

ChemoClave®

Needlefree Closed Systems and Closed
System Transfer Devices

The Most Cost-Effective Way to
Start Protecting Yourself Today



PRACTIVET

Why ChemoClave®



- The worlds first needlefree closed systems and closed system transfer devices for the safe handling of hazardous drugs
- Needlefree system assures compliance with safe handling policies
- Easy-to-use system requires no assembly of components
- ChemoClave CSTDs generate less biohazard waste than other CSTD's
- Lowest cost to implement
- Keeps practices in compliance with NIOSH & USP 800 guidelines



Safely Prepare

The ChemoClave system maintains a mechanically and microbiologically closed needlefree system during the preparation of hazardous drugs to help keep you safe and comply with recommended guidelines.



Safely Transport

By maintaining a closed system, ChemoClave helps you prevent leaks and spills during the transport of hazardous drugs from pharmacy to nursing.



Safely Administer

The ChemoClave system makes it safer for you and your patients by preventing accidental disconnects to minimize drug exposure without having to change any standard nursing protocols.



Safely Dispose

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

Risks of not using CSTD's

The Risks

The unsafe handling of hazardous drugs used to treat many forms of cancer has been recognized since the 1970's as a big health hazard to healthcare workers.

The toxicity of hazardous drugs and the dangers of prolonged exposure have been proven to cause hair loss, skin rashes, infertility, miscarriage, birth defects, and even leukemia or other forms of cancer in healthcare workers.^{1,2,3,4} Studies have shown that healthcare workers can be at risk of exposure to these drugs throughout their life cycle - from manufacturing and distribution, to use in the clinical or home care environment, and to waste disposal.

The Solution

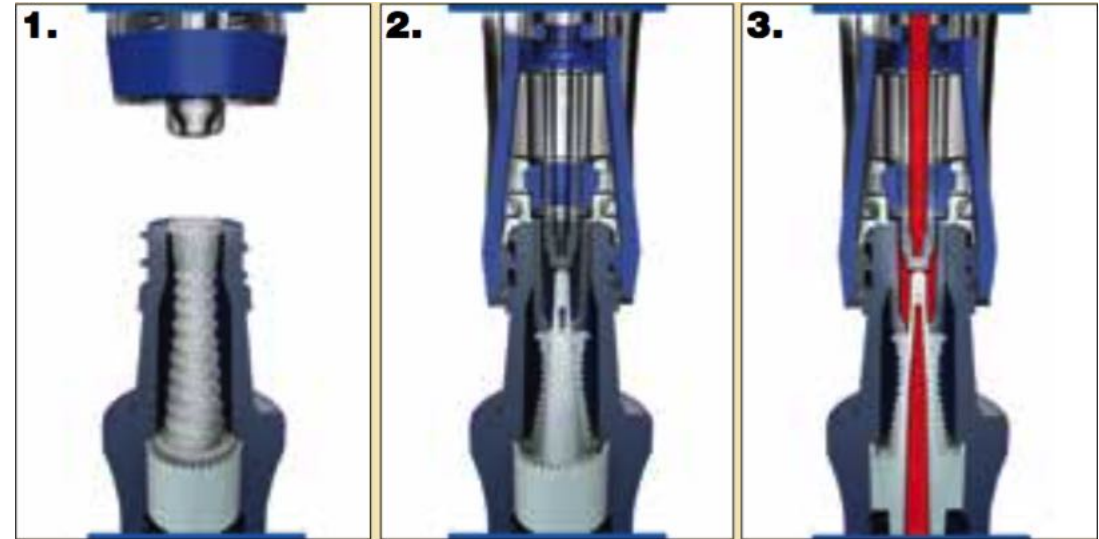
In response to the well-documented risks associated with handling hazardous drugs, ICU Medical has developed the ChemoClave system, the world's only needlefree closed system transfer device for the safe handling of hazardous drugs.

The ChemoClave system provides clinicians with a variety of needlefree vial access devices, a selection of needlefree bag spikes, and primary add-on and administration sets featuring the Spiros® CSTD Male Luer. These devices work independently or in conjunction to create and maintain a mechanically and microbiologically closed system throughout the preparation, transportation, administration, and disposal of hazardous drugs. At no point in the process is the clinician, patient, or environment exposed to any hazardous chemicals.



How does ChemoClave work?

1. The Spiros CSTD male luer and the Clave needle-free connector are closed until activated
 2. When the Spiros is connected to the Clave on the vial spike, the fluid path opens and allows the two-way transfer of fluids with the vial spike automatically equalizing vial pressure
 3. When the Spiros and Clave are disconnected, they automatically close and self-seal
- We recommend a 3 count upon disconnect to ensure the mating surfaces have time to clear



ChemoClave Demo Video

<https://www.youtube.com/watch?v=UmytQorUOEU&feature=youtu.be>

How Effective is ChemoClave?

Evaluation of surface contamination with cyclophosphamide following simulated hazardous drug preparation activities using two closed-system products

Zock M, Soefje S, Rickabaugh K, J Oncology Pharm Practice. 2010; Aug 10

PURPOSE

This study evaluated the effectiveness of two closed-system drug transfer products, the ChemoClave™ Oncology Preparation and Delivery System by ICU Medical, Inc., and the PhaSeal® Preparation and Delivery system by BD (Becton, Dickinson and Company), in preventing contamination in a typical pharmacy workplace.

MATERIALS AND METHODS

The ChemoClave system, and the PhaSeal system were evaluated in a two-day comparative study simulating hazardous drug preparation in a controlled laboratory setting. Cyclophosphamide (CP) was the hazardous drug marker. Samples were collected from gloves, workbench, airfoil, and floor before and after each trial. Forty vials of lyophilized cyclophosphamide were divided into two groups of 20 vials each. Wipe samples were collected before each trial and after cleaning with SurfaceSafe®.

Data

ChemoClave system: CP was detected on the exterior of some of the vials. None was found on the BSC airfoil/grille or on the floor; however CP was detected on the workbench and gloves. Researchers noted it was possible that the chemical contamination on the vials “contributed to the low level detected on the BSC workbench” and was spread from the vials to the technician’s gloves, and ultimately to the workbench.

PhaSeal system: No CP was detected on the exterior of the vials. CP was detected on the BSC workbench. Because no CP was detected on the exterior of vials or gloves, surface transfer is unlikely to have occurred. On two occasions the Luer Lock protective needle caps failed to retract when withdrawn from the vial, exposing the needles. In addition to creating a needlestick hazard, droplets that would have ordinarily been contained could have contaminated the workbench.

Table 2. Summary of pre-trial sample results

Surface description	Surface area (cm ²)	Prior to ChemoClave™ trial		Prior to PhaSeal® trial	
		Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)	Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)
Floor	4400	nd ^a	<0.004	nd	<0.004
Airfoil/grill	2000	nd	<0.008	nd	<0.008
Workbench	4400	nd	<0.004	nd	<0.004

^and = not detected (cyclophosphamide < 15.7 ng).

Table 3. Summary of post-trial sample results

Surface description	Surface area (cm ²)	Following ChemoClave™ trial		Following PhaSeal® trial	
		Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)	Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)
Floor	4400	nd ^a	<0.004	nd	<0.004
Airfoil/grill	2000	nd	<0.008	nd	<0.008
Workbench	4400	468	0	622	0
Gloves	2 gloves	377	na ^b	nd	na

^and = not detected (cyclophosphamide < 15.7 ng).

^bna = not applicable

Results & Conclusion

The ChemoClave and PhaSeal systems, when operated properly, are similarly effective. Vial contamination may have contributed to the low level of CS observed on the BSC workbench following the ChemoClave trial. Work practices and procedures regarding product operation may have contributed to the low level of CS observed on the BSC workbench following the PhaSeal trial. Work practices and procedures regarding product operation appeared to be an important factor in hazardous drug containment and needle safety when using PhaSeal, but not when using ChemoClave, which requires fewer steps and it is needlefree.

On one occasion while performing a separate study, the internal needle of the PhaSeal system became unintentionally exposed with a fluid droplet observed on the needle tip.

Not only did we find contamination in the workspace as a result of this but the exposed needle could have been a hazard for a potential needle stick

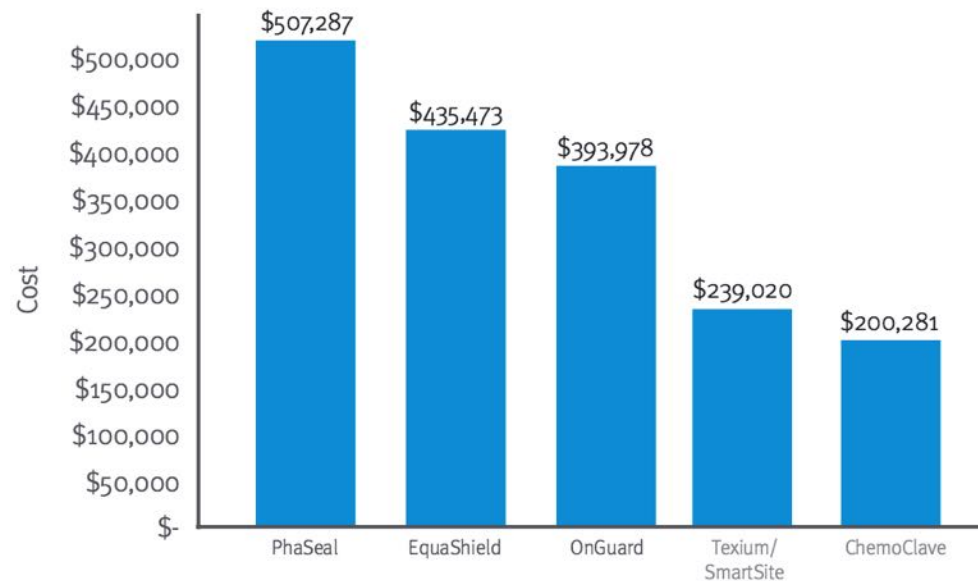
The Photo shows the exposed needle with fluid a fluid droplet



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

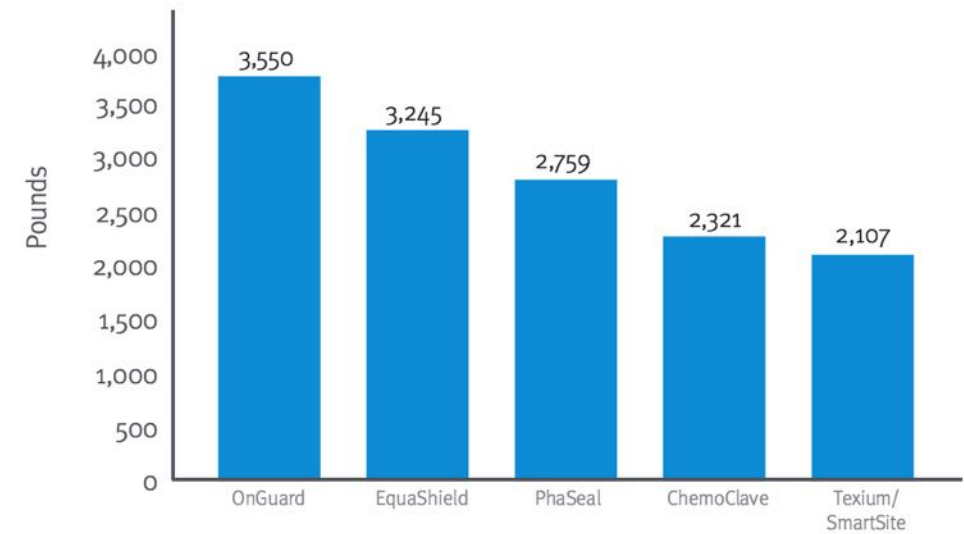
Cost and Biohazard Comparisons

Chart 1: Total Annual Costs Associated with Implementing Competing CSTDs



Component cost may vary slightly due to manufacturing price changes, contract pricing, and/or volume discount pricing. Texium/SmartSite is marketed as a closed system, not a CSTD.

Chart 2: Total Annual Biohazardous Waste Generated by Competing CSTDs



Calculations are based on an average of 1,276 monthly infusions over 12 months for a total of 15,312 infusions annually. Texium/SmartSite is marketed as a closed system, not a CSTD.

ChemoClave®

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

Closed System Male Adapter

The 'Spiros' is our closed male adapter that will connect to all syringes that come in contact with chemotherapy drug

When administering chemo drugs – ALWAYS use luer lock syringes

The Spiros will also be used on the male end of the admin set that are used to administer drug via infusion – it will luer onto the patient port when ready to give infusion

The Spiros comes in a spinning and non-spinning model. The benefit to the spinning Spiros is you cannot accidentally disconnect your Spiros from your syringe – the spinning is what we recommend

Closed Male Luer



Spiros (AH2000S - Spinning)
(AH2000 - Non-Spinning)
For use on a syringe or administration set

Diluting Drug before Administering

The syringe to syringe transfer set is used when you must dilute your drug

- Draw up drug with Spiros on syringe
- Draw up flush using the bag spike
- Luer drug syringe on one side of transfer set and your flush syringe on the other

BE SURE to push the flush into the drug syringe

If you need to draw up drug in a 1ml syringe and need to dilute more volume than the drug syringe will allow, follow the above instructions and add these steps:

- Attach a Spiros to your flush syringe
- Push drug into larger syringe
- Flush the transfer device behind the drug into the flush syringe



Syringe Transfer Set (AH33)
Use to transfer from syringe to syringe

Vial Adapter

Vincristine Vials w 13mm Tops	 Vial Spike, 13 mm (AH62) Allows for access to small vials with 13 mm closures
	 Vented Vial Spike, 13 mm (AH72) Allows for access to small vials with 13 mm closures and automatically equalizes pressure
Drugs that DO NOT need to be reconstituted Filtered air equalized pressure in vial If you overdraw DO NOT reinject into vial	 Universal Vented Vial Spike (AH70) Large vent offers better flow rates and reliability, skirted configuration available
Drugs that MUST be reconstituted The external balloon will capture any particles If you overdraw you MUST put vial back right side up to reinject	 Vial Spike (AH80) Allows access to vials having 20 mm/28 mm closures, and external balloon equalizes pressure for reconstitution

Patient Ports

The MicroClave port can attach to any butterfly catheter or IV catheter to administer Drug	 MicroClave Port (AH3300) Attaches to the catheter hub for needlefree venous access
The MicroClave T connector attaches to any IV catheter	 7" T-Port Extension with MicroClave (AH7002) Attaches to the catheter hub for needlefree venous access

Giving Drug Via Administration Set

The admin set with integrated clave drip chamber allows you to infuse your bag with your drug needle free

- Spike bag and prime your line
- Connect a 'Spiros' to the male end of your line once the line is primed
- Draw up your drug – luer drug syringe onto the Clave above the drip chamber and infuse your bag

Once treatment is given you can flush with a regular needleless syringe at the MicroClave Y Site

Upon disconnect from patient, the Spiros on the end of the line will keep the admin set sealed and safe for disposal

If you prefer to manually push your drug at the Y-site of your administration set and do not need the integrated infusion port, we have several admin sets that have the MicroClave Y-site. These sets will allow you to connect your drug syringe with the Spiros directly to the Y-site.

You will do the following:

- Spike bag and prime your line
- Connect a 'Spiros' to the male end of your line once the line is primed
- Administer Drug
- Flush with a regular needleless syringe at the MicroClave Y Site



92" Admin Set with Integrated Clave Drip Chamber, MicroClave Y Site and rotating luer with filter cap (AH3019 - 20 Drop) (AH7185 - 60 Drop)



80" 15 Drop Admin Set w/MicroClave Injection Site (AH7181)
103" 15 Drop Admin Set w/MicroClave Injection Site (AH7195)

Flushing Protocol

Because the Clave & MicroClave adapters are designed to accept standard male adapters & syringes, you DO NOT need a safety device on your flush syringe

Insert bag spike into your flush bag and use a syringe without a needle to draw up flush with the Clave bag spike and flush your patient port after your drug dose



Bag Spike (AH10)
For use on any solution container

Vial Adapter Instructions

AH70 & AH 80



- › If required, reconstitute per manufacturers instructions.
- › Remove cover by pulling the tab.



Upright on
Flat Surface

- › Place the vial in the upright position on a flat surface.
- › Connect and slowly infuse diluent into the vial.
- › Do not infuse more than 100cc's of diluent.



Don't
Infuse

- › Never infuse fluid or air into vial when inverted.



- › Invert to withdraw.
- › Then, immediately remove the 1-2cc air bubble.
- › Withdraw fluid from the vial.

Storage Tip:

Always store vial in upright position on flat surface.

Safety Recommendations

- Upon arrival to the clinic, take your chemotherapy vials outside and thoroughly cleanse them with alcohol. These vials may be contaminated from the production facility.
- When administering chemo, wear 2 pairs of gloves on each hand, a mask, and a gown. All of which should be disposed of upon completion of administering the drug.
- If you do not have a hood, we recommend drawing up your drug outside of the clinic as an extra safety precaution.
- NEVER store chemo drugs in the same refrigerator as food. They should be stored in a drug exclusive refrigerator.
- Please contact your PractiVet fluid therapy specialist to help solidify your oncology safety protocol



USP <800> CSTD Compliance

Rumors Are Circulating Enforcement Will Start In January 2018 In Animal Health

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.

Resources & Links to Studies

- http://www.icumed.com/media/69877/m1-1266_zock_study_summary_rev_o2_blue.pdf
- http://www.icumed.com/media/122043/M1-1309_Cost_Determination_of_CSTDs_Study_Summary_Rev02_PressReady.pdf
- <http://www.icumed.com/media/122037/M1-1298%20Cost%20and%20Waste%20Comparison%20Study%20Summary%20Rev.%2003.pdf>

For more info, please go to our manufacturer's website

- <http://www.icumed.com/products/oncology/hazardous-drug-closed-systems-and-cstds/chemoclave.aspx>



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