Know the Facts
About Closed-Systems Drug Transfer Devices (CSTDs)

Author: Kerry Mahar, RN, MSN, AOCN, Clinical Nurse Specialist, Dana-Farber Cancer Institute

Exposure Risks

Many procedures utilized in the administration of hazardous drugs have the potential for leakage and accidental spills, thus putting healthcare workers like yourself, and those within your environment of care, including patients and family members, at risk for exposure to these agents.

"Warning! Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects and possibly leukemia or other cancers (NIOSH 2004).” ¹

The highest risk of exposure for nurses is associated with preparation and administration, primarily through inhalation of aerosolized drug, direct contact (eyes, skin, mucosa), and ingestion (eating, drinking, chewing gum).

Inadvertent exposure to these drugs has serious health consequences; common acute symptoms include nausea, vomiting, headache, dizziness, hair loss, and liver damage.

Multiple reputable, peer-reviewed publications, including the National Institute for Occupational Safety and Health (NIOSH) Alert, have reported the impact hazardous drug exposure has on the reproductive systems and the developing fetus, including:

- Significantly higher rates of spontaneous abortions ²
- Infertility ²
- Still births ²
- Low birth weight and congenital malformations and abnormalities ²

The first ever published national survey was released in 2007 which assessed nurses’ extent and frequency of exposures to common health care hazards. Results indicated a 42% higher rate of cancer for nurses who experience frequent, long-term exposure to chemotherapeutic medications through preparation and administration, than for other nurses. ³

The Oncology Nursing Society (ONS), NIOSH, The International Society of Oncology Pharmacy Practitioners (ISOPP), USP<797> and the American Society of Health-System Pharmacists (ASHP) have recommended the use of a closed-system drug transfer device (CSTD) to prevent the risk of hazardous drug exposure.
Defining a Closed-System Drug Transfer Device

NIOSH and ISOPP define a closed-system drug transfer device as:

“A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.” 1, 4

With a variety of drug preparation and administration systems available, it is important to make sure, as recommended by NIOSH, that peer-reviewed, independent, published studies be provided for each component of the system to validate it’s effectiveness and that it meets the NIOSH definition of closed. 1, 4, 5

ISOPP stipulates that all manufacturers of transfer and administrative devices for chemotherapy should disclose three important pieces of information to potential users of these products.

1. The manufacturer must disclose whether the device covers all steps in the preparation process and which routes of administration the containment is guaranteed. If the device covers only some of the steps, the manufacturer should clearly indicate where the closed properties are not retained.

2. The manufacturer must disclose the studies that show that the device eliminates or reduces contamination in daily practice, can retain it’s closed characteristics when more than one preparation or administration is performed and to what degree.

3. A product described as a closed-system must be “leak-proof and airtight” 4 — therefore vented, filtered devices are not closed.

A product cannot be ‘semi-closed.’ 4
B.Braun OnGuard™ System by Teva Medical

- OnGuard has no third party, peer-reviewed, published data on clinical effectiveness. 6
- OnGuard claims clinical efficacy with a document that states, “OnGuard can not physically be regarded as a closed system according to the NIOSH definition since air can pass in and out of the system during preparation.” 6
- OnGuard is a ‘filtered’ product, therefore does not meet the NIOSH and ISOPP definition of closed.
- OnGuard is manufactured in Israel and their government does not consider this system closed. 7
- 2008 Court ruling on the OnGuard System validates the system is not closed. 8

Spiros™ Male Connector and Clave® by Hospira/ICU Medical

- No third party, peer-reviewed, published clinical data.
- No references regarding effectiveness on reducing contamination and long term exposure.
- White papers and paid company advertorials are available, however they are written by paid company employees and are not clinical evidence.
- Device is marketed as having an option to be ‘semi-closed’ (Reminder: ISOPP stipulates that a device cannot be semi-closed) 4
- New Genie system anticipated to have same ‘open’ Spiros/Clave wet connections.

Alaris Smartsite®/Texium™ System by Cardinal Health

- No third party, peer-reviewed, published clinical data.
- Smartsite is a ‘filtered’ product and therefore does not meet the NIOSH and ISOPP definition of closed.
- 2007 reports ‘recall’ due to leakage incidents with the closed male luer. 9

PhaSeal® System by Carmel Pharma

- PhaSeal has over 10 peer-reviewed, independent, published studies validating its clinical effectiveness. 11-26
- PhaSeal is clinically proven to be airtight and leakproof from preparation to administration to waste disposal.
- PhaSeal meets the NIOSH definition of closed.

"The PhaSeal System is the only clinically proven closed-system drug transfer device on the market. This system is designed to prevent leakage of drugs into the environment during preparation and administration (ONS 2005).” 10
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"PhaSeal has been in the US market since 2000 and is still the only clinically proven product available. No one has been able to match the quality and efficacy of this device to date. It truly is 'The Gold Standard' in safe handling."

References

8. Teva Sweden AB vs. Carmel Pharma AB. (2007), Göteborg Administrative Court of Appeal.