WHITE PAPER

Spiros®: Mechanically and Microbiologically Closed Male Luer

INTRODUCTION

Hazardous drugs used in the therapeutic treatment of many cancers are most commonly delivered to a patient intravenously. Unfortunately, traditional IV equipment, including tubing and plastic components used to deliver medications, can be degraded by exposure to hazardous drugs, damaging the plastic and releasing chemicals into the fluid path that can ultimately be delivered to the patient.

Furthermore, the health risks posed by exposure to these agents for healthcare workers has prompted organizations such as the National Institute for Occupational Safety and Health (NIOSH) and the United States Pharmacopeia (USP ‹797› and ‹800›) to recommend the use of specialized closed system transfer devices (CSTDs) to reduce clinician exposure to these hazardous drugs.[1,2]

This paper describes the ways in which certain drugs interact with specific compounding and administration devices. It also describes the compatibility validation process used by ICU Medical to prove that the ChemoClave® CSTD system meets standards required for hazardous drug compounding and administration. To comply with these requirements and be considered a complete CSTD, the Spiros closed male luer was designed as a mechanically and microbiologically closed device and engineered to prevent the escape of fluids and aerosols, as well as the ingress of microorganisms during clinical use.

MECHANICALLY CLOSED

A device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system is considered mechanically closed. ICU Medical's CSTD systems have been shown in microbial ingress testing to prohibit transfer of contaminants over a seven-day period.[3] The Spiros provides this important benefit by employing a passive safety feature whereby the device is always in the "closed" position unless it is activated by attaching it to a needlefree connector, thus activating the fluid path. When placed on the end of a syringe or IV tubing, the Spiros will passively remain closed to prevent drips or leaks. In the event of accidental disconnect, the Spiros will automatically return to the closed, or fail-safe position. This feature requires no intervention by the healthcare worker.

Table 1.

Test Procedure	Specification	Results	Statistical Confidence Level
Activated Leak Test: Place Spiros on syringe and attach the needlefree connector to access fluid path. Verify that no external leakage occurs from the connection.	› 60 psig for 10 seconds	PASS	99.99%
Unactivated High-Pressure Leak Test: Place Spiros on syringe and apply pressure. Verify that no leakage occurs from closed male luer of Spiros.	› 60 psig for 5 seconds	PASS	99.99%
Unactivated Low-Pressure Leak Test: Attach Spiros to IV set and hang at 36" head heights. Verify that there are no drips or leaks from closed male luer of Spiros.	No Formed Drops of Fluid Allowed	PASS	99.99%

In studies to validate the safety and efficacy of the Spiros as required by the FDA, three different studies were performed to verify the ability of Spiros to perform as a "closed" device in conditions that mimic clinical practice.

MICROBIOLOGICALLY CLOSED

In order to validate the Spiros as a microbiologically closed device, an outside contract laboratory was consulted to validate the ability of the Spiros to prevent bacterial contamination. Bacterial ingress is a substantial risk for immune-compromised patients receiving chemotherapy, and special care should be taken to address the risk of catheter-related bloodstream infection (CRBSI). The Spiros is not only designed to protect the healthcare worker from exposure to hazardous drugs, but also to protect the patient from bacterial ingress into the chemotherapy administration system.

MICROBIAL INGRESS STUDY

TLC Laboratories, Inc. of Irvine, California was contracted to independently perform a microbial ingress study on the Spiros.

PROTOCOL

Samples of the Spiros luer were aseptically attached to 20 mL syringes filled with normal saline. The tips of the Spiros were then artificially contaminated with staphylococcus epidermidis at a concentration of 8.8 x 10^5 by touching the tips to the bacterial inoculum and then allowing the tips to dry. The tips of the Spiros were then disinfected by swabbing with 70 percent isopropyl alcohol using an aggressive circular motion for three seconds. The positive control units were processed by manually activating the fluid path of the Spiros using an open female connector and then inoculating. The negative control units were processed by eliminating the touch contamination procedure. The Spiros syringe assemblies were then attached to a female luer on a filter funnel unit to activate the fluid path. The entire contents of the 20 mL syringe were infused through the Spiros and over the filter to capture any bacterial growth. Results are shown in the adjacent table.

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Table 2.

	Total CFU / Sample
Population Verification Samples	3.9 x 10^2
Test Samples (No.20)	0
Positive Control Samples	5
Negative Control Samples	0

RESULTS

Results of the study confirmed that at no time did the Spiros allow bacteria to penetrate into the fluid path. Additionally, the study demonstrated that the Spiros can effectively be disinfected with a standard isopropyl alcohol swab. For added assurance, the Spiros may also be protected with a nonactivating cap that prevents touch contamination of the male luer during storage and transport.

References
1. NIOSH Alert. Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. CDC. 2004;165.
2. USP General Chapter ‹800›: Hazardous Drugs – Handling in Healthcare Settings. US Pharmacopeial Convention Pharmacopeial Forum (PF). Feb. 1, 2016.
3. Microbial Ingress Study for ChemoClave Devices. M1-1474 Rev. 01