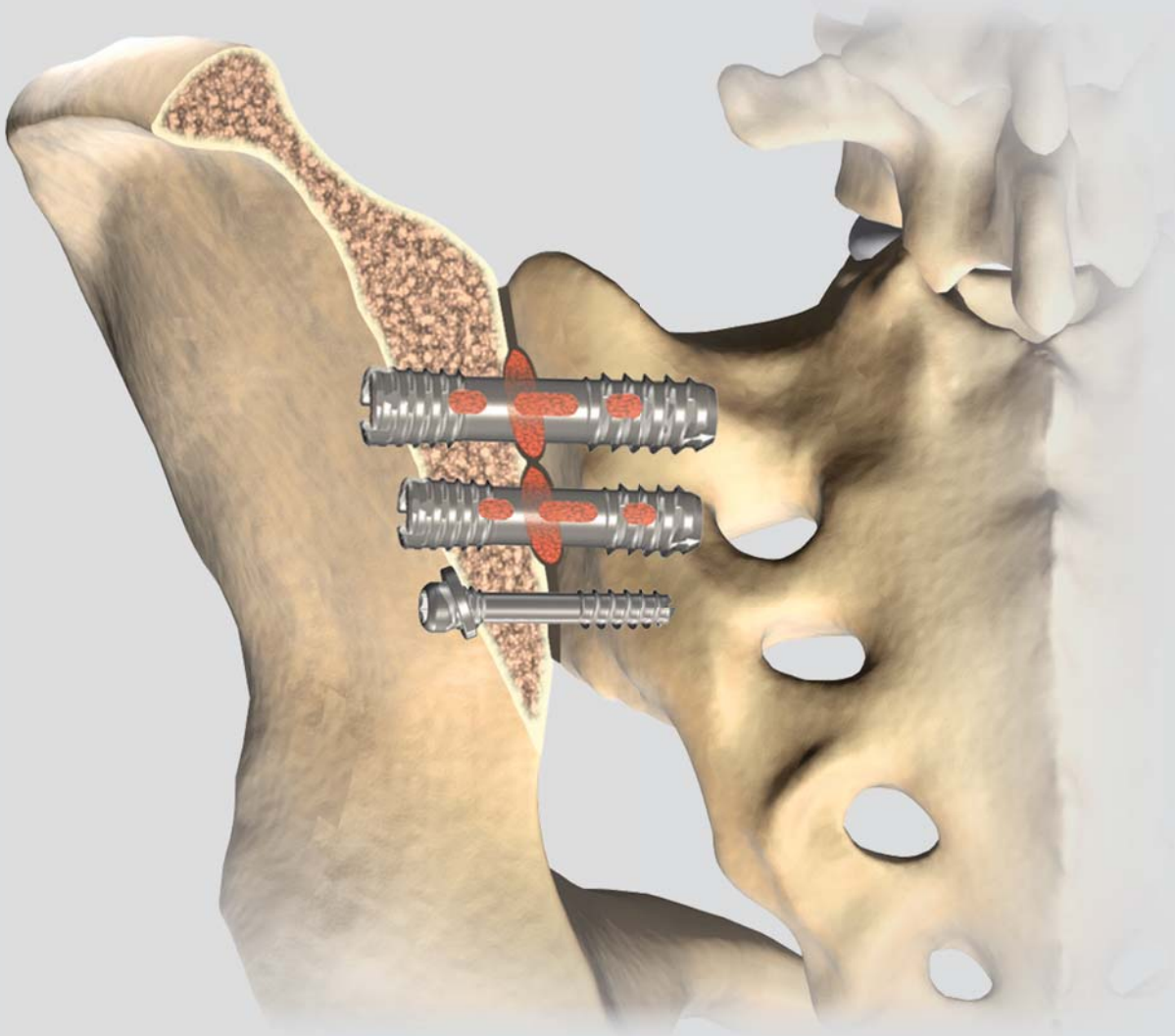


TriCor™ Sacroiliac Joint Fusion System

Surgical Technique



TriCor Sacroiliac Joint Fusion System

Surgical Technique

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Description, Indications & Contraindications

INTRODUCTION

The *TriCor* System allows for fusion and stabilization of the SI Joint in eligible patients where appropriate non-surgical treatment has failed. The *TriCor* Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions. The device optionally incorporates a proprietary dual-pitch compression-thread design and titanium plasma coating to stabilize the SI Joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to promote fusion. The *TriCor* System is a true bony fusion and arthrodesis system. The implant and instrumentation suite allows for direct exposure and preparation of the SI Joint surface, placement of bone graft into the SI Joint space under direct visualization, and placement of bone graft directly within the *TriCor* Implant itself.

The *TriCor* System consists of different diameter implants in various lengths and thread configurations to accommodate variations in patient anatomy. The *TriCor* Sacroiliac Joint Fusion System is manufactured from titanium alloy in accordance with ASTM F136, as well as an optional version where exterior surfaces are coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. All implants are intended as single use only and should not be reused under any circumstances.

Note: 12.5mm anchor implants are plasma-coated, 7mm locking implants are not coated.

INDICATIONS

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

CONTRAINDICATIONS

Contraindications for the *TriCor* Joint Fusion System are similar to those of other systems of similar design, and include, but are not limited to:

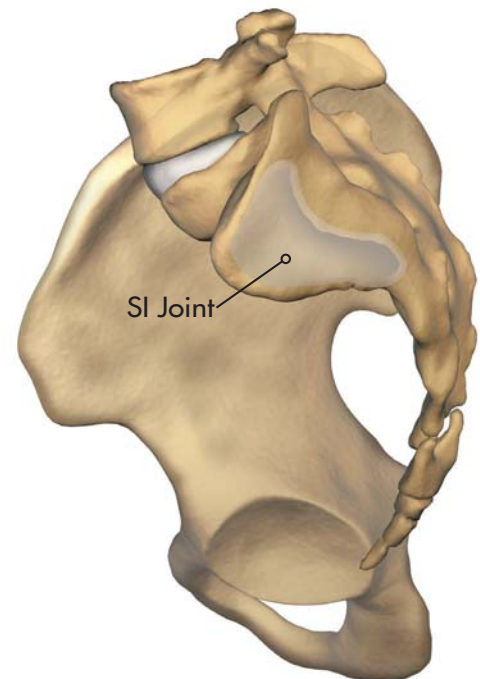
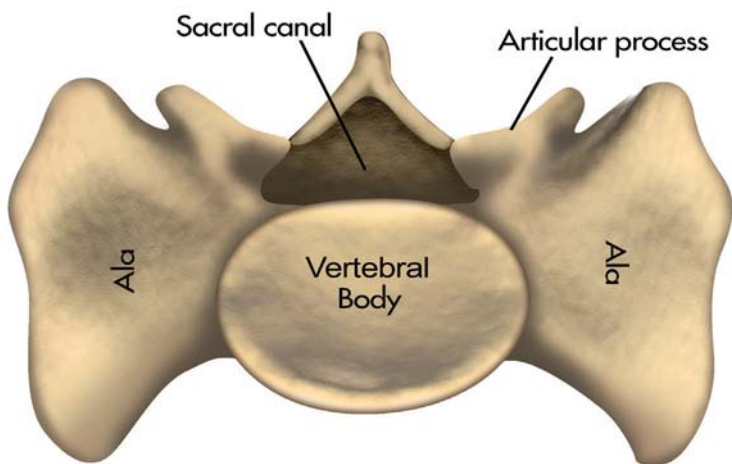
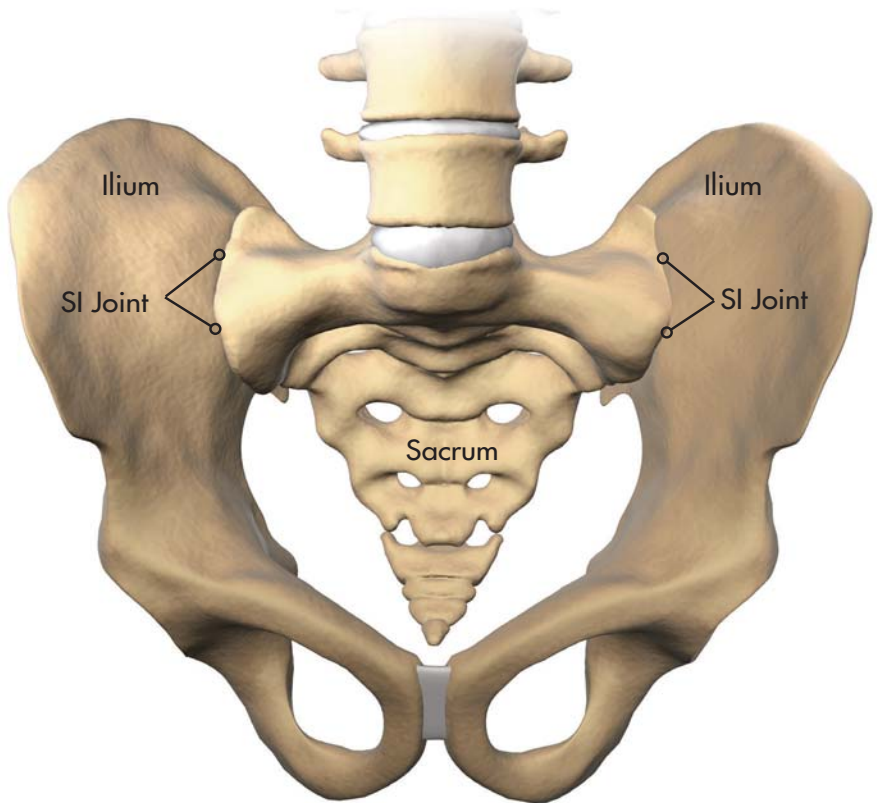
1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Reuse or multiple uses.

Anatomy Overview

Structural Anatomy

Sacroiliac Joint

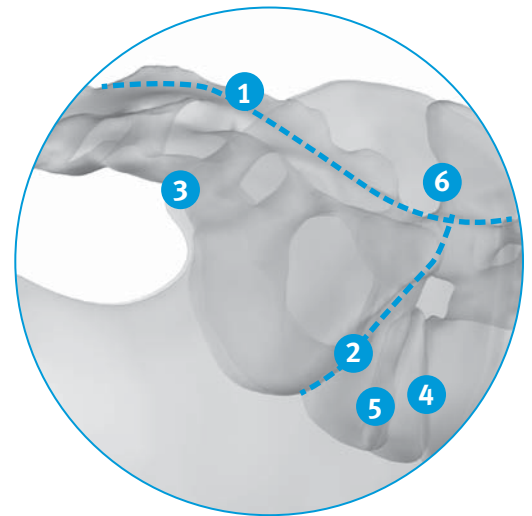
- Bicondylar synovial joint
- Joins the sacrum to the pelvis
- Weight-bearing, shock absorber
- “Kidney-bean” shape
- Strengthens ligamentous support and irregular articular surfaces help to resist shear forces



Imaging Techniques

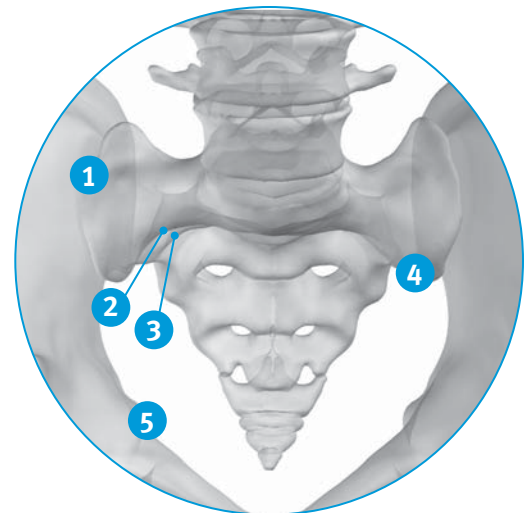
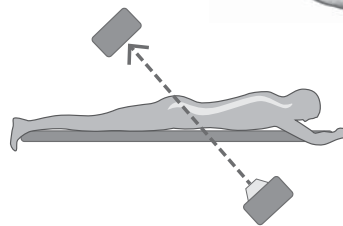
Lateral View

- 1 Posterior Sacral Wall (PSW)
- 2 Ala (2 lines superimposed)
- 3 Anterior Sacral Wall
- 4 Inferior Endplate L5
- 5 Superior Endplate S1
- 6 Greater Sciatic Notch



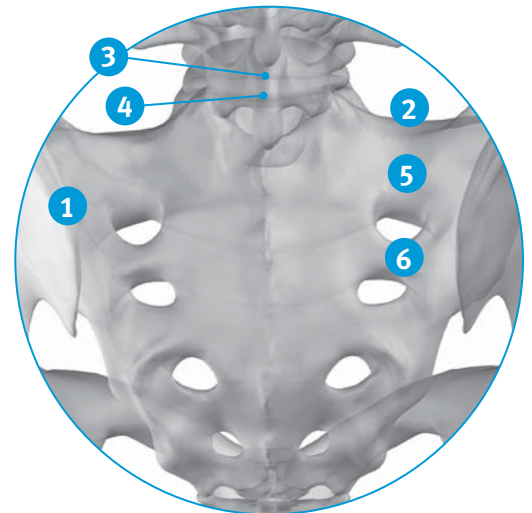
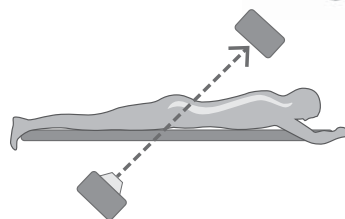
Inlet View (20-25 degrees Caudally)

- 1 SI Joint
- 2 S1 Foramen
- 3 S2 Foramen
- 4 L5 Nerve
- 5 Pelvic Brim

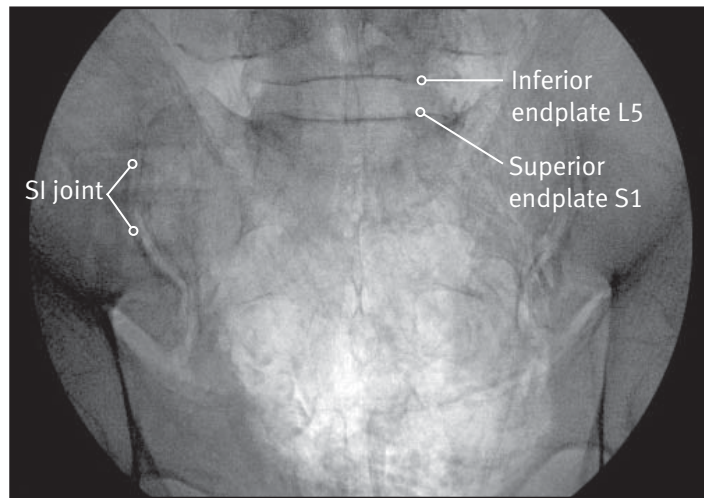
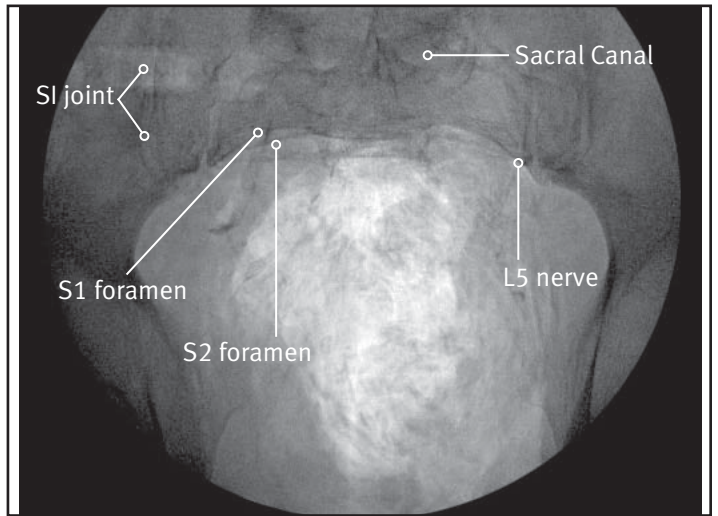
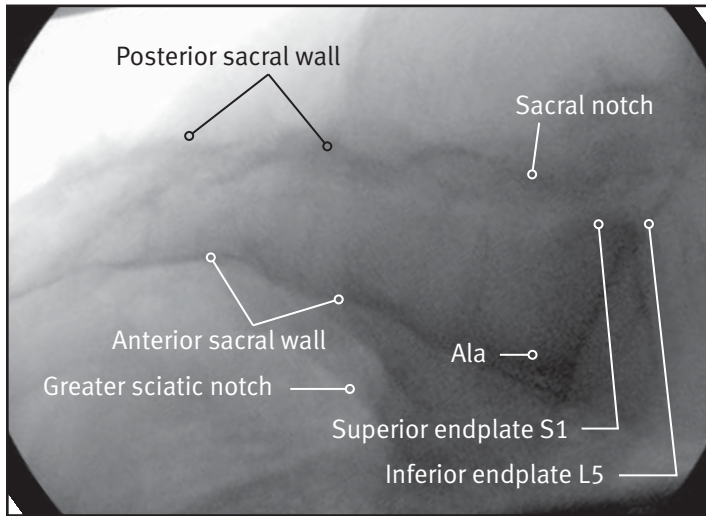


Outlet View (40-60 degrees Cephalad)

- 1 SI Joint
- 2 Superior Alar Surface
- 3 Inferior Endplate of L5
- 4 Superior Endplate of S1
- 5 S1 Foramen
- 6 S2 Foramen



Patient Preparation



Intraoperative Imaging

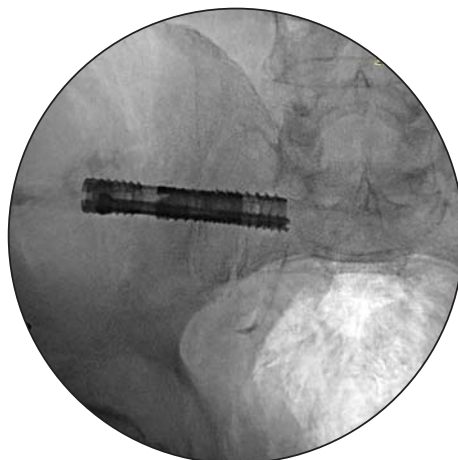
Lateral View

In order to obtain a true lateral view, align the alae so they are superimposed over one another.



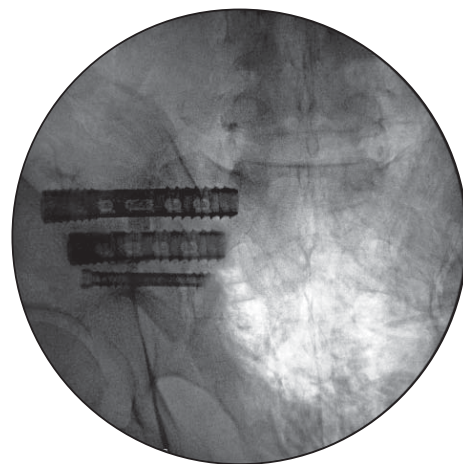
Inlet View

Tilt the C-Arm until a clear, strong pelvic brim is seen; the anterior wall of the sacrum will appear as one line.



Outlet View

The SI joint, ilium, sacrum and sacral foramen will be visible.



Pre-Op Planning

Operating Room Setup

- Patient positioned in a prone position
- Jackson or Flat table preferably
- C-Arm positioned on non-operative side

Open

Surgical Technique

Posterior Skin Incision

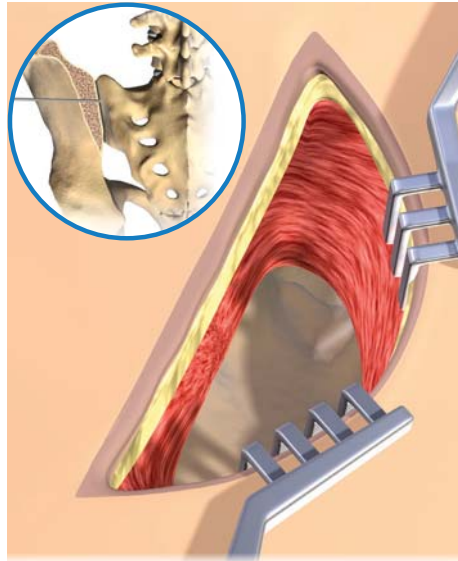


Fig. 1 ▲

Step 1

Make an incision along the posterior two-thirds of the iliac crest following the posterior superior iliac spine. Use preferred retraction method to access and visualize the symptomatic SI joint. Cut into the ilium and remove a block of bone as well as any necessary cartilage. Once the cartilage removal is complete, place the bone back so it contacts the sacral bone. Make sure the block is secure in order to prepare for the SI joint for bony arthrodesis. (Fig. 1)

NOTE: The Right Angled Curette or any other preferred medical instruments may be used to decorticate, remove cartilage and prepare the SI joint for bony arthrodesis.

Lateral Skin Marking and Incision

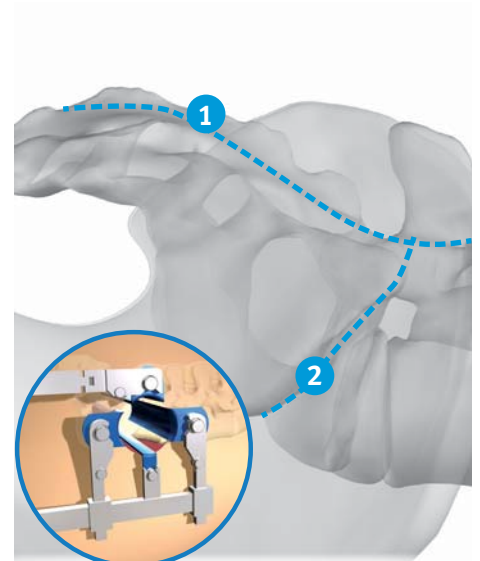


Fig. 2 ▲

Step 2

Use the Exchange Pin to mark the Posterior Sacral Wall (PSW, #1) and Sacral Alar Line (#2) with a marking pen.

Make a skin incision along the Posterior Sacral Wall, approximately 3-5cm in length, starting at intersection with sacral ala skin marking.

Beginning in the Lateral View, take the Trocar Steinmann Pin and insert the Steinmann Pin through the skin incision approximately 1cm anterior to the Posterior Sacral Wall and 1cm inferior to the ala. (Fig. 2)

NOTE: Use the #1 Tissue Shield to stabilize the Trocar Steinmann Pin for impaction.

Instruments



Trocar Steinmann Pin
07.02212.021
(X079-0054)



#1 Tissue Shield
07.02212.016
(X079-0045)

Steinmann Pin Placement



Fig. 3a ▲

Step 3

Confirm placement in three views:

Lateral View

Place the Trocar Steinmann Pin approximately 1 cm anterior to the PSW and 1 cm inferior to the ala. (Fig. 3a)

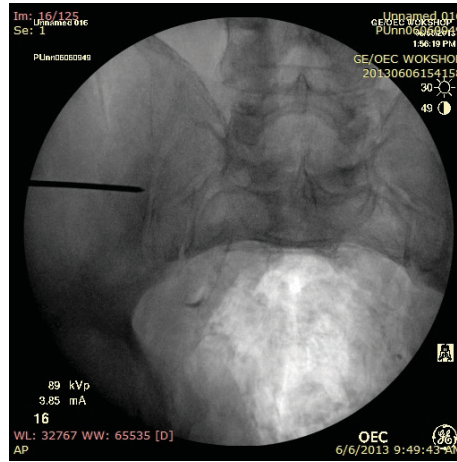


Fig. 3b ▲

Inlet View

The angle of the Trocar Steinmann Pin should be heading towards the middle of the sacrum. (Fig. 3b)



Fig. 3c ▲

Outlet View

The Trocar Steinmann Pin should be parallel to S1 endplate. Mallet the Steinmann Pin in final desired depth in Outlet view. (Fig. 3c)

NOTE: Blunt or Threaded Steinmann Pins are available to replace the Trocar Steinmann Pin after placement, if desired.

Instruments



Mallet
07.02212.019
(X034-0915)

Measure



Fig. 4 ▲

Step 4

Position #2 or #3 Tissue Shield over the Steinmann Pin. While keeping the Tissue Shield in place, use the Steinmann Pin Depth Gage/Guide to select the appropriate implant. Insert the Steinmann Pin Depth Gage/Guide underneath the inserted Steinmann Pin and dock onto the proximal end of the Tissue Shield. Measure with the #3 Tissue Shield for 12.5mm Implants and measure with #2 Tissue Shield for 7mm implants. Remove the Tissue Shield. (Fig. 4)

NOTE: Utilize the correct side of the Steinmann Pin Depth Gage/Guide; it is indicated for #2 and #3 Tissue Shields.

Drill Assembly



Fig. 5 ▲

Step 5

Attach the Drill bit to the Ratcheting T-Handle or cordless power drill using the provided Jacobs Chuck. (Fig. 5)

NOTE: Make sure the flat portion of the Jacobs Chuck attachment fits flush to the walls if using a cordless power drill.

NOTE: The drill flutes are designed to capture the autogenous bone graft for reuse in the 12.5mm anchor implant.

Drill

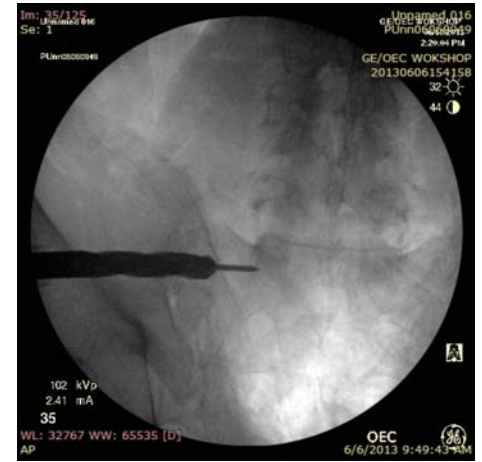


Fig. 6 ▲

Step 6

Place the Drill bit over the Steinmann Pin slowly advancing until the ilium is reached. Make sure the Drill is co-linear with the pin to avoid binding on the pin.

Using the Outlet view, confirm accurate placement of the Drill Bit over the Steinmann Pin. Under fluoroscopic guidance continue to advance the Drill just across the sacroiliac joint, through the sacral cortex. Try to preserve the sacral bone for re-packing the implant. (Fig. 6)

NOTE: Once the Drill reaches the SI joint, exercise caution advancing into the sacrum.

NOTE: Once the Drill bit has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Drill bit while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Instruments



Steinmann Pin Depth Gage/Guide
07.02212.001 (X079-0084)



Drill, Cannulated
07.02212.012 7.5mm (X079-0034)
07.02212.024 12.5mm (X079-0063)



Ratcheting T-Handle
07.02212.031 (N60000472)



Jacobs Chuck Adaptor
07.02212.032 (N60001630)



Tissue Shields
07.02212.017 #2 (X079-0106)
07.02212.018 #3 (X079-0107)



Exchange Pin
07.02212.028 (X079-0089)

Tap Assembly



Fig. 7 ▲

Step 7

Attach the Tap to the Ratcheting T-Handle (Fig. 7)

NOTE: Do not tap under power.

Tap



Fig. 8 ▲

Step 8

Place the Tap over the Steinmann Pin, slowly advancing until you reach the ilium. Make sure the Tap is co-linear with the pin to avoid binding on the pin.

Using the Outlet view, confirm placement. Under fluoroscopic guidance continue to advance the Tap across the sacroiliac joint, through to the sacral cortex. Try to preserve sacral bone for re-packing into the implant. (Fig. 8)

NOTE: Once the Tap reaches the SI joint exercise caution advancing into the Sacrum.

NOTE: Once the Tap has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Tap while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Decortication and Sacroiliac Joint Visualization

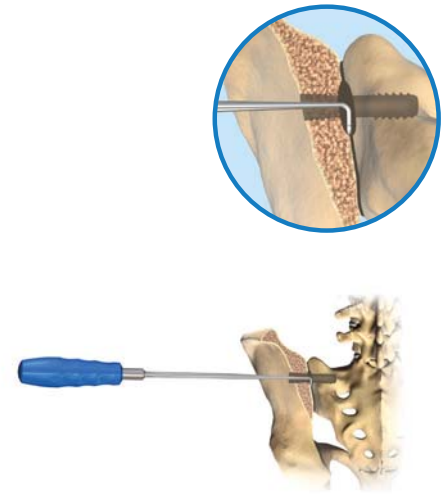


Fig. 9 ▲

Step 9

Take the Right Angle Curette and follow along the Steinmann Pin down to the SI joint. Once a tactile feel has been achieved, confirm in the Outlet View to verify placement in the joint. Rotate the instrument to prepare the SI joint space for bony arthrodesis. Remove the instrument once the site has been properly prepared. (Fig. 9)

NOTE: A standard 2mm scope may be used through the #3 Tissue Shield for additional SI joint visualization.

Instruments



Right Angle Curette
07.02212.020
(X079-0053)



Tap, Cannulated
07.02212.013 7mm
(X079-0035)
07.02212.025 12.5mm
(X079-0064)

**Bone Graft Pre-Pack
(12.5mm Implant Only)**



Fig. 10 ▲

Step 10

Use the Graft Packing Block to pre-pack selected implant with preferred bone grafting choice. Place the distal tip of the implant on the block and insert the bone graft into the implant through the proximal end. (Fig. 10)

CAUTION: Do not over pack as implant will obtain patient autograft during implantation.

TriCor System Bone Graft Volumes (Approximate)
12.5mm implants

LENGTH	VOLUME
30mm	1.50cc
35mm	1.70cc
40mm	2.00cc
45mm	2.20cc
50mm	2.50cc
55mm	2.70cc
60mm	3.10cc
65mm	3.30cc
70mm	3.50cc

Instruments

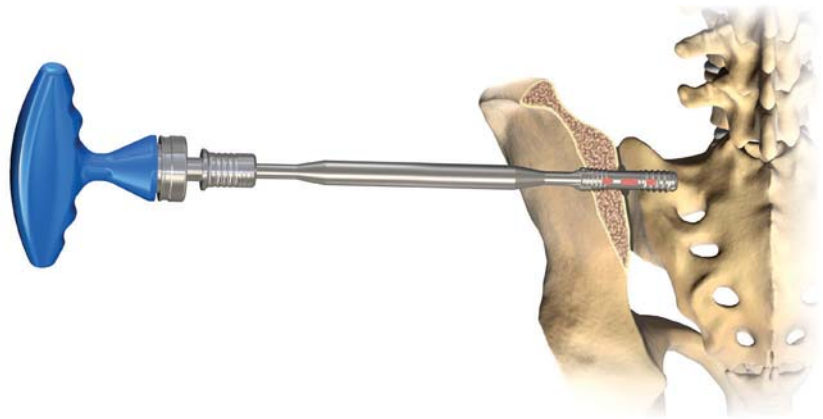


Fig. 11 ▲

Step 11

Select the Implant Screwdriver and place onto the Ratcheting T-Handle. Select the corresponding implant and place onto the distal tip of the driver, making sure the implant is fully seated with the driver shaft. Insert the distal end of the implant over the Steinmann Pin and advance the implant, under fluoroscopy, to desired depth. (Fig. 11)



12.5mm Graft Packing Block
07.02212.003
(X079-0067)



12.5mm Implant Screwdriver
07.02212.023
(X079-0060)

Implant Loading and Final Placement

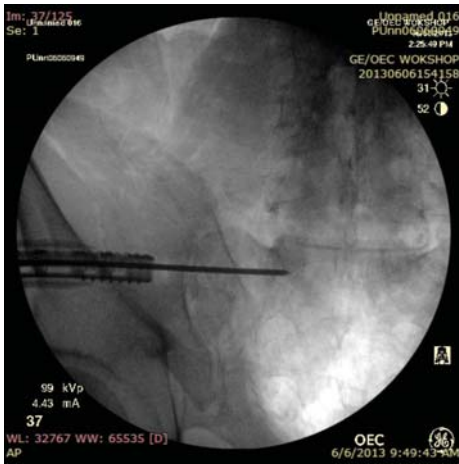


Fig. 12a ▲

Step 12

Outlet View

Implant progression. Initial placement.
(Fig. 12a)

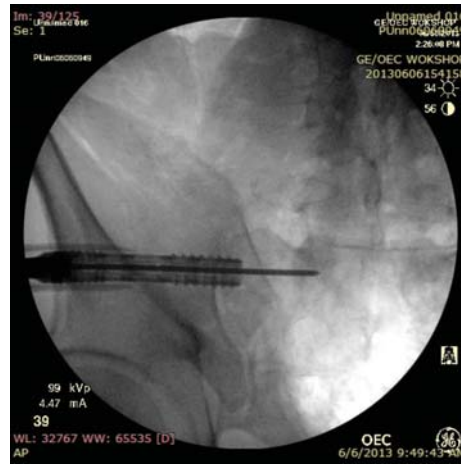


Fig. 12b ▲

Outlet View

Implant progression.
(Fig. 12b)

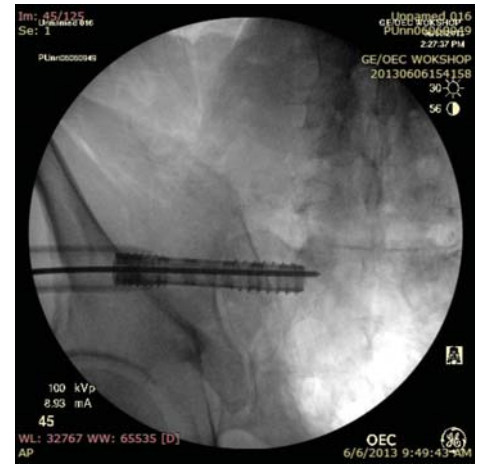


Fig. 12c ▲

Outlet View

Implant progression. Fully seated.
(Fig. 12c)

Steinmann Pin Depth Gage



Fig. 13 ▲

Step 13

Using the first Steinmann Pin, insert the fixed portion of the Steinmann Pin Depth Gage/ Guide over the already inserted pin. Under fluoroscopy in the Lateral View, insert the second pin following the curve of the sacrum. Confirm in the three views (Lateral, Inlet, Outlet) that the second Steinmann Pin placement is accurate. Repeat steps above for implant insertion of the subsequent implants. (Fig. 13)

Bone Graft Post Fill (12.5mm Implant Only)

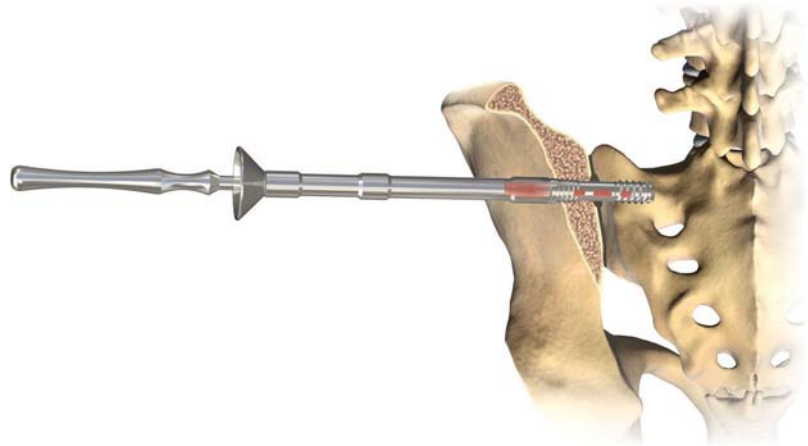


Fig. 14 ▲

Step 14

After the Second Steinmann Pin placement is confirmed, insert the Bone Graft Funnel over the Steinmann Pin from the first implant. Rotate the funnel until fully engaged with the implant. Remove the Steinmann Pin from the first implant once the Bone Graft Funnel is in place. Next, insert the preferred bone graft through the Bone Graft Funnel, following with the Graft Tamp until fully seated with the implant. (Fig. 14)

Instruments



Steinmann Pin Depth Gage/
Guide
07.02212.001
(X079-0084)



Trocar Steinmann Pin
07.02212.021
(X079-0054)



12.5mm Graft Funnel
07.02212.029
(X079-0080)



Graft Tamp
07.02212.002
(X079-0048)

Second Implant Targeting

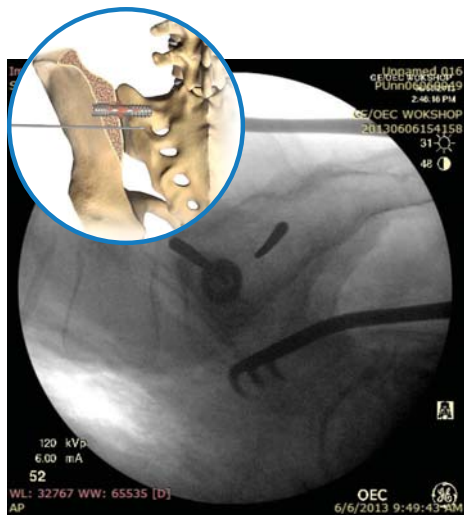


Fig. 15a ▲

Step 15

Repeat Step 3 for placement of the second Trocar Steinmann Pin.

Lateral View (Fig. 15a)

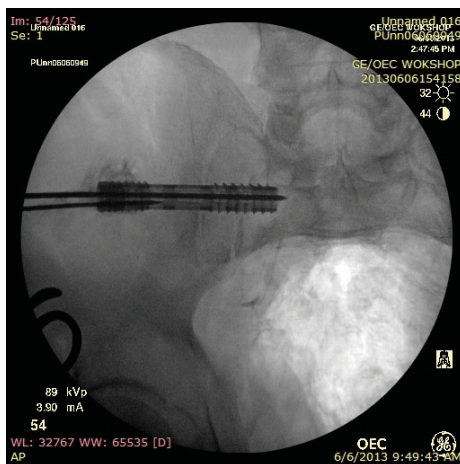


Fig. 15b ▲

Inlet View (Fig. 15b)

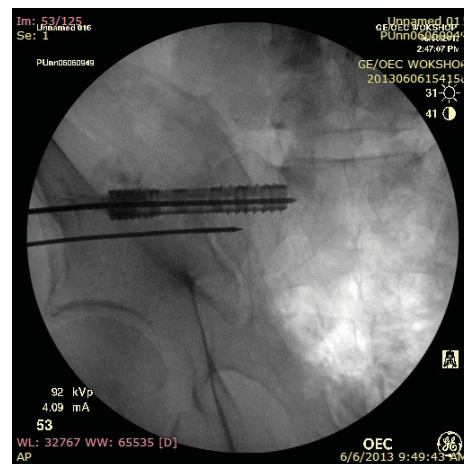


Fig. 15c ▲

Outlet View (Fig. 15c)

Second Implant Insertion

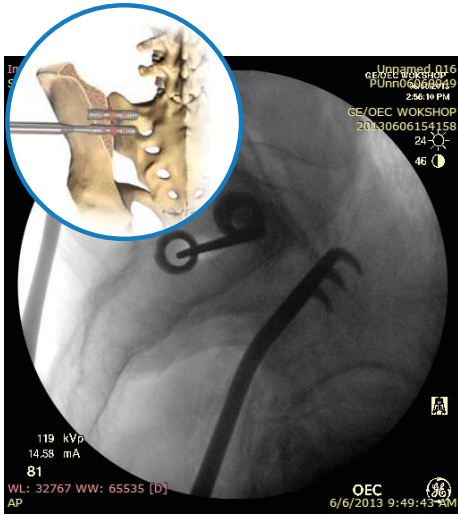


Fig. 16a ▲

Step 16

Repeat Steps 4-14.

Lateral View (Fig. 16a)

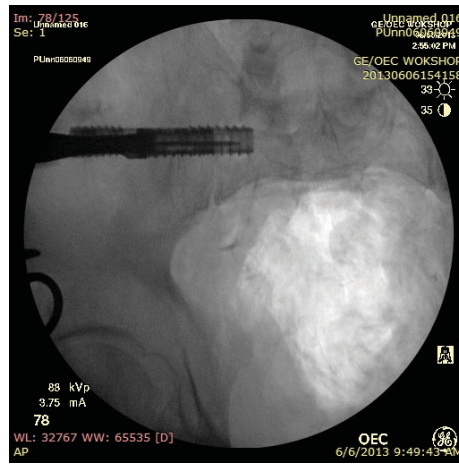


Fig. 16b ▲

Inlet View (Fig. 16b)

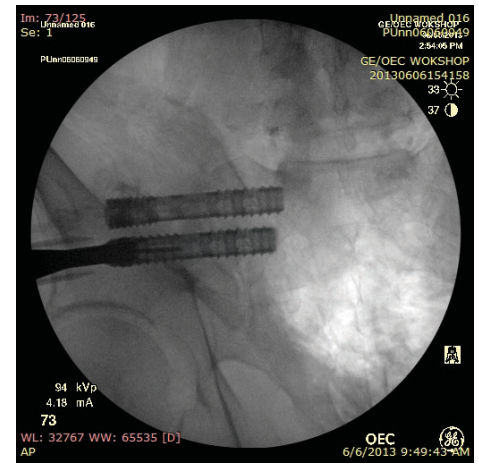


Fig. 16c ▲

Outlet View (Fig. 16c)

Instruments

Third Implant Targeting

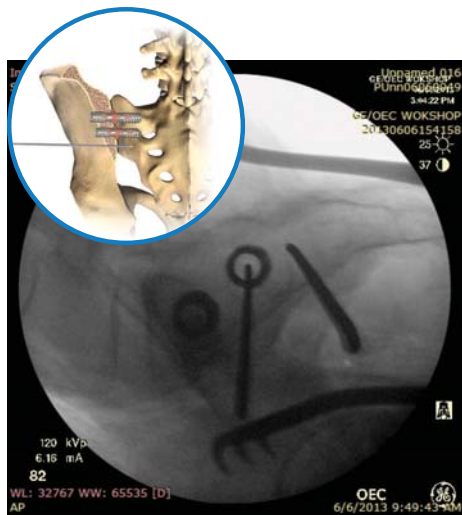


Fig. 17a ▲

Step 17

Repeat Step 3 for targeting of the third implant.

Lateral View (Fig. 17a)

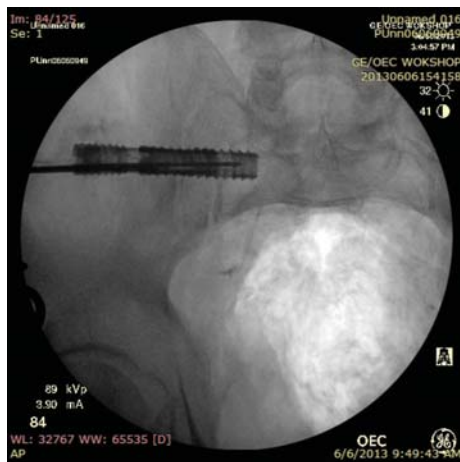


Fig. 17b ▲

Inlet View (Fig. 17b)



Fig. 17c ▲

Outlet View (Fig. 17c)

Instruments

Third Implant Insertion

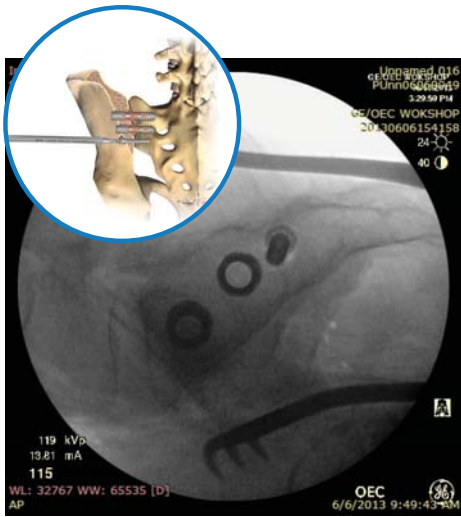


Fig. 18a ▲

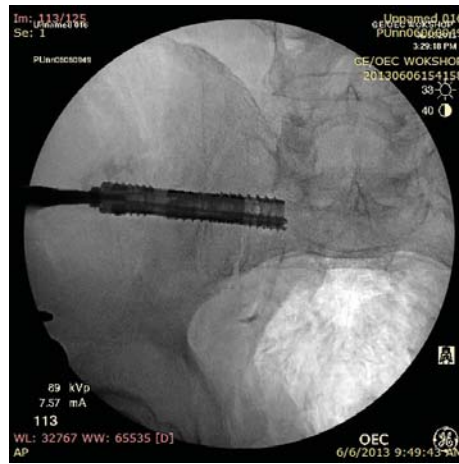


Fig. 18b ▲

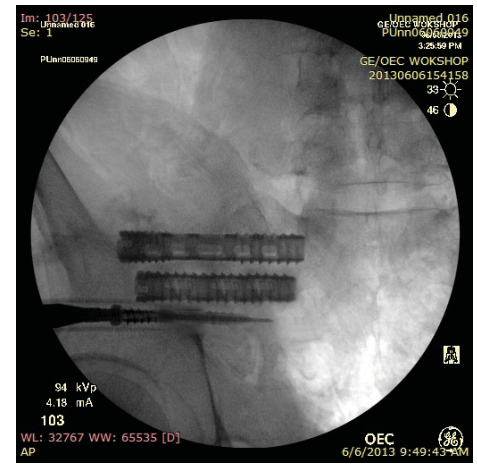


Fig. 18c ▲

Step 18

Repeat Steps 4-14.

Lateral View (Fig. 18a)

Inlet View (Fig. 18b)

Outlet View (Fig. 18c)

Instruments

Final Implant Construct

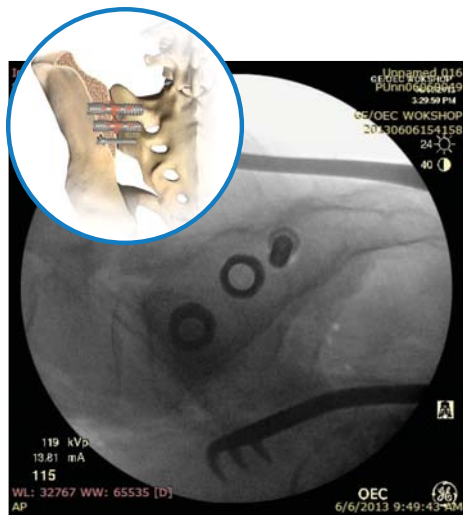


Fig. 19a ▲



Fig. 19b ▲

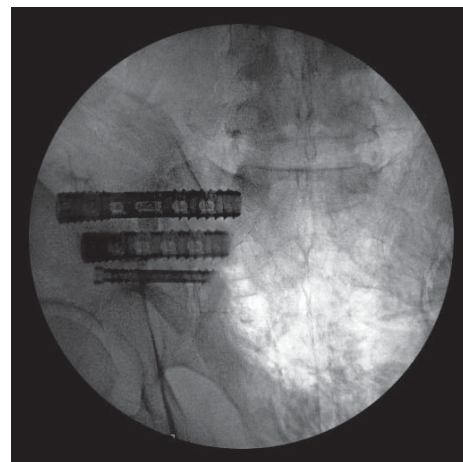


Fig. 19c ▲

Step 19

Confirm final implant placement using Lateral, Inlet and Outlet views under fluoroscopy.

Lateral View (Fig. 19a)

Inlet View (Fig. 19b)

Outlet View (Fig. 19c)

Instruments

Tissue Shield Surgical Technique

Skin Marking

Skin Incision

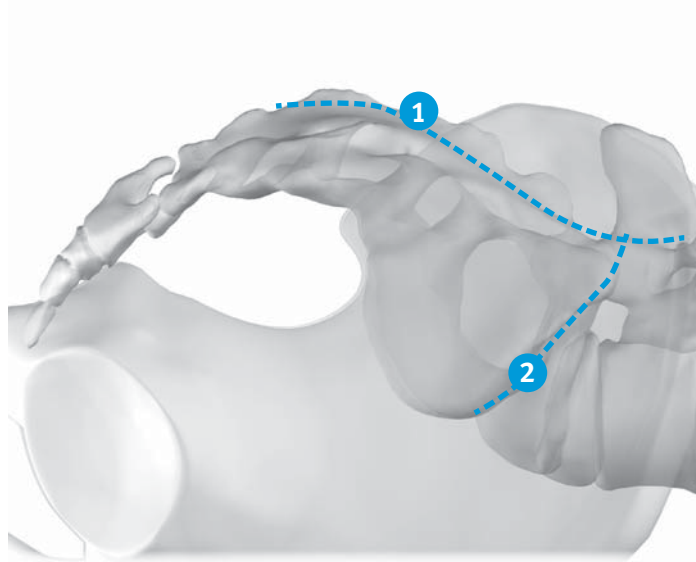


Fig. 20 ▲

Step 1

Use the Exchange Pin to mark the Posterior Sacral Wall (PSW, #1) and Sacral Alar Line (#2) with a marking pen. (Fig. 20)

Step 2

Make a skin incision along the Posterior Sacral Wall, approximately 3-5cm in length, starting at intersection with sacral ala skin marking.

Beginning in the Lateral View, insert the Trocar Steinmann Pin through skin incision approximately 1cm anterior to the Posterior Sacral Wall and 1cm inferior to the ala. (Fig. 20)

Instruments

Exchange Pin
07.02212.028
(X079-0089)

Steinmann Pin Placement



Fig. 21a ▲

Step 3

Confirm placement in 3 views:

Lateral View - Place Steinmann Pin approximately 1cm anterior to PSW and 1cm inferior to ala. (Fig. 21a)

NOTE: Use the #1 Tissue Shield to stabilize the Trocar Steinmann Pin for impaction.

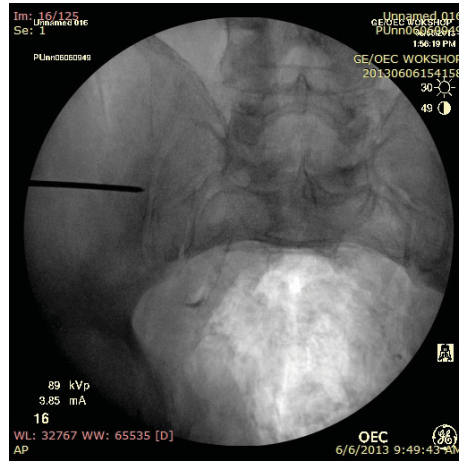


Fig. 21b ▲

Inlet View - The angle of Steinmann Pin should be heading towards the middle of the sacrum. (Fig. 21b)



Fig. 21c ▲

Outlet View - The Steinmann Pin should be parallel to the S1 endplate. Mallet the Steinmann Pin in final desired depth in Outlet view. (Fig. 21c)

NOTE: Blunt or Threaded Steinmann Pins are available to replace the Trocar Steinmann Pin after placement, if desired.

Instruments



Steinmann Pins
07.02212.021 Trocar
 (X079-0054)
07.02212.022 Threaded
 (X079-0057)
07.02212.027 Blunt
 (X079-0086)



Mallet
07.02212.019
 (X034-0915)



#1 Tissue Shield
07.02212.016
 (X079-0045)

Tissue Shield Placement

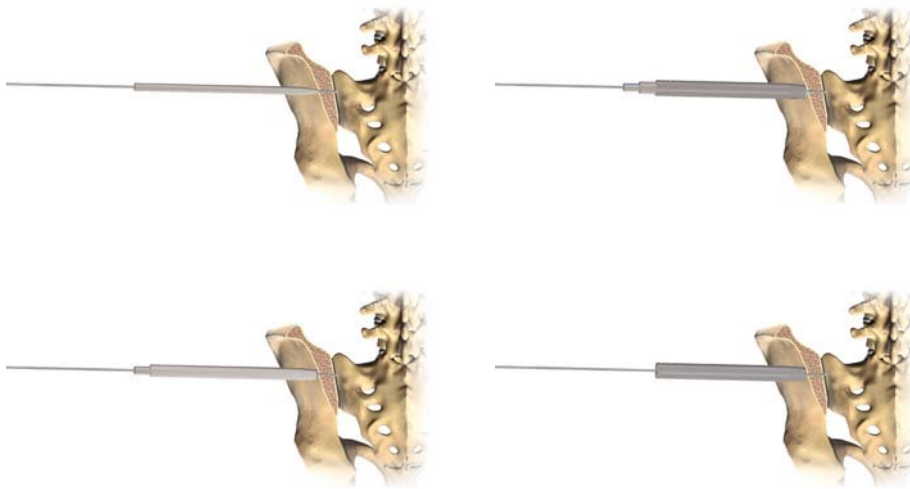


Fig. 22 ▲

Step 4

Drop #1, 2 and 3 Tissue Shields, in sequence, over the Steinmann Pin. Once the #3 Tissue Shield is in place, remove the #1-2 Tissue Shields. (Fig. 22)

NOTE: *Optional Tissue Shield Guide Handle may be used for added stability.*

Measuring/Implant Selection



Fig. 23 ▲

Step 5

While keeping the Tissue Shield in place, use the Steinmann Pin Depth Gage/Guide to select appropriate implant. Insert the Steinmann Pin Depth Gage underneath the inserted Steinmann Pin and dock onto the proximal end of the Tissue Shield. Measure with #3 Tissue Shield for 12.5mm implants and measure with #2 Tissue Shield for 7mm implants. (Fig. 23)

NOTE: *Utilize the correct side of the Steinmann Pin Depth Gage/Guide; it is indicated for #2 and #3 Tissue Shields.*

Instruments



Tissue Shields
07.02212.016 #1
 (X079-0045)
07.02212.017 #2
 (X079-0106)
07.02212.018 #3
 (X079-0107)



Tissue Shield Guide Handle
07.02212.030
 (X079-0090)



Steinmann Pin Depth Gage/
 Guide
07.02212.001
 (X079-0084)

Drill Assembly

Drill

Tap Assembly



Fig. 24 ▲

Fig. 25 ▲

Fig. 26 ▲

Step 6

Attach the Drill bit to the Ratcheting T-Handle or cordless power drill using the provided Jacobs Chuck. (Fig. 24)

NOTE: Make sure the flat portion of the provided Jacobs Chuck attachment fits flush to the walls if using the cordless power drill.

NOTE: The drill flutes are designed to capture the autogenous bone graft for reuse in the 12.5mm anchor implant.

Step 7

Place the Drill bit over the Steinmann Pin slowly advancing until the ilium is reached. Make sure that the Drill is co-linear with the Pin to avoid binding on the Pin.

Using the Outlet view, confirm accurate placement of the Drill bit over the Steinmann Pin. Under fluoroscopic guidance, continue to advance the Drill just across the sacroiliac joint, through the sacral cortex. Try to preserve sacral bone for re-packing the implant. (Fig. 25)

NOTE: Once the Drill reaches the SI joint, exercise caution advancing into the sacrum.

NOTE: Once the Drill bit has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Drill bit while keeping pressure on the Exchange Pin to ensure that the Steinmann Pin remains in place.

Step 8

Attach the Tap to the Ratcheting T-Handle. (Fig. 26)

CAUTION: Do not tap under power.

Instruments



Drill
07.02212.012 7mm
(X079-0034)
07.02212.024 12.5mm
(X079-0063)



Ratcheting T-Handle
07.02212.031
(N60000472)



Jacobs Chuck Adaptor
07.02212.032
(N60001630)



Exchange Pin
07.02212.028
(X079-0089)



Tap, Cannulated
07.02212.013 7mm
(X079-0035)
07.02212.025 12.5mm
(X079-0064)

Tap



Fig. 27 ▲

Step 9

Place the Tap over Steinmann Pin, slowly advancing until you reach the ilium. Make sure that the Tap is co-linear with the pin to avoid binding on the pin.

Using the Outlet view, confirm placement. Under fluoroscopic guidance continue to advance the Tap across the sacroiliac joint, through to the sacral cortex. Try to preserve sacral bone for re-packing into the implant. (Fig. 27)

NOTE: Once the Tap reaches the SI joint exercise caution advancing into the sacrum.

NOTE: Once the Tap has reached the desired depth as indicated by the markings on the shaft, place the Exchange Pin down the cannulated portion of the driver until it reaches the proximal tip of the Steinmann Pin. Slowly remove the Tap while keeping pressure on the Exchange Pin to ensure that the Steinmann Pin remains in place.

Instruments



Right Angle Curette
07.02212.020
(X079-0053)



12.5mm Graft Packing Block
07.02212.003
(X079-0067)

Decortication and Sacroiliac Joint Visualization

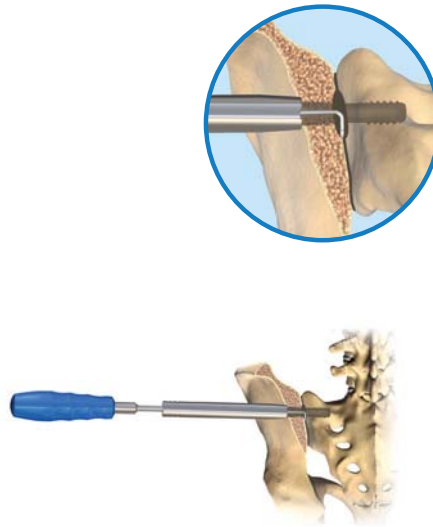


Fig. 28 ▲

Step 10

Take the Right Angle Curette and place through the #3 Tissue Shield. Once a tactile feel has been achieved, confirm in the Outlet view to verify placement in the joint. Rotate the instrument to prepare the SI joint space for bony arthrodesis. Remove the instrument once the site has been properly prepared. (Fig. 28)

NOTE: A standard 2mm scope may be used through the #3 Tissue Shield for additional SI joint visualization.

Bone Graft Pre-Pack (12.5mm Implant only)



Fig. 29 ▲

Step 11

Use the Graft Packing Block to pre-pack selected implant with preferred bone grafting choice. Place the distal tip of the implant on the block and insert the bone graft into the implant through the proximal end. (Fig. 29)

CAUTION: Do not over pack as implant will obtain patient autograft during implantation.

TriCor System Bone Graft Volumes (Approximate)
12.5mm implants

LENGTH	VOLUME
30mm	1.50cc
35mm	1.70cc
40mm	2.00cc
45mm	2.20cc
50mm	2.50cc
55mm	2.70cc
60mm	3.10cc
65mm	3.30cc
70mm	3.50cc

Implant Loading and Final Placement

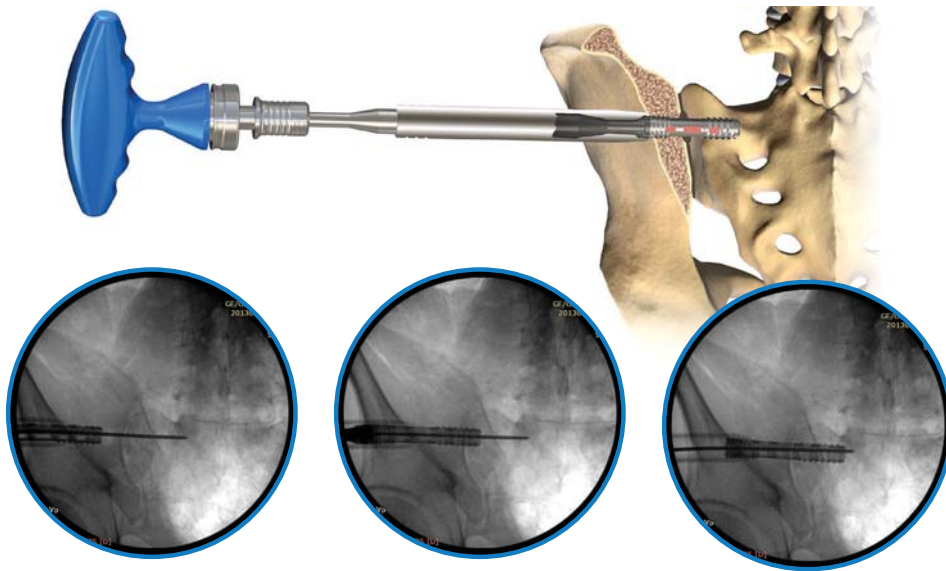


Fig. 30 ▲

Step 12

Select the Implant Screwdriver and place onto the Ratcheting T-Handle. Select the corresponding implant and place onto the distal tip of the driver, making sure the implant is fully seated with the driver shaft. Insert the distal end of the implant over the Steinmann Pin and advance the implant, under fluoroscopy, to desired depth. (Fig. 30)

Steinmann Pin Depth Gage



Fig. 31 ▲

Step 13

Using the first Steinmann Pin, insert the Steinmann Pin Depth Gage/Guide starting in the 0° position over the already inserted pin. Under fluoroscopy in the Lateral view, insert the second pin at the 20° marker while following the curve of the sacrum. Confirm in the three views (Lateral, Inlet, Outlet) that the second Steinmann Pin placement is accurate. Repeat steps above for implant insertion of the subsequent implants. (Fig. 31)

Repeat steps 13-19 on pages 14-19 using the Tissue Shield for the remaining two implants.

Instruments



Steinmann Pin Depth Gage/
Guide
07.02212.001
(X079-0084)



Implant Screwdriver
07.02212.010 7mm
(X079-0030)
07.02212.023 12.5mm
(X079-0060)

Bone Graft Post Fill (12.5mm Implant only)

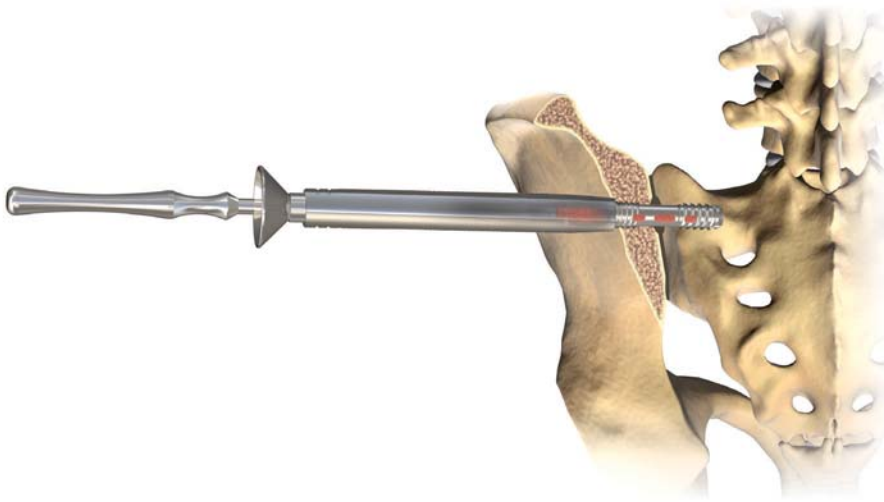


Fig. 32 ▲

Step 14

After the Second Steinmann Pin placement is confirmed, insert the Graft Funnel through the #3 Tissue Shield and over the Steinmann Pin from the first implant. Rotate the Graft Funnel until fully engaged with the implant. Remove the Steinmann Pin from the first implant once the Graft Funnel is in place. Next, insert the preferred bone graft through the Graft Funnel, following with the Graft Tamp until fully seated with the implant. (Fig. 32)

Step 15

Repeat steps 4-14 on pages 20-26 of the Tissue Shield Technique for the remaining two implants. Refer to pages 16-19 for images showing implant placement.

Instruments



12.5mm Graft Funnel
07.02212.029
(X079-0080)



Graft Tamp
07.02212.002
(X079-0048)

Implant Removal and Adjustment

Surgical Technique

Implant Removal and Adjustment



Fig. 33 ▲

After the Second Steinmann Pin placement:

Option #1 – 12.5mm Implant - Attach the Ratcheting T-Handle to the 12.5mm Implant Screwdriver, and locate the proximal end of the implant that needs adjusting. Fully seat the distal end of the Implant Screwdriver into the desired implant. With the Ratcheting T-Handle, rotate counterclockwise to adjust or fully remove the implant. (Fig. 33)

Option #2 – 12.5mm Implant - Using palpation and fluoroscopy, locate the proximal end of the implant that needs adjusting. Insert the distal end of the 12.5mm Implant Removal Instrument into the desired implant until the initial fenestration is reached. Rotate the implant removal tool

counterclockwise or pull axially to adjust or fully remove the implant.

NOTE: The knob at the proximal end of the 12.5mm Implant Removal Tool must be pulled proximally during insertion into the implant. Next, upon finding the fenestration, the knob is pushed forward and locked to retain the implant.

7mm Anchor Implant - Attach the Ratcheting T-Handle to the 7mm Adjustment Screwdriver, and, locate the proximal end of the implant that needs adjusting. Fully seat the distal end of the Implant Screwdriver into the desired implant. With the Ratcheting T-Handle, rotate counterclockwise to adjust or fully remove the implant.

Instruments



12.5mm Implant Screwdriver
07.02212.010
(X079-0030)



7mm Adjustment Screwdriver
07.02212.011
(X079-0033)



Ratcheting T-Handle
07.02212.031
(N60000472)



12.5mm Implant Removal
Instrument
07.02212.033
(X079-0099)

Instrument Visual Guide



Ratcheting T-Handle
07.02212.031
(N60000472)



Jacobs Chuck Adaptor
07.02212.032
(N60001630)



#1 Tissue Shield, Stainless Steel, 9mm
07.02212.016
(X079-0045)



#2 Tissue Shield, Stainless Steel, 13mm
07.02212.017
(X079-0106)



#3 Tissue Shield, Stainless Steel, 16mm
07.02212.018
(X079-0107)



Tissue Shield Guide Handle
07.02212.030
(X079-0090)



Implant Screwdrivers, Cannulated
07.02212.010 7mm
(X079-0030)
07.02212.023 12.5mm
(X079-0060)



Drills, Cannulated
07.02212.012 7mm
(X079-0034)
07.02212.024 12.5mm
(X079-0063)



Taps, Cannulated
07.02212.013 7mm
(X079-0035)
07.02212.025 12.5mm
(X079-0064)



Bone Awl, Cannulated
07.02212.014
(X079-0042)



12.5mm Graft Packing Block
07.02212.003
(X079-0067)



Mallet
07.02212.019
(X034-0915)



12.5mm Graft Funnel
 07.02212.029
 (X079-0080)



Graft Tamp
 07.02212.002
 (X079-0048)



Steinmann Pin Depth Gage/Guide
 07.02212.001
 (X079-0084)



Right Angle Curette
 07.02212.020
 (X079-0053)



12.5mm Implant Removal Instrument
 07.02212.033
 (X079-0099)



7mm Adjustment Screwdriver
 07.02212.011
 (X079-0033)



Cannula Cleaner
 07.02212.015
 (X079-0043)



Steinmann Pin
 07.02212.021 Trocar
 (X079-0054)
 07.02212.022 Threaded
 (X079-0057)
 07.02212.027 Blunt
 (X079-0086)



Exchange Pin
 07.02212.028
 (X079-0089)

Tray Layouts

TriCor Sacroiliac Joint Fusion Instrument and Implant System

07.02211.400

Implants		
Part Number	Description	Quantity
07.02211.001	Cannulated Screw, Dual Thread, Ø7mm x 30mm	2
07.02211.002	Cannulated Screw, Dual Thread, Ø7mm x 35mm	4
07.02211.003	Cannulated Screw, Dual Thread, Ø7mm x 40mm	4
07.02211.004	Cannulated Screw, Dual Thread, Ø7mm x 45mm	4
07.02211.005	Cannulated Screw, Dual Thread, Ø7mm x 50mm	4
07.02211.006	Cannulated Screw, Dual Thread, Ø7mm x 55mm	2
07.02211.007	Cannulated Screw, Dual Thread, Ø7mm x 60mm	4
07.02211.008	Cannulated Screw, Dual Thread, Ø7mm x 65mm	2
07.02211.009	Cannulated Screw, Dual Thread, Ø7mm x 70mm	2
07.02211.010	Washer, 13mm	4
07.02211.011	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 30mm	2
07.02211.012	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 35mm	2
07.02211.013	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 40mm	3
07.02211.014	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 45mm	3
07.02211.015	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 50mm	3
07.02211.016	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 55mm	3
07.02211.017	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 60mm	3
07.02211.018	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 65mm	2
07.02211.019	Cannulated Screw, Dual Thread, Plasma Coated, Ø12.5mm x 70mm	2

Instruments					
Part Number	Description	Quantity	Part Number	Description	Quantity
07.02212.001	Steinmann Pin Depth Gage/Guide	1	07.02212.017	#2 Tissue Shield, Stainless Steel, 13mm	1
07.02212.002	Graft Tamp	1	07.02212.018	#3 Tissue Shield, Stainless Steel, 16mm	1
07.02212.003	Graft Packing Block, 12.5mm	1	07.02212.019	Mallet	1
07.02212.004	Sterilization Case	1	07.02212.020	Right Angle Curette	1
07.02212.007	Steinmann Pin Holder (Trocar)	1	07.02212.023	Ø12.5mm Implant Screwdriver, Cannulated	2
07.02212.008	Steinmann Pin Holder (Threaded)	1	07.02212.024	Ø12.5mm Drill, Cannulated	2
07.02212.009	Instructions for Use	1	07.02212.025	Ø12.5mm Tap, Cannulated	1
07.02212.010	Ø7mm Implant Screwdriver, Cannulated	2	07.02212.026	Steinmann Pin Holder (Blunt)	1
07.02212.011	Ø7mm Adjustment Screwdriver, Cannulated	1	07.02212.029	Ø12.5mm Graft Funnel	1
07.02212.012	Ø7mm Drill, Cannulated	2	07.02212.030	Tissue Shield Guide Handle	2
07.02212.013	Ø7mm Tap, Cannulated	1	07.02212.031	Ratcheting T-Handle, 1/4" Drive	1
07.02212.014	Bone Awl, Cannulated	1	07.02212.032	Jacobs Chuck Adaptor, 1/4" Square	1
07.02212.015	350mm Stylet (.090"), Cannula Cleaner	1	07.02212.033	Ø12.5mm Implant Removal Instrument	1
07.02212.016	#1 Tissue Shield, Stainless Steel, 9mm	1			

Single Use Instruments		
Part Number	Description	Quantity
07.02212.021	Ø2.4mm x 300mm (.094") Steinmann Pin (Trocar)	5
07.02212.022	Ø2.4mm x 300mm (.094") Steinmann Pin (Threaded)	5
07.02212.027	Ø2.4mm x 300mm (.094") Steinmann Pin (Blunt)	5
07.02212.028	500mm Exchange Pin	2

Warnings and Precautions

WARNINGS

As with any surgical system, the *TriCor* Sacroiliac Joint Fusion system should be used by experienced surgeons with specific training in the use of the spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be

so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic and neurosurgical implants, none of the *TriCor* Sacroiliac Joint Fusion System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudoarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The *TriCor* Sacroiliac Joint Fusion System has not been evaluated for safety and compatibility in the MR environment. The *TriCor* Sacroiliac Joint Fusion System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and Zimmer Spine cannot make any claims regarding the safety of Zimmer Spine implants and devices with any specific MR system.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

Disclaimer:

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

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