EN

ProSeal™ CSTD
SubCut Connector

REF 422130

Priming Volume 0.13 ml
External Fitting Male Luer Lock (ISO 80369-7) and ProSeal 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.

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

The ProSeal SubCut Connector enables fluid transfers between ProSeal Injector (syringe adaptor) and standard Female Luer Lock connector or needle-free connector.

The ProSeal SubCut Connector includes a ProSeal Injection Site at one end and a Male Luer Lock at another end. The ProSeal Injection Site end is intended for connection to other devices with ProSeal Injector (syringe adaptor).

The Male Luer Lock end has a valve mechanism and is in a normally closed state. The valve opens when it is securely connected to a Female Luer Lock, and closes when it is disconnected. When the valve mechanism is open, the colored nozzle sleeve ring will protrude from its white collar.

DIRECTIONS - Use Aseptic Technique

1. Connect the ProSeal Injection Site end of the ProSeal SubCut Connector to the ProSeal Injector (syringe adaptor).
2. The entire device is swab-able and compatible with common disinfectant including 70% isopropyl alcohol.
3. Connect the Male Luer Lock end of ProSeal SubCut Connector to any standard Female Luer Lock connector or needle-free connector for fluid transfer.
4. When connecting, keep twisting ProSeal SubCut Connector until a few clicks and colored nozzle sleeve ring protrudes from its white collar which indicates the connection is secure and valve is opened.
5. When disconnecting, hold the housing of ProSeal SubCut Connector and push while twisting. Keep twisting until fully detached.

* Do not pull ProSeal SubCut Connector while twisting.

6. Discard used ProSeal SubCut Connector 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, TPE, ABS, 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.