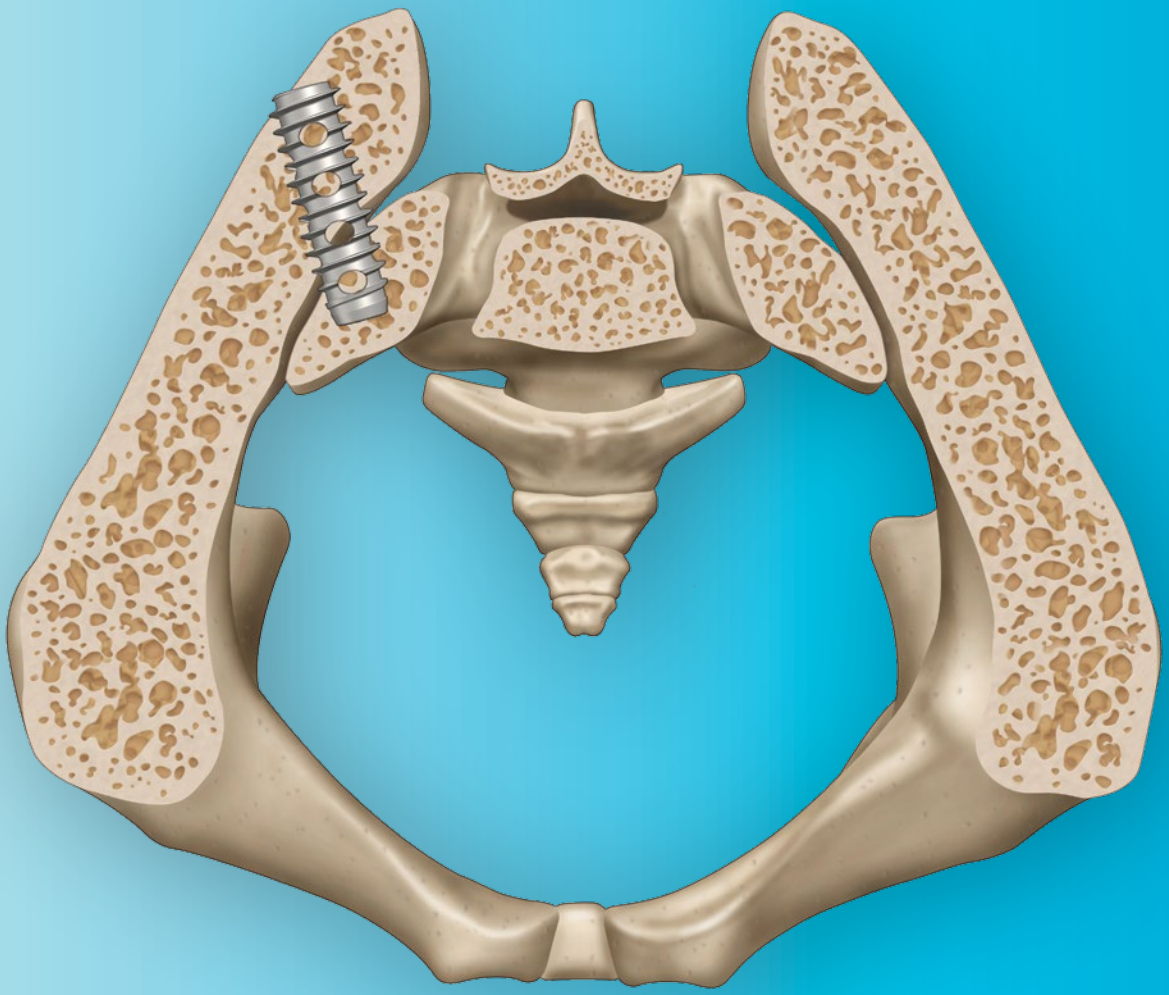
Medtronic

RIALTO™

SI Fusion System

Surgical Technique

MICHELSON TECHNOLOGY AT WORK



Medtronic

RIALTO™

SI Fusion System

Surgical Technique

Device Description

The RIALTO™ SI Fusion System consists of cannulated, fenestrated screws designed to enhance Sacroiliac Joint fusion and to provide fixation of large bones and large bone fragments of the pelvis. The screws are offered in various lengths to accommodate patient anatomy.

For fusion of the SI joint one, two, or three screws may be placed at surgeon's discretion.

Indications for Use

The RIALTO™ SI Fusion System is intended for Sacroiliac Joint fusion for conditions including Sacroiliac Joint disruptions and degenerative sacroiliitis.

Positioning

Position the patient prone **(Figure 1)**.

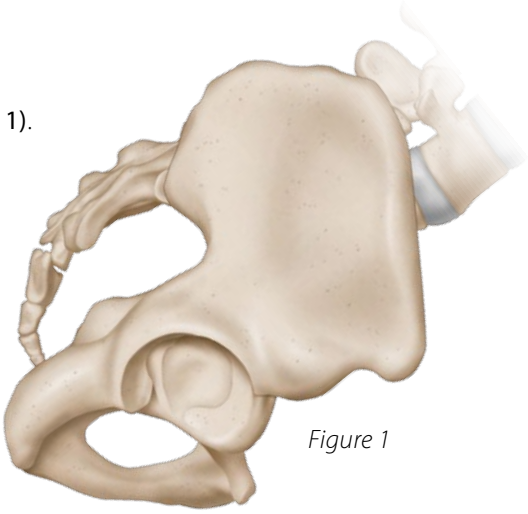
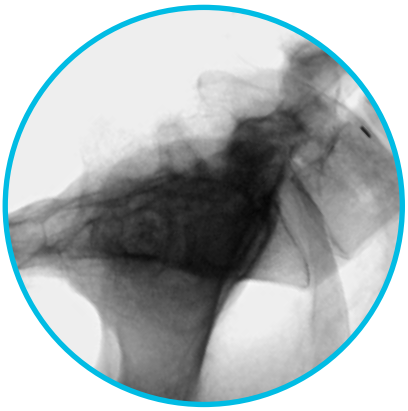


Figure 1



Lateral View

Palpate the posterior superior iliac spine (PSIS) **(Figure 2)** which is located approximately 3cm inferior and lateral to the L5/S1 joints.

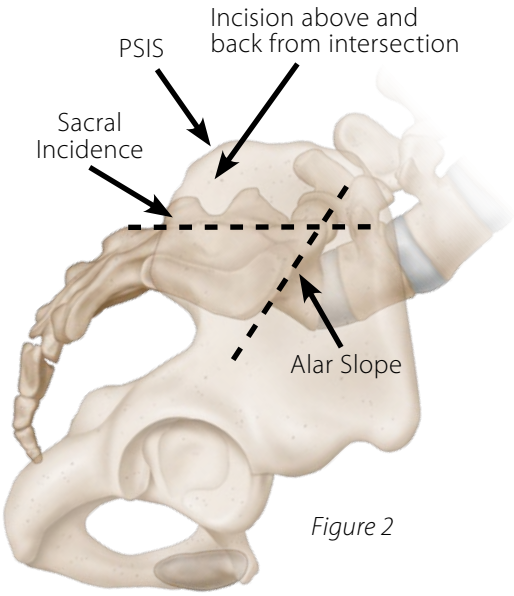
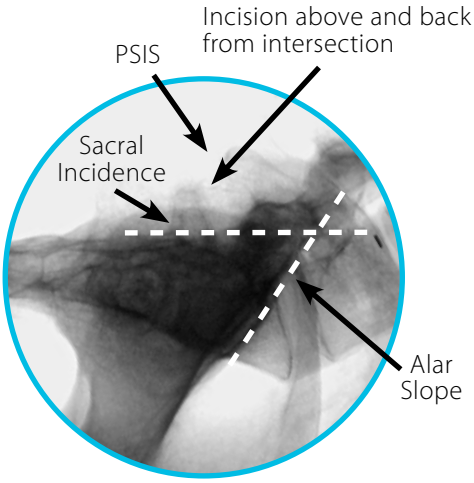


Figure 2



Lateral View

Needle or similar surgical tool, such as a guidewire, may be placed perpendicularly through the tissue down to the PSIS **(Figure 3)** as a reference.

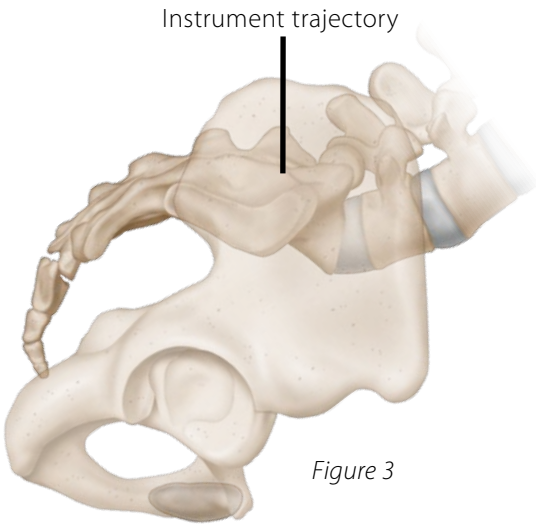
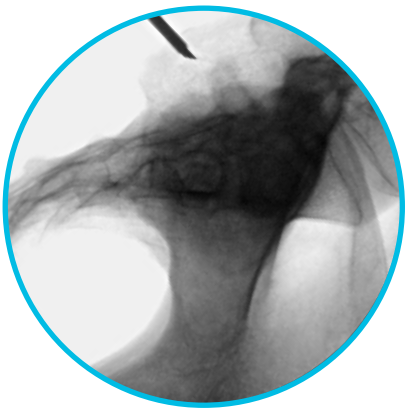


Figure 3



Lateral View

Take preliminary fluoroscopy to confirm PSIS location.

An alternative method of determining the cephalic to caudal location of the PSIS may be obtained using a sacral outlet view. In addition, this view may be used to determine the initial point of the incision. In general, the section of the PSIS that will accommodate the implants is located between the S1 and S2 foramen as shown (**Figure 4a**).

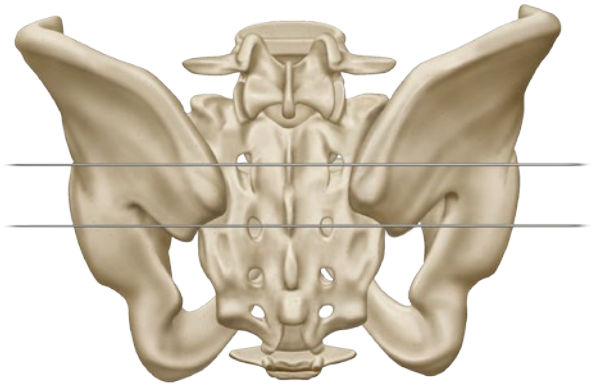
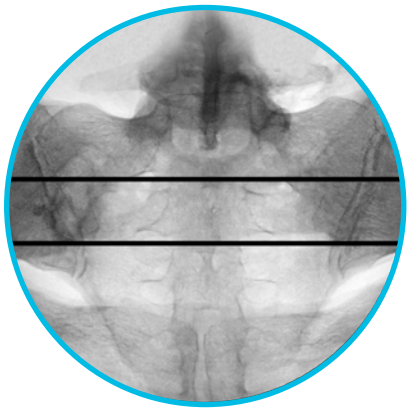


Figure 4a



Sacral Outlet View

Exposing Ilium

To expose the Ilium at site of implantation, incise and elevate the fascia away from the PSIS. Use a retractor, such as a Weitlaner, to expose the PSIS and hold tissue out of the way **(Figure 4b)**.

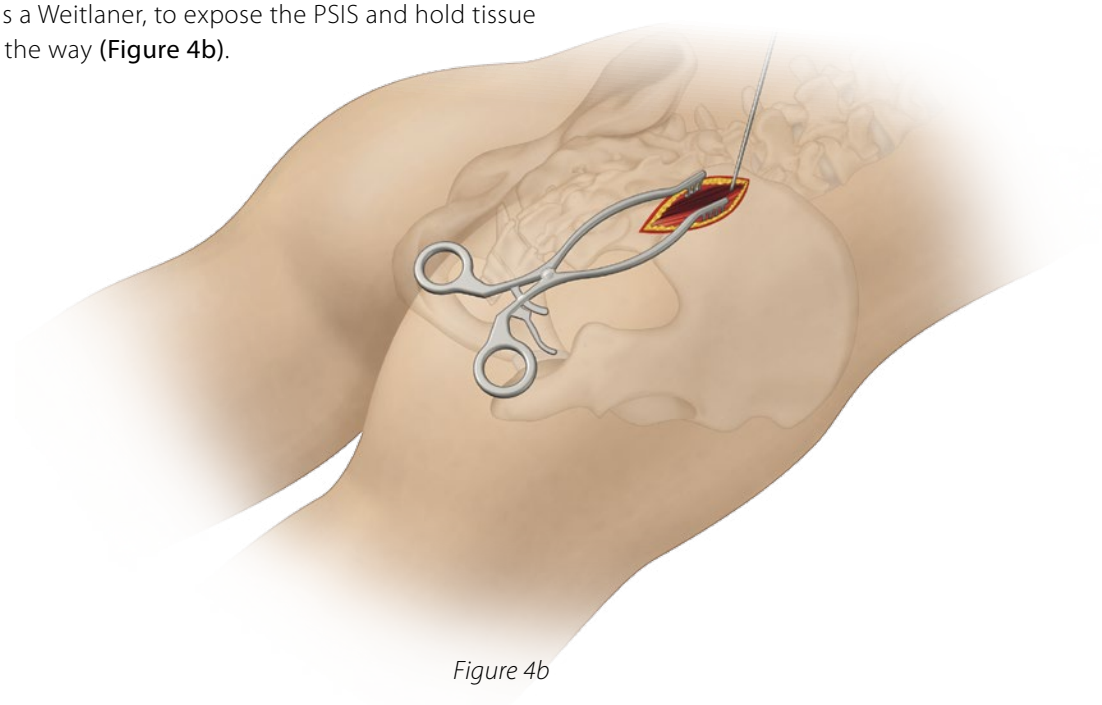


Figure 4b

Guidewire Placement

Advance the guidewire through the Ilium, across the joint, and into the Sacrum **(Figure 5)** to a depth of approximately 4cm-5cm.

- Starting point on the lateral aspect of the PSIS.
- Trajectory toward the Sacral Promontory: approximately 10-15 degrees lateral to medial and 0-10 degrees cranial to caudal, these angles will vary with patient anatomy and positioning.

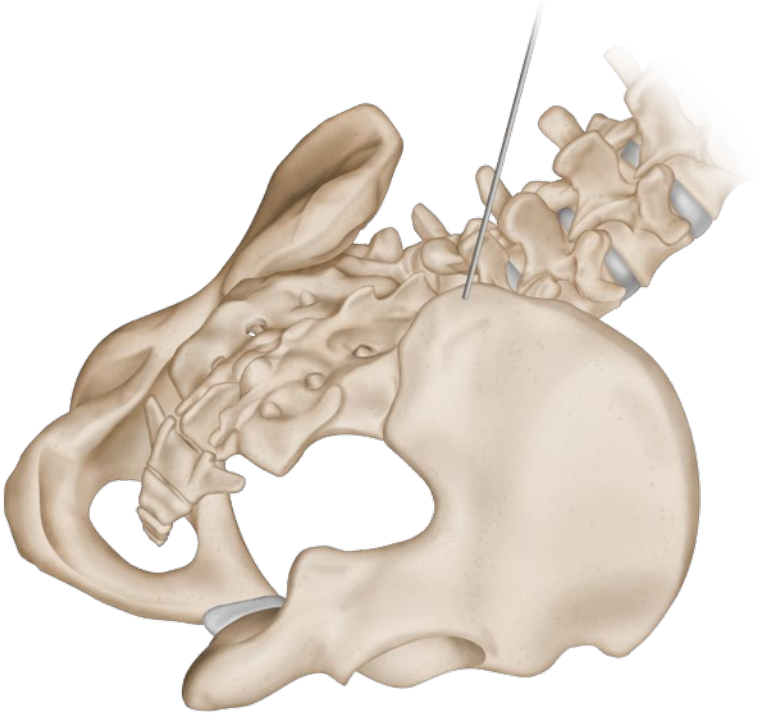
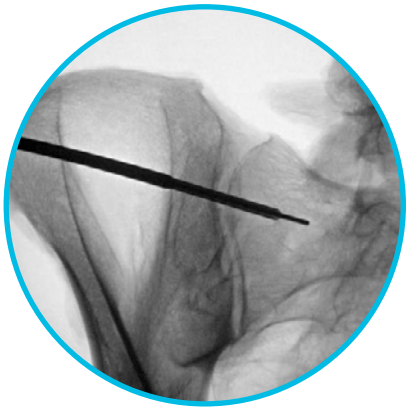


Figure 5



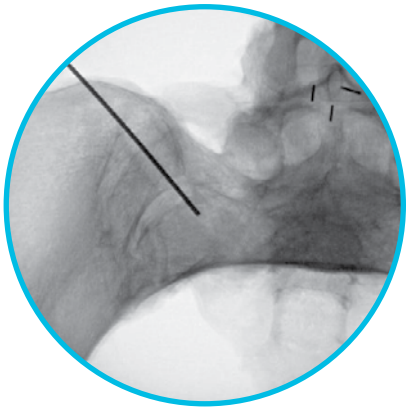
Posterior Oblique View

Verify Guidewire Placement

Guidewire placement through the Ilium, across the SI Joint, and into the Sacrum should be confirmed utilizing radiographic imaging. The distal end of the guidewire should remain approximately one centimeter from the Anterior Sacral Cortex.

Views may include:

AP, Lateral, Posterior Oblique, Inlet and Outlet views.



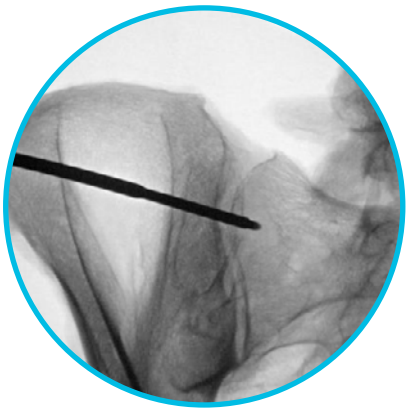
Sacral Inlet View

Screw Selection

Select the appropriate screw length based on individual patient anatomy.

» Screw length should be approximately 1cm short of the Anterior Sacral Cortex.

» Bone graft material may be packed into screws.

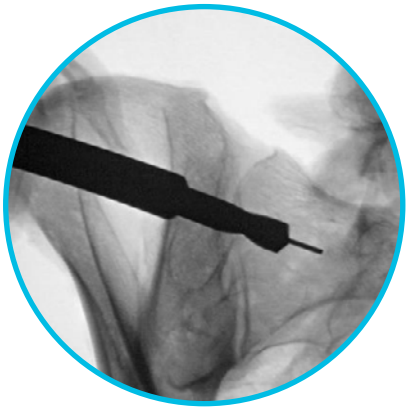


Posterior Oblique View

Drill

Set the depth stop on the drill to the selected implant length. Drill over the guidewire until the depth stop makes contact with the Ilium.

Drill position should be confirmed with radiographic imaging. Guidewire may be removed upon completion of drilling step.



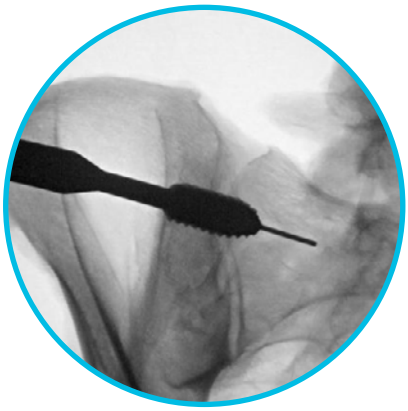
Posterior Oblique View

Note

Radiographic imaging should be utilized to ensure the guidewire does not advance during drilling step.

Note

At this point the surgeon may utilize standard surgical instruments, such as angled curettes, through the drilled channel, to access and debride the Sacroiliac Joint.



Posterior Oblique View

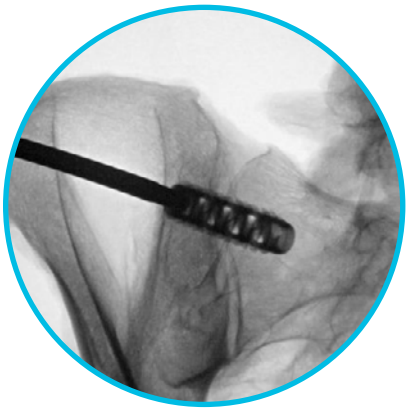
Tap

Set the depth stop on the tap to the selected implant length. The tap may be utilized over the guidewire. Advance the tap until the depth stop makes contact with the Ilium. The tap position should be confirmed with radiographic imaging. The guidewire, if used, should be removed upon completion of the tapping step.

Screw Insertion

Place implant on end of driver. Screw implant into prepared channel until the implant head is flush with Ilium. Implant position should be confirmed with radiographic imaging **(Figure 6)**.

Depth stop may be used with driver to provide visual confirmation of flush or 5mm countersunk.



Posterior Oblique View

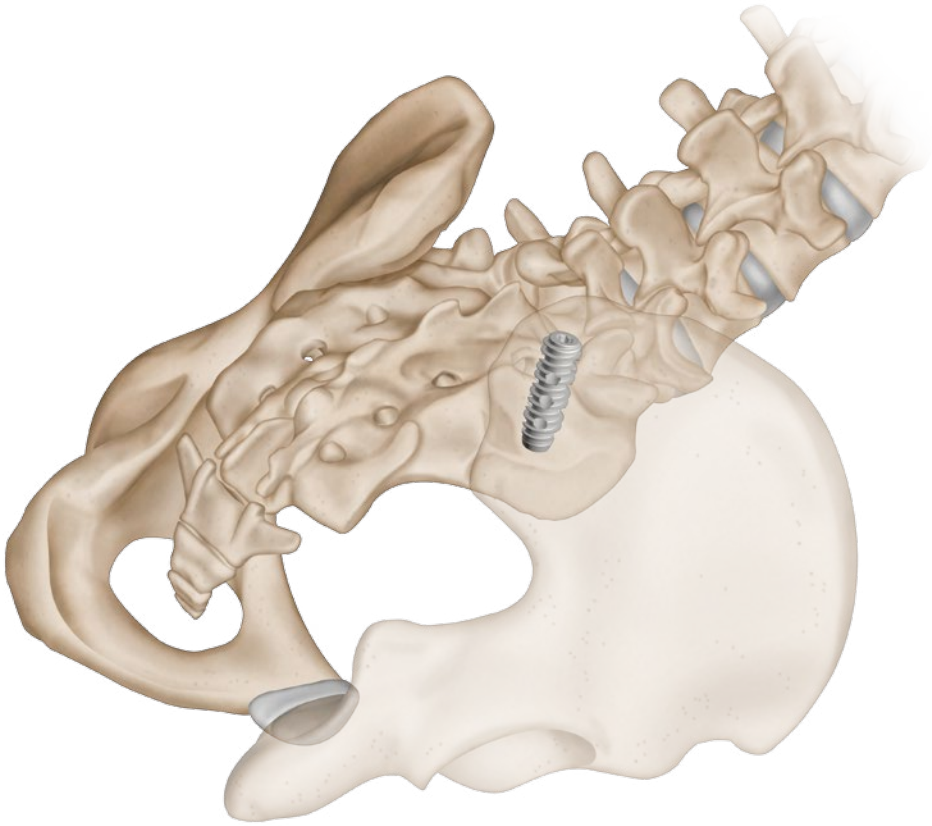


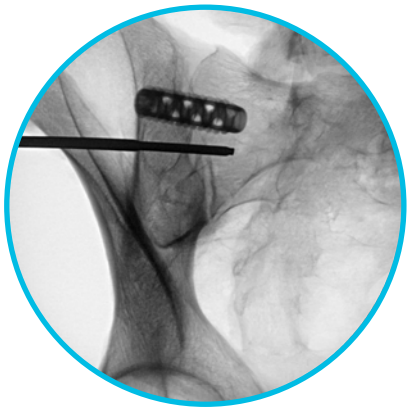
Figure 6

Screw Insertion *Continued*

As needed, place additional implants with 8mm to 10mm spacing between their outer diameter.

» Confirm trajectory via fluoro before placing second screw, following procedure for placing the first screw **(Figure 7)**.

Wherever possible, close the fascia over the PSIS with resorbable sutures.



Posterior Oblique View

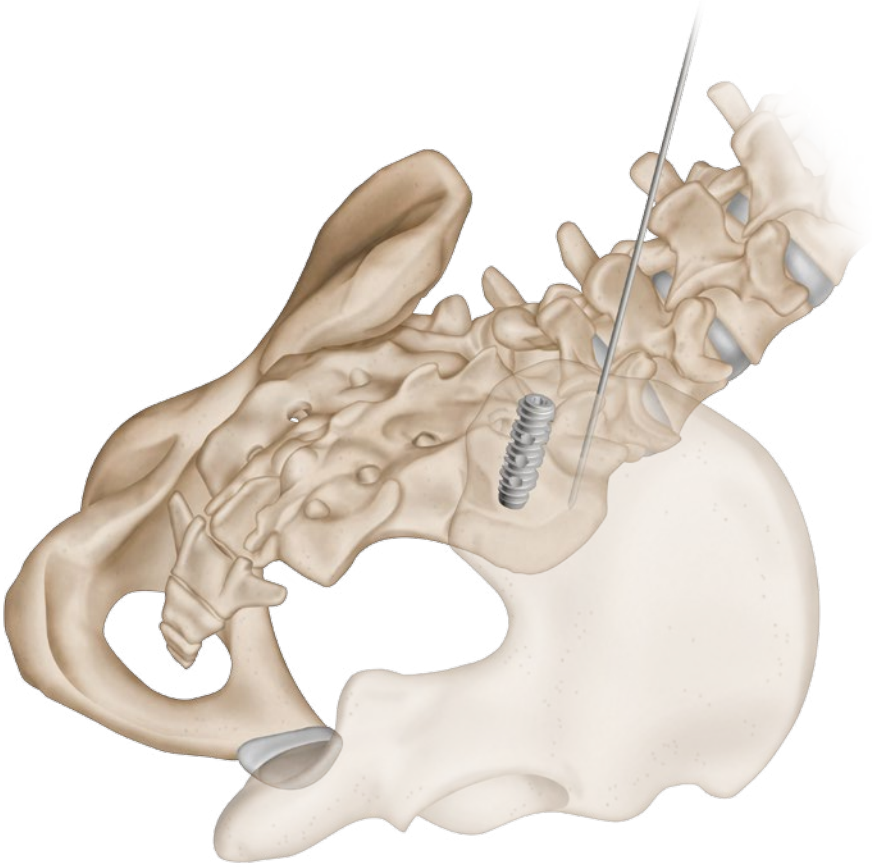
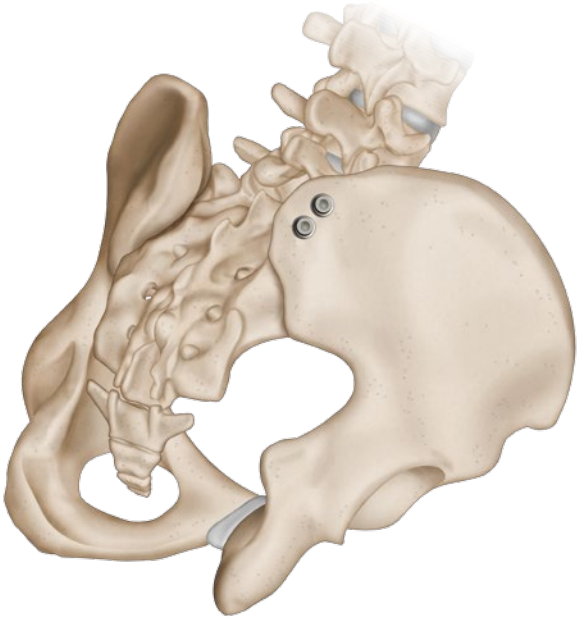
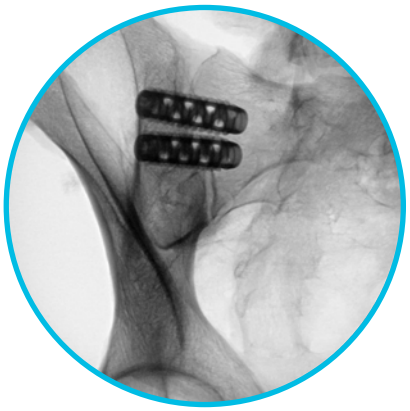


Figure 7

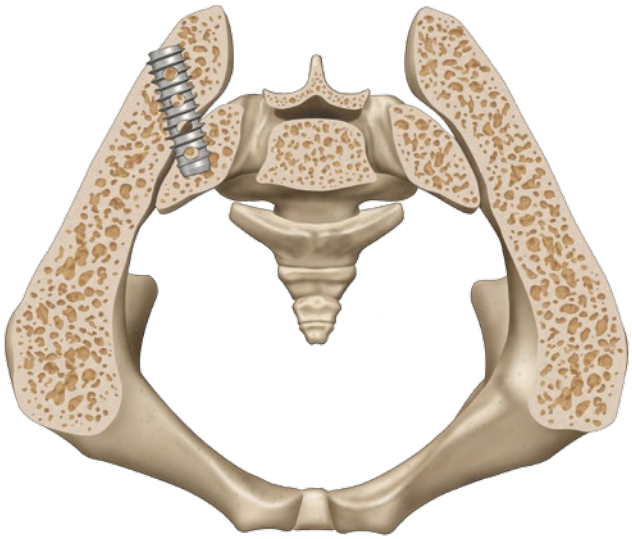
Final Placement



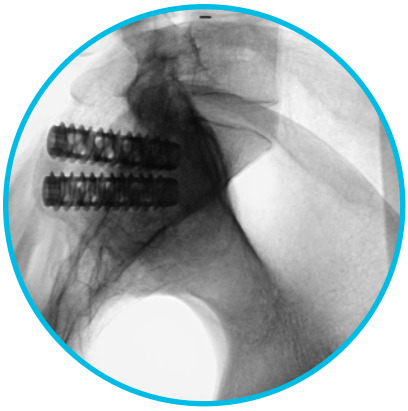
Oblique View



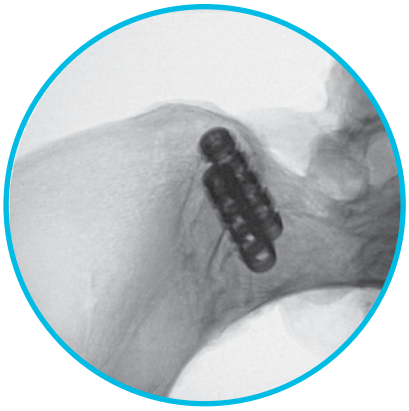
Posterior Oblique View



Axial View



Lateral View



Sacral Inlet View

Implant Removal

If implant removal becomes necessary, position the patient prone and make an incision two to three centimeters above posterior of the Sacrum as previously described. Retract in the same area adjusting as needed to find the head of the screw. The driver can also be used to remove the screw.

Product Ordering Information

RIALTO™ SI Fusion System Implants

Part Number	Implant Description (Size)
9000240	Large Screw 12mm × 40mm
9000250	Large Screw 12mm × 50mm
9000260	Large Screw 12mm × 60mm

Surgical Instruments that May Be Used with RIALTO™ SI Fusion System

Part Number	Instrument Description (Size)
9010000411	Funnel
9010000412	Tamp
9010000505	2.0mm Guidewire
9010000507	Depth Stop
9010000508	8.6mm Drill
9010000509	12mm Tap
9010000510	T27 Tapered Driver
9010000515	2mm Guidewire with Trocar End

Summary of Important Product Information for the RIALTO™ SI Fusion System

PURPOSE

This device is a fusion device intended for stabilization use and to promote bone fusion of the sacroiliac joint. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations. This device is manufactured from medical grade titanium alloy and is provided non-sterile.

DESCRIPTION

The RIALTO™ SI Fusion System consists of cannulated devices of various widths and lengths used to provide temporary stabilization when fusion of the sacroiliac joint is desired. Autograft and/or allograft may be placed in conjunction with the RIALTO™ SI Fusion System. This device may be implanted via a minimally invasive approach.

No warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use titanium or titanium alloy implants with stainless steel in the same construct.

INDICATIONS

The RIALTO™ SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS

The RIALTO™ SI Fusion System is contraindicated for patients with the following conditions:

- Deformities.
- Tumor resection.
- Infection local to the operative site and/or signs of local inflammation.
- Failed previous fusion.
- Suspected or documented allergy or intolerance to the component materials.

POTENTIAL ADVERSE EVENTS

The following are specific potential adverse events which should be understood by the surgeon and explained to the patient. These do not include all adverse events, which can occur with any surgical procedure, but are important factors to consider which are specific to metallic internal stabilization devices. Potential adverse events specific to this device are:

- Post-operative infection, wound necrosis or wound dehiscence.
- Pain, discomfort, or abnormal sensations caused by the presence of the implant.
- Metal sensitivity, or allergic reaction to a foreign body, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
- Migration, loosening, or fracture of the implant.
- Decrease in bone density due to stress shielding.

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

WARNING(S)

A successful result is not always achieved in every surgical case.

Patients who are pregnant or who are planning to become pregnant should not utilize this procedure.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.

Patients with previous surgery at the treated area may have different clinical outcomes compared to those without a previous surgery.

Proper patient selection and compliance will affect the results.

An implanted device should never be re-used unless otherwise specified. Implants which have come in contact with the patient are designed for single patient use only. Do not reuse, reprocess, or re-sterilize used implants. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death. Unused implants that have not been in contact with the patient or the patient's blood may be re-sterilized and used in subsequent procedures.

PRECAUTION(S)

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

FOR US AUDIENCES ONLY

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

Please contact Customer Service or your Sales Representative for the most up-to-date revision of the package insert for current indications, warnings, precautions and other important medical information.

Notes

www.medtronic.com

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

For more information visit
www.myspinetools.com

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

Medtronic