

Customised materials for flexible use

Device designers are constantly on the lookout for versatile plastics to enhance biocompatibility. Customised products need an expert distributor to continually supply the devices market.

Medical TPUs (Thermoplastic Polyurethane) can be used for many medical applications due to their high strength, biocompatibility, flexural endurance and processing versatility. They are appreciated by device designers who encounter demanding tissue or blood contact situations. Velox GmbH, based in Hamburg, Germany, specialises in the distribution of these highly versatile medical TPUs within Europe, produced by Lubrizol Advanced Materials Inc.

Medical TPUs can be used in applications where good strength or flexibility is needed, and offer good biocompatibility and processing versatility.

The company originally started out distributing the high barrier plastic Barex®, but discovered that it could fill a niche in the European market by sourcing other speciality raw materials such as special polymers. Instead of selling commodities it began offering global corporations one distribution partner with Europe-wide contacts.

Specialist offerings

'Concentrating on specialities means that for our principals, who make the raw materials, we act as their sales force; we can start with a project at its infancy,' explains Siobhan Bastiansen, product manager for

the medical market at Velox in Hamburg.

'We sit down with designers, knowing that the entire process could take three years or longer before any product will be bought from us. The customer needs small samples to begin with, onsite technical support and a long time for approvals, but we believe in each project.'

Velox has exclusive agreements with their manufacturing partners; they can expect Velox to act as their sales force. In return, the raw material producer is a close partner for the production of the raw material.

'They share their technical knowledge of the products, and we become their local technical experts, sharing with them our market and sales experience in Europe,' says Bastiansen.

Velox has three divisions: plastics, inks, and rubber and paints. The company's product range for medical applications also includes Barex, which is used for the packaging of surgical equipment and pharmaceutical products and NuSil which include implantable silicone fluids, gels, adhesives and elastomers. Medical TPUs are mainly used for catheter tubing and different types of devices which come into contact with blood and tissues. Other

applications include injection moulded pieces such as pacemaker leads, hubs and luer, and some more exotic applications like the root-filling pen device designed by Pfaff GmbH.

Advantages of TPUs

Medical TPUs can be used in applications where good strength or flexibility is needed, and offer good biocompatibility and processing versatility. TPUs come in a wide hardness range from very soft and flexible like silicone to hard like a rigid plastic. Velox can provide materials with a hardness range of between 72 Shore A and 84 Shore D.

TPUs are highly resistant to tension and stretching, have a good biocompatibility, are resistant to impact and show stability to hydrolysis and an elasticity even at low temperatures. They also can be sterilised by gamma rays and ethylene oxide and are versatile in processing.

'One benefit of our materials is that they are made in a batch system,' explains Bastiansen. 'In a batch system, as the raw materials are mixed to make the polymer, other additives can be introduced. This means that each mixture can be customised.'

'If a device designer wants their TPU in blue, or to have a certain percentage of radiopaque marker the custom additives can be dosed at the time of polymerisation. With many raw material suppliers, you don't get that flexibility. The batch system allows us to customise the product and make exactly what the medical device manufacturer needs.'

Velox supplies TPUs as standard products with 20% and 40% barium sulphate, so they can be seen under X-ray. The company is ISO-certified to the standards of ISO 9001: 2000, which is applied to the sale and distribution of raw materials. ●

company profile

Velox GmbH is a Hamburg based European distributor for specialist raw materials such as plastics, rubber, pain and ink. The company was founded by its managing directors Bernard Goursaud and Max Schlenzig in 1993 and employs a total of 92 people in 14 European countries. The company is active for more than 70 raw material suppliers worldwide.

further information

Website: www.velox.com

Small and safe

A German company has developed a revolutionary device that helps dentists save time when performing root canal procedures and minimises the risk of bacterial infections for patients.

Root canal treatment is one of the most feared dental procedures. Not only does it take a lot of time, it is often very painful and can end up in bacterial infection of the roots. This means another trip to the dentist and further expense. German company Pfaff GmbH System Innovation Spritzgiesstechnik has, in collaboration with the dentist Dr Karl-Friedrich Reichenbach, developed a revolutionary medical device which helps dentists to fill the root not only quickly – saving up to half an hour in treatment time – but also makes the root filling absolutely airtight and bacteria-free.

The pin is directly inserted into the root canal, the surrounding tooth warms the pin up to body temperature and the memory material stretches and fills the root canal completely and airtight. No bacteria can get into the root. Finally the entrance cavity is sealed with a normal plastic filling material.

No other instruments or machines are necessary, because the root-fill-pin can be inserted into the root canal with tweezers and the root filling can be inserted in one step. The biggest advantage of the pin is cost reduction, as further appointments are then unnecessary.

The cone-shaped pin is made from Carbothane® TPU – a flexible thermoplastic polyurethane which exhibits some memory properties.

Saving time and money

The cone-shaped pin is made from Carbothane® TPU – a flexible thermoplastic polyurethane which exhibits some memory properties and is produced in a plastic injection moulding process. Its exterior dimensions are 0.5mm (smaller radius) and 0.9mm (bigger radius) and it is 20mm long before the pin has been stretched.

The root-fill-pin replaces the traditionally used gutta-percha pins, where up to five pins are melted and injected to fill the root canal passages.

In Germany alone it is estimated that using this revolutionary root-fill-pin technique will result in savings of about €850 million.

Pfaff GmbH started the development of the root-fill-pin in 2005 and has received ongoing support from Velox, who supplied them with expertise and samples of TPUs to test, and Merck GmbH. Velox was recommended by the Technical University Berlin (Technische Universität Berlin), with whom the company works closely.

Flexible materials

Sourcing the right mix of plastic material proved to be challenging during the development of the pin. The TPU needed for the pin had to be of excellent biostability, otherwise it would be rejected by the patient and the dentist would have to take it out.

It also needs to have a very strong X-ray marker, because it is inserted deep into the jawbone and has to be hard and stay straight when inserted into the root cavity. A special Carbothane TPU grade has been chosen as having the correct mix of properties.

Furthermore, the polymer had to have a memory to return to its original shape and thickness, as Adolf Pfaff, managing director at Pfaff, explains: 'When the pin is injected into the root, it is stretched lengthways and changes its measurements. What would be normally 1mm radius on top and 0.5mm radius on the bottom end, changes to 0.8mm on top and 0.3mm on the bottom end when the pin is stretched.

'When the pin is inserted into the root canal and it reaches the body temperature of 36° Celsius, the pin returns to its original size, which means it presses itself firmly against the wall and makes the hole airtight. This is the big advantage of the memory material.'

The response to the root-fill-pin has so far been very positive. Developing the root-fill-pin has cost around €120,000. It is currently undergoing trials at the Freiburg Dental University Clinic under the supervision of Professor Hellwig and Dr. med. dent. Schirmeister. Once it is approved and a distribution partner has been found, the product will be available on the market in 2008. ●

company profile

Pfaff-GmbH System Innovation Spritzgiesstechnik was founded by Adolf Pfaff in 1992 and is based in Waldkirch in the Black Forest region of Germany. The company specialises in products for the medical market, technical products and drinking water technology. In 2006 managing director Adolf Pfaff was awarded the Freiburger Innovationspreis (Freiburg Innovation Prize) for the root fill pin device.

further information

Website: www.pfaff-sis.de