



Case Study: Key Issues in High Cavity Mold Design

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Overview

High cavity molds enable medical manufacturers to tap economies of scale when fabricating high volume single-use products by reducing the number of machines needed to achieve required production volumes. Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, recently designed a 64-cavity mold for a customer. This case study looks at the challenges and lessons learned in the project.

The Challenge

The customer had a small part that was forecasted to do 12 million pieces in its first year of production and then grow to 24 million in the second year. The team at Forefront determined that a 64-cavity mold was needed to support the anticipated second year volumes. Previously, the largest mold Forefront had designed and fabricated contained 16 cavities.

There were several areas of challenge in mold design including:

- Optimizing the mold to fit an existing 220-ton injection molding machine
- Designing the correct assembly layout of the mold
- Designing the right de-molding process for the part release from the mold as this product is not a rigid.
- Hitting the 22 second cycle time necessary to stay within cost targets.

Forefront Medical's engineering team used its standardized process to assess customer requirements and develop a Design Development Plan (DDP). The tooling design process includes a design for manufacturability (DFM) phase, followed by development of the mold specification. The DFM document outlined requirements for core cavity, sliders, gating position/size and location, and the results of computer simulated mold flow analysis. The goal was to ensure efficient molding with minimal scrap and elimination of secondary finishing processes with as few design iterations as possible. The DFM recommendations also proposed use of a robot arm for the de-molding process.

NX-Siemens software was used for tool, hot runner and cooling system designs. Mold-flow software was used for mold-flow analysis and to support Design of Experiments (DoEs) to optimize the design and molding parameters that were not part of Forefront's existing library of injection parameters. Mold Flow software was utilized for molding process simulations to test assumptions prior to tool fabrication.

As originally designed, the mold was too large for a 220-ton injection molding machine. Utilizing a higher tonnage machine would increase cost since the machine consumes more space and energy, so the team needed to change the mold assembly layout to reduce the size of the mold. A key challenge was that this part was small and formed by the both the core, cavity and sliders. A non-complicated part will be formed by simply core and cavity.

The team needed to develop a design that had sufficient space between cavitation, runners and a comfortable ejection system. They designed a mold without thin steel, positioned the layout accordingly,



so that a single hot runner tip would inject the plastic to two parts and designed a hot runner system that met those requirements. This reduced the space required enough to utilize the lower tonnage machine of 220 Ton.

The specially formulated low density polyethylene (PE) material selected for this part also presented a challenge. This specialty PE is flexible, which doesn't work with a standard ejection system for de-molding. A robot arm assisted by a balloon-type pneumatic system was added to the de-molding process to eliminate this issue.

The final area of focus involved optimizing the process to ensure a 22-second cycle time was achievable. One key constraint in achieving that cycle time was cooling requirements. The parts needed sufficient time to cool during the mold opening and closing process. Providing sufficient cooling time required optimization and synchronization of the mold opening, cavity release and part ejection process. The design team estimated cycle times during mold flow analysis and then worked with production time to fine tune process to the targeted 22 second cycle time.

The Result

The mold has completed the validation process and the production process is achieving desired quality levels. The customer's goals for cost and scalability were achieved.

About Forefront Medical

Forefront Medical is a global medical device contract manufacturer with five locations. Singapore is Forefront's headquarters, as well as home to our Design Engineering Center and specialty manufacturing. Jiangsu and Xiamen, China, are additional manufacturing locations and are also China FDA Registered. Shanghai, China, Farmington, CT USA and Riel, Netherlands are regional Business Development offices which assure our technical sales teams are close to our customers for local, responsive assistance.

We have developed extensive capabilities with implantable PEEK micro-molded components, laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding and multi-lumen catheters, infusion sets, wire reinforced tubes, optically clear components, patient monitoring devices and other specialty products.

Each of our locations has state of the art manufacturing capabilities that include class 100K clean rooms for extrusion and injection molding, complimented by class 10K clean rooms for assembly and packaging. Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485, ISO 9001 and FDA Registered. Forefront is a wholly owned subsidiary of VicPlas International Ltd, who is listed on the SGX Main Board, Singapore stock exchange.

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