NEW

PEEK-OPTIMA®
HA ENHANCED BIOMATERIAL

ENHANCED PERFORMANCE

from the leaders of PEEK

TWO PROVEN BIOMATERIALS. ONE SUPERIOR COMBINATION.

Invibio®
biomaterial solutions

Two clinically proven biomaterials, together in one innovative compound.

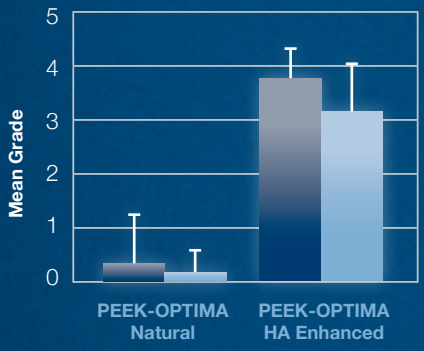
Hydroxyapatite (HA), a well-known osteoconductive material that enhances bone apposition, has been completely integrated with PEEK-OPTIMA®, the leading PEEK-based biomaterial with over 10 years of clinical history.

THE RESULT: a strong, versatile and highly effective biomaterial that offers a superior solution for bone apposition[1].

	PEEK-OPTIMA HA ENHANCED	PEEK-OPTIMA NATURAL
Mechanical Strength	✔	✔
Modulus Similar to Cortical Bone	✔	✔
Imaging Compatibility	✔	✔
Biocompatibility	✔	✔
Enhanced Bone Contact[1]	✔	

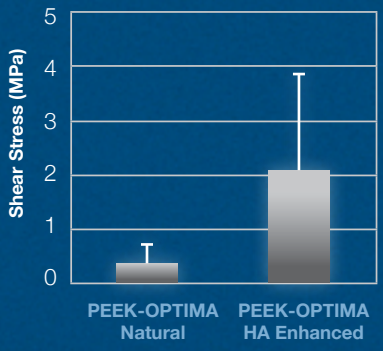
PEEK-OPTIMA HA Enhanced has similar properties to PEEK-OPTIMA Natural, but also encourages enhanced bone-on growth

Bone Contact Comparison



PEEK-OPTIMA HA Enhanced promotes greater bone contact in vivo[1]

Push Out Strength at 4 weeks



4 weeks 12 weeks

PEEK-OPTIMA HA Enhanced increases interfacial shear strength with bone 4 weeks following implantation[1]

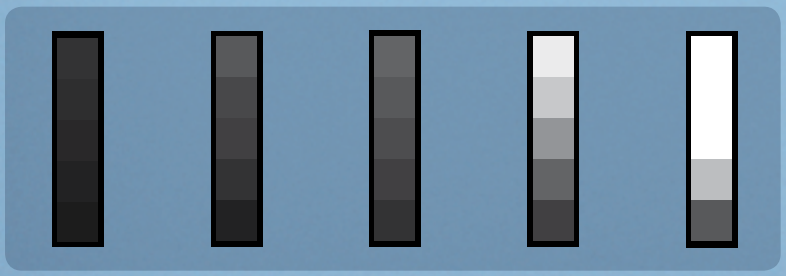
A material enhancement in spinal device technology.

Spinal fusion continues to be the most popular procedure for treating spinal pathologies. Although published fusion rates for PEEK devices are high,[2,3] recently the trend for interbody fusion devices has been to look for ways to enhance bone apposition on the surface of the device.

Invibio PEEK-OPTIMA HA Enhanced provides the accepted high performance characteristics of PEEK-OPTIMA Natural, the leading spinal interbody device material, plus Hydroxyapatite (HA) to enhance bone apposition. This new combination is a promising solution for medical applications where early bone-on growth is required, such as spinal interbody fusion.

PROPERTY	IMPACT (KJ/M^2)	FLEX STRENGTH (MPa)	FLEX MODULUS (GPa)	TENSILE STRENGTH (MPa)	TENSIL ELONGATION AT BREAK (%)
PEEK-OPTIMA Natural	7.6	164	4.1	100	40
PEEK-OPTIMA HA Enhanced	5.4	152	4.4	94	12.4
Cortical Bone	2-5 (un-notched)	173	18	80-150 (longitudinal)	1.4

PEEK-OPTIMA HA Enhanced has mechanical properties similar to PEEK-OPTIMA Natural and a modulus closer to bone than does titanium, thus reducing stress shielding[4]



PEEK-OPTIMA Natural | PEEK-OPTIMA HA Enhanced | PEEK-OPTIMA Image Contrast (Low) | PEEK-OPTIMA Image Contrast (High) | Metallic

With a high degree of radiolucency and no imaging artifacts, PEEK-OPTIMA HA Enhanced has similar visibility to PEEK-OPTIMA Image Contrast.

Superior surface cover with an integrated compound.

Hydroxyapatite (HA) is fully integrated into the PEEK-OPTIMA Natural biomaterial to provide a complete homogenous compound, ensuring it is present on all surfaces of a machined device.

This material innovation eliminates the investment of time and resources associated with applying a surface coating, and simplifies the validation process.

SCANNING ELECTRON MICROGRAPH: Well dispersed HA in the PEEK matrix

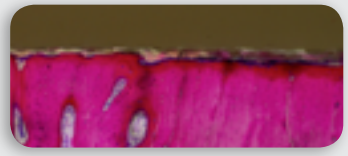
*HA available on **all machined surfaces** for enhanced bone-on growth*

*Typical coating technologies only applied to **vertebral body contact surfaces***

Early bone apposition generates greater bone contact.[1]

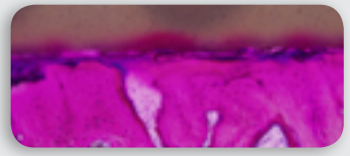
Invibio PEEK-OPTIMA HA Enhanced Biomaterial demonstrates enhanced bone apposition within 4 weeks compared with PEEK-OPTIMA Natural in a pre-clinical in vivo study using a sheep model.[1]

PEEK-OPTIMA Natural



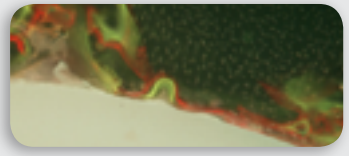
Areas of direct bone contact, but with some gaps

PEEK-OPTIMA HA Enhanced



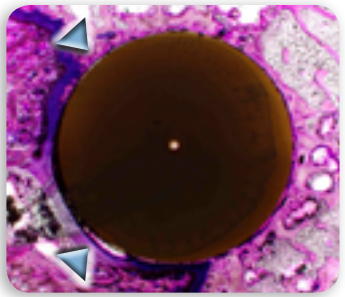
High degree of direct bone contact early in the healing process

PEEK-OPTIMA HA Enhanced

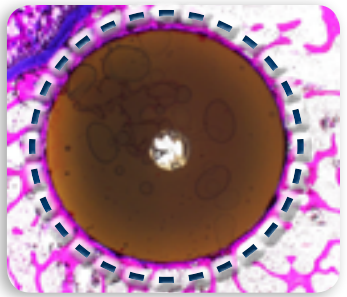


Early bone mineralization (alizarin red labelling)

Enhanced bone contact continues for up to 12 weeks.



PEEK-OPTIMA Natural



PEEK-OPTIMA HA Enhanced

Enhancements in bone apposition are maintained at 12 weeks following implantation

LEFT: the blue arrows indicate gaps between the bone and implant.

RIGHT: the dashed line indicates continuous bone contact.

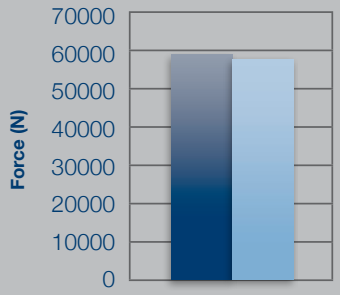
High performance in application-specific tests.

Compressive strength tests to ASTM F2077 using a generic cervical fusion device, and impact testing with a generic PLIF design, demonstrate that PEEK-OPTIMA HA Enhanced delivers the same high performance as PEEK-OPTIMA Natural – even after repeated sterilization.

Example of cage used in ASTM testing of static compressive strength testing

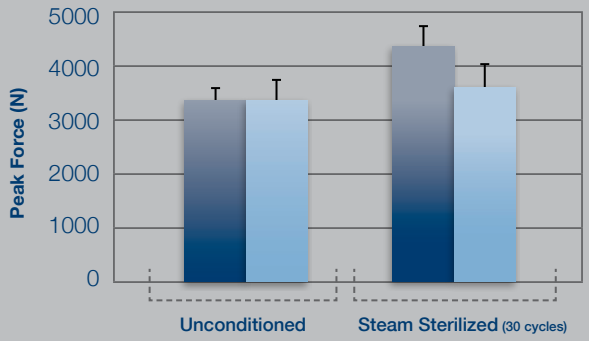
Example of cage used in ultimate impact strength testing

Static compressive strength



Equivalent performance to PEEK-OPTIMA Natural in compressive strength testing to ASTM F2077

Ultimate impact strength



Equivalent ultimate impact strength to PEEK-OPTIMA Natural before and after repeated steam sterilization

PEEK-OPTIMA Natural PEEK-OPTIMA HA Enhanced

Available only from Invibio – the world leader in implantable PEEK biomaterials.

Consistent high-quality and performance. Reliable delivery. Simple processing that helps streamline production. PEEK-OPTIMA HA Enhanced expands upon the advantages Invibio has offered customers since transforming the spinal device industry with the introduction of the PEEK-OPTIMA polymer family almost 15 years ago. Invibio continuously innovates and extends value-added services that support our customers in overcoming challenges in the ever-evolving spine industry.

To learn more about PEEK-OPTIMA HA Enhanced Biomaterial, visit www.invibio.com.

Invibio Ltd.
Technology Centre, Hillhouse International
Thornton Cleveleys,
Lancashire FY5 4QD
United Kingdom

Tel: +44 (0) 1253 898000
FAX: +44 (0) 1253 898001

Invibio Ltd.
300 Conshohocken State Rd
West Conshohocken, PA USA

866-INVIBIO (468 4246)
Tel: +484 342 6004
FAX: +484 342 6005

For further information call us toll free at 866-INVIBIO or +44 (0)1253 898000 or please visit our website at:

www.invibio.com

REFERENCES

1. Study evaluated the bone ingrowth and ongrowth 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. Niu et al. J Spinal Disord Tech. 2010;23(5):310-6.
3. Chou et al. J Clin Neurosci. 2008;15(11):1240-5
4. Values shown are typical material properties and those shown for cortical bone are indicative of those found in the literature.

PO-ENG-B-00 (10/09.12)