integrated
passive needlestick protection
for ready-to-fill syringes

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SAFETY-ENGINEERED NEEDLE TECHNOLOGIES FROM TIP-TOP GAINING RECOGNITION AMONGST SYRINGE MANUFACTURERS

UPDATE

In this article, Barry Liversidge, Managing Director at tip-top, provides an update on how discussions with pharmaceutical companies and syringe manufacturers have confirmed that tip-top's minim and mini-Max safety needle systems offer a simple, safe, and cost effective way to provide passive needlestick protection for prefilled syringes.

Today worldwide, there are five principal manufactures of standard glass syringes – BD, Gerresheimer, Schott, Nuova Ompi and MGlas and, to all intents and purposes, these companies make almost identical prefillable syringe products to very similar specifications.

However, none of these syringe producers markets a prefillable syringe with inbuilt integrated needlestick protection; which means that pharmaceutical companies buying from these syringe makers, must then secondary-package their injectable drug products, with 'clip-on' accessories to provide some form of needlestick protection – because this is the only way to comply with requirements for syringe-based injectable drugs to be marketed with safety-engineered sharps protection.

It is important to consider why there are five independent manufactures producing almost identical prefillable syringe products; especially as the expression "product differentiation" seems to dominate the drug delivery industry. Nevertheless it is a fact, that the vast majority of parenteral drugs are packaged almost identically because over many years the prefilled syringe has become a universally preferred way to supply a ready-to-use injectable drug, and therefore pharmaceutical compa-

"SYRINGE MANUFACTURERS AND PHARMACEUTICAL COMPANIES RECOGNISE HOW TIP-TOP'S MINI-MAX SYSTEM WILL INTEGRATE PASSIVE NEEDLESTICK PROTECTION ONTO READY-TO-FILL SYRINGES WITHOUT HAVING TO REDESIGN THE PRIMARY DRUG CONTAINER."

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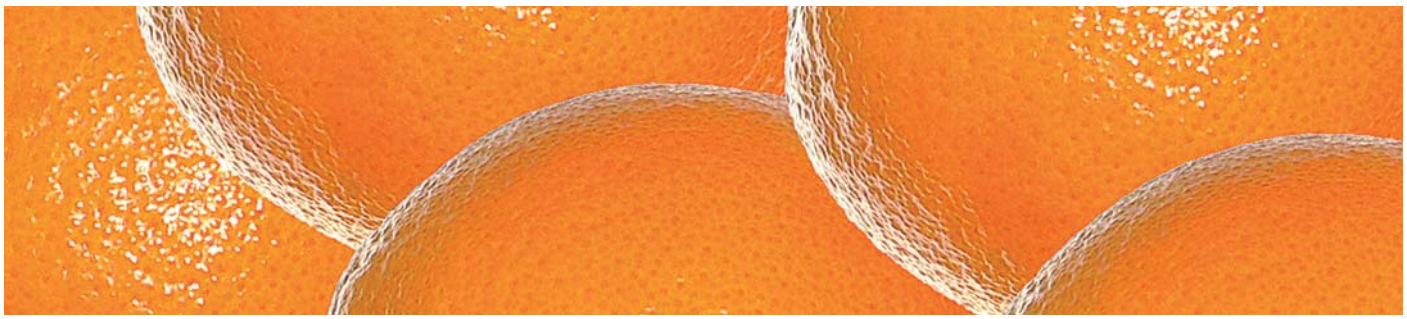


Historically, oranges were a popular choice for training injection techniques, because the outer peel and inner pulp simulates the "feel" of performing an injection.

Figure 1: mini-Max is fitted by the syringe manufacturer onto standard syringes. There are no compatibility issues with existing ready-to-fill infrastructures.

"IT IS IMPORTANT TO CONSIDER WHY THERE ARE FIVE INDEPENDENT MANUFACTURES PRODUCING ALMOST IDENTICAL PREFILLABLE SYRINGE PRODUCTS."

nies have generated a huge demand for a universal 'multi-sourced' product, and this demand has been satisfied by these five syringe producers.

Today however, the proliferation of needlestick legislation throughout the world, threatens the utility of the prefilled syringe because, whilst the ready-to-use convenience of the prefilled syringe defines its utility, if the syringe is not provided with safety-engineered needlestick protection, then it is not ready-to-use..!

The mini-Max system can enable existing manufactures to provide prefillable syringes with integrated passive needlestick protection, without having to redesign the primary drug container. And because the mini-Max system can be fitted to any manufacturer's syringe, the pharmaceutical industry's demand for a 'multi-sourced universal product', is easily satisfied.

Since their launch at the 2010 PDA *Universe of Prefilled Syringes and Injection Devices* conference in Las Vegas, NV, US, tip-top's innovative needlestick prevention technologies have been well received by both device manufactures and pharma companies. The minim and mini-Max devices, have attracted considerable interest from the major stakeholders in all quarters of the injectable drug delivery industry; and in particular syringe manufacturers and pharmaceutical companies recognise how tip-top's mini-Max system could integrate passive needlestick protection onto ready-to-fill syringes without having to redesign the primary drug container.

The mini-Max system is designed to maintain the fusion that exists between elastomeric

Figure 2: mini-Max comprises only a few plastic parts that do not require gluing or welding, and there is no metal spring.

component manufactures and syringe producers; so that passive needlestick protection can be integrated onto existing prefilled syringes, without major changes to Drug Master Files.

Furthermore, the mini-Max system is fitted by the syringe manufacturer onto standard syringes before the syringes are nested into the popular ready-to-fill Tray & Tub format. Thus, there are no compatibility issues with existing ready-to-fill infrastructures, due to the small size and shape of the mini-Max device (see Figure 1).

The advantages of mini-Max extend beyond the benefits of a system that will integrate seamlessly into existing syringe manufacturing and drug filing lines. mini-Max comprises only a few plastic parts (Figure 2) that do not require gluing or welding together, and there is no metal spring, yet the device is less than a quarter of the size and weight of clip-on secondary packaged safety-needle accessories.

Significantly, we estimate that 100 million prefilled syringes fitted with the mini-Max

Figure 3: Once assembled and packaged, staked-needle syringes fitted with mini-Max (left in blister pack and centre boxed) use only half the storage space, and are around 30% lighter, than the same syringes fitted with secondary-packaged clip-on safety shields (right).

system, (instead of a clip-on accessory) would save 500 tonnes of plastic polymer, and that means 500 tonnes less plastic waste going into the environment.

Once filled and packaged, staked-needle syringes fitted with mini-Max take up around half the storage space, and are around 30% lighter, than syringes fitted with secondary packaged clip-on safety shields (see comparison in Figure 3).

The consequential savings arising from the mini-Max design cannot be understated. These significant savings are both financial and environmental:

- Reduced manufacturing cost of goods
- Reduced assembly and production costs – removing secondary packaging lines
- Reduced shipping and transport costs
- Reduced warehousing and cold-chain storage costs
- Freeing up costly space requirements on retail and hospital pharmacy shelves
- Reduced volumes of sharps waste – both storage and disposal
- Reduced environmental load – less waste and lowering demand for raw materials.

Syringes fitted with a mini-Max are used in the same way as the familiar, standard (non-safety-engineered) prefilled syringe; the difference is that mini-Max shields the needle before use, and automatically re-shields the needle after use, without the need for user intervention (Figure 4).

CONCLUSION

The key to understanding the mini-Max system is to recognise tip-top's commitment to facilitate the integration of passive needlestick protection onto EXISTING prefillable syringes, produced by EXISTING syringe manufacturers, for inclusion into EXISTING 'tray and tub' ready-to-fill formats.

tip-top's business model, is to make available the mini-Max technology, to enable syringe manufacturers to produce and supply products that fully comply with medical and pharma industries' requirement for better safety-engineered needle-based devices; whilst also removing the inconvenience and cost associated with having to provide secondary-packaging lines to fit needle-shielding accessories .

tip-top will be exhibiting (stand 24) at the 2011 PDA Universe of Prefilled Syringes and Injection Devices conference in Basel, Switzerland, this November.

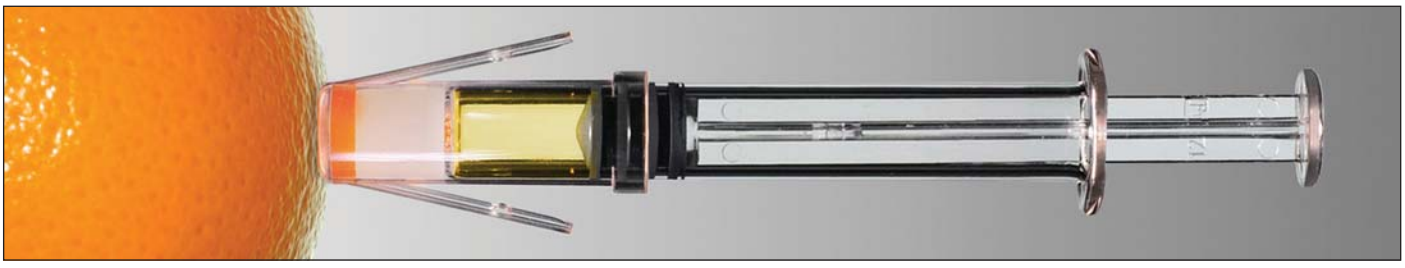
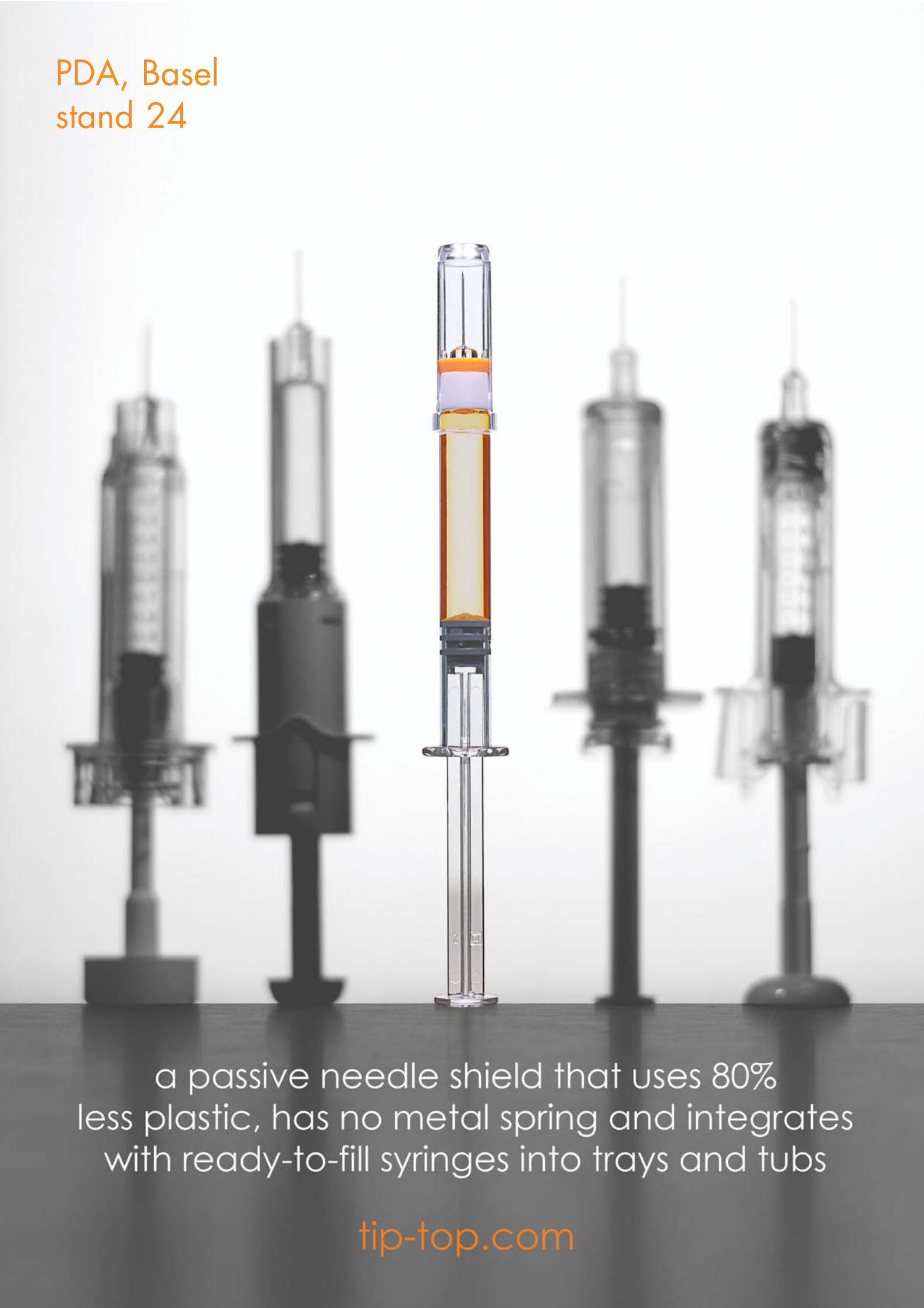


Figure 4: An industry-standard safety needle system by simply replacing the ordinary needle cover on a ready-to-fill glass syringe.

PDA, Basel
stand 24



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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