Case Study: Specialty Syringe Production

January 15, 2015

Overview: Specialty syringe production can present a range of design and manufacturing challenges since the product's mechanism is more complex than standard syringes, and may require stronger focus on material compatibility issues and complex mold tooling. In this case, Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, was designing a safety syringe for a customer who had no internal design team.

There are two different models: a 5-milliliter and a 10-milliliter safety syringe. Each model consists of ten different components for the individual syringe. This spatiality vacuum safety syringe is technologically more advanced than the normal 3-component syringes available in the market with a barrel, plunger and a plunger seal.

The Challenge

The customer provided 3D computer-aided design (CAD) files and Forefront's engineering team utilized its standardized process to assess customer requirements create Design Development Plan (DDP) and refine the customer specification. The 3D CAD models provided by the customer were analyzed and the CAD geometry was fine-tuned to work appropriately within molding constraints. Design reviews which included functional analysis and risk evaluation were completed.

There were several potential issues identified in the design phase that needed to be addressed:

- There were 10 parts in the syringe that needed to assemble together precisely and correctly in order to perform the specified mechanical functions
- Material selection needed to meet both medical grade standards and be compatible with desired functionality requirements
- The cosmetic aspect of the parts needed to meet the customer's appearance and transparency requirements
- The target volume quantity is 72 million units annually which added complexity to the mold scale-up strategy.

Determining the correct materials involved some trial and error. The team originally proposed using thermoplastic elastomer (TPE) with polypropylene. The customer felt that the original polypropylene (PP) selected did not provide adequate transparency in the syringe barrel so Forefront worked out an enhanced grade of PP resin from the supplier. Thermoplastic polyolefin (TPO) was selected for the plunger seal to provide optimum motion.

The material selection and qualification process was shortened because Forefront maintains a database of approved materials which includes a full range of medical-grade polymers. While the best material will vary depending on application, cost considerations and desired functionality, Forefront's team is often able to recommend pre-approved materials choices to reduce product development time.

Forefront takes a vertically integrated approach to tooling fabrication. The tooling design process included a design for manufacturability (DFM) phase, followed by development of the mold specification. Mold-flow analysis tools were used to "virtually" test that design assumptions will support molding with minimal scrap and minimization of secondary finishing processes. This level of computer analysis minimizes design iterations on tooling.

Forefront's team determined that a single cavity mold could be developed that would simultaneously mold the 10 components utilized in syringe for volume production. Family molds were created for the prototype stage.

The Results

Final prototypes are currently undergoing customer evaluation. The mold fabrication process will include a testing and debugging phase which incorporates a dry run and analysis of product first off tool (FOT). Design assumptions related to target labor utilization and run rate will be evaluated during the validation process. Changes will be made if that analysis indicates assumptions were flawed. Production processes will undergo a similar development and validation phase. The goal is to lower cost and provide superior quality by minimizing use of secondary processes.

About Forefront Medical Technology

Forefront Medical Technology 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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