



integrated
passive needlestick protection
for ready-to-fill syringes

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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 response 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 integrat-



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.”

ed 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

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 it 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 1/2 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 1/2 or 5/8 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

“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.”

the needle would normally of course be inserted into the patient’s skin at this point. The needle is never exposed with mini-Max.)

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

minim[®]

PASSIVE SAFETY NEEDLE FOR LUER CONNECTION TO ANY SYRINGE

- super-compact and lightweight robust design
- guards against needle-stick injury before during and after use
- securely packaged with tamper evident closure, ideal for inclusion into parenteral drug offering
- minimum size – minimum cost – minimum risk

INTEGRATED NEEDLESTICK PROTECTION

from this next-generation safety needle which has no metal spring and uses only a few plastic components to lower costs and reduce sharps waste.

Small, compact and yet robust, this safety needle provides protection before, during and after injection.



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”

tip-top

INTUITIVE, SIMPLE & RELIABLE ULTRA-LOW-COST NEEDLE SAFETY DEVICES

In the previous issue of ONdrugDelivery, tip-top introduced its innovative designs for needle safety devices. Here, Barry Liversidge, Managing Director, tip-top.com Ltd, outlines the latest tip-top developments and describes the benefits of the company's mini-Max and minim devices.

The need for effective needlestick protection is well established and accepted within the pharmaceutical and medical industries. With legislation already passed in the US, Europe is now specifically addressing the healthcare industry's concerns for a harmonised approach to providing effective and affordable needlestick prevention devices. The implementation of this co-ordinated approach will reduce the prevalence of needlestick injuries, and make the delivery of parenteral drugs safer for both the caregiver and the patient.

So, here at tip-top, we are now in the process of inviting pharmaceutical companies to participate in a validation programme that will demonstrate the efficacy of our range of innovative safety-engineered needlestick

protection devices. This process will involve our two flagship products – the mini-Max integrated needlestick protection system for prefilled staked-needle syringes, and minim, a standalone passive safety needle for Luer connection to any syringe. These safety-engineered devices can provide the simplest, safest and most cost effective way to make delivering injectables safer.

mini-Max and **minim** were introduced and described in detail in an earlier article, which was published in the October 2010 issue of ONdrugDelivery. The article, "*tip-top: Truly Passive Integrated Needlestick Protection For Prefilled Syringes*", can be viewed as a PDF at:

www.ondrugdelivery.com/Tip Top.pdf



Figure 1: mini-Max is attached by the syringe manufacturer before the syringes are nested into the 'trays and tubs' used on many of today's filling lines.

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Figure 2: Syringes fitted with mini-Max (shown in their blister pack, left and boxed, centre) are approximately 50% less bulky than those fitted with clip-on needle guards (shown boxed, right).

TIP-TOP'S TECHNOLOGIES PROVIDE CHANGE, WITHOUT DISRUPTION...

tip-top's safety needle systems have been designed to work with any existing syringe manufacturer's products – including those from BD, Gerresheimer, M Glas, Nuova Ompi and Schott form vitrum, amongst others. The mini-Max design therefore maintains the integrity of the standard prefilled syringe as the primary drug container without having to change the internal components of the prefilled syringe

mini-Max is fitted to standard ready-to-fill staked-needle syringes and is fitted by your chosen syringe supplier as a safe and simple alternative to ordinary needle covers. The syringes with mini-Max attached (see Figure 1) are then nested into ordinary trays and tubs that are purchased today, ensuring no changes, and avoiding the need for expensive additional secondary packaging equipment.

mini-Max will be available with all the popular rubber formulations so your existing primary contact materials remain unchanged, eliminating the need for new stability studies.

And mini-Max's sister product minim, a stand-alone fully passive safety needle, can replace unsafe Luer injection needles, (that are bundled

along with a drug offering) with a fully-passive safety needle – that is then fitted to the syringe by the user at the time of administration.

BENEFITS OF MINIM AND MINI-MAX: AT A GLANCE:

1. Works with any standard staked needle or Luer Lock prefilled syringe
2. No change or additions to your current manufacturing process
3. A cost-effective solution, that provides fully-passive needlestick protection to ensure compliance amongst healthcare professionals and self-medicating patients alike.
4. Ultra-compact design minimises storage space and reduces sharps waste, to lessen the burden on the environment.
5. Simple design builds-in reliability.
6. Needle uniquely protected before & after injection
7. Tamper evident & available for most common needle lengths

LOW-COST, COMPACT DESIGN

tip-top has spent years refining and simplifying its designs, and this has resulted in the

most cost-effective devices available. The ultra-compact format of mini-Max means that, (compared with typical clip-on secondary-packaged needle-guards), it would require 500 tonnes less polymer to produce 100 million units. That means 500 tonnes less plastic to be purchased, shipped, warehoused, moulded, stored and transported.

Yet the mini-Max system is not just about low cost effectiveness – the simplicity of the system provides other significant benefits. For example, staked-needle syringes fitted with mini-Max are approximately 50% less bulky than those fitted with clip-on needle guard accessories (as illustrated in Figure 2), and with a weight reduction of around 35%, a reduction in shipping and storage costs is guaranteed. Such a dramatic bulk saving is particularly important if the drug product needs to be maintained in cold-chain storage.

Similarly, because of the considerable space saving advantages of the mini-Max system, hospitals, healthcare providers, and patients will be thankful for the savings mini-Max can provide by reducing both storage costs and sharps waste.

INTUITIVE, SIMPLE, RELIABLE

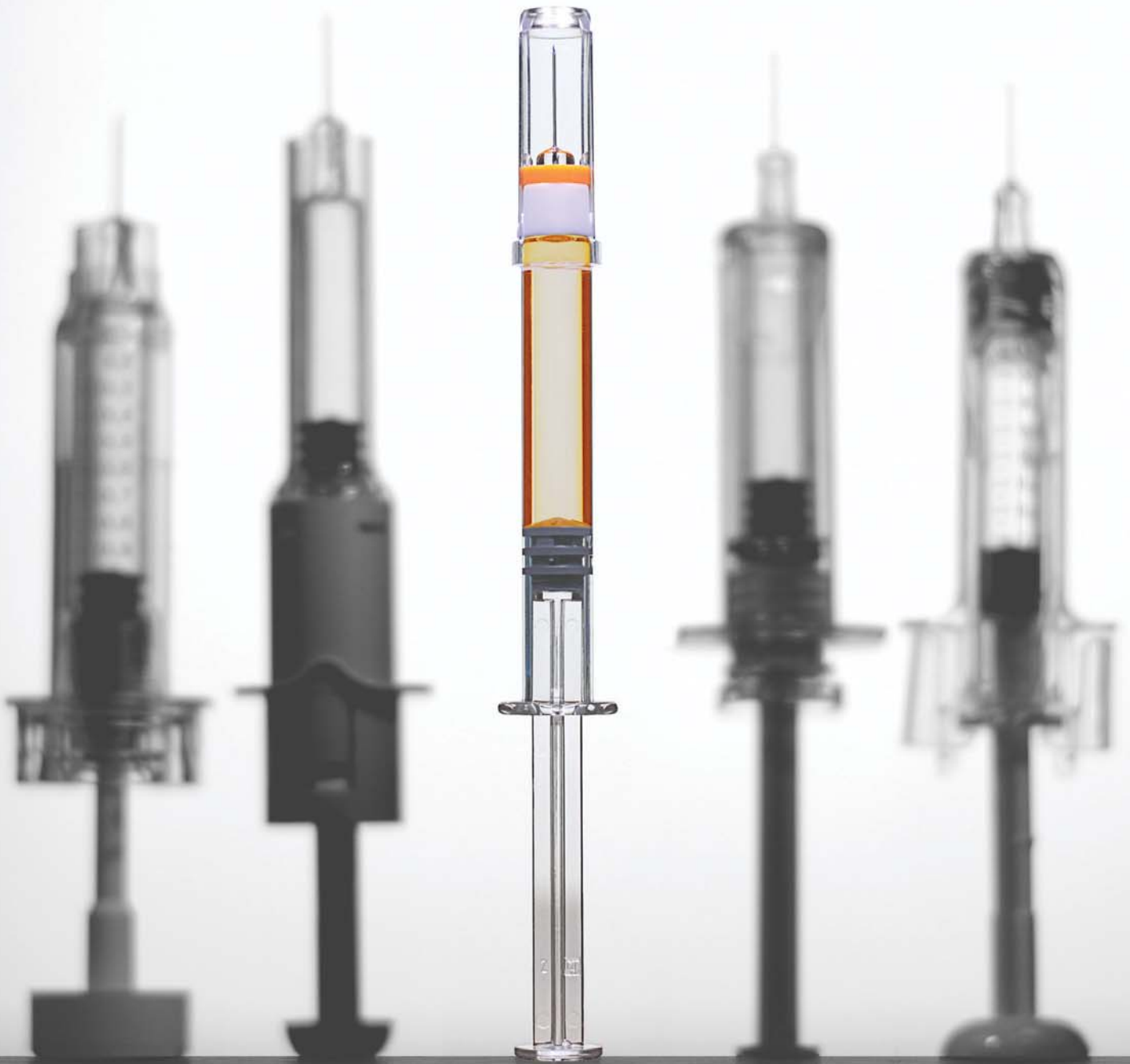
By constantly challenging conventional thinking, tip-top has after many years managed to miniaturise safe needle shields down to their very essence. Both mini-Max and minim require only a few moulded parts, and have no need for a metal spring. And because these devices activate independently of any user input, they will comply with the demands of the most rigorous safety regulations.

Our devices protect the needle both before and after the injection, they are extremely compact and so do not encumber the healthcare provider or patient during the delicate activity of administering an injection (see Figure 3). These devices are incredibly simple and intuitive to use, require minimal or no training and will promote compliance in the use of safer needles.

tip-top will be exhibiting (stand 566) at the upcoming Pharmapack conference in Paris, France.



Figure 3: tip-top devices are very compact and so do not encumber the healthcare provider or patient during the delicate activity of administering an injection.



a passive needle shield that uses 80% less plastic, has no metal spring and integrates with ready-to-fill syringes into trays and tubs

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