Extreme Molding

Biocompatible injection-molded microcomponents change lives

By Kip Hanson, Contributing Editor

Cover Story

Accumold

These hearing instrument components were made via two-shot micromolding.

Parkinson's patients and chronic pain sufferers are often treated with implantable pulse generators to stimulate the brain and central nervous system. Those with heart conditions may have a defibrillator placed inside their chest. The deaf are fitted with cochlear implants, while some people with eye conditions find relief through implanted intraocular lenses. These are but a few of the medical devices that would be nearly impossible to manufacture without micromolding technology and biocompatible materials.

Surgical staples to skateboard wheels

While the materials themselves may not be household names, many of the products made from them are, and some may even be found in your recycling bin. Thermoplastic elastomer (TPE) is used in hammer handles and urinary catheters alike. Polyglycolide (PGA) is biodegradable, making it an excellent choice for disposable water bottles as well as for reconstructive surgery components. Spark-plug boots, hydrocephalus shunts and the weather seal around your front door are largely made from high-consistency silicone rubber (HCR). Because of its high expense, you won't be hauling any polyetheretherketone (PEEK) to the curb on recycling day, but it's a favorite in the operating room, and is used for everything from bone screws to spinal cages, dental implants to repairing skulls.

Molded parts are everywhere, but there's a world of difference between molding a motorcycle helmet and micromolding the brain shunt you'll need when you don't wear one. Aaron Johnson, vice president of marketing for micromolding specialist Accumold, Ankeny, Iowa, referred to the manufacture of these ultrasmall parts as "extreme molding."

"We define micromolding in terms of size, obviously, but the process also accommodates

components with feature-rich designs and difficult-to-meet tolerances. These are usually in the ±5µm range, but often go much tighter than that."

Some of Accumold's parts measure less than 1mm in length. Aside from their small size, these components often have thin walls, microholes and complex fluid channels. "Parts like these push the limit of what is possible with molding and plastics," Johnson said.

The process of molding plastic biomaterials may be similar to that used for GI Joes and LEGOs, but there's one clear distinction: cost. Any material destined for use inside the human body carries a premium, one that covers the costs of FDA certification, regulation, testing and potential litigation, should something go awry.

For example, PEEK, when purchased for non-implant use, costs about $60 per lb. "Implantable-grade PEEK runs 10 times that," Johnson said. "Because of this, efficient mold designs are critical. You have to pay close attention to sprue and runner length, minimizing material waste as much as possible."

Mikrotech LLC is another micromolder concerned with mold efficiency. John Whynott, technical director for the Kenosha, Wis., company, agreed that material costs skyrocket when biocompatibility is required. "Components that come into contact with body tissue and fluids must be biocompatible," he said. Two common test standards the material must meet are USP class VI and ISO 10993-1. Because of these regulations, Whynott said that "only a small number of polymers are available for medical applications, and an even smaller number can be used for implants."

Phillips Medisize

A group of plastic micromolded parts, including some made from bioresorbable materials.

After a component has been approved for internal use, the next question is how long can it stay there? This depends on its usage classification: limited (less than 24 hours), prolonged (longer than 1 day and less than 30 days) and permanent (longer than 30 days).

Physically, there is no difference between these materials, Whynott explained. They mold the same and are often purchased from the same supplier. The longer a material is expected to stay in the body, however, the more extensive the testing and traceability requirements, a factor that accounts for much of the cost of implantable-grade polymers.

The best way to combat the high cost of a biocompatible material is to use less of it with a highly efficient molding machine. "Not all molding equipment is the same," Whynott said. "Conventional machines with reciprocating screws have a large melt cushion, large runner size and inconsistent shot-to-shot consistency. Micromolders use platen-style ram machines to push the material into the mold, similar to a fluid-dispensing machine. This gives better control over the shot size (the amount of material injected per cycle). And because the runner is much smaller—typically around 10 percent that of a conventional machine—there's less material compression. This translates to better part quality."

Dow Corning

Silastic LSRs are ideal for intricate designs and close-tolerance parts.

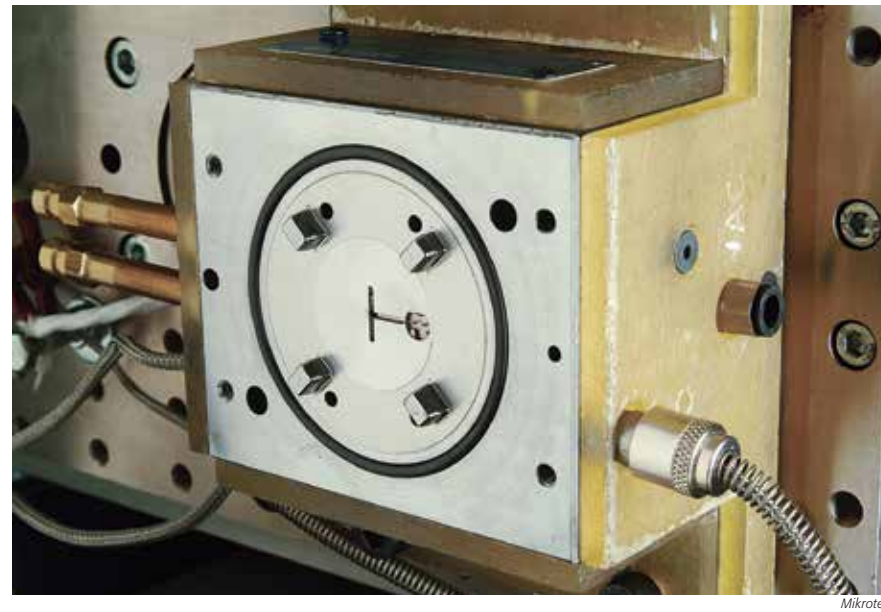
Polymer morphology

Thermoplastic polymers fall into two categories: amorphous and semicrystalline. Amorphous polymers have a randomly ordered molecular structure that does not have a clearly defined melting point. Instead, they soften gradually as temperature rises, but seldom are as easy flowing as semicrystalline polymers. They shrink uniformly both in the direction of flow and transverse to flow, and generally exhibit lower part shrinkage with less tendency to warp than their semicrystalline counterparts.

Amorphous polymers also have good bond and weld-line strength but poor resistance to stress cracks. Two examples

of this are polycarbonate and polyetherimide, more commonly known as Lexan and Ultem, respectively. Both are commonly used in medical devices and both are challenging to mold, since the lack of a sharp melting point means parts must be held in the mold until the material settles into place. As compared to semicrystalline, "the cycle time is often twice as long for parts made of amorphous polymers," Whynott said.

Semicrystalline polymers, on the other hand, have highly ordered molecular structures and distinct melting points. They remain solid until a given quantity of heat is absorbed, then rapidly turn into a low-viscosity liquid. Whynott said these materials are susceptible to part shrinkage and have a tendency to warp. Semicrystalline polymers also have excellent chemical, stress-crack and fatigue resistance, but very poor weld-line strength. PEEK and Nylon are two popular semicrystalline polymers whose smooth flow characteristics make them ideal for parts with sharp details and thin walls.



Mikrotech

A single-cavity micromold that produces proximal bushings from polyphenylsulfone. Air is evacuated from the mold via a vacuum assist prior to injecting the plastic, making the cavity easier to fill.

Straddling the fence

Salt Lake City-based Biomerics LLC is a micromolder with a twist. In addition to providing injection-molded components to the medical device and biotech industries, Biomerics also develops and compounds its own brand of raw materials, the Quadra family of polyurethanes.

Biomerics Vice President of Engineering Dan Brittingham said this makes the company somewhat unique. "Many compounders steer clear of the end products made with their materials, for fear of liability. We've been able to carve out a market segment by partnering with our customers and registering along with them on many of their products."

The FDA registration process for implantable devices is complex. This challenge—together with the potential for litigation, especially for long-term implants—is largely responsible for the high cost of these devices. Brittingham provided one conceptual example. A designer develops a catheter designed for groin-to-chest use. After extensive clinical trials, the FDA approves the device for human use and assigns it a three-digit code to indicate what it can be used for. But, if the product designer then wants to extend its use from the groin to the neck—a 6" or so difference from the chest to neck—a new application must be submitted and much of the testing has to be redone at a cost of several million dollars or more, Brittingham said.

Catheters and other devices made from flexible, implantable materials are generally limited to either urethane or silicone, Brittingham said. Both offer biocompatibility, but urethane has better mechanical properties. "Angio-catheters, for example, frequently must withstand internal pressure greater than 100 psi, which precludes the use of silicone tubing. And, many pacemaker leads utilize a special grade of urethane that can withstand the continual tugging of the heart muscle."

Biomerics

An overmolded, urethane-based introducer sheath is used during medical procedures such as angioplasty and stent placement.

Despite urethane's superior mechanical strength, however, silicone is usually the elastomer of choice, primarily due to its superior biodurability and often lower cost. Where most implant-grade silicone sells in the neighborhood of $12 per lb., a pacemaker-grade urethane might cost upwards of $350 per lb.

Ubiquitous silicone

Jim Curtis, applications engineer and technical service specialist at global silicone provider Dow Corning Corp., Midland, Mich., said silicone is used in everything from antigas medication to molded cardiovascular components. "Silicone excels in high-tech medical applications due to its tremendous thermal and chemical stability, permeability to gases, biocompatibility and lack of reactivity."

In the case of silicone implants, many are manufactured using the Liquid Injection Molding System (LIMS), a process developed and trademarked by Shin Etsu Silicones of Japan (Shin-Etsu Silicones of America is based in Akron, Ohio). It differs from conventional plastic injection-molding processes in that the raw material, liquid silicone rubber (LSR), is not heated. Instead, two different materials are mixed at the time of molding in a manner similar to mixing a two-part epoxy.

The difference is one of chemistry. Part A and Part B are both comprised of silicone, but the first has been formulated to include a catalyst, while the other, Part B, contains a crosslinker and an inhibitor. Mix the two together and a chemical reaction begins, one that ultimately leads to cured silicone rubber. Equal amounts of Part A and B are forced together through a static mixer—a baffled tube offering a tortuous flow path—before being pumped into the mold cavity. The resultant mix is then cured for approximately 20 to 30 seconds, or longer, depending on part size and complexity.

LSR is a thermosetting material and is molded at near-room temperature so that the viscous liquid can flow into the complex nooks and crannies of a micromold. The process is somewhat magical when you consider the great variety of end products—anything from a soft, cushiony material to one hard enough for a hockey puck, all made from silicone differing only slightly in chemical makeup.

Tough enough

Phillips-Medisize Corp. uses the LIMS/LSR process to make microscale implants. Phillips Chief Technology Officer Bill Welch described one such product, a surgically implanted assembly less than 5mm in length and containing multiple components and materials. "The product includes both overmolding and assembly, thereby making both the tooling and the part handling critical to meeting specification."

Phillips Medisize

Parts made via metal-injection molding are typically molded from 17-4 and 316 stainless.

Headquartered in Hudson, Wis., this contract manufacturer specializes in design, development and advanced injection molding, as well as assembly of medical devices. Polymers aren't the only biomaterials molded at Phillips-Medisize, however. Through metal-injection molding, stainless steel is used to make orthodontic and other dental components. MIM starts with a feedstock, a compound of fine metal powders and polymers.

These raw materials are hot-mixed and extruded into pellets to formulate a consistent mixture. The granulated feedstock is fed into a MIM machine similar to a plastic injection-molding machine. Once molded, components go through debind and sintering processes, where the binder is removed and densification takes place. This leaves only the molded part, with densities of 97 to 99 percent of theoretical.

"Technically, not all orthodontic and dental components are implants," Welch said. "But these products require biocompatible material and can be made with extreme detail and accuracy." Like its plastic counterparts, MIM requires custom equipment—in Phillips-Medisize's case, hardened and coated screws and barrels on the injection-molding machines. The catalytic debind process is used as well as both batch and continuous sintering furnaces.

Another consideration is part handling and cleanliness. Welch explained that the trimming and deflashing performed with many larger injection-molded parts is not possible with microparts. "We design the tools so that parts come out at net shape," he said.

Devices for use inside the human body must also be clean, so manufacturers typically operate to ISO clean room standards. Phillips-Medisize maintains Class 8, or better, clean rooms for its different molding processes, depending on customer requirements, and pays special attention to possible particulate matter from the equipment.

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Aside from the molding process, there's the tooling aspect to consider. "You need high-speed spindles, special cutting tools, super-precision machining and EDMing to make the molds," Welch said. "The volumes can be millions or more units per year, so tool design and robustness is critical."

In any event, this isn't easy work. Medical patients who have had a catheter, defibrillator or any one of dozens of other medical devices installed should be glad people like Welch and his biomolding colleagues are there to deliver the goods.

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