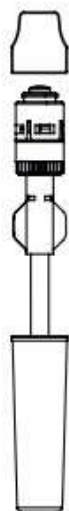


ProSeal™ CSTD Catheter Adaptor

REF 422090

Priming Volume 0.7 ml
External Fitting Urinary Catheter



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



Rx

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

The ProSeal Catheter Adaptor is the interface for any standard Foley catheters. When connected to the drainage port on a catheter and engaged with a ProSeal Injector (Syringe Adaptor), fluid can be administered to the catheter in a closed system.

The injection site on ProSeal Catheter 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. Connect the ProSeal Catheter Adaptor to the drainage port on a standard Foley catheter.
2. Prior to every access, swab the 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) onto ProSeal Catheter Adaptor for fluid administration into the catheter.
4. Discard used ProSeal Catheter Adaptor with Foley catheter intact in accordance to disposal procedures for biohazardous materials of your facility.

Contraindication

The device is contraindicated whenever:

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

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.