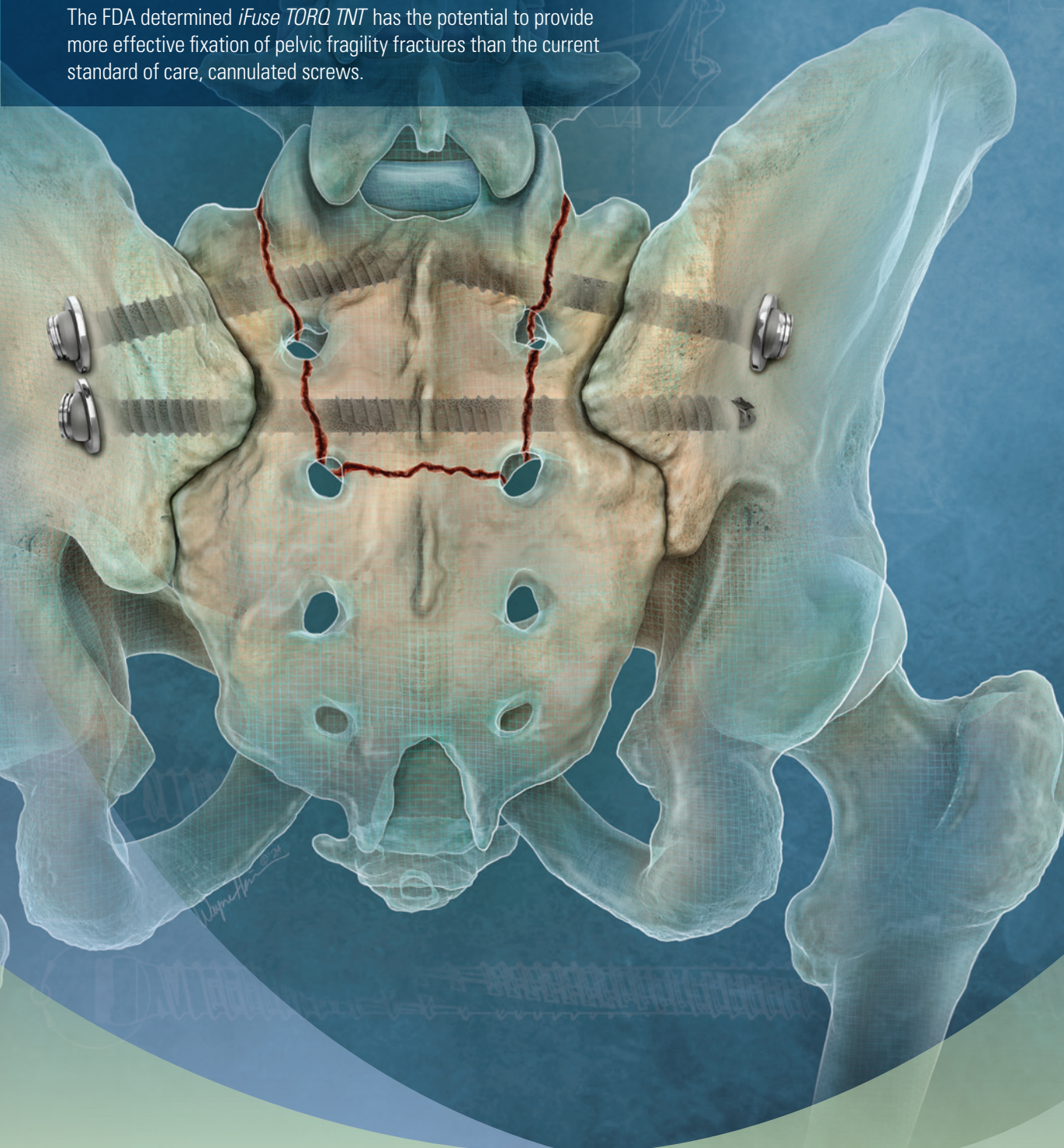


iFuse TORQ TNT™ Implant System

FDA Breakthrough Device Designation

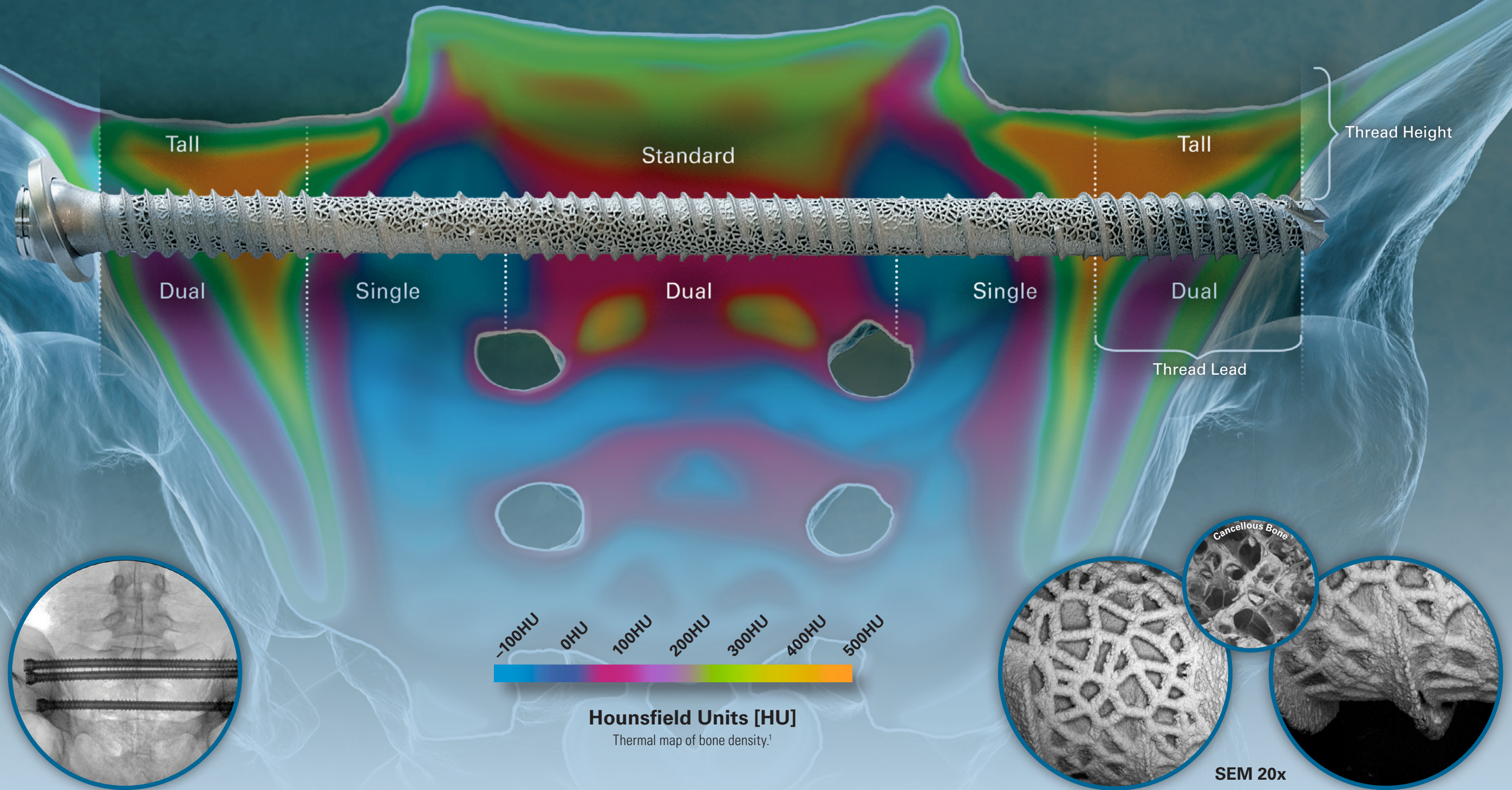
The FDA determined *iFuse TORQ TNT* has the potential to provide more effective fixation of pelvic fragility fractures than the current standard of care, cannulated screws.



iFuse TORQ TNT – Actual Size – 170 mm

Pelvic Bone Density-Driven Design

iFuse TORQ TNT™ Implant: The first 3D-printed, porous threaded implant with lengths capable of spanning the posterior pelvis, passing through the ipsilateral ilium, sacrum, and through the contralateral ilium (**through and through, "TNT"**).



PELVIS-SPECIFIC 8.7 MM DIAMETER
Fits 95% of S1 Corridors Suitable for a 7.3 mm Transsacral Screw²
150% stronger in bending vs 7.3 mm stainless steel screw^{3,4}

BONE DENSITY-DRIVEN DESIGN
Variable Thread Heights and Leads Tailored to the Posterior Pelvis
Designed to reduce loosening through pelvis-specific fixation

FuSlon 3D™ SURFACE
3D-Printed Porous Lattice
Designed for osseointegration

TORQLock™ THREADS
Hooked Profile
Designed to reduce toggle

iFuse TORQ TNT™ Implant System – Pelvic Bone Density-Driven Design



PN	Description
870070	8.7 x 70 mm iFuse TORQ TNT Implant
870075	8.7 x 75 mm iFuse TORQ TNT Implant
870080	8.7 x 80 mm iFuse TORQ TNT Implant
870085	8.7 x 85 mm iFuse TORQ TNT Implant
870090	8.7 x 90 mm iFuse TORQ TNT Implant
870095	8.7 x 95 mm iFuse TORQ TNT Implant
870100	8.7 x 100 mm iFuse TORQ TNT Implant
870105	8.7 x 105 mm iFuse TORQ TNT Implant
870110	8.7 x 110 mm iFuse TORQ TNT Implant
870115	8.7 x 115 mm iFuse TORQ TNT Implant
870120	8.7 x 120 mm iFuse TORQ TNT Implant
870125	8.7 x 125 mm iFuse TORQ TNT Implant
870130	8.7 x 130 mm iFuse TORQ TNT Implant
870135	8.7 x 135 mm iFuse TORQ TNT Implant
870140	8.7 x 140 mm iFuse TORQ TNT Implant
870145	8.7 x 145 mm iFuse TORQ TNT Implant
870150	8.7 x 150 mm iFuse TORQ TNT Implant
870155	8.7 x 155 mm iFuse TORQ TNT Implant
870160	8.7 x 160 mm iFuse TORQ TNT Implant
870165	8.7 x 165 mm iFuse TORQ TNT Implant
870170	8.7 x 170 mm iFuse TORQ TNT Implant
501939-0016	16 mm iFuse TORQ TNT Washer
501939-0021	21 mm iFuse TORQ TNT Washer

References

1. Bone density mapping based on Thiesen DM, *et al.* The three-dimensional bone mass distribution of the posterior pelvic ring and its key role in transsacral screw placement. *Sci Rep.* 2020 Mar 30;10(1):5690.
2. Gardner MJ, *et al.* Quantification of the upper and second sacral segment safe zones in normal and dysmorphic sacra. *J Orthop Trauma.* 2010 Oct;24(10):622-9. —Data analyzed for S1 dimensions
3. SI-BONE Technical Study 301122-TS-A. Fatigue Testing of 7.3mm Fully Threaded Cannulated Screw. (*Mechanical data, including computational modeling, is not necessarily indicative of human clinical outcomes.*)
4. SI-BONE Test Report 301321-R-A. Static and Dynamic Cantilever (ASTM F2193) Testing of the iFuse TORQ TNT Implants. (*Mechanical data, including computational modeling, is not necessarily indicative of human clinical outcomes.*)

Indications

The iFuse TORQ TNT™ Implant System is indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ TNT Implant System is indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.

The iFuse TORQ TNT Navigation Instruments are intended to be used with the iFuse TORQ TNT Implant System to assist the physician in precisely locating anatomical structures in iFuse TORQ TNT Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ TNT Navigation Instruments are intended to be used with the Medtronic StealthStation System.

Healthcare professionals should refer to the Instructions For Use for indications, contraindications, warnings, and precautions at <https://si-bone.com/label>.

There are potential risks associated with iFuse procedures. They may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit <https://si-bone.com/risks>

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Implant System

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