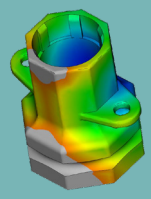
MANAGING COST AND SPEED – DESIGN FOR MANUFACTURABILITY (DFM) CONSIDERATIONS FOR PLASTIC MEDICAL



BY CLINT BADOWSKI, CAPLUGS

Designing a component with consideration for the manufacturing process can reduce production times and costs while ensuring repeatable quality.

MEDICAL caplugs®

MANAGING COST AND SPEED – DESIGN FOR MANUFACTURABILITY (DFM) CONSIDERATIONS FOR PLASTIC MEDICAL

Design for manufacturability (DFM) typically is understood as designing a product in a manner that promotes predictable and repeatable manufacturing performance while ensuring speed of project within budget. However, the process for achieving these goals varies from company to company, and unique DFM considerations apply to plastic medical products.

DFM guides not only fabrication, but also product development steps that affect manufacturing cost and timelines. Accordingly, early engagement between a medical product maker and a plastic/resin component supplier is vital. The partners collaborate up front to identify risks, assign clear responsibilities (to both the component supplier and the customer), and set timelines.

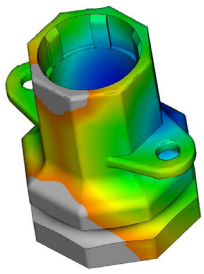
DESIGN FOR MORE INTUITIVE PRODUCT DEVELOPMENT

Transitioning the conversation from executive-level discussion to engineering-level discussion as soon as possible helps identify potentially costly risks sooner, resulting in a clear design directive or driving design direction. Simply put, engineers working on such products often ask critical questions that less technically minded executives might miss.

Assigning responsibilities early in the collaboration prevents scenarios where both parties are essentially waiting on the other to complete a task, each assuming the other has responsibility for it. Timelines, too, can be better predicted through early collaboration. For example, referencing historic data can help predict how long it might realistically take to produce a product. Such data also can support shortening those timelines, though initial tooling costs or design costs generally go up when products are expedited in this way, since resources or personnel may be pulled from another project and applied to the priority job. Negotiation between partners is necessary to determine which steps can be taken and how much time can be cut.

The use of computer software can also speed up the design and development process. These tools, like finite element analysis and mold flow/filling simulation software (Figs. 1 & 2), are invaluable when designing a custom product. For example, Caplugs may receive a request to build a new tool and run a part with a particular gate location and size specified. However, software analysis may reveal that the requested gate location or size could lead to defects or poor mold release, resulting in quality issues and less-than-optimal production cycle times. This could, in turn, lead to changing critical mold features, gate location or gate size before the tool is built, reducing wasted time and cost while ensuring product repeatability and a streamlined manufacturing process.

Using finite element analysis, engineers can also research part performance under a load or stress. For example, the software can predict the amount of force required to insert or apply a pressed-fit component. The simulation can be followed with a prototype component to verify through internal



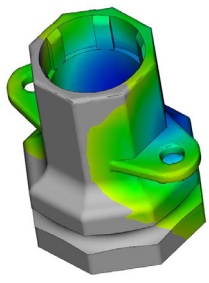


Fig. 1 (L) and Fig. 2 (R) – In this image, a simulated part is filled with plastic using a mold-filling software. Blue- and green-shaded areas represent where plastic first enters the mold, while yellow- and orange-shaded represent areas filled in later in the fill. Caplugs uses this plot to understand how plastic will flow into a mold and help determine potential issues caused by a specific gating location.

testing, and prototypes can be shared with the manufacturer for their own testing. These insights foster a more accurate quoting and design process, as well as ensure production capacity will be available when a project kicks off.

Customers also benefit from this simulation by receiving a more thorough explanation not only of which methods, tools and materials we are using, but why, allowing for a more collaborative design/development process and fewer product revisions. When a component features critical dimensions, simulation software lets users arrive at the end dimension more quickly than "going in blind." While a typical process may take three or four revisions, utilizing these software programs can produce an end dimension in as little as a single revision, saving weeks – if not months – on the certification process.

DFM AND MEDICAL PLASTICS

It is difficult to separate development discussion from manufacturing since effective DFM positively impacts both. A combination of expertise, production resources and simulation software serve DFM by saving time and expense on a project's materials, the production process applied, dimensional performance and more.

Materials

Materials selection is an involved process, particularly when considering DFM. Most commodity plastics can be used in standard manufacturing equipment and are often available in high volumes, making production easier to ramp up and eliminating the need for special-order material. However, some engineered plastic resins require specialized equipment (e.g., specialty injection molding screws, material dryers, special hot runner or hot tip designs, etc.) or may have unique considerations, such as requiring more or less draft, a larger or smaller gate size, or thicker/thinner wall thickness requirements.

Additionally, the environment where a part will be used can play a role, with some materials offering greater resistance to harsh chemicals, high heat or highly abrasive uses. A manufacturing partner like Caplugs can help evaluate these considerations and develop an approach that balances use requirements, performance features and cost factors in production.

Production Process

Numerous manufacturability considerations affect which manufacturing process is utilized. Options for parts may

Fig. 3 – The ISO Class 8 cleanroom at Caplugs' headquarters in Buffalo, N.Y., is certified to manufacture medical components that meet ISO13485 standards.

include injection molding, extrusion, blow molding, vinyl dip or thermoforming, and the right option can depend on the material selections and end use. Once the manufacturing process is decided, other factors such as an injection molded part's gating location or an extrusion-made part's continuity (i.e., does it need to be cut or trimmed, or is it a continuous roll?) can further refine the requirements for production.

Again, mold simulation software can help at this stage in development. It can quickly analyze a gating location to show why it works or why it will present problems. This answers the vital question, "can you actually fill the mold?" and saves users the risk of having to scrap a tool because the gating location was suboptimal. Simulation also can indicate how a part dimension will be affected by shrinkage, defects, sink marks, weld lines or other issues.

For example, a component may need to exhibit no surface blemishes that could harm a user or detract from its aesthetics, and changing gate location usually is the easiest way to significantly alter a part. For this condition, mold simulation also empowers a molder like Caplugs to respond to customers who request particular gate locations. For instance, a customer might want the gate to be in one location on the part, but working with the software can reveal unforeseen problems on part dimensions and highlight a problem before it reaches production.

Of course, more complicated design features (e.g., bosses, ribs and undercuts) also can cause surface defects addressable through simulation. Simulation results provide a conversation starting point between partners seeking a solution, be it reducing the number of such features, reducing the size, or coring out from behind, which reduces the overall thickness of that feature.

Volume

In addition to determining which and how many machines can be applied to a project, DFM must examine cavitation: how many cavities will fit in a given tool, what size press will that tool require to run, and will this cavitation meet the required demand? More cavities will typically reduce per-part costs since higher cavitation means every shot produces more parts, but this will typically increase the initial tooling cost.

However, some parts may feature difficult geometry ill-suited to use with a higher cavitation tool. Specifically, a determination needs to be made as to how the part can be injection molded. This could limit the cavitation in the tool due to space or action restrictions. Every slide, lifter and collapsible core can be simulated before a tool is ever made. Further, if a molder like Caplugs is quoting a lower-budget tool, customers have insight into how their costs will be affected by adding actions like slides, lifters or collapsible cores.

Sterile Production, Storage & Shipping

Some products must be produced in cleanrooms to meet specific cleanliness/sterilization classifications. DFM helps to determine whether the machine quantities and sizes available in those rooms will be sufficient for a project (in the context of other ongoing or planned projects, as well). Other components can be molded in a standard manufacturing environment and then sterilized afterward, which may provide a solution for products made from certain materials.

CUSTOM PART COSTS > OFF-THE-SHELF PART COSTS = FALSE

Custom parts (and custom tooling to create those parts) often get a bad rap: they are too expensive or they come accompanied by burdensome lead times. Neither characterization is true when working with a custom medical molder, where both commercial off-the-shelf (COTS) parts and custom parts drop in per-component price as production volume increases.

Regarding custom part lead times, some companies like Caplugs have in-house capabilities to produce prototype parts quickly, meaning customers can often have sample parts in hand within a day or so. Customers then can check fit and performance, as well as use the prototypes in designing the rest of the product's componentry, helping bridge the time between initial design and production parts coming out of the tool. Some prototypes can be made using the exact plastic designated for the application (e.g., ABS, polypropylene or nylon), allowing a product to be functionally tested, while other prototypes can be made with other materials that provide higher dimensional accuracy for test fitting purposes, further speeding turnaround times. This prototyping process alone can reduce product failure rates, saving time and cost.

COTS parts, too, come with benefits: low initial cost, high availability and predictable performance. However, choosing a COTS component and getting it wrong – perhaps the component doesn't fit properly or work as intended (e.g., maybe the tolerances needed to be designed tighter to ensure better fit) – can result in a manufacturer turning to a custom part anyway. The manufacturer now is behind schedule and paying even more to have that component's design and production expedited.

Additionally, a design mindset that rules out the use of custom parts can cause engineers to change their designs completely to fit around a particular COTS part. They may end up spending more time and money on the product's overall design just trying to fit one or more COTS parts where a custom component would have been faster and less cumbersome. Working alongside a manufacturing partner like Caplugs can help both parties streamline the design

process, reducing complexities, time lost in development and costs from overdesigning a part or underpreparing for its protection.

CONCLUSIONS

Design, material considerations, manufacturing and end use all must be balanced when developing a new plastic medical product. Designing with consideration for the manufacturing process can reduce production times and costs, as well as simplify development of transport, storage and protection solutions. DFM also contributes to commercialization by helping make the final product more rapidly and efficiently produced at scale.

Engaging a vendor earlier in the process opens additional options to meet timelines, budgets, part performance goals and more. Designing products with a vendor or manufacturing processes in mind can help identify ways to create a more efficient design. Software also can facilitate optimized production and consistent results. Ultimately, effective DFM enables experts to weigh in on material and design choices that are not only more efficient, but can also offer added performance features/attributes.

ABOUT THE AUTHOR

Clint Badowski is a product engineer at Caplugs and works closely with clients from all backgrounds to assess, design and develop customized parts for specific projects and applications. A graduate of Penn State Behrend with a degree in plastics engineering, Badowski has spent nearly 15 years in product development across multiple industries, including medical, consumer and industrial goods, packaging and electrical components.

ABOUT CAPLUGS

Caplugs has been a leader in plastic molding since 1948. Built to cater to our customers' plastic component needs, Caplugs boasts six different manufacturing processes to offer a variety of solutions and be a long-term partner for a wide range of projects. Today, Caplugs has 10 facilities across the globe and supplies 29 of the top 30 medical device OEMs. Caplugs has the certifications, processes, and infrastructure to support the requirements of the medical industry. Customers can choose from the 40,000+ catalog parts that are in stock or, for those with their own designs, work with our team of engineers through DFM review and recommendations to prototyping and full production. Caplugs builds and maintains tools in-house, ensuring quality, consistency, and efficiency.

Speak with one of our medical experts today by calling 888-CAPLUGS, emailing sales@caplugs.com or visit us online at caplugs.com/medical.

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