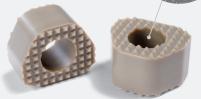


### **TECHNOLOGY OVERVIEW**

#### An innovative choice

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





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



15+ Years of Clinical History

#### 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** 

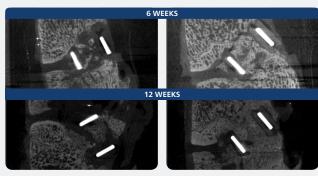
PEEK-OPTIMA HA Enhanced

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

### **Cervical Spine Fusion Study<sup>2</sup>**

- 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** 

**PEEK-OPTIMA HA Enhanced** 

#### **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



Image courtesy of Timothy Bassett, M.D.

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

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

► Timothy Bassett, M.D. SouthEastern Spine Specialists, Tuscaloosa, AL



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

"Clinical and radiographic results as good as or better than traditional PEEK interbody devices, with consistently good outcomes."<sup>3</sup>

Brad G. Prybis, M.D.
Carrollton Orthopaedic Clinic, Carrollton, GA



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

"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."

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



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#### 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.

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