In-line Plastic Part Serialization for Improved Traceability

EMPIRE PRECISION

In-line serialization is helping manufacturers meet strict traceability guidelines and reduce risk for:

Medical Devices – Subject to the FDA's Unique Device Identification (UDI) requirements

Firearms – Subject to ATF data logging requirements

Meeting Traceability Needs with Laser Marking

In-line serialization of manufactured components is rapidly becoming an essential in many industries. In applications ranging from medical disposables to pharmaceutical and food packaging, automotive parts manufacturing, and firearms components, careful identification and tracking requirements compel parts manufacturers to adapt to this new challenge. The plastics industry is no exception, and companies who mold plastic components for many uses are in the process of extensive re-tooling and re-thinking to meet this need.

Particularly in areas subject to governmental monitoring and control, parts traceability brings a new paradigm to companies involved in polymer fabrication and molding. The FDA's new Unique Device Identification (UDI) requirements, for example, are imposing strict marking controls on some types of medical consumables, and this activity is expected to escalate. In the manufacturing sector, compliance with ISO quality standards can often mean that the supplier's plastics molding team needs to build mechanized, computer-controlled marking into its fabrication and assembly process. The ATF (Alcohol, Tobacco, and Firearms Administration) now requires meticulous marking and logging of many parts used in today's firearms, including polymer components, introducing a significant amount of additional handling and higher risks in the event of failure or discrepancies. And there can be other advantages in addition to meeting regulatory and quality-driven requirements. The capability for marking that becomes an integral part of the product itself provides enhanced opportunity for product labeling and branding.

The range of marking requirements includes various types of human-readable and machine-readable traceability codes, including:

- 1-dimensional (1D) and 2-dimensional (2D) encodings, including 2D data matrix codes
- Alphanumeric date/time/source data, including country of manufacture
- Serial numbers, lot numbers, and other materials and manufacturing codes
- UPC and other barcode encoding
- Graphics supporting product identification and use.

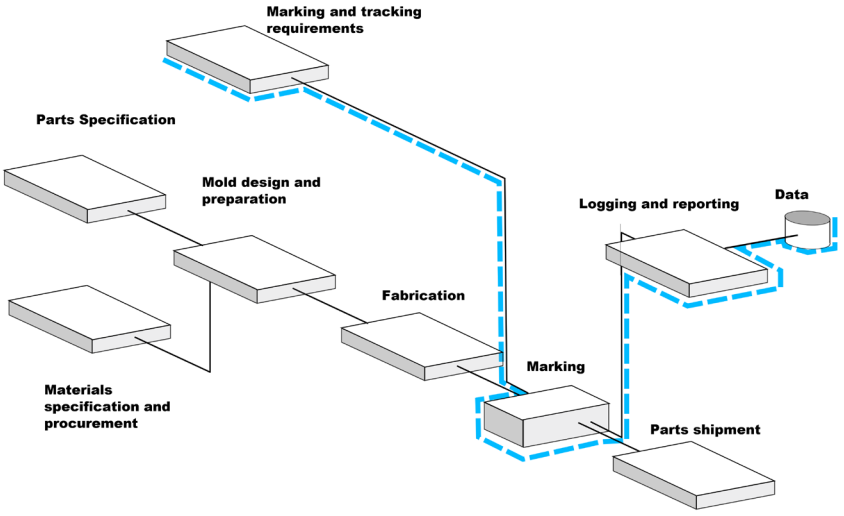
Historically, encoding and branding information were added as a separate process, after parts left the manufacturing floor, as an interim step before final assembly or packaging. While this may still be practical for some plastic parts, regulatory compliance, cost of handling, and other factors are putting the marking burden on the parts manufacturers themselves. Along with these new demands for marking is the need to store and be able to provide reliable data. The molder of a plastic component may even be required to provide computerized information that allows full traceability for many types of manufactured parts, extending over the parts' lifetime.

Of particular interest in the polymer industry is the use of laser marking. An array of large and small marking systems providers, such as FOBA, SIC Marking, Schmidt Marking Systems, Epilog Laser Systems, Laser Star, and many others, now offer a range of laser marking solutions to address the problem. The laser marking devices now available range from mountable marking devices to full-scale systems that include adjustable tables and plotter-like apparatus as well as sophisticated software control solutions for rapid, automated parts marking and encoding.

Changing the Plastic Fabrication Workflow

Particularly due to regulatory compliance concerns, the impact on workflow can be significant for permanent product marking, and the plastics industry is stepping up to the plate.

The simplified workflow diagram below shows some of the impact of these new requirements on the overall fabrication process. The familiar steps of obtaining the parts specification and materials procurement, along with mold design and preparation leading to parts fabrication, all follow the well-known pattern. A blue dashed line indicates where in-line marking is added.



The new workflow for plastics fabricators adds in-line marking as well as data logging, reporting, and storage.

As we can see from the new workflow sequence, the fabricator's work isn't done when the plastic parts cool and are removed from the molding line. The added processes bring a new information-intensive component into play, with data logging and storage integrated into the workflow process. Data needs to be written onto the plastic part as a finishing stage in the manufacturing process and any needed data for batch information, date/time stamping, and parts identification added.

Marking and tracking requirements obtained from the customer, where applicable, specify what type of marking or encoding is needed and indicate the relative process complexity. For lightweight applications like branding and labeling, these requirements may be as simple as marking each part with the same manufacturer logo and part number, so that only a minimal amount of data might need to be stored for the batch.

For firearms, medical devices, and other types of manufactured items, data management becomes more critical. Not only may the marking or encoding change with each successive molded part, such as with an encoded time stamp, serial number, or other individually identifiable marking, but the corresponding logging and data reporting requirements increase accordingly. Data integrity becomes an auditable item.

To comply with regulatory parts marking requirements, the laser marking equipment is programmed to index through a sequence that gives each part a separate mark. When this occurs, the logging and reporting process generates an entry that may include date and time stamp, batch number,

The laser marking solutions available today range from mountable devices to full-scale systems that allow for rapid, automated parts marking and encoding.

and other data collected for the individual part. This tracking information is then stored as data, such as on a local computer or processor, to be provided to the customer with the ordered parts as they ship as well as retained as a backup.

When the fabricator provides a marking that is an encoding, such as a UPC label, there can also be the additional step of reading and interpreting the laser encodings for quality assurance and in-house tracking. This can mean purchase and maintenance of additional instrumentation, with the training and labor costs associated with developing a qualified staff. Laser marking adds a new dimension to the plastics fabrication task and needs to be built into the scheduling and cost of a job.

Getting the Laser Solution You Need

Many companies now offer laser marking components and systems for the parts manufacturer. In sorting through the many options that are available for marking molded plastics, the plastics fabricator will consider a number of factors.

Volume Requirements & Automation

One key consideration is volume requirements, now and in the future. This factor can help determine the level of automation needed. Smaller-scale marking systems may require positioning parts separately and can demand more operator attention than some of the flatbed scanner units available. When manual positioning is used, a tiny pilot beam can be used for guidance, to pinpoint the starting point or central point for a write operation.

Some of the more automated systems include features like positioning and repeat operation, allowing the laser marker to scan each part in a fixture, automatically shifting its starting position in sequence, in order to accurately engrave multiple components in one setup. Features like autofocus and motorized table positioning can help to speed up the setup, minimizing the needed operator time between jobs. Other, less automated solutions may not offer all of the "bells and whistles" of fully automated equipment, but they allow the fabricator to customize in-house solutions that are better designed for particular jobs and customers.

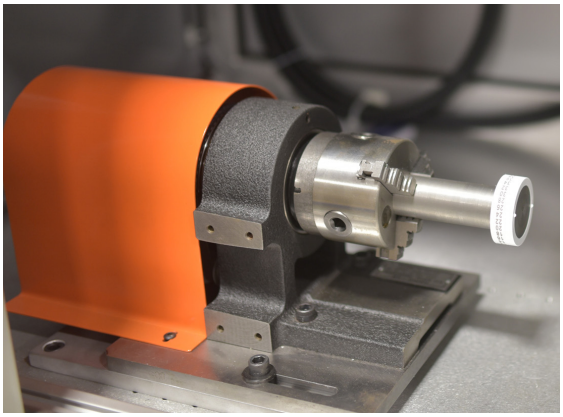
Power Requirements

Laser power can originate from a number of sources. Many of today's systems use laser light generated from fiber lasers, but CO2 and other laser types are also offered. Various levels of laser power are also available, such as 10W, 20W, and 30W systems.

For the bulk of plastics work, relatively lower-powered systems seem to work equally well with higher powered systems. Higher speeds are possible using higher power, as is expected. The laser marking devices generally are adjustable, allowing setup procedures to specify power percentages, pulse frequency, and scanning speed.

Raster vs. Vector Marking

The laser can operate in a raster scanning or vector mode, depending on the system type and setup. In raster scanning, the laser beam is rapidly traced along the surface in a linear back-and-forth pattern and actuated as needed over its travel path to direct energy to the surface one point at a time. In vector marking, the laser traces edges, lines, and curves of the pattern that is to be engraved. Vector marking generally works best for markings that consist of single-line fonts.



Laser marking adds a new dimension to the plastics fabrication process and needs to be built into the scheduling and cost of a program.

Software Solutions

Many laser marking systems come packaged with software solutions that allow the operator to generate the marked image or to import the marker graphics from other software packages, such as the familiar AutoCAD® (Autodesk Inc.), Adobe Illustrator® (Adobe Systems Incorporated), and CorelDraw® design software (Corel Corporation), for example. Some of the control software is operated just like a conventional print driver, minimizing the time required for operator training.

Low-maintenance Marking

Irradiation of the plastic parts surface by the intense laser beam causes ablation, removing a tiny, but visible, portion of the surface material by evaporation or sublimation. Because the laser is typically housed in a sealed assembly that restricts access and contact as well as airborne pollution, the laser source itself requires almost no maintenance and can provide trouble-free operation for years.

Plastic Materials

Some of the complexity in choosing a laser solution relates to the polymer materials themselves. Various types of plastics react to laser marking in different ways, and one up-front consideration will be how much resolution is needed or is even possible.

Because the laser generates significant amounts of heat as it etches or ablates the surface material, the fabricator needs to know exactly how much power is going to be applied, for how long, as well as to consider the thickness and resiliency of the materials, likelihood for warping or distortion, and factors such as visibility when a part is fitted into place in final assembly. The systems manufacturers can assist on this aspect of laser marking, and the experienced plastics molder will develop an awareness of the operating parameters that work best for particular materials.

Advantages to Fabricators and Customers

At Empire Precision Plastics, we've learned to think beyond the regulatory burdens and requirements for laser marking and to consider its advantages. For our customers, positive identification of plastic components can help to prevent costly mistakes further down the line, in distribution and product assembly. With the laser doing all the work, the added cost of adding a logo, internal control number, or even an internet address to a part is incremental and can have appreciable benefits to anyone who uses or handles the part.

Improving parts identification and traceability has significant advantages for the fabricator as well. At Empire Precision Plastics, we're able to track all sorts of control information on our materials and processes and relate them to parts that we may receive questions about years later. Not only can we fabricate and mark plastic parts at high volumes with highly automated molding and laser marking processes, but we'll also have the potential ability to track and provide information on individual parts that are designed with laser marking information. The investment for this value-added service advances our ability to serve customers as a supply chain partner.

Contact Empire Precision at 1.800.541.7135 or info@empireprecision.com to speak with an expert who can who can guide you through multiple considerations for cost reduction and improved performance.

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