Zavation – SInapse® SI Fusion System- SIJ Fusion (P/L)

Surgical Technique Guide

TABLE OF CONTENTS

IMAGING STEPS

1. Start in a True Outlet View. The purpose of this view is to Mark S1 Endplate and S2 Foramen.
2. Swing to Outlet/Oblique View (~30* Degrees). Mark Lateral Border of the Ilium as well as the SI Joint. Mark (2) finger widths (2 – 3 cm) off of the Apex of the Ilium to make ½ inch incision.
3. Swing back to true Outlet View to dock Jamshidi needle (*2 – 3 taps). Goal: needle's Cephalad/Caudal trajectory should be lined up straight across the S1 body. (*Parrel with S1 Endplate)
4. Swing to Inlet View: Verify Medial/Lateral Trajectory and advance slightly (*2-3 taps).
5. Swing to a Lateral View for a secondary verification (to Outlet View) that your Cephalad/Caudal Trajectory is correct. Advance the needle no further than the SI joint.
    i. **In the Lateral View, verify that the Jamshidi's trajectory is no more Cephalad than the convergence of the Sacral ala and the anterior Sacral wall.**
        a. **If the placement of the needle is caudal/dorsal to this point, the inlet view is no longer a "safety view" for final pin, wire, and screw advancement.**
    ii. By ONLY advancing to the joint in a Lateral View, and not beyond, the chances of placing the Jamshidi in a dangerous area is greatly reduced.
6. **Optional:** Outlet/River View: Verify Jamshidi is across the Joint.
7. Swing to an Inlet View to verify that the Medial/Lateral trajectory is still desirable. If trajectory is acceptable, proceed with advancing the needle into the Sacrum.
    i. Remove inner-stylet -> insert Pin to desired screw depth -> Remove Access Cannula.
    ii. Place dilator 1 over Pin and verify that the dilator is flush with the ilium.
    iii. Measure screw depth off of Pin, with Depth Measurement Guide.
        a. Please note, to off-set fully countersinking the screw(s), consider downsizing 5mm.
    iv. Remove depth measurement guide and place dilator 2 over dilator 1 and then remove dilator 1.
    v. **Optional:** Drill over the Pin to desired depth.
    vi. Insert desired length screw over Pin and advance until fully seated.
        a. Continue to monitor Pin advancement.

INTRODUCTION

The SInapse™ SI Fusion System

Device Description: The SInapse™ System consists of bone screws in various lengths and graft hole configurations to accommodate variations in patient anatomy. The SI Screw System is manufactured from Titanium alloy in accordance with ASTM F136. All implants will be provided non-sterile and are intended for single use only. Subject instruments are intended for us only with Zavation pedicle or OCT screws.

Indications: The SInapse™ System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Figure 1

Noun (Synapse)
New Latin *synapsis*, from Greek, juncture, from *synaptein* to fasten together, from *syn-* + *haptein* to fasten

STEP 1 PATIENT SETUP

The patient should be positioned prone on the operative table. EMG and somatosensory evoked potentials are utilized during the procedure for increased safety. Using EMG, the following muscles are monitored during surgery:

- L5 root, the anterior tibialis
- S1 root, the gastrocnemius
- S2 root, rectal sphincter

Figure 2

STEP 2 INCISION LOCATION

Outlet View:

1. Mark S1 Endplate
2. Mark PSIS/Superior Portion of the S2 Foramen
    i. *20 - *30 Degrees Cephalad Tilt for Men
    ii. *30 - *45 Degrees Cephalad Tilt for Women

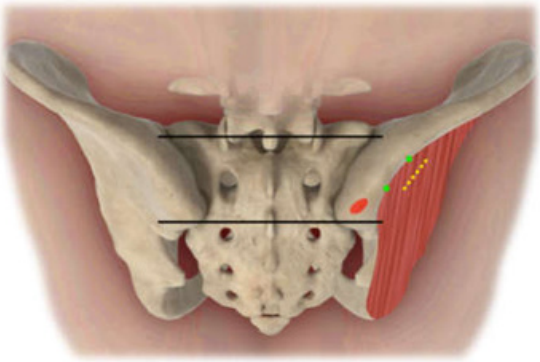


Figure 3

Outlet - Oblique (River View):

1. Mark the SI Joint (*Optional)
2. Mark the lateral border of Ilium
3. Make ½ inch incision one-two finger widths (2 to 4 cm) lateral to the mark that denotes the lateral border of the ilium. In an obese patient, the incision should be slightly more lateral.
4. Insert access needle and feel for the apex of the ilium.
5. Drop the needle off the edge of the ilium (2 to 3 cm), and slightly advance the needle into the ilium
    i. Optimal Angle: 20–30 Degrees (Ipsilateral)

STEP 3 PLACEMENT OF 1ST PIN

In Outlet – Oblique / Outlet Views:

1. The incision and needle through the apex of the ilium.

2. Drop the needle off the edge of the ilium (2 to 3 cm), and slightly advance the needle into the ilium.

3. Confirming that the needle is in contact with the lateral wall of the ilium can be achieved in the Oblique Riverview orientation (Figure 6).

4. A true outlet view is used to acquire proper Cephalad/Caudal alignment. The trajectory should be aligned straight across the S1 body, midway between the S1 endplate and S1 neuroforamen (Figure 4), and it should be parallel with the S1 endplate. If not in TRUE outlet view, the needle may appear to be straight across, but may actually be angled in a cephalad or caudal biased trajectory (Figure 5). This trajectory can be confirmed with Lateral Imaging.

5. When desired trajectory is achieved, assure that the access needle is seated firmly in the ilium, and adjust fluoroscopic imaging to the inlet view.

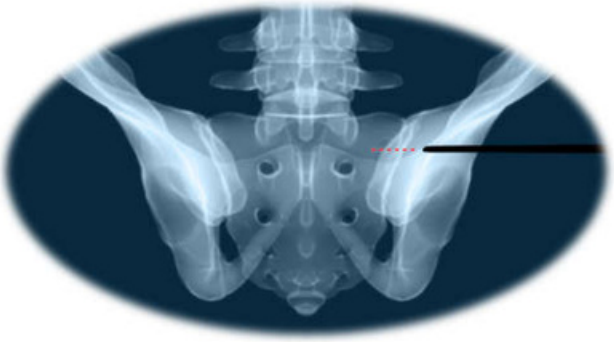


Figure 4

Figure 5

Figure 6

STEP 4 PLACEMENT OF 1ST PIN cont.

In Inlet View: An Inlet View is used to acquire the proper Medial/Lateral alignment and the proper pin and implant depth. The needle's Medial/Lateral trajectory should align the introducer needle to the anterior 1/3 of Sacrum, lateral to sacral neuroforamen (Figure 7).

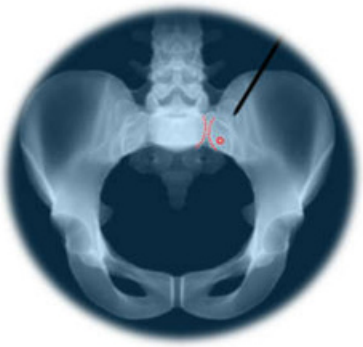


Figure 7

Note: The access needle does not have to be driven to the anterior 1/3 of the Sacrum. As long as the access needle is driven across the joint, the Steinmann Pin can be tamped to the desired depth.

STEP 5 PLACEMENT OF 1ST PIN cont.

In Lateral View:

1. Verify that the Jamshidi's trajectory is no more Cephalad than the convergence of the sacral ala and the anterior sacral wall (Figure 8).
2. Advance Jamshidi to the joint (Figure 9).
    i. By only advancing to the joint, and not beyond, the chances of placing the Jamshidi in a dangerous area is greatly reduced.
3. Return to Inlet view. (Figure 10)

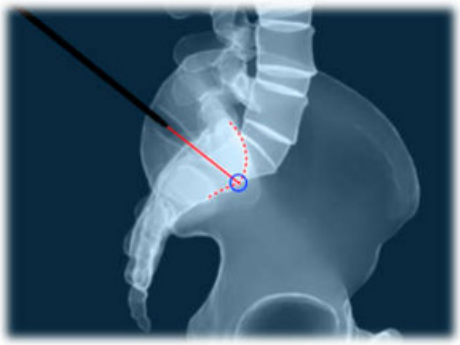


Figure 8

***Steer clear of the Ala**
Caudal to the Ala
Lateral to the S1 Foramen
Don't breach anterior portion of the Sacrum

STEP 6

4. Return to River view (optional) (figure 11)

Figure 9

***Advance only to the joint**

Figure 10

Figure 11

STEP 7 PLACEMENT OF 1ST PIN cont.

Medial Lateral Trajectory Confirmation (Inlet): Verify that the Medial/Lateral trajectory is still desirable. If trajectory is acceptable, proceed with advancing the needle to the desired depth into the sacrum.

Figure 12

STEP 8

In Inlet View:

1. Remove the inner stylet of the access needle and insert the desired pin through the access cannula.
2. Tamp the pin to the desired depth in the sacrum (Figure 13).
    i. Keep in mind that the screw length selection process will be based on the depth of the Steinmann Pin.
3. While holding the guide pin in place, remove the access cannula.

Figure 13

STEP 9 DILATOR PLACEMENT

Medial Lateral Trajectory Confirmation (Inlet):
Slide dilator 1 over guide pin and advance until it is pressed firmly against the ilium (Figure 14).

Note: This dilator is used in implant measurement, so it is crucial that the tip of the dilator is seated firmly against the bone.

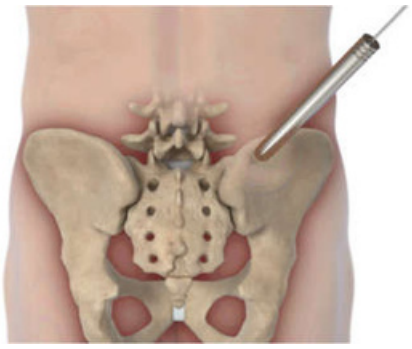


Figure 14

STEP 10 SCREW LENGTH SELECTION

In Inlet View: While holding pressure on dilator one, slide the screw sizing template over the wire until it sits flush on dilator one (Figure 15). Turn the template until the laser etched line on the Steinmann Pin can be visualized (Figure 16).

When choosing a screw length, keep in mind that a 5mm undersized screw should be selected if the plan is to countersink the implant.

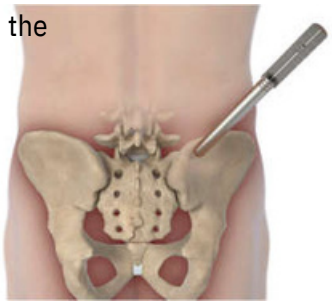


Figure 15

Figure 16

STEP 11 WORKING CANNULA

In Inlet View: Slide the working cannula (Dilator 2) over dilator
1 and ensure that it is seated firmly on the ilium.

Taking care to ensure that the Steinman Pin is not retracted, dilator 1 is removed and the working cannula offers a direct path to the ilium (Figure 17).

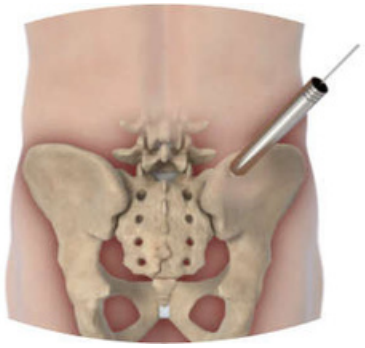


Figure 17

STEP 12 DRILL (OPTIONAL)

In Inlet View:

1. If desired, choose the appropriate diameter drill, and slide it over the Steinmann Pin (figure 18).

2. Turning the handle clockwise and applying downward pressure, drill to the desired depth.

   i. Take care to keep the drill in line with the Steinmann Pin, as off-axis pressure can cause unwanted pin advancement.

   ii. Take intermittent fluoroscopy shots to ensure that pin is not advancing with the drill (Figure 19).

3. When removing the drill, pull back on the drill while rotating the handle clockwise (if bone autograft harvest off the drill is desired) and ensure that the Steinmann Pin is not being retracted with the drill.

   i. The use of a transition pin (same as primary Steinmann Pin) may be necessary to ensure that the Steinmann Pin stays in place upon removal of drill.

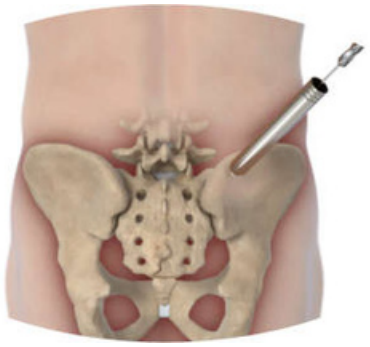


Figure 18

Figure 19

STEP 13 DRIVER AND SCREW ASSEMBLY AND INSERTION

In Inlet View: To prep the screw for implantation, place a Steinmann Pin through the screw cannula, and fill the screw with allograft or autograft. Remove the Steinmann Pin and connect the Ratcheting Straight Handle or Ratcheting T- Handle to the Screwdriver (Figure 20-21). Load the appropriately sized screw onto the Screwdriver (Figure 16) and insert the screw and Screwdriver over the Steinmann Pin (Figure 22). Under imaging guidance, advance the screw clockwise to the desired depth (Figure 23). Remove the Screwdriver, by turning the attachment sleeve knob counter-clockwise, once insertion is complete. Once screwdriver is detached, remove the Steinmann Pin and proceed to the second screw.

Figure 20 & 21

Note: Observe the Steinmann Pin to ensure no further advancement occurs. If the implant appears to be advancing the Pin, the ratcheting handle can be removed, and the Pin can be retracted.

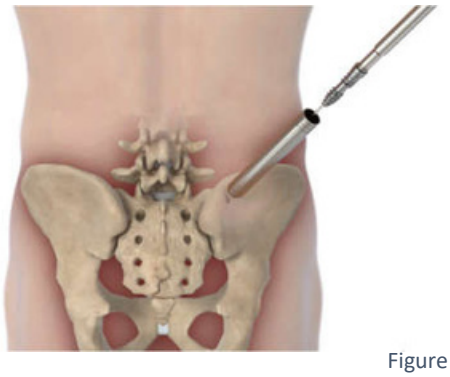


Figure 22

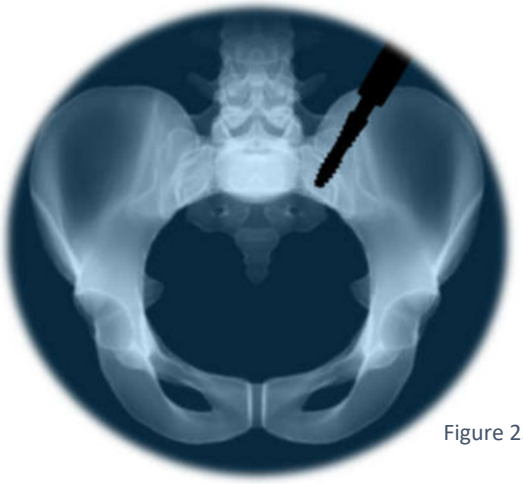


Figure 23

STEP 14 PLACEMENT OF 2nd PIN

In Outlet – Oblique / Outlet Views:

1. Insert access needle and feel for the apex of the ilium.

2. Drop the needle off the edge of the ilium (2 to 3 cm), and slightly advance the needle into the ilium. The needle should be around 15mm caudal to 1st Pin location (Figure 24), but this can change based on patient anatomy.

   i. Confirming that the needle is in contact with the lateral wall of the ilium can be achieved in the Oblique Riverview orientation (Figure 25).

3. A true outlet view is used to acquire proper Cephalad/Caudal alignment. The access needle's Cephalad/Caudal trajectory should be lined up with the S1 neuroforamen (Figure 26). If not in TRUE outlet view, the needle may appear to be straight across, but may actually be angled in a cephalad or caudal biased trajectory (Figure 1). This trajectory can be confirmed with Lateral Imaging (Figure 27).

4. When desired trajectory is achieved, assure that the access needle is seated firmly in the ilium, and adjust fluoroscopic imaging to the inlet view.

Figure 24

Figure 25

Figure 26

Figure 27

STEP 15 PLACEMENT OF 2nd PIN cont.

In Inlet View: An Inlet View is used to acquire the proper Medial/Lateral alignment and the proper pin and implant depth. The needle's Medial/Lateral trajectory should align the introducer needle to the anterior 1/3 of Sacrum, lateral to sacral neuroforamen (Figure 28).

Figure 28

The first and second implant should be aligned in the inlet view, so centering the access needle with the first implant is common practice.

In Lateral View:

1. The second pin should be around 15mm caudal to the original pin placement, and the trajectory should be parallel to the original pin.
2. Advance the Jamshidi to the joint. By only advancing to the joint, and not beyond, the chances of placing the Jamshidi in a dangerous area is greatly reduced.
3. Return to Inlet view.

Figure 29

In Inlet View:

Verify that the Medial/Lateral trajectory is still desirable. If trajectory is acceptable, proceed with advancing the needle to the desired depth into the sacrum.

Repeat steps 6-11 to place 2nd screw.

Verify Screw placement with final imaging.

Figure 30

STEP 16 FINAL SCREW PLACEMENT

STEP 17 DEVICE RETRIEVAL EFFORTS

If the fixation device is malpositioned and the surgeon feels that removal is indicated, the removal process for the fixating implant should be followed by adequate post-operative management to avoid re-fracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the fixation implant, thus eliminating the risk associated with any second surgery.

Should it be necessary to remove a SI Screw, the patient is positioned in a similar fashion as for screw insertion. Biplane fluoroscopy is brought into the operative field. The wound is reopened utilizing standard surgical technique. Using the Screwdriver (770-1007) under fluoroscopic guidance, the head of the screw to be removed is engaged and rotated counterclockwise until the screw is out

Materials:
The SI Screw System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Contraindications:
Contraindications for the SI Screw System are similar to those of other systems of similar design, and include, but are not limited to:

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Reuse or multiple uses.

Potential Adverse Events:
Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.

11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (pseudarthrosis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:

As with any surgical system, the SI Screw System should be used by experienced surgeons with specific training in the use of the spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

MR Safety:

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The SI Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the SI Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are

placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation. Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. As with all orthopedic and neurosurgical implants, none of the SI Screw System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death. Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The SI Screw System has not been evaluated for safety and compatibility in the MR environment. The SI Screw System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and X-spine cannot make any claims regarding the safety of X-spine implants and devices with any specific MR system. Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives. **Implant Selection:** The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.

Intraoperative:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
4. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
5. Implants should not be reused under any circumstances.

Postoperative:
Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity.
3. Rigid external orthosis/bracing should be utilized until fusion is confirmed clinically and radiographically.
4. During explantation, care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):
For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays as long as the inspection criteria provided below are acceptable for the tray.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.
Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.
1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.
2-Containment and Transportation: Avoid damage and minimize time before cleaning
3-Preparation for Cleaning: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap and screw drivers and remove drills,

<table>
<tr><td colspan="2">taps and awl that are left in the drill guides. (note that these items are normally stored in their dedicated tray already disassembled).</td></tr>
<tr><td colspan="2">4-Thoroughly clean instruments per one of the following (Manual or Automated)</td></tr>
<tr><td>Manual</td><td>Automated</td></tr>
<tr><td>4.1 Pre-Cleaning-Manual:</td><td>4.1 Pre-Cleaning-Automated: Automated washing shall be conducted in a validated washer-disinfector.</td></tr>
<tr><td>Prepare a pH neutral, enzymatic detergent soak per the instructions of the enzymatic solution manufacturer.
Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
Change the soak solution if the solution becomes visibly soiled.
While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen
Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear.</td><td>An example of a validated cycle used for cleaning validation includes:
Wash 45ºC 4 minutes dose pump 4 (detergent) 5mL
Wash 60ºC 3 minutes
Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water 1 minute
Rinse 60ºC 1 minute</td></tr>
<tr><td>4.2 Cleaning-Manual:
Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under running critical water, such as reverse osmosis, distilled, and/or deionized water for at least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into</td><td>4.2 Washer Disinfector: Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Thermal Disinfection A0 93ºC
A0 value: A03000
Dry 123ºC air 14 minutes</td></tr>
</table>

any lumens, crevices, grooves, or slots and flush them completely until the water runs clear. • Dry the exterior of the instruments with a clean, soft cloth. Use clean compressed air or 70% isopropyl alcohol to dry any lumens or crevices where water may become trapped.	
Inspection: • Visually inspect each disassembled device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean. • Check disassembled instruments with long slender features for distortion • Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization:

The SI Screw System should be sterilized by the hospital using the recommended cycle: Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes 30
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	Minutes

Instrument Maintenance: Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Follow lubricant manufacturer's instructions. **Product Complaints:** Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products, LLC, 3670 Flowood Drive., Flowood, MS 39232, USA, Telephone: 601-919-1119.

IMPLANTS

Zavation SInapse™ Screw

* Screw:

* 11mm and 12.5mm External Thread

- 35-70mm Lengths
- Cannulated and Fenestrated
- Integrated bone growth windows
- Threaded Engagement to Driver
- T 45 Hexalobe Drive
- Material: Titanium per ASTM F-136
- • See attached drawing for additional information.

Implants (Standard Tray Build)		
Part#	**Description**	**QTY**
770-XXXXX	**Posterior Lateral SI Screw**	
770-11035	11.0mmx 35mm 11.0mmx	4
770-11040	40mm 11.0mmx 45mm	4
770-11045	11.0mmx 50mm 11.0mmx	4
770-11050	55mm 11.0mmx 60mm	4
770-11055	11.0mmx 65mm 11.0mmx	4
770-11060	70mm 12.5mmx 35mm	4
770-11065	12.5mmx 40mm 12.5mmx	4
770-11070	45mm 12.5mmx 50mm	4
770-12535	12.5mmx 55mm 12.5mmx	4
770-12540	60mm 12.5mmx 65mm	4
770-12545	12.5mmx 70mm	4
770-12550		4
770-12555		4
770-12560		4
770-12565		4
770-12570		4

Screw Lengths (mm):

35 40 45 50 55 60 65 70

INSTRUMENTS

Device View	Part #	Description Implants
IMPLANTS		
	770-XXXXX	**Zavation SI Screw** • Screw: 9mm External Thread 25mm, 30mm, 35mm, 40mm, 45mm and 50mm Lengths • Cannulated • Smooth shank option for 30mm, 35mm, 40mm, 45mm, and 50mm. • Integrated bone growth windows • Internal Installation Thread: .3750 • 4mm Hex Drive • Material: Titanium per ASTM F-136 • See attached drawing for additional detail
INSTRUMENTS		
	Z-1003-MT	**Large Ratcheting Handle:** • Quick release • Forward and Reverse options • Used with driver shaft • ¼ drive • Material: Stainless steel with silicon handle
	Z-1008-MT	**Cannulated Ratcheting T-Handle** • Works for all SI Screw lengths • Material: Stainless steel

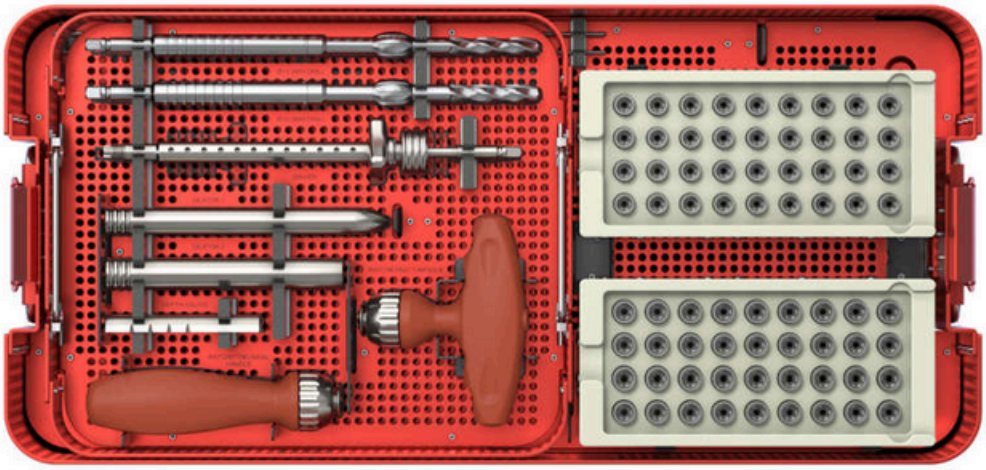
	770-1002	**Dialator:** • Fits ALL SI Screw sizes • Material: Stainless steel
	770-1003	**Dialator 2:** • Fits ALL SI Screw sizes • Material: Stainless steel
	770-1004	**Depth Gauge** • 35-75 mm • Material: Stainless steel
	770-1005-XXX	**Universal Drill:** • Works for all SI Screw lengths • Material: Stainless steel
	770-1007	**T-45 Driver** • Works for all SI Screw lengths • Material: Stainless steel
	VCF-1022	**Bevel Tip Introducer Cannula** • 12cm Insertion Depth • 8 Gauge Cannula o 4.2 mm OD o 3.85 mm ID • 10 Gauge Cannula o 3.5 mm OD o 3.1 mm ID • Diamond Tip Style • Luer lock Syringe Connector • Depth Markings
	VCF-1023	**Diamond Introducer** • 12cm Insertion Depth • 8 Gauge Cannula o 4.2 mm OD o 3.85 mm ID • 10 Gauge Cannula o 3.5 mm OD o 3.1 mm ID • Diamond Tip Style • Luer lock Syringe Connector • Depth Markings

INSTRUMENTS cont.

Instruments (Standard Tray Build)		
Part#	**Description**	**Quantity**
770-1002 770-1003 770-1004	Dilator 1 Dilator 2 Depth Gauge Drill 11mm Drill 12.5mm 2.25mm K-Wire,	2 2
770-1005-110	12 inch Screwdriver 2.5mm K-Wire,	1
770-1005-125	12 inch Cannulated Ratcheting T-Handle	1
770-1006 770-1007 770-1008	Cannulated Ratcheting Axial Handle Mallet Kocher	1 5
Z-1008-MT Z-1003-MT 540-1012 G11-41		2 5 1
		1
		1
		1

Addition Instruments (Available Upon Request)		
Part#	**Description**	**Quantity**
VCF-1022	Beveled Introducer	1
VCF-1023	Diamond Introducer	1
770-1001	400mm NiTi Guide Wire	1
740-2016	Wire Puller	1
ZAV-1303	2.5mm K-Wire, 15 inch	1

TRAY LAYOUT

TRAYS	
Top Tray	
Bottom Tray