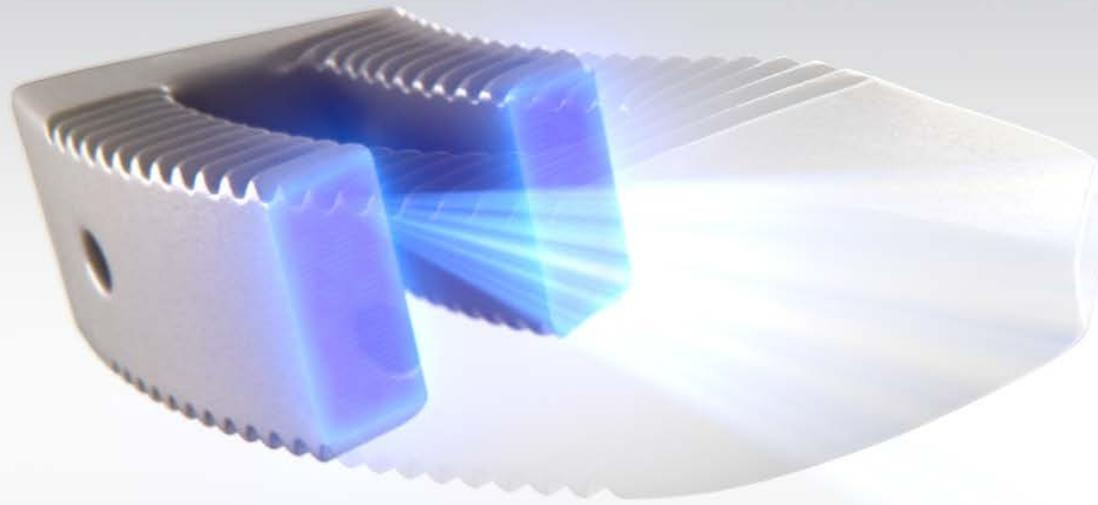


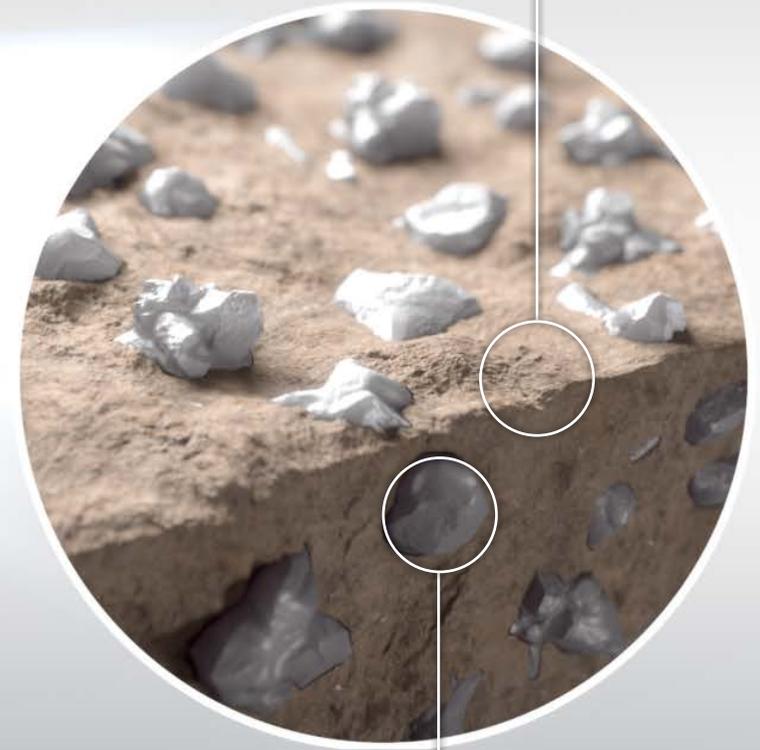


⊕ WELCOME TO OUR
MOST ADVANCED PEEK
SOLUTION ON THE MARKET





▶ **PEEK-OPTIMA™**



▶ **HA**

PEEK-OPTIMA™ HA ENHANCED

Integrated with hydroxyapatite throughout.

Unlike interbody fusion devices that are coated, PEEK-OPTIMA HA Enhanced devices have hydroxyapatite crystals on all surfaces which results in earlier bone on-growth and greater new bone formation on a fully osteoconductive implant.



HYDROXYAPATITE CRYSTAL INTEGRATION

Hydroxyapatite crystal integration both enables the full device to actively participate in the fusion process and prevents the potential for coating delamination during cage insertion.

OPTIMIZE BONE ON-GROWTH

▶ **Enhanced Bone Apposition¹**

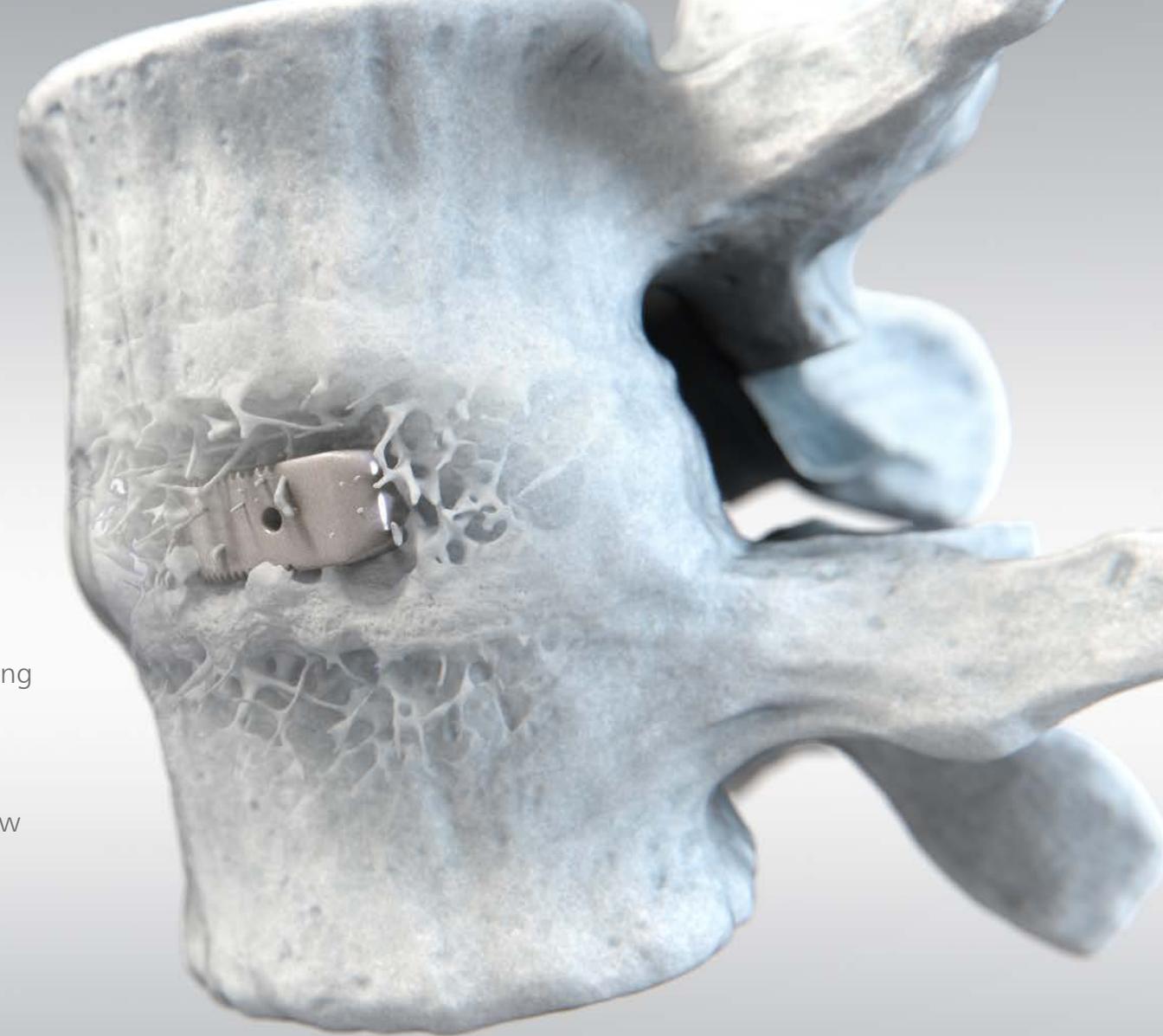
PEEK-OPTIMA HA Enhanced polymer resulted in over 75% direct bone contact after 4 weeks in a long bone ovine study

▶ **Greater New Bone Formation²**

PEEK-OPTIMA HA Enhanced resulted in greater new bone formation at 6 weeks compared with PEEK-OPTIMA Natural in an ovine cervical fusion study

▶ **Higher Quality of New Bone Bridging²**

PEEK-OPTIMA HA Enhanced resulted in a higher quality of new bone bridging at 6 and 12 weeks compared with PEEK-OPTIMA Natural in an ovine cervical fusion study



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.



“ I’m impressed by the solid arthrodesis around the PEEK-OPTIMA™ HA Enhanced implant seen as early as 3 months”

Sigurd Berven MD

Department of Orthopaedic Surgery at UCSF



“ I’m routinely seeing evidence of bone bridging and fusion as early as 3 months. I’m fascinated by the cortical appearing bone surrounding the cage.”

Christoph Hofstetter MD

University of Washington Medical Centre



“ Omnia Medical strives to develop novel products at an affordable price while achieving superior surgical outcomes. In line with these goals, we have selected to incorporate PEEK-OPTIMA™ HA Enhanced into our VBR and upcoming interbody cage portfolio. We value the 20+ year history of success demonstrated with Invibio’s PEEK-OPTIMA™ polymer and the fully integrated hydroxyapatite (HA) crystals that allow our devices to act as a catalyst for faster fusion.”

Steve Anderson

Vice President of Marketing – Omnia Medical



“ NGMedical team has been developing innovative product systems since 2001 and many solutions that are widely used as standards today, derive from our team of experienced scientists in cooperation with surgeons. We trust Invibio as a partner to help us continue setting the standards for innovation. The BEE HA Cervical cage was developed to optimize fusion while maintaining both radiolucency and elasticity that is similar to bone. Invibio’s PEEK-OPTIMA™ HA Enhanced is a simple innovation that meets the needs of the market, allowing for entirely osteoconductive implants.”

Peter Weiland

CEO - NG Medical



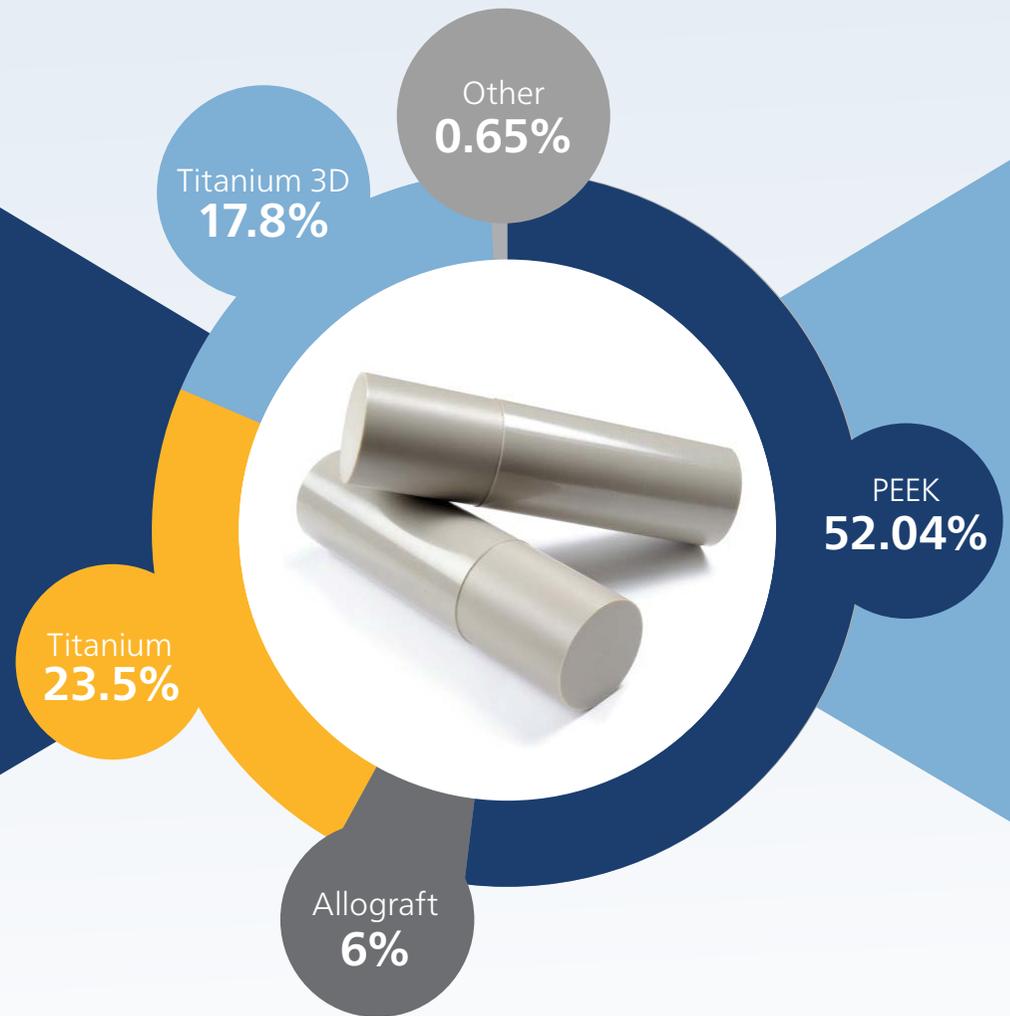
“ At Innovasis we believe that better access to information provides better outcomes, for both the surgeon and the patient. This is why we have established the HA PEEK Data Registry that allows surgeons to collect patient outcomes and fusion data in a secure, HIPAA-compliant database that can be accessed on a real time basis. We feel confident about our PEEK-OPTIMA™ HA Enhanced devices as we know we’re using a technology backed by clinical data.”

David Oka

Vice President of Business Development and Compliance - Innovasis

PEEK solutions continue to be the preferred material of choice for thousands of surgeons in the US, year on year.

US Market Share of Interbody Device Materials: IQVIA, Spinemarket, Inc., 2020



- ▶ Innovasis Ax™ Stand-Alone ALIF system from Innovasis made with PEEK-OPTIMA™ HA Enhanced



155%

growth in PEEK-OPTIMA™
HA Enhanced cleared
devices in last 5 years



- ▶ EVOL®HA-DLIF from Cutting Edge Spine made with PEEK-OPTIMA™ HA Enhanced



- ▶ Boxcar® VBR system from Omnia Medical made with PEEK-OPTIMA™ HA Enhanced

Launching a PEEK-OPTIMA HA Enhanced device could be easier than you thought

Already have a PEEK-OPTIMA product in the market?

The Special 510(k) Program is intended to facilitate the submission, review, and clearance of a change to a manufacturer's own legally marketed predicate device ("existing device") that is already authorized for commercial distribution through 510(k) clearance. Invibio has a long standing relationship with the FDA, NMPA and European Authorities under the Medical Device Regulation (MDR 2017/745) - so we can help you navigate regulatory pathways



PEEK-OPTIMA™
HA Enhanced is
versatile for a range
of applications across
multiple market
segments



Spine



Sports Medicine



Foot and Ankle

ARE YOU LOOKING TO EXPAND GLOBALLY?

We'll help you enter & evaluate new markets

China is emerging as a market with huge commercial potential for PEEK-OPTIMA™ HA Enhanced devices, as the market seeks high quality, affordable technologies to meet demand. The first PEEK-OPTIMA™ HA Enhanced device clearances are expected in 2021-22 opening up the Regulatory pathway options in China.



In China, The National Medical Products Administration (NMPA) regulates drugs and medical devices.

Invivio has a long-standing relationship with the NMPA and can help you navigate your path to commercialization:

▶ Help you navigate the Chinese regulatory pathways

▶ Provide you with supporting documents

▶ Facilitate workshops between you and the NMPA

SUPPORT, EVERY STEP OF THE WAY

Helping you upgrade your PEEK quickly and cost effectively

+ Pre-launch technology support

Manufacturing and testing vendor selection, and support with failure analysis

+ Clinical relations support

Physician engagement to drive adoption, and salesforce education

+ Pre- and post-launch regulatory support

Submission guidance, and engineering and regulatory recommendations

+ Marketing support

Product launch through joint marketing and PR

+ Evaluate new markets

Support your business case for entering new geographies, or market segments such as sports medicine, foot & ankle or spine devices



⊕ **Ready to grow your company
with the latest gold standard in
PEEK?**

Contact us today to get started with a
PEEK-OPTIMA™ HA Enhanced sample.

[CONTACT US](#)



Invibio

BIOMATERIAL SOLUTIONS

Victrex plc and/or its group companies ("Victrex plc") believes that the information contained in this document is an accurate description of the typical characteristics and/or uses of the product or products, but it is the customer's responsibility to thoroughly test the product in each specific application to determine its performance, efficacy, and safety for each end-use product, device or other application. Suggestions of uses should not be taken as inducements to infringe any particular patent. The information and data contained herein are based on information we believe reliable. Mention of a product in this document is not a guarantee of availability.

Victrex plc reserves the right to modify products, specifications and/or packaging as part of a continuous program of product development. Victrex plc makes no warranties, express or implied, including, without limitation, a warranty of fitness for a particular purpose or of intellectual property non-infringement, including, but not limited to patent non-infringement, which are expressly disclaimed, whether express or implied, in fact or by law.

Further, Victrex plc makes no warranty to your customers or agents, and has not authorized anyone to make any representation or warranty other than as provided above. Victrex plc shall in no event be liable for any general, indirect, special, consequential, punitive, incidental or similar damages, including without limitation, damages for harm to business, lost profits or lost savings, even if Victrex has been advised of the possibility of such damages regardless of the form of action.

INVIBIO™, PEEK-OPTIMA™, INVIBIO BIOMATERIAL SOLUTIONS™ are trade marks of Victrex plc or its group companies.

▶ www.invibio.com

 a victrex company

