

When Performance Matters Most

DAIKYO _____
Crystal Zenith®
THE CLEAR SOLUTION



Innovation for High-Value Medications

Traditional glass containment and delivery systems work well in traditional applications.

But for high-value biologics and biopharmaceuticals, glass vessels can pose serious problems.

Some of the most respected names in the industry have faced US Food and Drug Administration (FDA) recalls due to breakage, delamination and glass particulate issues—patient health, risking reputations and market leadership, often at tremendous expense.

Daikyo Crystal Zenith®, a cyclic olefin polymer containment and delivery system, was designed as a high performance alternative to glass. It's an integrated lifecycle solution that is designed to protect drug safety, purity and efficacy from development through delivery—in a flexible, customizable and filling line and delivery device compatible platform.

For more than 90 years, West's innovative solutions have helped pharmaceutical companies deliver lifesaving medications safely and effectively, for better patient outcomes.



Daikyo Crystal Zenith®

RIGHT FROM THE START

Of all the research, planning and analysis that goes into the creation of a promising new therapy, the choice of a containment system might seem like a minor decision. In fact, it could be one of the most important.

The High Performance System for High-Value Medications

- Custom-formulated cyclic olefin polymer (COP)
- High break resistance (in shipping, production or use)
- Compatible across wide pH range
- Can eliminate pH shift
- Protein compatible (mitigates aggregation)
- Very low extractables or leachables
- No silicone oil, tungsten residue or glue
- Tight dimensional tolerances
- Excellent temperature characteristics (autoclave sterilization/cold storage compatible)
- Clean room manufactured
- 100% camera vision inspected
- Extremely transparent and lightweight
- Customizable shapes and sizes
- Avoids FDA cautions about glass
- Zero ash incineration
- From collaborative, innovative partner

The Crystal Zenith (CZ) polymer addresses the need for a clear, biocompatible material that overcomes problems inherent in glass vials, syringes and cartridges. Drug containment and delivery systems manufactured from the versatile, technologically advanced CZ polymer are ideal for high-value molecules, biologicals and biopharmaceuticals, where glass may be a less desirable option because of issues such as chemical interactions and breakage.

As a full product lifecycle solution, CZ can eliminate a host of serious problems downstream, including shortages and recalls caused by containment and delivery system defects or interactions. In fact, since 2006 there have been over 25 FDA recalls for breakage and another 20+ for particulates—recalls of over 100 million drug units in total.

By using CZ from the start, you can move your molecule from the research and development lab, through development and clinical trials, into commercialization, all in containers manufactured from the same polymer. This can help eliminate worries about unexpected interactions, breakage issues or storage concerns.

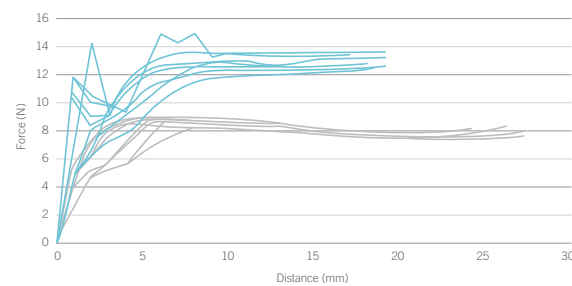
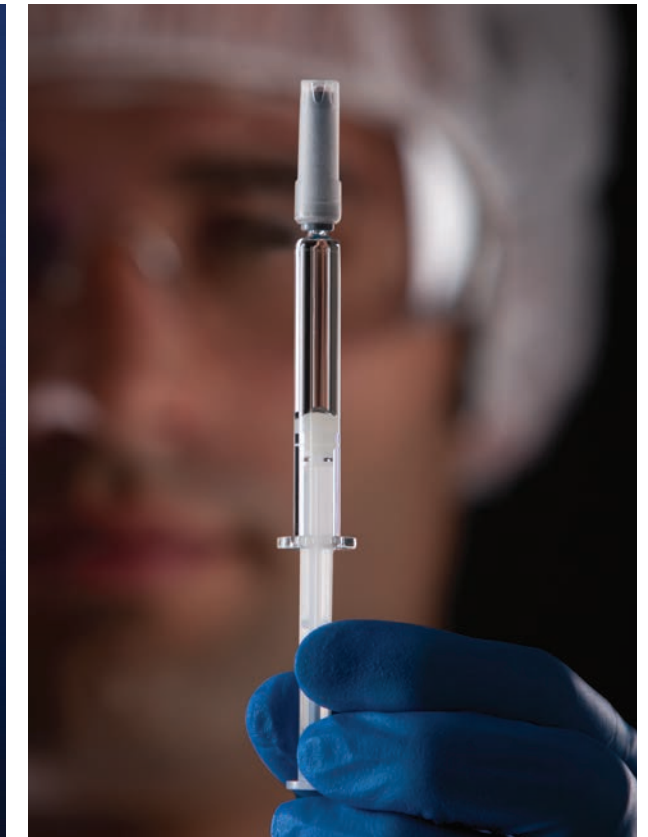
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CZ: The First Silicone Oil- and Tungsten-Free Insert Needle Syringe

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The Insert Needle Syringe system offers:

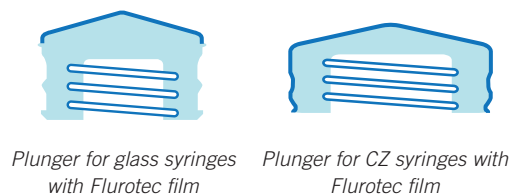
- Superior flange strength and breakage resistance
- Superior functional performance without silicone oil
- Reduced protein aggregation
- Suitable for high-viscosity products
- Consistent plunger release and travel forces over time
- Excellent dimensional tolerance
- Heat and cold compatibility
- Sterile and validated to help meet compliance requirements
- Direct introduction into aseptic and barrier isolator filling lines
- Compatibility with auto-injectors, including the West ConfiDose® system



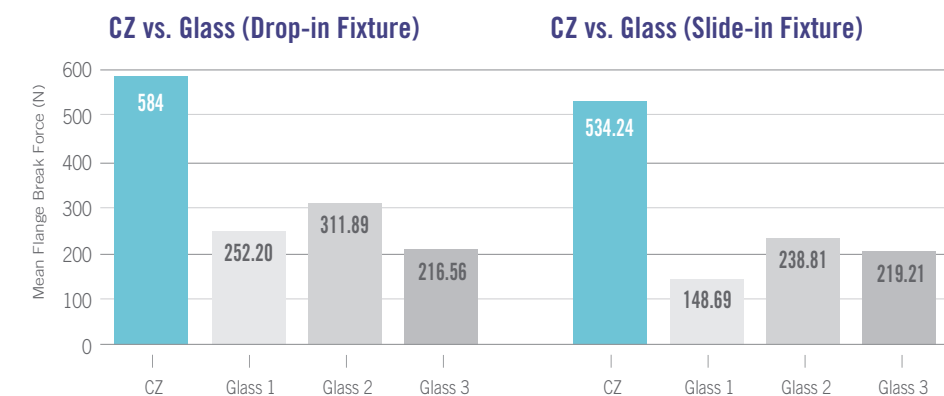
CZ Insert Needle Syringe System

The CZ Insert Needle Syringe system was designed to maintain purity, integrity and efficacy of premium biopharmaceutical therapies. The system minimizes the potential contamination issues associated with glass, in turn reducing the resulting risk of product waste, delays and possible recalls.

Daikyo Fluotec® barrier film is applied to the insert needle syringe plunger. Fluotec helps minimize extractables and leachables, while providing superior functional performance without silicone oil.



CZ's Superior Syringe Flange Strength Tested



CZ barrels consistently outperformed glass in drop-in and slide-in mechanical force tests comparing 1 mL CZ barrels to 1 mL glass barrels from three glass suppliers.



Off the Shelf or Custom, CZ Vials and Bulk Containers Outperform

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Vials and Bulk Containers

High Performance, Low Interaction

Daikyo Crystal Zenith vials and bulk containers are high quality, transparent, break resistant container closure systems that help maintain the stability, purity and efficacy of drug products. CZ's low reactivity reduces the risk of drug contamination, and unlike glass, CZ containers don't form flakes or lamellae.

Compatible with extreme temperatures, CZ is a superior alternative for biopharmaceutical drug products requiring cold storage or shipping.

All CZ vials and bulk containers are manufactured in an ISO Class 7 cleanroom environment and 100% camera vision inspected. Options for R&D include screw-cap containers for bulk storage, and vial-based container closure systems for use from preclinical trials through commercialization.

CZ vs Glass: Eliminating Delamination Risk

Glass vials can delaminate, allowing particulates to contaminate medications. This is likely to occur in parts of glass vials that have been flamed during manufacturing, such as the base or shoulder, and is especially prevalent with high pH medications, such as many biologics, biopharmaceuticals and other new and advanced therapies. CZ vials are an excellent solution. Unlike glass, CZ's unique polymer will not delaminate.

No Delamination in CZ Photomicrograph Contact Surface – 57 Days @pH10



Glass Vial



Crystal Zenith Vial



CZ Luer Lock Syringes: Quicker Time to Market; Significantly Lower Risk

CZ Luer Lock Syringes Offer:

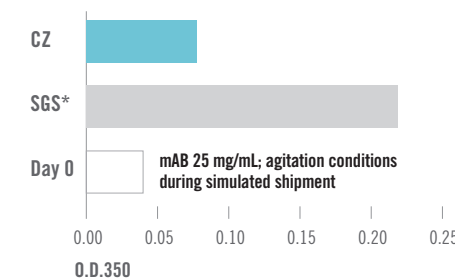
- Superior performance without silicone oil
- Reduced protein aggregation
- Suitability for high-viscosity products
- Predictable plunger release and travel forces over time
- Direct introduction into aseptic and barrier isolator filling lines
- Excellent dimensional tolerance
- Heat and cold compatibility
- Superior flange strength
- Sterile and validated to help meet compliance requirements
- Effective, sterile delivery when coupled with a standard needle or delivery device
- Fit standard devices, including the West NovaGuard™ SA safety needle



CZ Luer Lock Syringes

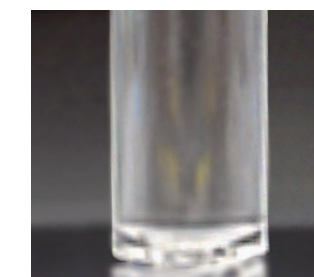
CZ luer lock syringes fit a variety of standard devices, with superior strength and protection compared to glass. Daikyo Flurotec® barrier film applied to the plunger and tip cap helps minimize extractables and leachables and provides superior plunger performance without silicone oil. For customers, Flurotec film helps reduce the risk of contamination.

Silicone Oil Free, CZ Syringes Minimize Aggregation

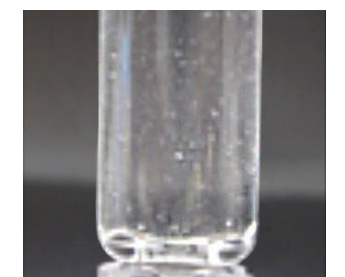


*Siliconized glass syringe.

Silicone Oil | Cosmetic Issue | Compatibility Issue | Safety Concern



CZ Syringe
No Silicone Oil



Glass Syringe
Siliconized

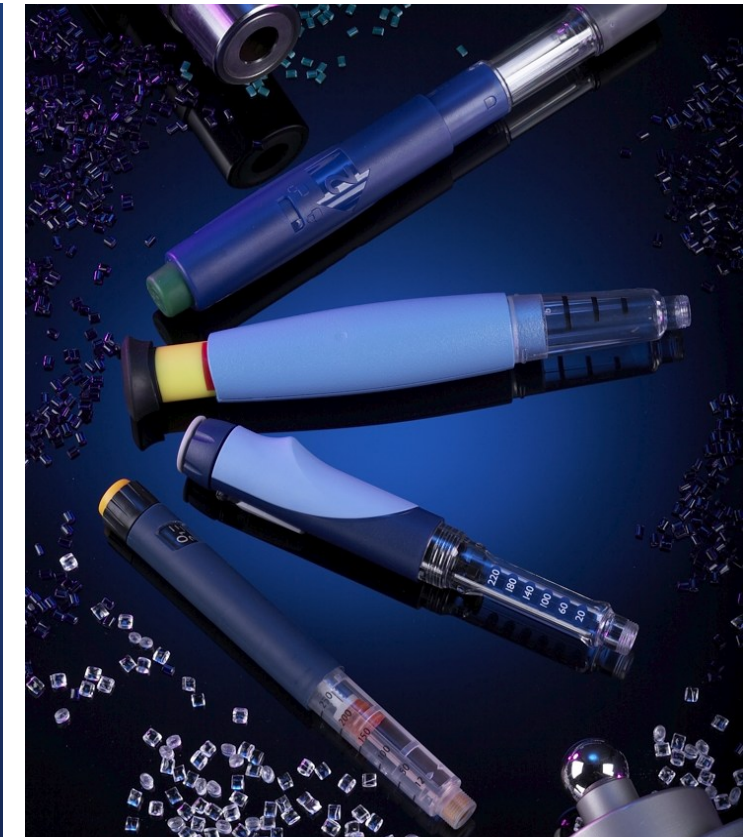
Characterization of Protein Aggregation & Adsorption on Prefillable Syringe Surfaces; Reza Esfandiary, Sangeeta B. Joshi and C. Russell Middaugh, University of Kansas; and Vinod Vilivalam, West Pharmaceutical Services, Inc.; 2008.

CZ Cartridges: Predictable, Reliable, Versatile in a Variety of Devices

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CZ Cartridges Offer:

- Tight dimensional tolerances inside and out
- Consistent fit and predictable performance in devices
- Suitable for auto-injectors and pen delivery systems
- Predictable travel forces
- Superior barrier protection
- Suitable for high-viscosity drugs
- Applicable for long-term or cold storage requirements



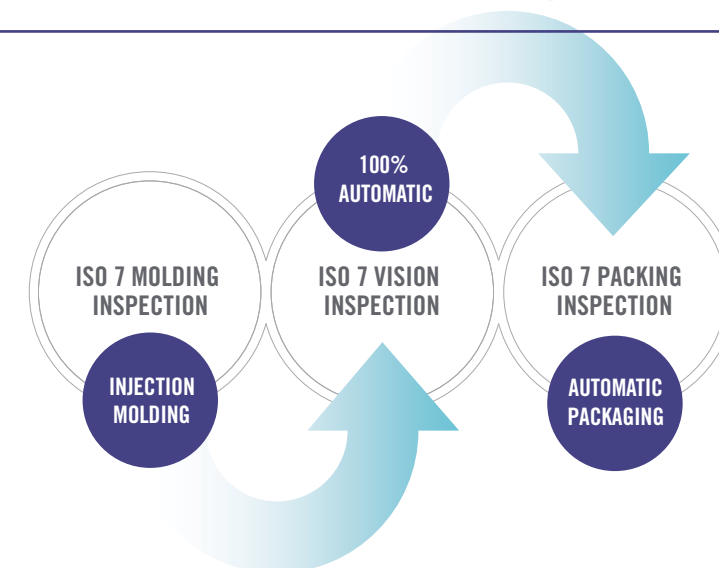
CZ Cartridges

Cleanroom Manufactured, 100% Camera Vision Inspected, Delivered Sterilized



Delivery devices such as multi-use pens demand cartridge technology that's predictable and safe, with tight dimensional tolerances, and often suitable for high-viscosity drugs and long-term or cold storage.

CZ cartridges meet these needs. Developed for the demands of the growing number of biologics in use in home-based auto-injector treatment, CZ cartridges combine the superior performance of the CZ polymer with predictable functionality, safety and compatibility with a variety of devices.



Custom Systems, Competitive Advantages

Every day, West is working by our partners' side to design and manufacture drug packaging and delivery systems that will bring their drugs from concept to patient more efficiently, reliably and safely. We support our partners with:



EXPERIENCE: More than 90 years of experience solving problems and creating better processes and products



EXPERTISE: Extensive pharmaceutical industry knowledge and regulatory expertise with links to industry leaders



COLLABORATION: Every step of the way from concept to commercialization



UNDERSTANDING: Solutions for the challenges and pressures of a global market



CARE: We understand that our partners trust us with their most valuable assets and assume that responsibility with the highest respect



Innovation and Collaboration

West has a long-standing tradition of working with our client partners to create custom delivery system solutions. We welcome the opportunity to help address your specific needs.

Within an increasingly complex competitive environment, a drug's delivery system can be a key point of differentiation, just as thoughtful, user-friendly design can be a significant benefit to patients managing serious conditions.

One of CZ's core strengths is design flexibility. Complex shapes and configurations, and custom sizes and unique solutions that would not be possible with glass can be achieved relatively easily with the CZ system.

CZ: Expanding the Capabilities of Delivery Systems

For example, a drug might require a specialized syringe barrel or a custom molded finger grip in its delivery system. A syringe or cartridge intended for use in a self-injection system may require extremely tight dimensional tolerances. An injection system may require an inserted rather than adhered needle or a manufacturing process free of tungsten.

When West developed and tested the SmartDose® electronic wearable injector, engineers built it around a Daikyo Crystal Zenith cartridge.

CZ's superior performance, dimensional tolerances, versatility and predictability are important reasons the SmartDose electronic wearable injector is uniquely capable of meeting the requirements of high-value biologics.

Superior Products; Exacting Manufacturing Standards



To maintain the highest quality standards, West manufactures the 1 mL Crystal Zenith insert needle syringe in an ISO Class 7 cleanroom.

Higher Performance, Lower Risk

Daikyo Crystal Zenith® is the delivery standard for pharmaceuticals in Japan, in use in over 26 products. CZ is quickly gaining traction in Europe and the US on the strength of performance advantages and potential for risk—and associated cost—reduction.

West maintains two dedicated ISO 7 cleanrooms for automated manufacturing and microbiological and functional testing of Crystal Zenith, along with additional climate-controlled and monitored warehouse space.

CZ products are manufactured by West in Scottsdale, Arizona, and by Daikyo Seiko, Ltd., in Japan.

West 
By your side
for a healthier world™



The technologically advanced Daikyo Crystal Zenith polymer is the lifecycle solution for next-generation biologic and biopharmaceutical treatments.

A custom formulated cyclic olefin polymer, CZ helps ensure that your medication is as pure, safe and effective when it reaches your patients as it was when you developed it.

High break resistance

- Stronger than glass, CZ can withstand tremendous force, limiting the delays, costs and potential recalls associated with breakage in production, shipping or use.

Chemically stable

- CZ was custom formulated to limit chemical interactions, even under long-term storage. No delamination, lamellae, extractables or leachables means your product maintains its purity and efficacy.

Compatible with heat and cold; wide pH range

- CZ is suitable for products requiring cold shipment, cryogenic storage or steam autoclave sterilization, and maintains stability even with high pH formulations.

Silicone oil and tungsten free; high viscosity compatible

- The superior barrier protection of Daikyo Flurotec® film applied to the plunger means CZ syringes provide high performance—even with high-viscosity medications—without silicone oil. Tungsten is not used in the syringe production process either, eliminating another potential source of contamination.

Exacting tolerances; customizable shapes, sizes and configurations

- CZ vials, syringes and cartridges can be manufactured to extremely tight tolerances, for performance, production and dosing peace of mind. More versatile than glass, CZ can meet almost any custom need.

An innovative solution

- The CZ system demonstrates Daikyo's and West's commitment to developing breakthrough solutions for complex drug containment and delivery needs. How can we help you?

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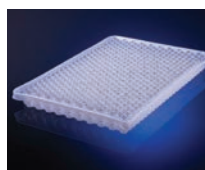
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Get All the Benefits of Using Daikyo Crystal Zenith® (CZ) Right From the Start.



CZ RU (Ready-to-Use) vials

- 0.5 mL conical
- 2 mL – 13 mm
- 5 mL – 20 mm
- 10 mL – 20 mm
- 50 mL – 20 mm
- 100 mL – 32 mm
- Tray configuration
- E-beam sterilization



CZ Bulk containers

- 0.5 mL to 250 mL
- Customizable
- Tray configuration

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High-Performance CZ Vials and Bulk Containers

CZ vials are ideal for:

- Biotechnology Drugs
- Small Molecules
- Cell Therapy
- Radiopharmaceuticals

- No Delamination
- Compatibility with High pH Products
- Break Resistance on Transport, Storage and End-User Handling
- Reduced Peptide/Protein Absorption
- Allow Cold and Cryogenic Storage and Shipment



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High Performance With Medications, High Break Resistance in Use



Available in luer lock and insert needle configurations, Daikyo Crystal Zenith® syringes offer high break resistance and superior performance without silicone oil, glue or tungsten.

Suitable for Sensitive Proteins

- No silicone oil applied to the barrel
- Insert needle: glue- and tungsten-free manufacturing
- Very low particle levels
- Flurotec® barrier film on the plunger and tip cap

Break Resistant

- No loss of high-value product during manufacture/transport
- Increases end-user safety
- Improves autoinjector functionality

High Functional Consistency

- Tight dimensional control with low dimensional variability
- Consistent gliding forces support use in delivery devices
- Components are 100% vision inspected, 100% x-ray inspected and 100% needle occlusion tested

Design Flexibility

- Very low restrictions for shapes and volumes
- Novel forms to overcome crowded device market
- Single-cavity prototyping available

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CZ Product Line

CZ RU (Ready-to-Use) Sterile (e-beam) Nested

CZ RU 1 mL Long Insert Needle 27G 1/2" Regular Wall and Thin Wall

- West 7028/55GY NS
- Daikyo D7-2 NS
- West 7028/55GY RNS

- CZ RU 1.5 mL insert needle

- CZ RU 1.0 mL luer lock
- CZ RU 5 mL luer lock

CZ Bulk Syringes

- 0.2 mL to 150 mL custom formats

- Luer lock and luer tip

- Bulk/rondo tray/custom format



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High-Performance Cartridges

Daikyo Crystal Zenith® Cartridges for Standard and Custom Uses



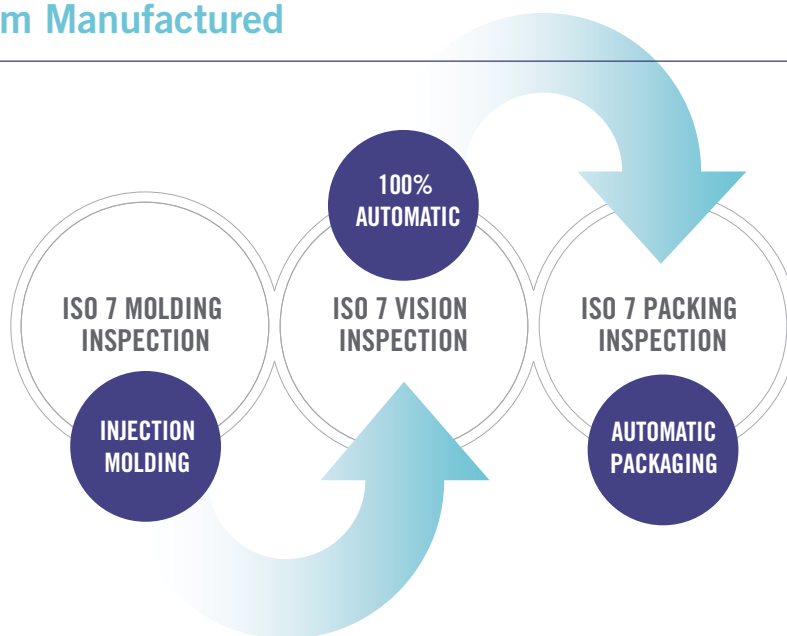
Predictable Functionality in a Variety of Devices

- 1 mL and 3 mL ISO cartridge
- Silicone oil free
- Superior barrier protection with Flurotec® film—septum and piston
- Sealable by plastic cap with inner liner
- Standard metal seal
- Multi-puncture elastomer formula
- Superior break resistance
- Custom design possible
- Predictable travel forces
- Suitable for high-viscosity drugs
- Applicable for long-term or cold storage requirements
- CZ RU SmartDose® cartridge



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Cleanroom Manufactured



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