Press release

Evonik supports VESTAKEEP® customers in the registration process of their implant devices – Master File submitted to the FDA

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Evonik has developed the VESTAKEEP® I polyetheretherketone series for medical applications that require high biocompatibility, in particular, those that are to come into long-term contact with body tissue. It has now submitted information on this PEEK series to the U.S. Food and Drug Administration (FDA) in a Device Master File. "FDA registration makes it easier for our U.S. customers to obtain approval for new medical products that use VESTAKEEP® I grades," says Dr. Herbert Groothues, responsible for quality processes at VESTAKEEP®, of the submission of the Master File. "In documentation comprising several folders, we have comprehensively presented the outstanding product properties of the VESTAKEEP® I series and the controlled process flows of its production." The series currently consists of the medium-viscosity compound VESTAKEEP® I 2 G, the high-viscosity compound VESTAKEEP® I 4 G, and the high-viscosity powder grade VESTAKEEP® I 4 P.

The regulatory authorities are rather exacting about the quality of medical devices intended for long-term contact with body tissues, so when registering these products in Europe or the U.S., a producer has to prove that the raw materials for the application field in question are suitable. The producer must also indicate how consistency of quality is ensured. This requires highly detailed information from the raw materials producer on the starting products, production processes, and quality testing and assurance measures used. The raw materials producer can submit this information, some of which is confidential, to the FDA in a Device Master File. When a producer of medical devices now applies for registration of a new product in the U.S., the FDA can use the appropriate documentation to directly research all the relevant information on the raw material used.

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PEEK polymers have been used in implant applications since the mid-1980s. Since 1999, PEEK has been the most important thermoplastic substitute for titanium implants. PEEK owes its excellent biocompatibility mainly to its high resistance to chemicals. The material is inert to body fluids and shows no adverse effects in the standardized biocompatibility tests that have been performed. One of its advantages over titanium is its high elasticity, which is of the same order as that of bone. This prevents the stress-shielding effect: In contact with the bone, the latter is not entirely shielded from mechanical stress and can therefore retain its strength for many years.

These outstanding material properties and the good processability are the main reasons, why PEEK polymers are increasingly used in implant applications. Typical applications are spinal and orthopedic implants, trauma implants (fixation of bone fractures, replacement of bone fragments) and dental implants.

Evonik's positioning of VESTAKEEP® polymers in the medical devices market makes an important strategic contribution to its marketing of high-performance polymers. Other products for this market segment are in the pipeline. “This underpins our goal of decisively shaping the PEEK market over the long term,” says Dirk Heinrich, global director of Marketing & Sales for VESTAKEEP®, looking to the future.

For further information please contact Dr. Herbert Groothues, e-mail: herbert.groothues@evonik.com.

Figure caption:
Thanks to its outstanding mechanical properties combined with high chemical resistance and excellent biocompatibility, the VESTAKEEP® I series opens up new possibilities in the field of medicine. (Photo: Sebastian Kaulitz / Fotolia.de)

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Company information
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