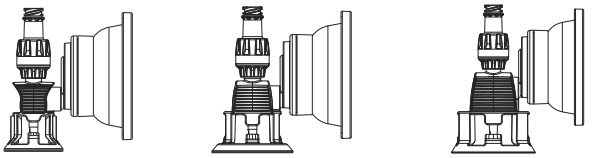
YUKON MEDICAL

Arisure® Closed Vial Adapter

REF **YM101** REF **YM102** REF **YM054**



13mm	20mm	28mm
Priming Volume: ~0.11 mL	Priming Volume: ~0.11 mL	Priming Volume: ~0.12 mL

Indications for Use

The Arisure Closed Vial Adapter is intended for use by healthcare professionals in a wide variety of healthcare environments including hospitals, healthcare facilities, and pharmacies for reconstitution or dispensing of medication and as a component of the Arisure Closed System Drug Transfer Device (CSTD). The Arisure Closed Vial Adapter is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents. When used with the Yukon Medical Arisure Closed Male Luer, the Arisure Closed Vial Adapter supports a drip-free, dry disconnection.

Precautions

- Follow standards of practice and facility policies and protocols for safe handling and disposal of hazardous drugs. The Arisure Closed Vial Adapter should be used in concert with personal protective equipment (PPE) and a fume hood, enclosure, or biological safety cabinet for preparation of hazardous drugs.
- Always use proper aseptic techniques for sterile medication preparation and administration. Follow standards of practice and facility protocols for intravenous (IV) admixture preparation and delivery, including disinfection of IV access ports. Failure to follow disinfection directions may result in unintended device performance.
- Do not spray package with cleaning agents as damage to labeling may occur.
- Do not use if package is open or damaged.
- Device is not intended for direct infusion.
- Do not attach the Arisure Closed Vial Adapter to the medication vial at an angle, as unintended device performance or damage may occur.
- Do not use blunt cannula or needles with the needle-free valve or damage to the needle-free valve can occur.
- The Arisure Closed Vial Adapter should be discarded after 168 hours or after 10 activations with the Arisure Closed Male Luer, whichever comes first.
- Do not attach the Arisure Closed Vial Adapter to (or detach from) the Arisure Closed Male Luer or other mating male Luer at an angle. Damage to valve may occur.
- Arisure devices contain polycarbonate and acrylonitrile-butadiene-styrene (ABS). Do not use these devices with undiluted drug products that are contraindicated for use with polycarbonate and ABS, including those containing concentrated *N*,*N*-Dimethylacetamide (DMA). For enquiries regarding workflow for specific drugs, please contact Medical Information at Yukon Medical (medaffairs@yukonmedical.com).
- Pharmaceutical products prepared using the Arisure CSTD should be administered as soon as possible. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information. Use of the Arisure CSTD does not modify, extend, or supersede the manufacturer's label recommendations for drug storage and admixture stability. If desired, it is the responsibility of the compounding pharmacist to establish beyond use dates for compounded sterile preparations.
- Device does not contain Polyvinyl Chloride (PVC).

STERILE R DEHP-FREE

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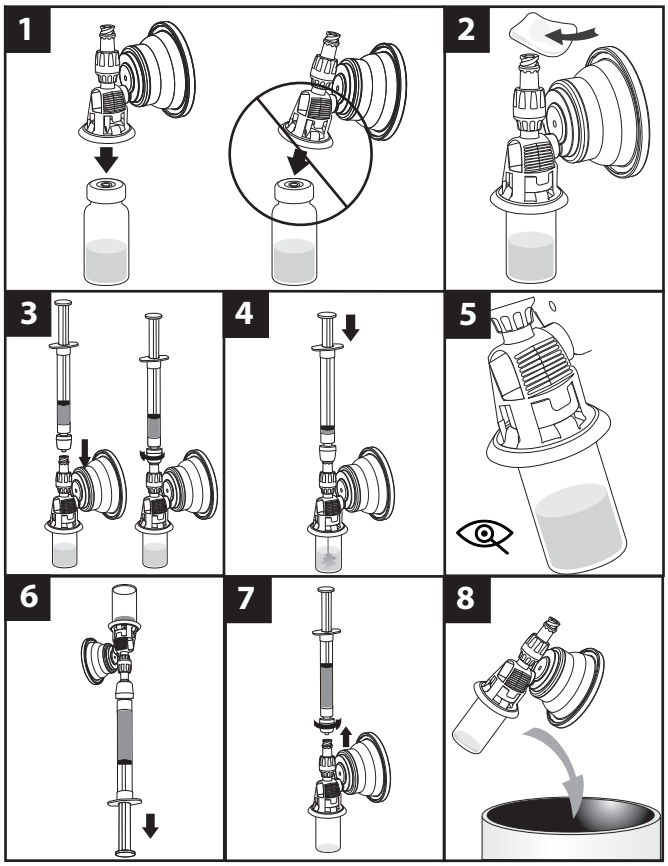
Rx Only



Directions

1. With the spike centered on the medication vial stopper, attach the Arisure Closed Vial Adapter in a straight vertical downward motion until the retention tabs lock onto the vial. **Do not attach at an angle.** If the vial adapter spike does not completely pierce the vial stopper, a 1/4 turn may ensure complete piercing.
2. Prior to every access, swab the top of the needle-free valve with 70% isopropyl alcohol (IPA) or 70% IPA/3.5% Chlorhexidine (CHG).
   - Disinfect the valve by thoroughly scrubbing the top of the valve with disinfecting pad for at least 15 seconds using circular motions.
   - Shift to a new area of the pad at least once during the 15 second scrubbing period.
   - Allow to dry (approximately 30 seconds).
3. Connect a mating Luer syringe to the needle-free valve.

   NOTE: If a closed system transfer is required, the syringe must be equipped with an Arisure Closed Male Luer.
   - An optimal connection is a straight on connection in which the locking threads come to a physical stop. Over-tightening can lead to device damage.
4. If required, inject diluent into the vial according to drug manufacturer package instructions.

   NOTE: The expansion chamber will begin to inflate and retain the vapor displaced during injection of liquid into system.
5. Visually inspect the medication vial for particulates. If particulates are present, discard the vial (without disconnecting the device) and start with a new vial and new Arisure Closed Vial Adapter.
6. Invert the system and aspirate fluid from vial into the syringe.

   NOTE: Expansion chamber will remain inflated.

   NOTE: Do not inject while the vial is inverted. Filter damage may result.
7. Disconnect the syringe from the needle-free valve.
8. Without disconnecting the Arisure Closed Vial Adapter from the vial, dispose in accordance with applicable regulations or facility protocols.

Does not contain DEHP* DEHP-FREE SS-EN 15986:2011*	Indicates the medical device does not contain bis (2-ethylhexyl) phthalate (DEHP).
Not made with natural latex rubber LATEX 5.4.5	Indicates dry natural rubber latex is not a material of construction within the medical device or the packaging of a medical device.
For prescription use only** Rx Only 21CFR801.109**	Caution: Federal Law restricts this device to sale by or on the order of a physician.
Non-pyrogenic 5.6.3	Indicates a medical device that is non-pryogenic.
Do not use if package is damaged 5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
Catalog Number REF 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.

Consult instructions for use 5.4.3	Indicates the need for the user to consult the instructions for use.
Do not re-use 5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Use-by date 5.1.4	Indicates the date after which the medical device is not to be used.
Batch Code LOT 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
Sterilized using irradiation STERILE R 5.2.4	Indicates a medical device that has been sterilized using irradiation.
Caution 5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Manufacturer 5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
Authorized representative in the European Community EC REP 5.1.2	Indicates the Authorized Representative in the European Community.

All symbols in these tables are from ***ISO 15223-1:2012 - Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 General requirements***, except where specifically noted.

*This symbol is from ***SS-EN 15986:2011 - Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates***

This symbol is from ***21CFR801.109 - Code of Federal Regulations Title 21 Chapter I Subchapter H Part 801 Section 109 Prescription Devices*