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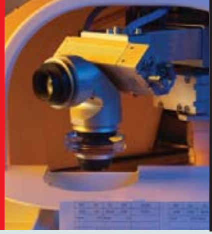

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Factors for successful silicone molding

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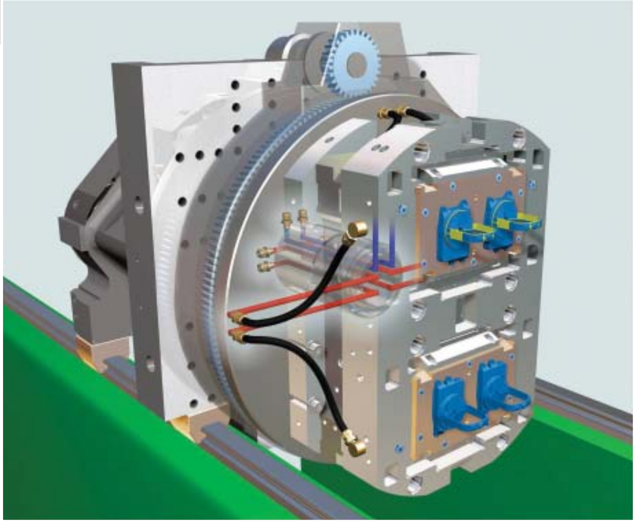
These silicone prototype inserts fit a representative production mold base, allowing exact production simulation.



The 2 + 2 mold handles a plastic substrate and a silicone overmold.

Four tips for successful silicone molding

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Although liquid silicone rubber (LSR) has been commonly used in Europe for a long time, some North American OEMs still view it as a "black magic" material because of a lack of internal expertise as compared to thermoplastics. But the performance advantages that LSR provides in medical devices and disposables are great. Therefore, leaving more about the material's proper use and how to select the best molding method and molder is important. Critical factors for a successful silicone molding program include:

Material selection. Engineering groups can take the path of least resistance and use existing approved materials already in their database. They really can't be faulted for doing this because it ensures the selection of a qualified and validated material, greatly reducing the risk of potential program delays or problems with biocompatibility.

However, LSR material providers have significantly improved their formulations over the last 10 years, so it doesn't make sense to rely only on familiar materials and potentially overlook performance gains, processing stability, and lower prices. The latest LSRs have improved upon original formulations and have closed the gap on the mechanical properties of high consistency silicone (HCR) — a material typically compression or transfer molded. LSRs can provide a better choice than HCRs because its platinum cure system takes significantly shorter cure times.

Also, LSRs come in sealed drums from material suppliers, reducing the risk of contamination. Materials typically have more batch-to-batch consistency because they are produced on a larger scale at the raw-material manufacturer and not on a two-roll open mill at a molder or custom mixer. Needless to say, in medical molding, material consistency is critical, based on the requirement to operate the process within a tightly validated window.

In addition, LSRs better suit automated production because of the material consistency and the large-drum delivery systems allow the extended runs without stoppage. HCR can have good tear resistance, compression set, and abrasion resistance, but an alternative and suitable LSR grade is typically available for most applications.

Another issue with material selection is a tendency for engineering groups to want to use thermoplastic elastomers instead of silicone. While thermoplastic elastomer (TPE) or thermoplastic vulcanizate (TPV) materials have improved over the years, silicone is still a better choice when it comes to sealing applications. TPEs don't reach liquid silicone rubber's clarity, biocompatibility, compression set, and temperature resistance. In addition, the raw-material pricing between LSR and a specialty grade TPE is not that different. It becomes even less of a factor when working with a silicone molder that uses the latest in flashless and automatic molding.

Vendor selection. Because of a lack of expertise in silicone at the OEM level, many molding programs are sourced based on an Internet search, a past relationship, or what company is closest or cheapest. But just because a company owns a silicone machine does not make it a qualified and experienced silicone molder. Silicone molding is much different from thermoplastics and can pose many unique problems. For example, strict silicone tooling requirements mean gating, venting, and demolding parts is always a challenge. So silicone experience counts a lot in part design, mold design, and the molding process.

Additionally, there is a wide variety of methods for molding silicone. OEMs should ask their suppliers if they use flash free tooling and automated molding or if they rely on human operators and secondary flash removal. Each approach has its own merits, but operators and secondary operations add more variables and costs into an already complicated process.

Prototype and production tooling. There are two kinds of prototype tooling. One type is intended just to give engineers a soft silicone part to touch and feel. This tooling can be made quickly and relatively inexpensively. Often, parts are compression or transfer molded with little regard to dimensions or part quality.

Prototypes when the next step is production are a different matter. One of the most important phases of a silicone project is the prototype stage. Not only does this give the OEM's product development organization molded parts to assemble and complete trial builds but this is the opportunity for the molder to get hands on with the part and process and understand how the component will behave in simulated production. Prototyping using the intended production in process and tooling is critical to success. Changes such as moving from a traditional hot runner in prototype to a valve-gated cold runner in production can affect shrink rates and how the part fills. Changing the gate diameter slightly can affect the shear rate of the material and alter dimensions. Compression molded or transfer molded prototypes moving to production develop different cavity pressures, altering dimensions and providing different mechanical testing results. Prototyping and producing with the same tooling and method is the best bet.

With silicone production tooling, the old expression, "You get what you pay for" is true. Expect to pay premium prices as compared to thermoplastics for a high-quality silicone tool. There are no SPI standards for tool quality such as in the thermoplastics industry, so it is hard to know what to expect. When discussing tooling with suppliers, OEMs should ask to see examples of similar parts they have produced and verify whether parts are as-molded or need secondary operations.

Also OEMs should find out where the tools are built and the tool maker's experience level. Processors using traditional hot runners means added piece price, so it is best to insist they research cold runners to eliminate runner waste. A high-quality silicone mold at the beginning of a project may seem like a large out-of-pocket expense, but the investment will pay for itself many times over during the life of the program in piece price and part consistency.

The use of technology. A lot of silicone molding has come up through the traditional rubber molding industry and with this have brought many bad habits in waste, tooling quality, and lack of process control. Fortunately, some silicone processors have made significant improvements. One is in flashless molding. Quality tools leave a maximum flash extension of only 0.001 to 0.002 in.

Another improvement is automatic molding. Process consistency and repeated cycle times are critical to the dimensional stability of molded parts. LSR molds are typically heated to approximately 400° F, so open time lets mold temperatures drop and results in part variation. Automatic molding means that machines control the cycle, not human operators.

Also helpful is the use of valve-gated cold runners. They let processors gate directly on parts without waste, which can speed-up curing. A more recent innovation: valve gates with a servo-controlled valve-gate pin that controls pin stroke. Processors can thereby tune each individual cavity for volume and ensure a balanced fill on multicavity molds.

Additionally, self-adhesive silicones are revolutionizing the overmolding of silicone onto plastic substrates. Traditionally, a primer and adhesive are applied to a substrate offline. This creates a secondary operation and forces the plastic and silicone operations to be done on separate machines.

In contrast, current materials mix chemical adhesives with the silicone, allowing the molding of the plastic and an immediate silicone overmold. Multimaterial injection machines can complete a silicone overmold in one production cell. For these reasons, don't neglect to think "two-shot molding" during the design phase.

Another advancement comes from servo-electric injection-molding machines. They provide process repeatability never before possible and help ensure part consistency. Additionally a closed-loop LSR metering system can measure and verify the exact percentage of LSR metered into the machine which can guarantee a 50-50 mix of the A and B components.

Design considerations

So, what are important design considerations for LSR parts? Silicone molds must be built to tight tolerances because LSR flashes at 0.0002 in., which is approximately 10 times tighter than a standard thermoplastics mold. It is therefore important to prove-out many factors at the prototype phase to ensure a smooth transition into production including where the last point of fill is, how the part fills based on the gating location, and the parting line locations selected. These are critical items to address potential gas-trap areas and the resulting need to use different venting techniques. Also critical is how the silicone part demolds. Because silicone is elastic, removing the part from the cavity can be difficult. Unlike thermoplastic molds, LSR molds don't typically use ejector pins or core pulls because of silicone flashing. Silicone molds usually are comprised of two or three plates. Molders are always looking for a feature that will give consistency to part location during the mold opening. For designers, this translates into the need to use an undercut in the part or some other design feature.

Note that what works for a 40-durometer silicone might not work for a 70-durometer silicone because the materials have a different modulus of elasticity. The higher the durometer of the material, the greater force it takes for the part to release from an undercut, making a retention feature more effective. However, when the retention feature is too large, silicone materials are prone to hot tear, so there is a delicate balance to maintain. Parts that don't consistently stay in one location of the mold make automating extremely difficult.

Another consideration is how the silicone part shrinks. Silicone shrink rates are typically 2% to 3%, which is fairly high relative to thermoplastic materials. Most material suppliers do not publish specific guidelines for shrink rates of their materials and simulation software is not readily available or proven for silicone. What's worse is it's typical to get a nonlinear shrink of the part, based on geometry. Therefore, determining the correct shrink can be difficult. That's why the need to prototype is so important to a molder and the need to work with an experienced silicone processor is essential.

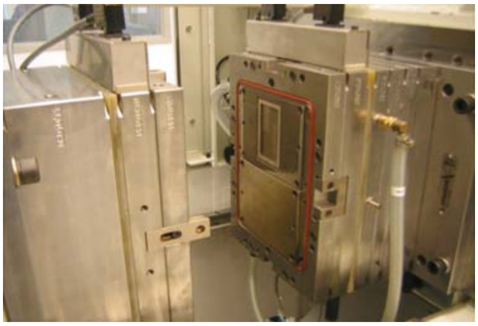
Choices pose challenge

Medical OEMs have more choices than in the past of molders for silicone projects. Because silicone is still relatively unknown to many, it is easy to accept the first opinion that sounds like it makes sense.

However, the capabilities and experience of molders are varied. Silicone molders that have been in business for years may not be using the latest techniques, while new companies might have the technology but not the needed experience in silicone processing.

Medical OEMs should look for companies that have a technical background in silicone, use the latest in technology, have a strong presence in the medical industry and can supply both high-quality thermoplastics and silicones from one source of responsibility. This helps eliminate multiple suppliers and streamlines the supply chain.

Finding the right mix in a molding partner takes a little research and a willingness to dive into the details but this can make all the difference in a successful program launch.



The tooling is an example of a 1 or 2 cavity valve-gated P type mold.

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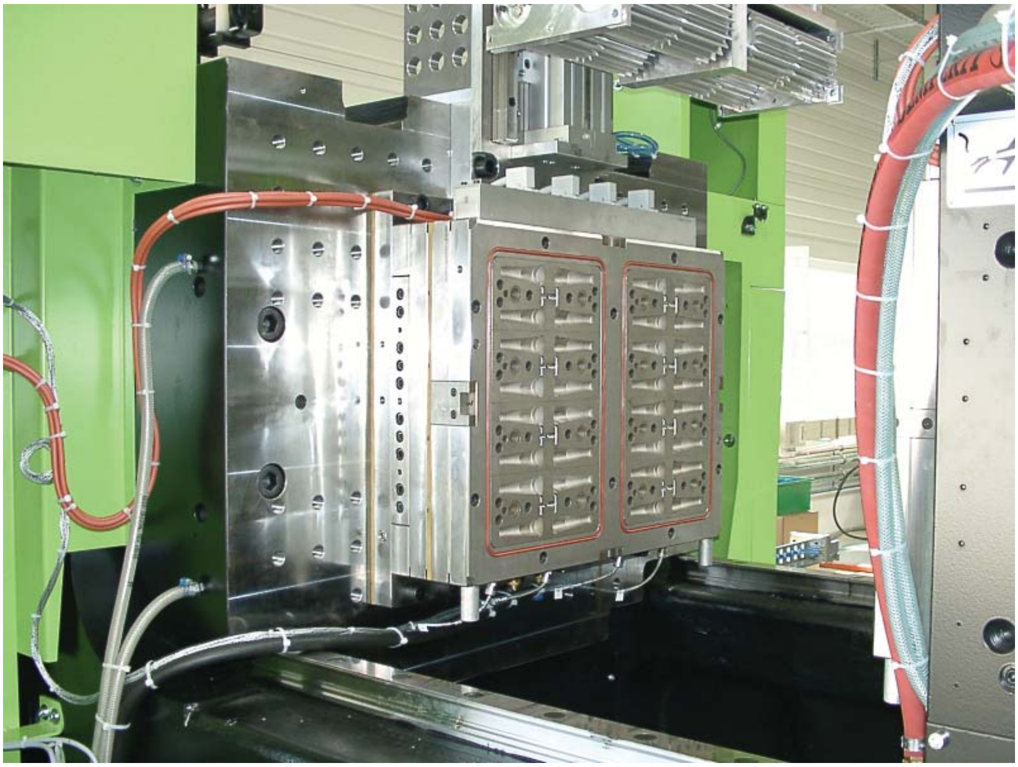

The high-quality silicone production mold uses automatic demolding for flashless and automatic operation.