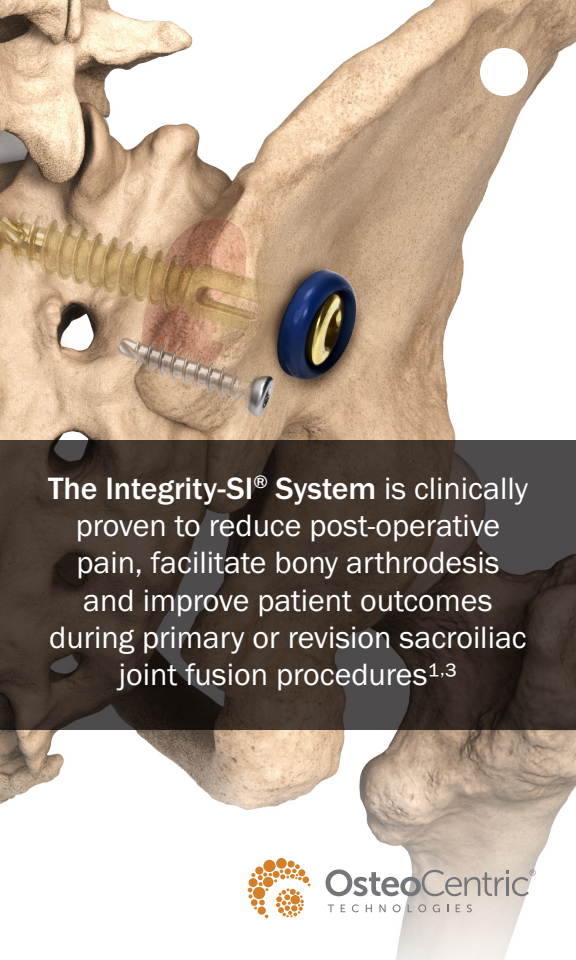


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Integrity-SI[®] Fusion System

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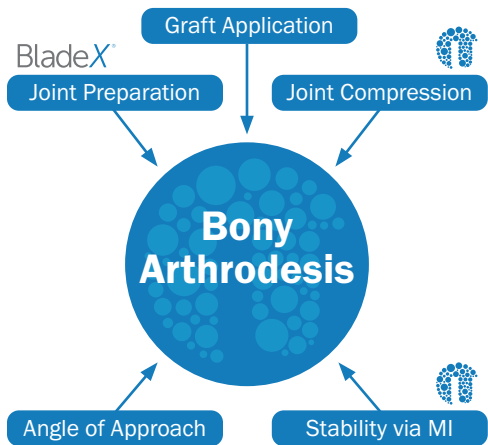


The Integrity-SI[®] System is clinically proven to reduce post-operative pain, facilitate bony arthrodesis and improve patient outcomes during primary or revision sacroiliac joint fusion procedures^{1,3}



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Integrity-SI Design Rationale



Enhanced by UnifiMI[®] Interface Technology

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Angle of Approach

With the patient positioned in prone, a direct perpendicular approach to the SI joint space is used. Approaching the SI Joint perpendicularly (vs. obliquely, which is commonly used) in its native alignment assures a safe starting and allows precise access to the joint for decortication and compression.

Joint Preparation

BladeX[®] allows for the surgeon to aggressively decorticate both sides of the SI joint. This creates bleeding cancellous bone on bleeding cancellous bone, a large zone within the joint for graft to be applied, and fusion to occur.

Graft Application

The Integrity-SI instrumentation allows for maximum autograft or allograft to be applied to the fusion zone and within the fusion barrel of the implant. A large fusion zone spanning the joint creates the ideal fusion environment.

Joint Compression

An 8mm, 10mm, or 12mm primary implant with a variable angle compressive washer creates compression across the SI joint helping initiate the body's natural healing process.

Construct Stability via UnifiMI

Utilizing UnifiMI Technology and a large compression washer, the Integrity-SI construct creates both initial and long-term stability at the bone interface on both sides of the SI Joint.



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

Sacroiliac joint fusion with definitive bridging bone through the sacroiliac joint



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UnifiMI[®]

An OsteoCentric
Technology



The System Utilizes the Proven Principles of Joint Fusion:

- Aggressive joint preparation
- Autologous bone grafting
- Industry-leading joint compression and mechanical stability

BladeX[®]

BladeX[®] allows surgeons to aggressively decorticate the SI joint – creating a massive zone for fusion to occur.



BladeX MIS Decorticator



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Clinical Performance



Read Full Study

Successful Primary SIJF Series

12 month Follow-up

Patient-Reported Outcomes and Computed Tomography Review After Minimally Invasive Fusion of the Sacroiliac Joint With Aggressive Joint Decortication and Joint Compression

William W. Cross III, MD; Marko N. Tomov, MD; Michelle Y. Hung, PA-C, MS; Jeffrey M. Muir, MSc, DC, MSc (Clin Epi)

+98%
Fusion Rate

Significant and clinically relevant improvements in pain and function with no reported complications

Journal: Orthopedics

Publication Date: September 6, 2023

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Clinical Performance



Read Full Study

Successful Primary SIJ Series

12-24 Month Follow-up

Minimally Invasive Sacroiliac Joint Fusion: 2-Year Radiographic and Clinical Outcomes with a Principles-Based SIJ Fusion System

*William W Cross, Arnold Delbridge, Donald Hales, and
Louis C Fielding*

79-94%
Fusion Rate

Significant and clinically relevant improvements in pain and function with no reported complications

Journal: The Open Orthopedics Journal

Publication Date: December 29, 2017



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Clinical Performance



Read Full Study

Largest Revision SIJ Series

12 month Follow-up

Patient-Reported and Radiographic Outcomes After Revision Sacroiliac Joint Fusion

*Jeremy C. Thompson, MD, Erick Marigi, MD, &
William W. Cross, III, MD*

88.9%
Fusion Rate

Definitive bone bridging
across the SIJ

Significant and clinically
relevant improvements
in pain and function with
no reported complications

Journal: International Journal of Spine Surgery

Publication Date: February 8, 2023

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Biomechanical Performance

Off-Axis Resistance, Compression, and Pullout⁵

- Significant increase in off axis resistance, compression, and axial pullout when compared to predicates.
- 166% more Compression and 33% increase in axial pullout resistance compared to the 10mm market leading implant option.

↑ 56%
Off-Axis
Resistance



12mm



10mm



8mm



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Biomechanical Performance

Axial Pullout Testing⁶

>89%
Pull-Out
Force

Greater than the market
leading implant option



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Biomechanical Performance

Compression & Stability⁴

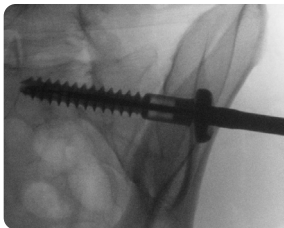
↑ 51%
Axial
Compression

More than the maximum compression force generated by leading market implant.

Triangular dowel implants were negligible as tended to act as spacers and cause more distraction than compression.



Integrity-SI Implant



Integrity-SI Implant
Full Compression



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Joint Compression & Mechanical Stability

UnifiMI thread design, bone volume engagement, load sharing and mechanical forces emphasize true compression, stimulating bone remodeling and encouraging arthrodesis.



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

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Joint Compression & Mechanical Stability



Variable Angle Compression Washer

- 24mm diameter
- +/-18° variable angle

Fusion Zone

- 4 lateral fenestrations - graft packing and thru-growth
- Non-threaded for compression-lag for long-term fixation
- Length based on pre-operative CT data

Surface Finish

- Grit blasted for on-growth

Insertion

- Polished distal tip
- Cannulated, self-tapping



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UnifiMI

Fastener Platform Technology

UnifiMI Fastener Technology instantly secures & stabilizes the bond between two components by creating a structural & functional mechanical connection.

UnifiMI

Bone to Implant Interface Performance Capabilities

Compression/
Wedge
Interface

Mechanical
Integration
Interface

Preserves Architecture & Biology of the Bone



Instantly Interlocks the Implant to Bone Circumferentially



Immediate Load Sharing Similar to Osseointegration



Preserves Primary Implant Stability



Tension Side of Implant Capable of Resisting Loads



Easily Removable



Affordable



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What is **Mechanical Integration**?

Mechanical Integration (MI) is a minimally invasive, bone preserving method that instantly secures and stabilizes implants to normal or compromised bone by creating a structural and functional connection, utilizing a unique thread geometry that circumferentially interlocks with the bone.



Preserve the architecture of the patient's bone during implant insertion



Sustain primary implant stability over time



Leverage MIS technology to accelerate the patient's healing journey

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How Does UnifiMI Prepare & Preserve Bone?

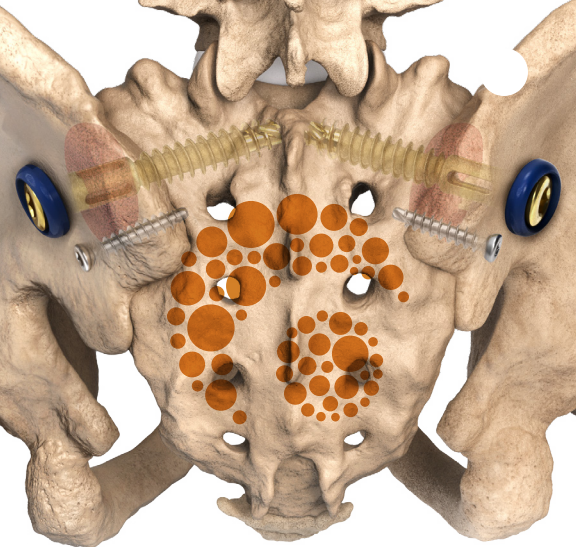
- Bone's innate structure and inter-connectivity play major roles in improving implant fixation and prolonging stability. UnifiMI implants and instruments are designed specifically with this fact in mind, creating a symbiotic relationship at the bone-implant interface.
- OsteoCentric drill bits are designed to preserve bone volume by drilling true cylindrical pilot holes which is beneficial when used with UnifiMI or any other implant technology.
- UnifiMI implants incorporate by design, proprietary self-tapping technology to advance bone chips forward to create a clean bone-implant interface maintaining the health of the patient's bone.
- Upon implantation, UnifiMI's patented thread geometries preserve the architecture of bone by minimizing outward forces applied to the mechanically integrated bone.



References

1. 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.
2. Cross WW, Delbridge A, Hales D, Fielding LC. Minimally Invasive Sacroiliac Joint Fusion: 2-Year Radiographic and Clinical Outcomes with a Principles-Based SIJ Fusion System. *Open Orthop J*. 2018 Jan 17;12:7-16. doi: 10.2174/1874325001812010007. PMID: 29430266; PMCID: PMC5791206
3. 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.
- 4-7. OsteoCentric Testing Data on file.





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