Gx® Syringe Systems
Gerresheimer is a leading global partner to the pharma and healthcare industry. With our specialty glass and plastic products, we contribute to health and well-being. We have worldwide operations and our 11,000 employees manufacture our products in local markets, close to our customers. With over 40 plants in Europe, North America, South America and Asia, we generate revenues of more than EUR 1.2 billion. Our comprehensive product portfolio includes pharmaceutical packaging and products for the safe, simple administration of medicines: Insulin pens, inhalers, prefilla ble syringes, injection vials, ampoules, bottles and containers for liquid and solid medicines with closure and safety systems as well as packaging for the cosmetics industry.
Gx® Syringe Systems

The business unit Gerresheimer Syringe Systems offers prefilled glass and plastic syringe systems and the relevant accessories. Our highly specialized expertise and pharma-compliant technologies enable us to offer high quality injection solutions to our customers in the pharmaceutical and biotech sectors. We offer our leading Gx RTF® (Ready to Fill) glass syringes in a wide range of designs and in a ready-to-fill state after washing, siliconization, pre-assembly and gas sterilization.
Gerresheimer Syringe Systems

System partnerships
The knowhow, professionalism and creativity of our product developers are available to you not only to optimize but also to customize your packaging solutions. With our expert knowledge about the special properties of glass as a primary packaging material, we accompany your project from A to Z.

- Global R&D capabilities
- Plants in Europe, Asia and Americas
- Technical support
- Drug master files to facilitate your product registrations

Quality standards
Our plants rigorously apply current good manufacturing practices (cGMP) and are certified in accordance with DIN EN ISO 9001, 13485 and/or 15378. Our products comply with Pharm. Eur., USP and JP and fulfill the requirements for glass primary packaging material.

- State-of-the-art technologies
- Continuous process improvements
- Visual inspection
- Clean room production

Gx® G3 syringes inspection

- Visual inspection of all areas of the syringe: Body, fingerflange, shoulder, cone
- Cosmetic control for cracks, particles, air strips
- 8 +2 high resolution cameras
- Up to 10 times higher resolution than usual systems
- Even very small defects of 25 µm can be detected (for comparison: a human hair has a diameter of 60 µm)
- Custom software capable of defect recognition and classification

Gx RTF® 4 technology investments
New generation of Gx RTF® (Ready-to-Fill) processing

- Lower reject rates in final vision control after filling
- Fulfillment of future and current regulatory requirements regarding washing process efficiency
- Constant syringe functionality
- Increases capacity and flexibility towards our customers
- Improved processability on filling lines
- Enhanced overall product cleanliness
- Constant quality of IPC and/or retain samples
## Content

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td><strong>Gx® Tubing</strong></td>
</tr>
<tr>
<td>7</td>
<td><strong>Gx® Glass Syringe Systems</strong></td>
</tr>
<tr>
<td>15</td>
<td><strong>Gx® Pen Cartridges</strong></td>
</tr>
<tr>
<td>16</td>
<td><strong>ClearJect™ COP Syringe Systems</strong></td>
</tr>
</tbody>
</table>

- Gx® Tubing
- Gx® Glass Syringe Systems
  - Gx® Bulk Syringes
  - Gx RTF® Syringes (Ready-to-Fill)
  - Gx RTF® Syringe components and accessories
  - Gx Baked-on RTF®
  - Gx RTF® Syringes in Gx® PharmaPlus Quality
- Gx® Pen Cartridges
- ClearJect™ COP Syringe Systems
In its two tubing production sites in Pisa (Italy) and Vineland, NJ (USA), Gerresheimer produces clear and amber borosilicate glass tubing of best hydrolytic quality. To meet our customers’ growing demand for highest quality performance we use state-of-the-art furnace technologies guaranteeing a homogeneous melting process which is checked by modern control systems and regular chemical analysis.

- Two tubing production sites
- 6 furnaces
- Clear and amber glass tubing
- Glass type I (compliant to Pharm. Eur./USP/JP)
- Expansion coefficient 33 and 51
- Diameters: 4 – 150 mm
- Wall weights: 0.18 – 8.00 mm
Gx® Syringe Systems for parenteral drugs

We supply a comprehensive range of prefillable syringe systems both as bulk products and in a ready-to-use format. These syringes under our leading trademark Gx RTF® (Ready-to-Fill) are washed, siliconized, preassembled and sterilized (ethylene oxide). System components and accessories complete the range and ensure ease-of-use and end-user safety. Our Gx® Syringes are perfectly tailored to your needs and at the same time fulfill the current requirements in the pharmaceutical industry.

- Type I glass (compliant to Pharm. Eur. / USP / JP)
- Sizes from 0.5 to 5 ml (5 ml bulk only)
- Wide range of pre-assembled needles
- Customized ceramic printing
- Proprietary baked-on siliconization (Gx Baked-on RTF®) for highly sensitive biopharmaceuticals
- Standardized packaging configurations suited to standard filling and packaging equipment
- Drug Master File Type III

System components

- Closure solutions for Luercone, Luerlock and Staked-in Needle formats
- Plunger stoppers in many different pharmaceutical elastomers
- Plunger rods in Polystyrene, Polypropylene or Polycarbonate
- Backstops for improved ergonomic handling and safety
### SPECIFICATIONS

#### Gx® Bulk Syringes Luercone

<table>
<thead>
<tr>
<th>Volume</th>
<th>Reference</th>
<th>Diameter</th>
<th>Depth</th>
<th>Length</th>
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<tbody>
<tr>
<td>0.5 ml</td>
<td>47.6</td>
<td>6.85</td>
<td>4.65</td>
<td></td>
</tr>
<tr>
<td>1.0 ml long</td>
<td>54.0</td>
<td>8.15</td>
<td>6.35</td>
<td></td>
</tr>
<tr>
<td>1.0 ml standard</td>
<td>35.7</td>
<td>10.85</td>
<td>8.65</td>
<td></td>
</tr>
<tr>
<td>1.5 ml</td>
<td>43.2</td>
<td>10.85</td>
<td>8.65</td>
<td></td>
</tr>
<tr>
<td>2.25 ml</td>
<td>54.4</td>
<td>10.85</td>
<td>8.65</td>
<td></td>
</tr>
<tr>
<td>3.0 ml</td>
<td>72.2</td>
<td>10.85</td>
<td>8.65</td>
<td></td>
</tr>
<tr>
<td>5.0 ml</td>
<td>66.8</td>
<td>14.45</td>
<td>11.85</td>
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#### Gx® Bulk Syringes Luerlock

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<thead>
<tr>
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<th>Depth</th>
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<tr>
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<td>4.65</td>
<td></td>
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<tr>
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</tr>
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<tr>
<td>5.0 ml</td>
<td>66.8</td>
<td>14.45</td>
<td>11.85</td>
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#### Gx® Bulk Syringes with Staked-in-Needle

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<th>Diameter</th>
<th>Depth</th>
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<tr>
<td>0.5 ml</td>
<td>47.6</td>
<td>6.85</td>
<td>4.65</td>
<td>1/2</td>
</tr>
<tr>
<td>1.0 ml long</td>
<td>54.0</td>
<td>8.15</td>
<td>6.35</td>
<td>1/2</td>
</tr>
<tr>
<td>1.0 ml standard</td>
<td>35.7</td>
<td>10.85</td>
<td>8.65</td>
<td>1/2</td>
</tr>
<tr>
<td>1.5 ml</td>
<td>43.2</td>
<td>10.85</td>
<td>8.65</td>
<td>1/2</td>
</tr>
<tr>
<td>2.25 ml</td>
<td>54.4</td>
<td>10.85</td>
<td>8.65</td>
<td>1/2</td>
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Applies to all products on this page: Other dimensions on request.
Gx RTF® Syringes (Ready-to-Fill)

**SPECIFICATIONS**

**Gx RTF® Syringes System Luercone**

<table>
<thead>
<tr>
<th>Volume</th>
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<th>H</th>
<th>L</th>
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<td>8.65</td>
<td></td>
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<td>54.4</td>
<td>10.85</td>
<td>8.65</td>
<td></td>
</tr>
<tr>
<td>3.0 ml</td>
<td>72.2</td>
<td>10.85</td>
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**Gx RTF® Syringes System Luerlock**

<table>
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<th>Ref.</th>
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<th>H</th>
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<tbody>
<tr>
<td>1.0 ml long</td>
<td>54.0</td>
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<td>6.35</td>
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</tr>
<tr>
<td>1.0 ml standard</td>
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<td>10.85</td>
<td>8.65</td>
<td></td>
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<tr>
<td>1.5 ml</td>
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<td>10.85</td>
<td>8.65</td>
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<tr>
<td>2.25 ml</td>
<td>54.4</td>
<td>10.85</td>
<td>8.65</td>
<td></td>
</tr>
<tr>
<td>3.0 ml</td>
<td>72.2</td>
<td>10.85</td>
<td>8.65</td>
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</table>

**Gx RTF® Syringes System with Staked-in Needle**

<table>
<thead>
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<th>Ref.</th>
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<th>H</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
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<td>47.6</td>
<td>6.85</td>
<td>4.65</td>
<td>1/2</td>
</tr>
<tr>
<td>1.0 ml long</td>
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<td>8.15</td>
<td>6.35</td>
<td>1/2</td>
</tr>
<tr>
<td>1.0 ml standard</td>
<td>35.7</td>
<td>10.85</td>
<td>8.65</td>
<td>1/2</td>
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<tr>
<td>1.5 ml</td>
<td>43.2</td>
<td>10.85</td>
<td>8.65</td>
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</tr>
<tr>
<td>2.25 ml</td>
<td>54.4</td>
<td>10.85</td>
<td>8.65</td>
<td>1/2</td>
</tr>
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</table>

 Applies to all products on this page: Other dimensions on request
Syringe Systems

Gx RTF® Syringe components and accessories
Modern drug delivery solutions for best ease of use

Canulas

- Steel-quality according to AISI 304
- Size acc. to DIN 9626

- Siliconization
  - Wiping with Dow Corning® 360 (12,500 cSt)
  - Curing with Dow Corning® MDX4/4159

SPECIFICATIONS

<table>
<thead>
<tr>
<th>Length</th>
<th>Diameter</th>
<th>Grinding</th>
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<tbody>
<tr>
<td>1/2 &quot; (12,7 mm)</td>
<td>25 G standard</td>
<td>3 bevel</td>
</tr>
<tr>
<td>5/8 &quot; (15,9 mm)</td>
<td>25 G thin wall</td>
<td>3 bevel XL</td>
</tr>
<tr>
<td></td>
<td>26 G standard</td>
<td>V® bevel</td>
</tr>
<tr>
<td></td>
<td>27 G standard</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27 G thin wall</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29 G thin wall</td>
<td></td>
</tr>
</tbody>
</table>

Needle shields

DESIGNS

- Flexible Needle Shield (FNS)
- Rigid Needle Shield (RNS)
- Proprietary Thermoplastic Elastomer Rigid Needle Shield (TERNS)

FORMULATIONS

- Datwyler FM 27
- Stelmi 4800 GS
- West 7025/65
- other formulations on request
Syringe Systems

Gx RTF® Syringe components and accessories
Modern drug delivery solutions for best ease of use

Luercone closures

**DESIGNS**
- Six Rip Tip Cap

**FORMULATIONS**
- Datwyler FM 27
- Datwyler FM 30
- West 1883
- West 7025/65
- West 7028/55
- other formulations on request

Tip Cap

**DESIGNS**
- Tip Cap

**FORMULATIONS**
- Datwyler FM 27
- Datwyler FM 30
- Stelmi 6580
- West 1883
- West 7025/65
- West 7028/55
- other formulations on request

Gx TELC®

**DESIGNS**
- Gx TELC® (Tamper Evident Luerlock Closure)
  - Indicates first aperture
  - Twist-off tip cap
  - No pop off

**FORMULATIONS**
- Datwyler FM 27
- Stelmi 6580
- West 7025/65
- other formulations on request
Gx RTF® Syringe components and accessories
Modern drug delivery solutions for best ease of use

Plunger stoppers

We offer you a wide range of plunger stoppers suitable for all our Gx RTF® syringe types. Stoppers are made from pharmaceutical elastomers and are available in different qualities: Bulk, ready-to-sterilize or ready-to-use. According to your needs, packaging options vary from nested plunger stoppers to PE bags. Packaging in port bags for use with isolators or RABS is an additional option.

SPECIFICATIONS

Sizes
- 0,5 ml
- 1,0 ml long
- 1,0 ml short – 3,0 ml

Materials
- Pharmaceutical elastomers
- Fluoropolymer coatings as an option

Packaging
- PE Bag
- Nested
- Port bag

FORMULATIONS

Datwyler FM 257
Datwyler FM 480
Datwyler FM 457
Stelmi 6213
Stelmi 6291 NR
Stelmi 6422 NR
Stelmi 6720
West 1883
West 4023/50
West 4416/50
West 4432/50
West PH 701/50C
West PH 701/55
West PH 701/60
other formulations on request

Coated Stoppers
Datwyler FM 257 Omniflex
West 4023/50 FluroTec®
West 4432/50 NovaPure®
other formulations on request
Syringe Systems

Gx RTF® Syringe components and accessories
Modern drug delivery solutions for best ease of use

**Gx® Plunger Rods**

For each syringe barrel, you will find the appropriate Gx® Plunger Rod to complete your syringe system.

**SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Sizes</th>
<th>Material</th>
<th>Colours</th>
<th>Thread</th>
</tr>
</thead>
<tbody>
<tr>
<td>· 0.5 ml</td>
<td>· Polypropylene</td>
<td>· Clear</td>
<td>· Standard</td>
</tr>
<tr>
<td>· 1 ml long</td>
<td>· Polystyrene</td>
<td>· Colored</td>
<td>· Compatible with FluroTec® plunger stoppers</td>
</tr>
<tr>
<td>· 1 ml short</td>
<td>· Polycarbonate (suitable for final steam sterilization)</td>
<td></td>
<td>· Snap-fit for 0.5 ml</td>
</tr>
<tr>
<td>· 1.5 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>· 1.5 - 2.25 ml</td>
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<td></td>
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</tr>
<tr>
<td>· 3 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Gx® Backstops**

Our Gx® Backstops are made from PP and combine two important functions: On the one hand, they enlarge the fingerflange for improved handling and on the other, they serve as safeguard for the plunger stopper.

- Ergonomic design
- Compatibility with round and cut finger flanges
- For syringes with small volume
- For high-viscous solutions
- For self-medication by patients
- For reconstituted lyophilisates
- For harmful drugs

**SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Colours</th>
<th>Sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Different colours available on request</td>
<td>· 0,5 ml</td>
</tr>
<tr>
<td></td>
<td>· 1,0 ml long</td>
</tr>
<tr>
<td></td>
<td>· 1,0 ml short – 3,0 ml</td>
</tr>
</tbody>
</table>
Gx Baked-on RTF®
Baked-on siliconization for sensitive drugs

Today, many of the new drugs developed by the pharmaceutical industry require special solutions to ensure long-term compatibility of the packaging material with the API (active pharmaceutical ingredient). The siliconization always generates silicone oil droplets to a certain amount which may interact with the drug. In the worst case, silicone-oil-induced protein aggregation in biotech derived drug products can lead to the rejection of the drug.

Our patented baked-on siliconization holds sensitive biotech drugs stable in solution and prevents it from becoming inactive. Gx Baked-on RTF® provides the syringe barrel with a lasting, stable and even glide coating and guarantees problem-free application over the whole shelf life of the drug.

- Thermal fixation of silicone oil emulsion
- Masking and inactivating the glass surface
- Reduced quantity of subvisible free silicone oil particles
- Long-lasting, stable, evenly distributed glide coating
- Low break loose forces and steady gliding forces
- Patented in Europe and the USA

Gx RTF® Syringes in Gx® PharmaPlus Quality
Highest cosmetic quality for biotech customers and other demanding segments

- Gx® PharmaPlus stands for superior cosmetic (visual) quality attributes
- Results from gentle-touch production processes avoiding glass-to-glass contact
- Uses dedicated camera inspection and / or visual inspection
- Independent from manufacturing lines
- A defined range of AQLs differentiates the product lines Gx® Pharma and Gx® PharmaPlus
  - Gx® PharmaPlus has tightened cosmetic AQLs
  - Gx® PharmaPlus has specified glue residuals
Gerresheimer is an approved supplier of cartridges for various pharmaceutical applications. Our Gx® Cartridges range from 1.5 to 3.0 ml in clear and amber (glass type I). To fulfill the quality demands by our customers, all our Gx® Cartridge lines are equipped with visual inspection systems for 100% dimensional control. In addition, our high quality most modern lines use visual inspection systems to check for cosmetic defects and line-scan cameras to control the glazed end. Final packaging performed under controlled environmental conditions.

- Pen cartridges
- Type I glass (compliant to Pharm. Eur. / USP /JP)
- Sizes from 1.5 to 3.0 ml, larger sizes on request
- Designs according to DIN ISO 13926-1; customized formats on request
- Visual inspection systems for 100% dimensional control
- Packaging options: PP-box, other options on request
- Suited to standard filling and packaging equipment
- Drug Master File Type III

### SPECIFICATIONS

<table>
<thead>
<tr>
<th>Size (ml)</th>
<th>Length (mm)</th>
<th>Diameter (mm)</th>
<th>Height (mm)</th>
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</thead>
<tbody>
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<td>1.5</td>
<td>8.65</td>
<td>6.85</td>
<td>56.95</td>
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<tr>
<td>1.8</td>
<td>8.65</td>
<td>6.85</td>
<td>62.00</td>
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<tr>
<td>3.0</td>
<td>11.60</td>
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<tr>
<td>3.0</td>
<td>11.60</td>
<td>9.65</td>
<td>62.30</td>
</tr>
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</table>

Other dimensions on request
ClearJect™ TasPack™
Innovative drug delivery platform based on cyclic olefines (COP)

ClearJect™ prefilled syringes, manufactured by Taisei Kako Co., Ltd., Japan, are made of COP (Cyclic Olefin Polymer) and offer an alternative to conventional prefilled Gx RTF® Glass Syringes. ClearJect™ meets the requirements of highly demanding drug products like sensitive biotech formulations, oncologic, ophthalmic and many other special applications. ClearJect™ syringes are supplied ready-to-use as TasPack™ (Taisei Advanced Sterile Packaging) to enable the use in standard PFS filling lines. ClearJect™ prefilled syringes are manufactured by Taisei Kako Co., Ltd., Japan. Gerresheimer Bünde is responsible for technical support and sales in the EU and the Americas.

- Glass like transparency
- Reduced oxygen transmission compared to other plastics
- High break resistance
- High pH tolerance, no pH-shift
- High precision injection molding ensures tight dimensional tolerances
- No metal ion leakage
- Tungsten free
- Low extractables and leachables
- Gamma sterilized
- Customized tip caps and plungers made from chlorobutyl elastomer formulation (gamma resistant) compliant to Pharm. Eur./USP/JP
- Accessories: Fingergrips and Backstops
- DMF type III
## ClearJect™ TasPack™

### Syringe formats

#### ClearJect™ Luercone

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1.0 ml</td>
<td></td>
</tr>
<tr>
<td>2.25 ml</td>
<td></td>
</tr>
<tr>
<td>5.0 ml</td>
<td></td>
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#### ClearJect™ Luerlock

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Description</th>
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<tbody>
<tr>
<td>0.5 ml</td>
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<tr>
<td>1.0 ml</td>
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</tr>
<tr>
<td>2.25 ml</td>
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</tr>
<tr>
<td>5.0 ml</td>
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#### ClearJect™ with needle

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 ml</td>
<td></td>
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</tbody>
</table>
ClearJect™ TasPack™ Components and accessories

A syringe system consists of the barrel, a plunger stopper (piston) with a plunger rod, a tip cap and an optional finger grip or backstop. All elastomer components are customized and manufactured by the Japanese company Sumitomo Rubber Industries (Osaka, Japan). Pistons and tip caps are made from the same chlorobutyl elastomer formulation.

Tip Caps

Tip Caps mounted on the TasPack™ syringes are manufactured by Sumitomo Rubber Industries. They are made of a gamma-sterilizable chlorobutyl elastomer formulation (formula P-134) which does not contain any natural rubber. They meet the requirements of current Pharm. Eur./USP./JP.

- Colour: grey
- Siliconization: silicone spray coating
- Available as ready-to-sterilize (RTS) or ready-to-use (RTU) version
- Packaging: Gamma resistant multilayer PE bag or steam sterilizable Tyvek® bag
- Documentation compliant to Pharm. Eur./USP./JP
- DMF Type III

Plunger Stoppers

Plunger stoppers (pistons) are manufactured by Sumitomo Rubber Industries. They are made of a gamma-sterilizable chlorobutyl elastomer formulation (formula P-134) which does not contain any natural rubber. They meet the requirements of current Pharm. Eur./USP./JP.

- Colour: grey
- Siliconization: silicone spray coating
- Available as ready-to-sterilize (RTS) or ready-to-use (RTU) version
- Packaging: Gamma resistant multilayer PE bag or steam sterilizable Tyvek® bag
- Documentation compliant to Pharm. Eur./USP./JP
- DMF Type III
ClearJect™ TasPack™
Components and accessories

**Plunger Rod**

The plunger rods consist of polystyrene or polypropylene. They are manufactured under clean room conditions and delivered non-sterilized.

**Finger grip and Backstop**

The finger grips and backstops are made of polypropylene. The finger grip supports easy handling for the user when the syringe is applied. In addition backstops prohibit an accidental pull-out of the elastomer piston e.g. in case of harmful medication. These components are manufactured under clean room conditions and delivered non-sterilized.

**Quality evidence**

- ISO 9001 and 14001 certificates for both Taisei Kako and Sumitomo Rubber Industries
- Product specifications and DMF type III for ClearJect™ TasPack™ syringes
- Product specifications, formulation characteristics and DMF type III for elastomer components (tip cap, piston)
- Product specification for plunger rods
- In-house monograph for COP material
- DMF type III for COP material
- Validated processes for sterilization, shelf life, transportation
More information

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