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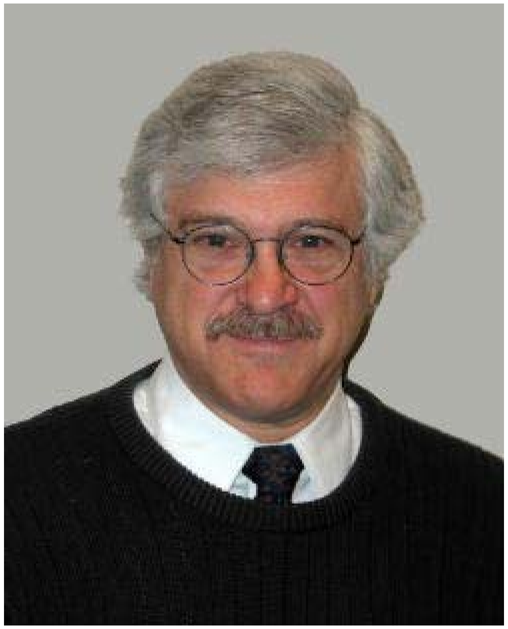
Overmolding Increased Benefits onto Medical Devices

Randy Pell, Senior Staff Design Engineer, MackMedical/Mack Molding; et. al.

An assortment of individuals from MackMedical/Mack Molding [1]—Lee Fox, regulatory compliance manager; Randy Pell, senior staff design engineer; Michael Hansen, Ph.D., senior technical development engineer; and Joan Magrath, VP, sales & engineering—were part of the staff written article, "Molders Address Biggest Device Issues [2]." Members of this group took time to present a full array of responses that were not able to be included in the article, so they are presented here.

Q: How can medical molders help device designers achieve compliance with the upcoming UDI rule?

Fox: Unique Device Identification (UDI) , a proposed rule with a lengthy phase-in period, asks for permanent marking of specific identifying information on all medical devices, from disposables to capital equipment to implantables. All classes are included. Initially, the identifier or label can be included with the device. Ultimately, it will need to be permanently attached to the device. The identifying information includes both fixed information (e.g., sterilized) as well as variable information, such as expiration dates and lot numbers.



Lee Fox, Regulatory Compliance Manager

Fixed information can be easily molded into the device. Variable information could be set with wheels and/or inserts, and molded in. Other methods could include laser etching, pad printing, or molding in an RFI chip.

Medical molders should stand ready to work with device designers to implement whatever method they deem appropriate, which will almost certainly be specific to each individual device. Currently, MackMedical is already laser marking batch or lot codes on reusable orthopedic devices for some customers.

Q: What features are most important to device designers to achieve through molding material selection?

Pell: I am involved with designing for manufacturability for all markets Mack supports, so I have a broad view of design features that cross over markets. Specific to our orthopedic customers, however, the desired features I hear about most from device designers include molding to tight tolerances, sterilization capability, soft touch and color.

For materials used in the surgical suite, it is critical that they be able to withstand harsh cleaning agents, gamma radiation, and the autoclaving process. The focus on patient safety and infection avoidance is tightened each day; materials must be able to meet the challenge.

Randy Pell, Senior Staff Design Engineer

Surgeons are becoming increasingly enamored with soft-touch handles on surgical instruments, which improve grip and minimize slipperiness. Handles can be overmolded in an ergonomic shape that fits the surgeon's hand, but can still interact with attachments or be hit with a mallet. A simple shaft of metal can be overmolded with a plastic resin to form the ergonomic shape. You can then overmold with a thermoplastic elastomer (TPE) to achieve a soft-touch grip, resulting in a double-shot overmolded handle. If the handle is a reusable item that needs to be sterilized, you have to create a part that has extremely small, or no, gaps that might trap contaminants from the surgical procedure. It is critical to design a feature in the metal that will hold the TPE resin in place so that it can't pull away and leave a gap.

Molding in color allows for branding and color-coding. For example, a device designer might want knee trial instruments to be color-coded by size so they're not as likely to be mixed up during surgery. Transparent materials are also desirable so the surgeon can see through the instrument for more accurate placement, to view movement of fluids through the part, or for improved x-ray views that won't show the part.

Q: What type of molding technique is gaining more interest with medical device engineers?

Dr. Hansen: We're seeing increasing interest in external gas-assist (EGA) molding, particularly for large, flat, external panels with cosmetic requirements. EGA has been proven to cut costs, lower tonnage requirements, minimize warpage, improve overall part quality, and reduce or even eliminate secondary operations. Other advantages of this molding technique include:

- No "shadow marks" on cosmetic surfaces
- Elimination of "fingering" – a defect resulting from gas that penetrates thinner-walled sections adjacent to the gas channels formed when using internal gas-assist
- More even gas distribution, since internal gas pressure dissipates with increasing distance from the gas channel
- No open holes for gas pin locations or overspills
- Minimized knit lines and hesitation marks created by part design and/or flow patterns
- No sink marks on visible cosmetic surfaces
- Lower clamp force requirement, resulting in significant press tonnage reduction and lower costs

Michael Hansen, Ph.D., Senior

- Reduced wear on molds due to lower operating pressures
- Reduced power consumption since smaller presses are used
- More freedom in part design (rib-to-wall ratio can be 1:1 or even higher)
- Consistent packing pressure

Technical Development Engineer

Resulting parts are very similar in appearance to compression molded parts due to the addition of a micro-thin layer of nitrogen gas to the surface adjacent to the cosmetic side of the part.

Increasing cost pressure in the medical market is forcing suppliers to be more creative. The goal is always to mold as much function into parts as possible while minimizing material, cost, secondary operations and assembly. At the same time, you want to make the part structural with ribbing to improve its functionality – then the part is not only a skin, but also a structural member of the frame. This can be achieved by EGA—another of its big advantages.

The other gas-assist molding technique we use a lot is the more conventional internal gas-assist method. This is particularly good for tube or rod-shaped parts, like handles; large, cover-shaped structural parts, like side panels; and complex parts with both thin and thick sections. Sometimes the gas channel can actually become a functional part of the application, e.g. fluid transport.

Pell: In the area of surgical instrumentation for knee and hip surgery, we're seeing more use of overmolding – over both metal and plastic. Rather than machining an entire instrument from metal, OEMs are cutting costs by molding over a simple piece of metal, using the metal only where needed (cutting area, for example) and molding the rest of the instrument in plastic. Because we can mold in such complex geometries, it saves our customers from machining an entire device, plus we can mold as many as needed – much less costly than machining.

We can also mold over plastic, which is often used to attain branding with a company name, logo or color. Or if the part requirements call for a tight tolerance, very thick, totally closed part, molding over plastic is a good solution, producing solid surfaces, both top and bottom, and very thick parts. Combining this technique with an autoclaveable resin meets the stringent requirements of a reusable device. For single-use instruments, however, you can hollow out the part with internal gas-assist molding. The whole part can be closed from the outside, except for the hole at the gas injection point. Because bacteria could accumulate there, this technique can only be employed for single use parts. You will use less resin, however, and it will be less expensive material because it doesn't need to withstand autoclaving.

Mack also combines internal gas-assist and overmolding for surgical instrument handles. The result is a lighter weight handle with an ergonomic soft touch that is inherently strong due to its tube-like structure. This method also uses less resin.

Finally, Mack has also patented a technique where we mold over magnets, completely sealing them in plastic. This technique achieves the functionality of a magnetic metal part, and at the same time, all the advantages inherent in plastic.

Q: Where is medical molding headed over the next five to ten years?

Magrath: Ten to 15 years ago, thin-wall molding meant 2 mm and gas-assist was revolutionary. Today, thin-wall is .5 mm and gas-assist is an everyday process. Technology has changed so much, yet we're just at the tip of the iceberg.


Joan Magrath, VP, Sales & Engineering

3D printing, for example, is going to be huge in a decade. I don't think it will be at all uncommon for a dentist to have a piece of equipment in his office that will print out a crown while you wait in his chair.

High-performance materials will continue to evolve, driven by rapid technology growth in medical equipment. With more and more wireless technology, materials will have to address the need to protect equipment from both outside interference and emissions. As electronics perform at higher and higher levels, so must materials.

The chain reaction continues with equipment. To process the higher performing materials and more complex parts, molding equipment must also change. Manufacturers have already taken presses to new levels to accommodate performance consistency, energy usage, flow properties, sequential injection and more. So today, molding machines are really computers. The next steps will certainly involve larger electric machines and greater energy efficiencies.

But beyond all of the expected technology advancements is the looming question of location. Where will the industry be? Where is the brainpower? Where is the human capital to make it happen? As manufacturing has waned in the United States, we've missed an entire generation of young adults who didn't go into the trades or technical fields, and now we're suffering a deficit of skilled labor, welders, craftsmen and engineers. So what are we going to do to develop the next wave of talent? To cultivate and educate design engineers, processing engineers, and electronics engineers? This is an area where the states can really step up to the plate to work in conjunction with businesses to develop training programs and technical schools.

Which brings me to my final question—where is the incentive? Injection molding is a capital-intense business. Companies must invest significant dollars upfront to bring these businesses to fruition. This can only happen in a business-friendly environment where government and business are friends and trusted allies. Will that be in the U.S., Ireland, India? I would argue that it will be in the country where government incentivizes business, through lower tax rates or tax credits, to invest in the technology, equipment and people to make it happen. And I hope that will be here. When the business footprint is established, good things follow.

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