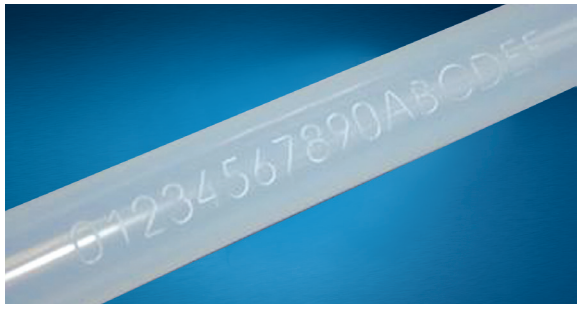
IN-LINE LASER MARKING OF SILICONE TUBING

Problem: Pharmaceutical companies require components to be marked for lot traceability but problems occur within secondary processing and with traditional printing techniques

Solution: Laser marking, performed in-line and without adding ink or any by-product to the extrusion



In-line laser marking is the process of choice for the permanent marking of tubing without adding any ink or material to the extrusion. Performed in-line with the extrusion process, not as a secondary procedure, laser marking is cost efficient, flexible, reliable, and proven to be safe.

The pharmaceutical industry is driving the market for printing and marking technologies as many pharmaceutical companies now require full lot traceability down to the component level. Popular marking methods include pad printing, rotary printing, and silk screening; these methods all require the addition of ink as a print medium. This often brings up questions about the biocompatibility of various inks. Additionally, the application methods, particularly uncontained printing applications like screen printing, can be in conflict with cleanroom manufacturing processes. Inks need time to dry and are therefore applied in secondary batch processes with a minimum dry time. If the ink is not dry the printed information can be illegible and other products in contact with the ink may become contaminated. Batch processing, performed as a secondary operation, poses the risk for potentially mixing up products with another batch which corrupts the purpose of lot traceability.

In order to overcome these issues, Freudenberg Medical has implemented an innovative solution for laser marking silicone tubing without adding any downstream processes. With the Freudenberg method silicone tubing is laser marked, on-the-fly, in parallel to the extrusion process. An ERP system provides the information to be printed on the tube; it is transferred directly to the printer via barcode. The digital transfer of information eliminates human error and avoids mixing product or applying the wrong information. With each work order data is electronically transferred to the laser system and the focus point of the laser is adjusted to the specifications of the extruded product. The letter size is set in accordance with the tubing's outer diameter and markings are only applied to the surface of the outer diameter. The in-line printing process will adjust automatically to the production speed without putting any additional constraints on the extrusion line speed; this is a significant benefit. This process can be used over a wide range of diameters and is very flexible in terms of applying frequently changing characters. Print data can include any information required from article or material number to lot number and production date.

A Superior Solution

In-line laser marking is superior to silk screening and pad printing processes, both of which require additional material to be applied to the tube and therefore additional validation processes are required with these methods. Ink can rub off or smear if it does not dry properly and risks occur if the wrong type of ink is used. With laser marking no ink, pigment, material, or media is added to the extrusion. In addition no additives or by-products are used to facilitate laser marking so there is no danger of cleanroom contamination by ink or colors. Laser marks are achieved through a photochemical reaction on the outer layer of the tube, near the surface; the inner diameter does not see any alteration. The result is a durable mark which cannot be wiped or rubbed off. Extensive testing has been made to fine tune the wavelength of the laser in order to achieve the best results and provide clear letters and no burn marks.

The Test Results

Our engineers have conducted research on both laser marked and non-marked silicone tubing using tensile strength tests and cytotoxic residue tests and have determined there to be no significant change in the mechanical properties of the silicone tubing. To test the presence of possible cytotoxic residue related to the laser marking process, samples of both laser marked and non-marked tubes were sent to a certified contract research organization. The results indicated that the test materials did not release substances in cytotoxic concentrations during a constant 24 hour contact period. For the complete test results please contact a Business Development representative.

The end result proves laser marking to be a cost effective, reliable, and fail safe procedure for the permanent marking of silicone tubing when full lot traceability down to the component level is required.

About Freudenberg Medical

Freudenberg Medical is a global partner for the design, development and manufacture of innovative medical device technologies. With 11 manufacturing operations and more than 1,500 associates worldwide, Freudenberg Medical offers a wide range of capabilities from high precision silicone and thermoplastic components and tubing to coating technology, finished devices, and solutions for minimally invasive and catheter-based devices.

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