

Vial2Bag Advanced™ 20mm Admixture Device: Instructions for Use

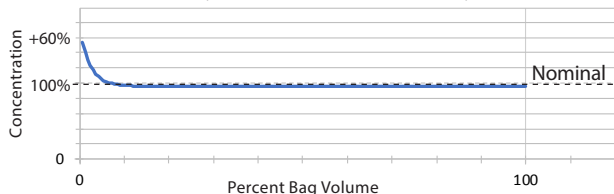
Indication for Use

The Vial2Bag Advanced™ 20mm Admixture Device is indicated to serve as a connection between a 50, 100 or 250mL IV bag, vial with 20mm 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.

WARNING

- Do not omit dilution/mixing steps (Step 2); failure to dilute and/or mix drug product may result in delivery variance of +60% of target concentration at beginning of delivery.

Improperly Mixed/Diluted Delivery Profile

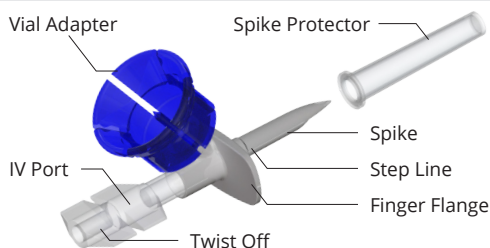


- Do not attach a Vial2Bag Advanced™ 20mm Device to another Vial2Bag Advanced™ 20mm Device.
- Do not use with IV bags other than those stated in the Indications for Use.
- Do not use with Lipids.

Precautions

- Single-use only device.
- Do not use if device or package is damaged.
- Contents are sterile and non-pyrogenic.
- Vial must remain attached to device to avoid leakage.
- Reuse compromises safety and efficacy and may cause contamination due to loss of sterility.
- Dispose of used device in accordance with applicable regulations.
- Re-sterilization may damage the device.
- After reconstitution, use in condition recommended by the manufacturer.
- It is the Healthcare Professional's responsibility to ensure any special considerations or instructions listed on the Package Insert of the drug are adhered to, in preparation of the drug for administration.

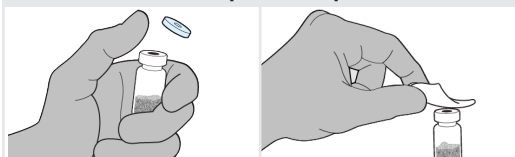
Vial2Bag Advanced™ 20mm Admixture Device



Preparations

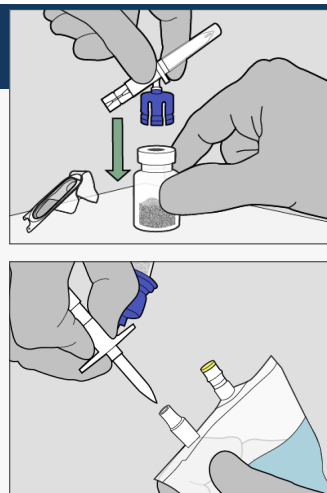
- Use aseptic technique.
- Remove cap from vial and disinfect per drug manufacturer's recommendations.

Use Aseptic Technique



1 ATTACH VIAL2BAG ADVANCED™ 20MM DEVICE TO VIAL

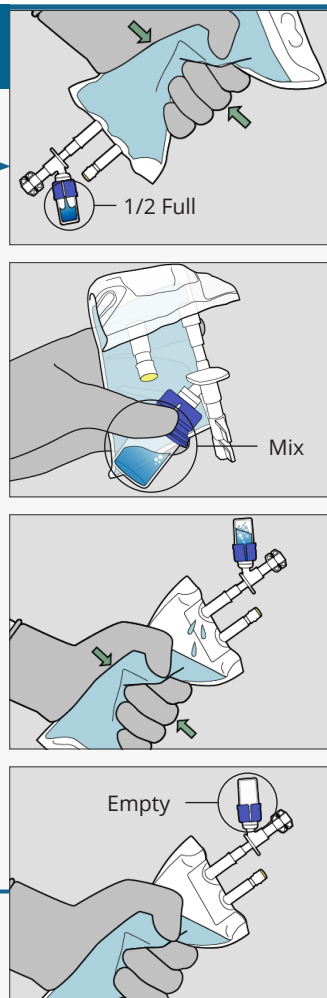
- Place vial on a stable, flat surface
- Hold Vial2Bag Advanced™ 20mm Device by the finger flange
- Push Vial2Bag Advanced™ 20mm Device into center of vial until it is attached
- Remove Vial2Bag Advanced™ spike protector
- Spike Vial2Bag Advanced™ 20mm Device into IV bag until it is up to the step line



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
- Mix per drug manufacturer's package insert
- 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™ 20MM 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™ IV port until it is tightly secured
- Empty drug from vial, if needed
- Leave vial in place
- Do not rotate vial

