



Invibio® TRAUMA
PEEK-OPTIMA® Ultra-Reinforced

A NOVEL ALTERNATIVE TO METAL.

▶ From the Leaders of PEEK



**Semi-rigid fixation
with improved fatigue
performance and
radiolucency.**



Materials. Manufacturing. Knowledge.

Helping you move from idea to device innovation.

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

Invibio offers unparalleled depth of knowledge and breadth of experience in the design, manufacture and commercialization of medical devices containing PEEK-based polymers. We welcome the opportunity to partner with device manufacturers to address unmet clinical needs by developing next-generation trauma devices composed of PEEK-OPTIMA[®] polymers.

PEEK-OPTIMA[®] Ultra-Reinforced¹

The leading alternative to metals.

PEEK-OPTIMA Ultra-Reinforced combines the high performance material properties of PEEK-OPTIMA Natural Polymers² with additional strength imparted by carbon fiber, providing an alternative to metal traditionally used in internal fracture fixation procedures. PEEK-OPTIMA Ultra-Reinforced offers:

- ▶ Reduced stiffness compared to metal
- ▶ Excellent mechanical strength with high fatigue resistance
- ▶ Biological inertness and low tissue adhesion
- ▶ Radiolucency with no imaging artifact
- ▶ Proven biocompatibility

1. Previously known as ENDOLIGN[®]

2. Previously known as PEEK-OPTIMA[®] Unfilled

From materials to advanced clinical solutions.

Invio's research and development in composite technologies have led to the commercialization of PEEK-OPTIMA® Ultra-Reinforced, a PEEK-based continuous carbon fiber reinforced material that is being used in next-generation trauma devices.

Invio employs proprietary manufacturing steps in which PEEK-OPTIMA Ultra-Reinforced tapes and rods are formed into composite devices. The manufacturing techniques can be adjusted to deliver mechanical properties that are optimized for specific applications and shapes that complement the natural contours of bone.



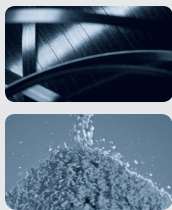
▶ *PEEK-OPTIMA
Ultra-Reinforced Tape*



▶ *PEEK-OPTIMA
Ultra-Reinforced Rod*

Invio is the only biomaterial solutions provider that offers the capabilities required to deliver commercial PEEK-based trauma devices. We work with our partners to overcome design, manufacturing and regulatory challenges by offering value-added services throughout the development process, including:

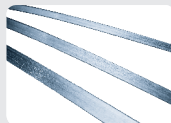
- ▶ Vertically integrated supply chain to assure product availability
- ▶ Design for manufacturing, prototyping and validation services
- ▶ Material characterization, application specific testing and analysis capabilities
- ▶ Cutting-edge composite processing knowledge and manufacturing equipment
- ▶ Regulatory submission guidance with FDA device master file access



Continuous
Carbon Fiber &
PEEK-OPTIMA
Powder



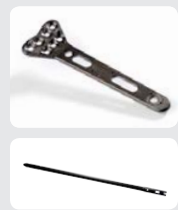
Proprietary
Invio
Processing



PEEK-OPTIMA
Ultra-Reinforced
Tape



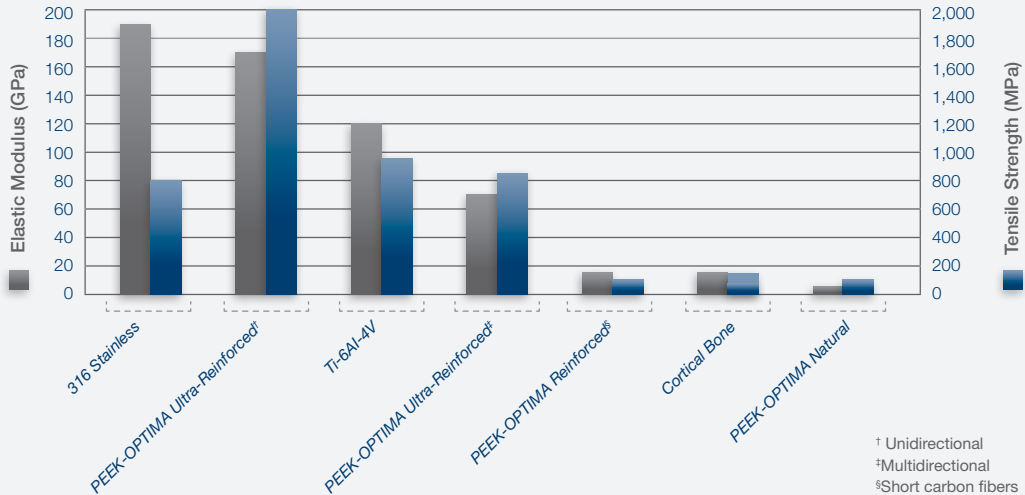
Manufactured
to Design
Specifications



Finished
Bone Plate &
IM Nail Devices

Semi-rigid fixation with tailored stiffness.

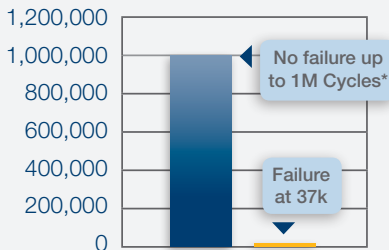
PEEK-OPTIMA® Ultra-Reinforced provides mechanical strength that is similar to metal, but with a modulus that's closer to bone.³



Superior fatigue strength in ASTM testing.⁴

Dynamic testing of trauma fixation devices demonstrates that implants made with PEEK-OPTIMA Ultra-Reinforced have a higher fatigue strength compared to similar implants made of Titanium.

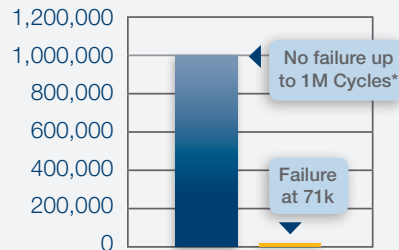
ASTM F1264
Bending Fatigue - Intremedullary Fixation Devices



Cycles to failure at 1767N continuous Load

■ 10 mm PEEK-OPTIMA Ultra-Reinforced Rod
■ 10 mm Ti-6Al-4V Rod

ASTM F382
Bending Fatigue - Metallic Bone Plates



Cycles to failure at 340N continuous Load

■ 2 mm PEEK-OPTIMA Ultra-Reinforced Plate
■ 2 mm Ti-6Al-4V Plate

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

3. Kurtz, SM (2012). PEEK Biomaterials Handbook. Elsevier. p.35, ISBN: 978-1437744637.

4. Data on file at Invivo. Biomechanical testing is not indicative of clinical performance.

Biologically inert with low tissue adhesion.

PEEK-OPTIMA® Ultra-Reinforced is an inert biomaterial with a very low rate of tissue adhesion. Compared to titanium implants, use of biologically inert materials in internal fracture fixation may:

- ▶ Reduce tissue adhesion to the implant
- ▶ Simplify implant removal
- ▶ Allow for more conservation of bone during revision surgeries

Radiolucency with no imaging artifact.

PEEK-OPTIMA Ultra-Reinforced is inherently radiolucent and artifact-free. Compared to radiopaque implants composed of metal, PEEK-OPTIMA Ultra-Reinforced implants allow for better bone fragment visualization during image-guided intraoperative fracture reduction procedures. Implant radiolucency also aids in post-operative visualization of callus formation for improved healing assessment.

PEEK-OPTIMA Ultra-Reinforced Rod*



Immediate
post-op



1 week
post-op



6 week
post-op

Stainless Steel Rod*



Immediate
post-op



1 week
post-op



6 week
post-op

*Ovine model implanted with 10 mm intramedullary nail. All diagnostic images are from the same specimen.

Biocompatible.

PEEK-OPTIMA Ultra-Reinforced exceeds the requirements of ISO 10993 standards for long term implantable medical devices and are included in the FDA Master File. Testing demonstrated no evidence of cytotoxicity, systemic toxicity, irritation or macroscopic reaction response.

▶ **Available only from InVibio. Learn more about PEEK-OPTIMA Ultra-Reinforced Biomaterial at www.invibio.com.**



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► Invibio.com

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