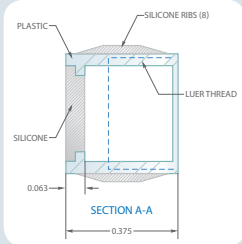
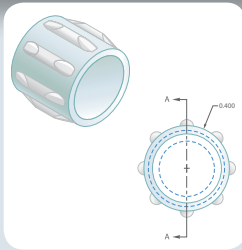


Two-Shot Silicone-Thermoplastic Molding

D E S I G N G U I D E

TWO-SHOT SILICONE-THERMOPL



Saint-Gobain, a world leader in the development of high-performance polymer products, offers an innovative, cost-saving solution for medical OEMs. Two-shot silicone-thermoplastic molding is a new technology for the development of medical device components that molds both a silicone and thermoplastic part in one press, and in one process.

How two-shot works

With traditional molding techniques, silicone and thermoplastic parts are molded individually and assembled as one completed medical device component. The two-shot process eliminates costly secondary operations and assembly, which are the main contributors to increasingly higher part costs. Two-shot molding allows for improved part performance and more consistent part quality, due to the reduction of misalignments that can result with the traditional insert or overmolding processes. Two-shot also eliminates one tool, and the related tool validation costs. Most importantly, two-shot technology provides design engineers with increased freedom in part design, so designers aren't limited by designing for assembly. The two-shot process enables you to bring your medical device components to the market faster — and with considerable savings.

Your partner in two-shot success

Saint-Gobain offers unparalleled knowledge and experience in the two-shot molding process and materials. We are committed to partnering with you in the development of a manufacturable, functional part design that meets your specific product requirements. Our partnership begins at the early stages of the design process, when expectations of part functionality are determined and defined. What's more, our engineers will support you throughout the

entire life cycle of your product — from development into full production.

Understanding two-shot silicone-thermoplastic processing at the design stage is critical to developing a successful two-shot part. Following are some points to consider when using two-shot molding for your part design.

Benefits of two-shot molding

- Reduced part cost
- Elimination of assembly
- Improved part performance and quality
- Increased bond strength between device components
- Greater design freedom — design without assembly
- Reduced part handling
- Reduced validation costs
- Product to market faster

Basic Design Considerations

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.

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.

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.

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.

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.

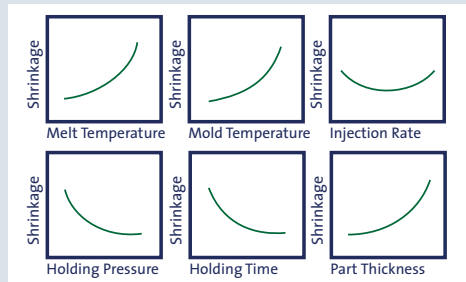
RESEARCH YOUR MATERIALS IN ORDER TO DEFINE SHRINKAGE. **Thermoplastic:** Shrinkage of a thermoplastic part can vary significantly, depending on the base thermoplastic and additives or fillers. Typical shrinkages of thermoplastics vary from 2-5%. The optimal shrinkage value to reference is the one supplied 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.

Two-Shot Thermoplastic Materials Shrinkage %:

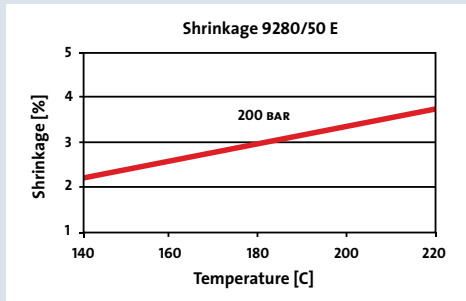
THERMOPLASTIC MATERIAL	SHRINKAGE %
PEEK (unfilled)	1 - 1.5
Polycarbonate (unfilled)	0.5 - 0.7
Polycarbonate (30% glass filled)	0.3 - 0.5
Nylon (unfilled)	1 - 1.7
Nylon (30% glass filled)	0.4 - 0.7
Polyester (unfilled)	1.5 - 2
Polyester (30% glass filled)	0.1 - 0.5

Factors Affecting Shrinkage in Thermoplastics:



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.

Mold Temperature Affect on Shrinkage in Silicone:



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.

Saint-Gobain is the world's leading producer of engineered, high-performance polymer products. Our core competency lies in our process technologies — technologies that transform difficult-to-process materials into useful products for industry. These materials include fluoropolymers (PTFE, PFA and FEP), silicone rubber and a range of other high-performance engineered polymers. Our tradition of excellence goes back more than 300 years through our parent company, Compagnie de Saint-Gobain, one of the world's top 100 industrial corporations, with operations in more than 50 countries. We leverage our global technology to provide worldwide advanced materials research, polymer processing and manufacturing support unmatched by any competitor.

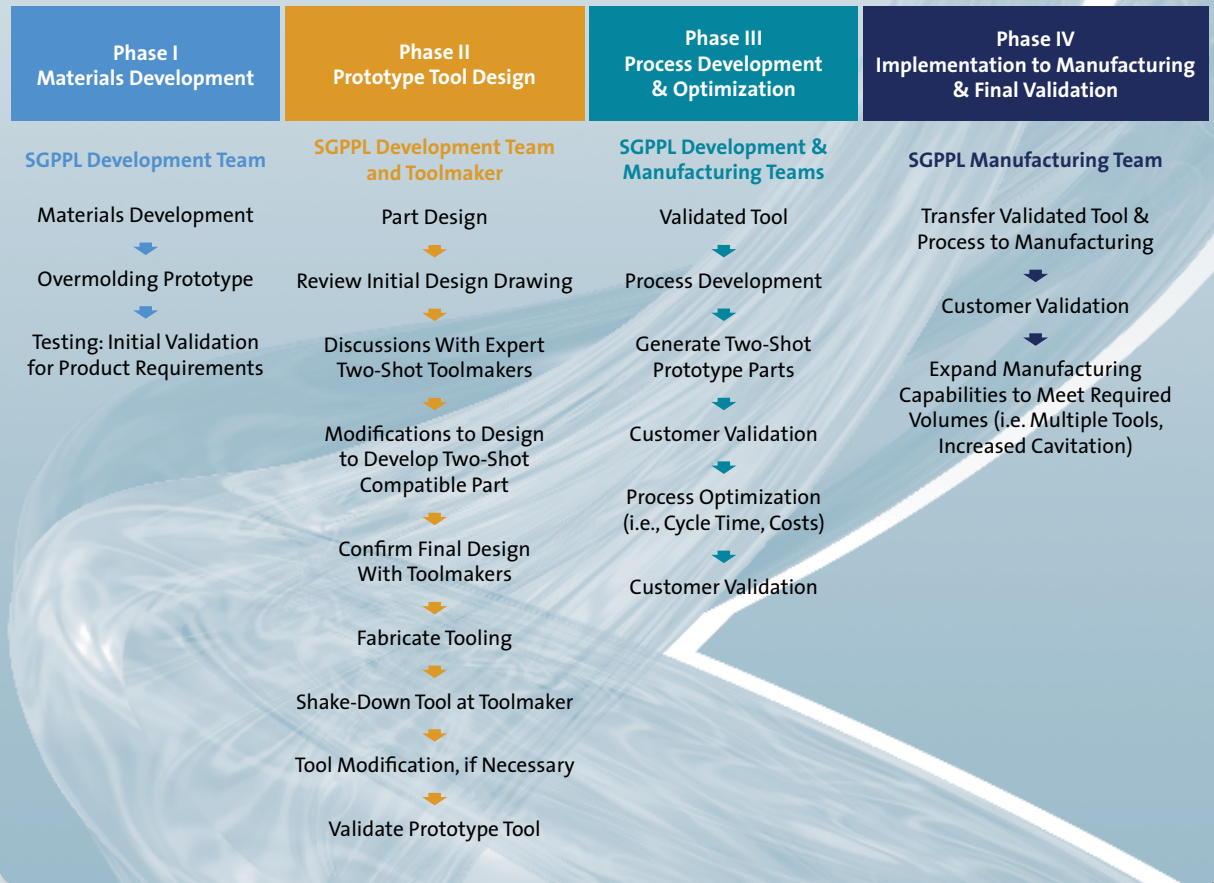
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 - Medical Components [21 CFR 820.3(c)], intended for processing or use in the manufacture or assembly of medical devices before the finished medical device is packaged/labeled; Medical Components are intended to be included as part of the finished, packaged, and labeled device [21CFR820.3(c)].
 - Finished Devices [21CFR820.3(l)] made on behalf of medical device manufacturers [21 CFR 807.20(a)(2)] under contract-manufacturing agreement. In accordance with the United States' jurisdiction, Saint-Gobain complies with the FDA's requirements for contract manufacturers of finished devices."



Partnering with you every step of the way

Saint-Gobain partners with customers throughout the entire two-shot design and production process — from development to optimization to full production. Our engineers will work closely with you

during all phases of production to ensure development of a two-shot part that meets your specific application needs.



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