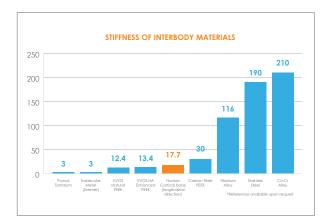
PEEK-OPTIMA® HA ENHANCED



TWO PROVEN BIOMATERIALS. ONE SUPERIOR COMBINATION.

Invibio Biomaterial Solutions' PEEK-OPTIMA® HA Enhanced is a material enhancement in spinal device technology. Hydroxyapatite (HA), a well-known osteoconductive material, is fully integrated with PEEK-OPTIMA® Natural, making it available on all surfaces of a device. This innovative compound encourages bone on-growth while providing the strength, versatility, and performance advantages of its proven and popular predecessor. PEEK-OPTIMA® HA Enhanced offers a truly superior solution for bone apposition.



Modulus similar to human cortical bone, thus reduces the potential for stress shielding and the potential for subsidence.

Subsidence testing results better than 95% of the market as per FDA funded study (data on file at CES)



101 Waxhaw Professional Park, Suite A Waxhaw, NC 28173, USA

> +1 704-243-0892 +1 704-731-2559

www.cuttingedgespine.com

🖪 🄰 in 🖸

HARRING THE REPORT OF THE REPORT

BIOACTIVE Cervical Interbody System



Copyright © 2018 Cutting Edge Spine, Inc. All Rights Reserved



Early bone apposition generates greater

bone contact.' Invibio PEEK-OPTIMA® HA Enhanced polymer demonstrates enhanced bone apposition within 4 weeks compared with PEEK-OPTIMA® Natural in a pre-clinical in vivo study using a sheep model.' 1. Study evaluated the bone on-growth of PEEK-OPTIMA® 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. NASS (North American Spine Society) 2016 Annual Meeting, Boston, MA, October 26 to 28, 2016. Over 3,400 registered members attended

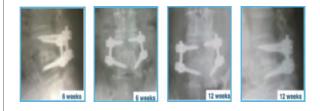
PEEK-OPTIMA® Natural

PEEK-OPTIMA® HA Enhanced



PEEK-OPTIMA® Natural (a) shows areas of direct bone contact, but with some gaps PEEK-OPTIMA® HA Enhanced (b) shows high degree of direct bone contact early in the healing process

Images courtesy of Tim Bassett, MD



In a study presented at NASS, by Tim Bassett, MD, early clinical experience with PEEK-OPTIMA® HA Enhanced for lumbar fusion (CES implant) was found to have very rapid visible bone fusion in the interbody region in as little as 6 weeks on plain radiographs, correspondingly good clinical results². Results confirmed by 6 month CT scan. No biologics were used in this study.

	PEEK-HA OPTIMA® Enhanced	PEEK-HA OPTIMA® Natural	Titanium
Modulus Similar to Cortical Bone	~	~	
Radiolucent	~	~	
Biocompatibility	×	~	×
Enhanced Bone Contact ¹ on all surfaces	~		

IMPLANT SPECIFICATIONS

6 footprints

Early bone apposition¹

Tantalum beads for visual orientation

Radiolucent

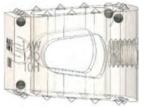
- Similar elastic modulus to cortical bone
- Large graft chamber to promote bone fusion
- 4° and 7° lordotic angles

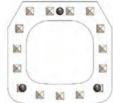
Anti-migration teeth to resist migration in all directions

Lateral windows to allow vascularization of central bone graft

5-10mm Heights (1mm increments)

Chamfered posterior corners to allow for posteriorly placed bone graft





Footprint (width x depth)	Angle (4°,7°)		Height (5,6,7,8,9,10)						
12X12 Small	~	~	~	~	~	~	~	~	
14X12 Medium	~	~	~	~	~	~	~	~	
14X14 Medium Deep	~	~	~	~	~	~	~	~	
16X12 Large	~	~	~	~	~	~	~	~	
16X14 Large Deep	~	~	~	~	~	~	~	~	
18X16 Extra Large	~	~			~	~	~	~	

KIT COMPOSITION

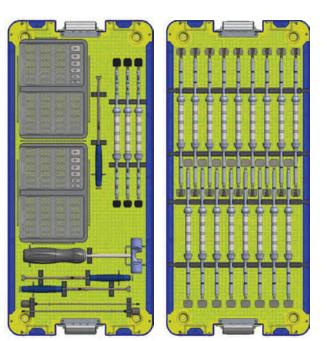
Threaded inserter with or without stops

Implant specific double ended trials

Footprint specific double ended rasps

Forked mallet

- Implant manipulator
- Inner inserter shaft
- Modular implant caddy





www.cuttingedgespine.com