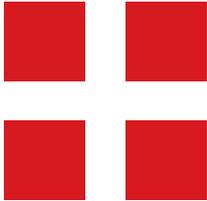


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Plastics Protecting
Intellectual Property
Against Illegal Fakes

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COUNTERFEITING: Are your devices at risk?

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IS IT TIME TO PROTECT YOUR BRAND? BEYOND THE PROBLEM OF FAKE PHARMACEUTICALS LIES AN EQUALLY ALARMING TREND TOWARD IMITATION MEDICAL DEVICES. BUT AN EMERGENT GROUP OF TECHNOLOGIES CAN HELP STOP COUNTERFEITERS IN THEIR TRACKS.

Counterfeiting most often conjures up images of paper currency or designer goods such as purses and shoes. However, this real and growing problem increasingly affects medical device manufacturers as well.

According to the World Health Organisation (WHO), as much as 6-8% of the US\$300 bn global medical device market is comprised of counterfeit goods. In this particular instance, counterfeit goods are identified as:

- Remanufactured or refurbished single use devices which are introduced back into the supply stream;
- Outright counterfeits or clones; and
- Equipment that has been modified to accept counterfeit consumables like ink cartridges or paint.

Although most counterfeiters concentrate on low cost, high turnover, high demand products, counterfeit medical devices can be high value products. Compounding the problem is the fact that many counterfeit devices are usually packaged to a high standard and difficult to distinguish from the genuine article.

Counterfeiting in medical devices occurs at various levels of the value chain, from device components to finished products. Finished products affected by counterfeiting have included blood glucose monitoring systems, surgical sutures, catheters and heart valves. In the case of device components, counterfeiting has also been seen in cardiovascular and orthopaedic product lines.

Unfortunately, the first indication that a counterfeiter has convincingly reproduced a device often happens when the device either fails in some way or causes harm to a patient.



<< From stethoscopes to syringes, the influx of imitation medical devices threatens to erode not only revenues, but also brand equity. Find out how to take action against these risks with authentication technologies. >>

Rather than reacting to these disasters and incurring the resulting liabilities, some healthcare device brand owners are taking a proactive stand by investigating and implementing anti-counterfeiting tools. Also known as authentication technologies, they provide a means to positively identify a device as genuine. Let's investigate the current situation and solutions along with the true cost of counterfeit devices.

Not just a luxury goods problem

Make no mistake—counterfeiting is a significant and mounting problem that negatively impacts consumers, businesses and entire economies. Several watchdog organisations estimate that this practice represents a cost of over US\$1 tn to the combined economies of the world. While accurate totals are difficult to generate—because these activities take place without any enforcement or regulation—the combined economic impact estimate includes all counterfeit goods and digital piracy, from consumer

electronics and apparel to after-market automotive parts and pharmaceuticals.

Luxury goods, which many consider to be the biggest problem, represent only 4% of the total, according to the non-profit organisation International Anti-Counterfeiting Coalition. (IACC—<http://iacc.org>).

How does this trend affect healthcare brand owners? The US Department of Homeland Security reported recently that counterfeit medical devices and pharmaceutical products seized last year were valued at US\$83 mn. Counterfeiters may target products such as pharmaceutical ingredients, stethoscopes, blood glucose monitors, diagnostic equipment, contact lenses, condoms, and surgical mesh.

In one high profile case, the FDA seized over a million forged diagnostic test strips (used by diabetic patients to monitor their blood glucose concentrations) with additional supplies later recalled by the genuine manufacturer when the false lot numbers were identified. These fake test strips returned inaccurate blood glucose values, so that patients using them could have taken too much or too little insulin.

Aside from the loss of revenue, brand-owner issues caused by counterfeiting, while sometimes hard to quantify, are costly and damaging. Some of these issues include:

- Erosion of brand equity;
- Damage to the brand owner's reputation;
- Potential liabilities;
- Loss of brand integrity; and
- Protection, investigation, and litigation expenses.

These hidden risks and costs can be just as damaging, if not more so, than the revenue drain that knockoffs represent. So what can you do about the problem?

Beyond the RFID chip: international authentication methodology standard ISO 12931

Casino chip manufacturers have been using RFID chips to ensure authenticity and traceability for a number of years, but this technology is only one of many in the currently available arsenal.

In response to the growing issue of counterfeiting, the International Organization for Standards (ISO) issued ISO 12931:2012 last year. It specifies best practice performance criteria and evaluation methodology for authentication

solutions used to establish product authenticity throughout the entire product life cycle. It's intended to guide all types and sizes of organisations in determining the authentication elements they need to combat the risks of counterfeiting. These elements can be part of the device or product itself and/or its packaging.

According to the ISO, authentication is the act of establishing whether a product is genuine or fake. There are three main technology areas that comprise these solutions:

- **Overt:** element detected by one or more of the human senses—examples include fragrances, visible tags such as holograms and laser marking, or tactile moulded features;
- **Covert:** element hidden from human senses and made visible by the use of a tool—examples are microscopic particles (called taggants or tracers), thermo-chromic additives, RFID chips, and invisible pigments detected by infrared light; and
- **Forensic analysis:** lab or field testing protocol that requires a device to be destroyed or rendered useless in order to verify the presence of an authentication element or intrinsic attribute; requires specialised equipment and a skilled expert.

For medical devices and pharmaceutical packaging, the proper mix of overt and/or covert technologies added as a masterbatch to the polymer components can deliver a powerful shield to protect brands and their products. For example, two or more micro-taggants can be used in combination with each other to achieve a "unique signature" level of protection.

Strategies and solutions

Because of the cost and risk associated with an influx of counterfeit products, governments as well as companies are starting to develop strategies to deal with this issue, including:

- Tightening supply chain control and management; techniques including approval of customers and suppliers;
- Strengthening law enforcement relationships;
- Accelerating the supply chain;
- Ensuring IP is used in a disciplined fashion on all products; and
- Using available brand protection technologies to help identify fakes, forgeries, copies and counterfeits.

Healthcare brand owners are actively investigating this last strategy and in response PolyOne recently developed a customisable portfolio of overt, covert and forensic technologies that can be incorporated into masterbatch solutions for a number of processing techniques. A host of factors were critical to brand owner needs, including an ability to test in the field, to identify and track products in the value chain, and to defend their brand against unjustified complaints and liability/warranty claims—all while safely expanding into new geographic markets.

The combined resource and service portfolio, called Percept Authentication Technologies, includes masterbatch or compounding development tailored to the application, as well as confidential, expert assistance with technology choice, design, usage, process, product, and specification development. These services are intended to shorten product development times and maintain quality levels while providing an added level of security to protect supply chain integrity. Masterbatches can be based on a variety of polymers: PP, PE, PC, PVC, PS, ABS, PC/ABS, Acetal (POM), PET, PBT, TPU, TPE, polyamides and other engineering thermoplastics.

PolyOne will be featuring this new technology at K 2013, the world's largest plastics trade show, in hall 8A, stand J13. K will be held in Düsseldorf, Germany, on October 16-23, 2013.

<< Over a million ersatz blood glucose test strips were seized by US officials after a detailed investigation. The strips did not accurately display a patient's blood glucose levels, which could have contributed to the over or under dosage of insulin. Luckily, these strips were identified and removed from the market in time to avoid health risks. >>



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<< Blood glucose monitors are among the medical devices that have been affected by counterfeiting. Masterbatch solutions within the polymer housing may enable healthcare consumers to positively identify genuine products easily and avoid fakes that can be potentially dangerous. >>



Leaders in the fight against medical knockoffs

- **2012 US National Defense Authorization Act:** Mandates anti-counterfeiting technologies be implemented by the US Department of Defense and Homeland Security and government contractors detect and avoid counterfeit parts in the military supply chain.
- **UL/Interpol:** UL is an independent safety science company. Interpol is the International Criminal Police Organisation. Together, they conduct anti-counterfeiting courses that help law enforcement, regulatory authorities and private sector IP crime investigators to identify counterfeit cables that carry the UL mark. UL also put controls in place to reduce the opportunity for fake UL certified cables to enter the American market. (<http://www.iipcc.org/FAQ.html>)
- **GIPC:** Global Intellectual Property Center is leading a worldwide effort to champion intellectual property rights as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges. (<http://www.theglobalipcenter.com>)
- **IMPACT:** International Medical Products Anti-Counterfeiting Taskforce is the working group of the World Health Organization (WHO) that identifies and removes counterfeit drugs from the global supply chain.