Double Sided Gating with Needle Valve

**Glass Substitute.** A new hot runner system was recently developed for the production of prefillaible disposable syringes of COC, with its core component being a sidegate needle valve nozzle that was tailored to comply with these plastics' high viscosity and temperature sensitivity. It provides for safe processing and high gating quality, which is critical with pharmaceutical packagings. The modular design of the mold enables production of different syringe models in a variety of sizes and with various tips.

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Pharmaceutical primary packagings such as ampules, vials or prefillaible syringes pose high demands to the materials employed. The packaging must protect the pharmaceutical from environmental impact, not reacting with its contents, so as not to affect the stability and therapeutic effects of the substances. While glass used to be the preferred material, it is increasingly replaced by plastics today.

Mainly cyclic-olefin-copolymers (COCs) are used for these applications. Their purity and transparency equals that of glass, while the materials have better chemical and physical properties: They are lighter, though more break-resistant than glass, while offering excellent barrier properties against water steam, and they have only a minimum share of extractable substances that might react with the pharmaceutical, thus complying with pharmaceutical regulations.

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TOOLING

Prefillable Disposable Syringes – A Difficult Subject

Due to the demand for vaccines growing at a global scale, and as a result of the rise in the biopharmaceutical market, prefillable disposable syringes for injectable medicine are increasingly required. They are comfortable and safe to use for both the physician and the patient. In addition, they are more cost-effective, because less medicine remains, as compared to the ampule-syringe combination, which is particularly interesting if used with expensive biopharmaceuticals.

However, manufacturing these prefillable syringes from COC means an enormous challenge to plastics processors: First, the syringe bodies’ tube-shaped geometry with its narrow, long cores, and with its openings on both sides, calls for side gating. Second, processing COC involves high demands in terms of mold design and hot runner layout. Cyclic-olefin-copolymers are highly viscous and extraordinarily sensitive to temperature impact – possibly leading to pressure loss, with the high injection speeds required. Quality requirements to dimensional stability and hygiene for pharmaceutical packagings make high process safety and clean and hygienic gating crucial aspects to be considered during production.

Layout for Stressfree Material Processing

For lateral injection molding, Otto Männner GmbH in Balingen, Germany, specialist in precision forming and hot runners, offers a hot runner system with needle valve nozzles (type: Sidegate). In this nozzle specially developed for side gating (Fig. 1), the needles do not move in the direction of mold close and open, but rather in a right angle. The nozzle body, including its pneumatic unit, sits in mold direction, as usual. At the same time, a pneumatically driven control needle operates the valve needles positioned vertically. Thanks to this patent nozzle, the user is able to make use of the benefits provided by the Männner hot runner systems with cylindrical needle valve, i.e. defined open and close of the needle valves, gating quality, material saving, and, most of all, the high process safety – even with side gating.

High pressure is required when processing cyclic-olefin copolymers, due to their high viscosities. Featuring large flow diameters, Männner hot runner systems allow for processing of the plastic material in a way as stressfree as possible. Moreover, the needle opening stroke was increased in the sidegate nozzle for COC processing, in order to step up the flow diameter inside the nozzle itself, too, thus diminishing the high pressure losses included in these special polymers. This way, components with significantly higher weights and/or volumes can be produced by injection molding. The valve needle of the new nozzle, in analogy with the other needle valve nozzles of the supplier from Baden in the Southern part of Germany, is precentered right in the nozzle.
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Fig. 3. The various cavity inserts of the mold are exchangeable, thus enabling the production of different syringe sizes.

Fig. 4. The stripper plate moves forward to demold the syringe bodies (figures: Männer).

runner system at processing temperature did the melt show any degradation effects.

Two Gating Points and a Safe Demolding Mechanism

Männer uses two gating points, each at the side walls of the component (Fig. 2), thus eliminating weldlines in larger syringe bodies. A 2-fold hot runner and two single-point nozzles are employed here. The concept was specially developed for this application, reducing flow paths of the highly viscous melt and improving cavity filling when producing large tube-shaped bodies.

Injection at the side walls incurs demolding of the syringe bodies at a 90° angle to the valve needles. At closing, the needle dips into the molding by a few hundredth of millimeters. So as to prevent the valve needle from damaging the surface of the syringe body at demolding, the needle experiences a brief back stroke when the mold opens. During this patent back stroke movement, the valve needle remains in the connecting orifice, thus avoiding uncontrolled exit of the melt. The needle, which is still heated from the friction of injection, is removed from the molding by the back stroke. This way, better cooling behavior of the sprue is achieved along with a flawless surface – even though it is impossible, due to the small space available, to include active cooling in this area.

The mold system serving to produce disposable syringes of COC consists of a modular mold with two cavities and a 4-fold hot runner system with four single-point nozzles (Fig. 3). Exchangeable cavity inserts allow for various sizes of syringes to be manufactured. Large syringe bodies are injection molded from two gating points each, small syringes from just one. A stripper plate helps demold the syringe bodies (Fig. 4).

Flexible Mold Solution for up to 64 Cavities

Other than with conventional units with their mandrel and stripper plates sitting at the moving side, these structural elements are integrated at the side of the nozzles, here. This is how this mold solution offers perfect freedom of design at the ejector side, concerning the syringe tip, be it for instance a thread or luer lock, enabling the production of complete disposable syringes by overmolding a needle insert. The concept (patent pending) allows for up to 64 cavities, and is currently undergoing field tests.

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A Whole Case of Safety

Mold Insert Leak Pressure Test Unit.
Checking temperature control circuits for density is part of toolmakers’ everyday business. Until today, this could only be done with the mold sitting in the machine. Should the tempering medium leak in a certain spot, elaborate work has to be done. The mold must be dismounted from the machine to detect the leak. And it must be cleaned before it can be remounted.

The patent mold insert leak pressure test unit by Strack Norma GmbH &Co. KG in Lüdenscheid, Germany, named Z7755, now allows for testing the mold before mounting. Potential leaks can thus be eliminated beforehand. Set-up and idle times are considerably reduced, because mold set-up is accelerated. According to producer information, this saves 90% of costs.

The Z7755 kit comes with the test unit itself, along with three pairs of different size adapters that can be used for the common M5/M6, M8/M10 and M12 sizes. All components are supplied in a handy storage case. Customers have the option of ordering a test pump and connector.

→ www.strack.de

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