tip–top

TRULY PASSIVE INTEGRATED NEEDLESTICK PROTECTION FOR PREFILLED SYRINGES

Having carefully observed trends in the parenteral drug delivery sector for almost two decades, tip-top has distilled and miniaturised passive needle shield design down to its very essence. Here, tip-top's Managing Director, Barry Liversidge, introduces mini-Max, an ultra-simple, very low-cost, fully integrated needle shield, compatible with, and non-disruptive to, existing prefilled syringe manufacturing, sterilisation, filling and packaging infrastructure. It requires no modification to the primary drug container. Its functionality is truly passive and it is the first such device to provide full needle shielding pre- and post-injection. minim, its sister product, is a second-generation passive safety needle, based on the same technology.

THE TREND TOWARDS SAFER SHIELDING NEEDLES

Over the past decade, the market has accelerated its respone to the growing demand for safer needles by developing a variety of safety needle systems and devices. Significantly, the trend (shown in Figure 1) clearly shows that this endeavour is addressing the need for fully-passive shielding needles that activate automatically, and without any user intervention.

The concept of safely shielding needles is well understood and accepted throughout the medical world. However, some existing safety-engineered devices for prefilled syringes provide only limited needlestick protection, despite the high costs associated with this type of secondary packaging. Other concerns relate to the bulk and waste generated by these 'clip-on' accessories.

INTEGRATED NEEDLESTICK PROTECTION

These three industry buzzwords – *integrated needlestick protection* – relate to **ready-to-fill** syringes of the type supplied to industry in standard nest and tub formats, which are manufactured with an integral needlestick protection capability.

When this type of syringe leaves a fill-finish packaging line, needlestick protection is already integrated into the total drug product offering, without the need for a secondary packaging process to 'add-on' a needlestick protection device. And of course avoiding the need to 'bundle' or add a separate standalone safety needle along with the prefilled syringe.

A fully integrated needlestick protection system is an extremely attractive concept, espe-

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Figure 1: The trend towards safer passive needle shielding.

Figure 2: A viable industry-standard safety needle system by simply replacing the ordinary needle cover on a ready-to-fill glass syringe.

cially when the system can integrate into existing ready-to-fill syringe formats without the need for radical changes to the primary drug container or any changes or modifications to the internal syringe components.

THE READY-TO-FILL STAKED NEEDLE SYRINGE OF THE FUTURE

The ideal prefilled syringe of the future will be low cost and have integrated needlestick protection 'built-into' the syringe. *In our opinion, clearly this must be achieved without causing any disruption to the primary drug container*.

A viable industry-standard safety needle system for ready-to-fill syringes that can be implemented by simply replacing the ordinary needle cover on a ready-to-fill glass syringe, with a mini-Max fully passive needle shield (see Figure 2).

mini-Max only requires a few extra plastic components to deliver fully-passive integrated needlestick protection to a standard ready-to-fill syringe (see Figure 3), and mini-Max is less than one quarter of the size and weight of other needle shielding devices, and importantly, there is no need for a metal spring of any kind. These factors reduce cost of materials, transport, and storage and greatly simplify the assembly process

Figure 3: mini-Max only requires a few extra plastic components to deliver fully passive integrated needlestick protection to a standard ready-to-fill syringe

"A VIABLE INDUSTRY-STANDARD SAFETY NEEDLE SYSTEM CAN BE CREATED BY SIMPLY REPLACING THE ORDINARY NEEDLE COVER ON A READY-TO-FILL GLASS SYRINGE, WITH A MINI-MAX FULLY PASSIVE NEEDLE SHIELD."

Hopper feeds and vibratory bowls on assembly line machines can be much smaller in size and there is no requirement for components to be glued or welded together. Mould tool manufacturing costs are lower and the density of cavities per mould/bolster can be higher.

Mini-Max can generate significant production cost savings. For example, when compared with the typical 'clip-on', secondary-packaged safety device in use today, the production of 100 million mini-Max units would use 500 tonnes less polymer. That's 500 tonnes less plastic to be purchased, shipped, warehoused, process moulded, stored, assembled and transported.

One of the most important points to highlight about mini-Max is that is has been specifically developed to be totally non-disruptive to the hard-fought status quo of the prefilled syringe as the established universal industry standard.

Firstly, its design maintains the integrity of the standard prefilled syringe as the primary drug container. No internal components of the prefilled syringe are modified. Even the standard plunger rod remains unchanged. Secondly, mini-Max complements the ready-to-fill syringe by integrating seamlessly into existing nest and tub drug filling and packaging lines (see Figure 4).

That latter point is key and warrants some further explanation, as follows. The mini-Max is fitted by the syringe manufacturer onto either 1ml Long or 1ml Standard syringes having either ½ or 5/8 inch needles, simply by replac-

Figure 4: mini-Max integrates seamlessly into existing nest and tub drug filling and packaging lines

Figure 5: mini-Max is fitted by the syringe manufacturer onto either 1 ml Standard (left) or 1 ml Long (right) syringes having either ½ or ⅝ inch needles, simply by replacing the ordinary needle covers on the syringe.

ing the ordinary needle covers on syringe, as shown in Figure 5. This provides integral needlestick protection for the standard prefilled syringe, removing any need for downstream secondary packaging machinery.

The size and shape of mini-Max mean that syringes with the device added are compatible with the standard ready-to-fill infrastructure and can be nested into standard tubs.

USING MINI-MAX

From the point of view of the user, be they medical professional or patient, the key is the true fully-passive design. The user simply removes the cover, as normal, and administers the injection, as normal – the shield automatically covers the needle when the needle leaves the skin of the patient, and automatically locks securely to guard against needlestick injury. Figure 6 shows the mini-Max in action: before, during and after injection. (Note that in the middle "during" image the needle would normally of course be inserted into the patient's skin at this point. The needle is never exposed with mini-Max.)

"MINI-MAX HAS BEEN SPECIFICALLY DEVELOPED TO BE TOTALLY NON-DISRUPTIVE TO THE HARD-FOUGHT STATUS QUO OF THE PREFILLED SYRINGE AS THE ESTABLISHED UNIVERSAL INDUSTRY STANDARD."

When it comes to disposal, the small size of mini-Max means that it takes-up much less space in a sharps box compared with other safety devices, to ease medical waste disposal issues.

CROSS-OVER DEVICE

From the user's point of view, another trend observed by tip-top and accounted for in the design of mini-Max is the increasing

need for parenteral drugs to be self-administered by patients. The design of mini-Max can provide patient-centric features, for example concealing the needle and helping easier adherence to proper aseptic injection techniques to enable patients to safely self-administer their medication.

Mini-Max is also the ideal Crossover Device – able to provide the mandatory safety required when used in a healthcare setting by medical professionals, but also equally 'at home' when used away from a hospital setting.

For patients requiring the additional functionality of an auto-injector, mini-Max presents no obstacle since it can be utilised into a spring-powered single-use or re-usable auto-injector that takes a standard prefilled syringe.

SUMMARY

In summary, the mini-Max safety shield, and its sister product the minim safety needle (see boxed text), represent the distillation of needle safety to the optimum, by minimising cost, yet maximising protection.

For the user, tip-top's designs provide integrated pre- and post-injection safety that is truly fullypassive. For the industry, it provides the needle safety that the market, legislation and common sense increasingly demand, and as is the case with the mini-Max system, requires no disruption to the existing standard prefilled syringe production and filling infrastructure and, critically, with no modification or changes to the universally standard primary drug container of choice, the prefilled syringe.

tip-top holds more than 20 pending or granted patents covering many safety-engineered needle designs, including mini-Max and minim. The company has a strong independent source of funding and many years' of experience in the design of innovative engineered solutions, including more than two decades of experience in the design and production of plastic injection mould tools. Product development contracts with leading companies in the industry have been signed for previous devices, and interest in both mini-Max and minim from all quarters of the prefilled syringe industry has been very positive.

tip-top would welcome the opportunity to discuss the future development of its needle safety shielding devices, with interested parties. tip-top will be exhibiting at the upcoming PDA conference *Universe of Prefilled Syringes and Injection Devices*, in Las Vegas, NV, US, and at *Pharmapack* in Paris, France (February 23-24, 2011).

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"A PASSIVE NEEDLE SHIELDING SYSTEM FOR READY-TO-FILL SYRINGES"

Figure 6: mini-Max as it appears before, during and after injection.

"DESIGNED AND DEVELOPED TO INTEGRATE INTO STANDARD NEST AND TUB FILL FINISH FORMATS WITHOUT CHANGING OR DISRUPTING THE DRUG CONTAINER"