



STOPPERS FOR VIALS

When filled and finished drug product is rejected due to visible and sub-visible particulates, the costs are high. Reduce this risk with cleaner, more consistent packaging components



Packaging Can Be A Risky Business

Contamination and particulate attributed to elastomer components and packaging can be a source of risk and variability, putting the quality of your drug product and the ultimate safety of your patients at risk. Sensitive pharmaceuticals and biopharmaceuticals demand high-quality packaging to maintain drug purity and efficacy.



Rejects and Recalls Can Be Costly

Product rejects impact your bottom line due to increased costs from investigating quality issues, wasting drug product and operational downtime.



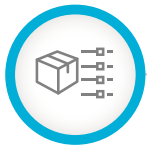
No Barrier is Unbreachable for a Leachable

FluroTec™ barrier film reduces leaching but it does not negate the need to conduct comprehensive extractables and leachables studies.



Regulatory Scrutiny Has Increased

Global regulatory concern over particulate and resulting actions are evident throughout the industry. Recent research has shown that 38% of FDA injectable drug recalls are due to particulate or lack of sterility attributable to container closure.¹



Quality Packaging Begins With Consistency

Selecting packaging components manufactured under the principles of Quality by Design offers reduced variability. Components that can be relied on to perform every time to the same exacting standards can help increase end-of-line product yields and reduce total cost of ownership. When you choose the highest quality elastomer components, you help meet the ultimate goal - patient safety.



Learn more about NovaPure stoppers [here](#).

1. <https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls> and <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/recalls-biologics> (Accessed February 14, 2025)

MITIGATE RISK WITH PREMIUM QUALITY

NovaPure® Stoppers for Vials

NovaPure stoppers address the most critical challenges of drug containment with:

- Tight visible and sub-visible particulate specifications
- Proven protection of FluroTec® barrier film
- Lot-to-lot extractables testing and analysis
- Rigorously controlled product dimensions

NovaPure stoppers for vials help you:

- Reduce quality issues associated with particulates
- Protect sensitive drug products with exceptional cleanliness and barrier properties
- Meet increasingly demanding regulatory standards
- Reduce Total Cost of Ownership

West offers enhanced transparency to NovaPure customers via:

- Access to a comprehensive library of process and product documents
- Key extractables reporting to monitor material consistency and minimize variability of leachables
- Regulatory support, including a Drug Master File in Common Technical Dossier (CTD) format for US & Canada



	Configuration	Quality Treatments
	13mm serum stopper	FluroTec® Barrier Film B2 Lubricity Coating Westar® RS Wash & RU Sterilization Processes Envision™ Full Vision Verification
	20mm serum stopper	
	13mm lyo stopper	
	20mm lyo stopper	

Contact West today at [westpharma.com](https://www.westpharma.com).