GERRESHEIMER

Gx® syringe systems and glass cartridges

www.gerresheimer.com

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Our strengths

Quality, innovation, flexibility

Gerresheimer AG

Gerresheimer AG is a globally leading partner in the pharmaceutical and healthcare industries. With our special products made of **glass** and **plastics** we contribute to the health and well-being of all. We have nearly 10,000 employees worldwide and production sites located close to all of our customers and their markets. With more than 40 factories in Europe, North and South America, and Asia, we reach sales of around 1.4 billion Euros.

Medical Systems business unit

Our Medical Systems business unit produces prefillable syringes made of glass and plastics, cartridges and vials made of glass, as well as customized injection molded plastic assembly units. For the global players of pharmaceutical and medical technologies industries we produce inhalers, insulin pens, auto injectors, laboratory disposables, point-of-care tests, lancing devices and lancets, as well as catheters and much more.

- 7 production facilities in Europe, Asia, North and South America
- 100,000 sqm (1,080,000 sqft) production area
- 50,000 sqm (540,000 sqft) clean room according to ISO 14644-1 ISO classes 7, 8, and 9 or GMP classes C and D

Gerresheimer Bünde GmbH

Gerresheimer Bünde is our Center of Excellence for prefillable glass syringes, glass cartridges and glass vials. Here we develop and produce both standard products and customized product solutions. Utilizing more than 25,700 sqm (277,000 sqft) – 700 sqm (7,550 sqft) of clean room class C and 3,100 sqm (33,400 sqft) of clean room class D space – we produce high quality primary packaging 7 days a week, 24 hours a day. The strictest requirements for glass bodies are met on highly precise production systems. These are planned and built by our in-house engineering department and fulfill the most modern requirements.

Quality

Gap-free control along the whole value added chain

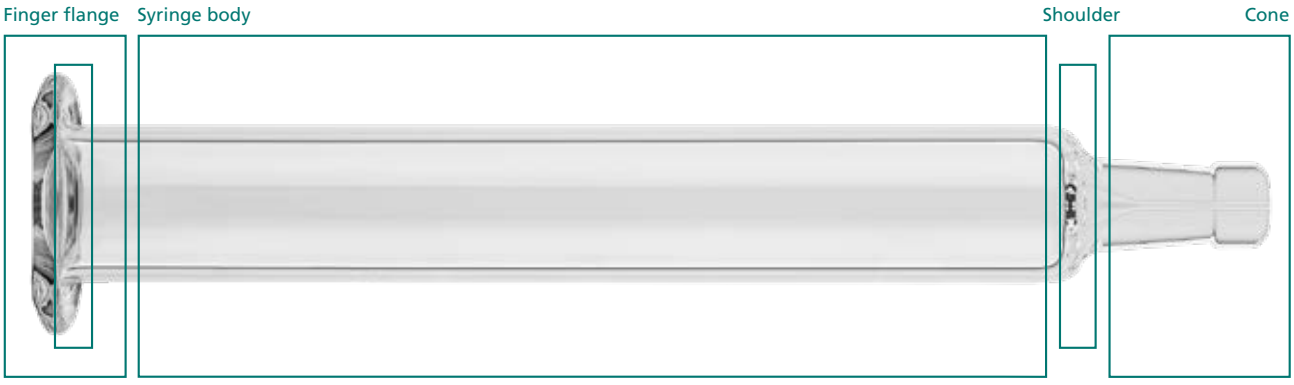
Our quality standards

The quality management of the Bünde location is certified according to the international standards ISO 9001, EN ISO 13485, and EN ISO 15378. Our products meet the requirements of Ph. Eur. (European Pharmacopoeia), USP (US Pharmacopoeia), JP (Japanese Pharmacopoeia), and the DIN ISO requirements for glass primary packaging material. A DMF Type III (Drug Master File) is available.

Our quality control

Each of our production lines is equipped with in-line, proprietary camera inspection systems that have been developed internally for the inspection of geometrical parameters and cosmetic-visual defects. The result is a fully automated, 100 % visual inspection – 360° product inspection – of the entire syringe body. The cosmetic-visual inspections differentiate between cracks and scratches, particles and air pockets. All data is documented in combination with a CAQ system. Even small errors of 25 µm can be detected (diameter of a hair is 60 µm). This is only one step in our 100 % inspection system along the entire value added chain.

State-of-the-art visual inspection for 360° product inspection and strict process control



QUALITY MANAGEMENT ACCORDING TO:

- ISO 9001
- EN ISO 13485
- EN ISO 15378
- DMF Type III

PRODUCTS FULFILL THE REQUIREMENTS IN ACCORDANCE WITH:

- Ph. Eur., USP, JP
- DIN ISO requirements for glass primary packaging material

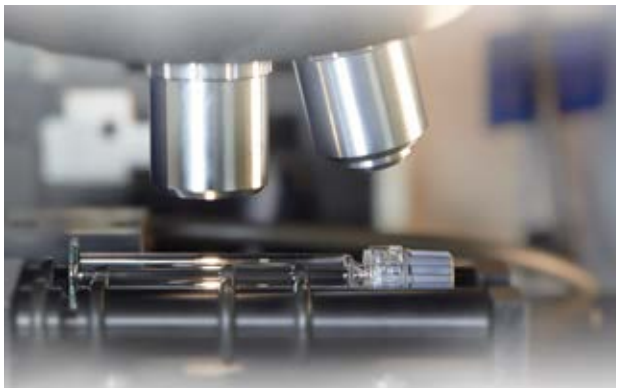
Innovation

Understanding the patient is where development begins

We offer our customers development know-how and development capacities in our worldwide Technical Competence Centers in Europe, the USA and Asia. Here we have development specialists who are familiar with the challenges and procedures of drug development and of the related packaging material. We advise you on matters involving the right packaging material for your special active ingredient.

Product designers, engineers, technicians, and skilled workers from the plastic and glass segments work hand in hand here and develop solutions for primary packaging as well as drug delivery devices. We work together with you closely, ideally already at an early development stage of the medication, because pharmacists and primary packaging manufacturers must look for innovative solutions right from the start, both with regard to the active agent and to the primary packaging material or drug delivery device, because the latter is an integral component of every medication.

Our Technical Competence Centers are continuously working on new syringe configurations with regard to finger flange, cone types, diameters, sizes, and syringe barrel surface coatings. Here we develop new production technologies and processes like the patented baked-on siliconization process or the metal-free technology for cone forming. In our own internal development laboratory we are optimizing silicone oil distribution, syringe performance and syringe functionality. In this way we develop primary packaging that meets the specific requirements of your individual active agent.



In our own internal development laboratory we are working on silicone oil distribution, syringe performance, and syringe functionality.

We offer development know-how and development capacities in our worldwide Technical Competence Centers.

Small batch production

In order to be able to quickly and flexibly address the needs of our customers, we have, independent of our production location for syringes in Bünde and Pfreimd, established small series production with a clean room of the GMP classes C and D for prefillable syringes and cartridges of glass in our Technical Competence Center in Wackersdorf, Germany. Here we can quickly and flexibly produce clinical samples without complications for approval, prototypes for process and technology development, and small series.

Prefillable glass syringes

Solutions matching your needs

High-tech program

We offer an extensive portfolio of prefillable glass syringes (Type I glass) that are adapted to the current requirements of the pharmaceutical industry and fulfill the requirements of modern filling systems.

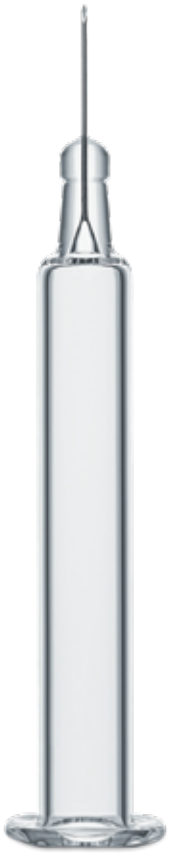
Our syringe assortment includes:

- Bulk and "ready-to-fill" format
- Filling volumes of 0.5 ml to 5.0 ml
- Integrated cannulas in the most varied formats
- Luer cone and Luer lock systems, needle syringes
- Round and cut finger flange
- Various options for siliconization (spray and baked-on siliconization)
- Innovative components (closure systems, plunger stoppers, plunger rods, backstops)
- Optional: syringes with reduced tungsten content, low subvisible particle load
- Most varied possibilities for printing (metal-free paints, ceramic printing on glass, various designs of graduation, dose mark, various colors and other options upon request)
- Individual solutions upon request

Glass syringes as bulk goods Gx® bulk

Bulk syringes are washed, sterilized, and filled by the customer. We deliver the unsterilized bodies in flat trays (Rondo trays). Our product range encompasses syringe sizes from 0.5 ml to 5.0 ml, syringe versions with Luer cone and Luer lock systems, as well as syringes with glued in cannulas in the most varied versions.

Rondo tray
Packaging in clean room GMP class D



Glass syringes "ready-to-fill" Gx RTF®

The trend with syringes is clearly toward "ready-to-fill" (RTF) syringes. With our sterile Gx RTF® syringes, we are regarded as the technology leader in this area with more than 15 years of production experience. We wash, siliconize, assemble with needle shield or tip cap and sterilize Gx RTF® syringes with ethylene oxide (EtO), which means that they are delivered completely prepared for aseptic filling. Gx RTF® syringes are packed in nests for easy handling and filling. These nests are suitable for all of the usual filling systems. The product portfolio encompasses syringe sizes from 0.5 ml to 3.0 ml, syringe versions with Luer cone, Luer lock, and glued in cannulas in many various configurations.

Gx RTF® syringes nested by:

- 100 (10×10) for 0.5 ml, 1.0 ml long, 1.0–3.0 ml
- 160 (10×16) for 0.5 ml, 1.0 ml long

Gx RTF® packaging

Gx® Needle syringes

- Gx® bulk and Gx RTF® format
- Type I glass
- Syringe sizes from 0.5 ml to 2.25 ml (additional formats upon request)
- Integrated cannulas in various versions with regard to cannula length, diameter, bevel
- Standard and thin-wall cannulas
- Various needle shields
- Round and cut finger flange
- Various options for siliconization
- Most varied possibilities for printing (metal-free paints, ceramic printing on glass, various designs of graduation, dose mark, various colors and other options upon request)
- Syringes can be provided as a complete system with plunger stopper, plunger rod, and backstop
- Tungsten specification
- Limit value and detection method for glue leachables
- Drug Master File Type III
- Individual solutions upon request

0.5 ml	47.6	6.85	4.65	½
1.0 ml long	54.0	8.15	6.35	½
1.0 ml standard	35.7	10.85	8.65	½ ⅝
1.5 ml	43.2	10.85	8.65	½ ⅝
2.25 ml	54.4	10.85	8.65	½

Further formats upon request

Needle shields

The needle shield protects the cannula against damages up to injection, and keeps the syringe sterile until use. Our program encompasses flexible needle shields (FNS) and rigid needle shields (RNS).

EtO-sterilizable rubber formulas:

Datwyler FM27, Stelmi 4800 GS, West 7025/65, project-related formulas and needle shields upon request

Gx InnoSafe®

Integrated and passive safety system

The integrated passive safety system prevents needle stick injuries and reuse. When being used, the safety system is activated automatically and requires no additional action by the user. Pharmaceuticals customers can process the syringes without an additional assembly step on the existing lines in the nested state. The integrated flexible needle shield is available in all customary available elastomers for pharmaceutical applications.

RNS
Rigid Needle Shield

FNS
Flexible Needle Shield

Gx InnoSafe®
integrated and passive safety system
(available from 2020)

Cannulas

Our offering encompasses stainless steel cannulas of the most varied lengths, diameters and bevel types. They ensure intramuscular or subcutaneous injections with the least pain possible. The steel quality of the cannulas used corresponds to AISI 304, the sizes to standard DIN 9626.

Cannula properties

- **Siliconization** in the RTF process with Dow Corning® 360
- **Cannula length:** ½" (12.7 mm) and ⅝" (15.9 mm)
- **Diameter:** 23G, 25G, 26G, 27G, 29G
- **Standard and thin-wall cannulas**
- **Bevel:** 3 Bevel, 3 Bevel XL, V Bevel®

23 G thin-wall cannula
½" (12.7 mm)
3 Bevel

25 G cannula
⅝" (15.9 mm)
3 Bevel

26 G thin-wall cannula
½" (12.7 mm)
3 Bevel XL

27 G cannula
½" (12.7 mm)
3 Bevel

27 G cannula
½" (12.7 mm)
3 Bevel XL

27 G thin-wall cannula
½" (12.7 mm)
3 Bevel

27 G cannula
½" (12.7 mm)
V Bevel®

29 G thin-wall cannula
½" (12.7 mm)
V Bevel®

Finger flanges

Small round

Standard round

Cut

Gx® Luer lock syringes

- Gx® bulk and Gx RTF® format
- Type I glass
- Syringe sizes from 0.5 ml to 3.0 ml (additional formats upon request)
- Various closure systems
- Round and cut finger flanges
- Various options for siliconization
- Optional: syringes with reduced tungsten content or tungsten free
- Most varied possibilities for printing (metal-free paints, ceramic printing on glass, various designs of graduation, dose mark, various colors and other options upon request)
- Drug Master File Type III
- Syringes can be provided as a complete system with plunger stopper, plunger rod, and backstop
- Individual solutions upon request

0.5 ml	47.6	6.85	4.65
1.0 ml long	54.0	8.15	6.35
1.0 ml standard	35.7	10.85	8.65
1.5 ml	43.2	10.85	8.65
2.25 ml	54.4	10.85	8.65
3.0 ml	72.2	10.85	8.65

Further formats upon request

Closure systems

Tip Cap
(Mushroom)

EtO-sterilizable rubber formulas:

- Datwyler: FM27/FM30
- Stelmi: 6580
- West: 1883, 7025/65, 7028/55
- Other formulas available upon request

Gx TELC®
Tamper Evident
Luer lock closure

EtO-sterilizable rubber formulas:

- Datwyler: FM27
- Stelmi: 6580
- West: 7025/65
- Other formulas available upon request

Gx TELC®

Advantages of the Gx TELC® closure system

- Patented integrated Luer lock closure system
- Luer lock adapter with tamper-evident property
- Convenient and intuitive opening caused by soft touch surface and easy grip design
- No unintentional pop off
- Manufactured of polycarbonate (Luer lock adapter) and Medical Grade Thermoplastic Elastomer (sealing cap with tamper-evident flags) using two-component injection molding
- TPE parts offer color coding of the syringe
- Insert is made of pharmaceutical rubber like FM27, 7025, 7028, 6580 GS can be chosen
- Specified opening and spinning forces
- Fulfills ISO 594 requirements
- Steam, gamma and EtO sterilization possible

Finger flanges

Small round

Standard round

Cut

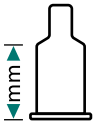
Gx® Luer cone syringes

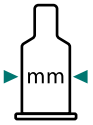
- Gx® bulk and Gx RTF® format
- Type I glass
- Syringe sizes from 0.5 ml to 5.0 ml (bulk only), additional formats upon request
- Dual chamber syringe 2.25 ml and 5.0 ml (bulk only)
- Closure system Six Rib Tip Cap
- Round and cut finger flange
- Various options for siliconization
- Optional: syringes with reduced tungsten content or tungsten free
- Most varied possibilities for printing (metal-free paints, ceramic printing on glass, various designs of graduation, dose mark, various colors and other options upon request)
- Syringes can be provided as a complete system with plunger stopper, plunger rod, and backstop
- Drug Master File Type III
- Individual solutions upon request

Six Rib Tip Cap

EtO-sterilizable rubber formulas:

- Datwyler: FM27, FM30
- West: 1883, 7025/65, 7028/55
- Other formulas available upon request





0.5 ml	47.6	6.85	4.65
1.0 ml long	54.0	8.15	6.35
1.0 ml standard	35.7	10.85	8.65
1.5 ml	43.2	10.85	8.65
2.25 ml	54.4	10.85	8.65
3.0 ml	72.2	10.85	8.65
5.0 ml (bulk only)	67.6	14.45	11.85

Further formats upon request

Dual chamber syringe
Available in 2.25 ml and 5.0 ml (bulk only)

Finger flanges

Small round

Standard round

Cut

Syringe system components and accessories

For user-friendliness and safety

Plunger stoppers

Our product program encompasses a large selection of plunger stoppers from leading providers. We offer various sizes, materials and qualities, "ready-to-sterilize" or "ready-to-use". Depending upon the customer requirement, various packaging options are available.

Sizes

- 0.5 ml
- 1.0 ml long
- 1.0 ml standard – 3.0 ml

Materials

- Pharmaceutical elastomer
- Optional: Coating with fluoropolymers (West FluroTec®, West NovaPure®, OmniflexCP®)

Formulas:

- Stelmi: 6291 NR, 6422 NR, 6720
- West: 1883, 4023/50, 4416/50, 4432/50, PH 701/50C, PH 701/55, PH 701/60
- Datwyler: FM257, FM457, FM480
- Other formulas available upon request

Coated stoppers

- Datwyler: OmniflexCP®
- West: 4023/50 FluroTec®
- West: 4023/50 NovaPure®

Packaging for plunger stoppers

- PE bags (standard packaging)
- Nested
- Rapid Transport Port Bags for isolators or RABS

0.5 ml 1.0 ml long 1.0 – 3.0 ml

Gx® plunger rods

In order to complete the syringe system, we offer appropriate plunger rods in the most varied sizes, materials, and colors.

Sizes

- 0.5 ml
- 1.0 ml long
- 1.0 ml standard
- 1.5 ml – 2.25 ml
- 3.0 ml

Materials

- Polypropylene
- Polystyrene
- Polycarbonate (suitable for steam sterilization)

Colors

- Clear
- Colored

Thread

- Standard
- Compatible with "FluroTec®" plunger stoppers
- Snap-fit for 0.5 ml

Gx RTF® syringes are perfectly adapted to the needs of end users and fulfill all requirements of the pharmaceutical industry. Our syringes can be provided as a complete system with plunger stoppers, plunger rod, and backstop.

Gx® backstop

The backstop reduces the opening diameter of the syringe body and simultaneously enlarges the finger flange with ergonomically shaped wings. In this way it fulfills two functions. First, the backstop prevents the plunger stopper from being pulled out of the syringe. Second, the backstop eases the handling of the syringe thanks to an enlarged finger flange area. This is helpful with viscous medications or in the case of counterpressure from the tissue, and in addition to this also benefits even patients with limited motor capacity when injected by the user.

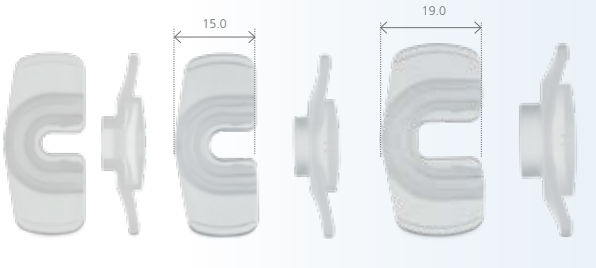
Our backstop is made of plastic and manually clipped to the finger flange of the glass syringe. It is thereby compatible both with round and cut finger flange shapes. The backstop is available in various colors and can be used as a visual indicator for the user in order to prevent confusion. Differentiation from the competition and the expansion of existing systems in the product lifecycle are additional advantages of the Gx® backstop.

Sizes

- 0.5 ml
- 1.0 ml long
- 1.0 ml standard – 3.0 ml

Materials

- Polypropylene



Closure systems Gx TELC®

Patented integrated Luer lock closure system

Plunger stoppers

"Ready-to-use" or "ready-to-fill" in various versions

Gx® backstop

For purposes of differentiation, better handling, and increased safety through ergonomic design

Gx® plunger rods

Available in various sizes, materials, and colors

Prefillable glass syringes

for sensitive active ingredients

The biotechnologically manufactured active ingredients with highly complex, protein-based molecules should interact as little as possible with the packaging. Gerresheimer continually develops new production technologies and processes for interior coating, cone forming, needle assembly and many other aspects. We create packaging solutions with the highest quality standards with regard to active agent-packaging interaction. This results in syringes with reduced free silicone oil, metal-free syringes and syringes with reduced tungsten residue.

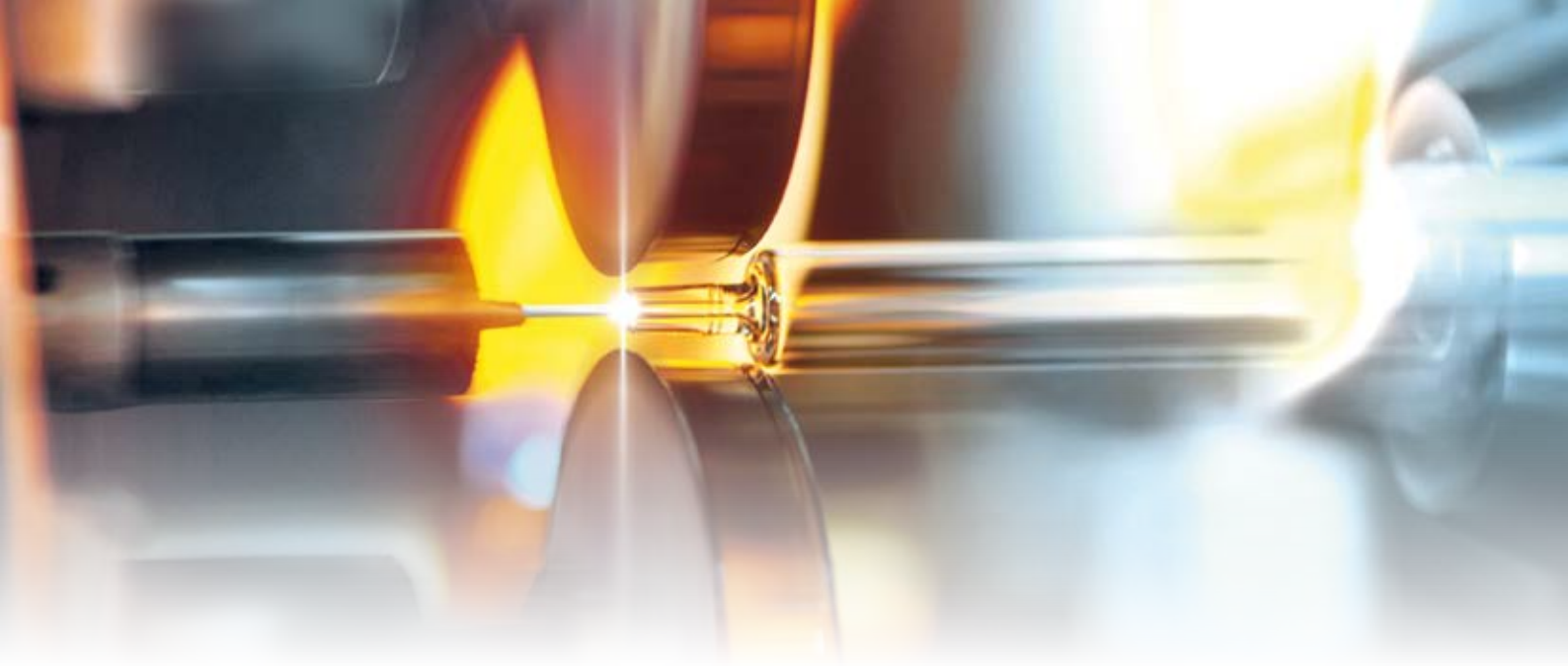
Silicone-oil reduced Gx Baked-on RTF® syringes

Gx RTF® glass syringes plus baking process patented in Europe and the USA

Complete coating with the lowest possible quantities of silicone oil: We achieve this with the baked-on siliconization patented in Europe and the USA. In this procedure, a silicone oil emulsion is applied to the body of the Gx RTF® syringes and subsequently thermally fixated on the surface by heating. The use of additional chemicals is not necessary.

Advantages of the Gx Baked-on RTF® syringe

- Reduced interaction risk between drug formulation and silicone oil
- Drastically reduced amount of silicone oil droplets below the visibility threshold
- Masking and inactivation of the glass surface
- Long-term stable, evenly distributed, and chemically inert lubricity coating
- Very even break loose and gliding force profile
- Ensures optimal functionality and drug formulation stability over the period of medication storage
- Patented in Europe and USA



Metal-free Gx RTF® syringes

Gx RTF® glass syringes plus patented, metal-free technology for cone forming

Biotechnologically manufactured drugs can interact with tungsten residue from syringe production. Gerresheimer offers metal-free glass syringes for such cases. The pin used for cone forming doesn't consist of tungsten in this case, but instead of a special ceramic. External studies have proven that in this way we can produce syringes free of residues.

- The pin used to shape the cone is made of a special ceramic
- Available for Luer lock and Luer cone syringes
- The Fresenius Institute conducted a study confirming that no ceramic residue can be detected in the syringe
- Non-cytotoxic according to ISO 10993-5

Gx RTF® glass syringes plus an additional cleaning step to reduce glass and tungsten particles

We also can offer on our standard manufacturing process of syringes an additional cleaning step using a washing machine following by the forming of the glass. Through the combination of water and ultrasonic bath, our internally developed, multi-stage treatment system thereby reduces not only the load of glass particles by up to 90 percent, but also reduces the tungsten load dramatically.

The drum of a washing machine for the cleaning of syringes in order to reduce glass and tungsten residuals

Prefillable polymer syringes

for sensitive active ingredients

A third option for the packaging of highly sensitive, biotechnologically manufactured drugs is the use of polymers like Cyclo Olefin Polymer (COP) as syringe material. The production process has no potential for tungsten residuals. We offer a wide range of prefillable plastic syringes of the Gx RTF® ClearJect® and ClearJect® brand especially for such applications. They are produced of COP (Cyclo Olefin Polymer) in an injection molding process in accordance with cGMP. COP syringes are distinguished by a high degree of break resistance and a glass-like transparency. They can be used directly for aseptic filling. COP releases no alkali ions, which means that the risk of a pH value shift is eliminated. Production with the injection molding process enables flexible designs – even customer-specific designs are possible. In comparison to glass more precise production tolerance are possible thanks to the exact injection molding. This makes a higher degree of customized solutions possible, for example, when a lower remaining volume is required.

Your advantages

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 residue volume

Excellent compatibility with medical products

- Wide variety of design options and high flexibility for customer-specific requirements
- Outstanding syringe functionality with regard to
  - break loose and gliding forces
  - pull-off force of the needle shield
- Compatible with auto injectors

Compatible with auto injectors

Gx RTF® ClearJect® Needle syringe 1.0 ml long

- Manufactured in Germany
- Elastomer components from Aptar Stelmi, West, Datwyler
- Gerresheimer plunger rods and backstops

ClearJect® Luer lock and Luer cone syringes from 0.5 ml to 5.0 ml.

- Manufactured by our partner Taisei Medical Co. Ltd. in Japan
- Elastomer components from Sumitomo Rubber Industries, Japan
- Taisei plunger rods and backstops

Gx RTF® ClearJect® polymer needle syringes

- Syringe size of 1.0 ml long available (further formats upon request)
- Design corresponds to ISO 11040-6
- Clean room production according to GMP class C
- Glue-free: The cannula is not glued in, but is instead insert-molded
- High viscosity silicone oil for reduced particles
- Tungsten-free production
- Syringes can be provided as a complete system with commercially available components (needle shields, plunger stoppers, plunger rods, backstops, finger flange enlargements)
- Gamma-sterilization
- Standardized nest/tub format for easy usage on filling lines

1.0 ml long	76.7	8.15	6.35	½

Further formats upon request

Low interaction potential of the syringe with the medication

No aggregation due to metal or tungsten residues

Glue-free: The cannula is not glued in, but is instead insert-molded during the injection molding process

High pH tolerance

High viscosity silicone oil for reduced particles

Minimal extractables and leachables

Optimized permeation rate

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).

Gerresheimer plastic components

Gx® 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

Commercially available and registered rubber components

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

Cannula

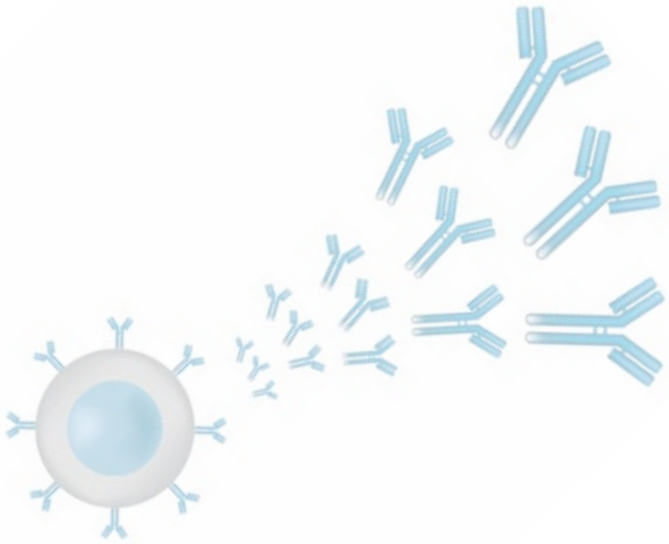
The syringe is supplied with a thin-walled, 27-gauge, ½" (12,7 mm) stainless-steel cannula with three bevels. The steel quality corresponds to AISI 304, and the size to standard DIN 9626.

Needle Shield

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

Packaging

The Gx RTF® ClearJect® syringes are packed in standarized nest (160 syringes)/tub format for easy use on filling lines.



ClearJect®

Polymer Luer cone and Luer lock syringes

ClearJect® COP polymer syringes are manufactured by our partner Taisei Medical Co. Ltd. in Osaka, Japan. Gerresheimer assumes responsibility for the sales and technical consultation for ClearJect® COP polymer syringes for customers in Europe and Americas. They fulfill Japanese quality requirements, especially with regard to cosmetic defects. The syringes are produced on a fully automated line, 100% camera-monitored, and packed under clean room conditions. The ClearJect® polymer syringes are available in the "ready-to-use" format (TasPack®) and can be processed on existing filling lines. They correspond to the international quality standards USP, EP and JP. The portfolio encompassed syringes sizes from 0.5 ml to 5.0 ml.

ClearJect® syringes nested by:

- 100 (10×10) for 0.5 ml, 1.0 ml, 2.25 ml
- 64 (8×8) for 5.0 ml

"Ready-to-use" format TasPack®
ClearJect® TasPack® is a trademark owned by Taisei Kako Co. Ltd.

ClearJect®
Luer cone syringe

ClearJect®
Luer lock syringe

ClearJect®
Luer cone syringes

- Syringe sizes from 1.0 ml to 5.0 ml available
- Gamma-sterilization according to ISO 11137
- Siliconization with highly viscous silicone oil (low particle load)
- Tungsten-free production
- Syringes can be provided as a complete system with plunger stoppers, plunger rod, and finger flange enlargement
- Is delivered in the "ready-to-use" format as TasPack® (Taisei Sterile Packaging)
- Standardized nest/tub format for easy usage of filling lines
- Fulfills existing Ph. Eur., USP and JP requirements
- Individual solutions upon request

Closure system

The ClearJect® Luer cone syringes are equipped with a Tip Cap. These are manufactured of latex-free chlorobutyl rubber (formula P-134, P-101A) and correspond to the Ph. Eur., USP and JP requirements. The manufacturer is Sumitomo Rubber Industries Ltd.

Tip Caps

Tip Caps manufactured of latex-free chlorobutyl rubber

1.0 ml

2.25 ml and 5.0 ml

1.0 ml long	54.0	9.15	6.35
2.25 ml	54.5	11.15	8.65
5.0 ml	67.85	15.05	12.45

Further formats upon request

ClearJect®
Luer lock syringes

- The Luer lock adapter is manufactured together with the syringe "in one cast" so it is fully integrated in one piece, which means that the ClearJect® syringes are inherently more robust and better suited for viscous medications like, for example, hyaluronic acid, and easier to administer for the end user
- Syringe sizes from 0.5 ml to 5.0 ml available
- Gamma-sterilization according to ISO 11137
- Siliconization with highly viscous silicone oil (low particle load)
- Tungsten-free production
- Syringes can be provided as a complete system with plunger stoppers, plunger rod, and finger flange enlargement
- Is delivered in the "ready-to-use" format as TasPack® (Taisei Sterile Packaging)
- Standardized nest/tub format for easy usage of filling lines
- Fulfills existing Ph. Eur., USP and JP requirements
- Individual solutions upon request

0.5 ml	54.1	9.40	4.65
1.0 ml long	53.85	11.20	6.35
2.25 ml	54.5	11.20	8.65
5.0 ml	67.85	15.05	12.45

Further formats upon request

Closure system

The ClearJect® Luer lock syringes are equipped with a Tip Cap. These are manufactured of latex-free chlorobutyl rubber (formula P-134, P-101A) and correspond to the Ph. Eur., USP and JP requirements. The manufacturer is Sumitomo Rubber Industries Ltd.

Tip Caps

Tip Caps manufactured of latex-free chlorobutyl rubber

0.5 ml

1.0 ml, 2.25 ml and 5.0 ml

0.5 ml

1.0 ml

2.25 ml

5.0 ml

Syringe system components for ClearJect® syringes

For user-friendliness and safety

Plunger stoppers

Our product program encompasses plunger stoppers of various sizes. They meet the requirements of Ph. Eur., USP and JP and are produced by the Japanese company Sumitomo Rubber Industries (Osaka, Japan). Plunger stoppers from other manufacturers are compatible with most ClearJect® formats and the dimensions fit the syringes.

Sizes

- 0.5 ml
- 1.0 ml long
- 2.25 ml
- 5.0 ml

Materials

Gamma-sterilized chlorobutyl rubber formula (formula P-134, P-101A) containing no natural rubber of any kind. They are spray-siliconized and are available as a "ready-to-use" version.

Colors

- Grey

Packaging

- Gamma-resistant, multi-layer PE bag (RTU)

0.5 ml 1.0 ml long 2.25 ml 5.0 ml

Plunger rods

To complete the syringe system, we offer the respectively suitable plunger rods. Other materials and colors are available at customer request.

Sizes

- 0.5 ml
- 1.0 ml long
- 2.25 ml
- 5.0 ml

Materials

- Polypropylene
- Polystyrene

Colors

- White
- Other colors on request

Finger flange enlargement

With this accessory, the finger flange area is enlarged by ergonomically shaped wings making it easier to utilize the syringe. It is clipped mechanically to the finger flange of the plastic syringe.

Sizes

- 0.5 ml
- 1.0 ml long
- 2.25 ml
- 5.0 ml

Materials

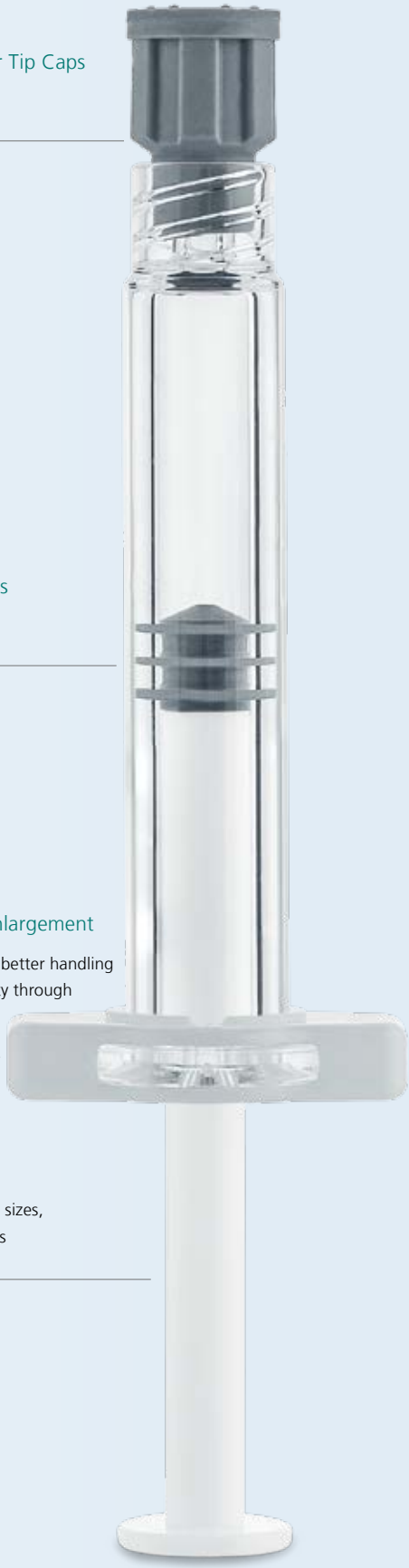
- Polypropylene
- Polystyrene

Colors

- White
- Other colors on request

Examples

0.5 ml | 1.0 ml | 1.0 ml and 2.25 ml | 5.0 ml



Needle shield or Tip Caps

In various versions

Plunger stoppers

In various versions

Finger flange enlargement

For differentiation, better handling and increased safety through ergonomic design

Plunger rods

Available in various sizes, materials and colors

Gx® Glass cartridges

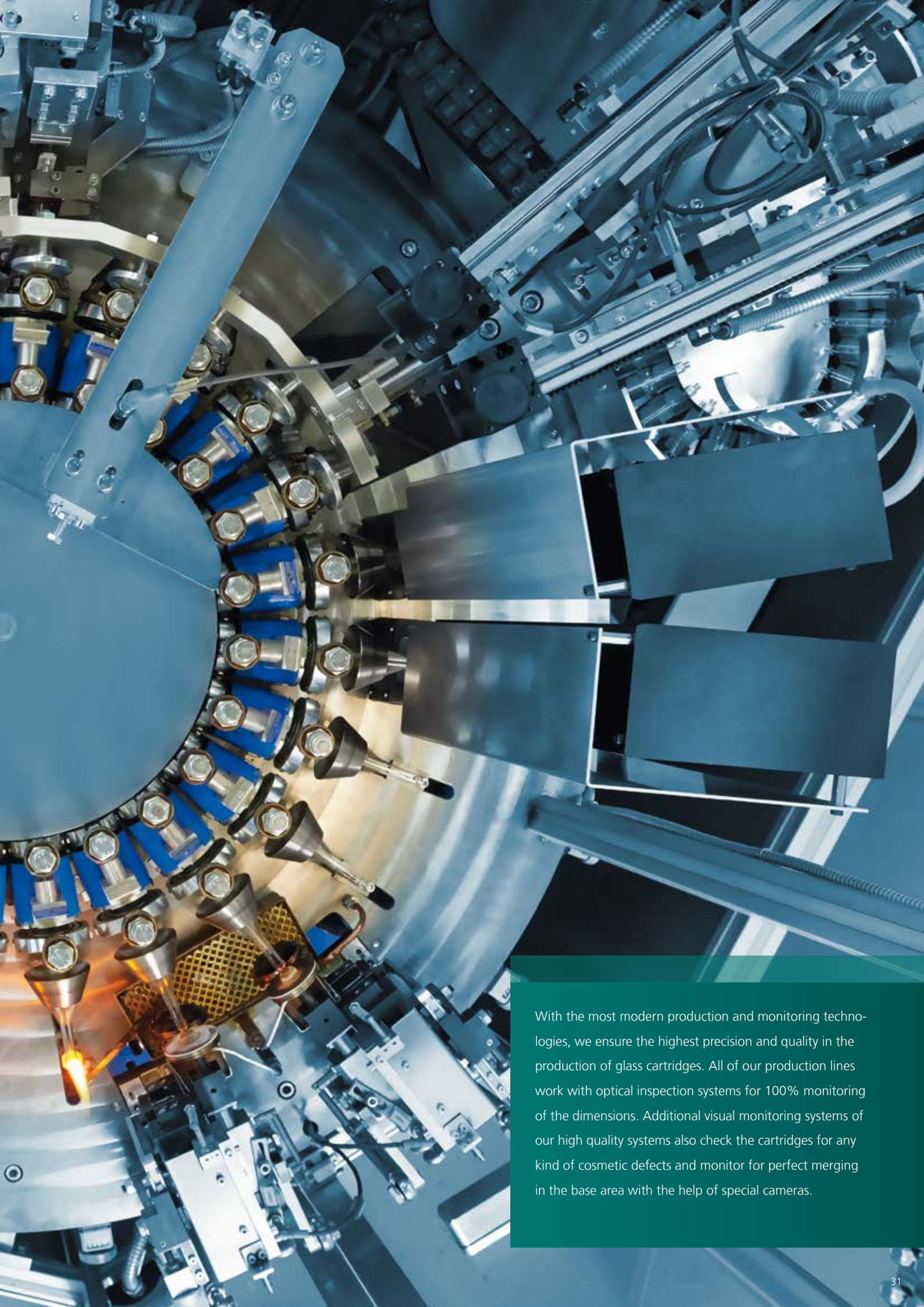
For more than 60 years now we have been producing high quality cartridges that fulfill the requirements of modern filling systems on state-of-the-art production lines. Our program encompasses cartridges made of Type I glass in the size of 3.0 ml (further formats on request).

By using state-of-the-art production technologies and camera monitoring, we ensure maximum precision and quality. Our production lines are equipped with optical inspection systems for 100% monitoring of the dimensions. Other visual monitoring systems of our high quality systems also check the cartridges for any kind of cosmetic defects and monitor for perfect merging in the base area with the help of special cameras.

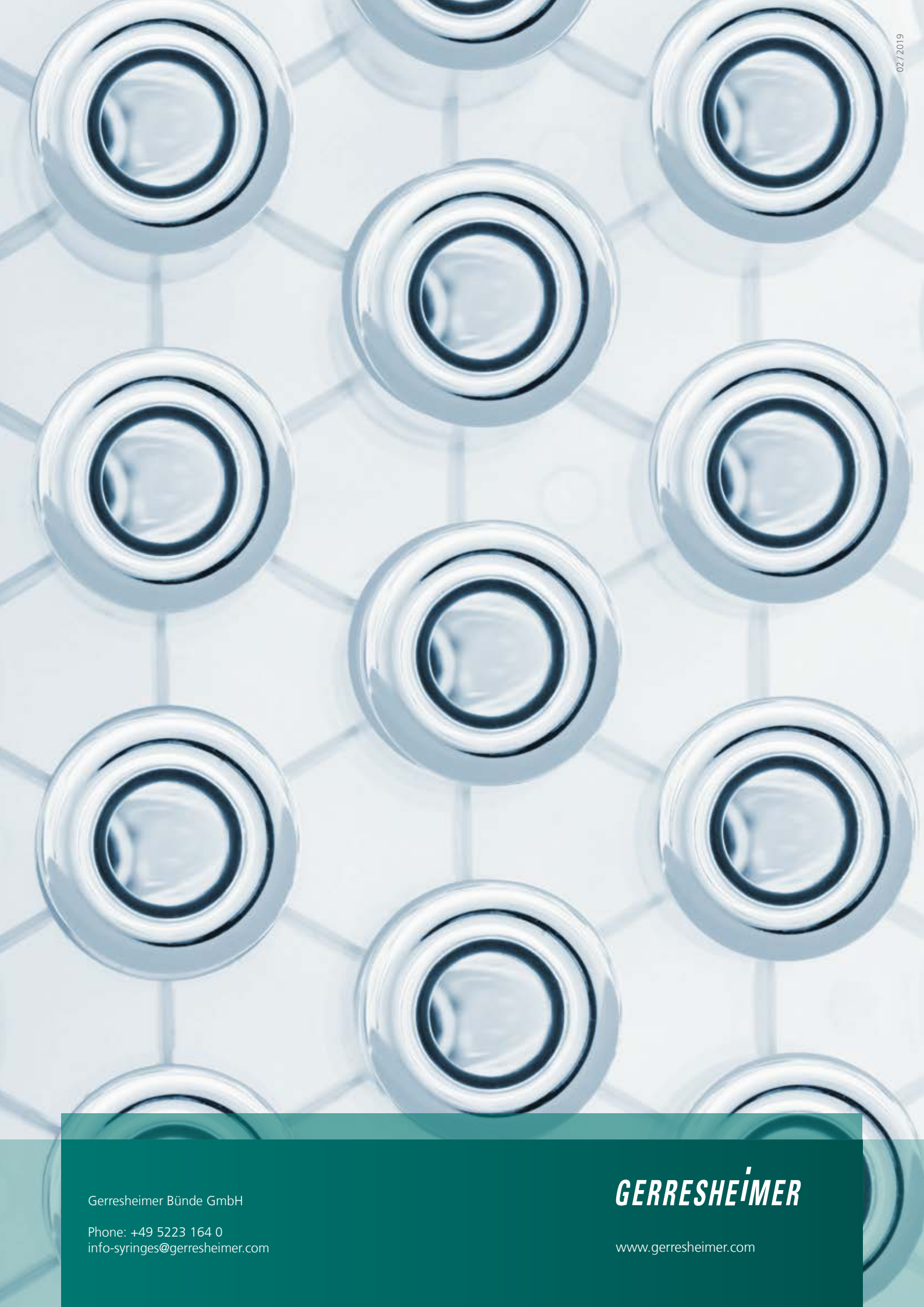
Our cartridges are packaged in polypropylene boxes under controlled environmental conditions. Other packaging possibilities round off our offering. Our team of experts develops individually tailored product solutions for the most varied tasks.

ml	mm	mm
3.0	9.70	62.30
3.0	9.65	62.30

Further formats upon request



With the most modern production and monitoring technologies, we ensure the highest precision and quality in the production of glass cartridges. All of our production lines work with optical inspection systems for 100% monitoring of the dimensions. Additional visual monitoring systems of our high quality systems also check the cartridges for any kind of cosmetic defects and monitor for perfect merging in the base area with the help of special cameras.



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