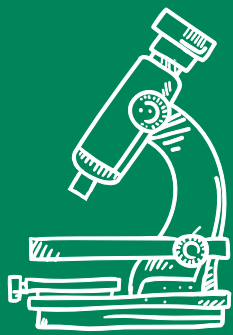


## A simple formula for biotech success



Discovery



Solution



Improved Lives



**PLAJEX**<sup>™</sup>  
Ready-to-Fill Polymer Syringe

**PLAJEX<sup>™</sup> Ready-to-Fill Polymer  
Syringe for Biotech Formulations**

## Introducing PLAJEX™ 2.25 ml with Tapered Needle for Biotech Formulations

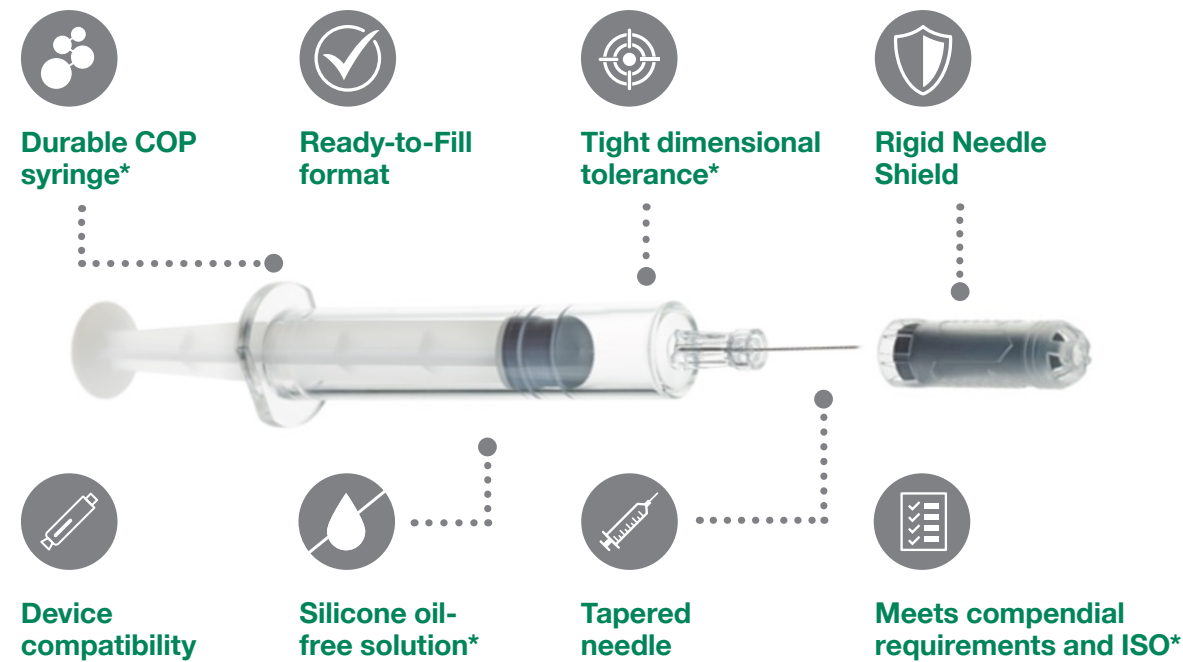
# A simple formula for biotech success

We know you face distinct challenges developing biotech products that are safe, effective and simple to administer. You need a next-generation primary container solution for complex biotech formulations to:

- **Keep sensitive biotech drugs stable** by eliminating silicone oil and other risk materials that can impact stability of biotech formulations
- **Provide compatibility with injection devices** by tight dimensional tolerances of the syringe and industry network
- **Accelerate development and market timelines** with design and production flexibility built in

Engineered for smooth drug product integration throughout development and manufacture, PLAJEX™ 2.25 ml with Tapered Needle can help accelerate product development and reduce project risk with an integrated platform approach.

### Precisely engineered for today's challenging biotech formulations



- **COP-based barrel** – helps keep sensitive drugs stable offering low extractables and excellent gas barrier properties compared with other polymers
- **Ready-to-Fill format** – For smooth filling process integration
- **Tight dimensional tolerance** – by precise polymer molding technology facilitates smooth injection device integration
- **Rigid needle shield** – Designed for autoinjector capability
- **Industry network for smooth device integration** – with confirmed compatibility with a certain commercial injection devices
- **i-coating™ technology** – replaces silicone oil to lubricate the syringe system, mitigating generation of subvisible particles
- **Tapered needle technology** – increases design space to deliver high viscosity medications without compromising patient comfort
- **Meets compendial requirements and ISO\*** – USP, EP and JP

\*Data on file

## Designed for manufacturing and process development

- **Smooth fill & finish integration** – either by offering **Terumo's in-house CDMO (Contract Development and Manufacturing Organization) capability**, or supporting filling sites selected by customer
- **Compliance with global regulations and standards** – meets applicable ISO standards as well as a range of global compendial requirements, including United States Pharmacopeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP)

### Tapered Needle

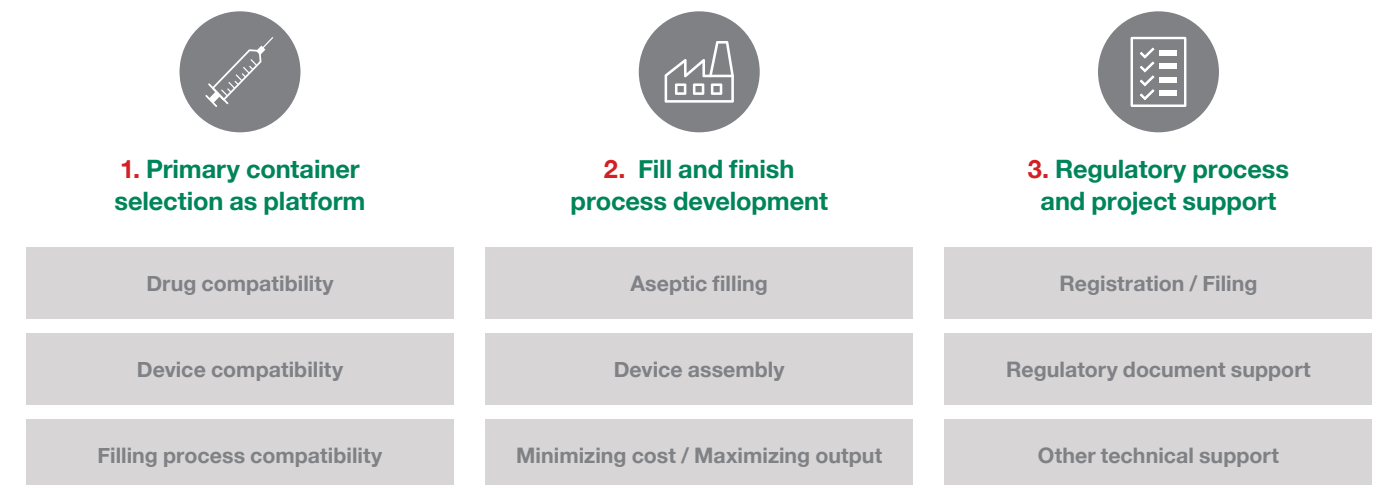
Tapered needle is a conically shaped needle enabled by Terumo's proprietary needle cannula manufacturing technology. It has a smaller diameter at the tip (patient side) and larger diameter at the bottom (drug side) to improve injectability while keeping a needle size of only 29G at the point of patient contact<sup>1</sup>.



### Smooth development and commercialization

- **Technical support** – for a smooth fill & finish integration with our established relationship with major CMOs and filling equipment suppliers
- **Documentation support** – technical reports, certificates, and regulatory documents at each phase of your development project

### Smooth integration throughout, for project risk management and optimised time to market



Terumo Pharmaceutical Solutions

<sup>1</sup> Advantages of a tapered needle for use in pre-filled biopharmaceutical products, Terumo internal study (March 2019)

## General specifications

| Specification              | Description  |
|----------------------------|--|
| Syringe barrel material    | Cyclo Olefin Polymer (COP)   |
| Syringe size               | 2.25 mL<br>Reference to ISO 11040-6: 2019  |
| Needle options             | 29G 1/2" Tapered needle<br>27G 1/2" Thin Wall needle (straight)  |
| Syringe barrel lubrication | Silicone oil-free  |
| Needle shield              | Rigid needle shield<br>Chloro butyl-diene blend polymer, polypropylene   |
| Flange shape               | Cut flange<br>Reference to ISO 11040-6: 2019   |
| Barrel packaging           | 10 x 10 Nest/Tub format (100 syringes per tub)   |
| Barrel sterilization       | Autoclave (Steam)<br>Reference to EN ISO 17665-1: 2006   |
| Plunger stopper            | i-coating™ stopper<br>Reference to ISO 11040-5: 2012<br>Chloro butyl rubber (CIIR) with silicone resin coating |
| Stopper packaging          | Double Tyvek® bag or Rapid Transfer Port bag   |
| Stopper sterilization      | Autoclave (Steam)<br>Reference to EN ISO 17665-1: 2006   |
| Plunger rod                | Polypropylene  |



\*Data on file

**TERUMO** PHARMACEUTICAL SOLUTIONS

**PLAJEX™**  
Ready-to-Fill Polymer Syringe

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