

Leakproof Connection Integrity Test For Devices Intended for Handling Hazardous Drugs



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OBJECTIVE

To determine if the ICU Medical System, B. Braun OnGuard™ System, Cardinal Health/Alaris System or PhaSeal® System connections are leak proof or have the potential to allow drugs to escape into the environment during the preparation and administration phases of hazardous drug handling.

METHODS

Four transfer devices were tested:

- The ICU Medical System (Spiros™ Male Connector & Clave® Connector)
- The B. Braun OnGuard™ System (Vial Adaptor & Syringe Adaptor) by Teva Medical Ltd.
- The Alaris System (SmartSite® Vented Vial Access Device & Texium™ Male Luer) by Cardinal Health
- The PhaSeal® System (Protector & Injector Luer Lock) by Carmel Pharma

A liquid with low pH was used as a substitute for active drug. Litmus paper was used as a pH indicator. Blue litmus paper turns red under acidic conditions.

Syringes were filled with fluid and injected into vials attached to the above transfer devices. After aspirating back and disconnecting, the connections of each device were pressed against litmus paper to detect the presence of any fluid.

Every component of each device was tested for 10 manipulations.

RESULTS

Visible leakage occurred outside of the components on the ICU Medical System Spiros™ and Clave® connections, the B. Braun OnGuard™ System and the Cardinal Health/Alaris System during all manipulations.

No leakage was observed in any of the manipulations with the PhaSeal® System by Carmel Pharma.

Spiros™ Male Connector & Clave® by ICU Medical Inc.



B. Braun OnGuard™ Vial Adaptor & Syringe Adaptor by Teva Medical Ltd.



Alaris SmartSite® Vented Vial Access Device & Texium™ Male Luer by Cardinal Health



PhaSeal® Protector & Injector Luer Lock by Carmel Pharma

