



West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, PA 19341
www.westpharma.com

12/4/2023

Subject: West Receives FDA 510(k) Clearance for Vial2Bag Advanced® 13mm Admixture Device

Dear Valued Customer,

West Pharmaceutical Services, Inc. (West) is pleased to announce the United States Food and Drug Administration (FDA) 510(k) clearance of the Vial2Bag Advanced® 13mm admixture device, a universal^{1,2}, needle-free admixture device for immediate use IV drug prep.

We understand the importance of having the 13mm device as part of the portfolio of IV drug admixture devices and providing our customers with more solutions to admix drugs at the point of care (POC). West has worked in close collaboration with FDA, ISMP, and hospital pharmacists to ensure the 13mm device meets the highest standards for both safety and efficacy.

The addition of the Vial2Bag Advanced® 13mm admixture device complements our existing Vial2Bag Advanced® 20mm admixture device, with the two products providing options for the reconstitution and transfer of drugs using either a 13mm or 20mm vial and an IV bag before administration to the patient. The innovative, needle-free, and easy-to-use device is ideal for immediate use and can optimize pharmacy clean room time, while assisting in standardizing admixture systems to maximize the efficiency of point-of-care nursing.

Key features of the admixture devices in West's portfolio make them effective tools to assist healthcare providers in immediate use preparation, in accordance with USP <797>:

Innovative Design

The Vial2Bag Advanced® 13mm and 20mm admixture devices each have a dual channel design to provide dedicated fluid pathways into and out of the IV bag and an enhanced vial spike design that improves the connection to the drug vial³. In addition, the needle-free design helps to reduce potential needlestick injuries.

Optimal Patient Care

The devices provide a simple solution for just-in-time IV medication preparation, improving timeliness at point of care with easy-to-implement immediate use solution.

Effective Waste Reduction⁴

The devices can reduce drug and IV fluid waste⁴ and offer universal^{1,2} compatibility with all manufacturers' IV bags in 50mL, 100mL, or 250mL that contain an ISO standard IV port and are suitable for use with liquid and powder medications with standard 13mm and 20mm closure vials.⁵



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We appreciate your patience and are excited to introduce this new point-of-care solution for our customers and the patients you serve. We understand that a point-of-care solution is needed now more than ever in the current healthcare climate, and we are pleased to offer a solution to improve quality of care.

Keep the Orange and Blue in View

West uses the distinctive orange and blue colors - make sure you're benefiting from authentic West quality.



Please contact Progressive Medical Inc., West's exclusive US distributor for more information on the Vial2Bag Advanced® admixture devices.

Vial2Bag Advanced® 13mm admixture device will be officially launched at the [American Society of Health-System Pharmacists'](#) Midyear Clinical Meeting on Dec. 3- 7, in Anaheim, CA. Visit the Progressive Medical Inc. Booth #500 to learn more.

Sincerely,

Cindy Reiss-Clark
Chief Commercial Officer
West Pharmaceutical Services, Inc

Prescription use only. Intended for U.S. healthcare professional use only.

¹The Vial2Bag Advanced® 13mm and 20mm admixture devices are currently compatible with manufacturers' IV bags in 50mL, 100mL, or 250mL that contain an ISO standard IV port (ISO 8536-4 standard IV spike)

²Compatibility of the Vial2Bag Advanced® 13mm and 20mm admixture devices with all drug products has not been confirmed.



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³ As Compared to the now-discontinued Vial2Bag DC, which is no longer available in commerce and has been replaced with devices in the Vial2Bag Advanced[®] admixture device portfolio.

⁴ Study results yielded from a single-center retrospective analysis performed from June 2017 to July 2018 by an academic medical center using West's older Vial2Bag DC device, which is no longer commercially available and has been replaced with devices in the Vial2Bag Advanced[®] admixture device portfolio.

⁵ The Vial2Bag Advanced[®] 13mm and 20mm admixture devices are 510(k) cleared by the United States Food and Drug Administration (FDA). The use of the Vial2Bag Advanced[®] 13mm and 20mm admixture devices should not be interpreted as modifying, extending, or superseding a drug manufacturer's labeling recommendations for storage and expiration dating, unless otherwise limited by USP <797> compounding standards. Refer to drug manufacturer's labeling and use instructions for recommendations, USP <797>, and applicable institution policy for shelf life and sterility information of reconstituted product and admixture device compatibility. Compatibility of the Vial2Bag Advanced[®] 13mm and 20mm admixture devices with all drug products has not been confirmed. Do not use the Vial2Bag Advanced[®] 13mm and 20mm admixture devices with lipids. Failure to follow the instructions provided may result in inadequate medication reconstitution, dilution, and/or transfer, possibly leading to overdose or underdose and/or delay in therapy. Products shown are for INFORMATION purposes only and may not be approved for marketing in specific regions. Please contact your West Pharmaceutical Services, Inc. (West) representative for product availability.

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