

# Planning Your Medical Molding Project



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Medical molding encompasses a broad scope of products. Molded components play a role in various types of medical devices, from extrusions that transfer and filter blood, to implantable devices and surgical components. As technology continues to evolve, medical molding helps product developers continue to innovate and create cutting edge products. Pacemakers, surgical robots and ever-shrinking laparoscopic devices wouldn't be possible without medical molding. Through continued product innovation, medical molding has improved the tools available to physicians, and by extension, the level of patient care.

Medical products are held to more stringent standards than other products on the market. Because medical products play a significant role in patient health and longevity, the development and validation processes are much longer than for other consumer products. Quality and validation requirements can quadruple your development timeline, but this time is necessary to accommodate additional prototyping, small-batch production runs and biotesting. These steps are absolutely required for implantable and other components that come in contact with blood and tissue.

## Key Considerations for Medical Molding Projects

Medical molding requires special attention in various areas that do not necessarily apply to traditional molding projects. To get the best result, work with a manufacturer who specializes in medical molding and can address these key considerations.

Specific ISO certifications are essential for medical molding manufacturers. These designations are reviewed on an annual basis by external auditors, and should be verified before you start working with a new partner. At a minimum, manufacturers must be ISO 13485 certified to demonstrate that their processes and procedures adhere to a comprehensive quality management system. Fulfillment of this standard also helps achieve compliance with European regulatory requirements.

Clean rooms are a critical element of the medical molding process and help ensure the cleanliness and quality of the final product. These rooms have low levels of environmental pollutants such as dust and chemical vapors. The contamination level in clean rooms is controlled and specified by the number of particles per cubic meter at a specified particle size. Staff must wear protective clothing and the materials that are permitted into the space are highly regulated.

Selecting the right molding material for your medical components is paramount. A highly consistent material must be used in order to reduce the risk of variation between runs. Even an incremental difference in component dimensions can result in improper function and increased risk to the patient. The equipment used to create medical components is also incredibly important. A quality manufacturer will maintain and update their machines to ensure consistency. Newer electric equipment runs more cleanly, without excessive vapors or oil from hydraulics that introduce particulates to the environment.

Because the standards around medical molding are so stringent, it is essential to thoroughly train your staff to ensure they are in compliance. A dedicated medical molding manufacturer will train its staff on specific elements of the process, including how to function within a clean room, component handling, which materials are permitted around medical components and technical procedures specific to the machines that are used in production. A higher level of training reinforces the tenets of scientific molding, which focuses on process control, efficiency, scrap reduction, validation and documentation.

The testing process for medical components is more intensive, and requires additional attention at each stage of production. The base material must be tested for biocompatibility before a prototype is created. Each component of the assembly must be tested individually using varied environmental conditions. Offsite testing is required for implantable components, which can extend the development process.

All of these elements, along with a manufacturer's length of time in the industry, breadth of experience and proposed costs, should be considered when choosing a partner for your medical molding project.

Specially-developed gum silicone compound for a catheter tip device



## MRPC: Your Medical Molding Partner

Over the past 20 years, MRPC has steadily grown their competency in medical molding. The company started out using natural rubbers and transitioned to synthetics and liquid silicone rubber (LSR) as these new materials gained traction in the market. Thanks to this broad skill-set and capabilities in various multi-material production methods, MRPC can be a single source for your medical molding projects. There are various product benefits that come from combining multiple materials into a single component, including improved ergonomic features, superior fit and performance, enhanced product integrity and reliability, and safety. Working with a single manufacturer also lowers production costs by minimizing shipping and handling within your supply chain.

MRPC has been ISO 13485 certified since 2008, and undergoes annual audits to maintain this designation. The company specializes in compound development and has specialized equipment for medical molding. In addition, our facility hosts five certified Class 10,000 and 100,000 clean rooms with a combined space of 52,000 square feet.

MRPC has developed a breadth of knowledge by creating a wide variety of molded components for medical industry use. Recent projects include:

- A disposable Y-body connector used to mix and apply a two-component surgical adhesive. This complex assembly consists of seven separate components, including two molded plastic luer fittings, two check valves, a plastic molded Y-body connector, a co-extruded silicone tube (composed of silicone co-extruded over a metal wire) and a molded silicone tip. MRPC molds each of the silicone and plastic components, extrudes the tube, chemically adheres each part together and packages the complete assembly into a sterilizable Tyvek pouch.
- An innovative micro-molded neurostimulation lead. This component involves two layers of overmolding. The first is a tiny Nitinol metal ring that is overmolded with an implantable PEEK material. This overmolding is then primed and overmolded again with an implantable grade silicone seal on one end. This component measures only 0.080" in diameter and weighs less than a gram.
- A polycarbonate dental packaging vial and cap. MRPC created a threaded design that allowed the cap to snap into place, but still be unscrewed normally. The client's packaging process could then be automated, while maintaining the sterilization of the vial.

MRPC's experienced engineering staff can help design and develop your medical components. Through prototyping, our team can work out any design issues and make any necessary modifications to make the component more effective. MRPC works to streamline and improve component designs through overmolding, and specializes in combining various materials and elements into a single component. Our team adds value and helps drive costs down by enabling you to work with a single manufacturer to produce your entire component.

Liquid silicone rubber overmolded onto rigid thermoplastic for assembly into a multi-port laparoscopic device



Custom-formulated polyisoprene molded into a duckbill component for a laparoscopic device





## About MRPC

MRPC is a single-source provider of innovative medical device components and assemblies, specializing in clean room molding with a focus on silicone and thermoplastic molding, two-material molding, micromolding and silicon extrusion. As an FDA-registered manufacturer, MRPC is committed to providing our customers with the highest level of expertise through extensive staff training, industry certifications and a long history of success.

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≡ ISO 9001:2008 ≡