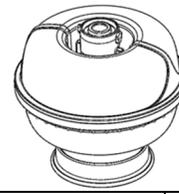


Halo®

Closed Vial Adaptor

Instructions for Use

REF CVA130
REF CVA200
REF CVA280



Description

The Halo® Closed Vial Adaptor is a closed vial access system intended for use in the reconstitution and transfer of antineoplastic and hazardous drugs from vial to patient in a healthcare setting. The system is compatible with standard vials having 13mm, 20mm, and 28mm Outer-Diameter (OD) necks, which correspond to CVA130, CVA200, and CVA280 models respectively. Sterile (ethylene oxide). Sterile unless package is damaged. Rx Only.

Indication for Use

The Halo® system is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Halo® system also prevents microbial ingress for up to 7 days.

Precaution

Do not use if protective caps are loose or displaced. When using drug vials with thick concave rubber stoppers, make sure that the white parts of the Closed Vial Adaptor and Closed Syringe Adaptor are in contact and that the pressure equalization works.

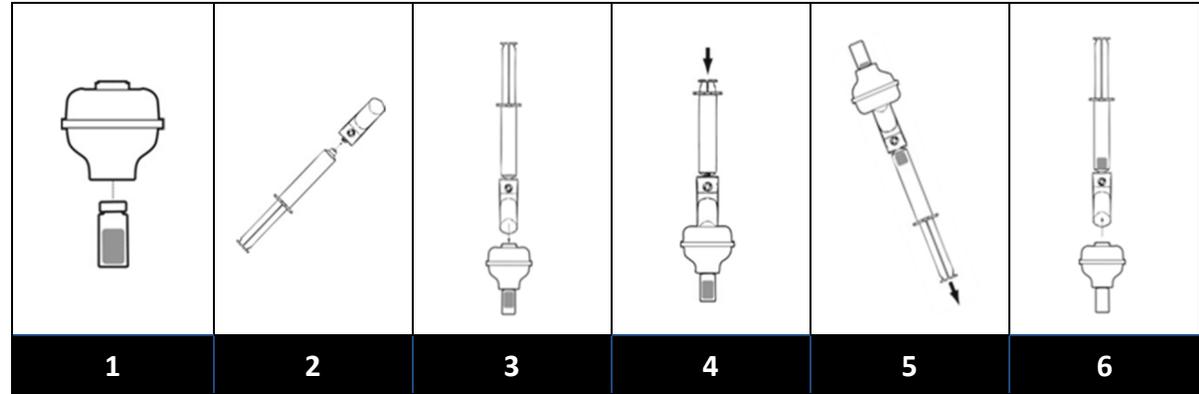
The sealing membranes are validated for up to 14 perforations. The performance of the sealing membrane may be reduced after multiple perforations. Discard after 14 perforations. Disinfect the CVA and CSA mating seals by swabbing with 70% isopropyl alcohol (IPA) or other validated method before each reconnection.

Warning

The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding a manufacturer labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and **USP compounding guidelines** for shelf life and sterility information.

Symbol Legend

REF	Catalogue number		Caution, consult accompanying documents
LOT	Batch code		Sterilized using ethylene oxide
	Do not re-use		Use by date
	Do not use if package is damaged	Rx ONLY	Caution: Federal law (US) restricts this device to sale by or on the order of a physician
	Temperature limits to which the device can be safely exposed		Manufacturer Corvida Medical, Inc.



Instructions

1. Disinfect the vial stopper by swabbing with 70% isopropyl alcohol (IPA) or other validated method. Allow to dry. Place the vial on a flat, solid surface. Remove the protection cap on the bottom of the Closed Vial Adaptor (CVA). Center the CVA over the vial. Push down firmly until the CVA is fully seated over the vial cap and neck. The CVA is fully seated when you feel it snap on the vial. The full seating establishes that the permanent CVA-to-vial connection is completed.
2. Draw a volume of air equivalent to the dose or required volume of diluent into a luer-locking syringe. Connect the luer-locking tip of the syringe to the Closed Syringe Adaptor.
3. Hold and Push the Closed Syringe Adaptor down onto the connection interface until fully engaged.
4. Keeping the vial upright, push the air or the diluent into the vial. The expansion chamber will inflate.
5. Invert the system and while holding the Closed Vial Adaptor withdraw the plunger of the syringe to draw the drug. The expansion chamber will deflate.
6. Pull the Closed Syringe Adaptor to separate from the connection interface.
7. Dispose without disconnecting the Halo® components.

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FRESENIUS KABI
 Fresenius Kabi USA, LLC
 Three Corporate Drive
 Lake Zurich, Illinois 60047
 www.fresenius-kabi.us
 +1 800-933-6925