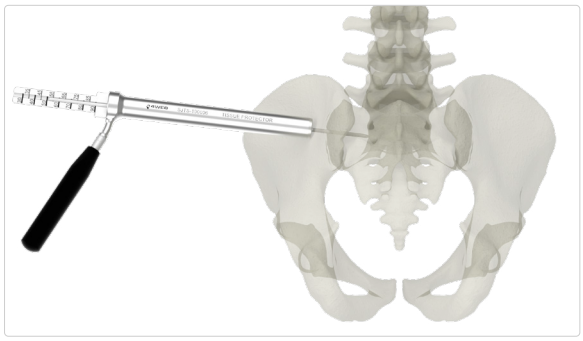


Figure 12

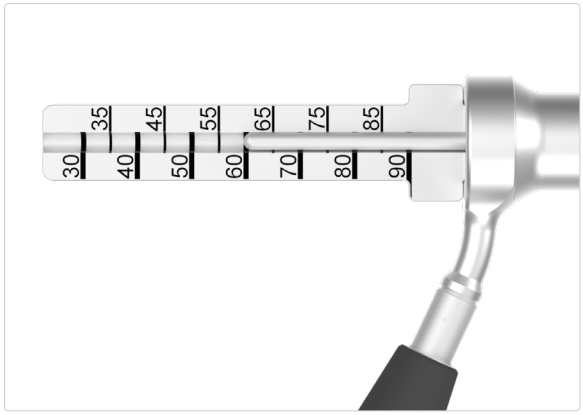


Figure 13a

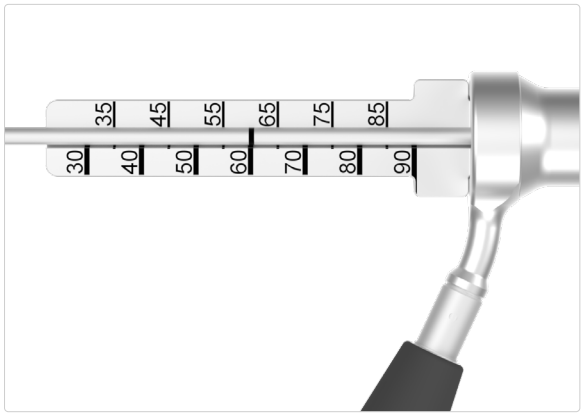


Figure 13b

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. 14). The arrow should point to the distal (patient) end. At the desired depth (Fig. 15a), rotate the Depth Stop until the arrow faces up, locking it in place (Fig. 15b). The Drill depth is shown with 60mm in the cut out (Fig. 16).

Figure 14

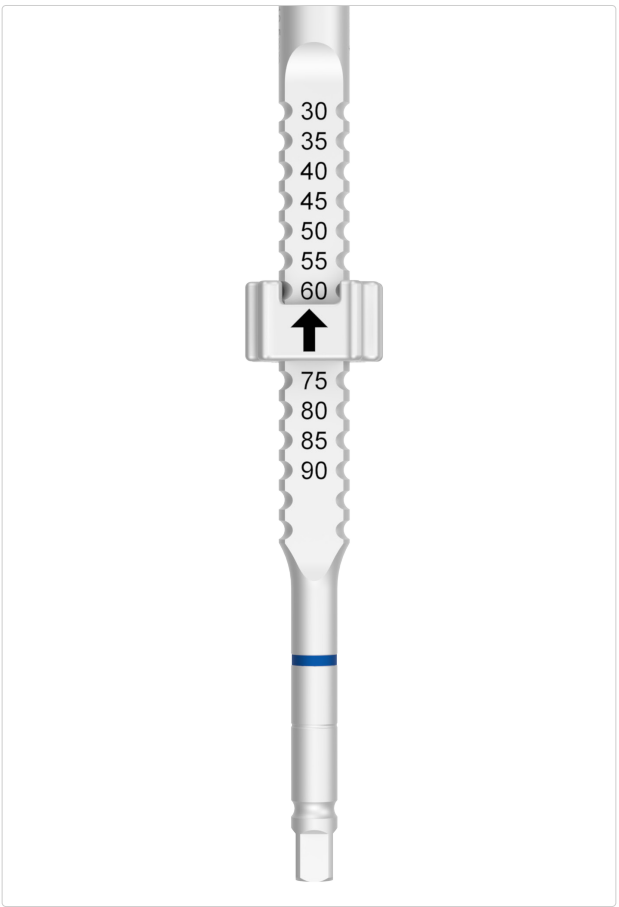


Figure 16

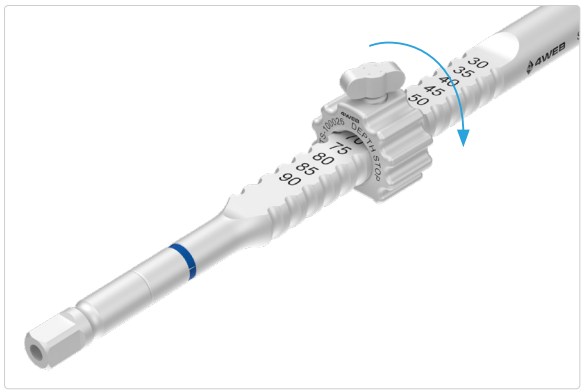


Figure 15a

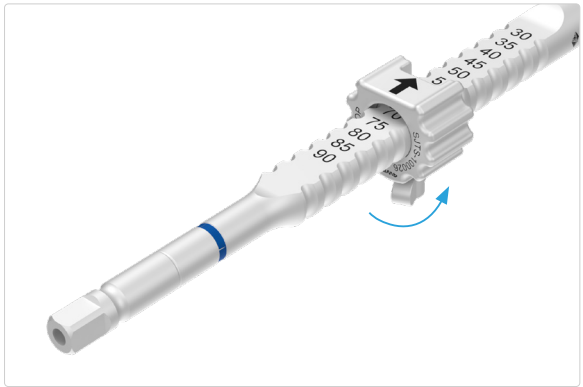


Figure 15b

Attach the assembled Drill to the T-handle or Adapter 1/4" Square to Hudson (SJTS-100023) if necessary (Fig. 17). Under fluoroscopy in the outlet view, drill through the ilium. The Drill should pass across the SI joint and the cortex of the sacrum (Fig. 18). 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.

Figure 17

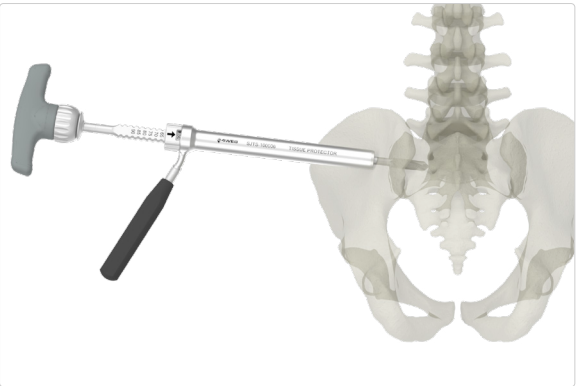


Figure 18

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.

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 SJTS 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 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). The Tap depth is shown with 60mm in the cut out (Fig. 21).

Figure 19

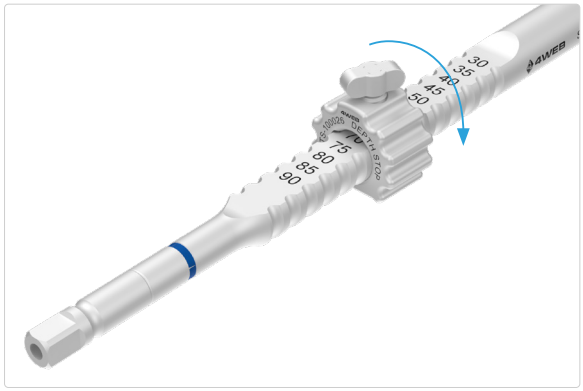


Figure 20a

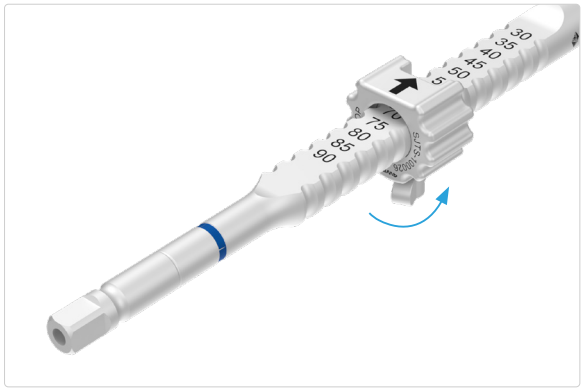


Figure 20b

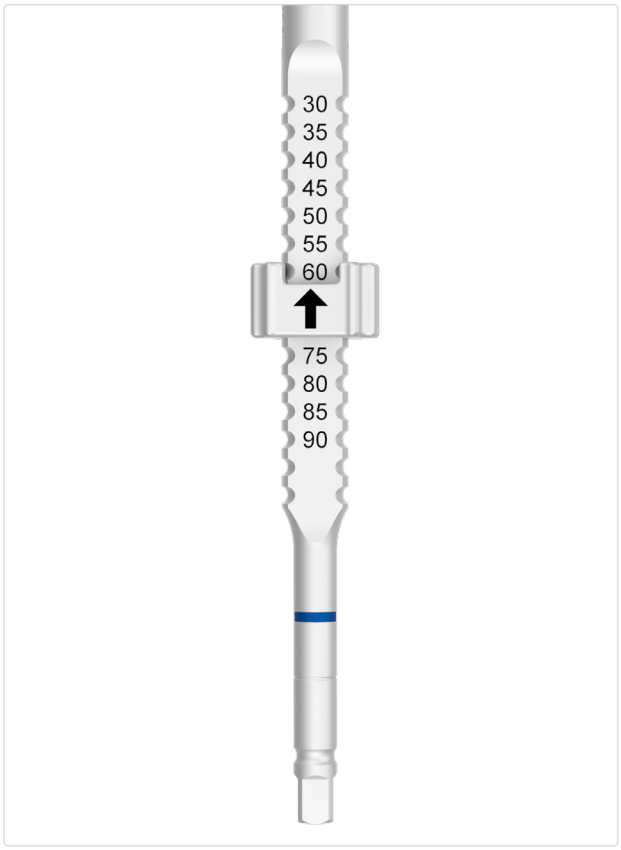


Figure 21

Assemble the appropriate Tap (SJTS-10101X) to the T-handle (Fig. 22). Insert the tap over the Steinmann Pin and into the Tissue Protector (Fig. 23).

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. 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.
3. 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.
4. Excessive advancement of the Tap may cause nerve damage, hemorrhage, or other possible adverse events listed in the instructions for use.
5. Take care to monitor Tap advancement if using with power.
6. 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.
7. Continued rotation of the Tap without advancement may result in the stripping of internal threads into the bone.
8. 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).
9. Do not use non-compatible taps with the SJTS.
10. Utilize the blunt Steinmann Pin when removing the Tap to prevent the sharp Steinmann Pin from withdrawing.
11. Fracture Repair: Surgeon should evaluate tapping past the fracture zone to minimize risk of fracture displacement during implantation.

Figure 22

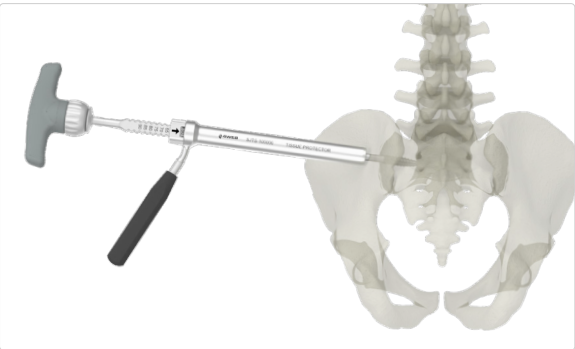


Figure 23

IMPLANT Ø	TAP Ø	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. Full 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. 24). 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 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. 25).

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

Figure 24

Figure 25

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. 26).

Under fluoroscopic guidance in the outlet view, advance the implant into position (Fig. 27). 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 21.

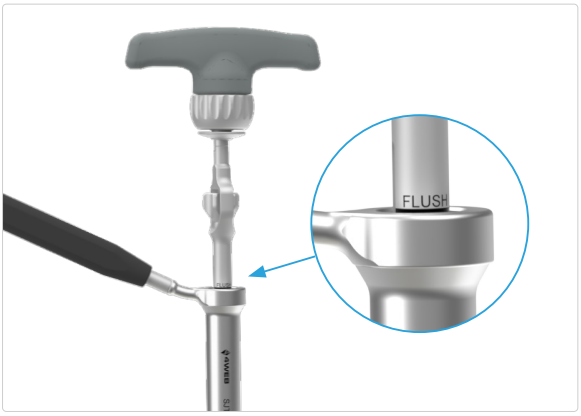


Figure 26

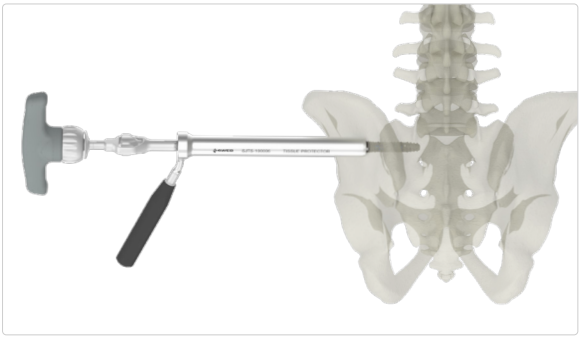


Figure 27

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/inserter. 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.
14. Fracture Repair: Surgeon should evaluate implant has extended through or past the fracture zone to minimize risk of fracture displacement during implantation.

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. 28). 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 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. 29). 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 outlet view, advance the implant into position over the Steinmann Pin (Fig. 30). 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. 31).

Figure 28

Figure 29

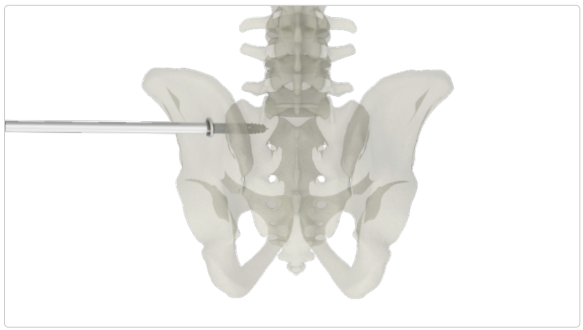


Figure 30

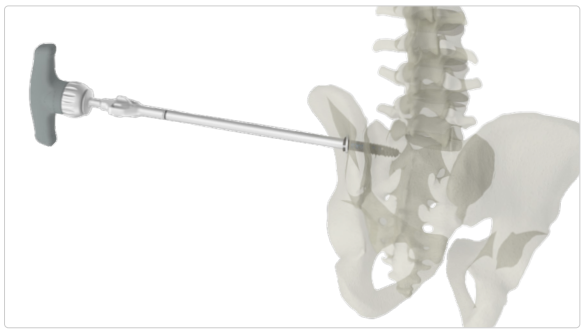


Figure 31

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.
12. Fracture Repair: Surgeon should evaluate implant has extended through or past the fracture zone to minimize risk of fracture displacement during implantation.

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. 32).

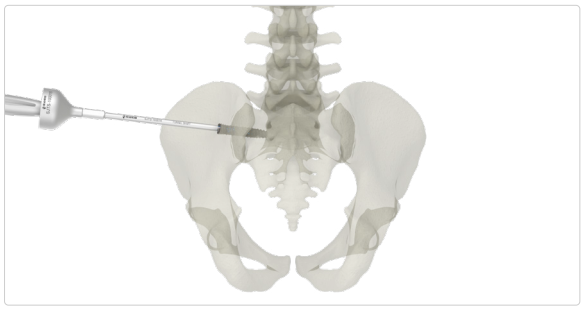


Figure 32

Option 2:

Insert the Funnel Shaft over the Steinmann Pin and secure to the implant by turning clockwise to engage threads (Fig. 33). Remove the Steinmann Pin. Attach the syringe to the Funnel Shaft standard luer fitting and pack the implant (Fig. 34). Remove the syringe and use the Plunger to complete packing. The Plunger is designed to extend to the tip of the Funnel Shaft (Fig. 35).

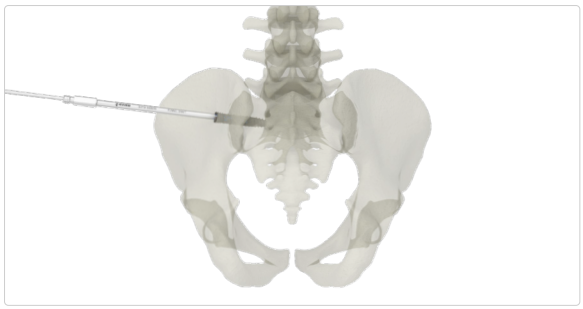


Figure 33

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.

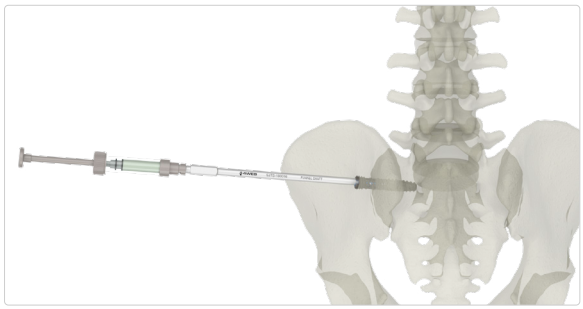


Figure 34

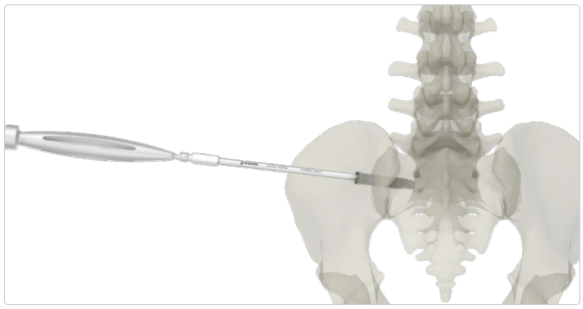


Figure 35

MULTIPLE PIN PLACEMENT

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

Note: Minimum spacing should be 12.8mm for Ø10.5mm implants, 14.2mm for the Ø12.0mm implants, and 15.7mm for the Ø13.5mm 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.

There is an Adjustable Pin Guide (SJTS-100018) (Fig. 36) and three Fixed Pin Guides with spacing of 14mm, 16mm, and 19mm (SJTS-1000XX) (Fig. 37).

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 pin guides during imaging.

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.

Under fluoroscopic guidance in the outlet view (Fig. 38), place a Steinmann Pin into the guide and secure it into the sacrum and ilium per the Single Pin Placement section on page 8.

Notes:

1. When advancing the pin, avoid penetrating the sacral canal and/or foramen.
2. 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.
3. Consider adding additional distance between implants in the unlikely case a chisel is needed to remove implants in the future.

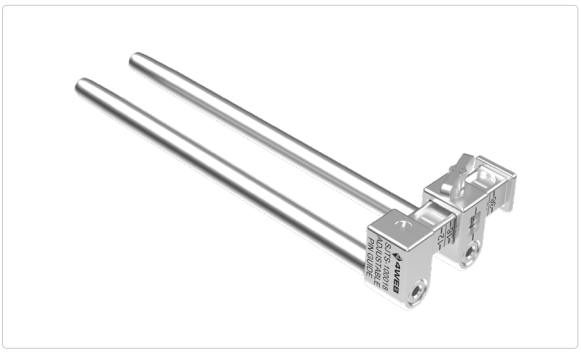


Figure 36

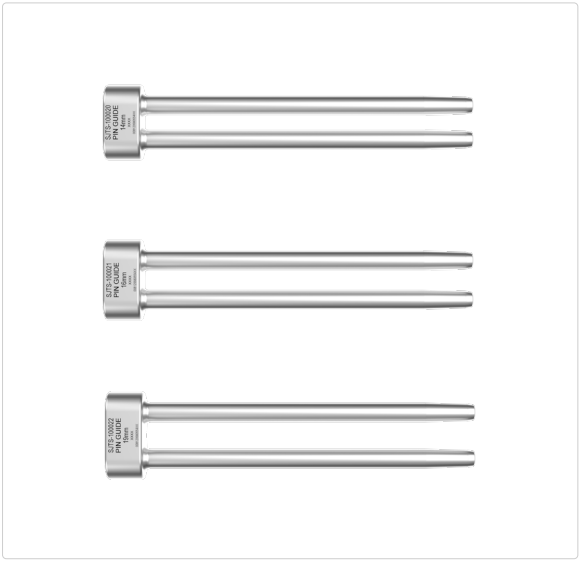


Figure 37

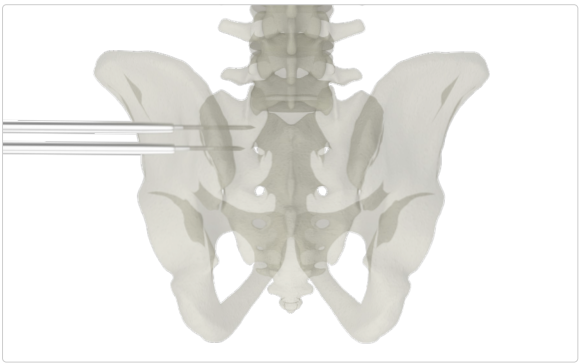


Figure 38

FINAL FLUOROSCOPIC VIEWS

Verify lateral (Fig. 39a), inlet (Fig. 39b), outlet (Fig. 39c), and outlet oblique (Fig. 39d) 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 39a

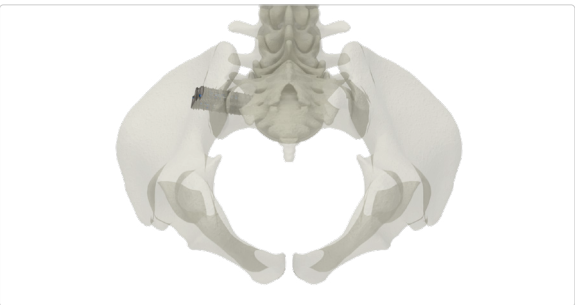


Figure 39b

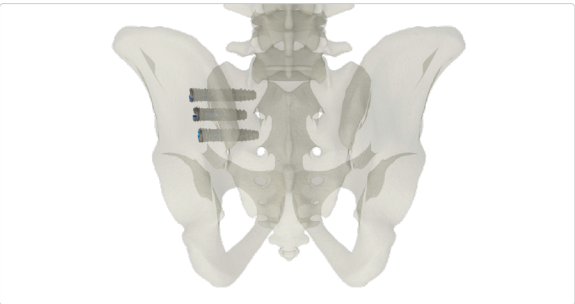


Figure 39c

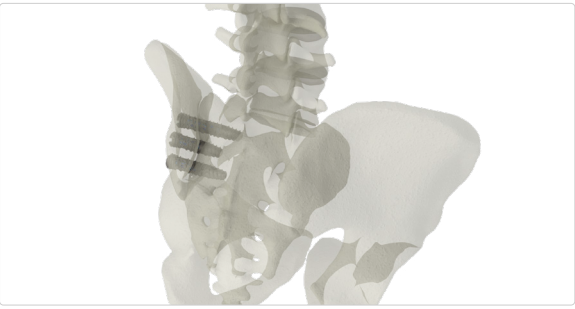


Figure 39d

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 Dilator (SJTS-100005) and Tissue Protector (SJTS-100006) to create a working channel and to protect the soft tissue (Fig. 40). Remove Dilator, leaving Tissue Protector and the Steinmann Pin.

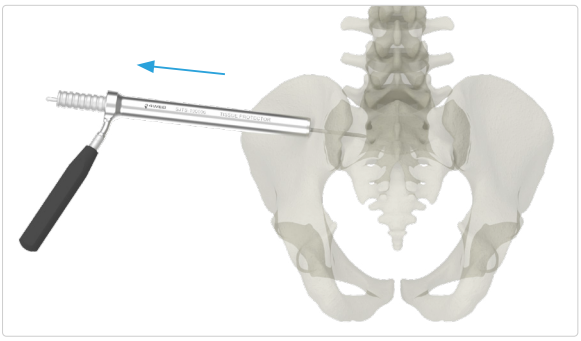


Figure 40

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 thread 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. 41).

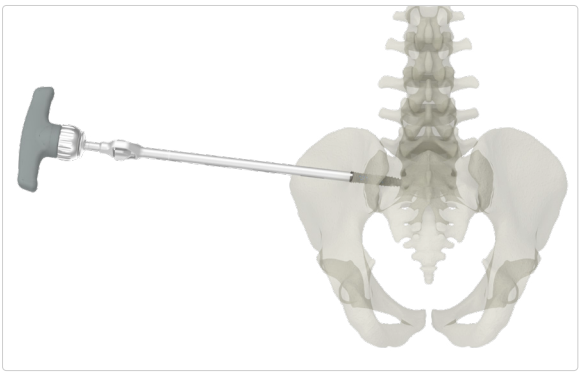


Figure 41

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

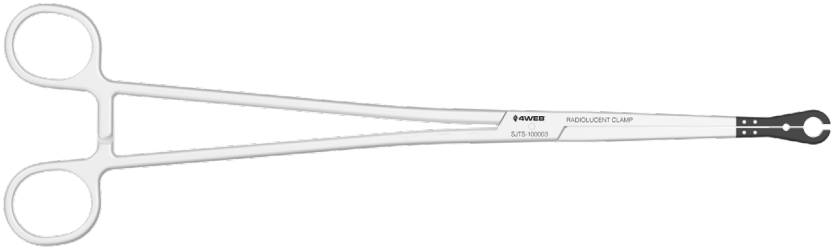
PART NUMBER	DESCRIPTION
SJTS-100201	SJTS STEINMANN PIN SHARP 270MM

SJTS-100202	SJTS STEINMANN PIN BLUNT 270MM

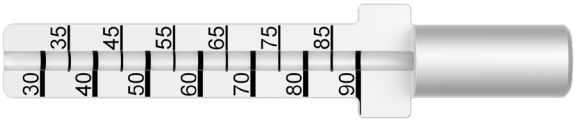
SJTS-100301	SJTS STEINMANN PIN SHARP 350MM

SJTS-100302	SJTS STEINMANN PIN BLUNT 350MM

SJTS-100003	SJTS RADIOLUCENT CLAMP



PART NUMBER	DESCRIPTION
SJTS-100004	SJTS MEASUREMENT TOOL



SJTS-100005	SJTS DILATOR

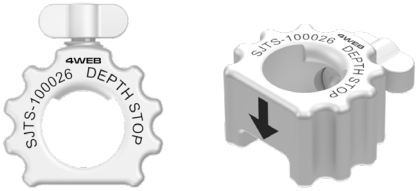
SJTS-100006	SJTS TISSUE PROTECTOR

SJTS-100025	SJTS TISSUE DISSECTOR

PART NUMBER	DESCRIPTION
SJTS-100007	SJTS T-HANDLE 1/4" SQUARE (CANNULATED)

SJTS-100008	SJTS INLINE HANDLE 1/4" SQUARE (CANNULATED)

SJTS-100026	SJTS DEPTH STOP



SJTS-100010	SJTS CANNULATED DRILL 10.5MM

SJTS-100012	SJTS CANNULATED DRILL 12.0MM

PART NUMBER	DESCRIPTION
SJTS-100013	SJTS CANNULATED DRILL 13.5MM

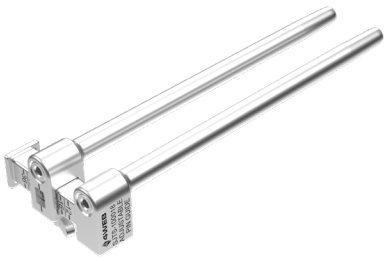
SJTS-100014	SJTS INSERTER

SJTS-100015	SJTS FUNNEL

SJTS-100016	SJTS FUNNEL SHAFT

SJTS-100017	SJTS PLUNGER

PART NUMBER	DESCRIPTION
SJTS-100018	SJTS ADJUSTABLE PIN GUIDE

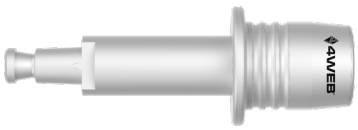


SJTS-100020	SJTS PIN GUIDE 14MM

SJTS-100021	SJTS PIN GUIDE 16MM

SJTS-100022	SJTS PIN GUIDE 19MM

SJTS-100023	ADAPTER 1/4" SQUARE TO HUDSON

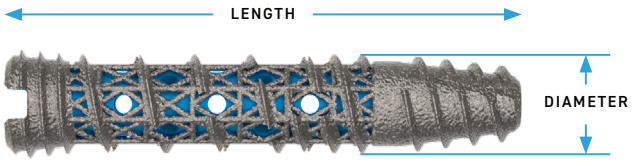


PART NUMBER	DESCRIPTION
SJTS-101010	SJTS CANNULATED TAP 10.5MM

SJTS-101012	SJTS CANNULATED TAP 12.0MM

SJTS-101013	SJTS CANNULATED TAP 13.5MM

IMPLANT CATALOG

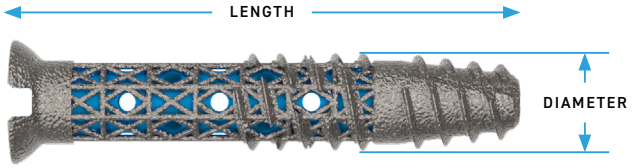


THREADED SIJ FUSION DEVICES

	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

* Sizes available upon request.

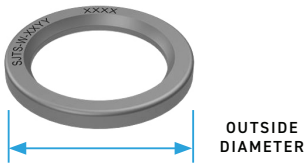


THREADED SIJ FUSION DEVICES - LAG*

	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.

2801 NETWORK BLVD. SUITE 620
FRISCO, TX 75034
4WEBMEDICAL.COM
INFO@4WEBMEDICAL.COM
800.285.7090
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