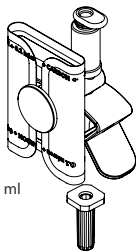


ToxiSeal Universal Vial Adaptors With External Balloon

REF 420670



Closed System Drug Transfer Device
External Balloon Pressure Equalization Volume 80 ml
Air Filter Pore Size 0.1 µm
Fits Vial Neck 13 ~ 28 mm

NOT MADE with NATURAL RUBBER LATEX or DEHP



EC REP

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Indications for Use:

The ProSeal Closed System drug Transfer Device (CSTD) mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal system also prevents the introduction of microbial contaminants into the drug or fluid path for up to 168 hours or 7 days.

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STERILE EO



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Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

ToxiSeal Universal Vial Adaptors with External Balloon seal the closure of the vial to which it is attached. Ambient air passes through a hydrophobic 0.1 micron sterile filter before enters the drug vial.

The external balloon collects drug aerosols and volatile organic compounds released due to un-equalized pressure in the vial during compounding.

The injection site on the ToxiSeal Universal Vial Adaptor with External Balloon and all its corresponding interface membranes exhibit a dry connection with the communicating surfaces in a fluid transfer. The use of this component and its appropriate ProSeal CSTD connecting component reduces the risk of microbial ingress for up to 168 hours or 7 days.

DIRECTIONS - Use Aseptic Technique

1. Flip off the protective cap on vial spike and attach ToxiSeal Universal Vial Adaptor with External Balloon firmly to vial.
2. Prior to every access, swab top of Injection Site with 70% isopropyl alcohol (15 seconds) and allow to dry (approximately 30 secs).
Dry Time is dependent on temperature, humidity, ventilation area.
3. Attach ProSeal Injector (Syringe Adaptor) to the Injection Site of ToxiSeal Universal Vial Adaptor with External Balloon.
4. For drugs require reconstitution, hold the vial upright and inject diluent. Do not inject diluent more than the volume indicated for pressure equalization.
5. For liquid drugs, the one way valve allows solution to be withdrawn without injecting air into external balloon. Invert vial to withdraw fluid. Avoid pushing syringe plunger when the vial is inverted as excessive pressure may compromise the filter membranes.
6. Discard used ToxiSeal Universal Vial Adaptor with External Balloon with vial intact in accordance to disposal procedures for biohazardous materials of your facility.

Contraindications

The device is contraindicated whenever:

- The drug to be prepared is contraindicated to ABS, stainless steel, polypropylene and polyisoprene.

Warnings

- Use accepted IV and pharmacy practice.
- The performance of the self-sealing membrane of the device is reduced after multiple perforations.
- Do not re-use to avoid contamination.
- Only use the device model that matches the vial neck size and vial stopper type.

Precautions

- Do not use when caps and /or components are loose.
- The device is sterile unless packaging is damaged. Do not use when packaging is damaged.