iFuse Bedrock Granite® Implant System

Fixation. Fusion. Foundation.™

- FDA: Breakthrough Device Designation
- Medicare: Eligible for New Technology Add-on Payment (NTAP)*

* Actual amount may vary based on facility eligibility, applicable payment rates, and case specifics. NTAP applies only to Breakthrough Device Designation (BDD) indications. Check with facility for eligibility details or visit *si-bone.com/reimbursement* for more information.

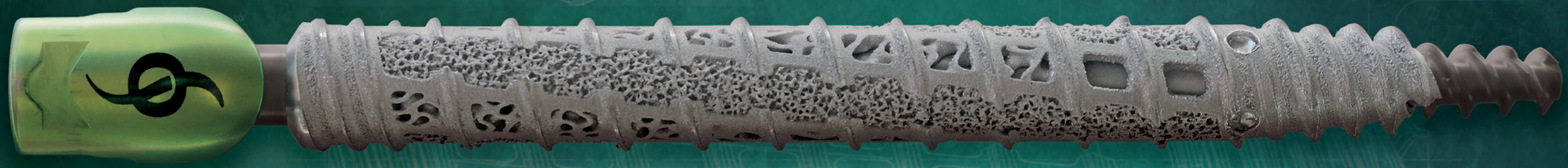
60% Increase in Pelvic Stability with a 2nd iFuse Implant in a FEA[1]

SI-BONE®

Sacropelvic Solutions™

Fixation. Fusion. Foundation™

Breakthrough features address the 23.7% lumbopelvic fixation failure rate.[2]



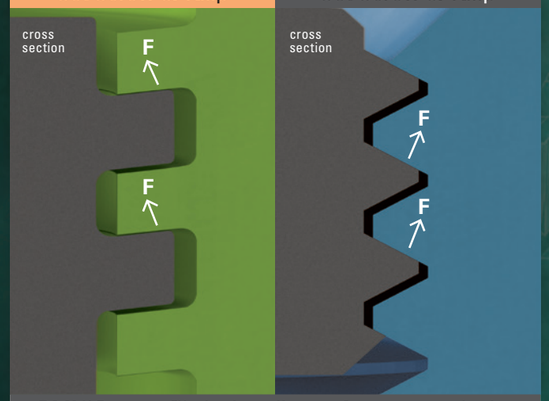
iFuse Bedrock Granite® designed to reduce

Set Screw Expulsion | Screw Breakage | Screw Loosening | Postop SI Joint Pain

OMNICapture™ Tulip & Set Screw

Negative-Rake Square Threads | 115 in-lb Final Torque

Designed to mitigate tulip splay and expulsion

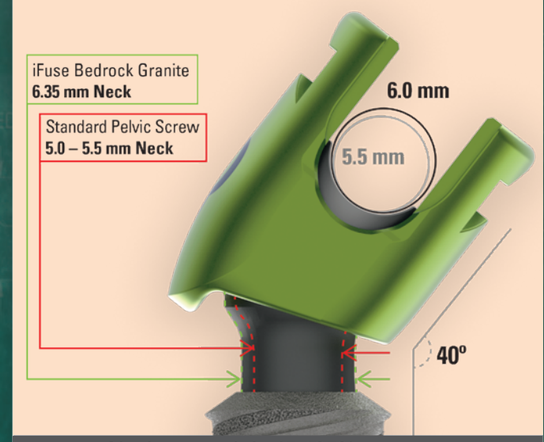


OMNICapture™ design directs force towards the center axis of tulip instead of away from it.

Robust Cannulated Core

Large Neck & Internal Shank

Designed for spinopelvic stresses

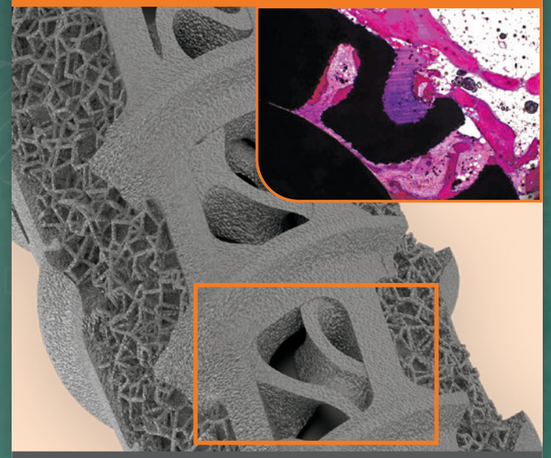


Neck strength is 45-105% stronger than commonly used pelvic screws[3]

IntelliHarvest® Technology

Macroporous Graduated Fenestrations

Self-harvest bone

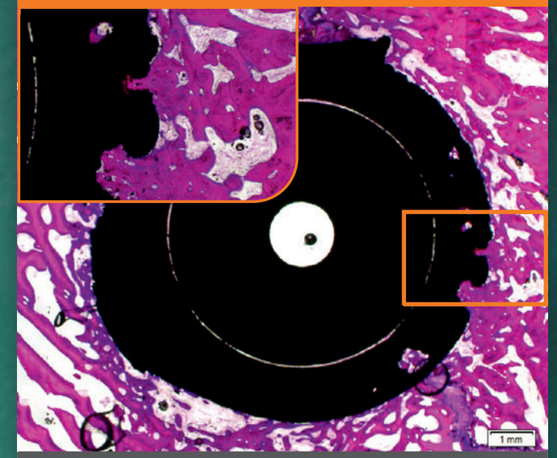


T = 12 Weeks – Sheep Bone Incorporation**

FuSIon 3D™ Surface

3D Printed Microporous Lattice

Mimics cancellous bone[4]



Time = 6 Weeks – Sheep Bone Incorporation**

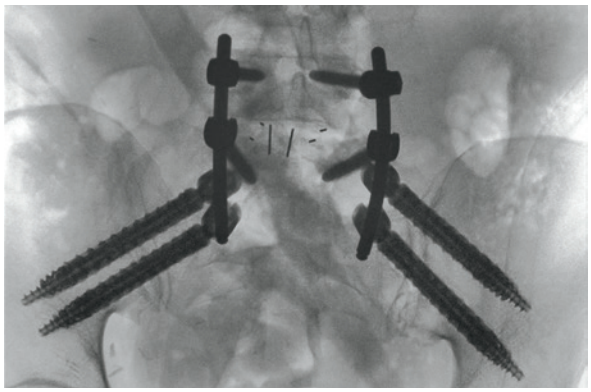
** Sheep data not necessarily indicative of human clinical outcomes.

iFuse Bedrock Granite® Implant System

	Length (mm) Open Head Tulip	Diameter (mm) 9.5	10.5	11.5
	40	095040BG	—	—
	45	095045BG	—	—
	50	095050BG	105050BG	—
	60	095060BG	105060BG	—
	70	095070BG	105070BG	115070BG
	80	095080BG	105080BG	115080BG
	90	095090BG	105090BG	115090BG
	100	095100BG	105100BG	115100BG
	110	095110BG	105110BG	—
	120	095120BG	105120BG	—

	Length (mm) Closed Head Tulip			
	50	095050CH	105050CH	—
	60	095060CH	105060CH	—
	70	095070CH	105070CH	115070CH
	80	095080CH	105080CH	115080CH
	90	095090CH	105090CH	115090CH
	100	095100CH	105100CH	115100CH
	110	095110CH	105110CH	—
	120	095120CH	105120CH	—

Description	Standard Part No.
Set Screw	501117



Simultaneous multi-level lumbar fusion and SI joint fusion in high-risk patients for post-op SI joint pain provides value-based healthcare[5]

High risk patients defined as:

- Multi-level lumbar fusion to the sacrum
- High BMI
- High pelvic incidence

References

1. Panico M, *et al. Int J Spine Surg.* 2023 Aug;17(4):598-606. doi: 10.14444/8481. Epub 2023 Jul 17. *(Finite element analysis data is not necessarily indicative of clinical performance.)*
2. Eastlack RK, *et al.* International Spine Study Group. Rates of Loosening, Failure, and Revision of Iliac Fixation in Adult Deformity Surgery. *Spine.* 2022 Jul 15;47(14):986-994. doi: 10.1097/BRS.0000000000004356. Epub 2022 Jul 15.
3. SI-BONE Technical Study 301110-TS.
4. SI-BONE 300803-R
5. Ackerman SJ, *et al.* Cost-Utility Analysis of Sacroiliac Joint Fusion in High-Risk Patients Undergoing Multi-Level Lumbar Fusion to the Sacrum. *Clinicoecon Outcomes Res.* 2022 Aug 8;14:523-535.

INDICATIONS FOR USE

The *iFuse Bedrock Granite®* Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

When connected to compatible pedicle screw systems with 5.5 or 6.0 mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

ADDITIONAL COMPATIBILITY INFORMATION

Compatible pedicle screw system rods include all the conditions listed below

1. 5.5- or 6.0-mm in diameter
2. Cross section is circular and non-threaded
3. Made of:
   - Titanium alloy (Ti-6Al-4V ELI per ASTM F136),
   - Cobalt chrome (Co-28Cr-6Mo per ASTM F1537 or 35Co-35Ni-20Cr-10Mo per ASTM 562)
4. Not additively manufactured
5. Not coated with additional materials (e.g., Hydroxyapatite)
   - Note: Anodization (color or type II) does not alter the material

Healthcare professionals should refer to the Instructions For Use for indications, contraindications, warnings, and precautions at *www.si-bone.com/label.*

There are potential risks associated with iFuse procedures. They may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *www.si-bone.com/risks.*

iFuse Bedrock Granite®
Implant System

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