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## MEDICAL DEVICE PACKAGE SECURITY

By Dave Olson, WebLabel

One of my most memorable experiences with package security in the medical device arena was a very personal one. I had just undergone three umbilical hernias repaired with surgical mesh. Being both bored and in possession of a Percocet prescription, I headed back to work a bit earlier than what my doctor had recommended. As I checked my emails the fifth one I read had the headline, “FDA Issues Alert on Counterfeit Polypropylene Mesh Used in Hernia Repair”. They talked about Ethicon’s Prolene product so I immediately called my doctor who assured me, after finally deciding it wasn’t some sort of practical joke I was trying to play on him, that I had the Bard mesh. Nonetheless, it was a very disconcerting thing, especially since the main problem with the fake stuff was sterility. The way that this counterfeit mesh was identified was through the packaging; the quality and fit of the counterfeit mesh did not match the real product.

In this article, I want to discuss the various methods that can be used to ensure package integrity. While the focus will be on making sure your original product gets to the end user without being compromised, many of the same techniques can be used to help thwart knockoffs of your product, such as the one that occurred with Ethicon’s surgical mesh.

The easiest, simplest, and most cost effective method of preventing tampering with the enclosed product is the lowly box seal. This can be a paper or film label but both have the same characteristics. They are very difficult to remove and leave a mess if you try to. You can visually see if anyone has attempted to tamper with your product or if someone is attempting to return it after it has been opened. To achieve this, the label material has a very weak face stock and a very aggressive adhesive. Usually very light paper stocks, 45lb. or less are used as well as destructible vinyls, polypropylenes, and acetates. The scratch off label on the back of phone cards is an example of the clear film version of this product. Labels of this type are commonly used on the shelf carton that contains the terminally sterilized product, either in a lid/tray combination or a pouch style package. One of the drawbacks of this simple label is that you need some method to open it, usually a fingernail (tough when you are gloved in an OR situation) or a scalpel. At Web Label we developed a ‘peel strip’ that is large enough and accessible enough to be opened by gloved personnel. This makes opening the package much easier and cleaner for the end users and also adds another level of security because it is much harder to duplicate than a simple box seal label.

This type of tamperproof label is an example of an overt security method. The level of security can be increased by adding covert features to the label. A simple and relatively inexpensive method is printing an invisible message using a UV visible varnish. A small \$15 UV blacklight will allow you to read the message yet leaving it not visible to the naked eye. Another similar technique involves the use of color shifting inks. These inks are temperature sensitive and shift colors when they are touched by human hands or some other heat source.

The highest level of security for packaging involves the use of microtaggants that are added to the ink. 3M developed this technology to help track explosives used in bombings and it has become more accessible and economical over the years. This increases the security of the package, making it more difficult to alter or counterfeit. You can actually get a proprietary 'signature' microtaggant that is assigned to your company. This also raises the level of technology needed for detection. Instead of the human eye with the tamperproof label or the UV message with a small UV light source, you now need at the very least a microscope and possibly a handheld detection device.

Medical device package security is even more critical with the recent spate of publicity regarding device failure. A company needs to make sure that the product that gets to the end user is the one that they produced and controlled throughout their quality and manufacturing processes. Security labeling, in various overt and covert formats, can greatly impact this goal at a minimal cost to the device manufacturer.

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