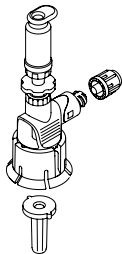


ProSeal™ Vial Adaptor with One Way Valve

REF 420570

One Way Valve on Air Pathway
Air Filter Pore Size 0.1 µm
Fits Vial Neck 20 mm
ProSeal CSTD Injection Site



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



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

ProSeal Vial Adaptor with One Way Valve allowed air to be injected into the vial through the Female Luer Lock port and creates a positive pressure inside the vial. The one way valve maintains the positive pressure and increases the liquid flow rate during transfer. The hydrophobic 0.1 µm air filter sterilize the air enters the vial.

The Injection Site on the ProSeal Vial Adaptor with One Way Valve 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. Attach ProSeal Vial Adaptor with One Way Valve firmly to vial.
2. Flip off the protective cap on the Injection Site.
3. 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.
4. Attach ProSeal Injector (Syringe Adaptor) to the Injection Site of ProSeal Vial Adaptor with One Way Valve.
5. Draw air* into an empty syringe and connect to Female Luer Lock port on device. Push plunger to inject air into the vial to expel the liquid from vial to the final container.
6. Discard used ProSeal Vial Adaptor with One Way Valve with vial intact in accordance to disposal procedures for biohazardous materials of your facility.

*The air will be sterilized by 0.1 µm air filter before entering the vial.

Contraindications

The device is contraindicated whenever:

- The drug to be prepared is contraindicated to polycarbonate, 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.

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.