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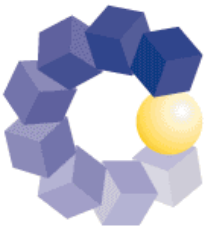

Press release No. 1 – COMPAMED 2011

Excellent feedback at the 5th COMPAMED Spring Convention – a taste of things to come at COMPAMED 2011

In the limelight: New materials, and how they are processed and tested

Medical technology is set to remain a German domain, at least until 2020. The trend report published by the Association for Electrical, Electronic and Information Technologies (VDE, Frankfurt am Main) for 2011, for which some 1,300 member companies and universities were surveyed, shows that Germany is the most innovative country in this field by a long way. Almost two thirds (64%) of respondents view Germany as having a clear lead on the USA (30%). The general consensus is that Germany will remain largely unchallenged until the end of the current decade, with 57% anticipating that medical technology made in Germany will defend its lead ahead of the USA (26%), the rest of Europe (9%) and emerging countries in Asia. This international comparison reveals the great importance of medical technology in Germany – especially against the backdrop of a dynamic and growing global health market and increasing competition between manufacturers.

These are also the reasons behind the increasing international interest in COMPAMED in Düsseldorf, the leading international trade fair for the suppliers' market in medical manufacturing. COMPAMED 2011, High tech solutions for medical technology (16 – 18 November), will take place in parallel with the world's largest medical trade fair, MEDICA 2011 (16 – 19 November), which will once again cover the entire medical technology supply chain – from materials and components to systems and intermediate products as well as complete systems and services. "On the basis of the excellent response and registrations to date, we expect to see at least 600 exhibitors and about 10,000 square metres of space to be booked in Halls 8a and 8b", predicts Joachim Schäfer, Managing Director at Messe Düsseldorf.

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As in previous years, the first key exchange of ideas on current trends in the industry took place at the COMPAMED Spring Convention, which was held in Frankfurt/Main on 10 May that was organised by Messe Düsseldorf and IVAM, the International Association of Microtechnology (Dortmund). With 90 participants this year, the Spring Convention grew by 50% relative to 2010.

The 5th meeting of its kind, the focus this time was on new materials, how they are processed and handled and on their use in medical devices. New plastics and metal alloys, ceramics and composites (composite materials) are often the starting point for innovations in medical technology. This is also the case for biodegradable polyester which is based on lactic acid and glycolic acid, produced under the brand name “RESOMER” by Evonik Röhm GmbH (Darmstadt). These polymeric materials are ideal for use as sutures, for screws, plates and nails, as slow-release drug carriers and also for stents. “The advantages of our polymers are obvious: The implants don’t need to be removed, they don’t cause any allergic reactions, are strong enough for the intended purpose, i.e. the time it takes a bone to heal, and are easy to sterilise”, emphasises Dr. Harald Liedtke, Head of Technical Marketing at Evonik Röhm. In addition to this, the length of time they remain in the body can easily be varied between a few weeks and up to more than 4 years by varying the copolymers used. Other ways of fine tuning them for tailor-made applications are the “toolkits” of monomers, variation of their position in the polymer chain, the microstructure of these chains, the molecular weight and the terminal groups – providing a wealth of ways of influencing the properties to synthesise the “ideal” molecule for a specific purpose.

PEEK – a polymer for implants subjected to mechanical loads

Polyetheretherketone, or PEEK for short, is another plastic that is enjoying a growing success story in medical technology – especially for implants that are subjected to mechanical loads. The material has been tested and approved for permanent use in human implants thanks to its good biocompatibility. “Our PEEK-OPTIMA offers an excellent and balanced combination of mechanical, physical and chemical properties”, explains Roland Gröger, Medical Market Development Manager at

Invibio Europe, who is responsible for dental, pharmaceutical and cardiovascular applications, in particular. Invibio Ltd. (Thornton Cleveleys, UK) is the market leader for this material for use in medical applications. Due to its semi-crystalline structure it has ideal X-ray properties and excellent radiolucency for computer and magnetic resonance tomography, without showing losses due to scattering or artefacts. Over and above this, this polymer also has another advantage, improving bonding between the bone and the implant as its elastic modulus is very similar to that of the outer cortical layer of the bone. In order to ensure purity and prevent infection, modern sterilisation methods use aggressive chemicals, elevated vapour pressures in autoclaves or high doses of radiation. Products made of PEEK-OPTIMA give the user great freedom in this respect, since they are suitable for use with any of the common methods of sterilisation, which is another reason why PEEK has taken over some 80 – 90% of the market from titanium in some areas.

Many new materials that actually have good properties fail because they cannot be processed or machined in order to be used for the intended purpose. For this reason, The Fraunhofer Institute for Manufacturing Technology and Advanced Materials (IFAM, Bremen) has developed a powder injection moulding process for biocompatible materials. “The process is available for serial production and allows highly complex parts to be made even without the need for machining to finish them”, explains Dr. Philipp Imgrund, Head of the Department of Biomaterials Technology at the IFAM. In the process also referred to as “metal injection moulding” (MIM), metal powder is mixed with an organic binder system at a ratio of 65 to 35 percent, although the binder is then removed again when it is melted and formed. It is then sintered to consolidate it to its final density. In addition to using various metals, this method can also be performed using ceramics such as alumina, zirconia or hydroxyapatite (HA). HA is a component of natural bone and is biodegradable. “Mixtures of HA and polylactic acid are especially interesting, as the mechanical properties of dense composite materials of this kind are extremely similar to human bone material”, says Imgrund. The first potential uses are interference screws for fixation of cruciate ligaments in the knee. Microstructuring of parts made using the

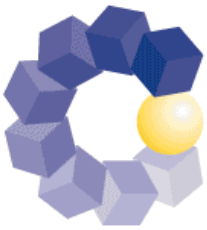
MIM process improves their bioactivity and governs tissue-specific cell behaviour.

Cardiovascular implants – a market worth billions

The global market for cardiovascular implants is currently estimated to be worth around 15 billion dollars – making it extremely attractive. On top of this, surface coating techniques for catheters and stents are a field of growing importance, as they make novel and personalised therapy and medical treatment possible. “Coatings increase the functionality, lifetime and cost effectiveness, improve the guidance and positioning of the parts, as well as making them easier to handle and reducing the risk of injury to the patient”, says Professor Hans-Wilhelm Engels, Head of the Innovation Community Council and Head of Innovation & Specialties at Bayer MaterialScience, where he is responsible for materials for medical devices. The materials that can be used for coatings include hydrophilic and hydrophobic polymers such as polyvinylpyrrolidone (PVP), polyethylene glycol/polyethylene oxide (PEG/PEO), polyvinyl alcohol (PVA) and hyaluronic acid. Since many of these compounds are water soluble they need to be stabilised by cross-linking. Just recently, Bayer presented “Baymedix CD 500”, a new coatings platform for tailored drug release. These stable coatings make it possible to release a wide variety of different drugs, ranging from tiny molecules up to protein therapeutics, in a controlled way. The biocompatibility of these systems has been demonstrated both by in vitro as well as in vivo tests. “Over and above this, we are also already working on optimised systems for biodegradable stents”, Engels adds.

Surface roughness – 3D measurement on the nanoscale

One of the decisive factors for the quality of implants, apart from selecting the right material, is achieving the ideal surface structure. For instance, the biocompatibility is clearly dependent on the surface roughness. This is especially the case for dental implants, where the roughness on the nanoscale (a billionth of a metre) is decisive for the protein binding capacity and thus for the speed at which they can grow into the jaw bone. In the light of this, Alicona Imaging GmbH (from Grambach near Graz, Austria) has developed an innovative 3D surface measurement technique that is ideally suited to the surface



characterisation of implants. “In order to perform the measurement cost effectively it is necessary to measure all of the relevant parameters with a single measuring system, and that is precisely what our InfiniteFocus is capable of doing”, explains Dr. Stefan Scherer, CEO of Alicona. It combines the possibilities presented by a Roughness Gauge with those of a form measuring instruments, thus offering all of the functions of an optical profilometer as well as a micro coordinate machine. Even for complex forms and different material properties, the user can achieve a resolution of as fine as 10 nanometres, even across large vertical and lateral scanning ranges. For complete measurement of the form it also has an optional rotation unit that can turn the sample through 360°. “We aren’t aware of any other optical measuring system like it, which can provide such well-founded information on the roughness, even over large measuring ranges”, says Dr. Frank Rupp, Head of the “Interface Analysis of Medical Materials” working group at the polyclinic in Tübingen.

Time to “split hairs”

New materials and other developments call for new processing methods, especially in medical technology. For instance, the diameter of standard stents is between 1.6 and 2.0 millimetres, but that of new versions in the coronary area is just between 0.2 and 0.6 millimetres. This demands novel cutting methods with a cut width of less than 20 micrometres, just as the use of polymers does. “Here we can justifiably talk about splitting hairs, because a human hair is two to three times as thick”, explains Dieter Mairhörmann, Sales Manager Medical Industry at ROFIN-BAASEL Lasertechnik GmbH & Co. KG in Starnberg. To make such fine and high precision cuts in plastics, ROFIN uses what are known as femtosecond lasers, which allow cold material processing, avoiding the normal thermal process. ROFIN sells its technology under the trade name “StarFemto”, which it claims is the most advanced laser system in the world and is capable of cutting both polymers as well as metals such as stainless steel, platinum and Nitinol while remaining within the tight manufacturing tolerances of less than the width of a human hair.

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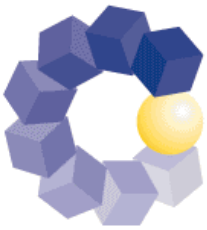

The record number of participants on the one hand and the intense interest in questions and discussion on the other show just how current the topics covered at the 5th COMPAMED Spring Forum were, making it an excellent start ahead of COMPAMED 2011. The slogan In Düsseldorf for this coming November is thus: To be continued!

Information on COMPAMED 2011, exhibitors and their products is available online from: http://www.compamed.de

Editorial note: Klaus Jopp, freelance technical writer for science and technology, Hamburg

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