

In 2010, more than 950 exhibitors from a total of 32 countries presented their products, machinery, technologies and services at Medtec

(photo: UBM Canon)

Biocompatible Thanks to the Process

Trends at the Exhibition. In the medical device field, materials and end products must satisfy extremely demanding requirements. Adhesives are being used to an ever-increasing degree to join individual components, with a trend toward techniques employing light-curing adhesives

PETER KLINGAUF

It is undeniable that the differences between materials serve as the driving force behind product development – especially in the field of medical devices. Here, the requirement profile is particularly complex: in almost no other sector do the safety of the materials used, the manufacturing process employed and the efficacy of the final products have such an important role.

According to information from the Association of German Engineers (Verein Deutscher Ingenieure; VDI) more than half of all medical products are made from plastic. The versatility of this class of materials makes it almost universally

Translated from *Kunststoffe* 2/2011, pp. 105–107

Article as PDF-File at www.kunststoffe-international.com; Document Number: PE110685

useful. Plastics are found in the form of containers that hold infusion solutions, components in the medical devices, syringes, bandages, catheters, tubing and implants. Behind the scenes, adhesives play a key role. Recent developments and advances in medical technology will be demonstrated by the exhibitors at Medtec Europe 2011, which is being held from March 22–24 in Stuttgart, Germany (Title photo and Fig. 1).

Adhesive Bonding as an Alternative to Other Joining Techniques

Inexpensive plastics and their flexible relatives, elastomers, are our preferred materials when it comes to medical devices. Adhesives are ideal for bonding these materials, and even glass, metal, ceramics and paper can be bonded not only with plas-



Fig. 1. Gregor Bischof, manager of the Medtec Europe Trade Fair at UBM Canon, explains: "Plastics processing has been an important component of the medical technology trade fair for years." (photo: UBM Canon)

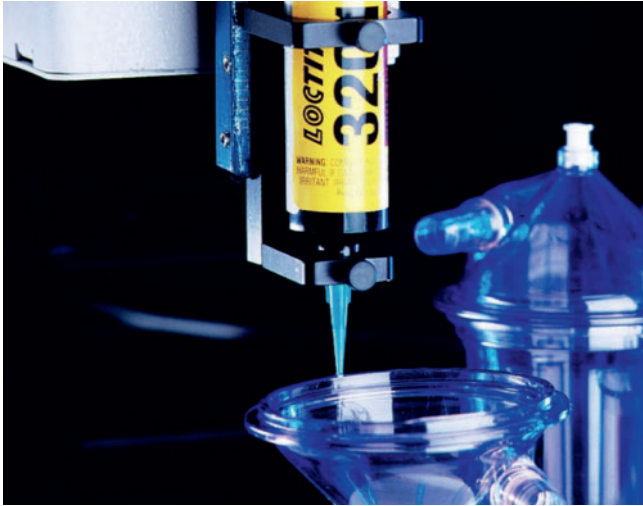


Fig. 2. Under the Loctite brand, Henkel offers a wide range of special adhesives developed specifically for manufacturing medical items such as syringes, catheters, blood filters and cannulae
(photo: Henkel)

equipment for dispensing, curing and monitoring. According to the manufacturer, the modular equipment available under the Loctite brand guarantees bubble-free dispensing to ensure compliance with the high standards for reliability that apply to medical products. In addition, depending on the application, different light-curing systems are available for irradiation of large areas or pinpoint targets.

Biocompatibility Testing

New materials such as function plastics or matrix materials are becoming increasingly important as well. However, before they can be marketed, the manufacturer must demonstrate their safety. The materials must be biocompatible, either as temporary implants, such as catheters, or as long-term implants, such as artificial joints. For materials in contact with living tissue, special requirements must be satisfied: The material must not injure the organism, and, conversely, the biological environment must not compromise the properties of the plastic.

Testing of biomaterials and medical products for their biocompatibility is performed by a testing laboratory (Fig. 3). De-

tics but also with each other. “Adhesive bonding can, in the meantime, be used as an alternative for all other joining techniques”, states Dr. Hermann Handwerker, director of European applications technology for Loctite Adhesives at Henkel AG & Co. KGaA, Düsseldorf, Germany. Today, adhesive bonding is the preferred technique in applications previously involving clamping, screwing or welding. In contrast to other approaches, use of adhesives is not only more practical, but also provides a stronger and more uniform bond between materials explained Dr. Handwerker. At the same time, the range of materials available increases without having to accept any decrease in product appearance (Fig. 2).

In principle, the applications for adhesives are almost unlimited in the field of medical technology. Moreover, surface treatments that ensure good adhesion even between difficult to bond materials such as polypropylene or polyethylene have been developed.

Light-curing Adhesive Bonding Techniques

Light-curing adhesives are playing an ever more important role. This will be seen at the exhibition. They are ideal for bonding clear and transparent materials with a so-called perfect appearance. The adhesives cure within seconds when exposed to UV radiation or visible light without any additional introduction of heat. In addition, they are fluorescent. In conjunction with their rapid processing, these adhesives permit comprehensive in-line monitoring at maximum productivity. Furthermore, they remain liquid until irradiated, allowing exact alignment of the parts to be bonded prior to curing. Because they are a single-component sys-

tem, time-consuming and costly mixing is eliminated.

Four major factors must be observed for industrial processing of light-curing adhesives: the emission spectrum of the curing system, the intensity of the light, the transparency of the materials to be bonded and required curing properties. Selection of the equipment used and configuring the equipment for the particular adhesive are essential for the quality of the adhesive joint. In addition to adhesives, Henkel offers the necessary



Fig. 3. The biocompatibility of plastics is assessed in testing laboratories. This allows mistakes during product development to be avoided early on
(photo: BMP)



Fig. 4. The all-electric injection molding machine satisfies the requirements for use in a cleanroom. At the trade fair, polystyrene Petri dishes (right) were molded using an 8+8-cavity mold (supplier: Plastisud, Castelnaudary, France) at a cycle time of 3.6 s (photos: Engel)

pending on the application for the material or the product, individual test areas are selected as part of a testing strategy. Several service providers around the world have specialized in tests of this sort, e.g. BMP Labor für medizinische Materialprüfung GmbH in Aachen, Germany. Depending on the type of contact in the patient and its duration, the compatibility is tested with respect to cells, blood or tissue on the basis of selected parts of the Standard DIN EN ISO 10993.

Risks for the patient and expensive mistakes during development can be avoided if these testing laboratories become part of the product development process long before clinical trials. In the experience of BMP, there is often insufficient attention devoted to the effects of the combination of individual components, the sterilization process and preparation of the product. It is not uncommon to find bioincompatibilities in the end product that would have detected if the company had started testing earlier.

Production under Cleanroom Conditions

The production environment requires special attention as well. High product integrity, absolute cleanliness and precision during manufacturing as well as complete documentation and traceability are essential requirements. With this in mind, the medical area of Engel Austria GmbH, Schwertberg, Austria, has developed a number of features such as the patented exhaust system of the machine barrel. Thanks to the exhaust system, hardly any particles or heat escape from the machine

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into the cleanroom. The injection molding machine manufacturer will be appearing at the exhibition for the first time this year.

The fully covered ways of the tiebarless "victory" injection molding machine are also targeted at ensuring cleanliness. Thanks to these covers, the clamping unit is entirely grease-free. In the estimate of Christoph Lhota, manager of the medical group, "the trend is to fully electric machines with appropriate capabilities on both the injection and clamp ends". For this reason, the company is exhibiting a fully electric system based on the "e-motion" series with high-speed clamping and ejector motions (Fig. 4). The

engineering required was "enormous", stated Lhota, but the result justified the investment: compared to a conventional hydraulic injection molding machine, the system produces Petri dishes at 25 % higher output and 65 % less energy.

Coatings and Miniaturization

Modification of plastic surfaces opens up additional fields of application, but these entail risks as well. For instance, plastics with antibacterial or antimicrobial coatings have been developed in recent years. This type of surface modification is intended to affect the behavior of or kill bacteria or other microorganisms. Cells and tissue, on the other hand, must not be affected adversely by the type of coating under any circumstances. For this reason, "the biocompatibility of these coatings must be established already during the development stage", states Dr. Ute Müller, general manager of BMP.

The potential of adhesives has also not yet been exploited completely. As a case in point, Dr. Handwerker points to miniaturization: "Without this joining technique, it would not have been possible to reduce the diameter of a syringe cannula to today's user-friendly size". Last but not least, the usually colorless adhesives used in the medical field are beneficial from an esthetic standpoint. ■

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