

BIOCORP

NEWGUARD™: SAFER PREFILLED SYRINGES & FEWER CHANGES

Given the rising number of guidelines to reduce risks of needlestick injuries, pharmaceutical companies have been searching for systems to ensure safe syringe use. Despite great innovations, adopting new safety systems has always been a trade-off between safety and the cost of implementing new processes. Now, Biocorp can offer Newguard™, a new passive safety system integrated on prefilled syringes without such compromises being required. Jean Vuillecard, Product Innovation Manager, Philippe Lesaulnier, Business Development Manager, and Eric Dessertenne, Head of Business Development, of Biocorp, explain more.

THE CHALLENGE OF INTEGRATING SAFETY SYSTEMS TO PFS

The frequent exposure to needles increases the risk of needlestick injuries. Given the rising number of reported incidents among healthcare workers, guidelines and best practices have been issued to avoid unnecessary handling and use of needles by encouraging the use of devices with safety features, and to promote education and safe work practices.

“Biocorp has been developing a passive safety system requiring no change for pharma companies.”

Hence, delivery systems – reducing the steps involved in drug administration and needle handling – have been preferred by the industry. Indeed, in addition to better cost-effectiveness, the switch from vials to prefilled syringes (PFS) brings comfort to end users in terms of safety and user-friendliness.

This growing trend has been followed by an increase in the number of safety devices preventing injuries. ‘Clip-on’ safety systems were added on PFS after the filling process in order to avoid any major regulatory changes. Although add-on systems bring increased safety to the syringes, they require additional assembly steps at the end of traditional PFS filling processes.

Today, integrated safety systems upgrade PFS with safety features without involving additional steps for pharmaceutical companies or the contract manufacturing organisations (CMOs) in charge of the filling operations. But despite great products, moving towards brand new safety systems appears to be challenging. Indeed, introducing changes appears to be costly and requires time-consuming efforts regarding the regulatory constraints and the industrial processes take years to be implemented.

To overcome these challenges and speed up adoption of innovative safety systems for PFS, Biocorp has been developing a passive safety system requiring no change for pharma companies. Therefore, traditional industrial processes remain unchanged while providing patients and healthcare providers with an innovative and effective safety system preventing injuries before and after injections.



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Figure 1: Newguard™, a passive safety system integrated with PFS.

**NEWGUARD™,
A PASSIVE SAFETY
SYSTEM INTEGRATED
WITH THE PFS**

Newguard™ is a passive safety system integrated with PFS (Figure 1) and designed to be compatible with any existing syringe manufacturer's products. Newguard™ combines two functions in a single product: the function of a rigid needle shield (RNS) and the function of a safety device. The ultra-compact version fits 0.5 mL and 1 mL PFS and a specific version is available for 1 mL short and 2.25 mL syringes.

Newguard™ is the result of Biocorp's commitment to develop innovative solutions with simple implementation processes. Applying design for lean manufacturing methods in product and process development, Biocorp's R&D team has designed a solution providing an effective safety system for handling PFS, with minimal impact on industrial processes. As a consequence, every step of the PFS production process remains unchanged – despite the addition of Newguard™ – thus ensuring a cost-effective solution and a smooth and simple implementation for pharmaceutical companies and CMOs.

Indeed, integrating Newguard™ with a PFS is similar to the process of adding standard flexible/rigid needle shields on syringes. The assembly process takes place on the syringe manufacturer's production line for sterile format in nest packaging. Newguard™ is integrated with the syringes, replacing the RNS mounting. Thus, the number and the sequence of operations remain identical.

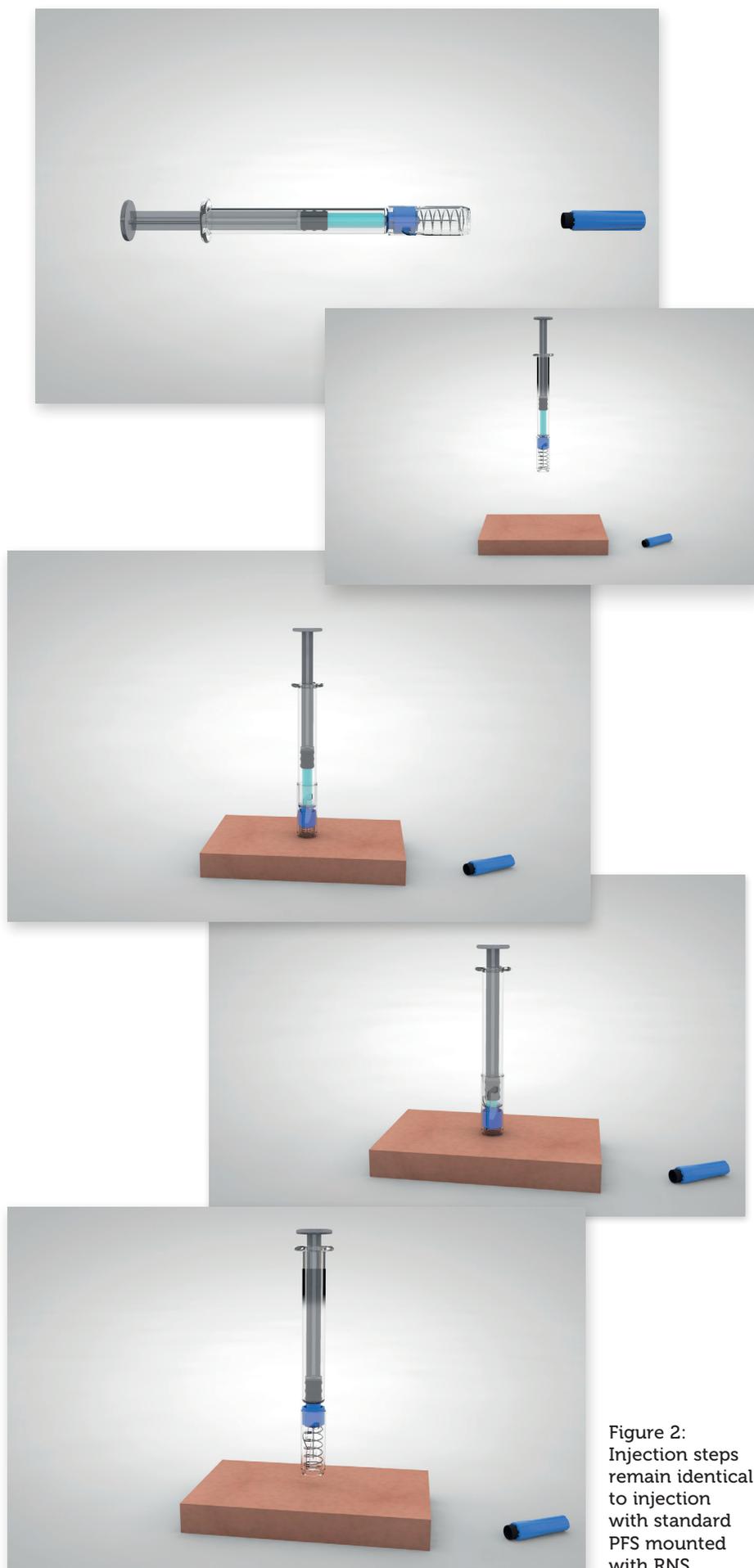


Figure 2: Injection steps remain identical to injection with standard PFS mounted with RNS.



Figure 3: Newguard™ is compatible with 0.5 and 1 mL PFS and fits nest tray packaging.

“Newguard™ is definitely a cost-effective solution upgrading the safety standards of PFS without changes being required.”

The same applies for end-users: the injection process should remain unchanged compared with a PFS equipped with a RNS (Figure 2). As a matter of fact, adoption of new passive safety systems integrated to PFS is strongly related to the balance between benefits and inconvenience perceived by end users.

This is the reason why Newguard's design has been welcomed by patients and healthcare providers. Human factors studies revealed Newguard's shape is very close to a traditional PFS; it looks less daunting and more familiar thus making patients feel safe before, during and after injections. This sense of safety has been enhanced with Newguard's “spring effect” adding comfort and confidence at the end of the injection process.

ENHANCE SAFETY WHILE KEEPING PROCESSES UNCHANGED

Upgrading your PFS with Newguard™ doesn't require you to change your procurement strategy, supply chain or regulatory files.

Newguard™ has been designed to ensure full compatibility with glass syringes and elastomers available on the market. Hence, it offers an open source solution meaning pharmaceutical companies and CMOs are free to choose partners. Adding the Newguard™ safety system doesn't require a change to the purchasing strategy. Since Newguard™ is delivered pre-assembled on the PFS, it avoids an increase in the number of items to be purchased. Similarly, Newguard™ is a passive safety system compatible with PFS 0.5 and 1 mL. Therefore, purchasing a unique passive system suitable for both 0.5 and 1 mL PFS allows a reduction in the cost per unit.

Newguard™ is a new generation of passive systems designed to reduce the total cost of operations (TCO). Indeed, the filling process remains unchanged

as well as the packaging process. As the Newguard™ is assembled directly on PFS, available in bulk or packaged on validated nests (Figure 3) and/or tubs and sterilised like standard PFS, there is no requirement to change the secondary packaging or the sterilisation process. The supply chain remains unchanged.

Newguard™ is definitely a cost-effective solution upgrading the safety standards of PFS without changes being required. The primary packaging remains intact avoiding constraining and time-consuming modification of the regulatory files. Furthermore, the filling operation remains unchanged and doesn't require additional process validation.

CONCLUSION

Newguard™ is a unique safety solution for PFS and generates new benefits for pharmaceutical companies in terms of supply chain, TCO and packaging, and meets both the economic criteria and the end-users' protection requirements.



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BIOCORP

Add safety, *your way*



NewGuard™

An integrated passive safety system for your PFS

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