

OsteoCentric® Integrity-SI® Fusion System

Clinical & Biomechanical Design Rationale

The Integrity-SI System is clinically proven to reduce post-operative pain, facilitate bony arthrodesis and improve patient outcomes during primary or revision sacroiliac joint fusion procedures.^{5,7}

Angle of Approach

Perpendicular approach to the SIJ provides a safe pathway between the foramen, targets the body of S1 found to be the densest region of the sacrum to ensure optimal fixation^{1,2} and allows for uniform decortication of the SI joint.

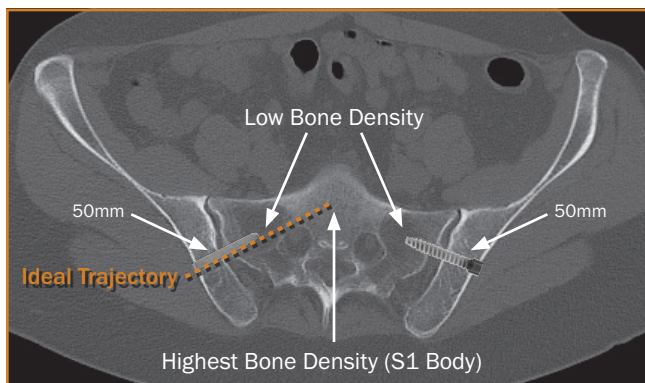
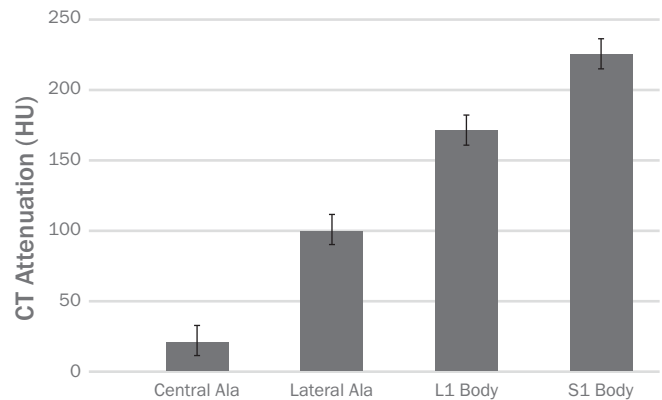


Figure 1



Sacral bone density, variations by region.¹

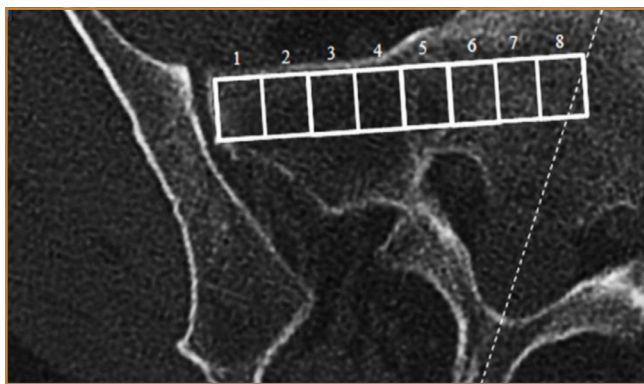
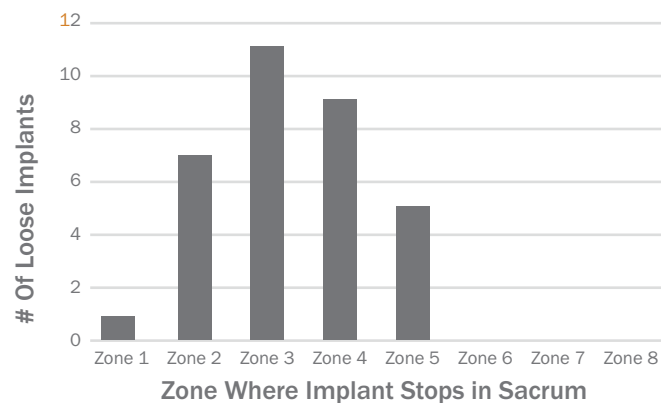


Figure 2



Distribution of bone density along the safe sacroiliac screw corridor correlates with typical loose implants identified in zone 3 of the sacrum.²

The Integrity-SI System was designed to address the short comings of other SIJ Systems currently on the market. Reports of implant loosening and revision surgery in the literature have increased in frequency as this surgery has become more common. Related complications include: Implant mal positioning, radiolucency, implant loosening, non-unions, nerve root impingement, and recurrent postoperative pain.^{8,9,10}

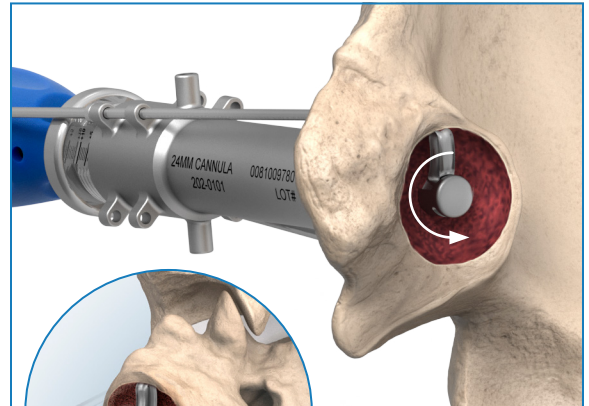
BladeX[®] Joint Preparation & Graft Application

Decortication has been shown to promote the fusion process by exposing subcortical blood and marrow, encouraging vascularization, osteogenic and inflammatory factors to promote the bone growth necessary to achieve fusion³.

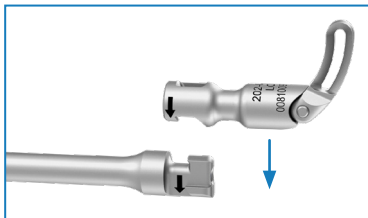
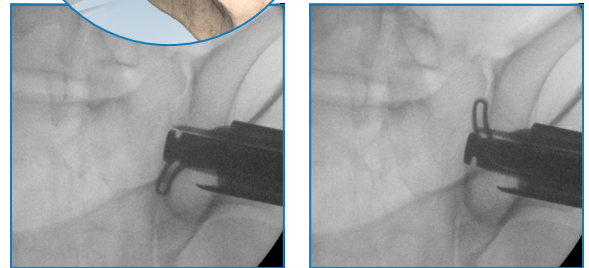
The combination of decortication, graft placement and fixation with threaded implants has been shown to promote fusion of the SIJ.^{4,5}

Proprietary BladeX[®] Joint Prep Instrument

Designed based on the proven principles of joint fusion: aggressive joint preparation and autologous bone grafting, complemented by industry-leading joint compression.



BladeX Cutting



Blade Connection

Features

- Rigid cutting element
- Open cutting geometry for 'no clog' design
- Excellent visualization of joint preparation



38mm Blade (Disposable)



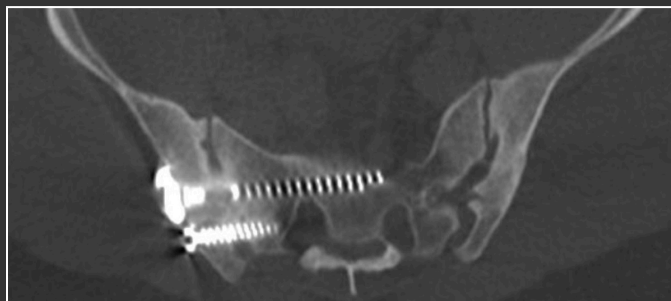
Full surgeon control of resection diameter

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Joint Compression & Mechanical Stability

UnifiMI® thread design, bone volume engagement, load sharing and mechanical forces emphasize true compression, stimulating bone remodeling⁶ and encouraging arthrodesis.^{3, 7}



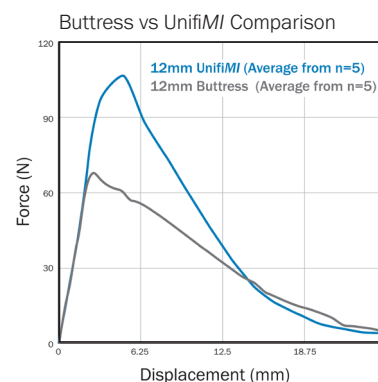
Sacroiliac joint fusion with definitive bridging bone through the sacroiliac joint



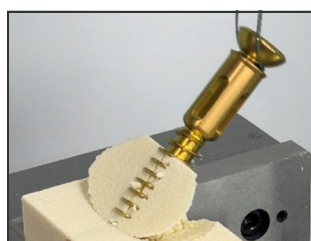
Mechanical Testing Information

Integrity-SI Fusion Fastener implants with UnifiMI demonstrated significantly higher yield loads in modified cantilever loading than Integrity-SI Fusion Screw Implants with standard buttress threads when tested to failure in 15 PCF Bone Foam blocks. The mean yield load for the Integrity Fasteners was significantly greater (1.6 times higher) than Integrity Screws with buttress threads. These results demonstrate the marked improvement in biomechanical fixation and stability that Mechanical Integration can provide an existing implant when converted to UnifiMI.

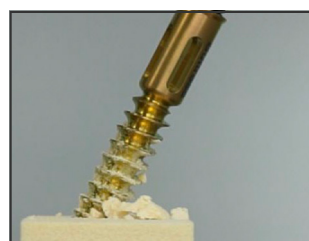
Sample #	Integrity Screws (Buttress) Yield Load (N)	Integrity Fasteners (UnifiMI) Yield Load (N)
1	61.96	102.97
2	65.89	106.08
3	71.65	118.36
4	67.38	108.07
5	70.12	101.72
Mean ± S.D.	67.40 ± 3.79	107.44 ± 6.59



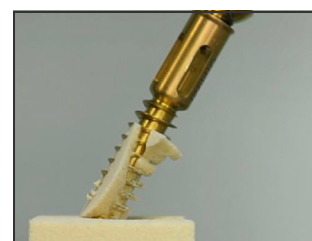
Integrity screw with Buttress threads - very little bone foam still attached to implant



Integrity fastener with UnifiMI threads - bone foam still attached to the implant



Post-test view of Integrity-SI Screw (Buttress) test



Post-test view of Integrity-SI Fastener (UnifiMI) test

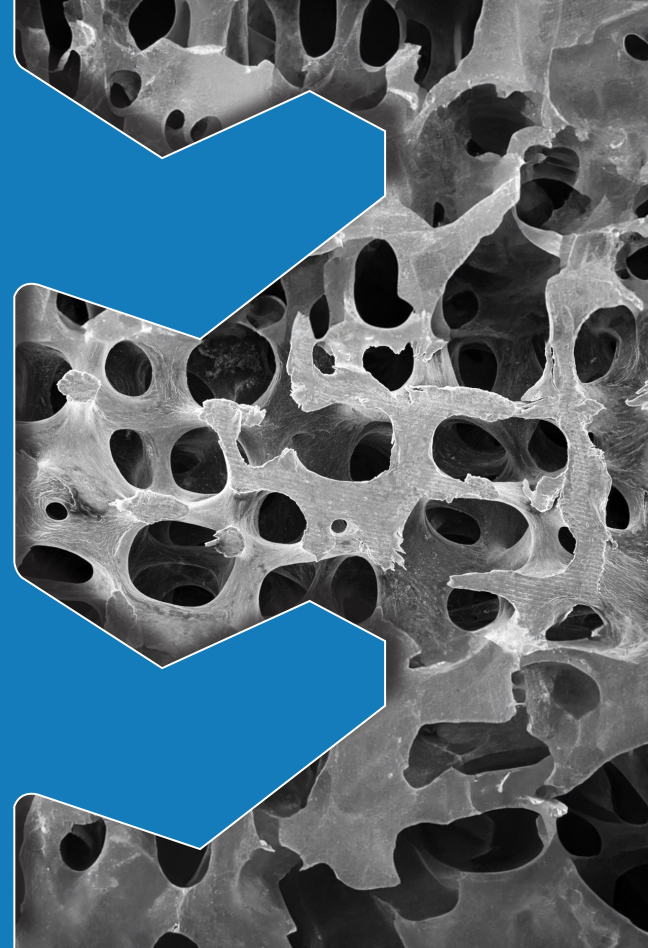


UnifiMI™
An OsteoCentric
Technology

Mechanical Integration Technology

Unique thread geometry instantly and circumferentially interlocks with bone by entrapping and containing bone between the thread form.

Mechanical Integration creates a structural and functional connection between an implant and bone which transfers and shares loads in a similar manner to biological integration (Osseointegration).



References

1. Hoel RJ, Ledonio CG, Takahashi T, Polly DW Jr. Sacral bone mineral density (BMD) assessment using opportunistic CT scans. J Orthop Res. 2017 Jan;35(1):160-166. doi: 10.1002/jor.23362. Epub 2016 Aug 26. PMID: 27391403.
2. Sacroiliac Implant Length and Loosening: CT Analysis of Radiographically Loose Components Compared to Controls. Scott Mitchell, MD; Allison Rixey, MD; William Cross, MD. Ortho. Trauma Association Meeting, Oct. 17 – 20, 2018
3. Slappey G, Toribatake Y, Ganey TM, Ogden JA, Hutton WC. Guidelines to decortication in posterolateral spine fusion. J Spinal Disord. 1998 Apr;11(2):102-9. Erratum in: BEQ 1998 Jun;11(3):275. PMID: 9588465.
4. McAfee PC, Regan JJ, Farey ID, Gurr KR, Warden KE. The biomechanical and histomorphometric properties of anterior lumbar fusions: a canine model. J Spinal Disord. 1988;1(2):101-10. PMID: 2980068.
5. Cross WW 3rd, Tomov MN, Hung MY, Muir JM. Patient-Reported Outcomes and Computed Tomography Review After Minimally Invasive Fusion of the Sacroiliac Joint With Aggressive Joint Decortication and Joint Compression. Orthopedics. 2024 Mar-Apr;47(2):101-107. doi: 10.3928/01477447-20230901-04. Epub 2023 Sep 6. PMID: 37672779.
6. Pace, N. (2018) From Sméagol to Gollum: Mechanical Stress and Bone Remodelling. Open Journal of Orthopedics, 8, 148-167. doi: 10.4236/ojo.2018.84018.
7. Thompson JC, Marigi E, Cross WW 3rd. Patient-Reported and Radiographic Outcomes After Revision Sacroiliac Joint Fusion. Int J Spine Surg. 2023 Apr;17(2):250-257. doi: 10.14444/8421. Epub 2023 Feb 8. PMID: 36754573; PMCID: PMC10165668.
8. Kyle Schoell, Zorica Buser, Andre Jakoi, Martin Pham, Neil N. Patel, Patrick C. Hsieh, John C. Liu, Jeffrey C. Wang, Postoperative complications in patients undergoing minimally invasive sacroiliac fusion, The Spine Journal, Volume 16, Issue 11, 2016, Pages 1324-1332, ISSN 1529-9430, <https://doi.org/10.1016/j.spinee.2016.06.016>.
9. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Devices (Auckl). 2013 May 29;6:77-84. doi: 10.2147/MDER.S44690. PMID: 23761982; PMCID: PMC3673964.
10. Whang PG, Darr E, Meyer SC, Kovalsky D, Frank C, Lockstadt H, Limoni R, Redmond AJ, Ploska P, Oh M, Chowdhary A, Cher D, Hillen T. Long-Term Prospective Clinical And Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants. Med Devices (Auckl). 2019 Sep 26;12:411-422. doi: 10.2147/MDER.S219862. PMID: 31576181; PMCID: PMC6769032.



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