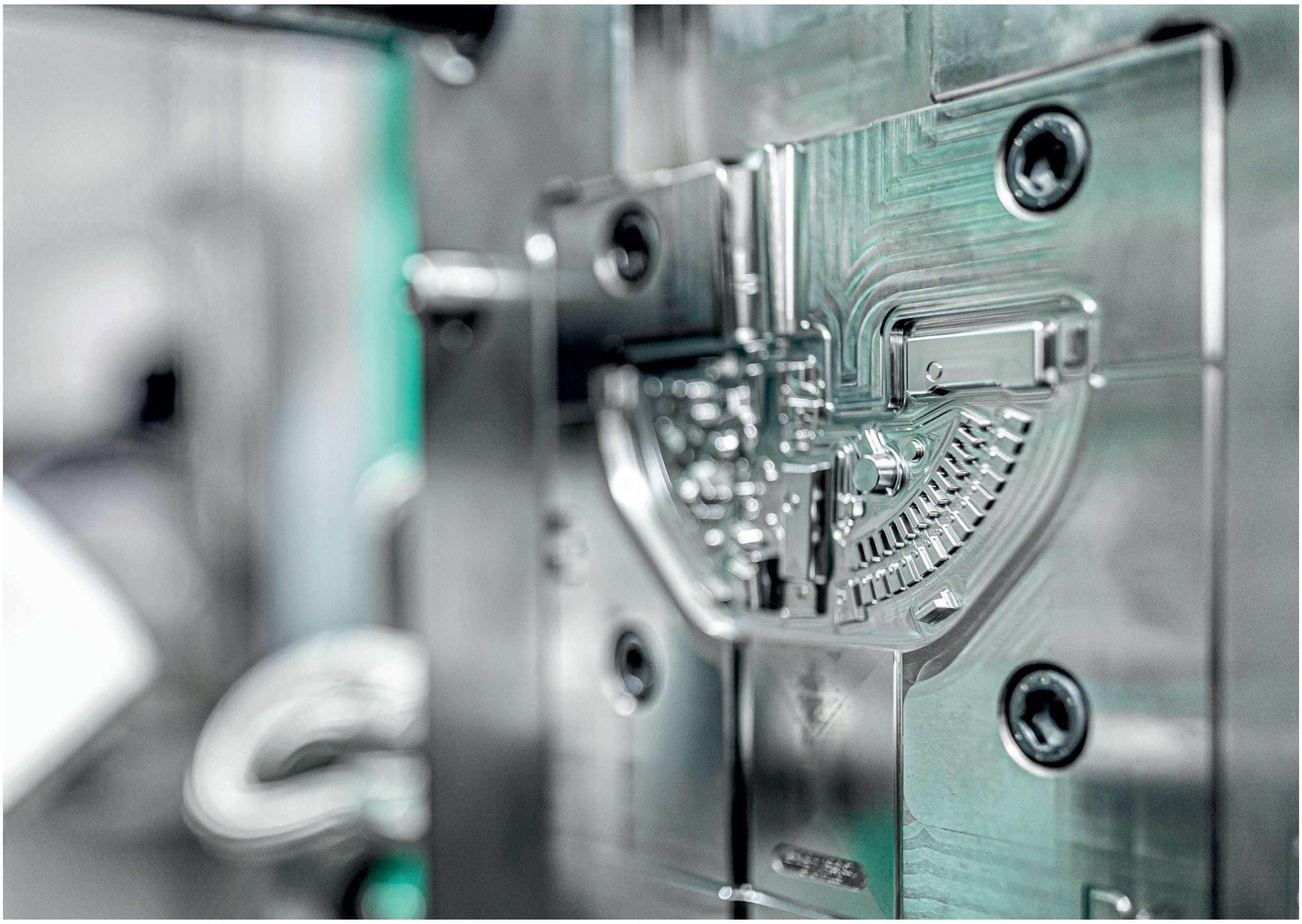
Manufacturing Materials to Laboratory Standards

Plastics: the Obvious Choice

High transparency, materials and processes that are cleanroom-suitable: such challenges in the production of laboratory materials demand enormous know-how in mold making. Rodinger Kunststoff-Technik supports their customers all the way from product development and prototype molds to a product ready for serial production.



Tiny structures in the cavity of a Lab-on-a-Chip cartridge: complex and filigree geometries such as these can be efficiently manufactured by injection molding thanks to high-precision mold technology and special plastics. © RKT

Plastic is the material of choice in medical technology: beginning with packaging products, from the external components of an insulin pen, to single-use diagnostic articles and products that come in contact with substances that are later reintroduced to the body. Different areas for the application of plastics have their own regulations and approvals that are listed according to their Medical Grades. Fundamental requirements for Medical Grade Plastics include complete traceability of products and raw materials used, biocompatibility, chemical resistance, sterilizability, and security of supply.

Even though plastics later dominate serial production, they are often tested under laboratory conditions against alternative materials such as glass, metal, or silicone during the development phase. To begin with, and mainly for reasons of economy and availability of such products, standard items are used that are already on the market. These include, among other things, petri dishes, titer plates, cuvettes, or glass slides. Since processes are analyzed in the laboratory, whether by microscopy, camera technology, or fluorescence measurement, transparency is one of the main challenges to the materials used, which is primarily given with glass. Plastics also come in transparent varieties. Nonetheless, glass exhibits a somewhat higher transparency.

In many cases of application, such as complex LabChips, however, standard items are unsuitable for principal trials.

When it comes to detailed process development for series production, complex geometries and microfluidic channels require different materials, such as special plastics. They enable such filigree structures to be produced with a low energy input.

First prototypes can be created by deep-drawing or with silicone or synthetic resin casts. Here the one-off costs of the molding tools are manageable. By contrast, the production of plastic parts for a laboratory environment is relatively complex and brings qualitative compromises with it. Once serial production by injection molding finally begins, the cost ratio is exactly the opposite: the investment in a mold is high, but plastic parts can be produced with it in large quantities with high reproducibility.

Compromises in Optics and Freedom of Design

The use of plastics in the serial production of medical and diagnostic products can involve certain restrictions. Challenges may arise especially where the optics are involved. To be sure, there are some very transparent plastics, but they cannot compete with the optical properties of glass. There are also limitations to freedom of design. Parts that are to be injection molded always have to be designed for easy demolding. Moreover, the required demolding angles also limit freedom of design. Part walls always have to be angled slightly in the direction of demolding, generally 0.5 to 3°, in rare cases up to 10°. "This is scarcely visible to the naked eye, but absolutely necessary for demolding," explains Harald Höcherl, Head of Processing Technology at Rodinger Kunststoff-Technik GmbH (RKT). "But, as a rule, these preconditions don't give us any production problems."

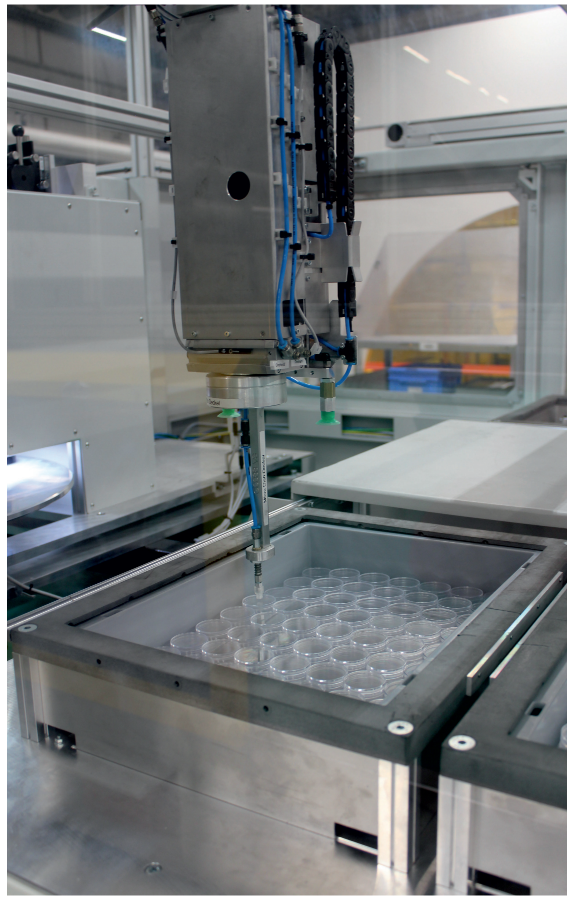
Which Plastics are Medically Compatible?

Which plastic is suited for which medical or medical-technical application is an open question. COC plastics are often used in medical technology – diagnostics in particular – since they are highly transparent, exhibit very low optical anisotropies, and are also biocompatible. Where mass-produced or disposable items are involved, mainly standard plastics such as PP, PE, or PS are chosen, their mechanical properties permitting. Parts with high mechanical specifications, for example, the interior of insulin pens, are manufactured from engineering thermoplastics, such as POM, PA, or PPA. To substitute for metals, engineering plastics with high fiber contents (glass fiber or carbon fiber) are favored. Housing parts are generally produced from impact resistant plastics, such as ABS, PC/ABS, polyamides or PBT.

"When any number of different plastics are processed, it all depends on which particular technical finesse and tricks are needed to achieve the best result with each plastic." comments Harald Höcherl. For example, an especially small part can prove a challenge to machine technology if it requires special equipment to be injection molded. On the other hand, there is a trick that prevents transparent COC plastics from yellowing. Harald Höcherl: "COC is very sensitive to oxygen and combines with the same during the melting phase, resulting in yellowing. That is why the surrounding air has to be flooded with nitrogen when it is processed. This keeps oxygen away during the melting process." Beyond that, COC is relatively brittle and subject to stress cracking. This calls for a somewhat sharper angle of demolding. Cleanroom requirements also present a challenge for specific diagnostics parts. Depending on customer specifications, it must be determined which cleanroom class the product requires, and whether additional germ contact tests are necessary. RKT accordingly designs the production cells to be suitable for cleanrooms.

Tightness and Cleanroom Compatibility Make Mold Making Tricky

RKT specializes in accompanying the process development of medical-technical parts all the way to serial production. When it is a matter of testing the feasibility of injection molding complex geometries, a pre-engineering is performed to begin with, then, in the ideal case, a prototype mold is built. The challenge for the mold maker is how to combine the customer's product specifications in an article design that is, at the same time, plastic-compatible »



Transparency is one of the most important criteria for the selection of plastics for medical-technical components. Transparent covers – stacked as illustrated – are enabled by analytic processes using microscopy, camera technology, or fluorescence measurement. © RKT

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Highest demands are made on precision mold making to produce cartridges with filigree structures (for micro-fluidic applications). Article function and downstream assembly processes have to be taken into consideration during the design phase. © RKT

In the cleanroom: the plastic material not only has to be suited for its later product functions, but also has to withstand the demands of drying and sealing processes. © RKT

and as economical as possible. Supposed small details in the specifications, such as sealing function or flatness requirements, can drive up the cost of the mold and cycle time for plastic parts. Moreover, part function and subsequent assembly have to be considered during the design process. Otherwise, problems will arise. Where LabDisks are involved, for example, no ejectors may be arranged in the area of the microfluidic channels, since they can later impair the channels with bits of flash or other impurities. Instead, ejectors are provided on the other side of the article. In addition, the seal function within the disk must not be impaired. The channels often lie very close together and have to be kept clearly apart.

Tightness can also suffer from additional ejector markings. The rule is that downstream processes have to be taken into account when designing and configuring the article: Where and how should the article be picked up and centered? Is it to be filled? How can it be meaningfully further processed?

High Precision – Starting with the Prototype Mold

Based on the article's specifications, the suitable plastics are considered, selected, and tested on the prototype. Based on the sample part, the product is developed and perfected further. Precision and tolerances are decisive here. Tightness requirements depend for one thing on the specifications and for another on the part area. The laboratory chips mentioned have an accuracy requirement of ± 5 µm, which is very high. In order for the microchannels to be milled, all parameters – machine, staff, mold – have to be optimally matched with each other in order to achieve such precision reproducibly. An extreme precision of ± 5 µm is also usually required for the parting lines to open and release the part. The mold halves may be bent or arched depending on the contour of the article. Wherever they touch, there must be a high degree of tightness, depending on the viscosity of the plastic used. Once the final parameters for making the mold have been established based on the protype, a serial mold is created which, depending on component complexity, can achieve guaranteed output quantities of millions of parts.

Additional factors that influence the processes on the way to serial production – in the medical field especially – are stiff requirements for hygiene and cleanliness which are also regulated in diverse standards such as DIN EN ISO 13485 or the GMP guidelines (Good Manufacturing Practice) they are based on.

For the cleanroom production of many products such as laboratory chips, the class ISO 8 is required for injection molding, in some cases also ISO 7 for assembly processes, to ensure that the production environment is analyte-free (no entering of foreign DNA).

Conclusion: Plastics Beat Glass

For large outputs and smooth-running processes, the injection molding of plastics is an efficient method for producing high-quality medical technical parts in compliance with high medical-technical standards. Glass certainly has its advantages in terms of transparency for optical testing processes, however, in terms of economy and handling in serial production, plastic has the edge. ■