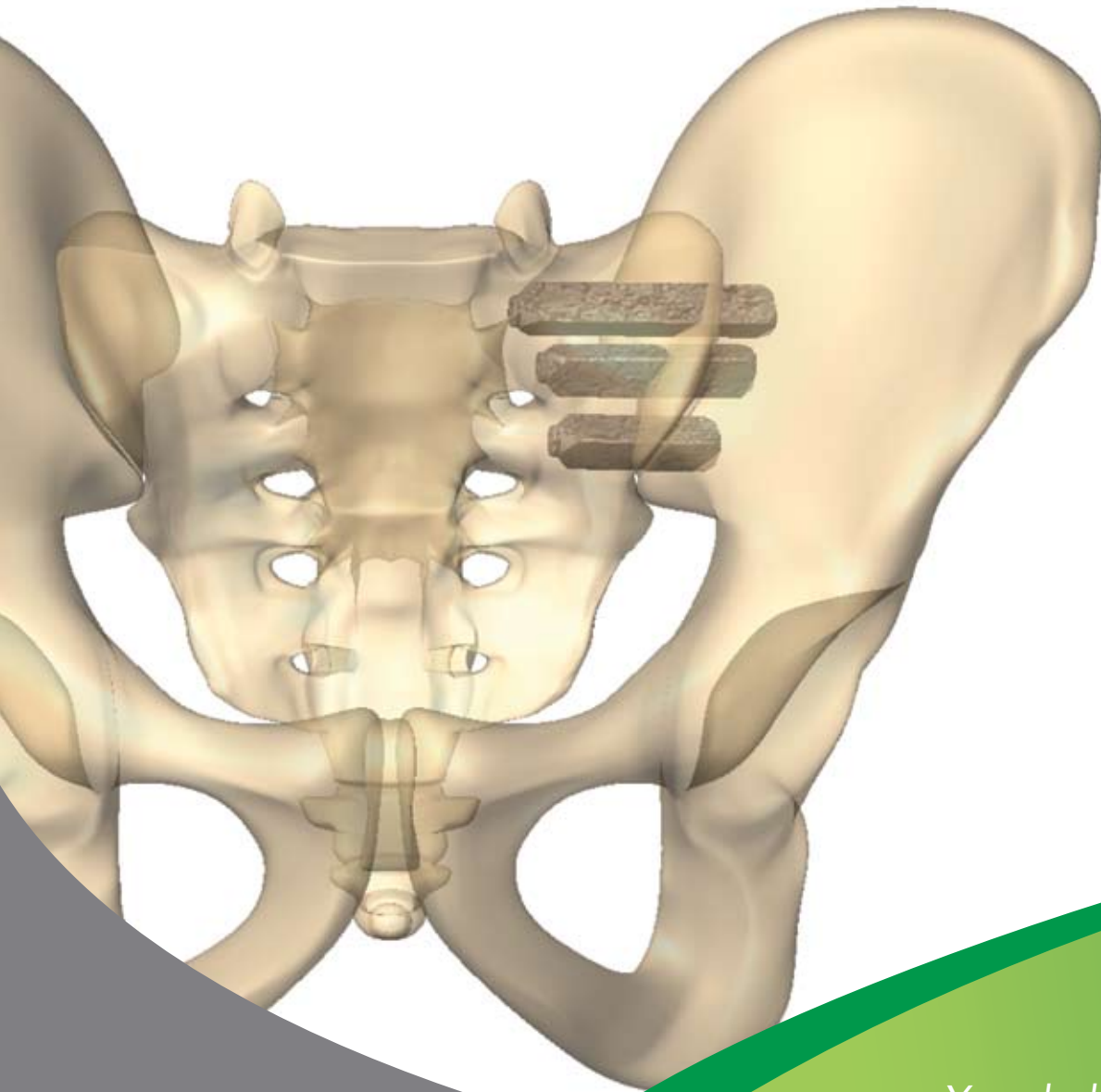


SI-BONE™ iFuse Implant System™



You do have options...

Sacroiliac Joint Fusion with the
iFuse Implant System
SI Joint Fusion Simplified

An Advanced Approach to Surgical Management of SI Joint Dysfunction

Up to 25% of all low back pain is SI Joint in origin – but the diagnosis of SI Joint disease is frequently overlooked.

(Reference: Cohen, et al.¹)

Why the SI Joint?

- ▲ It's common to link low back pain with protruding disc even when neurological signs are absent. (Reference: Weksler, et al.²)
- ▲ It is common for pain from SI Joint dysfunction to mimic discogenic or radicular low back pain. Many patients go on to receive lumbar fusion instead of SI Joint fusion – so SI Joint disease should be strongly considered in differential diagnosis of low back pain.

(Reference: Weksler, et al.²)



iFuse Implants
Actual size: 35-55mm length,
7mm diameter

Now there's an approach to surgical management of SI Joint dysfunction that's easier and less invasive than traditional open surgery.

The iFuse Implant System consists of porous plasma spray coated implants, surgically inserted across the SI Joint to create fixation leading to fusion—from the inside. This creates a biomechanically rigorous fixation/fusion system, designed to support reliable fixation/fusion and acute weight bearing capacity.

With the iFuse Implant System, there is no need for:

- ▲ BMP in conjunction with autologous bone graft
- ▲ Additional pedicle screws and rods
- ▲ Hollow modular anchorage screws
- ▲ Cannulated compression screws
- ▲ Threaded cages within the joint
- ▲ Fracture fixation screws

PRODUCT BENEFITS

- Less invasive than traditional open surgery with no extensive soft tissue stripping
- Straightforward surgical approach
- Implant profile and design minimizes rotation and micromotion
- Rigid titanium implants provide immediate post-op SI Joint stability
- Porous plasma spray coating with irregular surface designed to support stable bone fixation/fusion
- Larger implant surface area designed to maximize post-surgical weight bearing capacity
- Biomechanically rigorous implant designed specifically to stabilize the heavily loaded SI Joint



The iFuse Advantage

The iFuse Implant System is designed to be the product and surgical fusion/fixation method of choice:

Less invasive surgical solution to open surgical SI Joint fusion

- ▲ Minimal incision size
- ▲ Minimal soft tissue stripping
- ▲ Minimal tendon irritation
- ▲ Reduced risk of infection

Simplified surgical procedure anticipated...

- ▲ Just drill, broach, insert Implants and close
- ▲ Cannulated delivery system
- ▲ Simple technique reduces OR time—less than 1 hour versus 2-3 hours
- ▲ Minimal blood loss
- ▲ Less post-surgical call-back to OR
- ▲ Fewer complications
- ▲ Less pain with small incision

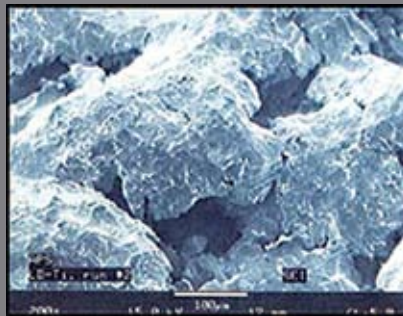
Decreased length of stay

- ▲ 1 day versus 3-4 days

Potential for earlier patient weight bearing

- ▲ Improved patient perception of stability

Clinical case study reports (data on file).



SEM of CP Titanium magnified 100x

Static Shear Strength	48.63 Mpa (7052)
Static Tensile Strength	69.21 Mpa (10,036)

Note: All information regarding APS process was obtained from the APS Materials Website (www.apsmaterials.com). Used with permission.

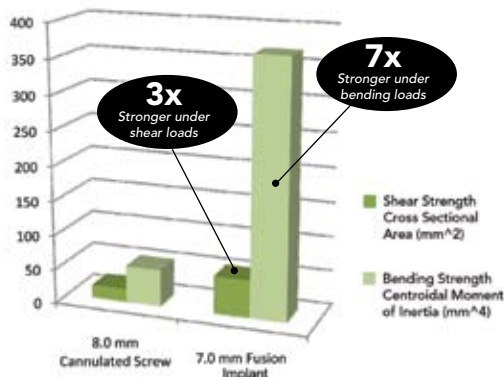
iFuse Implant System versus traditional SI Joint fixation

- ▲ Bony interference with iFuse Implant System versus none with screws
- ▲ No conflicts with lumbar fusion devices
- ▲ Stronger construct versus other SI Joint fixation

Cost-effective solution

- ▲ Reduced length of stay
- ▲ Less complications
- ▲ Direct costs: single product versus traditional methods
- ▲ Pre-certification easier with single day stay

Shear and Bending Strength Comparison



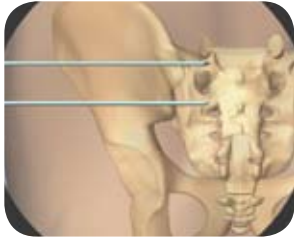
Stronger than Screws

A generic 8.0 mm cannulated screw was used with a 3.4 mm cannula. Shear strength is based on cross sectional area near the center of the screw and Implant. Bending strength is calculated on the Euler-Bernoulli equation.

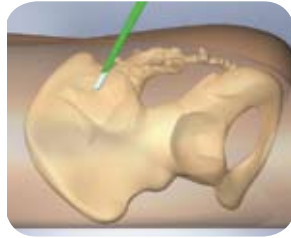
Typical Diagnostic Techniques

- ▲ Faber Test
- ▲ CT-guided injection
- ▲ X-ray/MRI of SI Joint

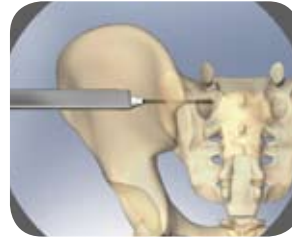
Surgical Technique



1) Locate area for incision



2) Make ~ 3 cm incision



3) Insert Steinmann Pin



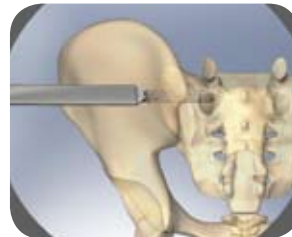
4) Determine length of iFuse Implant



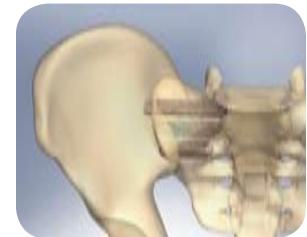
5) Drill



6) Broach



7) Insert iFuse Implant



8) Repeat, as needed, for additional iFuse Implant placement

Ordering Information

To order your iFuse Implant System, contact your local SI-BONE distributor or SI-BONE.

iFuse Implant Part Numbers

		Implant Length (mm)					
		30	35	40	45	50	55
Implant Diameter (mm)	4.0	4030	4035	4040	4045	n/a	n/a
	7.0	7030	7035	7040	7045	7050	7055

Disposables

Description	Part Number	Description	Part Number
Steinmann Pin, 2.0 mm	500079	Steinmann Pin, 3.2 mm	500078
Push Pin, 2.0 mm	500091	Push Pin, 3.2 mm	500090
Steinmann Pin, 2.0 mm, Blunt	500096	Steinmann Pin, 3.2 mm, Blunt	500095
Cannulated Drill 4.0 mm x 2.0 mm long	500082	Cannulated Drill 7.0 mm x 3.2 mm long	500076

¹Cohen, Steven P. Sacroiliac joint pain: a comprehensive review of anatomy, diagnosis, and treatment. *Anesthesia and analgesia*. 2005 Nov; 5(101): 1440-53.

²Weksler, Velan, et al. The role of sacroiliac joint dysfunction in the genesis of low back pain: the obvious is not always right. *Archives of ortho and trauma surgery*. 2007 Dec; 10(127): 858-8.

