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Nvision Biomedical Technologies: First FDA clearance for an osteotomy wedge system made of PEEK-OPTIMA™ HA Enhanced

Growing product portfolio for lower extremities made of the innovative, bone on-growth biomaterial

San Antonio, Texas/ Thornton Cleveleys (UK), October 28, 2020 – [Nvision Biomedical Technologies](#), a San Antonio-based medical device and implant manufacturer, has FDA clearance for the first osteotomy wedge system made from PEEK-OPTIMA HA Enhanced, a polymer from [Invibio Biomaterial Solutions](#) ('Invibio'). The Trigon® Stand-Alone Osteotomy Wedge Fixation System has osteoconductive properties that promote multi-directional bone healing and improved fixation without introducing material-related bio-incompatibility reactions. Additionally, the Trigon system utilizes Structural Encoding® to enable the Unique Device Identification (UDI) required by the FDA.

"Nvision's Trigon Osteotomy Wedge system, along with the entire foot and ankle line, is incorporating multiple technologies that I believe will be major factors in the future of reconstructive distal extremity surgery," said Dr. Kyle Vaughn, founder of Paradise Valley Foot and Ankle in Phoenix Ariz.

The Trigon system, made from PEEK-OPTIMA HA Enhanced, enables a standard surgical technique that allows direct and exact placement of implant and screws without additional plating. Nvision collaborated with Invibio for the FDA 510(k) submission to obtain clearance for the new implant.

PEEK-OPTIMA HA Enhanced provides a potential for earlier fusion/union for foot and ankle implants, a surgeon's primary goal for fusion surgery. It does so because Hydroxyapatite (HA) is fully integrated within the matrix of Invibio's PEEK-OPTIMA Natural. As it is integrated, not coated, the HA is available on all surfaces of a finished device. In combination with a modulus of elasticity closely matching that of actual bone, PEEK-OPTIMA HA Enhanced has the potential to promote faster bone ongrowth and healing. Its radiolucent properties result in artifact-free imaging with the ability to easily monitor the healing process.

After initially focusing on spinal implants, Nvision is now applying many of the same advanced technologies to lower extremity surgery, having launched the Vector® Hammertoe Correction System into the market in March 2019. An industry first, the hammertoe system was the initial foot and ankle implant made from the advanced, biocompatible PEEK-OPTIMA™ HA Enhanced. It was also the first lower extremity (Proximal Interphalangeal Joint



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Arthrodesis) implant to use Structural Encoding, the patented technology platform licensed from Watershed Idea Foundry. Earlier this year, Nvision also launched the Trigon titanium wedge, which utilizes additive manufacturing and 3D-printed medical-grade titanium alloy (Ti-6Al-4V) material.

“The ability to innovate with advanced materials, designs, and manufacturing processes allows us to add products to our portfolio that give surgeons the opportunity to achieve the best outcomes for their patients,” said Tom Zink, Senior Vice President of Product Development.

With a focus on driving innovation for the foot and ankle segment, Nvision has several new products in the pipeline utilizing PEEK-OPTIMA HA material.

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About Nvision Biomedical Technologies

Nvision is a San Antonio-based medical device and implant manufacturer focused on providing surgeons with implants paired with instrumentation and biologics that simplify and improve surgery procedures to help patients get back to their quality of life. Nvision is committed to developing and manufacturing thoughtfully designed products combined with exceptional service that keep the patient, surgeons, healthcare providers, and distribution partners in mind. Nvision is aligned with surgeon thought leaders, key researchers, and development engineers from prestigious institutions to design, test, and bring to market the most innovative concepts. Find out more at www.nvisionbiomed.com

About Invibio Biomaterial Solutions

Invibio, part of the Victrex plc group of companies, is a global leader in providing high-performance biomaterial solutions to medical device manufacturers. The company provides PEEK-OPTIMA™ polymers, advanced technical research and support and manufacturing of components for spine, trauma and orthopaedic and dental medical segments for the development of long-term implantable medical devices. Today, Invibio’s PEEK-OPTIMA™ polymers are used in approximately 13 million implanted devices worldwide. JUVORA™, INVIBIO™, PEEK-OPTIMA™, INVIBIO BIOMATERIAL SOLUTIONS™ are trademarks of Victrex plc or its group companies. All rights reserved. Find out more at <https://invibio.com/>

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Victrex is an innovative world leader in high-performance PEEK and PAEK polymer solutions focusing on the strategic markets of automotive, aerospace, energy (including manufacturing and engineering), electronics and medical. Every day, millions of people use sustainable products and applications containing our materials – from smartphones, aeroplanes and cars to oil and gas operations and medical devices. With over 40 years’ experience, we are developing world leading solutions with PEEK and PAEK-based polymers and selected semi-finished and finished parts which shape future performance for our customers and our markets, deliver environmental and societal benefits, and drive value for our shareholders. Find out more at www.victrex.com



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Media Contacts

Invibio Biomaterial Solutions media contact

Miriam Kingsley, Marketing Communications Manager, miriam.kingsley@invibio.com, Phone +44 (0) 1253 898000

Nvision Biomedical Technologies media contact

Bonnie Caver, bonnie@replighthouse.com, Phone 512-217-5397

Victrex media contact

Beate Sauer, PR & Marketing Communications Manager, bsauer@victrex.com, Phone +49 61 92 / 96 49 19

Corporate, Financial Media or Investor Relations Enquiries

Andrew Hanson, Director of Investor Relations & Corporate Communications, ahanson@victrex.com, Phone +44 12538 98121

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