

# The iFuse Implant System® Difference

## Clinical Evidence



Consistent positive clinical outcomes supported by:

- multiple studies
- multiple outcomes
- multiple time-points

*All patients were treated for SI joint disruptions or degenerative sacroiliitis.*

## Rapid and Sustained Pain Relief – VAS Pain



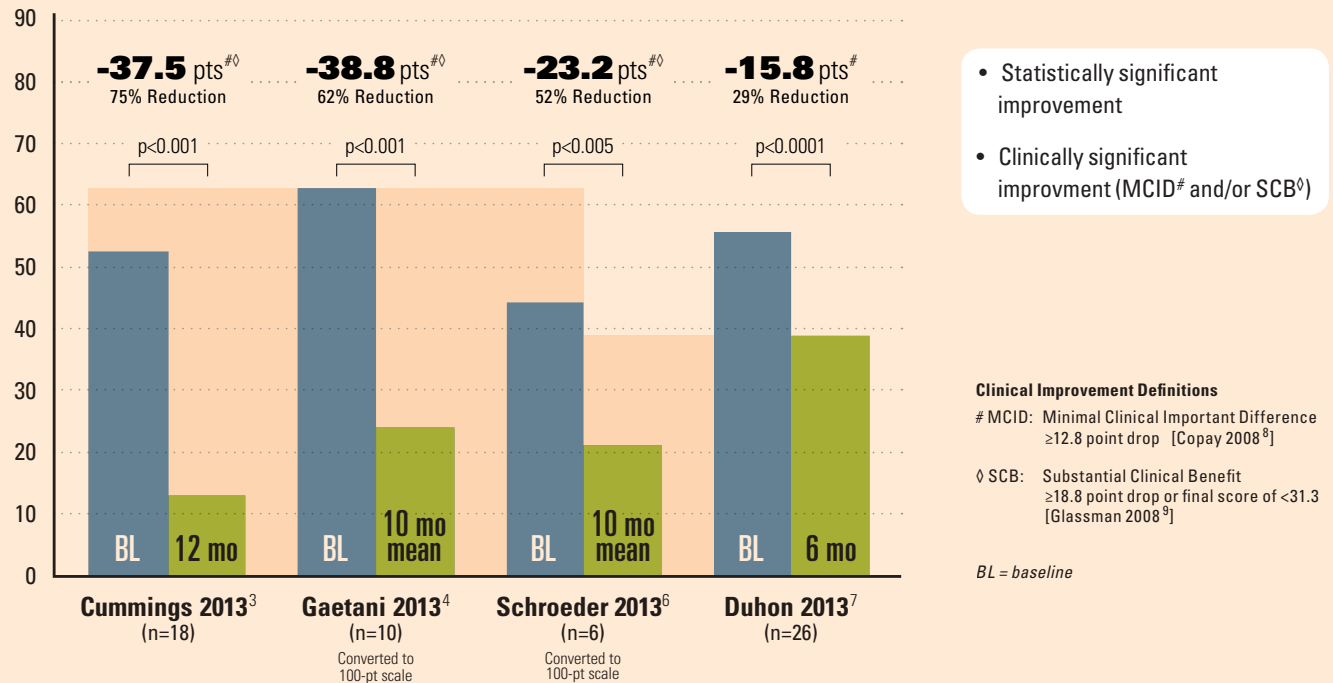
## Improvement in Quality of Life

	Measurement	Improvement Baseline to Follow-up		p-value
		Mean	Percent	
<b>Cummings 2013<sup>3</sup></b> 12 mo follow-up (n=18)	<b>SF-12 PCS</b>	+11.2	<b>34.7%</b>	<0.005
	<b>SF-12 MCS</b>	+20.4	<b>54.0%</b>	<0.001
<b>Gaetani 2013<sup>4</sup></b> 10 mo mean follow-up (n=10)	<b>Roland-Morris Disability</b>	-14.6	<b>83.0%</b>	<0.001
<b>Duhon 2013<sup>7</sup></b> 6 mo follow-up (n=26)	<b>SF-36 PCS</b>	+6.7	<b>21.8%</b>	0.003
	<b>SF-36 MCS</b>	+5.8	<b>14.1%</b>	0.008
	<b>EQ-5D</b>	+21.4	<b>49.8%</b>	0.0006

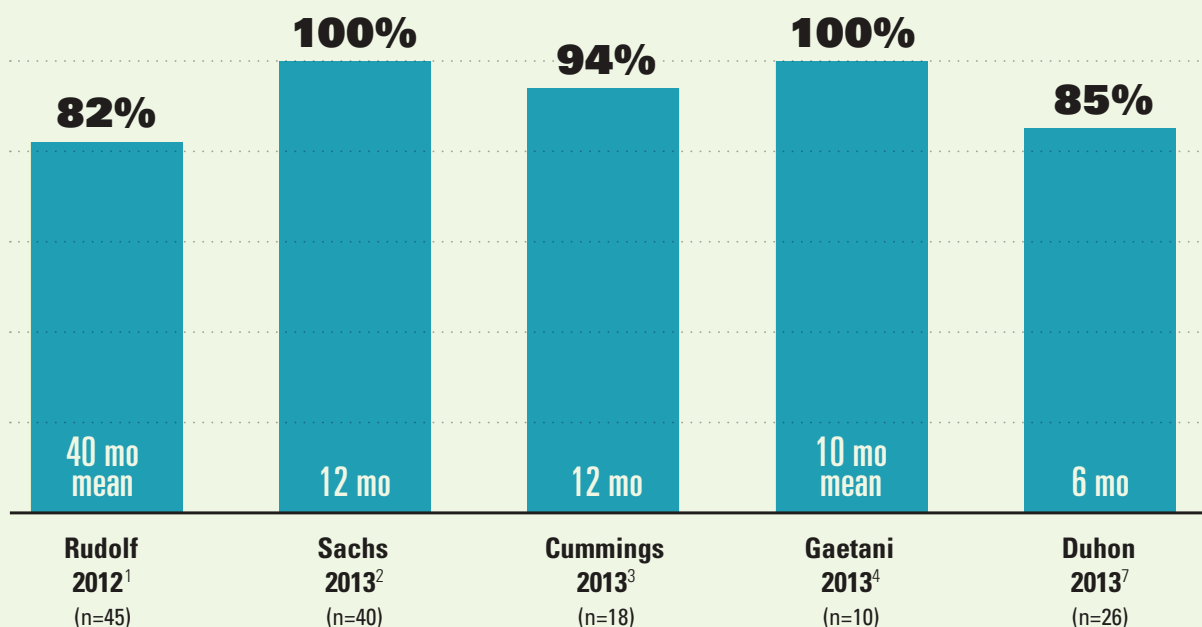
- Statistically significant improvement
- Consistent improvement across multiple quality of life measures

SF-12 = Short Form-12 Questionnaire  
 SF-36 = Short Form-36 Questionnaire  
 PCS = Physical Component Summary  
 MCS = Mental Component Summary  
 EQ-5D = EuroQol-5 Dimension Questionnaire

## Improvement in Back Function – Oswestry Disability Index



## High Patient Satisfaction



## Study Design and Reported Outcomes by Publication

	Rudolf 2012 <sup>1</sup>	Sachs 2013 <sup>2</sup>	Cummings 2013 <sup>3</sup>	Gaetani 2013 <sup>4</sup>	Graham Smith 2013 <sup>5</sup>	Schroeder 2013 <sup>6</sup>	Duhon 2013 <sup>7</sup>
N (iFuse patients)	50	40	18	10	113	6	26
Follow-up	40 mo mean	12 mo	12 mo	10 mo mean	24 mo	10 mo mean	6 mo
Design	Retro	Retro	Retro	Retro	Retro	Retro	Prospective
VAS Pain	•	•	•	•	•	•	•
SF-12 PCS			•				
SF-12 MCS			•				
SF-36 PCS							•
SF-36 MCS							•
EQ-5D							•
Roland-Morris Disability				•			
ODI			•	•		•	•
Patient Satisfaction	•	•	•	•			•

### References

1. Rudolf L\*†§. Sacroiliac Joint Arthrodesis-MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes. *Open Orthop J.* 2012;6:495-502.
2. Sachs D\*†, et al. Minimally Invasive Sacroiliac Joint Fusion: One-Year Outcomes in 40 Patients. *Adv Orthop.* 2013;2013:536128.
3. Cummings J Jr\*, et al. Minimally Invasive Sacroiliac Joint Fusion: One-year Outcomes in 18 Patients. *Ann Surg Innov Res.* 2013;7:12.
4. Gaetani P\*†, et al. Percutaneous Arthrodesis of Sacro-Iliac Joint: A Pilot Study. *J Neurosurg Sci.* 2013;57:297-301.
5. Graham Smith A\*†, et al. Open Versus Minimally Invasive Sacroiliac Joint Fusion: A Multi-Center Comparison of Perioperative Measures and Clinical Outcomes. *Ann Surg Innov Res* 2013;7:14.
6. Schroeder JE, et al. Early Results of Sacro-Iliac Joint Fixation Following Long Fusion to the Sacrum in Adult Spine Deformity. *HSS J.* 2013;10:30-5.
7. Duhon B\*†, et al. Safety and 6-Month Effectiveness of Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. *Med Devices (Auckl)* 2013;6:219-29.
8. Copay AG, et al. Minimum Clinically Important Difference in Lumbar Spine Surgery Patients: A Choice of Methods Using the Oswestry Disability Index, Medical Outcomes Study Questionnaire Short Form 36, and Pain Scales. *Spine J.* 2008;8:968-74.
9. Glassman SD, et al. Defining Substantial Clinical Benefit Following Lumbar Spine Arthrodesis. *J Bone Joint Surg.* 2008;90:1839-47.

### Key

\* Paid consultant of SI-BONE, Inc.

† Conducts clinical research for SI-BONE, Inc.

§ Ownership interest in SI-BONE, Inc.

**SI-BONE®** | **iFuse Implant System®**  
Minimally Invasive Sacroiliac Joint Surgery

SI-BONE, Inc.  
3055 Olin Avenue, Suite 2200  
San Jose, CA 95128  
t 408.207.0700  
f 408.557.8312  
info@si-bone.com  
www.si-bone.com

The iFuse Implant System® is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant. Please review the iFuse Instructions For Use for a complete discussion of contraindications, warnings, precautions, and risks.

SI-BONE and iFuse Implant System are registered trademarks of SI-BONE, Inc.  
©2014 SI-BONE, Inc. All rights reserved. 8809.062714