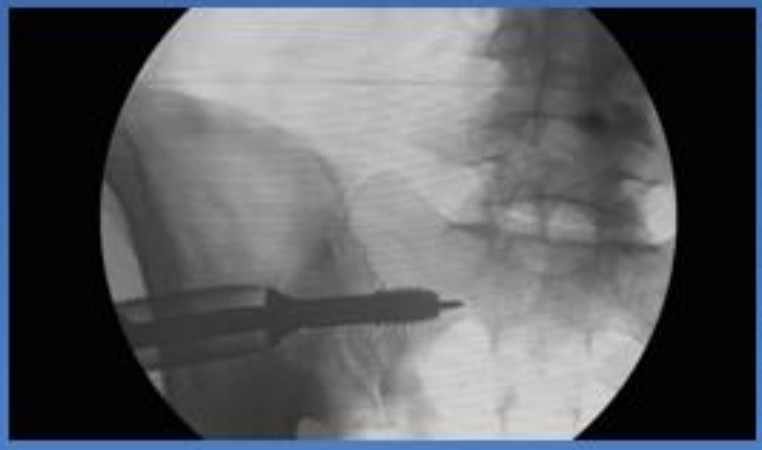
VYRSA™ fix

SI JOINT FIXATION SYSTEM



SURGICAL TECHNIQUE GUIDE

VYRSA™ TECHNOLOGIES

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IMPORTANT INFORMATION

NON-STERILE PRODUCT

BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The VYRSA™ Fix SI Joint Fixation System is a threaded bone screw used to provide structural stability in skeletally mature individuals. VYRSA™ Fix is comprised of implants of various diameters and lengths to fit the needs of individual patient anatomy. The bone screws are designed as a highly compressive screw with a hollow cannulation which are applied to the Sacroiliac Joint to provide long-term fixation and stabilization in order to initiate fusion. Fenestrations on the larger diameter bone screw are designed to allow bone growth through the implant.

MATERIALS

The VYRSA™ Fix bone screws are manufactured from a Titanium alloy (Ti-6AI-4V) per ASTM-F136.

INDICATIONS FOR USE

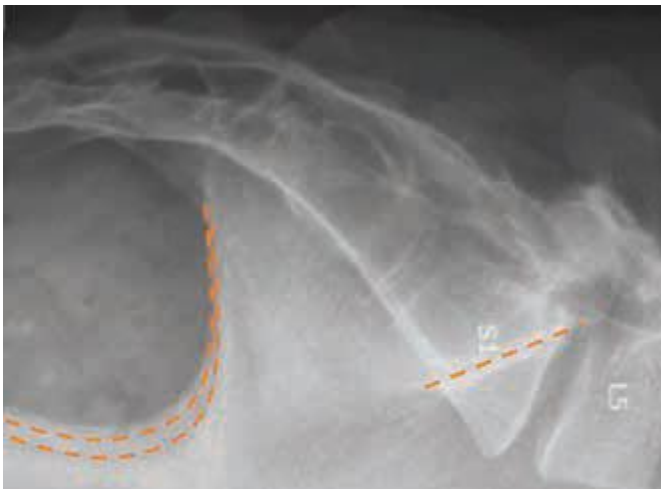
The VYRSA™ Fix SI Joint Fixation System is intended to provide fixation and stabilization of large bones, including the sacrum and ilium. It is intended for use in skeletally mature patients as an adjunct to sacroiliac joint fusion in the treatment of degenerative sacroiliitis, or sacroiliac joint disruptions.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

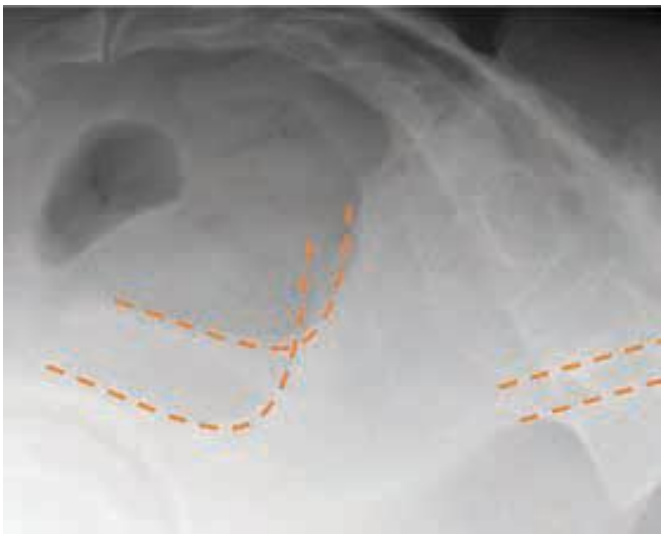
APPROACH

LATERAL ALIGNMENT

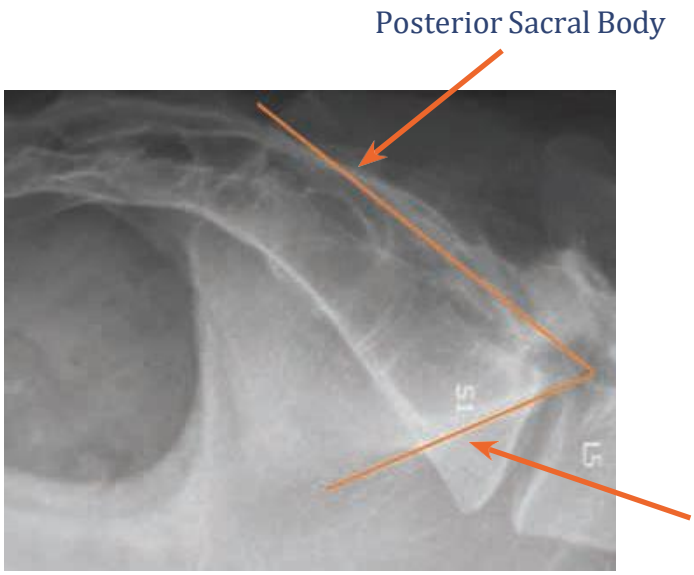
With the patient in the prone position, align the Fluoroscope with the location of Sacroiliac Joint. Ensure the Fluoroscope is directly lateral by aligning the right and left Sciatic Notches and Sacral Ala.



Correct Alignment



Incorrect Alignment



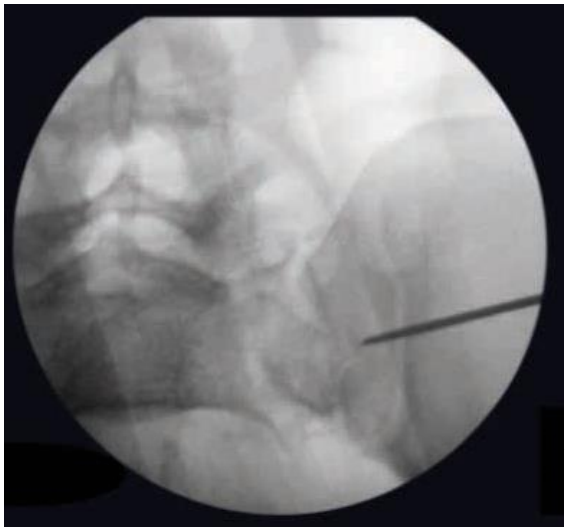
With the Fluoroscope still in the lateral position, place a Guide Wire along the skin and align with the angle of the Sacral Ala and mark the skin. Align the Guide Wire with the angle of the posterior surface of the Sacral Body and mark the skin.

STEINMANN PIN INSERTION

STEINMANN PIN ANGULATION

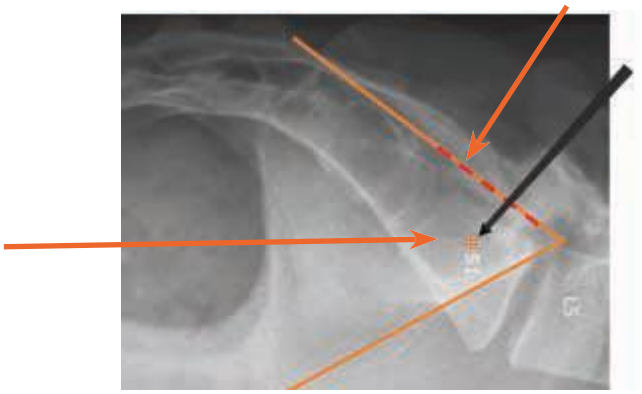
Make a 35 mm incision along the Posterior Sacral Body line starting approximately 10mm inferior to the Sacral Ala line.

Insert a Ø2.4mm Trocar Tipped Steinmann Pin (SCL-130-101, 400) through the lateral tissue to the surface of the Ilium. The Pin should be angled approximately 10° from the Coronal Plane and perpendicular to the Anterior Sacral wall. The Pin tip shall contact the Ilium 5-10mm anterior of the Posterior Sacral wall.



Before driving the Pin, confirm the angle and location of the Pin using Lateral, Inlet, and Outlet fluoroscopic imaging of the Sacroiliac joint. The Pin should be angled toward the anterior portion of the Sacral Body.

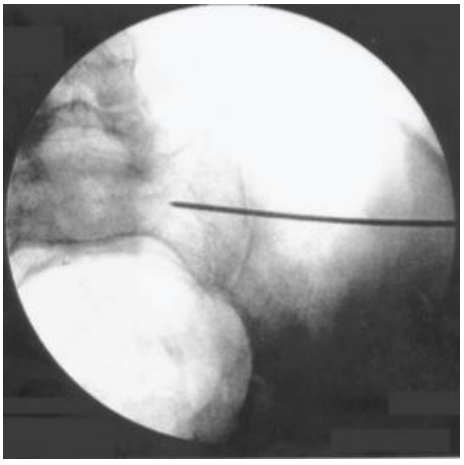
Location of the tip of Ø2.4 mm Steinmann Pin as it contacts the Ilium



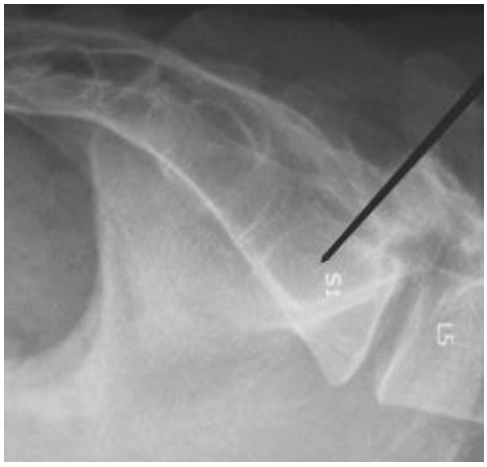
STEINMANN PIN INSERTION

When the location and direction of the Pin are confirmed, drive the Pin through the Ilium into the Sacrum. The Pin can be inserted above or between the Foramen of the Sacrum, but a minimum distance of at least 5mm should be maintained from the Pin to the edge of the nearest Sacral Foramen. During insertion, constantly confirm the location and direction with Lateral, Inlet, and Outlet Views using fluoroscopic imaging.

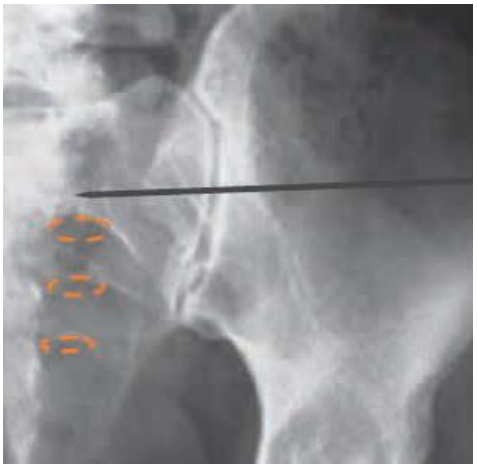
CAUTION: During insertion, maintain the recommended minimum distance of 5mm from the Foramen. If the Pin is approaching a Sacral Foramen remove it and reset the Pin to the correct angle or location.



Inlet View



Lateral View



Outlet View

LARGE SCREW INSERTION

DILATION

Insert the Primary Dilator (SCL-119-101) over the Steinmann Pin and through the periphery tissue until it contacts the Ilium. Insert the Secondary Dilator (SCL-119-102) and the Tertiary Dilator (SCL-119-103) in the same manner. If desired, the Handle Dilator (SCL-119-106) can be used in place of the Tertiary Dilator. After all three Dilators are in place, remove the two inner Dilators leaving the Pin and the Tertiary Dilator or Handle Dilator in place.

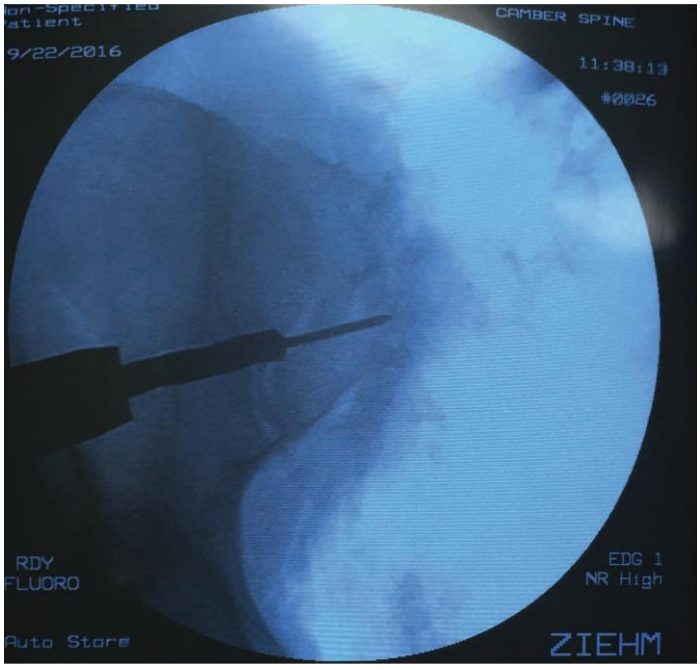
LARGE SCREW DEPTH MEASUREMENT

Place the Depth Gauge (SCL-129-101) on the end of the Tertiary Dilator and hold the Dilator against the Ilium. Read the measurement on the Depth Gauge. This reading corresponds to the depth of the Pin tip past the end of the Dilator, and ultimately the depth of the Drill Bit and length of Screw to be used in subsequent steps.

SCREW PREPARATION

Drill through the Ilium and into the Sacrum using the Ø11mm Drill Bit (SCL-125-104). Use the laser markings on the side of the Drill Bit to control the depth relative to the end of the Tertiary Dilator. Use continual A/P fluoroscopic imaging to confirm that Drill Bit is not proceeding into the Sacral Foramen, and that the Pin is not translating axially while drilling. If necessary, hold the proximal end of the Pin where it protrudes from the back of the drill.

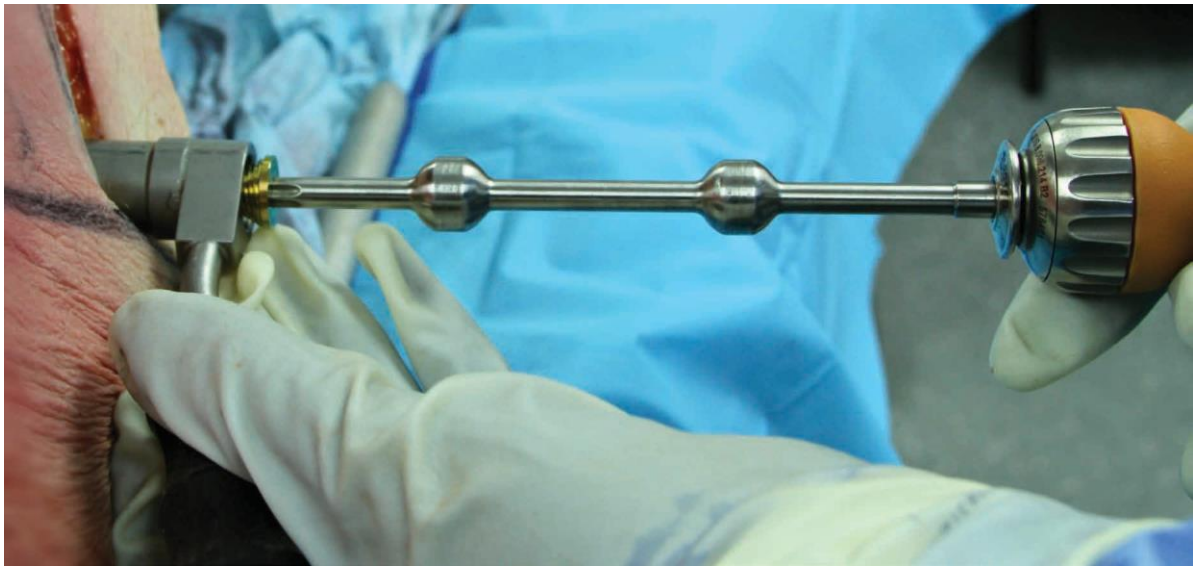
Caution: Constantly review A/P fluoroscopic imaging during this step to prevent axial translation of the Pin and drilling into the Sacral Foramen.



LARGE SCREW INSERTION

Select a large Ø11mm Screw (SCL-11-XXX) based on the length measured previously. If desired, pack the fenestration of the Screw with autograft from the drilling process. Attach the Ø11mm Driver (SCL-103-102) to the Ratcheting T-handle (CP-100-34 or VY-100-34). Place the selected Screw on the Driver, insert over the Pin and through the Tertiary Dilator.

Engage the Screw in the drilled hole and advance the Screw, rotating it clockwise until the proximal face of the Screw is flush with the Ilium. Confirm with fluoroscopy.



SMALL SCREW INSERTION

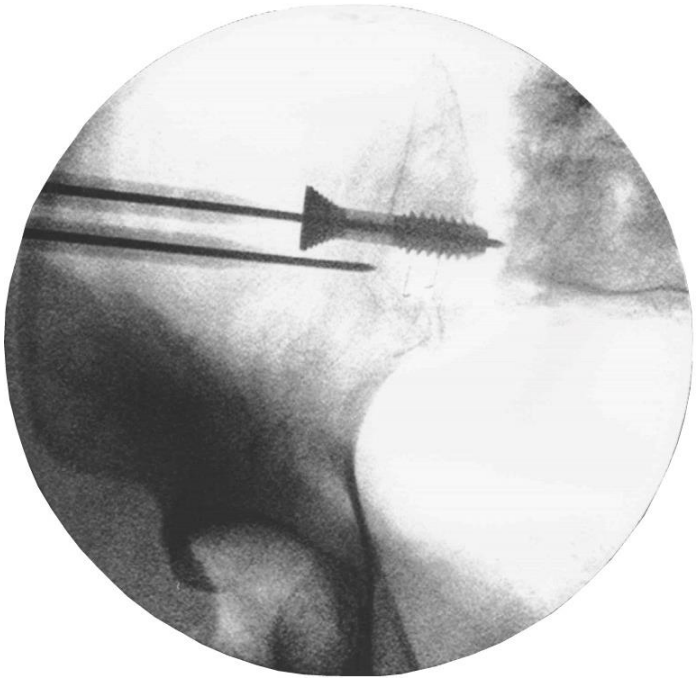
SECOND PIN POSITION

With the first Screw firmly in place, use the Pin Positioner (SCL-131-102) to determine the location of the second Pin. Place the Pin Positioner over the end of the Steinmann Pin in the large Screw.

Align the second hole of the Pin Positioner in line with the Posterior Sacral Body mark on the skin. Insert the Pin Positioner through the tissue so that it contacts the Ilium and verify its location using lateral fluoroscopy. Place a second Steinmann Pin through the second hole of the Pin Positioner.

Drive the Pin through the Ilium and into the Sacrum until firmly in place. Continually confirm the location and direction with Lateral, Inlet, and Outlet fluoroscopic imaging. Use the inlet view to adjust the angle of the second Pin to direct it toward the anterior portion of the Sacral Body.

Remove the Pin Positioner and the first Pin after inserting the second Pin firmly into the Sacrum.



Outlet View

Lateral View

SMALL SCREW DILATORS AND DEPTH

When using a small Ø7mm Screw, insert only the Primary and Secondary Dilators over the Pin. Remove the Primary Dilator and place the Depth Gauge on the end of the Secondary Dilator. Read the measurement on the Depth Gauge. This reading corresponds to the depth of the Steinmann Pin tip past the end of the Secondary Dilator, and ultimately the depth of the Drill Bit and Screw to be used in subsequent steps.

OPTIONAL DRILLING FOR SMALL SCREWS

The Ø7mm Screws have a self-drilling tip but can be inserted in a drilled hole using the Ø7mm Drill Bit (SCL-125-101) .

If the drilling option is chosen, drill through the Ilium and into the Sacrum using the Ø7mm Drill Bit. Use the gauge on the side of the Drill Bit to control the depth relative to the end of the Secondary Dilator. Use continual A/P fluoroscopic imaging to confirm that Drill Bit is not directed toward the Sacral Foramen, and that the Steinmann Pin is not translating axially while drilling. Hold the proximal end of the Pin where it protrudes from the back of the drill.

Caution: Constantly review A/P fluoroscopic imaging during this step to prevent axial translation of the Pin and drilling into the Sacral Foramen.

SMALL SCREW INSERTION

Select a Small Ø7mm Screw (SCL-07-XXX) based on the length measured previously. Attach the Ø7mm Driver (SCL-103-101) to the Ratcheting T-handle (CP-100-34 or VY-100-34). Place the selected Screw on the Driver, insert over the Pin and through the Secondary Dilator.

Advance the Screw, rotating it clockwise until the proximal face of the Screw is flush with the Ilium. Confirm with fluoroscopy.

ADDITIONAL PIN INSERTION

ADDITIONAL PIN LOCATION

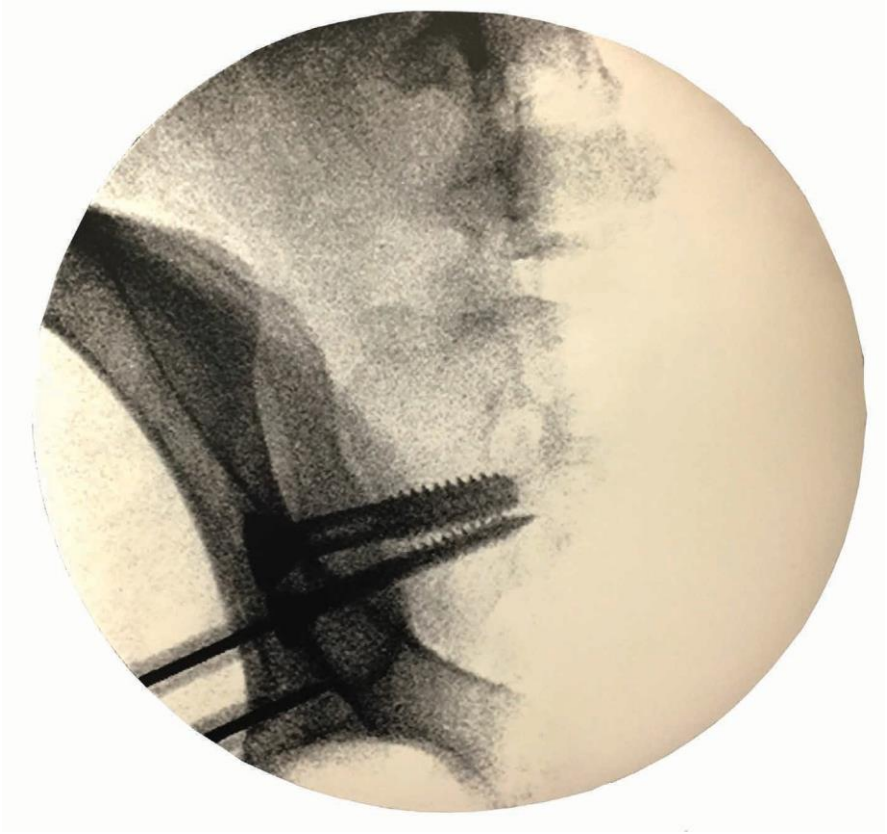
If additional Screws are required, use the Pin Positioner on the previously placed Steinmann Pin to determine the location of the additional Pin. Place the Pin Positioner over the end of the Steinmann Pin in the Small Screw. Align the second hole of the Pin Positioner in line with the Posterior Sacral Body mark on the skin. Insert the Pin Positioner through the tissue so that it contacts the Ilium and verify its location using a lateral view. Place an additional Steinmann Pin through the second hole of the Pin Positioner.

Drive the Pin through the Ilium and into the Sacrum until firmly in place. Continually confirm the location and direction with Lateral, Inlet, and Outlet fluoroscopic imaging. Use the inlet view to adjust the angle of the additional Pin to direct it toward the anterior portion of the Sacral Body.

ADDITIONAL SCREW PREPARATION AND INSERTION

To place additional Small Screws, please repeat the previous steps;

- Second Pin
- Small Screws Dilators and Depth
- Optional Drilling for the Small Screws
- Small Screw Insertion



REMOVAL TECHNIQUE

With the patient in the prone position, align the Fluoroscope using the Lateral Alignment procedure. Determine the location of the Screw that needs to be removed and make a mark on the skin. Make an appropriate incision at the center of the mark to allow for the Ø7mm or Ø11mm Screw to be removed.

Place a Trocar Tipped Steinmann Pin through the tissue and drive into the Screw Cannulation. Drive the Pin into the Screw so that it travels about half the length of the Screw Cannulation.

CAUTION: Do not surpass the tip of the Screw with the Steinmann Pin. Confirm with fluoroscopy.

Use the Primary, Secondary, and Tertiary/Handle Dilator to dilate the tissue to the required Screw diameter.

- For Small Screws, only the Primary and Secondary Dilators are necessary for removal.
- For Large Screws, the Primary, Secondary, and Tertiary/Handle Dilators are necessary for removal.

Select the appropriate Driver for removal and connect to a Ratcheting T-Handle (CP-100-34). Once the hex from the driver mallet matches the hex in the screw, lightly mallet to ensure a tight fit. Set the T-Handle in reverse and rotate counter-clockwise to remove the Screw.

- For Small Screws, select the Ø7mm Screwdriver (SCL-103-101)
- For Large Screws, select the Ø11mm Screwdriver (SCL-103-102)

SET CONTENTS

SMALL SCREW IMPLANTS

SCL-07-030	ø7.0mm Bone Screw, Cannulated, 30mm
SCL-07-035	ø7.0mm Bone Screw, Cannulated, 35mm
SCL-07-040	ø7.0mm Bone Screw, Cannulated, 40mm
SCL-07-045	ø7.0mm Bone Screw, Cannulated, 45mm
SCL-07-050	ø7.0mm Bone Screw, Cannulated, 50mm
SCL-07-055	ø7.0mm Bone Screw, Cannulated, 55mm
SCL-07-060	ø7.0mm Bone Screw, Cannulated, 60mm
SCL-07-065	ø7.0mm Bone Screw, Cannulated, 65mm
SCL-07-070	ø7.0mm Bone Screw, Cannulated, 70mm

LARGE SCREW IMPLANTS

SCL-11-035	ø11.0mm Bone Screw, Cannulated, 35mm
SCL-11-040	ø11.0mm Bone Screw, Cannulated, 40mm
SCL-11-045	ø11.0mm Bone Screw, Cannulated, 45mm
SCL-11-050	ø11.0mm Bone Screw, Cannulated, 50mm
SCL-11-055	ø11.0mm Bone Screw, Cannulated, 55mm
SCL-11-060	ø11.0mm Bone Screw, Cannulated, 60mm
SCL-11-065	ø11.0mm Bone Screw, Cannulated, 65mm

INSTRUMENTS

SCL-103-101	ø7.0mm Screwdriver
SCL-103-102	ø11.0mm Screwdriver
SCL-117-100	Chuck Adaptor
SCL-119-101	Primary Dilator
SCL-119-102	Secondary Dilator
SCL-119-103	Tertiary Dilator
SCL-119-106	Handle Dilator
SCL-125-101	ø7.0mm Drill Bit
SCL-125-104	ø11.0mm Drill Bit
SCL-129-101	Depth Gauge
SCL-130-400	ø2.4mm X 400mm Trocar Steinmann Pin
SCL-131-102 or SCL-131-103	Pin Positioner
CP-100-33	QC Cannulated Handle, Straight Ratchet
VY-100-34	QC Cannulated Handle,T-Handle Ratchet
VY-104-098	Mallet
VYFI-500-070	ø7.0mm Implant Caddy
VYFI-500-110	ø11.0mm Implant Caddy
VY-500-001	VYRSA Case Lid
VYFI-501-001	VYRSA Fix Instrument Tray
VYFI-500-400	400mm Pin Caddy Assembly

INSTRUCTIONS FOR USE (IFU)

PATIENT SELECTION

The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

CONTRAINDICATIONS

1. When there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated an allergy or foreign body sensitivity to any of the implant material;
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant;
3. Conditions that may place excessive stresses on the bone and implants, such as severe obesity, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patients;
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bone healing and may be at a higher risk for implant failure.
5. Women of childbearing age should be cautioned that fusion of the SI joint could cause potential issues with the movement of the bones in the pelvis during a vaginal delivery of a fetus. If pregnancy occurs after undergoing an SI joint fusion procedure, the women should review and discuss all alternate delivery options with her obstetrician..

WARNINGS

1. Inspect implant prior to use. Do not use if implant is damaged.
2. Correct selection of the implant is extremely important. The potential for satisfactory sacroiliac fixation is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present a limitation on the size, shape and strength of the implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand the unsupported stress of a full weight bearing indefinitely.
3. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation devices are load-sharing devices that are used to obtain fixation until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also cause early failure. Patients should be fully informed of the risks of implant failure.
4. Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of which can lead to fatigue fracture and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come in contact with other metal objects, therefore must be made from like or compatible metals.

5. Correct handling of the implant is extremely important. Excessive torque, when applied to long-handled insertion tools can cause stripping in the screw head or fracture the screw. Stripped or fractured implants should be removed and replaced.

6. Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS

Procedural:

1. The implantation of the VYRSA™ Fix should be performed only by experienced healthcare professionals with specific training in the use of this implant system as this is a technically demanding procedure presenting a risk of serious injury to the patient.

2. The healthcare professional must confirm that all necessary implants and instruments are on hand for the planned surgical procedure. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage.

3. The implants and instruments must be cleaned and sterilized before use.

4. Based on the fatigue testing results, the healthcare professional should consider the locations of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

5. The components of this system are designed to be used with VYRSA™ Technologies instruments and should not be used with components of any other system or manufacturer.

Post-Procedural:

1. The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.

2. The patient should be instructed in the limitation of physical activities which would place excessive stresses on the implant or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in/out of bed or other daily activities while minimizing rotational and bending stresses.

3. The removal of fixation after healing should be determined. If the fixation is not removed following the completion of its intended use, any of the following complications may occur: 1) Corrosion, with localized tissue reaction or pain; 2) Migration of implant position resulting in injury; 3) Risk of additional injury from postoperative trauma; 4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; 5) Pain, discomfort, or abnormal sensations due to the presence of the device, 6) Possible increased risk of infection; and 7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

POSSIBLE ADVERSE EFFECTS

While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials that are placed within the body to support potential fusion of the sacroiliac joint. However, due to the many biological, mechanical, and physiochemical factors that affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Possible adverse effects include, but are not limited to the following:

- Bending, loosening or fracture of the implants or instruments.
- Implant material sensitivity, or allergic reaction to a foreign body (including possible tumor formation).
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia.
- Vascular damage could result in catastrophic or fatal bleeding.
- Mal-positioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- Degenerative changes or instability in adjacent bones of the pelvis and spine.
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which might result in skin breakdown and/or wound complications.
- Nonunion or delayed union.
- Infection.
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral spinal fluid leakage) gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium).
- Pain or discomfort.
- Hemorrhage of the blood vessels and/or hematomas.
- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height).
- Potential difficulty in delivering a fetus vaginally due to restricted movement of the SI joint.
- Bursitis.
- Bone graft donor site pain.
- Inability to resume normal daily living activities.
- Reoperation or revision.
- Paralysis.
- Death

WARNINGS AND PRECAUTIONS:

1. The devices should only be used by healthcare professionals who have been trained in the use of this device. Information on laboratory and clinical training, as well as additional brochures with a detailed description of proper surgical technique, may be obtained from VYRSA™ Technologies. See the VYRSA™ Fix Surgical Technique Guide for instructions on the implant procedure.
2. Infection may occur immediately following implant fixation, fusion, or a long time afterwards due to transient bacteremia such as caused by dental treatment(s), endoscopic examination, or any other minor surgical procedure. To avoid infection at the implant fixation, or fusion site, it may be advisable to use antibiotic prophylaxis before and/or after such procedures.
3. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fixation and/or fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
4. If the implant has been in place for enough time for bone to have grown into the implant, removal may not be feasible.
5. Do not reuse implants; discard used, damaged, or otherwise suspect implants.
6. Single use only. Reuse of devices labeled as single use (implants, drills, tacks, trial rods, etc.) could result in injury or reoperation due to breakage or infection.
7. All implants are intended for SINGLE USE ONLY. Any used implant should be discarded. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to fatigue failure.
8. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the intended use, indications for use or for use that is contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.

MAGNETIC RESONANCE

The VYRSA™ Fix has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. The VYRSA™ Fix has not been tested for heating or migration in the MR environment.

IMPLANT CARE

1. Implants can either be shipped contained within a caddy or individually packaged, non-sterile. Care should be taken when handling the implants to avoid damaging the implant.
2. If an implant was shipped individually packaged, it should be carefully transferred to its appropriate caddy for sterilization and storage. All implants will be provided non-sterile.
3. All implants must be thoroughly inspected for any debris prior to sterilization. This includes prior to initial use. Implants are single-use, and not to be reprocessed. If any biologic material is found on the implant, remove the implant from the set. This implant is not to be used. If any debris or other material is present, contact a VYRSA™ Technologies representative using the information listed at the end of this document.
4. Implants should always be contained in their appropriate caddy for sterilization.
5. Implants are identified by both catalog numbers and lot numbers, listed on the implant itself, and additionally on the packaging if received individually packaged. These numbers should be recorded when used in surgery, or when calling for a replacement. Catalog number and lot numbers provide traceability to VYRSA™ Technologies and are crucial in the event of any necessary medical device reporting.

SINGLE USE ONLY

NOTE: Implants are single-use only and not to be reprocessed.

CLEANING

MANUAL CLEANING OF INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instrument(s), in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instrument(s) for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Flush device with deionized water, or equivalent, by placing the device under the water flow for a minimum of 3x.
15. Actuate parts, if applicable 3x, under running deionized water, or equivalent.
16. Rinse lumens, tubes, or cannula under running deionized water, or equivalent, 4x.
17. Use heat or lint-free cloth to dry devices following final rinse.

AUTOMATED CLEANING FOR INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instruments, in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.

12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Load the instrument(s) into the appropriate washer-disinfector.
15. Select the cycle which reflects the following parameters:

Phase	Recirculation Time (min)	Temperature	Detergent Type & Concentration
Pre-wash 1	01:00	Cold tap water	N/A
Wash 1	05:00	43°C tap water (Set point)	Enzymatic detergent per washer instructions
Rinse 1	01:00	Warm tap water	N/A
Pure Water Rinse	01:00	43°C deionized water	N/A
Dry Time	10:00	90°C	N/A

INSPECTION

All devices must be inspected for remaining soil or cleaning solution. The cleaning steps must be repeated until the device is free from soil and cleaning solution.

STERILIZATION FOR IMPLANTS AND INSTRUMENTS

WARNING: VYRSA™ Technologies does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10-6, VYRSA™ recommends the following parameters:

Method	Steam	Steam
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
Preconditioning Pulses	N/A	4
Temperature	132°C (270°F)	132°C (270°F)
Exposure Time	15 minutes	4 minutes
Drying Time	45 minutes	45 minutes
Open Door Drying Time	15 minutes	15 minutes

Note: An FDA Cleared Wrap must be used.
*VYRSA™ Technologies has validations for the above sterilization cycles and has the data on file. The validated sterilization parameters are compliant with the full cycle validation approach per ANSI/AAMI/ISO 17665-1, Annex D. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

SYMBOLS

Symbol	Definition	Reference
	Catalogue Number-Indicates the manufacturer's catalogue number to that the medical device can be identified	ISO 15223-1:2021 Symbol 5.1.6
	Batch code-Indicates the manufacturer's batch code so that the batch or log can be identified	ISO 15223-1:2021 Symbol 5.1.5
	Do not re-use-Indicates a medical device that is intended for one single use only	ISO 15223-1:2021 Symbol 5.4.2
	Non-sterile-Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021 Symbol 5.2.7
	Prescription Only-Caution: Federal law restricts this device to sale by or on the order of a physician	FDA 801.15(c)(1)(i)(F)
	Consult Instructions for Use-Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021 Symbol 5.4.3
	Manufacturer-Indicates the medical device manufacturer	ISO 15223-1:2021 Symbol 5.1.1
	Unique Device Identifier (UDI)-Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021 Symbol 5.7.10
	Date of Manufacture-Indicates the date when the medical device was manufactured	ISO 15223-1:2021 Symbol 5.1.3

FOR FURTHER INFORMATION

If further information on this product, or the Surgical Technique Guide, is needed please contact VYRSA™ Technologies at the number listed below:

Manufactured By:

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NOTES

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