

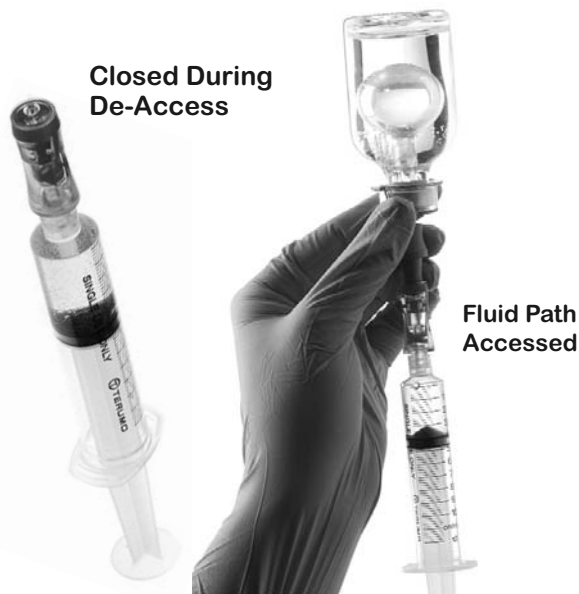
# SPIROS™: Mechanically and Microbiologically Closed Connector

## INTRODUCTION

The Spiros Closed Male Connector is a Microbiologically and Mechanically closed device that will prevent the escape of fluids or the ingress of micro-organisms during clinical use. The Spiros employs a passive safety feature where it is always in the 'closed' position until it is activated by attaching it to any luer activated NeedleFree Connector.

Organizations such as NIOSH and USP 797 have recommended the use of specialized IV equipment to help protect the healthcare worker from exposure to hazardous drugs and to protect the integrity of the drug itself.<sup>1,2</sup> The Spiros is intended to support both these needs with its passive safety design. While various Closed System Transfer Devices (CSTD) have been available for many years, they lack practicality in the patient administration area. The way in which chemotherapy is administered is very patient and facility specific, unique protocols and products, such as the administration pump, govern how clinicians must function. In this unique environment products must be intuitive to the clinician and must not require a large learning curve. **If safety products require active intervention by the clinician and are difficult to learn, the end likely result is the products are removed or the safety feature is bypassed and the product fails.** The Spiros is handled in the same way traditional luer lock connections are made. The safety feature is integral and non-defeatable, meaning it forces compliance with the safety policy; the clinician cannot remove or bypass the safety feature. Resulting from its traditional luer lock design, the Spiros also makes safe handling of hazardous drugs simple.

## MECHANICALLY CLOSED



The Spiros maintains a normally closed system until it is attached to a needlefree connector and the fluid path is activated. 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 and the function has been validated in accordance with the product's specifications (*PS00-00022*) by ICU Medical in the following way.

### Specifications

In order to validate the safety and efficacy of the Spiros as required by the FDA, ICU as the device manufacturer must perform validation studies for functions of the device. Three different test methods to verify the nature of the 'closed' feature were developed to mimic clinical practice and validate the product. The following table outlines the various studies and their results.

Test Procedure	Specification	Results	Statistical Confidence Level
<b>Activated Leak Test:</b> Place Spiros on Syringe and attach the needlefree connector to access fluid path and verify that no external leakage occurs from the connection.	> 20 psig for 10 seconds	PASS	99.99%
<b>Unactivated High Pressure Leak Test:</b> Place Spiros on syringe and apply pressure. Verify that no leakage occurs from closed male luer of Spiros.	> 20 psig for 5 seconds	PASS	99.99%
<b>Unactivated Low Pressure Leak Test:</b> Attach Spiros to IV set and hang at 36" head height. Verify that there are no drips or leaks from closed male luer of Spiros.	No Formed Drops of Fluid Allowed	PASS	99.99%

## MICROBIOLOGICALLY CLOSED

Risk of bacterial ingress is a substantial problem for immune compromised patients receiving chemotherapy. Care should be taken to ensure patient safety and 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 to protect the patient from bacterial ingress into their chemotherapy administration system.

In order to validate the ability for the Spiros to prevent bacterial contamination, *TLC Laboratories, Inc. of Irvine California* was independently contracted to perform a Microbial Ingress Study on the Spiros Closed Male Connector.

### Protocol

Samples of the Spiros Connector were aseptically attached to 20mL syringes filled with normal saline. The tips of the Spiros were then artificially contaminated with *staphylococcus epidermidis* at a concentration of  $8.8 \times 10^5$  by touching the tip to the bacterial inoculum and then allowed to dry. The tips of the Spiros were then disinfected using a 70% isopropyl alcohol swab 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 20mL syringe was then infused out through the Spiros and over the filter to capture any bacterial growth. Results are shown in the adjacent table.

### Results

Results of the study confirmed that at no time did the Spiros allow for bacteria to penetrate the closed male luer. Additionally, the study demonstrates that the Spiros can be effectively disinfected with a standard isopropyl swab during use. The Spiros Closed Male Connector is an effective barrier to bacteria and will maintain the integrity of the sterile solution container if properly disinfected before access. The Spiros may also be protected with a non-activating cap which will prevent touch contamination of the male luer for storage or transport purposes.



Inoculation site of the male luer tip and subsequent point of disinfection.

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

### References

- <sup>1</sup> NIOSH (US). Prevention of Occupational Exposure to Antineoplastics and Other Hazardous Drugs in Healthcare Settings. Sep-2004.
- <sup>2</sup> United States Pharmacopia (USP) 797. Pharmaceutical Compounding, Sterile Preparations. 2007.



951 Calle Amanecer, San Clemente, CA 92673, U.S.A.  
Tel: +1 949 366 2183 • www.icumed.com