

New Clinical Studies Show ICU Medical's ChemoLock™ Closed System Transfer Device Prevents Hazardous Drug Surface Contamination and Provides a Completely Dry Disconnect

Studies from researchers at Nebraska Methodist Hospital and University of Nebraska Medical Center showing the effectiveness of the newly launched system were presented yesterday at the American Society for Health-System Pharmacists Midyear meeting in Orlando, FL

ORLANDO, Florida, December 12, 2013 – [ICU Medical, Inc.](#) (NASDAQ: ICUI) today announced that two new studies presented yesterday at the American Society of Health-System Pharmacists (ASHP) Midyear Meeting and Exhibition in Orlando demonstrated that the company's newly launched [ChemoLock™ closed system transfer device](#) (CSTD) prevents hazardous drug surface contamination while eliminating leakage and providing a completely dry disconnect.

ChemoLock is the first and only needlefree CSTD to receive United States Food and Drug Administration (FDA) 510(k) clearance for pharmacy applications (product code ONB), as well as patient administration applications (product code FPA) and was officially launched this week at the ASHP meeting.

The studies, performed by researchers at [Nebraska Methodist Hospital](#) and [University of Nebraska Medical Center](#), are the first independent studies to verify the efficacy of the ChemoLock system. ChemoLock is designed to provide a new standard of safety for hazardous drug preparation, transportation, administration and disposal. The system prevents the escape of hazardous drug or vapor concentrations outside the system, blocks the transfer of bacteria and other environmental contaminants into the system, and eliminates needlestick injuries while keeping patients and clinicians safe from hazardous drug exposure.

In the first study, titled [Evaluation of FDA-Approved ONB Closed-System Transfer Devices Utilizing Cyclophosphamide as a Marker](#), researchers performed surface wipe studies to determine the pre- and post- preparation levels of hazardous drugs on working surfaces, comparing the ChemoLock with Beckton Dickinson's PhaSeal® system. For the ChemoLock system, no cyclophosphamide (CP) was detected on working surfaces or the compounders' gloves following the preparations. For the PhaSeal system, CP was detected on the biological safety workbench following two of the trials and on one occasion the internal needle of the product became unintentionally exposed with a fluid droplet observed on the needle tip.

In the second study, titled [pH Liquid Integrity Test of FDA-Approved ONB Closed-System Transfer Devices](#), the researchers used litmus paper to test for simulated hazardous drug residual on the ChemoLock system components following 20 drug preparations and compared that to residual left on the PhaSeal system components and on a traditional needle and syringe after an equivalent number of preparations. Based on this testing, researchers observed that there was no leakage with the ChemoLock system but that visible leakage occurred with 1.7% of PhaSeal system preparations and 43% of traditional needle and syringe mixes.

The study conclusion stated that both CSTDs provided substantial improvement in safety over compounding with a needle and syringe but that PhaSeal "had two failed manipulations in a relatively small sample size." They added "the ChemoLock product had no litmus paper color changes and no visible droplets evident during manipulations."

The ChemoLock system consists of easy to use needlefree components that connect with an audible click, cannot be deactivated, and will passively aid in preventing both needlestick injuries and exposure to cytotoxic medications. No complex assembly is required prior to usage and the system remains completely closed throughout the entire safe handling process—including preparation, transportation, administration, and disposal—assuring both patient and caregiver safety as well as the sterility of the prepared medication.

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Contact: Tom McCall
Vice President, Chief Marketing Officer
949-366-4368
tmccall@icumed.com

About ICU Medical, Inc.: ICU Medical, Inc. develops, manufactures and sells innovative medical devices used in vascular therapy, oncology and critical care applications. ICU Medical's products improve patient outcomes by helping prevent bloodstream infections and protecting healthcare workers from exposure to infectious diseases or hazardous drugs. The company's complete product line includes custom IV systems, closed delivery systems for hazardous drugs, needlefree IV connectors, catheters and cardiac monitoring systems. ICU Medical is headquartered in San Clemente, California. More information about ICU Medical, Inc. can be found at www.icumed.com.