

Two-Shot Silicobe–Thermoplastic Medical Molding

Author: Sarah J. Voss, Product Specialist, Medical

Co-Authors: Mark Simon, Ph. D. Research & Development Manager
Danny Ou, Ph D. Research & Development, Research Associate
Adam Nadeau, Research & Development, Research Engineer

Abstract

Medical device original equipment manufacturers (OEMs) are facing intense pressure to create innovative designs and maintain the highest quality over a product's lifecycle, while also designing for low-cost manufacturing. Cost-saving, innovative two-shot medical molding may be just the solution.

Two-Shot Silicone – Thermoplastic Medical Molding

Introduction

Two-shot silicone-thermoplastic molding molds both a silicone and thermoplastic part in one press, and in one process. These parts are traditionally molded individually and assembled as one completed medical device component. The two-shot process eliminates costly secondary operations and assembly — the main contributors to increasingly higher part costs. This process allows for increased part performance and more consistent part quality, due to the reduction of misalignments in traditional insert or overmolding. Two-shot also allows for the elimination of one tool and associated tool validation costs. By molding two parts in one process, this technology provides design engineers with increased freedom in part design. Two-shot eliminates the need to design for assembly. The process offers the complete removal of otherwise timely and costly process steps. Two-shot in turn allows medical OEMs to bring high-quality, low-cost medical device components to the market faster.

The Need for Innovation

- Over 90% of medical device components are comprised of adjoining silicone and thermoplastic parts.
- The medical device industry is increasing its demand for high quality, low-cost, innovative medical device components.
- The combination of market demand and material technology provided a platform for a successful two-shot silicone - thermoplastic process.

OEM Challenges/Two-Shot Solutions

<u>Challenge</u>	<u>Two-Shot Solution</u>
Increased part costs, assembly issues and limitation in designing parts for assembly	Eliminates assembly
Part performance or quality issues	Eliminates misalignments of components during molding
Adhesion issues	Self-bonding silicones allows for stronger covalent bond
High tool validation costs	Eliminates one-tool validation
Designing two parts	Designing one part

Material Development for the Two-Shot Process

Two-shot is not a new manufacturing technology. Silicone-thermoplastic two-shot molding has been used extensively for more than 20 years in automotive and industrial applications, but has only recently been introduced into the medical device market. The medical market was slow to

adopt this process because until recently, there were no commercially available USP class VI self-bonding grades of silicone.

In the past two years, silicone manufacturers developed commercially available self-bonding silicones for the medical market that chemically bond to various rigid thermoplastic polymers during the two-shot molding process and maintain bond strength post sterilization. Different grades have been developed to bond to polycarbonate, polyester, polyamide (nylon), and polyetheretherketone (PEEK). The following self-bonding materials have been commercially developed to use in two-shot medical molding applications:

<u>Manufacturer</u>	<u>Material</u>	<u>Durometer</u>
Shin-Etsu	KE2090	30-70 Shore A
Momentive	LIM8000	40-70 Shore A
Wacker	LSR3071	40-50 Shore A
Saint-Gobain	BioSil® SB	10-70 Shore A

The bonding of the silicone to the thermoplastic component is accomplished during the silicone vulcanization process; no additional priming or surface treatment is needed for the substrate material. In other words, the silicone covalently bonds itself onto the TPE component during the curing process.

Understanding the Two-Shot Molding Process

Two-shot processing requires the knowledge of silicone-thermoplastic chemistry and adhesion characteristics. The materials must maintain appropriate processing temperatures in order to adhere to one another. In the material selection process, it is critical to first determine requirements for sterilization, clarity, and biocompatibility. Selecting a self-bonding silicone and thermoplastic material that is appropriate for your requirements is crucial. It is also important to choose a thermoplastic material with a high softening temperature that meets or exceeds 300 degrees F. Materials that offer high heat stability allow for less differentiation in thermal dynamics of the silicone and thermoplastic molds. The higher the softening point of the thermoplastic material, the higher the temperature the silicone can be cured at during processing. Higher temperatures allow for faster curing and shorter cycle time.

Once a thermoplastic material is selected, the thermoplastic thermal data can be used in running rheology testing on the silicone. Rheology testing is conducted to determine the temperature at which the silicone begins to cure and the cure profile value for various temperatures. This testing allows the processing temperatures to be chosen before molding.

After the materials and temperature processing range are determined, the two-shot process begins. When setting up the process, it is critical to first produce thermoplastic parts only. The thermoplastic process needs to be defined and optimized before any silicone is injected into the tool. As long as the temperatures selected were based on accurate analytical testing, the two-shot process should be set up as a standard thermoplastic process, and then a standard silicone process.

The study of thermodynamics is required for the two-shot silicone-thermoplastic molding process. Thermodynamics is a vital aspect in understanding the two-shot process. In this process, the purpose is to solidify a thermoplastic melt and try to heat and cure the liquid silicone rubber. A properly designed two-shot mold, based on thermodynamic principles, is the first step in being able to accurately process a two-shot part. Figure A represents the basic concept of a two-shot mold. The mold typically can be broken into four quadrants: three “cold” quadrants to cool the thermoplastic material and one “hot” quadrant for curing silicone.

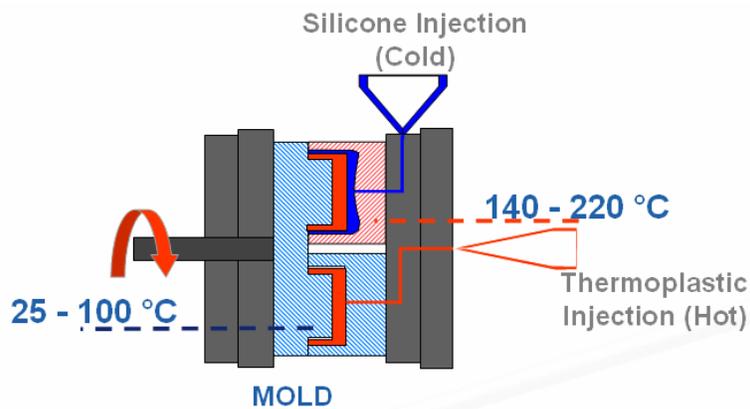


Figure A: Basic concept of a two-shot mold design.

Figure A represents the silicone and thermoplastic materials being in contact with each other in the tool during molding to heat one material, while cooling the other, making evident the importance of the thermal properties of the materials. The thermoplastic material is the first injection shot, the mold is then rotated 180 degrees and the silicone is injected into the mold. The mold will not open until the silicone curing process inside the mold is complete. The mold will then open and eject a completed silicone–thermoplastic medical device component.

Design Consideration for the Two-Shot Process

The key to a successful process is understanding the thermodynamics of the mold and choosing a material combination which can be compatible at the required thermal conditions. Partnering with a manufacturer with this experience will be crucial in developing and designing a successful two-shot part.

Designing medical device components that combine silicone and thermoplastic materials follow basic design considerations for the silicone and thermoplastic parts. Many applications that require high temperature use, low compression set, and purity, but in which thermoplastic materials are not suitable, can take advantage of silicone, which allows design for applications where thermoplastic materials cannot meet these specifications.

Understanding and considering two-shot silicone-thermoplastic processing at the design stage will result in a successful two-shot part. Understanding how a two-shot part is manufactured provides an advantage.

At the early stages in the design process, expectations of part functionality should be determined and clearly defined. The part should be examined for characteristics that are critical to function and design, including design locations of parting lines and gates.

After the basic design is complete and main characteristics are defined, the process of designing the part for two-shot molding begins. Typical thermoplastic and silicone design considerations can be used as a baseline for the two-shot silicone-thermoplastic molding process.

Below are basic design considerations:

1.) Choose a thermoplastic material that can withstand the processing temperature of silicone.

The silicone is cured in the high heat mold. As a result of the two-shot silicone-thermoplastic molding process, the thermoplastic material must withstand a high mold temperature without distorting. Materials with high heat distortion temperatures are recommended. These materials include (but are not limited to) polycarbonate, polyamide (nylon), polyetheretherketone (PEEK), and polyester.

2.) Avoid sharp corners.

Thermoplastic: Sharp corners not only affect the filling of the mold, but also affect the final properties of the part. Sharp corners in the material flow path can cause stresses in the material, creating uneven flow. Depending on the location, the uneven flow can lead to many defects such as non-fills, trapped air, and flow lines.

Silicone: Stay away from sharp corners to avoid tear and material flow issues. Sharp corners may create tears in the silicone during de-molding. Silicone will flow more easily into a rounded corner than a sharp corner, which will optimize your flow path and help prevent any possible flow defects.

A sharp corner may be acceptable in either a thermoplastic or a silicone part at the parting line. A sharp corner at this location is desirable because it provides a much better “shut-off” of material flow and it is easier to machine.

3.) Keep a constant or gradual transition in the wall thickness.

Thermoplastic: It is important to have uniform wall thickness. This will help mold filling and to prevent potential problems with warpage and sink marks in the completed part. If a part design has thick sections in load bearing areas, substitute by using uniformly thick ribs. Uniform wall thickness allows for more uniform fills and faster cycle times, which ultimately results in a more consistent and reliable part. If thicker sections are necessary, use gradual transitions.

Silicone: Unlike thermoplastics, silicone can have varying wall thicknesses. It is critical that the transition from a thin to a thick section is gradual. A gradual transition will help with mold filling. Keep in mind the thicker the wall, the longer it will take to cure the silicone, which increases the cycle time and cost. Silicone can also be molded into thin membrane sections of $0.015" \pm 0.0015"$ in thickness.

4.) Consider material gating locations from an aesthetic, processing, and functioning point of view.

Position the gate location in an aesthetically pleasing location. Consider the function and manufacturing of the part. Based on the critical areas which were previously defined, the gate needs to be located where it will not interfere with the functionality, such as a sealing surface or fitting location.

Thermoplastic: The gate should be located at a thicker section to help eliminate sink marks and voids. When picking a gate location, consider the material’s flow path. If there is a point in the part where the flow will split and then rejoin, causing a knit line (weld line), reexamine. Will this knit line be at a point of high stress? Knit lines are weak spots in the part and will be the first point of failure if located in high stress areas. If a knit line is unavoidable, properly locate the gate where the resultant weld line is in a non-load bearing area.

Silicone: One key advantage of two-shot silicone-thermoplastic molding is the ability to design the silicone layer to conceal the thermoplastic gate, providing a completed part look. It is important to know the location of silicone on the part. A part may have multiple silicone locations. In these cases, the injection location needs to be situated where the silicone can flow.

5.) Make sure all silicone features on the part can be filled.

A two-shot part may contain multiple two-shot features, such as soft-grip, sealing features, and membranes. In an effort to save on cost, depending on the part size, design the thermoplastic section to include runner segments to connect all silicone locations. For example, take a cylindrical part that contains a seal on the top and the bottom. Instead of gating the part on both sides and using two cold runner drops, the thermoplastic cylinder can be designed with recessed channels to allow silicone to flow down from one silicone sealing feature to the other sealing feature.

6.) Research your materials in order to define shrinkage.

Thermoplastic: Shrinkage of a thermoplastic part can vary significantly, depending on the base thermoplastic and additives or fillers. Typical shrinkages of thermoplastics vary from 2-5%. The optimal shrinkage value to reference is the one supplied directly from the manufacturer.

In a two-shot design, the thermoplastic base part is typically used to create “shut-off” locations. If shrinkage is miscalculated, the silicone will not fill properly. Therefore, understanding thermoplastic shrinkage, and consideration of shrinkage in the design is critical.

Silicone: Silicone varies significantly from thermoplastic. The liquid silicone is maintained at room temperature during plastication and is injected into a hot mold. During molding, the silicone will expand; however when it cools, it will shrink. Typical silicone shrinkage is 2% - 3%. Factors such as mold temperature, cavity pressure, flow direction, and post-cure will affect the amount of shrinkage.

7.) Design the part to optimize bonding.

It is important to optimize the part design to allow for the strongest bond. Allow for large areas of contact between the silicone and thermoplastic to create a larger area for bond. Also, where possible, include mechanical interlocks. This will provide chemical and mechanical forces functioning to bond the silicone and thermoplastic.

Conclusions

The cost-savings of two-shot molding are significant. However, the lead time for tooling is longer, and tooling costs are higher than traditional molding. Two-shot molding eliminates costly secondary operations and assembly, the main contributors to increasingly higher part costs. Two-shot molding eliminates the additional tooling and validation costs; improves part performance; provides higher, more consistent quality; and allows more freedom in component design.

Contact Us

Name: Angela Alt, Marketing Coordinator, Medical

Address: Saint-Gobain Performance Plastics
2316 W. Wisconsin Street
Portage, Wisconsin 53901

Email: Angela.R.Alt@saint-gobain.com

Website: www.medical.saint-gobain.com

Tel: 608.745.6117

Fax: 608.742.4731

Reference Websites

<http://www.ptonline.com/articles/200504fa1.html>

<http://www.devicelink.com/emdm/archive/07/10/014.html>

<http://www.devicelink.com/mpmn/archive/07/09/014.html>

References

Arburg: Practical Guide to Injection Molding” Edited by Vanessa Goodship pp.116-134, 242-249. Rapra Technology Limited and ARBURG Limited, 2004. ISBN: 1-85957-444-0.