

Gx RTF® ClearJect® Polymer Needle Syringes

**NEW Gx® SOLUTION** 2.25 ml needle syringe

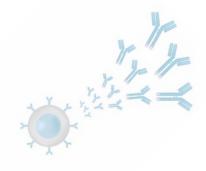




www.gerresheimer.com

## Gx RTF® ClearJect®

### COP (Cyclo-Olefin-Polymer) syringes for demanding, sensitive medications and high-viscosity agents



We offer a wide range of prefillable polymer syringes for sophisticated, sensitive medications, especially for biologicals, biosimilars and biobetters. The **Gx RTF® ClearJect®** line was developed in close cooperation between two Gerresheimer locations in order to create synergy between the syringe experts in Bünde and the plastic experts in Wackersdorf, Germany.

The material used for the syringes is a high performance polymer called COP (Cyclo Olefin-Polymer). Production in the injection molding process in accordance with cGMP ensures precise dimensions. The ready-to-fill syringes are distinguished by a high degree of break resistance and a glass-like transparency. They can be used directly for aseptic filling.

#### Advantages of the Gx RTF® ClearJect® needle syringes

#### Low interaction potential of the syringe with the medication

- Glue-free: The cannula is not glued in, but is instead insert-molded during the injection molding process
- No aggregation due to metal or tungsten residues
- High viscosity silicone oil for reduced particles
- Minimal extractables and leachables
- High pH tolerance, no shift in pH value
- · Optimized permeation rate

#### Safety and reliable functionality for the end user

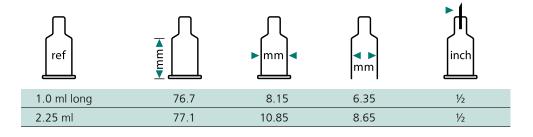
- High break resistance
- Tighter tolerances than glass
- Precise medication dosing thanks to minimal residual volume

#### Total cost of ownership

Our syringe system is economical thanks to the fact that the innovative syringe body is designed to use commercially available components throughout (needle shield, piston plungers, piston rods, backstops and finger support enlargements).

#### Excellent compatibility with medical products

- Wide variety of design options and high flexibility for customer-specific requirements
- · Outstanding syringe functionality with regard to
  - breakaway and gliding forces
  - pull-off force on the needle shield
- · Compatible with autoinjectors





#### Technical data

#### Syringe size

- 1.0 ml long and 2.25 ml available (further formats upon request)
- Design corresponds to ISO 11040-6

#### Production

- Clean room production according to GMP class C in Germany
- Gamma-sterilization

#### **Packaging**

Standardized nest/tub format for easy use on filling lines.

Syringes nested by:

- 160 (10×16) for 1.0 ml long
- 100 (10×10) for 2.25 ml





The next generation of pharmaceutical packaging for the next generation of active ingredients.



Commercially available and registered rubber components

#### Needle shield

The needle shield protects the cannula against damages up to injection, and keeps the syringe sterile until use. The Gx RTF® ClearJect® syringes are available with an Aptar Stelmi RNS (Rigid Needle Shield).



#### Cannula

The syringe is supplied with a thin-walled, 27-gauge, ½" (12.7 mm) stainless-steel cannula with three bevels. The steel quality corresponds to AISI 304, and the size to standard DIN 9626.

#### Piston plungers

- Fluoropolymer-coated plungers from West and Datwyler
- Uncoated piston plungers from SRI (Sumitomo Rubber Industries)
- Packaging for piston plungers:
   PE bag (standard), nested, Rapid
   Transport Port Bag for isolators
   or RABS



## Gerresheimer plastic components

#### Gx<sup>®</sup> piston rods

- Materials: polypropylene, polystyrene, polycarbonate
- Colors: transparent, colored
- Threading: standard, compatible with "FluroTec®" plungers



## Gx® backstops, finger support enlargements

- For distinction, improved handling and increased safety through ergonomic design
- Material: polypropylene
- Colors: transparent, colored



# Expertise in COP syringes

Custom-tailored, customer specific solutions for your specific active ingredient, area of use, or your corporate brand

Gerresheimer offers many years of experience both in the processing of the two primary materials of the pharmaceuticals and healthcare industries, glass and plastics, and in the production of primary packaging, medical devices, and drug delivery systems.

The development teams of our Bünde location, which specializes in glass, work hand in hand with the plastic experts in our **Technical Competence Centers** in Wackersdorf (Germany), Peachtree City (USA), and Dongguan City (China). Our experts for glass and plastics are happy to work together with you to develop your distinctive polymer syringe of COP or COC, coordinated to suit your specific active ingredient, area of use, or your corporate brand.

We offer you solutions for primary packaging (glass and plastics), drug delivery devices/medical devices and for combination products from one source, without interfaces, for a guicker time to market.

Our glass and plastic experts would be happy to work together with you to develop a distinctive polymer syringe made of COP or COC which is matched to your specific agent, area of use and company brand.

Request technical samples of the Gx RTF® ClearJect® syringes:

gxsolutions@gerresheimer.com www.gerresheimer.com/biotech-syringes

