Ferriot

How Injection Molding Happens

The Step by Step Production of a Medical Device Part

In any ER room or outpatient medical facility, patients and practitioners rely on sophisticated medical equipment to diagnose and treat illness. These range from machines that beep to those that deliver life-saving therapies, and they are usually housed inside plastic boxes that you may take for granted. But we don't.

At Ferriot, we've carved out and dominated a particular manufacturing niche: We make enclosures for the medical market. It's another market segment where we have accrued experience and insight. This paper is intended to provide a high-level overview of the manufacturing process for an injection molded product that is destined for a critical role in the care of someone's loved one.

In this industry, there are some unique challenges involved in the production of medical products, but the steps we'll describe apply generally to the manufacture of almost any injection molded product.

Plastic housing for medical equipment such as an infusion pump is often made by an injection molding process.

Types of Medical Injection Molding Projects

There are basically two categories of injection molding products that are typically produced for the medical market: certification-intensive products and those that are not extensively regulated. Original Equipment Manufacturers (OEM's) create devices that are classified by the FDA according to the nature of their function, and the function of a medical product is what dictates every aspect of its production, including how its plastic parts will be molded.

According to the FDA, the highest level of medical device class is Class III. These are usually true medical devices that have contact with the body, are implanted in the body, or deliver fluids to the body, like IV tubing, implants, and IV needles. When they involve injection molded parts, they usually must be produced in a clean room environment from the beginning of manufacture to finished use. An example would be a single use, sterile syringe.

The other types of products fall into FDA classifications I and II, including medical equipment. This is the kind of product Ferriot produces. This group of products includes medical carts, medical housings for IV pumps, housings for oxygen, home oxygen delivery systems seen in a hospital, and any of the cardiac EKG machines that would be rolled into a hospital room or clinical area. These are all, for the most part, products that are used in hospitals, but also can be intended for home use as well. The quality requirements for medical equipment products are a bit less stringent. Often times, products in Class III must be designed to eliminate or reduce the risk of failure because a person's life may be at risk. In the other classes, this is less so.

Keep It Classy. *"FDA classifies medical devices based on the risks associated with the device. Devices are classified into one of three categories—Class I, Class II, and Class III. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. For example, powered wheelchairs are classified as Class II devices. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed. For example, replacement heart valves are classified as Class III devices."*

--http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm

Class III equipment must pass FDA evaluation. There is also a host of other regulations that certify that the equipment is manufactured in a certain way. Large manufacturers will own the entire certification process, and will determine how much of a product's manufacture requires clean room processing. Some subcomponents can be molded outside of the clean room, then included in final assembly. Whether we are making Class II or lower, almost all of the parts for medical

devices Ferriot produces are typically sent back to the medical device manufacturer for assembly and final inspection. We certify our parts meet specific characteristics, but it's the medical device manufacturer that certifies the actual equipment.

Liability Matters

While legal advice is outside the scope of this document, it suffices to say that liability concerns drive nearly every aspect of medical device and medical equipment production. When a mission-critical molded product fails, it's the OEM who assumes responsibility for the outcomes. That's why the mindset for manufacture of medical products of all types tends toward a risk-averse, conservative approach. Ferriot's ISO compliance capabilities and client portfolio appeal to large medical OEM's who are looking for an experienced injection molding partner.

Engineers and product designers must consider a product's environment.

Scope and Evaluation Process

Medical OEM's must take several factors into consideration as they develop their manufacturing strategy. Following, we will discuss a few of these as they pertain to manufacturing a medical enclosure categorized as Class II or Class I.

Environment

The first thing to consider is the environment. Where and how will the end product be used? Is it intended for a hospital room, or is it in a piece of a larger object, such as an X-ray machine, or is it used during a blood draw procedure? There are various places within a hospital that are home to different activities. Some areas are sterile, some are moist and some are administrative areas.

Because all areas of a hospital must be cleaned to varying extents, it's important to determine which chemicals or cleaning agents will come in contact with the device or equipment enclosure. Over time, some of these chemicals can harm plastic if the wrong resin is chosen. Then, there are the wild card environmental factors present in a hospital setting such as flame or radiation exposure—and those create other interesting challenges!

Lifespan

Will the device be under continuous use, or will it see periodic use? It matters if an injection molded part is under stress once a day or once an hour. It also matters how much abuse or wear and tear the product might encounter during its life. If it's on a stand, must it have an impact rating for accidental tip-over, for example?

Recently, consumer product manufacturers have begun incorporating antimicrobial additives into their injection molded products. This "feature" has limited value, and has limited utility in plastic parts. Some manufacturers will put an antimicrobial additive in the plastics, but it's really not effective because, eventually, it wears out as the additive slowly leeches out of the plastic and loses its potency. Plus, any item containing such an additive still needs to be cleaned for dirt and dust, two contaminants that are unaffected by the antimicrobial.

Click to download the Resin Selection Guide to learn more about this aspect of injection molding production.

Resin Selection

Surprisingly, even this aspect of the manufacturing process is also dictated by the medical OEM's risk management profile. Most OEM's will already have research and findings on the best available resins for their applications and products. They often approach a contract manufacturer, like Ferriot, with a resin already chosen. This is due in part to several factors:

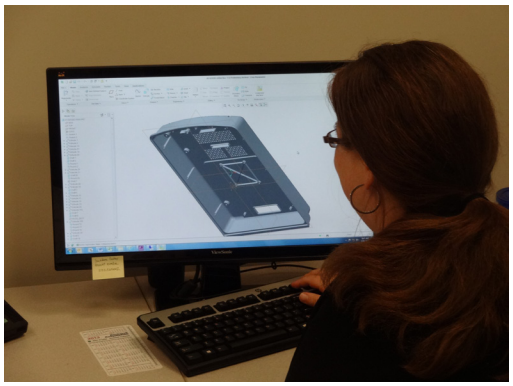
- There are not too many large-scale industrial resin producers in the market, so OEM's will often have established relationships with industrial resin suppliers.

- The environmental design factors have already been researched by the OEM and approved by that company's legal team. It's costly to conduct environmental studies, so when a resin was previously chosen for a similar product, OEM's will often go with what they know.

- Because this is one of the most critical design decisions an OEM can make, the requirements for the resin are coordinated with legal and quality teams, who look to mitigate risk.

Except for very small medical companies, start-ups, or truly new product innovation, most of the major manufacturers of medical equipment have the resin question mostly solved before they begin. If they don't, they'll rely on the resin supplier and their own advisors to select the correct plastic. See our Resin Selection Guide for a more thorough discussion of this topic.

As cleaning requirements continue to evolve, plastic resin suppliers are developing new compounds capable of resisting the new chemicals they are being exposed to. For example, resin used for certain equipment will see a lifetime of exposure to MRSA-killing cleaning agents. It's not just soap and water that's being used now; hospitals are using aggressive chemicals.


CAD designs are extensively evaluated.

Assessing the CAD (Computer Aided Design) Data

Early in this process, the OEM will have developed a CAD model to describe the product and obtain request for quotes from injection molding manufacturers. At Ferriot, the next step in the process is our engineering staff will conduct a Design for Manufacturability study, or DFM, to ensure the product is capable of being manufactured as specified. Using a combination of experience and analytical tools, the engineers will evaluate how the resin will flow into the proposed tool design, fill the cavity, pack, cool and eject to ensure the product can be manufactured and meets the quality requirements as designed.

Some large OEM's have internal capability to use their CAD renderings and sophisticated software to run simulations on the design before it's even an approved project. It's very important to run these analyses, no matter who is performing them.

A recent, non-medical application for a large molding project required our engineers to spend about three weeks conducting various flow and pack simulations to ensure the design could be manufactured to the customers' requirements. Pro tip: Before a supplier starts cutting steel, a Mold Flow Analysis (MFA) should be performed to make sure the part fills, packs and cools correctly thus avoiding costly downtime and tool revisions.

If the simulation reveals problems, our engineers alert the customer right away. Sometimes it's as easy as sending a picture informing them of areas that won't fill or pack during the process. Our engineers will propose changes to the tool or the product design in order to ensure manufacturability.

Financial Analysis

What is the optimal cost-per-part that will ensure profitability for the project? The answer to this question is satisfied by the medical device manufacturer. Their concerns include:

- Break even, run quantity and duration: This is based on detailed business analysis.

- Production planning: Project planning for the immediate future as well as longer term manufacture. Does the volume of production justify the cost of having more than one tool created at the same time, given that a tool typically lasts 10 years?

- Optimization: Shipping, secondary operations, and efficiencies are identified, as well as the business decisions that weigh per piece costs against long term profitability.

Ferriot provides pricing for the injection tool, molded part and secondary operations, but it's up to the OEM to decide what fits their budget constraints. For most OEM's, a request for quote from an injection molder like Ferriot means that the preliminary budget analysis justifies going forward; they are ready to proceed.

Limitations

An experienced contract injection molder can accommodate almost any thermoplastic resin, and nearly any design the medical device manufacturer may choose. However, depending on the product, some injection molding facilities may be unable to produce that part, due to the nature of the presses they have available. For example, some resins run at very high temperatures, requiring a specific kind of press. 'Micro-molding' of very small parts and single-piece fabrication of giant parts are other types of projects that may present challenges for the injection molder. Some injection molding operations have equipment that is economical for parts within a minimum and maximum size range. Very small or very large items are atypical projects for medical equipment—after all, a medical device is often wheeled into a hospital room—but this underscores the need for a creative and experienced engineering team who can achieve design goals that are adapted to the machines available at the best price per part.

Tool Production

After the scope and design have been completed, it's time to quote a tool. In almost

all cases, the customer will, for lack of a better term, "contract" with Ferriot to build a tool as part of the production of their injection molded part. On a handful of occasions, the customer has supplied the tool directly to us. However, when multiple entities are involved in transferring a mold, the risk for error is increased. That's why we prefer to keep this activity in-house.

In some cases, tool production represents another opportunity for cost savings. For example, if the volume justifies it (this has both a volume and a cost implication) a tool might be adapted from single part production to multiple part production. Imagine a part that's four inches by four inches by four inches. A tool could be created with one cavity, run one at a time, or the tool could be created with four cavities of the same part and run four at a time. That would typically drop the cost of the per piece price. It would increase the tool cost, but it would reduce the piece price. Here, a customer truly benefits from solid advice based on experience.

Next, we go through the process of quoting the tool. Before tool production, we'll review the tooling with the customer to answer any questions and resolve any issues that might arise. Fabrication of the tool takes place domestically or overseas depending on the customer's desires and requirements. Ferriot is responsible for determining how the tool is to be built and to ensure conformance to the customer's long-term requirements. If the tool is built domestically, product samples will be produced in the production resin specified and inspected. Both part samples and inspection data will be reviewed and verified by Ferriot engineers for conformance to specification prior to tool shipment. It is the responsibility of Ferriot to make sure this process happens timely and seamlessly for its customers. The process is similar if the customer opts to have the tool manufactured outside the United States.

Inspection

During the scope and evaluation process, Ferriot's engineering team will develop key inspection criteria using the customer's CAD model and part drawings. The number of suggested inspection points varies based on the level of complexity and desired tolerances being produced. Once a stable molding process has been achieved, sample parts are pulled and a first article of inspection is conducted verifying the tool is capable of producing a part to specification. If issues are found, tool adjustments are made or in some instances part tolerances and/or dimensions are changed to match what the tool is capable of producing. This process and its verification is then repeated until all parties are satisfied.

First article samples and associated data are returned to the OEM for their testing and

approved sign off. If the FAI, or first article inspection has progressed satisfactorily, then our engineers proceed with PPAP, or production part approval process.

Release to Production

The PPAP document is prepared by Ferriot, and it can be anywhere from two pages to 100 pages long. It will include drawings, inspection data, control plans, etc. for the customer to approve. The production part approval process helps ensure that the process used to manufacture the product can consistently reproduce the product at stated production rates during subsequent production runs. We retain copies for our records, and await approval from the customer. After PPAP is approved, it's time for release to production.

At Ferriot, presses run side by side.

After everything has been approved, the OEM submits a purchase order for a specific run quantity. This triggers the plant team to begin set up of the mold. Nearly all projects that are produced in our injection molding facility are custom projects, meaning we manufacture to that specific purchase order. A few OEM's will require build to stock, so that we have parts available for them on a contingency basis. In this scenario, the OEM will consent to an agreement to build to a forecast. However, as with most injection molding contract manufacturers, the job is per the customer's orders.

Our plant operates dozens of active injection molding presses side by side. When it comes to the manufacture of medical equipment, injection molding presses for device enclosures run alongside equipment producing products for other markets. This allows us to keep costs down for the various customers we serve. This is part of the cost/benefit trade-off decisions medical OEM's will make prior to engaging a contract manufacturer like Ferriot.

Secondary Operations

Another advantage of flexibility is that additional operations can be performed to augment the part production. Medical manufacturers might request:

- Hot stamping
- Applying functional/cosmetic coatings such as EMI/RFI shielding or special paints
- Ultrasonic welding and insertion
- Heat staking
- Pad printing
- Drop shipping of final parts

Occasionally, we'll include secondary operations for medical equipment that may feature more complex value-add enhancements. For example, we make an IV pump for a large medical manufacturer, containing some internal parts that get inserted during the manufacturing process. However, there are other types of devices that are governed by specific ISO certifications that dictate how they are to be made, including rules about how to put specific items into a box! In most cases, our certification procedure is enough to ensure the quality of the injection molded product; Ferriot certifies that we will make a product to a specification, but we don't certify the end product, per se. Our customer can save on production costs by having us take the job up to a sub-assembled state before it returns to them (certified source) for final assembly and ship. Again, liability is one of the biggest risk factors involved in the production of medical equipment or devices. In any case, "one-stop shopping" with an experienced partner delivers peace-of-mind as well as convenience and cost efficiency.


Pad printing is a secondary operation.

Conclusion

What is the best advice to give a manufacturer who is considering an injection molded part—for medical equipment or otherwise? "Do your homework."

In the steps described in this document, it's notable that the majority of the process involves scoping, planning, and assessment. This is by design. It is entirely possible to prevent project cost overruns from errors in the development process of medical devices and medical equipment. With attention to the details of liability, planning and inspection, any OEM can achieve a quality product on time and within budget.

Appendix: Further Reading

Injection Molding Resin Selection Workbook

http://info.ferriot.com/injection-molding-resin-selection-workbook

Considerations to Take When Making Plastics for a Medical Setting

http://info.ferriot.com/considerations-to-take-when-making-plastics-for-a-medical-setting

Case Study | Custom Mold Manufacturing for Infusion Pumps

http://info.ferriot.com/case-study-custom-mold-manufacturing-for-infusion-pumps

Ready to Learn More? *To learn more about how to optimize your injection molded project, complete our Online Quote Form, available at* ***http://info.ferriot.com/request-a-quote****.*

Or, if you prefer, call us at ***(330) 786-3000*** *for immediate attention.*