Make your mark: Using UV light for medical device marking

by Frank Gaebler

June 26, 2017

Frank Gaebler, Coherent, describes how short ultraviolet lasers produce cost-effective permanent marks on plastic devices and packaging.

Marking medical devices, implants and disposables enhances traceability, improves long-term quality control, prevents counterfeiting, fraudulent returns and unregulated distribution, and facilitates compliance with increasingly strict government regulations. For example, several countries mandate marking of a unique device identifier (UDI), including date and location of manufacture. Marking also enables tracking; if any part is found to be defective; the entire batch can be flagged and recalled if necessary.

For device and implant manufacturers, the main marking requirements are permanence, and that the mark not interfere with product functionality, including avoidance of contamination or introduction of allergens. Ideally, marks should also be difficult to counterfeit. For pharmaceuticals (tablets, capsules and caplets) and their packaging, marking must be non-toxic, and usually includes a product identifier, the manufacturer's logo, and possibly the date of manufacture or lot number.

Limitations of ink marking

The main drawback of traditional printed marks is that they are often easy to remove or alter (especially if they're on a paper label). They can be difficult to read after shipping, handling or storage, and also permit purposeful counterfeiting. In addition, although the inks themselves are usually non-toxic, high speed printing involves mechanical handling that may require lubricants or solvents that might contaminate the product.

Limitations of thermal laser marking

Infrared lasers are well-proven as a superior option to traditional ink printing in many industries, but often are not ideal for medical devices and pharmaceutical products. The issue is that an infrared laser produces a surface mark through intense localised heating – either bleaching or charring the target material (eg paper cartons), or by actually removing material in a process akin to engraving. In addition to causing damage by thermal effects, these surface marks are also potential focal points for contamination in sub-cutaneous and intra-venal implantable devices.

Ultraviolet laser marking

An alternative method utilises pulsed ultraviolet (355 nm) lasers, which are readily available based on frequency tripled, diode-pumped, solid-state (DPSS) technology. Ultraviolet light is absorbed more strongly than longer wavelengths by nearly all materials, so much less laser power is needed to produce a high contrast mark. More importantly, UV light directly breaks interatomic bonds in the plastic substrate causing a cold, photochemical interaction with any fillers or pigments, thus avoiding any heat affected zone (HAZ) or changes to the surrounding material.

Most plastics that appear white utilise TiO_2 as a pigment, which strongly absorbs UV light and then undergoes a change in crystalline structure. This renders the substance dark, producing a smooth, highly legible mark *within* the bulk material, rather than at the surface. Because the mark is actually subsurface, it doesn't provide a possible home for bacteria, and it is nearly impossible to alter or deface without destroying the material itself. And, the higher absorption in the UV means that material can be processed with lower laser power (or pulse energy). Finally, since UV light can be more tightly focused than IR, ultraviolet lasers support complex, high resolution marks, such as 2D barcodes.

Despite these advantages, UV lasers haven't been widely employed in medical marking applications in the past because of their cost. But, over the past decade, companies such as Coherent have made improvements in UV laser lifetime, reliability and output power. These have been achieved through improvements in laser design, materials and the implementation of stringent cleanroom procedures during production. Also, automated assembly methods and economies of scale as sales volumes have increased have helped to reduce UV laser price by a factor of nearly five over this period. An example of this new generation of cost-effective UV lasers is the MATRIX 355 from Coherent. The figures show marks produced in the Coherent applications laboratory using this laser. They illustrate the contrast and readability, as well as the absence of visible thermal damage. In the case of the silicone rubber tubing, the laser was focused inside a transparent substrate. This is useful in silicone tubing used for intubation or other intravenous applications because it allows marking on the *inside* surface of the tube.

Unique Device Identification (UDI) medical device Coherent Ultraviolet lasers Issue 36

by Frank Gaebler