

PEEK-OPTIMA[®] HA Enhanced Polymer

For medical applications where bone ongrowth is required.

TECHNOLOGY OVERVIEW

An innovative choice

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



Size of Osteoblast



Interbody Fusion Device examples. These products are not cleared by the FDA for distribution in the United States.

Benefits

- Modulus similar to bone
- Reduced stress shielding
- Artifact-free imaging
- An osteoconductive surface for bone ongrowth

PEEK-OPTIMA Devices Implanted Worldwide

Years of Clinical History

REFERENCES

- 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 data
- 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

PRE-CLINICAL EVIDENCE

Potential performance advantages compared to PEEK-OPTIMA Natural

- Bone Defect Model¹
 - Earlier bone ongrowth with > 75% direct bone contact after 4 weeks
 - Enhanced bone apposition at 12 weeks

4 WEEK HISTOLOGY





PEEK-OPTIMA Natural

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

Fusion Mass



PEEK-OPTIMA Natural



CLINICAL EVIDENCE

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



"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

Southeastern Spine Specialists, Tuscaloosa, AL

Timothy Bassett, M.D.

"Clinical and radiographic

results as good as or better

outcomes."3

Brad G. Prybis, M.D.

than traditional PEEK interbody

devices, with consistently good

Carrollton Orthopaedic Clinic, Carrollton, GA

on CT scan.

Image courtesy of Timothy Bassett, M.D.



Solid two-level cervical fusion at 6 months

Image courtesy of Brad G. Prybis, M.D.



6 months

Image courtesy of Mark W. McFarland, M.D.

"I found that even in the most challenging of circumstances, I am seeing great bone consolidation and the patients are doing well early on and that's the most important outcome."3

Mark W. McFarland, D.O. Orthopaedic & Spine Center, Newport News, VA





More consistent and continuous degree of direct bone contact was observed.