

## VESTAKEEP® i-Grade PEEK biocompatibility has successfully been tested by CFDA testing centre

- Traditionally, metals were the materials of choice for spinal cages and other implants in the human body, but recently the high-performance plastic polyetheretherketone (PEEK) has proven a serious and even more desirable alternative.
- VESTAKEEP® i-Grade PEEK, belonging to Evonik's business line High Performance Polymers, now has obtained the Biocompatibility Test Report from a CFDA (China Food and Drug Administration) testing center, helpful to Evonik's customers for their product approval with VESTAKEEP®.

Evonik Specialty Chemicals (Shanghai) Co., Ltd., hereby proudly confirms that on March 5<sup>th</sup>, 2015, the CFDA affiliated and qualified testing center "Zhejiang Institute for the Control of Medical Devices" has completed the comprehensive testing of VESTAKEEP® i-Grade PEEK following the GB 16886 standard series. The set of tests included:

- Cytotoxicity
- Delayed-type Hypersensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Genotoxicity (Ames Test)
- Genotoxicity (Mammalian Cell Gene Mutation Test, covering both endpoints)
- Subchronic Systematic Toxicity (28d intravenous)
- Bone Implantation Test (26 weeks)

VESTAKEEP® i-Grade PEEK has successfully passed all above-mentioned tests, in vivo or in vitro, which indicate that VESTAKEEP® i-Grade PEEK is of excellent biocompatibility.

According to Dominique Straessler, Head of High Temperature Polymers, High Performance Polymers Asia, "obtaining this report allows us to enter the market in China and beyond and to give our customers a valuable alternative for their material of choice." This statement is further confirmed by the fact that multiple Chinese manufacturers of spinal cages have already approached Evonik and received first samples for

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their product development and clinical trials as part of their final CFDA approval process.

Implants for the human body place heavy demands on the material used. Implantable material must, after all, be well biocompatible and last a lifetime. In addition to PEEK's excellent biostability and biocompatibility, its x-ray transparency and elasticity are unreplaceable by metals.

VESTAKEEP® is also X-ray transparent and therefore invisible in computer tomography and magnetic resonance imaging, which allows easy monitoring of bone growth and structure during the healing process. Titanium and cobalt-chromium, on the other hand, are opaque to X-rays and generate artifacts that make it difficult to analyze the image.

The elasticity of PEEK closely corresponds to that of a bone. This allows an optimal transmission of force between the implant material and the natural bone, which can in turn have a positive effect on bone healing.

Historical areas of application for high-performance PEEK have been spinal implants, with a growing interest in orthopedic devices and recently accepted applications such as dental, skull implants, heart valve, and innovative applications such as gastrointestinal stent, implantable pump and hypoglossal nerve stimulation system.

In order to meet a variety of clinical demands, Evonik continues to create and develop PEEK polymers at the base of VESTAKEEP i-Grade PEEK, e.g., carbon fibers strengthened PEEK and visible PEEK on X-Ray. The potential of PEEK polymers is far from being exhausted.

### **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. In fiscal 2014 more than 33,000 employees generated sales of around €12.9 billion and an operating profit (adjusted EBITDA) of about €1.9 billion.

Evonik Industries has been producing specialty chemical products in the Greater China region (Mainland China, Hong Kong and Taiwan) since the late 1970's; with wide-ranging trading relations already in place prior to this in the region. Evonik regards Greater China as one of the driving forces of the global economy and we consequently endeavour to grow our business in the region. The company now has around 3,000 employees in the Greater China region, the regional sales reached over €1.1 billion in 2014.

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