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GX INNOSAFE – GREATER PROTECTION AGAINST NEEDLESTICK INJURIES

In this article, Wenzel Novak, PhD, Senior Global Director Business Development, Medical Systems, and Stefan Verheyden, Global Vice-President, Gx Biological Solutions, both of Gerresheimer, introduce Gx InnoSafe, a novel integrated passive needle safety system for preventing needlestick injuries and accidental reuse of syringes that minimises additional burden on healthcare workers during injection and can be integrated into existing pharmaceutical filling operations without the need for adaptation or conversion of processing lines.

Used syringes with exposed cannulas present a source of risk in surgeries, laboratories and hospitals the world over. Although existing needle protection systems reduce the risk of injury for the end user, they make prefilled syringes more complex for pharma companies to fill during manufacture and must be handled by medical specialists in the clinic. These challenges have left a gap in the market for an innovative needle safety system.

To tackle this unmet need, Gerresheimer has developed the Gx InnoSafe (Figure 1) – a syringe with an integrated passive safety system that:

- Avoids inadvertent needlestick injuries
- Prevents repeated use
- Is designed with pharmaceutical companies' production processes in mind
- Is optimised for simple and intuitive use by medical specialists.

In addition to these unique safety features, a special feature of the Gx InnoSafe syringe is that it can be processed on all existing filling lines without additional preparation or conversion steps. In addition, it is compliant with all appropriate regulations without additional investment, making it as painless as possible for pharmaceutical companies to integrate Gx InnoSafe into their production process.

GX INNOSAFE IN THE CLINIC

For healthcare workers, handling used hypodermic needles is a part of their day-to-day job. However, in some cases, accidental needlestick injuries occur. It is estimated that around one

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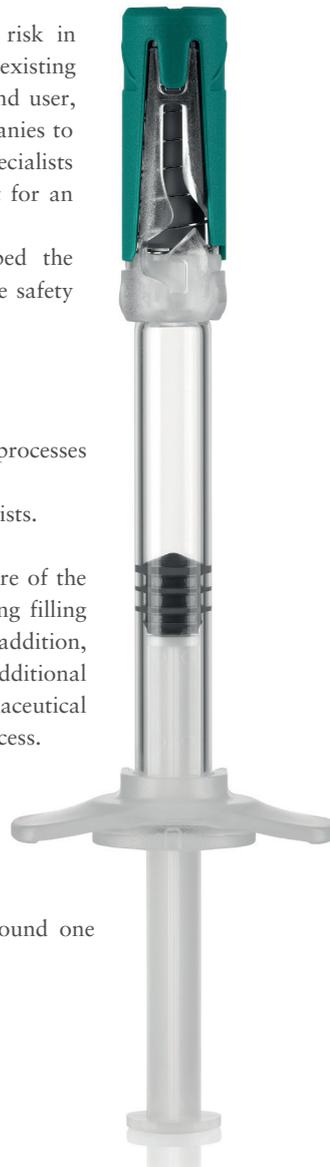


Figure 1: The Gx InnoSafe syringe by Gerresheimer.



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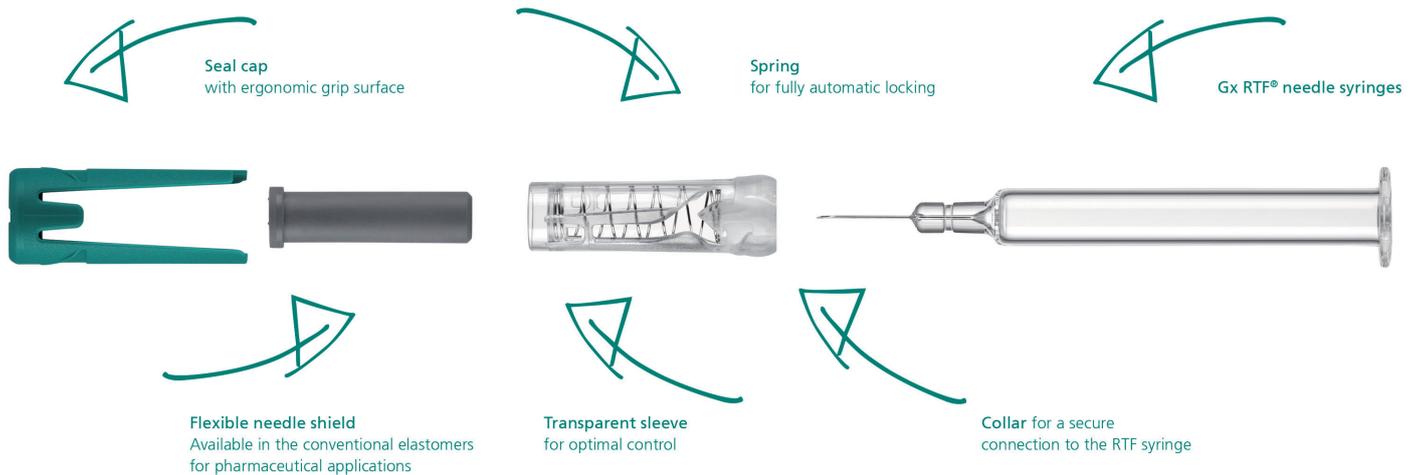


Figure 2: The design of Gx InnoSafe and Gx RTF glass syringe allows for injectable administration as usual with no extra steps.

million needlestick injuries occur in Europe every year, which, in the worst cases, can lead to the transmission of serious diseases or cause dangerous infections. There is also the risk of used syringes being used for a second time by accident.

Gx InnoSafe reliably protects against inadvertent needlestick injuries and prevents repeated use. Unlike many existing solutions, the needle shield mechanism is activated automatically and does not require any additional manipulation by the end user. As such, Gx InnoSafe is therefore what is known as a “passive needle protection system”. Furthermore, the fact that Gx InnoSafe syringes can be processed on filling lines in a nested state, without any major changes to manufacturing systems, is just as beneficial to pharmacists as it is to filling companies. Gx InnoSafe arrives in pharmacies fully assembled and ready-to-use, eliminating the need for an additional step to assemble the safety system, as is standard for needle safety systems currently on the market.

Gx InnoSafe was designed with clinicians and medical specialists in mind and, in addition to its benefits for pharma companies, the syringe is intuitive and easy to use. Clinical end-users want a safety system that:

- Does not change the familiar injection procedure
- Has intuitive and ergonomic handling
- Requires no additional manual activation to secure the cannula before it is disposed of.

As part of the manufacturing process, the Gx InnoSafe safety system is installed

“After the removal of Gx InnoSafe’s ergonomic sealing cap with an integrated, flexible needle shield, the syringe is placed on the injection site, the cannula is inserted into the patient’s tissue and the active ingredient is injected – just as with a standard syringe.”

on Gx ready-to-fill (RTF) glass syringes in a cleanroom environment, just like a standard needle shield. The syringe body is completely visible so that the presence of the API, its purity and its administration can be observed and monitored.

Gx InnoSafe’s design places no demands on the injection process, meaning that the drug can be administered as usual without additional burden (Figure 2). After the removal of Gx InnoSafe’s ergonomic sealing cap with an integrated, flexible needle shield, the syringe is placed on the injection site, the cannula is inserted into the patient’s tissue and the active ingredient is injected – just as with a standard syringe.

The safety system cannot be activated inadvertently because the mechanism is not preloaded before the injection – the system is only activated when the cannula is inserted, and it automatically ensures that the safety

mechanism is permanently locked when the syringe is removed from the injection site. This guarantees that the cannula is reliably covered, meaning that the syringe cannot be reused, thus preventing needlestick injury.

GX INNOSAFE IN PHARMACEUTICAL MANUFACTURING

Gx InnoSafe provides advantages for pharmaceutical companies in the filling process of RTF syringes. The safety system is



Figure 3: Gx InnoSafe is fully compatible with standard nest-and-tub formats.

installed during the RTF process entirely automatically, and it is fully checked for any punctures and positioning with a visual inspection. The syringes are then packaged into trays of 100 in nest-and-tub format, including the safety system, and are then sealed and sterilised with ethylene oxide gas (Figure 3). They can be processed on existing filling lines without any additional preparation or assembly steps.

The design of the safety mechanism avoids inadvertent activation during filling, packaging and transport. The flexible needle shield part is available in all standard market elastomers for pharmaceutical applications.

Every filler can fill the InnoSafe safety syringe easily, without the need for additional investments on existing filling lines for syringes. It is precisely this feature of the Gx InnoSafe syringe that differs from conventional safety syringes and is a world first.

CONCLUSION

The Gx InnoSafe syringe represents a step forward in syringe safety systems, both from a clinical and pharmaceutical filling perspective. For healthcare workers, Gx InnoSafe passively prevents needlestick injuries and accidental reuse of syringes without requiring any additional steps or expertise on top of well-established administration practices. For pharma companies, Gx InnoSafe can be reliably and easily integrated into existing production

lines and filling processes without the need for expensive and complex preparation and conversion work. Gx InnoSafe is ready to integrate for pharma and ready to use for clinicians.

ABOUT THE COMPANY

Gerresheimer is a leading international partner to the pharmaceutical and healthcare industries. The company contributes to health and well-being with its range of

glass and plastic products. Gerresheimer has a worldwide presence, with around 10,000 employees; locations in Europe, Asia, and North and South America; and an annual turnover of around €1.4 billion (£1.3 billion). The company's product offering includes insulin pens, inhalers, micro pumps, prefillable syringes, injection vials, ampules, bottles and containers for liquid and solid medications with sealing and safety systems, as well as packaging for the cosmetics industry.

ABOUT THE AUTHORS

Wenzel Novak, PhD, began his career working on keratinocytes for wound healing as head of laboratory in a Swiss biotech-company. He then joined Gerresheimer in charge of project management and, as head of production for presterilised syringes, he designed the manufacturing area, built up the process and quality systems and operated the start-up phase of production. He then took role as Chief Innovation Officer at a pharmaceutical equipment supplier, developing new methods of sterilisation and filling processes. During two years spent working in the US, he developed the market for cell and gene therapy equipment. In 2018, Dr Novak returned to Gerresheimer in a new global senior role for business development. He studied biology and gained his PhD in physics at the Max Planck Institute for Neurochemistry (Munich, Germany).

Stefan Verheyden has been active in the pharma and biopharma industry for more than 25 years. He started his career in product management in the lab chemicals industry, before moving into leading sales and business development roles in production chemistry, raw materials and APIs at two major companies. After 20 years Mr Verheyden moved into the pharma packaging industry, taking over a global role as Senior Vice-President at one of the players within the industry. He moved to Gerresheimer in 2017, heading both the syringe business as well as a new business unit supporting the fast-growing biological market segment. Mr Verheyden studied chemistry at the University of Brussels (Belgium).

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Protection against needlestick injuries

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Gx InnoSafe®

- Protection mechanism is activated automatically
- No accidental reuse possible
- Delivered pre-assembled in nest and tub

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