

Vial2Bag Advanced® 13mm Admixture Device: Instructions for Use

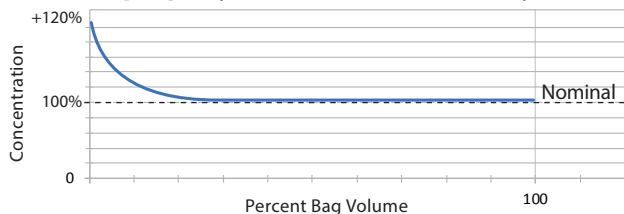
Indication for Use

- The Vial2Bag Advanced® 13mm admixture device is indicated to serve as a connection between a 50, 100 or 250mL IV bag, vial with 13mm closure, and an external IV administration set. The integrated vial adapter makes it possible to reconstitute and/or admix drugs prior to administration to the patient.
- Indicated for adolescent and adult patients only.

WARNINGS

- Do not omit dilution/mixing steps (Step 2)
- Failure to dilute and/or mix drug product may result in delivery variance of +120% of target concentration at beginning of delivery.

Improperly Mixed/Diluted Delivery Profile

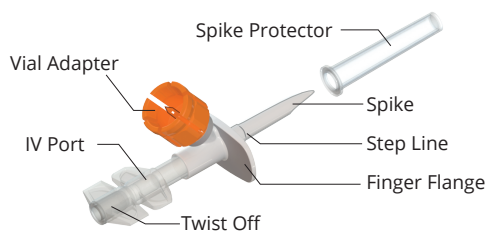


- Do not attach a Vial2Bag Advanced® 13mm admixture device to another Vial2Bag Advanced® admixture device.
- Do not use with IV bags other than those listed in the Indications for Use.
- Do not use with Lipids.

Precautions

- Federal (USA) law restricts sale of this device to physicians or on the order of a physician.
- Single-use only device.
- Do not use if device or package is damaged.
- Vial must remain attached to device to avoid leakage.
- After reconstitution, use in condition recommended by the drug manufacturer.
- Do not use in case of visible fragments in the system.
- Use by: see date on the device label.
- Reuse compromises safety and efficacy of the device and may cause contamination due to loss of sterility.
- Dispose of used device in accordance with applicable regulations.
- Re-sterilization may damage the device.
- Intended for use by Healthcare Professionals.
- Healthcare Professionals are responsible for adhering to the special consideration and Instructions of the prescribing information in preparation of the drug for administration.

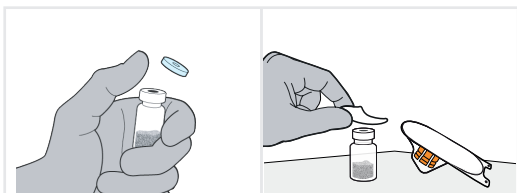
Vial2Bag Advanced® 13mm Admixture Device



- Contents are sterile and non-pyrogenic.

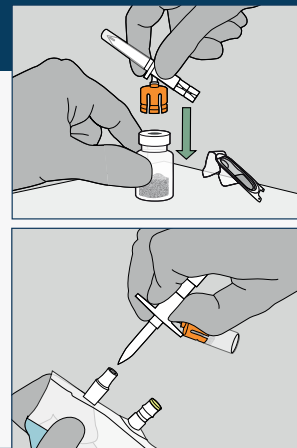
Preparations

- Remove cap from vial.
- Use aseptic technique.



1 ATTACH VIAL2BAG ADVANCED® 13mm ADMIXTURE DEVICE TO VIAL

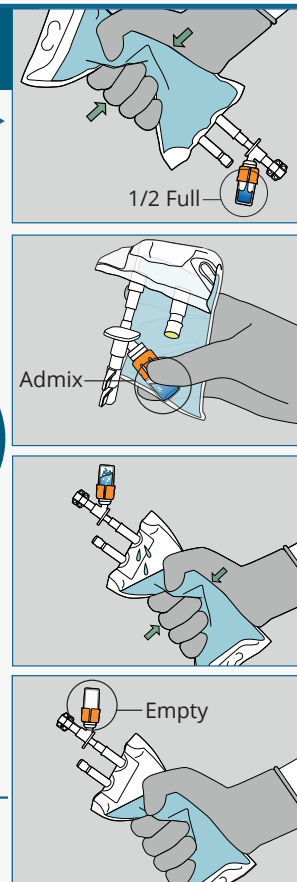
- Place vial on a stable, flat surface.
- Hold Vial2Bag Advanced® 13mm admixture device by the finger flange.
- Push Vial2Bag Advanced® 13mm admixture device into center of vial until it is attached.
- Remove Vial2Bag Advanced® 13mm admixture device spike protector.
- Spike Vial2Bag Advanced® 13mm admixture device into IV bag until it is up to the step line.



2 DISSOLVE OR DILUTE DRUG

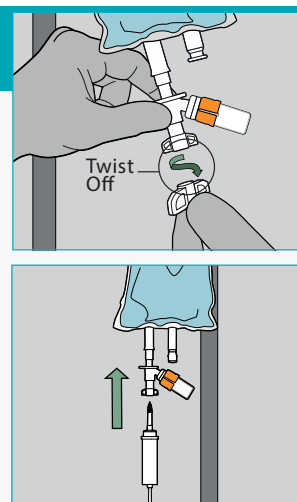
- Hold bag with vial down.
- Fill vial until half full by squeezing bag repeatedly.
- Fold the bag behind the vial.
- Hold vial and bag together.
- Admix per drug manufacturer's prescribing information.
- Hold bag with vial up.
- Empty vial by squeezing bag to force air into vial.
- Inspect vial for any remaining drug.
- Repeat until drug is dissolved and transferred.

REPEAT until drug is dissolved and transferred



3 CONNECT IV SET TO VIAL2BAG ADVANCED® 13mm ADMIXTURE DEVICE

- Twist off end to open IV Port.
- Remove protector from IV set spike.
- Spike the IV set per its instructions to the Vial2Bag Advanced® 13mm admixture device IV port until it is tightly secured.
- Empty drug from vial, if needed by repeating Step 2.
- Leave vial in place.
- Do not rotate vial.

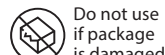


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Manufacturer: West Pharma. Services IL, Ltd. 4 Hasheizaf St. Ra'anana 4366411 Israel

Rx Only For prescription use only



Not made with natural rubber latex

Storage conditions:
• Storage temperature limit: 15°C - 25°C
• Keep away from sunlight

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STERILE EO Sterilized using Ethylene Oxide