

References

- Bone density mapping based on Thiesen DM, et al. The three-dimensional bone mass distribution of the posterior pelvic ring and its key role in transsacral screw placement. *Sci Rep.* 2020 Mar 30;10(1):5690
- Xu F, et al. The relationship between S1 screw loosening and postoperative outcome in patients with degenerative lumbar scoliosis. *BMC Musculoskeletal Disord.* 2022 Feb 28;23(1):186.
- SI-BONE Technical Study 303358-TS. (Results from animal testing are not necessarily indicative of human clinical outcomes.)

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, 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.

For Use for indications, contraindications, warnings, and precautions at [si-bone.com/label](https://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 [si-bone.com/risks](https://www.si-bone.com/risks).

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