Vialok® Vented Vial Access Device Filter Efficacy

Introduction

The Vialok Vented Vial Access Device (VVAD) is designed for ease of use on a variety of vials. The devices are designed with a 0.2µm hydrophobic air-venting filter that neutralizes vial pressure; minimizing aresols and surface contamination. This paper presents an overview of the methods and testing used to demonstrate the filter efficacy of the VVAD.

Procedure

Testing was performed by Nelson Laboratories (Salt Lake City, UT) on small and large 0.2µm filters in groups of seven. Filters were challenged with neutralized, polydispersed DOP particles with a mass median diameter of 0.33µm, which is considered the most penetrating aerosol size. The particle penetration was determined using two calibrated photometers that measured particles after flowing through the filters. Since multiple filters were housed in the acrylic disk testing apparatus, it was determined that if the percentage particle penetration of a test article was less than or equal to 0.014%, all seven vents in the filter disk were considered to have successfully met the requirement.

Results

All test samples exhibited filtration efficiency greater than or equal to 99.99% when challenged with aerosolized DOP particles with a mass mean diameter of 0.33 µm.

Table 1. Small 0.2µm Filter Test Results

Number Particle	Penetration (%)	Filtration Efficiency (%)
1 (7 vents)	NA*	NA*
2 (7 vents)	0.002	99.998
3 (7 vents)	NA*	NA*
4 (7 vents)	<0.001	>99.999
5 (7 vents)	0.001	99.999
6 (7 vents)	0.006	99.994
7 (7 vents)	0.002	99.998
8 (7 vents)	<0.001	>99.999

Table 2. Large 0.2µm Filter Test Results

Test Article Number Particle	Penetration (%)	Filtration Efficiency (%)
1 (7 vents)	0.013	99.987
2 (7 vents)	0.002	99.998
3 (7 vents)	<0.001	>99.999
4 (7 vents)	<0.001	>99.999
5 (7 vents)	0.001	>99.999

Conclusions

The small and large 0.2µm filters passed all testing. The results demonstrate that the Vialok Vented Vial Access Device can prevent 99.99% of particulates from exiting the vial and entering the outside environment.

Data on file at Yukon Medical. Vialok Vented Vial Access Device Filter Efficacy Whitepaper TSD 0.12.01.

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Vialok® Vented Vial Access Device Non-Coring

Introduction

The Vialok Vented Vial Access Device is designed so that the vial spike does not core the stopper during attachment. Exposure to cored fragments can cause latex allergy and embolization into small vessels causing ischemia[1]. This paper presents an overview of the methods and testing used to demonstrate the non-coring functionality of the Vialok Vented Vial Access Device.

Procedure

A test vial was prepared by attaching a new septum and aluminum cap to an empty vial. A Vented Vial Access Device (VVAD) was attached to the vial. A syringe was used to inject 5 mL of water into the vial, the vial was inverted, and the fluid was withdrawn. The syringe was detached, and the fluid was expelled onto a 5-micron filter membrane. The filter membrane and spike lumen were visually inspected, and coring was documented if there were any signs of particulate material.

Testing was performed on unaged and aged 13mm, 20mm, and Universal VVADs. The tested devices were accelerated heat aged to one year equivalent and the three years equivalent. The T=0 and T=6mo 13mm VVADs were tested with three types of stoppers (Lyo, Flurotec, and Siliconized).

Results

	Configuration	No aspired particulate	No particulate in fluid lumen
T=0yr	13mm VVAD	60/60 Pass	60/60 Pass
	20mm VVAD	108/108 Pass	108/108 Pass
	Universal VVAD	35/35 Pass	35/35 Pass
T=6mo	13mm VVAD	60/60 Pass	60/60 Pass
T=1yr	20mm VVAD	35/35 Pass	35/35 Pass
	Universal VVAD	35/35 Pass	35/35 Pass
T=3yr	20mm VVAD	35/35 Pass	35/35 Pass
	Universal VVAD	35/35 Pass	35/35 Pass

Vial Septum Coring Test Conclusions

The VVADs passed all testing. The results demonstrate that the Vialok Vial Access Devices do not core the stopper under normal use.

References

[1] Sakai O, Furuse M, Nakashima N. Cut-off fragments of rubber caps of bottles of contrast material: Foreign bodies in the drip infusion system. *Am J Neuroradiol* 1996;17:1194-5.

Data on file at Yukon Medical. Vialok Vented Vial Access Device Non-Coring Whitepaper TSD 010.01.

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Vialok® Vented Vial Access Devices Chemical Compatibility

Introduction

In addition to presenting health risks for healthcare workers, many common infusion drugs contain chemicals which can cause damage to infusion and compounding devices. Damage to devices has the potential to expose healthcare workers to spills and compromise their safety. One or more elements in common drug formulations increase the risk of damage to plastic devices. These elements include: drug preservatives (Benzyl Alcohol), excipients (Cremophor EL), infusate chemistries (low pH), or other formulation chemistries known to cause damage to plastics.

To demonstrate that the Vialok Vented Vial Access Devices (VVAD) are compatible with these types of drugs, several tests were conducted on the Arisure® Neutral Valve (ANV) which has the same geometry and material as the VVAD. These tests challenged the devices with prolonged, continuous, fluid path exposure to drugs which present a range of these formulation elements.

Procedure

The ANV was evaluated for chemical compatibility with exposure to Isopropanol (immersed in solution), Intralipid 20, and Taxol Analogue (luers filled via syringe). After 168 hours of exposure, devices were flushed with water and tested according to Table 1.

Results

Table 1 Arisure Neutral Valve (aged T=3 Year Real Time Aged)

Drug	Requirement	Result
Isopropanol (IMX-7)	Multiple Activation 224+ Extended Activation (7 day)	Pass
	Flow Rate 6L/hr	32/32 Pass
	Liquid/Air Leakage	80/80 Pass
	Power Injector Use	80/80 Pass
	Ultrasonic weld must withstand a separation force of 50 lbs	80/80 Pass
Intralipid 20 (LMX-7)	Multiple Activation 224+ Extedned Activation (7 day)	Pass
	Flow Rate 6L/hr	32/32 Pass
	Liquid/Air Leakage	80/80 Pass
	Power Injector Use	80/80 Pass
	Ultrasonic weld must withstand a separation force of 50 lbs	80/80 Pass
Taxol Analogue (TMX-7)	Multiple Activation 224+ Extended Activation (7 day)	Pass
	Flow Rate 6L/hr	32/32 Pass
	Liquid/Air Leakage	80/80 Pass
	Power Injector Use	80/80 Pass
	Ultrasonic weld must withstand a separation force of 50 lbs	80/80 Pass

Conclusions

The Vialok Vented Vial Access Devices passed testing. The results demonstrate that the VVAD is chemically compatible with common infusion drugs.

Data on file at Yukon Medical. Vialok Vented Vial Access Devices Chemical Compatibility Whitepaper TSD 008.01.

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