Invibio: FDA reclassified semi-rigid spinal stabilization systems providing new possibilities for treating patients

*The new category opens the door for semi-rigid devices such as PEEK rods to become available through the FDA 510(k) regulatory pathway.*

Thornton Cleveleys (UK) (PRWEB) March 08, 2017 -- The US Food and Drug Administration (FDA) has recently reclassified semi-rigid spinal stabilization systems from Class III to Class II (*) offering a regulatory pathway to 510(k) clearance in the United States for innovative devices using PEEK-OPTIMA™ polymer based rods from Invibio Biomatertial Solutions ("Invibio"). When compared to rigid systems, semi-rigid PEEK-OPTIMA rods can deliver similar benefits to titanium and are strong enough to stabilize the spine. The FDA decision supports the safety of semi-rigid systems and provides greater options for surgeons who prefer more flexibility than traditional rigid pedicle screw systems to achieve fusion.

Invibio collaborated closely with medical device manufacturers and the FDA to provide clinical and biomechanical data in support of the use of semi-rigid PEEK-OPTIMA rods for spinal stabilization. The pioneering development and reclassification is expected to assist the medical profession in achieving progress in enhanced spinal fusion systems and procedures.

Clinical evidence: Invibio to support OEMs further with their submissions to the FDA

"The down classification of PEEK-OPTIMA rods as a Class II technology for spinal fusion is a welcome and progressive development for the medical device market. Substantial evidence was presented in reaching this conclusion, including data from over 51,000 PEEK rod implantations. We now have a growing body of clinical evidence that systems based on Invibio’s PEEK-OPTIMA rods have clearly defined advantages over all-metal constructs and have the potential to drive the future of posterior spine stabilization,” commented John Devine, Invibio medical business director.

“Healthcare globally is under pressure to control costs which is why Invibio offers PEEK-OPTIMA spinal rod components to the manufacturer. Compiling evidence that supports the safety and clinical benefits of our materials enables us to also provide an efficient route to market for our customers in terms of manufacturing and regulatory clearance. We look forward to working with our customers to achieve clearance for semi-rigid systems in order to offer improved options for surgeons and ultimately patients,” concluded Devine.

Metal alternative offers distinct advantages

For some time, the medical profession has been aware that spinal-rod components made from PEEK-OPTIMA polymers may be used as an alternative to metal to achieve semi-rigid fixation with posterior pedicle screw systems as an adjunct to fusion. And in fact, they offer distinct advantages over stabilization systems constructed from a metal such as titanium.

“PEEK-polymer solutions are widely recognized for spinal interbody fusion and are frequently used. The versatile PEEK-OPTIMA has a modulus close to that of human bone, and this allows it to be a natural bridge between very rigid metal implants, such as the titanium constructs, and more dynamic approaches. In fact, PEEK-polymer implants offer numerous benefits, including radiolucency, which of course metals don't allow, while retaining the stability of titanium,” commented Dr. Thierry Desjardins, Neurosurgeon (Cagnes-sur-Mer,
France), who has been using PEEK-OPTIMA spinal rods since June 2011 and has always been reluctant to use too rigid a system as this could accelerate degeneration at adjacent spinal segments.

Semi-rigid rods to bridge treatment gap: improved load sharing can encourage fusion

Semic-rigid rods composed of metal are not without challenges, including, but not limited to, rod breakage, the loosening of screws, and accelerated degeneration at adjacent spinal segments. The high stiffness inherent in all-metal constructs is believed to contribute to these clinical challenges and negatively impact patient outcomes.1,2 In addition, a metal such as titanium lacks artifact-free imaging, and inevitably this impacts the ability of surgeons to position stabilization systems accurately.

PEEK-OPTIMA polymer based stabilization, on the other hand, effectively functions as a 'bridge' approach. Rods made from the material have sufficient strength to reduce the range of motion2,3 in order to stabilize the treated segment4, but possessing a modulus similar to that of cortical bone, they still allow physiological movement on adjacent upper and lower segments.3 As a result, clinical results increasingly suggest that PEEK-OPTIMA spinal rod components preserve or slow down the degeneration of adjacent discs.5 As a consequence, patients may benefit from improved load sharing to encourage fusion,2,6,7 and more physiologic loading at adjacent levels, which may decelerate degeneration.8,9

To learn more, please visit Invibio at the AAOS Annual Meeting – Booth 3545 – March 15-17, 2017

For more information please visit http://bridgethefusiongap

(*) The US Food and Drug Administration (FDA) renamed dynamic stabilization systems as "semi-rigid systems," and defined them as a sub-type of pedicle screw systems, now referenced as "thoracolumbosacral pedicle screw systems". Further information for the final ruling can be found at “Orthopedic Devices: Reclassification of Pedicle Screw Systems, Henceforth To Be Known as Thoracolumbosacral Pedicle Screw Systems, Including Semi-Rigid Systems.”

REFERENCES
30 cases. Eur Spine J, 21(1), S50-S54.

About Invibio Biomaterial Solutions
Invibio, a Victrex plc company, 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 medical segments for the development of long implantable medical devices. Today, Invibio’s PEEK-OPTIMA™ polymers are used in more than five million implanted devices worldwide.

INVIBIO™, PEEK-OPTIMA™, INVIBIO BIOMATERIAL SOLUTIONS™ are trademarks of Victrex plc or its group companies. All rights reserved.

About Victrex plc
Victrex, headquartered in the UK, is an innovative world leader in high performance polymer solutions focused on the Aerospace, Automotive, Electronics, Energy and Medical markets. Every day, millions of people rely on products or applications which contain our polymers, from smartphones, aeroplanes and cars to oil & gas operations and medical devices. With over 35 years’ experience, we are delivering leading edge solutions to shape future performance for our customers and our markets, and to drive value for our shareholders. Find out more at www.victrexplc.com

Copyright ©2017 Invibio Ltd.
Contact Information
Barbara Pasciak
Invibio Biomaterial Solutions
+1 (484) 342-6041

Andrew Hanson
Victrex
http://www.victrex.com
+44 12538 98121

Online Web 2.0 Version
You can read the online version of this press release here.