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Injection moulding: Innovation driver in medical technology

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Injection-moulded plastic parts are part and parcel of everyday life. Be they mobile phone casings, beverage crates, toy figures, gearwheels for adjustment mechanisms, bumpers on cars, drinking cups, CDs and DVDs, or syringe bodies in medical technology, injection mouldings are encountered everywhere in all sizes, ranging from a few micrograms to several kilograms. Uniting several components in a single injection moulding, integrating as many functions as possible in a single component, and converting production methods comprising several steps into a single-stage process – these are the chief innovation goals in the injection moulding sector.

It is in medical technology above all that injection moulding offers scope for endless possibilities. Along with ongoing progress in process engineering, the development of new types of materials is opening up additional fields of application. Sterilisability, biocompatibility, antimicrobial finishes, special barrier properties, nano- and microsystems technology, and biodegradable and absorbable materials are just some of the key areas in which materials developers are advancing progress in this vital field. Medical technology will continue to be a sector with an exciting future and a driving force for wide-ranging innovation.

However, anyone wanting to gain a foothold in medical technology has to be not only innovative and engage in high-quality and cost-effective production, but also master the guidelines that additionally apply in this sector.

Safety across the board
Compared to other sectors, the standard of quality and documentation here is outstanding. Production to GMP guidelines is a must. Continuous monitoring, compliance with the hygiene regulations and the full documentation of all process data over a period of years are integral to these guidelines.

In view of these requirements, the status of component supplier to medical technology obviously is not something that can be acquired overnight. "The rules that apply here have to be mastered and embraced throughout the company organisation. Smaller companies, in particular, are often at a disadvantage in that they cannot afford to go to these lengths. However, anyone who gains a foothold here has a pretty secure position, because switching suppliers also involves a high degree of regulatory effort," says Christoph Brand, General Manager of **Polymec AG** in Langendorf, Switzerland, explaining the situation from the point of view of a supplier certified to ISO 13485.

Under these conditions, it goes without saying that product development takes place in extremely close cooperation between the medical technology or pharmaceutical company on the one hand and the supplier on the other. Systems suppliers are in a strong position particularly on this market. Numerous suppliers provide a full one-stop service covering everything from the development and production of the injection moulds to the injection moulding process itself and the assembly, packaging and inspection of the medical technology products.

Cleanliness from start to finish
The production of medical and pharmaceutical injection mouldings is closely associated with cleanroom technology.

KraussMaffei EX injection moulding machine

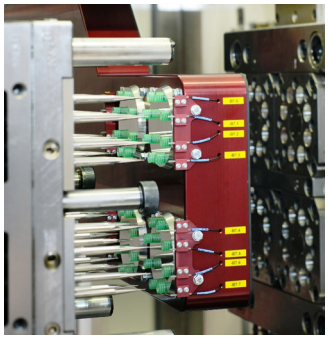
Whether these are single-use products such as syringes and pipette tips or functional components such as inhalers, the demand is always for hygienically impeccable products with 100% quality. For this, the manufacturers of injection moulding machines get together with cleanroom specialists to offer a variety of cleanroom solutions tailored to the article being produced and factory conditions. A simple and inexpensive approach is the mounting of a laminar-flow unit over the clamping plates for the injection mould. This excludes any exchange with unclean outside air. The injection moulding machine itself stays in the gray room and the injection mouldings are fed for further processing via an airlock into the cleanroom proper. Even if a cleanroom tent is placed over parts of the injection moulder, the latter can still be operated from outside the cleanroom. The most elaborate solution involves the operation of the injection moulding machine in the cleanroom itself. Along with operating staff wearing special clothing, the machines and moulds themselves are also potential sources of particulate contaminants. The all-electric injection moulding machines now rapidly gaining ground can fully exploit their advantages here. Compared to conventional hydraulic machines, they generate barely any waste heat and, as a result of their encapsulated drive units, are free of lubricants and other abraded particles that might contaminate the injection mouldings.

Rexam Pharma GmbH, for instance, appreciates the benefits of electric injection moulding machines at its plant in Neuenburg (Germany). The plant specialising entirely in the production of medical and pharmaceutical articles operates with almost one hundred injection moulding machines in a cleanroom. Among them are **EX** fully electric injection moulders from **KraussMaffei Technologies GmbH,** Munich (Germany). The managers value not only the machines' reliability and cleanliness, but also their process control which is more precise and easier to adjust than that of hydraulic machines.

Mass production with maximum precision
Last year, at its Küssnacht plant in Switzerland, **Gerresheimer Medical Plastic Systems** also started gradually replacing its lines for the production of cuvettes with new high-performance equipment – including fully electric **Elion** injection moulding machines from **Netstal-Maschinen AG,** Näfels, Switzerland. Gerresheimer manufactures these cuvettes on behalf of a leading diagnostics group.

Elion 1750 injection moulding machine
from Netstal-Maschinen AG

These single-use articles are employed in photometric laboratory tests, among other things for identifying the blood groups of donor or transfusion blood. The optical components have to meet extreme quality standards. They must not react with the test substances employed nor show any shortcomings such as impurities or scratches. Furthermore, continuity of supplies must be assured, because delivery bottlenecks might make the performance of vital tests impossible.



Cleanroom-compatible
removal gripper from
Hekuma GmbH

Single-use medical articles are items that are usually mass-produced fully automatically and to an exceptionally high standard of

quality under 100% quality control. For production to be cost-effective, every tenth of a second counts. The manufacturers of the necessary automation systems are constantly refining their handling strategies. The requisite speed is provided by ever lighter and slimmer removal systems with optimised drives. An extremely fast cleanroom-compatible removal gripper was launched by **Hekuma GmbH,** Eching (Germany), at the end of 2009. What the supplier claims to be the fastest removal system currently available for pipette tips achieves with its linear axis acceleration rates up to 10 g and travel speeds of up to 1,200 mm/s. Within just 0.25 seconds, this removal gripper enters the injection mould, removes the pipettes from a 32-cavity mould, carries out a presence check and exits the mould again.

The injection moulds used for the mass production of medical technology items also of course have to be highly precise, cleanroom-compatible and at the same time economical. Along with the realisation of thin-walled products to save materials and cycle time, there is also a demand for multiple cavities and sophisticated cooling systems. Multi-level moulds with up to 192 + 192 cavities are made, for example, by the Swiss mouldmaker **Schöttli AG** from Diessenhofen. Over 90 % of their cleanroom-compatible moulds for medical technology components are exported.

Injection mouldings in the human body

However, it is not only single-use items that originate in the injection mould. For when it comes to replacement parts for the human body, injection moulding is a preferred process. Particularly spectacular are "components" for use in the inner organs. For instance, the Moscow-based company **Roscardioinvest** produces a new generation of tri-leaflet heart valves from a modified polyamide. The mechanical heart valve weighing only 0.25 g proved to be a severe test for its developers. The main challenge was to design the mould in such a way that the valves are free of sprue and ejector marks. This is absolutely essential so that neither clots nor turbulence can form at the mechanical cardiac valve. Until now, the only way to achieve this was by subsequently polishing the valves. The world's first mould for the fully automatic, finishing-free injection moulding of such heart valve leaflets has been developed and made by **Köbelin Formenbau GmbH,** Eichstetten (Germany). The mould was approved for series production last year.

Microtechnology for the tiniest parts and structures

Numerous high-precision components find their way into the human body by other avenues, among them components for use in minimally invasive surgery. Such functional parts are becoming steadily smaller, more complex and more precise – the trend towards miniaturisation in medical technology is advancing apace. **BCR Plastics AG** in Vallorbe in Switzerland, for example, manufactures miniaturised guide elements for stents that can only be viewed properly under a magnifying glass.

Microtechnology also plays a major role in diagnostics. Microstructures are required here particularly in microfluidics. A fine example is the "lab-on-a-chip", which is a miniature analysis system with a network of intelligently interconnected microchannels. These are far less expensive to produce from plastics than from glass or silicon. Working in this field since 1999, **Greiner Bio-One GmbH** in Frickenhausen (Germany) has engineered highly diversified microfluidic product solutions and engages in extensive research.

Microscopically small surface structures can be utilised in implant technology for the controlled growth of human cells. Scientists at the **Fraunhofer Institute for Manufacturing Technology and Applied Materials Research (IFAM)** in Bremen (Germany) are busy investigating suitable solutions made of plastics, ceramics and metal. For all three materials groups, IFAM makes use of injection moulding technology and operates a Microsystem 50 from **Wittmann Battenfeld GmbH,** Kottingbrunn, Austria for this purpose. IFAM's researchers focus not only on microstructured surfaces, but also on ultra-small implants. By applying micro metal injection moulding (µ-MIM), they thus produce delicate heart valve rings made of biocompatible titanium. And even replicas of the tiniest bone in the human body, the stirrup in the ear, can be produced in series as micro injection-mouldings made of titanium, biocompatible stainless steel or aluminium oxide.

These and many other examples show that injection moulding technology is playing an increasingly important role in the health sector. With innovative product developments, it has captured for itself a large market with huge growth potential. And not least thanks to the long-term supply agreements customary in the health industry sector, medical technology is becoming increasingly attractive for many suppliers.

As the world's leading trade fair for the plastics industry, K 2010 – Plastics and Rubber – will present the latest state of materials, machine and mould technology for the production of medical and medical technology plastic components. K 2010 is taking place in Düsseldorf from 27 October to 3 November 2010.

Adresse:
http://www.gupta-verlag.com/rubber/news/k-2010/8381/injection-moulding-innovation-driver-in-medical-technology