

## State-of-the-Art Elastomeric Components for Prefillable Syringes

**The recent growth in demand for elastomeric components such as plungers, needle shields and tip caps for prefillable syringe systems is being driven by the growth of high-value, sensitive drugs. With the increased sensitivity of many drug products, the requirements for clean delivery system components and compatibility between components and the drug product have accelerated. To meet the requirements for high-value drugs and to mitigate the risk of packaging-related failures, West offers high-performance packaging components for prefillable syringes.**

**With more than 80 years' experience, West Pharmaceutical Services is the source for parental packaging components, technical support and analytical laboratory services. West applies its knowledge of pharmaceutical packaging and regulatory-driven laboratory testing to help biopharmaceutical companies avoid risks in new product development and get to market without undue delay.**

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### Barrier Coating for Syringe Plungers

West FluroTec® film, applied to the drug contact side of syringe plungers, provides an effective barrier against organic and inorganic extractables, minimizing the interaction between the drug and the plunger while maintaining plunger seal integrity. FluroTec can reduce the leaching of extractables into the packaged drug and minimize the adsorption and absorption processes, which helps avoid the risk of product loss and failure during long-term storage. This benefit helps protect the drug's strength and prolong shelf life. Additionally, the FluroTec film provides very good sliding force.

West FluroTec plungers for prefillable syringes are designed according to the ISO 11040 suggestions for glass dimensions part 4, and are available in:

- 1 mL long
- 1 mL standard
- 5 mL standard
- 10 mL

Additional sizes and configurations are available on request.

### Lubricity Coating for Plungers

Among the characteristics that must be evaluated when selecting a plunger for a prefillable syringe system are break-loose force, sliding force and the presence of free

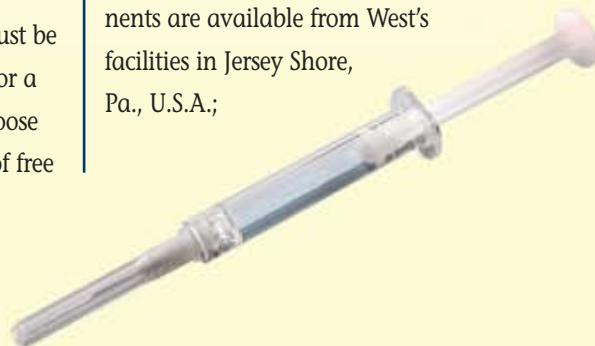
silicone oil. To achieve acceptable functional characteristics and low silicone oil, West offers plungers treated with a combination of FluroTec film and B2-Coating. B2 provides excellent gliding properties without free silicone oil. B2 is a cross-linkable coating that is sprayed on the plungers. B2-Coating helps reduce the amount of silicone oil particles in the packaged drug, which can help protect the drug product from aggregation and loss of activity.

B2-Coating can be applied to any of West's elastomeric formulations and does not alter the plunger's chemical properties.

### Validated Final Treatment for Plungers

To ensure consistently clean components for their filling operations, many pharmaceutical manufacturers specify Westar® RS ready-to-sterilize plungers for prefillable syringe systems. By specifying Westar RS plungers, biopharmaceutical manufacturers may be able to reduce costs associated with capital expenditures for plunger preparation and validation studies for washing and, if applicable, siliconization.

The Westar RS process is a validated procedure for manufacturing ready-to-sterilize components. Westar RS components are available from West's facilities in Jersey Shore, Pa., U.S.A.;



LeNouvion, France; Eschweiler, Germany; and Singapore. To expedite drug application approvals, each site is supported by its own Type V Drug Master File.

Westar RS components are tested and certified to meet specified bioburden, bacterial endotoxin, particulate and, if applicable, silicone oil levels.

Westar RS processed syringe components meet the following specifications:

- Bacterial endotoxin levels of 0,25 Endotoxin Units (EU)/ml
- Bioburden level of 5 Colony Forming Units (CFU) per 100cm<sup>2</sup> surface area
- Particulate matter content 3,4 PCI (Proved Clean Index)
- Specified silicone level when applied

## Use-Specific Packaging

Plungers for prefillable syringes are shipped in a bag appropriate for the customer's sterilization process. Ready-to-sterilize plungers are shipped in a bag that can be placed directly into a sterilization unit. West can also pack the plungers in bags that can be docked to isolator ports.

Combining the FluroTec and B2-Coating with a validated Westar RS or Ready-to-Use process brings the highest dimension of value to your products.

# New Needle Shields and Tip Caps for Resisting Ozone Degradation



Cracking has long been a problem with elastomeric needle shields and tip caps. Cracked components can cause leaks that could result in a loss of drug potency, and they pose a safety risk to the person administering the drug and to the patient. What's more, cracked needle shields and tip caps have resulted in costly product recalls.

## The Solution

Formula 7028/55 is West's new formulation for needle shields and tip caps. Components manufactured from the new elastomer are highly resistant to ozone cracking and are much less susceptible to frosting or hazing.

Formula 7028/55 is a polyisoprene thermoset-based elastomer. In ozone cracking tests, components molded from Formula 7028/55 have out-performed other polyisoprene and natural rubber elastomers.

Components molded from Formula 7028/55 are compatible with steam, gamma and EtO sterilization and are compliant with Ph.Eur. Type I and with applicable USP standards.

## The Characteristics

- High resistance to ozone cracking
- Free of dry natural rubber, nitrosamine and precursors
- Compatible with steam, gamma and EtO sterilization
- Non-cytotoxic (ISO 10993-5 test)
- Low coring properties
- Low in extractables
- No MBT and derivatives
- Low susceptibility to frosting and hazing

## The Product Offering

The following products molded from Formula 7028/55 are readily available:

### Needle Shields

- 27G, ½ inch
- 25G, ⅝ inch

### Tip Caps

- Luer Lock
- Luer Cone

West will work with customers to develop applications for other uses.

**For further information, please contact Claudia Petersen, Senior Manager, Biotechnology.**

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