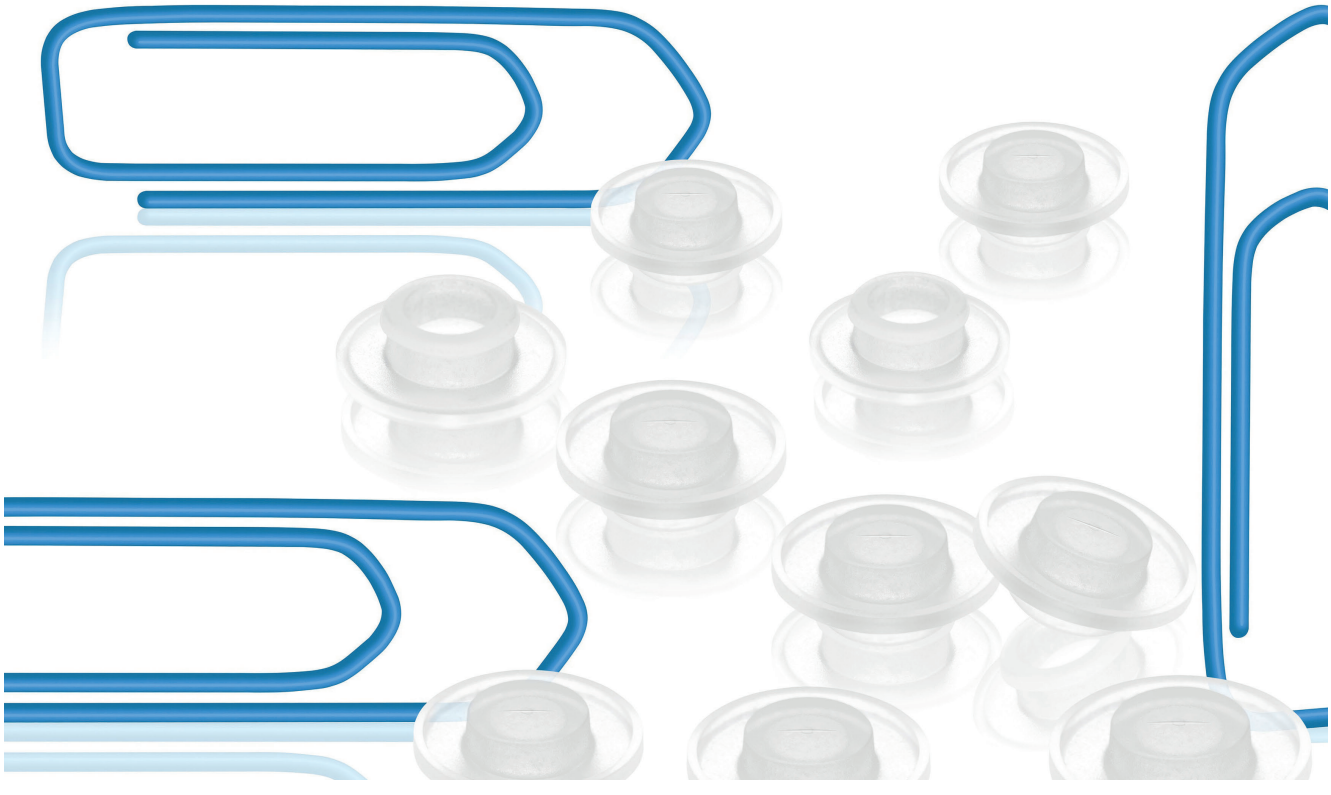
Transparency in Production

KraussMaffei Delivers a Customized Solution for LSR Processing

Space-saving machine concepts for demanding production environments are booming, and not just in the medical and pharmaceutical industries. A real-life example of a slit micro-membrane for pharmaceutical glass vials shows how intelligent machine functions make an important contribution to supporting machine operators and continuous documentation of the production process.



Injection molding and slitting of an LSR membrane for a glass-vial closure for pharmaceutical products make high demands on precision © KraussMaffei

Processing liquid silicone rubber (LSR) is demanding and, in the medical sector, must include detailed documentation of the injection molding process. Many converters are already successfully using KraussMaffei's SilcoSet technology to produce LSR parts in cleanroom conditions. The machine supplier has installed multiple cleanroom cells up to and including the highly demanding aseptic GMP grade A (resp. to class ISO 5 under DIN EN ISO 14644–1). KraussMaffei offers a wide range of solutions for more common cleanroom requirements (classes ISO 7 and 8 under DIN EN ISO 14644–1). It has developed and implemented various combinations of injection molding machines and cleanrooms and tailored them to specific tasks at customers.

Many customer projects are handled in close cooperation with a nominated mold maker, who usually supplies the corresponding mold direct. KraussMaffei has a large network of mold makers and material manufacturers and can handle projects via one central contact person. This close cooperation makes it possible to implement production solutions that feature stable manufacturing processes.

Compact Automation in Cleanroom Conditions

As an example, consider the production of slit micro-membranes (shot weight 0.0375 g), which serve as closures for glass vials containing pharmaceutical products (**Title figure**). The customer's specifications for this are as follows:

- ISO 7 cleanroom as per DIN EN ISO 14644–1,
- self-sufficient cell with minimal space requirement and integrated automation,
- cycle time max. 30 s,

- 8-cavity application,
- defined membrane slitting to ensure part functionality,
- packaging conducted within the production cell,
- full documentation of the production process.

The various components are chosen to reflect the customer's specified cleanroom class. For example, laminar flow modules for circulating low-particle air through the clamping unit are installed above the enclosure of the automation system and the injection molding machine.

The fully automated, cleanroom-capable production cell (**Fig. 1**) features space-saving kinematics. The automation system has a footprint of approx. 1000 by 1800 mm and includes a cleanroom-capable Kuka KR Agilus CR industrial robot, which, thanks to powder coating and special seals, is ISO class 2-compliant (as per DIN EN ISO 14644–1) and is designed for use with demanding applications. The line also includes a bagging system comprising conveyor belt, "good parts" sorting and integrated camera-based parts monitoring.

Fig. 1. Compact automation system with its own laminar flow box, packaging station and camera for parts inspection © KraussMaffei

Combination Gripper for Membrane Slitting and Parts Removal

One of the most important customer requirements is a compact mold featuring small cavity distances and a controlled removal of the micro parts (7.50 mm across and 0.35 mm thick). The gripper, with its footprint of 230 by 240 mm, must be able to center itself in the mold, slit the components to specification and then remove them with precision from the mold (**Fig. 2**). For this, the various gripper functions are arranged in sequence. There is no point in slitting the membranes after removal as the soft silicone cannot be repositioned precisely enough, and a misplaced slit would jeopardize membrane functionality.

Therefore, three centering devices are used to position the gripper, when it is in slitting mode, precisely and reproducibly on the mold. Eight small stainless steel blades (30 mm long, 5 mm wide, 0.3 mm thick) then extend to a specified length and pierce the membrane. The position and penetration depth of each knife can be adjusted separately. The membranes are slit by the knives while they are still inside the mold.

The slit in each membrane is just 3 mm long. Demolding is then done with eight pneumatic parallel grippers, which pull off the delicate parts by their 0.35-mm edge. The gripper design allows for thermal expansion of the hot mold and the gripper components. As a result, the gripper's sensors and electrical components can cope with mold temperatures of 170 to 180 °C. Cavity spacing can be affected by even slight changes in mold temperature. In that event, the micro-membranes would be damaged when gripped or the slit in each membrane would be in the wrong position. The entire gripper has therefore been designed specifically so that all its kinematic components and those in contact with the product can be finely adjusted.

After removal, the robot moves the gripper in front of a camera system, which checks for part completeness. To increase the contrast with the very thin, transparent components and thus to ensure reliable detection of the micro-membranes, the base of the gripper has been colored black.

The gripper then transfers the membranes to the packaging machine, which bags the micro-parts. A separate QR code (**Fig. 3**) is generated for each cycle via the machine controller and is printed on the corresponding bag to allow for individual tracking of product-specific process data. Should a customer wish to conduct a quality assurance check, for example, »

Fig. 2. Combination gripper for membrane slitting and parts removal © KraussMaffei

Fig. 3. A QR code is generated via the machine controller and printed on the bags produced in a given cycle so that product-specific process data can be individually tracked. A real-life example is shown here © KraussMaffei

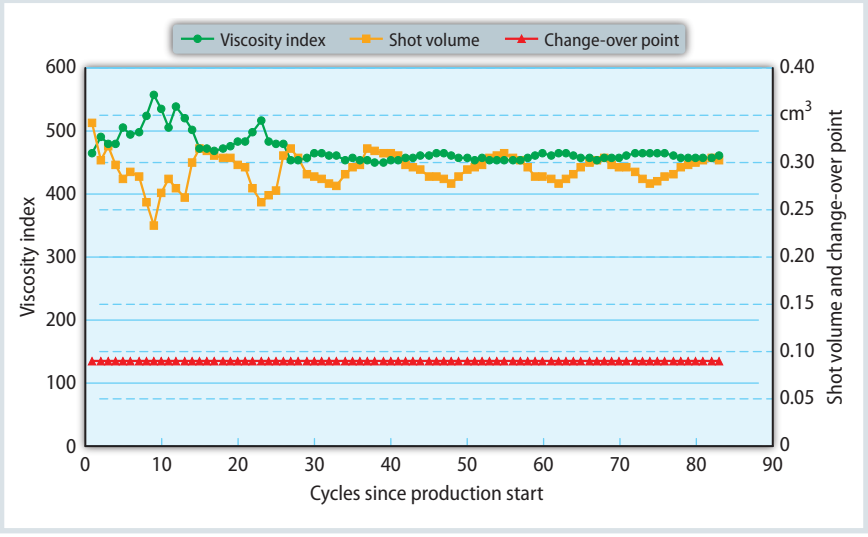


Fig. 4. Change in viscosity index and resulting injected volume for startup at an unchanged change-over point after a ten-minute standstill. The rising viscosity leads to a lower shot volume

Source: KraussMaffei; graphic: © Hanser

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Project Partners

The membrane application described in this paper was developed in close cooperation with Automated Packaging Systems GmbH & Co. KG, gwk Gesellschaft Wärme Kältetechnik mbH, iba AG, Petek Reinraumtechnik GmbH, Momentive Performance Materials Inc, Nexus Elastomer Systems GmbH and SensoPart Industriesensorik GmbH.

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he can retrieve the product data in question using any handset. Finally, the packaged products are discharged from the cleanroom cell on the conveyor belt and are ready for further dispatch.

Three-Stage Process Monitoring

Such delicate products with their demanding production specifications call for a stable production process. The design of the production cell already ensures a stable process. A further way to optimize the manufacturing process is afforded by intelligent machine functions. The manufacturing process can be monitored in three stages:

- Tolerance monitoring of cycle values (current values log),
- active adjustment of the injection molding process (APC plus),
- evaluation of high-resolution curves.

For many converters, tolerance monitoring of cycle values such as plasticizing time or maximum melt pressure is their preferred process-analysis tool. Such data can only be evaluated after the part has been manufactured. Thus, all that is established at that point is whether the part is "good" or scrap. Tolerance monitoring is

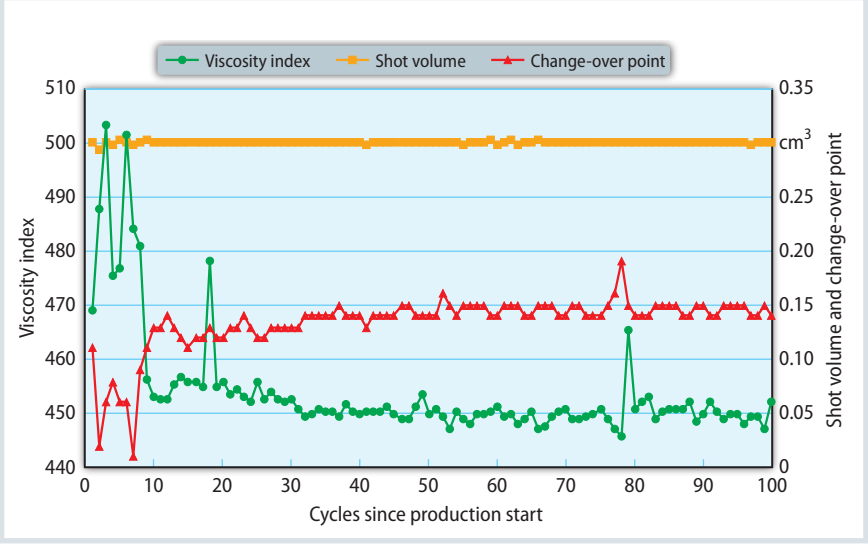

Fig. 5. Startup curves after a ten-minute shutdown when APC plus is used. The viscosity index, shot volume and the change-over point adjusted by APC plus are shown. The shot volume is virtually unchanged Source: KraussMaffei; graphic: © Hanser

therefore only suitable for assessing the result – not for influencing the injection molding process itself. Yet this is necessary, e.g., to mitigate fluctuations in material viscosity when material is changed or other disruptions occur.

APC plus (Adaptive Process Control) is an intelligent machine function from KraussMaffei that enables the injection molding process to be corrected without interrupting the injection process. First, one or more good parts are produced to provide a positive reference for what constitutes an ideal part. The viscosity of the material used to produce the ideal part is also determined and stored in the machine controller. The APC plus then takes over. During injection, it calculates the deviation in the material's viscosity from that of the reference and adjusts the change-over point in the same shot. This means that the shot volume is the same as that in the reference, despite any process fluctuations.

It therefore does not matter whether a temperature fluctuation, a pigment change or a material change is the cause of the viscosity change. APC plus responds each time to the calculated viscosity index of the injected material volume, and also takes account of LSR's specific compression.

Similar to the case for tolerance monitoring, limit values need to be specified for APC plus too, especially for the manufacture of medical devices. This ensures that any major change in viscosity index that would breach the tolerance value for the change-over point generates a reject signal or stops production. The feedback control exerted over the injected volume of material ensures that the parts always have identical weights.

Safe Restart with State-Dependent Process Control

APC plus benefits not only production, but also production restarts after a shutdown. A series of tests conducted during manufacture of the membrane reveals that just 10 min downtime is enough to affect the material's viscosity. However, this is the amount of time needed by one machine operator to clean the injection mold, an operation which is usually scheduled once per shift. When the machine is restarted after a ten-minute standstill and at an unchanged change-over point, the viscosity rises by up to 25 % and lowers the shot volume in the test by roughly 20 %. The resulting fluctuation in material viscosity affects the shot volume and the shot weight (**Fig. 4**).

The reduced shot volume can give rise to selective underfilling of the parts and prevent the 8 grippers from getting a proper hold of the membranes by their 0.35-mm edges. The viscosity fluctuation thus causes an undesirable production interruption during startup and the operator is obliged to remove the parts manually. This in turn increases the mold-open times and makes it harder to achieve a stable cycle; it also ties the operator to the machine for longer.

By contrast, in a second series of tests conducted with activated APC plus control, the change-over point is adjusted in response to the viscosity index so as to keep the shot volume virtually constant. The viscosity curve rises by up to 13 % (**Fig. 5**). As a result, the shot weight remains almost identical, and automated removal by the gripper is possible right from the start. This keeps down the manpower level needed at the machine and, with an eye to cleanroom environment, minimizes movements at the machine.

All production parameters – including the process adjustments which APC plus had to make – are stored in high resolution and are available for detailed data documentation and analysis. This enables customers to define and monitor individual process parameters so that disturbing factors can be identified and parts quality be further optimized.

Conclusion

Intelligent machine functions such as APC plus offer advantages, particularly for LSR processing, by automatically compensating for fluctuations in material viscosity within specified tolerance limits and ensuring a consistent shot weight. This is essential in the case reviewed in this paper because the closure for pharmaceutical vials is removed by gripping the delicate edge of the membrane. APC plus therefore provides advantages during both production and startup.

Finally, comprehensive documentation and data evaluation are assured by high-resolution recording of all production parameters. With regard to boosting the transparency and efficiency of parts production, a wide range of solutions is possible, such as the described use of QR code labeling, and other digital solutions. KraussMaffei is an expert provider of modular production solutions for medical LSR products and cleanroom applications in this area. ■