

SAMBA™ SCREW SYSTEM

Minimally Invasive Surgical Solution
for Sacroiliac Joint Disruption



MEDICAL
DESIGNS LLC.

Surgical Instruments Designed by Medical Professionals

SAMBA™
SCREW
(9mm x 50mm L)



SI Joint Fusion with the SAMBA™ Screw System

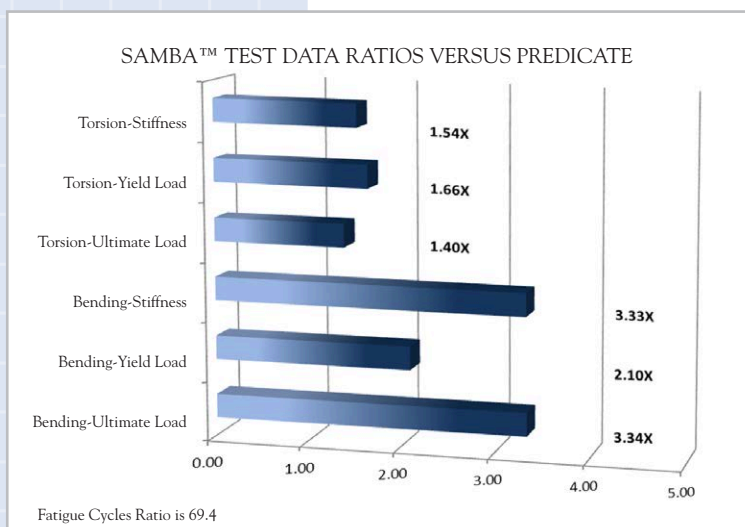
The sacroiliac joint is a documented source of lower back pain. Review of the literature shows that in up to 30% of patients with lumbago, the sacroiliac joint is the most likely source of pain. The stress across the sacroiliac joint following lumbar fusion, especially at the L5-S1 level, appears to be the most common etiology. Other causes include trauma, postpartum, heavy weight lifting, and arthritis. In a small subset of patients, the sacroiliac joint discomfort is of unknown 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.*

INDICATIONS

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

FEATURES

- The SAMBA™ Screw is a hollow-body titanium threaded fusion device, designed with multiple orifices on its shaft to promote arthrodesis across the Sacroiliac Joint (SI joint).
- The SAMBA™ Screw incorporates radial slots along the screw's body intended to optimize surrounding bone access to the bone substitute, allowing greater bone growth through the SAMBA™ Screw.
- Specifically designed instrument to enable delivery through the SAMBA™ Screw of additional osteogenic and osteoconductive material into the Sacroiliac Joint.
- Tapered screw tip to aid in guidance through pilot hole.
- Multiple long flutes to reduce torque and increase fixation.
- Low profile screw head prevents soft tissue irritation.
- Implant threaded in place in a controlled manner.
- Precision machined devices in a range of lengths to accommodate patient anatomy. Available in 6 lengths in 5mm increments, 25mm – 50mm.



Predicate:

Synthes 6.5mm TI Cannulated Screw Fully Threaded 50mm (408.466)

Axial Pullout Test

(SAMBA™ n=5 , Synthes n=3)

Static Torsion Test

(SAMBA™ n=5 , Synthes n=1)

Static Cantilever Bending Test

(SAMBA™ n=5 , Synthes n=1)

Dynamic Cantilever Bending Test

(SAMBA™ n=8 , Synthes n=2)

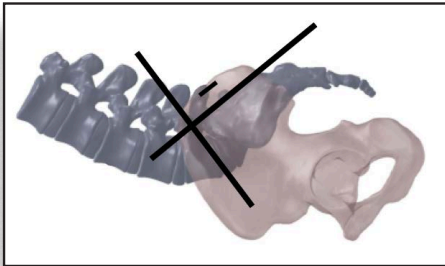
Note: Test Reports on file at Medical Designs, LLC.

*References

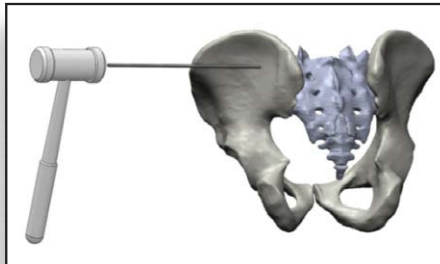
- Schwarzer AC, April CN, Bogduk N: The Sacroiliac Joint in Chronic Low Back Pain in Spine 1995;20:31-37.
- Dreyfuss P, Dreyer SJ, Cole A, Mayo K: Sacroiliac Joint Pain. J Am Acad Orthop Surg 2004; 12:255-265
- Van der Wurff P, Hagmeijer RH, Meyne W: Clinical Tests of the Sacroiliac Joint. A Systemic Methodological Review. Part 2: Validity. Man Ther 2000; 5:89-96.

Surgical Technique

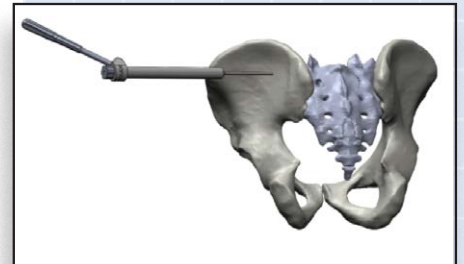
SAMBA™
SCREW SYSTEM



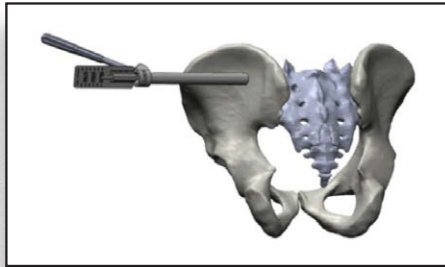
(Fig. 1) Implant location and incision



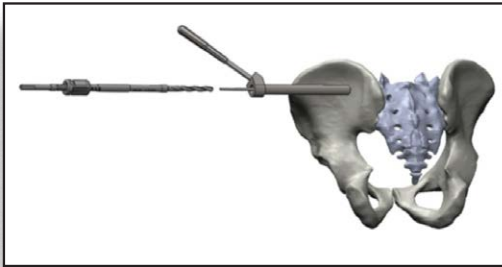
(Fig. 2) Placement of the Steinmann Pin



(Fig. 3) Drill Guide Insertion



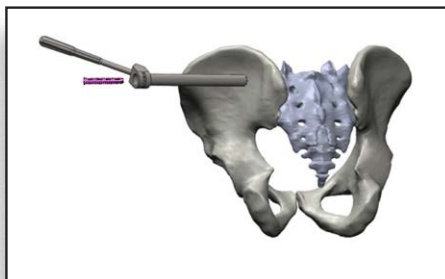
(Fig. 4) Selection of SAMBA™ Screw



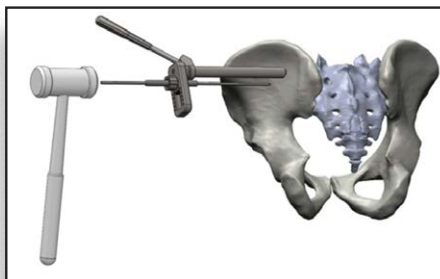
(Fig. 5) Drilling of Pilot Hole



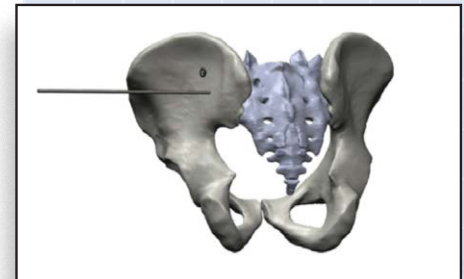
(Fig. 6)
Fill SAMBA™
Screw with
Demineralized
Allograft (or
Autograft) Bone



(Fig. 7) Placement of the SAMBA™ Screw



(Fig. 8) Position Parallel Guide



(Fig. 9) Placement of additional SAMBA™ Screws

As with any surgical procedure, the physician should be trained on proper surgical technique. A Surgical Manual that provides a detailed description of proper surgical technique may be obtained through Medical Designs, LLC. There are risks and considerations associated with surgery and use of the SAMBA™ Screw Implant. A complete listing of contraindications, warnings and potential adverse events, can be found in the SAMBA™ Screw Instructions for Use.

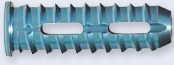
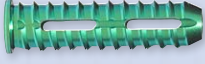



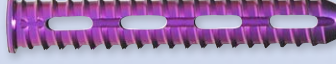
SURGICAL BENEFITS

- Minimally Invasive Surgical (MIS) approach.
- Technique designed to prevent nerve injury.
- Safe, fast and promotes fusion across the SI Joint with immediate stabilization.
- Great pullout strength with low chance of migration of implant.
- Implant is flush with Ilium for greater patient comfort.
- Fewer steps compared to other techniques.
- Specialized instruments designed to implant the SAMBA™ Screw.
- Comprehensive system requires minimal instrumentation.

ORDERING INFORMATION

To order the SAMBA™ Screw System, please contact Medical Designs, LLC at 888-276-7271 or inquire online at www.medicaldesignsllc.com

SAMBA™ Screw Implants (9mm Diam.)

SAMBA™ Screw	Length	Model Number
	25mm	11-1109-FD1
	30mm	11-1109-FD2
	35mm	11-1109-FD3
	40mm	11-1109-FD4
	45mm	11-1109-FD5
	50mm	11-1109-FD6

Disposables

Description	Model Number
 Packing Tube	11-1109-FD8-2
 Variable Drill Bit	11-1109-FD9-1
 Sharp Steinmann Pin, 9", Ø 3.20mm	11-1109-FD16
 Short Blunt Steinmann Pin, 229mm, Ø 3.20mm	11-1109-FD20
 Long Blunt Steinmann Pin, 457mm, Ø 3.20mm	11-1109-FD21

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