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Two Component Molding Solves Medical Design Challenges and Reduces Costs

Device manufacturers count on their supply chain partners for answers. What processes can be adjusted to add value and reduce cost? What methods can be used to streamline manufacturing processes, reduce SKUs, and improve part quality? One way is by moving from single component molding to two-component molding.

What is Two-Component Molding

Two-component molding is a method of combining parts that require different characteristics or material properties that one material alone cannot provide. It is a sophisticated injection molding process that requires specialized equipment and a high level of engineering beyond single material injection molding.

Resins with different properties are combined in a single part often to improve functionality, product differentiation, aesthetic appeal, or marketability over traditional designs. The process is commonly referred to as two-shot, 2K or 2C molding and often involves the combination of hard thermoplastics and a soft thermoplastic elastomer (TPE). In some applications the material properties of TPEs are not sufficient so thermoplastics are utilized alongside a silicone elastomer.

One example of a product produced using a two-component method is a medical device housing. A housing requires material that is durable to ensure the protection of interior components but also requires material that will deliver aesthetic appeal. A device handpiece is another example, a product that needs to be rigid or sturdy, but at the same time requires material to provide good grip and handling to facilitate user control.

Combining multiple materials can provide enhanced physical properties, such as resistance to certain media, UV shielding, and resistance to drug migration into the outside wall. With hard-soft two-component molding, the hard component provides the strength (typically the base or substrate), while the soft component acts as a sealant, insulation, or generates good haptics.

Advantages of Two-Component Molding

The two-component injection molding process adds value for the device manufacturer because they do not have to spend the capital to build and validate two different molds. This process also reduces assembly or eliminates it altogether while reducing the amount of part numbers, which further simplifies the overall manufacturing process.

Other advantages include:

- Lower costs with fewer steps, fewer parts, less assembly, and less manual labor
- Higher quality due to fewer defects, as manual labor leads to defects -and potential contamination
- Reduction in waste
- Improved quality, aesthetics, and functionality by combining different materials with different physical properties
- Reduction in cycle time provides faster manufacturing and throughput
- Combining multiple part performance into one component

The overall cost with two-component molding is lower because there are fewer steps involved in manufacturing a product. If the right materials are selected the components will form a strong chemical bond to the underlying surface which eliminates the need and associated costs for some secondary finishing operations such as priming, painting, or coating. When these steps are combined into a single injection molding process, it increases part quality, reduces waste, boosts throughput, and decreases overall production costs.

Medical device manufacturers understand the need to provide aesthetic appeal in order to help their products stand out against the competition. TPEs are a good way to improve aesthetics since they come in a wide range of colors and can be tinted to provide visual appeal or engineered with a custom finish.

Medical applications ideal for two-component molding include:

- Sealings or gaskets integrated into a housing or the outer case of a part
- IVD cartridges, e.g.,TP with integrated seal
- Luer connectors with strain relief
- Stem connectors or manifolds for pharmaceutical filling lines
- Housings with TPE for aesthetics, feel, or haptic sensation
- Syringe piston seals
- Hubs and connectors with a kink resistant portion
- Soft touch handle grips and components with ergonomic and aesthetic features
- Multicolor parts
- Parts with molded seals, flexible hinges, or movable components
- Technical parts that reduce vibration, dampen noise

The Two-Component Molding Process

Two-component injection molding is achieved by molding one material over or onto another material. The process of overmolding combines multiple materials into one molded part. It typically consists of two materials, a rigid substrate covered in whole or in part by a more pliable material such as a thermoplastic elastomer or thermoplastic polyurethane. This two-component injection molding process is the most efficient method to produce parts with two plastic materials, which gives the designer multiple functions in one design or in one part.

Technically a two-component part can be realized with two machines. A component is produced in machine 1 and then loaded into machine 2 to mold the second component. This process duplicates the effort with the use of two machines and two molds. A more sophisticated two-component process utilizes one machine with rotating cavity plates or sliders or a combination of the two. Machines with up to six barrels are the latest evolution in multi-component technology and can deliver even more functionality to a medical device designer. These machines can incorporate multiple resins with unique performance properties or colors.

For additional cost saving benefits, a hot runner system or systems can be added to the molding operation to eliminate runner waste. The addition of a hot runner system decreases cycle time and results in better process control and ultimately improved part quality while also achieving further cost reductions.

Material Selection

Choosing the right material is essential to a device's success in its application and in the marketplace. When it comes to selecting materials for a two-component application, the most critical factor is making sure the materials are compatible. Materials must bond together both chemically and physically in order to produce a strong finished part with a long service life. If materials are not compatible the result may be component deformation or other bonding failures like delamination, in which the different material layers fall apart.

TPEs are typically used for the overmolded soft-touch layer and they represent a rapidly evolving segment of material science. Advanced TPEs have been developed that expand the capabilities for bonding high-performance thermoplastic resins to hard plastic substrates and their performance, appearance and functionality are constantly improving. The higher-bonding properties between TPEs and substrate base materials give two-component molding a manufacturability advantage over standard single material injection molding, broadening the range of applications and design possibilities. However, a complete understanding of how the selected materials interact at all stages during the process is essential for high-quality, efficient production.

The Role of Bonding

Some material combinations are compatible for bonding while others require pretreatment such as an additional coating layer that is compatible with both materials in order to forge the bond. Other materials are not compatible and require bonding which can be achieved by a variety of methods or a combination of methods listed below:

- Choose materials that are compatible with each other
- Modify one component to improve compatibility with the second component
- Choose materials that have similar surface energies
- Use mechanical interlocks, where a component is designed to flow around the injected component
- Use surface treatments such as plasma activation
- Use wet chemical treatments to apply a primer layer

Some applications make specific use of components that do not bond to each other. By using incompatible polymers, designs can be assembled in-mold during the molding process. With this approach parts can be produced with a hinge, pivot point, or sliding element without the need for additional assembly or downstream processing steps.

A working example of this would be a stopcock made of two dissimilar materials. The substrate is typically a hard thermoplastic such as a polycarbonate, which does not typically bond to a number of different TPE's. This two-component manufacturing step would result in a handle able to turn to operate the stopcock without the secondary operation of assembly.

Conclusion

The two-component molding process is an efficient and cost-effective way to provide custom plastic parts using two or more resins or colors in one operation. As a supply partner it is important to make customers aware of advanced manufacturing techniques and deliver innovative ideas so that they can leap ahead of their competition. A good supplier will advise the customer on the best processing methods and the most cost-efficient solutions to achieve their goals while enabling the customer to focus on the application and regulatory aspects.

Medical device manufacturers will save money by working with contract manufacturers that embrace two-component molding and other innovative ideas to reduce manufacturing costs. The end result is higher quality, less waste, simplified validation, and a streamlined process with fewer parts in the final device. Ultimately, it results in an improvement in the overall customer experience.

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