

# ProSeal™

Closed System Transfer Device

Ref 421010 ProSeal Injector  
Ref 422010 ProSeal Injection Site  
Ref 420020 ProSeal Vial Adaptor 20 mm, Pressure 20 ml  
Ref 420010 ProSeal Vial Adaptor 13mm, Pressure 20 ml  
Ref 420030 ProSeal Vial Adaptor 20 mm, Pressure 50 ml  
Ref 420040 ProSeal Vial Adaptor 28 mm, Pressure 60 ml

Ref 423010 Mini Bag Set With ProSeal Injection Site  
Ref 423040 Extension tube 30 cm Y Site/NFC and ProSeal Injection Site  
Ref 423030 Extension Tube 30 cm with ProSeal Injection Site  
Ref 423011 ProSeal Transfer Spike 20 mm neck & ProSeal Injector Combo  
Ref 423020 ProSeal Transfer Spike 20 mm neck with ProSeal Injection Site  
Ref 422030 Bag Adaptor

Ref 424010 Fixture for ProSeal Vial adaptor assembly

Exposure safe

Vial to Patient



EC REP

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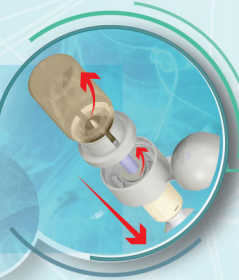


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## PRESSURE EQUALIZATION

When connected to a drug vial, the ProSeal Vial Adaptor equalizes the pressure difference between the vial and itself. Without a pressure equalization system, differences in pressure can lead to the generation of fine aerosols that may escape into the air and expose the environment, patients, and health care professionals to hazardous drugs. Other CSTDs use an integrated filter to cleanse escaping air contaminated with hazardous drug vapors or aerosols. In the ProSeal Vial Adaptor the expandable chamber seals the escaping filtered air within the device itself.



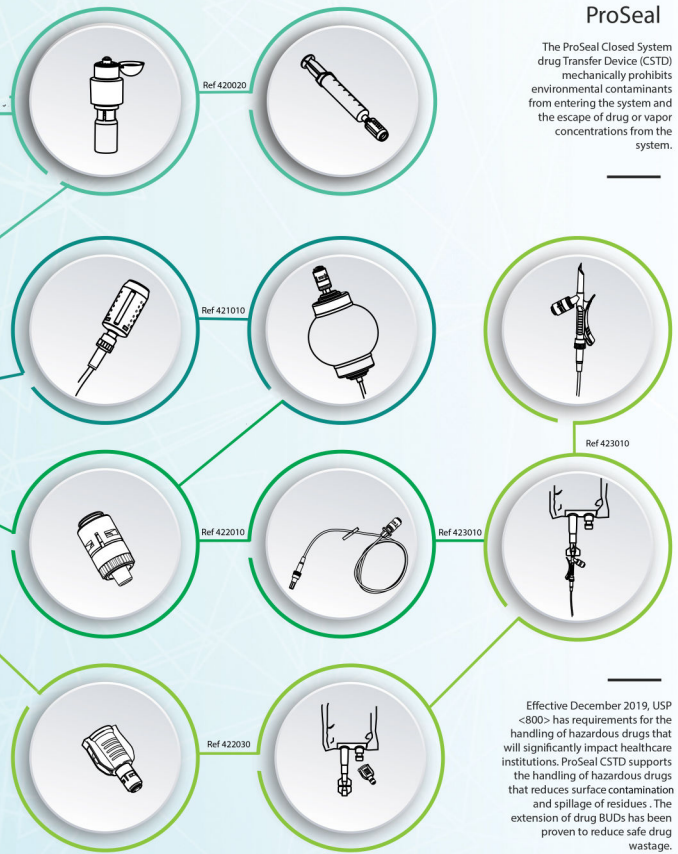
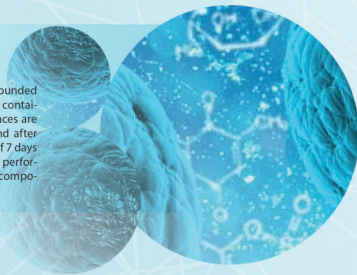
## DRY CONNECTION

Dry connectors are an important feature of CSTDs and the corresponding injection sites as it confirms the lack of leakage of droplets, aerosols or vapors. A surrogate marker like fluorescein is used to confirm the absence of fluid residues on the injected surfaces. The ProSeal Injection Site and all its corresponding interface membranes exhibits 100% efficiency in achieving a dry connection in the communicating surfaces in a fluid transfer.



## MICROBIAL INGRESS

The efficiency of CSTD in preserving the microbiological integrity of compounded products is demonstrated through a microbial challenge test. This is such that containers of growth media is fitted with ProSeal Injection Sites. The membrane surfaces are artificially contaminated with suitable inoculum of suitable microorganism and after swabbing with disinfectant, several samples are taken. At the end of test period of 7 days the container is incubated to check for microbial growth. All manipulations are performed under ISO 5 conditions to simulate the real-life situation. ProSeal CSTD components are confirmed to prevent microbial ingress of at least 168 hours (7 days)



## ProSeal

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.

Effective December 2019, USP <800> has requirements for the handling of hazardous drugs that will significantly impact healthcare institutions. ProSeal CSTD supports the handling of hazardous drugs that reduces surface contamination and spillage of residues. The extension of drug BUDs has been proven to reduce safe drug wastage.