

TECHNOLOGY OVERVIEW

PEEK-OPTIMA™ Polymers for a Non-Metal Solution

- ▶ Modulus similar to bone
- ▶ Reduced stress shielding
- ▶ Radiolucent
- ▶ Artifact-free imaging
- ▶ Eliminates the risk of allergies from metal
- ▶ Lightweight and warmer compared to metal

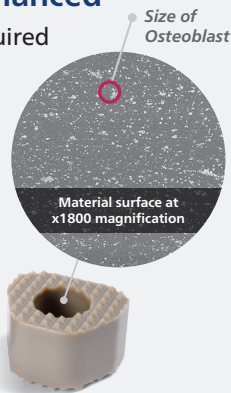
For Use in Foot and Ankle Applications



PEEK-OPTIMA HA Enhanced

When bone ongrowth is required

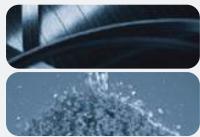
- ▶ PEEK-OPTIMA Natural + Hydroxyapatite (HA)
- ▶ HA fully integrated, *not coated*, making it available on all surfaces of a finished device



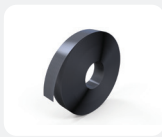
Interbody Fusion Device example. This product is not cleared by the FDA for distribution in the United States.

PEEK-OPTIMA Ultra-Reinforced

Provides strength and fatigue resistance¹ demanded by high-load implant applications



Continuous Carbon Fiber & PEEK-OPTIMA Polymer



PEEK-OPTIMA Ultra-Reinforced Tape



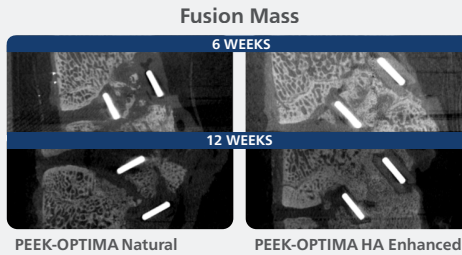
Tailored Stiffness

PEEK-OPTIMA™ HA Enhanced

Potential Performance Advantages Compared to PEEK-OPTIMA™ Natural

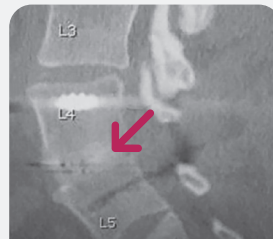
Ovine Cervical Spine Fusion Study²

- ▶ Greater new bone formation at 6 weeks
- ▶ Higher quality new bone bridging at 6 & 12 weeks
- ▶ Bone ongrowth on the endplates and all faces of the interbody device
- ▶ Superior mechanical performance outperforming allograft in 46% of the instances



Early Clinical Results for Cervical and Lumbar Spinal Fusion

- ▶ Indicate potential patient benefits and reveal specific improvements
 - Solid fusions as early as 6 months
 - Positive clinical outcomes at early time points
 - Improvements in overall pain and neurological function



Solid lumbar fusion at 6 months on CT scan.

Image courtesy of Timothy Bassett, M.D.

"Dense bone apposition at the bone/implant interface on CT scan."³

"Very rapid visible bone fusion occurred in the interbody region in six weeks, according to plain radiographs, with correspondingly good clinical results."³

▶ **Timothy Bassett, M.D.**
SouthEastern Spine Specialists, Tuscaloosa, AL

PEEK-OPTIMA™ Ultra-Reinforced

Potential to Enhance Healing Compared to Metal Plates

- ▶ Earlier and greater callus formation⁴
May improve secondary bone healing
- ▶ Greater material fatigue life¹
May provide an increased window of opportunity for healing to occur before fatigue-induced implant failure could occur

150%
GREATER CALLUS FORMATION

50X
GREATER FATIGUE RESISTANCE

Imaging Benefits When Unobstructed Views are Required

- ▶ 360° fracture visibility⁵
Radiolucency offers circumferential visibility of the fracture site during and after the procedure

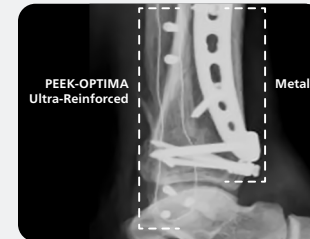


Photo courtesy of Joshua Niemann, M.D.

"The biggest benefits of the PEEK-OPTIMA Ultra-Reinforced products are radiographic visibility... I've seen an overall decrease in radiation exposure at the time of surgery because the C-arm doesn't have to adjust. You can see what you're doing, you can see your reduction."³

▶ **Joshua J. Niemann, MD**
Kansas City, MO

- ▶ Potential visualization benefits during surgery for Charcot reconstruction



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REFERENCES

1. Data on file at Invibio. Mechanical Benchmark of Carbon Fiber PEEK-OPTIMA™ Ultra-Reinforced vs Ti 6Al-4V Plates undergoing Static and Dynamic Testing per ASTM F382-99 (2008).
2. Study evaluated the in vivo response to PEEK-OPTIMA Natural, PEEK-OPTIMA HA Enhanced and allograft in a cervical spine fusion model in sheep. Data on file at Invibio. This data has not been correlated with human clinical experience.
3. Testimonials presented have been provided by practicing orthopedic surgeons. Their view and experience are their own and do not necessarily reflect those of others. "Invibio" disclaims any liabilities or loss in connection with the information herein.
4. Jo Wilson, PhD, Matthew Cantwell; Polyether Ether Ketone (PEEK) Carbon Fiber Composites May Improve Healing of Fractures Stabilized with Intramedullary Nails. (Basic Science Focus Forum, paper #4, 2014) 155.
5. Caforio M, Perugia D, Colombo M, Calori GM, Maniscalco P. Preliminary experience with Piccolo Composite, a radiolucent distal fibula plate, in ankle fractures. Injury. 2014 Dec;45 Suppl 6:S3-S38.

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