

Extremity Medical Receives FDA Clearance for New Hammertoe Anchor Implant Made of Solvay's Zeniva® PEEK

Industry's First PEEK Hammertoe Fusion Device Boasts Unique Design to Ensure Stability and Maintenance

ROSEMONT, Ill., June 11, 2014 – Extremity Medical LLC, Parsippany, N.J., an entrepreneurial-based manufacturer of orthopedic implants for the distal extremities, has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its new HammerFiX™ IP fusion system made of Zeniva® polyetheretherketone (PEEK) resin 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. Solvay made the announcement at the 10th Annual Orthopedic Manufacturing & Technology (OMTEC) exposition June 11-12 in Rosemont, Ill.

The HammerFiX™ implant is the first cannulated hammertoe device made of the non-resorbable polymer PEEK in the U.S., according to Jamy Gannoe, Extremity Medical's president and co-founder. It is used for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

“Zeniva® PEEK's exceptional properties have enabled us to develop a next-generation hammertoe fixation product that is differentiated among our competition in terms of material and design,” said Gannoe.

The HammerFiX™ implant, machined from 6-mm-diameter Zeniva® PEEK rod stock, was designed for stability and maintenance of the correction. The inherent elasticity of Zeniva® PEEK aids in the delivery of the implant in the phalanx. The reverse helical thread pattern of the implant's barbed segment allows for a technique which provides additional compression across the joint.

The implant's design also provides an option to temporarily pin the corrected phalanx to the metatarsal with a guide wire in order to minimize metatarsophalangeal joint subluxation during healing. Zeniva® PEEK is also radiolucent which enables the surgeon to better visualize the fusion site via x-ray without the shadows and opacity of titanium.

The HammerFiX™ implant comes in three sizes – 2.8 mm, 3.4 mm, and 4 mm – to accommodate the size variation of the phalanges.

“This application demonstrates the superior toughness and ductility of Zeniva® PEEK over the competition,” said Shawn Shorrock, Global Director of Regulatory Affairs for Solvay Specialty Polymers' healthcare business. “These unique properties, plus the well-established history of biological safety for Zeniva® PEEK, will continue to support its growth in the orthopedic market.”

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 which offers exceptional biocompatibility and hardness; Veriva® polyphenylsulfone (PPSU), which provides unsurpassed toughness combined with transparency and excellent biocompatibility; and Eviva® polysulfone (PSU), which offers toughness in a strong, transparent polymer.

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About Extremity Medical LLC

Extremity Medical is a young, yet fast-moving, entrepreneurial company with a strong engineering culture at its foundation. The company develops next-generation products to address the challenging needs of surgeons specific to treating the distal extremities, including the hand, wrist, foot, and ankle. It is focused on identifying unmet needs and developing unique solutions for fusion, fixation, and motion-preserving systems for the upper and lower extremities.

Extremity Medical was founded in northern New Jersey in 2008. Founders Matthew Lyons and Jamy Gannoe are biomechanical engineers experienced in creating and growing successful, fast-moving companies based on orthopedic, cardiovascular, and general surgery technologies. For more information, visit www.extremitymedical.com.

About Solvay Specialty Polymers

Solvay Specialty Polymers 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 and Cable, and other industries. Learn more at www.SolvaySpecialtyPolymers.com.

Solvay (www.solvay.com) is an international chemical Group committed to sustainable development with a clear focus on innovation and operational excellence. It is realizing over 90% of its sales in markets where it is among the top 3 global leaders. Solvay offers a broad range of products that contribute to improving quality of life and the performance of its customers in markets such as consumer goods, construction, automotive, energy, water and environment, and electronics. The Group is headquartered in Brussels and its companies, which employ about 29,400 people in 56 countries, generated EUR 9.9 billion in net sales in 2013 (pro forma). Solvay SA is listed as **SOLB** on NYSE Euronext (www.euronext.com) in Brussels and Paris. Bloomberg (www.bloomberg.com) = **SOLB:BB** and Reuters (www.reuters.com) = **SOLB.BR**.

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