

Safety by Design: Improved Seal Technologies

Pharmaceutical companies face a delicate balancing act in bringing products to market. They have to manage their costs tightly, reduce manufacturing cycle time and maintain the highest possible quality standards. Further, their processes must adhere to regulatory guidances that encourage using clean components in filling operations. They can't afford to expose their drug products to risks associated with unsuitable components.

To help comply with regulatory guidances, pharmaceutical manufacturers rely on packaging components from West. In this issue of *The Source*, we'll introduce West's superior seal technologies that can protect the safety of your packaged product.

West's Flip-Off® CCS (clean, certified, sterilized) seals help keep contamination from getting into the vial and protect the injection site on the vial stopper.

West Spectra™ ID seals can enhance patient safety, combat drug counterfeiting and help keep your supply chain secure.

Westar® RS Lined Seals are the solution for aseptic drug processing. The seals are manufactured and processed to strict specifications for endotoxin, bioburden and provide effective control for particulate.

West's Seal Technologies – Enhanced Protection for your Drug Product

The Solution for Aseptic Processing

According to the United States Food and Drug Administration (FDA) guidance for aseptic processing, a vial is considered to be closed only after the seal is applied and crimped to the vial. The FDA's position, in combination with a stringent clean manufacturing concept, requires pharmaceutical seals to be cleaned and sterilized prior to use. The EC Guide of GMP, Annex 1, states: "The container closures system for aseptically filled vials is not fully integral until the aluminium cap has been crimped into place on the stoppered vial." Furthermore, it emphasizes the crimping to be done in a Class A environment.

To address biopharmaceutical manufacturers' needs for secondary closures in aseptic filling operations, West offers Flip-Off® CCS – clean, certified and sterilized – seals. These seals undergo the same exacting manufacturing process as standard West Flip-Off seals. In addition, the validated manufacturing process of the Flip-Off CCS seals includes washing the plastic buttons in a pharmaceutical washer before their assembly to the coated aluminium shells. The special abrasion-minimizing coating and the button washing process allows West to provide a low particle burden specification equal to or lower than a Proved Clean Index of 10. The use of gamma stable polypropylene resin buttons

also allows West to gamma sterilize the Flip Off CCS seals. This, in combination with a defined bioburden of equal to or less than 5 colony forming units per 100cm² prior to sterilization, helps assure the reliability of the validated gamma irradiation process. The secure sterilization process and the improved cleanliness address requirements for capping vials in a clean room.

Flip-Off CCS seals are available in 13mm and 20mm sizes in a wide range of colours for appropriate product differentiation. Flip-Off CCS seals are double-packed in heat-sealed polyethylene bags. The bags are protected by an additional polyethylene bag to help reduce particulate at the customer's site. All these features and efforts show that Flip-Off CCS seals are specially designed to be used in a sterile manufacturing environment.



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Patient Safety and Supply Chain Security

Pharmaceutical companies design their drug products with patient safety in the forefront. Dosage and administration errors and product misidentification can be harmful to patients. With West Spectra™ ID seals, drug manufacturers can enhance patient safety, combat drug counterfeiting and keep their supply chain secure. West Spectra ID security technologies can be integrated directly into West Flip-Off seals.

West Spectra ID offers printing and embossing on the plastic button, providing overt messaging, immediate product recognition and product differentiation with a range of colour selections. Item-level information such as a vial's contents, product or brand name, dosage or strength of the product is clearly visible. Important information such as cautionary statements and storage instructions printed on the plastic button can enhance patient safety. Printing and embossing on the underlying aluminium

shell adds another layer of information, product authentication and patient safety as the information remains visible up to the point of drug product administration.

The Lined Seal Solution for Aseptic Drug Processing

Regulatory guidances encourage pharmaceutical companies to use clean components. West supports pharmaceutical companies with continuously improved processes to provide products of high quality standards. Westar® RS (ready to sterilize) Lined Seals provide a solution to help pharmaceutical companies mitigate risk and meet manufacturing guidances.

Westar RS Lined Seals are available in standard cartridge sizes (7.5mm, 8mm and 11mm) and vial sizes (13mm and 16.5mm). Westar RS Lined Seals are manufactured to strict specifications for endotoxin and bioburden, provide effective control for particulate matter and help assure consistent component preparation. Customers receive

Westar RS Lined Seals washed, rinsed in Water for Injection (WFI) and packed for direct introduction into steam sterilizers. After sterilization, the seals are ready for capping. Westar RS Lined Seals eliminate the need for washing and rinsing operations at manufacturer's sites.



Discover West's True Edge® Technology

High-speed filling of drug formulations requires reliable packaging components manufactured to precise specifications. TrueEdge seals are precision engineered to help prevent costly filling line interruptions caused by inconsistent cap dimensions.

In order to achieve uniform quality standards globally and assure standardized production, West developed TrueEdge® technology for manufacturing Flip-Off seals and other related products.

With TrueEdge technology, customers can be assured that their seals will meet tight dimensional standards. The TrueEdge process virtually eliminates skirt height variation, which helps promote successful crimping on high speed filling machines.

For the end user, TrueEdge technology provides a seal that is easy and safe to open. What's more, after the plastic button is removed, there are no rough edges that can catch a swab used to clean the injection site on the exposed stopper.

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