

***GERRESHEIMER***



# Gx RTF® ClearJect®

Pre-fillable COP (Cyclo-Olefin-Polymer)  
Needle Syringe



# Gx RTF® ClearJect®

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

Gerresheimer Medical Systems offers a range of pre-fillable COP syringes produced by our partner Taisei Medical Co. Ltd. in Japan. Gerresheimer is responsible for sales and technical support for ClearJect® syringes for customers in Europe and the US. We are expanding our product portfolio of COP syringes and are combining our trusted RTF® (ready-to-fill) design of glass syringes with ClearJect® to create the new **Gx RTF® ClearJect® brand**. This new COP syringe brand was developed so that we could offer our American and European customers an expanded product portfolio from a German production location in the future. In close cooperation with our partner Taisei Medical Co. Ltd., the new brand will be produced at the German production facility of Gerresheimer Medical Systems. The first product of this line is a 1.0 ml long needle syringe.

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

### High biocompatibility for challenging tasks

- Adhesive-free: The cannula is not glued in, but is instead insert-molded during the injection molding process
- Free of metal oxide residue
- Precisely monitored quantity of high-viscosity, and thus low-particulate, Dow Corning 360 MD (12,500 cSt) silicone oil
- Minimal extractables and leachables
- High pH tolerance, no shift in pH value
- Very low oxygen permeation rate in comparison to other plastics

### Safety and reliable functionality for the end user

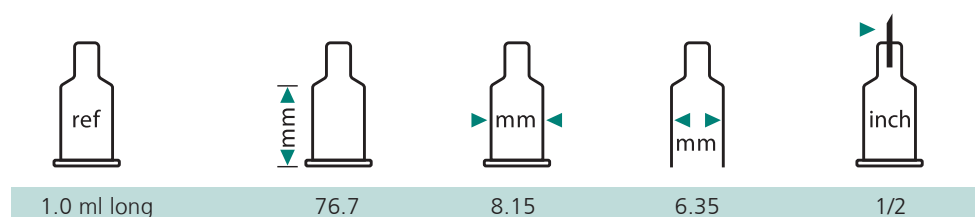
- High break resistance
- Tighter tolerances than glass
- Precise medication dosing thanks to minimal residual volume

### 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



\* ClearJect® is a trademark of Taisei Medical Co. Ltd.

## Technical data

### Syringe size

1.0 ml long, design inspired by  
ISO 11040-6 and registered.

### Cannula

The syringe is supplied with a thin-walled,  
27-gauge, 1/2-inch (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



### Gx® piston rods

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

### Packaging

Standardized nest/tub format  
for easy use on filling lines



### Needle shield

The needle syringe is available with an  
Aptar Stelmi **RNS** (Rigid Needle Shield)  
or the **Gerresheimer Gx TERNS®**  
(Thermoplastic Elastomer Rigid Needle Shield).



**RNS**  
Rigid Needle Shield



**Gx TERNS®**  
Thermoplastic Elastomer  
Rigid Needle Shield

## Advantages of needle shield element Gx TERNS®

- Patented needle shield
- Protects the cannula from damage
- Protects against needle puncture injuries
- Maintains needle sharpness and thus reduces patient pain and discomfort
- Pull-off force retained outstandingly well throughout the storage duration
- Manufactured using medical-grade thermoplastic elastomer (TPE) and polypropylene using a two-component injection molding procedure
- Steam, gamma and EtO sterilization are possible
- Suitable for use in autoinjectors
- Silicone oil-free
- Different colors for individual solutions



## 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

Just over a year ago, we merged two Gerresheimer business units, Syringe Systems and Medical Plastic Systems, to form the new Medical Systems business unit. In so doing, we have bundled our expertise in glass and plastic and our know-how in the development and production of syringes, customer-specific drug delivery systems and diagnostic and medical products under this umbrella. The synergies developed through cooperation between our location in Bünde specializing in glass and the plastic expertise of our Technical Competence Center in Wackersdorf are shown by the successful development of the Gx RTF® ClearJect® needle syringe made of COP.

COP is an interesting alternative to tried-and-tested glass syringes thanks to the growing demands of novel agents on their primary packaging. Medications for cancer therapy, for example, can be extremely aggressive to the point where the break resistance of a syringe is a decisive criterion for selection. Innovative biotech medications, in turn, are often effective in the smallest of doses and are frequently very expensive. Any interaction with the syringe material must be ruled out here.

COP meets all of these requirements. Syringes made of this material are resistant to breaking, as transparent as glass and hardly interact with the packaged medications at all.

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

**Request a technical sample of the new Gx RTF® ClearJect® syringe:**

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Manufacturing using the injection molding procedure enables design flexibility for your syringes. Thanks to precise injection molding, tighter production tolerances are possible in comparison to glass. Precise geometry reduces the dead volume in the syringe, leaving behind less of the expensive medication in the syringe. During the needle syringe injection molding procedure, the material is molded directly around the cannula. This means that the COP needle syringes are free of adhesives, metal ions and tungsten.

COP has a higher pH tolerance and, unlike glass, does not change the pH value while in storage. The oxygen permeation rate is small in comparison to other plastics, and the values for extractables and leachables are low.

In addition to COP, syringes can also be produced using COC (Cyclo-Olefin-Copolymer). COP exhibits superior mechanical properties, however. Tensile strength, fracture strain, flexural strength and impact resistance are better in comparison to COC, and the break resistance is also higher. However, we would be happy to produce COC syringes upon request.