**TriCor Sacroiliac Joint Fusion System**

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*Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon’s medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.*
System Overview

The TriCor System allows for fusion and stabilization of the SI joint in eligible patients where appropriate non-surgical treatment has failed. The TriCor System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions. The device optionally incorporates a proprietary dualpitch 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.
**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° Caudally)
1. SI Joint
2. S1 Foramen
3. S2 Foramen
4. L5 Nerve
5. Pelvic Brim

Outlet View (40°–60° 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.

**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

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 the SI joint for bony arthrodesis. (Fig. 1)

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

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
07.02212.034
(2079-0054)

#1 Tissue Shield
07.02212.016
(X079-0045)
Steinmann Pin Placement

Step 3
Confirm placement in three views:

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

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

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)
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 12.5 mm implants and measure with #2 Tissue Shield for 7 mm 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.

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 12.5 mm anchor implant.

Step 6
Place the Drill 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 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 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 while keeping pressure on the Exchange Pin to ensure the Steinmann Pin remains in place.

Instruments

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<tr>
<th>Instrument</th>
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<td>Drills, Cannulated</td>
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<td>Ratcheting T-Handle</td>
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<td>Jacobs Chuck Adaptor</td>
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<td>Tissue Shields</td>
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<td>Exchange Pin</td>
<td>07.02212.028 (X079-0089)</td>
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Tap Assembly

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

NOTE: Do not tap under power.

Tap

Step 8
Place the Tap over the Steinmann Pin, slowly advancing until you reach the ilium. Make sure the Tap is collinear 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

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)

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.

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)

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Instruments

12.5mm Graft Packing Block
07.02212.003
(X079-0067)

12.5mm Implant Screwdriver
07.02212.023
(X079-0066)
Implant Loading and Final Placement

Step 12
OUTLET VIEW
Implant progression. Initial placement.
(Fig. 12a)

OUTLET VIEW
Implant progression.
(Fig. 12b)

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

Instruments
**Steinmann Pin Depth Gage**

**Bone Graft Post Fill**
(12.5mm Implant Only)

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**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)

**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 Tampon until fully seated with the implant. (Fig. 14)

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**Instruments**

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

- **Trocar Steinmann Pin**
  07.02212.034 (Z079-0054)

- **12.5mm Graft Funnel**
  07.02212.029 (X079-0080)

- **Graft Tampon**
  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)**

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**TriCor™ Sacroiliac Joint Fusion System—Surgical Technique Guide**
Third Implant Targeting

Step 17
Repeat Step 3 for targeting of the third implant.

LATERAL VIEW (Fig. 17a)

Third Implant Insertion

Step 18
Repeat Steps 4–14.

LATERAL VIEW (Fig. 18a)
**Final Implant Construct**

**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**
**Skin Marking**

**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)

**Skin Incision**

**Step 2**
Make a skin incision along the Posterior Sacral Wall, approximately 3–5 cm in length, starting at intersection with sacral ala skin marking.

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

---

**Instruments**

**Exchange Pin**

07.02212.028

(X079-0089)
Steinmann Pin Placement

Step 3
Confirm placement in three 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.

INLET VIEW
The angle of Steinmann Pin should be heading towards the middle of the sacrum. (Fig. 21b)

OUTLET VIEW
The Steinmann Pin should be parallel to the S1 endplate. Mallet the Steinmann Pin to 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
07.02212.034 (X079-0054)
07.02212.035 (X079-0057)
07.02212.036 (X079-0086)

Trocar
07.02212.019 (X034-0915)

Mallet
07.02212.016 (X079-0045)

#1 Tissue Shield
07.02212.016 (X079-0045)
Tissue Shield Placement

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 and #2 Tissue Shields. (Fig. 22)

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

Measuring/Implant Selection

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

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**Step 6**
Attach the Drill 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 over the Steinmann Pin slowly advancing until the ilium is reached. Make sure that the Drill is collinear with the Pin to avoid binding on the Pin.

Using the Outlet View, confirm accurate placement of the Drill 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 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 while keeping pressure on the Exchange Pin to ensure that the Steinmann Pin remains in place.

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

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**Drill Assembly**

**Drill**

**Tap Assembly**

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**Instruments**

Drills, Cannulated
- 07.02212.012 (X079-0034)
- 07.02212.024 (X079-0063)

7mm

12.5mm

Ratcheting T-Handle
- 07.02212.031 (N60000472)

Jacobs Chuck Adaptor
- 07.02212.032 (N60001630)

Exchange Pin
- 07.02212.028 (X079-0089)

7mm

12.5mm

Tap, Cannulated
- 07.02212.013 (X079-0035)
- 07.02212.025 (X079-0064)
Step 9
Place the Tap over Steinmann Pin, slowly advancing until you reach the ilium. Make sure that the Tap is collinear 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.

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.

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)**

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</table>

**Instruments**

- Right Angle Curette
  - 07.02212.020 (X079-0053)
- 12.5mm Graft Packing Block
  - 07.02212.003 (X079-0067)
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)

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 15–18 using the Tissue Shield for the remaining two implants.
**Bone Graft Post Fill**

**12.5mm Implant Only**

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**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.

---

**Step 15**

Repeat steps 4–14 on pages 21–25 of the Tissue Shield Technique for the remaining two implants. Refer to pages 16–18 for images showing implant placement.

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**Instruments**

- **12.5mm Graft Funnel**
  - 07.02212.029 (X079-0080)
- **Graft Tamp**
  - 07.02212.002 (X079-0048)
Implant Removal and Adjustment
Surgical Technique

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 until the initial fenestration is reached. Rotate the implant removal tool counterclockwise or pull axially to adjust or fully remove the implant.

**Fig. 33 ▲**

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<th>Instruments</th>
<th>Code</th>
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**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
07.02212.034 Trocar
(Z079-0054)

07.02212.035 Threaded
(Z079-0057)

07.02212.036 Blunt
(Z079-0086)

Exchange Pin
07.02212.028
(X079-0089)
## Kit Contents

### TriCor Sacroiliac Joint Fusion Instrument and Implant System

**Kit Number:** 07.02211.400

### Implants

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### Instruments

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### Single-Use Instruments

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Important Information on the TriCor Sacroiliac Joint Fusion System

DEVICE DESCRIPTION
The TriCor System consists of different diameter implants in various lengths and thread configurations to accommodate variations in patient anatomy. The TriCor 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.

WARNINGS AND PRECAUTIONS
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 System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The TriCor System has not been evaluated for safety and compatibility in the MR environment. The TriCor 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 Biomet Spine cannot make any claims regarding the safety of Zimmer Biomet 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: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects and patient counseling information.

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Distributed by:
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