



Special *PP&P* Buyer's Guide: Closed System Transfer Devices

Using closed system drug transfer devices (CSTDs) is one strategy that hospitals are employing to reduce the risk of occupational exposure to hazardous drugs. Fluorescence studies demonstrate that compounding hazardous drugs using the traditional vial-to-syringe technique is one of the riskiest points of occupational exposure due to vial over-pressurization, which can lead to spraying and leakage. Without the aid of fluorescence, these sprays and spills go unnoticed and may lead to staff and patients being exposed to the contaminated finished product. CSTDs are designed to mitigate these consequences by creating a safer system for compounding personnel to reconstitute and transfer hazardous drugs from the drug manufacturer's container to the patient-specific product, and by allowing drug administration personnel to more safely administer these hazardous drugs to patients.

Guidelines to minimize hazardous drug exposure in the hospital have been around since 1981, and pharmacy and nursing practitioners have continued to pursue strategies to help protect themselves against coming into contact with these drugs through the use of personal protective equipment (PPE), compounding techniques, and drug administration practices. These practices have been summarized in two key reports—the National Institute for Occupational Safety and Health (NIOSH) health alert to employers titled *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* and the American Society of Health-system Pharmacists' (ASHP) *Guidelines on Handling Hazardous Drugs*.

To date, the Food and Drug Administration has approved four CSTDs, and more are anticipated to enter the market in the near future. The four companies with FDA-approved CSTDs on the market are B. Braun Medical Inc; Cardinal Health; Carmel Pharma, Inc; and ICU Medical, Inc. To be considered CSTDs under the NIOSH definition and ASHP guidelines, these devices must contain spills and leakage as well as aerosols and vapors. In addition, they should demonstrate these abilities in independent studies. The guidelines also state that the CSTDs should be used within a ventilated cabinet while following appropriate PPE and work practices.

When employing CSTDs one must keep in mind that consistent, proper usage of these systems is paramount to ensuring containment. Staff members



Photo courtesy of ICU Medical, Inc

should be observed regularly while using these devices, because if they do not understand the process or if they find a particular step difficult, they may not follow proper procedures. Additionally, it is important that all users, including those in pharmacy and nursing, report any failures the system may have so they can be promptly reported to the manufacturer. Remember, nursing is also an end-user and as such, should join pharmacy in the assessment and training processes. If nursing does not like the product selected, you run the risk of it not being used properly, thus losing the value of a closed system.

In order to help you in your quest to purchase CSTDs for your institution, we have compiled the following buyer's guide, which includes information on the four FDA-approved devices currently in the marketplace. Use this article as a starting point for your CSTD research.

If you are interested in receiving more information about any of the products listed in the guide, simply circle the corresponding numbers on the free reader service card bound in this issue. You can also go to www.findit.pppmag.com for additional information.

For more information on closed system transfer devices, check out "Assessing Vial Transfer Devices for Handling Hazardous Drugs" in the March 2009 issue of *PP&P*, or read it online at www.pppmag.com.



www.findit.pppmag.com

WHERE TO FIND: Closed System Transfer Devices

www.findit.pppmag.com

Vendor	Reader Service Number
B. Braun Medical Inc	1
Cardinal Health	2
Carmel Pharma, Inc	3
ICU Medical, Inc	4

▶ **Cardinal Health**
 Circle reader service
 number 2
 or visit www.cardinalhealth.com/alaris/solutions/closedsystem

Texium IV accessory products with SmartSite needle-free valve
 Texium IV accessory products are designed to partner with the company's SmartSite needle-free valve to create a closed system for the safe handling of hazardous drugs during the full continuum of care—from drug preparation to administration and disposal.



The cost-effective, easy-to-use system helps facilities comply with USP <797>, NIOSH, the Oncology Nursing Society (ONS), and ASHP guidelines for the safe handling of hazardous drugs.

Key features include no-drip-tip technology for the leak-free transfer of drugs and reduced surface contamination. It is also a passive safety system, which closes upon disconnection and protects against free flow. The lock-and-go design provides for a fast and easy connection to the SmartSite needle-free valve and incorporates an automatic safety lock to prevent accidental discharges from a syringe.



in contamination control for USP <797> compliance

USP <797> describes the cleaning practice for compounding sterile preparations. ITW Texwipe® provides the cleaning products for compliance:

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- Sterile 70% IPA
- Wipers and swabs
- Mopping systems

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- Isolator cleaning
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For more information, circle #5 on the Reader Service Card



Closed System Transfer Devices

- ▶ **ICU Medical, Inc**
Circle reader service number 4
or visit www.icumed.com

The Spiros Closed Male Connector, the CH-70, and the Genie Vial Access Device

ICU Medical's ChemoCLAVE System includes a complete line of closed, vial and bag access products for the safe preparation, transport, administration, and disposal of hazardous drugs. This system assures 100% compliance with NIOSH guidelines through the entire spectrum of hazardous drug delivery.

The Genie is a closed, needle-free, vial-access device that automatically equalizes vial pressure. As the desired volume of drug is extracted, the Genie balloon will automatically inflate to equalize pressure—reducing aerosols, vapors, and leaks caused by pressurization when accessing the vial. With this device, it is no longer necessary to push contaminated air into the vial to extract the desired amount of drug.

The CH-70 has a dual-venting feature to enhance equalization of the vial pressure during aspiration as well as limit filter occlusion. The universal design allows it to fit on any multi-dose vial including most single-dose small vials. The locking feature allows for security in handling and will eliminate slip-outs if hung.

The Spiros creates a closed system to protect the integrity of the IV fluid container whether it is on a syringe for transfer or, on the end of an IV set. The Spiros only opens when it is attached to a female connector, including needle-free connectors, and upon disconnect, the Spiros automatically self-seals and closes the system.



The CH-70 on different sized vials



From left to right: The Genie Vial Access Device and the Spiros Closed Male Connector

- ▶ **B. Braun Medical Inc**
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or visit www.bbraun.com

ONGUARD Contained Medication System with Tevadaptor Components



B. Braun's ONGUARD Contained Medication System with Tevadaptor Components is a latex-free, PVC-free system designed for the safe compounding and administration of hazardous IV drugs, such as those used in chemotherapy.

Compliant with the NIOSH definition of a CSTD, the ONGUARD system provides hazardous medication protection and automatic needlestick prevention to the nurses and pharmacists at the frontlines of drug preparation and administration.

To further protect workers and the patient-care environment, from admixture through delivery, the ONGUARD System also helps prevent liquid droplets

from exiting the dispensing units during use and incorporates automatic needle protection into the Tevadaptor Syringe Adaptor design.

▶ Carmel Pharma, Inc
 Circle reader service
 number 3
 or visit
www.carmelpharma.com

The PhaSeal System
 The PhaSeal System is designed
 to facilitate the safe preparation,



administration, and disposal of
 hazardous drugs. PhaSeal's air-
 tight expansion chamber and
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 and International Society of
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