

In peak health

It may have been in use in the medical industry for more than two decades but, next to its traditional metal alternatives, PEEK is still very much regarded as a novelty. Adding to this is the fact that the flexibility and adaptability of the material enables new applications and processes to be developed all the time, allowing it to reach a growing number of practitioners and patients. Working to support these innovations is speciality chemicals company **Evonik**. *Medical Device Developments* hears from its director of medical devices and systems, Marc Knebel.

What advantages does PEEK bring to medical applications?

Marc Knebel: Traditional materials for medical applications are metals like titanium, stainless steel or cobalt chrome. PEEK is the only material that can work as a true metal replacement. This is not only due to its unique mechanical properties, but also to its strong biocompatibility and biostability. PEEK is radiotranslucent, which helps to monitor the growth of tissue and will avoid X-ray interference. You can also be quite competitive in pricing on large volumes with technologies like injection moulding.

It is also becoming more clinically acceptable to use surface coatings to meet special requirements. PEEK has actually been used in the medical field for more than 20 years now and has a good track record, but is still 'new' compared with metal or stainless steel.

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What are PEEK's key applications in terms of the devices and medical segments in which it is being used?

The breakthrough of PEEK was in the spinal market for spacers/cages. In this field, it replaced, in most cases, traditional materials like titanium. After proof of concept in this application, many other applications opened the door for PEEK. Growing applications include suture anchors, interference screws, cranial implants and small bone deformity repair. Our business has even seen a lot of growth in unique cutting-edge applications such as cardiovascular, sleep apnoea and cancer treatment devices.

The primary material form has historically been extruded rods, where implants are machined from. However, there is a growing interest in using resin/granules for moulding implants where possible. This allows for less waste than using a machining process. The X-ray transparency and mechanical properties close to cortical bone have made PEEK one of the preferred materials.



Evonik's VESTAKEEP PEEK used in implantable spinal spacers.

The use of 3D printing to create medical devices, particularly patient-specific implants, is growing rapidly. Which of Evonik's PEEK products are best suited to 3D printing and how are they being used?

3D printing is in everybody's mind today. It is an evolving technology and, right now, it's unclear which medical segments and applications will become mainstream in the long term. There is a belief that everything will be possible in 3D printing one day and, at Evonik, we have multiple divisions working on different solutions.

I think that the most important thing is to really understand the opportunities and limitations of 3D printing. Evonik has technical-grade PEEK that can be 3D printed in a selective laser sintering (SLS) process. However, it is also true that the mechanical properties of this are vastly different to that of other PEEK processing technologies like injection moulding or extrusion. So, let's say the market is interesting but still has to be developed.

How else could you envisage 3D printing being used with your materials in future?

Outside PEEK, the major material being used in 3D printing in the SLS process is VESTAMID. For example, patient-specific drilling guides are a high-volume application. In combination with an X-ray scan, this technology opens up a new field of treatments specialised to the individual patient. When you have a part-number quantity of one, 3D printing is always a good option to consider. And, as all humans are unique, patient-specific solutions are always a quantity of one.

What other trends are influencing the way Evonik's products are being employed within medical devices and implants?

On one hand, populations are becoming older, but on the other, they are more active than ever before. This is something that medical-device manufacturers are taking into account when developing new applications. As a consequence, implants have to last longer, meaning you have to use the best materials you can find. Because of this, PEEK is more often entering the discussion.

Then, there is the topic of cost. Other regions of the world are developing economically and asking for higher-quality products, but are still not able to spend as much as the US or Europe can. This means the pricing of products is becoming more critical, which is another reason why injection-moulding technologies are increasingly being considered.

Earlier this year, the US Federal Trade Commission voted in favour of open competition in the US PEEK market. How are you responding to this new opportunity, and how could it benefit OEMs based in the US?

This is a new ball game: it changes the whole industry and introduces the possibility of engaging with large and medium-sized companies from a completely different perspective. That simply wasn't possible before. I think it is a great development – not only for us, but also for medical-device companies. It creates competition and makes it easier for US companies to choose their PEEK suppliers, and even change suppliers if they are not satisfied.

Our project pipeline has increased dramatically since the FTC decision and we are supporting more customers than ever that would like to change their existing supply chain.

How prepared is Evonik for the potential growth in US business; for example, with regard to US FDA approvals across its PEEK range?

Evonik's VESTAKEEP implant, Grade PEEK, is already used in many different applications cleared by FDA. This year, we expect to surpass the mark of 50 customer applications that have referenced our Drug Master File with FDA and gained clearance.

Along with spinal implants, we are also active in applications such as crano-maxillofacial, sports medicine, trauma and cardiovascular. We have a dedicated sales force in the US, with headquarters in Parsippany, New Jersey; and we are always ready to take new orders.

Evonik debuted a new polymer technology that adheres directly to modified fluorinated ethylene-propylene copolymer (EFEP) in 2014. What are the advantages of this system?

A catheter, which requires a balance of lubricity, low surface energy, chemical resistance, torque control, kink resistance and biocompatibility, could use a combination of materials.



High thermal and chemical resistance: Evonik's VESTAKEEP brand of PEEK polymers.

One such option would include using the Daikin-modified EFEP and a modified PEBA from Evonik. This material combination provides a direct bond and adhesion between the two materials, eliminating the need for adhesives or secondary manufacturing operations.

Last time you spoke to *Medical Device Developments*, Evonik was looking to expand into two new fields: dental and sports medicine. How are things progressing here?

Things are going well in these new fields. We have become an approved supplier of one of the largest sports-medicine companies in the world and our footprint in this segment continues to grow with small and medium-sized players. We have also increased our material portfolio to provide a more ductile grade in this niche market, where PEEK that is too brittle may not work for new creative designs.

We also entered the dental market successfully. The growth driver has been in Europe, but we are also seeing some interest jumping over to the US. In the dental market, we modified our portfolio to customer requirements and developed tooth colour, and other colours and grades.

Do you have any other upcoming developments you would like to share?

We are full of ideas and our product pipeline is fully loaded. It is important for us to focus on the right projects and establish priorities for achieving these. For the moment, I can't share too much, but we have several projects up and running in our development house in Alabama that we hope to turn into new business soon. ■

Further information

Evonik
www.evonik.com/vestakeep-medical

