ChemoLock™

Setting a Whole New Standard for Hazardous Drug Safety

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Why ChemoLock

- The bonded components and locking mechanism help eliminate accidental disconnects
- An audible ’click’ lets you know you’ve made a secure connection
- Components easily are customized to incorporate any administration process
- Prevents the escape of hazardous drug vapor
- Eliminates needle stick injuries
- The first needle free CSTD to receive FDA 510(K) clearance for both pharmacy compounding (ONB) and patient administration (FDA) applications

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Safety From Start To Finish

With the ChemoLock needlefree CSTD, it has never been easier to keep yourself safe from exposure to hazardous drugs.

Treating cancer patients takes compassion—it shouldn't take a toll on your health. But the fact is, while chemotherapy is the backbone of medical oncology, these powerful medications—along with many others—are extremely toxic to the clinicians who handle them. Prolonged exposure to hazardous drug vapors, drips, or spills has been shown to lead to hair loss, skin rashes, infertility, miscarriages, birth defects, and even forms of cancer. It doesn't have to be that way.

The system's automatic self-sealing technology requires no cumbersome assembly, and the bonded components cannot be accidentally disconnected.

In response to the well-documented risks associated with handling hazardous drugs, ICU Medical has developed ChemoLock to create a needlefree mechanically and microbiologically closed system for the safe handling of hazardous drugs. ChemoLock's intuitive and easy-to-use system locks with an audible click, ensuring a safe and secure connection has been made to minimize exposure to hazardous drugs and protect the patient preparation from external contamination.

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Safely Prepare

Stay safe and in compliance with recommended guidelines during the preparation of hazardous drugs thanks to the ChemoLock system's mechanically and microbiologically closed needlefree system.

Safely Transport

The ChemoLock system prevents leaks and spills during the transportation of hazardous drugs from pharmacy to nursing, while also protecting the sterility of the patient preparation.

Safely Administer

The easy-to-use ChemoLock system helps you keep patients and clinicians safe without having to change standard nursing protocols.

Safely Dispose

The ChemoLock system remains mechanically and microbiologically closed all the way through disposal to help eliminate potential drug exposure to you or the environment.

ChemoLock™

It is easy for you to choose the combination of components that best meets your needs

Closed Male Injector

ChemoLock Injector (AHCL2000S)

For use on a syringe or IV tubing

Vial Spikes

Vial Spike (AHCL80)

Allows access to vials having 20 mm/ 28 mm closures, and external balloon equalizes pressure for reconstitution

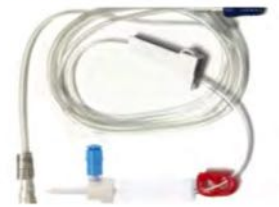
Universal Vented Vial Spike (AHCL70)

Large vent offers better flow rates and reliability; skirted configuration available

Vial Spike, 13 mm (AHCL62)

Allows for access to small vials with 13mm closures

Administration Sets and Components



110" Admin Set with Integrated ChemoLock Drip Chamber, MicroClave Y site (AHCL3300)

7" T-Port Extension with ChemoLock (AHCL7002))

Attaches to the catheter hub for venous access using ChemoLock devices

ChemoLock Port (AHCL2100)

For use on patient IV line

Flush and Dilute

ChemoLock Syringe Transfer Set (AHCL2101)

Use to transfer from syringe to syringe

Bag Spike (AHCL10)

For use on any solution container

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Evaluation of FDA-Cleared ONB Closed-System Transfer Devices Utilizing Cyclophosphamide as a Marker

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- In 2012 the FDA established a new category of CSTDs under a new ONB code that categorizes products to be used for safe handling
- Only two CSTDs have received FDA clearance for the ONB code: PhaSeal and ChemoLock
- This study examines the containment potential during the drug transfer process using cyclophosphamide (CP) as a marker for the ONB devices.
- Decontamination procedures were used to minimize CP contamination on vials and surfaces prior to the study
- Four common surface sampling zones were tested for contamination

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Data from Trials

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TABLE 1. SUMMARY OF ICU MEDICAL CHEMOLOCK TRIALS

Sample ID	Surface	Area, cm²	CP, ng	CP conc., ng/cm²	Comments
5296061	Field blank	na	nd	na	
5296062	Workbench left	400	nd	<0.00500	Decontamination
5296063	Workbench right	400	3.33	0.00833	
5296016	Grill	400	nd	<0.00500	
5296017	Airfoil	400	nd	<0.00500	
5296018	Gloves	na	nd	na	
5296019	Workbench left	400	nd	<0.00500	ChemoLock, Trial 1
5296020	Workbench right	400	nd	<0.00500	
5296021	Grill	400	nd	<0.00500	
5296022	Airfoil	400	nd	<0.00500	
5296023	Gloves	na	nd	na	
5296040	Workbench left	400	nd	<0.00500	ChemoLock, Trial 2
5296041	Workbench right	400	nd	<0.00500	
5296042	Grill	400	nd	<0.00500	
5296043	Airfoil	400	nd	<0.00500	
5296044	Gloves	na	nd	na	
5296045	Workbench left	400	nd	<0.00500	ChemoLock, Trial 3
5296046	Workbench right	400	nd	<0.00500	
5296047	Grill	400	nd	<0.00500	
5296108	Airfoil	400	nd	<0.00500	

na – not applicable nd – not detected (<2.00 ng/sample)

TABLE 2. SUMMARY OF PHASEAL TRIALS

Sample ID	Surface	Area, cm²	CP, ng	CP conc., ng/cm²	Comments
5296038	Field blank	na	nd	na	
5296039	Workbench left	400	nd	<0.00500	Decontamination
5296000	Workbench right	400	nd	<0.00500	
5296001	Grill	400	nd	<0.00500	
5296002	Airfoil	400	nd	<0.00500	
5296003	Gloves	na	nd	na	
5296004	Workbench left	400	nd	<0.00500	PhaSeal, Trial 1
5296005	Workbench right	400	nd	<0.00500	
5296007	Grill	400	nd	<0.00500	
5296064	Airfoil	400	nd	<0.00500	
5296065	Gloves	na	nd	na	
5296066	Workbench left	400	nd	<0.00500	PhaSeal, Trial 2
5296067	Workbench right	400	89.1	0.223	
5296068	Grill	400	nd	<0.00500	
5296069	Airfoil	400	nd	<0.00500	
5296080	Gloves	na	nd	na	
5296081	Workbench left	400	nd	<0.00500	PhaSeal, Trial 3
5296082	Workbench right	400	8.56	0.0214	
5296083	Grill	400	nd	<0.00500	
5296084	Airfoil	400	nd	<0.00500	

na – not applicable nd – not detected (<2.00 ng/sample)

Results & Conclusion

- Wipe samples collected from vials following the initial decontamination procedure and prior to use in the study were free of detectable CP.
- With the ChemoLock system no CP was detected on working surfaces or the compounders' gloves.
- With the PhaSeal system CP was detected on the biological safety workbench following trials 2 and 3 and no CP was detected on the technician's gloves.
- On one occasion during trial 2 of the PhaSeal system, the internal needle of the product became unintentionally exposed with a fluid droplet observed on the needle tip.
- The results of this study suggest that the ChemoLock system was effective in preventing detectable surface contamination during three separate trials of simulated compounding activities with known amounts of cyclophosphamide.
- It appeared that the PhaSeal system was effective in preventing detectable contamination when the product functioned as designed.

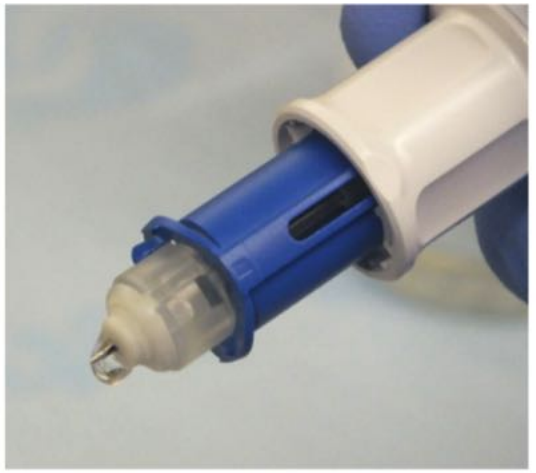

Photo 5. PhaSeal Protector with unintentionally exposed needle and visible fluid droplet.

USP <800> CSTD Compliance Reference

Quick Facts:

1. What is the difference between USP ‹797› and ‹800› as it relates to use of CSTDs?

- USP Chapter ‹797› only pertains to pharmacy preparation, not nursing administration, and does not include specific requirements.
- USP Chapter ‹800› applies new controls for nursing administration, requiring that a CSTD be used during administration of Hazardous Drugs (HDs).
  - This CSTD language is outlined in the Containment Supplemental Engineering Control (C-SECs) section of Chapter ‹800›. An SEC is an adjunct control (e.g., CSTD) that may be used concurrently with primary and secondary engineering controls. SECs offer additional levels of protection and may facilitate enhanced protection, especially when handling HDs outside of primary and secondary engineering controls (e.g., during administration).

2. What is the specific USP ‹800› language regarding CSTDs?

- Compounding: "CSTDs should be used when compounding HDs when the dosage form allows."[1]
- Administering: "CSTDs must be used when administering antineoplastic HDs when the dosage form allows."[1]

3. What is the USP ‹800› definition of a CSTD?

- USP ‹800› relies on the NIOSH definition of a CSTD, which is a drug-transfer device that "mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system."[2]

4. How do ICU Medical CSTD systems meet the NIOSH definition of a CSTD?

- ICU Medical's CSTD systems have been shown in microbial ingress testing to prohibit the transfer of environmental contaminants into the system over a seven-day period.[3,4]
- HD surface contamination testing has shown that ICU Medical CSTDs prohibit the escape of hazardous drug vapor concentration outside the system.[5]

5. Which ICU Medical CSTD systems meet the USP ‹800› requirement for CSTDs?

- Both ICU Medical ChemoClave® and ChemoLock™ CSTD systems meet the USP ‹800› requirement for CSTDs. Each system is comprised of a selection of vial adapters that mechanically prohibit the transfer of environmental contaminants into the system and the escape of vapor concentrations outside the system, as well as needlefree bag spikes and primary add-on and administration sets.

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References & Resources

- http://www.icumed.com/media/437895/m1-1455_chemolockwipestudy-summary_rev02-web.pdf
- http://www.icumed.com/media/437894/m1-1456_chemolocklitmusstudysummary_rev02-web.pdf
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- http://www.icumed.com/media/594731/M1-1546-ChemoLock-and-ChemoClave-Surface-Wipe-with-Methrotraxate-Summary-Rev01-Web.pdf

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