Two New Clinical Studies Show ICU Medical ChemoClave® System Improves Safety by Reducing Hazardous Drug Exposure and Eliminating Accidental Disconnects

Studies from two major children's hospitals presented at the Association of Pediatric Hematology/Oncology Nurses (APHON) Annual Conference in Louisville, KY September 19-21 highlight the effectiveness of the ChemoClave closed system and closed system transfer device

SAN CLEMENTE, Calif., September 19, 2013 – ICU Medical, Inc. (NASDAQ: ICUI) today announced that two new studies presented this week at the 37th Annual Association of Pediatric Hematology/Oncology Nurses (APHON) Annual Conference in Louisville, KY showed that the company's ChemoClave® closed system and closed system transfer device (CSTD) improves patient and clinician safety by reducing hazardous drug exposure and eliminating accidental needlesticks.

The studies were performed by clinicians at two major children's hospitals—The Center for Cancer and Blood Disorders at Children's National Medical Center in Washington DC, and Cook Children's Medical Center (CCMC) in Fort Worth, TX—who will be available to discuss their findings at the ICU Medical booth (#205) at the APHON conference.

In the study titled *Reducing Hazardous Drug Exposure: Are All Closed Systems Created Equal?* a research team from Children's National Medical Center reported on an initiative to reduce hazardous drug spills, blood exposure, and the risks associated with an open central venous catheter caused when a CSTD disconnects from a patient's IV tubing. The initiative was begun following "a dramatic rise in exposure to antineoplastic agents due to spills as a direct result of disconnections of the infusion tubing to the CSTD." (PhaSeal™, Beccton, Dickenson, and Company).

The safety improvement process was implemented in two phases. The first phase involved assembling an interdisciplinary team to identify the root cause of hazardous drug spills during patient administration. This team evaluated incident report data and consulted with PhaSeal CSTD manufacturer representative. Subsequent practice changes were instituted, and both nursing and pharmacy teams were reeducated. The outcomes of these changes were recorded and analyzed.

During the second phase, the interdisciplinary team researched alternative CSTD systems, including the ICU Medical ChemoClave needlefree CSTD, featuring the Spinning Spiros® closed male luer. The team conducted a trial of the system in June 2012, and implemented the product in November 2012.

In spite of efforts to reduce disconnects with the existing PhaSeal product, there continued to be disconnects on a regular basis, the researchers reported. After research and a product trial were completed, the team at Children's National Medical Center introduced and implemented the ChemoClave needlefree CSTD featuring the Spinning Spiros in November 2012. To date, there have been no exposures to hazardous drugs from disconnects following the conversion to the ChemoClave system.

"The Spiros closed male luer proved to be an effective solution for reducing disconnects and the potential for dangerous exposure to hazardous drugs and blood, and complications related to an open line," the researchers concluded, adding that the Spiros' "small size is ideal for our pediatric patients, increasing patient/family satisfaction."

In the study titled *Improving Chemotherapy Safety via Use of ChemoClave® System (Spiros®), Priming Technique, DoseEdge™, and Volutrols*, researchers from Cook Children's Medical Center took a multi-faceted approach to safety improvement aimed at reducing exposure to hazardous drugs during both pharmacy preparation and patient administration. In order to decrease the potential for aerosolization and leaks of dangerous chemotherapy drugs, CCMC implemented the ChemoClave CSTD, which included the Spiros closed male luer, needlefree vial access devices and bag spikes, and administration devices.

To facilitate the effective implementation of ChemoClave, ICU Medical provided in-servicing for both pharmacy and nursing staff and worked to create a custom administration set with a pre-bonded Spiros. ChemoClave made it possible for CCMC staff to prime tubing under the compounding hood, helping to minimize the risk of chemotherapy aerosolization and surface contamination in the medication room, while also decreasing the risk of microbial contamination of the patient line. In addition to the ChemoClave system, CCMC initiated a variety of practice changes including priming with chemotherapy drugs, utilizing the DoseEdge™ pharmacy system, and using volutrols for time-limited infusions.

As a result of these efforts, CCMC has not experienced any events related to chemotherapy leaks since February 2012. Following additional process changes in chemotherapy drug preparation and administration, overall central line associated bloodstream infection rates for the Hematology/Oncology and Stem Cell Transplant units decreased from 5.8 per 1,000 catheter days in 2009 to 1.6 per 1,000 catheter days in 2012.

“Implementation of the ChemoClave system, in combination with a variety of procedural improvements, correlated with a reduction to zero chemotherapy leaks or spills,” the researchers concluded.

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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.