Perspectives in Molding

What will medical device manufacturers have to look forward to in terms of molding for their upcoming products? In this new feature, MDT asked a variety of industry experts, from molding service providers to materials experts, what they saw as the next significant innovation in molding for medical device manufacturing. Here are a collection of their thoughts.

Q:

From where will the next significant innovation for molding come and what impact will this advancement have on medical device manufacturing?

Florian Schattenmann
Technology Leader, Momentive Performance Materials

The size, growth rate, and overall attractiveness of the healthcare market are among the key factors driving rapid innovation in molded medical devices. The continued development of new materials will play a critical role in the advancement of molding technology in the medical market. There are a number of trends that we can expect to drive this materials revolution. First, productivity and increased part complexity will lead to further optimization of processability and rheology. Second, improvements in mechanical and physical properties such as tear resistance as well as transparency and chemical resistance of molded parts should enable safe, precise, and reliable operation of medical devices with improved performance and productivity.

To address these market dynamics in the area of liquid silicone rubber (LSR) molding, current research and development efforts are focusing on faster and more efficient cure technologies; modification of the size, shape, and type of surface fillers; and the incorporation of property-enhancing monomers. Innovative high fluoro LSRs, for example, are being developed, offering superior chemical resistance for IV and other applications.

Perhaps the most profound impact of materials innovation for molded parts will come from the development of materials with additional, differentiating properties. This includes inherently antimicrobial materials for infection control during device operation as well as, further into the future, the incorporation of intrinsic diagnostic properties, allowing early visual indication of part failure and other physical phenomena. Non-leaching antimicrobial technologies, in particular, are expected to make their entry within the next few years, which should positively affect the critical issue of nosocomial infections.

Naturally, materials developments should not come at the expense of

processability and mechanical material performance. Keeping these dynamics in mind will ensure a period of vital innovation based on effective cooperation between material suppliers, equipment manufacturers, and mold designers.

Dr. Michael Hansen
Senior Technical Development Engineer, Mack Molding Company

The next significant innovations for molding will come from both highly advanced materials and processing technology. One example of new resins is SRP (Self Reinforced Polyphenylene). The resin has exceptional strength and stiffness without fillers, as well as chemical resistance, dimensional stability, and the ability to withstand the harsh conditions associated with steam and cold chemical sterilization. This will result in more applications being converted from very expensive metal components to molded plastic parts with metal-like properties.

Another avenue is the development of bio-based products like biopolyolefins, where 50% or more of the petroleum content is a bio-based material like starch or corn. The similar property profile and price point to traditional polyolefins makes biopolyolefins viable alternatives in new and existing applications.
Nano-materials are gaining acceptance in medical applications and other markets as barrier materials because of their improved stiffness, electrical conductivity, and improved flame retardancy, to name only a few possible property enhancements. Nano-materials, like organclays (but also carbon nanotubes), are increasingly used as filler in applications. Nanocomposites as filler will provide numerous opportunities for property improvement in medical applications.
From a process development perspective, the next generation will include water-assist injection molding, as well as the use of gas-assist technologies in combination with other processes like overmolding. To go even further, it is possible to use the gas-channel in a part as a functional element for fluid movement, storage, or pressure measurement. That will lead to cost savings, since the number of parts in an assembly can be consolidated.
In terms of gas-assist technology used in conjunction with overmolding, medical device manufacturers will be able to pay attention to both haptic (related to the sense of touch and/or feel) in applications, as well as part consolidation—like molding in a fluid channel. A current growth area for overmolding is in soft-touch handles for surgical tools, as well as carrying handles for units like an ambulance AED (automated external

defibrillator). Another is a soft-touch base for a glucose reader.

Bradley A. Cleveland
President and CEO, Protomold
Historically, injection molding has been a labor-intensive process requiring specialists for each step. First, a functional tool (mold) would be produced in several weeks and then transferred to a production molder, which produced the sample and, eventually, production-volume parts for the device manufacturer. The time from concept to sample-part shipping could be anywhere from six to eight weeks. If the cycle had to be repeated due to changes in user requirements or device design, very little time would be saved in the next iteration. It was enough to drive a time-crunched designer insane.

With the advent, over the past decade, of 3D CAD and the Internet, major advances in this process are well underway. It is now possible for medical device manufacturers to get informative, interactive web-based quotations from vendors almost instantly, followed by the shipment of their injection molded parts the next business day. And this is accomplished by vendors offering both the tool making and molding operations under one roof. This has dramatically accelerated the development process for the device manufacturer; significantly increasing the likelihood of meeting today's stringent testing schedules. Over the next couple of years, we will see these innovative custom parts producers providing more online manufacturability analysis, even further reducing the number of design iterations and prototypes required before and during testing. Designers can expect interactive, graphical moldability evaluations with every quotation, including mold fill analysis and warp/shrink prediction. These capabilities will give the medical device designer the ability to virtually prototype the design prior to having physical parts made for the first time, further reducing overall project risk.

Tim Thellin
Product Manager, RedEye
Rapid prototyping/additive processes are already used for production applications. Early adopters are using this technology as a bridge to tooling and molding or in lieu of tooling and molding for short-run applications (100 to 2,000). Also, there will be utilization of additive technologies instead of traditional molding for more and more applications. The equipment for these processes will only improve over time in terms of repeatability, accuracy, reliability, and speed. Further, software is being developed to communicate with FDM systems so that the equipment can run more efficiently. In the future, these tools will automatically create the files that run on the systems, and download and optimize the capacity, all with little to no human intervention—a true "Direct Digital Manufacturing" application.

There will only be advances in the materials used in these additive processes. The properties of metal parts from additive metal processes are already good and often exceed casted parts. Thermoplastics are also improving and closing the gap with molded plastic part properties. Currently, materials are limited for additive technology, but will only increase as the demand for a wider selection of materials increases. Direct digital manufacturing allows companies to ramp up new product manufacturing without the delays of creating a traditional mold or through rapid tooling or plastic tooling. As companies rush to market to stay competitive, creating short runs of parts can shave weeks or even months off manufacturing time. Additive technologies can produce complex parts and shapes without typical manufacturing constraints. With digital manufacturing, designers have the freedom to create complex devices exclusively for the desired form, fit, and function. This technology also allows for an entire assembly to be produced as one piece, which eliminates all cost, time, and quality problems that result from an assembly operation. Because this technology is "digital" in nature, multiple iterations can be designed easily and cost effectively since there is no need to fix or create a new tool or mold. With only a change to the CAD data, new variations of products are immediately ready for production.

Matthew R. Grzeskowiak
Manager, Polymer Technologies, Tessy Plastics Corp.

While "innovations" in the decades old arena of injection molding may appear to have slowed according to some in the recent past, one area that continues to grow in popularity, and virtually by necessity, is the concept of micro-molding. In the age of ever growing "nano-technology," micro-molding has carved its niche in many industries as OEMs continue to strive to miniaturize their products to feed the consumer driven "smaller, faster, better" mentality. In order to continue minimizing injection molded part sizes, and therefore maximizing the need for micro-molding, further innovations will be required from two areas—material flow characteristics and increased equipment precision.

For years, material suppliers have been developing higher flow resins to support the growing requirements for thin-wall molding (i.e., wall thicknesses <0.04 in.) Additives and alternate polymerization processes have yielded resins capable of filling these thin walls; however, further innovation would benefit the micro-molding community with respect to materials that combine high flow with increased mechanical and physical property retention. These materials need to be capable of flowing consistently into intricate details within the micro-molded part, as well as performing similarly to their lower viscosity counterparts in challenging application environments.

From the equipment perspective, micro-molding challenges the tolerances of even the most sophisticated injection molding machines available today. Even with miniaturized barrel and injection units, these micro-molding systems stretch the limits of consistency and repeatability with smaller shot sizes and increased injection pressures. Further advancement of material injection systems would expand the ability to accurately mold miniature parts, lending the ability to confidently produce high precision components like those required by the medical industry.

Advances in either (or both) of these areas would impact medical device manufacturing with respect to the growth potential of new product offerings, especially within the surgical field. Miniature components have led to less invasive surgical equipment, which in turn leads to lower medical costs both in terms of patient recovery, as well as the volume of procedures that can be performed. Growth via new procedures (and therefore new equipment) will continue to revolutionize the medical

device industry in the near future, and additional advances in the area of micro-molding will lead the way.

Mark Rathbone
CEO, PTI Engineered Plastics
We see the next significant molding innovation in the area of materials, particularly with designer resins. Often hybrids or spin-offs of materials such as polyphenylene sulfide or liquid crystal polymer, these highly engineered grades are well-suited for many of the applications demanded by medical device end-users, mainly because they lend themselves to repeated sterilization without degradation.

Our medical customers are frequently asking for "multiple autoclaveable materials" in their recent RFQs and we see the industry reacting to this need. Molders will need to go through a process of discovery with the new resins and they'll find that a one-size-fits-all process will not work. As custom injection molders, it's critical to emphasize the scientific aspects of molding and learn how to tailor the process for each material and specific customer need.
As an example of what can be done with designer resins, we're now using a reformulated version of styrene to mold the plastic sleeve and other parts on an orthopedic bone replacement device.
For medical device manufacturers, the benefits are numerous. They can offer lightweight, durable plastic devices that can be sterilized and used again; plastic no longer has to mean disposable. In addition, they are better able to tie customer demand directly back to the initial material choice. Specific applications can be met through custom-designed resins. Also, the medical community has more choices. A device can be made out of a wider range of custom-developed materials. Finally, manufacturers are better positioned to support demand in emerging markets.
For these benefits and more, these designer resins are changing the game for medical device manufacturers. As molders, it's imperative for us to stay in step and provide the leadership needed for optimal competitiveness.

If you'd like to share your own comments on this topic or would like to suggest a question for a future edition of Perspectives, e-mail the editor at sean.fenske@advantagemedia.com **[1].**

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