

The Importance of Scientific Molding in MEDICAL DEVICE MANUFACTURING



KAYSUN
INJECTION MOLDING & ENGINEERING SOLUTIONS

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Manufacturers of complex medical devices cannot afford to lose any time getting their products to market. Advances in technology come rapidly and competitors are vying for market share. To ensure success, medical components must be designed and produced with ultimate precision and efficiency. That efficiency depends on eliminating production delays caused by flaws and inconsistencies in the manufacturing process.

Companies that design and produce complex medical devices containing precision-molded plastic components must be certain that those components will be formed with repeatable freedom from defect. The manufacturing process itself must also be repeatable across multiple production runs. Today's scientific molding procedures virtually guarantee top quality by removing all guesswork from the injection-molding process. Because data associated with a manufacturing process are recorded, that process can then be replicated as needed, even when production is transferred from one machine to another.

This white paper:

- Defines scientific molding principles
- Explains how specialized molding engineers contribute to the development and manufacture of precision-molded plastic medical components to create templates for repeatable production
- Explains the importance of injection-molding engineers' training and certification in state-of-the-art scientific molding practices in optimizing all aspects of production
- Examines the key benefits of today's scientific molding procedures in medical applications



What is Scientific Molding?

Scientific molding uses the key steps of the scientific method – developing a hypothesis, testing it, analyzing the results to draw a conclusion and proving the results are reproducible to develop a tightly controlled and repeatable manufacturing process that results in components consistently free of defects. Compared to the traditional “trial and error” molding process that relies on guesswork to bring components within specification, scientific molding uses sophisticated data collection and analysis techniques to document the specifications, settings and steps required to ensure reproducibility over time and across equipment. This practice is invaluable in designing and producing components for complex medical devices where precision can mean life or death.

The Scientific Molding Process

Scientific molding principles must be applied across all phases of medical device component manufacture: design of the part or product, design and building of the tool, qualifying the tool, material selection and the injection-molding process. Different engineers with specialized expertise oversee each of these phases as shown in the following diagram:

Figure 1: Scientific molding practices used during the manufacturing process

STAGE	OBJECTIVES
Part Design	Designers assess customer’s needs and requirements vs. their available resources. Specifics such as polymer selection, gating design, corner radii, draft and wall thickness are determined here.
Tool Design	Choose steel type, gate location; determine venting & cooling channel layout and ejector pin locations (overall mechanical design of tool).
Tool Build & Qualification (the heart of the scientific molding process)	Develop robust process: molding engineer conducts tests to define parameters and records data to form the template.
Production	Process technicians monitor production against template, identify and solve issues.
Assembly	Production techs perform dimensional checks.

Engineers trained in scientific molding have the expertise to understand what's happening with the material inside a tool, specifically in terms of viscosity. They can visualize rather than guess how the polymer flows into and behaves inside the tool. By recording data when the machine is producing at peak efficiency, those engineers create a template of process parameters to be replicated when:

- Specification issues arise during production
- An existing tool is set for a new production run
- Production is moved from machine to machine

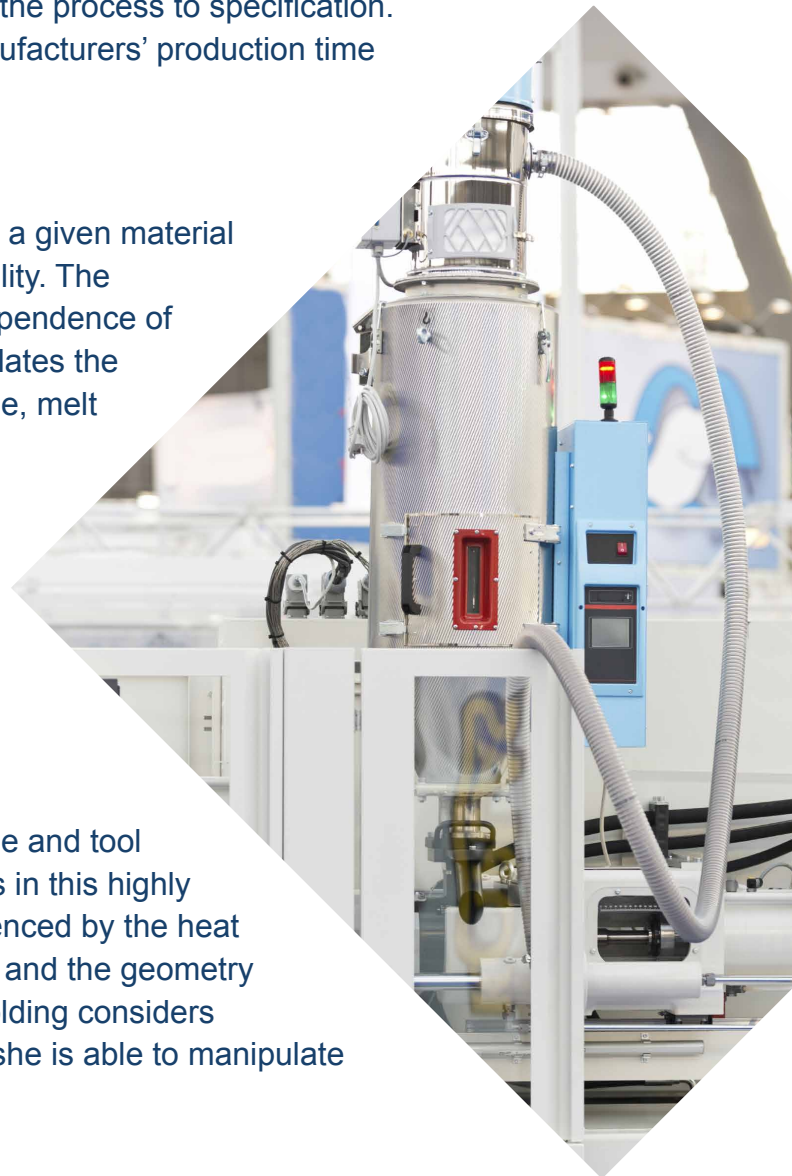
The insight of these specifically trained technicians is invaluable in designing successful medical device tools and molding processes, in identifying process issues quickly and accurately, and in determining and executing solutions to return the process to specification. Optimizing production in this way minimizes the manufacturers' production time and costs.

MOLDING VARIABLES

Determining and duplicating all of the parameters for a given material and molding situation is the key to process repeatability. The scientific molding engineer, well aware of the interdependence of all process variables, interprets the data and manipulates the parameters to achieve the ideal process. For example, melt temperature is affected by barrel temperature, screw speed and back pressure. The main molding variables are:

- temperature (of material and tool)
- material flow rate
- pressure (pack and hold)
- cooling time and rate

Other variables include material moisture rate, fill time and tool conductivity; all of which are affected by other factors in this highly complex process. Cooling time, for example, is influenced by the heat level in the material, the conductivity of the tool steel and the geometry of the part. Since an engineer trained in scientific molding considers everything from the perspective of the plastic, he or she is able to manipulate the variables as needed to return the process to conformation.



QUALIFYING THE TOOL

Qualifying the tool is the heart of the scientific molding process. In order to ensure manufacturing success through consistent and repeatable production of flawless molded components, the tool must be challenged completely before it's called into action. This is how its weaknesses are identified and corrected.

The process begins with the tool being put into the press so that the toolmaker and process engineer can thoroughly and systematically check every aspect of its mechanical functionality. For a starting point, they use the recommendations specified by the supplier of the material to be molded. These settings are entered in to the machine. Here is an example of what those recommendations might look like for polypropylene:

Figure 2: Specialty Compounds Polypropylene (PP)

Typical Injection Molding Conditions	English	SI Metric
Temperatures		
Rear Zone	380 - 420 °F	193 - 216 °C
Center Zone	390 - 430 °F	199 - 221 °C
Front Zone	400 - 440 °F	204 - 227 °C
Melt	375 - 450 °F	191 - 232 °C
Mold	90 - 150 °F	32 - 66 °C
Pressures		
Injection	10000 - 15000 psi	69 - 103 MPa
Hold	5000 - 10000 psi	34 - 69 MPa
Back	50 - 100 psi	0.34 - 0.69 MPa
Speeds		
Fill	1 - 2 in/sec	25 - 51 mm/sec
Screw	60 - 90 rpm	60 - 90 rpm
Drying		
Time & Temperature	2 hrs @ 175 °F	2 hrs @ 79 °C
Dew Point	n/a °F	n/a °C
Moisture Content	n/a %	n/a %

Next, the engineers conduct short-shot testing to assess the dynamic pressure loss and, in a multiple-cavity tool, to check for any imbalance among the cavities. This step is also the stage at which the rheology curve (or viscosity curve) is established to identify the best fill rate and pattern.

After this, the decoupled process is set up to do additional testing. Gate seal studies are performed from both the pressure curve and the weight of the sample components. These tests show if the gates seal fully and at what point on the tool cavity (or multiple cavities). The engineers examine the test components for any defects then record their findings along with recommendations for adjustments in the process or the tool in order to correct the defects. They also record data on the melt temperature, fill time, tool temperature, coolant flow, cycle time and pressure curves.

From there, the components go to quality control for examination of their measurements, shot-to-shot consistencies and overall quality. That information is used for any necessary adjustments to the tool before new samples are made. The new samples undergo the same quality testing with necessary adjustments made again as needed.

All of the process parameters are recorded, with their acceptable ranges shown, to form the template. This template will be followed throughout production to ensure optimum quality, efficiency and repeatability.

TESTING AND MONITORING

After the process engineer has verified that the tool is functioning optimally, production begins. The production engineer monitors process parameters according to the template with ongoing quality testing. If issues are identified, the specialist analyzes the data and forms a solution to return the process to conformation.

Some testing and monitoring methods used during tool development and production include:

- **Rheology curve (or viscosity curve).** Rheology testing helps to determine the optimal viscosity and injection speed making it a crucial part of the scientific molding process.



- **Velocity profiling** helps determine the fastest fill rate that can be used without causing flash or other aesthetic flaws.
- **Cavity pressure readings** show the actual pressure inside the tool, making this the best way to indicate the material's behavior where the eye can't actually see. This is really the core of scientific molding. Specialized training allows the engineer to visualize what's happening to the plastic inside the tool.
- **Gate seal** (or gate freeze) **studies**. During rheology studies, data measured during short-shot injections is used to create a viscosity curve that shows the ideal viscosity and first-stage injection speed. By analyzing injection speed, pressure and fill time along with gate-seal studies, the engineer determines the optimal tool parameters. Once these parameters are recorded as the template, it can be used to replicate the process across different machines.
- **Design of Experiments** (or Experimental Design) refers to a related group of tests used in setting up the process parameters and troubleshooting process issues. It allows the molder to make simultaneous adjustments to the variables, saving significant time over earlier troubleshooting methods based on intuition and guesswork instead of informed analysis of scientific data.

The eDART™ system may be used throughout the phases of scientific molding for testing as well as troubleshooting. The system is essentially a computer on wheels that can be rolled where needed to monitor molding variables, verify conformance to template, adjust process conditions, set timing and alarms, among other functions crucial to successful molding. The system is a collection of tools that can be configured to the job at hand. It contains software that holds and organizes the process data for the molding job, forming the templates and yielding the RJG graphs that the technicians use to achieve a robust and repeatable process. While the eDART is used only at particular points in the majority of molding situations, 30% of jobs are run with it constantly connected.

The Importance of Scientific Molding Training and Certification

The required training for scientific molding engineers is rigorous and extensive. Depending on his or her specialty, the engineer completes successive certification levels in order to develop the comprehensive skills necessary for reaching the objectives in any given precision-molding situation. Kaysun's scientific molding specialists receive most of their ongoing training in the discipline from industry leader RJG, Inc. Some of this organization's certification levels include Systematic Molding, Master Molder I and Master Molder II.

Successful scientific molding requires a combination of knowledge, experience, analytical skills and the proper equipment and tools. The capable engineer applies these resources to each unique molding situation.

Just as each manufacturing situation is one of a kind, so is each tool. It is the engineer's job to work with any tool and its unique "fingerprint" and all of the molding variables to make the best medical component for the client. Specially trained scientific molding engineers specialize in each phase of product development: tool design, building, and function, or molding production, ensuring process conformation to the template. Through their expert analysis, interpretation of the collected process data and their ability to solve issues, scientific molding engineers employ a scientific approach to design and document a robust and repeatable process that delivers consistently defect-free components.

How Scientific Molding Benefits the Medical Device Manufacturer

Reproducibility is important when it comes to scientific molding for medical equipment manufacturers. With a method governed by science, molding engineers ensure consistency and repeatability in production. The OEM can also count on getting the highest-quality medical device components time after time. A predictably efficient process delivers those defect-free components with minimal loss of materials at minimal time and cost. This outcome is especially important in manufacturing complex components.

Scientific molding done by qualified engineers virtually eliminates repeated non-conformance issues with a medical device component's dimensional specifications. This maximization of quality is what every manufacturer of complex medical devices strives for.

Kaysun Corporation: The Know-How to Ensure Success

Scientific molding is a complex process that runs through every phase in the production of precision-molded plastic components for medical applications. A tool with robust process capabilities assures the manufacturer of consistent quality and top efficiency, as does working with an experienced injection molder that holds [MedAccred Plastics accreditation](#) and has an in-house team of certified design and production engineers with a proven record of successfully bringing medical components to fruition.



To learn more about how Kaysun can help reduce the risks involved with designing and manufacturing complex medical devices, call us at **920-687-5800**. Our engineering and design teams will work closely with you to deliver a final product that meets all your design, quality and production goals.

