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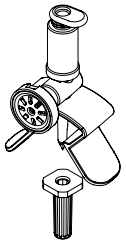
ToxiSeal Universal Vial Adaptors



REF 420660

Closed System Drug Transfer Device
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.

CE 0123 | STERILE EO | LATEX | DEHP FREE

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

ToxiSeal Universal Vial Adaptors seal the closure of the vial to which it is attached. The Air Vent assembly consists of 2 layers of filtration membranes, a hydrophobic 0.1 micron sterile filter and an activated carbon filter that absorbs drug aerosols and vapor.

The injection site on the ToxiSeal Universal Vial Adaptor 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 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. Invert Vial to withdraw fluid.
It is not required to administer air as pressure is automatically equalized. Avoid pushing syringe plunger when the vial is inverted as excessive pressure may compromise the filter membrane.
4. Discard used ToxiSeal Universal Vial Adaptor 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.