KAYSUN

INJECTION MOLDING & ENGINEERING SOLUTIONS

THE BENEFITS OF METAL-TO-PLASTIC CONVERSION

FOR MEDICAL APPLICATIONS

Custom Plastic Injection Molding Offers Distinct Advantages For Medical OEMs

Metal has been the primary choice of medical OEMs for decades. Its strength and durability were seen as unmatched – until relatively recently. Medical-grade polymers are becoming the preferred material for a broad range of medical devices and instruments. Why? Because of their versatility and ability to either completely replace metal or combine with metal to create an enhanced product with attributes that would otherwise not be possible.

Advantages of Metal-to-Plastic Conversion

1: REDUCED DEVICE WEIGHT

In some applications, medical polymers can be a direct substitute for metal, delivering similar device performance while reducing device weight by up to 50%. When and how "lightweighting" takes place depends upon the demands of the application and type of material selected.

In the operating room: Lower weights can play a significant role in helping to reduce surgeon fatigue during long procedures.

In the field: EMTs benefit from having lighter equipment to carry into critical situations where time is of the essence.

PLASTIC BY THE NUMBERS

Plastic Parts Are Typically Up To **50%** Lighter Than Metal Parts

2: INCREASED DESIGN FREEDOM

The plastic injection molding process allows designers to maximize function in a way that is not possible with metal parts. Injection molded parts can incorporate features such as living hinges or molded handles in a single injection step—an otherwise costly, multi-step assembly with metal parts. Eliminating secondary operations like assembly and welding is a key cost-reduction aspect of using custom injection molded plastic components.

Each of the more than 25,000 engineered polymer materials have unique characteristics that can improve product performance by enhancing:

- Strength
- Flexibility
- Transparency
- Biocompatibility
- Temperature and chemical resistance

Plus, new blends and hybrids can be custom-designed to meet very specific performance requirements. Another advantage is tensile strength that's comparable to metal. All of these attributes enable the product to more precisely meet the needs of the application.

PLASTIC BY THE NUMBERS

25,000+ — A Huge Variety Of Engineered Polymer Materials Means We Can Match For Nearly Any Application

3: IMPROVED FUNCTIONAL AESTHETICS

Plastics have an advantage over metal when it comes to aesthetics. Plastics are available in a variety of colors, surface finishes and textures that are much more eye-catching than metal.

Painting metal housings for electronic medical equipment is not practical, so colorization is limited to that of the base metal. On the other hand, injection molded devices allow for pigmentation to be incorporated directly within the plastic. Or, color can be completely withheld in most instances when natural transparency is desired.

This opens the door to some unique possibilities: medical instruments and devices can be color-coded for easy identification or, in the case of transparent polymers, surgeons can look through the instrument for improved visibility during procedures. Because the color is embedded within the material, it will not fade over time.

PLASTIC BY THE NUMBERS

$$$ —Overmolding REDUCES Overall Production Costs While Improving Product Viability And Meeting Design Goals

Incorporating Overmolding into the Injection Molding Process
The process of overmolding is where a single part is created using two or more different materials in combination. Typically the first material, referred to as the substrate, is partially or fully covered by subsequent materials (overmold materials) during the manufacturing process.

Overmolding combines a number of steps involved in making the product into a single, or two-shot, injection molding process without compromising quality or throughput.

Overmolding Benefits
Overmolding uses thermoplastic elastomers (TPEs) to add a soft-touch exterior that enhances the grip and "feel" of the medical device.

TPE overmolding also offers a stylish appearance that's attractive to users. Convenient color-coding is possible as multiple overmolds can be applied on one substrate. For example, a device may have a red "panic" button while using a different color on the outer grip.

Engineers and suppliers are continuously developing new TPE materials with expanded capabilities that give more versatility in product design, material combinations and application possibilities. The primary goals of these innovations are providing users with better ergonomics and comfort.

Overmolding Expertise
Not every injection molder can offer overmolding. The process requires an experienced injection molder with on-staff designers and engineers who possess special training and expertise in scientific molding and material selection, including polymer chemistry and behavior. Plus, advanced equipment with multi-shot capabilities is needed for successful outcomes.

4: REDUCED STERILIZATION BURDEN

Producing injection molded plastic medical instruments can significantly reduce the part cost. In some instances, the lower part cost actually creates a scenario wherein the medical device can be disposed of rather than sterilized and reused, minimizing the risk of infection and device prep time.

In addition to TPEs, there are a number of medical grade plastics that can be used for device housings and parts:

- Polycarbonate (PC)/Acrylnitrile-butadiene-styrene (ABS) blends are commonly used for device housings. They offer a good mix of impact resistance and aesthetics.
- Polybutylene terephthalate (PBT) provides high heat resistance. Additives serve as UV stabilizers and flame retardants; glass fiber can be added for strength.
- Acetal has a low-friction surface for internal functional components.

Antimicrobial agents such as silver ions can also be mixed into the plastic melt. The resulting final parts or products have microbe-resistant surfaces and therefore have longer product life cycles.

Meeting Additional Regulatory Compliance Requirements

Part Traceability — material additives can be used in the plastic injection molding mix to allow for unique laser marking identifications on each molded part, an imperative aspect of product safety and a critical element for any medical device manufacturing operation.

Cleanroom Manufacturing — for injection molding, a cleanroom environment is accomplished via enclosed tent, enclosed room or the entire building; an independent testing agency certifies air cleanliness; device sterilization, if needed, occurs after final assembly.

In the surgical suite, portable monitors must remain sterile and be able to withstand harsh cleaning agents and autoclaving. Not only do surgical devices need to be 100% reliable, they also need to meet FDA medical requirements. Select grades for TPEs are chemical-resistant, which fits well in these applications.

PLASTIC BY THE NUMBERS

Surgical Devices Require **100%** Reliability And Must Meet FDA Medical Sterilization Requirements

5: IMPROVED ENVIRONMENTAL COMPATIBILITY

Unlike like those made of metal, injection molded electronic medical device components can be used in the full range of environments in which they are necessary.

The magnetic properties of most metals preclude them from use near strong magnetic fields, as found in MRI environments. But plastics are immune to these magnetic fields, and injection molded devices present no safety hazards when used near or in conjunction with MRI machines.

Ease of use is another important medical design consideration for equipment, such as hand-held devices. Human-factors analysis is essential for determining the best ergonomic design. Overmolding creates an easy-grip surface and helps dampen vibration. Using more impact-resistant plastics can also minimize the risk of damage due to dropping.

The medical environment can be rough on electrical devices, especially in the field. Reinforced structural compounds can increase strength and stiffness, and provide resistance to impact, creep and fatigue.

Polymers are ideal for replacing metal or other materials, and formulas can be customized to meet cost and performance targets. Wear resistant thermoplastic compounds can incorporate internal lubricants that reduce wear and friction, thereby lengthening the service life of an application and reducing processing costs.

PLASTIC BY THE NUMBERS

Injection molding Achieves Extremely Tight Tolerances **(within +/- .001 inch)**

Examples of Improved Product Performance & Efficient Manufacturing

PULSE OXIMETERS

Production of a complex pulse oximeter showcased how custom plastic injection molding is more efficient than working with metals. Various models were designed for part commonality and to combine features across products, consolidating eight production lines into one.

Among the core design goals for this pulse oximeter family was to create fewer models with interchangeable attachments. These interchangeable attachments allow caregivers to connect any of three different peripherals to each device based on the needs of the patient, and may include reusable and disposable sensors for adult, pediatric and neonatal applications.

From a manufacturing perspective, this approach reduced the number of individual parts to be designed and produced. However, it also introduced a serious challenge since these attachments needed to be strong enough to stand up to rigorous use by emergency medical technicians in moving vehicles, as well as constant use by in- and out-patient facility staff. Snap tabs needed to allow the peripheral adapters to be easily and repeatedly attached and removed without breaking.

A back casing used on three models was molded from a polycarbonate/ABS blend, Sabic Cycoloy CX 2244ME, because a polycarbonate alone could not offer the required resistance to the chemical cleaners. Cycoloy also offered excellent moldability, impact resistance, and a UL-94 V0 flame-retardant rating at <1mm.

For the remainder of the pulse oximeter casings, the design team came up with two fronts and overmolded windows that not only universally fit the range of keypads and display screens but also were compatible with the common back casing.

Here, the injection molder selected Sabic Lexan 945A polycarbonate for its ability to maintain clarity and resist fogging. This resin is a non-filled, injection moldable grade that is non-chlorinated, non-brominated and flame retardant.

Other parts included a white case with a rubbery boot in several colors to signify model type. The products have in-mold decorating to read-out metrics/symbols such as blood pressure readings. The combination of resins and polymers resulted in a rugged, lightweight product.

AEDS

Automated External Defibrillators (AEDs) are also manufactured more efficiently with custom plastic injection molding. These life-saving portable units must be protected from impact, weather and a host of other factors. An overmolded TPE layer reduces shock, provides a watertight seal, is UV-resistant and insulates the interior unit from the kinds of abuse that occur in the fast-paced emergency environment where defibrillators are often used.

Along with durability comes the need to protect the battery and intricate internal electronics and machinations within medical devices. Injection molded plastic components can be precisely designed and consistently reproduced to seal out moisture, dust and other potentially corrosive agents. This ensures reliable performance and brings AEDs into stringent FDA compliance.

In addition, complex channels and extremely tight tolerances (within +/- .001 inch) can be achieved with injection molding — customer and molder engineers should work together to ensure part design meets these exacting specifications for internal components of medical electronics.

HANDHELD DEVICES

Handheld devices also benefit from the custom plastic injection molding process. As in all fields, the use of handhelds in the medical field is growing. The devices themselves are becoming smaller while incorporating increased functionality.

Consequently, these devices also require components that hold tight tolerances. The polymers used for molding these devices provide the desired impact and scratch resistance, clarity of the screen, ergonomic benefits and resistance to heat and extreme weather conditions.

In the case of handhelds, along with other medical electronic devices, overmolding reduces the number of steps involved in manufacturing. Because the soft-touch layer forms such a strong chemical bond with the underlying surface, the binding eliminates the need for some secondary operations such as priming, painting or coating. By combining these steps into a single injection molding process, overmolding increases quality, reduces waste, boosts throughput and decreases overall production cost.

ENCAPSULATED DEVICES

Custom plastic injection molding is also great for encapsulated devices. An available thermoplastic compound can protect sensitive microelectronic components from moisture and other environmental conditions. The compound improves hermeticity — or sealability — in the precise lead frame injection molding process.

Injection Molding Provides a Choice

When considering injection molding, OEMs don't have to choose between devices that are strictly metal or plastic. In some cases, a metal instrument can be made better, or more efficiently, by combining metal and plastic; e.g., plastic overmolding of a metal substrate. Or, plastic can be used to replace a complex portion of a device when certain features are too expensive to machine out of metal.

Injection molding is well suited to producing complex geometries, while metal may be a better option for handles or device components that transmit or sustain heavy force. In either case, medical-grade polymers offer designers a wide range of choices for maximizing the benefits of their product design.

The Right Custom Injection Molder is Key to a Smooth Conversion

A custom injection molder with extensive experience in meeting exacting standards for medical devices is invaluable. Kaysun Corporation's engineering team has performed metal-to-plastic conversion for many companies across a wide range of industries, including medical, automotive and defense. We'll help you comply with regulations, lower total costs and/or reduce product weight while delivering improved design, flexibility and performance. Contact us today to begin your consultation.

Looking for a custom injection molding partner that's committed to collaborative, value-added partnerships? Ready to gain a competitive advantage? Contact Our Team

KAYSUN
INJECTION MOLDING & ENGINEERING SOLUTIONS

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