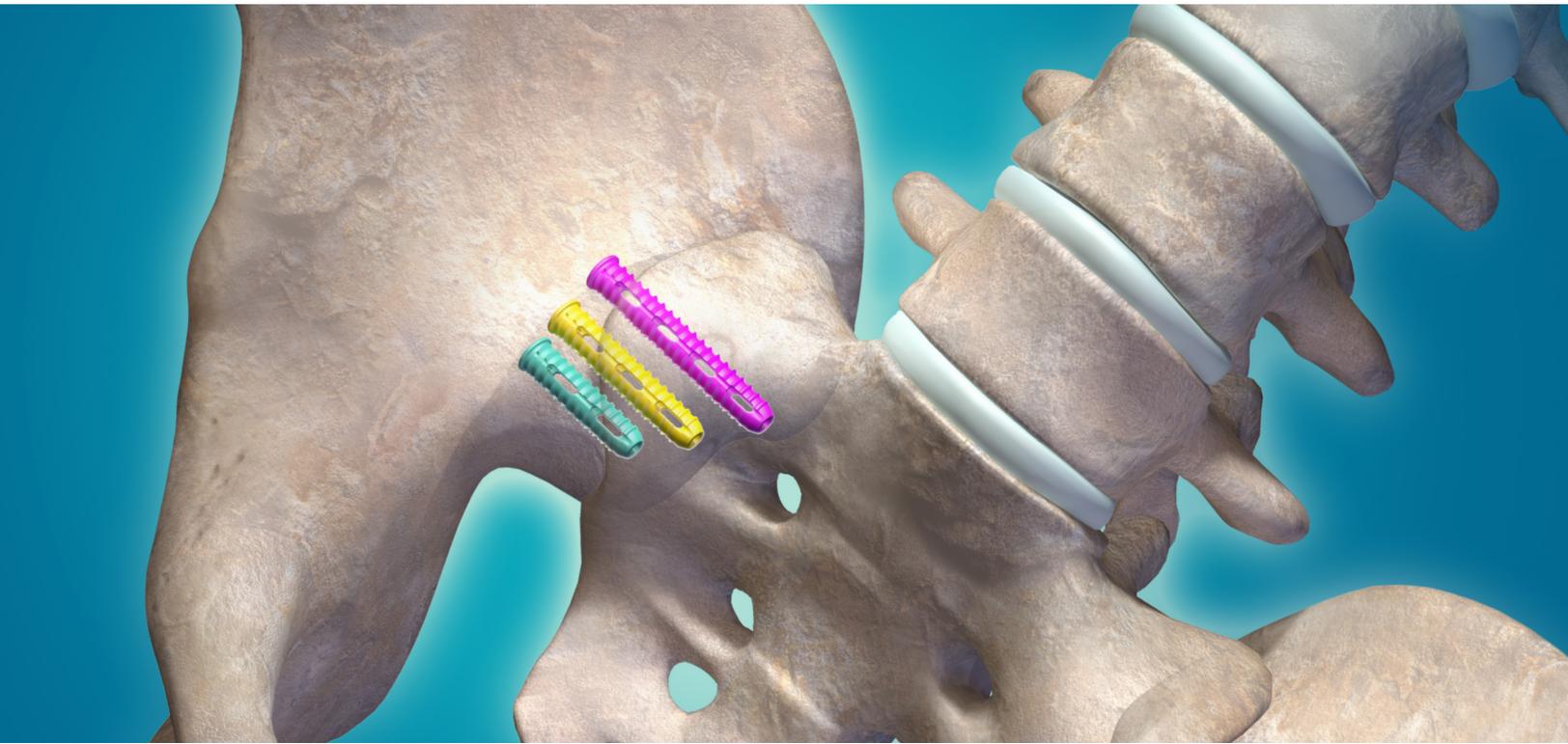


SambaScrew[®]

SI Fixation System



Sacroiliac Joint Fixation

OPERATIVE TECHNIQUE

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION

The sacroiliac joint is a documented source of lower back pain. Review of the literature shows that in up to 30% of patients with lumbago, the sacroiliac joint is the most likely source of pain. The stress across the sacroiliac joint following lumbar fusion, especially at the L5-S1 level, appears to be the most common etiology. It is more common in females. This condition is diagnosed by the patient's history, physical findings, radiological investigations and sacroiliac joint injections which is the gold standard to confirm this condition. Sacroiliac joint fixation or arthrodesis is indicated in patients with severe, chronic sacroiliac joint pain who have failed extensive conservative measures, or in acute cases of trauma.

REFERENCE

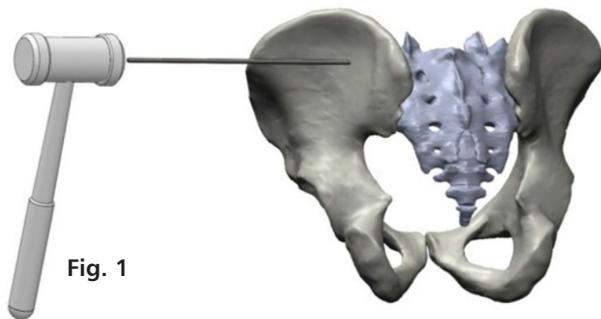
Schwarzer AC, April CN, Bogduk N: The Sacroiliac Joint in Chronic Low Back Pain in Spine 1995;20:31-37.

Dreyfuss P, Dreyer SJ, Cole A, Mayo K: Sacroiliac Joint Pain. J Am Acad Orthop Surg 2004; 12:255-265

Van der Wurff P, Hagmeijer RH, Meyne W: Clinical Tests of the Sacroiliac Joint. A Systemic Methodological Review. Part 2: Validity. Man Ther 2000; 5:89-96.

The SambaScrew Instruments and Implants are provided non-sterile and must be cleaned and sterilized in the provided sterilization tray and caddy prior to each use, as described in the SambaScrew System Instructions for Use.

Note: All instruments, with the exception of the Steinmann Pins (11-1109-16, 11-1109-20, and 11-1109-21), Variable Drill Bit (11-1109-9-1), and Packing Tube (11-1109-8-2) are reusable. The Steinmann Pins, Drill Bit, and Packing Tube are single use devices and should be discarded after use.



Surgical Technique

1. PREOPERATIVE PATIENT SETUP

The patient should be positioned prone on the operative table. C-arm fluoroscopy is used to provide lateral and Ferguson's views. EMG and somatosensory evoked potentials may be 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

2. INCISION LOCATION

Utilizing 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 cm below and approximately 1 cm superior to these two lines respectively and extended caudal parallel to the sacrum posterior cortical wall skin mark, and should measure approximately 2-3 cm. In an obese patient the incision should be slightly more posterior. The soft tissue should be dissected down all the way to the ilium.

3. PLACEMENT OF STEINMANN PIN

The sharp, 9 inch Steinmann Pin should be advanced all the way through the incision to the ilium. Utilizing 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. 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. Neuromonitoring can be used to ensure the safety of the nerve root. NOTE: 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 elevating the hand by 10-15 degrees. Under fluoroscopic control, the pin should be advanced using a mallet across the sacroiliac joint. The final position of the tip of the pin should be approximately 1 cm from the anterior sacral wall, avoiding entrance into the pelvis and just lateral posterior to the S1 neuroforamen (**Fig. 1**).

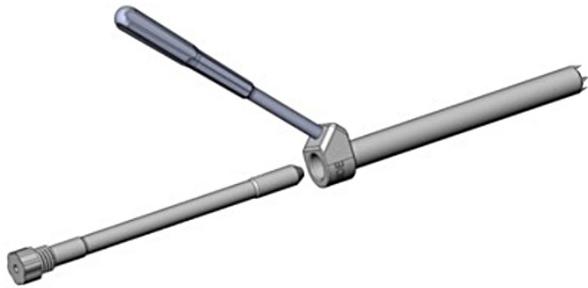


Fig. 2

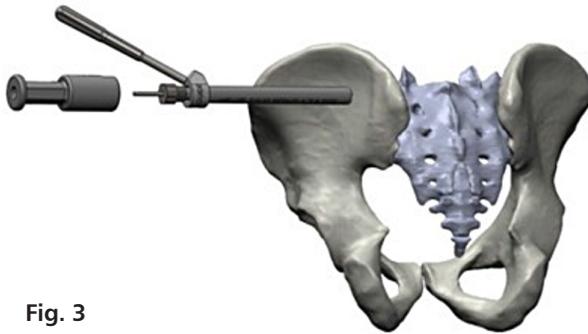


Fig. 3

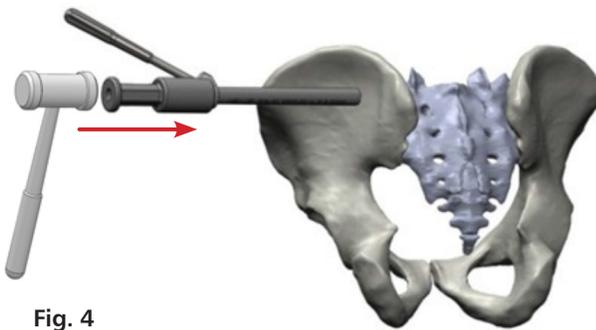


Fig. 4

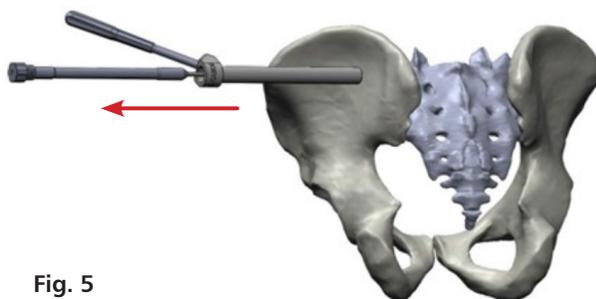


Fig. 5

4. DRILL GUIDE ASSEMBLY AND DRILL GUIDE INSERTION

Assemble the Pin Sleeve and Drill Guide by inserting the Pin Sleeve through the Drill Guide and threading until the Pin Sleeve stops rotating (**Fig. 2**). Once assembled, the Pin Sleeve's tapered trocar tip will protrude beyond the tip of the Drill Guide; the Drill Guide has spikes that will anchor the Drill Guide to the ilium. Insert the assembled Drill Guide over the Steinmann Pin until the Pin Sleeve tip is firmly against the ilium and unscrew the Pin Sleeve from the Drill Guide while simultaneously advancing the Drill Guide. The Striker Tube is installed onto the Drill Guide (**Fig. 3**) and using a mallet, tap the Striker Tube until the Drill Guide is secured and no movement identified (**Fig. 4**). Once the Drill Guide is secured to the ilium, remove the Striker Tube and Pin Sleeve from the Drill Guide (**Fig. 5**).

Note: Do not over tighten Pin Sleeve into Drill Guide.

Note: Drill Guide handle should be perpendicular to the patient's spine.

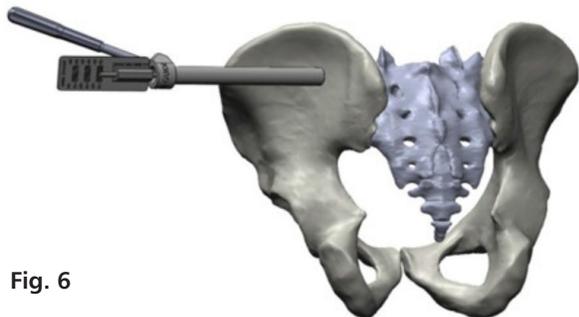


Fig. 6

5. SELECTION OF SambaScrew LENGTH

Slide the Drill Gauge over the Steinmann Pin until it makes contact and rests flat on the Drill Guide (Fig. 6). Read the Drill Gauge according to where the top of the Steinmann Pin is measured; this number represents the length of SambaScrew to select. Remove Drill Gauge.



Fig. 7

6. DRILLING OF PILOT HOLE

Once the appropriate SambaScrew length has been selected, place the Adjustable Drill Collar (security stop) over the Variable Drill Bit to prevent over-penetration (Fig. 7). Connect the Variable Drill Bit to the Drill Bit T-handle and tighten the chuck using the key provided. Alternatively, the Variable Drill Bit may be connected to an electrical drill. Under fluoroscopy, a pilot hole is created stopping just short of the tip of the Steinmann Pin (Fig. 8). The Adjustable Drill Collar will control the depth of the pilot hole. Once the desired depth is reached, the Variable Drill Bit is then removed along with the Steinmann Pin.

Note: If the Variable Drill Bit, instead of sliding over the Steinmann Pin, appears to be advancing the Steinmann Pin, the Steinmann Pin should be removed and replaced by a blunt Steinmann Pin or the pilot hole drilled without Steinmann Pin guidance.

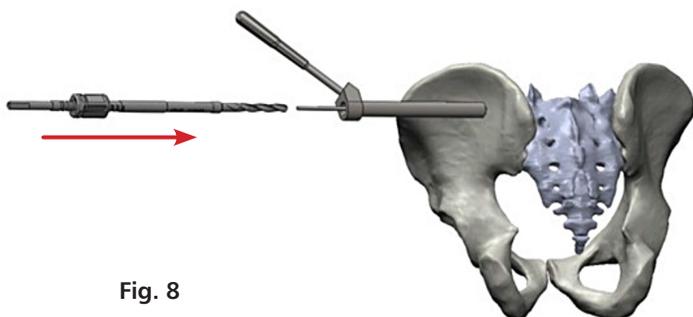


Fig. 8

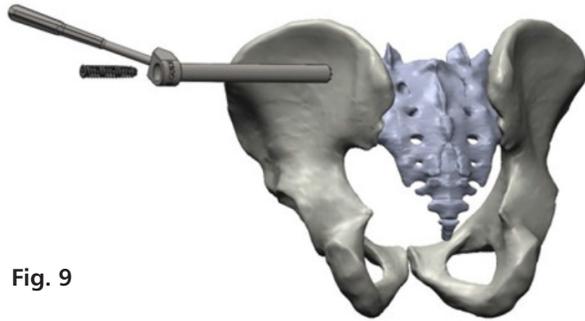


Fig. 9

7. PLACEMENT OF SambaScrew AND FIXATION

The SambaScrew may be filled with allograft or autograft prior to insertion. Slide the SambaScrew into the Drill Guide until it rests on the ilium (**Fig. 9**). Insert the Cannulated Driver Bit into the Drill Guide and align the Driver Bit with the SambaScrew. Under fluoroscopic guidance, advance the SambaScrew into the pilot hole until the screw head stops against the ilium. In addition, the laser marking on the Cannulated Driver Bit will indicate when to stop advancing the screw. Remove the Cannulated Driver Bit once this procedure is complete.

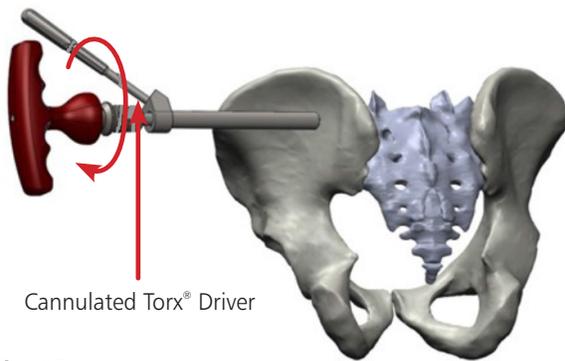


Fig. 10

8. ADDITIONAL PACKING OF SambaScrew AND/OR SACROILIAC JOINT WITH ALLOGRAFT BONE (step is optional)

Remove the Steinmann Pin and with the Drill Guide still in place, the implant and/or Sacroiliac Joint may be packed with additional allograft using the Packing Plunger Assembly (**Fig. 11**). Once the amount of allograft has been determined, usually 2cc to 4cc, the Packing Plunger Assembly is loaded and engaged with the SambaScrew. The allograft is then injected into the SambaScrew and SI joint. The allograft will penetrate the screw, ilium, the sacrum and the sacroiliac joint. The surgeon may use allograft or autograft.

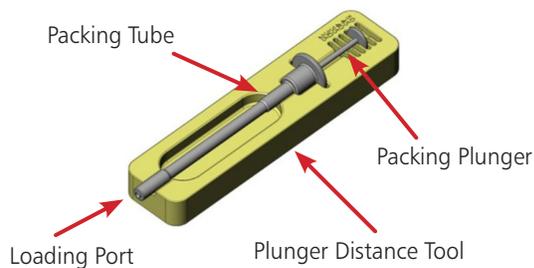


Fig. 11

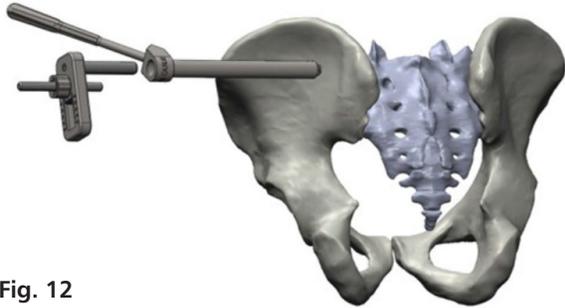


Fig. 12

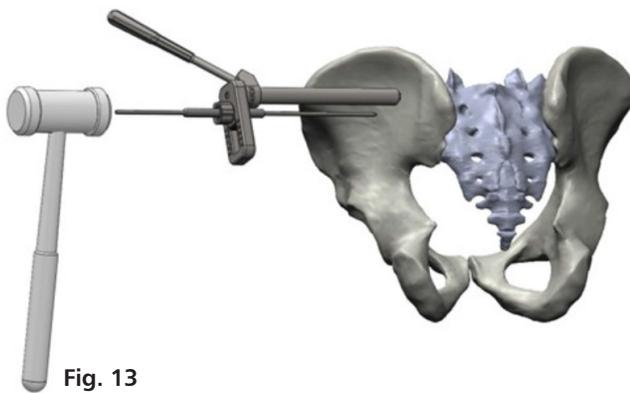


Fig. 13

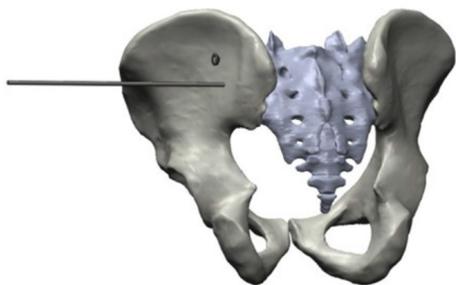


Fig. 14

9. PLACEMENT OF MULTIPLE SambaScrew SCREWS

For adequate fixation it is recommended that three (3) SambaScrews be implanted with the option of using 2 or 4 implants also available due to variations in anatomy.

With the Drill Guide in place, attach the Parallel Guide Assembly (**Fig. 12**). The distance between successive SambaScrews should be set on the guide prior to insertion into the Drill Guide. This instrument will fit into the Drill Guide, or over the Steinmann Pin if present. The second pin guide will guide the direction of the second Steinmann Pin (**Fig. 13**). The second SambaScrew 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 tube. Using a mallet, the Steinmann Pin is advanced across the sacroiliac joint, again under biplane fluoroscopy guidance (**Fig. 13**).

NOTE: Always be sure not to advance the Steinmann Pin or the Drill Bit too far, especially at the level of a neuroforamen. The Steinmann Pin is usually stopped lateral to the level of the S1 and S2 neuroforamen. Once the second Steinmann Pin is in the desired position, the Parallel Guide Instrument, Drill Guide and first Steinmann Pin (if present) are removed and the entire procedure is repeated for insertion of the second implant (**Fig. 14**). A third or fourth implant may be inserted using the same technique. The third implant should be located just above the S2 neuroforamen. If correct measurement of the implant is performed, the SambaScrew head should stop at the ilium and not compromise any deeper structure. Prior to wound closure, all implants should be visualized by fluoroscopy not only in the lateral and Ferguson's views, but also in the oblique, AP and inlet views to assure proper position of the implants which should be across the sacroiliac joint without violating the spinal canal, the neuroforamen(s), the anterior sacral cortical wall and the sacral ala.

IMPLANT REMOVAL

In order to remove a SambaScrew, the patient is positioned in a similar fashion as for screw insertion. The wound is reopened utilizing standard surgical technique. Using the Cannulated Driver Bit under fluoroscopic guidance, the head of the screw is engaged and rotated counter-clockwise until the screw is out.

If the surgeon desires to replace the screw, prior to its removal, a short Steinmann pin should be inserted through the cannulated Driver. The screw is then removed as described above, and the Steinmann pin is used as a guide for the new screw. Use standard protocol for wound closure and postoperative care.

Warning: If the screw has been in place for a sufficient amount of time for bone to have grown into the screw, removal may not be feasible.

Instrument/Implant Catalog

Instruments

	Model Number	Description
	11-1109-FD7	Parallel Guide Set <ul style="list-style-type: none"> • Includes Parallel Guide Frame • Parallel Guide Locking Nut • Parallel Sliding Block
	11-1109-FD8-1	Packing Plunger
	11-1109-FD9-2	Adjustable Drill Collar
	11-1109-FD10	Drill Guide
	11-1109-FD11	Pin Sleeve
	11-1109-FD12	Drill Gauge

Instruments

	Model Number	Description
	11-1109-FD13	Striker Tube
	11-1109-FD14	Cannulated Driver Bit
	11-1109-FD15	Plunger Distance Tool
	11-1109-FD17	Driver Bit T-Handle
	11-1109-FD18	Drill Bit T-Handle with Key

Disposable Instruments

	Model Number	Description
	11-1109-FD8-2	Packing Tube
	11-1109-FD9-1	Variable Drill Bit
	11-1109-FD16	Sharp Steinmann Pin, 9"
	11-1109-FD20	Short Blunt Steinmann Pin, 229mm
	11-1109-FD21	Long Blunt Steinmann Pin, 457mm

11-1005 Implant Caddy

	Part Number	Description
	11-1109-1	9mm x 25mm
	11-1109-2	9mm x 30mm
	11-1109-3	9mm x 35mm
	11-1109-4	9mm x 40mm
	11-1109-5	9mm x 45mm
	11-1109-6	9mm x 50mm

Description:

The SambaScrew SI Fixation System is a temporary, multiple component system consisting of non-sterile instruments and non-sterile, medical-grade titanium (Ti-6Al-4V ELI) implants. The system consists of a 9mm diameter, cannulated screw with multiple orifices on its shaft. The Steinmann Pins, Variable Drill Bit, and Packing Tube are single use devices and should be discarded after use.

Indications for Use:

The SambaScrew SI Fixation System is intended for fixation of sacroiliac joint disruptions. This fixation device is to only be used in skeletally mature patients.

Contraindications:

The SambaScrew SI Fixation System is contraindicated for use in patients with:

1. Open wounds, infection, presence of tumor, pregnancy, osteoporosis, certain metabolic disorders affecting osteogenesis, certain inflammatory/neuromuscular conditions, and certain neuromuscular deficits which would place an unusually heavy load on the device during the healing period.
2. The implant is made from Ti-6Al-4V ELI (medical-grade titanium alloy). The fixation implant is contraindicated in any individual with a known or suspected allergy, sensitivity or intolerance to metal.

Potential Adverse Events:

Potential adverse events include, but are not limited to:

1. Allergic reaction or metal sensitivity to foreign body.
2. Cardiovascular system compromise.
3. Death.
4. Decrease in bone density due to stress shielding.
5. Device bending, disassembly, fracture, loosening, migration and/or repulsion, or subsidence.
6. Dural tears, neural structure injury.
7. Fixation implant migration with or without bone fracture.
8. Fracture of pelvis or sacrum.
9. Gastrointestinal complications (i.e., ileus or bowel perforation).
10. Hemorrhage.
11. Incisional complications (i.e., dehiscence, hematoma).
12. Infection (Incisional or implant site).
13. Loss of spinal mobility or function.
14. Loosening or fracture of fixation implant.
15. Malfunction of fixation device and/or instruments.
16. Malposition of the fixation device.
17. Migration of fixation implant.
18. Neurological injury/deficit which may range from paresthesias to muscle paralysis, loss of rectal or bladder sphincter control, radiculopathies.
19. Organ, connective tissue or nerve damage.
20. Osteoarthritis.
21. Pain, discomfort or abnormal sensation due to device presence.
22. Persistent low back pain.
23. Reproductive system compromise.
24. Screw back-out or breakage possibly leading to local pain, perforation or irritation of adjacent structures.
25. Sepsis.
26. Urological compromise (i.e., infection/retention).
27. Vascular injury.
28. Wound hematoma.

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

Warnings and Precautions:

1. The SambaScrew device should only be used by surgeons who have been trained in the use of this device. Information on laboratory and clinical training, as well as additional brochures with a detailed description of proper surgical technique, may be obtained from Orthofix. See the SambaScrew SI Fixation System Surgical Manual for instructions on the implant procedure.
2. Infection may occur immediately following implant fixation or a long time afterwards due to transient bacteremia such as caused by dental treatment(s), endoscopic examination or any other minor surgical procedure. To avoid infection at the implant fixation site, it may be advisable to use antibiotic prophylaxis before and/or after such procedures.

 Manufactured by:
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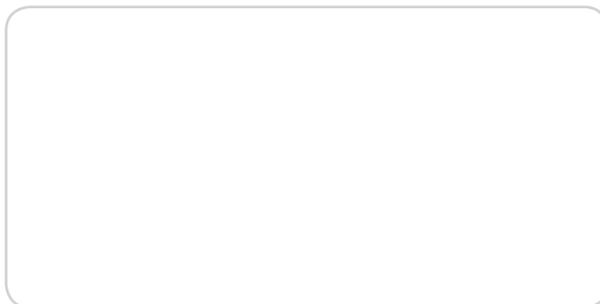
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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

