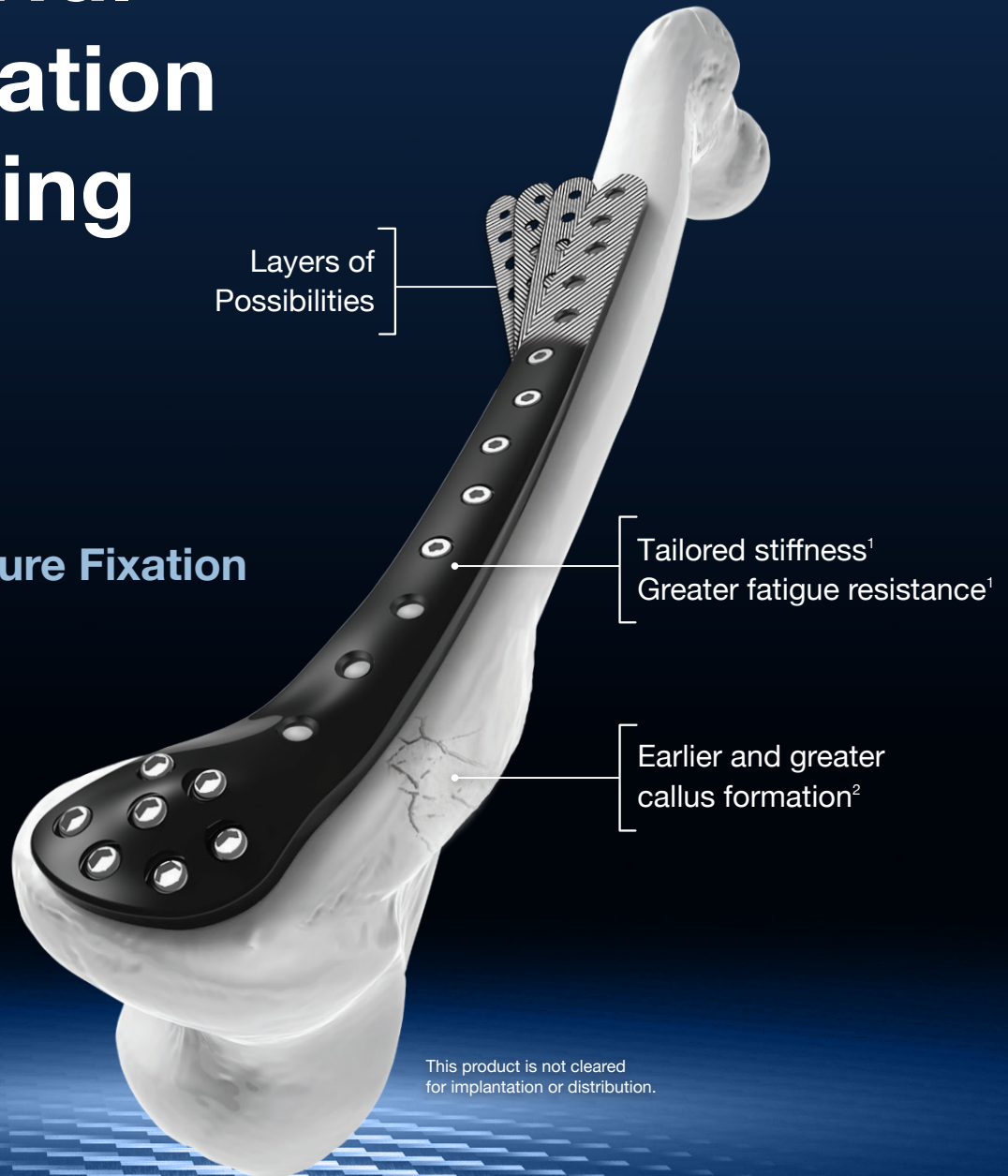


Invibio TRAUMA

Materials. Manufacturing. Knowledge.

A Powerful Combination for Healing

Non-Metal Fracture Fixation



It's time for a solution that fits the challenge.

Surgeons have been using metal for internal trauma fixation for more than 50 years with generally good outcomes. However, complications related to non-unions, delayed unions and implant failure continue to be a challenge.¹ As the number of patients with risk factors for complications rises due to growing numbers of patients with co-morbidities such as obesity, diabetes and osteoporosis,²⁻⁴ surgeons need more treatment options to address the unique challenges.⁵

Invivo Trauma Device Technology provides a new solution to this challenge. Our technology assists medical device manufacturers in the delivery of innovative anatomic plates for semi-rigid fracture fixation and benefits surgeons operating on higher-risk patients.

Worldwide population with risk factors for implant-related complications:²⁻⁴



37.5%
OBESITY



9.5%
DIABETES



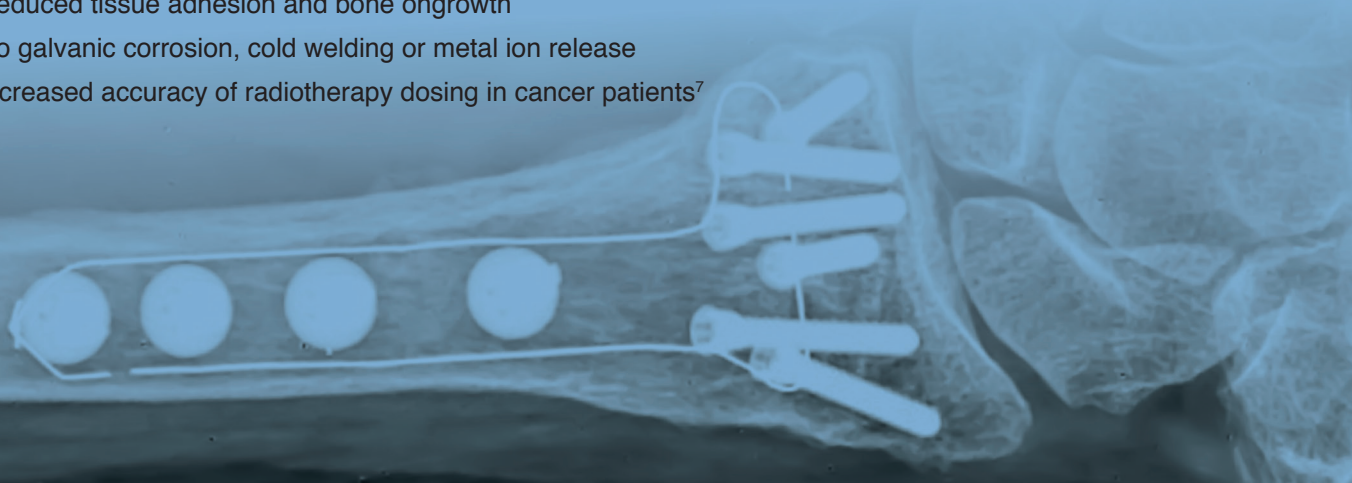
26.5%
OSTEOPOROSIS

Introducing PEEK-OPTIMA Ultra-Reinforced polymer.

Invivo has developed composite technologies that may offer benefits over metal trauma plate solutions for challenging patient populations. PEEK-OPTIMA Ultra-Reinforced, a composite of PEEK-OPTIMA Natural polymer reinforced with continuous carbon fibers, provides the strength and fatigue resistance demanded by high-load implant applications.

Compared to metals typically used in anatomic trauma plates, PEEK-OPTIMA Ultra-Reinforced polymer provides:

- ▶ Similar mechanical strength⁶
- ▶ 50x greater fatigue resistance⁶
- ▶ Reduced stiffness due to modulus closer to bone
- ▶ Radiolucency and artefact-free imaging
- ▶ Reduced tissue adhesion and bone ongrowth
- ▶ No galvanic corrosion, cold welding or metal ion release
- ▶ Increased accuracy of radiotherapy dosing in cancer patients⁷



A photograph of surgeons in an operating room, wearing blue scrubs, surgical masks, and caps, looking down at a patient. The image is slightly blurred and has a soft blue tint.

A Whole New Treatment Option with One Simple Change.

With trauma fixation devices made with PEEK-OPTIMA™ Ultra-Reinforced polymer, surgeons can achieve semi-rigid fixation using standard OR techniques and instrumentation.

“If you’re looking for the ideal implant to get fracture healing, you want something that’s durable, that’s going to have...more cycles to fatigue. You want something that’s close to normal cortical bone, modulus of elasticity-wise, to get most ideal or biologic type fixation.”

▶ **Joshua J. Niemann, MD**
Dickson-Dively Orthopedic Group
Kansas City, Missouri

“With PEEK-OPTIMA Ultra-Reinforced, you can see what you’re doing in all planes. With a metal plate, your vision is obscured. You can’t see how good your reduction is. Being able to see exactly what you’re doing is a huge benefit. It forces you as a surgeon to be better, to be more accurate, and I think that, ultimately, is a benefit for the patient.”

▶ **David J. Hak, MD, MBA**
Denver Health / University of Colorado

“What I’ve seen in my practice is that osteoporotic patients who are smokers who are not healthy people are having the same healing rates or better [with plates made with PEEK-OPTIMA Ultra-Reinforced polymer] than patients who are young, healthy with standard metal implants.”

▶ **Adam W. Rives, MD**
Liberty Orthopedics
Liberty, Missouri

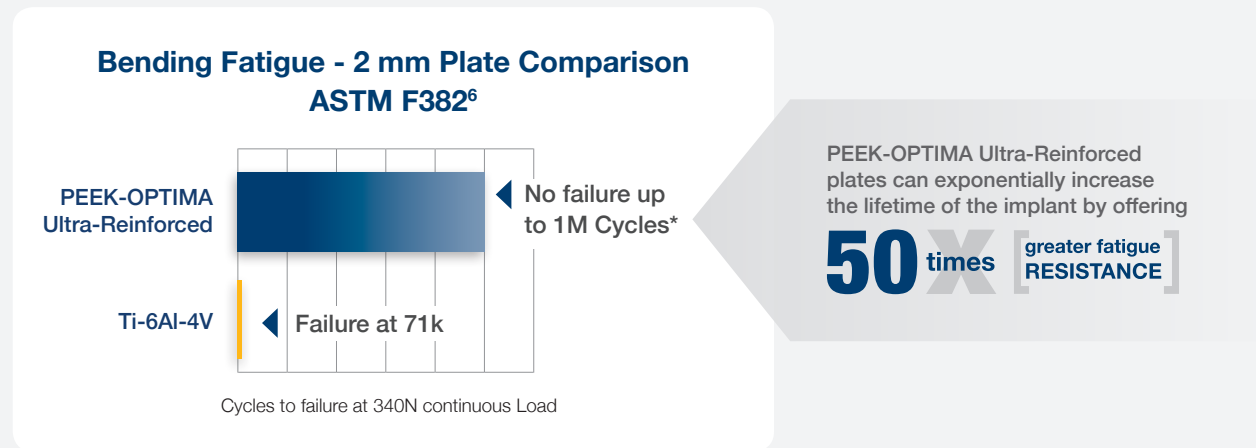
Invio - The Worldwide Innovator in Implantable PEEK Biomaterials.

Invio is a proven partner to medical device manufacturers and leading provider of biomaterial solutions. Our revolutionary polymers, unsurpassed manufacturing support, and deep device knowledge have enabled device companies around the world to bring innovations to market for over 15 years.

Enhance the potential for high-risk patients to heal.

Improved fatigue performance.

Plates containing PEEK-OPTIMA Ultra-Reinforced polymer have a 50x greater fatigue life than equivalent metal plates,⁶ providing an increased window of opportunity for healing to occur before fatigue-induced implant failure occurs.



*While the test was stopped at 1M cycles, the devices didn't fail up to that point.

Greater dynamic loading.

Unlike metallic materials, PEEK-OPTIMA Ultra-Reinforced polymer enables designers to tailor the modulus of elasticity of implants, resulting in treatment options that are less rigid than equivalent all-metal constructs. Semi-rigid fracture fixation can increase dynamic loading at the fracture site, helping to promote bone regeneration and secondary healing and minimize bone loss and implant loosening due to stress shielding.⁸

Potential for increased callus formation.⁹

Results of pre-clinical testing demonstrate significant callus formation with implants made of PEEK-OPTIMA Ultra-Reinforced throughout the 12 week study period - particularly within the initial 6 week period. Compared to equivalent metallic constructs, specimen that received PEEK-OPTIMA Ultra-Reinforced implants showed 158% more callus at two weeks. Studies have shown a link between callus formation and secondary bone healing.

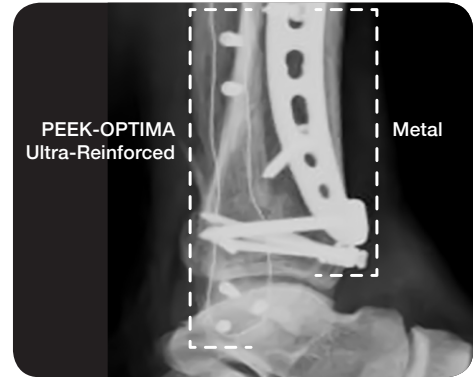


▲ Callus observed at four and twelve weeks following implantation of IM nails made with PEEK-OPTIMA Ultra-Reinforced polymer within an ovine tibial osteotomy model.

Gain insight during reduction and throughout the healing process.

PEEK-OPTIMA Ultra-Reinforced polymer offers additional benefits due to its imaging characteristics. Implants composed of this material are radiolucent, offering surgeons circumferential visibility of the fracture site before and after the procedure.

- ▶ Ease reduction and ensure proper alignment for healing to occur due to unimpeded visibility of the fracture.
- ▶ Potentially reduce the use of fluoroscopy during surgery.
- ▶ Gain better visibility of fracture healing during follow-up visits and increase confidence in returning patients to load-bearing activities.
- ▶ Capture better MRI and CT diagnostics with artefact-free imaging.
- ▶ Improve visibility of surrounding anatomy in polytrauma patients.



▶ *Radiolucent PEEK-OPTIMA Ultra-Reinforced polymer offers greater visibility than metal.*

Photo courtesy of Joshua J. Niemann, MD.

Lower the burden of revision surgeries.

The improved fatigue strength achieved with PEEK-OPTIMA Ultra-Reinforced could potentially reduce complications related to implant failure. In cases where implant removal is required, plates made with PEEK-OPTIMA Ultra-Reinforced polymer eliminate cold welding problems associated with the use of metal components and minimize bone ongrowth onto the implant. This can ease implant removal, reducing operating times by as much as 2.3x and associated revision surgery costs by as much as 50% compared to metal plates.¹⁰⁻¹¹

Revision Complications Comparison Time & Cost



▶ **Available only from Invibio. Learn more about Invibio Trauma Device Technology at InvibioTrauma.com.**



▶ *To ensure your device is made with Invibio Trauma Device Technology, look for our logo on the label.*



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▶ **InvibioTrauma.com**

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