In this article, William Dierick, Technology Development Manager, Global Pharmaceutical Solutions, Terumo, highlights the product profile and features of K-Pack Surshield™, offering distinct benefits for healthcare professionals and patients, as well as benefits from a manufacturing perspective to the pharmaceutical industry.

For parenteral medication in luer prefilled syringes, pharmaceutical companies often co-package hypodermic needles within the drug package presentation to provide the healthcare professionals and self-injecting patients with the convenience to administer the medication in an efficient manner, enhancing the adoption of the appropriate injection practice for the specific drug and adherence to the therapy by patients.

With decades of expertise and core competences in parenteral drug delivery and injection technology, Terumo strives continuously to research and develop advanced and innovative devices that meet market needs. In 2011, Terumo launched K-Pack Surshield™, a next-generation sharps protection technology (see Figure 1).

With K-Pack Surshield™, Terumo offers the pharmaceutical industry an optimal technological solution to market Injectable drugs with injection devices that allow them to be compliant with established regulations and legislation concerning the prevention of sharps injuries, such as the European Council Directive 2010/32/EU.

For the latter, EU Member States had to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive or ensure that the social partners had introduced the necessary measures by agreement by May 11, 2013.

K-Pack Surshield™ is an innovative hypodermic needle with an integrated passive sharps protection feature for use with (pre)-filled syringes. The device geometry is designed to allow for automated manipulations during the packaging process, making it ideal for bundling and inclusion into the secondary packaging of parenteral medication (Figure 2).

Designed in particular for subcutaneous and intramuscular injection applications, a route of administration for many parenteral pharmaceutical and biopharmaceutical drugs, K-Pack Surshield™ is a hypodermic needle with a passively actuated feature that provides protection against accidental needle stick injury and hence minimises the risk of transmission of blood-borne pathogens from needle-stick injuries.

The encapsulating protection feature is integrated with the needle and therefore the needle is never exposed; neither before, during nor after injection. As a...
truly passive system, the protection mechanism is "armed" during needle insertion, thus the protection system cannot be bypassed. The needle fits to (pre)-filled syringes with standard 6% luer slip or 6% luer lock conical fittings (see Figure 3).

K-Pack Surshield™ is regulated as a medical device, independently of the pharmaceutical product, meaning the pharmaceutical industry does not have to invest in and validate additional assembly operations. This minimises resource requirements and may assist in limiting regulatory hurdles that would otherwise be encountered when implementing sharps-protection features along with the parenteral drugs that are placed onto the market.

As such, this innovative device offers specific product features and benefits, described below.

**User criteria and benefits**
- Truly passive system; easy to use
- Efficient and permanent cover of the sharps
- Not possible to skip a crucial step to activate
- Needle sharps not exposed, before, during and after injection
- Does not require more time to use
- Clear view of syringe contents and access to syringe label
- Permanent and visual indication of activation
- Ergonomics appropriate for injection technique
- Terumo’s needle quality for patient comfort

From a manufacturing perspective, the inclusion/bundling of K-Pack Surshield™ needles into the secondary packaging, together with the injectable medicine also offers the pharmaceutical industry with specific benefits:

**Features and benefits from manufacturing perspective**
- Compact design, individually packed, requiring minimal space
- Product configuration suited for automated manipulations
- Colour coding on tamper-evident label for in-line product detection by vision systems
- Does not require an additional assembly step (less investment compared with add-on systems)
- Less involvement of pharma companies for product and process validation (time-to-market)
- Own regulatory status as a medical device (time-to-market)
- Safety feature activation does not require interaction with the syringe; does not affect the syringe performance (e.g. dose accuracy)
- Provided by a global operating company with core competences in needle manufacturing

Furthermore, K-Pack Surshield™ needles fulfil the requirements of:
- EN ISO 7864 – Sterile hypodermic needles for single use
- ISO 23908 – Sharps Injury Protection – requirements and test methods: sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Having obtained regulatory approvals, K-Pack Surshield™ was launched in 2011 with industrial-scale production facilities installed at the manufacturing site in Leuven, Belgium, utilising state-of-art injection moulding technology and fully automated assembling equipment with on-line vision control systems for 100% in-line inspection to ensure optimal quality and functionality of the device.

Upon commercialisation of this new device, Terumo engaged in several negotiations with the pharmaceutical industry and was pleased to announce that a global pharmaceutical company selected its K-Pack Surshield™ needle for purchase and first commercial shipments of the device were started early 2012.

The customer, whose identity remains confidential, market the innovative safety needle together with drugs for applications in fields such as hepatitis and liver transplantation. In particular, patients who self-inject these medications are expected to benefit from this new drug and device solution.

Currently, more applications are being introduced and shipments of products began for such new application.

To service the customers in true partnership spirit, Terumo assists the pharmaceutical companies to prepare for marketing the products by providing training and educational materials, as well as assistance to prepare for regulatory documentation.

The value and benefits of this innovative device were also underscored by receiving the prestigious Pharmapack 2012 Manufacturers Award in the category “Safety Device”, showing recognition to Terumo efforts to innovate in this field of application and contributing to the health and safety of both healthcare professionals and patients.
Next generation of sharps protection technology

- Truly passive system
- Sharps never exposed
- Easy to use
- Compact, individually packed
- Suited for automated manipulations
- Terumo’s high quality needle

K-Pack Sureshield™

Hypodermic needle with integrated passive sharps protection