

## **Evonik's VESTAKEEP® PEEK reaches milestone number of FDA clearances**

Medical device FDA 510K clearances surpass 80 with VESTAKEEP® PEEK

PARSIPPANY, N.J., March 14, 2017 – Evonik Corporation's VESTAKEEP® PEEK, used by medical device customers for the design and development of surgical implants, recently surpassed a milestone of more than 80 devices cleared by the U.S. Food and Drug Administration (FDA).

Medical OEM's usually take one of two paths to have their devices reviewed and approved or 'cleared' by the FDA to be implanted in the body. One is a Premarket Approval (PMA) which is the most stringent process the FDA has, often requiring years of testing and clinical trials to prove the implant has sufficient safety and effectiveness for the intended use. The other is the Premarket Notification, or 510K process, that is most common and desired. This process typically takes 90 days or less and references a predicate device already cleared in the market by the FDA. Though VESTAKEEP® PEEK has over 80 customer devices cleared under the 510K process, it has also been used in devices approved under the more stringent PMA process, demonstrating that it is an outstanding material for even the most challenging application designs.

Evonik's VESTAKEEP® PEEK was developed to address the medical device industry's needs for high performance biocompatible materials. VESTAKEEP® PEEK's high fatigue resistance and toughness has proven to be critical in the successful development of these devices that see high stress loads during surgical implantation and throughout the healing process.

As a select material of choice by the medical device industry, Evonik's VESTAKEEP® PEEK has been used in the development of medical devices and technologies in the orthopedic, spine, sports medicine, cardiovascular, extremities, Cranio Maxillofacial, dental, and oncology market segments. "Achieving this milestone with our customers demonstrates the overwhelming acceptance and growth of VESTAKEEP® in the medical marketplace." said Vikram Chatur, Vice President and General Manager for High Performance Polymers for Evonik. "This could only happen with Evonik's commitment to the medical device industry. With our strengths in R&D and innovation, we'll continue to develop the VESTAKEEP® portfolio to grow our business and to advance PEEK polymer technologies for improving healthcare worldwide."

Medical device companies and surgeon inventors alike are developing new surgical device technologies with the high performance and biocompatible properties of VESTAKEEP® PEEK. Through innovation, industry partnerships, and strong customer collaboration, Evonik will further establish its market leadership to bring advanced PEEK polymer technologies to the global medical device industry.

For additional information about Evonik in North America, please visit:

[http://corporate.evonik.us/region/north\\_america](http://corporate.evonik.us/region/north_america).

For additional information about VESTAKEEP® PEEK, please visit:

<http://www.evonik.com/medical>

<http://www.vestakeep.com>

#### **Company information**

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Profitable growth and a sustained increase in the value of the company form the heart of Evonik's corporate strategy. Its activities focus on the key megatrends health, nutrition, resource efficiency and globalization. Evonik benefits specifically from its innovative prowess and integrated technology platforms. Evonik is active in over 100 countries around the world with more than 35,000 employees. In fiscal 2016 the enterprise generated sales of around €12.7 billion and an operating profit (adjusted EBITDA) of about €2,165 billion.

#### **Disclaimer**

In so far as forecasts or expectations are expressed in this press release or where our statements concern the future, these forecasts, expectations or statements may involve known or unknown risks and uncertainties. Actual results or developments may vary, depending on changes in the operating environment. Neither Evonik Industries AG nor its group companies assume an obligation to update the forecasts, expectations or statements contained in this release.

#### **For more information, contact:**

Robert Brown

Evonik Corporation

Tel: +1 973 929-8812

Cell: +1 973 906-4635

Email: [robert.brown@evonik.com](mailto:robert.brown@evonik.com)

