Overview of 4040 LyoTec® Stoppers



Designed with the Future in Mind



Ultra-low extractables & leachables protect
product quality while
providing broad drug
compatibility

Formula optimized for low moisture content to prevent cake degradation

Risk-mediated supply with strong inventory positions & qualified alternative sources of raw materials Well-characterized extractables inform decision-making & enable risk assessment

Optimized drying properties improve steam sterilization throughput & save time

Platform portfolio & global supply network strategy with strong West commitment

Low level of particulates achieved through both raw material selection & West processing

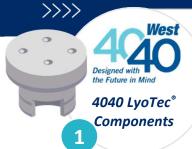
Compatibility with steam sterilization or gamma irradiation provides processing flexibility

Closed System
Transfer Device
(CSTD)
compatibility
testing performed





V



V

Westar® Select Quality Delivered to Your Door:

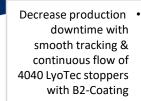
- · High-quality washed & sterilized components with validated processes
- Westar® processes globally recognized since 1995
- Total residual moisture ≤ 0.2% H₂O for 4040 LyoTec® RU stoppers



- Choose from STERILIZABLEBAG™ packaging or ported bag packaging options for production flexibility
- Save time with convenient, ready-touse (RU) steam sterilized stoppers or select Ready-to-Sterilize (RS)
- Reduce rejects & failures due to defects with West Envision™ verification option
- · Sterilize with steam or gamma irradiation (<45 kGy) to integrate into your manufacturing processes



· Simplify global supply chain management with stopper designs compatible with various blowback geometries





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through 4040 LyoTec stopper's igloo design - proven effective in eliminating stopper twinning

Optimize process performance •

Minimize clumping or sticking of • stoppers in the feeder bowl with LyoTec stoppers & B2-Coating



Feeder **Bowl**

Improve steam sterilization throughput with 4040 LyoTec component's optimized drying properties





Transport to Lyophilizer

 Increase stability on the vented vial during transport & the lyophilization cycle with this igloo design



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Lyophilization

costly clean-up -LyoTec stoppers do not stick to the pressure plates of the lyo chamber

Reduce downtime,

drug product loss &



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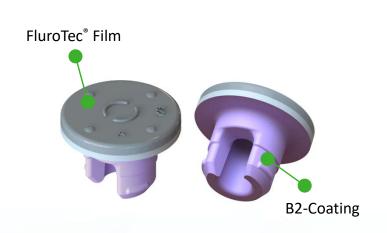
Transport to Capping

- Avoid potential contamination & loss of product due to stopper pop-up/pop-off during transport to capping.
- Rest assured during capping delays, 4040 LyoTec stoppers demonstrate container closure integrity without capping.



4040 LyoTec® Portfolio – Comprised of a State-of-the-Art Elastomer – Advancing Quality & Manufacturability





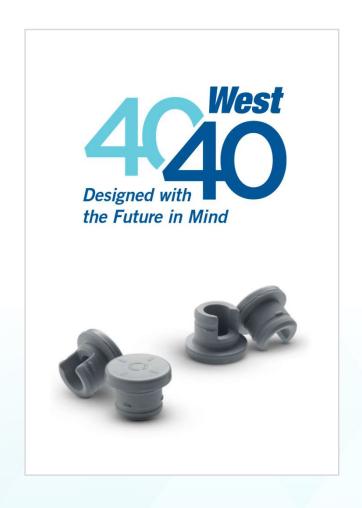
Igloo design eliminates mechanical twinning & increases stability on vial in the vented position

Size	STERILIZABLEBAG™ Packaging	Ported Bag Packaging	Finish	Quality Process
13mm (V-50-I)	Small - 1,000 Standard - 5,000	SSB - 8,000 GLC - 10,000	Ready-to-Sterilize	Westar [®] Select
				Envision [™] Verification
			Ready-to-Use	Westar® Select
				Envision [™] Verification
20mm (S-87-I)	Small - 450 Standard - 2,000	SSB - 2,000 GLC - 2,500	Ready-to-Sterilize	Westar® Select
				Envision [™] Verification
			Ready-to-Use	Westar [®] Select
				Envision [™] Verification

Speak to your West TCS or Sales representative to obtain product samples

Technical Reports & Knowledge Center Information







Technical Reports

- TR 2019/211: Evaluation of Container Closure Integrity for 4040/40 Lyophilization Stoppers
- TR 2019/212: Evaluation of Needle & Vial Adapter Compatibility for 4040/40 Lyophilization Stoppers
- TR 2019/215: Evaluation of Removal & Insertion Force for 4040/40 Lyophilization Stoppers
- TR 2021/237: Evaluation of Machine Performance of 4040/40 Lyophilization Stoppers
- TR 2021/238: 4040/40 Lyophilization
 Stoppers Aging and Gamma Irradiation
 Study



Supporting Information

- Formulation Characteristics for 4040/40 Gray
- Regulatory Compliance Bulletin for: 4040/40 Gray
- Sample Quality Certificate
- Uncontrolled Drawings
- Biocompatibility Package: 4040/40 Gray
- Regulatory Compliance Bulletins for FluroTec[®] Film & B2-Coating
- Probable Material Extractables List
- Extractable Elements Data Sheet*
- Nitrosamines Data Sheet*

*Available upon request



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