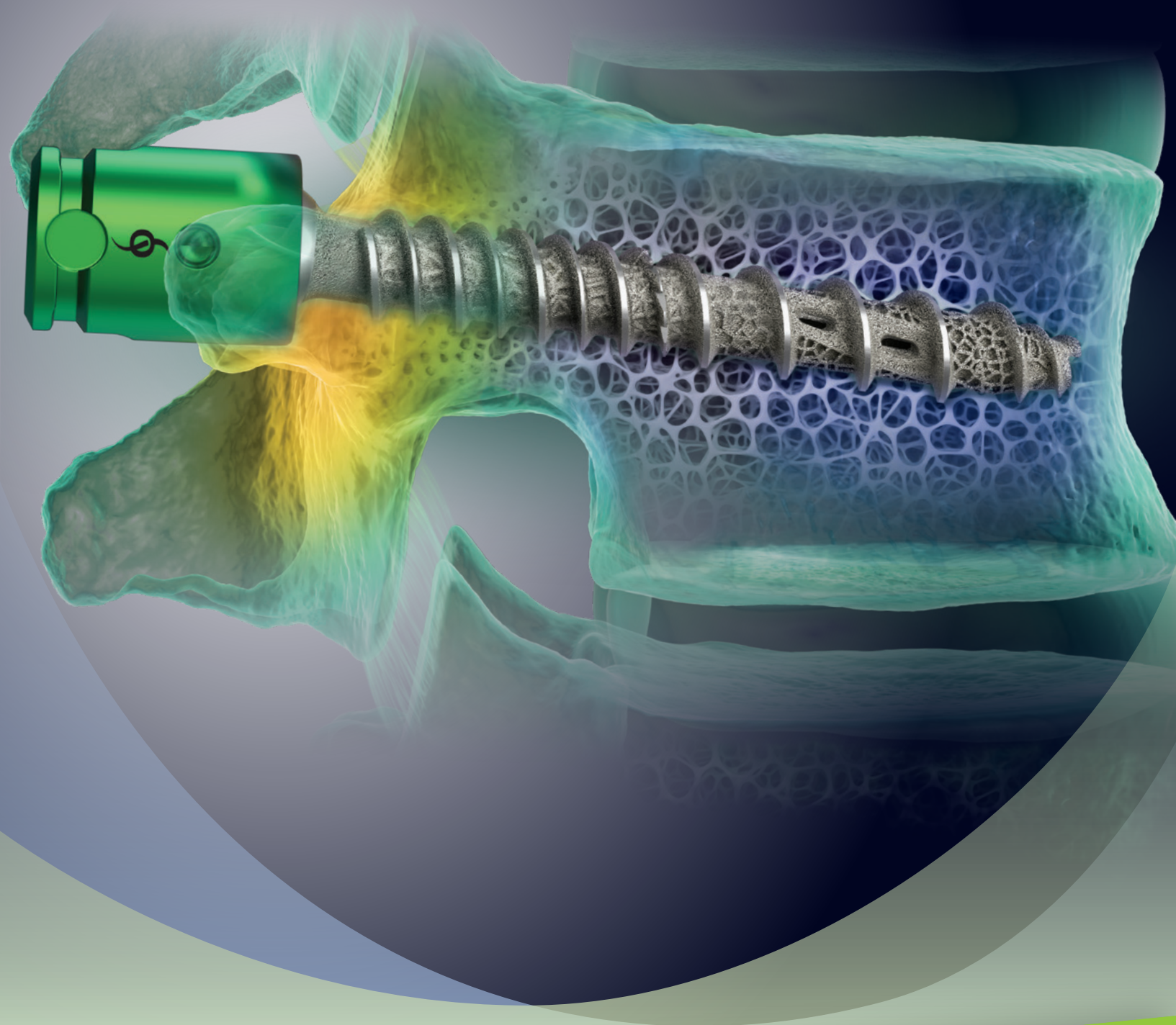


Spinopelvic Fixation

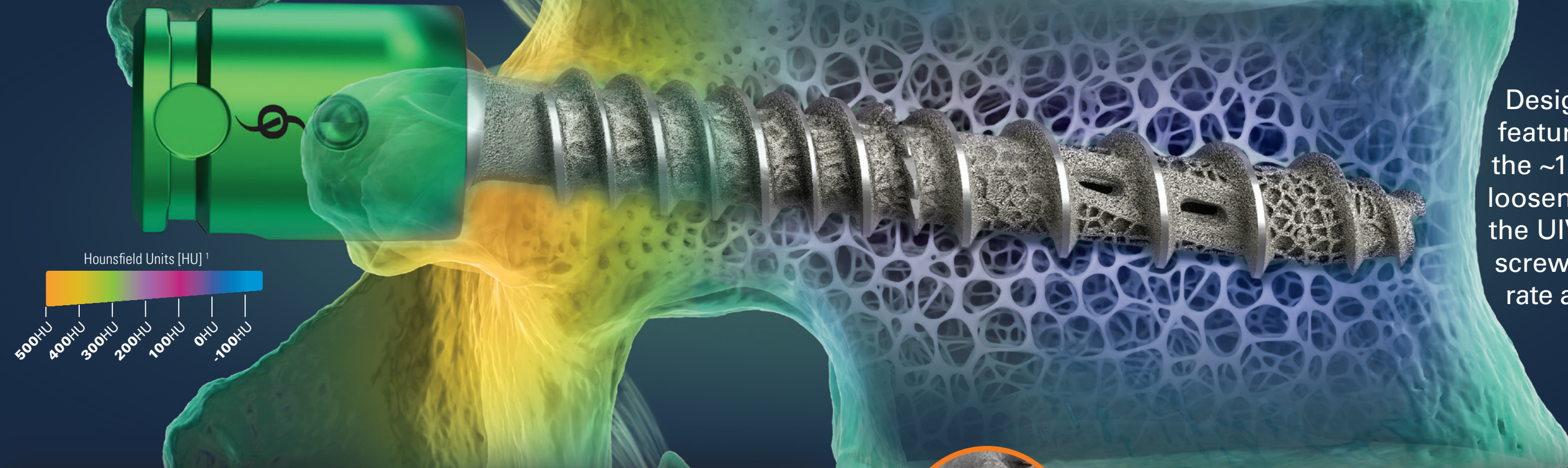
iFuse Granite Onyx™ Implant System

Vertebral Body Density-Driven Design

FDA
Breakthrough
Device
Designation



Vertebral Body Density-Driven Design.



Designed with features to address the ~16% screw loosening rate at the UIV and ~39% screw loosening rate at the LIV²⁻⁹

Enhanced Pedicle Purchase

Full height thread stop, Dual Diameter
Increased proximal engagement

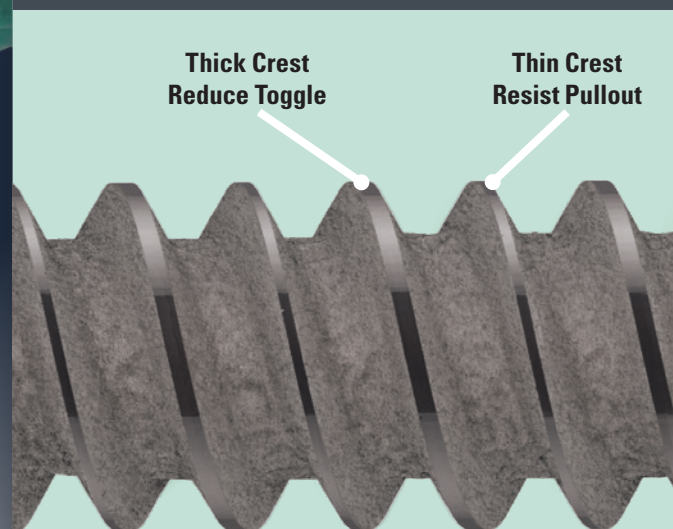
No thread lead out on Onyx vs. machined screws



Dual Diameter

Anatomy-Specific Design

Variable thread forms and leads
Designed to reduce loosening

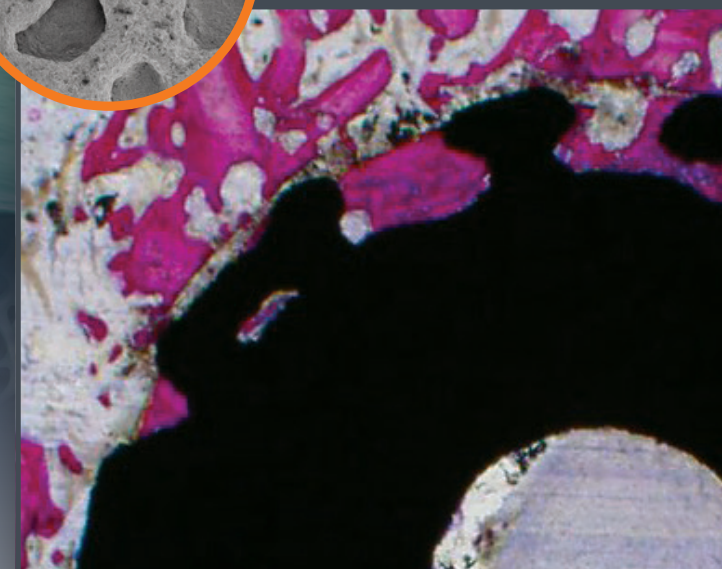
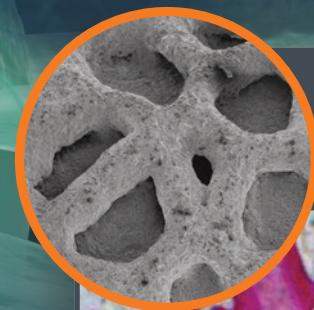


Thick Crest
Reduce Toggle

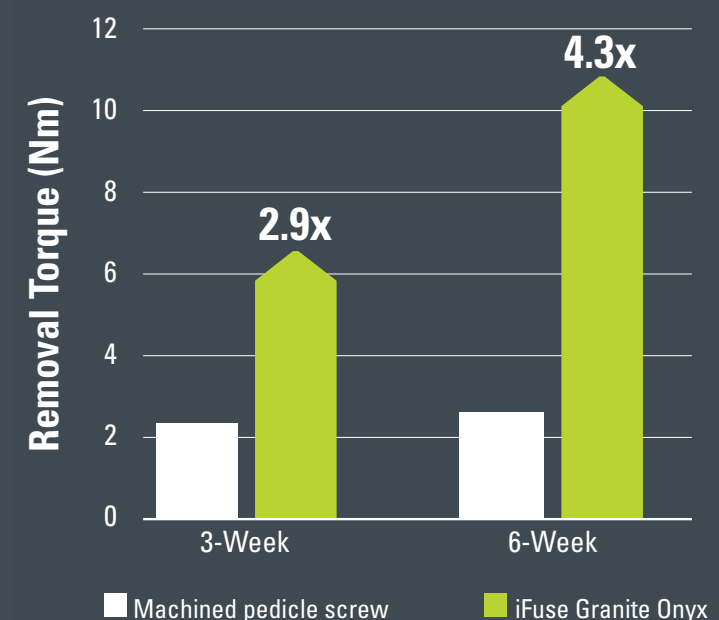
Thin Crest
Resist Pullout

iFuse Surface Technology

Trabecular lattice surface and vertebral body fenestrations
Designed for progressive fixation through osseointegration

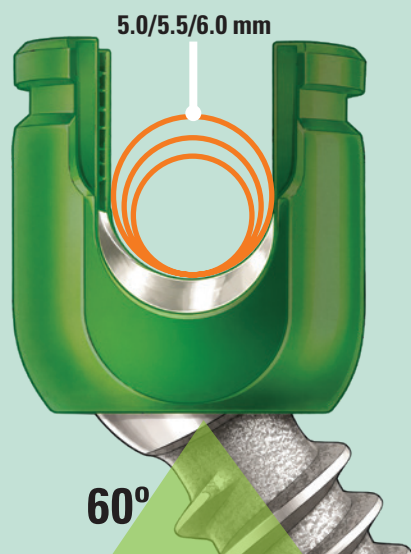


3-Week: bone on growth and ingrowth¹⁰
– Sheep data not necessarily indicative of human clinical outcomes –



iFuse Granite Onyx™ Implant System

Polyaxial Tulip General Rod Compatibility 106 in-lbs. final tightening torque



Equivalent strength to a machined screw of same diameter¹¹

References

1. Xu F, et al. *BMC Musculoskeletal Disord*. 2022 Feb 28;23(1):186.
2. Arena et al. *J Neurosurg Spine* 2024
3. Yuan et al. *Global Spine J* 2021
4. Uehara et al. *Spine* 2017
5. Ohba et al. *Spine Surg Relat Res* 2019
6. Odland et al. *Int J Spine Surg* 2025
7. Xu et al. *BMC Musculoskeletal Disord* 2022
8. Yuan et al. *Global Spine J* 2021
9. Finger et al. *EurSpine J* 2014
10. SI-BONE 303358-TS
11. SI-BONE; 303106-R, 303131-TS, 303282-R, 303149-TS

INDICATIONS FOR USE

When connected to compatible pedicle screw systems with 5.0-, 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Granite Onyx™ Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of 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, and/or
- failed previous fusion.

When connected to compatible pedicle screw systems with 5.0-, 5.5- or 6.0- mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Granite Onyx Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis,

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		Diameter (mm)		
		5.5	6.5	7.5
Length (mm)	25	055025BG	065025BG	075025BG
	30	055030BG	065030BG	075030BG
	35	055035BG	065035BG	075035BG
	40	055040BG	065040BG	075040BG
	45	055045BG	065045BG	075045BG
	50	055050BG	065050BG	075050BG
	55	055055BG	065055BG	075055BG
	60	055060BG	065060BG	075060BG
	65	055065BG	065065BG	075065BG

5.0/5.5 Set Screw	6.0 Set Screw
503260	503261



7.5 x 65 mm iFuse Granite Onyx Implant, actual size.

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 Granite Onyx Navigation instruments are intended to be used with the iFuse Granite Onyx Implant System and the Medtronic StealthStation System to assist the surgeon in precisely locating anatomical structures in iFuse Granite Onyx 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.

The Onyx iGPS instruments are compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse Granite Onyx Implant System and the Globus ExcelsiusGPS® Robotic Navigation System (including the Globus Excelsius3D® Imaging System), which is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

ADDITIONAL INFORMATION

Healthcare professionals should refer to 503346 iFuse Granite Onyx Implant System Instructions for Use for contraindications, warnings, and precautions at www.si-bone.com/label.

There are potential risks associated with the iFuse Granite Onyx Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit www.si-bone.com/risks.

Complaints and adverse events relating to use of the procedure and/or device should be reported to SI-BONE, Inc. Toll Free: (855) 511-1545 or E-mail qara@si-bone.com

iFuse Granite Onyx® Implant System



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