CHEMISTRY THAT MATTERS™

LASER MARKING SOLUTIONS FOR MEDICAL DEVICES

The healthcare industry is transforming the safety, compliance, and tracking of medical devices with the guidance of the U.S. Food and Drug Administration (FDA) under the Unique Device Identification (UDI) labeling program. UDI process goals include improving device traceability and recall in the case of a safety risk or adverse event, and reducing medical errors.

INDUSTRY CHALLENGES

Under the FDA's regulation, 21 CFR 801.45, any device required to carry a UDI on its label must also have this information directly marked on the product itself, if it is intended to be used more than once and to be re-processed before each use. Laser marking is potentially well suited for UDIs on thermoplastic device components, even those treated with a coating. The laser creates a high resolution, permanent mark that can withstand the repeated cleaning and sterilization to which medical devices are subjected. As a digitally programmable system, laser marking can accommodate diverse part geometries and types of marks.

POTENTIAL ADVANTAGES OF LASER MARKING FOR UDI

Benefit	Description
Permanence through lifecycle – even after cleaning and sterilization	Laser marking delivers an intense, directed beam of energy to the surface of a thermoplastic part permanently burning the marked area. Compared to alternative marking methods, there is lower risk of unexpected interactions from chemical cleaning or sterilization methods due to the permanence of the mark.
Flexibility, speed & efficiency	Laser marking is a digitally programmable system that easily allows customization for UDI including serial numbers and barcodes. The laser marking process can help increase throughput as it uses writing speeds up to 2,500 mm/sec. This flexibility provides medical device manufacturers the freedom to quickly modify the label, mark products, and release for commercialization.
Suited for multiple geometries	While laser marking is most effective when a flat, fixed, focal point is used, non-flat surfaces can also be successfully marked. On a flat surface, marks can achieve up to 1000 dots per inch resolution resulting in intricate detail and text legible as small as 0.5 mm. This is an advantage compared to other labeling methods where space may be an issue.

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SABIC's broad product portfolio for the healthcare industry, offering a range of performance capabilities, can be considered for single use to long term reusable medical device applications. Materials such as NORYL™ or ULTEM™ resins may be good candidates for reusable medical devices exposed to low temperature hydrogen peroxide or extended autoclave sterilization cycles. Other materials, such as VALOX™, XENOY™ or XYLEX™ resins, may be good candidates for applications requiring good chemical resistance to healthcare disinfectants.

LASER MARKING SOLUTIONS

Many of SABIC's healthcare materials are excellent candidates for applications requiring laser marking. SABIC's Color Xpress™ technologists are available to provide assistance to help ensure the correct color package formulation is selected for laser marking optimization.

SABIC's transparent thermoplastics, such as LEXAN™ resin, can be used to achieve a light-to-white colored laser mark by applying a patented process. Ask your SABIC representative for more information.

LASER MARKING PERFORMANCE

Resin Family	Marking Capability		
	Light on Dark	Dark on Light	Marks on Transparent
LEXAN™ PC resins			
HP resins	+	++	++
XYLEX™ PC/Polyester resins			
HX resins	+	++	++
CYCOLOY™ PC/ABS resins			
HC resins	+	++	n/a
ULTEM™ PEI resins			
HU resins	+	++	-
NORYL™ PPE + PS resins			
HNA resins	+	++	n/a
VALOX™ PBT and/or PET resins			
HX resins	+	++	n/a

Rating: Excellent ++ Good + Fair - Poor 0
Note: Results may vary by color package formulation

CONTACT SABIC TODAY FOR YOUR HEALTHCARE LASER MARKING NEEDS

- Dedicated healthcare team - available to provide guidance on materials for medical device applications requiring laser marking
- Custom color capability - allows medical device manufacturers to achieve brand compliance as well as a high resolution, permanent laser mark
- Technical expertise – provides guidance on laser marking equipment settings for improved resolution, precision and readability
- In house testing - may be available to help ensure the candidate materials, color packages and machine settings are optimized to produce high quality laser marks

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