Case Study – Medical Device Contamination Concerns

Global Manufacturers of sterile surgical medical tools are selecting FDA compliant inks for their medical products and packaging in response to contamination concerns

One such global manufacturer reviewed their use of inks for the printing of product identifications on their surgical instruments and their packaging. They were looking for a provider of medical device inks that fulfilled the following supplier requirements: the ability to formulate inks that adhere to materials with specific surface tensions, manufacturing according to current good manufacturing practices (cGMP), formulations composed of FDA compliant direct and/or indirect food additives, and an ISO 9001:2015 registered quality management system.

Medical Device Inks

Medical device inks are used to print product names or codes onto devices, apply markings to catheters and syringes, or print usability and other identifying information on to the outside of packaging. Ink is applied during the product assembly as well as during the packaging process and before instrument and package sterilization. Performance characteristics specify that the inks must have excellent adhesion, are scratch resistant and must be impervious to heat, steam, blood and other bodily fluids. As part of the product packaging process they are frequently included in the sterilization of the product and its packaging and as such must be able to withstand the demands of standard sterilization techniques such as EtO and autoclave.

FDA Compliant Systems

Surgical medical instruments and devices are manufactured under strict FDA guidelines, designed to ensure their products consistently meet applicable requirements and specifications to prevent contamination. Printing inks for medical devices are not regulated by the FDA and as such do not fall under the Code of Federal Regulations. However, the customer was very concerned about any potential contamination of its devices, and therefore opted for a medical device ink formulated exclusively of FDA compliant raw materials.

Colorcon No-Tox® Products

Colorcon No-Tox® Products was the logical partner for this challenge. As a leader in the development and manufacturing of US FDA and EU compliant printing inks for the medical device market, Colorcon offers over 50 years of experience in FDA formulated inks. By working hand-in hand with the client's engineering and product development teams early in the product development process, Colorcon was able to develop a range of medical device inks that adhered well to the various substrates utilized by the client. With materials ranging from polyethylene to polypropylene to Tyvek, No-Tox® inks were formulated to meet the requirements of adhesion and handling, providing the right solutions sought by the client while using only FDA compliant raw materials. Colorcon's collaboration with their clients' product development and engineering teams early in the process allowed for maximum flexibility in the ink formulation. At the point where materials and substrates are defined, the right input into printability and adhesion can ensure that a project is delivered on time and on budget.

About Colorcon No-Tox® Products

Colorcon No-Tox® Products is a leading manufacturer of US FDA and EU compliant printing inks for the medical device market. All medical device inks comply with FDA 21 CFR, are manufactured in a cGMP, FDA and ISO 9001:2015 registered facility, and come with a written regulatory compliance guarantee.