

Daikyo Crystal Zenith® Prefillable Syringe System: The Market's First Silicone-Free, Ready-to-Use System

West has introduced the market's first silicone-free, ready-to-use prefillable syringe system. The Daikyo Crystal Zenith® syringe offers pharmaceutical and biopharmaceutical companies a total system solution that can mitigate the risks associated with glass syringes.

"More drugs are coming to market in prefillable syringe systems," said Mike Schaefer, Vice President,

Marketing, Europe. "High-value drugs require a delivery system that will protect their potency from the time they are filled to the time of administration. The characteristics of the Crystal Zenith syringe are superior to glass and will provide important benefits to pharmaceutical and biopharmaceutical companies, the people who administer the drugs and, most important, for patients."

West introduced the Crystal Zenith prefillable syringe system to the European market at Interpack in April. The company's first offering is a 1mL luer lock system that is designed for packaging and administering large-molecule biopharmaceuticals and vaccines.

The syringe barrel is manufactured from Crystal Zenith, a proprietary cyclic olefin polymer developed by Daikyo Seiko, Ltd., that is market-proven in Europe, Japan and the United States. Crystal Zenith is break resistant, which helps reduce product loss during filling, shipping, storage and administration. The material is highly transparent and drainable, can be autoclaved at 121 °C and has excellent low-temperature characteristics, including tolerance of freeze drying and liquid-nitrogen exposures.

The Crystal Zenith prefillable syringe system includes a piston and nozzle cap with Daikyo Flurotec® barrier film on the drug contact surfaces. Flurotec film imparts lubricity, so there is no need to apply free silicone oil to the syringe barrel or piston to enhance functionality. As a result, manufacturers can eliminate the presence of silicone oil from the syringe barrel and piston transferring to the drug product, a cause of protein aggregation and a possible source of immunogenicity risk and product returns. More importantly, the



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absence of silicone oil dramatically reduces the age-related variability of the Crystal Zenith syringe system's functional properties compared to systems currently in the market.

To decrease the risk of incompatibility between the components and the drug, Flurotec film provides an effective barrier against organic and inorganic extractables. The fluorocarbon film reduces sorption of the drug product and improves drainability.

The combination of a Daikyo Crystal Zenith syringe barrel or cartridge and a fully laminated Flurotec piston creates a unique silicone-oil-free system that provides consistency in the critical functional properties of piston release and travel force, making the system the ideal choice for auto-injector applications.

Daikyo Seiko manufactures the Crystal Zenith syringe system at its facility in Japan using automated, world-class processes in a clean room environment. The components are vision inspected for a virtually defect-free product. Daikyo and West worked together to develop a packaging system that is appropriate for introducing the pistons and syringe barrels directly into aseptic and barrier isolator filling lines.

Daikyo Crystal Zenith® and Daikyo Flurotec® are registered trademarks of Daikyo Seiko, Ltd.

The Defect-Free Solution

To help mitigate packaging system risks, West is pleased to offer its innovative Envision™ components.

West employs technically advanced, automated vision inspection systems to ensure that each item packed for delivery to your facility meets enhanced quality specifications for visible and subvisible particulate and contamination. West will work with you to design and validate a closure component from the output of this procedure that is developed to meet your specific needs.

Envision components are inspected for:

- Loose and embedded contamination
- Trimming defects
- Molding defects
- Hair and fiber
- Other defects specific to a particular product or customer specification

Here's how you can benefit from envision syringe plungers and stoppers:

- Reduce the occurrence of finished final drug product loss by component quality issues
- Improve manufacturing processes by optimizing throughput
- Position your company as a high-quality solution for your customers
- Help control manufacturing costs through:
 - Reduced waste
 - Reduced rework
 - Reduced need for supplementary resources such as QA, engineering and production planning

To learn how Envision components can provide a virtually defect-free component solution for your manufacturing operation, call your West account manager or a Technical Customer Service Representative.

Envision™ is a trademark of West Pharmaceutical Services, Inc., in the United States and other jurisdictions.

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Westar® RS Lined Seals:

The Lined Seal Solution for Aseptic Drug Processing

In today's manufacturing environment, regulatory guidances encourage filling operations to utilize clean components in high-quality environments. To meet these guidances, pharmaceutical manufacturers worldwide have relied on packaging components designed and manufactured by West. Westar RS (ready-to-sterilize) lined seals provide a clean component solution to help pharmaceutical companies mitigate risk and meet manufacturing guidances.

Westar RS lined seals are manufactured to strict specifications for endotoxin and bioburden, provide effective control for particulate, and help assure consistent component preparation.

Customers receive Westar RS lined seals as a ready-to-sterilize product; the seals do not require further washing. After sterilization, the seals are ready for capping.

Westar RS lined seals are available in standard cartridge sizes (7.5mm, 8mm and 11mm) and vial sizes (13mm and 16.5mm).

To learn how to incorporate Westar RS lined seals into your manufacturing process, contact your West account manager.

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