Insertion of Fenestrated Sacropelvic Fixation System

iFuse Bedrock Granite™

SI-BONE, Inc.

ICD-10 C&M Committee Meeting

March 8, 2022

Background and Clinical Need

- Spinal deformity is commonly treated with long construct surgery, often anchored with sacropelvic and pelvic screw fixation
- There are both **advantages** and **disadvantages** to traditional pelvic fixation
- There is a clear **clinical need** to:
  - Improve foundational fixation for long constructs
  - Promote bony fusion of the SI joint, to reduce both motion and the consequent pain
- Currently there is not a technology that attaches to the fixation construct *and* facilitates fusion

Pelvic Fixation Advantages

- Large channels of quality ilium bone / Ability to use larger screws
- Ease of screw placement
- Patients with lumbosacral diagnoses that received successful pelvic fixation enjoyed lower rates of reoperation over the longer term++

Pelvic Fixation Disadvantages

- Significant fixation failure rates up to 30%*, including screw loosening, lower rod fracture, and screw fracture
- SI Joint pain following long construct fusion is also well documented, with incidence rates up to 23% associated with 4-level+ lumbar fusions+
- Unsuccessful pelvic fixation has resulted in higher reoperation rates within the first year, suggesting that early fixation failures may arise from current pelvic fixation techniques++

* Incidence of Pelvic Fixation Failure: Retrospective Review of ISSG Data, International Spine Study Group

\+ Unoki E, et al. Fusion of Multiple Segments Can Increase the Incidence of Sacroiliac Joint Pain After Lumbar or LumboSacral Fusion. SPINE Vol 41:12, 2016

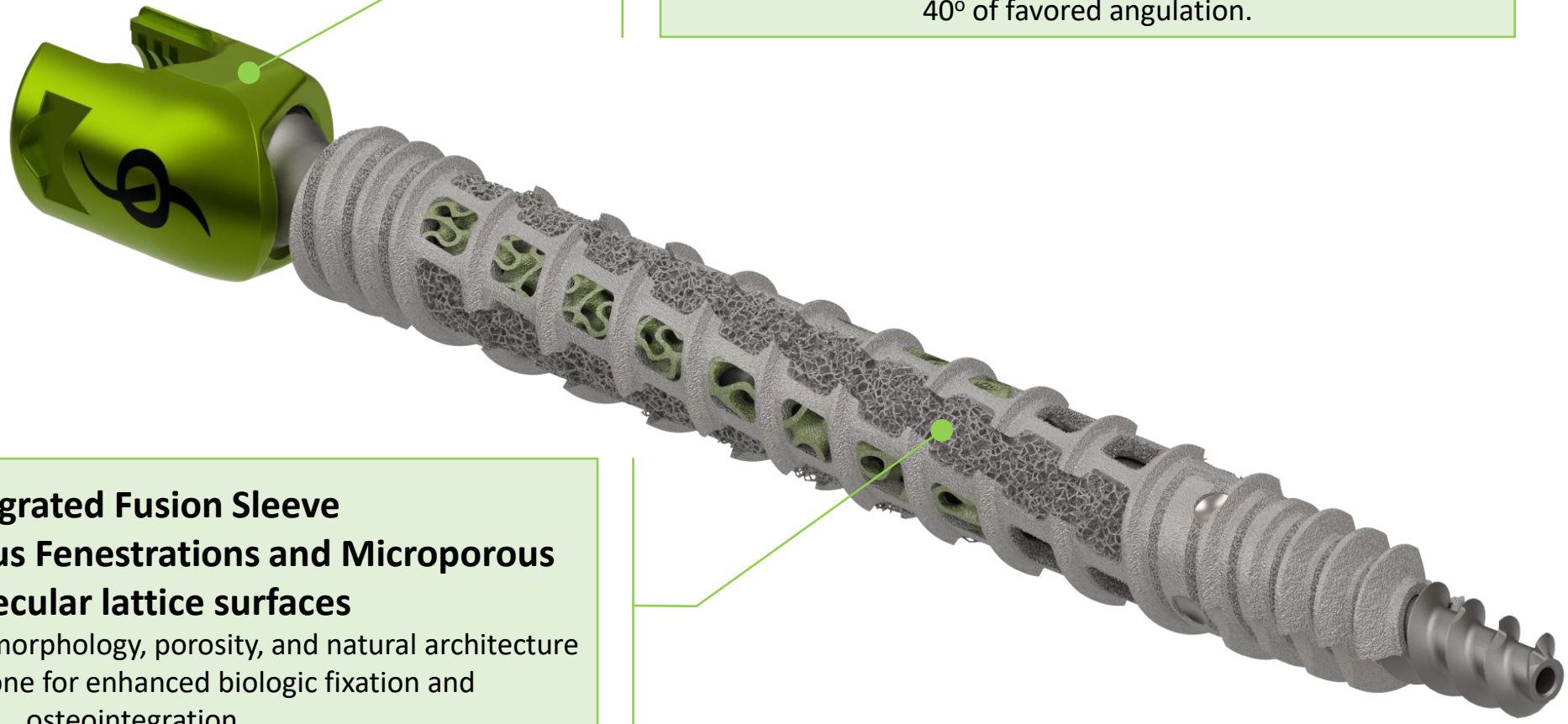
++ Data on file. Watson Policy Analysis. Medicare Inpatient Hospital Claims – Pelvic Fixation in Spinal Fusion for Patients with Lumbosacral Diagnoses 2012 - 2019

SI-BONE iFuse Bedrock™ Granite Implant

- Fusion System, Threaded Screw Post with Tulip Connector and Fusion Sleeve
- Pelvic Fixation + Fusion Implant designed to:
  - Biologically integrate with host bone ilium and sacrum
  - Increase foundational fixation strength and spinal construct stiffness
  - Facilitate sacroiliac joint (SIJ) fusion when used with commercially available SIJ fusion promoting devices resulting in:
    - Decreased spinopelvic fixation failure
    - Decreased SIJ range of motion → decreased incidence of SIJ pain
- Design
  - Porous fusion sleeve with threaded length
    - Microporous surfaces and macroporous fenestrations facilitate biological integration (bone ingrowth, ongrowth, through growth)
  - Solid threaded screw post
  - Polyaxial tulip connector and set screw
    - Connects to longitudinal spinal rods (5.5 and 6.0 mm)
    - Compatible with commercially available posterior pedicle screw fixation systems

iFuse Bedrock™ Granite | Key Features & Benefits

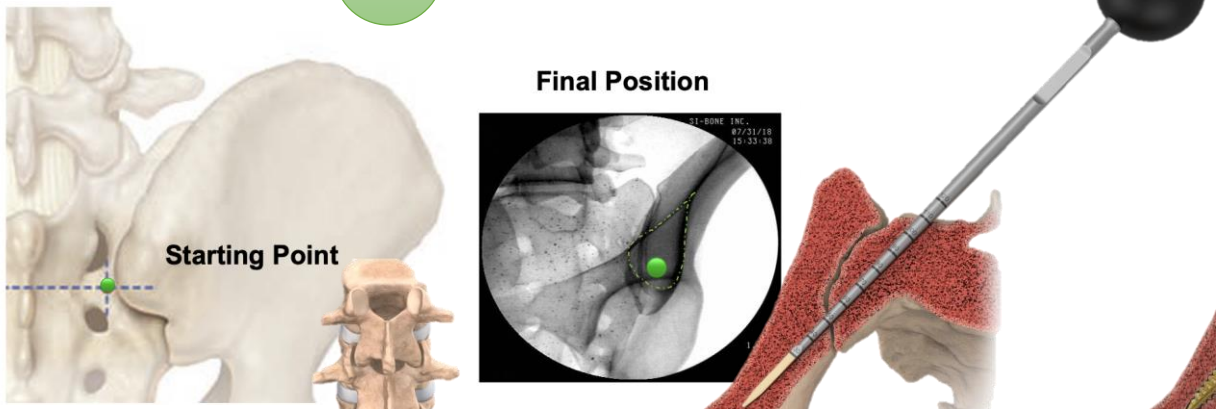
Deformity Construct Specific
Tulip & Set Screw
Compatibility with 5.5mm and 6.0mm posterior rod constructs.
40° of favored angulation.



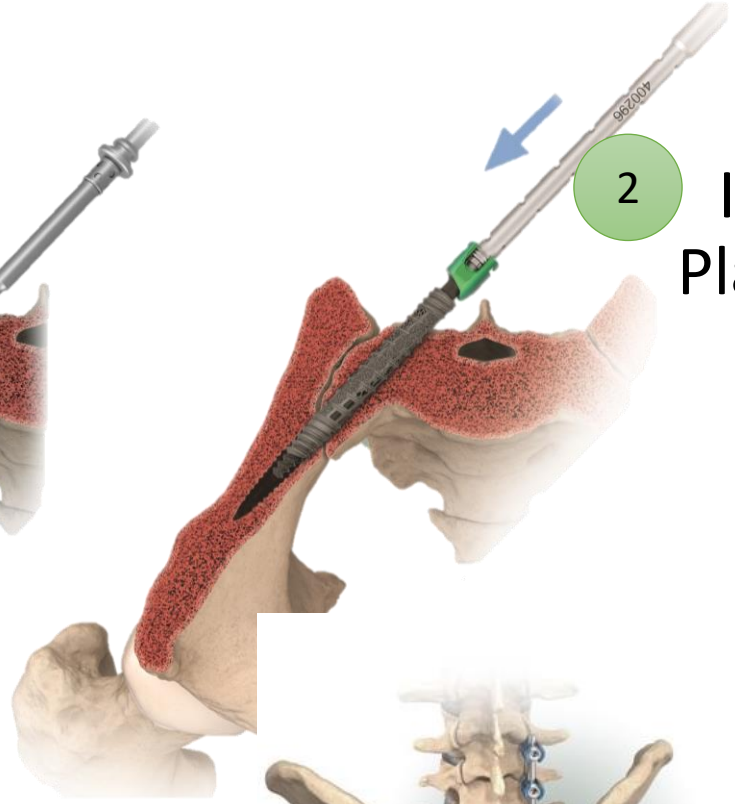
Integrated Fusion Sleeve
with Macroporous Fenestrations and Microporous trabecular lattice surfaces
Designed to mimic the morphology, porosity, and natural architecture of cancellous bone for enhanced biologic fixation and osteointegration.

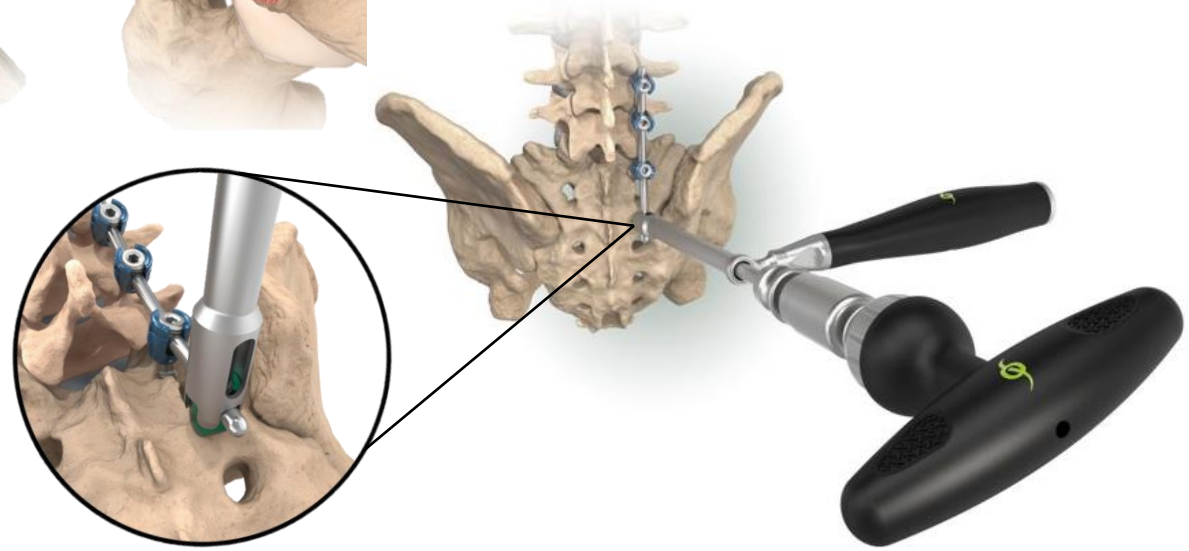
iFuse Bedrock™ Granite | Procedural Steps

1 Pilot Hole Prep & Tap



2 Implant Placement





3 Final Tightening & Locking @ 115 in-lbs

Sample Op Note / Documentation

- Op note / dictation sample:
  - With the instrumentation complete from L2 to L5, I performed sacropelvic fixation to facilitate the fusion of the sacroiliac joint and provide foundational fixation for the spinal construct.
  - According to my pre operative plan, I drilled to the appropriate trajectory to place the S1 alar-iliac and the S2 alar-iliac fixation devices, affixing the sacrum to the pelvis, across the sacroiliac joint to provide immediate stabilization and promote fusion (arthrodesis) of the sacroiliac joint.
  - I first passed the long guidewire. With the guide wires in place, I then tapped the dorsal cortex of the sacrum to initiate the screw entry site.
  - I then implanted bilateral S1alar-iliac and S2 alar-iliac fusion/fixation devices consisting of the integrated osteointegration fusion sleeve with threaded screw post and tulip connector to facilitate bone integration and sacroiliac joint fusion.
- Potential naming conventions:
  - “iFuse Granite sacro-alar-iliac fixation device with integrated threaded screw tulip connector and osteointegration fusion sleeve”
  - “iFuse Bedrock™ Granite”
  - “iFuse Granite”
  - “Bedrock Granite”
  - “Granite”
  - “Sacropelvic fusion/fixation with tulip connector and sleeve”