

Thompson MIS is FDA Cleared for Spinal Implants Made of Solvay's Zeniva® PEEK

Versatile Thermoplastic Biomaterial Brings Exceptional Performance in Spinal Fusion Application

ALPHARETTA, Ga., November 12, 2014 – Thompson MIS, Salem, N.H., a leading supplier of minimally invasive spinal implants and delivery systems, has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its MIS TLIF spacer made of Zeniva® polyetheretherketone (PEEK) resin from Solvay Specialty Polymers. Zeniva® PEEK – part of Solvay's Solviva® line of 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. Solvay made the announcement at the North American Spine Society's annual meeting Nov. 12-15 in San Francisco.

The BoneBac® TLIF spacer, made from Zeniva® PEEK rod, is a transforaminal lumbar interbody fusion spacer. These spacers are implanted in the lumbar disc space to enable fusion of the adjacent bony surfaces of the vertebrae. Minimally invasive surgery is made easier with the BoneBac® TLIF spacer due to its patented geometry that allows for direct injection of graft while the inserter is still attached, thus resulting in a more complete fill when packing the disc space. The BoneBac® TLIF spacer also provides surgeons two options of implant insertion: insert and rotate and straight insertion thereby increasing the amount of disc restoration in comparison to other TLIF systems.

"The ability to completely fill the disc space after the device has been positioned is important for high-quality fusion," explained Dan Farley, president of Thompson MIS. "The spacer is an important element of the overall system because it empowers the adoption of minimally invasive surgery techniques by spine surgeons for transforaminal lumbar interbody fusion."

Zeniva® PEEK is a comparable alternative to metals such as titanium for these intervertebral implantable devices, according to Thompson MIS. The material offers many important benefits including biocompatibility and chemical inertness. 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.

Thompson MIS uses Zeniva® PEEK rod stock and performs high-precision machining to produce a full range of sizes and configurations.

"We're excited about the commercial success of Zeniva® PEEK in the spinal fusion market," said Shawn Shorrock, Global Director of Regulatory Affairs for Solvay Specialty Polymers' healthcare business. "The ongoing acceptance of Zeniva® PEEK has validated our approach to the spinal 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 Proniva® self-reinforced polyphenylene (SRP), one of the world's stiffest and strongest unreinforced thermoplastics that offers exceptional biocompatibility and hardness; 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 rods and plates for machined components.

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® BoneBac is a registered trademark of Thompson MIS.

About Thompson MIS

Thompson MIS, based in Salem, N.H., is a privately-held medical device company that is focused on minimally invasive therapies for treating conditions of the spine. Through the advancement of novel technologies and techniques, Thompson MIS empowers surgeons to adopt minimally invasive spine surgery for the purpose of improving outcomes for patients, enabling surgeon excellence, and reducing healthcare costs. The company embraces the challenges presented by the future of medicine and pledges to identify physician and patient needs and provide unsurpassed, innovative solutions. For more information, call (603) 912-5306 or visit www.thompsonmis.com.

About Solvay Specialty Polymers

Solvay Specialty Polymers (www.solvayspecialtypolymers.com) is a leading global supplier of high-performance thermoplastics for permanent and prolonged exposure implants and limited exposure devices. The company has expanded its focus on the healthcare industry to meet the growing needs of its global customers by providing global technical and regulatory support. Solvay is building on its 25-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 & Gas, Packaging, Plumbing, Semiconductors, Wire & Cable, and other industries. Learn more at www.solvay.com.

As an international chemical group, **SOLVAY** assists industries in finding and implementing ever more responsible and value-creating solutions. Solvay generates 90% of its net sales in activities where it is among the world's top three players. It serves many markets, varying from energy and the environment to automotive and aeronautics or electricity and electronics, with one goal: to raise the performance of its clients and improve society's quality of life. The group is headquartered in Brussels, employs about 29,400 people in 56 countries and generated 9.9 billion euros in net sales in 2013. Solvay SA (**SOLB.BE**) is listed on **NYSE Euronext** in Brussels and Paris (Bloomberg: **SOLB:BB** - Reuters: **SOLB.BR**).

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