

# GENIE™: Mechanically and Microbiologically Closed Vial Access

## INTRODUCTION

The Genie Vial Access Device is a Microbiologically and Mechanically closed device that will prevent the escape of fluids and aerosols, or the ingress of micro-organisms during clinical use. The Genie 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 in order to aspirate fluid from a medication vial.

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 Genie 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 one or more of the mechanically and microbiologically closed elements. In order to ensure complete product integrity the device must be Microbiologically closed which in turn, means the access point requires sterility, or way to achieve sterility. This is also known as being "swabable". A Swabable device allows for disinfection of the access point to ensure every subsequent access is done under sterile conditions. Furthermore, there must be evidence to support that under normal use, as the access site becomes contaminated, that bacteria cannot penetrate. A CSTD that is not swabable, cannot be considered Microbiologically Closed.

The way in which chemotherapy is prepared is very patient and facility specific. Unique protocols and products such as the location of the preparation room in conjunction with the patient area, govern how clinical personnel 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 Genie is handled in the same way traditional vial access devices are handled and include the familiar luer lock connections. Vial pressure equalization is automatic and requires no clinician intervention. 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. Because of its intuitive design, Genie makes the safe handling of hazardous drugs simple.

### Closed During De-Access



### Fluid Path Accessed



## MECHANICALLY CLOSED

The Genie maintains a normally closed system through three functional areas. 1) Connection of the spike and vial stopper; 2) The balloon within the vial enclosure; and 3) The CLAVE needlefree Connector which is integrated as the access site for syringes.

Specifications: In order to validate safety and efficacy of the Genie as required by the FDA, validation studies were performed. Three different tests were developed to verify the nature of the 'closed' feature when the Genie is attached to a vial.

The connection of the Genie to the vial stopper and the characteristics of the integral balloon found within the vial closure are validated by attaching the Genie to a vial, inverting it and aspirating on three separate occasions. This verifies the balloon inflates properly and there is no leakage from the vial closure.

The CLAVE is closed until it is accessed by a standard luer locking syringe. Upon disconnect from the CLAVE, it automatically self seals and returns to the closed or "fail safe" position. The CLAVE maintains a positive backpressure rating to greater than 60psig for leakage out of the vial and a negative (vacuum) pressure for ingress to -9.5psig. This function has been validated in accordance with the CLAVE Performance Specification.

<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.

## MICROBIOLOGICALLY CLOSED

The Genie's barrier to bacterial ingress has been validated in two ways. The CLAVE connector which serves as the access site for syringes to infuse and aspirate is validated in a unique microbial ingress study. The study includes a rigorous simulated use model to demonstrate that with repeated access and swabbing with Isopropyl alcohol, the CLAVE, and therefore the vial contents will remain sterile. The second feature is the balloon which, allows for the outside ambient air to enter it while aspirating fluid from the vial in order to equalize pressure. The air passes through an orifice from the outside of the vial and into the interior of the balloon. The silicone balloon then acts as a filter for the air, and allows the air to pass through the balloon into the vial over time, until the balloon deflates. The resulting affect is that the Genie is under a constant negative pressure; air is always being drawn into the vial through the balloon, while no elements, including air or vapor ever pass back out through the balloon. It is a constant one-way street. A unique viral study was used to demonstrate that the balloon prevents any contaminants or vapors from passing through the balloon walls. Outside contract laboratories were consulted to develop the protocols and perform both studies.

### CLAVE Extended Use Vial Access Study

The Genie Vial Access Device is intended for use on multi-dose containers through the swabable access site of the CLAVE. In order to validate the CLAVE's ability to maintain a sterile barrier and protect the contents of a medication vial over time, an extended, multi-dose study was developed.

Protocol: Twenty (20) samples of a CLAVE multi-dose vial access device were attached to individual, sterile, 50mL medication vials. The CLAVE access sites were then inoculated with *Staphylococcus epidermidis* at a nominal population of  $5.0 \times 10^5$ . The vials were then placed on a laboratory counter in an uncontrolled and non-sterile environment for thirty (30) days. On twenty-six of the thirty calendar days, each CLAVE was swabbed with 70% Isopropyl alcohol and then accessed with a 3cc syringe. The four days where no access occurred were due to non-working weekend days at the laboratory. Approximately 2mL of fluid was withdrawn from the vial and then the vial was returned to the counter to rest. Each aspiration was processed through a filter funnel unit and then plated to determine positive bacterial growth. A total of 676 test sample aspirations were taken over the study period.

Results: All twenty vials demonstrated no bacterial growth at the end of the 30 study period. There were four false contamination events out of the 676 samples, however none matched the challenge organism and because the vials all remained sterile, it was determined to be laboratory error in the handling of the sample. This study demonstrates that the CLAVE can maintain a microbiological barrier for a period of 30 days when used on a multi-dose container.

### Genie Balloon Viral Barrier Challenge

The Genie balloon assists in the equalization of vial pressure when fluid is being aspirated from a medication vial. When the balloon is inflated, air can thereafter pass through the walls of the balloon and into the medication vial over time therefore, maintaining a negative pressure on the vial at all times. A study using viral contamination of the internal walls of the balloon was developed to demonstrate that no elements beyond air, have the ability to pass through the balloon wall either in or out of the vial.

Protocol: Phi-X174 bacteriophage was selected for the study as it is one of the smallest known viruses at 25-27nm and is effectively smaller than vapor particles which can result from the evaporation of fluids. Fifty (50) Genie test samples were inoculated with the virus by using a needle to infuse into the balloon interior while it was inflated. Test samples were studied for seven days and on each of the seven days, the CLAVE was swabbed and accessed with a syringe, and 1mL of fluid was removed for analysis. A total of 350 test samples were taken over the study period.

Results: All fifty vials demonstrated no viral contamination at the end of the seven day period. This study demonstrates that the Genie balloon is an effective barrier to prevent the passage of contaminants and vapors, and will maintain the sterility of the drug vial.

