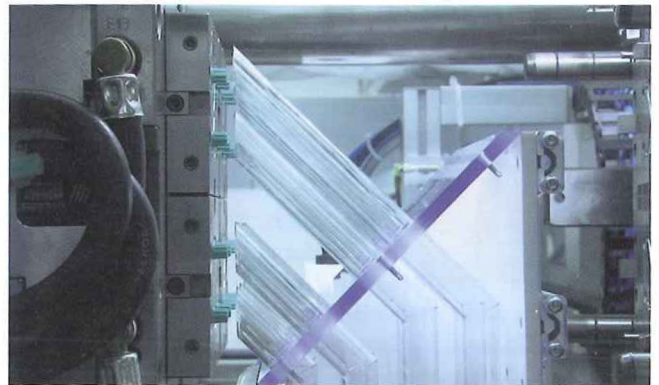


A Mold Meeting Clinical Requirements



TELC is a tamper-proof closure system for prefillable syringes. During clean-room production, each cavity is served individually by a patented handling system (figures: Gerresheimer Bünde, Braunform)

Closure System for Prefillable Syringes.

Gerresheimer Bünde GmbH, in close collaboration with Braunform GmbH, Bahlingen, Germany, initiated the TELC development project. The abbreviation stands for “tamper evident Luer lock closure,” a tamper-proof closure system for prefillable syringes. The closure is injection molded from two components and sets just as high standards for the design, styling and material selection as for the mold making and clean-room production conditions.

A technical innovation of the series mold is the low-particle unscrewing of the Luerlock adapter and low-particle shearing off of the sprue after injection. Very thin, unsupported cores are used be-

cause of the delicate contour for the tamper-proof tabs, which indicate that the closure has already been opened. A self-developed cam-operated needle-valve hot-runner system is also used for the cap. Other technical challenges are the cap’s thick walls, which must be openable with a defined torque, and the clean contour separation of the two components.

To minimize risks, the 16+16-cavity injection mold with rotary plate was preceded by a close-to-production pilot mold. The special material combination of the pharmaceutical primary packaging results in a large temperature gradient in the mold: At one side, the Luerlock adapter is formed from a high-temperature resistant, tough polycarbonate (PC) at a mold temperature of about 100 °C. At the other side, the unscrewing cap with

tamper-proof tabs is molded from a thermoplastic elastomer (TPE) at 40 °C. Besides the temperature difference and the high pressure, the process must also ensure that the hard/soft combination is sterilizable and does not chemically bond to itself. To prevent burning and black spots in the PC components, the manufacturer’s instructions must be strictly followed.

Because of the critical material selection, the TELC is injection molded in a dedicated production cell under Class 5 clean-room conditions according to ISO 14644-1, and each cavity is served individually by a patented handling system. The customer-specific rubber seals are subsequently used in the assembly process.

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