

Sacroiliac Joint Fusion or Pelvic Fracture Fixation with Threaded Implant

iFuse TORQ TNT™ Implant System SI-
BONE, Inc.

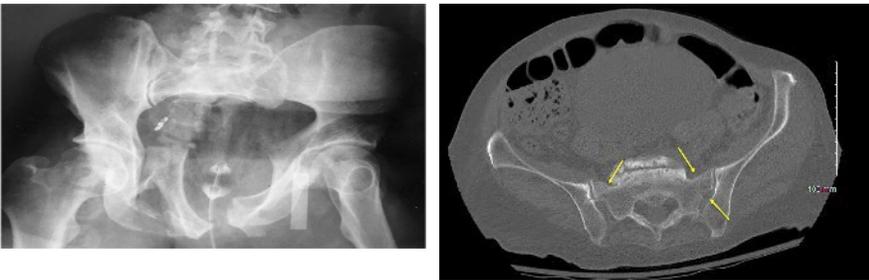
ICD-10 C&M Committee Meeting Update
March 2025



Types of Pelvic Fractures

Acute Fractures and Post-Acute SI Joint Dysfunction

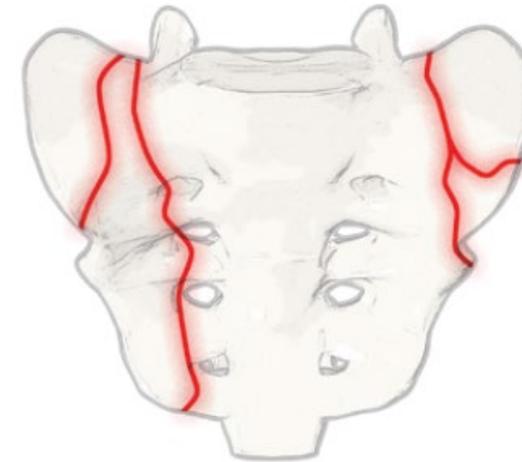
- **Acute fractures** (also called *traumatic fractures*) are caused by a recent direct blow or impact
- In low-energy trauma, fracture implies existence of poor bone quality (e.g., *osteoporosis*)
- Low-energy fracture is a synonym of **fragility fracture**



Bakker G, et al. *J Korean Neurosurg Soc.* 2018;61(2):258–266. doi:10.3340/jkns.2017.0188

Non-Traumatic Fractures

- A **non-traumatic fracture** is a break of a weakened bone without any identifiable trauma or following a minor injury that would not ordinarily break a healthy bone
- A non-traumatic fracture is a synonym of **insufficiency fracture**



Examples of Sacral Fractures¹

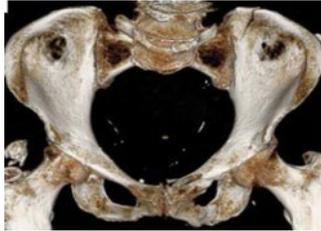


Pelvic Fracture Patient Care Continuum



Patient in pain

- A break of a weakened bone without any identifiable trauma or following a minor injury that would not ordinarily break a healthy bone



Patient presentation

- Typically, osteoporotic bone, elderly
- Severe pain in the pelvis/low back with restricted mobility
- Fracture often seen in imaging workup



Observation

- 24 to 48-hour monitoring for pain control and mobility
- Evaluation for treatment



Minimally invasive surgery or conservative treatment

- Goal: efficient return of mobility and degree of independence
- Least invasive surgical option is preferable



Potential short & long-term sequelae

- Numerous complications associated with prolonged bedrest
- Pelvic and/or back pain
- Fracture progression
- Recurrence or worsening of symptoms



Non-Traumatic Sacral Fx Complications

Nonsurgical Management:

14-45 day avg. hospital stay¹⁻³

29-61% risk of thromboembolic disorder^{4,5}

14-27% mortality rate at 1 year^{1,3}

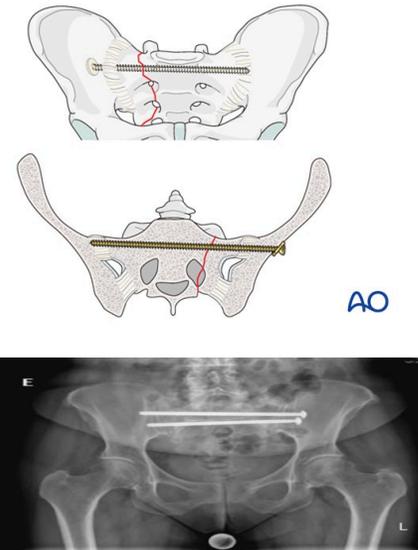
Issues with Previous Surgical Management (before TNT™):

Surgical risk factors; hypertension, dyspnea, 51% morbidity, 7% mortality⁶

Increased postop delirium and cognitive dysfunction⁷

20% risk of iliosacral screw backout⁸

32% risk of extravasation in sacroplasty procedures⁹

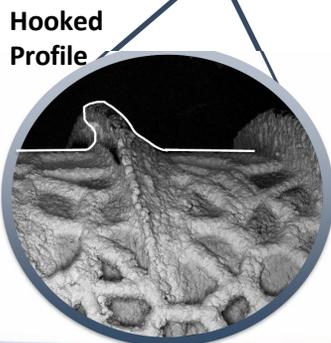
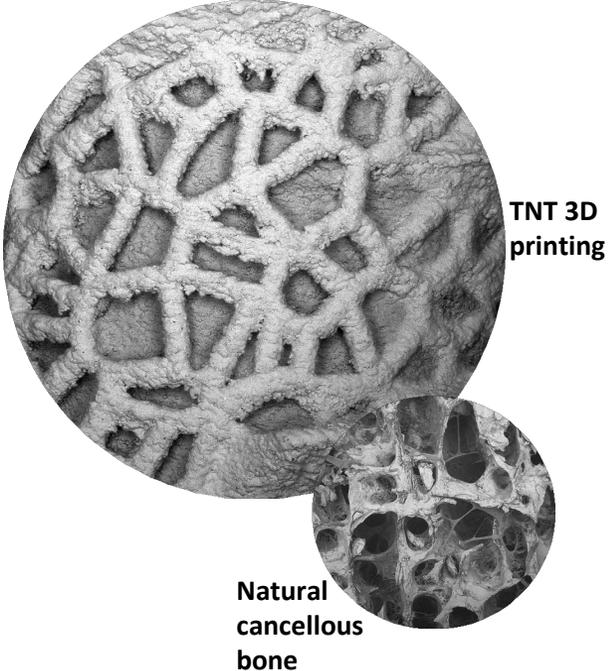
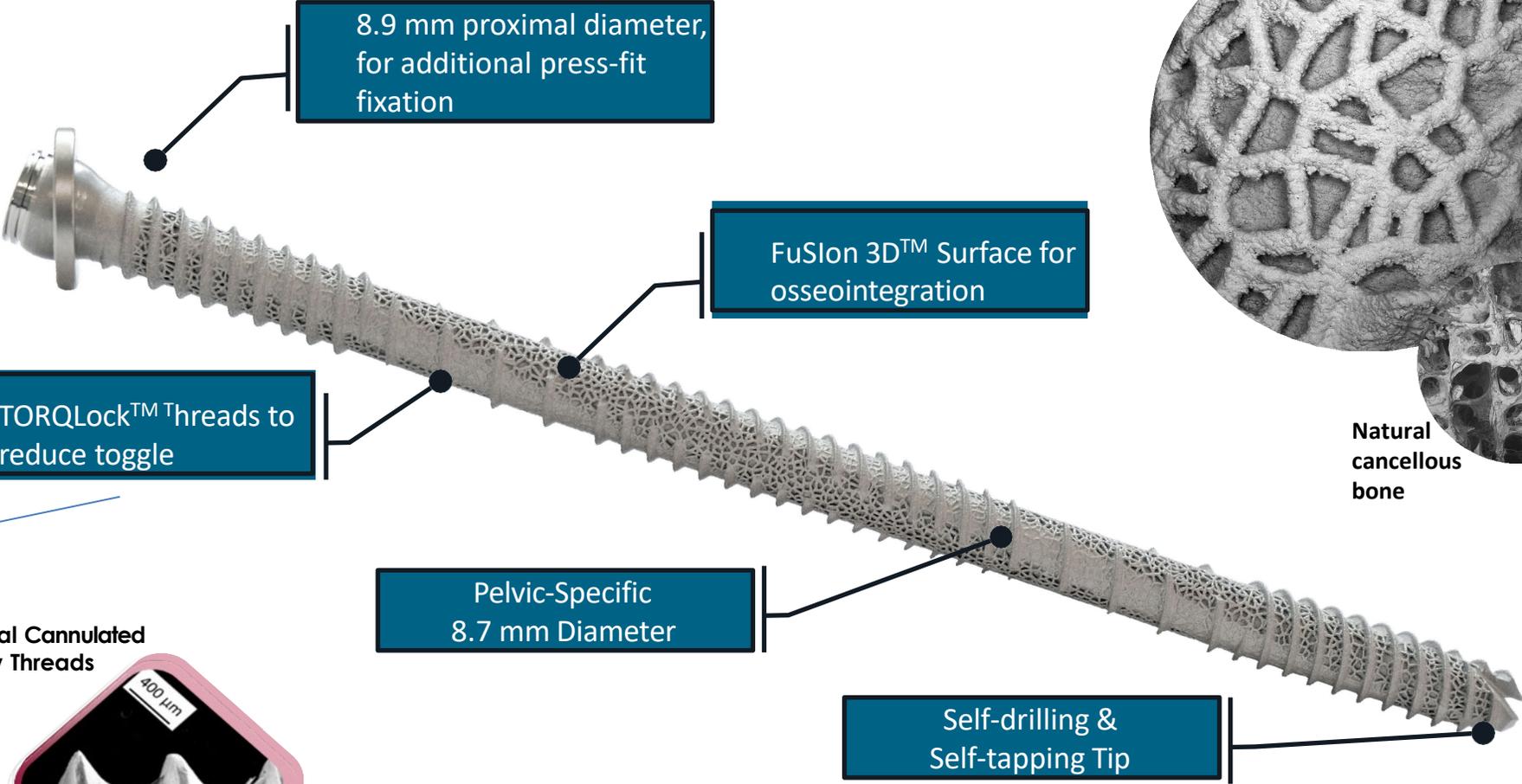


Smooth transsacral transiliac screws

1. Taillandier J, et al. *Joint Bone Spine*. 2003;70 (4):287-289.
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3. Morris R, et al. *Postgrad Med J*. 2000;76 (900):646.
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5. Geerts WH, et al. *N Engl J Med*. 1994;331:1601-6.

6. Turrentine FE, et al. *J Am Coll Surg*. 2006 Dec;203(9):865-77.
7. Strom C, et al. *Anaesthesia*. 2014 Jan; 69(Suppl 1): 35-44.
8. Eckardt H, et al. *Injury*. 2017;48(12):2717-23.
9. Bastian JD, et al. *Acta Orthop Belg*. 2012 Feb;78(1):100-5.

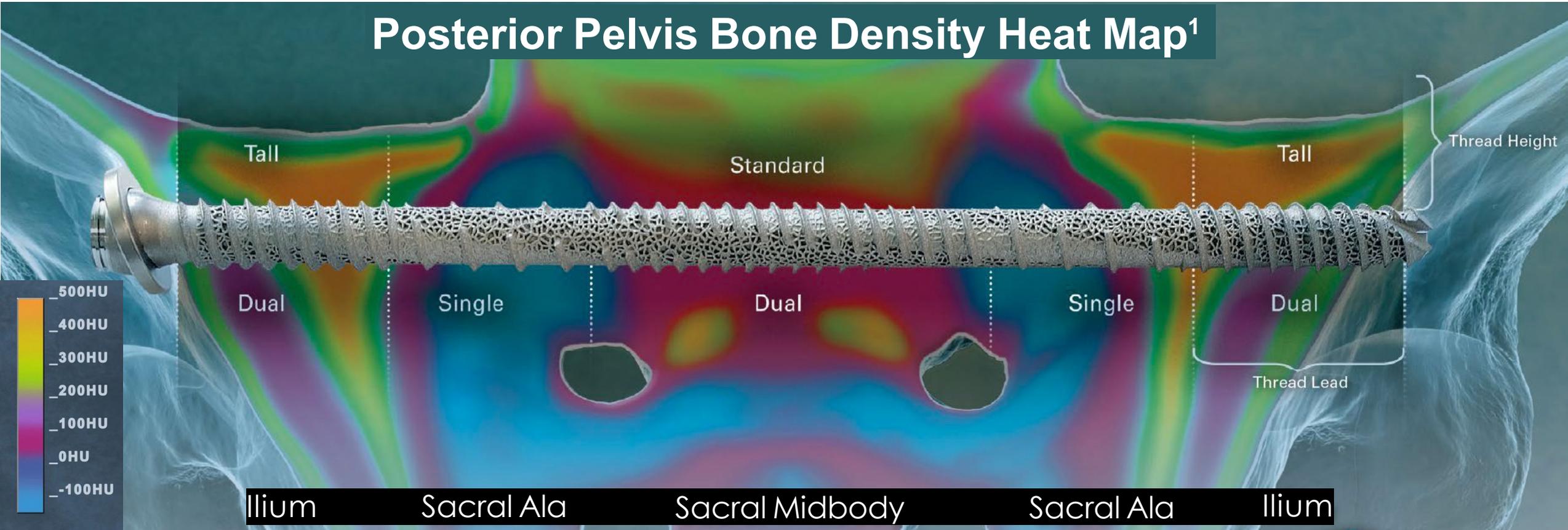
iFuse TORQ TNT™ – Breakthrough Device



VS.

Pelvic Bone Density-Driven Design

Posterior Pelvis Bone Density Heat Map¹



Variable Thread Heights and Lengths Tailored to the Posterior Pelvis

Designed to reduce loosening through pelvic-specific fixation

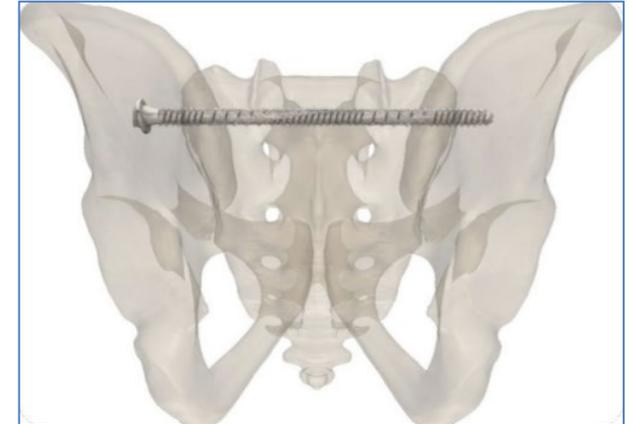
1. Bone density mapping based on Thiesen – *Sci Rep* 2020

Potential Benefits of TNT™

- Advantages of TNT™ in postoperative periods, with the goal of minimizing the risk of screw back-out and fixation failure, include:
 - **Early advantages:** Earlier weight-bearing (i.e., early ambulation)
 - Early mobilization is likely to reduce the severe negative consequences of prolonged bedrest in the elderly
 - **Late advantages:** Ensuring secure screw fixation in the early postoperative period is important since underlying poor bone quality increases the risk for delayed fracture healing and implant failure
 - Decreases the chance of back-out, where a revision may be needed
 - Medicare claims data analysis reveals reoperations for pelvic instrumentation occur 6mos to 1yr postoperative

iFuse TORQ TNT™ Indications: Fracture Fixation and Sacroiliac Joint Fusion

- The iFuse TNT™ Implant System is indicated for **BOTH**
 - Fracture fixation of the pelvis, including acute, nonacute and non-traumatic fractures
 - Sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Whether the TNT™ implants achieve fixation or fusion depends on the number and configuration of implants, which is dependent upon individual patient conditions and the surgeon's judgement.
- Generally, at least two points of fixation are required to achieve fusion of the sacroiliac joint.
- Typically, a single TNT™ implant across the pelvis would achieve pelvic fixation, while two TNT™ implants across the pelvis could potentially achieve both fracture fixation and sacroiliac joint fusion.



A single iFuse TORQ TNT™ implant generally achieves fracture fixation.



Two iFuse TORQ TNT™ implants could achieve both fracture fixation and sacroiliac joint fusion.

Procedure to implant iFuse TORQ TNT™

1

Pin (guide wire)
placement



2

Drill / Tap



3

Implant



- The iFuse TORQ TNT™ implant spans the osseous pelvis, traversing **varying bone structures and densities**.
- The implant is placed with a starting position on the lateral aspect of the ipsilateral ilium.
- The implant is then advanced across the ipsilateral ilium, across the sacrum and across the contralateral ilium, terminating in the lateral cortex of the contralateral ilium.
- A **guide wire is placed** through the skin and advanced to the lateral aspect of the ipsilateral ilium, and advanced across the ipsilateral ilium, through the sacrum, and across the contralateral ilium. (1)
- Surgeon measures the depth of the guide wire.
- Surgeon then **drills and/or taps over the guide wire** to the level of the mid sacral body. (2)
- The surgeon then places a transiliac transsacral (through and through) **iFuse TORQ TNT™ implant** with a washer. (3)
- After placement of this implant, fluoroscopic imaging is used to confirm acceptable position of the iFuse TORQ TNT™ implant.
- A second transiliac transsacral implant may on occasion be placed at the same or at the adjacent level.

TNT™ Sample Operative Note – Fracture Fixation

Implant Placement & Trajectory: A transiliac-transsacral (through and through) iFuse TORQ TNT™ cannulated, threaded implant was placed across the right ilium through the sacrum and across the left ilium terminating in the lateral cortex of the left ilium.

Patient Background: 64-year-old woman with osteoporosis, sustained a ground-level fall, experiencing immediate onset of severe posterior pelvic pain that progressively worsened. Workup demonstrates posterior pelvic ring fracture involving the sacral ala on left and right sides.

Procedure:

- We established the start point under multiplanar fluoroscopy.
- The guide wire for the cannulated threaded implant was placed through the skin to the lateral aspect of the right ilium at the level of the S2 body. The guide wire was then advanced across the right ilium, through the sacrum, and across the left ilium under fluoroscopic guidance utilizing a power wire driver.
- Imaging confirmed acceptable position and trajectory of the guide wire.
- We subsequently measured, drilled, and then placed a transiliac-transsacral (through and through) style 8.7 mm diameter x 135 mm fully threaded iFuse TORQ TNT™ cannulated threaded implant with a small diameter washer.
- After placement of this implant, imaging demonstrated acceptable position of the left and right sacral fracture fragments and acceptable position of the sacroiliac joints bilaterally.
- **Potential naming conventions:**
 - “iFuse TORQ TNT™ Porous, 3D-Printed, Titanium Implant with Bone Density-Specific Thread Pattern”
 - “iFuse TORQ TNT™”
 - “iFuse TNT™”
 - “TORQ TNT™”
 - “TNT™”



TNT™ Sample Operative Note – Fracture Fixation and SIJ Fusion

Implant Placement & Trajectory: Two iFuse TORQ TNT™ threaded implants placed transiliac-transsacral to achieve fracture fixation and sacroiliac joint fusion

Patient Background: 77-year-old female with osteoporosis (T-score -2.75) and history of prior fractures. Sustained a ground-level fall, resulting in sacral insufficiency fracture extending into bilateral SI joints. Persistent pain and inability to mobilize with nonsurgical treatment.

Procedure:

First Implant (S2 Level): 125 mm iFuse TORQ TNT™ threaded implant with the small diameter washer.

- Guide Pin starting point and trajectory are determined under multiplanar fluoroscopic imaging.
- Guide Pin is then advanced across the ipsilateral ilium, the ipsilateral sacroiliac joint, the sacrum, the contralateral SI joint and the contralateral ilium to the level of the lateral cortex of the contralateral ilium.
- 4.5mm drill used to create a channel through ipsilateral ilium, sacrum, and contralateral ilium. The 125 mm iFuse TORQ TNT™ threaded implant with the small diameter washer is then placed across the posterior pelvis from right to left.
- Final placement confirmed via fluoroscopy for optimal positioning and cortical engagement.

Second Implant (S1 Level): 140mm iFuse TORQ TNT™ implant with a small diameter washer.

- Identical technique as first implant but positioned through S1 corridor with the same transiliac-transsacral trajectory.
- Final placement of the implant confirmed with fluoroscopic imaging.

Potential naming conventions:

- “iFuse TORQ TNT™ Porous, 3D-Printed, Titanium Implant with Bone Density-Specific Thread Pattern”
- “iFuse TORQ TNT™”
- “iFuse TNT™”
- “TORQ TNT™”
- “TNT™”



Summary

- The iFuse TORQ TNT™ Implant System has received BDD for use in pelvic fractures with an FDA 510(k) clearance on August 19, 2024
- The unique Breakthrough features of the iFuse TORQ TNT™ Implant System provide advantages in improved fixation, with early and late postoperative benefit to Medicare patients
- The iFuse TNT™ Implant System is indicated for BOTH:
 - Fracture fixation of the pelvis, including acute, nonacute and non-traumatic fractures
 - Sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis
- An NTAP application was submitted for the iFuse TORQ TNT™ Implant System for FY 2026

