Maxim Surgical Achieves FDA Clearance for New Spinal Implants Made of Solvay's Zeniva PEEK

Solvay Specialty Polymers

Thermoplastic Biomaterial Delivers High Performance in New MaxFuse-C Cervical Interbody Fusion System

Maxim Surgical, a new designer and manufacturer of spinal implants, has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its new MaxFuse-C™ cervical interbody fusion system made of Zeniva® polyetheretherketone (PEEK) rods from Solvay Specialty Polymers. Zeniva® PEEK – part of Solvay's line of Solviva® Biomaterials – has a modulus very close to that of bone plus excellent toughness and fatigue resistance. The FDA clearance was based in part on Solvay's well-developed master access file for Zeniva® PEEK.

The cervical interbody fusion system made from Zeniva® PEEK rod is hollow so that bone can grow through the device, fusing the adjacent bony surfaces of the vertebrae. The cervical spacer for the spinal fusion market is Maxim's first orthopedic implant.

Zeniva® PEEK offers numerous advantages over metals such as titanium for spinal implants. The material offers many important benefits including biocompatibility, chemical inertness, and a modulus of elasticity that is close to that of bone. Based on biocompatibility testing, Zeniva® PEEK demonstrates no evidence of cytotoxicity, sensitization, irritation, or acute systemic toxicity, and meets the ASTM F2026 standard. It also boasts high strength and stiffness and has radiolucent properties which enable x-ray procedures without interference.

The MaxFuse-C™ cervical interbody fusion system is machined from 16-mm and 20-mm diameter Zeniva® PEEK rods. It is available in two footprints – 15-mm x13-mm and 17-mm x 14-mm in both neutral and six degree lordotic options – offering surgeons flexibility in meeting different patient anatomies. The system also provides a large graft window which facilitates a bigger graft volume for fusion. Maxim offers an easy-to-use single tray system which includes simplified instrumentation for all of their available implant options. Maxim plans to explore the future use of Zeniva® PEEK in a range of other spinal fusion products.

"We're excited about the commercial success of Zeniva® PEEK in the orthopedic implantable market," said Shawn Shorrock, global healthcare market manager for Solvay Specialty Polymers. "The ongoing acceptance of Zeniva® PEEK has validated our approach to the orthopedic implant market and we're encouraged by the momentum we've generated."

The manufacturing site for Zeniva® PEEK and other Solviva® Biomaterials in Alpharetta, Ga., is ISO 13485 registered and the relevant aspects of current Good

Manufacturing Practices are also applied. Solvay's biomaterial manufacturing processes are carefully validated and enhanced controls provide product traceability. In addition, all materials are tested in an ISO 17025 accredited lab.

In addition to Zeniva® PEEK, Solvay's Solviva® Biomaterials line includes Veriva® polyphenylsulfone (PPSU), which provides unsurpassed toughness combined with transparency and excellent chemical resistance; Eviva® polysulfone (PSU), which offers toughness in a strong, transparent polymer; and Proniva® self-reinforced polyphenylene (SRP), one of the world's stiffest and strongest unreinforced thermoplastics that offers exceptional chemical resistance and hardness. These sterilizable products are available in injection molding and extrusion grades as well as rods and plates for machined components.

About Maxim Surgical

Maxim Surgical, based in Richardson, Texas, is a privately held medical device company which is focused on the development of innovative solutions for the spinal fusion device market. Founded in 2011, the company's primary mission is to provide surgeons and their patients with high-quality medical implants with a value approach. Maxim has a close partnership with key industry leaders and has a world-class development team to manufacture leading-edge implant products at a cost savings for the surgical spinal fusion market. Learn more at www.maximsurgical.com [1].

About Solvay Specialty Polymers

Solvay Specialty Polymers is a leading global supplier of high-performance thermoplastics for implantable and non-implantable medical devices. The company has expanded its focus on the healthcare industry to meet the growing needs of its global customers. Solvay is building on its 20-year history as a key material supplier in the healthcare field, devoting considerable new resources to help customers be more efficient and cut costs. Metal-to-plastic replacement remains a key focus for manufacturers, but increased cost pressures pose a new challenge as the market continues to grow at a double-digit pace. Solvay also continues to devote considerable research and development activities to polymer technology and commercialization of new and unique material options for medical OEMs and processors.

Solvay Specialty Polymers manufactures over 1500 products across 35 brands of high-performance polymers – fluoropolymers, fluoroelastomers, fluorinated fluids, semi-aromatic polyamides, sulfone polymers, aromatic ultra polymers, high-barrier polymers and cross-linked high-performance compounds – for use in Aerospace, Alternative Energy, Automotive, Healthcare, Membranes, Oil and Gas, Packaging, Plumbing, Semiconductors, Wire and Cable, and other markets. Learn more at www.solvayspecialtypolymers.com [2].

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