



OVERVIEW OF 4040 LYOTEC® STOPPERS

Designed with the Future in Mind



- Ultra-low extractables & leachables protect product quality while providing broad drug compatibility^{1,2}
- Ready-to-use stoppers released to a tighter standard moisture specification
- Demonstrated to be suitable for multi-dose pharmaceutical applications
- Well-characterized & documented extractables profile informs risk assessment²
- Designed for processing more consistently on fill-finish lines & minimizing risk of sticking to lyo shelves
- Platform portfolio strategy with global supply network and strong West commitment

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

Designed with

the Future in Mind

West

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- Compatibility with steam sterilization or gamma irradiation provides processing flexibility
- Closed System Transfer Device (CSTD) compatibility testing performed

4040 LYOTEC® PORTFOLIO COMPRISED OF A STATE-OF-THE-ART ELASTOMER

Advancing Quality & Manufacturability

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 Quality Envision™ Verification
			Ready-to-Use	Westar [™] Select Quality Envision [™] Verification
20mm (S-87-I)	Small - 450 Standard - 2,000	SSB - 2,000 GLC - 2,500	Ready-to-Sterilize	Westar [™] Select Quality Envision [™] Verification
			Ready-to-Use	Westar™ Select Quality Envision™ Verification

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

FluroTec® Film •—



4040 LYOTEC® COMPONENTS HELPING YOU THROUGH EVERY STEP OF THE LYOPHILIZATION PROCESS







Westar[™] Select Quality Level



Customize to Fit Your Needs



3 Simplify Inventory Management



- High-quality washed & sterilized components with validated processes globally recognized since 1995.
- Total residual moisture ≤ 0.2% H₂0 for ready-to-use (RU) 4040 LyoTec* stoppers.



- Optional West Envision® verification to reduce rejects and failures due to defects.
- Stopper designs compatible with various blowback geometries.

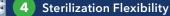


6 Decrease Production Downtime

- 4040 LyoTec stoppers with B2-Coating enable smooth tracking and continuous flow during aseptic filling.
- Optimize Feeder Performance



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



 Sterilize RS stoppers with steam or gamma irradiation (<45kGy) to integrate into your manufacturing processes.



7 Secure Stopper During Transport



Reduce Lyophilizer Downtime



Avoid Potential Contamination & Drug Product Loss

- Igloo Design improved the stability of the stopper in the vented position during transport and the lyophilization cycle.
- FluroTec* film applied to the top of the LyoTec stopper averts sticking to the lyo shelves.
- LyoTec stoppers reduce Lyophilizer downtime, drug product loss and costly clean-up due to spills.
- 4040 LyoTec stoppers design minimizes the risk of stopper pop-up/pop-off during transport to capping.

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References:

- 1. West Stability Report 741-SSR
- 2. West 541-EXR; Material Characterization available with CDA

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