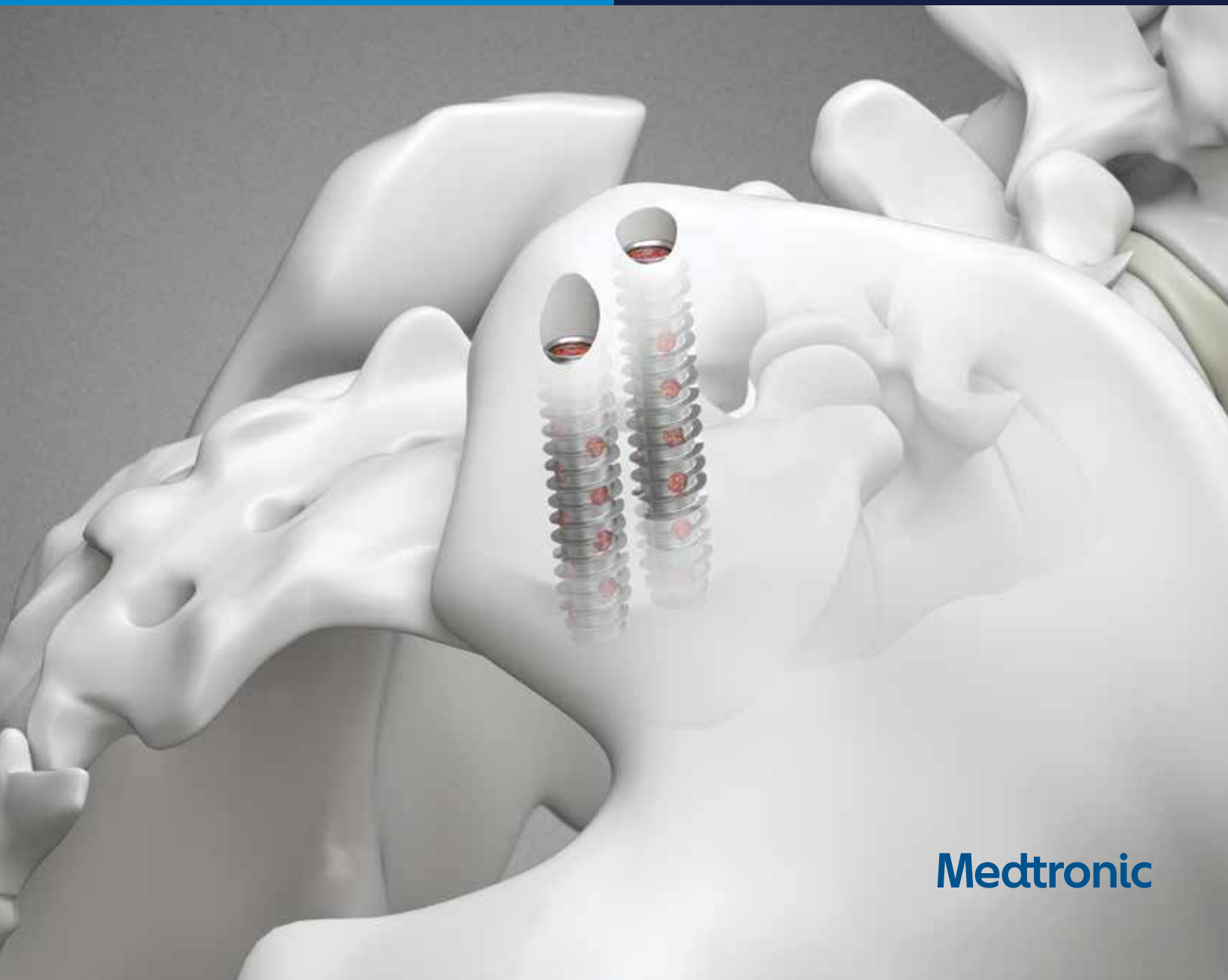
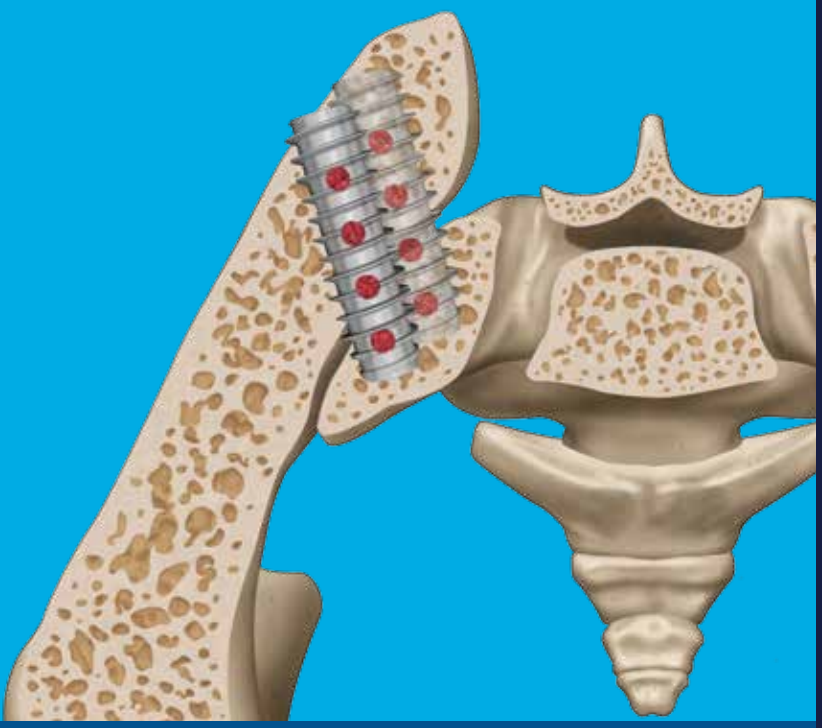
SURGICAL
TECHNIQUE

Rialto™
SI Fusion System



Medtronic



DEVICE DESCRIPTION

The Rialto SI Fusion System consists of cannulated, fenestrated threaded devices designed to enhance Sacroiliac Joint fusion. The threaded devices are offered in various lengths to accommodate patient anatomy.

For fusion of the SI joint one, two, or three threaded devices 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.

INSTRUMENTS

Adjustment Driver
7426000

Drill 8.6mm
7426002

Tap 12mm
7426003

T27 Threaded Driver
7426004

Depth Stop Assembly
7426001

IPC® POWEREASE® System

Funnel
7426005

Tamp
7426006

Packing Fixture
7426009

Packing Fixture Lid
7426010

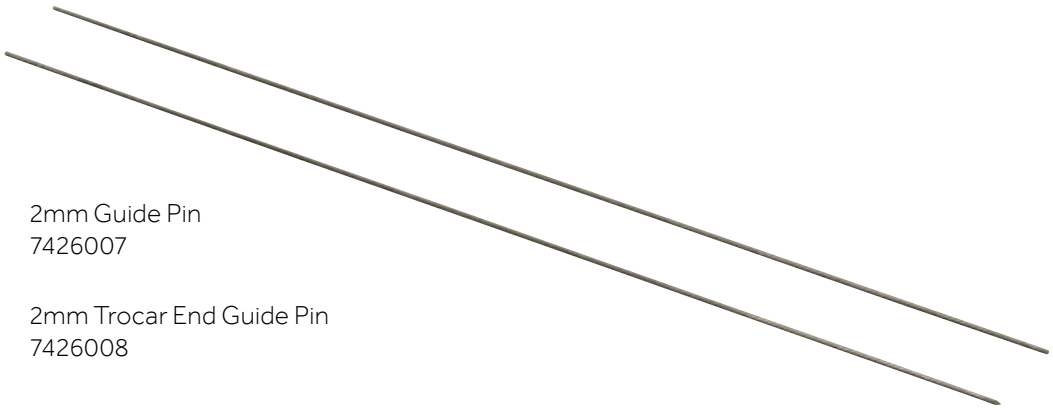
1/4" Quick Connect Handle
G900000

1/4" Quick Connect T-Handle
G900100

Recommended Disposables (Not included in the Instruments Sets.)

PAK Needles
8670009
8670010
8670015

Trocar Bevel



2mm Guide Pin
7426007

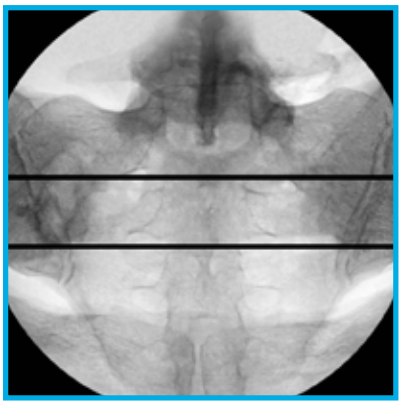
2mm Trocar End Guide Pin
7426008

FLUOROSCOPIC VIEW WORKFLOW

The descriptions and intended uses of the four fluoroscopic views obtained during the procedure are listed below. It may be helpful to establish these images prior to making the skin incision.

Sacral Outlet View

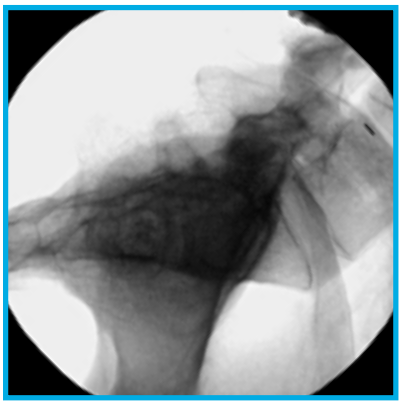
- Visualize the sacral foramina.
- May be used to approximate the location of the PSIS between the S1 and S2 foramen.



Sacral Outlet View

Lateral View

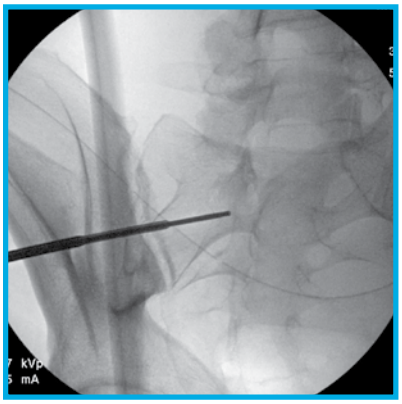
- Place the PAK Needle or preferred instrument at the desired entry point.
- Trajectory should be at or inferior to the sacral promontory and may be close to parallel to the S1 endplate.



Lateral View

Posterior Oblique View (PO)

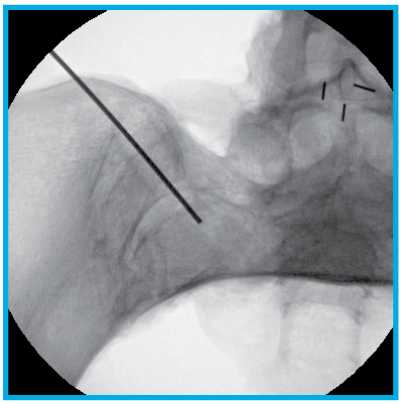
- Visualize the lateral wall of the PSIS, SI Joint, cranial and caudal borders of the Sacral Ala.
- Advance instrumentation through and past the joint utilizing this view.
- Confirm the instruments have crossed the SI Joint.
- Once the joint is crossed there is no need to continue into the anterior cortex of the Ala.
- The increased diameter step of PAK Needle shaft is 40mm from the tip which can be used as an estimate for the size of implant to use.



Posterior Oblique View (PO)

Sacral Inlet View

- Visualize the anterior sacral cortex of the Sacral Ala and the Pelvic Rim.
- Confirm that the instruments and implants have not violated anterior wall of the Sacral Ala.



Sacral Inlet View

POSITIONING

Position the patient prone **(Figures 1a and 1b)**.

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

Take preliminary fluoroscopy to confirm PSIS location.

Figure 1a

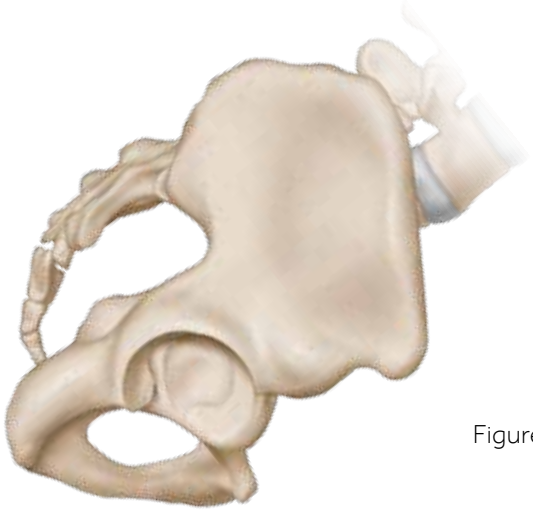
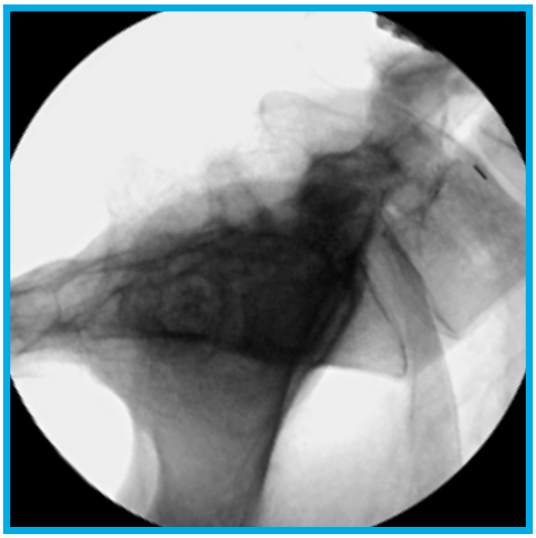


Figure 1b



Lateral View

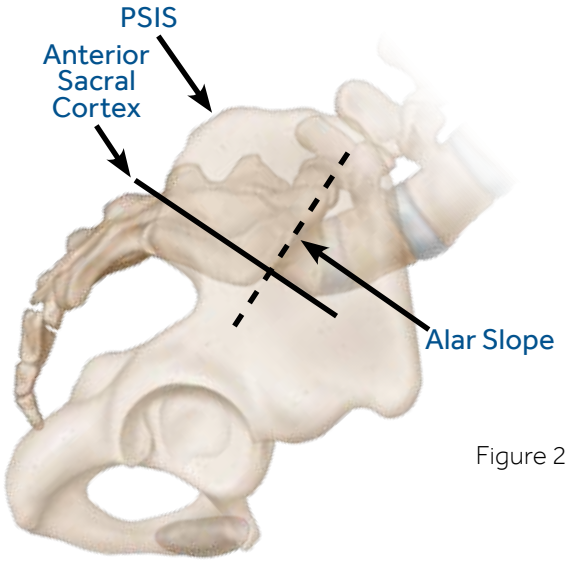
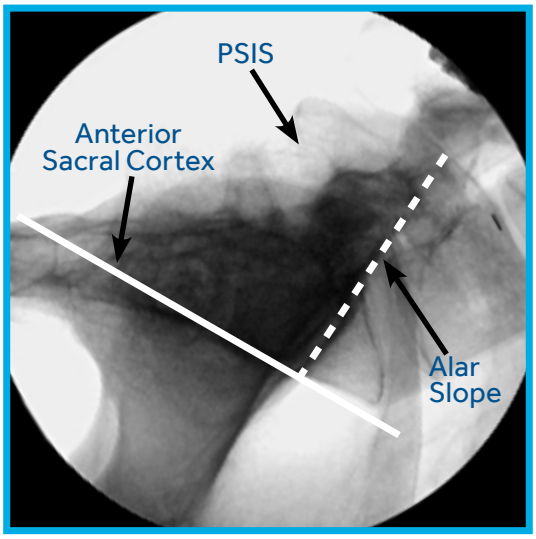


Figure 2



Lateral View

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 (**Figures 3a and 3b**).

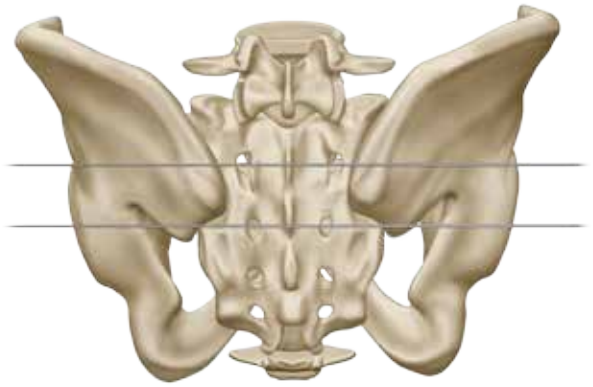


Figure 3a

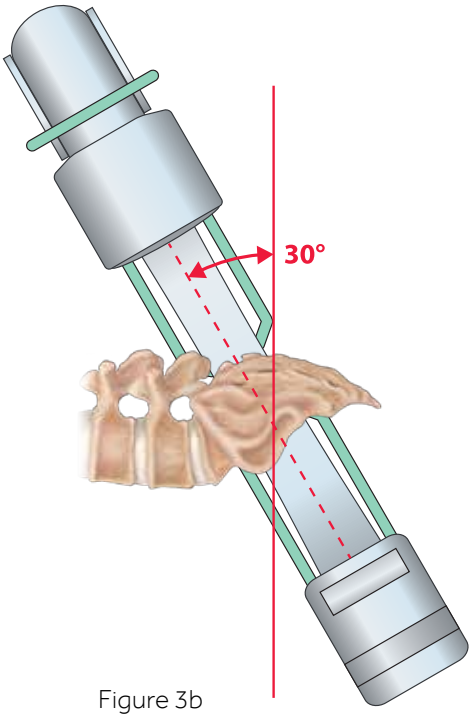
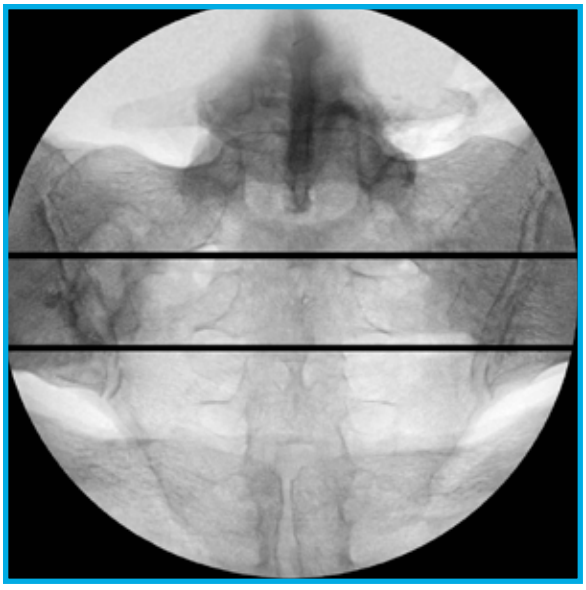


Figure 3b



Sacral Outlet View

EXPOSING
ILIUM

To expose the Ilium at the site of implantation, make a 20mm longitudinal incision approximately 10mm lateral of the PSIS 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 4)**.

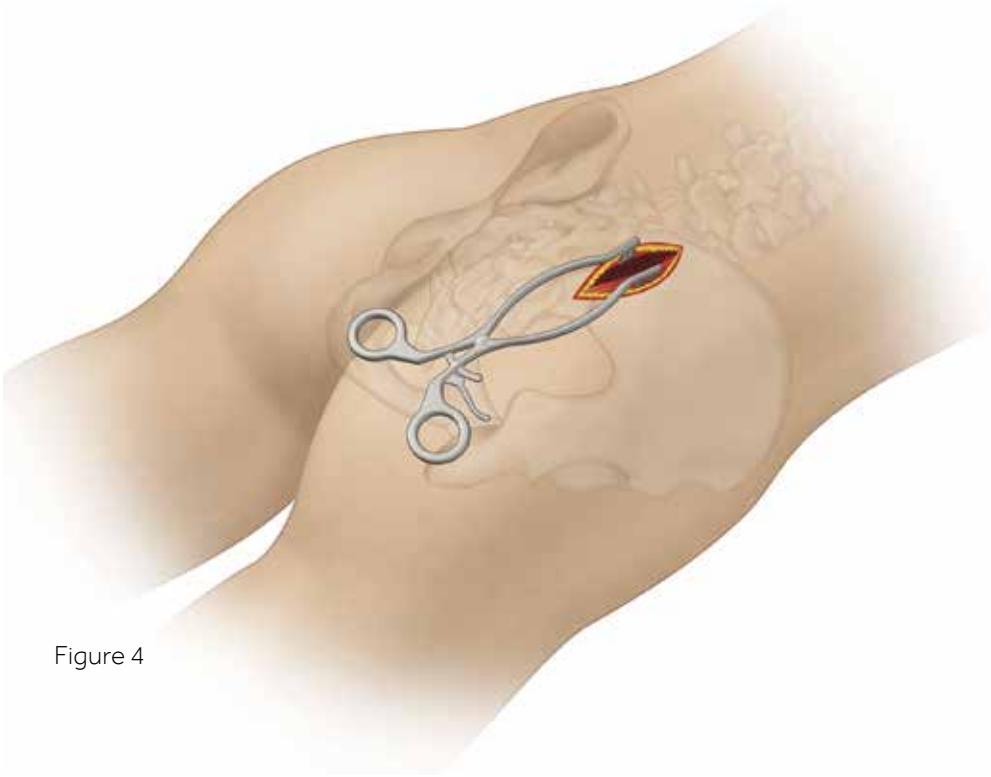


Figure 4

GUIDEWIRE PLACEMENT

Position the C-Arm to obtain a lateral image **(Figure 5a)**. This lateral view can be used to determine the orientation of the S1 endplate, the approximate ventral sacrum, and the sacral promontory. Place a PAK Needle through the incision and rest just lateral of the PSIS. Fluoroscopic imaging will confirm the cephalad-to-caudal trajectory of the PAK Needle. The trajectory should be generally parallel to the S1 endplate or pointed toward the sacral promontory **(Figure 5b)**.

Note

It may be helpful to place the caudal threaded device first to ensure adequate space is available along the PSIS.

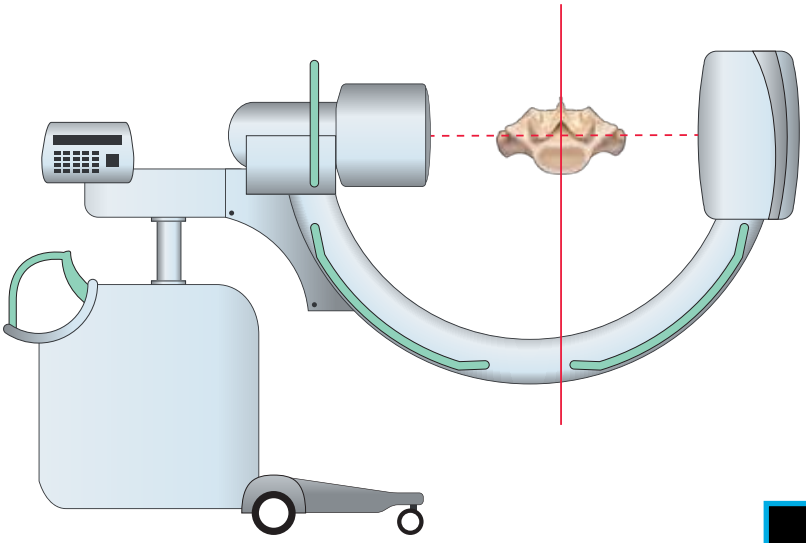


Figure 5a

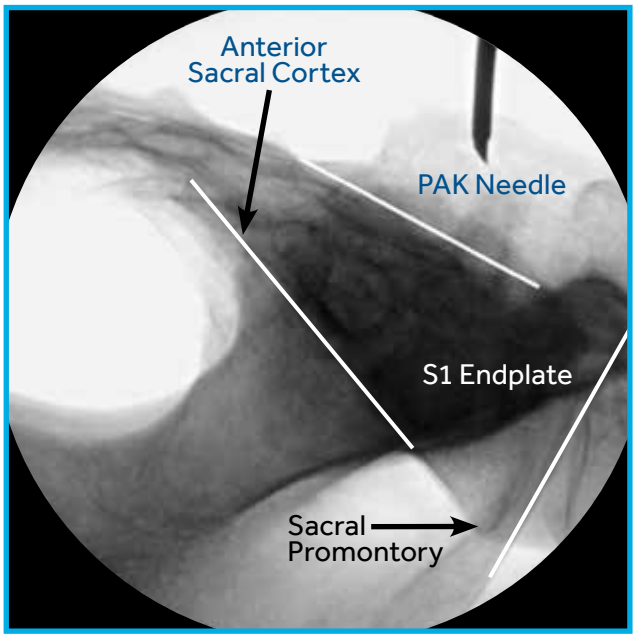


Figure 5b

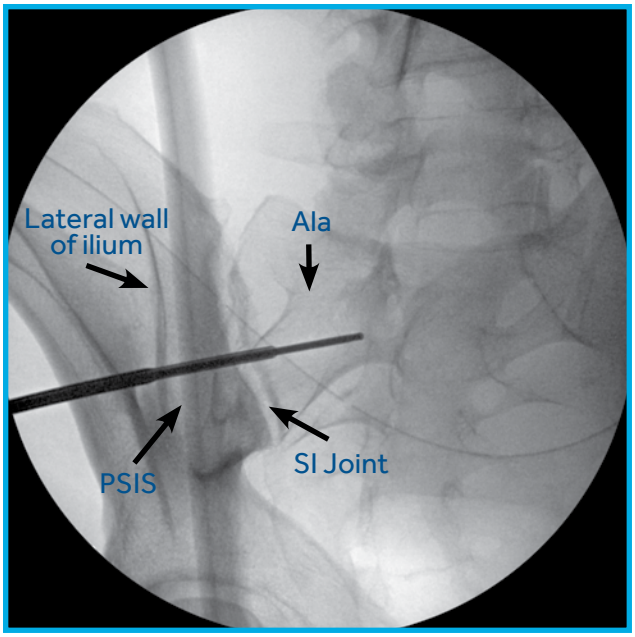
Advance the PAK Needle through the Ilium, across the joint, and into the Sacrum to a depth of approximately 4cm-5cm. Rely on a posterior oblique fluoroscopic view (shown on right) and tactile feedback to confirm crossing the SI joint with the PAK Needle.

- 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.

Image Guidance Suggestion

The oblique views are taken with the C-Arm positioned at a 25-30 degree angle to the AP plane **(Figure 6)**. An acceptable radiograph will demonstrate a closely collimated, centered SI joint with the anterior and posterior joint margins superimposed. The left posterior oblique image demonstrates the right SI joint as the side up, and the right posterior oblique image demonstrates the left SI joint side up. This view can show the lateral aspect of the PSIS, which is the incision site.

PAK Needle placement through the Ilium, across the SI Joint, and into the Sacrum should be confirmed utilizing radiographic imaging.



Posterior Oblique View

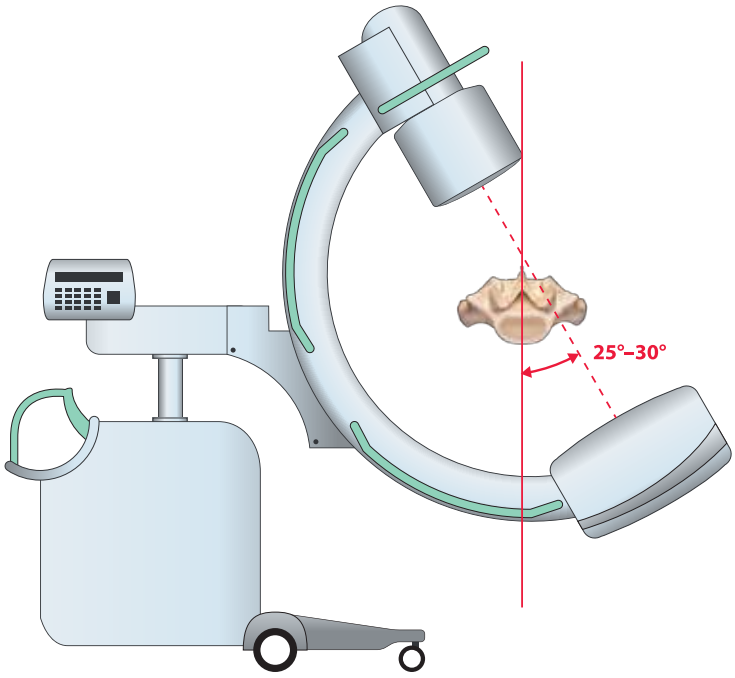
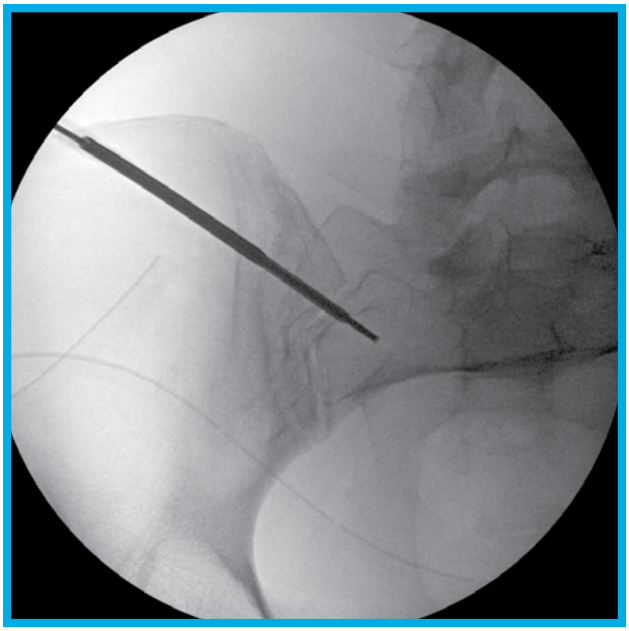


Figure 6

VERIFY
GUIDEWIRE PLACEMENT

The sacral inlet fluoroscopic view is taken with the C-Arm typically positioned at a 25-30 degree angle caudally to the AP plane **(Figure 7)**. An acceptable radiograph will demonstrate the complete, circular pelvic ring. Anatomically, this plane will be parallel to the anterior sacrum and thus the actual angle of the C-arm may vary. This view is critical for confirming depth and for avoiding violation of the anterior pelvic rim.



Sacral Inlet View

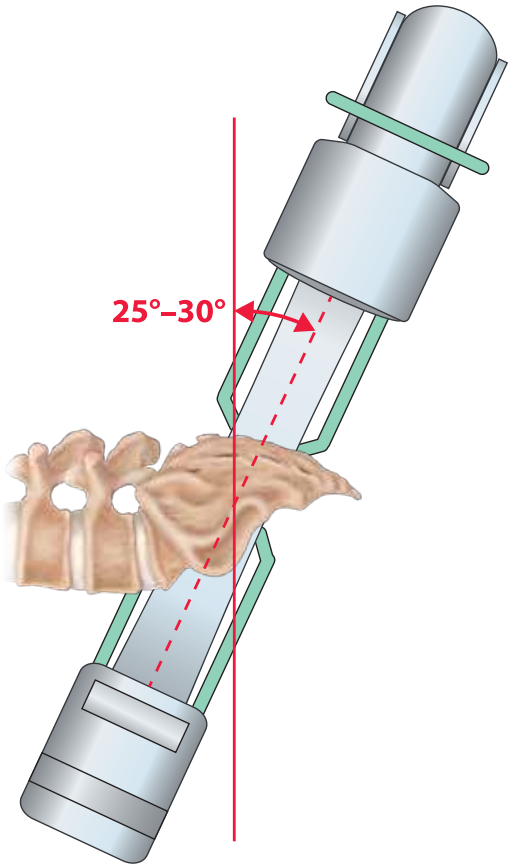


Figure 7

Once the PAK Needle placement has been verified using fluoroscopy, remove the inner stylet from the PAK Needle and insert the guidewire, either 7426007 or 7426008 **(Figure 8)**. These two guidewires are unique for the Rialto SI Fusion Device procedure. The distal end of the guidewire should remain approximately one centimeter from the Anterior Sacral Cortex. To confirm that the guidewire has not breached the Anterior Sacral cortex, move the C-Arm to the Sacral Inlet view.

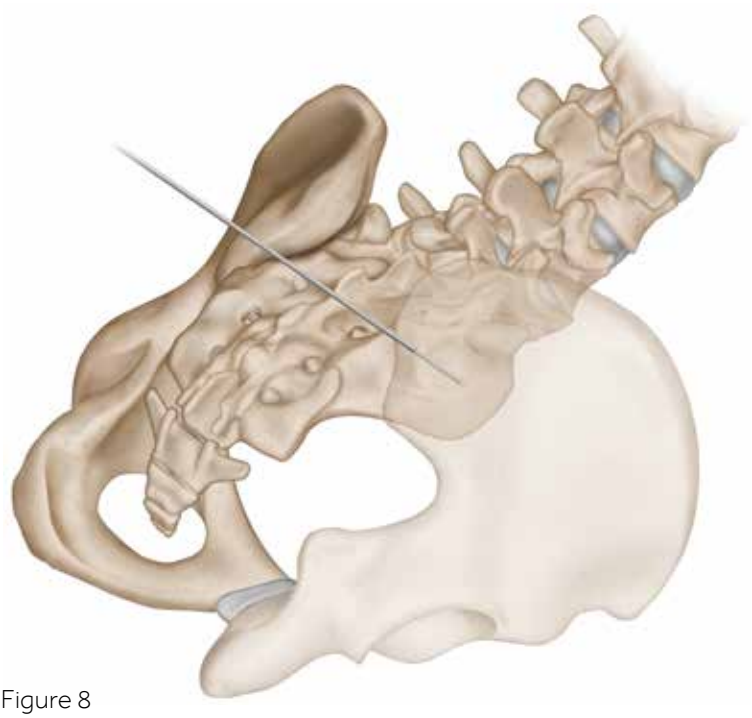


Figure 8

IMPLANT SELECTION

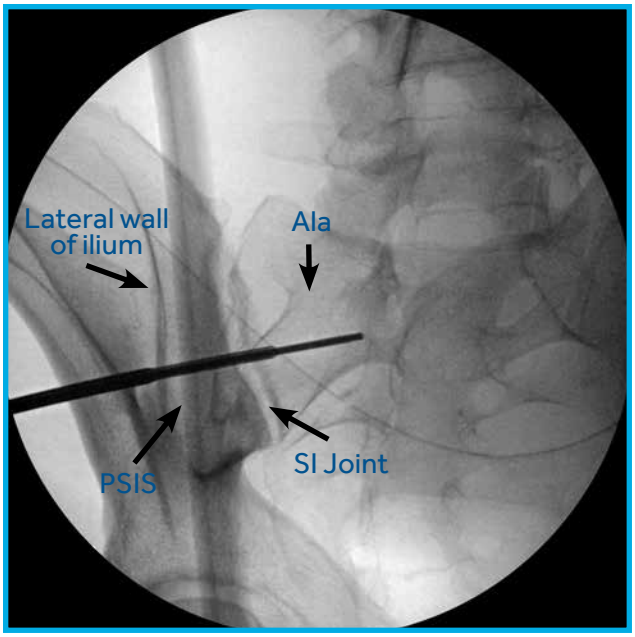
Select the appropriate implant length based on individual patient anatomy. Following implant placement, the recommended implant length will allow the head of the implant to be flush with the Ilium and the tip of the implant crossing the Sacroiliac Joint with at least one centimeter of penetration into the Sacral Ala. The implant should not penetrate the anterior Sacral Cortex.

Note

The PAK Needle diameter begins to increase 40mm from the tip of the instrument. The distal end of the largest diameter of the PAK Needle is 45mm from the tip. These increases can be visualized on fluoroscopy and are helpful when determining implant length.

Verify the PAK Needle lengths described above with a measuring device prior to use.

The drill and adjustable Depth Stop Assembly used in combination and under fluoroscopy can also be used to estimate the implant size. This process is described in the Drill section.



Posterior Oblique View

CONNECTING TO **IPC POWEREASE DRIVER**

The IPC Powerease System* may be used for drilling, tapping, and threaded device insertion. The IPC Powerease System is a system of powered surgical instruments designed specifically for use in spine surgery.

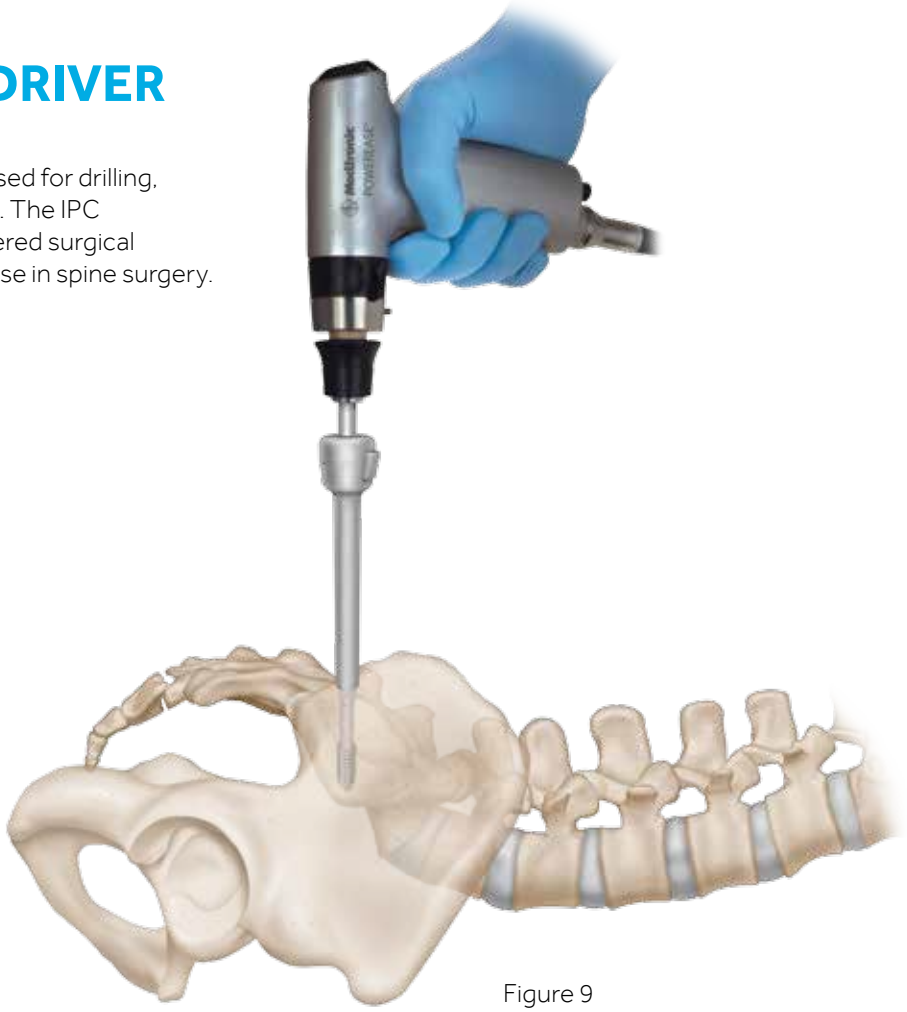


Figure 9

To assemble an instrument with the POWEREASE® Driver align the connection end with the Quick Connect on the POWEREASE® Driver and insert until the connection end of the instrument is fully seated within the Quick Connect of the Driver **(Figures 9a and 9b)**.

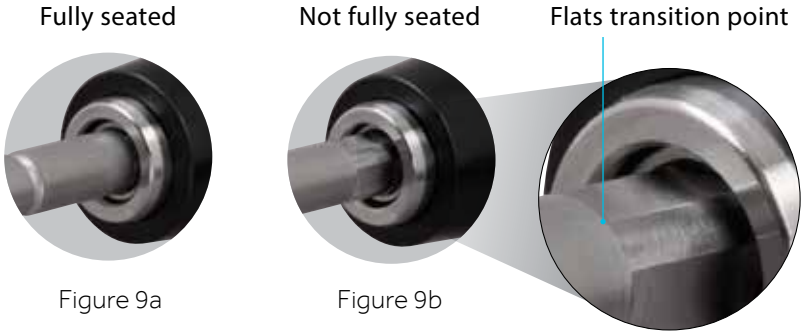


Figure 9a

Figure 9b

Flat sides should be fully inserted and not be visible.

*The IPC Powerease System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic Sofamor Danek USA, Inc.

DRILL

Set the depth stop on the drill to the selected implant length **(Figure 10)**. Drill over the guidewire until the depth stop makes contact with the Ilium.

If an implant needs to be estimated, set the Depth Stop Assembly on the 40mm depth marking and progressively drill while taking fluoroscopic images.

If the Depth Stop Assembly bottoms out on the ilium prior to being at the desired length, adjust the Depth Stop Assembly to the next setting. Repeat this process until an implant length can be estimated.

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

Note

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

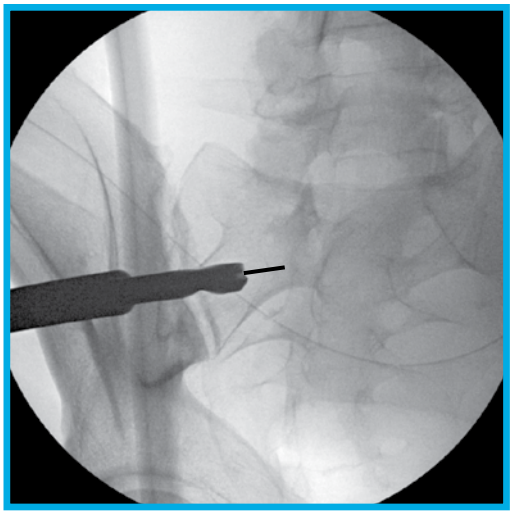
Note

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.

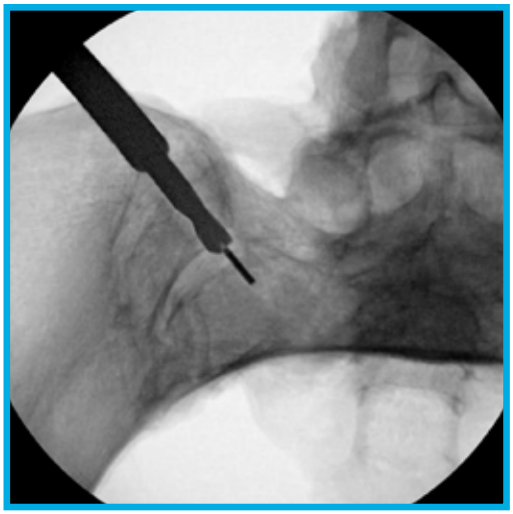
TAP

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.

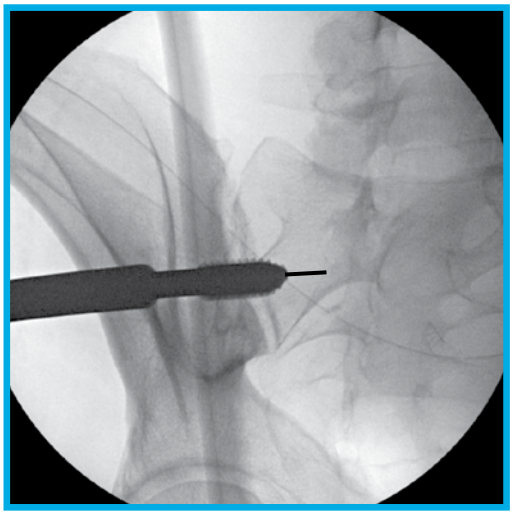
Figure 10



Posterior Oblique View



Sacral Inlet View



Posterior Oblique View

BONE GRAFT
PACKING

The Rialto Threaded Device should be packed with autograft or allograft material **(Figure 11a)**. The 40, 50, and 60mm implants will hold approximately 1.1cc, 1.5cc, and 1.9cc respectively **(Figure 11b)**.

Figure 11a

Figure 11b

IMPLANT
INSERTION

Thread the implant on the end of driver. Advance the threaded device into prepared channel until the implant head is flush with Ilium. Implant position should be confirmed with radiographic imaging **(Figure 12)**.

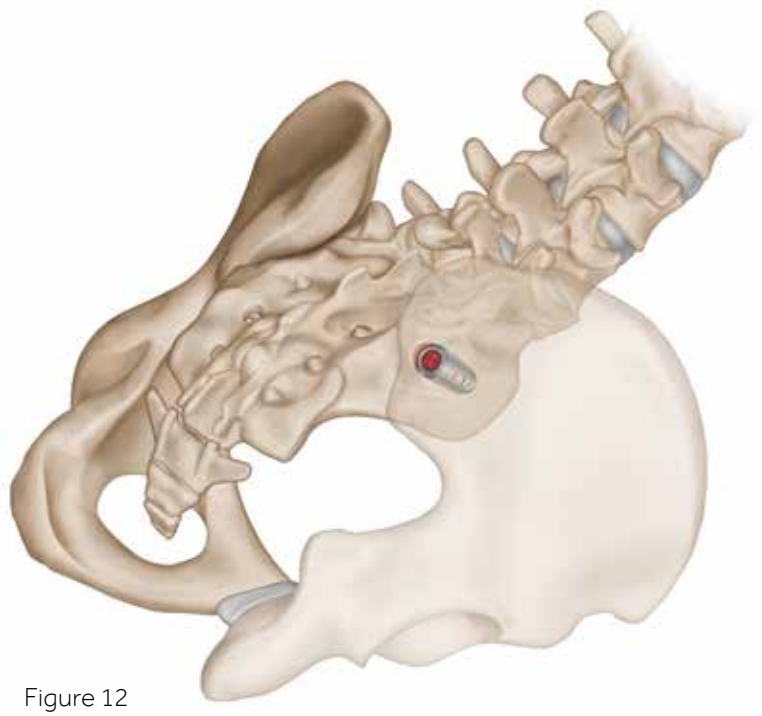
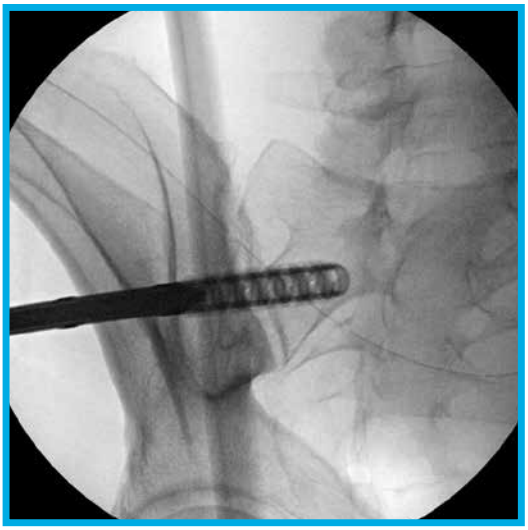
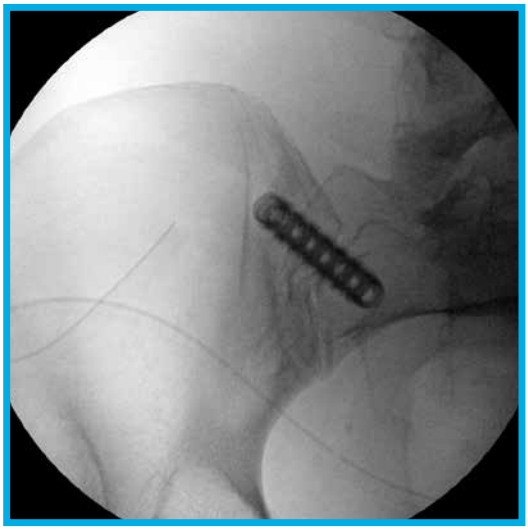


Figure 12





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

- Confirm trajectory via fluoroscopy before placing the second implant such that the distal ends of the implants do not collide, following the same procedure used for placing the first implant **(Figure 13)**.

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

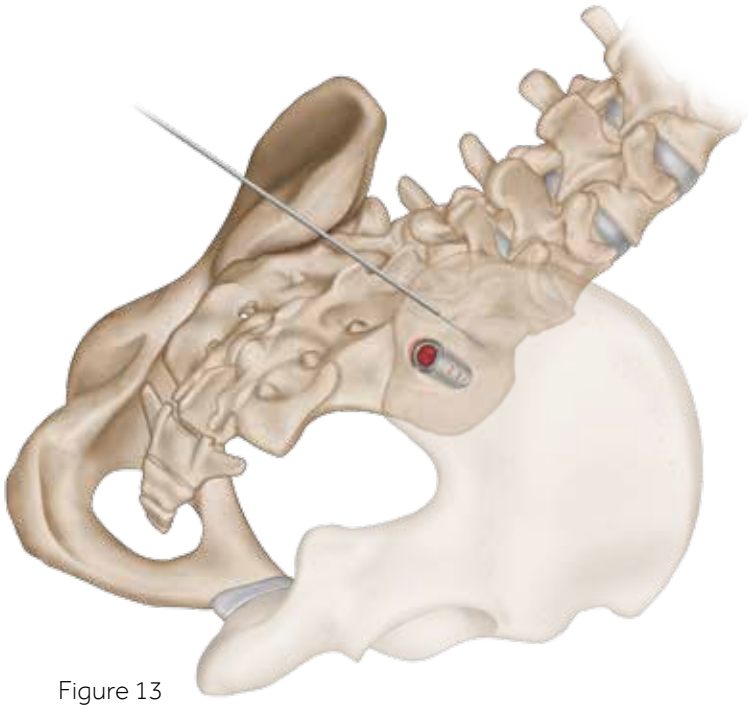
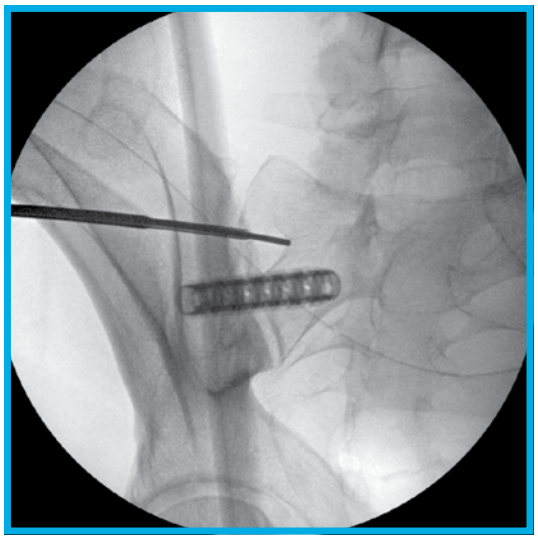
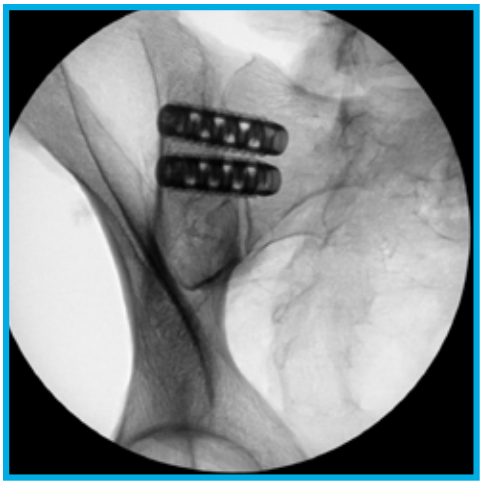


Figure 13

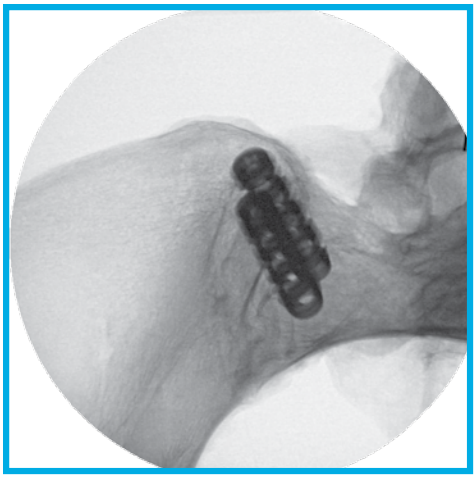


Posterior Oblique View

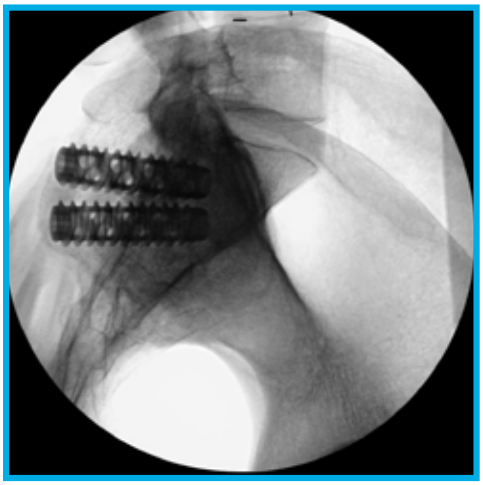
FINAL **PLACEMENT**



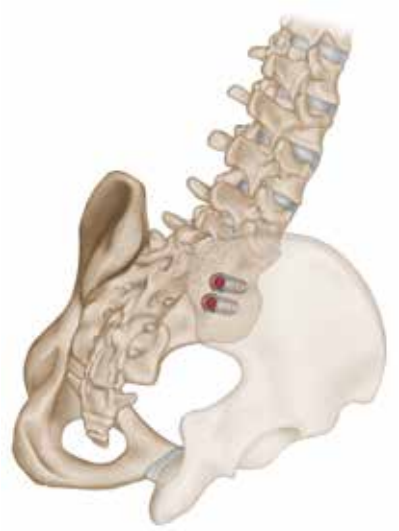
Posterior Oblique View



Sacral Inlet View



Lateral View



Oblique View

Lateral 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 Rialto System threaded device. The driver can also be used to remove the implant.

SURGICAL
TECHNIQUE

NAVIGATED RIALTO SI FUSION SYSTEM

INSTRUMENTS AND SET-UP

NAVIGATED RIALTO SI FUSION SYSTEM

INSTRUMENTS
AND EQUIPMENT

O-arm® Image
Acquisition System

Mobile Viewing
Station

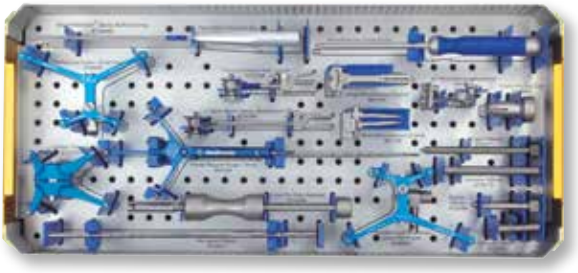
O-arm Imaging System

Staff Cart
with Camera

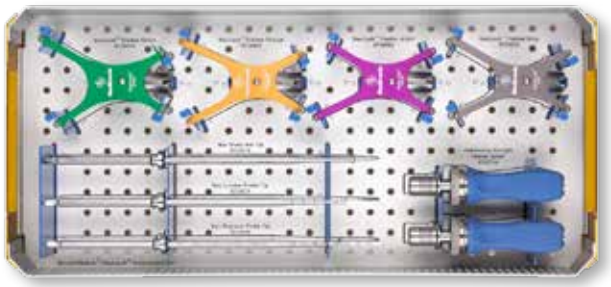
Surgeon
Monitor

StealthStation® S7® System

Powerease System
with Navlock Tracker



StealthStation Spine Referencing Set
(9734495)



StealthStation NavLock® Instrument Set
(9734833)

Spheres
(8801074)

Disposable Perc Pin
100mm (9733235)
150mm (9733236)

O-arm Sterile Tube Drape (optional)
(9732722)

Pilot Drill
NAV7426002

Funnel
7426005

Tamp
7426006

Packing Fixture
7426009

Packing Fixture Lid
7426010

Rialto Awl Tip Tap
NAV7426000

Driver
NAV7426001

EQUIPMENT AND **ROOM SET-UP**

For navigated surgery the OR should be equipped with the O-arm Image Acquisition System, the Mobile Viewing Station (MVS), and the StealthStation S7 System (**Figure 14a**). Plug the MVS into a power source; connect the MVS to the O-arm System, and power on the system. Next, power on the StealthStation S7 System and start the Synergy® Spine Software. Connect the MVS to the StealthStation S7 System network port with a network cable or a crossover cable.

The equipment set-up for Navigated Percutaneous Fixation Procedure has the StealthStation S7 Staff Cart with Camera positioned near the patient's feet.

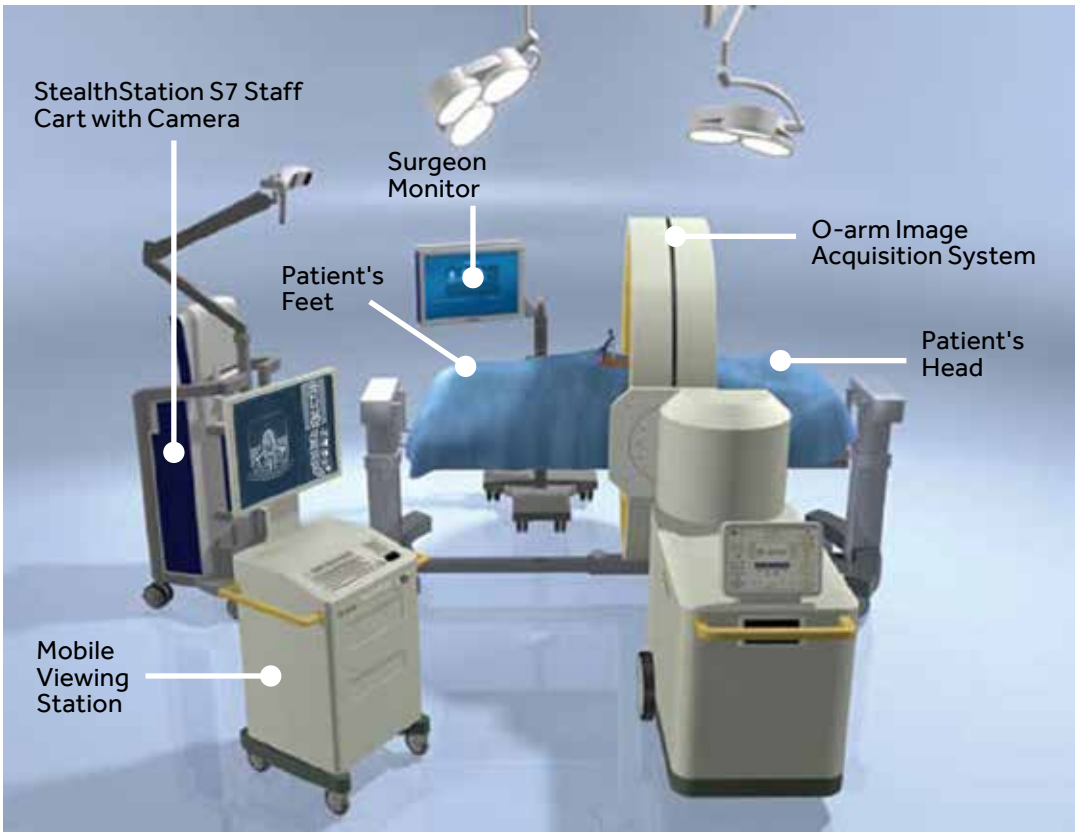


Figure 14a

When positioning the O-arm System for the procedure, place it around the patient table approximately seven inches closer caudally from the anatomy to be imaged (**Figure 14b**). The gantry should then be translated in the direction of the patient's feet for imaging. This will allow the gantry to be placed in a "park" position and remain in the sterile field throughout the procedure, if desired (**Figure 14c**).

The camera should be positioned at the foot end of the patient table so that the camera has an unobstructed line-of-sight to the Reference Frame which will be placed into the patient. Position the surgeon's monitor near the patient's side, opposite from the surgeon.

Place the patient in the prone position, lying flat on a Jackson Spine top table or a Jackson table with the Wilson frame.

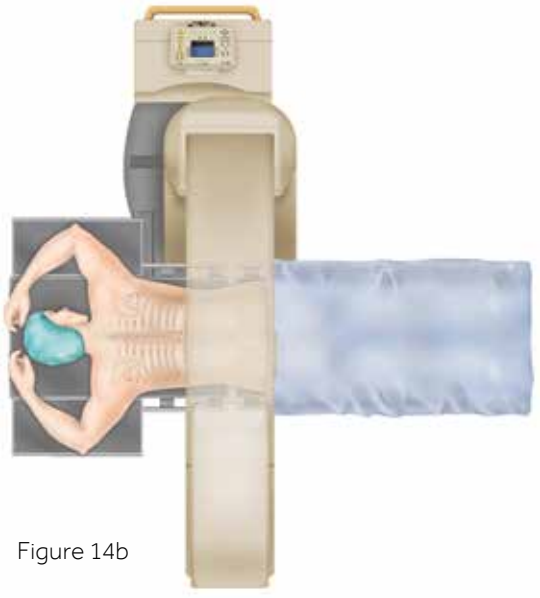


Figure 14b

Helpful Hint

If the O-arm System will remain in the sterile field during the procedure, drape the O-arm System gantry using the O-arm IAS Sterile Tube Drape during the positioning of the system. If the O-arm System will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient prior to positioning in the sterile field maintaining sterility around the patient while closing the gantry of the O-arm System (**Figure 14d**).

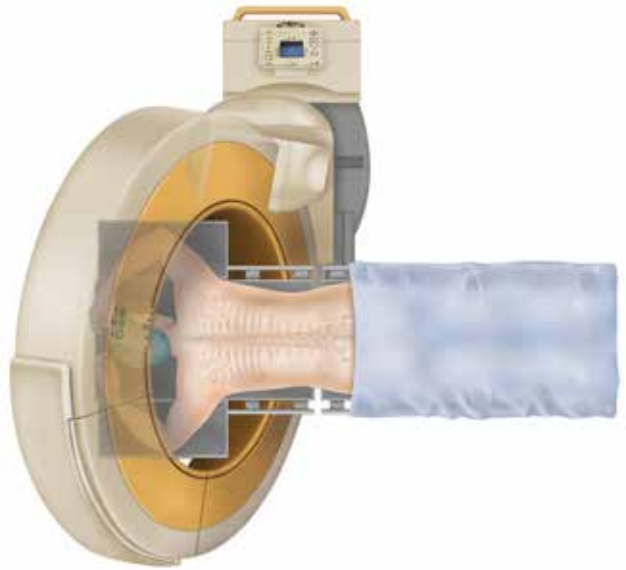


Figure 14c

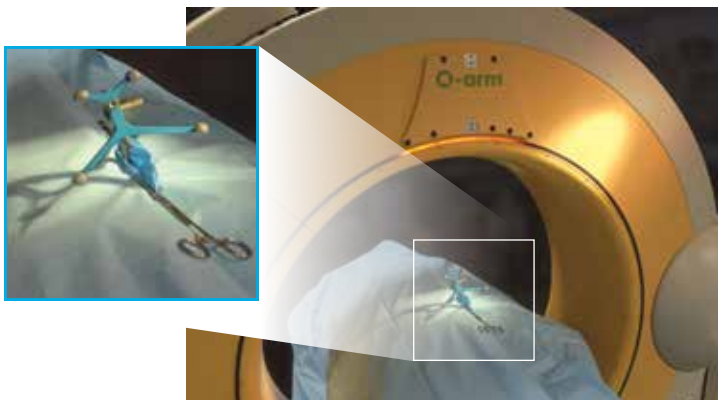


Figure 14d

In the Synergy Spine Software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

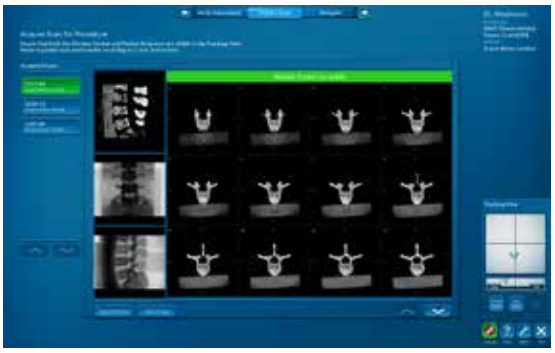
Synergy Spine Software Workflow

1. Select Surgeon

2. Select Procedure
Select the procedure type by selecting the imaging modality: O-arm Imaging, Optical Tracking.

3. Set up Equipment
Ensure that all lines to essential equipment are green. If lines are dashed orange, check connections/cables.

4. Verify Instruments
Check that the toolcards for all navigated instruments needed for the procedure are shown on this screen. Instruments can be verified now or at a later step, but the toolcard for the instrument must appear on this screen to be verified and tracked.



5. Acquire Scan
The system will remain on this screen until the O-arm System image acquisition step has been performed.

RIALTO SI FUSION
PROCEDURAL WORKFLOW

VERIFY INSTRUMENTS

- Navigated Probe
- Navigated Drill/Tap
- Navigated Pilot Drill, if used
- Navigated Driver
- Navigated PAK Needle, if used

PLACE REFERENCE FRAME

- Percutaneous Reference Pin with Percutaneous Reference Frame

- OR -

- Spinous Process Clamp with Small Passive Reference Frame

ACQUIRE 3D IMAGE

- Drape patient, bring O-arm System in field, and remove after image acquisition

- OR -

- Drape O-arm System, bring in and leave in field after image acquisition

ACCESS PREPARATION THREADED DEVICE(S)

- Determine entry points
- Mark skin
- Make skin incisions

TAP/PLACE THREADED DEVICE(S)

- Drill/Tap and use reverse projection to determine length and diameter
- Save projection to mark entry point
- Place threaded device(s) pre-packed with Autograft or Allograft

ACQUIRE 3D CONFIRMATION IMAGE

- Assess implant placement

INSTRUMENT **VERIFICATION**

Attach the Spheres to a blue Reference Frame from the Spine Referencing Set and the Navlock Trackers from the Navlock Set. Check the Spheres to ensure they are secure. Next, attach the Navlock Trackers to the instruments.

Place each instrument tip into the divot in the blue Reference Frame and hold perpendicular (**Figure 15a**) and visible to the camera until a confirmation color is seen. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly (**Figure 15b**).

- Successful verification is indicated by a chime and a transition to green on the instrument toolcard.
- Failed verification is indicated by a "bonk" sound and indicates that the instrument may be positioned improperly in the divot or is bent/damaged. Inspect the instrument; if it is bent/damaged, do not use.
- If no sound is heard when the instrument is touched to the divot, this may indicate that the camera cannot see either the instrument or the frame.

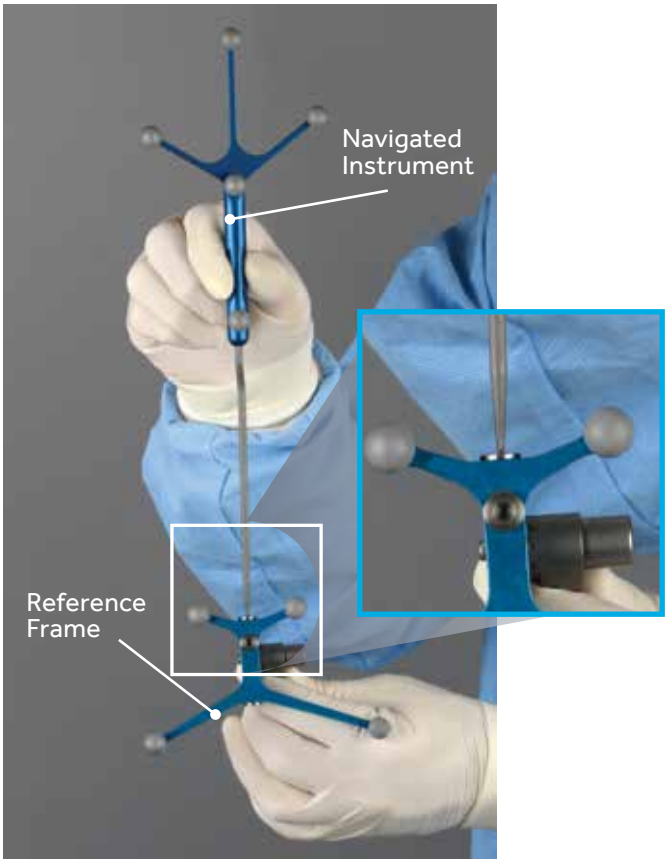


Figure 15a

Helpful Hint

Assigning an instrument to a specific-colored Navlock Tracker will eliminate the need to switch the tracker from one instrument to the next throughout the procedure. As an example, the grey tracker could be assigned to the tap and the orange tracker could be assigned to the driver.

Helpful Hint

OR Staff can verify instruments before the surgeon enters prior to reference frame placement.

Figure 15b

PATIENT
POSITIONING

NAVIGATED RIALTO SI FUSION SYSTEM

REFERENCE FRAME PLACEMENT

When performing a Navigated SI Fusion Procedure use of the Percutaneous Reference Pin with the Percutaneous Reference Frame is recommended. Pins are available in 100mm and 150mm lengths.

The preferred method, places the pin down the contralateral posterior superior iliac spine (PSIS) much like the trajectory of an iliac screw, which drops the reference frame out of the way and does not pose potential line-of-sight obstacles between the camera and the implant placement (**Figure 16a**). This option is described below.

Using palpation, locate the PSIS on the patient. Mark the skin approximately 10mm medial and inferior to the PSIS to verify the appropriate location to place the pin.

Make a stab incision and locate the Cannula with the Dilator over the PSIS. Place the Dilator/Cannula into the incision through the tissue until it contacts bone. Once docked, the Dilator/Cannula assembly is tapped with a mallet to make an indentation in the bone for the pin. While holding the Cannula in place remove the Dilator and insert the pin through the Cannula. Place the Tap Cap on the pin and rotate the cap so the arrow on the Tap Cap points toward the camera. Orient the Pin/Tap Cap assembly approximately 30° toward the midline of the patient and then angle it 30° toward the foot of the patient.

Use an impactor to drive the pin into the bone until the Tap Cap contacts the top of the Cannula (**Figure 16b**). Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin (**Figure 16c**).

Alternatively, for bilateral implant placement, the Spinous Process Clamp with the Small Passive Reference Frame can also be used. The clamp should be firmly attached to the spinous process of L5. With the camera positioned at the patient's feet, the clamp should be within an unobstructed view of the camera and the instruments.

Helpful Hint

To keep the frame close to the patient and out of the way of surgical instruments, use the 100mm Percutaneous Reference Pin, if possible.

Important

Ensure the Reference Frame is properly secured to anatomy. Neglecting to verify that the Reference Frame is secured could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

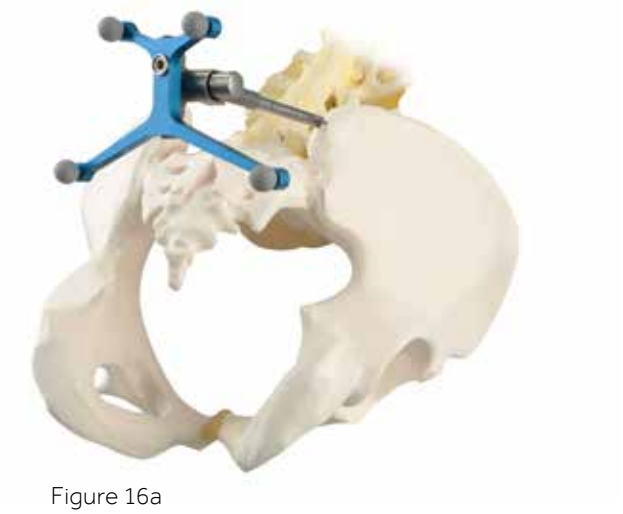


Figure 16a

Figure 16b

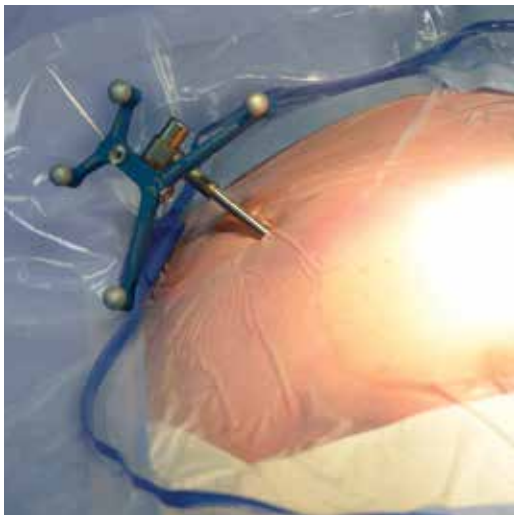


Figure 16c

IMAGE ACQUISITION

At any time when fluoroscopy is used (2D or 3D acquisition) all personnel who are not wearing protective lead apparel should stand at least 15 feet (457.2cm) from the O-arm System with a certified moveable lead shield between themselves and the O-arm System to avoid unnecessary radiation exposure (**Figure 17**).

Establish the surgery site using 2D fluoroscopy scout images as needed. On the control panel, select the patient size, anatomy, and orientation. With the patient isocenter, position the O-arm System gantry to perform a 3D spin. Following the 3D spin, the images are transferred automatically to the StealthStation System. Should 2D images or a second 3D spin be desired, four preset O-arm System gantry positions may be set up and saved. Once the images are transferred, the O-arm System can be moved out of the way and into the park position.

O-arm System Isodose Curve

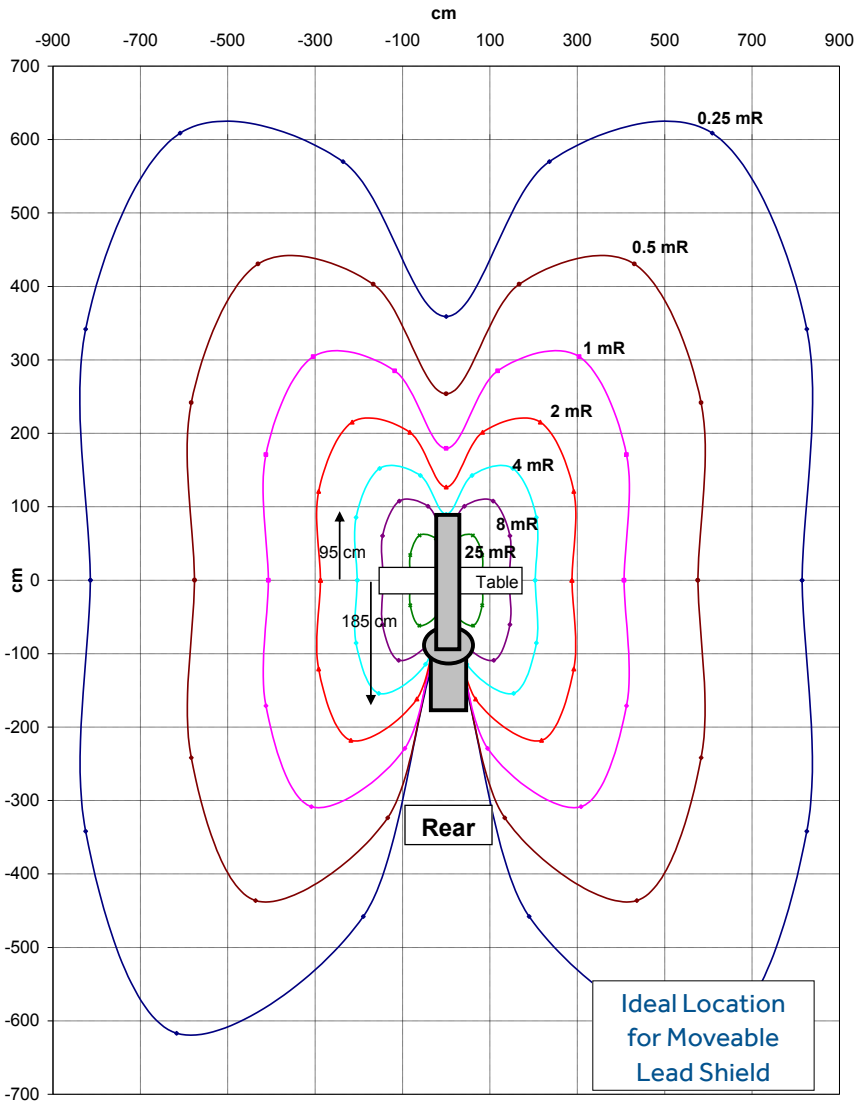


Figure 17

Scatter plot showing the shape of isodose curves for the maximum technique factors

- Protocol: Abdomen HD3D XL
- Technique: 120 kVp, 600 mAs

PROCEDURE STEPS

NAVIGATED RIALTO SI FUSION SYSTEM

ACCESS

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

Use the Navigated Probe or the Navigated PAK Needle to identify the trajectory for tapping and mark the skin directly over where the threaded devices will be placed **(Figure 18a)**. The trajectory should start slightly lateral to the PSIS and cross the SI Joint into the Sacral Ala. Confirm the trajectory with images 1 and 2 on the StealthStation monitor. Under "Select Projection" on the StealthStation System, add a tip extension to the tip of the instrument (**Figure 18b**). The projection may be lengthened as needed to accommodate patient size.

Figure 18a

Note

It is often beneficial to plan for both implant trajectories prior to making the initial incision. This can be done through the "save plan" function on the StealthStation. The plan should allow for at least 1cm of bone between each implant **(Figure 18c)**.

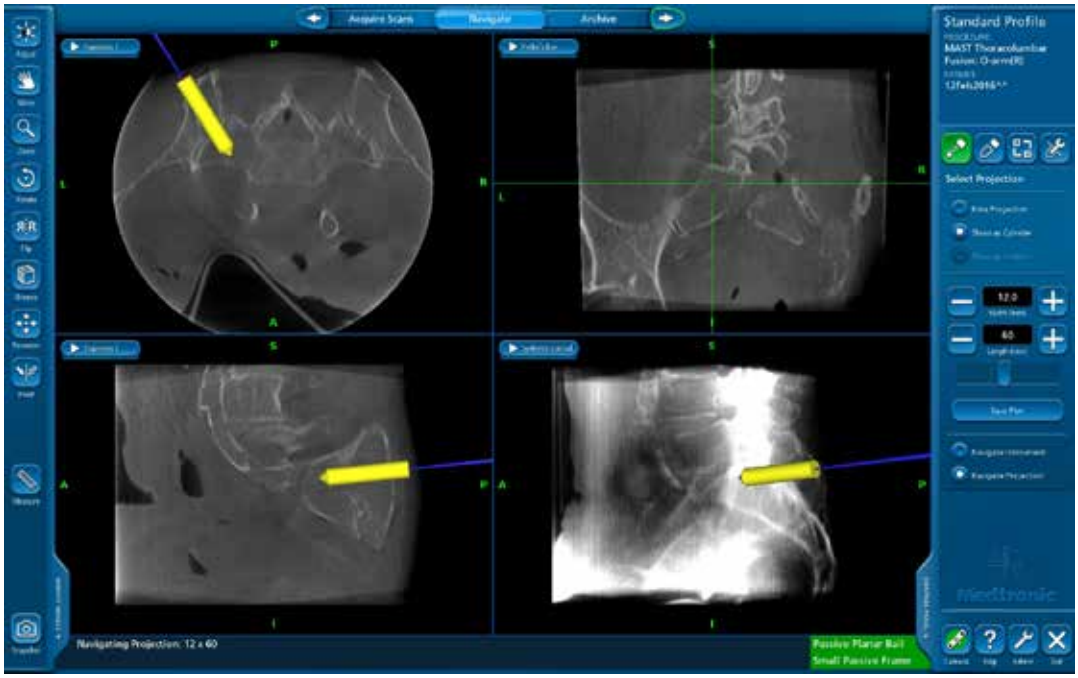


Figure 18b

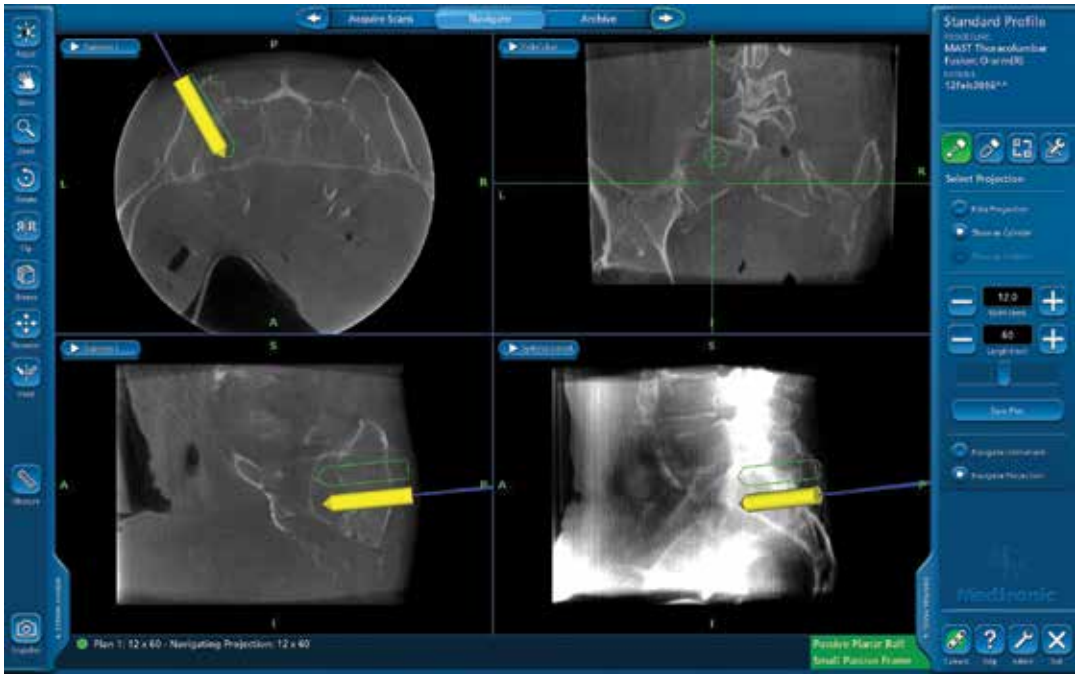


Figure 18c

EXPOSING **ILIUM**

Once the PSIS is located and the surgical plan has been established, make a 20mm incision approximately 10mm lateral of the PSIS. Use a retractor, such as a Weitlaner, to expose the PSIS and hold tissue out of the way **(Figure 19a)**.

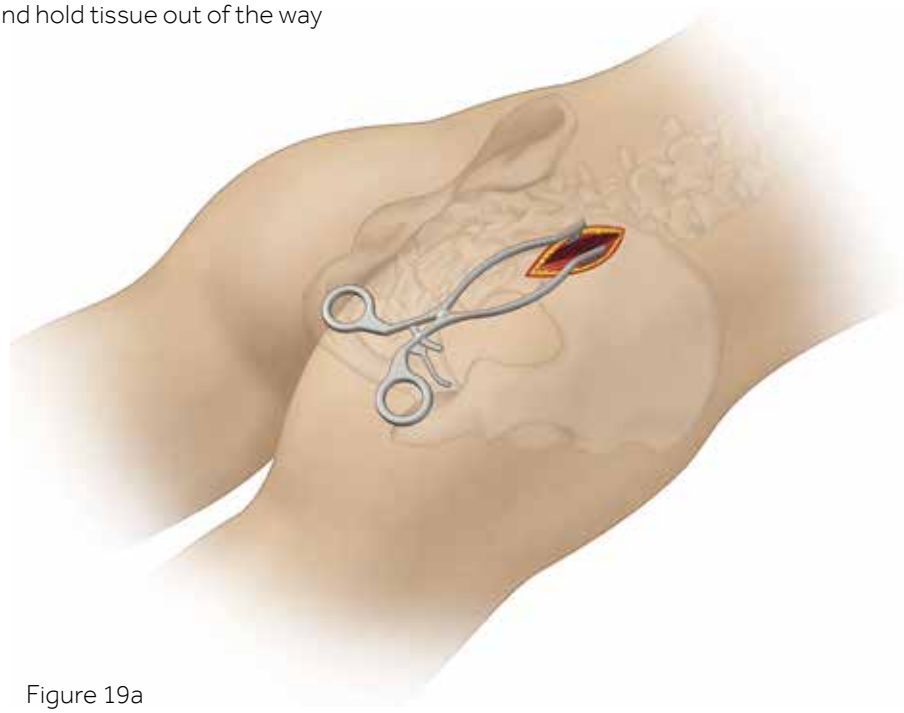


Figure 19a

CONNECTING TO **POWEREASE DRIVER**

To assemble an instrument with the POWEREASE® Driver align the connection end with the Quick Connect on the POWEREASE® Driver and insert until the connection end of the instrument is fully seated within the Quick Connect of the Driver **(Figures 19b and 19c)**.

Figure 19b

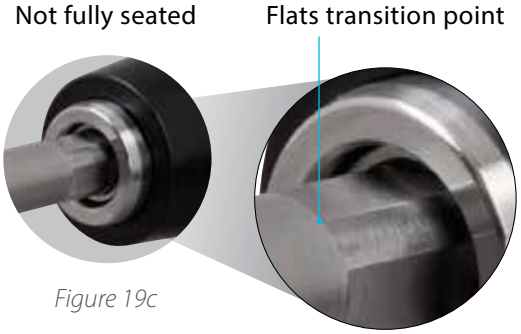


Figure 19c

Flat sides should be fully inserted and not be visible.

TAPPING AND IMPLANT LENGTH **MEASUREMENT**

Insert the Rialto Awl Tip Tap instrument into the skin incision and verify the trajectory on the surgeon monitor. Advance the instrument until it crosses the SI Joint and is approximately 10-15mm into the Ala. Advance the tap to its desired depth (**Figure 20a**). Once the tap has been advanced to the ideal depth, create a reverse projection in the "Select Projection" menu and then select "Save Plan" (**Figure 20b**). The saved plan should reflect the final implant diameter and length. This will save the trajectory to be used as a virtual guidewire which may be recalled during subsequent implant placement. This projection also indicates the implant length and diameter for subsequent implant placement. Remove the Tap for threaded device placement. The IPC Powerease System may be used for tapping and threaded device insertion. The IPC Powerease System is a system of powered surgical instruments designed specifically for use in spine surgery (**Figure 20c**).

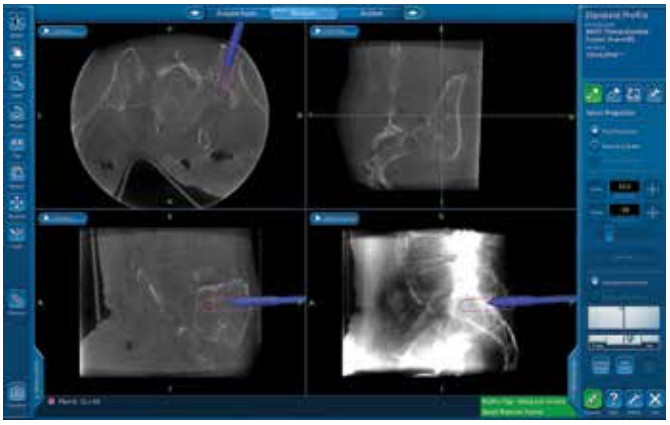


Figure 20a

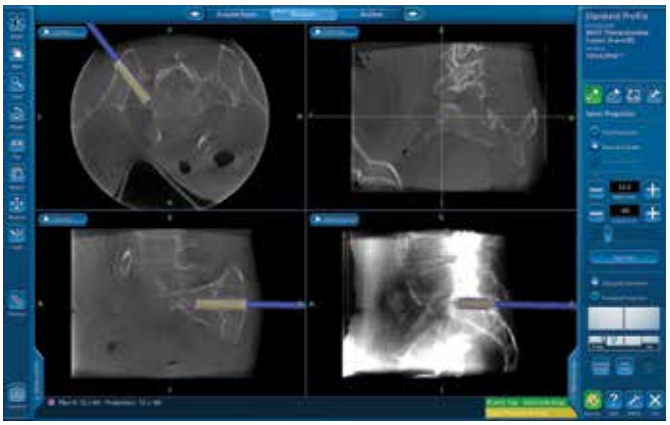


Figure 20b

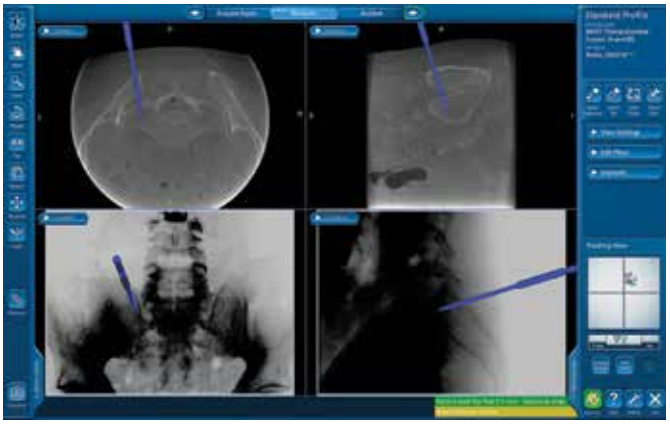


Figure 20d

Helpful Hint

To establish the tap trajectory across the joint, a smaller diameter Pilot Drill may be used prior to the Rialto Awl Tip Tap step, if desired (**Figure 20d**)

Figure 20c

BONE GRAFT **PACKING**

The Rialto Threaded Device should be packed with autograft or allograft material **(Figure 21a)**. The 40, 50, and 60mm implants will hold approximately 1.1cc, 1.5cc, and 1.9cc respectively **(Figure 21b)**. The cutting flutes of the Rialto Awl Tip Tap may be a source for autograft **(Figure 22).**

Figure 21a

Figure 21b

Figure 22

THREADED DEVICE INSERTION

Next, thread the navigated driver into the implant and ensure the driver is completely threaded into the implant (**Figure 23a**). Place the distal tip of the implant into the previously tapped hole using direct visualization and referencing the saved plan on the StealthStation (**Figure 23b**). Once the implant is aligned with the saved plan, advance the implant being careful that the implant assembly is not advanced beyond the anterior sacral cortex of the Ala (**Figure 23c**). For additional implant placement, follow the previous steps according to the saved plan.

The IPC Powerease System* may be used for tapping and threaded device insertion (**Figure 23d**). The IPC Powerease System is a system of powered surgical instruments designed specifically for use in spine surgery.

Figure 23a

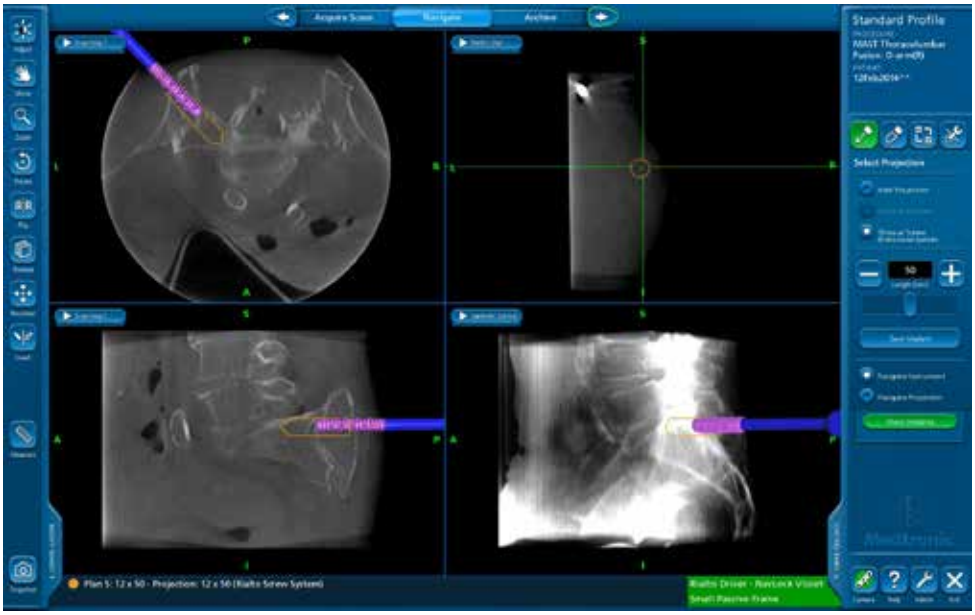


Figure 23b

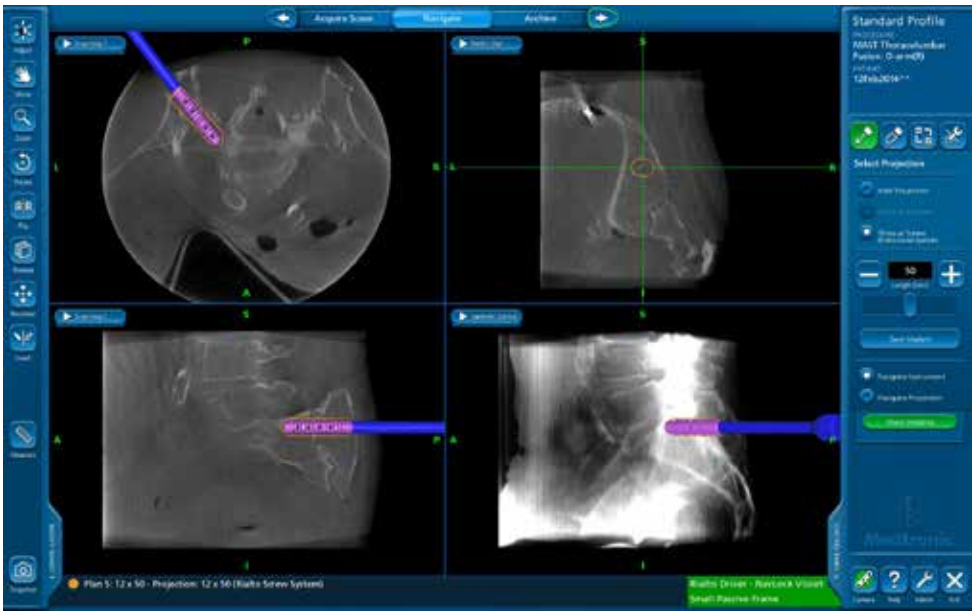
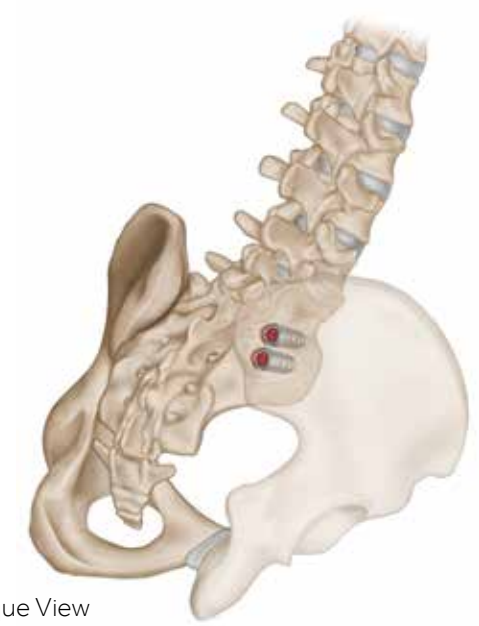


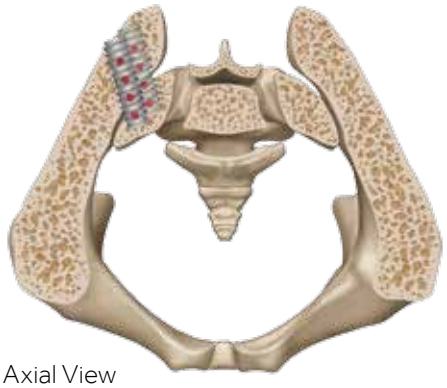
Figure 23c

Figure 23d

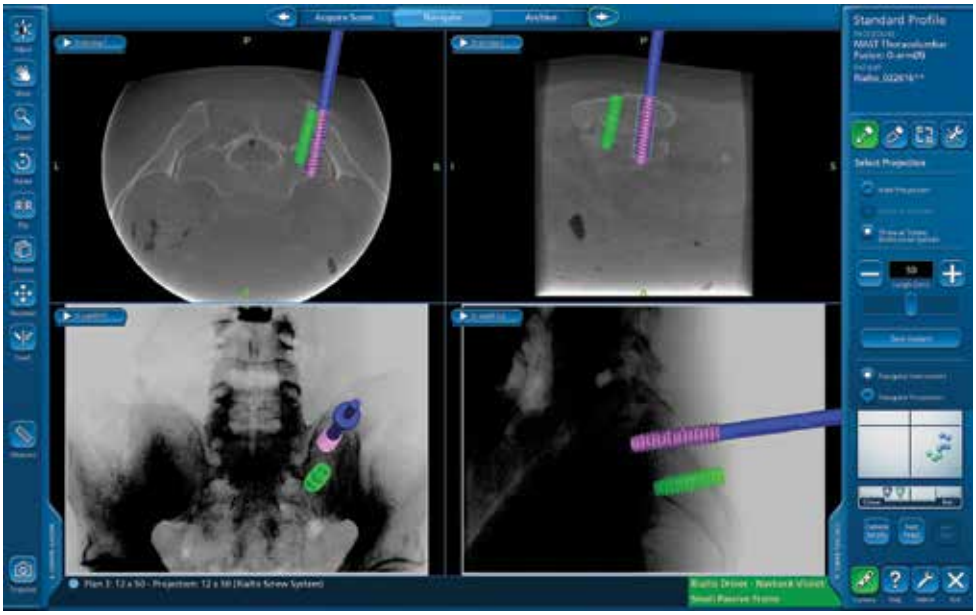
FINAL **PLACEMENT**



Oblique View



Axial 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 threaded device. The driver can also be used to remove the threaded device.

CONFIRMATION

NAVIGATED RIALTO SI FUSION SYSTEM

CONFIRMATION
IMAGE ACQUISITION

The Reference Frame should be left in place during the confirmation image acquisition to ensure that navigation can still be performed if any changes are required.

With the patient isocenter, position the O-arm System to perform a 3D image acquisition (**Figure 24a**). During the acquisition process all personnel who are not wearing protective lead apparel should stand at least 15 feet from the O-arm System with a certified moveable lead shield between themselves and the O-arm System to avoid unnecessary radiation exposure. Perform the image acquisition to confirm implant placement (**Figure 24b**). Following confirmation, the Reference Frame should be removed.

Figure 24a

Figure 24b

PRODUCT ORDERING INFORMATION

Rialto SI Fusion System Implants (Sterile)

Part Number	Implant Description (Size)
74200001240	12mm × 40mm Threaded Device
74200001245	12mm × 45mm Threaded Device
74200001250	12mm × 50mm Threaded Device
74200001255	12mm × 55mm Threaded Device
74200001260	12mm × 60mm Threaded Device

Standard Surgical Instruments that may be used with Rialto SI Fusion System

Part Number	Instrument Description
7426000	Adjustment Driver
7426001	Depth Stop Assembly
7426002	8.6mm Drill
7426003	12mm Tap
7426004	T27 Threaded Driver
7426005	Funnel
7426006	Tamp
7426009	Rialto SI Fusion Graft Packing Fixture
7426010	Rialto SI Fusion Graft Packing Fixture Lid
G900000	1/4" Quick Connect Handle
G900100	1/4" Quick Connect T-Handle

Disposables, Sterile (Not included in the instrument sets.)

Part Number	Instrument Description
7426007	2mm Guide Pin
7426008	2mm Trocar End Guide Pin
8670009	Beveled/Trocar PAK Needles
8670010	Beveled PAK Needles
8670015	Trocar PAK Needles

Navigated Surgical Instruments that may be used with the Rialto SI Fusion System

Part Number	Instrument Description
NAV7426000	Rialto Awl Tip Tap
NAV7426001	Driver
NAV7426002	Pilot Drill
7426005	Funnel
7426006	Tamp
7426009	Rialto SI FUSION Packing Fixture
7426010	Rialto SI FUSION Packing Fixture Lid

SUMMARY OF IMPORTANT PRODUCT INFORMATION ON THE RIALTO™ SI FUSION SYSTEM

PURPOSE

This device is a fusion device intended for stabilization 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 instructed as to its mechanical and material applications and limitations. This device is manufactured from medical grade titanium alloy and is provided sterile.

DESCRIPTION

The RIALTO™ SI Fusion System consists of cannulated devices of various widths and lengths used to provide 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.
- Suspected or documented allergy or intolerance to the component materials.

POTENTIAL ADVERSE EVENTS

The following are 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.

WARNINGS

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

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

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant, 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 spinal surgery.

Proper patient selection and compliance will affect the results.

An implanted device should never be re-used, reprocessed, or resterilized under any circumstances. Sterile packaged devices are never to be resterilized. 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.

PRECAUTIONS

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.

!USA 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.

Medtronic

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

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

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

medtronic.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.

Medtronic International Trading Sàrl
Case postale
Route du Molliau 31
CH-1131 Tolochenaz

Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

medtronic.eu

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

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.