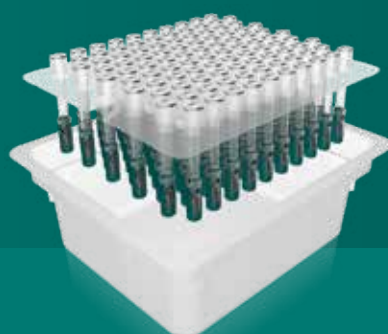




GERRESHEIMER

Gx InnoSafe®

Integrated and passive safety system
for prevention of needle stick injuries



www.gerresheimer.com



Gx InnoSafe®

Perfect in filling ...

THE BENEFITS AT A GLANCE

■ Integrated system

The safety system is assembled fully-automatically in the RTF (ready-to-fill) process like a standard needle shield.

■ 100 % in-line quality assurance

Potential needle piercing and safety system position checked by visual inspection.

■ No significant changes during pharmaceutical filling

The syringes are delivered packed, sealed and sterilized with ethylene oxide gas (EtO) including safety system in a 100 hole tray (nest) and in a tub. The pharmaceutical company can process the syringes on existing filling lines without additional preparation and assembly steps.

■ Safe in production

The design of the safety solution prevents undesired activation during filling, packaging or transport.



... and use

THE BENEFITS AT A GLANCE

■ Fully automatic and passive locking

The needle protection mechanism is activated at the end of the injection without further handling steps by the user.

■ Ergonomic

The ergonomic grip surface ensures better hold when removing the safety system protection shield.

■ Safe in use

No accidental triggering, as the safety system isn't preloaded.

■ Intuitive operation avoids end user errors

The actual injection procedure is unchanged from that of conventional needle syringes.

■ Transparent for better control

The syringe body is completely visible in order to be able to optimally see and check for the presence of the active agent, its purity and the administering.



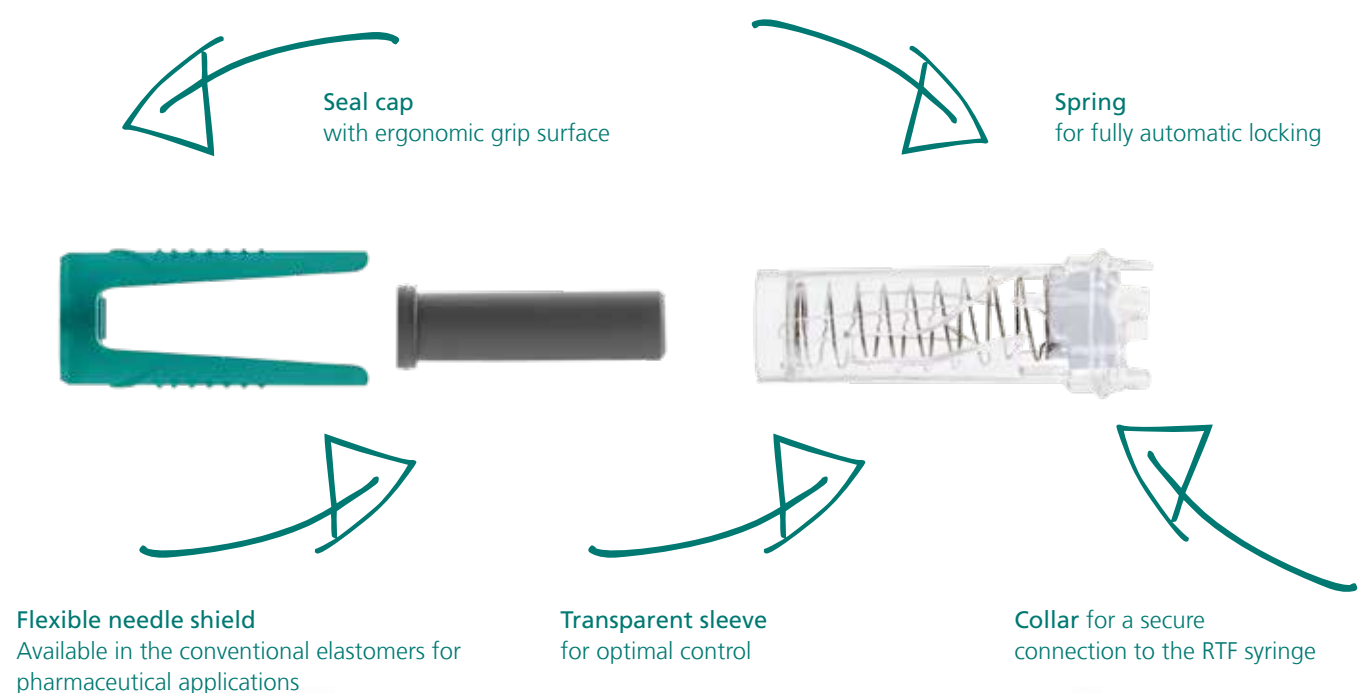
Gx InnoSafe®

Integrated and passive safety system for prevention of needle stick injuries

Used syringes with their exposed cannulas are an omnipresent source of danger in doctor's surgeries, labs or hospitals. One careless movement is enough for healthcare professionals to injure themselves with unprotected, used syringe cannulas or to come into contact with aggressive active agents. In the worst case scenario, this can result in serious infections. There is also a danger that already used syringes may be used again a second time by accident. This is where safety instruments are called for that are optimized to both the production processes in pharmaceutical companies and to provide simple and intuitive use by healthcare professionals.

With Gx InnoSafe®, Gerresheimer now offers a syringe with an integrated safety system that

- prevents unintentional needle stick injuries,
- excludes the possibility of accidental reuse and
- takes the needs of pharmaceutical companies and end users equally into account.



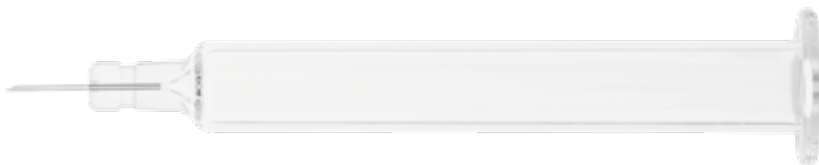
Integrated system:
production-optimized for pharmaceutical companies

The safety system is installed fully-automatically like a standard needle shield in the clean room onto Gx RTF® glass syringes and checked to 100 percent by visual inspection for potential needle piercing and safety system position. The syringes are then packaged, sealed and sterilized with ethylene oxide gas (EtO) including safety system in a 100 hole tray (nest) and in a tub. They can be processed on existing filling lines without additional preparation and assembly steps. The design of the safety mechanism ensures that unintentional activation during filling, packaging and transport is avoided. The Flexible Needle Shield is available in all customary available elastomers for pharmaceutical applications.

With the introduction of the new product line Gx InnoSafe® is available for the 1.0 ml long Gx RTF® glass syringes with ½" cannula. Further syringe versions follow.



Gx RTF® needle syringes



Simple and safe

Passive system: activation without additional handling steps

The injection itself is administered as usual. Following removal of the ergonomic seal cap with integrated Flexible Needle Shield, the syringe is positioned at the injection point, the cannula inserted into the tissue and the active agent injected like with a conventional syringe. The syringe body is completely visible in order to be able to optimally see and check for the presence of the active agent, its purity and the administering.



Remove seal cap

Ergonomic grip surface ensures better hold when removing the needle protection part.



Positioning of the safety system at the injection point

The two guide pins of the collar are found in the start position of the curved track.

Accidental triggering is prevented, as the mechanism isn't preloaded.



Insertion of the cannula into the injection point to the required piercing depth

The guide pins move along the curved track to the end position.

The spring is compressed in the process.



Accidental triggering of the safety system is prevented, as the mechanism isn't preloaded prior to the injection. The system is first activated with the piercing of the cannula and then automatically ensures when removing the syringe from the injection point that the safety mechanism is permanently locked. In this way, the cannula is reliably covered and reuse of the syringe is excluded.



Pushing of the piston rod to the end position



Removal of the syringe from the injection point



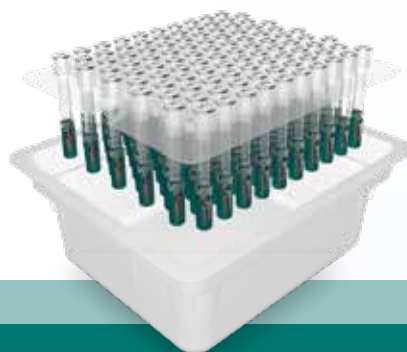
Safety system is activated without further handling steps by the user



Gx InnoSafe®

Passive system:
optimized to the needs of the user

The user wants to have a safety system which remains the injection process unchanged, ensures an intuitive and ergonomic handling and does not require any additional operating steps for securing the cannula prior to disposal. In contrast with many existing solutions, the needle protection mechanism for Gx InnoSafe® is automatically activated and requires no further handling steps by the end user.



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