OsteoCentric
SI FUSION

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.

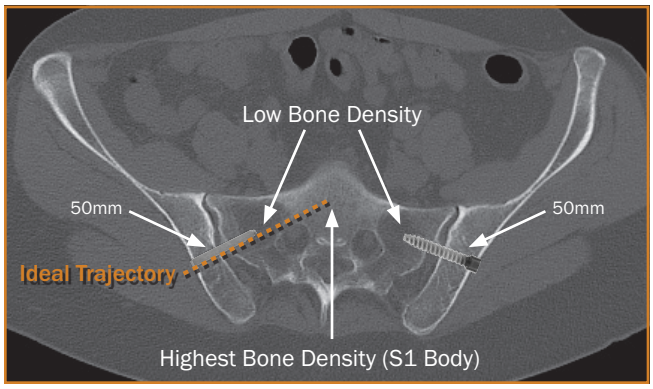
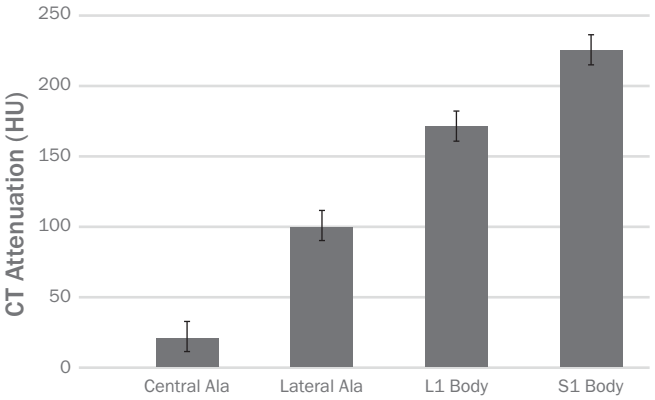


Figure 1



Sacral bone density, variations by region.[1]

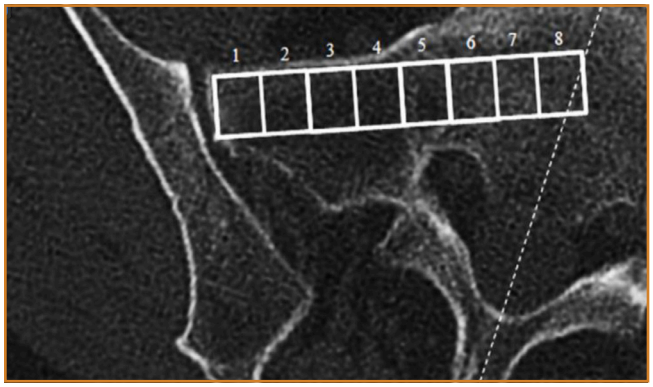
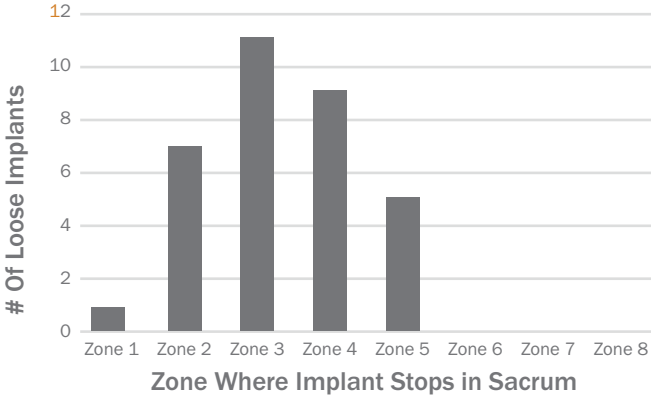


Figure 2



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

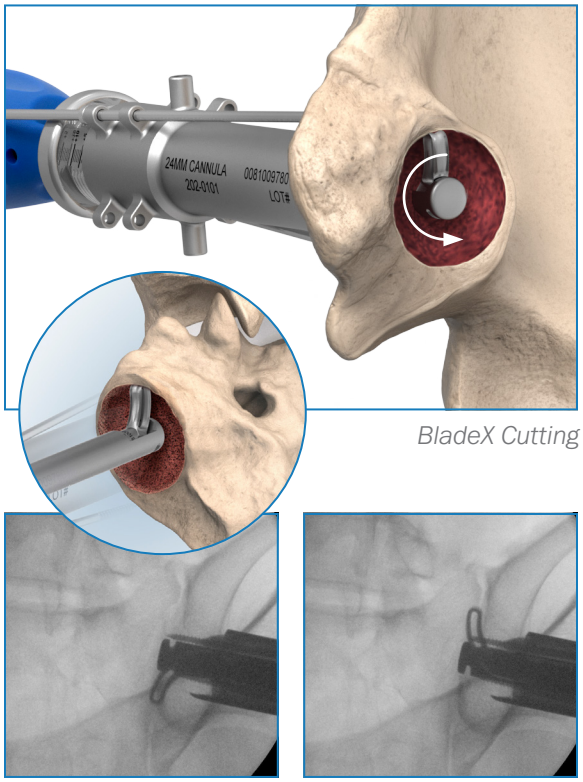
The Integrity-SI System was designed to address the short comings of other SIJ Systems currently on the market. Reports of implant loosening and revision surgery in the literature have increased in frequency as this surgery has become more common. Related complications include: Implant mal positioning,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

BladeX®

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 fusion[3].

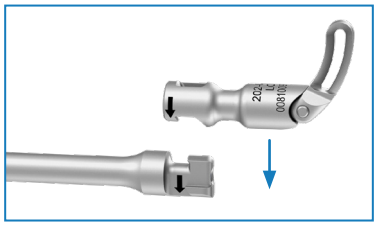
The combination of decortication, graft placement and fixation with threaded implants has been shown to promote fusion of the SIJ. [4,5]



BladeX Cutting

Proprietary BladeX™ Joint Prep Instrument

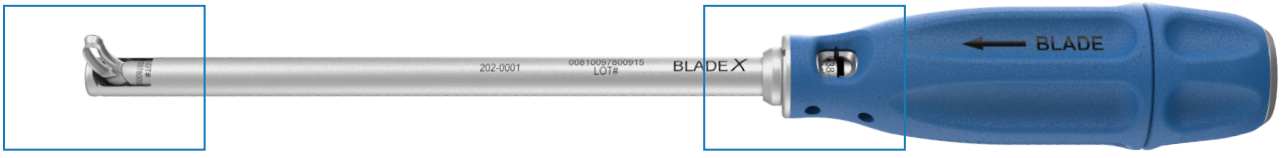
Designed based on the proven principles of joint fusion: aggressive joint preparation and autologous bone grafting, complemented by industry-leading joint compression.



Blade Connection

Features

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

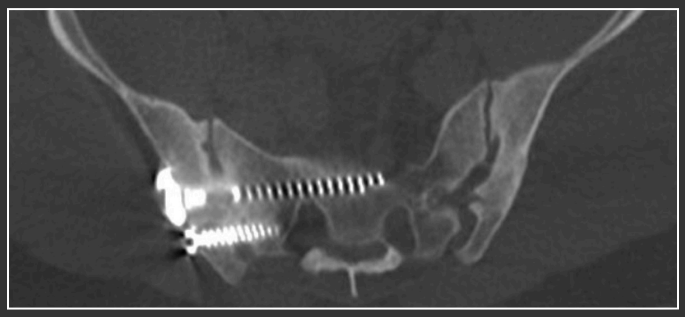


38mm Blade (Disposable)

Full surgeon control of resection diameter

Joint Compression & Mechanical Stability

Unifi*MI*™ thread design, bone volume engagement, load sharing and mechanical forces emphasize true compression, stimulating bone remodeling[5] and encouraging arthrodesis.[3, 7]



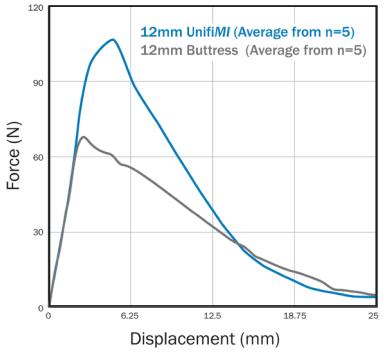
Sacroiliac joint fusion with definitive bridging bone through the scaroiliac joint

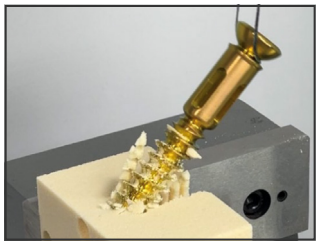
Mechanical Testing Information

Integrity-SI Fusion Fastener implants with Unifi*MI* 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 Unifi*MI*.

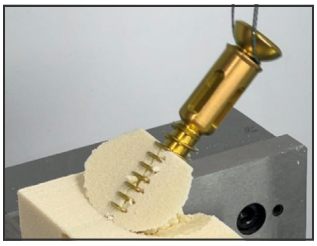
Sample #	Integrity Screws (Buttress) Yield Load (N)	Integrity Fasteners (Unifi*MI*) Yield Load (N)
1	61.96	102.97
2	65.89	106.08
3	71.65	118.36
4	67.38	108.07
5	70.12	101.72
Mean ± S.D.	**67.40 ± 3.79**	**107.44 ± 6.59**

Buttress vs Unifi*MI* Comparison





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

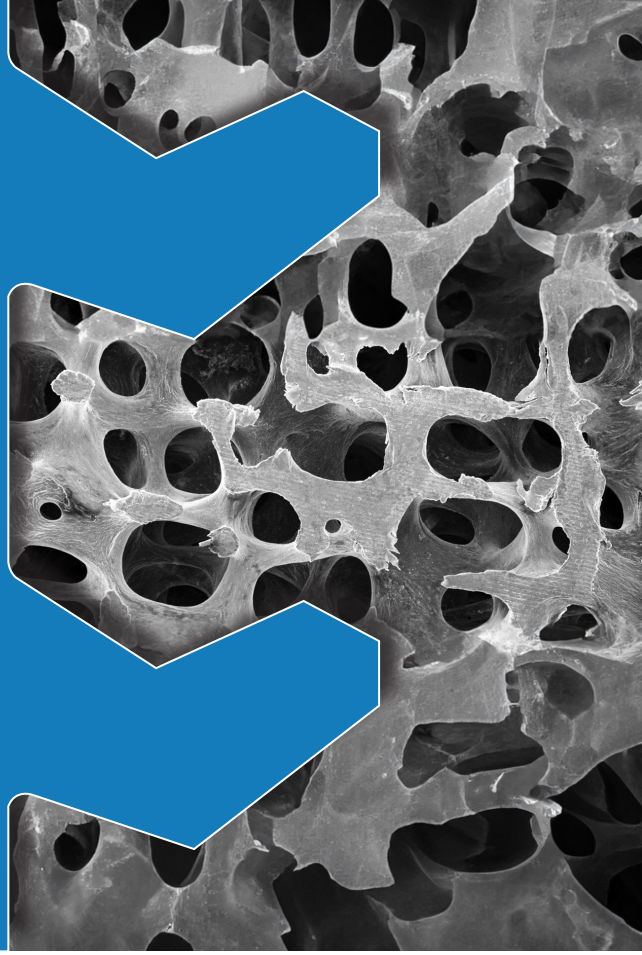


Integrity fastener with Unifi*MI* threads - bone foam still attached to the implant

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

Post-test view of Integrity-SI Fastener (Unifi*MI*) 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

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