



In-Mold Labeling Enhances Product Durability in Medical Devices

Providing recognizable branding, instructions, and/or user interface features on a medical device can be a significant challenge; when coupled with ensuring the solution does not create cleaning concerns and will not wear, that obstacle to success becomes even greater. This article examines the benefits of in-mold labeling/decorating (IML/IMD) for medical devices and how the technology resolves these and other challenges.

Technologies and Innovations

IML/IMD technologies have been in the marketplace for many years. Continuous innovation in materials, processes, tooling, equipment, etc., has provided the building blocks for successful design and execution of IML/IMD for medtech devices. These innovations include IML/IMD compatible materials (PP, PET, TPE/U, etc.), customizable printed hard-coats, formable hard-coated polyester films, printed electronics, and improvements in touchscreen technologies.

IML/IMD gives designers great latitude in terms of textures, colors, graphics, and a feel that is more in tune with the needs of clinicians, physicians, and patients. This flexibility allows designers to design for user experience and emotional connection as opposed to designing for manufacturability.

IML/IMD makes it possible to include repeatable registered graphics, optically clear windows, and a wide variety of color and design variations. Conductive entities, such as RFID, EMI shielding, antennas, and capacitive touchscreens can also be added.

Chemicals and systems required in the sterilization process of medical devices for bacteria and viruses are very harsh and drive stringent durability requirements for film, surface inks, and coatings. Traditional methods of product decoration, such as hot stamping, heat transfers, pad printing, and painting are not always able to meet the validation requirements for medical devices. Pressure sensitive appliqués allow foreign materials to contaminate the edges, and eventually leach behind the appliqués, making complete sterilization impossible. IML/IMD has substantially improved the chemical resistance of these devices by creating perfectly sealed surfaces with almost no possibility for entry for contaminants.

Economic and Environmental Aspects

By integrating design, graphics, and conductive features into the molding process, secondary operations, such as pad printing and spray painting are eliminated, reducing the possibility of scrap and increasing throughput for these operations. The use of preprinted and color-matched graphics eliminates the need to purchase pre-colored resins, which can cut costs anywhere from 5 to 40%. The supply chain benefits realized when decorative plastics are sourced from a single location can be as much as 30%. The reduction in order-to-delivery supply chain eliminates WIP, inventory, and obsolescence. Additionally, engineering costs and complexity are minimized when decorative plastics are sourced from a single location.

IML/IMD can be considered a green process since the use of similar film and molding resins make the components recyclable and enables them to meet the requirements of international recycling regulations, such as the European Union's RoHS and WEEE. Additionally, screen printing is much cleaner and emits lower levels of volatile organic compounds when compared to other application methods, such as spray coating technologies.

The IML/IMD Process

The IML/IMD process for medical devices begins by selecting a film that meets the required durability, flexibility, chemical resistance, and hardness properties. Once the film has been selected, it is decorated through a printing process. Ink selection is based upon the performance specifications. These can include opacity, transmissivity, IR and RF transparency, chemical resistance, elongation, adhesive strength, bright metallic graphics, and conductivity requirements of the ink/film combination.

Printing

Printing can be performed on either the first surface or second surface of the selected film. First surface printing is less durable and has the inks exposed to the outside/user environments. Second surface printing is more durable as it embeds the printed graphics between the chosen film and the molded resin. The film itself then defines abrasion, scratch, chemical, and UV resistance properties as opposed to the printed graphics having exposure to the environment. In either first or second surface printing, ink selection is of utmost importance. The performance of the printed inks either against the environment, the film, and/or against the molding resin define the success of the

IML/IMD application. Printing technologies that are compatible with the IML/IMD process are screen, offset, digital, gravure, and transfer.

Forming

Forming can be the next process after printing (when 3D part geometry requires decoration). Three-dimensional forming methods include vacuum, hydro, pressure, or combinations thereof. Proprietary ink and coating systems have been developed to withstand the temperatures and elongation associated with forming and molding. Sophisticated methods are used to predict graphic location when the 2D printed sheet is formed into the 3D shape. Pre-distortion is critical to achieve a visually appealing product. Graphic position tolerances are defined by material composition, thickness, depth of draw, and forming method used.

Cutting

After printing and forming, the insert is precision die-cut. The die cutting operation can be automated depending on the size of the part, the application, and the production volume. Consistency during cutting is critical as the applique edge relative to the mold parting line can crush in the tool if in too long or be visually displeasing if too short.

Molding

During the IML/IMD process, the decorated insert is placed into the cavity or onto the core of an injection mold tool using either manual, semi-manual or fully automated robotic systems. The applique is held in place using friction, static, vacuum, or a combination thereof. The desired molding resin is shot either behind, over, or in between the insert(s), bonding the film surface to the molding resin and yielding the finished part.

Quality Control

Quality control throughout the entire IML/IMD process must be utilized. Slight changes in material chemistries, 3D form shapes, and/or die trimmed sizes can have catastrophic effects. Total process control and monitoring are essential to prevent deviation. Beyond the functional aspects of the molded part, the quality of the graphics must also be controlled. Throughout the IML/IMD process, the product is visually inspected numerous times; either by human eye or automated vision systems. Final inspections are routine, which include critical dimension reporting, final inspection, packaging, and auditing.

Summary

Serigraph continuously innovates our materials, processes, tooling, equipment, etc. to implement successful building blocks for final design and execution of IMD/IML parts for medical grade devices. Serigraph can provide customizable printed hard-coats and our designers give great latitude in terms of textures, colors, graphics, and a feel that is more in tune with the needs of clinicians, physicians, and patients. We do this by maintaining high levels required for the sterilization process that each medical device requires making sure they are free of bacteria and viruses. In order to do this our IMD/IML process is very intensive from printing, forming, cutting, molding, and quality control.

Partner With Us

By providing innovative, eye-catching technologies and services Serigraph enables customers to differentiate their brands and stand out at the point of decision.

To learn more about what Serigraph can do for you visit us at: www.serigraph.com or email us: info@serigraph.com

