SURGICAL TECHNIQUE GUIDE

TRITON™

Sacroiliac Joint Fixation System

ChoiceSpine™

ChoiceSpine™

choicespine.com

Spine the Right Way.℠

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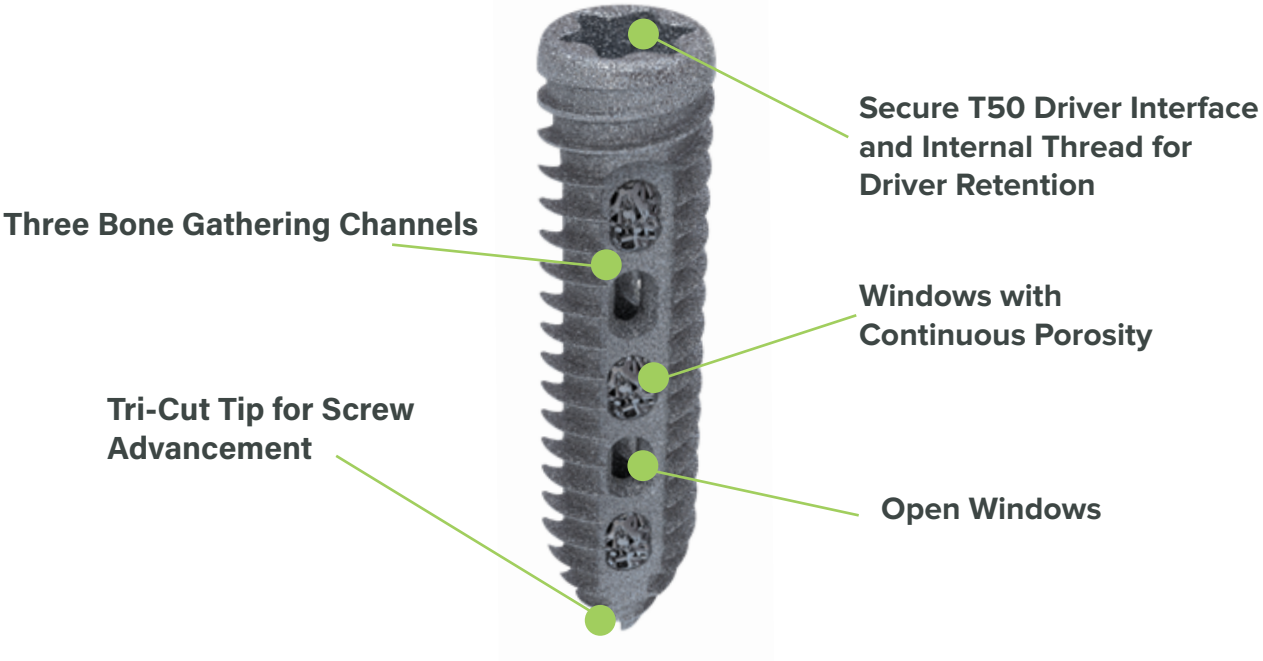
TRITON™

SI Joint Fixation System

Introduction

The ChoiceSpine TRITON™ Sacroiliac Joint Fixation System is intended for sacroiliac joint fixation for conditions including degenerative sacroiliitis and sacroiliac joint disruption. TRITON™ is a titanium 3D manufactured cannulated screw with open and porous graft windows. TRITON™ offers various lengths and diameters to accommodate different patient anatomies.



Description	Screw Major Diameter	Screw Minor Diameter	Length
Secondary	Ø8mm	Ø6mm	30,35,40,45,50,55,60mm
Primary	Ø12mm	Ø9mm	30,35,40,45,50,55,60,65mm
Revision	Ø14mm	Ø11mm	35,40,45,50,55,60,65mm

Simple Instrumentation

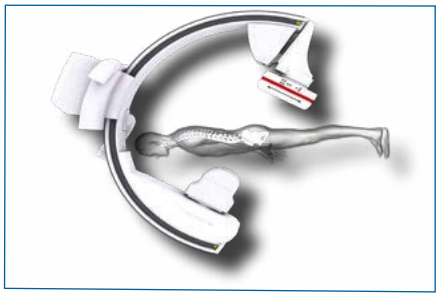
Bone Gathering Channels

Fixation

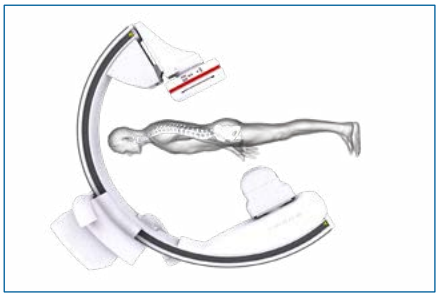
Patient Setup and Operative Imaging

Adequate pre-operative planning is always recommended prior to surgical intervention.

Position the patient in the prone position. The surgical procedure requires three (3) main C-Arm images: Inlet View, Outlet View and Lateral View.

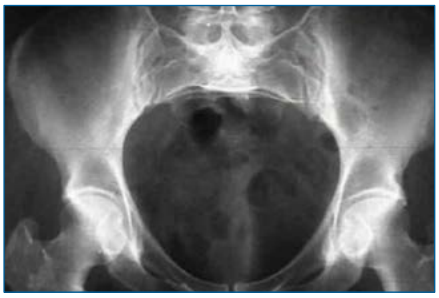


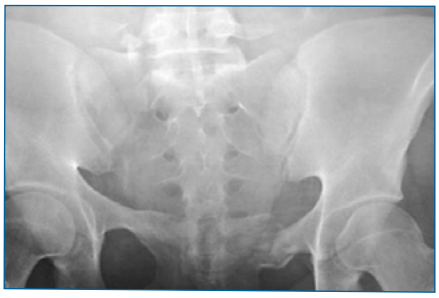
Inlet view: Allows the Pelvic Brim to be viewed.

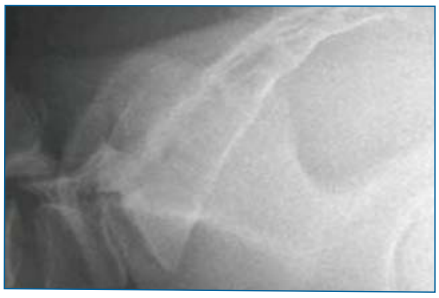


Outlet View: Allows the Sacral Foramen to be viewed.

Lateral View: Allows the Alar Lines, Posterior/Anterior Sacral Walls and the S1 Endplate to be viewed.







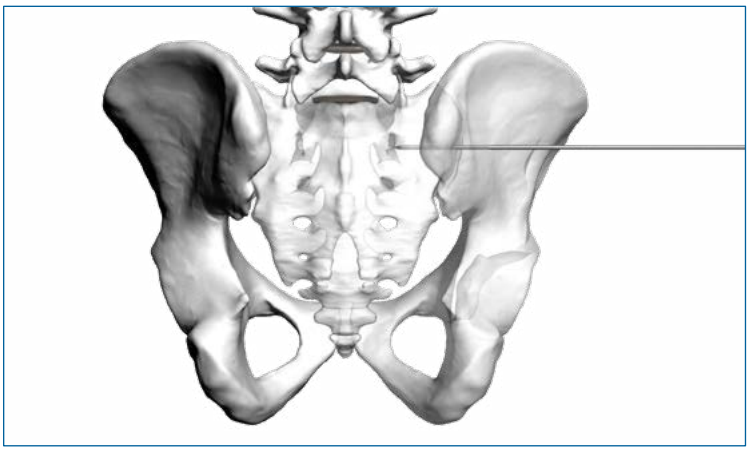
Patient Markings, Incision, and Targeting

Utilizing the lateral image, locate the Superimposed Alar Slope, Anterior Sacral Wall and Posterior or Linear Sacral Wall with the Steinmann Pin or Exchange Pin. Mark the skin to create a triangular working area for Screw positioning.

Incise along the Posterior Sacral Wall starting at the intersection with the sacral alar marking approximately 3-5cm in length.

Steinmann Pin Positioning

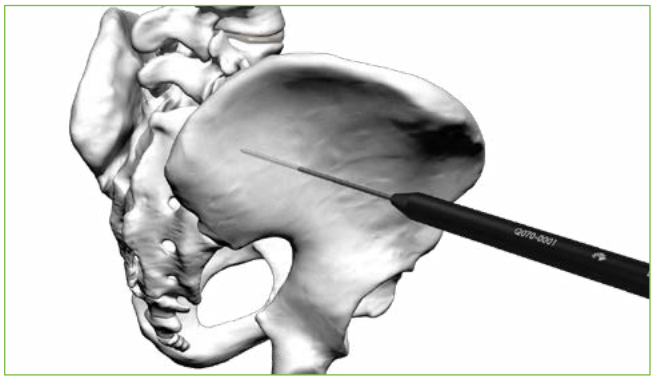
The **Steinmann Pin** should be inserted across the joint 1cm distal from the alar line and in the middle of the sacrum in the Outlet View. Depending on the patient anatomy, the **Steinmann Pin** should point just above the S1 nerve root foramen seen on the Outlet View. The final position of the **Steinmann Pin** should be in the middle portion of the sacrum in the Inlet View lateral, to the lateral S1 neuroforamen.

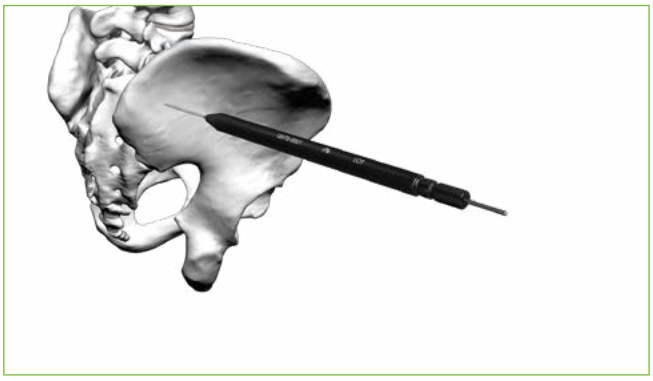


Impact the **Steinmann Pin** into the ilium and sacrum at the desired trajectory and depth using the **Mallet (Q070-0022)**. Slide **Dilator 1 (Q070-0001)** over the **Steinmann Pin** for additional Pin stability during impaction if desired. The **Pin Holder (Q070-0006)** may be used to stabilize the **Steinmann Pin** or **Dilator 1** while targeting the intended Screw position and trajectory.

Tissue Dilation

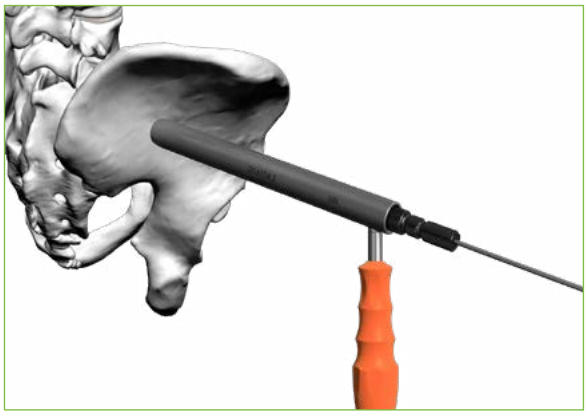
Place **Dilator 1 (Q070-0001)** over the **Steinmann Pin** until flush against the iliac cortex.



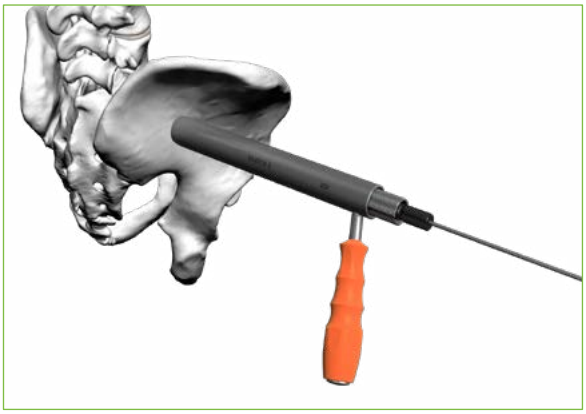


Snap the **Depth Gauge (Q070-0005)** onto the proximal end of **Dilator 1**. Select an appropriate Screw length by reading the **Depth Gauge** measurement that aligns with the proximal end of the **Steinmann Pin.** If the **Steinmann Pin** does not directly align with the gauge markings, it is recommended to select the shorter Screw length.

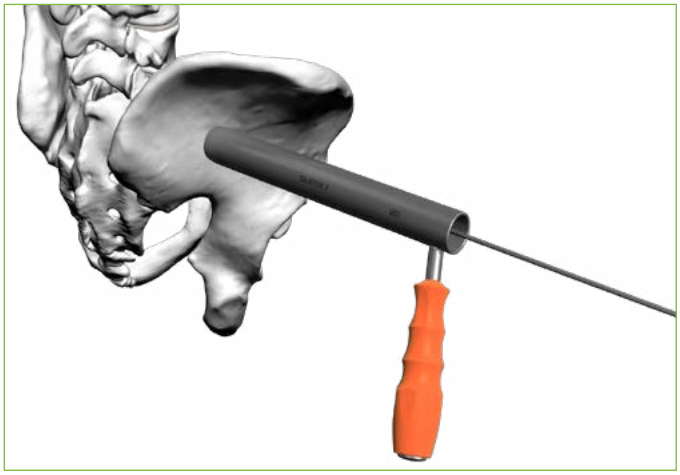
Slide **Dilator 2 with Handle (Q070-0002)** over **Dilator 1** if implanting a Ø8mm or Ø12mm Screw.



Slide **Dilator 2 without Handle (Q070-0003)** and **Dilator 3 with Handle (Q070-0004)** over **Dilator 1** if implanting a Ø14mm Screw.



Remove internal **Dilator(s)** leaving the final **Dilator** and **Steinmann Pin** in place.

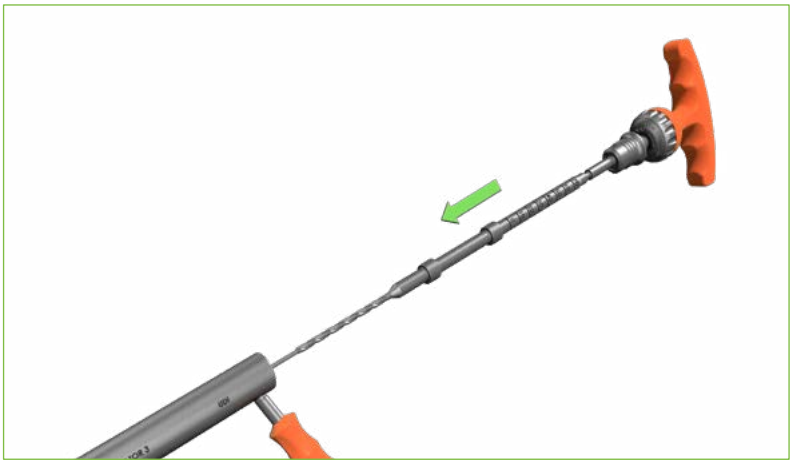


Screw Hole Preparation

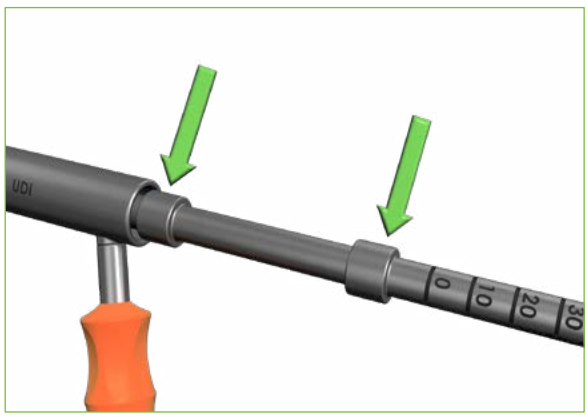
Multiple instruments are available for screw hole preparation which can be utilized based on surgeon preference.

The **Drills** and **Taps** are undersized to the corresponding Screw diameters and have depth markings indicating prepared depth relative to the proximal end of the final **Dilator**.

Connect the **Ratcheting T-Handle (E070-0045)** to the selected screw preparation instrument and guide the instrument over the placed **Steinmann Pin** and through the final **Dilator.**



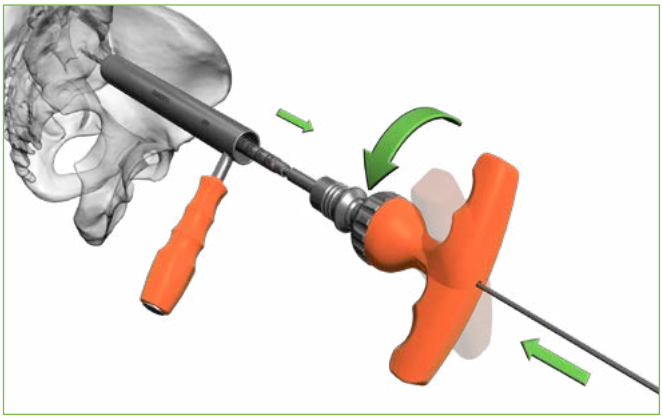
Collars are present on all screw preparation instrumentation for alignment through **Dilator 2.** The **Dilator 3 Adaptor (Q070-0014)** can be attached between the collars on the screw preparation instrument (**Tap** or **Drill)** for proper alignment through **Dilator 3.**



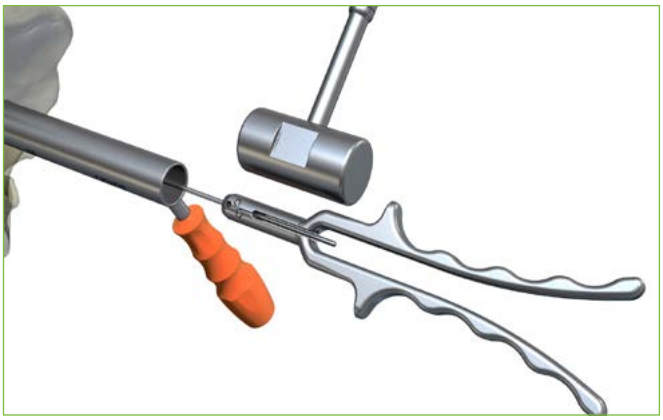
Advance the screw preparation instrument to the desired depth using a clockwise rotation.

Note: Screw preparation instruments are compatible with power. Optional Jacobs Chuck (E070-0055) is required for power compatibility.

Remove the Screw preparation instrument using a counterclockwise rotation. Prior to removing the instrument over the **Steinmann Pin**, insert an **Exchange Pin** through the cannulation of the instrument. While keeping lateral to medial directed force on the **Steinmann Pin**, remove the instrument over the **Steinmann Pin**. Remove the instrument and **Exchange Pin** from the surgical working area.

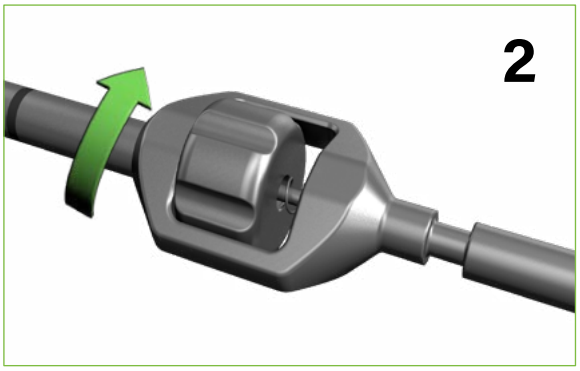


In the event of unintentional **Steinmann Pin** advancement, the **Pin Puller (Q070-0012)** can adjust the Pin position by guiding the instrument over the **Steinmann Pin**, squeezing the handles together, and pulling proximally. Impact the **Pin Puller** with the **Mallet** if additional force is required to retract the **Steinmann Pin**.



Screw Insertion

Aseptically remove the desired Screw from the sterile packaging. Unscrew the top of the plastic storage tube while holding the bottom containing the Screw. Attach the **Ratcheting T-Handle (E070-0045)** onto the proximal end of the **Screwdriver (Q070-0007)**. Load the **Screwdriver** onto the Screw by mating the hexalobe features and rotating the **Screwdriver** knob clockwise to engage the internal threads of the screw. Rotate the knob until finger tight. Remove Screw from the plastic storage tube.

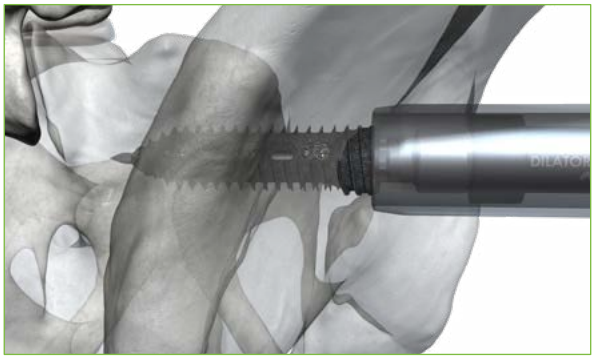


***CAUTION:* SCREW THREADS ARE SHARP. AVOID GLOVE AND TISSUE CONTACT WITH SCREW THREADS.**

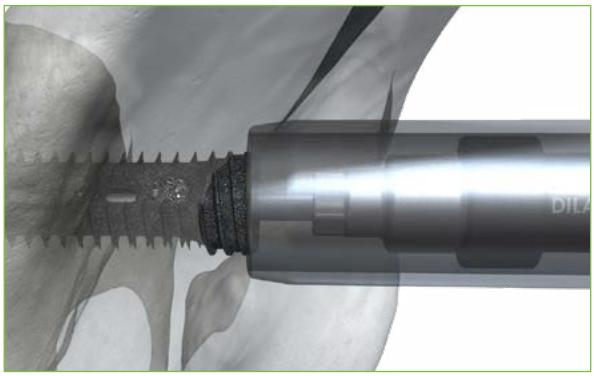
Guide the Screw and **Screwdriver** through the final **Dilator** and over the **Steinmann Pin**. If implanting a Ø14mm Screw, the **Dilator 3 Adaptor** may be attached between the collars of the **Screwdriver** for proper alignment through **Dilator 3**.

***CAUTION:* ENSURE SCREW INSERTION THROUGH FINAL DILATORS TO PROTECT SOFT TISSUE FROM DAMAGE.**

Under fluoroscopic guidance, advance the Screw into the ilium towards the sacrum by rotating the **Screwdriver** clockwise. Use caution to avoid **Steinmann Pin** advancement during Screw insertion. As the laser mark band on the **Screwdriver** approaches the proximal end of the final **Dilator**, confirm the Screw is seated to the desired depth and/or tightness.

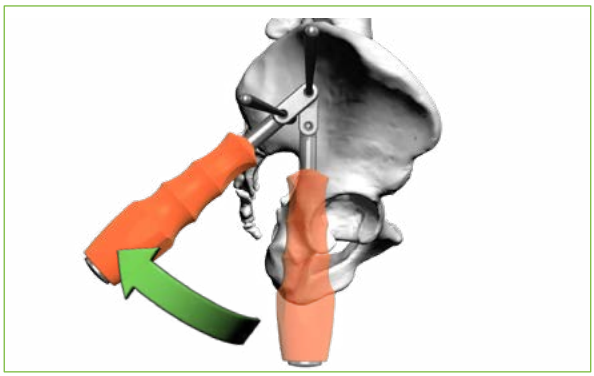


Rotate the knob counterclockwise to disengage the **Screwdriver** from the Screw. Remove the **Screwdriver** out of the final **Dilator** over the **Steinmann Pin**. Use an **Exchange Pin**, if necessary, to keep **Steinmann Pin** in position.

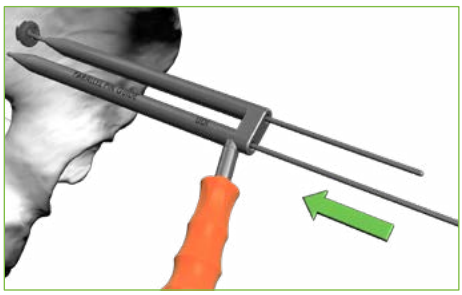


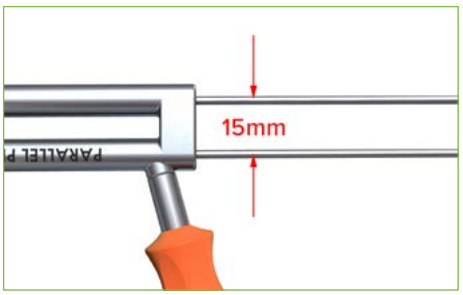
Placement of Second and Third Steinmann Pins

Remove the final **Dilator** over the **Steinmann Pin** assuring the Pin stays in place. Slide one of the **Parallel Pin Guide (Q070-0008)** tubes over the first **Steinmann Pin**. **Rotate the Pin Guide** to position the second tube to the next **Steinmann Pin** location.

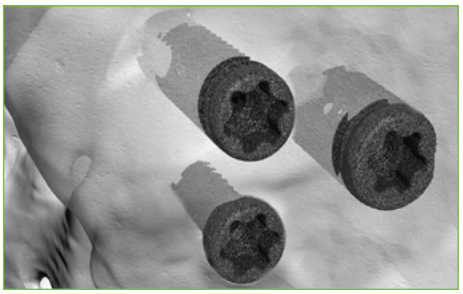


Impact the second **Steinmann Pin** through the second **Pin Guide** tube. Remove the **Parallel Pin Guide** and repeat tissue dilation, Screw hole preparation, and Screw insertion steps.





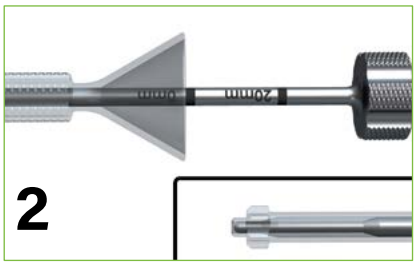
Utilize the **Parallel Pin Guide** for a second time to position the third **Steinmann Pin** for the final Screw placement. Standard Screw positioning techniques are linear or triangular.

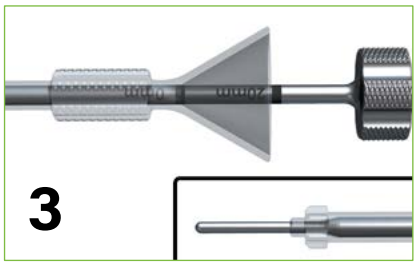


For adequate fixation, it is recommended that three Triton Screws are implanted. Two to four implants may be used due to variations in anatomy.

Bone Graft Delivery

Screw post-packing can be achieved using the **Bone Funnel (Q070-0016)** and **Bone Plunger (Q070-0018)**. Prepack the **Bone Funnel** with the desired graft material. Remove the **Steinmann Pin** from the Screw and seat the hexalobe end end of the Funnel into the hexalobe of the Screw head, which can be confirmed utilizing an inlet/outlet view. Push the **Bone Plunger** through the filled cannula of the **Bone Funnel** to advance the graft material. The **Bone Plunger** has 0mm and 20mm depth markings to indicate plunger positioning past the distal tip of the **Bone Funnel**.



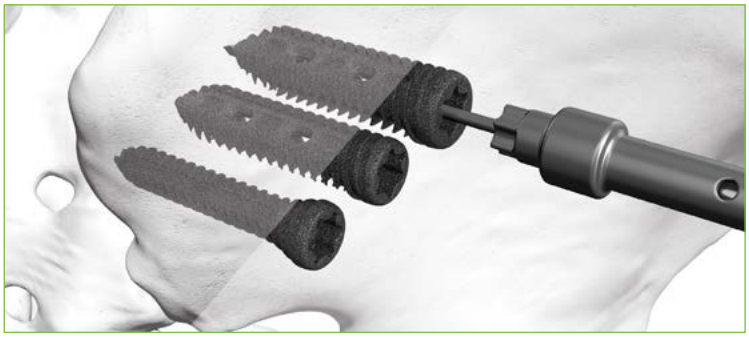


NOTE: STRATOGEN® HA/TP PUTTY or 100 DBM is recommended for this application.

Screw Removal

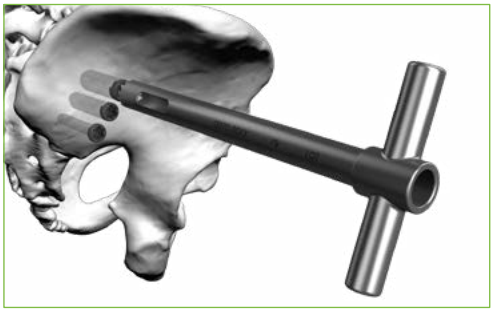
Primary Removal Method:

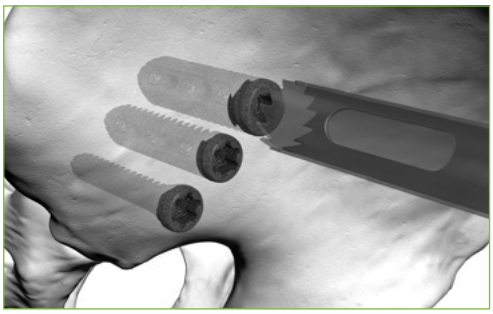
Reattachment of the **Screwdriver** should be the primary method of Screw removal. Clear any tissue to access the Screw head. If necessary, introduce the **Steinmann Pin** into the cannulation of the Screw and guide subsequent **Dilators** to retract and protect soft tissue. Remove the internal **Dilators** leaving the final **Dilator** and **Steinmann Pin**. Attach the **Ratcheting T-Handle** to the **Screwdriver**. Guide the **Screwdriver** over the **Steinmann Pin** and seat the hexalobe of the **Screwdriver** into the hexalobe of the Screw. Rotate the **Screwdriver** knob clockwise to engage internal threads in the screws. Rotate the **Screwdriver** counterclockwise to remove the Screw from the surgical site.



Secondary Removal Method:

If the primary removal method is not successful due to fusion, **Trephine Removal Tools (Q070-0019 and Q070-0020)** and a **Reverse Removal Tool (Q070-0021)** are alternative methods for Screw extraction. Align the **Trephine Removal Tool** over the Screw head. Rotate the t-bar handle clockwise to the desired depth. If necessary, insert the **Reverse Removal Tool** into the Screw head, and rotate counterclockwise to engage the Screw. Maintain counterclockwise rotation to remove the Screw from the sacroiliac joint.





CAUTION: ***THE THREADS ARE SHARP. UTILIZE THE TISSUE RETRACTION INSTRUMENTS TO PROTECT SOFT TISSUE DURING SCREW REMOVAL.***

Instrument List

Part Number	Description	Qty
Q070-0001	Dilator 1	1
Q070-0002	Dilator 2 with Handle	1
Q070-0003	Dilator 2 without Handle	1
Q070-0004	Dilator 3 with Handle	1
Q070-0005	Dilator 1 Depth Gauge	2
Q070-0006	Pin Holder	1
Q070-0007	Screwdriver	2
Q070-0008	Parallel Pin Guide	1
Q070-0012	Pin Puller	1
Q070-0014	Dilator 3 Adaptor	2

Part Number	Description	Qty	
Q070-0016	Bone Funnel	2	
Q070-0018	Bone Plunger	1	
Q070-0022	Mallet	1	
Q070-D008	Ø8mm Drill	1	
Q070-D012	Ø12mm Drill	1	
Q070-D014	Ø14mm Drill	1	
Q070-T008	Ø8mm Tap	1	
Q070-T012	Ø12mm Tap	1	
Q070-T014	Ø14mm Tap	1	
E070-0045	Ratcheting T-Handle 1/4" Square	2	
gS 78.5824	Steinmann Pin 12" Trocar-Blunt	6	
KI-094-20	Exchange Pin 20", Blunt-Blunt	3	

Optional Instruments

E070-0055	Jacobs Chuck Adaptor
Q070-0019	Removal Instrument Ø12
Q070-0020	Removal Instrument Ø14
Q070-0021	Reverse Removal Tool

Implant List

Part Number	Description	Qty
S-QT10-0830	Triton™, Screw, Ø8x30mm Sterile	1
S-QT10-0835	Triton™, Screw, Ø8x35mm Sterile	1
S-QT10-0840	Triton™, Screw, Ø8x40mm Sterile	2
S-QT10-0845	Triton™, Screw, Ø8x45mm Sterile	2
S-QT10-0850	Triton™, Screw, Ø8x50mm Sterile	2
S-QT10-0855	Triton™, Screw, Ø8x55mm Sterile	1
S-QT10-0860	Triton™, Screw, Ø8x60mm Sterile	1
S-QT10-1230	Triton™, Screw, Ø12x30mm Sterile	2
S-QT10-1235	Triton™, Screw, Ø12x35mm Sterile	3
S-QT10-1240	Triton™, Screw, Ø12x40mm Sterile	4
S-QT10-1245	Triton™, Screw, Ø12x45mm Sterile	4
S-QT10-1250	Triton™, Screw, Ø12x50mm Sterile	4
S-QT10-1255	Triton™, Screw, Ø12x55mm Sterile	4
S-QT10-1260	Triton™, Screw, Ø12x60mm Sterile	3
S-QT10-1265	Triton™, Screw, Ø12x65mm Sterile	1
S-QT10-1435	Triton™, Screw, Ø14x35mm Sterile	1
S-QT10-1440	Triton™, Screw, Ø14x40mm Sterile	2
S-QT10-1445	Triton™, Screw, Ø14x45mm Sterile	2
S-QT10-1450	Triton™, Screw, Ø14x50mm Sterile	2
S-QT10-1455	Triton™, Screw, Ø14x55mm Sterile	1
S-QT10-1460	Triton™, Screw, Ø14x60mm Sterile	1
S-QT10-1465	Triton™, Screw, Ø14x65mm Sterile	1

Triton™ Sacroiliac Joint Fixation System Instructions for Use

STERILE R Rx only

ChoiceSpine, LLC
400 Erin Drive
Knoxville, TN 37919
USA

Description:
The Triton™ Sacroiliac Joint Fixation System is a multiple component system consisting of non-sterile instruments and sterile, cannulated Ø8mm, Ø12mm and Ø14mm Screws offered in multiple lengths. The Triton SI Screws are manufactured from medical-grade titanium alloy (Ti-6Al-4V ELI) per ASTM F3001, Class C. The implants feature 3 fluted channels for bone collection and a tapered proximal tip. The Ø12mm and Ø14mm Screws feature multiple open and porous-filled windows for packing and disbursement of autograft and allograft materials.

Indications for Use:
The Triton™ Sacroiliac Joint Fixation System is intended for fixation of sacroiliac joint disruptions, and intended for the sacroiliac joint fusion for conditions including; - Sacroiliac joint disruptions
- Degenerative sacroiliitis
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Contraindications:
Contraindications include, but are not limited to:
- Open wounds, infection, presence of tumor, pregnancy, osteoporosis, certain metabolic disorders affecting osteogenesis, certain inflammatory/neuromuscular conditions, and certain neuromuscular deficits which would place an unusually heavy load on the device during the healing period.
- The implant is made from Ti-6Al-4V ELI (medical-grade titanium alloy). The fixation implant is contraindicated in any individual with a known or suspected allergy, sensitivity, or intolerance to metal.

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 ChoiceSpine. See the Triton™ Sacroiliac Joint Fixation System 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 screw has been in place for a sufficient amount of time for bone to have grown into the screw, 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, pins, 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.
9. The Triton™ Sacroiliac Joint Fixation System has not been evaluated for safety and compatibility in the MR environment. The Triton™ Sacroiliac Joint Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Triton™ Sacroiliac Joint Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects:
The potential risks identified with the use of this system, which may require additional surgery include:
- Allergic reaction or metal sensitivity to foreign body
- Cardiovascular system compromise
- Death
- Decrease in bone density due to stress shielding
- Device bending, disassembly, fracture, loosening, migration and/or retropulsion, or subsidence
- Dural tears, neural structure injury
- Implant migration with or without bone fracture
- Fracture of pelvis or sacrum
- Gastrointestinal complications (i.e., ileus or bowel perforation)
- Hemorrhage
- Incisional complications (i.e., dehiscence, hematoma)
- Infection (incisional or implant site)
- Loss of spinal mobility or function
- Malfunction of fixation device and/or instruments
- Malposition of the fixation device
- Neurological injury/deficit which may range from paresthesias to muscle paralysis, loss of rectal or bladder sphincter control, radiculopathies
- Organ, connective tissue or nerve damage
- Pain, discomfort or abnormal sensation due to device presence
- Persistent low back pain
- Reproductive system compromise
- Screw back-out or breakage possibly leading to local pain, perforation or irritation of adjacent structures.
- Sepsis
- Urological compromise (i.e., infection/retention)
- Vascular injury
- Failure to osseointegrate
- Persistent low back pain
- Reproductive system compromise
- Screw back-out or breakage possibly leading to local pain, perforation or irritation of adjacent structures.
- Sepsis
- Urological compromise (i.e., infection/retention)
- Vascular injury
- Failure to osseointegrate

Single-Use Only:
Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Storage and Handling:
Implants should be stored in their original, sealed packaging in clean, dry conditions. The packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. In order to ensure sterility, implants must be used before the end of the expiration date indicated on the outer package label. Prior to use, inspect the packaging and labeling for integrity. If the device has been opened, damaged or adulterated in any way, it must not be used. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

How Supplied:

STERILE R The Triton™ Sacroiliac Joint Fixation System implants are supplied "STERILE" (gamma radiation) with a SAL of 10^{-6} and intended for single use only. The sterility can only be assured if the packaging is intact. Do not use this device if the sterile packaging has been opened or damaged. Contact your local sales representative or distributor for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery.

NON STERILE The Triton™ Sacroiliac Joint Fixation System instruments are provided clean but non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:
All instruments are supplied to the health care facility clean but non-sterile. Implants are single use only but need to be sterilized before each use. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The instruments are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

Caution: Delays in reprocessing and prompt removal of soil on a device could create conditions favorable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and disinfection/sterilization. Organic contamination may inactivate or prevent full penetration of a disinfectant or sterilant.

Recommended Cleaning:
The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling. When appropriate, disassemble instruments prior to cleaning.

Automated Cleaning:
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz per 1 gal water
Wash 1	2:00	60°C	Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instrument(s) from washer & visually inspect for soil. Repeat if necessary.

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.

5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Inspection:
The implants should be inspected after processing, prior to sterilization. Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

Limitations and Restrictions:
Repeated sterilization according to these instructions has a minimal effect on Choice Spine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these Choice Spine implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Sterilization:
Choice Spine instruments and implants are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments and implants are recommended to be steam sterilized by the hospital using the following process parameters (Alternative methods or cycles may be used but should be validated according to hospital practices and procedures):
All devices must be placed in appropriate caddy/case prior to steam sterilization.

Steam Sterilizer Type: Pre-vacuum
Temperature: 132°C
Duration: 4 minutes
Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

Single Use Only:
Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Patient Education:
It is essential to provide preoperative instructions to the patient. The patient should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the Raven Lumbar Plate System components, please call Choice Spine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information

Surgical Technique Manual:
The Triton™ Sacroiliac Joint Fixation System Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

Product Complaints:
The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to ChoiceSpine immediately. Furthermore, if any of the implants "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence.
When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint

Caution:
Federal Law (USA) restricts this device to sale by or on the order of a physician.

Information:
See choicespine.com for more information.
See choicespine.com/patents/ for patent information.

For product complaints please contact:

Choice Spine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:

Choice Spine, LLC
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045
customerservice@choicespine.com

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
	Authorized representative in the European Community
	MR Conditional

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Spine the Right Way.℠

TRITON™

SI Joint Fixation System

ChoiceSpine™

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