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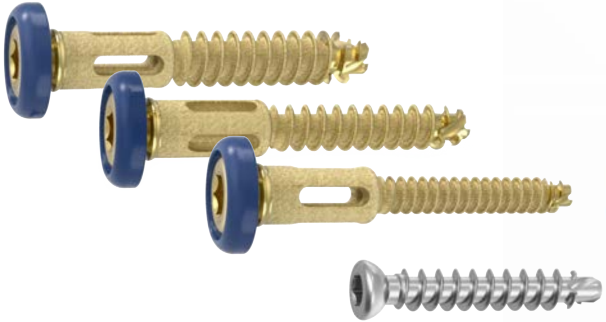
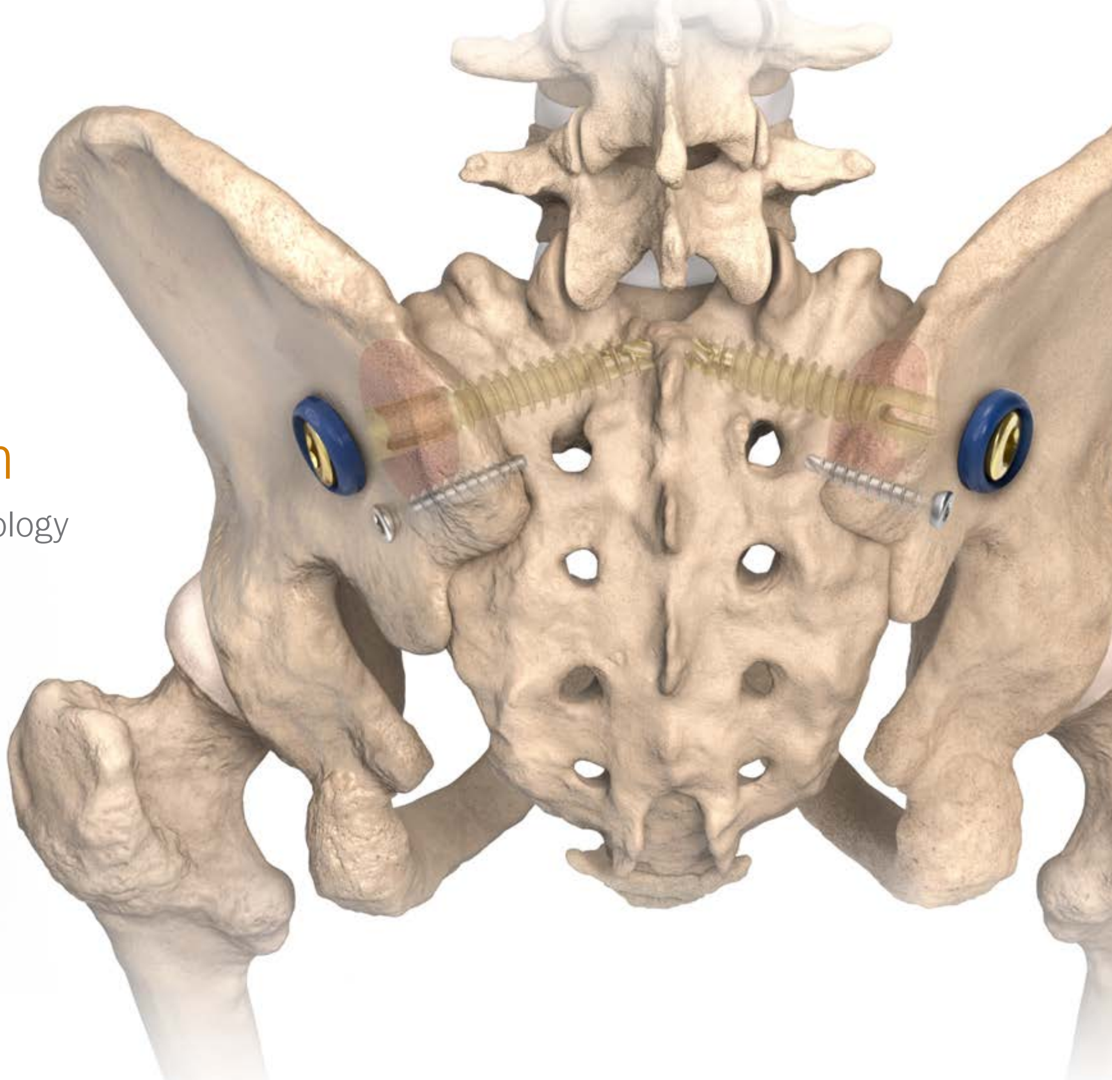
TECHNOLOGIES

Integrity-SI® Fusion System

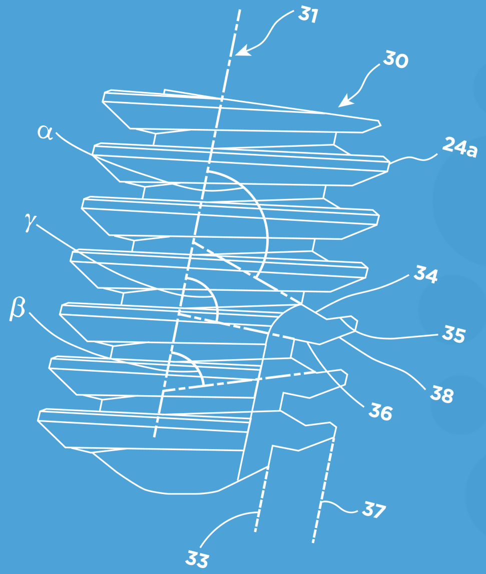
Featuring BladeX® and UnifiMI™ Technology





On the Docket

Unifi*MI* Introduction



Design Rationale

Surgical Technique

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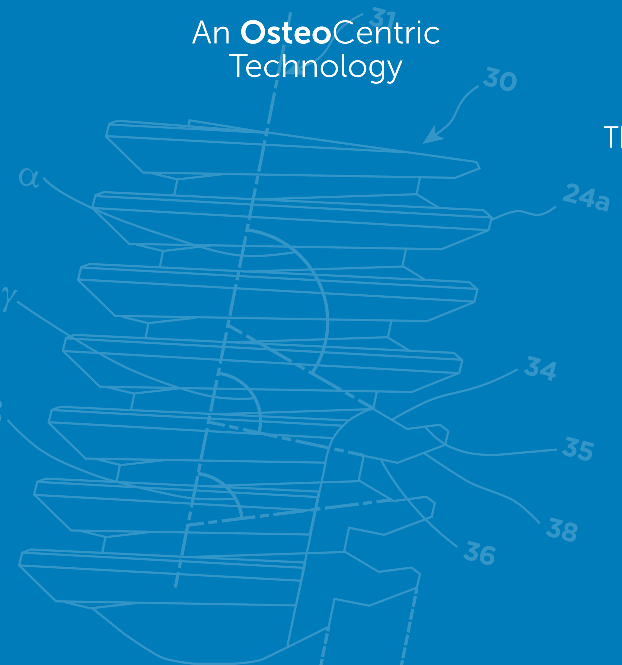
UnifiMI

An OsteoCentric Technology



Thread Profile

Integrated Bone

Mechanical Integration (MI)

Integrated thread geometry provides primary stability to instantly secure an implant to normal or compromised bone by entrapping and containing bone between the thread form.

Benefits Include:

- Instant and Lasting Multi-Axial Stability
- Circumferential Load Sharing and Resistance
- Tapping Technology and Thread Form Preserves Native Architecture of Bone

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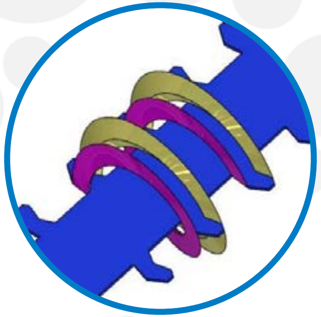
OsteoCentric Products Feature Unifi*MI*

Trailing Undercut

Provides circumferential resistance to axial pull-out and toggle

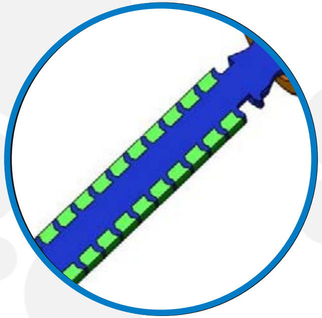


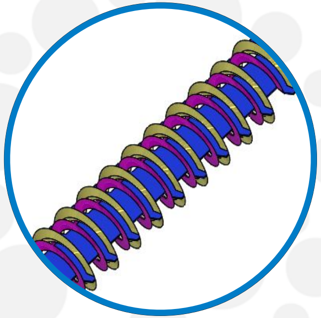
Leading Undercut

Leading undercut provides circumferential resistance to axial compression and toggle

Bone Capture

Interlocking of significant bone volume between threads provides immediate and lasting stability by sharing and resisting loads and reducing stress concentrations





Working Length

The unique undercut geometry resists loads and supports the implant within the bone down the entire thread length

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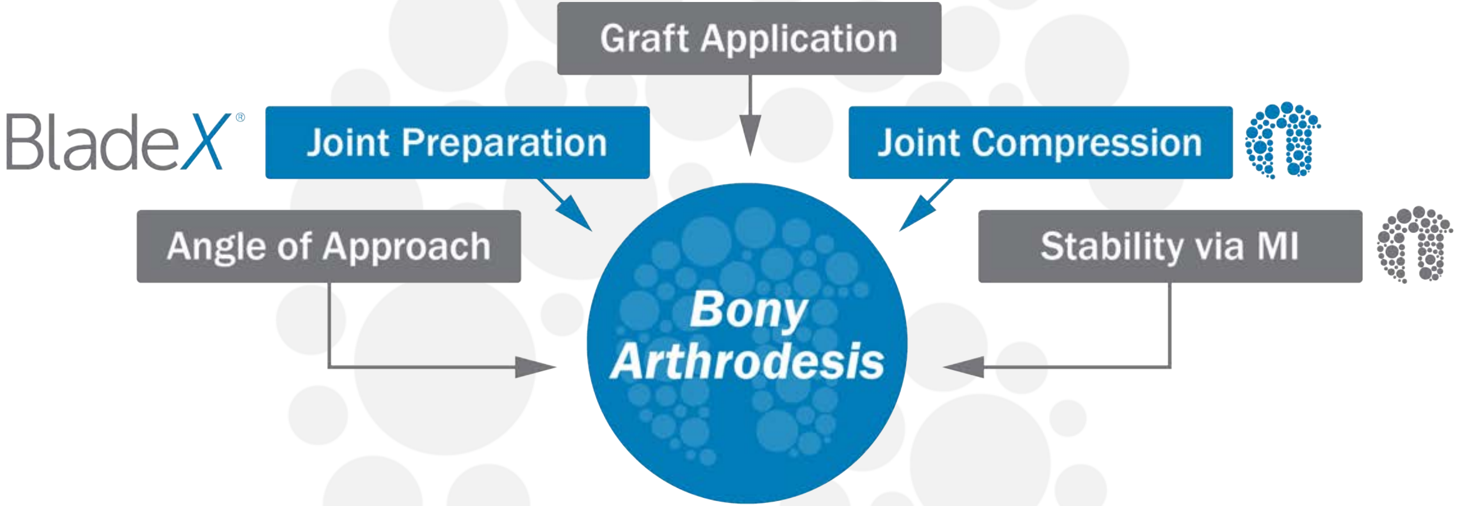
It's *immediate* fixation.
It's *immediate* stability.
Mechanical Integration
really seems to be
a technological
leap forward.
- *Robert D. Zura, M.D.*
OsteoCentric

Integrity-SI Design Rationale



Enhanced by Mechanical Integration

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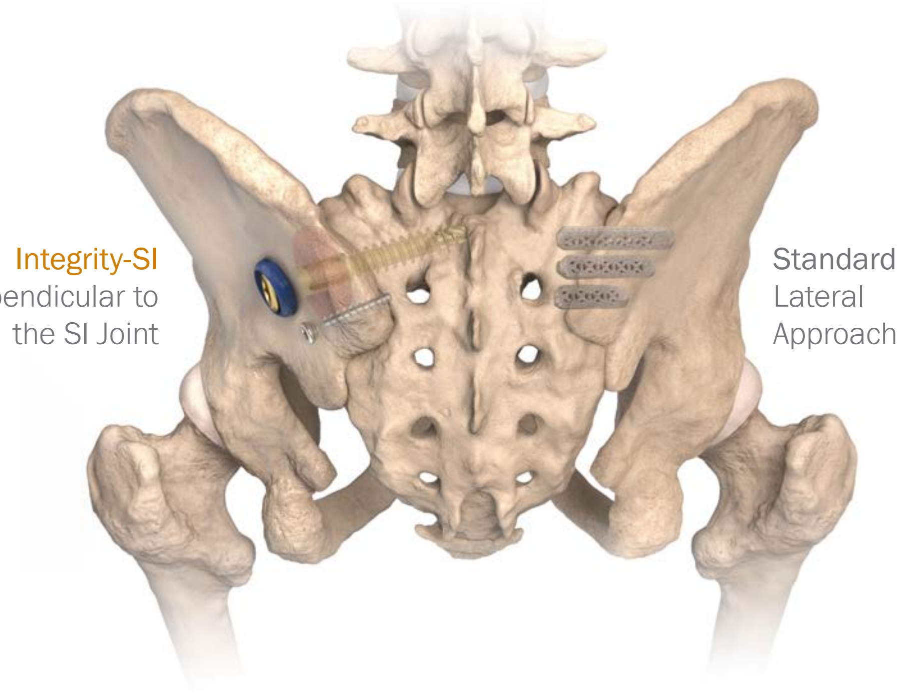
Angle of Approach

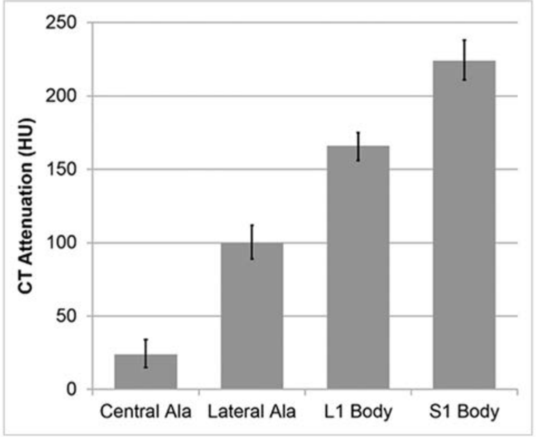
Based on Anatomical Analysis of CT Data

Integrity-SI
Perpendicular to the SI Joint



Standard Lateral Approach

Sacral Bone Density – Variations by Region



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.

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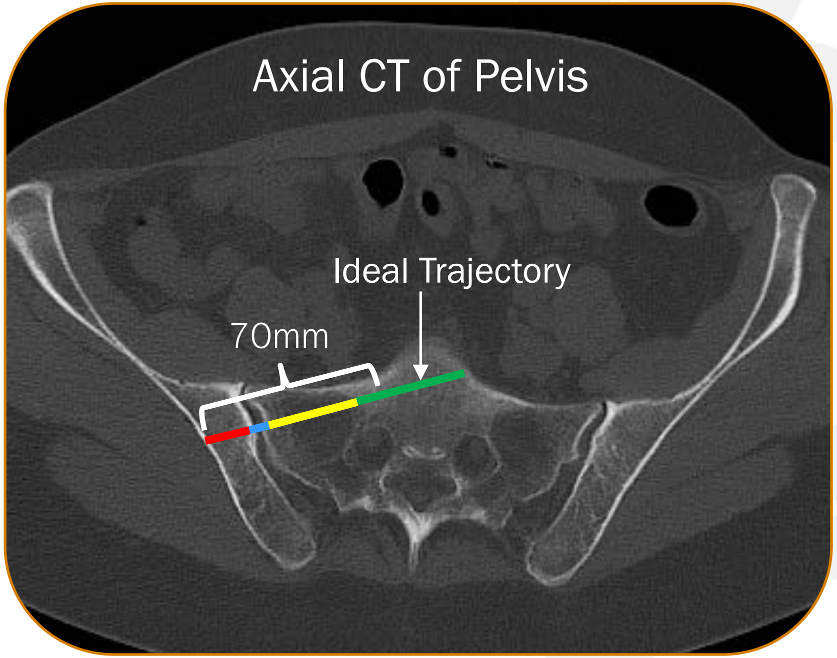
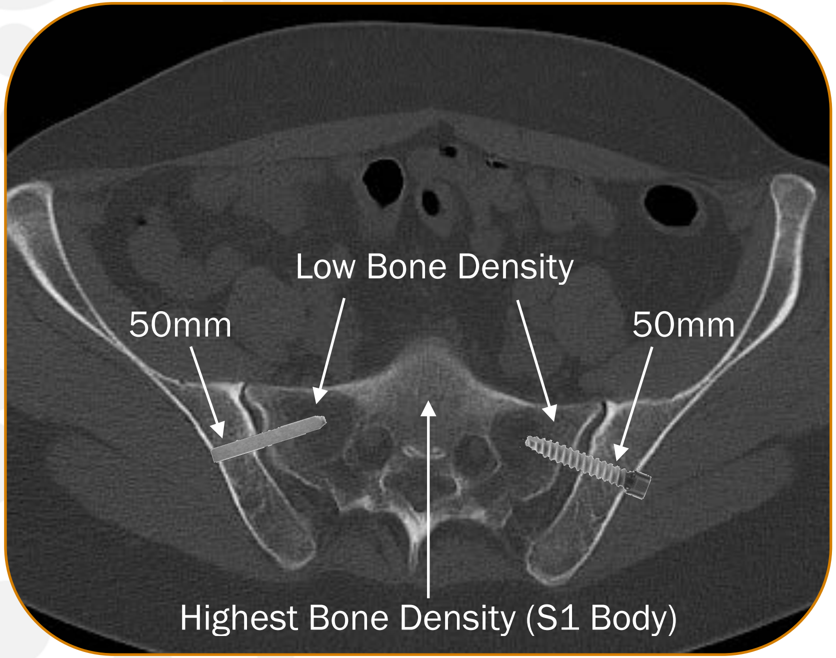
Angle of Approach

Based on Anatomical Analysis of CT Data





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Joint Preparation & Graft Application

Featuring BladeX® Technology

BladeX®
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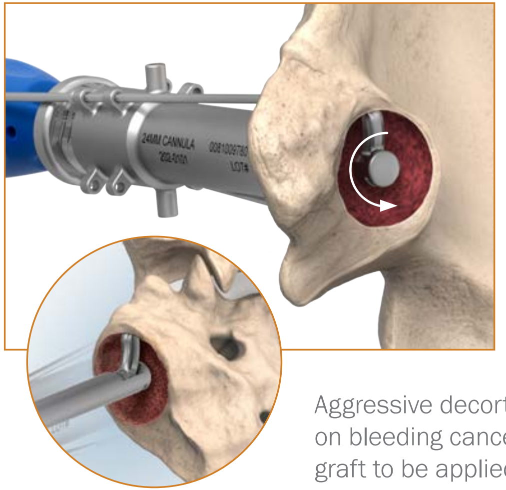
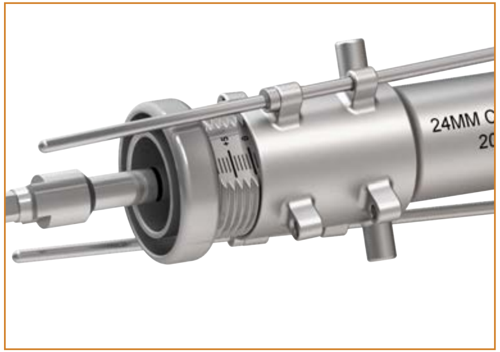
BladeX® MIS Decorticator

MIS Technique with precision instrumentation for rigid & aggressive joint preparation



Aggressive decortication creates bleeding cancellous bone on bleeding cancellous bone, a large zone within the joint for graft to be applied and an ideal environment for fusion to occur.

Precise depth control during joint preparation



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Joint Compression & Stability

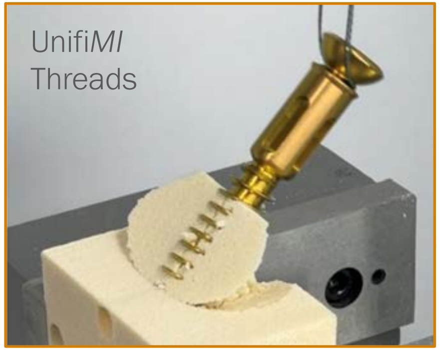
Via Unifi*MI*

Designed to Address Short-Comings of Other Systems

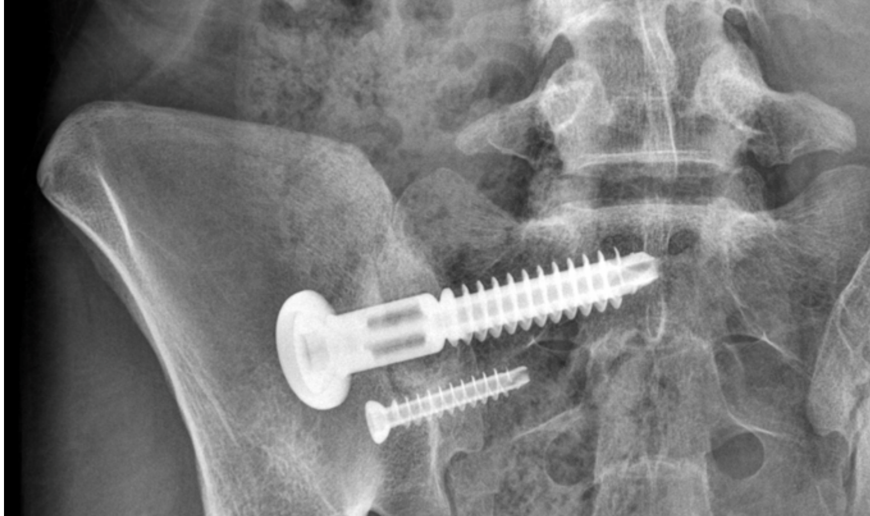
Utilizing Unifi*MI* Technology and a large compression washer, the Integrity-SI construct creates both initial and long-term stability at the bone interface on both sides of the SI Joint.

Post 'Pull Test' Isometric Views

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



Mean Yield Load (N) and Standard Deviation Data for all Specimens

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**

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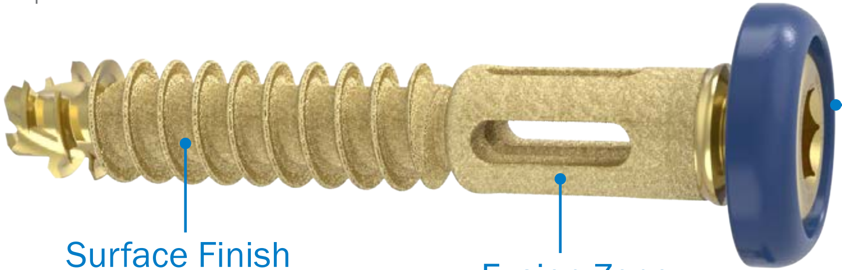
Joint Compression and Stability

Featuring UnifiMI™ Technology

UnifiMI
An OsteoCentric Technology

Anatomically designed fastener for long-term fixation and stability

- CT-Optimized fastener with fenestrated fusion zone
- Variable angle compression washer
- 8mm, 10mm, 12mm Diameter Options



Insertion

- Polished distal tip
- Cannulated, self-tapping

Surface Finish

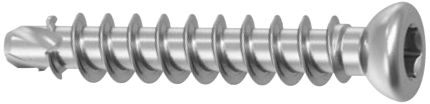
- HA and non-HA options
- Grit blasted for on-growth

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

Variable Angle Compression Washer

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



Bio-mechanical Fastener (optional)

- Cannulated, self-tapping, fully threaded
- Rotational stability

Bio-mechanical fastener may only be used in conjunction with a primary 10mm & 12mm implant

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Surgical Technique

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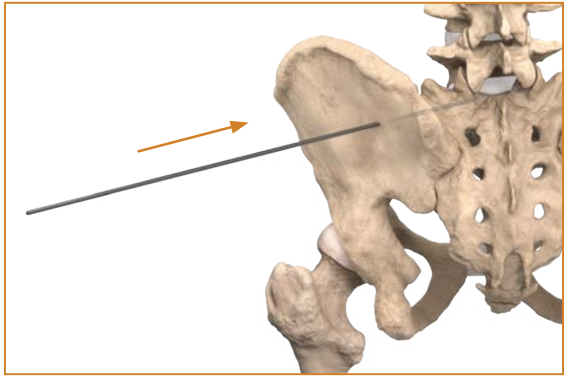
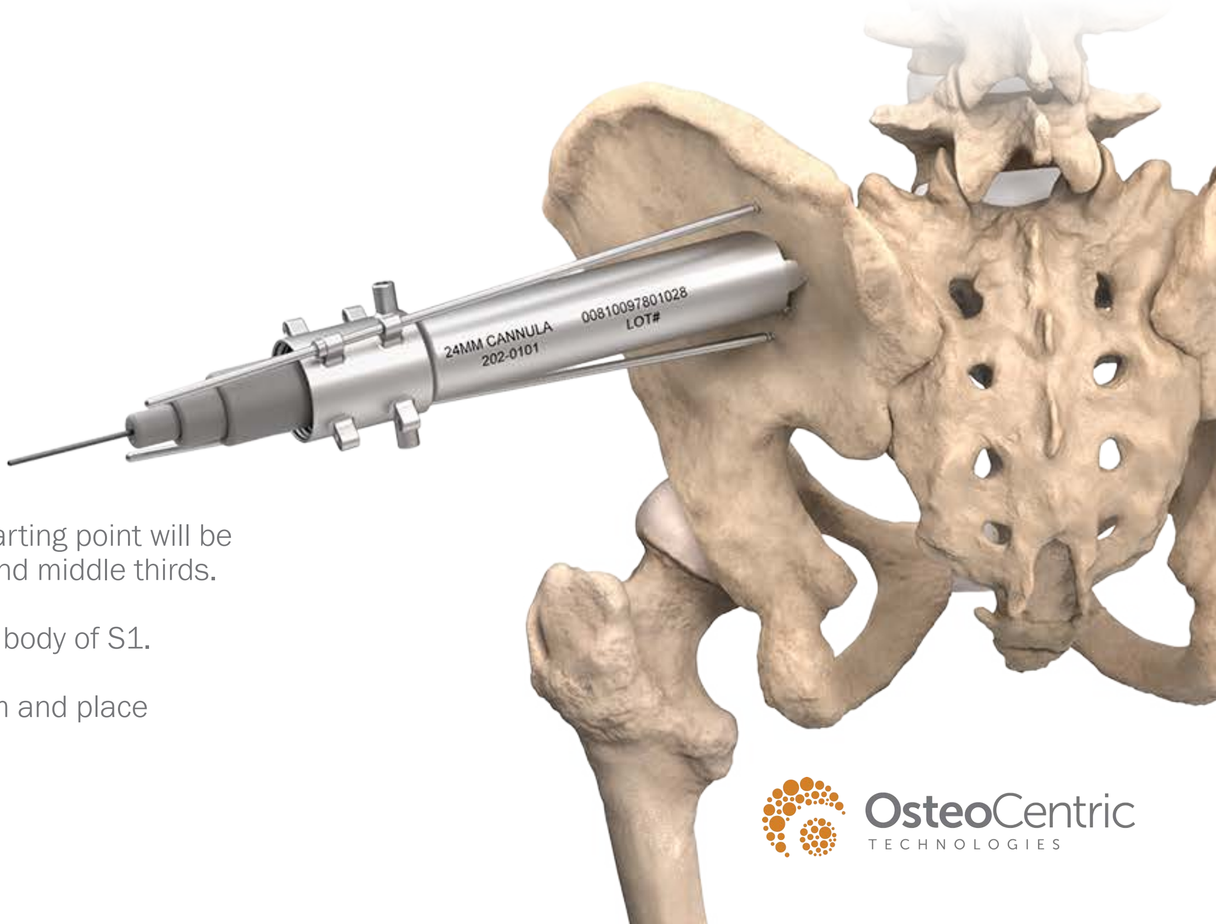
Angle of Approach, Guide Wire Insertion & Tissue Dilation



3.2mm Guide Wire



PSIS & Mid-axis of femur are “marked”, the starting point will be in the vicinity of the intersection of posterior and middle thirds.

Insert guide wire perpendicular to SI Joint into body of S1.

Dilate Tissue, Mallet working cannula into Ilium and place stabilizing pins into cannula.

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Measure Implant Length & Drill Minor Diameter

Measure for primary implant length.

Insert 12mm sleeve fully (bottom out).

Drill minor diameter.

12mm Sleeve

6.0mm Drill (10mm primary implant)

7.5mm Drill (12mm primary implant)

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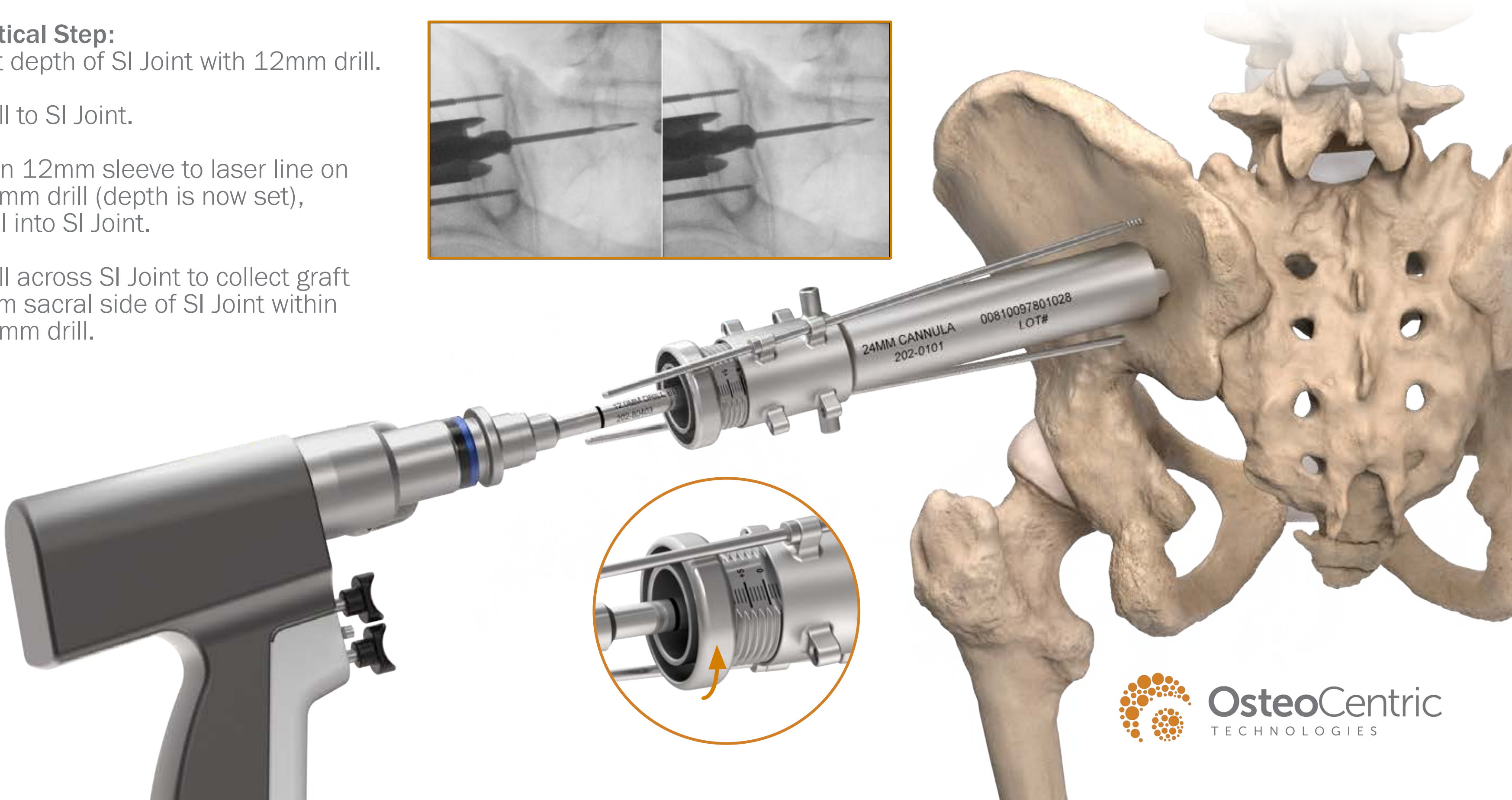
Set Depth of SI Joint & Bone Graft Collection

Critical Step:
Set depth of SI Joint with 12mm drill.

Drill to SI Joint.

Turn 12mm sleeve to laser line on 12mm drill (depth is now set), drill into SI Joint.

Drill across SI Joint to collect graft from sacral side of SI Joint within 12mm drill.



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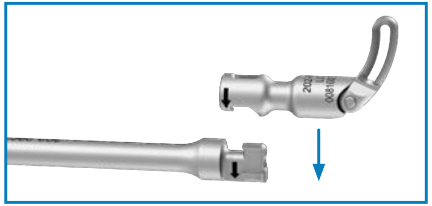
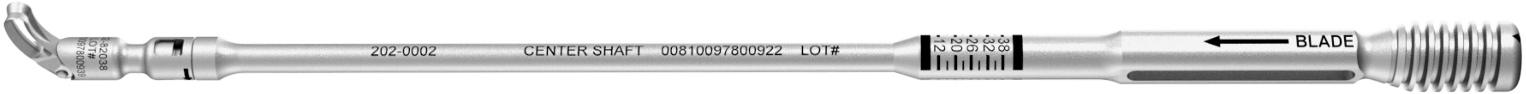
BladeX™ Joint Prep Instrument



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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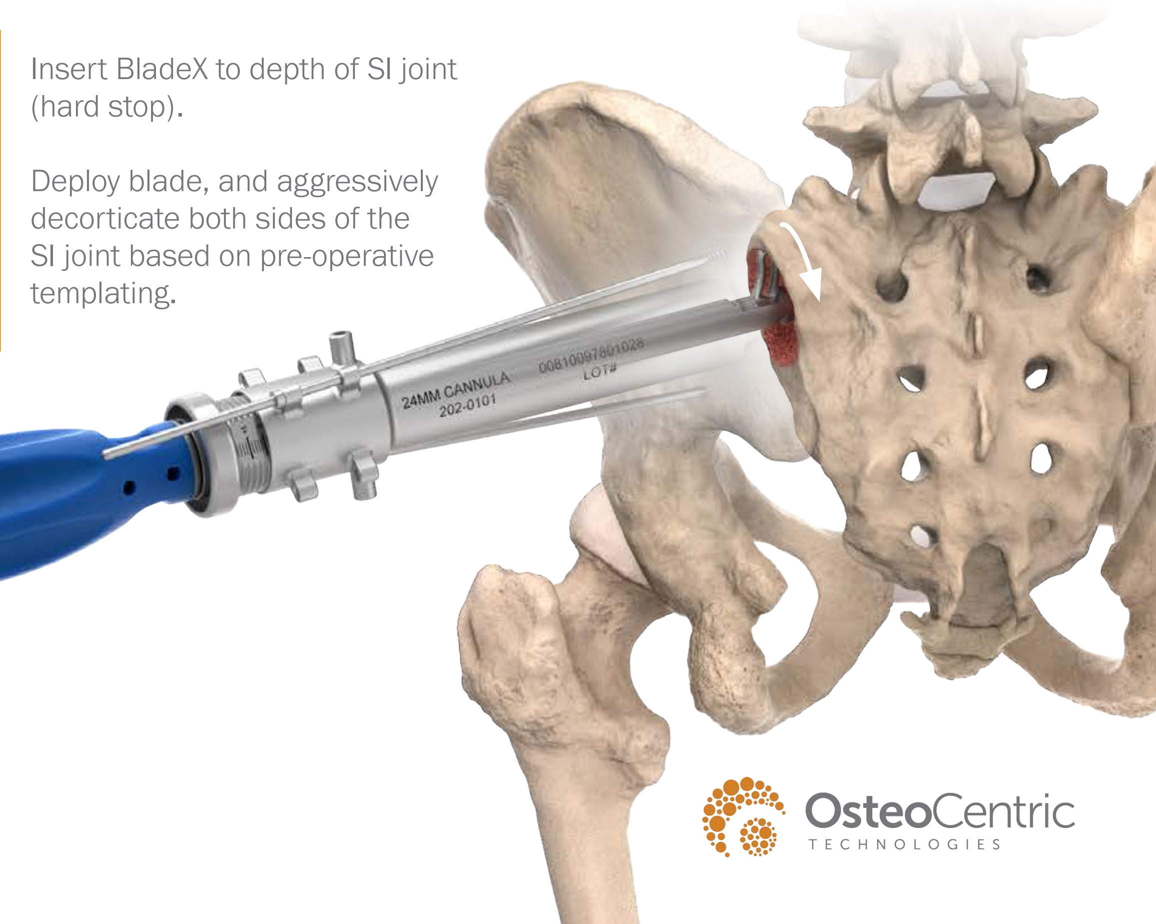
BladeX™ Joint Preparation - MIS Decortication

Insert BladeX to depth of SI joint (hard stop).

Deploy blade, and aggressively decorticate both sides of the SI joint based on pre-operative templating.



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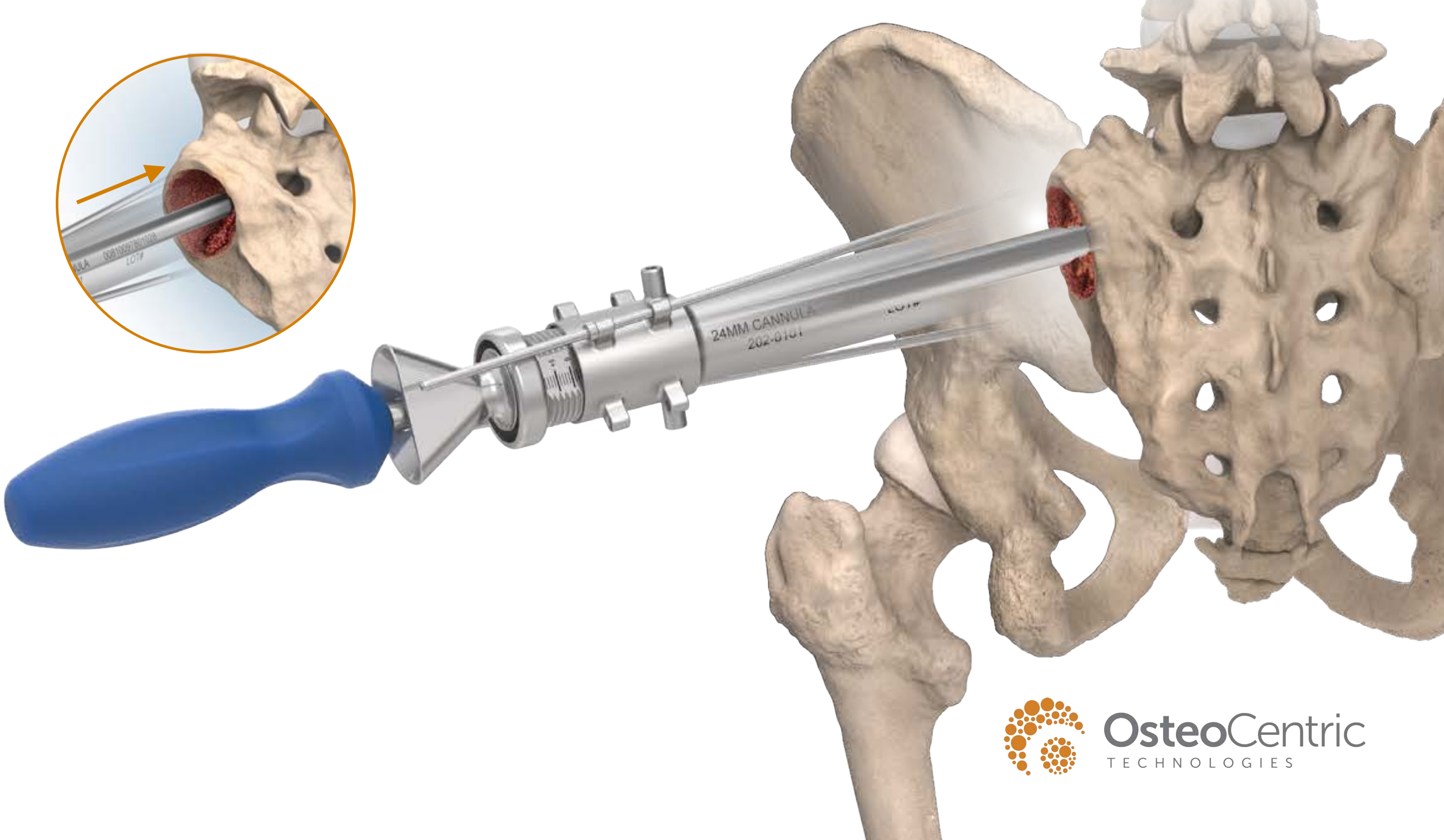
Joint Suction & Bone Graft Application

Ensure 12mm sleeve is set to deepest depth of decortication.



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Primary Integrity-SI Implant Insertion

Integrity-SI 12mm Implant

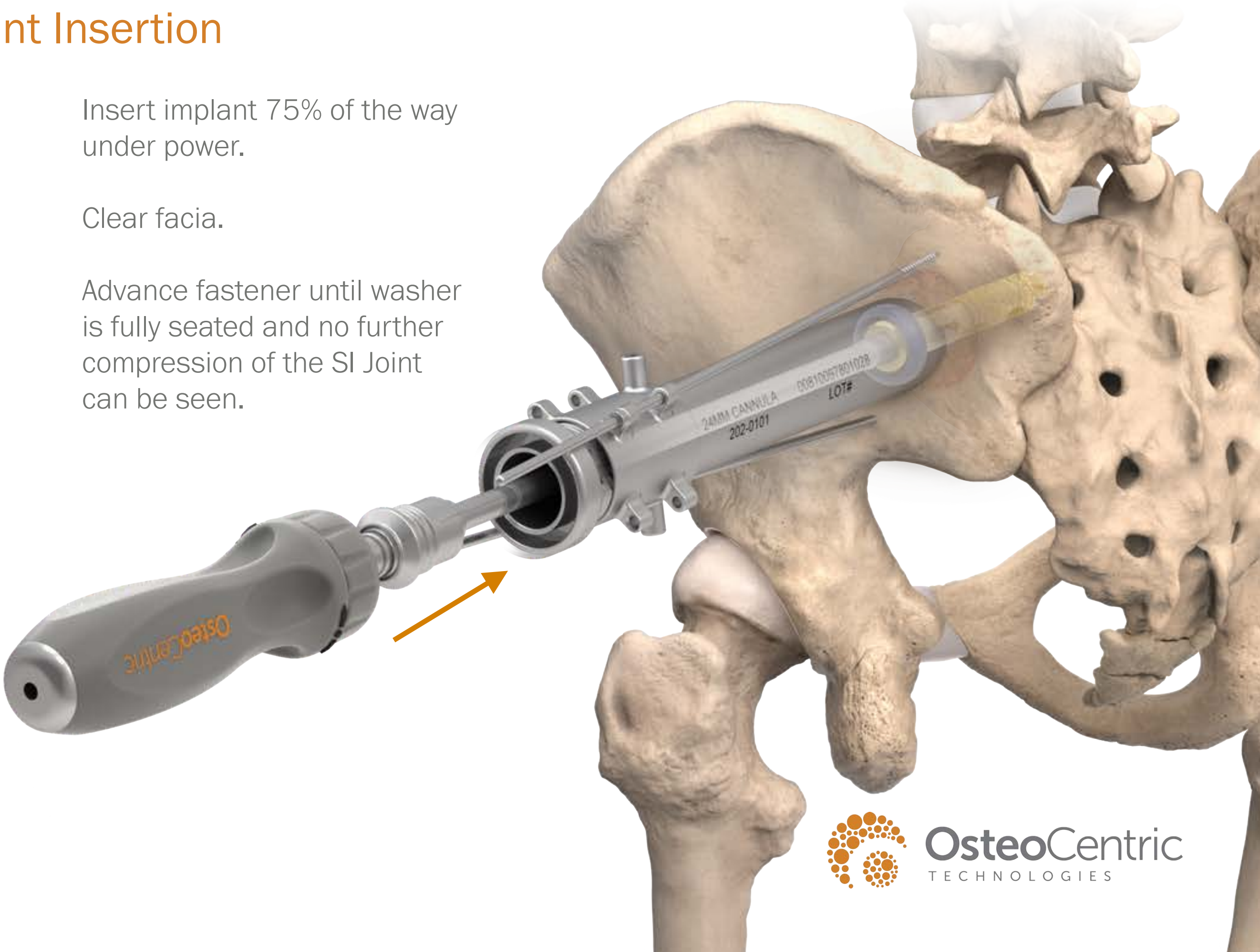
Integrity-SI 10mm Implant

Integrity-SI 8mm Implant

Insert implant 75% of the way under power.

Clear facia.

Advance fastener until washer is fully seated and no further compression of the SI Joint can be seen.



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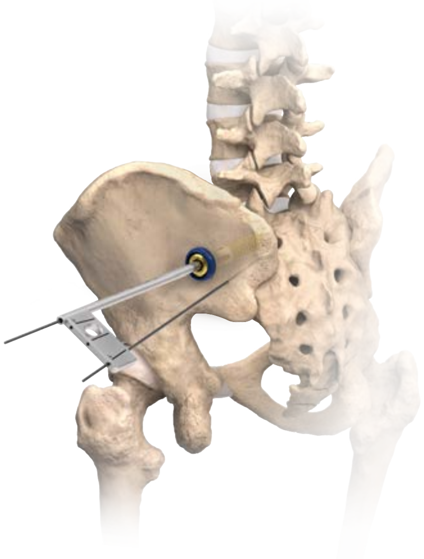
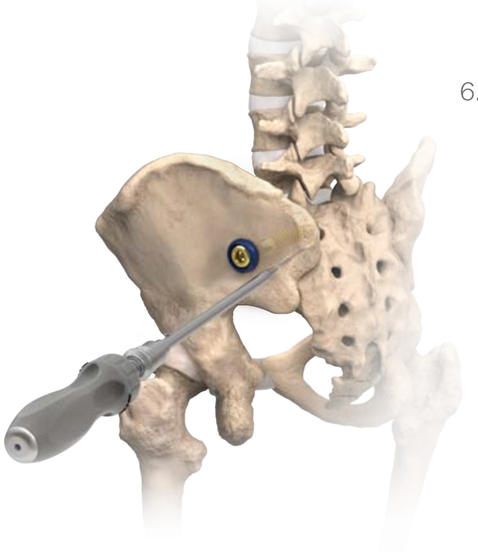
Integrity-SI 6.5mm Implant Insertion

Anti-Rotation Stability

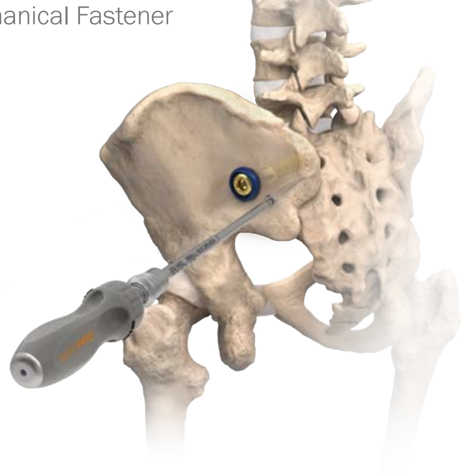


2.0 Wire Guide
and 2.0mm Guide Wire



6.5mm Biomechanical
Fastener Drilling

6.5 Biomechanical Fastener



6.5mm Biomechanical
Fastener Insertion

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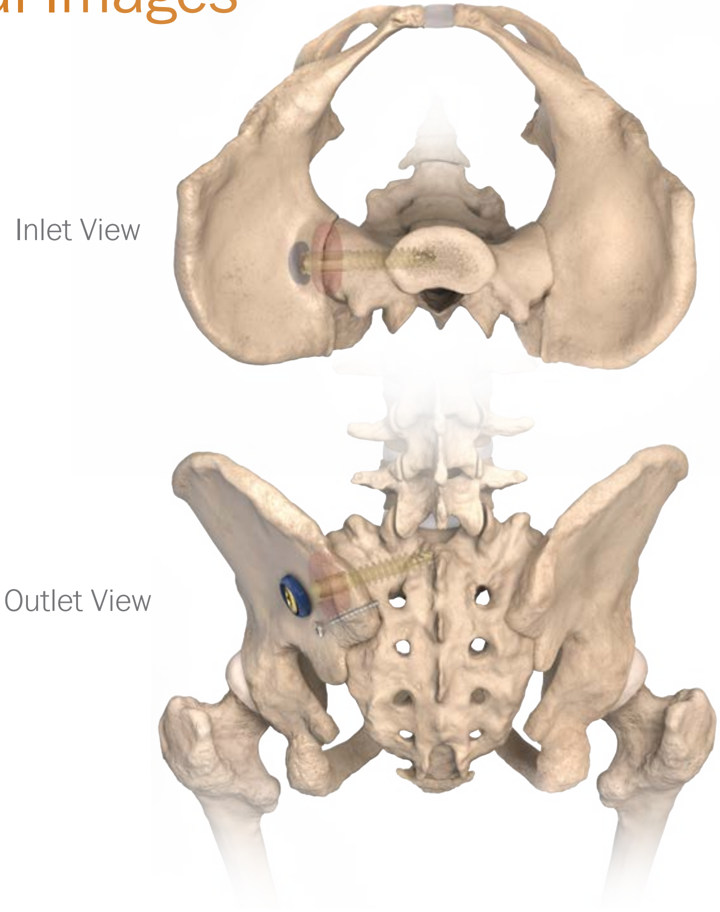
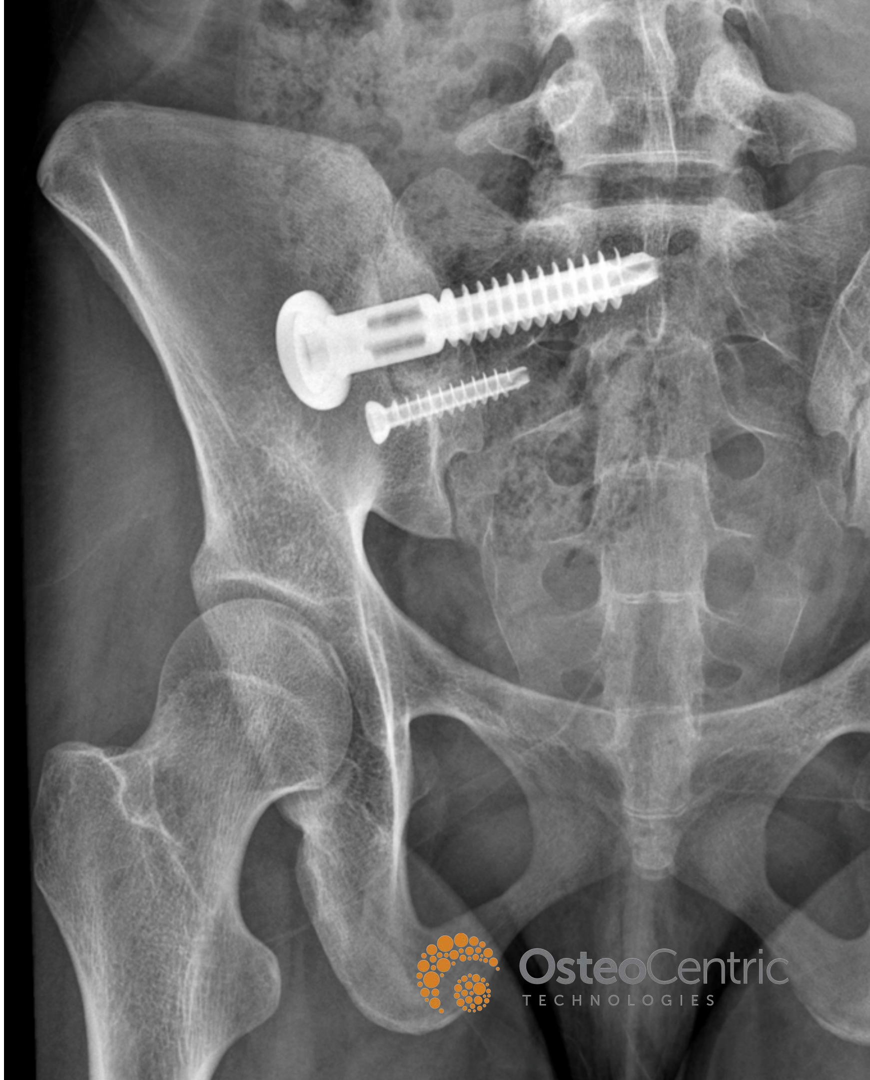
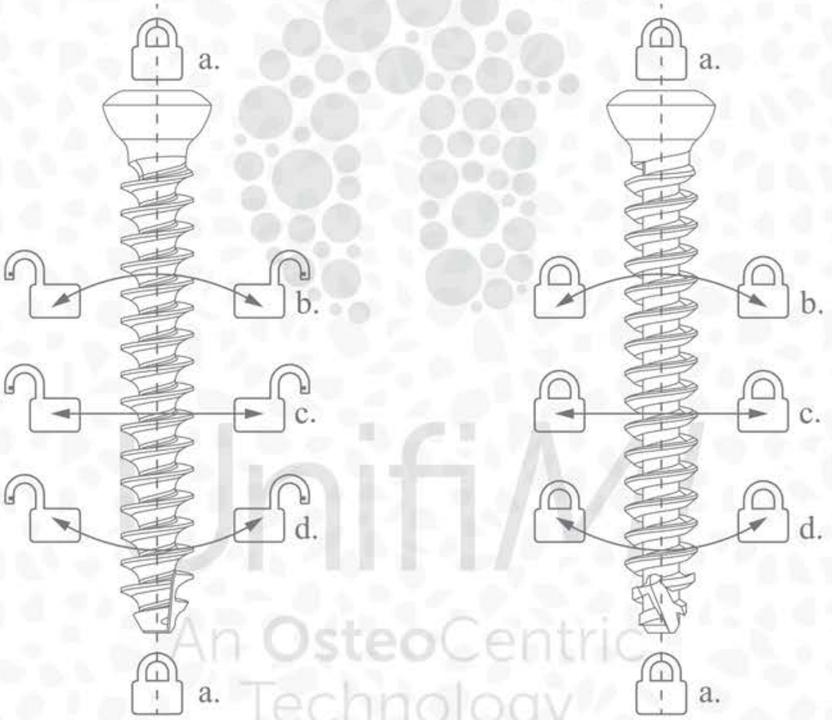
Final Images





Additional Information



Buttress Threads

Unifi*MI* Threads

Unifi*MI* - Supported by Testing and Research

Axial Pull-Out Testing
38% Improvement in axial pull-out strength vs standard orthopedic threads in human tibial bone.

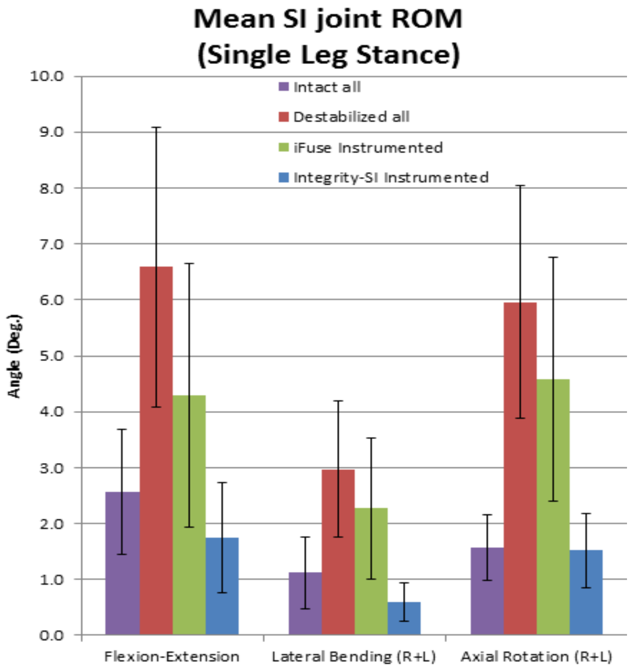
Peak Stripping Torque
67% increase in torsional resistance to stripping in both normal and osteoporotic human bone.

Pedicle Angulation/Pull-Out
Unifi*MI* pedicle screws showed significantly less angulation or "windshield wipering" during dynamic loading and superior yield strength in post-test axial pull-out.

Micromotion & Stiffness
After dynamic toggling, Unifi*MI* fasteners had 54% less displacement and maintained stiffness as compared to standard orthopedic screws.

Tibial Gap Model Studies
Non-locked Unifi*MI* screw/plate constructs performed equally or better than standard locked constructs in both cycle count and load magnitude in osteoporotic tibial gap models.

Clinical Safety & Efficacy
Initial publication of the first 29 patients to undergo surgeries using Unifi*MI* technology.



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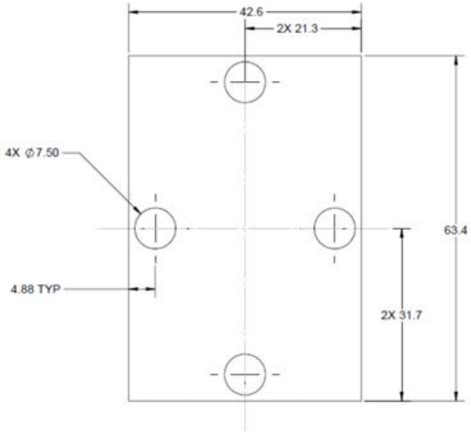
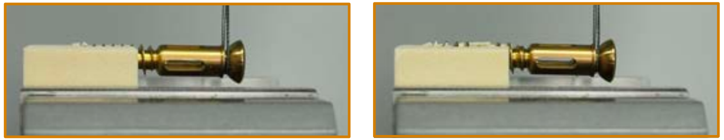
Evidence & Research - Test Setup

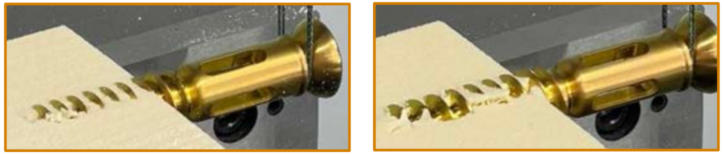


Engineering schematic of the bone block and pre-drilled hole locations

Example test specimen and level of insertion into the bone block



LEFT - Pre-test view of Integrity-SI Fastener (Unifi*MI*) test setup
RIGHT - Pre-test view of Integrity-SI screw (buttress) test setup



LEFT - Close-up view of Unifi*MI* threads and the preserved foam between the threads; RIGHT - Close-up view of the buttress threads and associated foam damage

Integrity-SI® Fusion implants with standard bone-implant interfaces based on common buttress threads and identical implants with a Mechanical Integration interface using Unifi*MI* were biomechanically tested in quasi-static, modified cantilever loading using 15 PCF bone foam blocks. Resultant load-displacement data demonstrated significantly higher yield loads (58% higher) for implants with Unifi*MI* as well as qualitative differences in failure modes.

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White Paper Test Results

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*.

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1	61.96	102.97
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Mean ± S.D.	**67.40 ± 3.79**	**107.44 ± 6.59**

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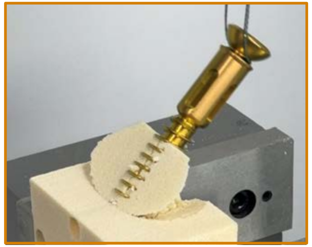
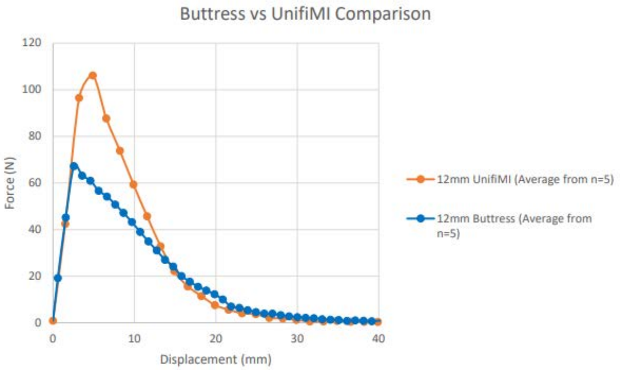
Integrity screw with buttress threads - very little bone foam still attached to implant



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

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



Mean Force Displacement Data for Integrity Fasteners with Unifi*MI* and Integrity-SI Screws with Buttress Threads

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

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