

Versatile Biomaterial Brings Exceptional Performance in Spinal Devices

Joseph Grande

DiFUSION Technologies' new interbody implants are made of Solvay's Zeniva PEEK, which has a modulus very similar to that of bone, along with toughness and fatigue resistance. The implants are for intervertebral body fusion of the thoracolumbar spine, and to be used with supplemental internal fixation. These implants are hollow, meaning the bone can grow through the device, and fuse the nearby bony surfaces of the vertebrae.

[DiFUSION Technologies Inc](#) [1]., a Texas-based supplier of minimally invasive spinal implants, recently received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its new Xiphos line of posterior interbody devices made of Zeniva polyetheretherketone (PEEK) resin from [Solvay Advanced Polymers, LLC](#) [2]. Zeniva PEEK—part of Solvay's line of Solviva Biomaterials—has a modulus very close to that of bone, along with toughness and fatigue resistance. The FDA clearance was based in part on Solvay's well-developed master access file for Zeniva PEEK.

The interbody implants, made from Zeniva PEEK rod, are for intervertebral body fusion of the thoracolumbar spine, and intended for use with supplemental internal fixation. Since the implants are hollow, the bone can grow through the device, fusing the adjacent bony surfaces of the vertebrae.

The Xiphos posterior interbody platform includes a range of implant shapes and sizes for varying patient anatomy and surgical preference, which allows for posterior, posterior oblique, and transforaminal approaches. These best-in-class implants are expected to serve as a platform for future development.

"We have found Zeniva PEEK to be markedly stronger than comparable competitive materials based on our biomechanical testing, offering the exceptional properties that are required in this critical application," says Derrick Johns, managing director and CEO of DiFUSION Technologies. The company plans to use Zeniva PEEK for future non-antimicrobial products.

Zeniva PEEK offers numerous advantages over metals such as titanium for these intervertebral implantable devices. The material offers many important benefits including biocompatibility, chemical inertness, and a modulus of elasticity that is closer to that of bone than traditionally used metals. Based on biocompatibility testing, Zeniva PEEK demonstrates no evidence of cytotoxicity, sensitization, irritation, or acute systemic toxicity. It also boasts high strength and stiffness, and has radiolucent properties which permit x-ray procedures.

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“With over 10 devices now cleared through the FDA via the 510(k) process, including six in spinal implants, we are excited about the growing acceptance of this material both in the market and the FDA,” states Shawn Shorrock, global healthcare market manager for Solvay Advanced Polymers. “We’ve made significant investments, and have performed all applicable required testing to ensure that our Zeniva PEEK meets or exceeds the critical regulatory performance standards set by the FDA.”

Zeniva PEEK and the entire line of Solviva Biomaterials are manufactured in compliance with the relevant aspects of ISO 13485, and under the relevant aspects of current Good Manufacturing Practices. Solvay’s biomaterial manufacturing processes are carefully validated, and enhanced controls provide product traceability. In addition, all materials are tested in an accredited lab that is ISO 17025 compliant.

Solvay is currently in active product trials with several medical device manufacturers using Zeniva PEEK, as well as other Solviva biomaterials.

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

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