KAYSUN CORPORATION
INJECTION MOLDING & ENGINEERING SOLUTIONS

OVERMOLDING FOR MEDICAL DEVICE MANUFACTURING

A Guide to Applications, Process and Benefits

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The World Health Organization estimates the worldwide number of people aged 65 years or older will top 2 billion by 2050 — a sharp increase from 605 million in 2000. That said, the home healthcare market has already started to reflect this major demographic shift, as patients are reducing their reliance on clinic and hospital services, and utilizing more personal medical devices or in-home services.

With the healthcare industry projected to have a $300 billion market share by 2020, the medical device boom is happening right now, and complex injection-molded plastic components play a key role in the design and functionality of such equipment. Overmolding is an injection molding process that provides medical OEMs with more choice for improved performance, appealing design, and better overall quality. It has become increasingly popular across a wide range of manufacturing industries, but for medical devices in particular, it helps overcome numerous hurdles by providing devices with protection in the field, easily identifiable features, chemical resistance, insulation for electrical connectors, and much more.

Obstacles Today's Medical OEMs Face

Before we discuss how medical OEMs can use overmolding to improve their devices, it's important to understand the underlying issues that impact today's medical manufacturing industry. Going from design phase to a finished product takes months, if not years, due to challenges and sometimes competing priorities such as:

- Compliance and regulations requirements
- Extended research, development, and innovation phases
- Product differentiation and resources
- Staying cost competitive
- Keeping up with technology advancements
- Short product development lead time in a highly competitive industry
- Consistent performance for end users in the field

Benefits of Overmolding for Plastic Components in Medical Devices

Knowing what today's medical device engineers and manufacturers are up against, complex injection molders can utilize the secondary process of overmolding to help reduce the overall manufacturing cost of medical devices and solve many of the problems listed above.

The unique process of overmolding results in the seamless combination of multiple materials into a single part or product—most typically, it covers a rigid skeleton with a thin, pliable, rubber-like thermoplastic elastomer (TPE) to reduce abrasions, add a no-slip grip, provide waterproofing, and chemical resistance (some applications can also utilize rigid materials that are overmolded to rigid substrates). TPE can also improve device performance by reducing shock and vibration, dampening sound and providing electrical insulation. An exterior TPE surface is especially useful as a barrier to environmental hindrances like moisture and oxygen, which is often critical in medical applications where shelf life and sterility are primary concerns.

Benefits of Overmolding for Medical Devices:

- Reduced abrasions
- No-slip grip
- Waterproofing
- Chemical resistance
- Reduced shock and vibration
- Sound dampening
- Electrical insulation
- Colorable for easy identification and appeal
- Dompatible with variety of surface finishes
- Streamlined assembly and secondary operations

Likewise, using TPE helps manufacturers who are constantly try to improve shelf appeal by making their products stand out from the competition, as it comes in a wide range of colors, can be tinted to provide visual appeal, and has the ability to be engineered with different finishes including matte or gloss. Clear TPE surfaces can even be overmolded onto patterned or customized substrates to include a corporate message, logo or other form of brand identification.

Lastly, a big reason why overmolding is popular across the medical industry is its rare ability to ***improve device viability and user satisfaction, yet still reduce overall production costs by minimizing the number of process steps, thus improving speed to market***. Rapid turnaround on new products is critical for gaining a competitive edge, particularly when racing to answer a medical crisis or introduce an innovative new device to market. ***Total part cost using overmolding is typically less compared to producing separate parts with traditional injection molding, which then has to be assembled.*** The overmolded TPE layer forms such a strong chemical bond with the hard plastic substrate, eliminating the need for some secondary finishing operations such as priming, painting, or coating, which further reduces the total cost. By combining these steps into one injection molding process, overmolding increases quality, saves time, reduces waste and boosts throughput in addition to decreasing overall production cost.

Examples of Overmolding in Medical Devices

With overmolding offering many benefits for medical applications, OEMs have utilized the process in a number of different ways. To give you an idea of the various medical applications best suited for overmolding, below are several examples of how it's commonly used today:

- **Handheld devices:** soft grips, vibration control and abrasion resistance
- **Surgical instruments:** non-slip grips, chemical resistance, and biocompatibility
- **Instrument housings:** impact resistance, noise and vibration control, and improved aesthetics
- **Monitors:** impact resistance, noise control and abrasion resistance, dust seal
- **Tubing or luer fittings:** liquid or gas seals
- **Electrical connectors:** insulation and color identification
- **Syringes:** chemical resistance, no-slip grips and built-in seals

Types of Overmolding

There are two types of overmolding techniques commonly used to combine the TPE layer and plastic substrate: **single-shot** (insert molding) and **two-shot** (multiple-shot molding). Many OEMs prefer insert molding when production runs are short, but when production runs are higher, companies will often select a multi-shot molding operation. Which process we use for a medical device component is determined by a number of factors, including product design, material selection, injection molding equipment, mold and tooling budgets, labor costs, and production volume — all of which are scoped by our engineering team as part of a comprehensive Design for Manufacturability study prior to production.

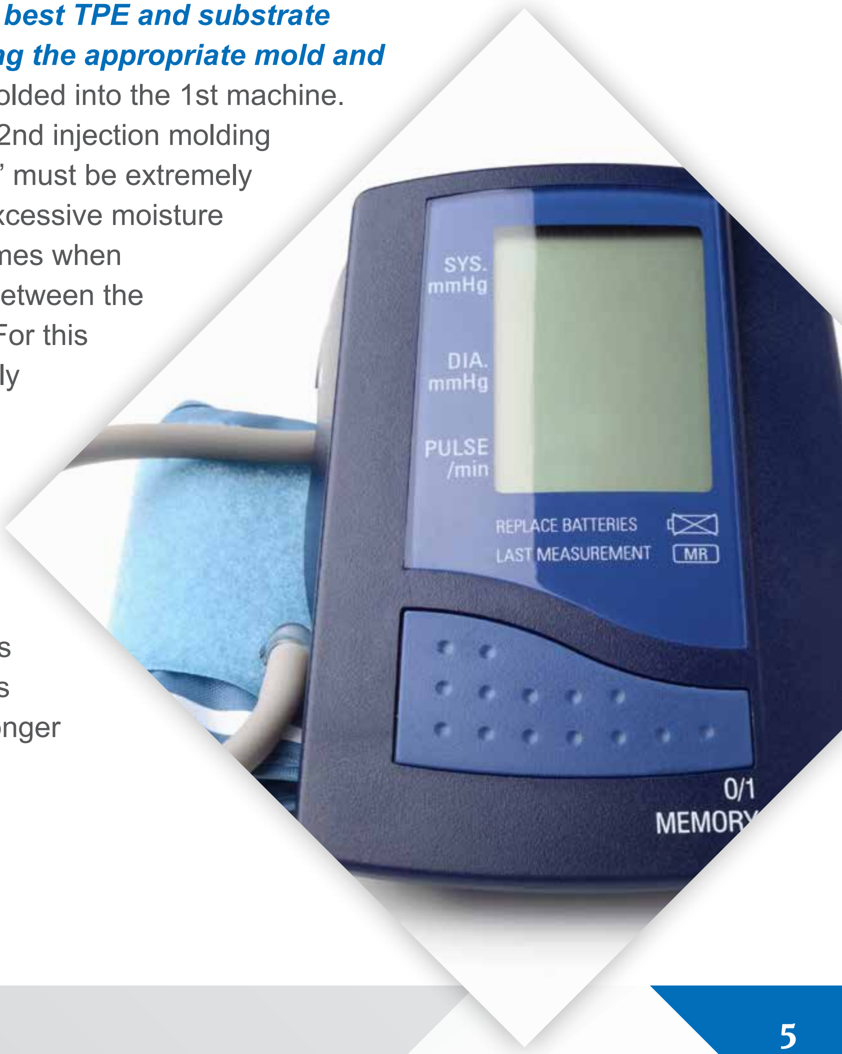
INSERT MOLDING

Of the two types of overmolding, insert molding is the most popular in American manufacturing, largely because standard, single-shot injection molding machines can be utilized instead of having to purchase advanced multi-shot molding equipment. Likewise, tooling expenses are also lower compared to multi-shot injection molding, and many injection molders are more comfortable with insert molding because it is closer to what they regularly do with their standard equipment.

The first step in insert molding is determining the best TPE and substrate material for optimal bonding, followed by designing the appropriate mold and tools. During the molding process, the substrate is molded into the 1st machine. The substrate is then placed in the mold cavity in the 2nd injection molding machine. The surface of this molded substrate "insert" must be extremely clean and free of contamination including dirt, dust, excessive moisture or skin oil. This means gloves should be used at all times when handling, as any pollutant will compromise the bond between the TPE and the substrate, causing weakness or failure. For this reason, substrates that are molded but not immediately used should be carefully stored and protected.

Finally, using a single-shot process, the TPE "skin" is molded over the substrate piece to create the final molded part or product.

Even though insert molding is easier for many molders because they can use their existing equipment, it does increase labor costs and cycle times because it is a longer process, making it ***more suitable for low-production runs or limited batches***.



MULTI-SHOT MOLDING

For multi-shot molding, advanced multi-barrel injection molding machines inject several materials into the same mold during a single cycle. This permits the TPE to be overshot on the substrate shortly after the substrate has been molded, resulting in a part or product that is manufactured completely in one automated process.

Multi-shot molding is more complex than insert molding, as it requires a higher level of precision and control, especially with initial product design, material selection, and tool and mold design. Furthermore, establishing process parameters and production design requires greater care, as does monitoring in-mold conditions during the multishot process.

Multi-shot equipment and tooling have advanced to support high-volume applications; complex rotating platens and automated tools also allow for higher cavitation that increases output. It is expensive and requires additional training to operate effectively, especially since multi-shot molding is a more complex process. The same holds true for development of the mold and tools; however, ***once designed and set up, multi-shot molding is an excellent choice for higher-production runs because of its shorter cycle times and faster speed to market***.

Material Selection is Critical for a Strong Bond

TPEs represent a rapidly evolving segment of material science, especially when it comes to their application in medical devices and equipment. These polymers have the characteristics of thermoset rubber, but can also be processed via injection molding—making them ideal for applications that require a rubber-like surface layer for softness, grip or style. In fact, ***TPEs are continuously being engineered to improve these characteristics, as well as chemical resistance, UV resistance, hardness, scratch resistance, clarity and UL standards.***

Given the numerous compliance and regulations medical OEMs must follow, having an in-depth knowledge of material science is essential for making a device that's up to standards, as well as efficient for overmolding. The proper chemical interaction/compatibility between the substrate and TPE is critical for strong bonding action, and if your medical device requires a chemically resistant material, for example, you'll need to select the proper resin that can do both. Even the slightest differences or incompatibility between materials can compromise the integrity of the bond and result in delamination, not to mention other negative consequences like inadequate chemical resistance.

Some TPEs exhibit surprisingly different bonding characteristics depending upon whether insert molding or multi-shot molding is used — a huge factor in substrate and process selection. After working with numerous medical OEMs throughout the years, however, Kaysun engineers know and test how the selected materials interact at all stages during the overmolding process, and stay current with advancing knowledge about how materials behave and interact under various production parameters. Through this, our engineers have learned how to save time (sometimes months) and money designing and prototyping the mold and tools, as well as structuring the production process using scientific molding to ensure repeatability — all while maintaining compliance with the often complex medical industry requirements.

OTHER MATERIAL SELECTION VARIABLES

For many medical engineers and designers, the greatest benefit overmolding provides is an improved device “touch” or “feel.” In order to accomplish this, the tactile quality of overmolded components depends on a variety of interactive material properties, including friction coefficient, hardness, and thickness. For example, the thinner the TPE layer is (even if the resin is very pliable), the harder it will feel since grip softness is largely determined by the thickness of the TPE layer, not material softness.

Another key property is coefficient of friction (COF), which varies according to the selected materials and the end-product application. Identifying the best combination of material properties that will meet production specifications often requires multiple material and design iterations. At Kaysun, our deep experience in material science for overmolded medical applications keeps these iterations to a minimum, reducing total costs and cycle time.

Though defining “feel” is one of the most challenging parts of the overmolding process, perhaps ***the most important property in the material selection process is the TPE melt temperature, which dictates how easily the TPE flows and its bondability***. Melt temperatures must be determined for each substrate being considered, in addition to the bond strength that is required for that part or device. It must also be carefully monitored and controlled during the process. Some operators, for instance, inaccurately assume that nozzle temperature is the same as melt temperature, often resulting in inferior bonding and product recalls.

Conclusion

As the medical industry continues to become more technologically advanced and more consumers shift towards in-home medical care options, there are many opportunities for overmolding to help improve the plastic components in medical devices, as well as functionality and quality of the end product itself.

By reducing the number of steps in the medical injection molding process and improving efficiencies, the overmolding engineers at Kaysun can help to increase throughput, improve quality, lower cost, simplify validation, and improve the overall user experience.

To learn more about how our engineering or overmolding capabilities can improve your next critical-use project, request a consultation with one of our engineers today.

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