Benefits And Challenges Of Silicone Overmolding For Medical Devices

MRPC

Manufacturing Trust Through Collaboration

Introduction

In today's market of designing and developing medical devices the inherent benefits of utilizing silicones is rapidly expanding. Silicone's benefits of sealing, heat resistance, flexibility, and bio-compatibility are well known and relied upon for enhancing the functional design of medical devices. Growth in device design is gaining rapid acceptance with the marriage of silicone to plastic, metal, fabric or other rigid to flexible materials. The addition of silicone to these rigid materials can offer greater performance capabilities like non other. These enhanced benefits are muti-faced to the device where silicone not only can increase device performance, but can also offer higher degrees of flexibility and comfort. Benefits favor the medical professional with flexibility, and repeatability with use of the silicone medical device.

Meanwhile silicone composite devices offer the patient comfort of use of the product, and reliable cleanliness. One example is the explosion of "wearable" medical devices. These devices are often silicone overmolded components to an array of rigid, electronic or mechanical subcomponents. The subcomponent sensor, microchip, blood, or fluid delivery vessel are often very sensitive to the environment and the silicone provides a protected, flexible barrier, all the while the silicone overmolded component aids in soft comfort to the end user while also protection from bacteria or contamination.

Device manufacturers who can excel in the development of silicone overmolded components will continue to lead the medical device design market well into the 21st century. As the use of silicone overmolded components continues to expand in use in operating rooms and on patients, further development is rapidly growing as fully implantable silicone overmolded devices are gaining widespread use.

The Overmolding Process

Overmolding is the manufacturing process in injection molding where a separate component, the substrate, is molded into a final component. Overmolding of thermoplastic to thermoplastic parts has been commonly applied in the industry and has evolved into full 2 shot molding. In traditional thermoplastic overmolding a substrate part, or parts, are molded in a separate molding operation. This plastic molded substrate part was then installed into a second injection mold and a second plastic material was then molded "over" the substrate creating the final part. With this thermoplastic overmolding component, the ability to maintain an intimate bond could be carried out in two ways.

1. First, if the two thermoplastic materials shared the same backbone, within their molecular structure, a chemical bond could be achieved creating a semi-permanent bond.
2. Second, If the two plastic materials were not compatible chemically, then a means of a mechanical bond was designed into the two parts to lock them together physically.

With silicone, be it Liquid Silicone Rubber (LSR) or High Consistency Rubber (HCR), you will not be able to create a chemical bond of the substrate material to the silicone overmold. A strong, natural bond can however be achieved when overmolding a silicone to a silicone substrate. Certainly, structural features can be designed into the substrate and silicone overmold to also create a mechanical bond between the two parts. However, the opportunity for some separation or movement of the two components may occur over time. In the case of medical devices this opportunity for slight separation of an overmolded part would be very undesirable. Small gaps in a silicone overmolded component could allow for bacteria or contamination to propagate further reducing the ability of the device to remain clean and sanitary.

The need to achieve a permanent bond when overmolding silicones is of utmost importance to the molding process. Manufacturers who understand and have extensive experience with the overmolding bonding process and the various nuances involved with different material substrates will deliver reliable and capable products to the medical device designer.

"The need to achieve a permanent bond when overmolding silicones is of utmost importance to the molding process.

Manufacturers who understand and have extensive experience with the overmolding bonding process and the various nuances involved with different material substrates will deliver reliable and capable products to the medical device designer."

Silicone Overmold Bonding Methods

Adhesive/Primer

As stated earlier when overmolding silicone to another material, the silicone will most commonly be non-compatible to naturally bond to the substrate surface. To achieve a permanent bond a conduit applied between the material's surfaces will be required. In this case, the most common means for bonding is by use of a silicone compatible primer. The widely used primers for silicone typically contain a reactive silane group suspended within a solvent based carrier. After applying to the substrate and subsequently exposed to moisture the silane groups become active thus promoting adhesion between the silicone and its mating substrate.

There are an array of primers available for medical applications. Well established manufacturers of LSR and adhesive materials such as Dow, Nusil, Elkem, Momentive or Masterbond, provide LSR primers suitable for medical devices and specially tailored for an array of substrate material types. Although readily available to the market, the challenge for the device molder may be in devoting the time and engineering resources into thoroughly evaluating and testing the application of these primers in a systematic method that provides reliable results. MRPC engineers understand this gap and devote resources to become an industry leader in understanding these reactions. Because the priming application in essence becomes an added step in the overmolding operation, it must be proven to be an effective and repeatable means while also being done within an efficient manner at a high production scale. During the overmolding process development phase of the program the evaluation of multiple primer types and methods may be necessary as the balance between effective bond, moldability and optimum cosmetic appearance after molding can be challenging.

Prepping The Substrate

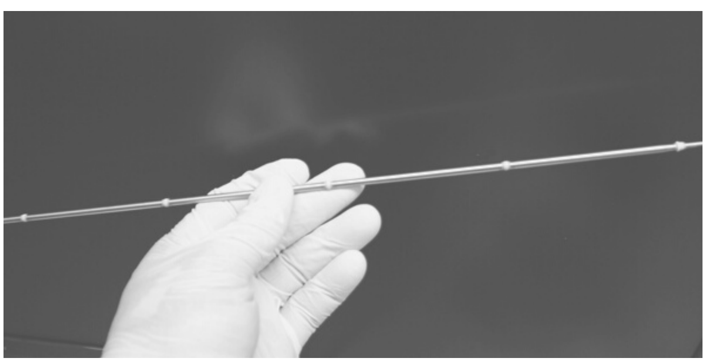
To maximize the effectiveness of the primer(s) applied to the substrate surface, the care taken in prepping these surfaces can be the most critical. Whether it be plastic, metal, or ceramic, the surface must be conditioned in such a way that it has active bonding sites on the surfaces for the primer to adhere. This can be accomplished by several methods. Generally speaking, the "wettable" the surface of the substrate is the higher likelihood for uniform adhesion of the primer to the bonding surface. Techniques such as applying a textured surface to the substrate, roughening or abrading the surface, cleaning/etching the surface with a solvent, flame, plasma, or corona treating are all potential means for effective surface treatment. When evaluating a medical device for effective bond after overmolding MRPC takes considerable effort to conduct a series of tests varying the conditions of the substrate surface prep. Plasma treatment for example can be an effective means of surface prep but is a very involved developmental activity requiring extensive experimentation to refine a recipe that is most suitable. MPRC engineers understanding of the plasma process, and the experience with many substrate material types, are successful with knowing what parameters to exploit but also conduct this step in an efficient and scalable suitable in a mass production environment.

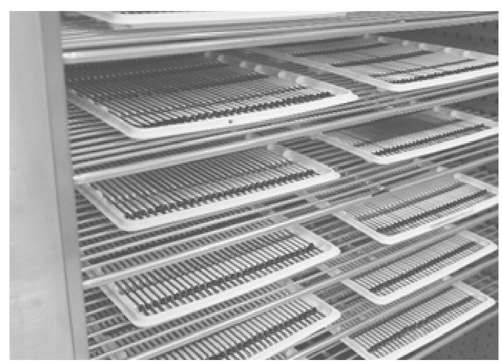
Silicone Overmold Bonding Methods (Cont.)

Applying Primers

Once properly prepped, application of primer to the surface can be done a number of ways. Brushing, dipping or spraying can all be done; however, each method can have challenges. Uniformity of the primer on complex geometry may limit some methods when trying to control areas where pooling or wicking may occur. Spraying can be advantageous, however controlling overspray onto undesirable areas of the substrate must be managed. Spraying also requires meticulous maintenance to the atomizing device components. Routine cleaning steps and measurement of spray patterns must also be developed into this process. Batch dipping of substrate parts can be effective and be an efficient means for production. However, consistent orientation may need to be considered. Also, dipping can pose a challenge not to over-coat a primer rendering it less effective. Brushing primer to a substrate can be effective yet is one of the more inefficient application methods. It can pose the greatest challenge to conduct efficiently in a mass production environment as it requires more time and is more labor intensive without the incorporation of automated activity.

Most suitable primers available for silicone overmolding typically are activated by humidity. This in turn becomes crucial to the process. The molder must develop a production capable means of isolating the primed substrate components in a controlled humid environment prior to overmolding. A typical example of this method can be shown in example A (see below). Here, MRPC engineers utilize a specialized chamber to isolate and expose primed substrate components at predetermined humidity level. Controls are then employed in the manufacturing process to accurately control timing from removal of humidified, primed substrates until the substrate is overmolded.





Example A: Silicone nodes bonded to titanium surgical blade requiring production-controlled humidification prior to overmolding.

Overmolding Process Development and Challenges

During the overmolding process, as silicone enters the mold and contacts the primed substrate, several molding parameters can have a considerable impact on the final molded part. These molding parameters impact both cohesiveness of the bond between the substrate and the overmolded silicone, and also the long-term integrity of the bond. Also, cosmetic consistency can be influenced by several molding parameters during this phase as material comes in contact with the primer. Cosmetic effects such as cloudy appearance, discoloration, blush, or air traps in some cases are a direct result of the primer on the surface of the substrate or often the primer may further propagate some of these conditions that already existed. Of utmost importance during the molding process is obtaining and maintaining maximum bond effectiveness. Regularly, as part of the overmolding process development, MRPC engineers execute Design of Experiments on what molding parameters maximize bond. One specific example was in the development process of overmolding 50 durometer LSR to a titanium surgical blade. In application these blades are ultrasonically vibrated at a frequency up to 55 kHz. In addition, the blades are subject to multiple sterile cleanings between surgeries. The silicone component molded to these blades needs the capability to withstand the rigors of this environment while maintaining a resilient bond. Molding trials of isolated and combined process interactions between fill rate, packing/holding time of the LSR, mold vs substrate temperature and cure times were challenged. Subsequent tensile tests to bond integrity revealed interaction between the elevated titanium blade temp coupled with pack pressure deemed the strongest bond. While a successful result in the LSR overmolding process, these optimized molding conditions are specific to this LSR to substrate application.

Similar to the above example, a separate application of LSR overmolded to a thermoplastic PPSU surgical handpiece required DOE techniques to optimize bond. Here again, a controlled variation of the molding process conditions revealed sub ambient substrate temp prior to molding coupled with a post cure operation maximized bond strength. The influence of primer to the overmolding process can challenge the molder's experience as to what process parameters are optimal. The balance between cosmetics, moldability, dimensional stability and ultimately primer performance can conflict with which parameters are ideal. Detailed and structured testing of the molding environment, substrate media and pre and post operations must be understood and identified to assure successful overmolding.

"Of utmost importance during the molding process is obtaining and maintaining maximum bond effectiveness.

Regularly, as part of the overmolding process development, MRPC engineers execute Design of Experiments on what molding parameters maximize bond."

Self-Bonding Silicones in Overmolding

A notably growing technology available to the LSR overmolding field is the advances in self-bonding LSR and HCR. As the name implies these materials do not require the extensive preparatory steps of the substrate to encourage bond to the substrate. Rather these silicones when molded, are engineered to form a bond with the substrate material. Bonding to substrate can be more ideal as adhesion promoters within the LSR are cohesively mixed within the material. In this case where previous challenges using primers applied consistently can be difficult, the self-bonding LSRs can bridge the gap with complex substrate geometry. Utilizing self-bonding LSRs, process parameters of the LSR overmolding have less burden on impacting the critical boundary layer required between substrate and the overmold material. In some cases, the self-bonding LSR also may not require the secondary post curing of the part to maximize bond strength. This may provide an advantage in the case of sensitive substrates that may be affected by exposure to multiple heat cycles.

With self-bonding LSRs however, there may be an increased burden on demolding of the final part from the mold. In the case of self-bonding LSR material there are active bond sites through the material. A bond thus wants to not only occur to the substrate itself but now also the surrounding tool surfaces. Achieving a good bond between the silicone and substrate while discouraging the self-bonding LSR to want to stick to the mold surfaces can become a challenge with some self-bonding materials. Typically, injection molding of standard LSR materials, if allowed, a rough or matted surface finish to the mold aids in release of the molded silicone from the mold cavity/core detail. With some self-bonding LSRs steps may need to be taken further to aid in part release. Plating the mold surface with low coefficient materials such as Nickel-Teflon or Tungsten Disulfide can aid in demolding of the overmolded part without compromising the adhesive bond between the silicone and substrate. Developmental trials on the effectiveness of various plating's may need to be incorporated during the sampling phase of the self-bonding LSRs as geometry, and substrate materials may dictate one plating to perform better than others. Cost of self-bonding LSRs are notably higher than LSRs containing no bonding agent. Also, the shelf life of self-bonding LSR is generally shorter than standard LSRs. It thus is the understanding of the cost/benefit relationship between the use of self-bonding primers vs applying a primer pre-molding as to which opportunity lends the most success.

Overmolding Process Methods

Development of a robust molding process when overmolding LSR has similar challenges to standard LSR molding. Process variables regarding rate of fill, pressures, temperature, and curing rate must all be optimized to assure molded integrity of the silicone. One notable advantage when molding LSR vs injection molding of thermoplastic materials, is LSR's inherent low viscosity. LSR materials in many cases require one tenth or even less the required injection pressures to fill the cavity than thermoplastic injection molding. Subsequently, packing the silicone out to achieve net shape can be done at a much lower or decreasing rate of pressure. This low-pressure environment prevents an advantage to overmolding a substrate as the likelihood of molding pressure to flex or distort the substrate component is greatly reduced. In addition, a substrate with complex geometry or thin flow paths can be filled more successfully without significant burden put on the rate at which the liquid silicone enters the cavity detail. However, these inherent easy flow, low pressure conditions with LSR can also create molding challenges. Overfilling or flashing along the substrate material can occur as LSR's material can continue flowing into extremely tight clearances. MRPC engineers meet these challenges of overmolding LSR by incorporating unique tooling approaches coupled with highly accurate LSR molding equipment. Typical tool approaches to overmolded substrates can incorporate multi-layered or flexible mold "shut-offs" to conform to the substrate, minimizing any gaps between the mold and substrate surfaces. Process control is maintained by the use of molding machines accurate down to 5% of the machines' overall shot capacity. These machines are further mated to closed loop, volumetrically controlled LSR dosing equipment which maintains consistent A/B ratio.

Mold temperature, cure rate and post cure studies are a full-on developmental process when overmolding LSR. LSR processes typically in mold temperature ranges of 260-400 F. These temperature ranges make it critical to understand the substrates' ability to withstand these temperatures without compromising material properties. Likewise in a situation where a primer has been applied prior to overmolding, preheating of the substrate can provide enhanced bond between the two components however very thin-walled elastomeric thermoplastic substrates, for example, may need to be presented sub-ambient prior to overmolding to prevent distortion due to the elevated mold heats.

It is the experiences with muti-material substrate applications where MRPC design and development teams have garnered extensive knowledge of the critical processing balances with overmolding applications.

Conclusion

Overmolding of silicones for medical device manufacturing poses challenges that must be overcome to achieve success. A thorough understanding of the reliable methods to combine silicones to device subcomponents depends greatly on developmental research, experience and a systematic means for testing and analyzing different methods. MRPC devotes its workforce to applying and continually refining robust overmolding techniques to meet the needs of their medical device partners. As medical device designs evolve the techniques and manufacturing methods to produce these products must remain at pace with these needs to apply engineered solutions.

About MRPC

MRPC is a world class, FDA Registered, and ISO 13485 certified full contract manufacturer of medical devices, instruments, and disposables. With full range product lifecycle capabilities including design assistance, development, and manufacturing, MRPC is a turn-key manufacturing partner to some of the world's largest medical device companies. Additionally, with thermoplastic, LSR, and rubber molding capabilities, clean room assembly and packaging, sterilization management and supply chain development, MRPC is able to provide a range of capabilities and flexibility unique to the medical device industry.

Contact Us

Phone
262-781-7122

Website
mrpcorp.com

Email
sales@mrpcorp.com

Locations

Headquarters
13161 W. Glendale Avenue
Butler, WI 53007-0246

Southeast Division
10610 75th Street
Largo, FL 33777

Northeast Division
12 Executive Dr
Hudson, NH 03051