

Solvay Booth #731 | OMTEC 2018

Solvay's high-stiffness Ixef® PARA enables Reign Medical to develop a more robust compression staple system for orthopedic and podiatric surgeries

Alpharetta, Ga., June 12, 2018 --- Solvay, a leading global supplier of specialty polymers, announced today that its Ixef® polyarylamide (PARA) resin delivered the high stiffness and biocompatibility that Reign Medical needed to develop its revolutionary new Clench® compression staple system, a single-use bone staple kit for orthopedic procedures targeting the hand and foot.

Reign Medical's innovative Clench® Staple System kit comprises a fully disposable sterile surgical tool set for fixating hand and foot bone fragments, osteotomy fixation and joint arthrodesis. Its design utilizes a patented threaded hub that allows surgeons to incrementally expand the implant for proper insertion, while retaining the mechanical properties of the Nitinol staples for continuous compression across the fusion site after implantation. The company specified Solvay's Ixef® GS-1022 PARA, a 50-percent glass fiber-reinforced grade, for several components: the implant sizer, the drill guide and each part of the implant delivery instrument, including its handle, the saddle on which the staple sits, and the threaded compressor that forces the staples fully open.

The mechanical strain on these components requires them to be molded from a very high-stiffness material, and Solvay's Ixef® PARA GS-1022 compound proved to be the optimal solution. Offering metal-like strength, rigidity and dimensional stability, this biocompatible polymer also provides an exceptional surface finish. Available in a range of gamma-stabilized colors, Ixef® PARA is optimized for sterilization using high-energy gamma radiation, showing no significant change in appearance or performance after sterilization. The material has been evaluated for ISO 10993 limited duration biocompatibility and is supported by an FDA Master Access File.

"Our impetus for this kit was to develop a more robust, single-use bone fixation system than currently available," said Daniel Lanois, the development engineer for Reign Medical's Clench® Staple System. *"Many competitive solutions use lower performing plastics that do not reliably withstand the force required to hold Nitinol staples open, causing the staples to disengage prematurely. After briefly considering polycarbonate and ABS blends, we chose Ixef® PARA primarily for its outstanding stiffness, which enabled even the smaller components of the delivery tool to reliably withstand the compression of the staples as well as the torsional, tamping and axial loads applied during fixation procedures."*

"Solvay's practice of open innovation promotes the success of customers like Reign Medical by enabling them to focus on their medical device design while we help navigate issues related to materials science and molding challenges," said Jeff Hrivnak, business manager for Healthcare at Solvay's Specialty Polymers Global Business Unit. *"Solvay also conducted a crystallinity study of molded prototypes of Clench® system components to validate the tool and ensure that parts were molded properly."*

Reign Medical's single-use Clench® Staple System received FDA clearance in early April this year. The company is now undergoing the beta test for its first production launch.

® Ixef is a registered trademark of Solvay

® Clench is a registered trademark of Reign Medical

Reign Medical

Reign Medical is a start-up medical device company that offers solutions to everyday foot and ankle surgery. The mission of Reign Medical is to become a driving force in the healthcare industry through innovative thinking, hard work and collaborative product development. In partnership with our highly regarded surgeon design team, Reign Medical shares the utmost commitment to delivering the best solutions and outcomes in surgical care. Reign Medical will continue to influence patient care through the development and release of new products to further improve patient healthcare.

Solvay

Solvay is an advanced materials and specialty chemicals company, committed to developing chemistry that address key societal challenges. Solvay innovates and partners with customers worldwide in many diverse end markets. Its products are used in planes, cars, batteries, smart and medical devices, as well as in mineral and oil and gas extraction, enhancing efficiency and sustainability. Its light-weighting materials promote cleaner mobility, its formulations optimize the use of resources and its performance chemicals improve air and water quality. Solvay is headquartered in Brussels with around 24,500 employees in 61 countries. Net sales were €10.1 billion in 2017, with 90% from activities where Solvay ranks among the world's top 3 leaders, resulting in an EBITDA margin of 22%. Solvay SA ([SOLB.BE](https://www.euronext.com/brussels/stocks/stocks/solvbe)) is listed on Euronext Brussels and Paris (Bloomberg: [SOLB.BB](https://www.bloomberg.com/quote/SOLB:BB) - Reuters: [SOLB.BR](https://www.reuters.com/markets/commodities/solv-br)) and in the United States its shares (SOLVY) are traded through a level-1 ADR program.

Solvay Specialty Polymers

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

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Solvay's Ixef® polyarylamide (PARA) resin delivered the high stiffness and biocompatibility that Reign Medical needed to develop its revolutionary new Clench® Staple System, a single-use surgical kit for orthopedic procedures targeting the hand and foot. Courtesy of Solvay.