

## Because Clean Sealing Matters

# Flip-Off® Plus<sup>RU</sup> Seals

International regulatory guidelines have significantly influenced clean crimping processes for drug manufacturers. Use of unsuitable seals can have an impact on clean crimping procedures and create risks for patients.



### THE LATEST REGULATORY GUIDANCE

Not only do regulatory guidelines require vial-capping in clean rooms or sterile suites, in many markets, sterilization validation now requires a known bioburden level before sterilization.

### DRUG SAFETY AND PATIENT PROTECTION

There is uncertainty about the potential bioburden contamination resulting from introducing unsterile components into the clean crimping area and the effect on patient safety. Uncharacterized bioburden loads on seals may lead to a gap in product understanding and sterilization performance.



### INCREASING OPERATIONAL EFFICIENCY

Because filling machines are becoming faster and more efficient, crimping procedures may impact reject rates related to failures within the crimping and capping process. End-of-line rejects of finished drug product can reduce operational efficiency and increase total costs of ownership. Using high-quality, sterile packaging components ensures a stable crimping performance, which minimizes the risk of external contamination, line stoppages and equipment downtime.



### PROCEED WITH CONFIDENCE

High quality Flip-Off Plus<sup>RU</sup> seals are manufactured to have full validation of sterilization and packaging, including a comprehensive certification package. TruEdge<sup>®</sup> manufacturing technology allows consistent seal processing with reproducible smooth and even bottom edges. Flip-Off Plus<sup>RU</sup> seals are certified for bioburden and cleanliness, offering a high level of confidence in the clean crimping process to help protect the patient.



Talk to your West representative and choose the right option for your product, and ultimately, for your patients' health.

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### Clean, Validated, Safe Seals

- Meet regulatory guidelines with industry-proven clean crimping processing that includes a validated bioburden level
- Reduce the risk of variability and its potential effects on drug quality, safety and efficacy, as well as overall costs
- Increase operational efficiency
- Address requirements for high-speed filling and reliable capping success by using TruEdge® manufacturing technology
- Provide excellent machineability and help maintain closure integrity
- Sterile solution for immediate use
- Offer a high level of confidence in the clean crimping process to help protect the patient
- Validated RU packaging concept (shelf life and transit simulation)

### Flip-Off® Plus<sup>RU</sup> Seals Help to Ensure:

- Time-to-market
- Avoidance of cost issues
- Contamination-free drug products and decreased recalls
- Market leadership
- Higher reputation
- Operational efficiencies

For more information about Flip-Off® Plus<sup>RU</sup> seals, visit our website at [westpharma.com](http://westpharma.com).