Solvay's Ixef PARA Replaces Stainless Steel in Disposable Cardiac Surgical Instruments

Ixef® polyarylamide (PARA) resin from Solvay Specialty Polymers USA, LLC, delivers high strength, rigidity, and moldability in new disposable surgical devices manufactured exclusively by Biorep Technologies, Miami, Fla., for Miami Instruments LLC, a medical device company dedicated to the design and development of specialized instrumentation for minimally invasive cardiac surgery (MICS) procedures. The high-performance thermoplastic replaces stainless steel, allowing for more economical production of single-use surgical instruments.

“Ixef® PARA’s strength and rigidity is similar to stainless steel and it can also be molded, allowing us to eliminate machining and realize a major cost reduction over stainless steel,” said Felipe Echeverri, engineering director for Biorep Technologies.

The tip of the Miami Instruments LLC Joseph Lamelas Knot Pusher™ and the Visor™ support bracket and S-Blade™ of the Joseph Lamelas Atrial Lift System™ are made of Ixef® 1022, a 50% glass-filled PARA compound that combines high stiffness with an ultra-smooth finish. The tensile and flexural strength of Ixef® compounds are similar to many cast metals and alloys at ambient temperature. The molded black parts minimize light reflectivity for the surgeon. They also can be sterilized with gamma ray radiation without any significant change in appearance or loss of mechanical properties, thereby eliminating the cost associated with repeated steam sterilization of reusable instruments.

Biorep selected Ixef® PARA over 30% glass-filled liquid crystal polymer (LCP) and 30% carbon-filled polyetheretherketone (PEEK) due to its higher rigidity and lower processing temperature (500°F [260°C]). The high-flow resin can also readily fill walls as thin as 0.02 inch (0.5 mm), even with glass loadings as high as 60%.

The hook-like tip on the knot pusher is 0.2 inches (5 mm) wide and 0.5 inches (12.7 mm) long. Meanwhile, the atrial lift retractor’s Visor™ support bracket (0.14 inches [3.56 mm] wide and 0.45 inches [11.43 mm] long) and S-Blade™ (1.4 inches [35.56 mm] wide and 0.5 inches [12.7 mm] long) are adhered together with a solvent bonding process or can be ultrasonically welded.

Ixef® PARA resins demonstrate no evidence of cytotoxicity, sensitization, intracutaneous reactivity or acute systemic toxicity, based on biocompatibility testing as defined by ISO 10993:1.

Biorep is also developing other surgical instruments and is considering Ixef® PARA resin for a range of metal replacement uses. The Joseph Lamelas Knot Pusher™ and the Joseph Lamelas Atrial Lift System™ are FDA registered products and are currently available in the U.S.

About Biorep Technologies
Biorep is a full-service, ISO 13485-certified, and FDA-compliant product development company with over 17 years of experience providing complete development services for medical and life sciences companies. The company specializes in discovering product opportunities, solving complex problems, and creating intellectual property to expand and protect client value in the market. Located in Miami, Biorep's unique facilities consist of a development center featuring design, development, assembly, and testing capabilities.

Services include Human Factors Engineering, User Interface Design, Systems Engineering (Mechanical, Electrical, Software), Usability Testing, Pilot Production Support, and Regulatory Compliance. Experienced and dedicated teams of design and engineering professionals are focused on building lasting partnerships which ensure that technological innovations become a reality. Biorep's clients include universities and Fortune 500 companies. The company's success and longevity in the product development industry is evidence of its commitment to delivering results and exceeding expectations. Learn more at www.biorep.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. Last year, Solvay announced a new organizational structure and a 50% increase in staffing for sales, marketing, and technology functions in the U.S. and Europe. Plans for further expansion in Asia-Pacific are also underway. 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 more products with more performance than any other polymer company in the world. The company supplies over 1500 products across 33 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 markets. Learn more at www.solvayspecialtypolymers.com [2].

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[1] http://www.biorep.com
[2] http://www.solvayplastics.com/sites/solvayplastics/EN/Companies/SolvaySpecialtyPolymers/Pages/Welcome.aspx