Designing Plastic Parts & Products For COMPLEX MEDICAL APPLICATIONS

KAYSUN

INJECTION MOLDING & ENGINEERING SOLUTIONS

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Medical equipment has one job to do: perform. Failure is not an option. There is no room for error when designing plastic parts and products for these applications. There is too much at stake given the potential for recalls, warranty claims, property damage and personal injury. No company can afford to damage its reputation and lose the trust of hard-earned customers because of equipment that is faulty.

Understanding all of the factors involved in manufacturing a plastic part or product is critical when it comes to ensuring optimum performance, especially when a part or product is involved in medical applications. Yet few design engineers have the level of knowledge necessary to evaluate and utilize plastics in a way that's consistent with the part or product's performance requirements.

The Stakes And Risks Are High

In medical device applications, plastic parts and products are typically more complex than other applications in terms of design elements, functional requirements and the levels of tolerances involved.

Some design engineers realize too late that a part that appears moldable in the design phase simply isn't feasible without first fixing flaws. Others discover that engaging an experienced molder to analyze parts can save time and costs, and reveal production options that can enhance quality and ensure reliable performance.

There is considerable potential to enhance or erode product quality, cost and performance when designing a plastic part or product for a medical application; therefore, a more comprehensive knowledge of mold processing and the factors that influence a design's quality and functionality is critical for design engineers.

Common Design Challenges

Here are some of the most common challenges encountered in the design phase of medical applications:

Materials: Choosing the right materials for a specific application is important. There are the tens of thousands of materials options available, and each uniquely impacts a part's form, fit and function. The breadth of choices alone makes the decision difficult, and the alternatives available to minimize cost without impacting quality must be considered. This is especially true with complex medical applications that often dictate the use of specialized resins.

Trapped steel: Trapped steel is the improper ejection of parts from a tool and can result from any number of design feature flaws. In complex tools, the relationship between the ejector pins and other moving parts, such as slides or lifters, must be analyzed to eliminate interference. Designing to include an adequate number of ejector pins is important. Inadequate or misplaced ejector pins will affect the dimensional consistency of the part.

Draft: Draft is the degree of sidewall or rib taper needed to allow the molded plastic part to be removed from the metal tool. Plastic parts are difficult to remove from the tool when the degree of taper of a side wall or rib does not allow the part to be removed, which creates the same issues as trapped steel.

Wall thickness: While it might specify a minimal wall thickness, the part design might not account for functional performance requirements and the practicalities involved in plastics processing. This opens up a host of issues that determine whether or not the part is moldable.

Gating: Gating is imperative in molding parts because it facilitates the flow of plastic into the tool cavity. The wrong type or size of gate, or the incorrect gate location, are issues that cause considerable problems in processing – problems that range from functionality to aesthetics.

Knit lines: Knit lines create blemishes on the part or product and can weaken the structural integrity of a part. These can be caused by multiple factors, many of which are rooted in design.

Cycle times: Efficient cycle times translate to lower cost. While integrated with melt temperatures, cooling and other variables, there is little question that part design impacts cycle times and the ability to hold down costs, speed time to market and ensure quality.

Over-specification: There is a tendency among design engineers to over-specify their designs. For example, the specified wall thicknesses may be greater than what is needed for a successful design. This adds cost without improving the fit and function of the part.

Late start: Many times, design engineers look to the molder and tool maker to develop the tool immediately following the acceptance of a quote in order to meet a tight production schedule. This gives molding experts little time to present recommendations that can optimize the design and forces any adjustments to be made in the tooling phase where costs will be higher.

While the challenges described here are common, they can be easily solved with the right approach and the appropriate level of design and injection molding expertise.

4 Key Ways To Improve The Chance Of Success

While virtually every medical device design and project is unique, design engineers who follow a few basic guidelines can significantly minimize, and in many cases eliminate, obstacles and increase the likelihood of success.

1. **Properly plan and focus on essentials**

   Success starts with a clear understanding of the end use of the medical device, followed by clear communication with the molder regarding the requirements to achieve proper fit and function. The key to proper planning is to share details associated with any known design challenges, material concerns or needed areas of improvement right from the start.

   It's also essential to recognize before processing begins all that's involved in the processes and the timelines associated with tooling, sampling and modifications. By planning ahead and communicating key issues, the team can avoid and, in many cases, eliminate unnecessary delays and costs without sacrificing quality or impacting part performance.

2. Involve the molder early and often

The importance of getting the molder in the mix early cannot be overstated. A molder who is engaged early in the medical equipment's design can identify problems before they happen. For example, a mold-fill analysis performed by a molder can pinpoint and help resolve issues that range from material selection to part and tool design. At this point the molder also has the opportunity to identify areas to cut costs, whether it is in weight, materials, specifications or processes involved in the project.

Another advantage of early involvement is the ability to expedite and strengthen the external certification/qualification process. Working together, the design engineer and molder can define testing protocols and quality measurement techniques to ensure all critical dimensions are monitored and accurately measured.

Ongoing communication and teamwork eliminates a host of problems that will otherwise grow exponentially more challenging (and costly), especially as it relates to part requirements and adjustments. Ultimately, early engagement equates to cost savings and improved time to market.

3. Leverage the knowledge of an expert

Like all successful professionals, medical device design engineers who excel at what they do surround themselves with experts. That includes reliance on an injection molder that holds MedAccred Plastics accreditation and can provide insight into the most important aspects of the process in an effort to improve product quality and performance, and reduce overall costs.

- **Feasibility:** Molders can provide input on the overall feasibility of a design and offer recommendations for increasing tool and part efficiencies.
- **Material selection:** The material that's selected has a significant impact on its performance. In medical devices, specialized resins are often required. To guide material selection and ensure optimum performance, molders can provide insights that may not be commonly known to design engineers.
- **Accelerate time to market:** Defining measurement techniques and performance expectations early on usually results in a more efficient qualification process and shorter time to market.
- **Problem solving:** Molders are in the position to identify potential problems and offer practical solutions. Whether it is trapped steel, insufficient draft, gating, heavy wall thickness, internal stresses, or any other challenges that aren't recognized in the design stage, the molder can often design alternatives to avoid these issues.

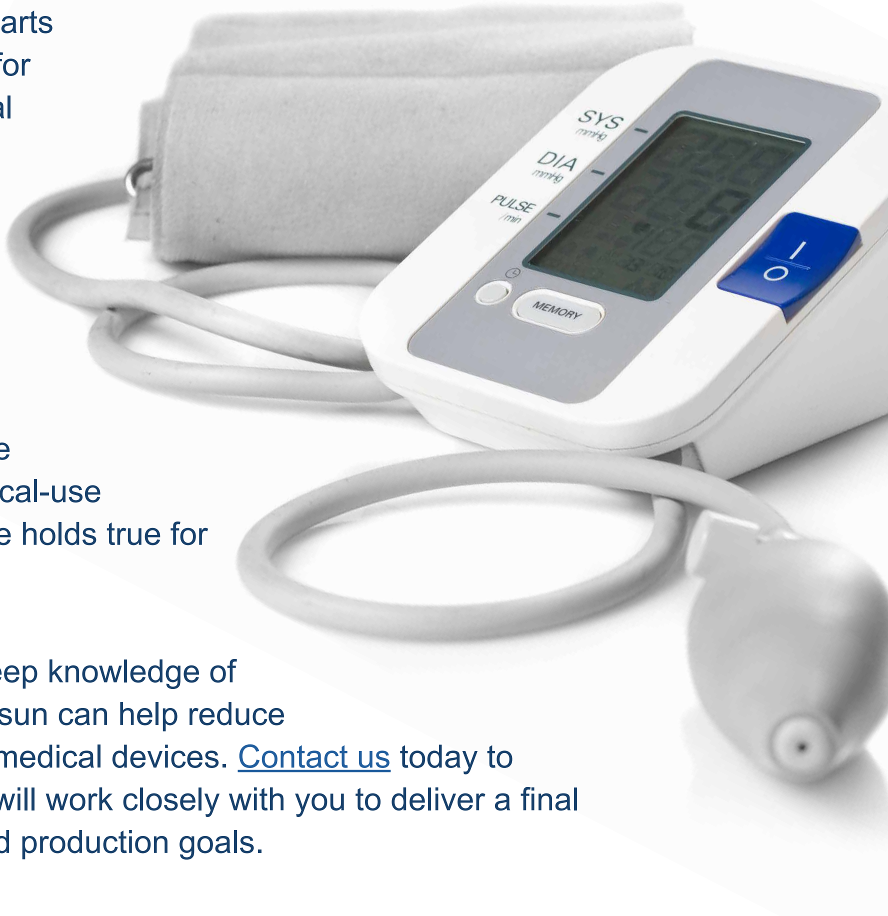
- **Manufacturing oversight:** A competent molder applies best practices to all phases of part manufacturing. This level of consistent control eliminates process variations, shortens cycle times, and ensures quality and repeatability from batch to batch.

- **Fewer pre-production tooling iterations:** During development, a cooperative relationship with your molder reduces the need for multiple, time-consuming tooling revisions. This allows more room for adjustments throughout the project, from start to finish.

4. Lasting Partnerships

The complexities involved in designing parts for critical-use medical applications, and the range of factors with the potential to improve the odds for success, places a premium on choosing the right molder.

The final factor in designing successful parts and products for medical applications is for design engineers to carefully vet potential injection molding partners. There's no substitute for a MedAccred Plastics accredited injection molder with proven experience in parts and products like those you may currently have in development. The ability of the molder to provide useful advice in all phases involved in the design and manufacture of complex, critical-use plastics parts is immeasurable. The same holds true for a lasting relationship built on trust.



With MedAccred Plastics accreditation and deep knowledge of the unique needs of the medical industry, Kaysun can help reduce the risks involved with designing for complex medical devices. Contact us today to learn how our engineering and design teams will work closely with you to deliver a final product that meets all your design, quality, and production goals.

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