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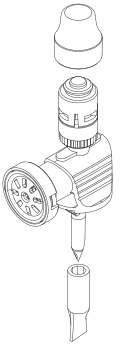
ProSeal™ ChemoPin



REF **420390**

Universal Vented Vial Spike
Air Filter Pore Size 0.1 µm
Carbon Filter Activated Carbon Fabric
Compatible with DMA (Dimethylacetamide)

NOT MADE with NATURAL RUBBER LATEX or DEHP

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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 PHT DEHP FREE

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

The ChemoPin allows easy transfer of fluids into and out of drug vials. It incorporates a spike for puncturing the rubber stopper of a vial and a ProSeal Injection Site on the port access that allows fluid transfer in a closed system.

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 fluid path of ChemoPin is made of copolyester material, which is compatible to DMA (Dimethylacetamide), a solvent found in certain chemotherapy drugs.

The injection site on the ProSeal ChemoPin 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. Remove the protective cap on vial spike and perforate the vial spike through the rubber stopper of vial completely.
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) Ref 421010 to the Injection Site of ProSeal ChemoPin.
4. For drugs that require reconstitution, hold the vial upright and inject diluent.
5. For liquid drugs, 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 ProSeal ChemoPin 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 copolyester, stainless steel, polypropylene, silicone, TPE 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.