

## PEEK-OPTIMA™ HA Enhanced

*For medical applications where bone ongrowth is required*

### PRODUCT SUMMARY

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Invibio™ PEEK-OPTIMA HA Enhanced provides the high-performance characteristics of PEEK-OPTIMA™ Natural, a leading spinal interbody device material, plus Hydroxyapatite (HA) to enhance bone apposition. This combination is an innovative solution for medical applications where early bone ongrowth is required, such as spinal interbody fusion and hammertoe and wedges for foot and ankle applications.

### PRODUCT INFORMATION

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- ▶ PEEK-OPTIMA HA Enhanced offers all the benefits of PEEK-OPTIMA Natural:
  - Modulus similar to bone
  - Reduced stress shielding
  - Artifact-free imaging
  - An osteoconductive surface for bone ongrowth
  
- ▶ PEEK-OPTIMA HA Enhanced is fully integrated, *not coated*, with the osteoconductive material, Hydroxyapatite (HA), making it available on all surfaces of a device.
  
- ▶ PEEK-OPTIMA HA Enhanced does not look different than PEEK-OPTIMA, but the hydroxyapatite particles, although naked to the eye, can be clearly seen on SEM images of the implant surface.
  
- ▶ PEEK-OPTIMA HA Enhanced makes hydroxyapatite available at all surfaces versus plasma spray coatings which have coverage on the endplates only.
  
- ▶ PEEK-OPTIMA HA Enhanced has mechanical properties similar to PEEK-OPTIMA Natural and a modulus closer to bone than titanium, thus reducing the potential for stress shielding.
  
- ▶ PEEK-OPTIMA HA Enhanced is radiolucent on X-rays and is artifact-free on CT scans and MRI, providing unobstructed views.

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- ▶ PEEK-OPTIMA HA Enhanced has been shown to improve bone apposition compared to unfilled PEEK-OPTIMA in a pre-clinical ovine model at 4 weeks and 12 weeks. These results do not necessarily correlate to human clinical outcomes.<sup>1</sup>
- ▶ PEEK-OPTIMA HA Enhanced has demonstrated greater new bone formation at 6 weeks, higher quality new bone bridging at 6 and 12 weeks and bone ongrowth on the endplates and all faces of the interbody device in an ovine cervical spine fusion study.<sup>2</sup>

### CLINICAL EVIDENCE

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- ▶ Early clinical results, using a PEEK-OPTIMA HA Enhanced device, for cervical and lumbar spinal fusion indicate potential patient benefits and reveal specific improvements:<sup>3-4</sup>
  - Solid fusions as early as 6 months
  - Positive clinical outcomes at early time points
  - Improvements in overall pain and neurological function

### CLINICAL APPLICATIONS

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- ▶ The compounding of PEEK-OPTIMA HA Enhanced polymer with Hydroxyapatite (HA) has the potential to enhance bone apposition and to deliver the same high-performance as PEEK-OPTIMA Natural even after repeated sterilization.
- ▶ PEEK-OPTIMA HA Enhanced is an innovative choice for medical applications where early bone ongrowth is required, for applications such as:
  - Spinal interbody fusion
  - Hammertoe and wedges for foot and ankle applications

### REFERENCES

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1. Study evaluated the bone ongrowth of PEEK-OPTIMA™ Natural and PEEK-OPTIMA™ HA Enhanced in a bone defect model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.
2. Walsh WR, et al. Does PEEK/HA Enhance Bone Formation Compared With PEEK in a Sheep Cervical Fusion Model? *Clin Orthop Relat Res.* 2016 Nov;474(11):2364-2372.

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3. Case Series: Early Clinical Results with PEEK-OPTIMA™ HA Enhanced Devices for Spinal Fusion. Webinar presented March 2017.
4. 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.



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