



RE: ICU Medical Oncology preparation and delivery systems including the Spiros™, Genie™ and CLAVE® Connectors as Applicable to;

- **NIOSH:** Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in the Health Care Setting. DHHS (NIOSH) 2004-165, Sep 2004.
- **ASHP:** Guidelines on Handling Hazardous Drugs. AJHP, 2006, 63:1172-93.
- **USP 797:** Pharmaceutical Compounding – Sterile Preparations. 2007.

Thank you for your interest in the Spiros and CLAVE Connectors for use with hazardous drugs. Each device and their accompanying vial spikes, bag spikes and tubing sets meet the recommended guidelines for each of the above mentioned publications for the entire Hazardous Drug Handling Process including; ***Preparation; Transport; Administration; and Disposal.***

The NIOSH Standard reads “*Consider using devices such as closed system-transfer devices, glovebags, needleless systems when transferring drugs from primary packaging (such as vials)*” p.13. The Spiros and CLAVE both qualify as closed, needleless transfer systems. Both products have a passive (fail-safe) closing technology where they automatically return to the closed position when there is a disconnect; accidental or intentional. NIOSH also specifically states to “*Never remove tubing from an IV bag containing a hazardous drug*”. The closed, integrated tubing sets have permanently bonded connections which eliminate the “add-on” components, the “un-spiking” of secondary bags and the potential for unsafe disconnect points. These systems are efficient from both an economic and educational standpoint to work within the current pharmacy-nursing protocols and do not require radical new practices and procedures.

The ASHP Recommendation reads: “*Closed-system drug transfer devices mechanically prevent the transfer of environmental contaminants into the systems and the escape of drug or vapor out of the system*”. Both the Spiros and CLAVE are passive safety designs that are always in the closed position until they are activated to infuse or transfer the drug.

The 2007 USP 797 introduced a section on Closed System Transfer Devices (CSTD) which discusses the handling of cytotoxic drugs. Both CLAVE and Spiros qualify as CSTD as they are passively closed devices until activated. All ICU Medical products are single packaged, sterile, and meet the requirements of ISO10993 for Biocompatibility. The product directions for use specify that they are each single patient or single container products which cannot be removed for secondary use or re-sterilization. The sterility of each product is validated in accordance with ANSI/AAMI/ISO 11137, 1994, Method 1.

Thank you again for your interest, if there are further questions or concerns please visit our website at www.icumed.com, or contact the corporate offices at 949-366-2183.

Best regards,

Alison D Burcar
ICU Medical, Inc.