

# In-Mold Decorating; Not Just for Durable, Multi-Use Devices



In-Mold Decorating (IMD) continues to be among the best solutions when it comes to decorative product durability and integrity. However, advancements in material science and print technologies now allow Serigraph to provide IMD solutions throughout the medical device spectrum at costs that align with your budget; from single use disposables to permanent surgical suite applications.

#### **IMD Process**

Engineered films with specific properties for formability, durability, clarity, etc. are commonly used within the IMD process. The armor-like properties of these films may be perfect for durable plastic solutions. Serigraph has developed the solution for commodity grade/lower cost resins and films for the decorative molding process. In the past, it was difficult to achieve printed ink adhesion and durability on low surface energy films like PP and PE. With the development of primers and adhesion promoters, we can now print highly durable 1<sup>st</sup> surface graphics on these materials. Additionally, there are options for ink transfer decoration (IMD) during the mold process that provides higher volume opportunities for low cost, full decoration with hard coated protection.

### **FDA Requirements**

The FDA has been rolling out the Unique Device Identifier (UDI) Final Rule since 2014. By 2020, all Class I, II, III and unclassified devices will be required to bear a UDI as a permanent marking on the device itself if the device is intended to be used more than once. Serigraph's serialized digital IMD technology or traditional IMD with laser etch compatible inks can provide the device labeling requirements as defined by the FDA. If

the device is disposable after single use but carries a requirement for serialization, the digital/laser etched IMD technology also naturally fits.

## Required Systems and Sterilization Process

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. IMD has substantially improved the chemical resistance of these devices by creating perfectly sealed surfaces with almost no possibility for entry for contaminants. Serigraph's solutions will stand up to autoclave, dishwasher, alcohol, Virex, etc. Our certified testing lab will perform near any exposure, durability, and/or cycle test.

#### 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.

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