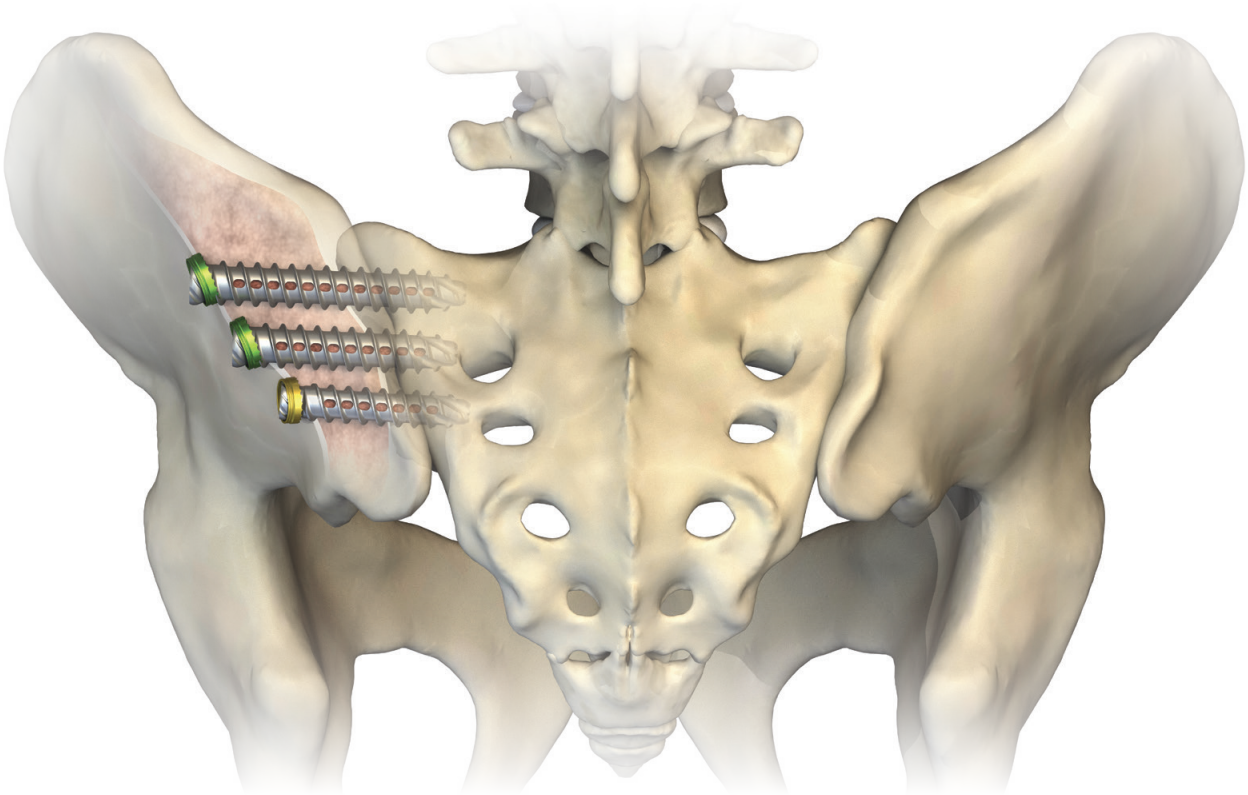
ORION

SACROILIAC JOINT FUSION SYSTEM



Surgical Technique Guide

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Product Description

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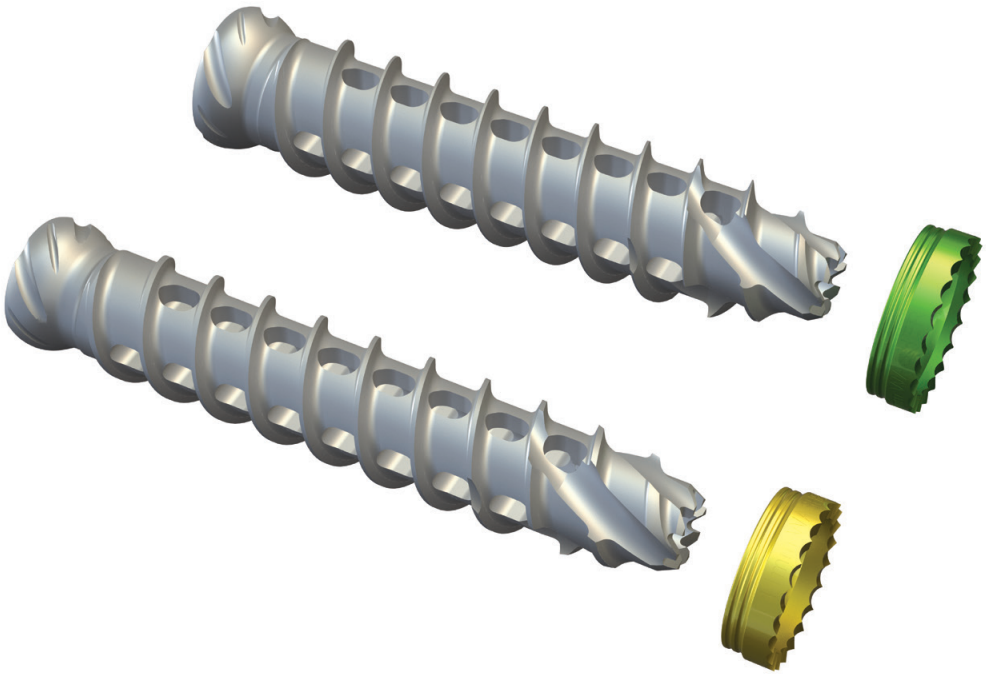
SACROILIAC JOINT FUSION SYSTEM

The **Orion Sacroiliac Joint Fusion System** consists of cannulated, fully threaded screws with double helix threads designed to be able to screw into pre-drilled bone. It is fabricated from medical grade titanium alloy, Ti-6Al-4V (ASTM F-136). The Orion System implants come in various sizes and lengths to accommodate patient anatomy. Optional washers are included for each screw diameter to aid in conformity to patient anatomy.



Indications for Use

Surgical Instrument System

The Orion Sacroiliac Joint Fusion System is comprised of various surgical instruments to be used to prepare the site to insert the system implants. All the instruments are made from surgical grade materials.

Indications for Use

The Orion Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Contraindications

Contraindications for use of the Orion Sacroiliac Joint Fusion System includes, but is not limited to:

- Infection
- Tumor
- Severe osteoporosis
- Mental or physical impairments that limit a patient's ability to comply with necessary limitation of postoperative instructions

Warnings and Precautions

The surgeon should be familiar with the procedure and use of the Orion Sacroiliac Joint Fusion System instruments prior to surgery.

The outcome and results obtained from this surgical procedure, as with any surgery, are highly dependent on the knowledge of surgical techniques, placement and sizes of implants used, management of the patient both pre and post operation, including the general health of the patient.

The implants used in the system are manufactured from titanium and use with implants of other metallic materials is not recommended.

The device has not been evaluated for safety in the MR environment. The device has not been tested for heating and/or migration in the MR environment.

The Orion System implants are single use devices and should never be re-used.

Surgical Technique Guide

Procedure

The implants and instruments used in the Pantheon Surgical Orion Sacroiliac Joint Fusion System are provided clean but non-sterile, and must be sterilized in the prior to each use, as described in the Pantheon Surgical Orion Sacroiliac Joint Fusion System Instructions for Use.

Note: All instruments, with the exception of the Steinmann Pins are reusable. The Steinmann Pins are single use devices and should be discarded after use.

Step One: Preoperative Patient Setup

The patient should be positioned prone on the operative table. Two C-arm fluoroscopy units are used to provide simultaneous lateral and Ferguson's views. EMG and somatosensory evoked potentials are utilized during the procedure for increased safety. Using EMG, the following muscles are monitored during surgery:

- L5 root, the anterior tibialis
- S1 root, the gastrocnemius
- S2 root, rectal sphincter

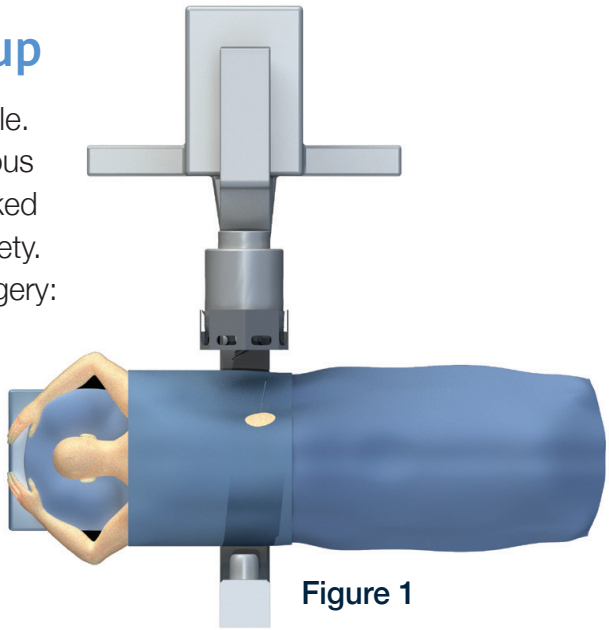


Figure 1

Step Two: Incision Location

Utilizing the lateral fluoroscopy, the skin is marked. Use a long, blunt Steinmann Pin to locate and mark the skin along the S1 endplate and sacrum posterior cortical wall. The incision location should start approximately 1-3cm below and approximately 1 cm posterior to these two lines respectively and extended caudal parallel to the sacrum posterior cortical wall skin mark, and should measure approximately 2-3 cm (Fig. 1). In an obese patient the incision should be slightly more posterior. The soft tissue should be dissected down all the way to the ilium.

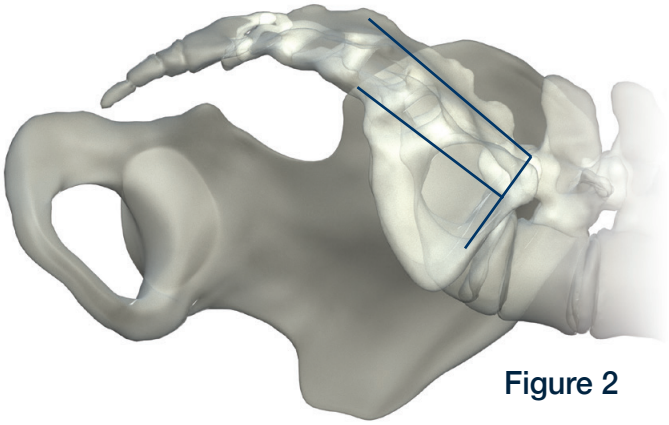


Figure 2

Step Three: Placement of Steinmann Pin

The sharp Steinmann Pin should be advanced all the way through the incision to the ilium. If desired, the Targeting Pin Impact Cap may be used to help advance the pin. Utilizing biplane fluoroscopy, the position of the entry point should be checked, as well as the direction of the pin. The entry point should be on a plane at the level of the posterior one-third of the sacrum vertebral body or just anterior to the sacral spinal canal, which is checked on the lateral fluoroscopy view. On the Ferguson view, the pin should point just above the S1 nerve root foramen. For safety reasons the pin should not be directed towards the S1 nerve root foramen, for if the pin is advanced too far it may injure this nerve root. Constant monitoring of somatosensory evoked potentials and EMG is of utmost importance. If the pin is positioned too superior it may injure the L5 nerve root as well as enter the sacral ala and this is not desired for fixation of the sacroiliac joint. On the lateral plane the pin should be directed anteriorly. This is accomplished by elevation of the hand by 10-15 degrees. Under biplane fluoroscopic control, the pin should be advanced using a mallet across the sacroiliac joint and the final position of the tip of the pin should be at approximately 1 cm from the anterior sacral wall, thus avoiding accidental entrance into the pelvis and just lateral to the level of the neuroforamen (Fig. 2).

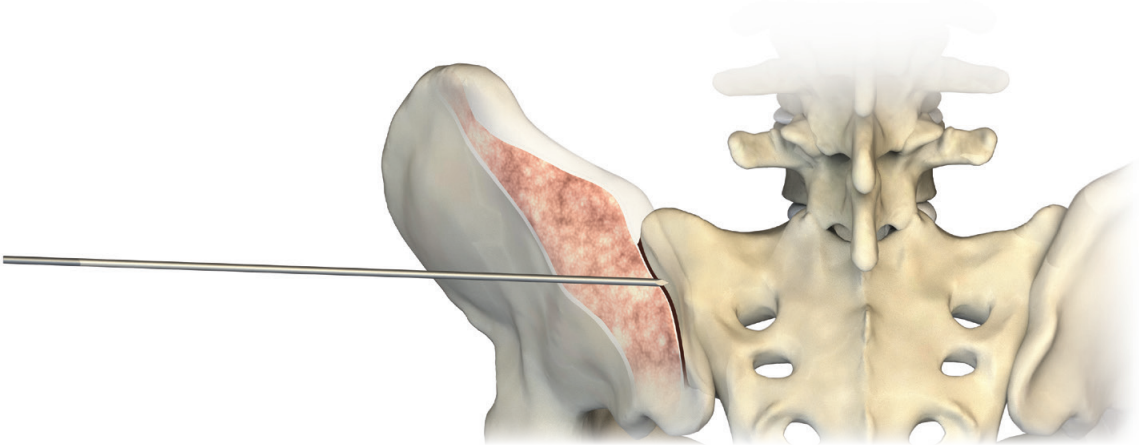


Figure 3

Step Four: Cannula Insertion

Slide the #1 Cannula down over the Steinmann Pin (Fig 3) until the distal tip interfaces with the ilium. Note the depth of the Steinmann Pin on the #1 Cannula for screw length selection (Fig. 4).

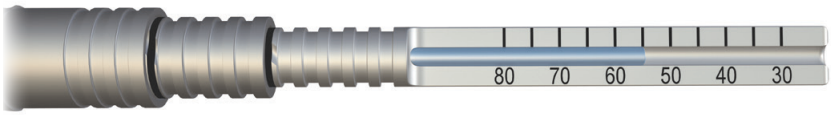


Figure 4

Next, slide the #2 Cannula over the #1 Cannula until the distal tip interfaces directly with the ilium. Finally, slide the #3 Cannula over the #2 Cannula until the distal tip interfaces directly with the ilium (Fig. 5).

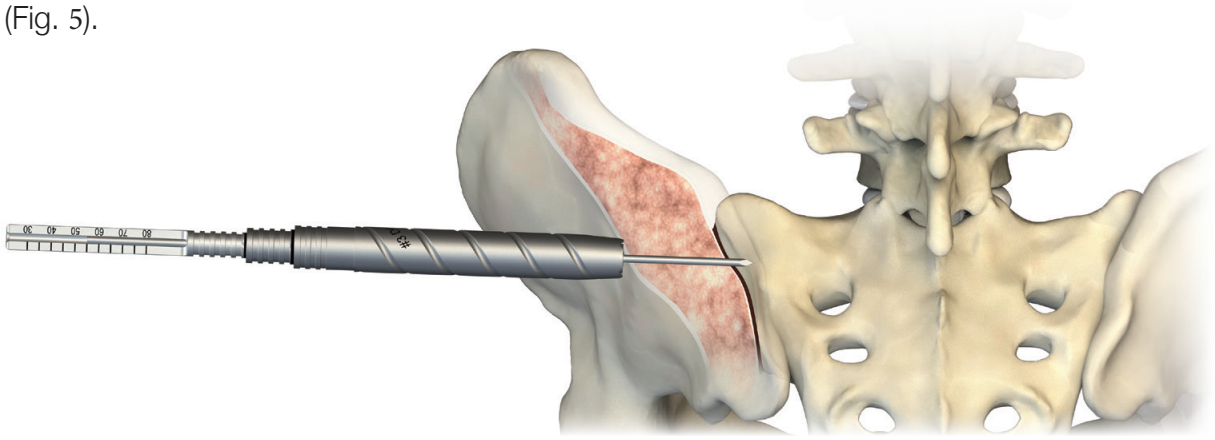


Figure 5

Once the #3 Cannula is firmly in place, the #1 and #2 Cannulas may be carefully removed. Be careful not to displace the Steinmann Pin during this step (Fig. 6).

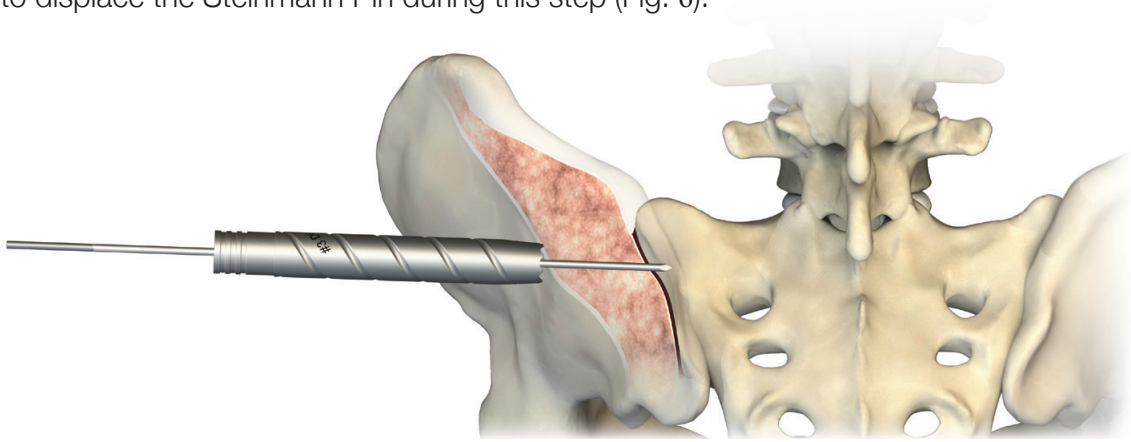


Figure 6

Step Five: Selection of Screw Diameter (and optional washer)

Select the diameter screw (11mm or 13mm) that is best suited for the patient's anatomy. An optional washer is available for use with both screw sizes (Fig. 7).

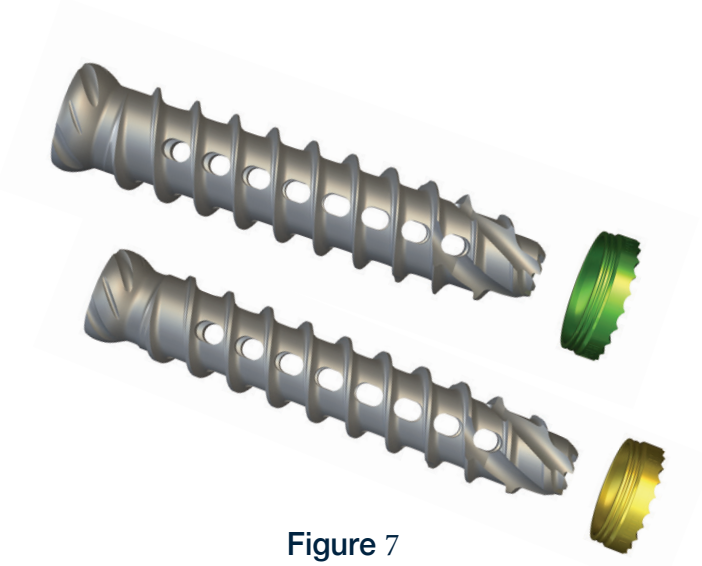


Figure 7

Step Six: Drilling of Pilot Hole

Once the surgical site has been properly dilated using the cannula, it is necessary to drill the pilot hole prior inserting the screw. To help prevent displacement of the Steinmann Pin the Blunt and Sharp Steinmann Pins may be coupled. Connect the appropriate size Drill Bit to an electrical drill system, and hand tighten the chuck and/or use the key for additional tightening. Under fluoroscopy, preferably the Ferguson view, a pilot hole is then created just short of the tip of the Steinmann Pin (Fig. 8). It is important to use fluoroscopy to control the depth of the pilot hole. Do not over- or under-drill. Once the desired depth is reached, the 11mm Drill Bit is then carefully removed. Use of the coupled Steinmann Pins helps keep them from migrating out during the removal of the Drill Bit.

Note: If the Drill Bit, appears to be advancing the Steinmann Pin, the Steinmann Pin should be removed and replaced by or coupled with a blunt Steinmann Pin.

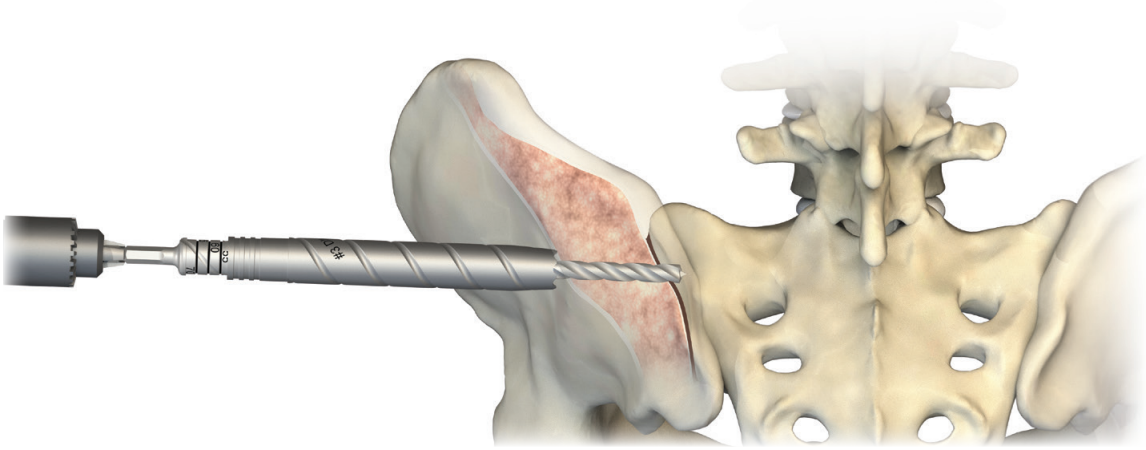
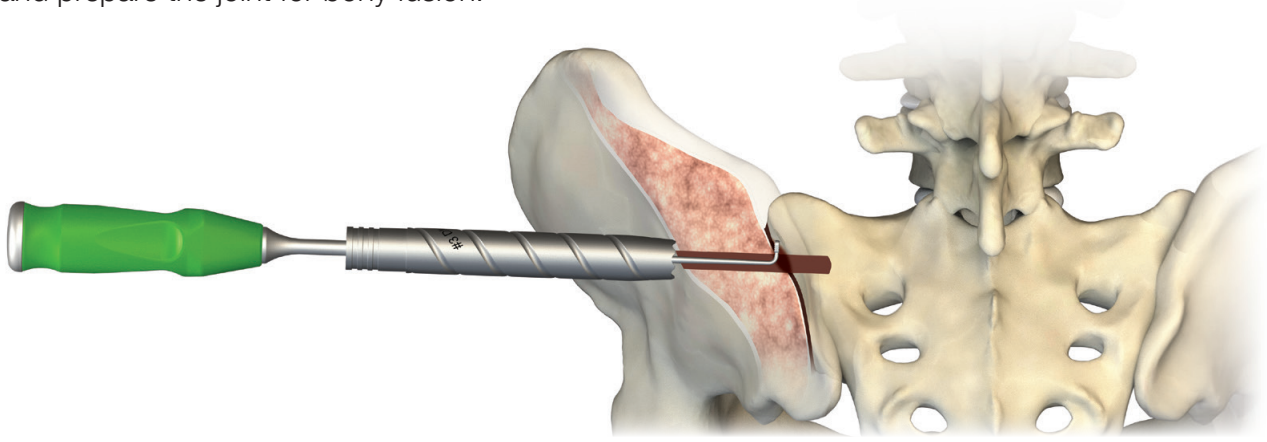


Figure 8

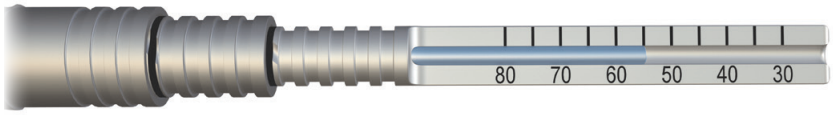
Step Seven: Preparation of the Joint

The Joint Decortication tool may be used through the #3 Cannula to remove ligamentous tissue and prepare the joint for bony fusion.



Step Eight: Selection of Screw Length

If not already determined in Step Four, the #1 Cannula/Pin Depth Guide may be slid over the Steinmann Pin until it makes contact and rests on the ilium. Read the markings to determine screw length needed. Remove the #1 Cannula/Pin Depth Guide and select appropriate length implant.



Step Nine: Placement of Screw and Fixation

The screw may be filled with bone allograft prior to insertion. Affix the screw onto the Implant Driver Sleeve by rotating the proximal thread of the screw head onto the distal thread of the Implant Driver Sleeve. Install the Implant Driver Shaft onto the cannulated Ratcheting T-Handle until an audible click is detected. Insert the assembled Implant Driver Shaft with T-Handle into the Implant Driver Sleeve until the shaft has properly seated into the screw at the distal end. Lock the shaft into place. Insert the driver with screw over the Steinmann Pin and into the #3 Cannula. Under fluoroscopy guidance, advance the selected screw into the pilot hole until the screw head stops against the ilium (Fig. 9). Unlock the Driver Shaft from the Implant Driver Sleeve and rotate the sleeve to release the screw from the instrument assembly. Carefully remove the driver inserter assembly once the implant is in position.

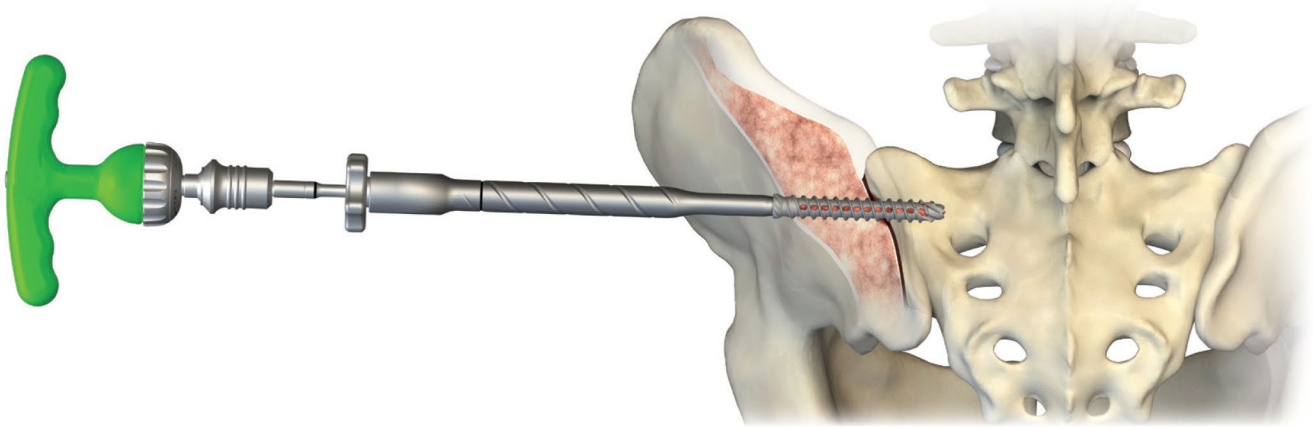


Figure 9

Step Ten: Additional Packing of Screw Bone Allograft

Prior to removing the Implant Driver Sleeve from the screw in the previous step, remove the Steinmann Pin. With the Driver Sleeve still in place, at the surgeon's discretion, the implant and/or Sacroiliac Joint may be packed with bone allograft using the Graft Packing Plunger (Fig. 10). Once the bone allograft, usually 2 cc to 4 cc, has been inserted into the Driver Sleeve, the Graft Packing Plunger is loaded into and forced down the Driver Sleeve which acts as a direct funnel to the screw. The bone allograft, which is usually a soft paste, penetrates the screw, ilium, the sacrum and the sacroiliac joint. This bone packing step is optional and may strengthen the construct by promotion of bone growth into the screw and sacroiliac joint.

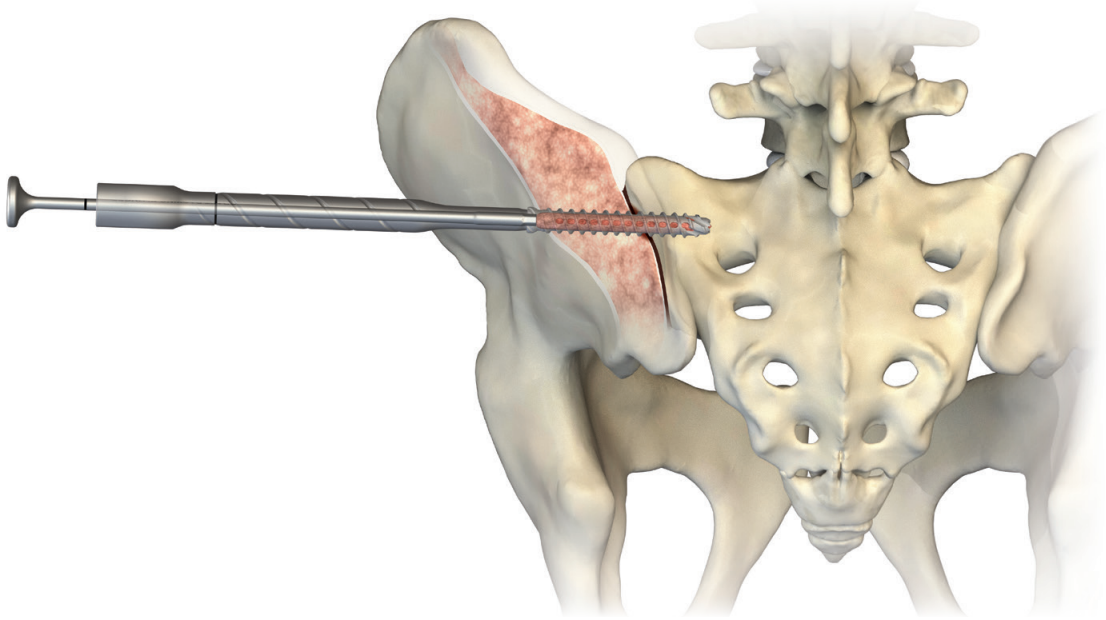


Figure 10

Step Eleven: Placement of Additional Screws

For adequate fixation, it is recommended that three (3) screws be implanted, but occasionally, due to anatomic variations of the sacroiliac joint, two (2) or four (4) implants may be used.

Install the shorter leg of the Parallel Pin Guide over the Steinmann Pin (if absent, replace prior to proceeding). The Parallel Pin Guide distance between successive screws should be chosen (14mm or 16mm) prior to use. The second leg of the Parallel Pin Guide Instrument will guide the direction of the second Steinmann Pin. The second screw entry point should be on a plane just anterior to the spinal canal at a level just below the S1 neuroforamen. Once a final position of the second pin guide has been determined using fluoroscopy, a second Steinmann Pin is placed into the second pin guide leg. Using a mallet, the Steinmann Pin is advanced across the sacroiliac joint, again under biplane fluoroscopy guidance (Fig. 11). The Steinmann Pin is usually stopped lateral to the level of the S1 and S2 neuroforamen.

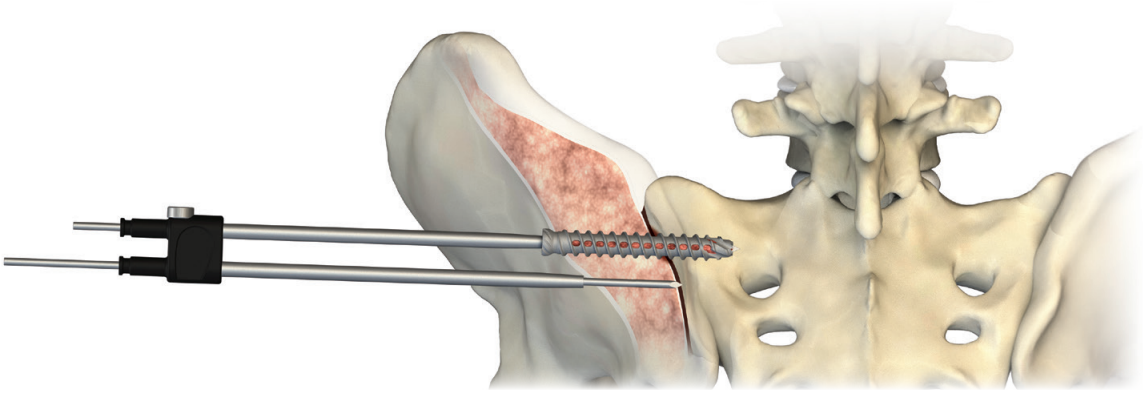
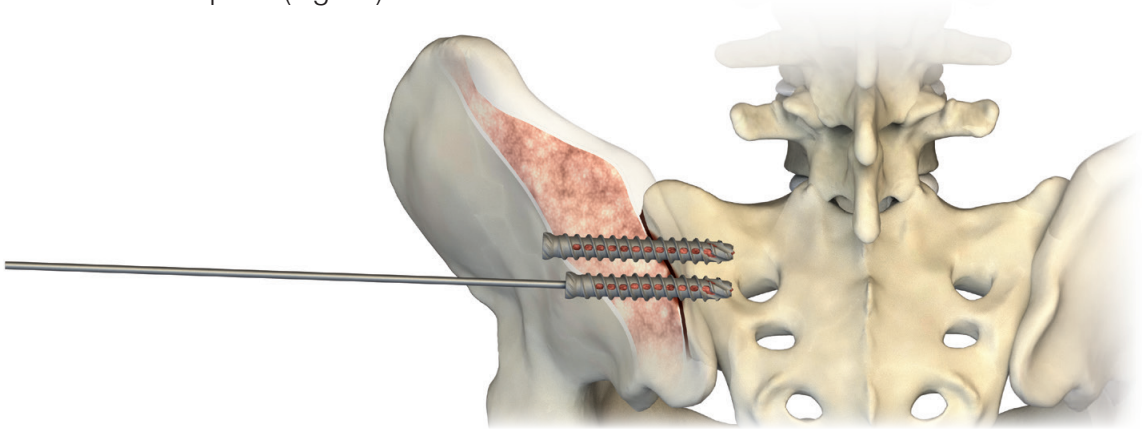


Figure 11

Once the second Steinmann Pin is in the desired position and parallel to the first implant, the Parallel Pin Guide instrument and first Steinmann Pin are removed and the entire procedure is repeated for insertion of the second implant (Fig. 11).



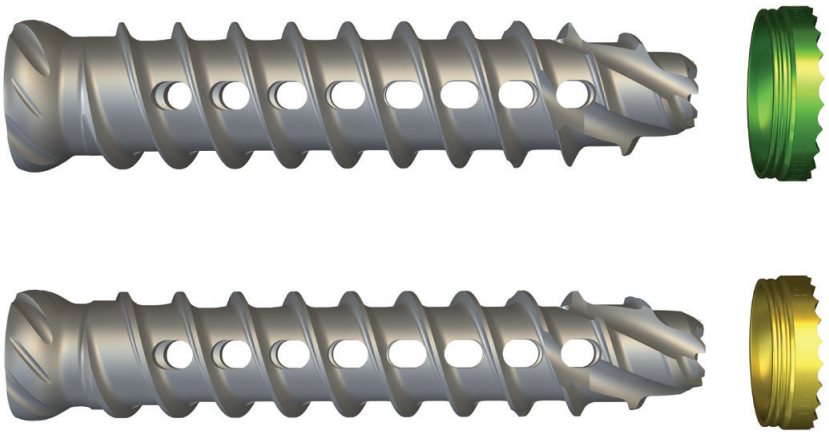
Step Twelve: Implant Removal and Adjustment

If the fixation device is malpositioned and the surgeon feels that removal is indicated, the removal process for the fixating implant should be followed by adequate postoperative management to avoid re-fracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the fixation implant, thus eliminating the risk associated with any second surgery.

Should it be necessary to remove a screw, the patient is positioned in a similar fashion as for screw insertion. Biplane fluoroscopy is brought into the operative field. The wound is reopened utilizing standard surgical technique. Attach the Ratcheting T-Handle to the cannulated Implant Driver Shaft. Under fluoroscopic guidance, insert the implant driver assembly over the head of the screw to be removed and engage the hex feature of the proximal screw head. Rotate counterclockwise
until the screw is out.

If the surgeon desires to replace the screw, prior to its removal, a short blunt Steinmann Pin should be inserted through the Implant Driver Shaft. The screw is then removed as described above, and the Steinmann Pin is used as a guide for the new screw. Wound closure and postoperative care, as per protocol.

Implant Guide



11mm Sacroiliac Anchor Implants

Item Number	Description
SIJ-M1130-C	Sacroiliac Anchor Implant, 11 x 30mm
SIJ-M1135-C	Sacroiliac Anchor Implant, 11 x 35mm
SIJ-M1140-C	Sacroiliac Anchor Implant, 11 x 40mm
SIJ-M1145-C	Sacroiliac Anchor Implant, 11 x 45mm
SIJ-M1150-C	Sacroiliac Anchor Implant, 11 x 50mm
SIJ-M1155-C	Sacroiliac Anchor Implant, 11 x 55mm
SIJ-M1160-C	Sacroiliac Anchor Implant, 11 x 60mm
SIJ-M1165-C	Sacroiliac Anchor Implant, 11 x 65mm
SIJ-M1170-C	Sacroiliac Anchor Implant, 11 x 70mm
SIJ-M1175-C	Sacroiliac Anchor Implant, 11 x 75mm
SIJ-M1180-C	Sacroiliac Anchor Implant, 11 x 80mm

13mm Sacroiliac Anchor Implants

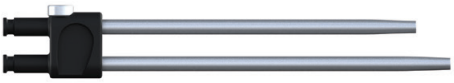
Item Number	Description
SIJ-M1330-C	Sacroiliac Anchor Implant, 13 x 30mm
SIJ-M1335-C	Sacroiliac Anchor Implant, 13 x 35mm
SIJ-M1340-C	Sacroiliac Anchor Implant, 13 x 40mm
SIJ-M1345-C	Sacroiliac Anchor Implant, 13 x 45mm
SIJ-M1350-C	Sacroiliac Anchor Implant, 13 x 50mm
SIJ-M1355-C	Sacroiliac Anchor Implant, 13 x 55mm
SIJ-M1360-C	Sacroiliac Anchor Implant, 13 x 60mm
SIJ-M1365-C	Sacroiliac Anchor Implant, 13 x 65mm
SIJ-M1370-C	Sacroiliac Anchor Implant, 13 x 70mm
SIJ-M1375-C	Sacroiliac Anchor Implant, 13 x 75mm
SIJ-M1380-C	Sacroiliac Anchor Implant, 13 x 80mm

Washers

Item Number	Description
SIJ-M11W-C	Washer, 11mm
SIJ-M13W-C	Washer, 13mm

Instrument Guide

SIJ-N016 Drill Bit

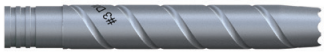


SIJ-N011 Parallel Pin Guide

SIJ-N011 Parallel Pin Guide

SIJ-N004 #1 Cannula

SIJ-N005 #2 Cannula



SIJ-N006 #3 Cannula

SIJ-N009 TARGETING PIN IMPACT CAP

SIJ-N003 Joint Decorticator

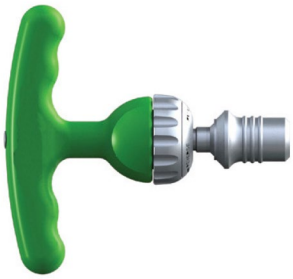
SIJ-N007 Steinmann Pin - Blunt

SIJ-N008 Steinmann Pin - Sharp

SIJ-N019 Steinmann Pin - Round

SIJ-N014 Graft Plunger

SIJ-N001 Implant Inserter



SIJ-N0013 Ratcheting T-handle