NEWGUARD – PAVING THE WAY FOR A NEW SAFETY STANDARD

Needlestick injuries remain a serious concern for pharmaceutical companies involved in injectable drugs. Biocorp has been developing NewGuard™, an integrated passive safety device to tackle this problem. Throughout the development phase, Biocorp defined key elements to ensure NewGuard™ will not require unnecessary changes to be made to the PFS manufacturing process. This innovative and cost-effective solution is now ready for launch. Philippe Lesaulnier, Business Development Manger, and Eric Dessertenne, Head of Business Development, both of Biocorp, explain more.

Enhancing safety for syringe use has been an increasing concern for pharmaceutical companies. Still all too often, the handling of prefilled syringes (PFS) leads to needlestick injuries. For this reason, Biocorp has been developing NewGuard™: an integrated passive safety device that gives protection before, during and after the injection process (Figure 1).

SUMMARY OF PRODUCT CHARACTERISTICS

NewGuard™ is a passive safety system that is integrated with PFS and designed to be compatible with any existing standard PFS (Figure 2). NewGuard™ combines two functions in a single product: a rigid needle shield (RNS) and a safety device (Figure 3). The ultra-compact version fits 0.5 mL and 1 mL PFS and specific versions will be available for 1 mL short and 2.25 mL syringes.

BENEFITS FOR END-USERS

Recent user studies conducted in the US and Europe with groups of patients and healthcare professionals have shown that the compact size of NewGuard™ and its safety features are highly appreciated (Figure 4). The all-in-one concept has also been much praised by end-users. This high level of acceptance confirmed the concept and design inputs of NewGuard™ on its main safety features, easy handling and downsizing approach.

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MEETING PFS MANUFACTURERS' REQUIREMENTS

Whilst developing a user-friendly device for end-users is essential, it is also important to ensure the whole manufacturing process is as efficient as possible. During the life cycle of a PFS, several stakeholders are responsible for assembling different pieces and filling the syringe. Apparent minor changes on PFS easily increase the total cost of ownership (TCO). Therefore, a holistic approach is required to understand the constraints of the rubber, glass and machine suppliers.

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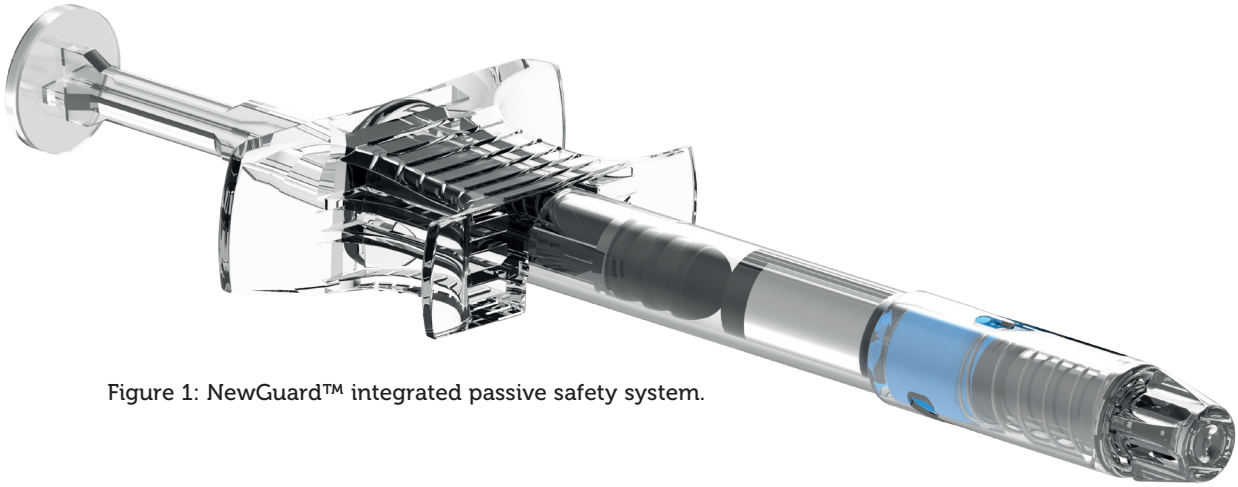

Figure 1: NewGuard™ integrated passive safety system.

Figure 2: NewGuard™ assembled with standard PFS.

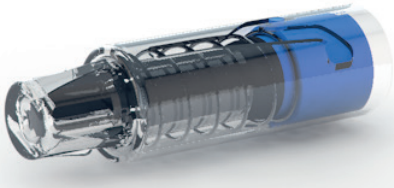

Figure 3: NewGuard™ combines a rigid needle shield and safety device.

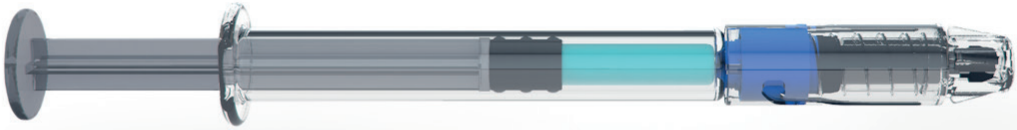

Figure 4: NewGuard™ has a compact size.

Taking into account these requirements, NewGuard™ is the result of Biocorp's commitment to develop innovative solutions with simple implementation processes. Biocorp's R&D team has demonstrated its capability to innovate by integrating all industrial requirements, from machine makers and glass and rubber manufacturers, into the design of NewGuard™.

As a consequence, every step of the PFS production process remains unchanged – aside from the addition of NewGuard™. Indeed, integrating NewGuard™ with a PFS is similar to the process of adding a standard flexible/rigid needle shield to a syringe. For sterile format products with nest packaging, the assembly process takes place on the syringe manufacturer's own production line. NewGuard™ is directly integrated with the syringes – replacing the RNS mounting. Thus, the number and the sequence of operations remain identical and use standard validated components.

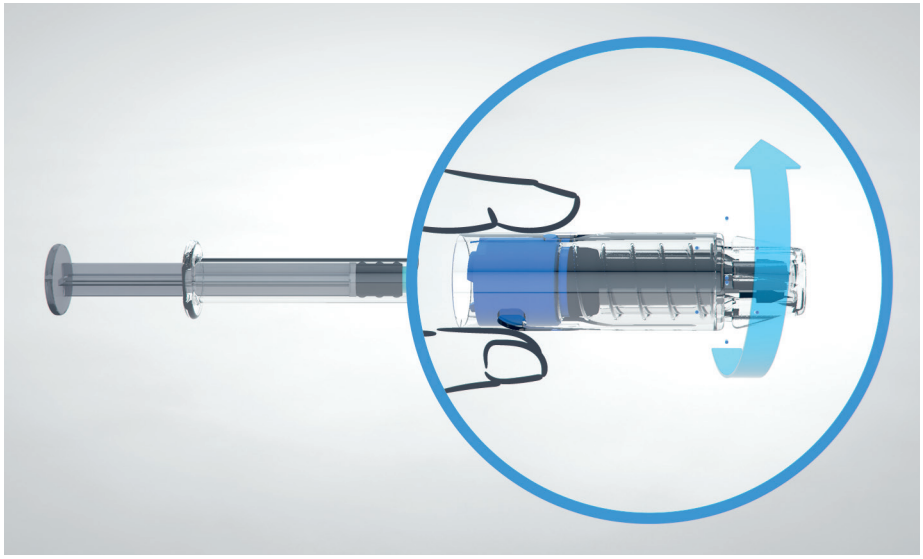

Figure 5: Unlocking NewGuard™ before use.

In addition, NewGuard™ prevents unintentional activation by requiring unlocking before use (Figure 5), avoids coring and pop-off issues, and protects the needle after use (Figure 6), which improves handling, transportation and storage – thus ensuring a cost-effective solution and a smooth, simple implementation for pharmaceutical companies and CMOs.

COMPETITIVE ADVANTAGE FOR PHARMACEUTICAL COMPANIES

Innovative drug delivery systems continue to play a critical role in pharmaceutical companies' strategies for biotherapies. Indeed, they can be a game changer that provides a competitive advantage (Figure 7). NewGuard's passive safety systems bring a solution to pharmaceutical companies by increasing both patient and healthcare professional safety on existing marketed products, providing product differentiation from biosimilars and addressing price-sensitive markets.

Regardless of the strategy, NewGuard™ answers user requirements and could be considered one of the most cost-effective solutions on the market. The product has a low TCO thanks its simple design and standard components – as well as its ready-to-fill process compatibility, reducing indirect assembly costs that could occur on pharma company's sites (Figure 8).

CONCLUSION

Compact, safe and simple, NewGuard™ is entering a new phase which will define a new market standard for PFS passive safety solutions.

ABOUT THE COMPANY

For 20 years, Biocorp has been designing, developing and manufacturing medical devices for the pharmaceutical industry, enhancing drug reconstitution, safety, packaging and delivery. Today, Biocorp continues to innovate in medical plastics, bringing new solutions to the market such as NewGuard™, an integrated passive safety system for PFS compatible with nest, and the Biopass, a reconstitution system with an integrated needle ready to inject. Recognised for its expertise in device R&D, Biocorp has incorporated software development capacities to develop connected drug delivery systems, including the DataPen®, a reusable smart pen injector that automatically transmits data to a treatment mobile app, helping patients to manage their treatment, and a range of add-ons and smart sensors for existing drug delivery devices (pen injectors, MDIs). In addition to its R&D activities, Biocorp also provides manufacturing services for plastic injection, process assembly and blister packaging.

Figure 6: The needle is protected after injection.

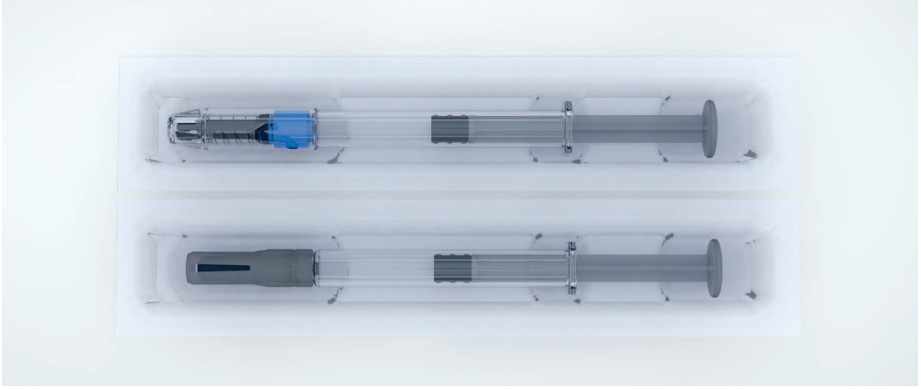

Figure 7: NewGuard™ allows biologics packaged in PFS to be differentiated against fierce competition.

Figure 8: NewGuard™ is compatible with ready-to-fill process.

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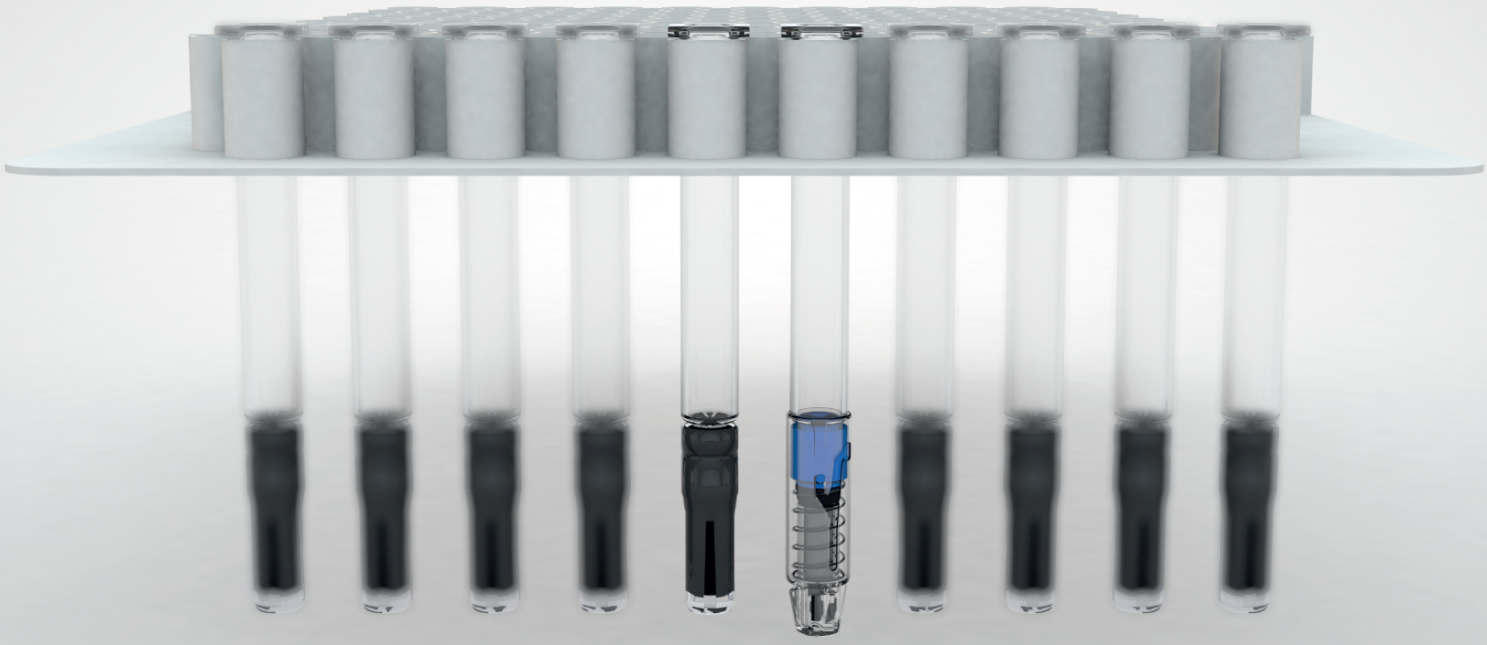

NewGuard™

An **integrated passive safety system** for your PFS

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