SI-TECHNOLOGY® Product Guide

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SI-TECHNOLOGY® SI-DESIS®
Sacroiliac Joint Fusion Screw System

INSTRUCTIONS FOR USE

SI-TECHNOLOGY, LLC

SI-TECHNOLOGY ®SI-DESIS® Sacroiliac Joint Fusion Screw System

CAUTION: Federal law restricts this device system to sale by or on the order of a physician. (Rx only)

DESCRIPTION

The SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System consists of screws designed to assist in the healing of sacroiliac joints for fusion by providing fixation of large bones and large bone fragments of the pelvis. The screws are **not** intended to replace normal body structures. The screws are offered in 6.5 mm diameter cannulated, partially threaded or fully threaded configurations in various lengths. Additionally, optional supplemental 5 mm diameter screws are offered in various lengths and are to be used **only** in conjunction with the 6.5 mm screws for supplemental screw fixation to accommodate patient anatomy. The screws are manufactured from titanium alloy per ASTM F136.

INDICATIONS

The SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System is intended for sacroiliac joint fusion for conditions including sacroiliac (SI) joint disruptions and degenerative sacroiliitis.

WARNINGS

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in serious life threatening complications, injury or death.
These warnings **do not** include all adverse effects which could occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.
One of the risks associated with this system is death.
Other potential risks which may require additional surgery include:
Possible adverse effects which may occur include, but are not limited to: delayed or failed fusion or pseudarthosis leading to implant breakage; infection; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; device fracture or failure; device migration or loosening; decrease in bone density; loss of pelvic mobility or function; inability to perform activities of daily living; graft donor site complications including pain, fracture, infection and wound healing problems; temporary or permanent tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, numbness or tingling; cauda equina syndrome; injury to blood vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional medical treatment including surgery may be required to attempt to correct some of these effects.

The SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System should be used only by experienced surgeons with specific training in the use of sacroiliac joint fusion / fixation systems because this is a technically demanding procedure presenting a risk of serious injury or death to the patient. Preoperative planning and patient anatomy should be considered prior to performing the sacroiliac joint fusion.

Patient sensitivity to implant materials should be considered and assessed prior to surgery. The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis or activities such as nicotine consumption may alter the healing process, thereby increasing the risk of implant failure and non-union.

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

The supplemental 5 mm diameter screws are to be used only in conjunction with the 6.5 mm screws for supplemental screw fixation.

PRECAUTIONS

The patient must be adequately instructed and informed of all the indications, contraindications, warnings, precautions and risks. Mental or physical impairment which compromises or prevents a patient's ability to understand or comply with necessary limitations, risks or precautions may place that patient at a particular risk during preoperative preparation or postoperative rehabilitation.

The implants are **single use only** and must never be reused. Never reimplant an explanted implant. Even though the implant may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage. Reuse is associated with serious risks to the patient including infection, non-union, implant failure, serious injury and death.

The presence of metallic implants may result in interference with imaging modalities.

The screws and system have 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 device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The implants must be handled with care and inspected prior to use as damage may have occurred during shipping, storage or handling. Do not alter the implant, alterations may lead to breakage of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to breakage.

Implanting metals and alloys in the human body subjects them to an aggressive chemical environment of salts, acids, and proteins, which can cause corrosion. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Additionally, mixing of implant components from different manufacturers is not recommended, for metallurgical, mechanical and functional reasons.

For safe and effective use of this implant system, the surgeon should be familiar with the system prior to the surgical procedure. Improper selection, placement, positioning, or seating of the implant may result in unusual loading conditions which could affect the long-term service life of the implant and may lead to implant breakage or migration. Careful attention should be taken in the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Pre-operative x-rays and/or CT scans should be measured in all planes to obtain a good approximation of what size range of implants might be needed during the surgical procedure. Additionally, the physician/surgeon should consider the location of implantation, patient weight, patient activity level, and other patient conditions which may significantly impact the performance of this system.

The patient should be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in premature failure of similar devices as these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing and metallic implants are not as strong as a normal, healthy bone. Attending clinicians may require non weight bearing or partial weight bearing for a period of time in accordance with standard medical practice. In every case, accepted surgical practices should be followed in post-operative care.

The patient should understand that stress on an implant can involve more than weight-bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in failure of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid refracture.

CONTRAINDICATIONS

The contraindications are similar to those of other systems of similar design and include, but are not limited to: any case not described in the indications for use; reuse or multiple uses; inadequate bone stock or quality; use with components from other systems; allergy or intolerance to metal components; patients with infection or significant risk of infection; local inflammation, fever, elevated white blood count, leukocytosis or morbid obesity; pregnancy; mental illness; tumor of sacral or ilial bone; deformities, abnormalities or anatomic variations that prevent or interfere with implant placement; any medical or surgical condition which would preclude the potential benefit of pelvic implant surgery; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; any patient unwilling or unable to follow post-operative instructions; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; or any case where the implant components selected for use would be too large or too small to achieve a successful result.

CLEANING

The system, including all instruments and implants must be disassembled (if applicable) and cleaned before sterilization.

Cleaning Precautions: Avoid excessively acidic or alkaline solutions. Do not exceed two hours soaking in any solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Failure to properly clean the instruments and implants may lead to serious injury, harm or death to the patient.

A. PRE-CLEANING

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Remove gross contaminants with a steady stream of lukewarm/cool water (below 110F/43C). Disassemble the devices where possible to expose all surfaces and clean separately.

B. MANUAL CLEANING

Immerse the devices in solution of purified water and enzymatic cleaner. Follow manufacturers' directions regarding concentration, temperature, and contact time. Use a syringe to ensure that solution reaches all parts of cannulations and close mating surfaces where necessary. Ensure that air is not trapped within features of the device when immersing in the solution.

After soaking is completed use nylon brushes to clean the devices thoroughly paying particular attention to features where soil may be shielded from the brushing. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, etc. Use a bottle brush of appropriate diameter for cannulations. Ensure that the brush passes the whole length of each cannulation at least three times.

If a device may not be disassembled, or has a long cannula, use an ultrasonic bath and process at the frequency, temperature, contact time, and concentration recommended by the enzymatic agent manufacturer. Immerse the device completely in solution of purified water and enzymatic agent and activate the ultrasonic bath.

Remove the instruments from the cleaning solution and transfer to a purified water bath and soak for 1 minute.

Thoroughly rinse with purified water for a minimum of 1 minute paying attention to flush lumens, blind holes and difficult to reach areas.

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning process.

C. AUTOMATED CLEANING (OPTIONAL)

If automated cleaning equipment is used, ensure the washer meets approved efficacy (Validated according to ISO 15883).

Load the medical devices into the washer. Ensure cannulations and blind holes are not horizontal. Articulating devices should be in the open position. Connect cannulations to the rinsing ports of the washer where possible. Make sure all instruments stay in place and do not touch or overlap each other.

Operate the washer-disinfector cycle.

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning process.

D. DRYING

Place on drying rack and allow to air dry until no water remains. Drying may be expedited by use of clean compressed air.

INSPECTION

Inspect all components of the system including all instruments and implants before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes and moveable parts.

If areas are difficult to inspect visually, check for blood by immersing of flushing the instrument in 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse instruments thoroughly with warm water.

If damage or biological residue is observed, the implant or instrument must be discarded.

Do not use if damage or wear is noted that may compromise the proper function of the instrument or instrument case. Contact customer service or your SI-TECHNOLOGY representative for a replacement.

If corrosion is noted, do not use and contact customer service or your SI-TECHNOLOGY representative for a replacement.

STERILIZATION

The SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System components including the instruments and implants are provided **NON-STERILE** and must be sterilized prior to use.

All implants and instruments should be cleaned and sterilized prior to surgery. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled within the instrument tray(s). Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be wrapped in a FDA cleared sterilization wrap and steam sterilized per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms. Cycle parameters must be established by the user.

The following is the recommended sterilization cycle:

Method:	Steam
Cycle:	Pre-Vacuum (Wrapped)
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

CONTACT INFORMATION

SI-TECHNOLOGY, LLC may be contacted at:
1-970-422-1212
A surgical technique manual may be obtained by contacting SI-TECHNOLOGY, LLC.

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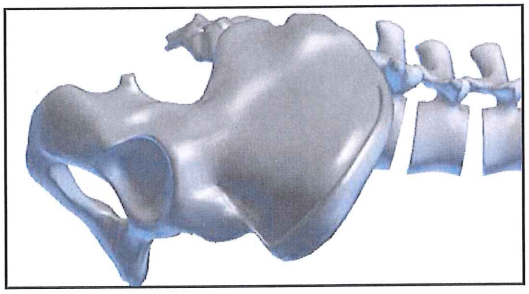
SI-TECHNOLOGY, LLC
SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System
Surgical Technique Guide

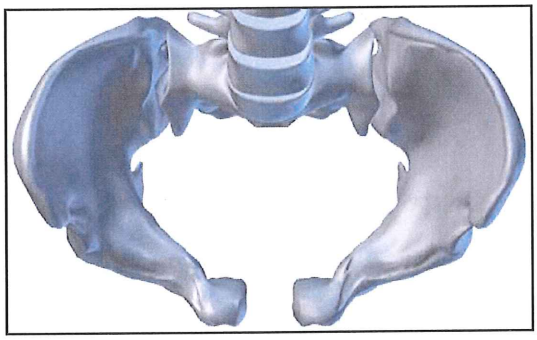
As with any surgical system, the SI-TECHNOLOGY® SI-DESIS® Sacroiliac Joint Fusion Screw System should only be used by experienced surgeons with specific training in the use of bone fixation and fusion systems and knowledge of the relevant anatomy because this is a technically demanding procedure presenting a risk of serious injury to the patient. This surgical technique document is general in nature and does not represent medical advice or recommendations. 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. See the Indications for Use ("IFU") document for applicable indications for use, contraindications, warnings, precautions and further important information.

The following fluoroscopic views may be used throughout the procedure and may be helpful in confirming appropriate depth, placement and positioning of the guide wire and final screw implantation:

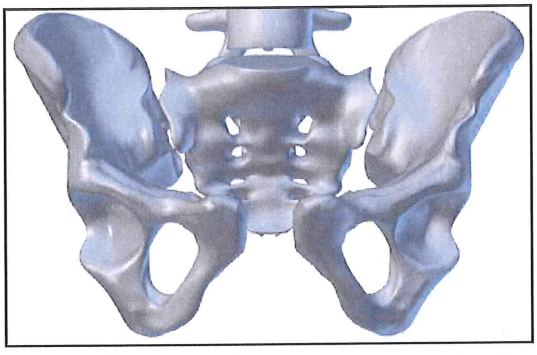
A. Lateral View



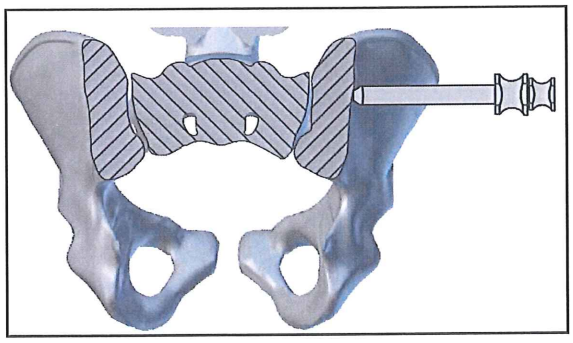
B. Inlet View

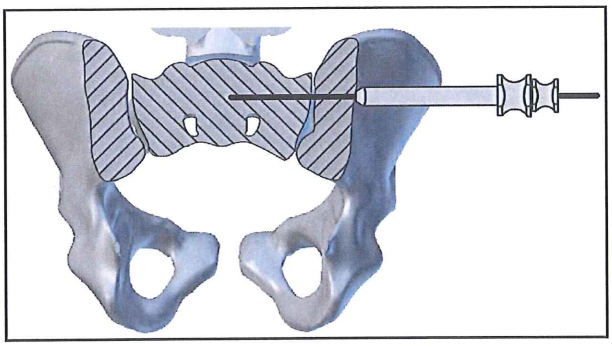


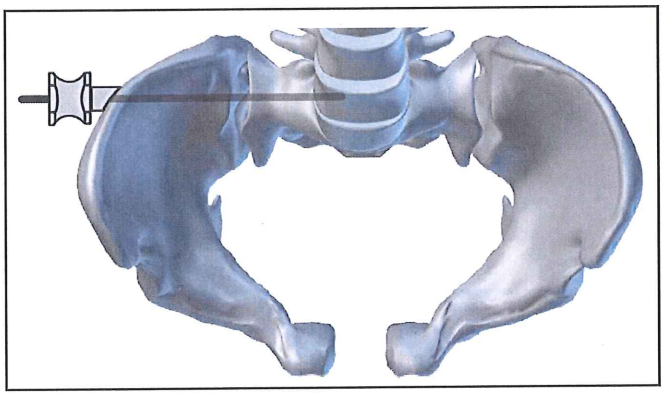
C. Outlet View

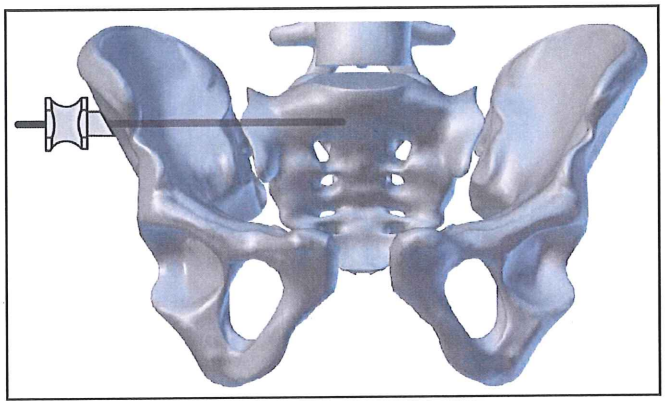


Step 1: Insert guide wire
Advance the percutaneous sleeve assembly (including protective sleeve, inner sleeve, and trocar) through a stab incision to the bone. Remove the trocar. Insert the 2.8 mm diameter, 300 mm length guide wire through the inner sleeve into the bone. Check for appropriate placement and depth under imaging guidance.

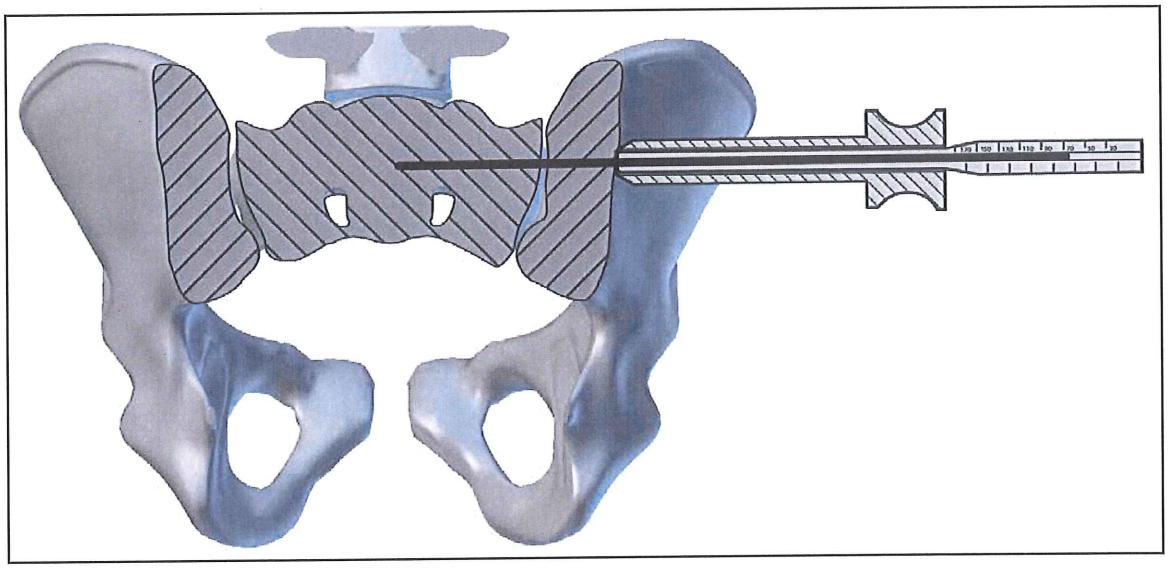




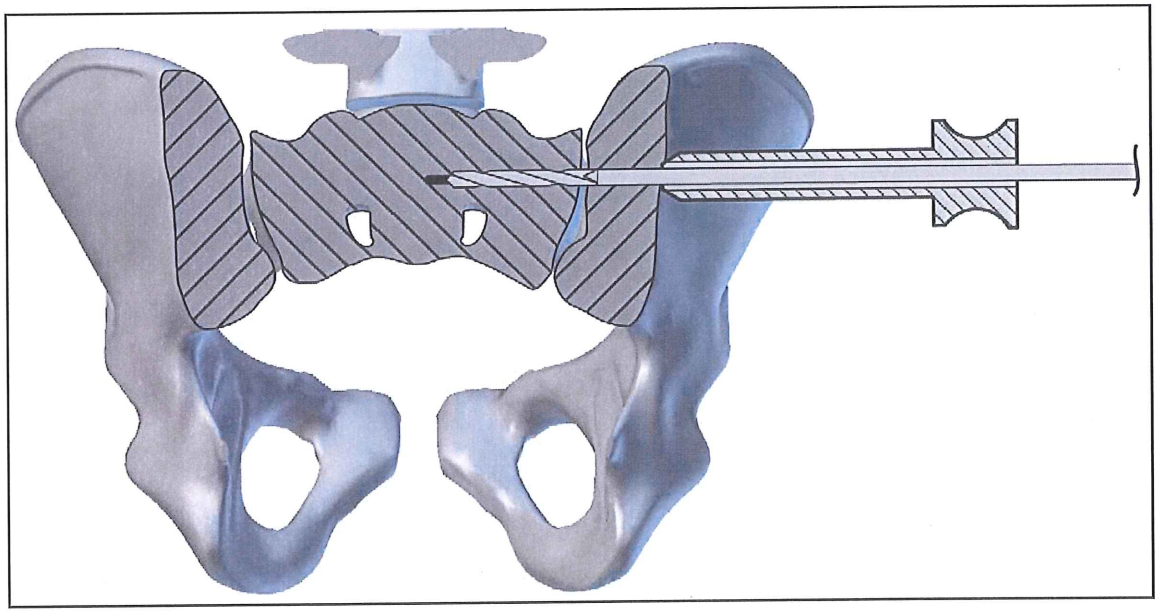




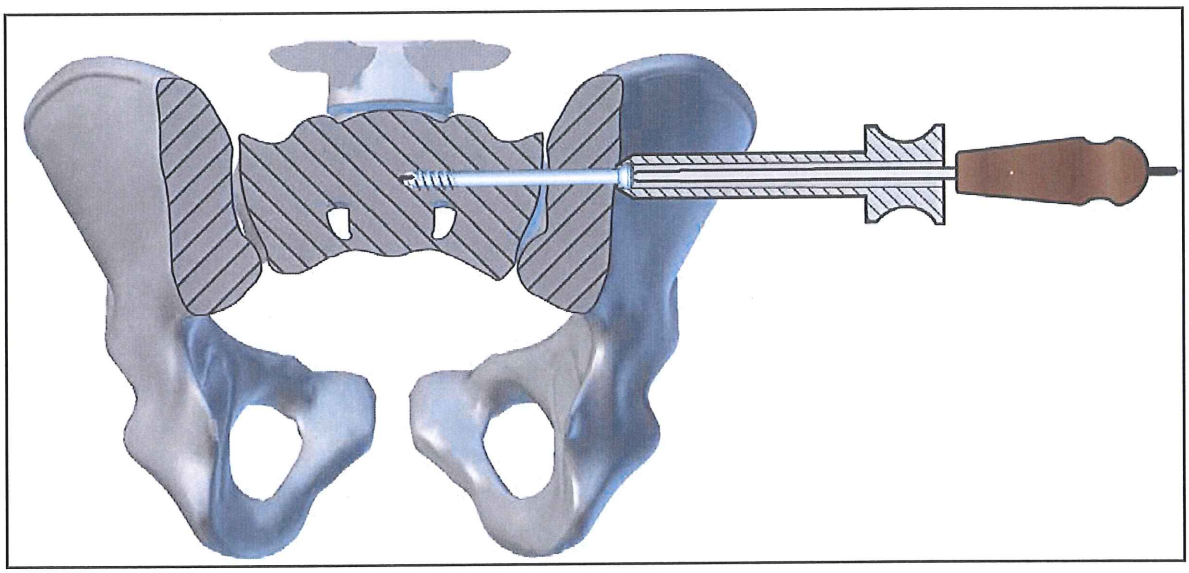
Step 2: Measure for screw length
Remove the guide wire sleeve and slide the tapered end of the cannulated screw measuring device over the guide wire and through the protection sleeve to the bone. Read the scale at the end of the wire to determine insertion depth of wire and appropriate screw length.



Step 3: Drill
Advance the 5.0 mm cannulated drill bit (2.9 mm cannulation, 300 mm length) over the guide wire through the protection sleeve, and advance into the bone, under imaging guidance. For the 5.0 mm screws, use 4mm drill bit, 300 mm length.



Step 4: Insert screw
Using a fully cannulated (2.9 mm cannulation) 4 mm hex screw driver, advance the screw over the guide wire through the protection sleeve, and advance into the bone under imaging guidance until it is fully seated. Remove all delivery components. Repeat as necessary for additional screws. A minimum of two 6.5 mm diameter screws are required. For the 5.0 mm screws, use 3.5 mm hex screw driver with a holding sleeve for 3.5mm hex screw driver



Step 5: Placement Confirmation
Using an imaging modality or other routine methods, confirm final placement of the screw(s) and close the incision(s).

OPTIONAL: SCREW REMOVAL

Using an imaging modality and/or direct visualization, locate the screw(s) which is desired to be removed. Place a guide wire through an incision, up to the screw head and through the cannulation of the screw. Advance the hex driver over the guide wire and up to the head of the screw to engage the drive recess of the screw. Rotate the driver counterclockwise to back out the screw. For non-cannulated screws, locate the proximal end of the screw, engage the screw's drive recess with the appropriate hex driver and rotate counterclockwise to remove the screw.

OPTIONAL: 5 mm Diameter Supplementary Screw

After having placed at least two 6.5 mm diameter screws across the joint, a supplementary screw with a 5 mm diameter may be placed to supplement the fixation construct. It is recommended that the non-cannulated 5 mm diameter screw be placed with the corresponding 3.5 mm hex driver while using a holding sleeve.

SI-TECHNOLOGY® SI-DESIS® SCREWS			
PART NUMBER	DIAMETER (mm)	TYPE	LENGTH (mm)
6537-30	6.5	16 mm thread (lag)	30
6537-35	6.5	16 mm thread (lag)	35
6537-40	6.5	16 mm thread (lag)	40
6537-45	6.5	16 mm thread (lag)	45
6537-50	6.5	16 mm thread (lag)	50
6537-55	6.5	16 mm thread (lag)	55
6537-60	6.5	16 mm thread (lag)	60
6537-65	6.5	16 mm thread (lag)	65
6537-70	6.5	16 mm thread (lag)	70
6537-75	6.5	16 mm thread (lag)	75
6533-30	6.5	Fully threaded	30
6533-35	6.5	Fully threaded	35
6533-40	6.5	Fully threaded	40
6533-45	6.5	Fully threaded	45
6533-50	6.5	Fully threaded	50
6533-55	6.5	Fully threaded	55
6533-60	6.5	Fully threaded	60
6533-65	6.5	Fully threaded	65
6533-70	6.5	Fully threaded	70
6533-75	6.5	Fully threaded	75
5032-30	5	Fully threaded	30
5032-35	5	Fully threaded	35
5032-40	5	Fully threaded	40
5032-45	5	Fully threaded	45
5032-50	5	Fully threaded	50
5032-55	5	Fully threaded	55
5032-60	5	Fully threaded	60
5032-65	5	Fully threaded	65
5032-70	5	Fully threaded	70
5032-75	5	Fully threaded	75

WARNING: In the USA, this product has labeling limitation.

See package insert for complete information.

The surgical technique shown is for illustrative purposes only.

The instruments depicted in this document may not be exactly the same as the instruments currently available.

Please contact SI-TECHNOLOGY, LLC directly for more information.

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Manufactured for:

SI-TECHNOLOGY, LLC

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