

# GENIE®: Mechanically and Microbiologically Closed Vial Access Device

## INTRODUCTION

Organizations such as The National Institute for Occupational Safety and Health (NIOSH) and the United States Pharmacopeia (USP <797>) have recommended the use of specialized IV equipment called closed system transfer devices (CSTD) to reduce patient and clinician exposure to these hazardous drugs.<sup>1,2</sup> While various CSTDs have been available for many years, they have historically lacked one or more features ensuring a completely closed device, such as having a mechanically or microbiologically closed element. To comply with these requirements and be considered a complete CSTD, the Genie closed vial access device was designed as a mechanically and microbiologically closed system 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. The Genie 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 any luer activated needlefree connector to aspirate fluid from a medication vial.

In studies to validate the safety and efficacy of the Genie as required by the FDA, three different tests were developed to verify the unique features of the Genie that allow it to maintain a closed system when attached to a vial. These features are 1) the connection of the spike and vial stopper; 2) the balloon within the vial enclosure; and 3) the CLAVE® needlefree connector that is integrated as the access site for syringes.

The connection of the Genie to the vial stopper and the characteristics of the integral balloon found within the vial closure were 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. Upon disconnect, the CLAVE automatically self seals and returns to the closed or “fail-safe” position, maintaining a positive backpressure rating to greater than 60 psig for leakage out of the vial and a negative (vacuum) pressure for ingress to -9.5 psig. This function was validated in accordance with the CLAVE performance specification.

## MICROBIOLOGICALLY CLOSED

In order to validate the Genie as a microbiologically closed device, outside contract laboratories were consulted to develop two separate validation protocols and perform studies to demonstrate the Genie’s two-pronged barrier to bacterial ingress: easily maintained sterility; and constant negative pressure. In order for a device to be considered microbiologically closed, the access point requires sterility; or a way to achieve sterility. This means the product must be “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 point becomes contaminated, bacteria cannot penetrate. A CSTD that is not swabable cannot be considered microbiologically closed.

The second microbiologically closed feature is the integral balloon that allows for 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, allowing air to pass through the balloon into the vial over time until the balloon deflates. The resulting effect is that the Genie is under a constant negative pressure; that is, air is always being drawn into the vial through the balloon, while no elements, including air or vapor ever passes

## GENIE Closed Vial Access Device



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.

#### **CLAVE EXTENDED USE VIAL ACCESS STUDY**

The Genie is intended for use on multi-dose containers and is accessed through the integrated bonded CLAVE needlefree connector. 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**

In the study, 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 30 days. On 26 of the 30 calendar days, each CLAVE was swabbed with 70% Isopropyl alcohol and accessed with a 3cc syringe through which approximately 2mL of fluid was withdrawn from the vial. The 4 days on which no access occurred were due to non-working weekend days at the laboratory. Over the study period, each of the 676 total test sample aspirations was processed through a filter funnel unit and then plated to determine positive bacterial growth.

#### **RESULTS**

All 20 vials demonstrated no bacterial growth at the end of the 30-day study period. There were 4 false contamination events among the 676 samples. None of the samples matched the challenge organism, and because the vials all remained sterile, contamination events were ascribed to errors in handling the affected samples. 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, maintaining a negative pressure on the vial and effectively preventing contaminants or vapors from entering. When a clinician aspirates fluid from the vial, the balloon allows for the outside ambient air to enter 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, allowing the air to pass through the balloon into the vial over time until the balloon deflates. 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 walls.

#### **PROTOCOL**

Phi-X174 bacteriophage was selected for the study, as it is one of the smallest known viruses at 25-27nm—smaller than vapor particles that can result from the evaporation of fluids. Using a needle to infuse the virus into the interior of the inflated balloon, 50 Genie test samples were inoculated and studied for 7 consecutive days. On each of the 7 days, the CLAVE was swabbed- and accessed with a syringe so as to remove 1mL of fluid 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-days, demonstrating that the Genie balloon is an effective barrier to prevent the passage of contaminants and vapors thus maintaining the sterility of the drug vial.

#### **REFERENCES**

1. NIOSH (US). Prevention of Occupational Exposure to Antineoplastics and Other Hazardous Drugs in Healthcare Settings. September 2004.
2. United States Pharmacopoeia (USP) 797. Pharmaceutical Compounding, Sterile Preparations. 2007.

