There is a need for new ideas for material, design, and production technologies. More than half of sales are achieved with products that are no older than three years. (Figure: Oechsler)

# CLEAN ROOM ENGINEERING AS WINDOW OF OPPORTUNITY

**SPECIAL PLASTICS OPEN DOORS TO NEW APPLICATIONS IN MEDICAL TECHNOLOGY Thanks to a high level of manufacturing competence, quality and flexibility, a position of leadership in the global medical technology market is within close reach of the German plastics industry.**

Next to Japan, Germany has the second largest medical device market in the world and has one of the best-functioning and best-funded health care systems. With a volume of expenditure of about Euro 240b per annum (about 11 % of GNP) this area employs about 4.26 million people. Since 2005 about 3 000 new patent applications in the medical sector have been registered annually in Germany. Above all, the area of medical technology has developed into an innovative high-tech industry. The pronounced innovative spirit of this industry is also apparent from the high level of investment in research and development, which, at 8%, is about twice as high as the industrial average. More than half of sales are achieved with products that are no older than three years.


## Authors

Dr. Wolfgang Sening, Manager Cluster Medizintechnik, Forum MedTech Pharma, Bayern Innovativ Office, Nürnberg, Tel. +49 (0)911/20671337
Dr. Jörn Leewe, Managing Director, Novumed Life Science Consulting, München, Tel. +49 (0)89/94469010


The medical technology sector is an increasingly attractive market for special plastic grades and their processors. Their share of the total volume of plastics processed in Germany – about Euro 50b – was about 1.5 % in 2005 and is steadily growing. Thus in 2005 about 50 % of all materials used in medical technology were plastics. Of the total, about 60 % were for consumables (hygiene sector 20 %, wound treatment 4 %, syringes and catheters 20 %, laboratory articles 3 %, dressing materials 14 %). At the same time, the overall market for pharmaceutical packaging is also booming and will reach about Euro 16.3b in 2007, about two thirds of which will be accounted for by plastics.

### Biocompatible Plastics Gaining Importance

The market offers a highly promising area of application, above all for biocompatible plastics. They have already reached a share of 5 % in the dental sector, 12 % in diagnostic systems, 10 % in surgical instruments, and 12 % in X-ray equipment. For extracorporeal applications cheaper plastics are generally used – PS, PC, and other materials have a joint market share of about 92 % – whereas high performance plastics are mainly used for intracorporeal applications – market share about 8 %, e.g. PTFE and PEEK.

There is a great need for new ideas for material, design, and production technologies for such varied applications as implants, stitching materials, or multifunctional components. However, the demands placed on the materials are very rigorous owing to the steadily increasing body of regulations in medical technology. Because of the specialist knowledge required and the expense involved only about 16 % of German injection moulders (Switzerland: 28 %) currently process plastics for medical technology in clean rooms. Some 37 % of German injection moulding companies (Switzerland: 26 %) manufacture for medical technology but do without clean room production. According to analyses conducted by the international network Forum MedTech Pharma with 550 corporate members and by Novumed Life Science Consulting, this is due to change in the medium to long term. A significant increase in investment by plastics processors in clean room production has already been noted. ■