

TRITON[®]

Sacroiliac Joint Fixation System





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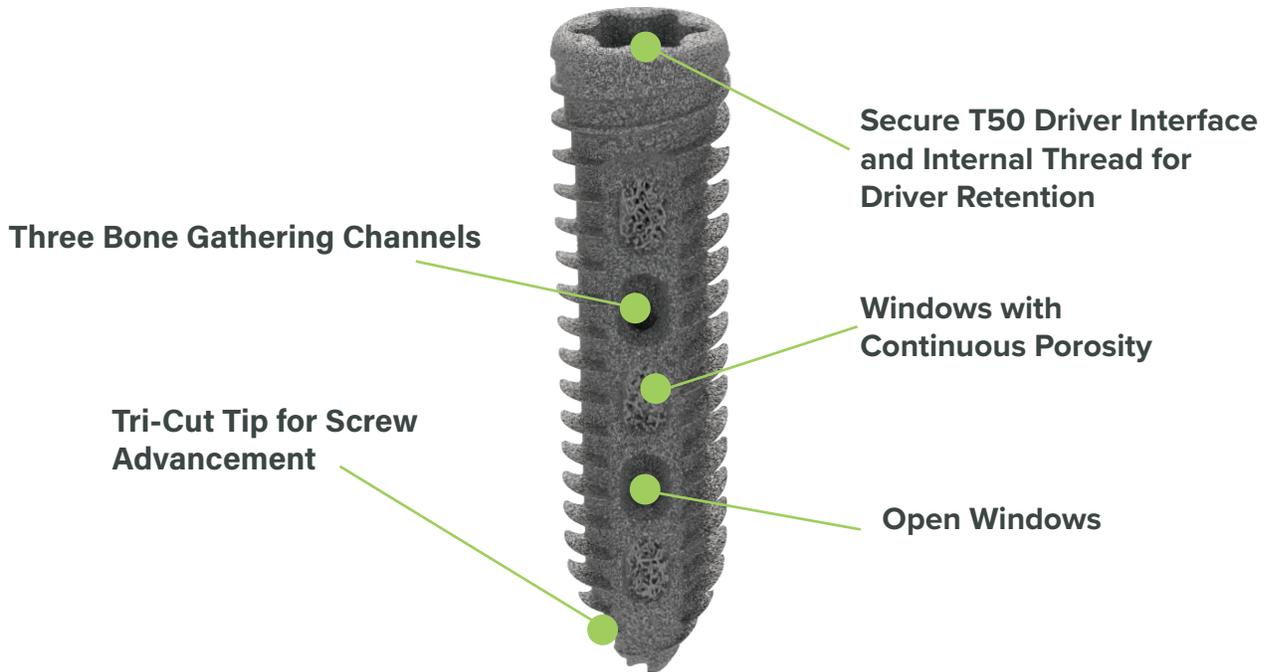
TRITON[®]

Sacroiliac Joint Fixation System

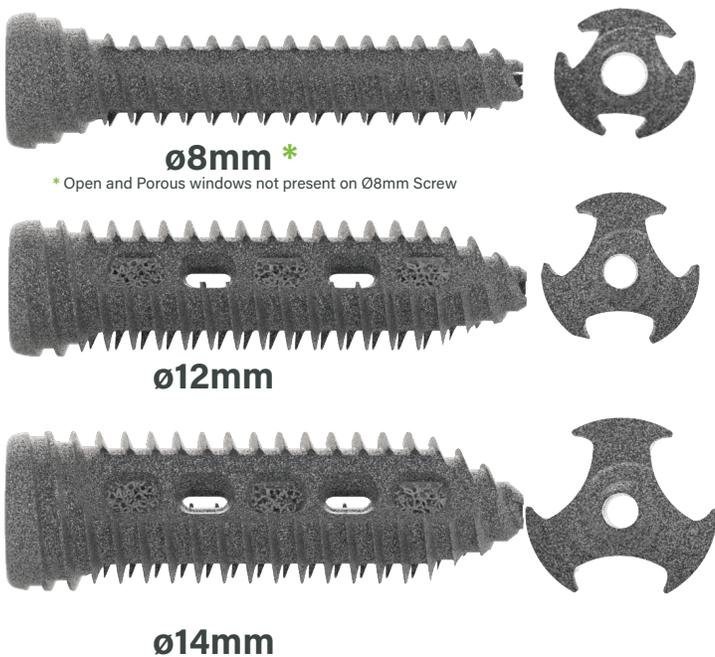


Introduction

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



ø8mm *
* Open and Porous windows not present on Ø8mm Screw

ø12mm

ø14mm

Simple Instrumentation



Bone Gathering Channels



Fixation



TRITON SI FUSION

Posterior Approach Technique- This technique is for a 2-screw fixation of the SI joint. The patient is placed in the prone position and secured to the table. Prior to iodine prep, single C-Arm Fluoroscopy imaging is used to identify key anatomical landmarks and to mark the incision point on the skin.

The fluoroscopic pelvis views utilized in this procedure are the lateral view, inlet view, outlet view, and teardrop 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.



Teardrop View: Allows the pelvis to be viewed

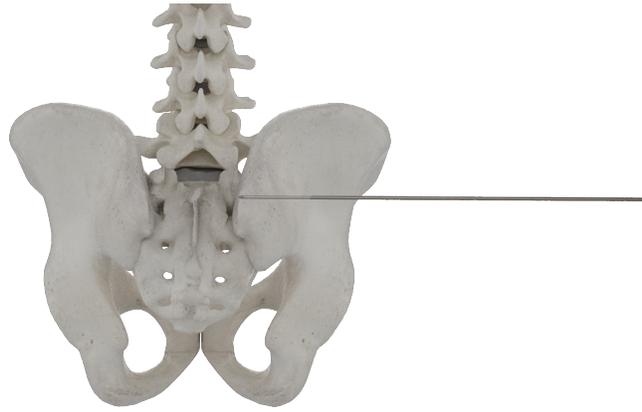


- The lateral view should be adjusted until the ala are superimposed to form 1 line on the image.
- The location of the C-arm and position of the C-arm should be noted or marked to allow the radiology technician to easily return to each of the 4 views.
- The position of the C-arm for the teardrop view is approximately 20 degrees towards the patient's head and 20 degrees contralateral to the side of the surgery

Prior to draping the patient, the location of the incision is marked on the skin. Place the C-arm in the teardrop view position for this marking. The ideal incision location is 1-2 finger breadths lateral to the lateral boarder of the teardrop. Mark this location on the skin. The incision typically extends approximately 1-2 cm

Drape the patient, ensuring the area around the skin marking is free of drapes or other obstructions. Start with the C-arm in the teardrop view of the pelvis. Confirm that draping has not altered the skin marking. Adjust the incision location if needed. Incise the skin and expose down to the posterior superior iliac spine (PSIS). A bovie is typically used to open the fascial layer.

The ideal starting point for the first screw is the 3 O'clock position on the teardrop view (need image indicating where 3 position is on teardrop x-ray). Take a bone marrow aspiration/biopsy needle and place the needle tip slightly above the 3 O'clock position on the anatomy forming the "teardrop" image. Angle no more than 5 to 10 degrees laterally and advance the needle into the posterior cortex of the PSIS.



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Move the C-arm back to the teardrop view and advance the needle across the joint. The trajectory of the needle should be perpendicular to the visible sacroiliac joint. Continue to advance the needle tip until it is 5-10mm past the contralateral side of the sacroiliac joint. Be careful not to advance the needle too far past the joint, as some advancement of the K-wire may occur during drilling or screw placement.



Move the C-arm to the inlet view. Check to ensure the needle and wire are within the Ala of the sacrum and are not violating the pelvic brim. Adjust the depth of the needle as needed.

Tissue Dilation

Move the C-arm back to teardrop view. Insert a blunt K-wire (M070-KN124) or exchange pin (KI-094-20) through the biopsy needle cannula. The biopsy cannula should then be removed, and Dilator 1 (Q070-0001) placed over the K-wire/pin.



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



NOTE: The depth gauge provided in the set, for screw length measurement, is for use with the sharp Steinman pins which are not recommended for use with the posterior approach technique. Screw length will be measured during the drilling step.

Slide "Dilator 2 with Handle" (Q070-0002) over Dilator 1 if implanting a Ø8mm or Ø12mm screw. Slide "Dilator 2 without Handle" (Q070-0003) over Dilator 1 and then slide Dilator 3 (Q070-0004) over "Dilator 2 without Handle" if implanting a Ø14mm screw. Remove the internal Dilator(s), leaving the final Dilator

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**.



Tissue Dilation

Under sizing screw preparation instrumentation may help in hard bone. With the C-arm in the teardrop view, guide the instrument over the K-wire/Pin and through the Dilator. Advance the instrument 5 to 10mm beyond the contralateral side of the SI joint.

The drills have 5mm depth markings on them. The drill depth marking that is flush or slightly above the proximal end of the dilator is the suggested screw length. Screw length selection can be adjusted 5mm above or below this suggestion based on desired depth of screw tip. The screw tip should extend at least 5mm beyond the SI joint to ensure the tapered tip of the screw is fully beyond the contralateral side of the joint.

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.

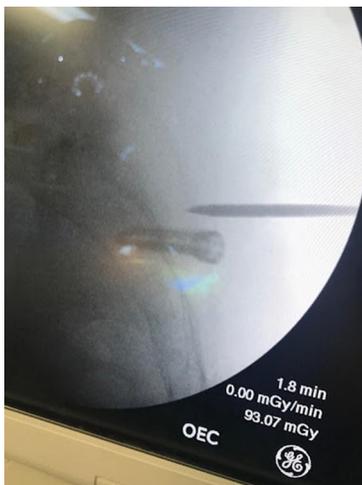
Guide the Screw and **Screwdriver** through the final **Dilator** and over the **Steinmann Pin**. If implanting a $\text{\O}14\text{mm}$ Screw, the **Dilator 3 Adaptor** may be attached between the collars of the **Screwdriver** for proper alignment through **Dilator 3**.



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

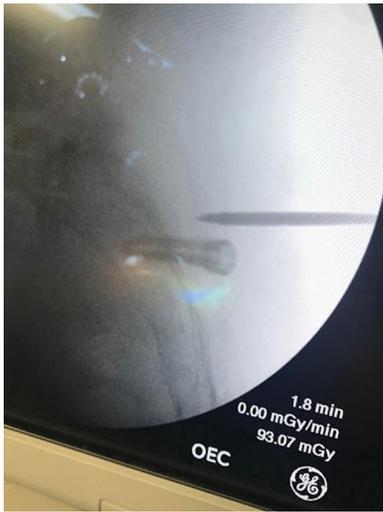
Place the screw over the K-wire and through the Dilator. (Note: Be sure to use the dilator during screw placement to prevent soft tissue and muscle trauma from the threads of the screw.) With the C-arm in the teardrop position, advance the screw through the bone. Use intermittent fluoroscopic imaging to ensure the trajectory of the screw matches the K-wire/Pin to limit/prevent K-wire/Pin advancement. Advance the screw to the desired depth. As the laser mark on the screwdriver becomes flush with the Dilator, this indicates that the screw is reaching a fully seated position. Fluoroscopic imaging and tactile feel should be utilized to determine the desired final position of the screw head.

Placement of the Second Screw



Move the X-ray machine into the lateral image position. Place the bone aspiration needle tip cephalad to the first screw, ensuring enough space is between the needle and first screw to allow the second screw to advance without interference between the 2 screws. The trajectory of the needle should be parallel to the first screw. Advance the needle into the PSIS just enough to hold that position. Move the C-arm to the teardrop position. In this view, the needle trajectory should be parallel to slightly divergent compared to the trajectory of the first screw.

Once the desired trajectory is established, advance the needle through the bone to the contralateral side of the SI joint. The needle should extend 5 to 10mm beyond the joint. Remove the needle and place the K-wire/Pin through the biopsy cannula. Repeat the steps used for preparing the first screw hole and inserting the first screw.



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 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

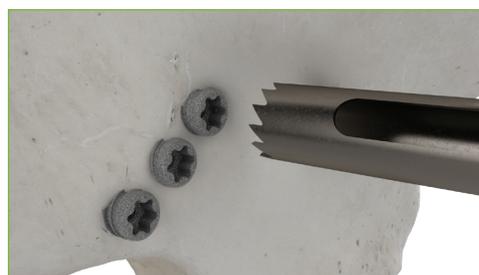
Primary Removal Method:

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	
<hr/>			
KI-094-20	Exchange Pin 20", Blunt-Blunt	3	
<hr/>			

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™ TI
Description

Spine the Right Way.™



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