

SambaScrew[®]

SI Fixation System



SambaScrew®

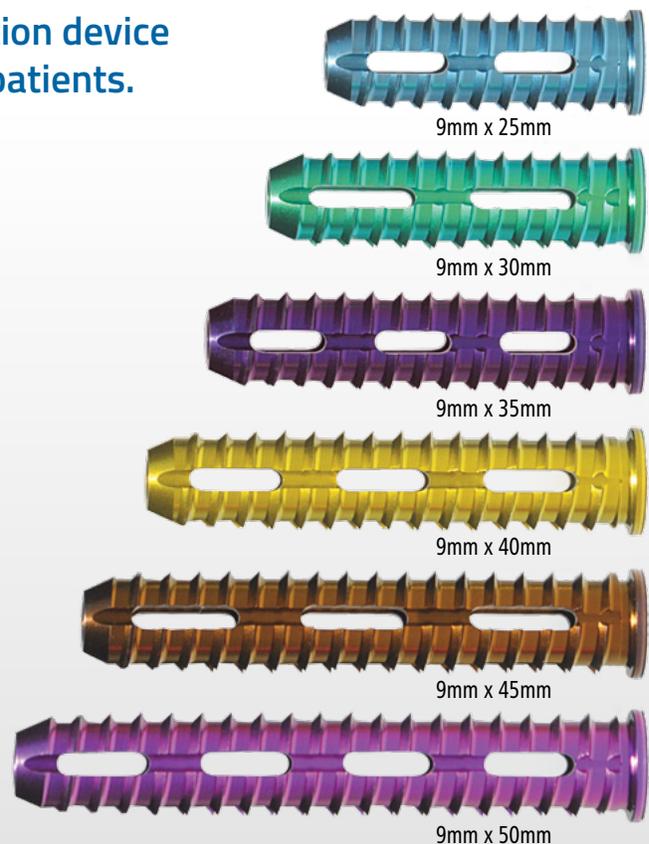
SI Fixation System

Complete Surgical Solution for Sacroiliac Joint Disruption

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.¹ The stress across the sacroiliac joint following lumbar fusion, especially at the L5-S1 level, appears to be the most common etiology.² It is more common in females. This condition is diagnosed by the patient's history, physical findings, radiological investigations and sacroiliac joint injections which are the gold standard to confirm this condition.³ 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.

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

- Reduced Steps. Drill. Screw. Repeat. Close.
- Fenestrations allow for visualization of bone growth
- Cannulated design enables packing and delivery of biologics
- Simple instrumentation for controlled implantation



SambaScrew® System Implants and Instruments

Instruments

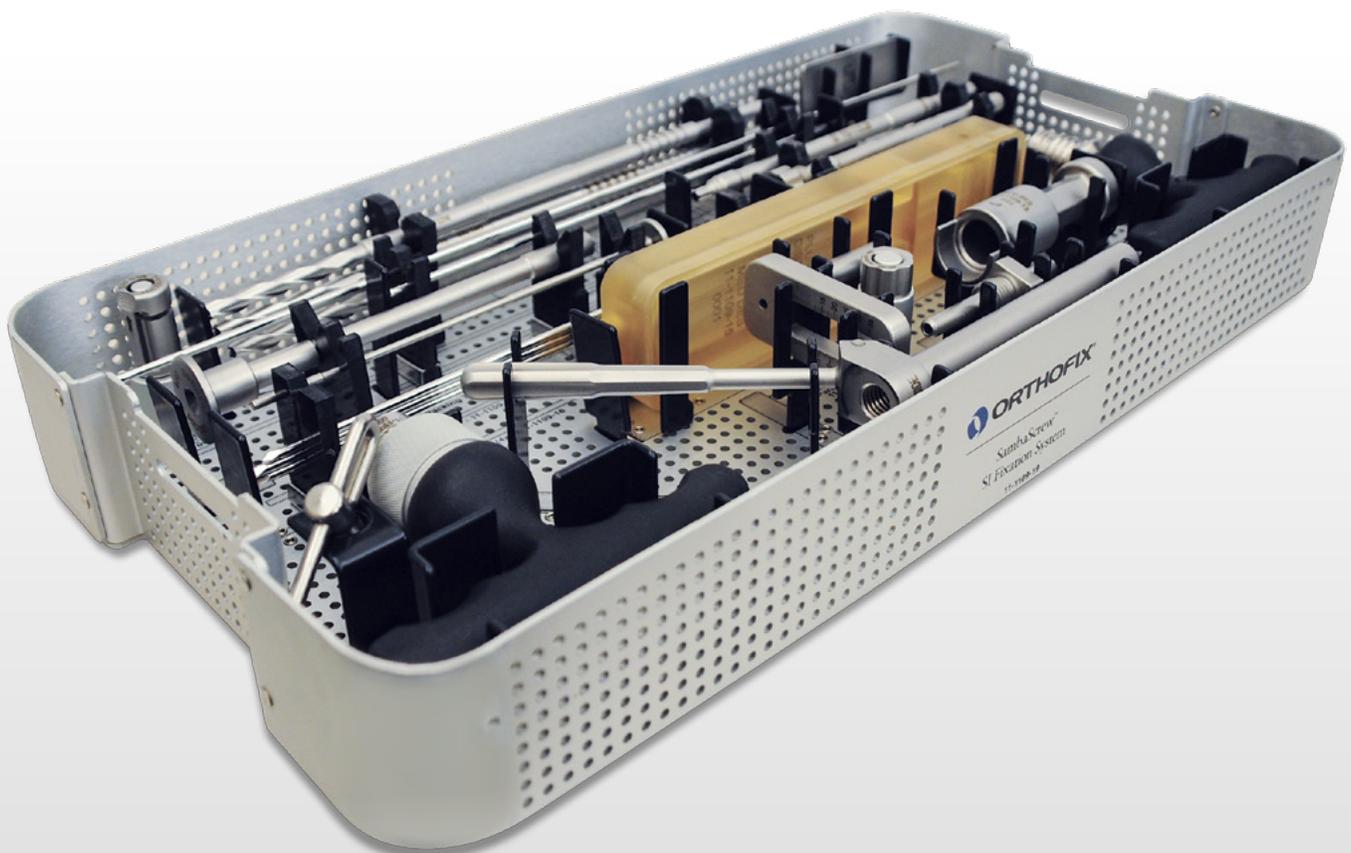
Model Number	Description
11-1109-FD7	Parallel Guide Set - Parallel Guide Frame - Parallel Guide Locking Nut - Parallel Guide Block
11-1109-FD8-1	Packing Plunger
11-1109-FD9-2	Adjustable Drill Collar
11-1109-FD10	Drill Guide
11-1109-FD11	Pin Sleeve
11-1109-FD12	Drill Gauge
11-1109-FD13	Striker Tube
11-1109-FD14	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

11-1005 Implant Caddy

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

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



References

1. Schwarzer AC, April CN, Bogduk N: The Sacroiliac Joint in Chronic Low Back Pain in Spine 1995;20:31-37.
2. Dreyfuss P, Dreyer SJ, Cole A, Mayo K: Sacroiliac Joint Pain. J Am Acad Orthop Surg 2004; 12:255-265
3. 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.

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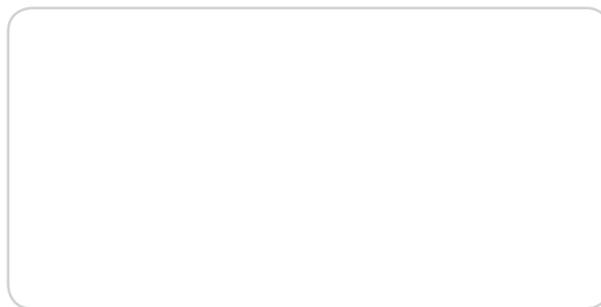
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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must 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.


ORTHOFIX®