

Quality time for better care



PHARMACEUTICAL

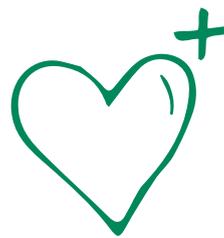
PLAJEX™ Ready-to-Fill Polymer Syringe for Biotech Formulations



Discovery



Solution



Improved Lives



A simple formula for biotech success

PLAJEX™ 2.25 ml with Tapered Needle for Biotech Formulations

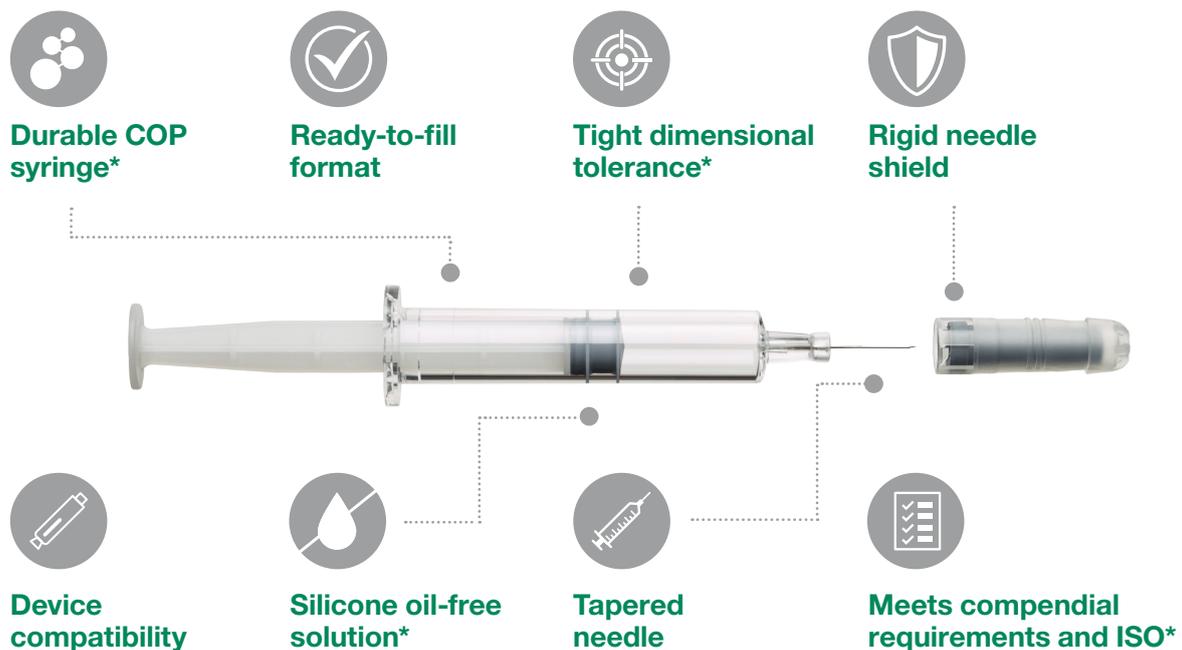
A simple formula for biotech success

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 compatibility

- **Industry network for smooth device integration** – with confirmed compatibility with 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
Images are for visualization purpose only.

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 your selected filling sites
- **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 Pharmacopeia (EP) and Japanese Pharmacopeia (JP)

Tapered needle

Our tapered needle is a conically shaped needle enabled by Terumo's proprietary 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 contact¹.



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



1. Primary container selection as platform

Drug compatibility
Device compatibility
Filling process compatibility



2. Fill and finish process development

Aseptic filling
Device assembly
Minimizing cost / Maximizing output



3. Regulatory process and project support

Registration / Filing
Regulatory document support
Other technical support

Terumo as a solution provider

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



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PLAJEX™
Ready-to-Fill Polymer Syringe

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