Keys to Success in Medical Micro Molding

August 27, 2014

Introduction

It's no secret that medical devices are getting smaller. Implants, tubing and drug delivery systems now often require injection molders capable of fabricating parts at a micro level. The smaller the part; the more complex the injection molding process since material behaves differently in smaller shot sizes. Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, has experience with both standard and micro molded products. This white paper describes the product development and process complexities found in micro molding in greater detail, plus looks at how these capabilities were successfully applied in a recent micro molding project.

Standard Injection Molding or Micro Molding—What's the Difference?

From a non-technical perspective, the logical assumption is that micro molded parts simply require a mold with smaller cavities. The reality is that there are significant differences between the processes including:

- Equipment and molds must be carefully matched
- Smaller shot sizes and specialized material require higher melting points and faster cooling cycles, which impacts material selection for molds, along with the mold design
- Process development often requires multiple design of experiments (DoE) to determine optimum settings for all variables within the process
- Specialized material cost can run several thousands of dollars per kilo so there must be minimal waste
- Small size limits the ability to rework after molding, so quality must be consistently high
- The mold fabrication and qualification process is significantly more complex and requires longer lead-time compared to a standard mold.

The Equipment and Mold Equation

Injection molding machines must be capable of injecting at higher pressure and speed when micro molding parts with small shot sizes. If a specialized material such as Polyetheretherketone (PEEK) is used the mold and screw material must be hardened to withstand a melting point at least one hundred degrees over the melting point of normal resins.

Molds are typically designed to take advantage of the smallest shot weight, which in micro molding is often under 0.010 grams. While a hot runner system is the optimum choice, the runner system and gating systems must be carefully designed, because if the material does not flow properly it will degrade. The mold needs both a heating and cooling system to control temperature changes precisely throughout the process.

Mold Design/Fabrication and Process Development Challenges

Automated mold flow analysis software is key to ensuring a correctly designed mold and tight process control. However, with micro molded parts there is not as comprehensive a library outlining material

selection impact on the mold, as is found with standard size parts. Consequently, there may be engineering research required prior to performing mold flow analysis.

Developing optimized injection parameters can also involve a lengthy development process. With standard molds and resins, developing injection parameters typically takes two hours. With micro molding, DoEs on injection pressure, injection speed and other variables must all be performed to determine the best mix of optimized parameters. This process typically takes a week, followed by three-to-four weeks for process validation.

Lead-time for mold fabrication and validation can also be longer. A standard mold can be built and validated in 8-10 weeks. A micro mold tool typically takes three-to-four times the machining duration and resources. At Forefront Medical, lead-times have been equalized by increasing technical resources applied to the tool fabrication. For example, while a standard tool might be fabricated by one person; a micro molded tool might require a team of ten people to fabricate and validate within an 8-10 week window.

Critical Contract Manufacturing Capabilities

To successfully meet these challenges, a contract manufacturer engaged in micro-molding needs a strong engineering team and excellent design tools. Given the amount of fine tuning that may be necessary during the mold design, fabrication and validation processes, there is also value in vertically-integrated tooling fabrication facilities with precision machining capabilities.

Familiarity with the specialized materials likely to be required is also important. To minimize the potential for counterfeiting, some resin manufacturers will only sell product to a limited number of injection molding facilities. For example, Forefront Medical is the only contract manufacturer within Asia approved by Solvay to purchase its PEEK materials. Additionally, Forefront Medical 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 Medical's team is often able to recommend pre-approved materials choices to remove the variable of regulatory materials approval lead-time from the product development process.

Finally, the ability to shorten lead-times by making a larger number of resources available is also critical to the success of many design efforts. Forefront Medical's vertically integrated tooling design capabilities, plus precision machining resources in its Singapore and Jiangsu facilities provide the resource scalability needed to support the added complexity of micro molding tooling. Rapid prototyping capability is also important. Forefront Medical uses its selective laser sintering (SLS) system to generate prototype parts for customers while the mold is in the development phase.

A Case Study: Micro Molding an Implantable Device

The team at Forefront Medical recently helped a medical device manufacturer with a micro molding challenge. A small part was needed for a product used in implantable tissue grafting. Forefront Medical's dedicated project engineering team worked with the customer to design a part that had the functional characteristics required for the application and was also manufacturable. PEEK was selected as the material.

Forefront Medical's project engineering team utilized Cimatron software for the tool, hot runner and cooling system design. They were able to use Moldflow software for DoEs to optimize the design and

molding parameters plus moldflow analysis once those parameters were established. Moldex3D software was utilized for molding process simulations to test their assumptions prior to tool fabrication.

The micro size of component was the major challenge. Forefront chose to modify their smallest machine to support this effort and this required significant work on the screw system to more precisely control the discharge of plastic on the screw. This part involved one third the volume of material compared to that of normal resin screw interface.

The thin wall of the part drove a strong focus on temperature and process control. Heaters needed to be added to the mold to reach an equilibrium state.

Part handling after molding was also a challenge. A de-ionizer was added to remove the electrostatic charge which otherwise would cause the small parts to stick to the mold. A standard handling robot could not be utilized because of the part size. Forefront was able to deliver first articles for customer functional testing in less than six months from project start.

Conclusion

Successfully micro molding medical parts requires engineering expertise, state-of-the-art tools and equipment, close coordination with the mold fabrication team and a focus on developing a design that addresses both the customer's functional goals and is manufacturable. The added complexity of micro molding adds lead-time to the process compared with standard molding. Selecting a supplier with the right mix of capabilities can help reduce this added lead-time.

Material cost and size drive a need for a mold to deliver superior quality parts with minimal waste and without secondary finishing operations. Specialized materials requirements may also limit regional supplier choices. A supplier experienced with medical plastics can eliminate or reduce regulatory materials approval lead-time. Longer tooling fabrication lead-times can be mitigated with additional engineering and in-house machining resources. Choosing a supplier with a strong engineering team and scalable resources helps ensure a smooth product development process and superior quality product.

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.

Visit www.forefrontmedical.com to learn more about our capabilities. For a confidential review of your project, please complete our enquiry form at: http://www.forefrontmedical.com/enquiry.html, email us at: appl_dev@forefrontmedical.com, or call +1 (860) 255-7610 (Europe and America's) / +86 21 6062 7177 (Asia).