Cutting Edge Technology

Otto Klumpp: DLC-Coated Standards in Cleanroom Production

Otto Klumpp GmbH has for many years processed, for example, highly transparent PC and high-performance plastics such as PPSU into sophisticated medical products. Since cleanliness and hygiene are essential for implants or blood-carrying systems, injection molding production and parts assembly are performed in the cleanroom. DLC-coated components also play an important role in in-house mold production.

For filters, Otto Klumpp uses resilient fabrics and stainless steels or alloys (Monel). The minimum mesh size for metal meshes is approx. 5 µm, for plastic meshes, it is approx. 1 µm – a thousandth of a millimeter
(© Otto Klumpp)

Where sharp-edged structures are necessary for the correct functioning of a plastic part in one place, they cause major headaches somewhere else. Martin Klumpp, CEO of Otto Klumpp GmbH, knows many clear examples of this from his own experience. The company based in Balingen, Southern Germany, has made a name for itself as a developer and manufacturer of sophisticated mold solutions and plastic parts, for example for use in medical technology.

The injection molder produces sharp-pointed injection needles from plastic in a form ready for use. The needles are mounted on syringes and are suitable for piercing the sterile closures (septums) of bottles containing pharmaceutical fluids in order to extract the liquid. The part geometry poses enormous challenges to the injection molding process, not only because of the flow path/wall thickness ratio. "We fill a 40-mm-long part with a cannula outer diameter of 1.6 mm and a circumferential wall thickness of 0.5 mm," explains Martin Klumpp. This process is further complicated by the high filler level of the material, a PA66 containing 50 % glass fibers.

However, the actual trick consists in completely filling the part, from the top piece, along its entire length, as far as the needle tip, without core deflection, since: every cavity contains a 0.6 mm-thin, long pin, which must ensure the parallelism of the walls during filling of the cavity. That is only possible if this pin does not bend or slip in the direction of the side wall. As is conventional for such cylindrical parts, it is side gated, but when asked about how they manage to keep the core precisely

centered, Klumpp says, "I don't want to say anything more about that." Only this much: the mold technology is patented.

Just No Sharp Edges

However, sharp edges and transitions must be avoided at all costs in the manufacture of a so-called cardiotomy reservoir for heart-lung machines. In combination with an oxygenator, which, as an artificial lung, maintains the gas exchange (oxygen/carbon dioxide), the entire blood circulation runs via this depot during heart operations.

One of the seven parts injection-molded from polycarbonate, which make up the tank, is a filling tube. Both its form and the transition to the discharge zone must ensure stress-free blood flow – otherwise mechanical stressing causes irreversible damage of the red blood corpuscles and a loss of the capability for gas transport (hemolysis).

In the cavities of the two-cavity mold, centrally located mold cores at one end encounter screwing counter-cores. "The associated surfaces must be precisely scraped, and no core deflection may occur during injection. This would result in sharp edges, which would literally slit open the blood corpuscles. That could even be fatal for the patient," says Klumpp, explaining the problem.

The circumstances are similar for a separation chamber, the heart of a blood-cell separator, which centrifuges blood at 2500 rpm, separating it into its components. Because of the high mechanical stresses that occur, the individual chamber parts must be firmly welded together; however this can only be done with a low weld depth in order to keep the amount of weld expulsion low and thereby avoid rough surface structures, which could damage the blood corpuscles. The specialists at Otto Klumpp succeeded in modifying the welding procedure appropriately.

The 40 mm-long injection needles with a diameter of 1.6 mm must be filled without core deflection
(© Otto Klumpp)

An autotransfusion reservoir significantly reduces the amount of donated blood required, and thus reduces the risk of AIDS or hepatitis. Directly after injection molding, the scale is labeled with an accuracy of 0.1 mm
(© Otto Klumpp)

Filter Fabrics Are Handled with Great Precision

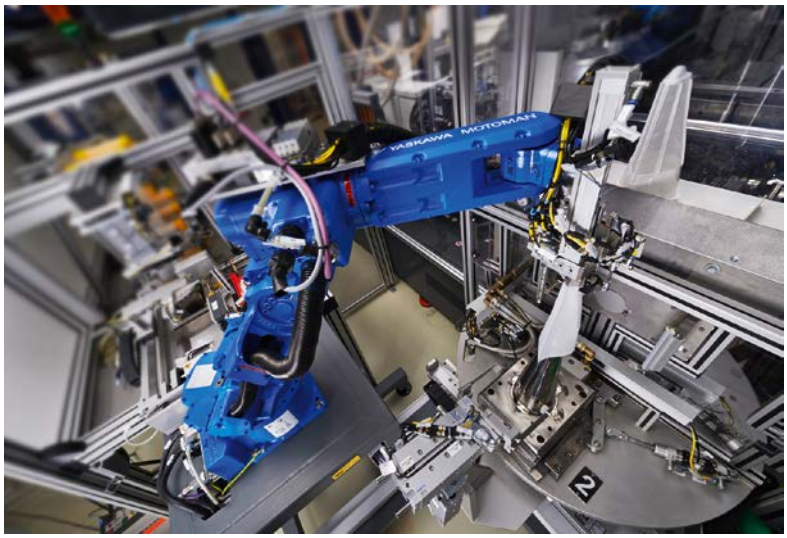
A basic component of the cardiotomy reservoir is a filter insert, which fits precisely into the contours of the plastic tank. For this part, Otto Klumpp developed a fully automated production cell, in which the filter fabric is supplied as a precisely fitting blank. In the cell, a six-arm robot grasps a tubular fabric and transfers it to a cassette system with conical core. According to Klumpp, "The tube is positioned with unique precision. There's a lot of expertise involved; this solution cannot be just purchased on the market."

The cassette is transferred into the mold, where the nonwoven fabric is overmolded with polypropylene. The plastic has a supporting function for the slack fabric, and thus makes the greatest possible filtration surface area available. On discharge, all filter inserts are inspected with a camera and finally packaged. The filter of the reservoir is required, for example, to keep back possible blood clots, which can form while the blood circulates outside the human circulatory system.

In filter technology, which besides medical and mold technology is treated as an independent business field (though there are often overlaps), Otto Klumpp has built up a wide expertise over the years. Other assemblies for extra-corporeal blood circulation, too, contain such filter units, for example a so-called adsorber for patients with high cholesterol levels (hypercholesterinemia), or a vacuum vessel of thin-walled polycarbonate for autotransfusion. This describes a process for intercepting the blood escaping during an operation, treating it and returning it to the body during the operation.

A Diabolic Material

Otto Klumpp faces other challenges when manufacturing a lid of PPSU for the microbial retention system of a sterilization container. In this container, medical instruments and surgical instruments »



In the cell, a six-arm robot grasps a tubular fabric and transfers it to a cassette system with conical core (© Otto Klumpp)

are sterilized with superheated steam, and in this way optimally prepared for the next use in the operating room. But the material is up to the job.

Polyphenylsulfones are characterized by resistance to many chemicals and repeated steam sterilization, though also by their stress-cracking sensitivity. Since the melts have high viscosity, high melt and mold temperatures are necessary to process them, in order to reduce molecular orientations and inherent stress. "The temperature control in the mold is very important. If everything does not work together harmoniously, the process is doomed to failure. PPSU can be a devil," comments Martin Klumpp.

According to the CEO, the stress level in the part must not exceed 5 MPa. "If it is above that, the product could rupture during use, for example during sterilization in the clinic," according to the 48-year-old. The six-arm-robot therefore hangs the still-hot parts on a sort of shelf after demolding in order to relax inherent stresses. The residence time is empirically tested, then the part is further processed by milling. Here, too, the process is concluded by a 100 % inspection of the part surface with a camera.

For the production of the plastic parts and filters for medical technology, Otto Klumpp has a total of 800 m^2 of cleanroom space in operation. Injection molding takes place in an ISO 8-class cleanroom, where, after removal from the mold, the parts are placed on a conveyor belt, on which they pass through a tunnel to final assembly. Here, in a class ISO 7 cleanroom, the plastic parts are manually processed, automatically welded or otherwise enhanced, and finally packaged.

Martin Klumpp considers it important to note that "our cleanrooms have all be measured, while the employees are actually in them and production is underway." To meet the high cleanliness requirements – ISO 7 means up to 10,000 particles of max. 0.5 µm size in one cubic foot of air – the employees wear special clothing and must pass through several vestibule systems before they enter the inner cleanroom.

Injection Molding with Extreme Requirements on Purity and Precision

In the cleanroom, there are 15 injection molding machines (clamping force range 250 to 2800 kN) , three of them fully electric. They are provided for special applications, for example: "Here we have parts with flatness requirements of plus or minus three hundredths," says Klumpp, and continues: "The expectations for the precision of an injection molded part are huge nowadays."

As regards precision, the molds (1 to 32-cavity), which Otto Klumpp produces in his own moldmaking shop – some of them for an output of 20 million parts per year – are high-precision tools. "Our moldmaking is fully air conditioned," stresses Martin Klumpp. Ultimately, whether for milling, cutting, grinding or EDM, an accuracy of ±3 µm is ensured. To improve the own productivity rates, in 2016, they invested in a linear cell for fully automated electrode production, diesinking EDM and hard machining, in which a 5-axis machining center, a diesinking EDM machine and a 3D measuring machine are connected by a linear robot, which we later supplemented with a 3-axis milling machine.

Martin Klumpp (right), CTO at Otto Klumpp GmbH, and Christian Ludwig, Head of the Germany-South sales region for Meusburger, beside a fully automated production line for cardiology filters in the cleanroom (© Hanser/C. Doriat)

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"We call it individual partial automation in mold making," according to the company head, who, together with his sister Claudia Klumpp, heads the company, founded in 1961, in the second generation.

Individual Partial Automation in Mold Making

Only a small portion of the molds are built for external companies; most of them remain at Klumpp. "In matters of filter elements or other special expertise that we have developed over many years, we don't disclose the information; in these cases, the parts are produced at Otto Klumpp," confirms the son of the company's founder. The company often first produces a pre-series mold for a project. Klumpp says, "It is constructed exactly like the series mold, except with a smaller number of cavities. If that works, then we can risk taking another step."

Thus, the 4-cavity mold, with which the injection needles mentioned above have been produced in series since 2015 is to be superseded by a 16-cavity mold that has already been completely engineered. The difficulty here does not lie with the steel: "The mold itself is relatively small, but all the trappings of control technology that we need to operate the mold is a huge amount of work."

For the standards, Klumpp refers to a tried-and-tested partnership. Up to 90 % of the products used are from Meusburger, preferably the high-precision, ready-bored mold and dies from low-stress, annealed high-grade steel. The advantage of this grade, according to Klumpp is that the platens do not warp. Because of the high dimensional stability, the number of machining steps can be reduced. "That is standard for our mold units, and a unique selling proposition. "It is possible to buy them cheaper, but not in this quality," says Christian Ludwig, Head of the Germany-South sales region for Meusburger, who was present at the on-site visit.

When the mold incorporates a special technical solution, Otto Klumpp keeps the injection mold production in house. Here, an 8-cavity mold (with DLC-coated ejectors) for a handle sleeve. With the illustrated unscrewing spindle unit, the internal thread of the dental product is demolded in the closed mold (© Hanser/C. Doriat)

In many molds, Otto Klumpp uses DLC-coated ejectors (top). Not quite so hard, but ideal for use in the cleanroom: the a-C:H:W coating (DLC doped with tungsten, bottom) on the fine centerings (© Meusburger)

Ground to an Undersize before DLC Coating

In addition, Meusburger principally supplies Klumpp with cleanroom-quality ejectors and centerings, with a diamond-like carbon (DLC) coating. The biggest advantage of the low-friction DLC coating, according to the standards manufacturer, is that the friction is reduced and the ejector can be used without lubrication, without the risk of wear. So that the DLC ejectors have the same outer diameters as the non-coated ones, the blanks are ground to an undersize in production. "That is important, since it means that previously uncoated products can be readily interchanged with DLC-coated variants," explains Ludwig. According to the trained mold-maker, the proportion of DLC-coated products in the incoming orders at Meusburger has now reached 22 %.

The trend is thus clearly towards peak performance – not only in medical technology. ■

Dr. Clemens Doriat, Editor