FLEXIBLE NON-METAL TRAUMA SOLUTIONS.

It’s time for a solution that fits.

Invibio Trauma Device Technology offers a differentiated trauma plate platform made with PEEK-OPTIMA® Ultra-Reinforced polymer.
Complications in fracture healing demand a new solution.

For several years, orthopaedic trauma medical device manufacturers have seen implant prices erode by 10% as the pace of innovation has slowed. Developments in anatomic plating and dynamic locking screws have offered incremental advancements in trauma fixation, but the number of surgical treatment options available to surgeons remains limited. Meanwhile, the number of patients with risk factors for complications continues to rise.\(^1\)\(^-\)\(^3\) Co-morbidities such as, obesity, alcohol and tobacco use, diabetes and osteoporosis, can lead to a higher risk of delayed or non-union complications.\(^4\) As a result, surgeons are seeking a wider range of fracture treatment options.

Invibio 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.

Introducing PEEK-OPTIMA Ultra-Reinforced polymer.

Invibio 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 features:

- Similar mechanical strength\(^5\)
- 50x greater fatigue resistance\(^5\)
- 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 patients\(^6\)

\(^*\) PEEK-OPTIMA Ultra-Reinforced is also known as ENDOLOGN.
Differentiate your products and gain market share.

Introducing a turnkey device technology from Invibio that allows medical device manufacturers to quickly design, validate and manufacture new semi-rigid anatomic plates composed of PEEK-OPTIMA® Ultra-Reinforced polymer. Our staff have specialized composites processing experience and offer trauma partners assistance throughout development and commercialization. Invibio has invested heavily in state-of-the-art tools and facilities that help device manufacturers get implants to market rapidly using a fraction of the investment that would be required to develop processing capabilities and supply chains internally.

With Invibio as your partner:

- Get to market up to 3 times faster (market entry in 12-18 months)
- Save as much as $1.8 million in start-up and development costs
- Redeploy R&D staff to other strategic initiatives in your business

Make a rapid market entry with Invibio Trauma Device Technology.

**DESIGN**
Expedited design, prototyping & validation guidance.

**MANUFACTURE**
Proprietary, on-site manufacturing capabilities ready for commercial production.

**REGULATORY**
Global regulatory coverage with local experts who can help overcome barriers to market entry.

**SUPPLY CHAIN**
One-stop solution from raw material production to finished device components.

**SALES SUPPORT & TRAINING**
Well-researched, meticulous data packaged for sales and marketing to drive new business.

1% MARKET SHARE = $30M REVENUE

*Earn an additional $30 million for every 1% market share captured by offering a differentiated technology.*
**Enhance the potential for high-risk patients to heal.**

Plates containing PEEK-OPTIMA® Ultra-Reinforced polymer have a 50x greater fatigue life than equivalent metal plates. This can increase the window of opportunity for healing to occur before fatigue-induced implant failure. These semi-rigid implants are more flexible, improve dynamic loading and may help promote bone regeneration and secondary healing. These features can be especially beneficial for patients at higher risk for delayed or non-union complications.

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**Improve OR efficiency and lower the burden of revision surgeries.**

Plates composed of PEEK-OPTIMA Ultra-Reinforced polymer are radiolucent so surgeons have better visibility of the fracture site under x-ray, easing fracture reduction and healing assessment. In cases where implants need to be removed, PEEK-OPTIMA Ultra-Reinforced eliminates cold welding problems associated with the use of metal components and minimizes bone-to-implant ongrowth. This can ease removal and reduce operating times by as much as 2.3x and associated revision surgery costs by as much as 50% compared to metal plates.\(^\text{5-9}\)

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

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**Bending Fatigue - 2 mm Plate Comparison**

**ASTM F382**

<table>
<thead>
<tr>
<th>Material</th>
<th>Fatigue Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEEK-OPTIMA Ultra-Reinforced</td>
<td>&gt; 1M Cycles*</td>
</tr>
<tr>
<td>Ti-6Al-4V</td>
<td>71k Cycles</td>
</tr>
</tbody>
</table>

Cycles to failure at 340N continuous Load

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

Photo courtesy of Joshua Niemann, M.D.
Design the future of non-metal trauma solutions.

With PEEK-OPTIMA Ultra-Reinforced polymer, implant designers have the ability to develop trauma plates with properties that precisely fit the intended application. Implant stiffness can be adjusted based on the composite plate design to meet a wide range of implant specifications. This offers designers infinitely more implant design flexibility than with metals.

Semi-rigid fixation with tailored stiffness.

Plates composed of PEEK-OPTIMA Ultra-Reinforced can be designed with a level of stiffness that ranges from lower than titanium to greater than stainless steel.

Available only from Invibio. Learn more about Invibio Trauma Device Technology at Invibio.com.
REFERENCES


7. Data on file at Invibio. Pre-clinical and biomechanical testing is not indicative of clinical performance.


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