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ICU Medical's Diana™ System May Help Compounding Pharmacies Avoid Drug Contamination

Automated Needlefree System is Microbiologically and Mechanically Closed and May Provide Safety, Sterility and Accuracy to Compounding and Hospital Pharmacies

SAN CLEMENTE, Calif., Oct. 22, 2012 – A recent high-profile incident involving drug contamination and patient deaths associated with a compounding pharmacy underscores the safety challenges associated with current drug compounding processes throughout the country. Fortunately, there is a system available today that may help ensure the sterility of drugs during the drug compounding process. The [Diana™ Hazardous Drug Compounding System](#), manufactured by ICU Medical, Inc. (NASDAQ: [ICUI](#)), is the world's only needlefree user-controlled automated compounding system for the safe reconstitution and preparation of hazardous drugs.

Originally designed to keep patients and clinicians safe from hazardous drug exposure during chemotherapy preparation, the completely closed Diana System may also keep the drugs themselves safe from exposure to outside contaminants. Organizations such as the National Institute for Occupational Safety and Health (NIOSH) and the United States Pharmacopeia (USP <797>) have recommended the use of closed systems to help protect the healthcare worker from exposure to hazardous agents and to protect the sterility and integrity of drugs.^{1,2}

The Diana system has been in clinical use in Europe for more than a year, and is just now being introduced in the United States, with the system's full market release planned at the [American Society of Health System Pharmacists \(ASHP\) Annual Meeting](#) in December. Clinical studies have demonstrated that the Diana System components are both microbiologically and mechanically closed.^{3,4} This feature may help ensure the safety of a drug throughout the compounding process, from the introduction of fluids for reconstitution, to the transfer of the drug from its original vial, and then to final transfer into a syringe or IV bag for patient use.^{5,6}

"If our technology can help prevent potential contamination in the drug compounding process, we stand ready to help," said ICU Medical Chief Executive Officer George Lopez, MD. "We designed Diana so that nothing can escape from the system to endanger a clinician, but as a completely closed system, nothing should be able to enter the system to contaminate the drug, either. We look forward to exploring this solution with compounding and hospital pharmacies in the U.S. after a successful track record in Europe."

The microbiologically and mechanically closed design of the Diana System is accomplished through a series of innovative needlefree components, including closed vial access devices, needlefree closed male luers and needlefree connectors. These components attach to all containers that are dispensing or receiving a drug in the compounding process, including the source drug vial, and any syringe or IV bag used in the process. As the drug moves through the automated compounding process and is prepared for its final patient packaging, the components protect the drug from exposure to environmental contaminants and protect the clinician from both exposure to the drug and accidental needlesticks.

The Diana system is designed to facilitate both low-volume and high-volume preparation of drugs, fits inside the pharmacy's biological safety cabinet and complements existing pharmacy workflows. The system also provides automated checks and reminders to improve workflow efficiency and safety.

The Diana system was inspired by Dr. Lopez' wife, Diana, who passed away from cancer in 2006. During her chemotherapy treatment, she heard health complaints from nurses who were becoming ill from exposure to chemotherapy drugs. She asked her husband to create a solution that would keep the patients and caregivers safe from any exposure, and the result is the Diana System.

1. NIOSH (US). Prevention of Occupational Exposure to Antineoplastics and Other Hazardous Drugs in Healthcare Settings. September 2004.
2. United States Pharmacopeia (USP) 797. Pharmaceutical Compounding, Sterile Preparations. 2007.
3. ICU Medical Laboratory Study Summary: Spiros®: Mechanically and Microbiologically Closed Male Luer
4. ICU Medical Laboratory Study Summary: Genie®: Mechanically and Microbiologically Vial Access Device
5. Moore A, Wiley K, Maloney K, Holmes M, Hospital of the University of Pennsylvania; Creating a Culture of Closure:

Implementation of the ICU Medical Chemotherapy Closed System for Antineoplastic Agent Administration; Presented at the Oncology Nursing Society Meeting, May 2012

6. The Role of Closed System Transfer Devices in Mitigating the Risks Posed to Healthcare Workers in the Handling of Hazardous Drugs, Jamie Kelly, Principal, Entropy Research, March 2011, <http://www.icumed.com/products/oncology.aspx?show=all>

Contact: Tom McCall
Vice President, Marketing
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.